Molina Healthcare (Molina) Clinical Criteria

Revised: July 9, 2021

TABLE OF CONTENTS

MOLINA® HEALTHCARE

ACROMEGALY AGENTS

Length of Authorization:	Noted below
Initiative:	SPC: Acromegaly Agents (IE 2462 / NCPDP 75 – GSN)

CLINICAL CRITERIA FOR INITIAL APPROVAL

SANDOSTATIN LAR—APPROVAL IS 6 MONTHS AND MAY BE RENEWED

Diagnosis of **Acromegaly**

- Patient is 18 years of age or older; **AND**
- Patient is being treated with octreotide acetate subcutaneously for at least 2 weeks and has shown a response and no adverse effects prior to starting therapy with the long-acting release (LAR) formulation; **AND**
- Patient diagnosis confirmed by elevated (age-adjusted) or equivocal serum IGF-1 as well as inadequate suppression of GH after a glucose load; **AND**
- Patient has documented inadequate response to surgery and/or radiotherapy, or it is not an option for the patient; **AND**
- Used as long-term maintenance therapy; **AND**
- Patient's tumor has been visualized on imaging studies (i.e., MRI or CT-scan); **AND**
- Baseline growth hormone (GH) and IGF-1 blood levels (renewal will require reporting of current levels)

Diagnosis of **Diarrhea Associated with Vasoactive Intestinal Peptide Tumors (VIPomas) (pancreatic neuroendocrine [islet cell] tumor, insulinoma, glucagonoma, somatostatinoma, and gastrinoma)**

- Patient is 18 years of age or older; **AND**
- Patient is being treated with octreotide acetate subcutaneously for at least 2 weeks and has shown a response and no adverse effects prior to starting therapy with the long-acting release (LAR) formulation; **AND**
- Patient has profuse watery diarrhea

Diagnosis of **Carcinoid Tumors/Neuroendocrine Tumors (e.g., GI tract, lung, thymus, pancreas, adrenal)**

- Patient is 18 years of age or older; **AND**
- Patient is being treated with octreotide acetate subcutaneously for at least 2 weeks and has shown a response and no adverse effects prior to starting therapy with the long-acting release (LAR) formulation; **AND**
- Patient has severe diarrhea/flushing episodes (carcinoid syndrome); **OR**
- Used to treat symptoms related to hormone hypersecretion in neuroendocrine tumors of the pancreas; **AND**
  - Patient has a gastrinoma, glucagonoma, or VIPoma; **OR**
- Use as primary treatment of unresected primary gastrinoma; **OR**
- Used for locoregional unresectable bronchopulmonary or thymic disease as primary therapy for low grade (typical) histology or as subsequent therapy if progression on first-line therapy (including disease progression on prior treatment with octreotide LAR in patients with functional tumors); **AND**
  - Used for management of hormone symptoms and/or somatostatin receptor positive disease determined by imaging (i.e., 68Ga-dotatate imaging PET/CT or PET/MRI or somatostatin receptor scintigraphy [octreotide scan]); **OR**

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

SANDOSTATIN LAR—APPROVAL IS 6 MONTHS AND MAY BE RENEWED *(CONTINUED)*

Diagnosis of **Carcinoid Tumors/Neuroendocrine Tumors (e.g., GI tract, lung, thymus, pancreas, adrenal)** ***(continued)***

- Patient has distant metastatic bronchopulmonary or thymic disease; **AND**
  - Used for somatostatin receptor positive disease and/or symptomatic hormonal disease if clinically significant tumor burden and low grade (typical) histology OR evidence of progression OR intermediate grade (atypical histology); **AND**
    - Used as primary therapy or as subsequent therapy if progression on first-line therapy; **OR**
  - Used for somatostatin receptor positive disease and/or hormonal symptoms if asymptomatic with low tumor burden and low grade (typical histology); **OR**
  - Used for somatostatin receptor positive disease and/or chronic cough/dyspnea with multiple lung nodules or tumorlets and evidence of diffuse idiopathic pulmonary neuroendocrine cell hyperplasia (DIPNECH); **OR**
- Used for the management of locoregional advanced or metastatic disease of the gastrointestinal tract; **AND**
  - Patient is asymptomatic with a low tumor burden; **OR**
  - Patient with a clinically significant tumor burden; **OR**
  - Patient has disease progression and is not already receiving octreotide LAR; **OR**
  - Patient has disease progression with functional tumors and will be continuing treatment with octreotide LAR; **OR**
- Used for tumor control of locoregional advanced and/or metastatic neuroendocrine tumors of the pancreas (*****Note:** for insulinoma **only**, patient must have somatostatin-receptor positive disease); **AND**
  - Patient is asymptomatic with a low tumor burden and stable disease; **OR**
  - Patient is symptomatic with a clinically significant tumor burden; **OR**
  - Patient has clinically significant progression and is not already receiving octreotide LAR; **OR**
- Used for locally unresectable or distant metastatic pheochromocytoma or paraganglioma if somatostatin receptor-positive and symptomatic.

Diagnosis of **Thyroid Cancer and Thymomas**

- Patient is 18 years of age or older; **AND**
- Patient is being treated with octreotide acetate subcutaneously for at least 2 weeks and has shown a response and no adverse effects prior to starting therapy with the long-acting release (LAR) formulation; **AND**
- Used as second-line therapy with or without prednisone; **AND**
  - Patient has unresectable disease following first-line chemotherapy for potentially resectable locally advanced disease, solitary metastasis, or ipsilateral pleural metastasis; **OR**
  - Patient has extrathoracic metastatic disease

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

SOMATULINE – INITIAL APPROVAL IS 3 MONTHS, ELIGIBLE FOR RENEWAL FOR 6 MONTHS

Diagnosis of **Acromegaly**

- Patient is 18 years of age or older; **AND**
- Patient has not received a long-acting somatostatin analogue (e.g., Octreotide LAR, Lanreotide SR, and Lanreotide autogel) within the last 4 weeks; **AND**
- Patient diagnosis confirmed by elevated (age-adjusted) or equivocal serum IGF-1 as well as inadequate suppression of GH after a glucose load; **AND**
- Patient has documented inadequate response to surgery and/or radiotherapy **OR** it is not an option for the patient; **AND**
- Patient's tumor has been visualized on imaging studies (i.e., MRI or CT-scan); **AND**
- Baseline growth hormone (GH) and IGF-1 blood levels (renewal will require reporting of current levels)

Diagnosis of **Gastroenteropancreatic neuroendocrine tumors (GEP-NETs)**

- Patient is 18 years of age or older; **AND**
- Patient has not received a long-acting somatostatin analogue (e.g., Octreotide LAR, Lanreotide SR, and Lanreotide autogel) within the last 4 weeks; **AND**
- Patient has unresectable, locally advanced or metastatic disease; **AND**
- Patient has non-functioning tumors without hormone-related symptoms; **AND**
- Patient has well or moderately differentiated disease.

Diagnosis of **Carcinoid Syndrome**

- Patient is 18 years of age or older; **AND**
- Patient has not received a long-acting somatostatin analogue (e.g., Octreotide LAR, Lanreotide SR, and Lanreotide autogel) within the last 4 weeks; **AND**
- Patient has documented neuroendocrine tumors with a history of carcinoid syndrome; **AND**
  - Used to reduce the frequency of short-acting somatostatin analog rescue therapy; **OR**
  - Used for treatment and/or control of symptoms.

Diagnosis of **Neuroendocrine Tumors (GI Tract, Lung, Thymus, Pancreas, and Pheochromocytoma/Paraganglioma)**

- Patient is 18 years of age or older; **AND**
- Patient has not received a long-acting somatostatin analogue (e.g., Octreotide LAR, Lanreotide SR, and Lanreotide autogel) within the last 4 weeks; **AND**
  - Used to treat unresectable primary gastrinoma; **OR**
  - Used for treatment of symptoms related to hormone hypersecretion and/or Carcinoid syndrome; **OR**
  - Used for tumor control in patients with unresectable, locally advanced, and/or metastatic disease.

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

OCTREOTIDE (SANDOSTATIN) – APPROVAL IS 6 MONTHS AND MAY BE RENEWED

Note: This criteria does not apply to Sandostatin LAR. Please refer to that criteria above.

Diagnosis of **Acromegaly**:

- Patient is 18 years or older

Diagnosis of **Vasoactive intestinal peptide tumors (VIPomas):**

- Patient is 18 years or older

Diagnosis of **Diarrheal States related to one of the following:**

- Patient is 18 years or older; **AND**
  - AIDS-related diarrhea; **OR**
  - Short bowel (ileostomy) syndrome; **OR**
  - Diarrhea caused by radiation treatment in cancer patients; **OR**
  - Chemotherapy-associated diarrhea

Diagnosis of **Dumping syndrome:**

- Patient is 18 years or older

Diagnosis of **Central Nervous System Cancers – Meningiomas**

- Patient is 18 years or older

Diagnosis of **Symptoms of Cushing's syndrome secondary to Neuroendocrine Tumors - Adrenal Gland Tumors**

- Patient is 18 years or older

Diagnosis of **Neuroendocrine Tumors (Pancreas, GI Tract, Lung, and Thymus)**

- Patient is 18 years or older

Diagnosis of **Carcinoid Tumors**

- Patient is 18 years or older

Diagnosis of **Pheochromocytoma/Paraganglioma**

- Patient is 18 years or older

Diagnosis of **Thymomas and Thymic Carcinomas**

- Patient is 18 years or older

Diagnosis of **Variceal bleeding**

- Patient is 18 years or older

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

MYCAPSSA® — APPROVAL IS 6 MONTHS AND MAY BE RENEWED

Initiative: MNC: Non-Formulary Product (IE 50698 / MR – GSN PatOverride)

Diagnosis of **Acromegaly**

- Patient is at least 18 years of age; **AND**
- Patient is being treated with somatostatin analogs (e.g., octreotide or lanreotide) for at least 6 months with stable doses for at least the last 3 months and has shown a response and no adverse effects prior to starting therapy with oral octreotide; **AND**
- Will be used as single-agent therapy; **AND**
- Patient will avoid concomitant therapy with acid-reducing agents (e.g., proton pump inhibitors, H2-receptor antagonists, or antacids) which may reduce bioavailability. If therapy is unavoidable, the patient will be monitored closely for signs and symptoms of acromegaly; **AND**
- Patient has not received a long-acting somatostatin analogue (e.g., octreotide LAR depot, lanreotide SR/auto gel, pasireotide LAR depot, etc.) within the last 4 weeks; **AND**
- Will not be used in combination with other short-acting somatostatin analogs (e.g., octreotide, lanreotide, pasireotide, etc.); **AND**
- Patient diagnosis confirmed by elevated (age-adjusted) or equivocal serum IGF-1 as well as inadequate suppression of GH after a glucose load; **AND**
- Patient has documented inadequate response to surgery and/or radiotherapy or is not a candidate; **AND**
- Used as long-term maintenance therapy; **AND**
- Patient's tumor has been visualized on imaging studies (e.g., MRI or CT-scan); **AND**
- Baseline growth hormone (GH) and IGF-I blood levels have been obtained (necessary for renewal).

CLINICAL CRITERIA FOR RENEWAL

SANDOSTATIN LAR

- Coverage can be renewed based on the following criteria:
  - Absence of unacceptable toxicity from the drug (e.g., cholelithiasis and complications of cholelithiasis [i.e. cholecystitis, cholangitis, pancreatitis], hyperglycemia, hypoglycemia, hypothyroidism, sinus bradycardia, cardiac arrhythmias, cardiac conduction abnormalities, depressed vitamin B_{12} levels); **AND**
  - Disease response with improvement in patient's symptoms including reduction in symptomatic episodes (such as diarrhea, rapid gastric dumping, flushing, bleeding, etc.) and/or stabilization of glucose levels or decrease in size of tumor or tumor spread; **OR**
  - **Acromegaly only:** Disease response as indicated by an improvement in signs and symptoms compared to baseline; **AND**
    - Reduction of growth hormone (GH) from pre-treatment baseline; **OR**
    - Age-adjusted normalization of serum IGF-1; **OR**
  - **Neuroendocrine tumors (gastrointestinal tract, bronchopulmonary, thymus, or pancreas only):** Patient has had disease progression and therapy will be continued in patients with functional tumors.

CLINICAL CRITERIA FOR RENEWAL *(CONTINUED)*

OCTREOTIDE (SANDOSTATIN)

- Absence of unacceptable toxicity from the drug (e.g., biliary tract abnormalities, hypothyroidism, goiter, sinus bradycardia, cardiac arrhythmias, cardiac conduction abnormalities, pancreatitis); **AND**
- Disease response with improvement in patient's signs and/or symptoms.

SOMATULINE—RENEWAL IS 6 MONTHS

- Absence of unacceptable toxicity from the drug (e.g., formation of gallstones, cardiovascular abnormalities [bradycardia, sinus bradycardia, and hypertension], uncontrolled blood glucose abnormalities [hyperglycemia, hypoglycemia], thyroid disorders [hypothyroidism]); **AND**
- Disease response with improvement in patient's signs and/or symptoms; **AND**

Acromegaly:

Disease response as indicated by an improvement in signs and symptoms compared to baseline; **AND**

- Reduction of growth hormone (GH) by random testing to < 1.0 mcg/L; **OR**
- Age-adjusted normalization of serum IGF-1.

Carcinoid Syndrome:

- Disease response with treatment as indicated by reduction in use of short-acting somatostatin analog rescue medication (e.g., octreotide) and a decrease in the frequency of diarrhea ad flushing events, when compared to baseline.

Treatment of and/or symptoms secondary to Neuroendocrine tumors:

- Disease response with treatment as indicated by an improvement in symptoms including reduction in symptomatic episodes (e.g., diarrhea, rapid gastric dumping, flushing, bleeding) and/or stabilization of glucose levels and/or decrease in size of tumor or tumor spread.

MYCAPSSA® — RENEWAL IS 6 MONTHS

- Absence of unacceptable toxicity from the drug (e.g., cholelithiasis and complications of cholelithiasis [e.g., cholecystitis, cholangitis, pancreatitis], hyperglycemia, hypoglycemia, hypothyroidism, sinus bradycardia, cardiac arrhythmias, cardiac conduction abnormalities, severe depressed vitamin B_{12} levels); **AND**
- Disease response as indicated by an improvement in signs and symptoms compared to baseline; **AND**
  - Reduction of growth hormone (GH) by random testing to < 1.0 mcg/L; **OR**
  - Age-adjusted normalization of serum IGF-1

ACTIMMUNE® (INTERFERON GAMMA1-B)

Length of Authorization:	6 months, may be renewed Mycosis Fungoides (MF)/Sezary Syndrome (SS) – up to 8 weeks of therapy total and may NOT be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75 – HICL, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

- Diagnosis of Chronic Granulomatous Disease (CGD)
  - Patient age is 1 year or older; **AND**
  - Patient diagnosis is confirmed by the following biochemical and genetic tests:
    - Patient has a mutation in one or more of the phagocyte oxidase (PHOX) genes (e.g., gp91, p47, p22, p67, and p40 phox-genes); **AND**
    - Patient has abnormal dihydrorhodamine (DHR) neutrophil function as measured on a quantitative assay (i.e., DHR-123 oxidation test); **AND**
  - Used to decrease the frequency and severity of serious infections, defined as a clinical event requiring hospitalization and the use of parenteral antibiotics; **AND**
  - Patient is receiving antibiotic prophylaxis therapy.
- Diagnosis of Severe Malignant Osteopetrosis (SMO)
  - Patient is between 1 month and 8 years of age; **AND**
  - Patient diagnosis is confirmed by all of the following radiographic and genetic tests:
    - Classical radiographic presentation (e.g., bone-within-bone, club shaped long bones, generalized osteosclerosis, transverse bands, etc.) on a skeletal survey; **AND**
    - Identification of a pathogenic sub-type mutation in the CLCN7 gene or other gene variants; **AND**
  - Patient has severe, malignant disease; **AND**
  - Intent of treatment is to delay the progression of disease; **AND**
  - Patient is receiving concurrent calcium and Vitamin D supplementation; **AND**
  - Patient is receiving concurrent calcitriol.
- Diagnosis of Mycosis Fungoides (MF)/Sezary Syndrome (SS)
  - Patient age is 18 years or older; **AND**
  - Used as systemic therapy with or without skin-directed or radiation therapy; **AND**
  - Patient does NOT have refractory stage IA MF with blood B1 involvement or progression to greater than stage IA disease while on skin-directed therapies

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: mental status changes, gait disturbances, dizziness, severe neutropenia and/or thrombocytopenia, severe elevations in liver enzymes (AST and/or ALT), severe hypersensitivity reactions, etc.; **AND**

Mycosis Fungoides/Sezary Syndrome

- May not be renewed

Chronic Granulomatous Disease

- Disease response as evidenced by all of the following:
  - Decrease in the frequency and severity of infection; **AND**
  - Decrease in the rate of hospitalizations and requirement for parenteral antibiotics.

Severe Malignant Osteopetrosis (SMO)

- Disease response as evidenced by stabilization or delayed progression of disease (disease progression is defined as any of the following: significant reduction in hemoglobin or platelet counts, a serious bacterial infection requiring antibiotics, or a 50 dB decrease in hearing or progressive optic atrophy); **AND**
- Patient age is ≤ 8 years old.

ADCETRIS® (BRENTUXIMAB VEDOTIN)

Length of Authorization:	6 months, may be renewed **Note:** • Treatment for cHL post-auto HSCT, primary cutaneous anaplastic large cell lymphoma (pcALCL), Mycosis Fungoides (MG)/Sezary Syndrome (SS), and Primary cutaneous CD30+ T-Cell Lymphoproliferative Disorders has a maximum of 16 cycles. • Treatment of previously untreated Stage III or IV classical Hodgkin Lymphoma (cHL) has a maximum of 12 doses. • Treatment of previously untreated Systemic Anaplastic Large Cell Lymphoma (sALCL) or other CD30-expressing Peripheral T-Cell Lymphomas (PTCL) has a maximum of 8 doses • Treatment of Breast-Implant Associated Anaplastic Large Cell Lymphoma (ALCL) has a maximum of 6 cycles as adjuvant therapy
Initiative:	MNC: Non-Formulary Product (IE 50698 / MR – GSN PatOverride)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Classical Hodgkin Lymphoma (cHL):**

- Patient is 18 or older; **AND**
- Patient is CD30 positive; **AND**
- Patient must not be receiving concomitant bleomycin; **AND**
- Used as a single agent; **AND**
  - Used as consolidation/maintenance therapy post-autologous hematopoietic stem cell transplant (auto-HSCT) in patients at high risk* for relapse or progression; **OR**
  - Patient has relapsed disease, after failure of auto-HSCT or after failure of at least 2 prior multi-agent chemotherapy regimens in patients who are not auto-HSCT candidates; **OR**
  - Used as second-line or subsequent systemic therapy (if not previously used) for relapsed or refractory disease; **OR**
  - Used as palliative therapy for relapsed or refractory disease in patients more than 60 years of age; **OR**
- Used in combination with bendamustine; **AND**
  - Used as second-line or subsequent systemic therapy (if not previously used) for relapsed or refractory disease; **OR**
- Used in combination with nivolumab; **AND**
  - Used as second-line or subsequent systemic therapy (if not previously used) for relapsed or refractory disease; **OR**
- Used in combination with dacarbazine; **AND**
  - Used as primary treatment in patients more than 60 years of age with stage I-II unfavorable or stage III-IV disease**; OR**
- Used in combination with doxorubicin, vinblastine, and dacarbazine (AVD); **AND**
  - Used as initial therapy for previously untreated Stage III or IV disease

**High risk for relapse or progression may be defined as:*

- Refractory disease, relapse within 12 months, or extranodal disease following frontline therapy OR 2 or more of the following: PET+ response at time of transplant, B symptoms, and/or > 1 salvage/subsequent therapy regimen)

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **T-Cell Lymphoma:**

- Peripheral T-Cell Lymphoma (PTCL)
  - Patient is 18 or older; **AND**
  - Patient is CD30 positive; **AND**
  - Patient must not be receiving concomitant bleomycin; **AND**
  - Used as a single agent after failure of at least one prior chemotherapy regimen for one of the following:
    - Systemic anaplastic large cell lymphoma (sALCL)
    - Peripheral T-cell lymphoma (PTCL) not otherwise specified
    - Angioimmunoblastic T-cell lymphoma (AITL); **OR**
  - Used in combination with cyclophosphamide, doxorubicin, and prednisone (CHP) as initial therapy for previously untreated:
    - Systemic anaplastic large cell lymphoma (sALCL)
    - Peripheral T-cell lymphoma (PTCL) not otherwise specified
    - Angioimmunoblastic T-cell lymphoma (AITL)
    - Enteropathy-associated T-cell lymphoma , monomorphic epitheliotropic intestinal T-cell lymphoma, nodal peripheral T-cell lymphoma with TFH phenotype, or follicular T-cell lymphoma
- Breast-implant associated anaplastic large cell lymphoma (ALCL); **AND**
  - Patient is 18 or older; **AND**
  - Patient is CD30 positive; **AND**
  - Patient must not be receiving concomitant bleomycin; **AND**
  - Used as a single agent or in combination with cyclophosphamide, doxorubicin, and prednisone (CHP) for adjuvant therapy; **AND**
    - Patient has localized disease to the capsule, implant, or breast with either lymph node involvement or radiation therapy is not feasible; **OR**
    - Patient has extended disease (stage II-IV)
- Adult T-cell leukemia/lymphoma
  - Patient is 18 or older; **AND**
  - Patient is CD30 positive; **AND**
  - Patient must not be receiving concomitant bleomycin; **AND**
  - Used as a single agent for acute disease or lymphoma; **AND**
    - Used as second-line or subsequent therapy for non-responders to first-line therapy; **OR**
  - Used in combination with cyclophosphamide, doxorubicin, and prednisone (CHP); **AND**
    - Used as first-line therapy or continued treatment in responders to first-line therapy for acute disease or lymphoma; **OR**
    - Used as subsequent therapy for non-responders to first-line therapy for chronic or smoldering disease
- Extranodal NK/T-cell lymphoma
  - Patient is 18 or older; **AND**
  - Patient is CD30 positive; **AND**
  - Patient must not be receiving concomitant bleomycin; **AND**
  - Used as a single agent for relapsed or refractory disease; **AND**
  - Patient has previously received at least 2 different prior lines of therapy including an asparaginase based combination chemotherapy regimen

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

- Hepatosplenic gamma-delta T-cell lymphoma
  - Patient is 18 or older; **AND**
  - Patient is CD30 positive; **AND**
  - Patient must not be receiving concomitant bleomycin; **AND**
  - Used as single-agent therapy; **AND**
    - Used for refractory disease as subsequent therapy after progression on two primary treatment regimens; **OR**
  - Used in combination with cyclophosphamide, doxorubicin, and prednisone (CHP); **AND**
    - Used as primary treatment or as an alternate induction regimen if not used during primary treatment

Diagnosis of **Primary Cutaneous Lymphomas**

- Mycosis fungoides (MF)/Sézary syndrome (SS)
  - Patient is 18 or older; **AND**
  - Patient is CD30 positive; **AND**
  - Patient must not be receiving concomitant bleomycin; **AND**
  - Used as a single agent; **AND**
    - Used as primary therapy in patients without stage IA MF with B1 blood involvement; **OR**
    - Used as subsequent therapy
- Primary cutaneous CD30+ T-cell lymphoproliferative disorders
  - Patient is 18 or older; **AND**
  - Patient is CD30 positive; **AND**
  - Patient must not be receiving concomitant bleomycin; **AND**
  - Used as a single agent; **AND**
    - Patient has primary cutaneous anaplastic large cell lymphoma (pcALCL); **OR**
    - Patient has cutaneous ALCL with regional nodes (excludes systemic ALCL); **OR**
    - Patient has lymphomatoid papulosis (LyP) with extensive lesions that is relapsed or refractory to treatment options (e.g., clinical trial, observation, retreatment with primary treatment, or treatment with alternative regimen); **OR**
  - Used in combination with cyclophosphamide, doxorubicin, and prednisone (CHP); **AND**
    - Patient has cutaneous ALCL with regional nodes (excludes systemic ALCL)
- B-cell lymphomas
  - Patient is 18 or older; **AND**
  - Patient is CD30 positive; **AND**
  - Patient must not be receiving concomitant bleomycin; **AND**
  - Diffuse large B-cell lymphoma (DLBCL) or high grade B-cell lymphoma
    - Used as second-line or subsequent therapy for partial response, no response, relapsed, progressive, or refractory disease in non-candidates for transplant
  - AIDS-related DLBCL, primary effusion lymphoma, or HHV8-positive DLBCL
    - Used as second-line or subsequent therapy for relapsed disease in non-candidates for transplant
  - CD30+ Monomorphic Post-Transplant Lymphoproliferative Disorders (PTLD)
    - Used as second-line or subsequent therapy for patients with partial response, persistent, or progressive disease after receiving chemoimmunotherapy as first-line treatment for B-cell type disease; **OR**
    - Used in combination with CHP (cyclophosphamide, doxorubicin, prednisone) for T-cell type disease
  - Histologic transformation of follicular lymphoma or nodal marginal zone lymphoma to diffuse large B-cell lymphoma (DLBCL) in patients who have received multiple lines of therapy for transformed or indolent disease

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug (e.g., progressive multifocal leukoencephalopathy, peripheral neuropathy, anaphylaxis and infusion reactions, hematologic toxicities [thrombocytopenia, neutropenia, and anemia], serious infections, tumor lysis syndrome, increased toxicity in patients with severe renal [CrCl < 30 mL/min] and hepatic impairment [Child-Pugh B or C], hepatotoxicity, pulmonary toxicity, serious dermatologic reactions, gastrointestinal complications, uncontrolled hyperglycemia)

AFINITOR® (EVEROLIMUS)

Length of Authorization:	6 months, eligible for renewal
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75 – HICL, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **renal carcinoma**

- Patient is 18 years of age or older; **AND**
- Patient does not have an active infection, including clinically important localized infections; **AND**
- Must not be administered concurrently with live vaccines; **AND**
- Patient has advanced disease; **AND**
- Patient has failed previous treatment with sunitinib or sorafenib; **AND**
- Patient has relapsed or metastatic disease; **AND**
  - Used in combination with bevacizumab in patients with non-clear cell histology; **OR**
  - Used as a single agent or in combination with lenvatinib; **AND**
    - Patient has non-clear cell histology**; OR**
    - Used as subsequent therapy

Diagnosis of **tuberous sclerosis complex (TSC)**

- Patient has subependymal giant cell astrocytoma (SEGA); **AND**
  - Patient does not have an active infection, including clinically important localized infections; **AND**
  - Must not be administered concurrently with live vaccines; **AND**
  - Patient is 1 year of age or older; **AND**
  - Patient is not a candidate for curative surgical resection; **OR**
- Patient has renal angiomyolipoma which does not require immediate surgery; **AND**
  - Patient is 18 years of age or older; **AND**
  - Patient does not have an active infection, including clinically important localized infections; **AND**
  - Must not be administered concurrently with live vaccines; **OR**
- Patient has partial-onset seizures; **AND**
  - Patient does not have an active infection, including clinically important localized infections; **AND**
  - Must not be administered concurrently with live vaccines; **AND**
  - Patient is 2 years or older; **AND**
  - Used in combination with other anti-epileptic drugs

Diagnosis of **Waldenström's macroglobulinemia/lymphoplasmacytic lymphoma**

- Patient is 18 years of age or older; **AND**
- Patient does not have an active infection, including clinically important localized infections; **AND**
- Must not be administered concurrently with live vaccines; **AND**
- Used as a single agent therapy; **AND**
- Patient has failed with primary therapy; **OR**
- Patient has progressive or relapsed disease

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **pancreatic endocrine tumors (Islet cell tumors, PNET)**

- Patient is 18 years of age or older; **AND**
- Patient does not have an active infection, including clinically important localized infections; **AND**
- Must not be administered concurrently with live vaccines; **AND**
- Patient has progressive disease; **AND**
- Used as a single agent; **AND**
- Patient has unresectable disease, locally advanced disease or metastatic disease

Diagnosis of **breast cancer**

- Patient is 18 years of age or older; **AND**
- Patient does not have an active infection, including clinically important localized infections; **AND**
- Must not be administered concurrently with live vaccines; **AND**
- Patient is postmenopausal; premenopausal with ovarian ablation/suppression**;** or male with suppression of testicular steroidogenesis; **AND**
- Patient has recurrent or locally advanced or metastatic disease; **AND**
- Patient has hormone receptor positive disease; **AND**
- Patient has HER2 (human epidermal growth factor receptor) negative disease; **AND**
- Patient previously failed with letrozole, anastrozole, or tamoxifen within 1 year; **AND**
- Must be used in combination with exemestane, fulvestrant, or tamoxifen

Diagnosis of **Neuroendocrine tumors (NET) of the lung, GI tract, or thymus**

- Patient is 18 years of age or older; **AND**
- Patient does not have an active infection, including clinically important localized infections; **AND**
- Must not be administered concurrently with live vaccines; **AND**
- Patient has progressive well-differentiated, non-functional disease of the lung or GI tract that is unresectable, locally advanced, or metastatic; **OR**
- Patient has clinically significant tumor burden or progressive advanced disease of the GI tract; **OR**
- Patient has unresectable or metastatic bronchopulmonary/thymic disease **: AND**
  - Used as subsequent therapy for progression on first-line therapy; **OR**
  - Patient has progression on first-line therapy OR progression with significant tumor burden and low-grade histology OR patient has intermediate grade histology

Diagnosis of **soft tissue sarcoma**

- Patient is 18 years of age or older; **AND**
- Must be used as a single agent; **AND**
- Patient does not have an active infection, including clinically important localized infections; **AND**
- Must not be administered concurrently with live vaccines; **AND**
- Used in combination with either imatinib, sunitinib or regorafenib after disease progression on single-agent tyrosine kinase inhibitor (imatinib, sunitinib, or regorafenib) therapy; **AND**
  - Used for gastrointestinal stromal tumors (GIST); **OR**
- Used as a single agent therapy for one of the following sub-indications:
  - PEComa
  - Angiomyolipoma
  - Lymphangioleiomyomatosis

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **classical Hodgkin lymphoma (HL)**

- Patient is 18 years of age or older; **AND**
- Patient does not have an active infection, including clinically important localized infections; **AND**
- Must not be administered concurrently with live vaccines; **AND**
- Used for refractory or relapsed disease as third-line or subsequent therapy; **AND**
- Must be used as a single agent

Diagnosis of **thymomas or thymic carcinomas**

- Patient is 18 years of age or older; **AND**
- Patient does not have an active infection, including clinically important localized infections; **AND**
- Must not be administered concurrently with live vaccines; **AND**
- Must be used as single agent therapy; **AND**
- Must be used for second line therapy

Diagnosis of **thyroid carcinoma (follicular, Hürthle cell, or papillary carcinoma)**

- Patient is 18 years of age or older; **AND**
- Patient does not have an active infection, including clinically important localized infections; **AND**
- Must not be administered concurrently with live vaccines; **AND**
- Patient has unresectable, recurrent, persistent, or metastatic disease; **AND**
- Disease is progressive and/or symptomatic iodine-refractory; **AND**
- Clinical trials or other therapies are not available or not available and/or appropriate for the patient

Diagnosis of **uterine cancer**

- Patient is 18 years of age or older; **AND**
- Patient does not have an active infection, including clinically important localized infections; **AND**
- Must not be administered concurrently with live vaccines; **AND**
- Used in combination with letrozole for endometrioid type disease; **AND**
- Used as one of the following**:**
  - Primary treatment, excluding patients with cervical involvement who are not surgical candidates when treatment is chemotherapy alone , **OR**
  - Adjuvant treatment for surgically staged patients, excluding patients with stage II disease and histologic grade 3 tumors, **OR**
  - Used as treatment of local-regional recurrent metastatic disease, excluding isolated metastases

Diagnosis of **subependymal giant cell astrocytoma (SEGA)**

- Patient is 18 years of age or older; **AND**
- Patient does not have an active infection, including clinically important localized infections; **AND**
- Must not be administered concurrently with live vaccines; **AND**
- Used as single agent adjuvant therapy

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug (e.g., grade 3 or 4 non-infectious pneumonitis; grade 2 or grade 3 stomatitis; grade 3 or grade 4 non-hematologic toxicities [excluding metabolic events]; grade 3 or grade 4 metabolic events [hyperglycemia, dyslipidemia], angioedema); **AND**

TSC-Associated Partial-Onset Seizures:

- Patient has responded to therapy compared to pretreatment baseline with disease stability or improvement as indicated by a reduction in seizure frequency

Oncology Indications:

- Tumor response with stabilization of disease or decrease in size of tumor or tumor spread

ALDURAZYME® (LARONIDASE)

Length of Authorization:	1 year, may be renewed
Initiative:	MNC: Non-Formulary Product (IE 50698 / MR – GSN PatOverride)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Mucopolysaccharidosis I (MPS I)**

- Patient is 6 months of age or older; **AND**
- Patient has a definitive diagnosis of MPS I confirmed by one of the following:
  - Detection of biallelic pathogenic mutations in the *IDUA* gene by molecular genetic testing; **OR**
  - Detection of deficient activity of the lysosomal enzyme α-L-iduronidase (IDUA); **AND**
- Diagnosis of Hurler (severe) or Hurler-Scheie (attenuated) forms of disease; **OR**
- Diagnosis of Scheie (attenuated) form of disease with moderate to severe symptoms; **AND**
- Patient has absence of severe cognitive impairment; **AND**
- Documented baseline value for urinary glycosaminoglycan (uGAG); **AND**
- Documented baseline values for one or more of the following:
  - **Patients of age 6 years or older**: percent predicted forced vital capacity (FVC), 6-minute walk test, joint range of motion, left ventricular hypertrophy, growth, quality of life (CHAQ/HAQ/MPS HAQ); **OR**
  - **Patients of age 6 months to under 6 years**: cardiac status, upper airway obstruction during sleep, growth velocity, mental development, FVC, and/or 6-minute walk test.

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug (e.g., anaphylaxis and severe hypersensitivity reactions, acute respiratory complications, acute cardiorespiratory failure, severe infusion reactions); **AND**
- Patient does not have progressive/irreversible severe cognitive impairment; **AND**
- Patient has a documented reduction in uGAG levels compared to pretreatment baseline; **AND**
- Patient has demonstrated a beneficial response to therapy compared to pretreatment baseline in one or more of the following:
  - **Patients 6 years or older**: stability or improvement in percent predicted FVC and/or 6-minute walk test, increased joint range of motion, decreased left ventricular hypertrophy, improved growth, improved quality of life (clinically meaningful change in the CHAQ/HAQ/MPS HAQ disability index); **OR**
  - **Patients 6 months to less than 6 years**: stability or improvement in cardiac status, upper airway obstruction during sleep, growth velocity, mental development, FVC, and/or 6-minute walk test.

ALECENSA® (ALECTINIB)

Length of Authorization:	6 months; may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75 – HICL, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Non-small Cell Lung Cancer**

- Patient is at least 18 years or older; **AND**
- Must be used as a single agent; **AND**
- Patient's disease is anaplastic lymphoma kinase (ALK)-positive as detected by FDA-approved or CLIA compliant test; **AND**
- Patient has advanced, metastatic, or recurrent disease (excluding locoregional recurrence or symptomatic local disease without evidence of disseminated disease) or mediastinal lymph node recurrence with prior radiation therapy; **AND**
  - Used as first line therapy; **OR**
  - Used as subsequent therapy; **AND**
    - Patient has previously failed with, or is intolerant to, treatment with crizotinib; **OR**
    - Used as continuation of therapy if used first-line, except in cases of symptomatic systemic disease with multiple lesions.

Diagnosis of **Central Nervous System (CNS) Cancers (Limited or Extensive Brain Metastases)**

- Patient is at least 18 years or older; **AND**
- Must be used as a single agent; **AND**
- Patient has ALK-positive non-small cell lung cancer as detected by an FDA-approved or CLIA-compliant test; **AND**
  - Used as initial treatment in patients with small, asymptomatic brain metastases; **OR**
  - Used for relapsed disease in patients with limited brain metastases and stable systemic disease or reasonable systemic treatment options; **OR**
  - Patient has recurrent limited brain metastases; **OR**
  - Used for recurrent disease in patients with extensive brain metastases and stable systemic disease or reasonable systemic treatment options.

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug (e.g., severe elevations in ALT/AST or bilirubin, severe myalgia, bradycardia, interstitial lung disease/pneumonitis, severe elevations in creatine phosphokinase [CPK], severe renal impairment).

ALIMTA® (PEMETREXED DISODIUM)

Length of Authorization:	6 months, may be renewed
Initiative:	MNC: Non-Formulary Product (IE 50698 / MR – GSN PatOverride)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Primary Central Nervous System (CNS) Lymphoma**

- Patient must be 18 years of age or older; **AND**
- Used as single agent therapy for relapsed or refractory disease; **AND**
  - Patient failed prior methotrexate (MTX)-based regimen without prior radiation therapy; **OR**
  - Patient previously received whole brain radiation therapy (RT); **OR**
  - Used in combination with whole brain RT in patients who received prior high-dose MTX-based therapy without prior RT with response <12 months; **OR**
  - Patient received prior high-dose therapy with stem cell rescue

Diagnosis of **Malignant Pleural* Mesothelioma**

- Patient must be 18 years of age or older; **AND**
- Used in combination with cisplatin- or carboplatin; **OR**
- Used as a single agent therapy for unresectable disease or subsequent therapy: **OR**
- Used in combination with bevacizumab and either cisplatin or carboplatin followed by single-agent bevacizumab maintenance therapy for unresectable disease

*****peritoneal, pericardial, and tunica vaginalis testis mesothelioma will be evaluated on a case by case basis

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Non-Squamous Non-Small Cell Lung Cancer (NSCLC)**

- Patient must be 18 years of age or older; **AND**
  - Used in combination with carboplatin or cisplatin; **AND**
    - Used as induction, neoadjuvant, or adjuvant therapy; **OR**
    - Used as concurrent chemoradiation; **OR**
    - Used as initial therapy for unresectable disease; **OR**
  - Used for recurrent, advanced, or metastatic disease (excluding locoregional recurrence or symptomatic local disease without evidence of disseminated disease) or mediastinal lymph node recurrence with prior radiation therapy; **AND**
    - Used as first-line therapy; **AND**
      - Used for PD-L1 ≥ 1% and genomic tumor aberration (e.g., EGFR, ALK, ROS1, and BRAF) negative; **AND**
        - Used in combination with pembrolizumab and either carboplatin or cisplatin in patients with PS 0-2; **OR**
        - Used in combination with cisplatin in patients with PS 0-1; **OR**
      - Used for PD-L1 < 1% and genomic tumor aberration (e.g., EGFR, ALK, ROS1, and BRAF) negative **or** for BRAF V600E-mutation positive tumors or NTRK gene fusion positive tumors; **AND**
        - Used as a single agent in patients with PS 2; **OR**
        - Used in combination with pembrolizumab and either carboplatin or cisplatin in patients with PS 0-1; **OR**
        - Used in combination with cisplatin in patients with PS 0-1; **OR**
        - Used in combination with carboplatin in patients with PS 0-2; **OR**
        - Used in combination with bevacizumab and either cisplatin or carboplatin in patients with PS 0-1; **OR**
    - Used as subsequent therapy; **AND**
      - Used as a single-agent for subsequent therapy (if not previously given) in patients with a PS 0-2; **OR**
      - Used for genomic tumor aberration (e.g., EGFR, ALK, and ROS1) positive and prior targeted therapy **or** for BRAF V600E-mutation positive tumors or NTRK gene fusion positive tumors **or** for PD-L1 expression-positive (≥ 1%) tumors and genomic tumor aberration (e.g., EGFR, ALK, ROS1, and BRAF) negative with no prior platinum doublet chemotherapy but with a PD-directed agent; **AND**
        - Used as a single agent in patients with PS 2; **OR**
        - Used in combination with pembrolizumab and either carboplatin or cisplatin in patients with PS 0-1; **OR**
        - Used in combination with cisplatin in patients with PS 0-1; **OR**
        - Used in combination with carboplatin in patients with PS 0-2; **OR**
        - Used in combination with bevacizumab and either cisplatin or carboplatin in patients with PS 0-1; **OR**
    - Used as maintenance therapy in patients with PS 0-2 who have achieved tumor response or stable disease following initial therapy; **AND**
      - Used as a single agent as continuation maintenance therapy following a first-line pemetrexed/platinum chemotherapy regimen; **OR**
      - Used as a single agent for switch maintenance following initial systemic therapy; **OR**
      - Used in combination with bevacizumab following a first-line bevacizumab/pemetrexed/platinum chemotherapy regimen; **OR**
      - Used in combination with pembrolizumab following a first-line pembrolizumab/pemetrexed and either carboplatin or cisplatin regimen

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Thymomas and Thymic Carcinoma**

- Patient must be 18 years of age or older; **AND**
- Used for second-line treatment of unresectable or metastatic disease; **AND**
- Used as a single agent

Diagnosis of **Ovarian Cancer (epithelial ovarian/fallopian tube/primary peritoneal cancer)**

- Patient must be 18 years of age or older; **AND**
- For persistent or recurrent disease; **AND**
- Patient is not experiencing an immediate biochemical relapse; **AND**
- Used as a single agent

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. (Examples of unacceptable toxicity include the following: bone marrow suppression (e.g., neutropenia, thrombocytopenia, anemia), renal impairment (CrCl < 45 mL/min),bullous and exfoliative skin toxicity, interstitial pneumonitis, radiation recall, etc.); **AND**

Non-squamous Non-small Cell Lung Cancer (continuation maintenance therapy)

- Used as maintenance therapy of locally advanced, recurrent, or metastatic disease; **AND**
  - Used as a single agent, following a first-line pemetrexed/platinum chemotherapy; **OR**
  - Used in combination with bevacizumab following a first-line bevacizumab/pemetrexed/platinum chemotherapy regimen; **OR**
  - Used in combination with pembrolizumab following a first-line pembrolizumab/pemetrexed/carboplatin or cisplatin regimen**.**

ALIQOPA™ (COPANLISIB)

Length of Authorization:	6 months, eligible for renewal
Initiative:	MNC: Non-Formulary Product (IE 50698 / MR – GSN PatOverride)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **B-cell lymphoma**:

- Patient aged 18 years or older; **AND**
- Must be used as a single agent; **AND**
- Patient has relapsed, refractory, or progressive disease; **AND**
- Patient has received at least two prior systemic therapies; **AND**
- Patient has one of the following diagnoses:
  - Follicular lymphoma (FL); **OR**
  - Non-gastric MALT lymphoma; **OR**
  - Gastric MALT lymphoma; **OR**
  - Nodal marginal zone lymphoma; **OR**
  - Splenic marginal zone lymphoma

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug (e.g., ≥ grade 3 infections, uncontrolled hyperglycemia, uncontrolled hypertension, non-infectious pneumonitis, ANC < 0.5 x 10^3 cells/mm^3, severe cutaneous reactions); **AND**
- Tumor response with stabilization of disease or decrease in size of tumor or tumor spread.

ALPHA 1 PROTEINASE INHIBITOR

Length of Authorization:	1 Year, eligible for renewal
Initiative:	SPC: Alpha-1 Proteinase Inhibitor (IE 2462 / NCPDP 75 – HICL)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Emphysema due to alpha-1-antitrypsin (AAT) deficiency:

- Diagnosis of emphysema confirmed with pulmonary function testing; **AND**
- Patient has alpha-1-antitrypsin (AAT) deficiency with PiZZ, Pi*Z (null), or Pi* ([PiMS, PiMZ] phenotypes; **OR**
- Patient has other rare AAT disease-causing alleles associated with serum alpha 1-antitrypsin (AAT level < 11 µmol/L (e.g., Pi [Malton, Malton]; **AND**
- Patient has AAT deficiency and clinical evidence of panacinar emphysema; **AND**
- Patient has low serum concentration of AAT ≤ 11 Um/L (35% of normal) or ≤ 80 mg/Dl (if measured by radial immunodiffusion) or ≤ 0.8 g/L (if measured by nephelometry); **AND**
- Patient is currently a **non-smoker**

RENEWAL CRITERIA

Authorizations can be renewed based on the following criteria:

- Disease response with treatment as defined by elevation of AAT levels above baseline and/or, substantial reduction in rate of deterioration of lung function as measured by percent predicted FEV1; **AND**
- Patient is a current non-smoker
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include hypersensitivity reactions.

Additional Clinical information:

- GLASSIA is contraindicated in IgA deficient patients with antibodies against IgA.
- GLASSIA is contraindicated in individuals with a history of severe immediate hypersensitivity reactions, including anaphylaxis, to Alpha1-PI products.

COVERED – PA REQUIRED
Aralast NP
Zemaira® vial
Prolastin® C vial

ALUNBRIG (BRIGATINIB)

Length of Authorization:	6 months, eligible for renewal
Initiative:	MNC: Non-Formulary Product (IE 50698 / MR – GSN PatOverride)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Non-Small Cell Lung Cancer (NSCLC):**

- Patient is at least 18 years old; **AND**
- Must be used as a single agent; **AND**
- Patient has advanced, metastatic or recurrent disease (excluding locoregional recurrence or symptomatic local disease without evidence of disseminated disease) or mediastinal lymph node recurrence with prior radiation therapy; **AND**
- Patient's disease is anaplastic lymphoma kinase (ALK) positive as detected by an FDA-approved or CLIA compliant test.

Diagnosis of **Central Nervous System Cancers-Brain Metastases:**

- Patient is at least 18 years old; **AND**
- Must be used as a single agent; **AND**
- Patient has brain metastases from ALK-positive Non-Small Cell Lung Cancer; **AND**
  - Used as initial treatment of with small, asymptomatic brain lesions; **OR**
  - Used for relapsed disease in patients with limited brain metastases and stable systemic disease or reasonable systemic treatment options; **OR**
  - Patient has recurrent limited brain metastases; **OR**
  - Used for recurrent disease in patients with extensive brain metastases and stable systemic disease or reasonable systemic treatment options

CLINICAL CRITERIA FOR RENEWAL

Authorizations can be renewed based on the following criteria:

- Tumor response with stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug (e.g., severe hypertension, bradycardia, interstitial lung disease/pneumonitis, visual disturbances, creatine phosphokinase [CPK] elevation, pancreatic enzyme elevation, severe hyperglycemia).

AMITIZA (LUBIPROSTONE)

Length of Authorization:	1 Year, eligible for renewal
Initiative:	MNC: Gastrointestinals: IBS Agents (IE 2462 / NCPDP 75 – HICL)

CLINICAL CRITERIA FOR APPROVAL

Diagnosis of **Opioid-Induced Constipation (OIC):**

- Patient is 18 years of age or older; **AND**
- Patient must have a diagnosis of OIC; **AND**
- Patient must have failed a trial of lactulose OR polyethylene glycol

Diagnosis of **Irritable Bowel Syndrome Constipation (IBS-C) or Chronic Idiopathic Constipation (CIC)**:

- Patient is 18 years of age or older; **AND**
- Patient must have a diagnosis of IBS-C **and** is female **or** have a diagnosis of CIC; **AND**
- Patient must have failed a trial of lactulose **or** polyethylene glycol

AMPYRA® (DALFAMPRIDINE)

Length of Authorization:	Initial: 6 months, Renewal: 1 year
Initiative:	MNC: Non-Formulary Product (IE 50698 / MR – GSN PatOverride)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Multiple Sclerosis (MS)**

- Patient is 18 years of age or older; **AND**
- Patient has no past medical history of seizures; **AND**
- Patient's creatinine clearance, determined within the last 6 months, is ≥ 50 mL/min; **AND**
- Confirmed diagnosis of MS as documented by laboratory report (i.e., MRI); **AND**
- Patient is currently on disease modifying therapy for MS (e.g., interferon beta-1a, interferon beta-1b, peginterferon beta-1a, glatiramer, teriflunomide, fingolimod, dimethyl fumarate, natalizumab, alemtuzumab, daclizumab, ocrelizumab); **AND**
- Expanded Disability Status Score (EDSS) ≥ 4 and < 7; **AND**
- Baseline timed 25 feet walk (T25W) between 8 and 60 seconds

CLINICAL CRITERIA FOR RENEWAL

- Patient has 20% improvement from baseline in timed 25 feet walk (T25W); **AND**
- Absence of unacceptable toxicity from the drug (e.g., seizures, renal impairment, anaphylaxis)

ANALGESICS: NARCOTICS: LONG-ACTING

Length of Authorization:	3–6 months, eligible for renewal 6 months for active oncology diagnosis with neoplasm related pain, hospice care/patient, or Palliative/End of Life Care
Initiative:	MNC: Narcotic Analgesics: Long-Acting (IE 2462 / NCPDP 75 – HICL, 50081 and 2193) MNC: MME Limitation Exceeded (IE 2709/NCPDP 76)

INITIAL CRITERIA FOR ALL LONG-ACTING NARCOTICS

Diagnosis of active oncology diagnosis with neoplasm related pain, hospice care patient, LTC/SNF patient, or Palliative/End of Life Care **ICD-10 Diagnosis Code (G89.3) can be entered by pharmacy at POS to bypass PA requirement for active oncology diagnosis**

- Approve for 6 months for palliative/end-of-life care, or hospice care
- Approve for 6 months for active oncology diagnosis with neoplasm related pain (ICD10 diagnosis code: G89.3)
- Approve for 6 months for sickle cell
- Approve for 6 months for patient who resides in an LTC facility or Skilled Nursing facility

Diagnosis of any other pain:

- Patient must be 18 years of age or older; **AND**
- Patient is inadequately controlled on short-acting (SA) opioid equivalent; **AND**
- Patient must require around the clock pain management; **AND**
- Patient must have chronic pain, greater than 3 months, **AND**
- Patient has a diagnosis of moderate to severe pain that can be defined by **ALL** of the following:
  - Non-responsive or inadequately responsive to non-pharmacologic treatment (i.e., physical therapy, pain psychology, alternative treatments);
  - Non-responsive or inadequately responsive to non-opioid analgesic treatment (i.e., NSAIDs, APAP, gabapentin, lidocaine patch, muscle relaxers)
  - Significantly impairs physical functioning (i.e., sleep, work, activities of daily living); **AND**
- The prescriber attests to monitoring the state prescription monitoring program (PMP) prior to prescribing any controlled medications (if available in the state); **AND**
- Patient does not have a documented history of opioid addiction or abuse; **AND**
- The patient is not currently undergoing active treatment for opioid addiction; **AND**
- The prescriber attests to having a treatment plan in place with the patient that addresses such things as benefits and harms of opioid use, expectations and goals of treatment, stipulations for continued treatment such as functional improvement, a single opioid prescriber and/or regular dispensing pharmacy; **AND**
- The prescriber attests to completing a urine drug screen at least annually, with date of last drug screen provided.
- The prescriber provides the underlying condition causing the patient pain; **AND**
- The prescriber has consulted with a pain specialist (prescriber must consult with pain specialist >90 MME/day); **AND**
- The patient has been offered counseling on the risks of overdose, addiction, and/or drug diversion; **AND**
- The patient is not on a benzodiazepine or sedative hypnotic; **AND**
- A naloxone kit is being prescribed; **AND**
- The prescriber provides a list of concurrent pain treatments being used (i.e., non-opioid medications, physical therapy, etc.)
- The patient is receiving or is scheduled to receive counseling for weaning opioids, undergoing active dose titration, or stabilized for a chronic condition that requires ongoing therapy:
  - If stable, can approve for 6 months; **OR**
  - If weaning or undergoing active dose titration, only approve for 3 months

  Note: Clinical judgment can be used by pharmacists for approval if all the above criteria is not met.

DRUG SPECIFIC CRITERIA IN ADDITION TO ABOVE CRITERIA

- **Butrans** will be approved based on **ALL** of the following criteria:
  - Not to be approved for acute or post-operative pain
  - Patient is not on a benzodiazepine
  - Patient is not on another opioid agonist
  - Patient does not actively abuse alcohol

CLINICAL CRITERIA FOR RENEWAL

- Initial request criteria must be met; **AND**
- Patient is stabilized on current regimen

90 MME MAXIMUM EDIT

Note: MME limit can be approved by technicians

A health professional may write for a prescription that is more than 90 MME per day if:

- The health professional is a board-certified pain specialist; **OR** has consulted with a board-certified pain specialist; **OR** if the consulting board certified physician is not available for consult within 48 hours, they must provide that the consultation will now occur subsequent to the prescription being issued; **OR**
- It is a continuation of a prior prescription order issued within the previous 60 days; **OR**
- It is an opioid with a maximum approved total daily dose in the labeling as approved by the U.S. Food and Drug Administration (FDA); **OR**
- It is for a patient who has an active oncology diagnosis or a traumatic injury, not including a surgical procedure; **OR**
- It is for a patient who is hospitalized; **OR**
- It is for a patient who is receiving hospice care, end-of-life care, palliative care, skilled nursing facility care or treatment for burns; **OR**
- It is for a patient who is receiving MAT for a substance use disorder

COVERED – PA REQUIRED
Butrans® (buprenorphine) **patch BRAND ONLY**
Fentanyl patches (generic for Duragesic®)
Morphine ER tab (generic for MS Contin®)
Tramadol ER tab (generic for Ultram® ER)
Xtampza® ER (oxycodone) **BRAND ONLY**

ANALGESICS: NARCOTICS: SHORT-ACTING

Length of Authorization:	Varies per diagnosis: See details below
Initiative:	MNC: Short-Acting Opioid: Acute Use (IE 2708, 7008, 2641, 15110/NCPDP 75, IE 2614/NCPDP 76) MNC: Short-Acting Opioid: Chronic Use (IE 2708, 7008, 2641, 15110/NCPDP 75, IE 2614/NCPDP 76) MNC: MME Limitation Exceeded (IE 2709/NCPDP 76)

5-DAY SUPPLY LIMIT OF NARCOTICS: SHORT-ACTING (MAX OF TWO 5-DAY SUPPLY IN ROLLING 30-DAY PERIOD)

Members may not receive more than two 5-day supplies in a 30-day period without a Prior Authorization on file

Requests that meet the following criteria can be approved for exclusion from the 5-day Supply Limitation:

- **Post-Surgical Procedures**
  - **Initial** prescriptions for short-acting opioid medications for post-surgical procedures are limited to a supply of no more than 14 days. Approve for treatment duration requested, not to exceed 14-day supply.
  - **Refill** prescriptions for short-acting opioid medications for post-surgical procedures are limited to no more than a 5-day supply. Approve for treatment duration requested, not to exceed 5-day supply.
- **Diagnosis of Active Cancer pain, Sickle cell, Palliative/End-of-Life Care or hospice patient**
  - Approve for 6 months for Palliative/End-of-Life Care or hospice patient
  - Approve for 6 months for active cancer pain or sickle cell
- **Patient resides in an LTC facility or Skilled Nursing facility**
  - Approve for 6 months
- **Children on opioid wean at time of hospital discharge**
  - Approve for the duration of the prescription
- **Traumatic injury (excluding post-surgical procedures)**
  - Approve for the duration of the prescription
- **Diagnosis of any other pain (Acute or Chronic):**
  - Patient must be 18 years of age or older; **AND**
  - Patient has a diagnosis of moderate to severe pain that can be defined by **ALL** of the following:
  - Non-responsive or inadequately responsive to non-pharmacologic treatment (i.e., physical therapy, pain psychology, alternative treatments); **AND**
  - Non-responsive or inadequately responsive to non-opioid analgesic treatment (i.e., NSAIDs, APAP, gabapentin, lidocaine patch, muscle relaxers); **AND**
  - Significantly impairs physical functioning (i.e., sleep, work, activities of daily living); **AND**
  - The prescriber attests to monitoring the state prescription monitoring program (PMP) prior to prescribing any controlled medications (if available in the state); **AND**
  - Patient does not have a documented history of opioid addiction or abuse; **AND**
  - The patient is not currently undergoing active treatment for opioid addiction; **AND**
  - The prescriber provides the underlying condition causing the patient pain; **AND**
  - The patient has consulted with a pain specialist (prescriber must consult with pain specialist >90 MME/day); **AND**
  - The patient has been offered counseling on the risks of overdose, addiction, and/or drug diversion, **AND**
  - The patient is not on a benzodiazepine or sedative hypnotic, **AND**
  - A naloxone kit is being prescribed; **AND**
  - The prescriber provides a list of concurrent pain treatments being used (i.e., non-opioid medications, physical therapy, etc.); AND

– **For Acute pain:**
  - If less than 30 days requested, authorize for indicated treatment duration permitting the other conditions above are met.
  - If greater than 30 days requested, authorize for 30 days only permitting the other conditions above are met. Requires reauthorization after 30 days.

  For Chronic pain:
  - The prescriber attests to having a treatment plan in place with the patient that addresses such things as benefits and harms of opioid use, expectations and goals of treatment, stipulations for continued treatment such as functional improvement, a single opioid prescriber and/or regular dispensing pharmacy; **AND**
  - The prescriber attests to completing a urine drug screen at least annually, with date of last drug screen provided.
  - If the patient is stable on current regimen, approve for 6 months
  - If the patient is weaning or undergoing active dose titration, approve for 3 months

Note: Clinical judgment can be used by pharmacists for approval if all the above criteria is not met.

90 MME MAXIMUM EDIT

Note: MME limit can be approved by technicians

A health professional may write a prescription that is for more than 90 MME per day if:

- The health professional is a board-certified pain specialist **OR** has consulted with a board-certified pain specialist; **OR** if the consulting board certified physician is not available for consult within 48 hours, they must provide that the consultation will occur subsequent to the prescription being issued; **OR**
- It is a continuation of a prior prescription order issued within the previous 60 days; **OR**
- It is an opioid with a maximum approved total daily dose in the labeling as approved by the U.S. Food and Drug Administration (FDA); **OR**
- It is for a patient who has an active oncology diagnosis or a traumatic injury, not including a surgical procedure; **OR**
- It is for a patient who is hospitalized; **OR**
- It is for a patient who is receiving hospice care, end-of-life care, palliative care, skilled nursing facility care, or treatment for burns; **OR**
- It is for a patient who is receiving MAT for a substance use disorder

ANDROGENS

STANDARD FORMULARY CRITERIA

Length of Authorization:	1 year
Initiative:	MNC: Androgens (IE 2462 / NCPDP 75 – HICL)

CLINICAL CRITERIA FOR INITIAL APPROVAL

- Documentation of low (low or normal for renewals) testosterone levels within the last year
  - Diagnosis of Primary hypogonadism (congenital or acquired) — testicular failure due to cryptorchidism, bilateral torsions, orchitis, vanishing testis syndrome; or orchidectomy; **OR**
  - Hypogonadotropic hypogonadism (congenital or acquired) — idiopathic gonadotropin or LHRH deficiency, or pituitary hypothalamic injury from tumors, trauma, or radiation.
    - If the above conditions occur prior to puberty, androgen replacement therapy will be needed during the adolescent years for development of secondary sexual characteristics. Prolonged androgen treatment will be required to maintain sexual characteristics in patients who develop testosterone deficiency after puberty; **OR**
  - Androgens may be used to stimulate puberty in carefully selected males with clearly delayed puberty. These patients usually have a familial pattern of delayed puberty that is not secondary to a pathological disorder; puberty is expected to occur spontaneously at a relatively late date. Brief treatment with conservative doses may occasionally be justified in these patients if they do not respond to psychological support. The potential adverse effect on bone maturation should be discussed with the patient and parents prior to androgen administration. An X-ray of the hand and wrist to determine bone age should be obtained every 6 months to assess the effect of treatment on the epiphyseal centers; **OR**
  - Replacement therapy in conditions associated with a deficiency or absence of endogenous testosterone; **AND**
  - Two pre-treatment serum total testosterone levels less than 280 ng/DL (9.7 nmol/L) taken at separate times (document lab value and date for both levels); **AND**
  - Patient is not taking:
    - Growth hormone (e.g., Genotropin, Humatrope, Norditropin, omni trop, Saizen, Serostim, Zorbtive); **OR**
    - Aromatase inhibitor (e.g., Arimidex [anastrozole] Femara [letrozole], Aromasin [exemestane]); **AND**
  - One of the following:
    - Significant reduction in weight (less than 90% of ideal body weight) (e.g., AIDS wasting syndrome)
    - Osteopenia
    - Osteoporosis
    - Decreased bone density
    - Decreased Libido
    - Organic cause of testosterone deficiency (e.g., injury, tumor, infection, or genetic defects)

Note: Per 2019 BEERS criteria update, testosterone should be avoided in patients greater than or equal to 65 years of age unless indicated for moderate to severe hypogonadism.

- Oral testosterone agents (other than Striant®) may be approved for a diagnosis of inoperable metastatic breast cancer (postmenopausal) or if the patient had tried and failed on Danazol®.
  - A trial on the injectable dosage form is not required.

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Androgens may be used secondarily in patients with advancing inoperable metastatic (skeletal) mammary cancer who are 1 to 5 years postmenopausal. Primary goals of therapy in these patients include ablation of the ovaries. Other methods of counteracting estrogen activity are adrenalectomy, hypophysectomy, and/or antiestrogen therapy. This treatment has also been used in premenopausal patients with breast cancer who have benefitted from oophorectomy and are considered to have a hormone-responsive tumor. Judgment concerning androgen therapy should be made by an oncologist with expertise in this field.

Contraindications:

- Known or suspected carcinoma of the prostate
- Known or suspected carcinoma of the breast
- Severe renal or cardiac disease
- Benign prostatic hyperplasia with obstruction
- Pregnancy
- Undiagnosed genital bleeding
- Breast Cancer

OXANDRIN®

Initiative: MNC: Non-Formulary Product (IE 50698 / MR – GSN PatOverride)

- Do not have to meet other criteria above
- Diagnosis of bone pain: for the relief of bone pain frequently accompanying osteoporosis
- Diagnosis of Protein catabolism: To offset the protein catabolism associated with prolonged administration of corticosteroids
- Diagnosis of weight gain: Adjunctive therapy to promote weight gain after weight loss following extensive surgery, chronic infections, or severe trauma, and in some patients who, without definite pathophysiologic reasons, fail to gain or maintain normal weight.

CLINICAL CRITERIA FOR RENEWAL

- Patient has had a disease response

Preferred drugs – PA REQUIRED
Androderm® PATCH (testosterone)
AndroGel® (testosterone)
Testosterone cypionate (generic Depo-Testosterone)
Testosterone enanthate

ANTI-ARRHYTHMICS

Length of Authorization:	1 year
Initiative:	MNC: Anti-Arrhythmic (IE 2462 / NCPDP 75 – HICL)

MULTAQ

INITIAL CRITERIA

- Patient is **NOT** taking any of the following antiarrhythmics:
  - Amiodarone (Cordarone®, Pacerone®);
  - Disopyramide, Disopyramide SA (Norpace®, Norpace CR®)
  - Dofetilide (Tikosyn®)
  - Flecainide (Tambocor®)
  - Ibutilide
  - Mexiletine
  - Propafenone, Propafenone SR (Rythmol®, Rythmol SR®)
  - Quinidine gluconate, Quinidine sulfate
  - Sotalol, Sotalol AF (Betapace®, Betapace AF®); **AND**
- Patient has a diagnosis of atrial fibrillation (AF) in sinus rhythm, **AND**
  - Patient has a history of paroxysmal or persistent AF; **AND**
  - Patient does **NOT** have PERMANENT AF (cannot be cardioverted into normal sinus rhythm) **OR** recent decompensated heart failure (HF) requiring hospitalization **OR** NYHA Class IV HF; **AND**
  - The patient has their cardiac rhythm monitored at least once every 3 months; **AND**
  - The patient is being monitored for liver and pulmonary toxicity at least once every 3 months; **AND**
  - The patient is **NOT** on greater than Simvastatin 10 mg; **AND**
  - The patient does **NOT** have severe hepatic impairment.

RENEWAL CRITERIA

- The patient is in sinus rhythm; **AND**
- The patient does **NOT** have new or worsening heart failure; **AND**
- The patient does **NOT** have liver injury; **AND**
- The patient does **NOT** have signs of pulmonary toxicity (i.e., shortness of breath, unproductive cough, etc.); **AND**
- The patient does **NOT** have hypokalemia and hypomagnesemia; **AND**
- The patient does **NOT** have QT prolongation; **AND**
- Patient is free of any other unacceptable toxicity from the medication.

DOFETILIDE (GENERIC TIKOSYN)

INITIAL CRITERIA

- Patient must be ≥ 18 years old; **AND**
- Must have a diagnosis of atrial fibrillation or atrial flutter; **AND**
- Patient requires either conversion to normal sinus rhythm or maintenance of normal sinus rhythm; **AND**
- Attestation that patient started dofetilide in the hospital for a minimum of 3 days; **AND**
- Patient will not receive concomitant therapy with any of the following contraindicated medications: verapamil, cimetidine, trimethoprim alone or in combination with sulfamethoxazole, ketoconazole, or hydrochlorothiazide alone or in combination with triamterene; **AND**
- Patient does not have congenital or acquired long QT syndromes; **AND**
- Patient does not have severe renal impairment (CrCl < 20 mL/min).

RENEWAL CRITERIA

- Patient continues to meet the above criteria; **AND**
- Patient has not experienced any treatment-restricting adverse effects (e.g., ventricular arrhythmias, hypokalemia)

COVERED
Amiodarone (generic for Cordarone®, Pacerone®)
Disopyramide (generic for Norpace®)
Flecainide (generic for Tambocor®)
Mexiletine (generic for Mexitil®)
Norpace CR® (disopyramide SA)
Pacerone® (amiodarone)
Propafenone (generic for Rythmol®)
Propafenone ER (generic for Rythmol SR®)
Quinidine gluconate
Quinidine sulfate
Dofetilide (generic for Tikosyn®) – PA required (see criteria above)
Multaq® (dronedarone) – PA required (see criteria above)

ANTICONVULSANTS

STANDARD FORMULARY CRITERIA

Length of Authorization:	1 year
Initiative:	MNC: Anticonvulsants (IE 2462 / NCPDP 75 – HICL, 50081 and 2193) SPC: Anticonvulsants (IE 2462 / NCPDP 75 – HICL, 50081 and 2193)—Sabril (vigabatrin), Onfi

CLINICAL CRITERIA

CLOBAZAM (GENERIC ONFI®)

- Diagnosis of adjunctive therapy for Lennox-Gastaut syndrome when used in combination with at least one other anticonvulsant; **AND**
- Patient is not taking any other benzodiazepines; **AND**
- Patients is not taking an opioid

COVERED
Carbamazepine (generic for Tegretol®, Epitol®)
Carbamazepine ER (generic for Tegretol XR®)
Carbamazepine SR 12 hour (generic for Carbatrol®)
Carbamazepine chewable tablet, suspension
Dilantin® Kapseal 30 mg (phenytoin)
Divalproex sodium EC (generic for Depakote®)
Divalproex sodium 24 hour (generic Depakote ER®)
Divalproex sodium sprinkles (generic Depakote® Sprinkles)
Epitol® (carbamazepine)
Ethosuximide capsule, solution (generic for Zarontin®)
Felbamate tablet, suspension (generic for Felbatol®)
Gabapentin capsule, tablet, solution (generic for Neurontin®)
Lamictal XR® kits (lamotrigine ER)
Lamotrigine tablet, chewable (generic for Lamictal®)
Lamotrigine ER (generic for Lamictal XR®)
Lamotrigine ODT (Lamictal ODT®)
Levetiracetam tablet, solution (generic for Keppra®)
Levetiracetam ER (generic for Keppra XR®)
Oxcarbazepine tablet, suspension (generic for Trileptal®)
Phenytoin tablet, ER capsule, suspension (generic for Dilantin®, Phenytek®)
Primidone (generic for Mysoline®)
Topiramate (generic for Topamax®), and topiramate sprinkles (generic for Topamax® sprinkles)

COVERED
Trokendi XR® (topiramate ER)
Valproic acid capsule, solution (generic for Depakene®)
Zonisamide (generic for Zonegran®)
Ziprasidone HCL (generic for Geodon®)
Banzel® (rufinamide) – PA required (refer to Banzel® criteria page)
Pregabalin IR capsule, solution (generic for Lyrica®) – PA required (refer to Lyrica® criteria page)
Clobazam (generic for Onfi®) – PA required (see criteria above)
Tiagabine (generic for Gabitril®) – PA required (refer to Gabitril® criteria page)
Vimpat® (lacosamide) – PA required (refer to Vimpat® criteria page)

ANTIFUNGALS: ORAL

Length of Authorization:	FOR THE DURATION OF THE RX OR UP TO A YEAR
Initiative:	MNC: Antifungals (IE 2462 / NCPDP 75 – GSN, 50081 and 2193) MNC: Non-Formulary Product (IE 50698 / MR – GSN PatOverride)

CLINICAL CRITERIA

ITRACONAZOLE (SPORANOX) CAPSULE/SOLUTION – APPROVAL FOR 6 MONTHS

- Patient has one of the following diagnoses:
  - Febrile neutropenia
  - Aspergillus
  - Blastomycosis
  - Histoplasmosis
  - Cryptococcosis
  - Coccidiomycosis
  - Oropharyngeal/esophageal candidiasis
  - Any candida krusei infection
  - Diagnosis of Onychomycosis
  - Any other systemic fungal infections including (but not limited to): Chronic mucocutaneous candidiasis, Allescheriosis, Chromomycosis, Paracoccidioidomycosis, Sporotrichosis; **AND**
- The patient is not a candidate for a preferred antifungal therapy, such as fluconazole (e.g., the patient has experienced an inadequate response, intolerance, or contraindication)

ONMEL - APPROVAL FOR 6 MONTHS

- Diagnosis of onychomycosis of the toenail caused by trichophyton rubrum or T. mentagrophytes; **AND**
- Cannot tolerate treatment with oral terbinafine or fail to respond to terbinafine; **AND**
- Has a medical reason why a generic itraconazole cannot be used.

VORICONAZOLE (VFEND) TABLET/SOLUTION – APPROVAL FOR 1 YEAR

INITIAL CRITERIA

- Patient is 2 years of age or older; **AND**
- Patient is diagnosed with one of the following infections:
  - Invasive aspergillosis; **OR**
  - Candidemia in non-neutropenics and other deep tissue Candida infections (disseminated infections in skin and infections in abdomen, kidney, bladder wall, and wounds); **OR**
  - Esophageal candidiasis; **OR**
  - Serious fungal infections caused by Scedosporium apiospermum and Fusarium species including Fusarium solani; **OR**
  - Patient is intolerant of, or refractory to, other therapy; **AND**
- The patient is not a candidate for a preferred antifungal therapy, such as fluconazole (e.g., the patient has experienced an inadequate response, intolerance, or contraindication, etc.); **AND**

VORICONAZOLE (VFEND) TABLET/SOLUTION – APPROVAL FOR 1 YEAR *(CONTINUED)*

INITIAL CRITERIA (CONTINUED)

- Patient does not have a contraindication to therapy:
  - Coadministration with cisapride, pimozide or quinidine, sirolimus, rifampin, carbamazepine, long-acting barbiturates, efavirenz, ritonavir, rifabutin, ergot alkaloids, and St. John's Wort
  - Hypersensitivity to therapy; **AND**
- For oral solution: Rationale for why the patient cannot take an oral tablet must be provided

RENEWAL CRITERIA

- Patient continues to require antifungal therapy; **AND**
- Absence of unacceptable toxicity from the drug

POSACONAZOLE (NOXAFIL) TABLET/SUSPENSION – APPROVAL FOR REQUESTED DURATION UP TO 6 MONTHS

INITIAL CRITERIA

- Patient is 13 years of age or older; **AND**
- Patient is severely immunocompromised and requires prophylaxis of invasive Aspergillus and Candida infections (e.g., hematopoietic stem cell transplant [HSCT] recipients with graft-versus-host disease [GVHD] or those with hematologic malignancies with prolonged neutropenia from chemotherapy); **AND**
- The patient is not a candidate for a preferred antifungal therapy, such as fluconazole (e.g., the patient has experienced an inadequate response, intolerance, or contraindication, etc.); **AND**
- Patient does not have any contraindications to therapy:
  - Concomitant use with ergot alkaloids, sirolimus, CYP3A4 substrates that prolong the QT interval (e.g., pimozide and quinidine), HMG-CoA reductase inhibitors that are primarily metabolized through CYP3A4 (e.g., atorvastatin, lovastatin, and simvastatin); **AND**
  - Hypersensitivity to therapy

RENEWAL CRITERIA

- Patient continues to require antifungal therapy; **AND**
- Absence of unacceptable toxicity from the drug

COVERED – NO PA REQUIRED
Fluconazole tablet, suspension (generic for Diflucan®)
Griseofulvin ultramicrosize tablets (generic for Gris-PEG®)
Griseofulvin micronized tablets (generic for Grifulvin V®)
Griseofulvin suspension (generic for Grifulvin V®)
Nystatin suspension, tablet, capsule
Terbinafine tablet, packets (generic Lamisil®)

ANTIPARASITICS

Length of Authorization:	1 month or length of therapy for parasite, eligible for renewal
Initiative:	MNC: Antiparasitics (IE 2462 / NCPDP 75 – GSN)

CLINICAL CRITERIA

- Albendazole (generic Albenza®) will be approved for: Hydatid disease (dog tapeworm) caused by *Echinococcus granulosus*, neurocysticercosis (pork tape worm) caused by *Taenia solium*, hookworm, and pinworm.
- Ivermectin (generic Stromectol®) will be approved for: intestinal (i.e., non-disseminated) strongyloidiasis due to nematode parasite, strongyloides stercoralis and onchocerciasis due to the nematode parasite *Onchocerca volvulus*.

STEP CRITERIA: NATROBA, SKLICE

- Patient has had a trial and failure of permethrin.

COVERED
Permethrin
Praziquantel (generic Biltricide®)
Emverm® tablet chew (generic mebendazole tablet chew)
Albendazole (Albenza®) – PA required (see criteria above)
Ivermectin (generic for Stromectol®)– PA required (see criteria above)
Natroba® (*spinosad*) – PA required (see criteria above)
Spinosad (generic for Natroba®)– PA required (see criteria above)
Sklice® (*ivermectin*) – PA required (see criteria above)

ANXIOLYLTICS

Length of Authorization:	Length of the prescription
Initiative:	MNC: Sedative/Anxiolytic QL Override (IE 7008/NCPDP 75)

PRIOR AUTHORIZATION REQUIRED WHEN MEMBER IS CONCURRENTLY TAKING > 1 ANXIOLYTIC DRUG WITHIN A 30 DAY OVERLAP TIME PERIOD

To include the following HSNS: 001617, 001620, 001610, 001612, 001615, 004846, 001616, 001894

The clinical pharmacist will use professional judgment whether to approve or escalate to MRIOA for denial.

COVERED – NO PA REQUIRED
Alprazolam 0.25 mg, 0.5 mg, 1 mg, 2 mg tablets, intensol
Alprazolam ER/XR 0.5 mg, 1 mg, 2 mg, 3 mg tablets
Alprazolam ODT 0.25 mg, 0.5 mg, 1 mg, 2 mg tablets
Buspirone 5 mg, 7.5 mg, 10 mg, 15 mg, 30 mg tablets
Chlordiazepoxide 5 mg, 10 mg, 25 mg capsules
Clonazepam 0.5 mg, 1 mg, 2 mg tablets
Clonazepam ODT 0.125 mg, 0.25 mg, 0.5 mg, 1 mg, 2 mg
Clorazepate 3.75 mg, 7.5 mg, 15 mg tablets
Diazepam 2 mg, 5 mg, 10 mg tablets
Diazepam 5 mg/mL conc/soln, 5 mg/mL vial/syringe
Lorazepam 0.5 mg, 1 mg, 2 mg tablets, oral conc, intensol
Oxazepam 10 mg, 15 mg, 30 mg capsules

ANZEMET (DOLASETRON)

Length of Authorization:	For requested duration, up to 6 months
Initiative:	MNC: MNC: Antiemetics (IE 2462 / NCPDP 75 – HICL)

CLINICAL CRITERIA FOR INITIAL APPROVAL

- Patient is 2 years of age or older; **AND**
- Medication will be used for the prevention of nausea and vomiting associated with moderately emetogenic cancer chemotherapy, including initial and repeat courses

CLINICAL CRITERIA FOR RENEWAL

- Patient continues to meet initial criteria; **AND**
- Absence of unacceptable toxicity from the drug

APREPITANT CAPSULES (EMEND)

Length of Authorization:	For requested duration, up to 6 months
Initiative:	MNC: Antiemetics (IE 2462 / NCPDP 75 – HICL)

CLINICAL CRITERIA FOR INITIAL APPROVAL

- Patient is at least 12 years of age; **AND**
- Used in combination with other antiemetic medications (e.g., corticosteroid and a serotonin receptor antagonists) for:
  - Prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy (HEC); **OR**
  - Prevention of nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy (MEC); **OR**
  - Prevention of postoperative nausea and vomiting

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug

ARCALYST® (RILONACEPT)

Length of Authorization:	6 months and may be renewed
Initiative:	MNC: Non-Formulary Product (IE 50698 / MR – GSN PatOverride)

CLINICAL CRITERIA FOR INITIAL APPROVAL

- Diagnosis of Cryopyrin-Associated Periodic Syndromes (CAPS)
- Must not be administered concurrently with live vaccines; **AND**
- Patient has been evaluated and screened for the presence of latent TB infection prior to initiating treatment; **AND**
- Patient is not on concurrent therapy with other IL-1 blocking agents (e.g., canakinumab, anakinra, etc.) **AND**
- Patient is not on concurrent treatment with another TNF inhibitor, biologic response modifier or other non-biologic immunomodulating agent (i.e., apremilast, tofacitinib, baricitinib); **AND**
- Patient does not have an active infection, including clinically important localized infections; **AND**
- Patient is over the age of 12; **AND**
- Patient has documented laboratory evidence of a genetic mutation in the Cold-Induced Auto-inflammatory Syndrome 1 (CIAS1), also known as NLRP3; **AND**
  - Documented diagnosis of Familial Cold Autoinflammatory Syndrome (FCAS); **OR**
  - Documented diagnosis of Muckle-Wells Syndrome (MWS); **AND**
- Patient has documented baseline serum levels of inflammatory proteins (C-Reactive Protein [CRP] and/or Serum Amyloid A [SAA], etc.); **AND**
- Patient has two or more of any of the CAPS-typical symptoms:
  - Urticaria-like rash
  - Cold-triggered episodes
  - Sensorineural hearing loss
  - Musculoskeletal symptoms
  - Chronic aseptic meningitis
  - Skeletal abnormalities

CLINICAL CRITERIA FOR RENEWAL

- Disease response as indicated by improvement in patient's symptoms from baseline **and** improvement in serum levels of C-Reactive Protein (CRP) and Serum Amyloid A (SAA) from baseline; **AND**
- Absence of unacceptable toxicity from the drug (e.g., severe hypersensitivity reactions, serious infections [including but not limited to tuberculosis], lipid profile changes); **AND**
- Patient is receiving ongoing monitoring for presence of TB or other active infections.

ARIMIDEX (ANASTROZOLE)

Length of Authorization:	1 Year, eligible for renewal
Initiative:	MNC: Miscellaneous: PA Required (IE 2462 / NCPDP 75 – GSN)

CLINICAL CRITERIA ANASTROZOLE

- Patient is 18 years of age or older; **AND**
- Patient is female; **AND**
- Patient is postmenopausal; **AND**
- Patient must have a diagnosis of one of the following:
  - hormone receptor-positive early breast cancer; **OR**
  - hormone receptor-positive or hormone receptor unknown locally advanced or metastatic breast cancer; **OR**
  - advanced breast cancer with disease progression following tamoxifen therapy.

ARMODAFINIL (NUVIGIL)

Length of Authorization:	1 Year
Initiative:	MNC: Non-Formulary Product (IE 50698 / MR – GSN PatOverride)

CLINICAL CRITERIA

- Diagnosis of Narcolepsy; OR
- Diagnosis of Obstructive Sleep Apnea- with CPAP; OR
- Diagnosis of Shift Work Disorder; OR
- Diagnosis of Hypersomnia, OR
- Diagnosis of fatigue related to cancer; OR
- Diagnosis of Fatigue related to multiple sclerosis
  - Tried and failed amantadine within the past year; **AND**
  - Tried and failed a stimulant; **AND**
  - Documented compliance with current therapy

AROMASIN® (EXEMESTANE TABLET)

Length of Authorization:	12 months
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

- Use as adjuvant treatment of postmenopausal women with estrogen receptor-positive early breast cancer who have received two to three years of tamoxifen and are switched to Aromasin for completion of a total of five consecutive years of adjuvant hormonal therapy; **OR**
- Diagnosis of advanced breast cancer in postmenopausal women whose disease has progressed following tamoxifen therapy; **AND**
- Patient does not have any of the following contraindications:
  - Known hypersensitivity to the drug or to any of the excipients

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug

ARRANON® (NELARABINE)

Length of Authorization:	6 months and may be renewed
Initiative:	MNC: Non-Formulary Product (IE 50698 / MR – GSN PatOverride)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **adult-young adult/adult T-cell acute lymphoblastic leukemia and T-cell lymphoblastic lymphoma**

- Patient is 18 years or older (unless otherwise specified); **AND**
  - Patient has not responded to or has relapsed following treatment with two or more chemotherapy regimens; **OR**
  - Used as induction and/or consolidation therapy as a component of COG AALL0434 regimen (daunorubicin, vincristine, prednisone, and pegaspargase); **AND**
    - Patient is 15 years or older; **AND**
    - Patient is Philadelphia chromosome-negative; **OR**
  - Used for relapsed/refractory disease; **AND**
    - Patient has Philadelphia chromosome-negative disease; **AND**
      - Used as a single agent; **OR**
      - Used in combination with etoposide and cyclophosphamide in young and fit patients; **OR**
    - Patient is Philadelphia chromosome-positive; **AND**
      - Patient is refractory to tyrosine kinase inhibitor therapy (e.g., imatinib, dasatinib, ponatinib, nilotinib, bosutinib).

Diagnosis of **pediatric acute lymphoblastic leukemia**

- Patient is 1 year or older; **AND**
  - Patient has not responded to or has relapsed following treatment with two or more chemotherapy regimens ; **OR**
  - Used as consolidation therapy as a component of COG AALL0434 regimen (daunorubicin, vincristine, prednisone, and pegaspargase); **OR**
  - Used for relapsed or refractory disease in combination with etoposide and cyclophosphamide

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug (e.g., any severe neurologic [central and/or peripheral] adverse reactions, severe anemia/leukopenia/anemia/thrombocytopenia, tumor lysis syndrome)

ARZERRA® (OFATUMUMAB)

Length of Authorization:	6 months, may be renewed (see renewal lengths under clinical criteria for renewal)
Initiative:	MNC: Non-Formulary Product (IE 50698 / MR – GSN PatOverride)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma** (SLL)

- Patient is 18 years or older; **AND**
- Patient must be screened for HBV infection (i.e., HBsAg and anti-HBc) prior to initiating therapy; **AND**
- Must not be administered concurrently with live vaccines; **AND**
- Used as first-line therapy in combination with chlorambucil; **OR**
- Used for relapsed or refractory disease; **AND**
  - Used as a single agent; **OR**
  - Used in combination with fludarabine and cyclophosphamide (FC); **OR**
- Used as extended treatment in patients with complete or partial response after 2 or more lines of therapy; **AND**
  - Used as a single agent; **OR**
- Used as first-line therapy in combination with bendamustine; **AND**
  - Patient does not have del(17p)/TP53 mutation; **AND**
  - Patient is not considered to be frail with significant comorbidities

Diagnosis of **B-Cell Lymphomas**

- Patient is 18 years or older; **AND**
- Patient must be screened for HBV infection (i.e., HBsAg and anti-HBc) prior to initiating therapy; **AND**
- Must not be administered concurrently with live vaccines; **AND**
- Follicular Lymphoma
  - Patient has grade 1-2 disease; **AND**
  - Used as a substitute for rituximab or obinutuzumab in patients experiencing rare complications such as mucocutaneous reactions including paraneoplastic pemphigus, Stevens-Johnson syndrome, lichenoid dermatitis, vesiculobullous dermatitis, and toxic epidermal necrolysis; **OR**
- MALT Lymphoma (Gastric or Non-Gastric) or Marginal Zone Lymphoma (Splenic or Nodal);**AND**
  - Used as a substitute for rituximab or obinutuzumab in patients experiencing rare complications such as mucocutaneous reactions including paraneoplastic pemphigus, Stevens-Johnson syndrome, lichenoid dermatitis, vesiculobullous dermatitis, and toxic epidermal necrolysis; **OR**
- Histologic Transformation of Nodal Marginal Zone Lymphoma to Diffuse Large B-Cell Lymphoma, Mantle Cell Lymphoma, Diffuse Large B-Cell Lymphoma, High Grade B-Cell Lymphomas, Burkitt Lymphoma, AIDS Related B Cell Lymphomas, Post-Transplant Lymphoproliferative Disorders, or Castleman's Disease; **AND**
  - Used as a substitute for rituximab or obinutuzumab in patients experiencing rare complications such as mucocutaneous reactions including paraneoplastic pemphigus, Stevens-Johnson syndrome, lichenoid dermatitis, vesiculobullous dermatitis, and toxic epidermal necrolysis.

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Waldenström's Macroglobulinemia/Lymphoplasmacytic Lymphoma**

- Patient is 18 years or older; **AND**
- Patient must be screened for HBV infection (i.e., HBsAg and anti-HBc) prior to initiating therapy; **AND**
- Must not be administered concurrently with live vaccines; **AND**
- Used as a single agent OR as part of combination therapy; **AND**
  - Patient is intolerant to rituximab; **AND**
    - Patient has previously failed primary therapy; **OR**
    - Patient has progressive or relapsed disease

CLINICAL CRITERIA FOR RENEWAL

Coverage can be renewed based upon the following criteria:

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug (e.g., hepatitis B virus reactivation/infection, progressive multifocal leukoencephalopathy, severe infusion reactions, tumor lysis syndrome, cytopenias [neutropenia, anemia, and thrombocytopenia])
- CLL/SLL (first-line) may be renewed to allow for a total of 12 cycles
- CLL/SLL (relapsed or refractory) may not be renewed (unless the provisions for extended treatment have been met).
- CLL/SLL (extended treatment) may be renewed to provide for a total of 2 years of therapy
- NHL/FL may be renewed to provide up to a total of 8 doses
- Waldenström's/Lymphoplasmacytic lymphoma may not be renewed

ASPARLAS® (CALASPARGASE PEGOL-MKNL)

Length of Authorization:	6 months and may be renewed
Initiative:	MNC: Non-Formulary Product (IE 50698 / MR – GSN PatOverride)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Acute lymphoblastic leukemia (ALL)**

- Patient age is 1 month up to 21 years old; **AND**
- Patient must not have a history of serious hypersensitivity, pancreatitis, severe hepatic impairment, thrombosis, or hemorrhagic events with prior L-asparaginase therapy; **OR**
- Must be used as a component of multi-agent chemotherapy; **AND**
- Patient has B-cell lineage acute lymphoblastic leukemia

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug (e.g., allergic reactions [including anaphylaxis], thrombosis, coagulopathy, severe hepatotoxicity, pancreatitis); **AND**
- Disease stabilization or improvement as evidenced by a complete response [CR] (i.e., morphologic, cytogenetic or molecular complete response CR), complete hematologic response or a partial response by CBC, bone marrow cytogenic analysis, QPCR, or FISH

ATOVAQUONE (MEPRON)

Length of Authorization:	1 Year
Initiative:	MNC: Non-Formulary Product (IE 50698 / MR – GSN PatOverride)

CLINICAL CRITERIA FOR APPROVAL

- For the treatment OR prevention of **Pneumocystis jirovecii pneumonia (PCP)**:
  - Patient must be 13 years of and older; **AND**
  - Patient cannot tolerate trimethoprim-sulfamethoxazole
- For the treatment of **Babesiosis**:
  - Must be used in combination with azithromycin
- For the treatment OR prevention of **Toxoplasma encephalitis in HIV patients**:
  - Patient cannot tolerate trimethoprim-sulfamethoxazole

AVASTIN® (BEVACIZUMAB), MVASI™ (BEVACIZUMAB-AWWB), ZIRABEV™ (BEVACIZUMAB-BVZR)

Length of Authorization:	6 months, May be renewed. For CNS cancers (symptom management), coverage will be provided for 12 weeks and may **not** be renewed.
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75 – HICL, 50081 and 2193) – Zirabev™ MNC: Non-Formulary Product (IE 50698 / MR – GSN PatOverride) – *Avastin® and MVASI™*

CLINICAL CRITERIA FOR INITIAL APPROVAL

Avastin® and MVASI™ - For new starts only, patient must have a documented failure, contraindication, intolerance, or ineffective response to a trial of Zirabev™

Diagnosis of **Colorectal Cancer (CRC)**

- Patient is at least 18 years of age; **AND**
- Patient has no recent history of hemoptysis (i.e., the presence of ≥ 2.5 mL of blood in sputum) **or** grade 3-4 hemorrhage; **AND**
- Patient must not have had a surgical procedure within the preceding 28 days or have a surgical wound that has not fully healed; **AND**
- Not used as part of adjuvant treatment; **AND**
  - Patient's disease is metastatic, unresectable or advanced; **AND**
    - Must be used as first- or second-line therapy in combination with a fluoropyrimidine (e.g., 5-fluorouracil/5-FU or capecitabine) or irinotecan- based regimen; **OR**
  - Used in combination with a fluoropyrimidine-irinotecan or fluoropyrimidine-oxaliplatin-based regimen (if not used first line) as second-line therapy for metastatic disease that has progressed on a first-line bevacizumab containing regimen.

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Non-Squamous Non-Small Cell Lung Cancer** (NSCLC):

- Patient is 18 years or older; **AND**
- Patient has no recent history of hemoptysis (i.e., the presence of ≥ 2.5 mL of blood in sputum) **or** grade 3-4 hemorrhage; **AND**
- Patient has had a surgical procedure within the preceding 28 days or has a surgical wound that has not fully healed; **AND**
- Used as first-line therapy for recurrent, locally advanced, unresectable, or metastatic disease in combination with carboplatin and paclitaxel; **OR**
- Used for recurrent, advanced, or metastatic disease (excluding locoregional recurrence or symptomatic local disease with no evidence of disseminated disease) or mediastinal lymph node recurrence with prior radiation therapy; **AND**
  - Used as first-line therapy for patients with EGFR, ALK, ROS1, BRAF, MET exon 14 skipping mutation, and RET rearrangement tumors negative and PD-L1 expression ≥ 1% with a PS ≤ 2 in combination with atezolizumab, carboplatin, and paclitaxel; **OR**
  - Used as first-line therapy in patients with PS ≤ 1 for patients with:
    - EGFR, ALK, ROS1, BRAF, MET exon 14 skipping mutation, and RET rearrangement negative tumors and PD-L1 < 1%; **OR**
    - BRAF V600E-mutation, NTRK gene fusion, MET exon 14 skipping mutation, or RET rearrangement positive tumors; **AND**
    - Used in combination with one of the following:
      - Carboplatin and pemetrexed; **OR**
      - Cisplatin and pemetrexed; **OR**
      - Atezolizumab, carboplatin, and paclitaxel; **OR**
  - Used as subsequent therapy in patients with PS ≤ 1 in patients with:
    - EGFR, ALK, ROS1, BRAF, MET exon 14 skipping mutation, or RET rearrangement positive tumors and prior targeted therapy**§** OR BRAF V600E-mutation positive disease or NTRK gene fusion positive tumors; **OR**
    - EGFR, ALK, ROS1, BRAF, MET exon 14 skipping mutation, and RET negative tumors with PD-L1 ≥ 1% and no prior platinum-doublet chemotherapy; **AND**
    - Used in combination with one of the following:
      - Carboplatin and either paclitaxel or pemetrexed; **OR**
      - Cisplatin and pemetrexed; **OR**
      - Atezolizumab, carboplatin, and paclitaxel; **AND**
  - Used as continuation maintenance therapy (*bevacizumab must have been included in patient's first-line chemotherapy regimen*) in patients with PS ≤ 2 who achieved a tumor response or stable disease after first-line systemic therapy; **AND**
    - Used as a single agent; **OR**
    - Used in combination with pemetrexed following a first-line bevacizumab/pemetrexed/platinum chemotherapy regimen; **OR**
    - Used in combination with atezolizumab following a first-line atezolizumab/carboplatin/paclitaxel/bevacizumab regimen; **OR**
  - Used in combination with erlotinib for sensitizing EGFR mutation positive disease as continuation of therapy following disease progression on erlotinib with bevacizumab for asymptomatic disease, symptomatic brain lesions, or isolated symptomatic systemic lesions.

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Cervical Cancer**:

- Patient is 18 years or older; **AND**
- Patient has no recent history of hemoptysis (i.e., the presence of ≥ 2.5 mL of blood in sputum) **or** grade 3–4 hemorrhage; **AND**
- Patient must not have had a surgical procedure within the preceding 28 days or have a surgical wound that has not fully healed; **AND**
- Patient's has persistent, recurrent, or metastatic; **AND**
- Used in combination with paclitaxel **and** either cisplatin, carboplatin, or topotecan.

Diagnosis of **Breast Cancer:**

- Patient is 18 years or older; **AND**
- Patient has no recent history of hemoptysis (i.e., the presence of ≥ 2.5 mL of blood in sputum) **or** grade 3–4 hemorrhage; **AND**
- Patient must not have had a surgical procedure within the preceding 28 days or have a surgical wound that has not fully healed; **AND**
- Patient must have recurrent or metastatic disease; **AND**
- Patient has a high tumor burden, rapidly progressive disease, or visceral crisis; **AND**
- Used in combination with paclitaxel; **AND**
- Patient must be human epidermal growth factor receptor 2 (HER2) negative; **AND**
  - Disease is hormone receptor negative; **OR**
  - Disease is hormone receptor positive with visceral crisis or refractory to endocrine therapy.

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Renal Cell Carcinoma (RCC):**

- Patient is 18 years or older; **AND**
- Patient has no recent history of hemoptysis (i.e., the presence of ≥ 2.5 mL of blood in sputum) **or** grade 3–4 hemorrhage; **AND**
- Patient must not have had a surgical procedure within the preceding 28 days or have a surgical wound that has not fully healed; **AND**
- Used in combination with interferon alfa for metastatic disease; **OR**
- Patient must have metastatic or relapsed disease; **AND**
  - Used as a single agent in patients with non-clear cell histology; **OR**
  - Used in combination with everolimus in patients with non-clear cell histology; **OR**
  - Used in combination with erlotinib in patients with non-clear cell histology papillary disease including hereditary leiomyomatosis and renal cell cancer (HLRCC).

Diagnosis of **Central Nervous System (CNS) Cancer**

- Patient is 18 years or older; **AND**
- Patient has no recent history of hemoptysis (i.e., the presence of ≥ 2.5 mL of blood in sputum) **or** grade 3–4 hemorrhage; **AND**
- Patient must not have had a surgical procedure within the preceding 28 days or have a surgical wound that has not fully healed; **AND**
- Used for symptom management related to radiation necrosis, poorly controlled vasogenic edema or mass effect as single-agent short-course therapy**; AND**
- Patient has a diagnosis of one of the following other CNS cancers:
  - Supratentorial astrocytoma/oligodendroglioma (low-grade infiltrative, WHO grade II); **OR**
  - Primary CNS lymphoma; **OR**
  - Meningiomas**; OR**
  - Brain, spine, or leptomeningeal metastases**; OR**
  - Medulloblastoma**; OR**
  - Glioblastoma or anaplastic gliomas**; OR**
  - Intracranial or spinal ependymoma (excluding subependymoma)**; OR**
- Used as a single agent **or** in combination with one of the following: carmustine, lomustine, or temozolomide in patients with recurrent anaplastic gliomas or recurrent glioblastoma; **OR**
- Used as single agent therapy for patients who received prior radiation therapy, who have progressive or recurrent disease and with a diagnosis of Intracranial and spinal ependymoma (excluding subependymoma); **OR**
- Used as single agent for patients with surgically inaccessible recurrent or progressive meningioma when radiation is not possible.

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Ovarian Cancer**:

- Patient is 18 years or older; **AND**
- Patient has no recent history of hemoptysis (i.e., the presence of ≥ 2.5 mL of blood in sputum) **or** grade 3–4 hemorrhage; **AND**
- Patient must not have had a surgical procedure within the preceding 28 days or have a surgical wound that has not fully healed; **AND**
- Patient has malignant stage II–IV granulosa cell sex cord-stromal tumors; **AND**
- Used as single agent therapy for relapsed disease; **OR**
- Patient has epithelial or fallopian tube or primary peritoneal cancers; **AND**
  - Patient has persistent or recurrent disease; **AND**
    - Bevacizumab has not been used previously; **AND**
    - Patient is not experiencing an immediate biochemical relapse (i.e., rising CA-125 without radiographic evidence of disease); **AND**
      - If platinum sensitive, used as a single agent or in combination niraparib or in combination with carboplatin AND either gemcitabine, paclitaxel † or PEGylated liposomal-doxorubicin; **OR**
      - If platinum resistant, used in combination with one of the following: oral cyclophosphamide, PEGylated liposomal doxorubicin, weekly paclitaxel, or topotecan, or may be used as a single agent; **OR**
  - Used in combination with paclitaxel and carboplatin for patients with rising CA-125 levels or clinical relapse in patients with no prior chemotherapy; **OR**
  - Used as maintenance therapy; **AND**
    - Used as a single agent or in combination with olaparib for stage II–IV disease if the patient experienced complete remission (CR) or partial remission (PR) to primary therapy that included bevacizumab; **OR**
    - Used as a single agent if previously used as part of combination therapy in patients with a partial or complete response following recurrence therapy for platinum-sensitive disease; **OR**
    - Used as continued maintenance therapy for endometrioid or serous histology in combination with paclitaxel and carboplatin for stable disease following neoadjuvant therapy; **OR**
  - Used as neoadjuvant therapy for endometrioid or serous histology in combination with paclitaxel and carboplatin; **AND**
    - Patient is a poor surgical candidate or has a low likelihood of optimal cytoreduction; **OR**
  - Used as adjuvant therapy in combination with paclitaxel and carboplatin; **AND**
    - Patient has pathologic stage II–IV disease and therapy used for one of the following histologic subtypes:
      - Carcinosarcoma (malignant mixed Müllerian tumors); **OR**
      - Clear cell carcinoma; **OR**
      - Mucinous carcinoma; **OR**
      - Grade 1 Endometrioid Carcinoma; **OR**
      - Low-grade serous carcinoma or borderline epithelial tumors (low malignant potential) with invasive implants**; OR**
    - Patient has endometrioid or serous histology and is a poor surgical candidate or has a low likelihood of optimal cytoreduction; **AND**
      - Used in patients after interval debulking surgery and with a response or stable disease to neoadjuvant therapy.

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Soft Tissue Sarcoma**:

- Patient is 18 years or older; **AND**
- Patient has no recent history of hemoptysis (i.e., the presence of ≥ 2.5 mL of blood in sputum) **or** grade 3–4 hemorrhage; **AND**
- Patient must not have had a surgical procedure within the preceding 28 days or have a surgical wound that has not fully healed; **AND**
- Used as a single agent for angiosarcoma; **OR**
- Used in combination with temozolomide for solitary fibrous tumor or hemangiopericytoma.

Diagnosis of **Endometrial Carcinoma**:

- Patient is 18 years or older; **AND**
- Patient has no recent history of hemoptysis (i.e., the presence of ≥ 2.5 mL of blood in sputum) **or** grade 3–4 hemorrhage; **AND**
- Patient must not have had a surgical procedure within the preceding 28 days or have a surgical wound that has not fully healed; **AND**
- Used as a single agent therapy for disease that has progressed on prior cytotoxic chemotherapy; **OR**
- Used in combination with carboplatin and paclitaxel for advanced and recurrent disease.

Diagnosis of **Malignant Pleural* Mesothelioma:**

- Patient is 18 years or older; **AND**
- Patient has no recent history of hemoptysis (i.e., the presence of ≥ 2.5 mL of blood in sputum) **or** grade 3–4 hemorrhage; **AND**
- Patient must not have had a surgical procedure within the preceding 28 days or have a surgical wound that has not fully healed; **AND**
- Patient has unresectable or metastatic disease; **AND**
- Used in combination with pemetrexed **and** either cisplatin or carboplatin followed by single-agent maintenance bevacizumab.

*peritoneal, pericardial, and tunica vaginalis testis mesothelioma will be evaluated on a case-by-case basis

Diagnosis of **Vulvar Cancer**:

- Patient is 18 years or older; **AND**
- Patient has no recent history of hemoptysis (i.e., the presence of ≥ 2.5 mL of blood in sputum) **or** grade 3–4 hemorrhage; **AND**
- Patient must not have had a surgical procedure within the preceding 28 days or have a surgical wound that has not fully healed; **AND**
- Used in combination with paclitaxel and cisplatin for squamous cell carcinoma; **AND**
- Patient has unresectable locally advanced, metastatic, or recurrent disease.

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Hepatocellular Adenocarcinoma**:

- Patient is 18 years or older; **AND**
- Patient has no recent history of hemoptysis (i.e., the presence of ≥ 2.5 mL of blood in sputum) **or** grade 3–4 hemorrhage; **AND**
- Patient must not have had a surgical procedure within the preceding 28 days or have a surgical wound that has not fully healed; **AND**
- Used as first-line therapy; **AND**
- Used for Child-Pugh Class A disease only**; AND**
- Used in combination with atezolizumab; **AND**
- Patient has locally advanced, unresectable or metastatic disease.

Diagnosis of **Small Bowel Adenocarcinoma**:

- Patient is 18 years or older; **AND**
- Patient has no recent history of hemoptysis (i.e., the presence of ≥ 2.5 mL of blood in sputum) **or** grade 3–4 hemorrhage; **AND**
- Patient must not have had a surgical procedure within the preceding 28 days or have a surgical wound that has not fully healed; **AND**
- Used as initial therapy; **AND**
- Patient has metastatic disease; **AND**
  - Used in combination with a fluoropyrimidine-based regimen (e.g., 5-fluorouracil/5-FU or capecitabine) in patients **not** appropriate for intensive therapy; **OR**
  - Used in combination with FOLFOX, CapeOX, or FOLFOXIRI in patients appropriate for intensive therapy.

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug (e.g., gastrointestinal perforations and fistulae, surgical/wound healing complications, hemorrhage, arterial and venous thromboembolic events [ATE & VTE], uncontrolled hypertension, posterior reversible encephalopathy syndrome [PRES], nephrotic syndrome, proteinuria, severe infusion reactions, ovarian failure, congestive heart failure [CHF])

NOTE: "Diagnosis-specific clinical criteria for renewal" section has additional diagnosis-specific renewal criteria

DIAGNOSIS-SPECIFIC CLINICAL CRITERIA FOR RENEWAL

CNS cancers – symptom management (short-course therapy): May not be renewed

Colorectal Cancer (after first-line bevacizumab-containing regimen):

- Patient's disease has progressed on a first-line bevacizumab-containing regimen **AND**
- Used in combination with a fluoropyrimidine-irinotecan or fluoropyrimidine-oxaliplatin-based regimen (if not used first line)

Malignant Mesothelioma – maintenance therapy:

- Must be used as a single agent

DIAGNOSIS-SPECIFIC CLINICAL CRITERIA FOR RENEWAL *(CONTINUED)*

Ovarian Cancer

- Used in combination with gemcitabine, for completion of initial therapy, up to 10 cycles total in platinum-sensitive or recurrent disease; **OR**
- Used as maintenance therapy**; AND**
  - Used as a single-agent for platinum-sensitive disease or recurrence**; OR**
  - Used as a single agent or in combination with olaparib for stage II-IV disease; **OR**
  - Used in combination with paclitaxel and carboplatin for endometrioid or serous histology following neoadjuvant therapy.

Non-squamous non-small cell lung cancer – continuation therapy:

- Used for recurrent, advanced, or metastatic disease (excluding locoregional recurrence or symptomatic local disease with no evidence of disseminated disease) or mediastinal lymph node recurrence with prior radiation therapy **AND**
  - Used as continuation maintenance therapy (*bevacizumab must have been included in patient's first-line chemotherapy regimen*) in patients with PS ≤ 2 who achieved a tumor response or stable disease after first-line systemic therapy; **AND**
    - Used as a single agent; **OR**
    - Used in combination with pemetrexed following a first-line bevacizumab/pemetrexed/platinum chemotherapy regimen; **OR**
    - Used in combination with atezolizumab following a first-line atezolizumab/carboplatin/paclitaxel/bevacizumab regimen; **OR**
  - Used in combination with erlotinib for sensitizing EGFR mutation positive disease as continuation of therapy following disease progression on erlotinib with bevacizumab for asymptomatic disease, symptomatic brain lesions, or isolated symptomatic systemic lesions.

AZOPT® (BRINZOLAMIDE)

Length of Authorization:	1 Year, eligible for renewal
Initiative:	MNC: Glaucoma Agents (IE 2462 / NCPDP 75 – HICL)

CLINICAL CRITERIA AZOPT

- Patient is 18 years of age or older; **AND**
- Patient must have a diagnosis of elevated intraocular pressure with open-angle glaucoma or ocular hypertension; **AND**
- Have had an adequate trial and failure, contraindication, or intolerance to a prostaglandin inhibitor or beta-adrenergic antagonist.

BALVERSA® (ERDAFITINIB)

Length of Authorization:	6 months, and renewable
Initiative:	MNC: Non-Formulary Product (IE 50698 / MR – GSN PatOverride)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Bladder Cancer/Urothelial Carcinoma**

- Patient must be at least 18 years old; **AND**
- Patient has had a baseline serum phosphate level measurement and it is within normal limits; **AND**
- Patient has received ophthalmological examinations (i.e., assessment of visual acuity, slit lamp examination, fundoscopy, and optical coherence tomography) at baseline and periodically throughout therapy; **AND**
- Patient phosphate intake is restricted to less than 800 mg per day; **AND**
- Patient will not be on concomitant therapy with any of the following:
  - Strong CYP2C9 or CYP3A4 inducers (e.g., rifampicin)
  - Serum phosphate level-altering agents before the initial dose increase period based on serum phosphate levels (e.g., potassium phosphate supplements, vitamin D supplements, antacids, phosphate-containing enemas or laxatives, certain medications)
  - Sensitive CYP3A4 substrates with narrow therapeutic indexes (e.g., amitriptyline, carbamazepine); **AND**
- Must be used as a single agent; **AND**
- Patient has a susceptible gene mutation or fusions in the FGFR-2 or FGFR-3 (fibroblast growth factor receptor) gene, as determined by an FDA-approved or CLIA-compliant test; **AND**
- Patient has one of the following diagnoses:
  - Locally advanced or metastatic urothelial carcinoma; **OR**
  - Local bladder cancer recurrence or persistent disease in a preserved bladder; **OR**
  - Local bladder cancer recurrence post-cystectomy; **OR**
  - Metastatic upper genitourinary tract tumors; **OR**
  - Metastatic or recurrent urothelial carcinoma of the prostate; **AND**
    - Patient does not have recurrence of stage T3-4 disease or palpable inguinal lymph nodes; **AND**
- Used as subsequent therapy after one of the following:
  - After at least one prior line of platinum-containing chemotherapy ; **OR**
  - After at least one prior line of checkpoint inhibitor-containing chemotherapy; **OR**
  - After prior systemic therapy that included both a platinum and checkpoint-inhibitor

*** Note:**

- If platinum treatment occurred greater than 12 months ago, the patient should be re-treated with platinum-based therapy if the patient is still platinum eligible (see below for cisplatin- or carboplatin-ineligible comorbidities).
  - Cisplatin-ineligible comorbidities may include GFR < 60 mL/min, PS ≥ 2, hearing loss of ≥ 25 decibels (dB) at two contiguous frequencies, or grades ≥ 2 peripheral neuropathy. Carboplatin may be substituted for cisplatin particularly in those patients with a GFR <60 mL/min or a PS of 2.
  - Carboplatin-ineligible comorbidities may include CrCl < 30 mL/min, PS ≥ 3, grade ≥ 3 peripheral neuropathy, or NYHA class ≥ 3.

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug (e.g., central serous retinopathy/retinal pigment epithelial detachment [CSR/RPED], severe hyperphosphatemia); **AND**
- Patient serum phosphate level is < 7.0 mg/dL

BAVENCIO® (AVELUMAB)

Length of Authorization:	6 months, and renewable
Initiative:	MNC: Non-Formulary Product (IE 50698 / MR – GSN PatOverride)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Merkel Cell Carcinoma (Molina)**

- Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., nivolumab, pembrolizumab, atezolizumab, durvalumab, cemiplimab) unless otherwise specified; **AND**
- Patient is at least 12 years of age; **AND**
- Used as a single agent**; AND**
- Patient has metastatic disease.

Diagnosis of **Bladder Cancer/Urothelial Carcinoma**

- Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., nivolumab, pembrolizumab, atezolizumab, durvalumab, cemiplimab) unless otherwise specified; **AND**
- Patient is at least 18 years of age; **AND**
- Used as a single agent; **AND**
- Used as subsequent therapy after previous platinum treatment*; **AND**
- Patient has a diagnosis of **one** of the following:
  - Locally advanced or metastatic urothelial carcinoma; **OR**
  - Local bladder cancer recurrence or persistent disease in a preserved bladder; **OR**
  - Local or metastatic bladder cancer recurrence post-cystectomy; **OR**
  - Metastatic upper genitourinary (GU) tract tumors; **OR**
  - Metastatic urothelial carcinoma of the prostate; **OR**
  - Recurrent or metastatic primary carcinoma of the urethra; **AND**
    - Patient does not have recurrent stage T3-4 disease or palpable inguinal lymph nodes.

*** Note:**

- If platinum treatment occurred greater than 12 months ago, the patient should be re-treated with platinum-based therapy if the patient is still platinum eligible (see below for cisplatin- or carboplatin-ineligible comorbidities).
  - Cisplatin-ineligible comorbidities may include GFR < 60 mL/min, PS ≥ 2, hearing loss of ≥ 25 decibels (dB) at two contiguous frequencies, or grade ≥ 2 peripheral neuropathy. Carboplatin may be substituted for cisplatin particularly in those patients with a GFR < 60 mL/min or a PS of 2.
  - Carboplatin-ineligible comorbidities may include GFR < 30 mL/min, PS ≥ 3, grade ≥ 3 peripheral neuropathy, or NYHA class ≥ 3.

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Renal Cell Carcinoma**

- Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., nivolumab, pembrolizumab, atezolizumab, durvalumab, cemiplimab) unless otherwise specified; **AND**
- Patient is at least 18 years of age; **AND**
- Used in combination with axitinib; **AND**
- Used as first line therapy; **AND**
  - Used for the treatment of advanced disease; **OR**
  - Used for relapsed or metastatic disease with clear cell histology.

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug (e.g., severe infusion reactions, hepatotoxicity, immune-mediated adverse reactions [e.g., pneumonitis, hepatitis, colitis, endocrinopathies, nephritis and renal dysfunction, myocarditis, pancreatitis, myositis, psoriasis, arthritis, exfoliative dermatitis, erythema multiforme, pemphigoid, hypopituitarism, uveitis, Guillain-Barré syndrome, systemic inflammatory response], major adverse cardiovascular events [MACE] when used in combination with axitinib)

BENLYSTA (BELIMUMAB)

Length of Authorization:	1 Year
Initiative:	MNC: Non-Formulary Product (IE 50698 / MR – GSN PatOverride)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Systemic Lupus Erythematosus (SLE)**

- Adult patient (18 years or older); **AND**
- Patient has a positive autoantibody test (e.g., anti-nuclear antibody [ANA] greater than laboratory reference range and/or anti-double-stranded DNA [anti-dsDNA] greater than 2-fold the laboratory reference range if tested by ELISA); **AND**
- Patient has failed to respond adequately to at least 2 standard therapies (anti-malarials, corticosteroids, non-steroidal anti-inflammatory drugs, immunosuppressives (excluding intravenous cyclophosphamide); **AND**
- Patient has one of the following:
  - Safety of Estrogen in Lupus National Assessment – Systemic Lupus Erythematosus Disease Activity Index (SELENA-SLEDAI) score of 6-12
  - British Isles Lupus Assessment Group (BILAG) A organ domain score ≥1
  - BILAG B organ domain score ≥ 2; **AND**
- Patient must not have an active infection; **AND**
- Patient has not received a live vaccine within 30 days before starting or concurrently with Benlysta; **AND**
- Patient does not have any of the following exclusion criteria:
  - Severe active central nervous system lupus
  - Severe active lupus nephritis
  - Individuals who are on other biologics or IV cyclophosphamide

CLINICAL CRITERIA FOR RENEWAL APPROVAL

- Adequate documentation of disease stability and/or improvement as indicated by the following when compared to baseline:
  - ≥4-point improvement in the SELENA-SLEDAI score; **OR**
  - No new British Isles Lupus Assessment Group (BILAG) A organ domain score or 2 new BILAG B organ domain scores; **OR**
  - No worsening (<0.30-point increase) in Physician's Global Assessment (PGA) score; **OR**
  - Seroconverted (negative) or had a 20% reduction in autoantibody level; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: depression; suicidal thoughts; serious infections; malignancy.

BLOOD FORMATION MODIFIERS – COLONY STIMULATORY FACTORS (CSF)

Length of Authorization:	4 months and may be renewed (unless noted below) Mozobil: Coverage will be one treatment cycle or four days and will be eligible for renewal for one additional treatment cycle. Leukine: see approval lengths below
Initiative:	SPC: Blood Modifiers (IE 2462 / NCPDP 75 – HICL) MNC: Non-Formulary Product (IE 50698 / MR – GSN PatOverride)

CLINICAL CRITERIA FOR INITIAL APPROVAL

NEULASTA®, FULPHILA®, UDENYCA®, ZIEXTENZO®, NYVEPRIA®

Note: for Neulasta® and Ziextenzo®, the patient must have a failure, contraindication, or intolerance to a trial of Nyvepria®, Fulphila®, and Udenyca®.

Indication	Approval length
Bone marrow transplantation (BMT) failure or engraftment delay	Coverage will be provided for 1 dose only and may not be renewed
Peripheral blood progenitor cell (PBPC) mobilization and transplant	Coverage will be provided for 1 dose only and may not be renewed
All other indications	Coverage will be provided for four months and may be renewed unless otherwise specified

- **Prophylactic use in patients with non-myeloid malignancy**
  - Patient is undergoing myelosuppressive chemotherapy with an expected incidence of febrile neutropenia of greater than 20%[§]; **OR**
  - Patient is undergoing myelosuppressive chemotherapy with an expected incidence of febrile neutropenia of 10% to 20%[§] **and** one or more of the following co-morbidities:
    - Age > 65 years receiving full dose intensity chemotherapy
    - Extensive prior exposure to chemotherapy
    - Previous exposure of pelvis, or other areas of large amounts of bone marrow, to radiation
    - Persistent neutropenia (ANC ≤ 1000/mm^3)
    - Bone marrow involvement by tumor

CLINICAL CRITERIA FOR RENEWAL

NEULASTA®, FULPHILA®, UDENYCA®, ZIEXTENZO®, NYVEPRIA® *(CONTINUED)*

- Patient has a condition that can potentially increase the risk of serious infection (i.e., HIV/AIDS with low CD4 counts)
- Recent surgery and/or open wounds
- Poor performance status
- Renal dysfunction (creatinine clearance < 50 mL/min)
- Liver dysfunction (i.e., elevated bilirubin > 2.0 mg/dL)
- Chronic immunosuppression in the post-transplant setting including organ transplant

Note: Dose-dense therapy, in general, requires growth factor support to maintain dose intensity and schedule. In the palliative setting, consideration should be given to dose reduction or change in regimen.

- **Patients who experienced a neutropenic complication from a prior cycle of the same chemotherapy**

  Note: Dose-dense therapy, in general, requires growth factor support to maintain dose intensity and schedule. In the palliative setting, consideration should be given to dose reduction or change in regimen
- **Patients acutely exposed to myelosuppressive doses of radiation (Hematopoietic Acute Radiation Syndrome [H-ARS])**
- Bone marrow **transplantation (BMT) failure or engraftment delay**
- Peripher**al blood progenitor cell (PBPC) mobilization and transplant**
- **Wilms Tumor (nephroblastoma)**
  - Patient has favorable histology disease; **AND**
  - Used in combination with a cyclophosphamide-based chemotherapy regimen (i.e., Regimen M or I only)

***Febrile neutropenia is defined as:**
– **Temperature:** a single temperature ≥ 38.3 °C orally or ≥ 38.0 °C over 1 hour; **AND** – **Neutropenia**: < 500 neutrophils/mcL or < 1,000 neutrophils/mcL and a predicted decline to ≤ 500 neutrophils/mcL over the next 48 hours
§ Expected incidence of febrile neutropenia percentages for myelosuppressive chemotherapy regimens can be found in the NCCN Hematopoietic Growth Factors Clinical Practice Guideline at NCCN.org

Note: Coverage for use in BMT failure or engraftment delay and PBPC mobilization and transplant may **not** be renewed.

Coverage for all other indications can be renewed based upon the following criteria:

- Patient continues to meet indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in initial section; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: splenic rupture, acute respiratory distress syndrome (ARDS), serious allergic reactions/anaphylaxis, sickle cell crisis, glomerulonephritis, leukocytosis, thrombocytopenia, capillary leak syndrome, potential for tumor growth stimulation of malignant cells, aortitis, myelodysplastic syndrome and acute myeloid leukemia, etc.

NEUPOGEN®, NIVESTYM®, ZARXIO®, GRANIX®

Note: for Nivestym® vial***, Zarxio®, Granix®***: ***the patient must have a failure, contraindication, or intolerance to a trial of Neupogen®*** and Nivestym® syringe.

- **Bone marrow transplant (BMT)**
- **Peripheral blood progenitor cell (PBPC) mobilization and transplant**
- **Prophylactic use in patients with non-myeloid malignancy**
  - Patient is undergoing myelosuppressive chemotherapy with an expected incidence of febrile neutropenia of greater than 20%[§]; **OR**
  - Patient is undergoing myelosuppressive chemotherapy with an expected incidence of febrile neutropenia of 10% or to 20%[§] **and** one or more of the following co-morbidities:
    - Age > 65 years receiving full dose intensity chemotherapy
    - Extensive prior exposure to chemotherapy
    - Previous exposure of pelvis, or other areas of large amounts of bone marrow, to radiation
    - Pre-existing neutropenia (ANC ≤ 1000/mm^3)
    - Bone marrow involvement with tumor
    - Patient has a condition that can potentially increase the risk of serious infection (i.e., HIV/AIDS with low CD4 counts)
    - Recent surgery and/or open wounds
    - Poor performance status
    - Renal dysfunction (creatinine clearance < 50 mL/min)
    - Liver dysfunction (elevated bilirubin > 2.0 mg/dL)
    - Chronic immunosuppression in the post-transplant setting including organ transplant.

Note: Dose-dense therapy, in general, requires growth factor support to maintain dose intensity and schedule. In the palliative setting, consideration should be given to dose reduction or change in regimen.

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

NEUPOGEN® NIVESTYM®, ZARXIO®, GRANIX® *(CONTINUED)*

- **Treatment of chemotherapy-induced febrile neutropenia**
  - Patient has been on prophylactic therapy with filgrastim or tbo-filgrastim *(**Note:** therapy should not be used concomitantly with pegfilgrastim)*; **OR**
  - Patient has not received prophylactic therapy with a granulocyte colony stimulating factor; **AND**
    - Patient has one or more of the following risk factors for developing infection-related complications:
      - Sepsis syndrome
      - Age greater than 65 years
      - Absolute neutrophil count [ANC] less than 100/mcL
      - Duration of neutropenia expected to be greater than 10 days
      - Pneumonia or other clinically documented infections
      - Invasive fungal infection
      - Hospitalization at the time of fever
      - Prior episode of febrile neutropenia
- **Patient who experienced a neutropenic complication from a prior cycle of the same chemotherapy**

  Note: Dose-dense therapy, in general, requires growth factor support to maintain dose intensity and schedule. In the palliative setting, consideration should be given to dose reduction or change in regimen.
- **Acute myeloid leukemia (AML)**
  - Used in patients receiving induction/consolidation or re-induction chemotherapy; **OR**
  - Used for relapsed or refractory disease
- **Bone marrow transplantation (BMT) failure or engraftment delay**
- **Severe chronic neutropenia**
  - Patient must have an absolute neutrophil count (ANC) < 500/mm^3; **AND**
  - Patient must have a diagnosis of one of the following:
    - Congenital neutropenia; **OR**
    - Cyclic neutropenia; **OR**
    - Idiopathic neutropenia
- **Myelodysplastic syndrome**
  - Endogenous serum erythropoietin level of ≤ 500 mUnits/mL; **AND**
  - Patient has lower risk disease (i.e., defined as IPSS-R [Very Low, Low, Intermediate], IPSS [Low/Intermediate-1], WPSS [Very Low, Low, Intermediate]); **AND**
  - Used for treatment of symptomatic anemia with no del(5q) mutation; **AND**
  - Patient is receiving concurrent therapy with erythropoiesis stimulating agents (ESAs)
- **Patients acutely exposed to myelosuppressive doses of radiation (hematopoietic subsyndrome of acute radiation syndrome)**
- **Management of CAR T-cell related toxicity**
  - Patient has been receiving therapy with CAR T-cell therapy (e.g., tisagenlecleucel, axicabtagene ciloleucel, brexucabtagene autoleucel, lisocabtagene maraleucel, etc.); **AND**
  - Patient is experiencing neutropenia related to their therapy
- **Wilms Tumor (Nephroblastoma)**
  - Patient has favorable histology disease; **AND**
  - Used in combination with a cyclophosphamide-based chemotherapy regimen (i.e., Regimen M or I only)

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

NEUPOGEN®, NIVESTYM®, ZARXIO®, GRANIX® *(CONTINUED)*

***Febrile neutropenia is defined as:**
– **Temperature**: a single temperature ≥ 38.3 °C orally or ≥ 38.0 °C over 1 hour; **AND** – **Neutropenia**: < 500 neutrophils/mcL or < 1,000 neutrophils/mcL and a predicted decline to ≤ 500 neutrophils/mcL over the next 48 hours
§ Expected incidence of febrile neutropenia percentages for myelosuppressive chemotherapy regimens can be found in the NCCN Hematopoietic Growth Factors Clinical Practice Guideline at NCCN.org

CLINICAL CRITERIA FOR RENEWAL

Absence of unacceptable toxicity from the drug (e.g., splenic rupture, acute respiratory distress syndrome [ARDS], serious allergic reactions/anaphylaxis, sickle cell crisis, glomerulonephritis, leukocytosis, capillary leak syndrome, potential for tumor growth stimulation of malignant cells, aortitis, alveolar hemorrhage and hemoptysis, thrombocytopenia, cutaneous vasculitis)

LEUKINE

LENGTH OF AUTHORIZATION

High Risk Neuroblastoma:

- When used in combination with dinutuximab, coverage will be provided for five months and may not be renewed.
- When used in combination with naxitamab, coverage will be provided for six months and may be renewed.

All other indications:

- Coverage will be provided for four months and may be renewed.

Covered for the following:

- Myeloid reconstitution after autologous or allogeneic bone marrow transplant (BMT)
- Peripheral blood progenitor cell (PBPC) mobilization and transplant
- Acute myeloid leukemia (AML) following induction or consolidation chemotherapy
- Bone marrow transplantation (BMT) failure or engraftment delay
- Patients acutely exposed to myelosuppressive doses of radiation (hematopoietic subsyndrome of acute radiation syndrome [H-ARS])

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

LEUKINE *(CONTINUED)*

- Treatment of chemotherapy-induced febrile neutropenia
  - Used for the treatment of chemotherapy induced febrile neutropenia in patients who have not received prophylactic therapy with a granulocyte colony stimulating factor; **AND**
  - Patient has one or more of the following risk factors for developing infection-related complications:
    - Sepsis syndrome
    - Age greater than 65 years
    - Absolute neutrophil count (ANC) less than 100/mcL
    - Duration of neutropenia expected to be greater than 10 days
    - Pneumonia or other clinically documented infections
    - Invasive fungal infection
    - Hospitalization at the time of fever
    - Prior episode of febrile neutropenia
- High-Risk Neuroblastoma
  - Used in combination with GD2-binding monoclonal antibodies (i.e., naxitamab, dinutuximab, etc.) for the treatment of high-risk neuroblastoma

CLINICAL CRITERIA FOR RENEWAL

High-Risk Neuroblastoma

- Use in combination with dinutuximab may not be renewed.
- Used in combination with naxitamab; **AND**
  - Patient continues to meet indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
  - Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include severe hypersensitivity reactions, severe effusions and capillary leak syndrome, severe supraventricular arrythmias, etc

All Other Indications

- Same as initial prior authorization policy criteria.

MOZOBIL®

Coverage for Mozobil® (plerixafor) is provided in the following conditions:

Peripheral mobilization of stem cells for autologous transplantation:

- Patient is at least 18 years of age; **AND**
- Diagnosis of non-Hodgkin lymphoma (NHL) **OR** Diagnosis of multiple myeloma (MM); **AND**
- Must be used in combination with one of the following: Neupogen® (filgrastim), Zarxio® (filgrastim-sndz), filgrastim-aafi, or Granix® (tbo-filgrastim)

CLINICAL CRITERIA FOR RENEWAL

MOZOBIL® *(CONTINUED)*

- Absence of unacceptable toxicity from the drug (e.g., severe hypersensitivity reactions/anaphylaxis, hematologic effects [e.g., leukocytosis, thrombocytopenia], splenic enlargement/rupture, tumor cell mobilization); **AND**
- Patient has had only one previous treatment cycle

Approve a one-time course of therapy (up to 4 days of therapy), which will be eligible for renewal for one additional treatment cycle.

Reference dosing:

Mozobil® – Recommended dose: [1]	• Begin treatment with Mozobil® after the patient has received G-CSF once daily for 4 days • Administer daily morning doses of G-CSF 10 mcg/kg for 4 days prior to the first evening dose of Mozobil® and on each day prior to apheresis • Administer Mozobil® approximately 11 hours prior to initiation of each apheresis for up to 4 consecutive days at the following dose: – 20 mg fixed dose or 0.24 mg/kg actual body weight for patients weighing ≤ 83 kg • 0.24 mg/kg actual body weight for patients weighing > 83 kg; not to exceed 40 mg/day

NPLATE®

Approval is for 3 months and may be renewed, except for Hematopoietic Syndrome of Acute Radiation Syndrome (HS-ARS) cannot be renewed.

Coverage for Nplate® (romiplostim) is provided in the following conditions:

- **Diagnosis of immune (idiopathic) thrombocytopenic purpura (ITP)**
  - Patient is not on any other thrombopoietin receptor agonist or mimetic (e.g., lusutrombopag, eltrombopag, avatrombopag etc.) or fostamatinib; **AND**
  - Must not be used in an attempt to normalize platelet counts; **AND**
  - Laboratory value for platelet count is current (i.e., drawn within the previous 28 days); **AND**
  - The patient is at increased risk for bleeding as indicated by platelet count less than 30×10^9/L (30,000/mm³); **AND**
  - Patient has acute ITP; **AND**
    - Patient is at least 18 years of age; **AND**
    - Patient has previously failed one of the following treatments for ITP:
      - Patient has failed previous therapy with corticosteroids; **OR**
      - Patient has failed previous therapy with immunoglobulins; **OR**
      - Patient has had splenectomy; **OR**
  - Patient with chronic ITP for at least 6 months (or meets the corticosteroid requirement below); **AND**
    - Patient is 1 year of age or older; **AND**
    - Patient has previously failed one of the following treatments for ITP:
      - Patient has failed previous therapy with corticosteroids (i.e., patient had no response to at least a 3-month trial or is corticosteroid-dependent); **OR**
      - Patient has failed previous therapy with immunoglobulins; **OR**
      - Patient has had a splenectomy

NPLATE® *(CONTINUED)*

- Diagnosis of **Myelodysplastic Syndromes (MDS)**
  - Patient is at least 18 years of age; **AND**
  - Patient is not on any other thrombopoietin receptor agonist or mimetic (e.g., lusutrombopag, eltrombopag, avatrombopag etc.) or fostamatinib; **AND**
  - Must not be used in an attempt to normalize platelet counts; **AND**
  - Laboratory value for platelet count is current (i.e., drawn within the previous 28 days); **AND**
  - Patient has lower risk disease [i.e., IPSS-R (Very Low, Low, Intermediate), IPSS (Low/Intermediate-1), WPSS (Very Low, Low, Intermediate)]; **AND**
  - Patient has severe or refractory thrombocytopenia (i.e., platelet count < 20 x 10^9/L or higher with a history of bleeding); **AND**
  - Patient progressed or had no response to hypomethylating agents (e.g., azacitidine, decitabine,), immunosuppressive therapy, or clinical trial
- Diagnosis of **Hematopoietic Syndrome of Acute Radiation Syndrome (HS-ARS)**
  - Patient is not on any other thrombopoietin receptor agonist or mimetic (e.g., lusutrombopag, eltrombopag, avatrombopag etc.) or fostamatinib; **AND**
  - Must not be used in an attempt to normalize platelet counts; **AND**
  - Laboratory value for platelet count is current (i.e., drawn within the previous 28 days); **AND**
  - Patient has suspected or confirmed exposure to radiation levels greater than 2 gray (Gy)

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug (e.g., thrombotic/thromboembolic complications, risk of progression of myelodysplastic syndromes to acute myelogenous leukemia); **AND**
  - **ITP**
    - Disease response indicated by the achievement and maintenance of a platelet count of at least 50 × 10^9/L (not to exceed 400 x 10^9/L) as necessary to reduce the risk for bleeding; **OR**
  - **HS-ARS**
    - Coverage cannot be renewed
  - **MDS**
    - Patient has not developed acute myeloid leukemia (AML) (**Note**: romiplostim induces an increase in immature white blood cells and peripheral blasts which is not indicative of development of AML); **AND**
    - Disease response indicated by an increase in platelet count compared to pretreatment baseline (not to exceed 450 x 10^9/L), reduction in bleeding events, or reduction in platelet transfusion requirements

BLOOD PRODUCTS

Length of Authorization:	See below
Initiative:	MNC: Non-Formulary Product (IE 50698 / MR – GSN PatOverride)

NO CLAIMS ARE ALLOWED TO BE ADJUDICATED FOR HEMOPHILIA DRUGS OUTSIDE OF CVS PHARMACY

CLINICAL CRITERIA FOR APPROVAL

ALPHANINE SD, ALPROLIX, BENEFIX, IDELVION, IXINITY, MONONINE, PROFILNINE, REBINYN AND RIXUBIS

Note: initial authorization will be provided for 3 months and may be renewed (unless noted below).

Coverage is provided in the following conditions:

Hemophilia B (congenital factor IX deficiency, a.k.a. Christmas disease)

- Diagnosis of congenital factor IX deficiency has been confirmed by blood coagulation testing; **AND**
- Therapy NOT used for induction of immune tolerance in patients with Hemophilia B [ONLY the following products]:
  - Alprolix
  - Rixubis
  - Ixinity
  - Idelvion
  - Rebinyn
  - AlphaNine SD
  - Mononine
  - BeneFIX; **AND**
- Used as treatment in at least one of the following:
  - Control and prevention of acute bleeding episodes (episodic treatment of acute hemorrhage); **OR**
  - Perioperative management (*Authorizations valid for 1 month); **OR**;
  - Routine prophylaxis to prevent or reduce the frequency of bleeding episodes (excluding Rebinyn); **AND**
    - Patient must have severe hemophilia B (factor IX level of < 1%); **OR**
    - Patient has at least two documented episodes of spontaneous bleeding into joints.

RENEWAL

- Patient continues to meet initial criteria; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include symptoms of allergic-anaphylactic reactions (anaphylaxis, dyspnea, rash), thromboembolic events (thromboembolism, pulmonary embolism), and development of neutralizing antibodies (inhibitors); **AND**
- Any increases in dose must be supported by an acceptable clinical rationale (e.g., weight gain, half-life study results, increase in breakthrough bleeding when patient is fully adherent to therapy, etc.); **AND**
- The cumulative amount of medication(s) the patient has on-hand will be taken into account when authorizing. The authorization will allow up to 5 doses on-hand for the treatment of acute bleeding episodes as needed for the duration of the authorization;

Treatment of acute bleeding episodes/treatment of spontaneous and trauma-induced bleeding episodes/on-demand treatment of bleeding episodes

- Renewals will be approved for a 6-month authorization period

Prevention of acute bleeding episodes/routine prophylaxis to prevent or reduce the frequency of bleeding episode

- Renewals will be approved for a 12-month authorization period

CLINICAL CRITERIA FOR APPROVAL *(CONTINUED)*

ALPHANATE, HUMATE-P ONLY

Note: Initial authorization will be provided for 3 months and may be renewed (unless noted below)

Coverage is provided in the following conditions:

Hemophilia A (congenital factor VIII deficiency)

- Diagnosis of congenital factor VIII deficiency has been confirmed by blood coagulation testing; **AND**
  - Used in treatment for control and prevention of bleeding episodes (episodic treatment of acute hemorrhage); **OR**
  - Routine prophylaxis to prevent or reduce the frequency of bleeding episodes; **AND**
    - Patient must have severe hemophilia A (factor VIII level of < 1%); **OR**
    - Patient has at least two documented episodes of spontaneous bleeding into joints; **OR**
  - Perioperative management (*Authorization is valid for 1 month)

Von Willebrand disease (vWD)

- Diagnosis of von Willebrand disease has been confirmed by blood coagulation and von Willebrand factor testing; **AND**
  - Treatment of spontaneous and trauma-induced bleeding episodes; **OR**
  - Used as surgical bleeding prophylaxis during major or minor procedures in patients with vWD in whom desmopressin is either ineffective or contraindicated *(*Authorization valid for 1 month)*; **AND**
- Alphanate is not indicated for patients with severe (type 3) vWD undergoing major surgery **or** treatment of spontaneous/trauma-induced bleeding episodes.

RENEWAL

Coverage can be renewed based upon the following criteria:

- Patient continues to meet initial criteria; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: symptoms of allergic-anaphylactic reactions (anaphylaxis, dyspnea, rash); thromboembolic events (thromboembolism, pulmonary embolism); and development of neutralizing antibodies (inhibitors); **AND**
- Any increases in dose must be supported by an acceptable clinical rationale (e.g., weight gain, half-life study results, increase in breakthrough bleeding when patient is fully adherent to therapy); **AND**
- The cumulative amount of medication(s) the patient has on-hand will be taken into account when authorizing. The authorization will allow up to 5 doses on-hand for the treatment of acute bleeding episodes as needed for the duration of the authorization;

Treatment of acute bleeding episodes/treatment of spontaneous and trauma-induced bleeding episodes/on-demand treatment of bleeding episodes

- Renewals will be approved for a 6-month authorization period

Prevention of acute bleeding episodes/routine prophylaxis to prevent or reduce the frequency of bleeding episode

- Renewals will be approved for a 12-month authorization period

CLINICAL CRITERIA FOR APPROVAL *(CONTINUED)*

ADVATE, ADYNOVATE, AFSTYLA, ELOCTATE, ESPERCOT, HEMOFIL M, KOATE, KOATE-DVI, KOGENATE FS, KOVALTRY, NOVOEIGHT, NUWIQ, RECOMBINATE, XYNTHA, AND JIVI

Note: Initial authorization will be provided for 3 months and may be renewed (unless noted below)

Coverage is provided in the following conditions:

Hemophilia A (congenital factor VIII deficiency)

- Diagnosis of congenital factor VIII deficiency has been confirmed by blood coagulation testing; **AND**
- The patient must be 12 years of age or older (Jivi only); **AND**
- Will not be used for the treatment of von Willebrand's disease; **AND**
- Used as treatment in at least one of the following:
  - Control and prevention of acute bleeding episodes (episodic treatment of acute hemorrhage); **OR**
  - Perioperative management (*authorizations valid for 1 month); **OR**
  - Used for routine prophylaxis; **AND**
    - Used to prevent or reduce the frequency of bleeding episodes; **OR**
    - Used to prevent or reduce the frequency of bleeding episodes and reduce the risk of joint damage in children without pre-existing joint damage (KOGENATE-FS **only**); **AND**
      - Patient must have severe hemophilia A (factor VIII level of < 1%); **OR**
      - Patient has at least two documented episodes of spontaneous bleeding into joints
- If the request is for Eloctate, Adynovate, Jivi, or Esperoct, the following criteria should be met in addition to above:
  - Patient is not a suitable candidate for a standard non- EHL factor VIII product.
  - A half-life study must be scheduled to determine the appropriate dose and dosing interval of the EHL product when initiated.
  - Prior to switching to Eloctate, Adynovate, Jivi, or Esperoct a half-life study should also be performed on current non- EHL factor VIII product to ensure that a clinical benefit will be achieved.

RENEWAL

- Patient continues to meet initial criteria; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include symptoms of allergic-anaphylactic reactions (anaphylaxis, dyspnea, rash), thromboembolic events (thromboembolism, pulmonary embolism), and development of neutralizing antibodies (inhibitors); **AND**
- Any increases in dose must be supported by an acceptable clinical rationale (e.g., weight gain, half-life study results, increase in breakthrough bleeding when patient is fully adherent to therapy, etc.); **AND**
- The cumulative amount of medication(s) the patient has on-hand will be taken into account when authorizing. The authorization will allow up to 5 doses on-hand for the treatment of acute bleeding episodes as needed for the duration of the authorization

Treatment of acute bleeding episodes/treatment of spontaneous and trauma-induced bleeding episodes/on-demand treatment of bleeding episodes

- Renewals will be approved for a 6-month authorization period

Prevention of acute bleeding episodes/routine prophylaxis to prevent or reduce the frequency of bleeding episode

- Renewals will be approved for a 12-month authorization period

CLINICAL CRITERIA FOR APPROVAL *(CONTINUED)*

OBIZUR

Note: Initial authorization will be provided for 3 months and may be renewed (unless noted below)

Coverage is provided in the following conditions:

Acquired Hemophilia A (acquired factor VIII deficiency)

- Diagnosis of acquired factor VIII deficiency has been confirmed by blood coagulation testing; **AND**
- Used as treatment of bleeding episodes; **AND**
- Is **not** being used for congenital Hemophilia A or von Willebrand disease

RENEWAL

- Patient continues to meet initial criteria; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include symptoms of allergic-anaphylactic reactions (anaphylaxis, dyspnea, rash), thromboembolic events (thromboembolism, pulmonary embolism), and development of neutralizing antibodies (inhibitors); **AND**
- Any increases in dose must be supported by an acceptable clinical rationale (e.g., weight gain, half-life study results, increase in breakthrough bleeding when patient is fully adherent to therapy, etc.); **AND**
- The cumulative amount of medication(s) the patient has on-hand will be taken into account when authorizing. The authorization will allow up to 5 doses on hand for the treatment of acute bleeding episodes as needed for the duration of the authorization.

FEIBA NF/FEIBA VF

Note: initial authorization will be provided for 3 months and may be renewed every 12 months thereafter (unless noted below)

Hemophilia A (congenital factor VIII deficiency)

- Diagnosis of congenital factor VIII deficiency has been confirmed by blood coagulation testing; **AND**
- Confirmation the patient has inhibitors to Factor VIII; **AND**
- Used as treatment in at least one of the following:
  - Control and prevention of acute bleeding episodes (episodic treatment of acute hemorrhage); **OR**
  - Perioperative management (*authorizations valid for 1 month); **OR**
  - Routine prophylaxis to prevent or reduce the frequency of bleeding episodes; **AND**
    - Patient has at least two documented episodes of spontaneous bleeding into joints; **OR**
  - Patient has a documented trial and failure of immune tolerance induction (ITI); **AND**
    - Patient has a documented trial and failure or contraindication to emicizumab-kxwh therapy

Hemophilia B (congenital factor IX deficiency, a.k.a. Christmas disease)

- Diagnosis of congenital factor IX deficiency has been confirmed by blood coagulation testing; **AND**
- Confirmation the patient has inhibitors to Factor IX; **AND**
- Used as treatment in at least one of the following:
  - Control and prevention of acute bleeding episodes (episodic treatment of acute hemorrhage); **OR**
  - Perioperative management (*authorizations valid for 1 month); **OR**
  - Routine prophylaxis to prevent or reduce the frequency of bleeding episodes; **AND**
    - Patient has at least two documented episodes of spontaneous bleeding into joints; **OR**
  - Patient has a documented trial and failure of Immune Tolerance Induction (ITI)

CLINICAL CRITERIA FOR APPROVAL *(CONTINUED)*

FEIBA NF/FEIBA VF *(CONTINUED)*

RENEWAL

- Patient continues to meet initial criteria; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include symptoms of allergic-anaphylactic reactions (anaphylaxis, dyspnea, rash), thromboembolic events (thromboembolism, pulmonary embolism), development of neutralizing antibodies (inhibitors), etc.; **AND**
- Any increases in dose must be supported by an acceptable clinical rationale (e.g., weight gain, half-life study results, increase in breakthrough bleeding when patient is fully adherent to therapy, etc.); **AND**
- The cumulative amount of medication(s) the patient has on-hand will be taken into account when authorizing. The authorization will allow up to 5 doses on-hand for the treatment of acute bleeding episodes as needed for the duration of the authorization; **AND**
- Treatment of acute bleeding episodes/treatment of Spontaneous and trauma-induced bleeding episodes/on-demand treatment of bleeding episodes
  - Renewal will be approved for a 6-month authorization period
- Prevention of acute bleeding episodes/Routine prophylaxis to prevent or reduce the frequency of bleeding episode
  - Renewals will be approved for a 12-month authorization period

NOVOSEVEN RT

Note: initial authorization will be provided for 3 months and may be renewed, unless noted below

Coverage is provided in the following conditions:

Hemophilia A (congenital factor VIII deficiency)

- Diagnosis of congenital factor VIII deficiency has been confirmed by blood coagulation testing; **AND**
- Confirmation patient has acquired inhibitors to Factor VIII; **AND**
- Used as treatment in at least one of the following:
  - Control and prevention of acute bleeding episodes (episodic treatment of acute hemorrhage); **OR**
  - Perioperative management (*authorizations valid for 1 month); **OR**
  - Routine prophylaxis to prevent or reduce the frequency of bleeding episodes when the following criteria are also met:
    - Patient has at least two documented episodes of spontaneous bleeding into joints; **OR**
    - Patient has documented trial and failure of Immune Tolerance Induction (ITI); **AND**
      - Patient has documented trial and failure or contraindication to Hemlibra

Acquired Hemophilia

- Diagnosis of acquired hemophilia has been confirmed by blood coagulation testing; **AND**
- Used as treatment for one of the following:
  - Control and prevention of acute bleeding episodes (episodic treatment of acute hemorrhage); **OR**
  - Perioperative management (*authorizations valid for 1 month)

CLINICAL CRITERIA FOR APPROVAL *(CONTINUED)*

NOVOSEVEN RT *(CONTINUED)*

Hemophilia B (congenital factor IX deficiency, a.k.a. Christmas disease)

- Diagnosis of congenital factor IX deficiency has been confirmed by blood coagulation testing; **AND**
- Confirmation patient has acquired inhibitors to Factor IX; **AND**
- Used as treatment for one of the following:
  - Control and prevention of acute bleeding episodes (episodic treatment of acute hemorrhage); **OR**
  - Perioperative management (*authorizations valid for 1 month); **OR**
  - Routine prophylaxis to prevent or reduce the frequency of bleeding episodes when the following criteria are also met
    - Patient has at least two documented episodes of spontaneous bleeding into joints; **OR**
    - Patient has documented trial and failure of Immune Tolerance Induction (ITI)

Congenital Factor VII Deficiency

- Diagnosis of congenital factor VII deficiency has been confirmed by blood coagulation testing; **AND**
- Used as treatment for one of the following:
  - Control and prevention of acute bleeding episodes (episodic treatment of acute hemorrhage); **OR**
  - Perioperative management (*authorizations valid for 1 month)

Glanzmann's Thrombasthenia

- Diagnosis of Glanzmann Thrombasthenia has been confirmed by blood coagulation testing; **AND**
- Used as treatment for one of the following:
  - Control and prevention of acute bleeding episodes (episodic treatment of acute hemorrhage); **OR**
  - Perioperative management (*authorizations valid for 1 month); **AND**
- The use of platelet transfusions is known or suspected to be ineffective or contraindicated

RENEWAL

- Patient continues to meet initial criteria; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include symptoms of allergic-anaphylactic reactions (anaphylaxis, dyspnea, rash), thromboembolic events (thromboembolism, pulmonary embolism), and development of neutralizing antibodies (inhibitors); **AND**
- Any increases in dose must be supported by an acceptable clinical rationale (e.g., weight gain, half-life study results, increase in breakthrough bleeding when patient is fully adherent to therapy, etc.); **AND**
- The cumulative amount of medication(s) the patient has on-hand will be taken into account when authorizing. The authorization will allow up to 5 doses on-hand for the treatment of acute bleeding episodes as needed for the duration of the authorization.

Treatment of acute bleeding episodes/treatment of spontaneous and trauma-induced bleeding episodes/on-demand treatment of bleeding episodes

- Renewals will be approved for a 6-month authorization period

Prevention of acute bleeding episodes/routine prophylaxis to prevent or reduce the frequency of bleeding episode

- Renewals will be approved for a 12-month authorization period

CLINICAL CRITERIA FOR APPROVAL *(CONTINUED)*

TRETTEN

Initial authorization: 3 months, renewal: 12 months (unless noted below)

Coverage is provided in the following conditions:

Congenital Factor XIII A-subunit deficiency

- Diagnosis of congenital factor XIII A-subunit deficiency has been confirmed by blood coagulation testing; **AND**
- Used for routine prophylaxis of bleeding

RENEWAL

Coverage can be renewed based upon the following criteria:

- Patient continues to meet initial criteria; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include symptoms of allergic-anaphylactic reactions (anaphylaxis, dyspnea, rash), thromboembolic events (thromboembolism, pulmonary embolism), and development of neutralizing antibodies (inhibitors); **AND**
- Any increases in dose must be supported by an acceptable clinical rationale (e.g., weight gain, half-life study results, increase in breakthrough bleeding when patient is fully adherent to therapy, etc.); **AND**
- The cumulative amount of medication(s) the patient has on-hand will be taken into account when authorizing. The authorization will allow up to 5 doses on-hand for the treatment of acute bleeding episodes as needed for the duration of the authorization.

Prevention of acute bleeding episodes/routine prophylaxis to prevent or reduce the frequency of bleeding episode

- Renewals will be approved for a 12-month authorization period.

COAGADEX

Initial authorization: 3 months, renewal: 6 months (unless noted below)

Hereditary Factor X deficiency

- Diagnosis of congenital factor X deficiency has been confirmed by blood coagulation testing; **AND**
  - Used for on-demand treatment and control of bleeding episodes; **OR**
  - Used for routine prophylaxis to reduce the frequency of bleeding episodes:
    - Patient must have severe factor X deficiency (factor X level of < 1%); **OR**
    - Patient has at least two documented episodes of spontaneous bleeding into joints; **OR**
  - Used for perioperative management of surgical bleeding in patients with mild and moderate deficiency (*authorizations valid for 1 month)

CLINICAL CRITERIA FOR APPROVAL *(CONTINUED)*

COAGADEX *(CONTINUED)*

RENEWAL

- Patient continues to meet initial criteria; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include symptoms of allergic-anaphylactic reactions (anaphylaxis, dyspnea, rash), thromboembolic events (thromboembolism, pulmonary embolism), and development of neutralizing antibodies (inhibitors); **AND**
- Any increases in dose must be supported by an acceptable clinical rationale (e.g., weight gain, half-life study results, increase in breakthrough bleeding when patient is fully adherent to therapy, etc.) ; **AND**
- The cumulative amount of medication(s) the patient has on-hand will be taken into account when authorizing. The authorization will allow up to 5 doses on-hand for the treatment of acute bleeding episodes as needed for the duration of the authorization; **AND**

Treatment of acute bleeding episodes/treatment of spontaneous and trauma-induced bleeding episodes/on-demand treatment of bleeding episodes

- Renewals will be approved for a 6-month authorization period

Prevention of acute bleeding episodes/routine prophylaxis to prevent or reduce the frequency of bleeding episode

- Renewals will be approved for a 6-month authorization period

CORIFACT

Initial authorization: 3 months, renewal: 12 months (unless noted below)

Coverage is provided in the following conditions:

Congenital Factor XIII deficiency

- Diagnosis of congenital factor XIII deficiency has been confirmed by blood coagulation testing; **AND**
- Used for routine prophylactic treatment; **OR**
  - Used for perioperative management of surgical bleeding (*authorizations valid for 1 month)

RENEWAL

Coverage can be renewed based upon the following criteria:

- Patient continues to meet initial criteria; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include symptoms of allergic-anaphylactic reactions (anaphylaxis, dyspnea, rash), thromboembolic events (thromboembolism, pulmonary embolism), and development of neutralizing antibodies (inhibitors); **AND**
- Any increases in dose must be supported by an acceptable clinical rationale (e.g., weight gain, half-life study results, increase in breakthrough bleeding when patient is fully adherent to therapy, etc.); **AND**
- The cumulative amount of medication(s) the patient has on-hand will be taken into account when authorizing. The authorization will allow up to 5 doses on-hand for the treatment of acute bleeding episodes as needed for the duration of the authorization; **AND**

Prevention of acute bleeding episodes/routine prophylaxis to prevent or reduce the frequency of bleeding episode

- Renewals will be approved for a 12-month authorization period

CLINICAL CRITERIA FOR APPROVAL *(CONTINUED)*

WILATE

Initial authorization: 3 months, may be renewed (unless noted below)

Coverage is provided in the following conditions:

von Willebrand disease (vWD)

- Diagnosis of von Willebrand disease has been confirmed by blood coagulation and von Willebrand factor testing; **AND**
- Used for perioperative management of bleeding (*authorization valid for 1 month); **OR**
  - Used as treatment of spontaneous and trauma-induced bleeding episodes in at least one of the following:
    - Patients with severe vWD; **OR**
    - Patients with mild or moderate vWD in whom the use of desmopressin is known or suspected to be ineffective or contraindicated

Hemophilia A (congenital factor VIII deficiency)

- Diagnosis of congenital factor VIII deficiency has been confirmed by blood coagulation testing; **AND**
- Used as treatment for control and prevention of bleeding episodes (episodic treatment of acute hemorrhage); **OR**
  - Routine prophylaxis to prevent or reduce the frequency of bleeding episodes; **AND**
- Patient must have severe hemophilia A (factor VIII level of < 1%); **OR**
  - Patient has at least two documented episodes of spontaneous bleeding into joints

RENEWAL

Coverage can be renewed based upon the following criteria:

- Patient continues to meet criteria identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include symptoms of allergic-anaphylactic reactions (anaphylaxis, dyspnea, rash), thromboembolic events (thromboembolism, pulmonary embolism), and development of neutralizing antibodies (inhibitors); **AND**
- Any increases in dose must be supported by an acceptable clinical rationale (e.g., weight gain, half-life study results, increase in breakthrough bleeding when patient is fully adherent to therapy, etc.); **AND**
- The cumulative amount of medication(s) the patient has on-hand will be taken into account when authorizing. The authorization will allow up to 5 doses on hand for the treatment of acute bleeding episodes as needed for the duration of the authorization; **AND**

Treatment of acute bleeding episodes/treatment of spontaneous and trauma-induced bleeding episodes/on-demand treatment of bleeding episodes

- Renewals will be approved for a 6-month authorization period

Prevention of acute bleeding episodes/routine prophylaxis to prevent or reduce the frequency of bleeding episode

- Renewals will be approved for a 12-month authorization period

CLINICAL CRITERIA FOR APPROVAL *(CONTINUED)*

VONVENDI

Initial authorization: 3 months, may be renewed (unless noted below)

Diagnosis of von Willebrand Disease (vWD)

- Patient is 18 years or older**; AND**
- Diagnosis of von Willebrand disease has been confirmed by blood coagulation and von Willebrand factor testing; **AND**
- Used as treatment of spontaneous and trauma-induced bleeding episodes in at least one of the following:
  - Patients with severe vWD; **OR**
  - Patients with mild or moderate vWD in whom the use of desmopressin is known or suspected to be ineffective or contraindicated; **OR**
  - Perioperative Management (**Note:** authorizations are for 1 month); **AND**
- Is **not** being used for routine prophylactic treatment of spontaneous bleeding episodes

RENEWAL

- Patient continues to meet criteria identified in initial criteria; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include symptoms of allergic-anaphylactic reactions (anaphylaxis, dyspnea, rash), thromboembolic events (thromboembolism, pulmonary embolism), and development of neutralizing antibodies (inhibitors); **AND**
- Any increases in dose must be supported by an acceptable clinical rationale (e.g., weight gain, half-life study results, increase in breakthrough bleeding when patient is fully adherent to therapy, etc.); **AND**
- The cumulative amount of medication(s) the patient has on-hand will be taken into account when authorizing. The authorization will allow up to 5 doses on-hand for the treatment of acute bleeding episodes as needed for the duration of the authorization; **AND**

Treatment of acute bleeding episodes/treatment of spontaneous and trauma-induced bleeding episodes/on-demand treatment of bleeding episodes

- Renewals will be approved for a 6-month authorization period.

CLINICAL CRITERIA FOR APPROVAL *(CONTINUED)*

HEMLIBRA (APPROVAL LENGTH: 3 MONTHS INITIAL, 12 MONTHS RENEWAL)

Hemophilia A (congenital factor VIII deficiency) with inhibitors

- Diagnosis of congenital factor VIII deficiency has been confirmed by blood coagulation testing; **AND**
- Patient has confirmed inhibitors to Factor VIII; **AND**
- Used as routine prophylaxis to prevent or reduce the frequency of bleeding episodes; **AND**
- Not used in combination with Immune Tolerance Induction (ITI); **AND**
- Patient has had at least two documented episodes of spontaneous bleeding into joints; **OR**
  - Patient had a documented trial and failure of immune tolerance induction (ITI); **OR**
  - Patient had a documented trial and failure of or is currently on routine prophylaxis with a bypassing agent (e.g., NovoSeven, Feiba)

Hemophilia A (congenital factor VIII deficiency) without inhibitors

- Diagnosis of congenital factor VIII deficiency has been confirmed by blood coagulation testing; **AND**
- Must be used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes; **AND**
- Patient must have severe hemophilia A (factor VIII level of < 1%): **OR**
  - Patient has had at least two documented episodes of spontaneous bleeding into joints; **AND**
- Patient is not a suitable candidate for treatment with shorter half-life Factor VIII (Recombinant) products at a total weekly dose of 100 IU/kg or less (as attested by the prescribing physician with appropriate clinical rational)

RENEWAL

- Patient continues to meet criteria for initial approval; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include symptoms of allergic-anaphylactic reactions (anaphylaxis, dyspnea, rash), thromboembolic events (thromboembolism, pulmonary embolism), and development of neutralizing antibodies (inhibitors); **AND**
- Patient has demonstrated a beneficial response to therapy (i.e., the frequency of bleeding episodes has decreased from pre-treatment baseline)

NO CLAIMS ARE ALLOWED TO BE ADJUDICATED FOR ANY HEMOPHILIA DRUGS OUTSIDE OF CVS PHARMACY

BOSULIF® (BOSUTINIB)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75 – HICL, 50081 and 2193) MNC: Non-Formulary Product (IE 50698 / MR – GSN PatOverride)

Grandfathered drug: Grandfathering criteria applies

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Chronic Myelogenous Leukemia (CML)**

- Patient is at least 18 years old; **AND**
- Patient will avoid concomitant use with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort); **AND**
- Patient will avoid concomitant use with moderate and strong CYP3A inhibitors (e.g., itraconazole, fluconazole, clarithromycin); **AND**
- Patient will avoid concomitant use with acid-reducing agents (i.e., proton pump inhibitors), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient's disease is confirmed by either a Philadelphia chromosome-positive (Ph+) or *BCR-ABL1* positive laboratory test result; **AND**
- Patient does not have any of the following *BCR-ABL1* mutations: T315I, V299L, G250E, or F317L (****Note:** This does **not** apply to patients receiving first-line or continued therapy); **AND**
  - Patient is resistant, or intolerant, or had an inadequate response to prior therapy, consisting of a 3 month trial or longer, with omacetaxine or a tyrosine kinase inhibitor (e.g., imatinib, dasatinib, ponatinib, nilotinib)†; **AND**
    - Patient has chronic, accelerated, or blast phase disease; **OR**
  - Used post-allogeneic hematopoietic stem cell transplant (HCT) ; **AND**
    - Used as follow-up therapy in patients with molecular relapse (BCR-ABL1 transcript positive) following complete cytogenetic response (CCyR); **OR**
    - Used for at least one year in patients with prior CCyR for accelerated or blast phase disease; **OR**
    - Used as follow-up therapy in patients with relapse or those who are not in CCyR; **OR**
  - Used as primary treatment ; **AND**
    - Used as a single agent for newly diagnosed chronic or accelerated or myeloid blast phase disease; **OR**
    - Used in combination with corticosteroids for lymphoid blast phase disease; **OR**
    - Used in combination with induction chemotherapy for disease in lymphoid blast phase or myeloid blast phase; **OR**
  - Used as switch therapy ; **AND**
    - Patient received initial treatment with one of the following: imatinib, dasatinib, or nilotinib; **AND**
    - Patient has *BCR-ABL1* transcript levels:
      - > 1% to 10% at 12 months; **OR**
      - > 1% to 10% at ≥ 15 months; **OR**
      - > 10% at any response milestone; **OR**
  - Used as continued therapy ; **AND**
    - Patient has *BCR-ABL1* transcript levels
      - ≤ 1% at any response milestone; **OR**
      - > 1% to 10% at 3, 6, or 12 months; **OR**
      - > 10% at 3 months

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Acute Lymphoblastic Leukemia (ALL)**

- Patient is at least 18 years old; **AND**
- Patient will avoid concomitant use with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort); **AND**
- Patient will avoid concomitant use with moderate and strong CYP3A inhibitors (e.g., itraconazole, fluconazole, clarithromycin); **AND**
- Patient will avoid concomitant use with acid-reducing agents (i.e., proton pump inhibitors), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient's disease is Philadelphia chromosome-positive (Ph+); **AND**
  - Used for relapsed or refractory disease; **AND**
    - Patient does not have any of the following *BCR-ABL1* mutations: T315I, V299L, G250E, or F317L; **AND**
      - Used as a single agent; **OR**
      - Used in combination with an induction therapy not previously used; **OR**
  - Used as maintenance therapy; **AND**
    - Used in combination with vincristine and prednisone with or without methotrexate and mercaptopurine; **OR**
    - Used post-hematopoietic stem cell transplant; **OR**
  - Patient is at least 15 years of age and < 65 years of age; **AND**
    - Used in a multiagent chemotherapy regimen for induction or consolidation therapy; **OR**
    - Used in combination with a corticosteroid for induction therapy; **OR**
    - Used in combination with vincristine and dexamethasone for induction therapy; **OR**
  - Patient is ≥ 65 years of age; **AND**
    - Used as induction therapy as part of one of the following regimens:
      - As a single agent or in combination with a corticosteroid; **OR**
      - In combination with vincristine and dexamethasone; **OR**
      - In combination with a multiagent chemotherapy regimen

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug (e.g., hepatic toxicity, renal toxicity, fluid retention, myelosuppression, gastrointestinal toxicity, cardiac failure, left ventricular dysfunction); **AND**
- Patient has been adherent to therapy; **AND**
- **Chronic myelogenous leukemia (CML) only**:
  - Treatment response as indicated by one of the following *BCR-ABL1* (IS) transcript levels:
    - ≤ 10% at 3 months; **OR**
    - ≤ 10% at 6 months; **OR**
    - < 1 % at 12 months and beyond

Note: Cytogenetic assessment of response may be used if quantitative RT-PCR (QPCR) using International Scale (IS) for *BCR-ABL1* is not available

- **Acute lymphoblastic leukemia (ALL) only**:
  - Treatment response or stabilization of disease as indicated by CBC, bone marrow cytogenic analysis, QPCR or FISH

BOTOX (ONABOTULINUMTOXINA)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Botulinum toxin (IE 50698 / MR – GSN)

CRITERIA FOR INITIAL APPROVAL

Note: For any cosmetic purpose, refer to the Excluded Drugs section

- Diagnosis of **Blepharospasm**
  - Patient age is 12 years or older; **AND**
  - Patient evaluated for any disorders which may contribute to respiratory or swallowing difficulty.
- Diagnosis of **Cervical Dystonia**
  - Patient age is 16 years or older; **AND**
  - Patient evaluated for any disorders which may contribute to respiratory or swallowing difficulty; **AND**
  - Patient has a history of recurrent involuntary contraction of one or more muscles in the neck; **AND**
    - Patient has sustained head tilt; **OR**
    - Abdominal posturing with limited range of motion in neck; **AND**
  - If the patient age is 18 years or older, the patient must have a documented failure, contraindication, intolerance, or ineffective response to a trial of Dysport
- Diagnosis of **Strabismus**
  - Patient age is 12 years or older; **AND**
  - Patient evaluated for any disorders which may contribute to respiratory or swallowing difficulty.
- Diagnosis of **Spastic conditions**
  - Patient age is 18 years or older; **AND**
  - Patient evaluated for any disorders which may contribute to respiratory or swallowing difficulty; **AND**
  - **ONE** of the following diagnosis:
    - Upper limb spasticity (i.e., used post-stroke for spasms)
      - Patient must have a documented failure, contraindication, intolerance, or ineffective response to a trial of Dysport.
    - Pediatric upper limb spasticity in patients whose age is 2 years or older (i.e., used post-stroke for spasms or for spasms related to cerebral palsy)
    - Lower limb spasticity (i.e., used post-stroke for spasms)
      - Patient must have a documented failure, contraindication, intolerance, or ineffective response to a trial of Dysport.
    - Cerebral palsy with concurrent equinus gait
      - Patient must have a documented failure, contraindication, intolerance, or ineffective response to a trial of Dysport
    - Spasticity due to multiple sclerosis or Schilder's disease
    - Acquired spasticity secondary to spinal cord or brain injuries
      - Patient must have a documented failure, contraindication, intolerance, or ineffective response to a trial of Dysport
    - Spastic plegic conditions including monoplegia, diplegia, hemiplegia, paraplegia (including hereditary spastic paraplegia) and quadriplegia
    - Hemifacial spasm

CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

- Diagnosis of **Severe Primary Axillary Hyperhidrosis**
  - Patient age is 18 years or older; **AND**
  - Patient evaluated for any disorders which may contribute to respiratory or swallowing difficulty; **AND**
  - Patient has tried and failed a ≥ 1-month trial of a topical agent (e.g., aluminum chloride, glycopyrronium); **AND**
  - Patient has history of medical complications such as skin infections or significant functional impairments; **OR**
  - Patient has had a significant burden of disease or impact to activities of daily living due to condition (e.g., impairment in work performance/productivity, frequent change of clothing, difficulty in relationships and/or social gatherings)
- Diagnosis of **Prophylaxis of Chronic Migraines**
  - Patient age is 18 years or older; **AND**
  - Patient evaluated for any disorders which may contribute to respiratory or swallowing difficulty; **AND**
  - Not used in combination with calcitonin gene-related peptide (CGRP) inhibitors (e.g., erenumab); **AND**
  - Patient is utilizing prophylactic intervention modalities (e.g., pharmacotherapy, behavioral therapy, or physical therapy); **AND**
  - Patient has failed an 8-week trial of any two oral medications (a total of 16 weeks) for the prevention of migraines (not all inclusive):
    - Antidepressants (e.g., amitriptyline, fluoxetine, nortriptyline)
    - Beta blockers (e.g., propranolol, metoprolol, nadolol, timolol, atenolol, pindolol)
    - Angiotensin converting enzyme inhibitors/angiotensin II receptor blockers (e.g., lisinopril, candesartan)
    - Anti-epileptics (e.g., divalproex, valproate, topiramate)
    - Calcium channels blockers (e.g., verapamil)
  - Patient has 15 or more migraine-like headache days per month for at least 3 months; **AND**
    - Headaches have diagnostic migraine-features, on at least 8 days per month for at least 3 months (see list of diagnostic migraine features with and without aura below); **AND**
    - Patient suspected migraines are relieved by a triptan or ergot derivative medication

Migraine Features
Migraine without aura: • At least five attacks have the following: – Headache attacks lasting 4–72 hours (untreated or unsuccessfully treated) – Headache has at least two of the following characteristics: • Unilateral location • Pulsating quality • Moderate or severe pain intensity • Aggravation by or causing avoidance of routine physical activity (e.g., walking or climbing stairs); **AND** – During headache, at least one of the following: • Nausea and/or vomiting • Photophobia and phonophobia

CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Migraine Features *(Continued)*

Migraine with aura:

- At least two attacks have the following:
  - One or more of the following fully reversible aura symptoms:
    - Visual
    - Sensory
    - Speech and/or language
    - Motor
    - Brainstem
    - Retinal; **AND**
  - At least two of the following characteristics:
    - At least one aura symptom spreads gradually over ≥ 5 minutes, and/or two or more symptoms occur in succession
    - Each individual aura symptom lasts 5 to 60 minutes
    - At least one aura symptom is unilateral
    - The aura is accompanied, or followed within 60 minutes, by headache

- Diagnosis of **Esophageal achalasia**
  - Patient age is 18 years or older; **AND**
  - Patient evaluated for any disorders which may contribute to respiratory or swallowing difficulty; **AND**
  - Patient is at high risk of complication from pneumatic dilation or surgical myotomy; **OR**
  - Patient has had treatment failure with pneumatic dilation or surgical myotomy; **OR**
  - Patient has had perforation from pneumatic dilation; **OR**
  - Patient has an epiphrenic diverticulum or hiatal hernia; **OR**
  - Patient has esophageal varices
- Diagnosis of **Focal Dystonias**
  - Patient age is 18 years or older; **AND**
  - Patient evaluated for any disorders which may contribute to respiratory or swallowing difficulty; **AND**
  - Focal upper limb dystonia
    - Patient has functional impairment; **OR**
    - Patient has pain as a result
  - Laryngeal dystonia
  - Oromandibular dystonia
    - Patient has functional impairment; **OR**
    - Patient has pain as a result
- Diagnosis of **Sialorrhea associated with neurological disorders**
  - Patient age is 18 years or older; **AND**
  - Patient evaluated for any disorders which may contribute to respiratory or swallowing difficulty; **AND**
  - Patient has Parkinson's disease; **OR**
  - Patient has severe developmental delays; **AND**
    - Patient has tried and failed, is unable to tolerate or has a contraindication to an adequate trial of oral therapy (e.g., glycopyrrolate, benztropine, atropine); **OR**
  - Patient has cerebral palsy; **AND**
    - Patient has tried and failed, is unable to tolerate or has a contraindication to an adequate trial of oral therapy (e.g., glycopyrrolate, benztropine, atropine); **OR**
  - Patient has amyotrophic lateral sclerosis

CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

- Diagnosis of **incontinence due to detrusor overactivity**
  - Patient age is 18 years or older; **AND**
  - Patient evaluated for any disorders which may contribute to respiratory or swallowing difficulty; **AND**
  - Patient has detrusor overactivity associated with a neurologic condition (e.g., spinal cord injury, multiple sclerosis) that is confirmed by urodynamic testing; **AND**
  - Patient has failed a 1 month or longer trial of **two** medications from either the antimuscarinic (i.e., darifenacin, fesoterodine, oxybutynin, solifenacin, tolterodine or trospium) or beta-adrenergic (i.e., mirabegron) classes
- Diagnosis of **Overactive bladder (OAB)**
  - Patient age is 18 years or older; **AND**
  - Patient evaluated for any disorders which may contribute to respiratory or swallowing difficulty; **AND**
  - Patient has symptoms of urge urinary incontinence, urgency, and frequency; **AND**
  - Patient has failed a 1 month or longer trial of **two** medications from either the antimuscarinic (i.e., darifenacin, fesoterodine, oxybutynin, solifenacin, tolterodine or trospium) or beta-adrenergic (i.e., mirabegron) classes
- Diagnosis of **Severe Palmar Hyperhidrosis**
  - Patient age is 18 years or older; **AND**
  - Patient evaluated for any disorders which may contribute to respiratory or swallowing difficulty; **AND**
  - Patient has tried and failed a ≥ 1-month trial of a topical agent (e.g., aluminum chloride); **AND**
  - Patient has failed with iontophoresis; **AND**
    - Patient has history of medical complications such as skin infections or significant functional impairments; **OR**
    - Patient has had a significant impact to activities of daily living due to the condition
- Diagnosis of **Chronic anal fissure**
  - Patient age is 18 years or older; **AND**
  - Patient evaluated for any disorders which may contribute to respiratory or swallowing difficulty; **AND**
  - Other causes of disease have been ruled out (e.g., Crohn's Disease); **AND**
  - Patient has failed on non-pharmacologic supportive measures (e.g., sitz baths, psyllium fiber, bulking agents); **AND**
  - Patient has tried and failed a ≥ 1-month trial of conventional therapy (e.g., oral/topical nifedipine, diltiazem, and/or topical nitroglycerin, bethanechol)

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include symptoms of a toxin spread effect (e.g., asthenia, generalized muscle weakness, diplopia, ptosis, dysphagia, dysphonia, dysarthria, swallowing/breathing difficulties), severe hypersensitivity reactions, severe pulmonary effects (e.g., reduced pulmonary function), corneal exposure/ulceration, retrobulbar hemorrhage, bronchitis/upper-respiratory tract infections, autonomic dysreflexia, urinary tract infection, urinary retention, etc.; **AND**
- Disease response as evidenced by the following:
  - Blepharospasms
    - Improvement of severity and/or frequency of eyelid spasms
  - Cervical dystonia
    - Improvement in the severity and frequency of pain; **AND**
    - Improvement of abnormal head positioning
    - Strabismus
    - Improvement in alignment of prism diopters compared to pre-treatment baseline

CLINICAL CRITERIA FOR RENEWAL *(CONTINUED)*

- Focal upper/lower limb spasticity
  - Decrease in tone and/or resistance, of affected areas, based on a validated measuring tool (e.g., Ashworth Scale, Physician Global Assessment, Clinical Global Impression [CGI])
- Hemifacial spasms
  - Decrease in frequency and/or severity of spasm, or a decrease in tone and/or improvement in asymmetry to the affected side of the face
- Severe primary axillary hyperhidrosis
  - Significant reduction in spontaneous axillary sweat production; **AND**
  - Patient has a significant improvement in activities of daily living
- Prophylaxis for chronic migraines
  - Not used in combination with calcitonin gene-related peptide (CGRP) inhibitors (e.g., erenumab); **AND**
  - Significant decrease in the number, frequency, and/or intensity of headaches; **AND**
  - Improvement in function; **AND**
  - Patient continues to utilize prophylactic intervention modalities (e.g., pharmacotherapy, behavioral therapy, physical therapy)
- Esophageal achalasia
  - Improvement and/or relief in symptoms (e.g., dysphagia, pain); **OR**
  - Improvement in esophageal emptying as evidenced by functional testing
- Focal dystonias
  - Focal upper limb dystonia
    - Improvement in pain and/or function
  - Laryngeal dystonia
    - Improvement in voice function or quality
  - Oromandibular dystonia
    - Improvement in pain and function
- Sialorrhea associated with neurological disorders
  - Significant decrease in saliva production
- Incontinence due to detrusor overactivity
  - Significant improvements in weekly frequency of incontinence episodes; **AND**
  - Patient's post-void residual (PVR) periodically assessed as medically appropriate
- Overactive bladder (OAB)
  - Significant improvement in daily frequency of urinary incontinence or micturition episodes and/or volume voided per micturition; **AND**
  - Patient's post-void residual (PVR) periodically assessed as medically appropriate
- Severe Palmar hyperhidrosis
  - Significant reduction in spontaneous palmar sweat production; **AND**
  - Patient has a significant improvement in activities of daily living
- Chronic anal fissure
  - Complete healing of anal fissure; **OR**
  - Symptomatic improvement of persistent fissures
- Spastic conditions, other (e.g., plegias)
  - Decrease in tone and/or resistance, of affected areas, based on a validated measuring tool (e.g., Ashworth Scale, Physician Global Assessment, Clinical Global Impression [CGI])

CLINICAL CRITERIA FOR RENEWAL *(CONTINUED)*

Max Units (per dose and over time):

Indication	# vials to build in FirstTrax℠	Per# days#
Blepharospasm	1 (200 unit vial)	84
Cervical Dystonia	2 (200 unit vial)	84
Strabismus	1 (100 unit vial)	84
Achalasia	1 (100 unit vial)	168
Upper Limb Spasticity	2 (200 unit vial)	84
Lower Limb Spasticity	2 (200 unit vial)	84
Chronic Migraine	1 (200 unit vial)	84
Severe Primary Axillary Hyperhidrosis	1 (100 unit vial)	112
Sialorrhea	1 (100 unit vial)	84
Neurogenic Bladder/Detrusor Overactivity	1 (200 unit vial)	84
Overactive Bladder	1 (100 unit vial)	84
Chronic Anal Fissures	1 (100 unit vial)	84
Palmar Hyperhidrosis	1 (200 unit vial)	168
Pediatric Upper limb spasticity	3 (100 unit vial)	84
Laryrngeal Dystonia	1 (100 unit vial)	84
Hemifacial Spasms	1 (100 unit vial)	84
Oromandibular Dystonia	1 (200 unit vial)	84
All other indications	2 (200 unit vial)	84

Available in 100 unit and 200 unit single-use vials.

***** The plan may only allow for a max of 30 days to be billed at a time, no day's supply override needs to be placed to allow these to pay. The pharmacy may process as the 30 days. These limitations will not allow the member to fill more than the allotted vials.

BUPRENORPHINE PRODUCTS FOR OPIATE ADDICTION

Length of Authorization:	**Buprenorphine:** Initial 3 months; 6 months for first renewal; 12 months for subsequent renewals **Sublocade:** Initial 6 months; Renewal 12 months
Initiative:	MNC: Opiate Abuse Treatment (IE 2462 / NCPDP 75 – GSN)

CLINICAL CRITERIA FOR SINGLE INGREDIENT BUPRENORPHINE: INITIAL REQUEST

Diagnosis of Opioid Dependence

For single-ingredient Buprenorphine ONLY:

- **PA required unless the member is pregnant; the prescriber must note the following ICD-10 codes on the prescription:**
  1. O09.91 – Supervision of high-risk pregnancy, 1st Trimester.
  2. O09.92 – Supervision of high-risk pregnancy, 2nd Trimester.
  3. O09.93 – Supervision of high-risk pregnancy, 3rd Trimester.
  4. O09.90 – Supervision of high-risk pregnancy – use for post-partum nursing mothers

Escalate to pharmacists for clinical judgment if:

- Concurrent use with opioids
- More than 1 strength or buprenorphine product is requested
- Buprenorphine single-ingredient product required due to contraindication to naloxone

CLINICAL CRITERIA FOR SINGLE INGREDIENT BUPRENORPHINE: RENEWAL REQUEST

- Initial request criteria must be met; **AND**
- The patient has been compliant with no gaps in therapy since initial authorization; gaps in therapy will need to be explained; **AND**
- The patient has had continued participation in substance abuse counseling **OR** give reason patient is unable to have counseling **OR** patient no longer needs counseling; **AND**
- Verbal or written attestation of regular urine drug screens including buprenorphine; recommend one test being within the past 60 days of the renewal request; it should **NOT** be negative for buprenorphine or positive for opioids.

CLINICAL CRITERIA FOR INITIAL REQUEST FOR SUBLOCADE–AHCCCS-MANDATED CRITERIA

Length of authorization: 6 months (Initial)

Buprenorphine extended-release injection (Sublocade®) is proven and/or medically necessary for the treatment of moderate to severe opioid use disorder in patients who meet **ALL** of the following:

- Patient has severe opioid use disorder (OUD) as defined by the DSM-5 OUD Diagnostic Tool and has a demonstrated history of non-adherence to oral medications; **AND**
- Patient is currently maintained on 8 mg to 24 mg per day dose of oral, sublingual, or transmucosal buprenorphine product equivalent for at least 7 days prior to initiation of extended-release buprenorphine injection; **AND**
- Patient has not, nor will receive supplemental, oral, sublingual, or transmucosal buprenorphine; **AND**
- Patient is receiving psychosocial interventions as part of a comprehensive medication assisted treatment (MAT) program; **AND**
- Prescriber meets DATA 2000 requirements and has been assigned a unique identification number specific to the prescription of medication assisted therapy (DEA-X); **AND**
- Prescriber checks the Arizona State Board of Pharmacy Controlled Substance Prescription Monitoring Program (CSPMP) database prior to each monthly injection; **AND**
- Sublocade dosing is in accordance with the U.S. Food and Drug Administration (FDA) approved labeling: 300 mg subcutaneously monthly for the first 2 months, followed by a maintenance dose of 100 mg or 300 mg monthly.

CLINICAL CRITERIA FOR RENEWAL REQUEST FOR SUBLOCADE–AHCCCS-MANDATED CRITERIA

Length of authorization: 12 months (Renewal)

- Physician documentation that the patient has experienced a positive clinical response to buprenorphine extended-release therapy, as defined by the provider; **AND**
- Patient has not, nor will receive supplemental, oral, sublingual, or transmucosal buprenorphine; **AND**
- Patient is receiving psychosocial interventions as part of a comprehensive medication assisted treatment (MAT) program; **AND**
- Prescriber meets DATA 2000 requirements and has been assigned a unique identification number specific to the prescription of medication assisted therapy (DEA-X); **AND**
- Prescriber checks the Arizona State Board of Pharmacy Controlled Substance Prescription Monitoring Program (CSPMP) database prior to each monthly injection; **AND**
- Sublocade dosing is in accordance with the U. S. Food and Drug Administration approved labeling: maintenance dose of 100 mg or 300 mg monthly.

Covered – PA Required
Buprenorphine SL (generic for Subutex®) No PA required for pregnant women – see above
Sublocade® *(buprenorphine)*

BRILINTA® (TICAGRELOR)

Length of Authorization:	1 Year, eligible for renewal
Initiative:	MNC: Platelet inhibitors (IE 2462 / NCPDP 75 – HICL)

CLINICAL CRITERIA BRILINTA

- Patient is 18 years of age or older; **AND**
- Patient must have a diagnosis of acute coronary syndrome (ACS) [e.g., unstable angina (UA), non-ST elevation myocardial infarction (NSTEMI), or ST-segment elevation myocardial infarction (STEMI)]; **AND**
- Patient does not have a history of intracranial hemorrhage or active pathological bleeding such as peptic ulcer or intracranial hemorrhage; **AND**
- Patient has been evaluated for potential clinically significant drug interactions, including the following:
  - **Avoid use of strong inhibitors of CYP3A** (e.g., ketoconazole, itraconazole, voriconazole, clarithromycin, nefazodone, ritonavir, saquinavir, nelfinavir, indinavir, atazanavir and telithromycin). Concomitant therapy with strong CYP3A inhibitors substantially increase ticagrelor exposure and so increase the risk of dyspnea, bleeding, and other adverse events.
  - **Avoid use with strong inducers of CYP3A** (e.g., rifampin, phenytoin, carbamazepine and phenobarbital). Concomitant therapy with strong CYP3A inducers substantially reduce ticagrelor exposure and so decrease the efficacy of ticagrelor.
  - **Avoid use of maintenance doses of aspirin above 100 mg per day** as there is reduced effectiveness of ticagrelor.
  - **Avoid simvastatin and lovastatin doses greater than 40 mg per day** as ticagrelor increases serum concentrations of these statins.

CALCITONIN GENE-RELATED PEPTIDE (CGRP) ANTAGONISTS

Length of Authorization:	Emgality, Ajovy: 3 months for initial approval; 2 years for renewal Aimovig: 3 months for initial approval; 1 year for renewal Nurtec, Ubrelvy: Twelve months for initial and renewal
Initiative:	MNC: Antimigraine Agents (IE 2462 / NCPDP 75 – GSN) MNC: Non-Formulary Product (IE 50698 / MR – GSN PatOverride)

CLINICAL CRITERIA FOR INIITIAL APPROVAL

EMGALITY

Migraine

- Patient is 18 years of age or older; **AND**
- Diagnosis of migraine with or without aura based on International Classification of Headache Disorders (ICHD-III) diagnostic criteria; **AND**
- Medication overuse headache has been ruled out by trial and failure of titrating off acute migraine treatments in the past; **AND**
- Patient has ≥ 4 migraine days per month for at least 3 months; **AND**
- Patient has tried and failed a ≥ 1-month trial of any two different classes of the following oral medications:
  - Antidepressants (e.g., amitriptyline, venlafaxine, etc.)
  - Beta blockers (e.g., propranolol, metoprolol, timolol, atenolol, etc.)
  - Anti-epileptics (e.g., valproate, topiramate, etc.)
  - Angiotensin converting enzyme inhibitors/angiotensin II receptor blockers (e.g., lisinopril, candesartan, etc.); **AND**
- Not used in combination with botulinum agents (e.g., Botox, Dysport, Myobloc, Xeomin)

Episodic cluster headache

- Patient is 18 years of age or older; **AND**
- Diagnosis of episodic cluster headache; **AND**
- Patient has experienced at least 2 cluster periods lasting 7 days to 365 days, separated by pain-free periods lasting at least three months; **AND**
- Requested by or in consultation with a specialist (including neurologist or pain specialist); **AND**
- Not used in combination with another CGRP inhibitor; **AND**
- Not used in combination with botulinum agents (e.g., Botox, Dysport, Myobloc, Xeomin)

CLINICAL CRITERIA FOR INIITIAL APPROVAL (*CONTINUED*)

AIMOVIG

Migraine

- Patient is 18 years of age or older; **AND**
- Patient must have an inadequate response, contraindication, or intolerance to **both Emgality AND Ajovy**
- Diagnosis of migraine with or without aura based on International Classification of Headache Disorders (ICHD-III) diagnostic criteria; **AND**
- Medication overuse headache has been ruled out by trial and failure of titrating off acute migraine treatments in the past; **AND**
- Patient has ≥ 4 migraine days per month for at least 3 months; **AND**
- Patient has tried and failed a ≥ 1-month trial of any two different classes of the following oral medications:
  - Antidepressants (e.g., amitriptyline, venlafaxine, etc.)
  - Beta blockers (e.g., propranolol, metoprolol, timolol, atenolol, etc.)
  - Anti-epileptics (e.g., valproate, topiramate, etc.)
  - Angiotensin converting enzyme inhibitors/angiotensin II receptor blockers (e.g., lisinopril, candesartan, etc.); **AND**
- Not used in combination with botulinum agents (e.g., Botox, Dysport, Myobloc, Xeomin)

AJOVY

Migraine

- Patient is 18 years of age or older; **AND**
- Diagnosis of migraine with or without aura based on International Classification of Headache Disorders (ICHD-III) diagnostic criteria; **AND**
- Medication overuse headache has been ruled out by trial and failure of titrating off acute migraine treatments in the past; **AND**
- Patient has ≥ 4 migraine days per month for at least 3 months; **AND**
- Patient has tried and failed a ≥ 1-month trial of any two different classes of the following oral medications:
  - Antidepressants (e.g., amitriptyline, venlafaxine, etc.)
  - Beta blockers (e.g., propranolol, metoprolol, timolol, atenolol, etc.)
  - Anti-epileptics (e.g., valproate, topiramate, etc.)
  - Angiotensin converting enzyme inhibitors/angiotensin II receptor blockers (e.g., lisinopril, candesartan); **AND**
- Not used in combination with botulinum agents (e.g., Botox®, Dysport®, Myobloc®, Xeomin®)

NURTEC

- Patient is 18 years of age or older; **AND**
- Diagnosis of migraine, with or without aura; **AND**
- Patient must NOT have headache frequency ≥ 15 headache days per month during the prior 6 months [indication is for acute use only]; **AND**
- Patient must NOT be concurrently using strong CYP3A4 inhibitors, strong or moderate CYP3A inducers, or P-gp or BCRP inhibitors; **AND**
- Patient must have tried and failed at least one of the following: NSAID, non-opioid analgesic, acetaminophen OR caffeinated analgesic combination; **AND**
- Patient must have tried and failed, or has a contraindication or intolerance to 2 generic triptans.

CLINICAL CRITERIA FOR INIITIAL APPROVAL (*CONTINUED*)

UBRELVY

- Patient is 18 years of age or older; **AND**
- Diagnosis of migraine, with or without aura; **AND**
- Patient must NOT have headache frequency ≥ 15 headache days per month during the prior 6 months [indication is for acute use only]; **AND**
- Patient must NOT be concurrently using a strong CYP3A4 inhibitor; **AND**
- Patient must have tried and failed at least one of the following: NSAID, non-opioid analgesic, acetaminophen OR caffeinated analgesic combination; **AND**
- Patient must have tried and failed, or has a contraindication or intolerance to 2 generic triptans.

CLINICAL CRITERIA FOR RENEWAL

EMGALITY, AIMOVIG, AJOVY

- Not used in combination with botulinum agents (e.g., Botox®, Dysport®, Myobloc®, Xeomin®); **AND**
- Patient demonstrated significant decrease in the number, frequency, and/or intensity of headaches; **AND**
- Patient has an overall improvement in function with therapy; **AND**
- Absence of unacceptable toxicity (e.g., intolerable injection site pain or constipation).

NURTEC, UBRELVY

- Patient must continue to meet initial criteria; **AND**
- Patient is experiencing symptom improvement; **AND**
- The patient is not experiencing any treatment-limiting adverse reactions of the medication

PREFERRED DRUGS – PA REQUIRED	NON-PREFERRED DRUGS – PA REQUIRED
EMGALITY 120 MG/ML SYRINGE	AIMOVIG
EMGALITY 120 MG/ML PEN	NURTEC
AJOVY	UBRELVY

CALQUENCE® (ACALABRUTINIB)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75 – HICL, 50081 and 2193) MNC: Non-Formulary Product (IE 50698 / MR – GSN PatOverride)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Mantle Cell Lymphoma (MCL)**

- Patient is at least 18 years of age; **AND**
- Patient does not have severe hepatic impairment (i.e., Child-Pugh class C); **AND**
- Patient will avoid concomitant use with the following drugs:
  - Strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.). If therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Strong CYP3A inhibitors (e.g., itraconazole, etc.). If therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Proton pump inhibitors (e.g., omeprazole, lansoprazole, pantoprazole, etc.); **AND**
- Used as single-agent therapy; **AND**
- Patient has received at least one prior therapy; **AND**
- Patient's has **not** received any prior treatment with a BTK-inhibitor (e.g., ibrutinib, zanubrutinib).

Diagnosis of **Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL)**

- Patient is at least 18 years of age; **AND**
- Patient does not have severe hepatic impairment (i.e., Child-Pugh class C); **AND**
- Patient will avoid concomitant use with the following drugs:
  - Strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.). If therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Strong CYP3A inhibitors (e.g., itraconazole, etc.). If therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Proton pump inhibitors (e.g., omeprazole, lansoprazole, pantoprazole, etc.); **AND**
- Used for previously untreated disease with or without del(17p)/TP53 mutation as single agent therapy or in combination with obinutuzumab; **OR**
- Used for relapsed or refractory disease with or without del(17p)/TP53 mutation as single agent therapy; **AND**
  - Patient does **not** have ibrutinib-refractory disease with BTK C481S mutations*, when BTK-mutation testing is available, and status has been assessed

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Waldenström's Macroglobulinemia/Lymphoplasmacytic Lymphoma (WM/LPL)**

- Patient is at least 18 years of age; **AND**
- Patient does not have severe hepatic impairment (i.e., Child-Pugh class C); **AND**
- Patient will avoid concomitant use with the following drugs:
  - Strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.). If therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Strong CYP3A inhibitors (e.g., itraconazole, etc.). If therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Proton pump inhibitors (e.g., omeprazole, lansoprazole, pantoprazole, etc.); **AND**
- Used as a single agent; **AND**
  - Patient has received at least one prior therapy; **OR**
  - Used for progressive or relapsed disease

*__Note__: Testing for BTK and PLCG2 mutations may be useful in patients receiving acalabrutinib and suspected of having progression. BTK and PSCG2 mutation status alone is not an indication to change treatment.

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treated as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug (e.g., hemorrhage, severe infections, myelosuppression [neutropenia, thrombocytopenia, anemia, lymphopenia], atrial fibrillation, second primary malignancies)

CAPRELSA® (VANDETANIB)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75 – HICL, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Thyroid Carcinoma**

- Patient is at least 18 years of age; **AND**
- Patient does not have uncorrected electrolyte abnormalities (e.g., hypocalcemia, hypokalemia, hypomagnesemia); **AND**
- Patient does not have long QT syndrome (i.e., QTcF interval > 450 milliseconds); **AND**
- Patient does not have a history of Torsades de pointes, congenital long QT syndrome, bradyarrhythmias, or uncompensated heart failure; **AND**
- Both patient **and** prescriber are enrolled in the Caprelsa REMS™ program; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, phenytoin, St. John's Wort, etc.); **AND**
  - Coadministration with anti-arrhythmic drugs (e.g., amiodarone, disopyramide, procainamide, sotalol, dofetilide, etc.); **AND**
  - Coadministration with QTc prolonging drugs (e.g., chloroquine, clarithromycin, dolasetron, granisetron, haloperidol, methadone, moxifloxacin, pimozide, etc.); **AND**
- Used as single agent therapy; **AND**
  - Patient has papillary, follicular, or Hürthle cell carcinoma; **AND**
    - Patient has unresectable recurrence, persistent disease, or distant metastases; **AND**
    - Patient has progressive and/or symptomatic disease that is radioactive-iodine refractory; **AND**
    - No alternative therapies are available or appropriate (e.g., clinical trial or systemic therapy); **OR**
  - Patient has medullary carcinoma; **AND**
    - Patient has unresectable locally advanced, recurrent, or metastatic disease; **AND**
    - Patient has asymptomatic, symptomatic, or progressive disease

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug (e.g., interstitial lung disease [ILD] or pneumonitis, severe skin reactions [i.e., toxic epidermal necrolysis and Stevens-Johnson syndrome], hypertension, QT prolongation, Torsades de Pointes, ventricular tachycardia, ischemic cerebrovascular events, hemorrhage, heart failure, reversible posterior leukoencephalopathy syndrome [RPLS], severe diarrhea [i.e., ≥ grade 3 severity], hypothyroidism, impaired wound healing).

CAYSTON® (AZTREONAM)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Respiratory Agents (IE 2462 / NCPDP 75 – HICL) MNC: Non-Formulary Product (IE 50698 / MR – GSN PatOverride)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Cystic Fibrosis**

- Patient is 7 years or older; **AND**
- Patient has a baseline percent predicted forced expiratory volume (FEV_1) (renewal will require reported measurement within previous 30 days); **AND**
- Confirmation that the patient is colonized with *Pseudomonas aeruginosa* per positive sputum culture; **AND**
- The patient is not colonized with *Burkholderia cepacia*; **AND**
- Confirmation the patient is not receiving treatment with other inhaled antibiotics and/or anti-infective agents, including alternating treatment schedules; **AND**
- Confirmation the patient has been colonized with pseudomonas aeruginosa per positive sputum culture; **AND**
- Patient has a documented failure, contraindication, or ineffective response at maximum tolerated doses to a minimum three-month trial on previous therapy with tobramycin inhalation; **OR**
- Patient's sputum culture shows resistance to tobramycin

CLINICAL CRITERIA FOR RENEWAL

Authorizations can be renewed based on the following criteria:

- Patient continues to meet initial criteria above; **AND**
- Disease response as indicated by one of the following:
  - Improvement or stabilization of lung function (measured by percent predicted FEV_1 within previous 30 days) compared to baseline
  - Decrease in decline of lung function (measured by percent predicted FEV_1 within previous 30 days) compared to baseline
  - Decrease in respiratory-related hospitalizations
  - Decreased use of intravenous antipseudomonal antibiotics
  - Reduced number of *P. aeruginosa* colony forming units (CFUs) in sputum
  - Reduced sputum bacterial density; **AND**
- Absence of unacceptable toxicity from the drug (e.g., allergic reactions and bronchospasms during nebulizer use).

CERDELGA® (ELIGLUSTAT)

Length of Authorization:	12 months and renewable
Initiative:	SPC: Miscellaneous: PA required (IE 2462 / NCPDP 75 – HICL)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Type I Gaucher Disease**

- Patient is 18 years or older; **AND**
- Must be used as a single agent; **AND**
- Patient's CYP2D6 phenotype has been determined by an FDA-cleared test as one of the following: extensive metabolizer (EM), intermediate metabolizer (IM), or poor metabolizer (PM); **AND**
- Patient does not have any of the following contraindications based on their CYP2D6 phenotype:
  - EM do not have moderate or severe hepatic impairment; **OR**
  - EM and IM are not taking a strong-moderate CYP2D6-inhibtor concomitantly with a strong-moderate CYP3A-inhibitor; **OR**
  - EM are not taking a strong-moderate CYP2D6-inhibtor with mild hepatic impairment; **OR**
  - IM or PM do not have any degree of hepatic impairment OR are taking a strong CYP3A-inhibitor; **AND**
- Patient has a documented diagnosis of type 1 Gaucher disease as confirmed by a beta-glucosidase leukocyte (BGL) test with significantly reduced or absent glucocerebrosidase enzyme activity; **AND**
- Patient's disease results in one of the following conditions:
  - Anemia (i.e., hemoglobin less than or equal to 11 g/dL [women] or 12 g/dL [men]) not attributed to iron, folic acid or vitamin B12 deficiency; **OR**
  - Moderate to severe hepatomegaly (liver size 1.25 or more times normal) or splenomegaly (spleen size 5 or more times normal); **OR**
  - Skeletal disease (e.g., lesions, remodeling defects and/or deformity of long bones, osteopenia/osteoporosis); **OR**
  - Symptomatic disease (e.g., bone pain, fatigue, dyspnea, angina, abdominal distension, diminished quality of life); **OR**
  - Thrombocytopenia (platelet count less than or equal to 120,000/mm^3); **AND**

CLINICAL CRITERIA FOR RENEWAL

Authorizations can be renewed based on the following criteria:

- Disease response as indicated by one or more of the following:
  - Improvement in symptoms (e.g., bone pain, fatigue, dyspnea, angina, abdominal distension, diminished quality of life)
  - Reduction in size of liver or spleen
  - Improvement in hemoglobin/anemia
  - Improvement in skeletal disease (e.g. increase in lumbar spine and/or femoral neck BMD, no bone crises or bone fractures)
  - Improvement in platelet counts; **AND**
- Absence of unacceptable toxicity from the drug (e.g., ECG changes and cardiac arrhythmias)

CEREZYME® (IMIGLUCERASE)

Length of Authorization:	12 months
Initiative:	SPC: Enzyme Deficiency (IE 2462 / NCPDP 78 – HICL)

CLINICAL CRITERIA FOR INITIAL APPROVAL

For new starts only in patients 4 years and older, patient must have a documented failure, contraindication, intolerance, or ineffective response to a trial of Elelyso® OR Vpriv®

Diagnosis of **Type 1 Gaucher Disease**:

- Patient age at least 2 years or older; **AND**
- Patient has a documented diagnosis of type 1 Gaucher disease as confirmed by a beta-glucosidase leukocyte (BGL) test with significantly reduced or absent glucocerebrosidase enzyme; **AND**
- Adults only (i.e., patients at least 18 years or older):
  - Patient's disease results in one of the following conditions:
    - Anemia (i.e., hemoglobin less than or equal to 11 g/dL [women] or 12 g/dL [men]) not attributed to iron, folic acid or vitamin B12 deficiency; **OR**
    - Moderate to severe hepatomegaly (liver size 1.25 or more times normal volume) or splenomegaly (spleen size 5 or more times normal volume); **OR**
    - Skeletal disease (e.g., lesions, remodeling defects and/or deformity of long bones, osteopenia/osteoporosis); **OR**
    - Symptomatic disease (e.g., bone pain, fatigue, dyspnea, angina, abdominal distension, diminished quality of life); **OR**
    - Thrombocytopenia (platelet count less than or equal to 120,000/mm^3); **AND**
- Must be used as a single agent

CLINICAL CRITERIA FOR RENEWAL

- Disease response as indicated by one or more of the following (compared to pre-treatment baseline):
  - Improvement in symptoms (e.g., bone pain, fatigue, dyspnea, angina, abdominal distension, diminished quality of life)
  - Reduction in size of liver or spleen
  - Improvement in hemoglobin/anemia
  - Improvement in skeletal disease (e.g., increase in lumbar spine and/or femoral neck BMD, no bone crises or bone fractures)
  - Improvement in platelet counts; **AND**
- Absence of unacceptable toxicity from the drug (e.g., hypersensitivity reactions)

CORGARD® (NADOLOL)

Length of Authorization:	24 months
Initiative:	MNC: Age Limit: Over Maximum (IE 2194/ NCPDP 60 HICL)

Plan has maximum age limit of 18 years old on nadolol. If patient is older than 18 years old, medication will reject for maximum age limit exceeded.

CRITERIA FOR APPROVAL FOR PATIENTS OLDER THAN 18 YEARS OLD

FOR CONTINUATION FOR THERAPY

- Nadolol is grandfathered by the plan.
- If the patient has been stable on this medication within the past 120 days, medication can be approved for 24 months.

FOR NEW THERAPY

- Patient has one of the following diagnoses:
  - Angina pectoris; **OR**
  - Patient has a diagnosis of hypertension; **AND**
- Patient does not have the following contraindications:
  - Bronchial asthma; **AND**
  - Sinus bradycardia and greater than first degree conduction block; **AND**
  - Cardiogenic shock; **AND**
  - Overt cardiac failure.

COTELLIC® (COBIMETINIB)

Length of Authorization:	6 months; may be renewed Coverage for the adjuvant treatment of melanoma is up to a maximum of 1 year of therapy
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75 – HICL, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis **of Cutaneous Melanoma**

- Patient is at least 18 years of age; **AND**
- Patient has BRAF V600 mutation-positive disease as detected by an FDA approved or CLIA compliant test; **AND**
- Left ventricular ejection fraction (LVEF) is within normal limits prior to initiating therapy and will be assessed at regular intervals (e.g., every 3 months) during treatment; **AND**
- Patient will avoid coadministration with all of the following:
  - Strong CYP3A4 inhibitors (e.g., fluconazole, itraconazole, etc.);
  - Moderate CYP3A4 inhibitors (e.g., erythromycin, clarithromycin, etc.), if short-term therapy (≤ 14 days) is unavoidable, the patient will be monitored closely for adverse reactions and/or dose modifications will be implemented;
  - Strong or moderate CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.); **AND**
- Patient has not received prior therapy with BRAF and/or MEK inhibitors (e.g., trametinib, encorafenib, dabrafenib, binimetinib) unless otherwise noted; **AND**
- Patient has unresectable or metastatic** disease; **AND**
  - Used in combination with atezolizumab and vemurafenib as first-line therapy; **OR**
  - Used in combination with vemurafenib; **AND**
    - Used as initial therapy or subsequent therapy; **OR**
    - Used as re-induction therapy for patients who experience disease control (i.e., complete response, partial response, or stable disease) from prior MEK inhibitor therapy, but subsequently have disease progression/relapse > 3 months after treatment discontinuation; **OR**
  - Used as adjuvant therapy in combination with vemurafenib in patients with unacceptable toxicities to dabrafenib/trametinib; **AND**
    - Patient has lymph node involvement following complete resection, complete lymph node dissection (CLND), therapeutic lymph node dissection (TLND), or nodal basin ultrasound surveillance; **OR**
    - Patient has clinical satellite/in-transit metastases or local satellite/in-transit recurrence with no evidence of disease (NED) after complete excision to clear margins

**Metastatic disease includes stage III clinical satellite/in transit metastases or local satellite/in-transit recurrence in patients with limited resectable and unresectable disease, unresectable nodal recurrence, and disseminated (unresectable) distant metastatic disease.

CLINICAL CRITERIA FOR INITIAL APPROVAL (CONTINUED)

Diagnosis of **Central Nervous System (CNS) Cancers**

- Patient is at least 18 years of age; **AND**
- Patient has BRAF V600 mutation-positive disease as detected by an FDA approved or CLIA compliant test; **AND**
- Left ventricular ejection fraction (LVEF) is within normal limits prior to initiating therapy and will be assessed at regular intervals (e.g., every 3 months) during treatment; **AND**
- Patient will avoid coadministration with all of the following:
  - Strong CYP3A4 inhibitors (e.g., fluconazole, itraconazole, etc.);
  - Moderate CYP3A4 inhibitors (e.g., erythromycin, clarithromycin, etc.), if short-term therapy (≤ 14 days) is unavoidable, the patient will be monitored closely for adverse reactions and/or dose modifications will be implemented;
  - Strong or moderate CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.); **AND**
- Patient has not received prior therapy with BRAF and/or MEK inhibitors (e.g., trametinib, encorafenib, dabrafenib, binimetinib) unless otherwise noted; **AND**
- Patient has BRAF V600E mutation-positive disease; **AND**
- Used as adjuvant treatment in combination with vemurafenib; **AND**
- Patient has incomplete resection, biopsy, or surgically inaccessible location; **AND**
- Patient has one of the following:
  - Pilocytic astrocytoma
  - Pleomorphic xanthoastrocytoma (PXA)
  - Ganglioglioma

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment defined as stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Left ventricular ejection fraction (LVEF) has not had an **absolute** decrease of > 10% from baseline and is not below the lower limit of normal (LLN) *(LVEF results must be within the previous 3 months)*; **AND**
- Absence of unacceptable toxicity from the drug (e.g., new malignancies, serous retinopathy and retinal vein occlusion, severe dermatologic reactions, severe photosensitivity reactions, severe hepatotoxicity, rhabdomyolysis, severe hemorrhagic events, cardiomyopathy)

Cutaneous Melanoma (re-induction therapy)

- Refer to initial criteria (see Cutaneous Melanoma – Used as re-induction therapy)

CYSTEAMINE (CYSTAGON, PROCYSBI, CYSTARAN)

Length of Authorization:	6 months, may be renewed annually thereafter
Initiative:	MNC: Non-Formulary Product (IE 50698 / MR – GSN PatOverride)

CLINICAL CRITERIA FOR INITIAL APPROVAL

- Patient must have a diagnosis of cystinosis confirmed by one of the following:
  - genetic analysis of the cystinosin (CTNS) gene
  - elevated cystine concentrations in polymorphonuclear (PMN) leukocytes
  - increased cystine content in cultured fibroblasts from amniotic fluid or in the placenta at the time of birth
  - cystine crystals in the cornea on slit lamp examination; **AND**
- For Cystagon and Procysbi:
  - Diagnosis of Nephropathic cystinosis; **AND**
  - Patient does not have a hypersensitivity to penicillamine; **AND**
  - Baseline values obtained for one or more of the following: growth/height, proximal renal tubular dysfunction (i.e., loss of electrolytes, amino acids, glucose), serum creatinine and creatinine clearance, etc.; **AND**
  - For Procysbi **only**:
    - Patient is age 1 year old or older; **AND**
    - Patient must try and have an inadequate response, contraindication, or intolerance to Cystagon (or patient is continuing treatment with Procysbi); **OR**
- For Cystaran:
  - Corneal cystine crystals are observed on slit lamp examination

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug; examples of unacceptable toxicity include:
  - Orals: severe skin rash, severe CNS symptoms (e.g., seizures, encephalopathy), gastrointestinal ulceration/bleeding, leukopenia, pseudotumor cerebri, skin or bone lesions, etc.
  - Ophthalmic: pseudotumor cerebri, sensitivity to light, severe eye pain/irritation, visual field defects, etc.; **AND**
- Patient has received a beneficial response to therapy including, but not limited to, the following:
  - Orals: decrease in WBC cystine concentrations, improvement in renal manifestations of disease (e.g., serum creatinine, calculated creatinine clearance, and/or loss of electrolytes, amino acids, glucose, etc.), and/or non-renal improvement (e.g., growth/height) compared to pretreatment baseline
  - Ophthalmic: stability or reduction in the photo-rated corneal cystine crystal score (CCCS), reduction of crystals upon slit lamp examination, and/or improvement in symptoms (i.e., photophobia) compared to pretreatment baseline

CYTOVENE (GANCICLOVIR) VIAL

Length of Authorization:	6 months
Initiative:	MNC: Antivirals (IE 2462 / NCPDP 75 – HICL)

CLINICAL CRITERIA FOR INITIAL APPROVAL

- Diagnosis of CMV retinitis; **OR**
- Prevention of CMV disease in transplant recipients; **AND**
- Patient does not have any of the following contraindications:
  - Experienced a clinically significant hypersensitivity reaction (e.g., anaphylaxis) to ganciclovir, valganciclovir, or any component of the formulation.

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug

DARAPRIM (PYRIMETHAMINE)

Length of Authorization:	12 months
Initiative:	MNC: Miscellaneous: PA Required (IE 2462 / NCPDP 75 – GSN)

CLINICAL CRITERIA FOR INITIAL APPROVAL

- Patient has a diagnosis of toxoplasmosis; **AND**
- Daraprim will be used conjointly with a sulfonamide, since synergism exists with this combination; **AND**
- Patient does not have any of the following contraindications:
  - Known hypersensitivity to pyrimethamine or to any component of the formulation; **OR**
  - Patients with documented megaloblastic anemia due to folate deficiency

CLINICAL CRITERIA FOR RENEWAL

- Patient must continue to meet above criteria; **AND**
- Absence of unacceptable toxicity from the drug

DDAVP (DESMOPRESSIN ACETATE TABLET)

Length of Authorization:	6 months
Initiative:	MNC: Miscellaneous: PA Required (IE 2462 / NCPDP 75 – GSN)

CLINICAL CRITERIA FOR INITIAL APPROVAL

- Diagnosis of **central** diabetes insipidus; **OR**
- Diagnosis of primary nocturnal enuresis; **AND**
- Patient had an inadequate response to non-pharmacologic intervention(s); **AND**
- Patient does not have any of the following contraindications:
  - Hyponatremia or a history of hyponatremia;
  - Moderate to severe renal impairment (CrCl < 50 mL/min);
  - Known hypersensitivity to desmopressin acetate or to any of the components of the tablets

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug

DEMECLOCYCLINE

Length of Authorization:	6 months
Initiative:	MNC: Miscellaneous: PA Required (IE 2462 / NCPDP 75 – GSN)

CLINICAL CRITERIA FOR INITIAL APPROVAL

- Patient is at least 8 years of age or older; **AND**
- FDA-labeled indication and dosage; **AND**
- Patient does not have any of the following contraindications:
  - Hypersensitivity to any of the tetracyclines or any of the components of the product formulation.

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug

DERMATOLOGICS: ISOTRETINOIN

Length of Authorization:	20 weeks (initial and renewal)
Initiative:	MNC: Retinoids (IE 2462 / NCPDP 75 – HICL and 50081/ 75 and 2194)

CLINICAL CRITERIA FOR INITIAL APPROVAL

- Must have diagnosis of severe cystic acne, unresponsive to other treatment **OR**
- Congenital ichthyosis (orphan drug designation); **OR**
- For other off label uses, must be prescribed by a dermatologist or oncologist for approval; **AND**
  - Forward to pharmacist for consideration of off-label use

FYI ONLY – iPLEDGE™ Patients must be enrolled to get drug; AND

- iPLEDGE™ enrollment required: Access the iPLEDGE™ system via the internet (www.ipledgeprogram.com) or telephone (1-866-495-0654) to obtain an authorization.

CLINICAL CRITERIA FOR RENEWAL

- Patient continues to meet the above criteria; **AND**
- At least 8 weeks has passed since completion of the first course; **AND**
- Patient has not developed any contraindications or other exclusions to its continued use.

COVERED – PA REQUIRED
Amnesteem®, Claravis®, Zenatane®, Myorisan®, Absorica®, isotretinoin

DERMATOLOGICS: TOPICAL RETINOIDS

Length of Authorization:	1 year
Initiative:	MNC: Immunomodulators: Topical (IE 2462/ NCPDP 75 – HICL and IE 50081 /75 and IE 2193) MNC: Age Limit: Over Maximum (IE 2194/ NCPDP 60 – HICL)

The preferred products will automatically pay for patients up to age 26 years old.

PA is required for patients who are older than 26 years old.

Maximum age limit override requests can be approved by technicians if criteria below is met for the preferred products.

INITIAL CRITERIA

Diagnosis of **Acne Vulgaris, or Keratosis Follicularis (also known as Darier's or Darier-White Disease)**

RENEWAL CRITERIA

- The patient has benefited from therapy; **AND**
- The condition has not progressed or worsened while on therapy; **AND**
- The patient has not developed any contraindications or other exclusions to its continued use.

ADDITIONAL INFORMATION TO AID IN THE FINAL DECISION

- All cosmetic-only products in HIC3 L9I, such as Renova® (*tretinoin emollient*), are not covered.
- Eligible products in HIC3 L9B are **not** covered without a medical (vs. cosmetic) indication.
- Examples of non-approvable, cosmetic diagnoses include photo damage, wrinkles, and lentigo.

COVERED – PA REQUIRED > 26 Years Old
Avita® gel (*tretinoin*)
Retin-A® gel and cream (tretinoin)
Tretinoin gel and cream (generic Retin-A)

DEXCOM G6

Length of Authorization:	Transmitter and Sensor - 12 months, Receiver - DOS
Initiative:	MNC: Non-Formulary Product (IE 50698 / MR – GSN PatOverride) MNC: Drug Exclusion (IE 2211/NCPDP 70 – HICL)

CLINICAL CRITERIA FOR APPROVAL

- Must have a diagnosis of diabetes; **AND**
- Is on an insulin regimen; **AND**
- Must be of 2 years of age or older; **AND**
- Must have tried and failed the preferred CGM, Freestyle Libre/Freestyle Libre 2, if patient is 4 years of age or older (PA is required for approval Freestyle Libre- See Freestyle Libre criteria); **AND**
- Member consistently monitors blood glucose ≥ 4 times a day, **OR**
- In the case of pediatrics has a need to be monitored that frequently however may not be done due to burden associated with monitoring in pediatrics.

DOPTELET® (AVATROMBOPAG)

Length of Authorization:	Thrombocytopenia due to CLD: Coverage is provided for one 5-day course of therapy and may not be renewed. Chronic ITP: Coverage is provided for three months and may be renewed.
Initiative:	MNC: Non-Formulary Product (IE 50698 / MR – GSN PatOverride)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Thrombocytopenia due to Chronic Liver Disease (CLD)**

- Patient aged 18 years or older; **AND**
- Patient is not on any other thrombopoietin receptor agonist or mimetic (e.g., romiplostim, eltrombopag, lusutrombopag, etc.) or fostamatinib; **AND**
- Avatrombopag is not being used to attempt to normalize platelet count; **AND**
- Laboratory values are current (i.e., drawn within the previous 28 days); **AND**
- Patient has thrombocytopenia due to chronic liver disease (CLD) and is scheduled to undergo a procedure with a risk of bleeding which would necessitate a platelet transfusion; **AND**
- Patient will not be undergoing any of the following procedures:
  - Neurosurgical intervention;
  - Thoracotomy;
  - Laparotomy;
  - Organ resection; **AND**
- The patient is at increased risk for bleeding as indicated by platelet count of less than < 50 x 10^9/L

Diagnosis of **Chronic Immune Thrombocytopenia (ITP)**

- Patient aged 18 years or older; **AND**
- Patient is not on any other thrombopoietin receptor agonist or mimetic (e.g., romiplostim, eltrombopag, lusutrombopag) or fostamatinib; **AND**
- Patient has had chronic ITP for at least 6 months (or meets the corticosteroid requirement below); **AND**
- Avatrombopag is not being used to attempt to normalize platelet count; **AND**
- Laboratory values are current (i.e., drawn within the previous 28 days); **AND**
- Patient has previously failed any of the following treatments for ITP:
  - Patient has failed previous therapy with corticosteroids (i.e., patient had no response to at least a 3-month trial or is corticosteroid-dependent); **OR**
  - Patient has failed previous therapy with immunoglobulins; **OR**
  - Patient has had splenectomy; **AND**
- The patient is at increased risk for bleeding as indicated by platelet count of less than 30 × 10^9/L (30,000/mm^3)

CLINICAL CRITERIA FOR RENEWAL

Diagnosis of **Chronic Immune Thrombocytopenia (ITP)**

- Patient continues to meet criteria identified in initial criteria; **AND**
- Absence of unacceptable toxicity from the drug (e.g., thrombotic/thromboembolic complications [blood clots]); **AND**
- Platelet count (within the preceding 28 days) does not exceed 400 x 10^9/L; **AND**
- Disease response indicated by the achievement and maintenance of a platelet count of at least 50 × 10^9/L as necessary to reduce the risk for bleeding

Diagnosis of **Thrombocytopenia due to Chronic Liver Disease (CLD)**: **Cannot** be renewed.

DOVATO® (DOLUTEGRAVIR LAMIVUDINE)

Length of Authorization:	1 year and may be renewed
Initiative:	MNC: Non-Formulary Product (IE 50698 / MR – GSN PatOverride)

CLINICAL CRITERIA FOR INITIAL THERAPY

- Diagnosis of one of the following:
  - HIV-1 with no antiretroviral treatment history; **OR**
  - Patients with HIV-1 replacing the current antiretroviral regimen that are virologically suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen with no history of treatment failure and no known substitutions associated with resistance to the individual components of Dovato
- Patient must be tested for Hepatitis B virus (HBV) before initiating; **AND**
- Patient must be 18 years of age or older; **AND**
- CrCl must be above 50 mL/min; **AND**
- Patient must not have severe hepatic impairment (Child-Pugh Score C); **AND**
- Patient must NOT be taking dofetilide; **AND**
- Women of reproductive potential must have a negative pregnancy test prior to treatment **AND** use effective contraception during treatment with therapy; **OR**
  - The prescriber has determined that the expected benefit from Dovato justifies the potential risk to the mother and fetus

CLINICAL CRITERIA FOR RENEWAL

- Patient must continue to meet above criteria; **AND**
- Patient has not experienced any treatment-restricting adverse effects

DUPILUMAB (DUPIXENT)

Length of Authorization:	6 months, may be renewed
Initiative:	MNC: Non-Formulary Product (IE 50698 / MR – GSN PatOverride)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of Atopic Dermatitis

- Patient is at least 6 years of age; **AND**
- Patient will not receive live vaccines during therapy; **AND**
- Will not be used in combination with other anti-immunoglobulin E (IgE) therapy (e.g., omalizumab, etc.); **AND**
- Prescribed by or in consultation with an allergist, immunologist, or dermatologist; **AND**
- Patient has moderate to severe atopic dermatitis (AD); **AND**
- Patient did not respond adequately (or is not a candidate) to a trial of a topical corticosteroid or topical calcineurin inhibitor (i.e., tacrolimus or pimecrolimus) OR a topical PDE4 inhibitor (e.g., Eucrisa).

Diagnosis of Chronic Rhinosinusitis with Nasal Polyps (CRNP)

- Patient is at least 18 years of age; **AND**
- Patient will not receive live vaccines during therapy; **AND**
- Will not be used in combination with other anti-immunoglobulin E (IgE) therapy (e.g., omalizumab, etc.); **AND**
- Patient has bilateral symptomatic sino-nasal polyposis with symptoms lasting at least 8 weeks; **AND**
  - Patient condition persists despite prior sino-nasal surgery; **OR**
  - Patient has failed treatment with or are ineligible to receive or were intolerant to systemic corticosteroids within the previous 2 years; **AND**
- Patient does NOT have an antrochoanal polyps; **AND**
- Patient does NOT have nasal septal deviation that would occlude at least one nostril; **AND**
- Other causes of nasal congestion/obstruction have been ruled out (e.g., acute sinusitis, nasal infection or upper respiratory infection, rhinitis medicamentosa, tumors, infections, granulomatosis, etc.); **AND**
- Physician has assessed baseline disease severity utilizing an objective measure/tool

Diagnosis of Asthma

- Patient age is at least 12 years of age; **AND**
- Patient will not receive live vaccines during therapy; **AND**
- Will not be used in combination with other anti-immunoglobulin E (IgE) therapy (e.g., omalizumab, etc.); **AND**
- Patient has moderate to severe* disease; **AND**
  - Patient must have asthma with an eosinophilic phenotype and a baseline blood eosinophil count of ≥ 150 cells/mcL; **OR**
  - Patient has oral corticosteroid dependent asthma; **AND**
- Must be used for add-on maintenance treatment in patients **REGULARLY** receiving BOTH of the following**:**
  - Medium to high-dose inhaled corticosteroids; **AND**
  - An additional controller medication (e.g. long-acting beta agonist, etc.).

CLINICAL CRITERIA FOR INITIAL APPROVAL (*CONTINUED*)

***Components of severity for classifying asthma as MODERATE may include any of the following (not all inclusive):**
• Daily symptoms • Nighttime awakenings > 1x/week but not nightly • SABA use for symptom control occurs daily • Some limitation to normal activities • Lung function (percent predicted FEV_1) >60%, but <80% • Exacerbations requiring oral systemic corticosteroids are generally more frequent and intense relative to mild asthma
***Components of severity for classifying asthma as SEVERE may include any of the following (not all inclusive):**
• Symptoms throughout the day • Nighttime awakenings, often 7x/week • SABA use for symptom control occurs several times daily • Extremely limited in normal activities • Lung function (percent predicted FEV_1) <60% • Exacerbations requiring oral systemic corticosteroids are generally more frequent and intense relative to moderate asthma

CLINICAL CRITERIA FOR RENEWAL

Diagnosis of Atopic Dermatitis

- Must not be used in combination with another monoclonal antibody (e.g., benralizumab, mepolizumab, omalizumab); **AND**
- Absence of unacceptable toxicity from the drug (e.g., hypersensitivity, conjunctivitis, keratitis, immunogenicity); **AND**
- Disease response as indicated by improvement in signs and symptoms compared to baseline.

Chronic Rhinosinusitis w/ Nasal Polyps

- Must not be used in combination with another monoclonal antibody (e.g., benralizumab, mepolizumab, omalizumab); **AND**
- Absence of unacceptable toxicity from the drug (e.g., hypersensitivity, conjunctivitis, keratitis, immunogenicity); **AND**
- Disease response as indicated by improvement in signs and symptoms compared to baseline.

Diagnosis of Asthma

- Must not be used in combination with another monoclonal antibody (e.g., benralizumab, mepolizumab, omalizumab); **AND**
- Absence of unacceptable toxicity from the drug (e.g., hypersensitivity, conjunctivitis, keratitis, immunogenicity); **AND**
- Improvement in asthma symptoms or asthma exacerbations as evidenced by decrease in **one or more** of the following:
  - Use of systemic corticosteroids
  - Two-fold or greater decrease in inhaled corticosteroid use for at least 3 days
  - Hospitalizations
  - ER visits
  - Unscheduled visits to healthcare provider; **OR**
- Improvement from baseline in forced expiratory volume in 1 second (FEV1)

ELAGOLIX SODIUM (ORILISSA®)

Length of Authorization:	Initial: 150 mg: 1 year, 200 mg: 6 months. Renewal: 150 mg: 1 year (maximum duration for this dose is 24 months), 200 mg: no renewal.
Initiative:	MNC: Non-Formulary Product (IE 50698 / MR – GSN PatOverride)

CRITERIA FOR INITIAL APPROVAL

Diagnosis of **endometriosis** (confirmed vs. presumptive)

- Patient is at least 18 years of age; **AND**
- Must be prescribed by, or in consultation with, a specialist in: gynecology, reproductive health, or endocrinology; **AND**
- Patient has failed an adequate trial of the following therapies:
  - Non-steroidal anti-inflammatory drugs (NSAIDs); **AND**
  - Hormonal contraceptives **OR** progestins (including oral or transdermal formulations, vaginal ring, intrauterine device, or injections); **AND**
- Pregnancy is excluded prior to initiating treatment; **AND**
- Patient will use effective non-hormonal contraception during treatment with Orilissa® and 1 week after stopping therapy; **AND**
- Patient does not have osteoporosis (which is defined as a Z score > -1.5 at spine and femur [total hip]); **AND**
- Patient does not have severe hepatic impairment (Child-Pugh C); **AND**
- Patient is not on concomitant strong organic anion transport polypeptide (OATP) 1B1 inhibitors (e.g., cyclosporine, gemfibrozil).

CLINICAL CRITERIA FOR RENEWAL

- Patient continues to meet the initial criteria; **AND**
- Provide verbal attestation that the patient does not have osteoporosis and provide the Z score (patient should not have a Z score > -1.5 at spine and femur [total hip]); **AND**
- Patient is considered to have clinically meaningful response to treatment.

ELAPRASE® (IDURSULFASE)

Length of Authorization:	1 year, eligible for renewal
Initiative:	SPC: Enzyme Deficiency (IE 2462 / NCPDP 75 – GSN)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of Hunter Syndrome or Mucopolysaccharidosis (MPS) II.

- Patient is at least 16 months old; **AND**
- Patient has absence of severe cognitive impairment; **AND**
- Diagnosis has been confirmed by one of the following:
  - Deficient iduronate 2-sulfatase (I2S) enzyme activity in white cells, fibroblasts, or plasma in the presence of normal activity of at least one other sulfatase; **OR**
  - Detection of pathogenic mutations in the *IDS* gene by molecular genetic testing; **AND**
- Documented baseline value for urinary glycosaminoglycan (uGAG); **AND**
- Documented baseline values for one or more of the following:
  - **Patients ≥ 5 years**: 6-minute walk test (6-MWT) and/or percent predicted forced vital capacity (FVC); **OR**
  - **Patients < 5 years**: spleen volume, liver volume, FVC, and/or 6-minute walk test

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug.
  Examples of unacceptable toxicity include the following: severe hypersensitivity including anaphylactic and anaphylactoid reactions, antibody development and serious adverse reactions, acute respiratory complications, acute cardiorespiratory failure, etc.; **AND**
- Patient does not have progressive/irreversible severe cognitive impairment; **AND**
- Patient has a documented reduction in uGAG levels; **AND**
- Patient has demonstrated a beneficial response to therapy compared to pretreatment baseline in one or more of the following:
  - **Patients 5 years or greater**: stabilization or improvement in 6-MWT and/or FVC; **OR**
  - **Patients < 5 years**: spleen volume, and/or liver volume or stabilization/improvement in FVC and/or 6-MWT

ELELYSO® (TALIGLUCERASE ALFA)

Length of Authorization:	1 year, eligible for renewal
Initiative:	SPC: Miscellaneous: PA required (IE 2462 / NCPDP 75 – GSN)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Type 1 Gaucher Disease**

- Patient is at least 4 years of age; **AND**
- Must be used as a single agent; **AND**
- Patient has a documented diagnosis of type 1 Gaucher disease as confirmed by a beta-glucosidase leukocyte (BGL) test with significantly reduced or absent glucocerebrosidase enzyme activity; **AND**
- Additional criteria for adults only (i.e., patients at least 18 years or older):
  - Patients disease results in one or more of the following:
    - Anemia (hemoglobin less than or equal to 11 g/dL [women] or 12 g/dL [men]) not attributed to iron, folic acid or vitamin B12 deficiency; **OR**
    - Moderate to severe hepatomegaly (liver size 1.25 or more times normal) or splenomegaly (spleen size 5 or more times normal); **OR**
    - Skeletal disease (e.g., lesions, remodeling defects and/or deformity of long bones, osteopenia/osteoporosis); **OR**
    - Symptomatic disease (e.g., bone pain, fatigue dyspnea, angina, abdominal distension, diminished quality of life); **OR**
    - Thrombocytopenia (platelet count less than or equal to 120,000/mm^3)

CLINICAL CRITERIA FOR RENEWAL

- Disease response as indicated by one or more of the following (compared to pre-treatment baseline):
  - Improvement in symptoms (e.g., bone pain, fatigue, dyspnea, angina, abdominal distension, diminished quality of life)
  - Reduction in size of liver or spleen
  - Improvement in hemoglobin/anemia
  - Improvement in skeletal disease (e.g., increase in lumbar spine and/or femoral neck BMD, no bone crises or bone fractures)
  - Improvement in platelet counts; **AND**
- Absence of unacceptable toxicity from the drug (e.g., severe hypersensitivity reactions)

ELIDEL (PIMECROLIMUS)

Length of Authorization:	1 Year
Initiative:	MNC: Immunomodulators: Topical (IE 2462 / NCPDP 75 – HICL)

STEP CRITERIA (NO GRANDFATHERING)

- Patient is ≥ 2 years old; **AND**
- Trial of ONE topical corticosteroid; **AND**
- Trial of Tacrolimus ointment.

Override criteria: May have a situation in which a topical steroid would be medically inappropriate (i.e., large BSA)

ELMIRON® (PENTOSAN)

Length of Authorization:	6 months
Initiative:	MNC: Miscellaneous: PA Required (IE 2462 / NCPDP 75 – GSN)

CLINICAL CRITERIA FOR INITIAL APPROVAL

- Diagnosis of interstitial cystitis
  - Patient has bladder pain or discomfort; **AND**
  - Patient is 16 years of age or older; **AND**
  - Must have tried and failed nonpharmacological interventions; Examples include: Application of heat or cold over the bladder or perineum; Avoidance of food or beverages that may exacerbate symptoms (such as caffeine, alcohol, artificial sweeteners, hot peppers); Bladder training

CLINICAL CRITERIA FOR RENEWAL

- The patient has benefited from therapy (e.g., decreased bladder pain, decreased frequency or urgency of urination); **AND**
- The patient's condition has not progressed or worsened while on therapy; **AND**
- The patient has not developed any contraindications or other exclusions to continued use of the medication.

EMFLAZA® (DEFLAZACORT)

Length of Authorization:	6 months
Initiative:	MNC: Non-Formulary Product (IE 50698 / MR – GSN PatOverride)

CLINICAL CRITERIA FOR INITIAL APPROVAL

- Patient must have documentation of a confirmed diagnosis of Duchenne muscular dystrophy (DMD); **AND**
- Patient is ≥ 5 years of age; **AND**
- Patient retains meaningful voluntary motor function (i.e., patient is able to speak, manipulate objects using upper extremities, ambulate, etc.); **AND**
- Patient should be receiving physical therapy; **AND**
- Patient has experienced one of the following unacceptable adverse reactions directly attributable to previous therapy with prednisone:
  - Patient has manifested significant behavioral changes negatively impacting function at school, home, day care, etc.; **OR**
  - Patient has experienced significant weight gain (e.g., crossing two percentiles and/or reaching 98th percentile for age and sex).

CLINICAL CRITERIA FOR RENEWAL

- Patient retains meaningful voluntary motor function (e.g., patient is able to speak, manipulate objects using upper extremities, ambulate, etc.); **AND**
- Patient continues to receive physical therapy; **AND**
- Patient has received benefit from therapy, which may include one or more of the following:
  - Stability or slowing of decline in motor function
  - Stability or slowing of decline in respiratory function
  - Stability or slowing of decline in sequelae related to diminished strength of stabilizing musculature (e.g., scoliosis, etc.)
  - Quality of life

EMSAM (SELEGILINE) PATCH

Length of Authorization:	1 year
Initiative:	MNC: Non-Formulary Product (IE 50698 / MR – GSN PatOverride)

Grandfathered drug: Grandfathering criteria applies

CLINICAL CRITERIA FOR INITIAL APPROVAL

- Patient is 18 years of age or older; **AND**
- Patient has a diagnosis of major depressive disorder (MDD); **AND**
- Rationale is provided for why the patient cannot take oral therapy; **AND**
- The patient has no contraindications to treatment:
  - Pheochromocytoma
  - Use of SSRIs, SNRIs, clomipramine, imipramine, meperidine, tramadol, methadone, pentazocine, propoxyphene, dextromethorphan (due to risk of serotonin syndrome) and carbamazepine (due to increased risk of hypertensive crisis)

Note: After stopping treatment with drugs contraindicated with EMSAM, a time period equal to 4 to 5 half-lives of the drug or any active metabolite should elapse before starting therapy with EMSAM.

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug

ENTRESTO® (SACUBITRIL – VALSARTAN)

Length of Authorization:	1 Year, eligible for renewal
Initiative:	MNC: Angiotensin II Receptor Antagonists (IE 2462 / NCPDP 75 – HICL)

CLINICAL CRITERIA ENTRESTO

- Patient is 18 years of age or older; **AND**
- Has a diagnosis of chronic heart failure (NYHA Class II-IV); **AND**
- Left ventricular fraction ≤ 40%; **AND**
- No history of angioedema related to previous ACE inhibitor or ARB therapy; **AND**
- No use of an ACE inhibitor within 36 hours of starting Entresto or during therapy; **AND**
- Trial and failure of one of the following:
  - ACE inhibitor
  - ACE inhibitor combination
  - ARB
  - ARB combination
- Deny for the following: patient is pregnant, or the patient has diabetes and is taking Tekturna (aliskiren).

EPIVIR HBV ORAL SOLUTION (LAMIVUDINE ORAL SOLUTION)

Length of Authorization:	• 6 months
Initiative:	SPC: Antivirals (IE 2462 / NCPDP 75 – HICL)

CLINICAL CRITERIA FOR INITIAL APPROVAL

- Patient is 2 years of age or older; **AND**
- Has a diagnosis of chronic hepatitis B virus infection associated with evidence of hepatitis B viral replication and active liver inflammation; **AND**
- Patient has been evaluated and screened for the presence of human immunodeficiency virus (HIV) prior to initiating treatment; **AND**
- Patient does not have a hepatitis C virus (HCV) or hepatitis delta virus co-infection prior to initiating treatment; **AND**
- Patient has not had a liver transplant; **AND**
- Patient does not have decompensated liver disease; **AND**
- Medication is prescribed by or in consultation with an infectious disease physician, gastroenterologist, hepatologist, oncologist or a transplant physician; **AND**
- Patient will not be on any concomitant medication that contains lamivudine or emtricitabine; **AND**
- Use of an alternative antiviral agent with a higher genetic barrier to resistance is not available or inappropriate (e.g., tenofovir, entecavir); **AND**
- Patient has difficulty swallowing solid dosage forms, or the dosage needed is not available in tablet formulation

CLINICAL CRITERIA FOR RENEWAL

- Patient must continue to meet above criteria; **AND**
- Patient has not experienced any treatment-restricting adverse effects such as but not limited to:
  - Lactic acidosis
  - Severe hepatomegaly with steatosis
  - Pancreatitis
  - Hepatic decompensation

EPLERENONE (INSPRA)

Length of Authorization:	12 months
Initiative:	MNC: Miscellaneous: PA Required (IE 2462 / NCPDP 75 – GSN)

CLINICAL CRITERIA FOR INITIAL APPROVAL

- Patient has a symptomatic heart failure with reduced ejection fraction (≤ 40%) (HFrEF) after an acute myocardial infarction (MI); **OR**
- Patient has a diagnosis of hypertension; **AND**
- Patient does not have any contraindications to therapy:
  - All indications:
    - serum potassium > 5.5 mEq/L at initiation; **AND**
    - creatinine clearance ≤ 30 mL/min; **AND**
    - Concomitant administration of strong CYP3A inhibitors (e.g., ketoconazole, itraconazole, nefazodone, troleandomycin, clarithromycin, ritonavir, and nelfinavir)
  - Hypertension:
    - Type 2 diabetes with microalbuminuria; **AND**
    - serum creatinine > 2.0 mg/dL in males or > 1.8 mg/dL in females; **AND**
    - creatinine clearance < 50 mL/min; **AND**
    - concomitant administration of potassium supplements or potassium-sparing diuretics (e.g., amiloride, spironolactone, or triamterene)

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug

ERIVEDGE® (VISMODEGIB)

Length of Authorization:	6 months, eligible for renewal
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75 – HICL, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Basal Cell Carcinoma**

- Patient is at least 18 years or older; **AND**
- Negative pregnancy test for women of child-bearing potential (Note: Females of reproductive potential should use effective contraception during and for at least 24 months after the last dose and males of reproductive potential should also do so during and for at least 3 months after the last dose); **AND**
- Patient has nodal or metastatic disease; **OR**
- Patient has locally advanced disease; **AND**
  - Disease has recurred following surgery or radiation therapy; **OR**
  - Patient is not a candidate for surgery and radiation therapy.

Diagnosis of **CNS Cancer – Medulloblastoma**

- Patient is at least 18 years or older; **AND**
- Negative pregnancy test for women of child-bearing potential (Note: Females of reproductive potential should use effective contraception during and for at least 24 months after the last dose and males of reproductive potential should also do so during and for at least 3 months after the last dose); **AND**
- Used as a single agent; **AND**
- Patient has recurrent disease; **AND**
- Patient has received prior chemotherapy; **AND**
- Patient has mutations in the sonic hedgehog pathway.

CLINICAL CRITERIA FOR RENEWAL

- Disease response as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include severe cutaneous adverse reactions (SCARs) (including Stevens-Johnson syndrome [SJS], toxic epidermal necrolysis [TEN]), drug reaction with eosinophilia and systemic symptoms (DRESS), premature fusion of the epiphyses, etc.

ERLEADA® (APALUTAMIDE)

Length of Authorization:	6 months, eligible for renewal
Initiative:	MNC: Non-Formulary Product (IE 50698 / MR – GSN PatOverride)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Prostate Cancer**

- Patient is at least 18 years old; **AND**
- Patient will receive a GnRH-analog or has had a bilateral orchiectomy; **AND**
- Will not be used in combination with other androgen receptor inhibitors (e.g., enzalutamide, darolutamide); **AND**
  - Patient has **non-metastatic** castration-resistant prostate cancer (NM-CRPC); **OR**
  - Patient has metastatic castration-sensitive prostate cancer (M-CRPC)

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug (e.g., seizures, excessive falls and/or fractures, signs and symptoms of ischemic heart disease, any other Grade 3 or above side effects that are intolerable to patient)

ETOPOSIDE CAPSULE

Length of Authorization:	12 months
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

- Diagnosis of small cell lung cancer; **AND**
- Patient does not have the following contraindication:
  - Previous hypersensitivity to etoposide or any component of the formulation

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug

FABRAZYME® (AGALSIDASE BETA)

Length of Authorization:	1 year
Initiative:	MNC: Non-Formulary Product (IE 50698 / MR – GSN PatOverride)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of Fabry's Disease:

- Patient is 8 years of age or older; **AND**
- Documented diagnosis of Fabry disease with biochemical/genetic confirmation by one of the following:
  - Males only: α-galactosidase A (α-Gal A) activity in plasma, isolated leukocytes, and/or cultured cells; **OR**
  - Plasma or urinary globotriaosylceramide (Gb_3/GL-3) or globotriaosylsphingosine (lyso-Gb_3); **OR**
  - Detection of pathogenic mutations in the *GALA/GLA* gene by molecular genetic testing; **AND**
- Baseline value for plasma GL-3 and/or GL-3 inclusions; **AND**
- Must not be used in combination with migalastat

RENEWAL CRITERIA

- Disease response with treatment as defined by a reduction in plasma GL-3 and/or GL-3 inclusions compared to pre-treatment baseline; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: severe hypersensitivity reactions, severe infusion site reactions, compromised cardiac function, etc.

FAMVIR (FAMCICLOVIR)

Length of Authorization:	1 Year, eligible for renewal
Initiative:	MNC: Antivirals (IE 2462 / NCPDP 75 – HICL)

CLINICAL CRITERIA FAMCICLOVIR

- Patient is 18 years of age or older; **AND**
- Patient must have a diagnosis of one of the following:
  - Immunocompetent Adult Patients:
    - Herpes labialis – treatment of recurrent episodes, **OR**
    - Genital herpes: treatment of recurrent episodes or suppressive therapy of recurrent episodes, **OR**
    - Herpes zoster (shingles), **OR**
  - Human Immunodeficiency Virus (HIV)-Infected Adult Patients:
    - Treatment of recurrent episodes of orolabial or genital herpes

FARESTON (TOREMIFENE)

Length of Authorization:	12 months
Initiative:	MNC: Miscellaneous: PA Required (IE 2462 / NCPDP 75 – GSN)

CLINICAL CRITERIA FOR INITIAL APPROVAL

- Patient is a postmenopausal female with metastatic breast cancer that is estrogen-receptor positive or unknown tumors; **AND**
- Patient does not have one of the following contraindications:
  - Congenital or acquired QT prolongation (long QT syndrome)
  - Hypokalemia
  - Hypomagnesemia
  - Hypersensitivity to toremifene

CLINICAL CRITERIA FOR RENEWAL

- Patient must continue to meet above criteria; **AND**
- Absence of unacceptable toxicity from the drug

FEMRING® (ESTRADIOL ACETATE)

Length of Authorization:	12 months
Initiative:	MNC: Miscellaneous: PA Required (IE 2462 / NCPDP 75 – GSN)

CLINICAL CRITERIA FOR INITIAL APPROVAL

- Diagnosis of moderate to severe vasomotor symptoms due to menopause; **OR**
- Diagnosis of moderate to severe vulvar and vaginal atrophy due to menopause; **AND**
- Patient does not have any of the following contraindications:
  - Undiagnosed abnormal genital bleeding
  - Known, suspected, or history of breast cancer
  - Known or suspected estrogen-dependent neoplasia
  - Active DVT, PE, or history of these conditions
  - Active arterial thromboembolic disease (for example, stroke and MI), or a history of these conditions
  - Known anaphylactic reaction or angioedema to Femring
  - Known liver impairment or disease
  - Known protein C, protein S, or antithrombin deficiency, or other known thrombophilic disorders
  - Known or suspected pregnancy

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug; **AND**
- Patient continues to meet initial criteria

FIRMAGON® (DEGARELIX)

Length of Authorization:	1 year
Initiative:	SPC: Hormonal Agents (IE 2462 / NCPDP 75 – HICL)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Advanced Prostate Cancer**

CLINICAL CRITERIA FOR RENEWAL

- Tumor response with stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug (e.g., prolongation of the QT-interval, severe hypersensitivity)

COVERED – PA REQUIRED
Firmagon® 2 x 120 mg kit
Firmagon® 80 mg kit

FORTEO® (TERIPARATIDE)

Length of Authorization:	1 year with up to 1 renewal (maximum of 2 years of therapy)
Initiative:	SPC: Osteoporosis Agents (IE 2462 / NCPDP 75 – GSN)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Osteoporosis in Women**

- Patient is at least 18 years or older; **AND**
- Patient must be post-menopausal; **AND**
- Confirmation patient is receiving concurrent calcium and vitamin D supplementation if dietary intake is inadequate; **AND**
- Patient has a documented diagnosis of osteoporosis indicated by one or more of the following:
  - Hip DXA (femoral neck or total hip) or lumbar spine T-score -2.5 and/or forearm DXA 33% (one-third) radius; **OR**
  - History of fragility to the hip or spine AND one of the following: T-score ≤ -1 or low bone mass; **OR**
  - T-score between -1 and -2.5 with a FRAX 10-year probability for major fracture ≥ 20% or hip fracture ≥ 3%; **AND**
- Patient is at high risk for fractures (see table below); **AND**
- Patient is not at increased risk for osteosarcoma (e.g., Paget's disease of bone or unexplained elevations of alkaline phosphatase, pediatric and young adult patients with open epiphyses, or prior external beam or implant radiation therapy involving the skeleton); **AND**
- Patient does not have bone metastases or a history of skeletal malignancies; **AND**
- Patient does not have metabolic bone disease other than osteoporosis; **AND**
- Patient does not have hypercalcemia or an underlying hypercalcemic disorder (e.g., primary hyperparathyroidism); **AND**
- Patient has not received therapy with parathyroid hormone analogs (e.g., abaloparatide, teriparatide) in excess of 2 years in total; **AND**
- Documented treatment failure (or contraindication or intolerance) to a minimum 12-month trial on previous therapy with oral bisphosphonates such as alendronate, risedronate, ibandronate, etc.; (**Note:** Ineffective response to therapy and contraindications to oral bisphosphonate therapy are included in table below); **AND**
- Documented treatment failure (or contraindication or intolerance) to a minimum 12-month trial on previous therapy with *RANKL*-blocking agents such as denosumab, etc..

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Primary or Hypogonadal Osteoporosis in Men**

- Patient is at least 18 years or older; **AND**
- Confirmation patient is receiving concurrent calcium and Vitamin D supplementation if dietary intake is inadequate; **AND**
- Patient has a documented diagnosis of osteoporosis indicated by one or more of the following:
  - Hip DXA (femoral neck or total hip) or lumbar spine T-score -2.5 and/or forearm DXA 33% (one-third) radius; **OR**
  - T-score ≤ -1 or low bone mass **and** a history of fragility fracture to the hip or spine; **OR**
  - T-score between -1 and -2.5 with a FRAX 10-year probability for major fracture ≥ 20% or hip fracture ≥ 3%; **AND**
- Patient is at high risk for fractures (see table below); **AND**
- Patient is not at increased risk for osteosarcoma (e.g., Paget's disease of bone or unexplained elevations of alkaline phosphatase, pediatric and young adult patients with open epiphyses, or prior external beam or implant radiation therapy involving the skeleton); **AND**
- Patient does not have bone metastases or a history of skeletal malignancies; **AND**
- Patient does not have metabolic bone disease other than osteoporosis; **AND**
- Patient does not have hypercalcemia or an underlying hypercalcemic disorder (e.g., primary hyperparathyroidism); **AND**
- Patient has not received therapy with parathyroid hormone analogs (e.g., abaloparatide, teriparatide) in excess of 2 years in total; **AND**
- Documented treatment failure (or contraindication or intolerance) to a minimum 12-month trial on previous therapy with oral bisphosphonates such as alendronate, risedronate, ibandronate, etc.; (**Note:** Ineffective response to therapy and contraindications to oral bisphosphonate therapy are included in table below).

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Systemic Glucocorticoid-Induced Osteoporosis**

- Patient is at least 18 years or older; **AND**
- Patient is being treated with sustained long-term glucocorticoid therapy (i.e., a mean daily dose of 5 mg or more of prednisone or its equivalent for 3 or more consecutive months); **AND**
- Confirmation patient is receiving concurrent calcium and vitamin D supplementation if dietary intake is inadequate; **AND**
- Patient has a documented diagnosis of osteoporosis indicated by one or more of the following:
  - Hip DXA (femoral neck or total hip) or lumbar spine T-score -2.5 and/or forearm DXA 33% (one-third) radius; **OR**
  - T-score ≤ -1 or low bone mass **and** a history of fragility fracture to the hip or spine; **OR**
  - T-score between -1 and -2.5 with a FRAX 10-year probability for major fracture ≥ 20% or hip fracture ≥ 3%; **AND**
- Patient is at high risk for fractures (see table below); **AND**
- Patient is not at increased risk for osteosarcoma (e.g., Paget's disease of bone or unexplained elevations of alkaline phosphatase, pediatric and young adult patients with open epiphyses, or prior external beam or implant radiation therapy involving the skeleton); **AND**
- Patient does not have bone metastases or a history of skeletal malignancies; **AND**
- Patient does not have metabolic bone disease other than osteoporosis; **AND**
- Patient does not have hypercalcemia or an underlying hypercalcemic disorder (e.g., primary hyperparathyroidism); **AND**
- Patient has not received therapy with parathyroid hormone analogs (e.g., abaloparatide, teriparatide) in excess of 2 years in total; **AND**
- Documented treatment failure (or contraindication or intolerance) to a minimum 12-month trial on previous therapy with oral bisphosphonates such as alendronate, risedronate, ibandronate, etc.; (**Note:** Ineffective response to therapy and contraindications to oral bisphosphonate therapy are included in table below)

  Note: Patients with extremely low BMD (T < -3.5) or a T < -2.5 with a history of fragility fractures are not subject to prior trial and failure requirements with bisphosphonates and/or denosumab

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

± Ineffective response is defined as one or more of the following:

- Decrease in T-score in comparison with baseline T-score from DXA scan
- Patient has a new fracture while on bisphosphonate therapy

‡ High risk for fractures include, but are not limited to, one or more of the following:

- History of an osteoporotic fracture as an adult
- Parental history of hip fracture
- Low BMI
- Rheumatoid arthritis
- Alcohol intake (3 or more drinks per day)
- Current smoking
- History of oral glucocorticoids ≥ 5 mg per day of prednisone for > 3 months (ever)

*** Examples of contraindications to oral bisphosphonate therapy include the following:**

- Documented inability to sit or stand upright for at least 30 minutes
- Documented pre-existing gastrointestinal disorder such as inability to swallow, Barrett's esophagus, esophageal stricture, dysmotility, or achalasia

Examples of contraindications to injectable bisphosphonate therapy include the following:

- Documented pre-existing hypocalcemia and disturbances of mineral metabolism
- Documented pre-existing renal insufficiency defined as creatinine clearance < 35 mL/min

Examples of contraindications to *RANKL*-blocking therapy include the following:

- Documented pre-existing hypocalcemia and disturbances of mineral metabolism
- Documented hypersensitivity to the active ingredient or its excipients

Examples of contraindications to sclerostin inhibitor therapy include the following:

- Documented pre-existing hypocalcemia and disturbances of mineral metabolism
- Documented pre-existing severe cardiovascular disease that precludes use

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug (e.g., symptoms of severe allergic reactions, hypercalcemia, unexplained elevations of alkaline phosphatase, renal or hepatic toxicity); **AND**
- Total length of therapy has not exceeded 2 years for parathyroid hormone analogs (e.g., abaloparatide, teriparatide); **AND**
- Disease response as indicated by one or more of the following:
  - Absence of fractures
  - Increase in bone mineral density compared to pretreatment baseline
  - Increase in bone formation markers (i.e., procollagen type 1 N-propeptide [P1NP])

FOSCAVIR® (FOSCARNET SODIUM)

Length of Authorization:	12 months
Initiative:	MNC: Antivirals (IE 2462 / NCPDP 75 – HICL)

CLINICAL CRITERIA FOR INITIAL APPROVAL

- Patient has one of the following diagnoses:
  - CMV retinitis in patients with acquired immunodeficiency syndrome (AIDS); **OR**
  - Acyclovir-resistant mucocutaneous HSV infections in immunocompromised patients; **AND**
- Patient does not have one of the following contraindications:
  - A clinically significant hypersensitivity to foscarnet sodium

CLINICAL CRITERIA FOR RENEWAL

- Patient must continue to meet above criteria; **AND**
- Absence of unacceptable toxicity from the drug

FREESTYLE LIBRE/FREESTYLE LIBRE 2

Length of Authorization:	Sensor - 12 months, Reader - DOS
Initiative:	MNC: Miscellaneous: PA Required (IE 2462 / NCPDP 75 – GSN)

CLINICAL CRITERIA FOR APPROVAL

FreeStyle Libre Criteria:

- Must have a diagnosis of diabetes; **AND**
- Must be of 18 years of age or older; **AND**
- Is on an insulin regimen; **AND**
- Member consistently monitors blood glucose ≥ 4 times a day.

FreeStyle Libre 2 Criteria:

- Must have a diagnosis of diabetes; **AND**
- Must be of 4 years of age or older; **AND**
- Is on an insulin regimen; **AND**
- Member consistently monitors blood glucose ≥ 4 times a day.

MCCZ has the following quantity limits on Freestyle Libre Sensors:

Freestyle Libre 10 day	3 sensors per 30 days
Freestyle Libre 14 day	2 sensors per 28 days
Freestyle Libre 2	2 sensors per 28 days

GABITRIL (TIAGABINE)

Length of Authorization:	12 months
Initiative:	MNC: Anticonvulsants (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

- Patient is at least 12 years of age or older; **AND**
- Used as adjunctive therapy in adults and children 12 years and older in the treatment of partial seizures; **AND**
- Patient does not have any of the following contraindications:
  - Hypersensitivity to the drug or its ingredients

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug

GEODON INJECTION (ZIPRASIDONE MESYLATE INJECTION)

Length of Authorization:	12 months
Initiative:	MNC: Non-Formulary Product (IE 50698 / MR – GSN PatOverride)

CLINICAL CRITERIA FOR INITIAL APPROVAL

- Patient is 18 years of age or older; **AND**
- Patient has schizophrenia with acute agitation; **AND**
- Patient does not have any of the following contraindications:
  - A known history of QT prolongation (including congenital long QT syndrome)
  - Recent acute myocardial infarction
  - Uncompensated heart failure
- Ziprasidone should not be given with the following QT-prolonging drugs:
  - dofetilide, sotalol, quinidine, other Class Ia and III anti-arrhythmics, mesoridazine, thioridazine, chlorpromazine, droperidol, pimozide, sparfloxacin, gatifloxacin, moxifloxacin, halofantrine, mefloquine, pentamidine, arsenic trioxide, levomethadyl acetate, dolasetron mesylate, probucol or tacrolimus; **AND**
  - Other drugs that have demonstrated QT prolongation as one of their pharmacodynamic effects and have this effect described in the full prescribing information as a contraindication or a boxed or bolded warning

CLINICAL CRITERIA FOR RENEWAL

- Patient must continue to meet above criteria; **AND**
- Absence of unacceptable toxicity from the drug

GILOTRIF® (AFATINIB)

Length of Authorization:	6 months, may be renewed
Initiative:	MNC: Non-Formulary Product (IE 50698 / MR – GSN PatOverride)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Non-Small Cell Lung Cancer (NSCLC)**

- Patient is 18 years of age or older; **AND**
- Patient has metastatic disease with squamous-cell histology that progressed after platinum-based therapy; **AND**
  - Used as single agent therapy; **OR**
- Patient has non-resistant epidermal growth factor receptor (EGFR) mutation(s) as detected by any FDA or CLIA-compliant test; **AND**
  - Used for recurrent, advanced or metastatic disease (excluding locoregional recurrence or symptomatic local disease without evidence of disseminated disease) or mediastinal lymph node recurrence with prior radiation therapy; **AND**
    - Used as a single agent; **AND**
      - Used as first-line therapy; **OR**
      - Used as continuation of therapy following progression on afatinib for asymptomatic disease, symptomatic brain lesions, or isolated symptomatic systemic lesions; **OR**
    - Used as subsequent therapy in combination with cetuximab, in patients who have progressed on EGFR tyrosine kinase inhibitor therapy; **AND**
      - Patient has asymptomatic disease, symptomatic brain lesions, or isolated symptomatic systemic lesions; **OR**
      - Patient is T790M mutation negative and has multiple symptomatic systemic lesions

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug (e.g., severe or prolonged diarrhea, severe cutaneous reactions, interstitial lung disease, hepatotoxicity, gastrointestinal perforation, ulcerative keratitis); **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **OR**
  - For continuation therapy following afatinib progression, disease response is defined as lack of continued disease progression, improvement in tumor size, or improvement in patient symptoms.

GLEEVEC® (IMATINIB)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75 – HICL, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Chronic Myeloid Leukemia (CML)**

- Patient is at least 1-year old; **AND**
- Patients disease is confirmed by either a Philadelphia chromosome-positive (Ph+) or BCR-ABL1 positive laboratory test result

  Note: **For brand Gleevec®**, for CML: for new starts only, patient must have a documented failure, contraindication, intolerance, or ineffective response to a trial of generic imatinib (generic Gleevec®) **and** Bosulif®*** ***(***following the NCCN guidelines surrounding genetic mutations)***

Diagnosis of **Acute Lymphoblastic Leukemia (ALL)**

- Patient is at least 1 year old; **AND**
- Patient's disease is Philadelphia chromosome-positive (Ph+)

Diagnosis of **Myelodysplastic/Myeloproliferative Disease (Such as Chronic Myelomonocytic Leukemia) (MDS/MPD)**

- Patient is 18 years of age or older; **AND**
- Patient's disease is associated with platelet-derived growth factor receptor beta (PDGFRβ) gene re-arrangements with 5q31-33 translocations or t(5;12) translocations as determined by an FDA-approved or CLIA-compliant diagnostic test

Diagnosis of **Hypereosinophilic Syndrome (HES) and/or Chronic Eosinophilic Leukemia (CEL)**

- Patient is 18 years of age or older

Diagnosis of **Dermatofibrosarcoma Protuberans (DFSP)**

- Patient is 18 years of age or older

  Note: Tumors lacking the t(17;22) translocation may not respond to imatinib.

Diagnosis of **Aggressive Systemic Mastocytosis (ASM)**

- Patient is 18 years of age or older; **AND**
  - Eosinophilia is present with FIP1L1-PDGFRA fusion gene; **OR**
  - Patient does not have the D816V c-Kit mutation as determined by an FDA-approved or CLIA-compliant diagnostic test

  Note: If c-Kit mutational status is unknown; coverage is provided for 3 months only (renewal will only be considered after determination of c-Kit mutational status).

Diagnosis of **Gastrointestinal Stromal Tumors (GIST)**

- Patient is 18 years of age or older

Diagnosis of **Cutaneous Melanoma**

- Patient is 18 years of age or older; **AND**
- Patient's disease has an activating KIT mutation as detected by a CLIA-compliant diagnostic test (e.g., FISH)

Diagnosis of **Desmoid Tumors (aggressive fibromatosis)**

- Patient is 18 years of age or older

Diagnosis of **Pigmented Villonodular Synovitis/Tenosynovial Giant Cell Tumors (PVNS/TGCT)**

- Patient is 18 years of age or older

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Chordoma**

- Patient is 18 years of age or older

Diagnosis of **AIDS-Related Kaposi Sarcoma**

- Patient is 18 years of age or older

Diagnosis of **Chronic Graft Versus Host Disease (GVHD)**

- Patient is 18 years of age or older; **AND**
- Patient has steroid-refractory chronic GVHD after hematopoietic cell transplantation

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug (e.g., cytopenias, severe hepatotoxicity, severe congestive heart failure and left ventricular dysfunction, edema and severe fluid retention, hemorrhage, gastrointestinal perforation, bullous dermatologic reactions, tumor lysis syndrome, renal toxicity); **AND**
- Disease response with treatment defined as stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Patient has been adherent to therapy; **AND**

Chronic Graft Versus Host Disease (GVHD) only:

- Response to therapy with an improvement in one or more of the following:
  - Clinician assessments (e.g., NIH Skin Score, Upper GI Response Score, NIH Lung Symptom Score)
  - Patient-reported symptoms (e.g., Lee Symptom Scale)

Aggressive Systemic Mastocytosis (ASM) only:

- Patient's disease does not have the D816V c-Kit mutation

Chronic Myeloid Leukemia (CML) only:

- Treatment response as indicated by one of the following:
  - Patient has *BCR-ABL1* (IS) transcript levels:
    - ≤ 10% at 3 months; **OR**
    - ≤ 10% at 6 months; **OR**
    - ≤ 0.1% or a ≥ 3-log reduction in *BCR-ABL1* mRNA from the standardized baseline, if qPCR (IS) is not available; **AND**

Note: A cytogenetic assessment of response may be used if the quantitative RT-PCR (QPCR) using International Scale (IS) for *BCR-ABL1* is not available.

- Patients meeting all of the following criteria may be candidates for discontinuation provided they received counseling on, and have consented to, the risks (including TKI withdrawal) and benefits of stopping TKI therapy:
  - Patient is 18 years or older; **AND**
  - Patient has received TKI therapy for ≥ 3 years; **AND**
  - Patient has no history of accelerated or blast phase CML (i.e., chronic phase only); **AND**
  - Patient had a stable molecular response (MR4; *BCR-ABL1* ≤0.01% IS) for ≥2 years (as documented on ≥4 tests performed ≥ 3 months apart); **AND**
  - Patient has quantifiable *BCR-ABL1* transcripts; **AND**
  - Patient can meet the ongoing monitoring requirements after discontinuation

GLYCOPYRROLATE- FORMOTEROL FUMARATE (BEVESPI AEROSPHERE®)

Length of Authorization:	1 Year
Initiative:	MNC: Miscellaneous: PA Required (IE 2462 / NCPDP 75 – GSN)

CLINICAL CRITERIA FOR INITIAL APPROVAL

- Patient has a diagnosis of COPD; **AND**
- Patient is 18 or older; **AND**
- Patient has rescue therapy on file (i.e., Proair®, Ventolin®, Proventil®, Xopenex®); **AND**
- Patient does not have any of the following:
  - Be using the medication for asthma
  - Have acutely deteriorating COPD
  - Be using the medication for relief of acute symptoms
  - Be using other LABAs
  - Be using other long-acting anticholinergic agents

CLINICAL CRITERIA FOR RENEWAL

- Patient continues to meet above criteria; **AND**
- Patient symptoms are clinically improving, as documented by provider; **AND**
- Patient demonstrates continued compliance, based on fill history (not using prn); **AND**
- Prescriber documents that nebulized therapy continues to be required.

GOUT AGENTS

Length of Authorization:	1 year
Initiative:	MNC: Gout Agents (IE 2462 / NCPDP 75 – HICL)

STEP CRITERIA

Febuxostat (generic Uloric®) may be approved if the following is true:

- If there has been a therapeutic failure of allopurinol.

Colchicine (generic for Colcrys®) may be approved if the following is true:

- If there has been a therapeutic failure of allopurinol.

COVERED
Allopurinol (generic for Zyloprim®)
Probenecid
Probenecid / Colchicine
Colchicine (generic for Colcrys®) – PA required (see criteria above)
Febuxostat (Uloric®) – PA required (see criteria above)

GRANISETRON TABLETS (KYTRIL)

Length of Authorization:	For requested duration, up to 6 months
Initiative:	MNC: Antiemetics (IE 2462 / NCPDP 75 – HICL)

CLINICAL CRITERIA FOR INITIAL APPROVAL

- Patient is 18 years of age or older; **AND**
- The medication will be used for the prevention of:
  - Nausea and vomiting associated with initial and repeat courses of emetogenic cancer therapy; **OR**
  - Nausea and vomiting associated with radiation, including total body irradiation and fractionated abdominal radiation.

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug

GRANISETRON IV (KYTRIL®)

Length of Authorization:	6 Months
Initiative:	MNC: Antiemetics (IE 2462 / NCPDP 75 – HICL)

CLINICAL CRITERIA

- Injections: patient is unable to take oral antiemetics; **AND**
- Diagnosis of Prevention & Treatment of post-operative nausea and vomiting, Breakthrough treatment for chemotherapy-induced nausea/vomiting or Prevention of nausea and vomiting associated with radiation treatment; **OR**
- Diagnosis of Prevention of chemotherapy induced nausea and vomiting (CINV); **AND**
  - Patient is receiving emetogenic chemotherapy

CLINICAL CRITERIA FOR RENEWAL

- Patient continues to meet criteria above; **AND**
- Patient has had a disease response; **AND**
- Patient is free of unacceptable toxicity from the drug. Examples of unacceptable toxicity include severe hypersensitivity reactions, serotonin syndrome, etc.

GROWTH HORMONE

Length of Authorization:	1 year, eligible for renewal (see *Criteria for Renewal* below)
Initiative:	SPC: Growth Hormone (IE 2462 / NCPDP 75 – GSN)

CLINICAL CRITERIA FOR INITIAL APPROVAL FOR PEDIATRIC PATIENTS (UNDER 18)

Note: Must be requested via fax with pertinent clinical documentation (most recent clinical notes, growth charts, lab results, growth hormone (GH) stimulation test reports)

Diagnosis of **Growth Hormone Deficiency (GHD)** **(Pediatric Patient)**

- Other causes of growth failure must be ruled out (e.g., malnutrition, hypothyroidism, hypocortisolism); **AND**
- Patient does not have a current acute critical illness after open heart surgery, abdominal surgery, or multiple accentual trauma; **AND**
- Patient does not have acute respiratory failure; **AND**
- Patient does not have active malignancy; **AND**
- Patient does not have active proliferative or severe non-proliferative diabetic retinopathy; **AND**
- **Patient must have a documented failure, contraindication, intolerance, or ineffective response to a trial of Norditropin® AND Genotropin®; AND**
- Open bony epiphyses; **AND**
- Patient has short stature as defined by height that is 2 SD or more below the mean for chronological age; **AND**
  - Patient has hypothalamic-pituitary defect (i.e. major congenital malformation, tumor, or irradiation) and a deficiency of at least one additional pituitary hormone; **OR**
  - Patient had an inadequate response to GH provocation tests on 2 separate stimulation tests as defined as a serum peak GH concentration < 10 ng/mL; **OR**
- Patient is a newborn; **AND**
  - Patient has congenital hypopituitarism with hypoglycemia; **AND**
  - Patient cannot attain a serum GH level > 5 mcg/L; **AND**
  - Patient has a deficiency of at least one additional pituitary hormone and/or the classical imaging triad (ectopic posterior pituitary and pituitary hyperplasia with abnormal stalk)

Diagnosis of **Noonan Syndrome** **(Pediatric Patient)**

- Other causes of growth failure must be ruled out (e.g., malnutrition, hypothyroidism, hypocortisolism); **AND**
- Patient does not have a current acute critical illness after open heart surgery, abdominal surgery, or multiple accentual trauma; **AND**
- Patient does not have acute respiratory failure; **AND**
- Patient does not have active malignancy; **AND**
- Patient does not have active proliferative or severe non-proliferative diabetic retinopathy; **AND**
- **Patient must have a documented failure, contraindication, intolerance, or ineffective response to a trial of Norditropin® AND Genotropin®; AND**
- Open bony epiphyses; **AND**
- Patient has a confirmed diagnosis of Noonan syndrome; **AND**
- Patient is prepubertal; **AND**
- Patient has short stature as defined by height that is 2 SD or more below the mean for chronological age

CLINICAL CRITERIA FOR INITIAL APPROVAL FOR PEDIATRIC PATIENTS (UNDER 18) *(CONTINUED)*

Diagnosis of **Turner Syndrome** **(Pediatric Patient)**

- Other causes of growth failure must be ruled out (e.g., malnutrition, hypothyroidism, hypocortisolism); **AND**
- Patient does not have a current acute critical illness after open heart surgery, abdominal surgery, or multiple accentual trauma; **AND**
- Patient does not have acute respiratory failure; **AND**
- Patient does not have active malignancy; **AND**
- Patient does not have active proliferative or severe non-proliferative diabetic retinopathy; **AND**
- **Patient must have a documented failure, contraindication, intolerance, or ineffective response to a trial of Norditropin® AND Genotropin®; AND**
- Open bony epiphyses; **AND**
- Diagnosis is confirmed by karyotyping; **AND**
- Patient has short stature as defined by height that is 2 SD or more below the mean for chronological age

Diagnosis of **Small for Gestational Age (SGA)** **(Pediatric Patient)**

- Other causes of growth failure must be ruled out (e.g., malnutrition, hypothyroidism, hypocortisolism); **AND**
- Patient does not have a current acute critical illness after open heart surgery, abdominal surgery, or multiple accentual trauma; **AND**
- Patient does not have acute respiratory failure; **AND**
- Patient does not have active malignancy; **AND**
- Patient does not have active proliferative or severe non-proliferative diabetic retinopathy; **AND**
- **Patient must have a documented failure, contraindication, intolerance, or ineffective response to a trial of Norditropin® AND Genotropin®; AND**
- Open bony epiphyses; **AND**
- Patient is 2 years of age or older; **AND**
- Patient failed to achieve catch-up growth by 2 to 4 years of age (i.e. obtaining a height of ≥ 3rd percentile); **AND**
- Patient has short stature as defined by height that is 2 SD or more below the mean for chronological age

Diagnosis of **Idiopathic Short Stature (ISS)** **(Pediatric Patient)**

- Other causes of growth failure must be ruled out (e.g., malnutrition, hypothyroidism, hypocortisolism); **AND**
- Patient does not have a current acute critical illness after open heart surgery, abdominal surgery, or multiple accentual trauma; **AND**
- Patient does not have acute respiratory failure; **AND**
- Patient does not have active malignancy; **AND**
- Patient does not have active proliferative or severe non-proliferative diabetic retinopathy; **AND**
- **Patient must have a documented failure, contraindication, intolerance, or ineffective response to a trial of Norditropin® AND Genotropin®; AND**
- Open bony epiphyses; **AND**
- All other causes of short stature have been excluded (i.e. renal, neoplastic, pulmonary, cardiac, gastrointestinal, immunologic, endocrine, metabolic, or any other disease than may result in short stature); **AND**
- Patient has short stature as defined by height that is 2.25 SD or more below the mean for chronological age

CLINICAL CRITERIA FOR INITIAL APPROVAL FOR PEDIATRIC PATIENTS (UNDER 18) *(CONTINUED)*

Diagnosis of **Prader-Willi Syndrome (PWS)** **(Pediatric Patient)**

- Other causes of growth failure must be ruled out (e.g., malnutrition, hypothyroidism, hypocortisolism); **AND**
- Patient does not have a current acute critical illness after open heart surgery, abdominal surgery, or multiple accentual trauma; **AND**
- Patient does not have acute respiratory failure; **AND**
- Patient does not have active malignancy; **AND**
- Patient does not have active proliferative or severe non-proliferative diabetic retinopathy; **AND**
- **Patient must have a documented failure, contraindication, intolerance, or ineffective response to a trial of Norditropin® AND Genotropin®; AND**
- Open bony epiphyses; **AND**
- Patient must not be severely obese, have a history of upper airway obstruction or sleep apnea, or have severe respiratory impairment; **AND**
- Diagnosis is confirmed by DNA-methylation genetic analysis; **AND**
- Patient has short stature as defined by height that is 2 SD or more below the mean for chronological age

Diagnosis of **Short Stature Homeobox-Containing Gene (SHOX) Deficiency** **(Pediatric Patient)**

- Other causes of growth failure must be ruled out (e.g., malnutrition, hypothyroidism, hypocortisolism); **AND**
- Patient does not have a current acute critical illness after open heart surgery, abdominal surgery, or multiple accentual trauma; **AND**
- Patient does not have acute respiratory failure; **AND**
- Patient does not have active malignancy; **AND**
- Patient does not have active proliferative or severe non-proliferative diabetic retinopathy; **AND**
- **Patient must have a documented failure, contraindication, intolerance, or ineffective response to a trial of Norditropin® AND Genotropin®; AND**
- Open bony epiphyses; **AND**
- Diagnosis is confirmed by molecular or genetic analysis; **AND**
- Patient has short stature as defined by height that is 2 SD or more below the mean for chronological age

Diagnosis of **Growth Failure Secondary to Chronic Kidney Disease (CKD)** **(Pediatric Patient)**

- Other causes of growth failure must be ruled out (e.g., malnutrition, hypothyroidism, hypocortisolism); **AND**
- Patient does not have a current acute critical illness after open heart surgery, abdominal surgery, or multiple accentual trauma; **AND**
- Patient does not have acute respiratory failure; **AND**
- Patient does not have active malignancy; **AND**
- Patient does not have active proliferative or severe non-proliferative diabetic retinopathy; **AND**
- **Patient must have a documented failure, contraindication, intolerance, or ineffective response to a trial of Norditropin® AND Genotropin®; AND**
- Open bony epiphyses; **AND**
- Patient has evidence of growth impairment as defined by one of the following:
  - Patient has short stature as defined height velocity Z-score is < -1.88; **OR**
  - Height velocity for age is less than the 3rd percentile that persists beyond 3 months; **AND**
- eGFR < 75 mL/min/1.73 m^2

CLINICAL CRITERIA FOR RENEWAL FOR PEDIATRIC PATIENTS (UNDER 18)

- Patient must have a documented failure, contraindication, intolerance, or ineffective response with trial of Norditropin® **and** Genotropin®; **AND**
- Absence of unacceptable toxicity from the drug (e.g., increased risk of neoplasms, intracranial hypertension, pancreatitis, glucose intolerance/development of diabetes mellitus, hypothyroidism, hypoadrenalism, severe hypersensitivity, fluid retention, slipped capital femoral epiphysis in pediatric patients, progression of preexisting scoliosis in pediatric patients, lipoatrophy)
- Patient has shown a beneficial response to treatment as evidenced by one or more of the following:
  - Improvement in height compared to pre-treatment baseline
  - Improvement in growth velocity compared to pre-treatment baseline

CLINICAL CRITERIA FOR INITIAL APPROVAL FOR ADULT PATIENTS (18+)

Diagnosis of **Growth Hormone Deficiency (GHD)** **(Adult Patient)**

- Other causes of growth failure must be ruled out (e.g., malnutrition, hypothyroidism, hypocortisolism); **AND**
- Patient does not have a current acute critical illness after open heart surgery, abdominal surgery, or multiple accentual trauma; **AND**
- Patient does not have acute respiratory failure; **AND**
- Patient does not have active malignancy; **AND**
- Patient does not have active proliferative or severe non-proliferative diabetic retinopathy; **AND**
- **Patient must have a documented failure, contraindication, intolerance, or ineffective response to a trial of Norditropin® AND Genotropin®; AND**
- Patient has organic GHD with ≥ 3 documented pituitary hormone deficiencies and low serum IGF-1 levels (< -2.0 standard deviation score [SDS]); **OR**
- Patient has organic GHD with ≤ 2 documented pituitary hormone deficiencies, low serum IGF-1 levels (< 0 SDS), and deficient GH levels; **OR**
- Patient has a history of one of the following: hypothalamic-pituitary tumors, surgery, cranial irradiation, empty sella, pituitary apoplexy, traumatic brain injury, subarachnoid hemorrhage, autoimmune hypophysitis, or Rathke's cleft cyst; **AND**
  - Patient has high clinical suspicion of GHD; **AND**
  - Patient has low serum IGF-1 levels (< 0 SDS); **AND**
  - Patient has deficient GH levels ; **OR**
- Patient is in transition from child-onset GHD; **AND**
  - Patient has organic GHD or congenital and/or genetic hypothalamic-pituitary defects with ≥ 3 documented pituitary hormone deficiencies and low serum IGF-1 levels (< -2.0 SDS); **OR**
  - Patient has organic GHD with ≤ 2 documented pituitary hormone deficiencies, low serum IGF-1 levels (< 0 SDS), and deficient GH levels; **OR**
  - Patient has idiopathic isolated childhood GHD or suspected hypothalamic GHD; **AND**
    - Patient has high clinical suspicion of GHD; **AND**
    - Patient has low serum IGF-1 levels (< 0 SDS); **AND**
    - Patient has deficient GH levels

CLINICAL CRITERIA FOR INITIAL APPROVAL FOR ADULT PATIENTS (18+) *(CONTINUED)*

Examples of Organic, Congenital, or Genetic Hypothalamic Pituitary Defects
Organic • Suprasellar mass with previous surgery and cranial irradiation **Congenital/Genetic** • Transcription factor defects (PIT-1, PROP-1, LHX3/4, HESX-1, PITX-2) • GHRH receptor-gene defects • GH-gene defects • GH-receptor/post-receptor defects • Associated with brain structural defects • Single central incisor • Cleft lip/palate • Perinatal insults

Examples of Pituitary Hormones
• Adrenocorticotropic hormone (ACTH) • Antidiuretic hormone (ADH) • Follicle stimulating hormone (FSH) • Growth hormone (GH) • Luteinizing hormone (LH) • Thyroid stimulating hormone (TSH) • Prolactin

Adult GH Deficiency Determination/Testing
• Patient has deficient GH levels as confirmed by any one of the following tests: – Insulin tolerance test (ITT): < 5 mcg/L; **OR** – Macimorelin-stimulation test: < 2.8 mcg/L; **OR** – Glucagon-stimulation test: • ≤ 3 mcg/L for patients with BMI < 25 kg/m^2 • ≤ 3 mcg/L for patients with BMI 25-30 kg/m^2 with a high pre-test probability • ≤ 1 mcg/L for patients with BMI 25-30 kg/m^2 with a low pre-test probability • ≤ 1 mcg/L for patients with BMI > 30 kg/m^2

CLINICAL CRITERIA FOR RENEWAL FOR ADULT PATIENTS (18+)

- Patient must have a documented failure, contraindication, intolerance, or ineffective response to a trial of Norditropin AND Genotropin®; AND
- Absence of unacceptable toxicity from the drug (e.g., increased risk of neoplasms, intracranial hypertension, pancreatitis, glucose intolerance/development of diabetes mellitus, hypothyroidism, hypoadrenalism, severe hypersensitivity, fluid retention, slipped capital femoral epiphysis in pediatric patients, progression of preexisting scoliosis in pediatric patients, lipoatrophy); **AND**
- Patient has shown a beneficial response to treatment as evidenced by at least one of the following:
  - Improvement in quality of life based on Quality of Life in Adult Growth Hormone Deficiency Assessment (QoL-AGHDA)
  - Objective improvements in biochemistry, body composition, or bone mineral density

DRUG-SPECIFIC INFORMATION

SEROSTIM®

Initiative: MNC: Non-Formulary Product (IE 50698 / MR – GSN PatOverride)

Diagnosis of **HIV Diagnosis with Wasting or Cachexia**

- Patient is at least 18 years old; **AND**
- Patient is receiving concomitant antiretroviral therapy; **AND**
- Patient does not have acute critical illness due to complications following surgery, accidental trauma, or acute respiratory failure; **AND**
- Patient does not have the presence of any active pre-existing malignancy; **AND**
- Patient does not have active proliferative or severe non-proliferative diabetic retinopathy; **AND**
- Patient has documented HIV infection or AIDS; **AND**
- Failure of at least one alternative appetite stimulant therapy (e.g., corticosteroids, dronabinol, megestrol, cyproheptadine); **AND**
  - Documented 10% unintentional weight loss compared to baseline body weight; **OR**
  - Documented body mass index (BMI) < 20 kg/m^2 that cannot be attributed to any condition other than HIV infection; **OR**
  - Documented 5% unintentional weight loss over 6 months persisting for at least 1 year
- Approval is for 6 months

RENEWAL FOR SEROSTIM®

- Adequate documentation of disease stability and/or improvement with treatment (i.e., Greater than or equal to 2% increase in body weight and/or BCM); **AND**
- Absence of unacceptable toxicity from the drug (e.g., intracranial hypertension, severe fluid retention/carpal tunnel syndrome, pancreatitis, impaired glucose tolerance/diabetes, development of neoplasms, serious hypersensitivity reactions, lipoatrophy)

ZORBTIVE

Initiative: MNC: Non-Formulary Product (IE 50698 / MR – GSN PatOverride)

Diagnosis of **treatment of short bowel syndrome**

- Patient is at least 18 years old; **AND**
- Patient does not have any pre-existing malignant neoplasms; **AND**
- Patient does not have acute critical illness due to complications following major surgery, multiple accidental trauma or acute respiratory failure; **AND**
- Patient does not have diabetic retinopathy; **AND**
- Patient must currently be dependent on intravenous parenteral nutrition for nutritional support
- Approval is for 4 weeks only and is not eligible for renewal

COVERED – PA REQUIRED
Genotropin® (*somatropin*)
Norditropin® (*somatropin*)

HEMATOPOEITIC AGENTS

Length of Authorization:	Non-ESRD: 45 days, may be renewed ESRD on Dialysis: 12 months, may be renewed
Initiative:	SPC: Hematopoietic Agents (IE 2462 / NCPDP 75 – HICL) MNC: Non-Formulary Product (IE 50698 / MR – GSN PatOverride)

CLINICAL CRITERIA FOR INITIAL APPROVAL

ARANESP®

- **Anemia Secondary to Myelodysplastic Syndrome (MDS)**
  - Patient is 18 years of age or older; **AND**
  - Initiation of therapy hemoglobin (Hb) < 10 g/dL and/or hematocrit (Hct) < 30%; **AND**
  - Lab values are obtained within 30 days of the date of administration (unless otherwise indicated); **AND**
  - Patient has adequate iron stores as demonstrated by serum ferritin ≥ 100 ng/mL (mcg/L) and transferrin saturation (TSAT) ≥ 20% (measured within the previous 3 months for renewal)*; **AND**
  - Other causes of anemia (e.g., hemolysis, bleeding, vitamin deficiency) have been ruled out; **AND**
  - Patient does not have uncontrolled hypertension; **AND**
  - Endogenous serum erythropoietin level of ≤ 500 mUnits/mL; **AND**
  - Patient has lower risk disease (i.e., defined as IPSS-R [Very Low, Low, Intermediate], IPSS [Low/Intermediate-1], WPSS [Very Low, Low, Intermediate]); **AND**
  - Patient has symptomatic anemia; **AND**
  - Patient must have a documented failure, contraindication, or intolerance or ineffective response with trial of Retacrit®; **OR**
  - Patient continuing treatment with Aranesp®
- **Anemia Secondary to Myeloproliferative Neoplasms (MPN) - Myelofibrosis**
  - Patient is 18 years of age or older; **AND**
  - Initiation of therapy hemoglobin (Hb) < 10 g/dL and/or hematocrit (Hct) < 30%; **AND**
  - Lab values are obtained within 30 days of the date of administration (unless otherwise indicated); **AND**
  - Patient has adequate iron stores as demonstrated by serum ferritin ≥ 100 ng/mL (mcg/L) and transferrin saturation (TSAT) ≥ 20% (measured within the previous 3 months for renewal)*; **AND**
  - Other causes of anemia (e.g., hemolysis, bleeding, vitamin deficiency) have been ruled out; **AND**
  - Patient does not have uncontrolled hypertension; **AND**
  - Endogenous serum erythropoietin level of ≤ 500 mUnits/Ml; **AND**
  - Patient must have a documented failure, contraindication, or intolerance or ineffective response with trial of Retacrit®; **OR**
  - Patient continuing treatment with Aranesp®

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

ARANESP® *(CONTINUED)*

- **Anemia Secondary to Chemotherapy Treatment**
  - Patient is 18 years of age or older; **AND**
  - Initiation of therapy hemoglobin (Hb) < 10 g/dL and/or hematocrit (Hct) < 30%; **AND**
  - Lab values are obtained within 30 days of the date of administration (unless otherwise indicated); **AND**
  - Patient has adequate iron stores as demonstrated by serum ferritin ≥ 100 ng/mL (mcg/L) and transferrin saturation (TSAT) ≥ 20% (measured within the previous 3 months for renewal)*; **AND**
  - Other causes of anemia (e.g., hemolysis, bleeding, vitamin deficiency) have been ruled out; **AND**
  - Patient does not have uncontrolled hypertension; **AND**
  - Patient is receiving concomitant myelosuppressive chemotherapy; **AND**
  - Patient's chemotherapy is not intended to cure their disease (i.e., palliative treatment); **AND**
  - There is a minimum of two additional months of planned chemotherapy; **AND**
  - Patient must have a documented failure, contraindication, or intolerance or ineffective response with trial of Retacrit®; **OR**
  - Patient continuing treatment with Aranesp®
- **Anemia Secondary to Chronic Kidney Disease (Non-Dialysis Patients)**
  - Lab values are obtained within 30 days of the date of administration (unless otherwise indicated); **AND**
  - Patient has adequate iron stores as demonstrated by serum ferritin ≥ 100 ng/mL (mcg/L) and transferrin saturation (TSAT) ≥ 20% (measured within the previous 3 months for renewal)*; **AND**
  - Initiation of therapy hemoglobin (Hb) < 10 g/dL and/or hematocrit (HCT) < 30%; **AND**
  - Other causes of anemia (e.g., hemolysis, bleeding, vitamin deficiency) have been ruled out; **AND**
  - Patient does not have uncontrolled hypertension; **AND**
  - Patient is one month or older; **AND**
  - Patient must have a documented failure, contraindication, or intolerance or ineffective response with trial of Retacrit®; **OR**
  - Patient continuing treatment with Aranesp®
- **Anemia Secondary to Chronic Kidney Disease (dialysis patients)**
  - Lab values are obtained within 30 days of the date of administration (unless otherwise indicated); **AND**
  - Patient has adequate iron stores as demonstrated by serum ferritin ≥ 100 ng/mL (mcg/L) and transferrin saturation (TSAT) ≥ 20% (measured within the previous 3 months for renewal)*; **AND**
  - Initiation of therapy hemoglobin (Hb) < 10 g/dL and/or hematocrit (HCT) < 30%; **AND**
  - Other causes of anemia (e.g., hemolysis, bleeding, vitamin deficiency) have been ruled out; **AND**
  - Patient does not have uncontrolled hypertension; **AND**
  - Patient age is 1 month or older; **AND**
  - Patient must have a documented failure, contraindication, or intolerance or ineffective response with trial of Retacrit®; **OR**
  - Patient continuing treatment with Aranesp®

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

PROCRIT®/EPOGEN®

- **Anemia Secondary to Myelodysplastic Syndrome (MDS)**
  - Patient is 18 years of age or older; **AND**
  - Lab values are obtained within 30 days of the date of administration (unless otherwise indicated); **AND**
  - Patient has adequate iron stores as demonstrated by serum ferritin ≥ 100 ng/mL (mcg/L) and transferrin saturation (TSAT) ≥ 20% (measured within the previous 3 months for renewal); **AND**
  - Initiation of therapy hemoglobin (Hb) < 10 g/dL and/or hematocrit (HCT) < 30% (unless otherwise specified); **AND**
  - Other causes of anemia (e.g., hemolysis, bleeding, vitamin deficiency) have been ruled out; **AND**
  - Patient does not have uncontrolled hypertension; **AND**
  - Endogenous serum erythropoietin level of ≤ 500 mUnits/mL; **AND**
  - Patient has lower risk disease (i.e., defined as IPSS-R [Very Low, Low, Intermediate], IPSS [Low/Intermediate-1], WPSS [Very Low, Low, Intermediate]); **AND**
  - Patient has symptomatic anemia; **AND**
  - Patient must have a documented failure, contraindication, or intolerance or ineffective response with minimum 3-month trial of Retacrit®; **OR**
  - Patient continuing treatment with Epogen®/Procrit®
- **Anemia Secondary to Myeloproliferative Neoplasms (MPN) - Myelofibrosis**
  - Patient is 18 years of age or older; **AND**
  - Lab values are obtained within 30 days of the date of administration (unless otherwise indicated); **AND**
  - Patient has adequate iron stores as demonstrated by serum ferritin ≥ 100 ng/mL (mcg/L) and transferrin saturation (TSAT) ≥ 20% (measured within the previous 3 months for renewal)*; **AND**
  - Initiation of therapy hemoglobin (Hb) < 10 g/dL and/or hematocrit (HCT) < 30% (unless otherwise specified); **AND**
  - Patient does not have uncontrolled hypertension; **AND**
  - Other causes of anemia (e.g., hemolysis, bleeding, vitamin deficiency) have been ruled out; **AND**
  - Endogenous serum erythropoietin level of < 500 mUnits/Ml; **AND**
  - Patient must have a documented failure, contraindication, or intolerance or ineffective response with minimum 3-month trial of Retacrit®; **OR**
  - Patient continuing treatment with Epogen®/Procrit®
- **Anemia Secondary to Rheumatoid Arthritis**
  - Patient is 18 years of age or older; **AND**
  - Lab values are obtained within 30 days of the date of administration (unless otherwise indicated); **AND**
  - Patient has adequate iron stores as demonstrated by serum ferritin ≥ 100 ng/mL (mcg/L) and transferrin saturation (TSAT) ≥ 20% (measured within the previous 3 months for renewal)*; **AND**
  - Initiation of therapy hemoglobin (Hb) < 10 g/dL and/or hematocrit (HCT) < 30% (unless otherwise specified); **AND**
  - Patient does not have uncontrolled hypertension; **AND**
  - Other causes of anemia (e.g., hemolysis, bleeding, vitamin deficiency) have been ruled out; **AND**
  - Patient must have a documented failure, contraindication, or intolerance or ineffective response with minimum 3-month trial of Retacrit®; **OR**
  - Patient continuing treatment with Epogen®/Procrit®

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

PROCRIT®/EPOGEN® *(CONTINUED)*

- **Anemia Secondary to Chemotherapy Treatment**
  - Patient is 5 years of age or older; **AND**
  - Lab values are obtained within 30 days of the date of administration (unless otherwise indicated); **AND**
  - Patient has adequate iron stores as demonstrated by serum ferritin ≥ 100 ng/mL (mcg/L) and transferrin saturation (TSAT) ≥ 20% (measured within the previous 3 months for renewal)*; **AND**
  - Initiation of therapy hemoglobin (Hb) < 10 g/dL and/or hematocrit (HCT) < 30% (unless otherwise specified); **AND**
  - Other causes of anemia (e.g., hemolysis, bleeding, vitamin deficiency) have been ruled out; **AND**
  - Patient does not have uncontrolled hypertension; **AND**
  - Patient is receiving concomitant myelosuppressive chemotherapy; **AND**
  - Patient's chemotherapy is not intended to cure their disease (i.e., palliative treatment); **AND**
  - There is a minimum of two additional months of planned chemotherapy; **AND**
  - Patient must have a documented failure, contraindication, or intolerance or ineffective response with minimum 3-month trial of Retacrit®; **OR**
  - Patient continuing treatment with Epogen®/Procrit®
- **Anemia Secondary to Chronic Kidney Disease (Non-Dialysis Patients)**
  - Lab values are obtained within 30 days of the date of administration (unless otherwise indicated); **AND**
  - Patient has adequate iron stores as demonstrated by serum ferritin ≥ 100 ng/mL (mcg/L) and transferrin saturation (TSAT) ≥ 20% (measured within the previous 3 months for renewal)*; **AND**
  - Initiation of therapy hemoglobin (Hb) < 10 g/dL and/or hematocrit (HCT) < 30% (unless otherwise specified); **AND**
  - Other causes of anemia (e.g., hemolysis, bleeding, vitamin deficiency) have been ruled out; **AND**
  - Patient does not have uncontrolled hypertension; **AND**
  - Patient is 1 month or older; **AND**
  - Patient must have a documented failure, contraindication, or intolerance or ineffective response with minimum 3-month trial of Retacrit®; **OR**
  - Patient continuing treatment with Epogen®/Procrit®
- **Anemia secondary to chronic kidney disease (dialysis patients)**
  - Lab values are obtained within 30 days of the date of administration (unless otherwise indicated); **AND**
  - Prior to initiation of therapy, patient should have adequate iron stores as demonstrated by serum ferritin ≥ 100 ng/mL (mcg/L) and transferrin saturation (TSAT) ≥ 20%*; **AND**
  - Initiation of therapy hemoglobin (Hb) < 10 g/dL and/or hematocrit (HCT) < 30% (unless otherwise specified); **AND**
  - Other causes of anemia (e.g., hemolysis, bleeding, vitamin deficiency) have been ruled out; **AND**
  - Patient does not have uncontrolled hypertension; **AND**
  - Patient must have a documented failure, contraindication, or intolerance or ineffective response with minimum 3-month trial of Retacrit®; **OR**
  - Patient continuing treatment with Epogen®/Procrit®

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

PROCRIT®/EPOGEN® *(CONTINUED)*

- **Anemia Secondary to Zidovudine-Treated, HIV-Infected Patients**
  - Patient is 8 months or older; **AND**
  - Lab values are obtained within 30 days of the date of administration (unless otherwise indicated); **AND**
  - Patient has adequate iron stores as demonstrated by serum ferritin ≥ 100 ng/mL (mcg/L) and transferrin saturation (TSAT) ≥ 20% (measured within the previous 3 months for renewal)*; **AND**
  - Initiation of therapy hemoglobin (Hb) < 10 g/dL and/or hematocrit (HCT) < 30% (unless otherwise specified); **AND**
  - Other causes of anemia (e.g., hemolysis, bleeding, vitamin deficiency) have been ruled out; **AND**
  - Patient does not have uncontrolled hypertension; **AND**
  - Patient is receiving zidovudine administered at ≤ 4,200 mg/week; **AND**
  - Endogenous serum erythropoietin level of ≤ 500 mUnits/mL; **AND**
  - Patient must have a documented failure, contraindication, or intolerance or ineffective response with minimum 3-month trial of Retacrit®; **OR**
  - Patient continuing treatment with Epogen®/Procrit®
- **Reduction of Allogeneic Blood Transfusions in Elective, Non-Cardiac, Non-Vascular Surgery**
  - Patient is 18 years of age or older; **AND**
  - Lab values are obtained within 30 days of the date of administration (unless otherwise indicated); **AND**
  - Patient has adequate iron stores as demonstrated by serum ferritin ≥ 100 ng/mL (mcg/L) and transferrin saturation (TSAT) ≥ 20% (measured within the previous 3 months for renewal)*; **AND**
  - Other causes of anemia (e.g., hemolysis, bleeding, vitamin deficiency) have been ruled out; **AND**
  - Patient does not have uncontrolled hypertension; **AND**
  - Hemoglobin (Hb) > 10 g/dL and ≤ 13 g/dL and/or Hematocrit (Hct) > 30% and ≤ 39%; **AND**
  - Patient is at high-risk of blood-loss from surgery that is elective, non-cardiac and non-vascular; **AND**
  - Patient is unwilling or unable to participate in an autologous blood donation program prior to surgery; **AND**
  - Patient must have a documented failure, contraindication, or intolerance or ineffective response with minimum 3-month trial of Retacrit®; **OR**
  - Patient continuing treatment with Epogen®/Procrit®

RETACRIT®

- **Anemia Secondary to Myelodysplastic Syndrome (MDS)**
  - Patient is 18 years of age or older; **AND**
  - Lab values are obtained within 30 days of the date of administration (unless otherwise indicated); **AND**
  - Patient has adequate iron stores as demonstrated by serum ferritin ≥ 100 ng/mL (mcg/L) and transferrin saturation (TSAT) ≥ 20% (measured within the previous 3 months for renewal)*; **AND**
  - Initiation of therapy hemoglobin (Hb) < 10 g/dL and/or hematocrit (HCT) < 30% (unless otherwise specified); **AND**
  - Other causes of anemia (e.g., hemolysis, bleeding, vitamin deficiency) have been ruled out; **AND**
  - Patient does not have uncontrolled hypertension; **AND**
  - Endogenous serum erythropoietin level of ≤ 500 mUnits/mL; **AND**
  - Patient has lower risk disease (i.e., defined as IPSS-R [Very Low, Low, Intermediate], IPSS [Low/Intermediate-1], WPSS [Very Low, Low, Intermediate]); **AND**
  - Patient has symptomatic anemia

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

RETACRIT® *(CONTINUED)*

- **Anemia Secondary to Myeloproliferative Neoplasms (MPN) - Myelofibrosis**
  - Patient is 18 years of age or older; **AND**
  - Lab values are obtained within 30 days of the date of administration (unless otherwise indicated); **AND**
  - Patient has adequate iron stores as demonstrated by serum ferritin ≥ 100 ng/mL (mcg/L) and transferrin saturation (TSAT) ≥ 20% (measured within the previous 3 months for renewal)*; **AND**
  - Initiation of therapy hemoglobin (Hb) < 10 g/dL and/or hematocrit (HCT) < 30% (unless otherwise specified); **AND**
  - Patient does not have uncontrolled hypertension; **AND**
  - Other causes of anemia (e.g., hemolysis, bleeding, vitamin deficiency) have been ruled out; **AND**
  - Endogenous serum erythropoietin level of < 500 mUnits/mL
- **Anemia Secondary to Rheumatoid Arthritis**
  - Patient is 18 years of age or older; **AND**
  - Lab values are obtained within 30 days of the date of administration (unless otherwise indicated); **AND**
  - Patient has adequate iron stores as demonstrated by serum ferritin ≥ 100 ng/mL (mcg/L) and transferrin saturation (TSAT) ≥ 20% (measured within the previous 3 months for renewal) *; **AND**
  - Initiation of therapy hemoglobin (Hb) < 10 g/dL and/or hematocrit (HCT) < 30% (unless otherwise specified); **AND**
  - Other causes of anemia (e.g., hemolysis, bleeding, vitamin deficiency) have been ruled out; **AND**
  - Patient does not have uncontrolled hypertension
- **Anemia Secondary to Chemotherapy Treatment**
  - Lab values are obtained within 30 days of the date of administration (unless otherwise indicated); **AND**
  - Patient has adequate iron stores as demonstrated by serum ferritin ≥ 100 ng/mL (mcg/L) and transferrin saturation (TSAT) ≥ 20% (measured within the previous 3 months for renewal) *; **AND**
  - Initiation of therapy hemoglobin (Hb) < 10 g/dL and/or hematocrit (HCT) < 30% (unless otherwise specified); **AND**
  - Other causes of anemia (e.g., hemolysis, bleeding, vitamin deficiency) have been ruled out; **AND**
  - Patient does not have uncontrolled hypertension; **AND**
  - Patient is 5 years of age or older; **AND**
  - Patient is receiving concurrent myelosuppressive chemotherapy; **AND**
  - Patient's chemotherapy is not intended to cure their disease (i.e., palliative treatment); **AND**
  - There is a minimum of two additional months of planned chemotherapy
- **Anemia Secondary to Chronic Kidney Disease (Non-Dialysis Patients)**
  - Lab values are obtained within 30 days of the date of administration (unless otherwise indicated); **AND**
  - Patient has adequate iron stores as demonstrated by serum ferritin ≥ 100 ng/mL (mcg/L) and transferrin saturation (TSAT) ≥ 20% (measured within the previous 3 months for renewal)*; **AND**
  - Initiation of therapy hemoglobin (Hb) < 10 g/dL and/or hematocrit (HCT) < 30% (unless otherwise specified); **AND**
  - Patient does not have uncontrolled hypertension; **AND**
  - Patient is 1 month or older; **AND**
  - Other causes of anemia (e.g., hemolysis, bleeding, vitamin deficiency) have been ruled out

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

RETACRIT® *(CONTINUED)*

- **Anemia Secondary to Chronic Kidney Disease (dialysis patients)**
  - Lab values are obtained within 30 days of the date of administration (unless otherwise indicated); **AND**
  - Patient has adequate iron stores as demonstrated by serum ferritin ≥ 100 ng/mL (mcg/L) and transferrin saturation (TSAT) ≥ 20% (measured within the previous 3 months for renewal)*; **AND**
  - Initiation of therapy hemoglobin (Hb) < 10 g/dL and/or hematocrit (HCT) < 30% (unless otherwise specified); **AND**
  - Other causes of anemia (e.g., hemolysis, bleeding, vitamin deficiency) have been ruled out; **AND**
  - Patient does not have uncontrolled hypertension
- **Anemia Secondary to Zidovudine-Treated, HIV-Infected Patients**
  - Patient is 8 months or older; **AND**
  - Lab values are obtained within 30 days of the date of administration (unless otherwise indicated); **AND**
  - Patient has adequate iron stores as demonstrated by serum ferritin ≥ 100 ng/mL (mcg/L) and transferrin saturation (TSAT) ≥ 20% (measured within the previous 3 months for renewal)*; **AND**
  - Initiation of therapy hemoglobin (Hb) < 10 g/dL and/or hematocrit (HCT) < 30% (unless otherwise specified); **AND**
  - Other causes of anemia (e.g., hemolysis, bleeding, vitamin deficiency) have been ruled out; **AND**
  - Patient does not have uncontrolled hypertension; **AND**
  - Endogenous serum erythropoietin level of ≤ 500 mUnits/mL; **AND**
  - Patient is receiving zidovudine administered at ≤ 4,200 mg/week
- **Reduction of Allogeneic Blood Transfusions in Elective, Non-Cardiac, Non-Vascular Surgery**
  - Lab values are obtained within 30 days of the date of administration (unless otherwise indicated); **AND**
  - Patient has adequate iron stores as demonstrated by serum ferritin ≥ 100 ng/mL (mcg/L) and transferrin saturation (TSAT) ≥ 20% (measured within the previous 3 months for renewal)*; **AND**
  - Initiation of therapy hemoglobin (Hb) < 10 g/dL and/or hematocrit (HCT) < 30% (unless otherwise specified); **AND**
  - Other causes of anemia (e.g., hemolysis, bleeding, vitamin deficiency) have been ruled out; **AND**
  - Patient does not have uncontrolled hypertension; **AND**
  - Hemoglobin (Hb) >10 g/dL and ≤13 g/dL and/or hematocrit (Hct) >30% and ≤39%; **AND**
  - Patient is at high-risk of blood-loss from surgery that is elective, non-cardiac and non-vascular; **AND**
  - Patient is unwilling or unable to participate in an autologous blood donation program prior to surgery

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

MIRCERA®

- **Anemia Secondary to Chronic Kidney Disease (dialysis patients)**
  - Patient is an adult (18 years or older); **OR**
    - Pediatric patients (5 years or older); **AND**
    - Patient is receiving hemodialysis; **AND**
    - Patient is converting from another erythropoiesis stimulating agent (ESA) after their hemoglobin was stabilized
  - Lab values are obtained within 30 days of the date of administration (unless otherwise indicated); **AND**
  - Patient has adequate iron stores as demonstrated by serum ferritin ≥ 100 ng/mL (mcg/L) and transferrin saturation (TSAT) ≥ 20% (measured within the previous 3 months for renewal); **AND**
  - Initiation of therapy hemoglobin (Hb) < 10 g/dL and/or hematocrit (HCT) < 30%; **AND**
  - Other causes of anemia (e.g., hemolysis, bleeding, vitamin deficiency) have been ruled out; **AND**
  - Patient does not have uncontrolled hypertension; **AND**
  - Patient must have a documented failure, contraindication, or intolerance or ineffective response with minimum 3-month trial of Retacrit®; **OR**
  - Patient continuing treatment with Mircera®
- **Anemia secondary to Chronic Kidney Disease (adult non-dialysis patients)**
  - Patient is 18 years or older; **AND**
  - Lab values are obtained within 30 days of the date of administration (unless otherwise indicated); **AND**
  - Patient has adequate iron stores as demonstrated by serum ferritin ≥ 100 ng/mL (mcg/L) and transferrin saturation (TSAT) ≥ 20% (measured within the previous 3 months for renewal); **AND**
  - Initiation of therapy hemoglobin (Hb) < 10 g/dL and/or hematocrit (HCT) < 30%; **AND**
  - Other causes of anemia (e.g., hemolysis, bleeding, vitamin deficiency) have been ruled out; **AND**
  - Patient does not have uncontrolled hypertension; **AND**
  - Patient must have a documented failure, contraindication, or intolerance or ineffective response with minimum 3-month trial of Retacrit®; **OR**
  - Patient continuing treatment with Mircera®

CLINICAL CRITERIA FOR RENEWAL

- Previous dose was administered within the past 60 days (otherwise follow “Initial” criteria); **AND**
- Anemia response compared to pretreatment baseline; **AND**
- Absence of unacceptable toxicity from the drug (e.g., severe allergic reactions [e.g., anaphylaxis, angioedema, bronchospasm], severe cardiovascular events [i.e., stroke, myocardial infarction, thromboembolism, uncontrolled hypertension], increased risk of tumor progression/recurrence in patients with cancer, seizures, pure red cell aplasia, severe cutaneous reactions [erythema multiforme, Stevens-Johnson syndrome/toxic epidermal necrolysis], “gasping syndrome” [central nervous system depression, metabolic acidosis, gasping respirations] due to benzyl alcohol preservative); **AND**
  - **Anemia Secondary to Myelodysplastic Syndrome** (MDS):
    - Hemoglobin (Hb) < 12 g/dL and/or hematocrit (HCT) <36%
  - **Anemia Secondary to Myeloproliferative Neoplasms (MF, Post-PV Myelofibrosis, Post-ET Myelofibrosis)**
    - Hemoglobin (Hb) < 10g/dL and/or hematocrit (HCT) < 30%

CLINICAL CRITERIA FOR RENEWAL *(CONTINUED)*

- **Reduction of Allogeneic Blood Transfusions in Elective, Non-Cardiac, Non-Vascular Surgery**
  - Hemoglobin(Hb) > 10 g/dL and ≤ 13 g/dL and/or hematocrit(Hct) between 30% and 39%
- **Anemia Secondary to Chemotherapy Treatment**
  - Refer to initial criteria
- **Anemia Secondary to Zidovudine Treated, HIV-Infected Patients**:
  - Hemoglobin (Hb) < 12 g/dL and/or hematocrit (HCT) < 36%
  - Patient is receiving zidovudine administered at ≤ 4,200 mg/week
- **Anemia Secondary to Chronic Kidney Disease (dialysis and non-dialysis):**
  - Pediatric patients: hemoglobin (Hb) < 12 g/dL and/or hematocrit (HCT) < 36%
  - Adults: hemoglobin (Hb) < 11 g/dL and/or hematocrit (HCT) < 33%
- **Anemia Secondary to Rheumatoid Arthritis:**
  - Hemoglobin (Hb) < 11 g/dL and/or hematocrit (Hct) < 33%
- **All other indications:**
  - Hemoglobin (Hb) <11 g/dL and/or hematocrit (HCT) < 33%

ADDITIONAL INFORMATION TO AID IN THE FINAL DECISION

- Symptoms of severe anemia include extreme weakness and fatigue, cold intolerance, tachycardia (rapid heartbeat), pulmonary distress, hypotension, angina, and congestive heart failure

HEPATITIS B THERAPY: ORAL

Length of Authorization:	1 year **eligible for renewal**
Initiative:	SPC: Antivirals (IE 2462 / NCPDP 75 – HICL)

CLINICAL CRITERIA

Diagnosis of **Chronic Hepatitis B *without* Cirrhosis- HBeAg POSITIVE**

- Patient is 2 years of age or older for Baraclude® or entecavir **or** 12 years of age or older for Hepsera®; **AND**
- Patient has been evaluated and screened for the presence of human immunodeficiency virus (HIV) prior to initiating treatment; **AND**
- Documented HBeAg positive; **AND**
- Documented HBsAg positive for at least 6 months; **AND**
- Documented evidence of active virus replication (HBV DNA level > 20,000 IU/mL); **AND**
- Documented evidence of active liver disease demonstrated by **one** of the following:
  - Persistent elevation in serum ALT > 2 times upper limits of normal (ULN)
  - Moderate to severe hepatitis or fibrosis on biopsy;
  - Necroinflammation on biopsy
  - Evidence of icteric ALT flares

Diagnosis of **Chronic Hepatitis B *without* Cirrhosis- HBeAg NEGATIVE**

- Patient is 2 years of age and older for Baraclude® or entecavir **or** 12 years of age or older for Hepsera®; **AND**
- Patient has been evaluated and screened for the presence of human immunodeficiency virus (HIV) prior to initiating treatment; **AND**
- Documented HBeAg negative; **AND**
- Documented HBsAg negative; **AND**
- Documented HBV DNA level $\geq$ 2000 IU/mL; **AND**
- Documented evidence of active liver disease demonstrated by **one** of the following:
  - Persistent elevation in serum ALT > 2 times upper limits of normal (ULN)
  - Moderate to severe hepatitis or fibrosis on biopsy;
  - Necroinflammation on biopsy
  - Evidence of icteric ALT flares

Diagnosis of **Chronic Hepatitis B *with* Compensated Cirrhosis**

- Patient is 2 years of age and older for Baraclude® or entecavir **or** 12 years of age or older for Hepsera®; **AND**
- Patient has been evaluated and screened for the presence of human immunodeficiency virus (HIV) prior to initiating treatment; **AND**
- Patient has compensated cirrhosis; **AND**
- Documented HBsAg positive for at least 6 months

Diagnosis of **Chronic Hepatitis B *with* Decompensated Cirrhosis**

- Patient is 2 years of age and older for Baraclude® or entecavir **or** 12 years of age or older for Hepsera®; **AND**
- Patient has been evaluated and screened for the presence of human immunodeficiency virus (HIV) prior to initiating treatment; **AND**
- Patient has decompensated cirrhosis; **AND**
- Documented HBsAg positive for at least 6 months

CLINICAL CRITERIA *(CONTINUED)*

Diagnosis of **Chronic Hepatitis B Post-liver Transplant**

- Patient is 2 years of age and older for Baraclude® or entecavir **or** 12 years of age or older for Hepsera®; **AND**
- Patient has been evaluated and screened for the presence of human immunodeficiency virus (HIV) prior to initiating treatment; **AND**
- Documented HBsAg positive pre-transplant; **OR**
- Documented HBV DNA positive pre-transplant

Diagnosis of **Recurrent Hepatitis B Pre-liver Transplant**

- Patient is 2 years of age and older for Baraclude® or entecavir **or** 12 years of age or older for Hepsera®; **AND**
- Patient has been evaluated and screened for the presence of human immunodeficiency virus (HIV) prior to initiating treatment; **AND**
- Patient is UNOS listed to receive a liver transplant; **AND**
- Documented HBsAg positive; **OR**
- Documented HBV DNA positive

Diagnosis of **HBV Carriers Currently on Cancer Chemotherapy or Immunosuppressive Therapy** (**For Baraclude® or entecavir only**)

- Patient is 2 years of age and older for Baraclude® or entecavir; **AND**
- Patient has been evaluated and screened for the presence of human immunodeficiency virus (HIV) prior to initiating treatment; **AND**
- Patient is carrier of HBV as confirmed by documented HBsAg and anti-HBc tests prior to starting cancer chemotherapy or immunosuppressive therapy

Diagnosis of **Chronic Hepatitis B in Patients Co-infected with HIV** (**For Baraclude® or entecavir only**)

- Patient is 2 years of age and older for Baraclude® or entecavir; **AND**
- Patient has been evaluated and screened for the presence of human immunodeficiency virus (HIV) prior to initiating treatment; **AND**
- Patient is unable to receive tenofovir; **AND**
- Used in combination with a highly active anti-retroviral therapy (HAART) that includes either lamivudine or emtricitabine

RENEWAL CRITERIA

Coverage can be renewed based upon the following criteria:

- Patient has not experienced a viral breakthrough; **AND**
- Absence of unacceptable toxicity from the drug (e.g., nephrotoxicity; lactic acidosis, and severe hepatomegaly with steatosis); **AND**
- Patient has decompensated cirrhosis or is post liver transplant; **OR**
- Patient is currently on chemotherapy or immunosuppressive therapy with baseline HBV DNA < 2,000 IU/mL level: Patient has not completed 6 months of therapy after completion of chemotherapy or immunosuppressive therapy; **OR**
- HBeAg Positive Only:
  - Confirmation patient has **not** achieved HBeAg seroconversion; **OR**
  - Patient has detectable serum HBV DNA; **OR**
  - Patient has **not** completed at least 6 months of additional treatment after appearance of anti-HBe; **OR**
- HBeAg Negative Only: Confirmation patient has **not** achieved HBsAg clearance; **OR**
- HIV co-infection only—Baraclude® or entecavir: Patient will continue on a HAART regimen

COVERED – PA REQUIRED
Adefovir (generic for Hepsera®)
Baraclude® solution (*entecavir*)
Entecavir tablet (generic for Baraclude®)

HEPATITIS C – AHCCCS-MANDATED CRITERIA

Length of Authorization:	Treatment duration requested if it is within prescribing guidelines for indication
Initiative:	SPC: Antivirals: Hepatitis

PA requests to be handled only by pharmacists. Escalate all requests to MAP: Pharmacist queue for clinical review.

CLINICAL CRITERIA FOR APPROVAL

Members shall meet ALL of the following requirements:

- Diagnosis of chronic hepatitis C infection status which has been confirmed by detectable serum HCV RNA by quantitative assay completed within the past 90 days from the date of the prior authorization request that includes the HCV genotype, viral resistance status (when applicable), hepatic status (Child Pugh Score) and HCV viral load,
- Adult age >18 years or adolescent age between 12 and 18 years old,
- Are prescribed HCV medications by, or in consultation with, a gastroenterologist, hepatologist, or infectious disease physician,
- Patient readiness has been assessed and patient attestation of compliance is submitted and on file in the member's medical record (prescribers shall use the CSPMP as a tool to aid in the review of compliance),
- The member agrees to complete the regimen and understands the risks of reinfection and other contributors to liver disease and/or damage, through a signed attestation,
- The prescribing clinician agrees to maintain HCV RNA levels obtained at 12 & 24-weeks post therapy completion to demonstrate the Sustained Virologic Response (SVR),
- Member has been screened for Hepatitis A and B and shall have received at least one Hepatitis A and at least one Hepatitis B vaccine prior to requesting treatment unless the member demonstrates laboratory evidence of immunity, and
- The member shall be in remission for the past three months from the request date for treatment and shall be engaged in a substance use disorder treatment program at the time of the prior authorization and over the course of the treatment if the member has/had a substance use disorder in the past 12 months.

REQUIRED DOCUMENTATION FOR SUBMISSION OF HCV PRIOR AUTHORIZATION REQUESTS

In order for a prior authorization request for HCV medications to be considered, the following minimum information shall be submitted for the member:

- HCV treatment history and responses,
- Evidence of Hepatitis A & B vaccinations or laboratory evidence of immunity,
- Current medication list, and
- Laboratory results for **ALL** the following:
  - HCV screen;
  - Genotype and current baseline viral load;
  - Total bilirubin;
  - Albumin;
  - INR;
  - CrCl or GFR;
  - LFTs;
  - CBC; **AND**
  - Drug/alcohol screen completed within the past 90 days.

CLINICAL CRITERIA FOR APPROVAL *(CONTINUED)*

TREATMENT MONITORING REQUIREMENTS

- Members prescribed HCV treatment shall participate in a treatment adherence program.
- Providers are required to monitor hemoglobin levels periodically when a member is prescribed ribavirin.

HEPATITIS C RETREATMENT REQUIREMENTS

For members who have HCV and a history of treatment with a DAA, the following criteria shall be met for DAA retreatment approval:

- The member was adherent to previous DAA therapy as evidenced by medical records and/or pharmacy prescription claims. If prior therapy was discontinued due to adverse effects from the DAA, the medical record shall be provided which documents these adverse effects and recommendation of discontinuation by treatment provider,
- If a member has a substance use disorder in the past 12 months from the request date for treatment, the member shall be in remission for the past three months from the request date for treatment and shall be engaged in a substance use disorder treatment program at the time of the prior authorization request and over the course of treatment if the DAA medications are approved,
- Member commits to the documented planned course of treatment including anticipated laboratory, imaging tests, and prescribing provider visits,
- Resistance-associated polymorphism testing, when applicable, has been completed and submitted with the prior authorization request when:
  - Required for regimens whereby the FDA requires such testing prior to treatment to ensure clinical appropriateness, and
  - Deemed medically necessary by the clinical reviewer prior to approval of the requested regimen.

Hepatitis C Retreatment shall not be approved when:

- The life expectancy is less than 12 months and cannot be remediated by treating the HCV infection, by transplantation, or by other directed therapy.
- A member was non-adherent to the initial DAA treatment regimen as evidenced by medical records and/or pharmacy prescription claims.
- Is considered an experimental service as defined in R9-22-203. Based on current evidence, this includes more than one retreatment with a DAA and requested retreatment regimens that include more than one DAA.

CLINICAL CRITERIA FOR APPROVAL *(CONTINUED)*

LIMITATIONS

Direct Acting Antiviral HCV treatment coverage is not provided for the following:

- Monotherapy of:
  - Daclatasvir (Daklinza),
  - Simeprevir (Olysio),
  - Sofosbuvir (Sovaldi),
- Direct Acting Antiviral Dosages greater than the FDA approved maximum dosage,
- Ombitasvir, Paritaprevir and Ritonavir (Technivie) or Ombitasvir, Paritaprevir and Ritonavir, Dasabuvir tablets (Viekira Pak) shall not be approved for members whose Child Pugh score is B or C,
- **Grazoprevir/elbasvir (Zepatier)** if the NS5A polymorphism testing has not been completed and submitted with the prior authorization request,
- Members when there is **documented non-adherence** to prior HCV medications, HCV medical treatment, or failure to complete HCV disease evaluation appointments and laboratory and imaging procedures,
- Members declining to participate in a treatment adherence program,
- Members declining to participate in a substance abuse disorder treatment program,
- Members whose comorbidities are such that their life expectancy is one year or less,
- Members currently using a potent P-gp inducer drug (St. John's wart, rifampin, carbamazepine, ritonavir, tipranavir, etc.), greater than one Direct Acting Antiviral drug regimen used for retreatment,
- Lost or stolen medication absent of good cause, or
- Fraudulent use of HCV medications.

COVERED – PA REQUIRED
Sofosbuvir/velpatasvir (generic for Epclusa®)
Mavyret® (glecaprevir-pibrentasvir)
Pegasys® (peginterferon alfa-2a soln)
Pegintron® kit (peginterferon alfa-2b)
Ribavirin capsule
Ribavirin tablet

HERCEPTIN® (TRASTUZUMAB), HERZUMA® (TRASTUZUMAB-PKRB), KANJINTI® (TRASTUZUMAB-ANNS), OGIVRI™ (TRASTUZUMAB-DKST), ONTRUZANT® (TRASTUZUMAB-DTTB), AND TRAZIMERA™ (TRASTUZUMAB-QYYP)

Length of Authorization:	6 months, may be renewed Use for neo-adjuvant and adjuvant breast cancer is limited to a total of 52 weeks of treatment
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75 – GSN, 50081 and 2193) – Trazimera and Kanjinti MNC: Non-Formulary Product (IE 50698 / MR – GSN PatOverride) – Herceptin, Herzuma, Ogivri, Ontruzant

CLINICAL CRITERIA FOR INITIAL APPROVAL

For Herceptin®, Herzuma®, Ogivri™, and Ontruzant®: for new starts only, patient must have a documented failure, contraindication, intolerance, or ineffective response to a trial of Kanjinti® AND Trazimera

Diagnosis of **breast cancer**:

- Patient is 18 years of age of older; **AND**
- Left ventricular ejection fraction (LVEF) is within normal limits prior to initiating therapy and will be assessed at regular intervals during treatment; **AND**
- Patients cancer is human epidermal growth factor receptor 2 (HER2)-positive; **AND**
- Used as adjuvant therapy in combination with a taxane-based regimen (e.g., docetaxel, paclitaxel) **or** as a single agent following anthracycline-based therapy **or** in combination with pertuzumab; **OR**
- Used as neoadjuvant or preoperative therapy in combination with a taxane-based regimen (e.g., docetaxel, paclitaxel); **OR**
- Used for recurrent or metastatic disease; **AND**
  - Used as a single agent in patients who have received one or more prior treatments for metastatic disease; **OR**
  - Used in first-line therapy in combination with paclitaxel; **OR**
  - Used in combination with endocrine therapy (e.g., tamoxifen, fulvestrant, or aromatase inhibition with or without lapatinib) in patients with hormone-receptor positive disease; **AND**
    - Patient is post-menopausal; **OR**
    - Patient is pre-menopausal and is treated with ovarian ablation/suppression; **OR**
    - Patient is a male receiving concomitant suppression of testicular steroidogenesis; **OR**
  - Used in combination with cytotoxic chemotherapy **or** lapatinib **or** pertuzumab and a taxane as first-line therapy **or** pertuzumab with or without cytotoxic therapy as one line of therapy beyond first-line therapy in patients who were previously treated with trastuzumab without pertuzumab; **AND**
    - Disease is hormone receptor-negative; **OR**
    - Disease is hormone receptor-positive and used with or without endocrine therapy

Diagnosis of **central nervous system cancer:**

- Patient is 18 years of age or older; **AND**
- Left ventricular ejection fraction (LVEF) is within normal limits prior to initiating therapy and will be assessed at regular intervals during treatment; **AND**
- Patients cancer is human epidermal growth factor receptor 2 (HER2) positive; **AND**
- Patient has leptomeningeal metastases from breast cancer; **AND**
- Trastuzumab will be administered intrathecally

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **gastric, esophageal and esophagogastric junction cancers:**

- Patient is 18 years of age or older; **AND**
- Left ventricular ejection fraction (LVEF) is within normal limits prior to initiating therapy and will be assessed at regular intervals during treatment; **AND**
- Patients cancer is human epidermal growth factor receptor 2 (HER2) positive; **AND**
- Used in combination with chemotherapy (excluding use with anthracyclines or in combination with DCF [docetaxel, carboplatin, and fluorouracil]) for first-line therapy; **AND**
- Patient has metastatic adenocarcinoma

Diagnosis of **uterine cancer:**

- Patient is 18 years of age or older; **AND**
- Left ventricular ejection fraction (LVEF) is within normal limits prior to initiating therapy and will be assessed at regular intervals during treatment; **AND**
- Patients cancer is human epidermal growth factor receptor 2 (HER2) positive; **AND**
- Used in combination with carboplatin and paclitaxel; **AND**
- Used for advanced (Stage III/IV) or recurrent uterine serous carcinoma.

Diagnosis of **colorectal cancer**

- Patient is 18 years of age or older; **AND**
- Left ventricular ejection fraction (LVEF) is within normal limits prior to initiating therapy and will be assessed at regular intervals during treatment; **AND**
- Patients cancer is human epidermal growth factor receptor 2 (HER2)-positive; **AND**
- Used in combination with pertuzumab or lapatinib in patients who have not previously received HER2-targeted therapy; **AND**
  - Used as primary therapy of unresectable advanced or metastatic RAS wild-type (WT) disease; **OR**
  - Used as subsequent therapy for progression of unresectable advanced or metastatic RAS WT disease; **AND**
    - Patient must have been previously treated with FOLFOXIRI, oxaliplatin-based therapy without irinotecan, irinotecan-based therapy without oxaliplatin, or fluoropyrimidine-based therapy without irinotecan or oxaliplatin; **OR**
  - Used as adjuvant therapy for resectable advanced or metastatic RAS WT disease in patients who are not candidates for intensive therapy

***HER2-positive overexpression criteria:**
• Immunohistochemistry (IHC) assay 3+; **OR** • Dual-probe in situ hybridization (ISH) assay HER2/CEP17 ratio ≥ 2.0 **and** average HER2 copy number ≥ 4.0 signals/cell; **OR** • Dual-probe in situ hybridization (ISH) assay **and** concurrent IHC indicating one of the following: – HER2/CEP17 ratio ≥ 2.0 **and** average HER2 copy number < 4.0 signals/cell **and** concurrent IHC 3+; **OR** – HER2/CEP17 ratio < 2.0 **and** average HER2 copy number ≥ 6.0 signals/cell **and** concurrent IHC 2+ or 3+; **OR** – HER2/CEP17 ratio < 2.0 **and** average HER2 copy number ≥ 4.0 and < 6.0 signals/cell **and** concurrent IHC 3+

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug (e.g., cardiotoxicity [i.e., left ventricular dysfunction, cardiomyopathy], pulmonary toxicity [i.e., pneumonitis], neutropenia, infusion-related reactions); **AND**
  - LVEF has not had an **absolute** decrease of ≥ 16% from pre-treatment baseline and is within the institutional normal limits; **OR**
  - LVEF has not had an **absolute** decrease of ≥ 10% from pre-treatment baseline and is below the institutional lower limits of normal; **AND**
- Use for neoadjuvant and adjuvant breast cancer treatment is limited to a total of 52 weeks of therapy

HEREDITARY ANGIOEDEMA

Length of Authorization:	Berinert, Firazyr, Kalbitor, Ruconest: 12 weeks and is eligible for renewal **Note:** The cumulative amount of medication(s) the patient has on-hand, indicated for the acute treatment of HAE, will be taken into account when authorizing. The authorization will provide a sufficient quantity in order for the patient to have a cumulative amount of HAE medication(s) on-hand in order to treat up to 4 acute attacks per 4 weeks for the duration of the authorization. Cinryze, Haegarda: 12 months and is eligible for renewal Takhzyro: 6 months, may be renewed annually thereafter
Initiative:	SPC: Hereditary Angioedema (IE 2462 / NCPDP 75 – HICL) MNC: Non-Formulary Product (IE 50698 / MR – GSN PatOverride)

CLINICAL CRITERIA FOR INITIAL APPROVAL

KALBITOR CRITERIA

Treatment of acute attacks of Hereditary Angioedema (HAE):

- Patient must be at least 12 years of age; **AND**
- Must be prescribed by, or in consultation with, a specialist in allergy, immunology, hematology, pulmonology, or medical genetics; **AND**
- Patient has a history of moderate to severe cutaneous or abdominal attacks **or** mild to severe airway swelling attacks of HAE (i.e., debilitating cutaneous/gastrointestinal symptoms **or** laryngeal/pharyngeal/tongue swelling); **AND**
- Confirmation the patient is avoiding the following possible triggers for HAE attacks:
  - Estrogen-containing oral contraceptive agents **and** hormone replacement therapy
  - Antihypertensive agents containing ACE inhibitors; **AND**
- Patient has one of the following clinical presentations consistent with HAE subtype, which must be confirmed by repeat blood testing:

HAE I (C1-Inhibitor deficiency)
• Low C1 inhibitor (C1-INH) antigenic level (C1-INH antigenic level below the lower limit of normal as defined by the laboratory performing the test); **AND** • Low C4 level (C4 below the lower limit of normal as defined by the laboratory performing the test); AND • Low C1-INH functional level (C1-INH functional level below the lower limit of normal as defined by the laboratory performing the test); **AND** – Patient has a family history of HAE; **OR** – Acquired angioedema has been ruled out (i.e., patient onset of symptoms occur prior to 30 years old, normal C1q levels, patient does not have underlying disease such as lymphoma or benign monoclonal gammopathy [MGUS], etc.).
HAE II (C1-Inhibitor dysfunction)
• Normal to elevated C1-INH antigenic level; **AND** • Low C4 level (C4 below the lower limit of normal as defined by the laboratory performing the test); **AND** • Low C1-INH functional level (C1-INH functional level below the lower limit of normal as defined by the laboratory performing the test).

KALBITOR CRITERIA *(CONTINUED)*

HAE with normal C1INH (formerly known as HAE III)
• Normal C1-INH antigenic level; **AND** • Normal C4 level; **AND** • Normal C1-INH functional level; **AND** • Repeat blood testing during an attack has confirmed the patient does not have abnormal lab values indicative of HAE I or HAE II; **AND** • Either of the following: – Patient has a known HAE-causing mutation (e.g., mutation of coagulation factor XII gene [F12 mutation], mutation in the angiopoietin-1 gene, mutation in the plasminogen gene, etc.); **OR** – Patient has a family history of HAE and documented evidence of lack of efficacy of chronic high-dose antihistamine therapy (e.g., cetirizine standard dosing at up to four times daily or an alternative equivalent, given for at least one month or an interval long enough to expect three or more angioedema attacks) **AND** corticosteroids. • Patient had an inadequate response or intolerance to an adequate trial of prophylactic therapy with an antifibrinolytic agent (e.g., tranexamic acid (TXA) or aminocaproic acid) and/or a 17α-alkylated androgen (e.g., danazol) unless contraindicated. Female patients may derive additional benefit from progestins[16,17,18] [Note: if the clinical status of the patient warrants on-demand treatment, this criterion will be waived, and sufficient on-demand therapy approved (if all other criteria are met) in order to treat two acute attacks of HAE. Approval of additional on-demand treatment will be contingent upon either fulfilling this criterion or case by case review in instances where the criteria has not been fulfilled and on-demand therapy is required as a bridge in the interim.]

BERINERT CRITERIA

For the **treatment of acute abdominal, facial, or laryngeal attacks of Hereditary Angioedema (HAE); AND**

- Must be prescribed by, or in consultation with, a specialist in allergy, immunology, hematology, pulmonology, or medical genetics; **AND**
- Patient must be at least 6 years of age; **AND**
- Patient has a history of moderate to severe cutaneous attacks without concomitant hives **or** abdominal attacks **or** mild to severe airway swelling attacks of HAE (i.e., debilitating cutaneous/gastrointestinal symptoms **or** laryngeal/pharyngeal/tongue swelling); **AND**
- Confirmation the patient is avoiding the following possible triggers for HAE attacks:
  - Estrogen-containing oral contraceptive agents **AND** hormone replacement therapy
  - Antihypertensive agents containing ACE inhibitors; **AND**
- Patient has one of the following clinical presentations consistent with HAE subtype, which must be confirmed by repeat blood testing:

HAE I (C1-Inhibitor deficiency)
• Low C1 inhibitor (C1-INH) antigenic level (C1-INH antigenic level below the lower limit of normal as defined by the laboratory performing the test); **AND** • Low C4 level (C4 below the lower limit of normal as defined by the laboratory performing the test); **AND** • Low C1-INH functional level (C1-INH functional level below the lower limit of normal as defined by the laboratory performing the test); **AND** – Patient has a family history of HAE; **OR** – Acquired angioedema has been ruled out (i.e., patient onset of symptoms occur prior to 30 years old, normal C1q levels, patient does not have underlying disease such as lymphoma or benign monoclonal gammopathy [MGUS], etc.)

BERINERT CRITERIA *(CONTINUED)*

HAE II (C1-Inhibitor dysfunction)
• Normal to elevated C1-INH antigenic level; **AND** • Low C4 level (C4 below the lower limit of normal as defined by the laboratory performing the test); **AND** • Low C1-INH functional level (C1-INH functional level below the lower limit of normal as defined by the laboratory performing the test).
HAE with Normal C1INH (also known as HAE III)
• Normal C1-INH antigenic level; **AND** • Normal C4 level; **AND** • Normal C1-INH functional level; **AND** • Repeat blood testing during an attack has confirmed the patient does not have abnormal lab values indicative of HAE I or HAE II; **AND** • Either of the following: – Patient has a known HAE-causing mutation (e.g., mutation of coagulation factor XII gene [F12 mutation], mutation in the angiopoietin-1 gene, mutation in the plasminogen gene); OR – Patient has a family history of HAE and documented evidence of lack of efficacy of chronic high-dose antihistamine therapy (e.g., cetirizine standard dosing at up to four times daily or an alternative equivalent, given for at least one month or an interval long enough to expect three or more angioedema attacks) **AND** corticosteroids; **AND** • Patient had an inadequate response or intolerance to an adequate trial of prophylactic therapy with an antifibrinolytic agent (e.g., tranexamic acid (TXA) or aminocaproic acid) and/or a 17α-alkylated androgen (e.g., danazol) unless contraindicated. Female patients may derive additional benefit from progestins[16,17,18] [Note: if the clinical status of the patient warrants on-demand treatment, this criterion will be waived, and sufficient on-demand therapy approved (if all other criteria are met) in order to treat two acute attacks of HAE. Approval of additional on-demand treatment will be contingent upon either fulfilling this criterion or case by case review in instances where the criteria has not been fulfilled and on-demand therapy is required as a bridge in the interim.]

RUCONEST CRITERIA

Treatment of acute abdominal, peripheral or facial attacks of Hereditary Angioedema (HAE); AND

- Must be prescribed by, or in consultation with, a specialist in allergy, immunology, hematology, pulmonology, or medical genetics**; AND**
- Patient must be at least 13 years of age; **AND**
- Patient has a history of moderate to severe cutaneous attacks without concomitant hives **or** abdominal attacks **or** mild to severe airway swelling attacks of HAE (i.e., debilitating cutaneous/gastrointestinal symptoms **or** laryngeal/pharyngeal/tongue swelling); **AND**
- Confirmation the patient is avoiding the following possible triggers for HAE attacks:
  - Estrogen-containing oral contraceptive agents AND hormone replacement therapy
  - Antihypertensive agents containing ACE inhibitors; **AND**
- Patient has one of the following clinical presentations consistent with HAE subtype, which must be confirmed by repeat blood testing:

RUCONEST CRITERIA *(CONTINUED)*

HAE I (C1-Inhibitor deficiency)
• Low C1 inhibitor (C1-INH) antigenic level (C1-INH antigenic level below the lower limit of normal as defined by the laboratory performing the test); **AND** • Low C4 level (C4 below the lower limit of normal as defined by the laboratory performing the test); **AND** • Low C1-INH functional level (C1-INH functional level below the lower limit of normal as defined by the laboratory performing the test); **AND** – Patient has a family history of HAE; **OR** – Acquired angioedema has been ruled out (i.e., patient onset of symptoms occur prior to 30 years old, normal C1q levels, patient does not have underlying disease such as lymphoma or benign monoclonal gammopathy [MGUS], etc.)
HAE II (C1-Inhibitor dysfunction)
• Normal to elevated C1-INH antigenic level; **AND** • Low C4 level (C4 below the lower limit of normal as defined by the laboratory performing the test); **AND** • Low C1-INH functional level (C1-INH functional level below the lower limit of normal as defined by the laboratory performing the test).
HAE with Normal C1INH (formerly known as HAE III)
• Normal C1-INH antigenic level; **AND** • Normal C4 level; **AND** • Normal C1-INH functional level; **AND** • Repeat blood testing during an attack has confirmed the patient does not have abnormal lab values indicative of HAE I or HAE II; **AND** • Either of the following: – Patient has a known HAE-causing mutation (e.g., mutation of coagulation factor XII gene [F12 mutation], mutation in the angiopoietin-1 gene, mutation in the plasminogen gene, etc.); **OR** – Patient has a family history of HAE and documented evidence of lack of efficacy of chronic high-dose antihistamine therapy (e.g., cetirizine standard dosing at up to four times daily or an alternative equivalent, given for at least one month or an interval long enough to expect three or more angioedema attacks) AND corticosteroids; **AND** • Patient had an inadequate response or intolerance to an adequate trial of prophylactic therapy with an antifibrinolytic agent (e.g., tranexamic acid (TXA) or aminocaproic acid) and/or a 17α-alkylated androgen (e.g., danazol) unless contraindicated. Female patients may derive additional benefit from progestins[16,17,18] [Note: if the clinical status of the patient warrants on-demand treatment, this criterion will be waived, and sufficient on-demand therapy approved (if all other criteria are met) in order to treat two acute attacks of HAE. Approval of additional on-demand treatment will be contingent upon either fulfilling this criterion or case by case review in instances where the criteria has not been fulfilled and on-demand therapy is required as a bridge in the interim.]

CINRYZE

Prophylaxis against angioedema attacks of Hereditary Angioedema (HAE)

- Patient is at least 6 years of age; **AND**
- Must be prescribed by, or in consultation with, a specialist in allergy, immunology, hematology, pulmonology, or medical genetics; **AND**
- Not used in combination with other prophylactic therapies targeting C1 inhibitor or kallikrein (i.e., Haegarda or Takhzyro); **AND**
- Patient has a history of one of the following criteria for long-term HAE prophylaxis
  - History of **two** or more severe HAE attacks per month (i.e., airway swelling, debilitating cutaneous or gastrointestinal episodes); **OR**
  - Patient is disabled more than 5 days per month by HAE; **OR**
  - History of at least one laryngeal attack caused by HAE; **AND**
- Treatment of patient with "on-demand" therapy (i.e., Kalbitor, Firazyr, Ruconest, or Berinert) did not provide satisfactory control or access to "on-demand therapy" is limited; **AND**
- Confirmation the patient is avoiding the following possible triggers of HAE attacks:
  - Estrogen-containing oral contraceptive agents **and** hormone replacement therapy
  - Antihypertensive agents containing ACE inhibitors; **AND**
- Patient has one of the following clinical presentations consistent with HAE subtype, which must be confirmed by repeat blood testing:

HAE I (C1-Inhibitor deficiency)
• Low C1 inhibitor (C1-INH) antigenic level (C1-INH antigenic level below the lower limit of normal as defined by the laboratory performing the test); **AND** • Low C4 level (C4 below the lower limit of normal as defined by the laboratory performing the test); **AND** • Low C1-INH functional level (C1-INH functional level below the lower limit of normal as defined by the laboratory performing the test); **AND** – Patient has a family history of HAE; **OR** – Acquired angioedema has been ruled out (i.e., patient onset of symptoms occur prior to 30 years old, normal C1q levels, patient does not have underlying disease such as lymphoma or benign monoclonal gammopathy [MGUS])
HAE II (C1-Inhibitor dysfunction)
• Normal to elevated C1-INH antigenic level; AND • Low C4 level (C4 below the lower limit of normal as defined by the laboratory performing the test); AND • Low C1-INH functional level (C1-INH functional level below the lower limit of normal as defined by the laboratory performing the test).
HAE with Normal C1INH (formerly known as HAE III)
• Prophylaxis for HAE with normal C1-INH is not routinely recommended and will be evaluated on a case by case basis. – Prior to consideration of long-term prophylaxis, the patient must have demonstrated: • An inadequate response or intolerance to an adequate trial of prophylactic therapy with an antifibrinolytic agent (e.g., tranexamic acid (TXA) or aminocaproic acid) and/or a 17α-alkylated androgen (e.g., danazol) unless contraindicated. Female patients may derive additional benefit from progestins; **AND** • Response to therapy from an agent indicated for the treatment of acute attacks (i.e., C1 esterase inhibitor, icatibant, ecallantide)

HAEGARDA

Prophylaxis to prevent Hereditary Angioedema (HAE) attacks

- Patient is at least 12 years of age; **AND**
- Must be prescribed by, or in consultation with, a specialist in allergy, immunology, hematology, pulmonology, or medical genetics; **AND**
- Not used in combination with other prophylactic therapies targeting C1 inhibitor or kallikrein (i.e., Cinryze or Takhzyro); **AND**
- Patient has a history of one of the following criteria for long-term HAE prophylaxis
  - History of TWO or more severe HAE attacks per month (i.e., airway swelling, debilitating cutaneous or gastrointestinal episodes)
  - Patient is disabled more than 5 days per month by HAE
  - History of at least one laryngeal attacks caused by HAE; **AND**
- Treatment of patient with "on-demand" therapy (i.e., Kalbitor, Firazyr, Ruconest, or Berinert) did not provide satisfactory control or access to "on-demand therapy" is limited; **AND**
- Confirmation the patient is avoiding the following possible triggers of HAE attacks:
  - Estrogen-containing oral contraceptive agents AND hormone replacement therapy
  - Antihypertensive agents containing ACE inhibitors; **AND**
- Patient has one of the following clinical presentations consistent with HAE subtype, which must be confirmed by repeat blood testing:

HAE I (C1-Inhibitor deficiency)
• Low C1 inhibitor (C1-INH) antigenic level (C1-INH antigenic level below the lower limit of normal as defined by the laboratory performing the test); **AND** • Low C4 level (C4 below the lower limit of normal as defined by the laboratory performing the test); **AND** • Low C1-INH functional level (C1-INH functional level below the lower limit of normal as defined by the laboratory performing the test); **AND** – Patient has a family history of HAE; **OR** – Acquired angioedema has been ruled out (i.e., patient onset of symptoms occur prior to 30 years old, normal C1q levels, patient does not have underlying disease such as lymphoma or benign monoclonal gammopathy [MGUS], etc.)
HAE II (C1-Inhibitor dysfunction)
• Normal to elevated C1-INH antigenic level; **AND** • Low C4 level (C4 below the lower limit of normal as defined by the laboratory performing the test); **AND** • Low C1-INH functional level (C1-INH functional level below the lower limit of normal as defined by the laboratory performing the test).
HAE with normal C1INH (formerly known as HAE III)
• Prophylaxis for HAE with normal C1-INH is not routinely recommended and will be evaluated on a case by case basis. – Prior to consideration of long-term prophylaxis, the patient must have demonstrated: • An inadequate response or intolerance to an adequate trial of prophylactic therapy with an antifibrinolytic agent (e.g., tranexamic acid (TXA) or aminocaproic acid) and/or a 17α-alkylated androgen (e.g., danazol) unless contraindicated. Female patients may derive additional benefit from progestins; **AND** • Response to therapy from an agent indicated for the treatment of acute attacks (i.e., C1 esterase inhibitor, icatibant, ecallantide)

TAKHZYRO™ (LANADELUMAB-FLYO)

Prophylaxis to prevent Hereditary Angioedema (HAE) attacks

- Patient is at least 12 years of age; **AND**
- Must be prescribed by, or in consultation with, a specialist in allergy, immunology, hematology, pulmonology, or medical genetics; **AND**
- Not used in combination with C1 inhibitor prophylaxis (e.g., Cinryze or Haegarda); **AND**
- Patient has a history of **one** of the following criteria for long-term HAE prophylaxis
  - History of **two** or more severe HAE attacks per month (i.e., airway swelling, debilitating cutaneous or gastrointestinal episodes)
  - Patient is disabled more than 5 days per month by HAE
  - History of at least one laryngeal attacks caused by HAE; **AND**
- Treatment of patient with "on-demand" therapy (i.e., Kalbitor, Firazyr, Ruconest, or Berinert) did not provide satisfactory control or access to "on-demand therapy" is limited; **AND**
- Confirmation the patient is avoiding the following possible triggers of HAE attacks:
  - Estrogen-containing oral contraceptive agents **and** hormone replacement therapy
  - Antihypertensive agents containing ACE inhibitors; **AND**
- Patient has one of the following clinical presentations consistent with HAE subtype**,** which must be confirmed by repeat blood testing:

HAE I (C1-Inhibitor deficiency)
• Low C1 inhibitor (C1-INH) antigenic level (C1-INH antigenic level below the lower limit of normal as defined by the laboratory performing the test); **AND** • Low C4 level (C4 below the lower limit of normal as defined by the laboratory performing the test); **AND** • Low C1-INH functional level (C1-INH functional level below the lower limit of normal as defined by the laboratory performing the test); **AND** – Patient has a family history of HAE; **OR** – Acquired angioedema has been ruled out (i.e., patient onset of symptoms occur prior to 30 years old, normal C1q levels, patient does not have underlying disease such as lymphoma or benign monoclonal gammopathy [MGUS], etc.)
HAE II (C1-Inhibitor dysfunction)
• Normal to elevated C1-INH antigenic level; **AND** • Low C4 level (C4 below the lower limit of normal as defined by the laboratory performing the test); **AND** • Low C1-INH functional level (C1-INH functional level below the lower limit of normal as defined by the laboratory performing the test).
HAE with normal C1INH (formerly known as HAE III)
• Prophylaxis for HAE with normal C1-INH is not routinely recommended and will be evaluated on a case by case basis. – Prior to consideration of long-term prophylaxis, the patient must have demonstrated: • An inadequate response or intolerance to an adequate trial of prophylactic therapy with an antifibrinolytic agent (e.g., tranexamic acid (TXA) or aminocaproic acid) and/or a 17α-alkylated androgen (e.g., danazol) unless contraindicated. Female patients may derive additional benefit from progestins; **AND** • Response to therapy from an agent indicated for the treatment of acute attacks (i.e., C1 esterase inhibitor, icatibant, ecallantide)

FIRAZYR

Treatment of acute attacks of Hereditary Angioedema (HAE):

- Patient must be at least 18 years of age; **AND**
- Must be prescribed by, or in consultation with a specialist in allergy, immunology, hematology, pulmonology, or medical genetics; **AND**
- Patient has a history of moderate to severe cutaneous attacks (without concomitant hives) **or** abdominal attacks **or** mild to severe airway swelling attacks of HAE (i.e., debilitating cutaneous/gastrointestinal symptoms **or** laryngeal/pharyngeal/tongue swelling); **AND**
- Confirmation the patient is avoiding the following possible triggers for HAE attacks:
  - Estrogen-containing oral contraceptive agents **and** hormone replacement therapy
  - Antihypertensive agents containing ACE inhibitors; **AND**
- Patient has one of the following clinical presentations consistent with HAE subtype, which must be confirmed by repeat blood testing:

HAE I (C1-Inhibitor deficiency)
• Low C1 inhibitor (C1-INH) antigenic level (C1-INH antigenic level below the lower limit of normal as defined by the laboratory performing the test); **AND** • Low C4 level (C4 below the lower limit of normal as defined by the laboratory performing the test); **AND** • Low C1-INH functional level (C1-INH functional level below the lower limit of normal as defined by the laboratory performing the test); **AND** – Patient has a family history of HAE; **OR** – Acquired angioedema has been ruled out (i.e., patient onset of symptoms occur prior to 30 years old, normal C1q levels, patient does not have underlying disease such as lymphoma or benign monoclonal gammopathy [MGUS], etc.)
HAE II (C1-Inhibitor dysfunction)
• Normal to elevated C1-INH antigenic level; **AND** • Low C4 level (C4 below the lower limit of normal as defined by the laboratory performing the test); **AND** • Low C1-INH functional level (C1-INH functional level below the lower limit of normal as defined by the laboratory performing the test).

FIRAZYR *(CONTINUED)*

HAE with Normal C1INH (formerly known as HAE III)
• Normal C1-INH antigenic level; AND • Normal C4 level; AND • Normal C1-INH functional level; AND • Repeat blood testing during an attack has confirmed the patient does not have abnormal lab • values indicative of HAE I or HAE II; AND • Either of the following: – Patient has a known HAE-causing mutation (e.g., mutation of coagulation factor XII gene [F12 mutation], mutation in the angiopoietin-1 gene, mutation in the plasminogen gene, etc.); OR – Patient has a family history of HAE and documented evidence of lack of efficacy of chronic high-dose antihistamine therapy (e.g., cetirizine standard dosing at up to four times daily or an alternative equivalent, given for at least one month or an interval long enough to expect three or more angioedema attacks) AND corticosteroids; AND • Patient had an inadequate response or intolerance to an adequate trial of prophylactic therapy with an antifibrinolytic agent (e.g., tranexamic acid (TXA) or aminocaproic acid) and/or a 17α-alkylated androgen (e.g., danazol) unless contraindicated. Female patients may derive additional benefit from progestins[16,17,18] [Note: if the clinical status of the patient warrants on-demand treatment, this criterion will be waived, and sufficient on-demand therapy approved (if all other criteria are met) in order to treat two acute attacks of HAE. Approval of additional on-demand treatment will be contingent upon either fulfilling this criterion or case by case review in instances where the criteria has not been fulfilled and on-demand therapy is required as a bridge in the interim.]

CLINICAL CRITERIA FOR RENEWAL

- Patient continues to meet criteria above; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: hypersensitivity reactions, serious thrombotic events (arterial or venous), laryngeal HAE attacks; **AND**

HAEGARDA, CINRYZE

- Significant improvement in severity and duration of attacks have been achieved and sustained

BERINERT, FIRAZYR, KALBITOR, RUCONEST

- Significant improvement in severity and duration of attacks have been achieved and sustained
  - The cumulative amount of medication(s) the patient has on-hand, indicated for the acute treatment of HAE, will be taken into account when authorizing. The authorization will provide a sufficient quantity in order for the patient to have a cumulative amount of HAE medication(s) on-hand in order to treat up to 4 acute attacks per 4 weeks for the duration of the authorization.

TAKHZYRO

- Significant improvement in severity and duration of attacks have been achieved and sustained
  - Patients who have demonstrated improvement/stabilization of disease and are well-controlled (e.g., attack free) for at least 6 months should attempt a trial of dosing every 4 weeks

HEXALEN® (ALTRETAMINE)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75 – GSN, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Ovarian Cancer** (Including Epithelial/Fallopian Tube/Primary Peritoneal)

- Patient 18 years and older; **AND**
- Must be used as a single agent; **AND**
- Patient must have persistent or recurrent disease; **AND**
- Therapy **not** used for the immediate treatment of a biochemical relapse

CLINICAL CRITERIA FOR RENEWAL

- Tumor response with stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug (e.g., GI intolerance unresponsive to symptomatic treatment; progressive neurotoxicity; white blood cell count (WBC) < 2,000/mm^3; granulocyte count < 1,000/mm^3; platelets < 75,000/mm^3.

HIV AGENTS

Length of Authorization:	1 year, may be renewed
Initiative:	SPC: Antivirals (IE 2462 / NCPDP 75 – GSN, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Fuzeon (enfuvirtide)

- Diagnosis of HIV-1; **AND**
- Patient must be ≥ 6 years of age

Truvada (emtricitabine/tenofovir)

- Diagnosis of HIV-1 or pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 in adults; **AND**
- Patient must be tested for Hepatitis B virus (HBV) with a negative result before initiating; **AND**
- Patient must weigh ≥ 17 kg; **AND**
- Patient must be ≥ 18 years of age
- NOT approved for the treatment of chronic Hepatitis B virus infection

Selzentry (maraviroc)

- Diagnosis of CCR5-tropic HIV-1 infection confirmed by a highly sensitive tropism assay; **AND**
- The requested medication will be used in combination with other antiretroviral agents

H. P. ACTHAR® (CORTICOTROPIN, ACTH)

Length of Authorization:	1 month; may be renewed
Initiative:	MNC: Non-Formulary Product (IE 50698 / MR – GSN PatOverride)

CLINICAL CRITERIA FOR INITIAL APPROVAL

- Diagnosis of Infantile spasms (West Syndrome)
  - Patient is less than 2 years old; **AND**
  - Clinical documentation indicating patient suffers from infantile spasms (West Syndrome); **AND**
  - Must be used as monotherapy; **AND**
  - Patient does NOT have a suspected congenital infection

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as indicated by resolution of symptoms and/or normalization of laboratory tests; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe infections, severe electrolyte imbalances, gastric bleeding or ulcer, hypertension, hypokalemia, severe depression, frank psychotic manifestations, posterior subcapsular cataracts, glaucoma, etc.

HUMULIN R U-500 (INSULIN HUMAN, REGULAR)

Length of Authorization:	12 months
Initiative:	MNC: Miscellaneous: PA Required (IE 2462 / NCPDP 75 – GSN)

CLINICAL CRITERIA FOR INITIAL APPROVAL

- Diagnosis of diabetes mellitus in adults and children requiring more than 200 units of insulin per day; **AND**
- Patient does not have hypersensitivity to Humulin R or any of its excipients.

CLINICAL CRITERIA FOR RENEWAL

- Patient must continue to meet above criteria; **AND**
- Absence of unacceptable toxicity from the drug

HUNTINGTON'S DISEASE CHOREA

Length of Authorization:	6 months, may be renewed [Xenazine] 1 year, may be renewed [Austedo]
Initiative:	MNC: Non-Formulary Product (IE 50698 / MR – GSN PatOverride)

CLINICAL CRITERIA FOR INITIAL APPROVAL

XENAZINE (TETRABENAZINE)

Diagnosis of **chorea associated with Huntington's disease**

- Patient is ≥ 18 years of age; **AND**
- Patient has been diagnosed with Huntington's disease; **AND**
- Patient is not pregnant; **AND**
- Patient has normal hepatic function (ALT < 3 times ULN); **AND**
- Patient is not receiving concomitant monoamine oxidase inhibitor (MAOI) therapy or MAOI therapy was discontinued at least 14 days prior to starting tetrabenazine; **AND**
- Patient is not receiving concomitant reserpine therapy or reserpine was discontinued at least 20 days prior to starting tetrabenazine; **AND**
- Patient is not receiving concomitant therapy with another vesicular monoamine transporter 2 (VMAT2)-inhibitor (e.g., deutetrabenazine, valbenazine, etc.); **AND**
- Patient is not actively suicidal; **AND**
- Patient does not have uncontrolled or untreated depression; **AND**
- If patient's dose is above 50 mg per day, then the patient must be genotyped for CYP2D6 enzyme to confirm the patient is not a poor metabolizer (PM); **AND**
- The patient has had an inadequate response to at least a 3-month trial with one of the following conventional treatments for chorea: amantadine or antipsychotics (e.g., risperidone, olanzapine, haloperidol, quetiapine, aripiprazole); **AND**
- Physician has assessed baseline disease severity utilizing an objective measure/tool (e.g., Total Chorea Score, Unified Huntington's Disease Rating Scale [UHDRS] or Physician-rated Clinical Global Impression [CGI])

AUSTEDO (DEUTETRABENAZINE)

Diagnosis of **Huntington's disease chorea:**

- Patient has been diagnosed with chorea related to Huntington's disease; **AND**
- Patient is able to swallow; **AND**
- Patient is ≥ 18 years; **AND**
- Patient should **not** meet the following:
  - History of untreated or inadequately controlled depression
  - Suicidal ideation
  - Concurrent therapy with another VMAT2 inhibitor (e.g., tetrabenazine, valbenazine), reserpine (within 20 days), or monoamine oxidase (MAO) inhibitors (e.g., isocarboxazid, phenelzine, rasagiline, safinamide, selegiline, tranylcypromine, etc.) within 14 days
  - Pregnancy
  - Hepatic impairment

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

AUSTEDO (DEUTETRABENAZINE) *(CONTINUED)*

Diagnosis of **Tardive Dyskinesia**

- Patient has been diagnosed with tardive dyskinesia; **AND**
- Patient is ≥ 18 years of age; **AND**
- Patient is able to swallow; **AND**
- Documentation that AIMS test has been completed (i.e., score or copy of AIMS assessment); **AND**
- Prescribed by or in consultation with a neurologist or psychiatrist (or other mental health provider), provided patient has reasonable access; **AND**
- Documentation or claims history of current or former chronic patient use of a dopamine antagonist (e.g., antipsychotic, metoclopramide, prochlorperazine, droperidol, promethazine, etc.); **AND**
- Patient should **not** meet the following:
  - Concurrent therapy with another VMAT2 inhibitor (e.g., tetrabenazine, valbenazine), reserpine (within 20 days), or monoamine oxidase (MAO) inhibitors (e.g., isocarboxazid, phenelzine, rasagiline, safinamide, selegiline, tranylcypromine, etc.) within 14 days
  - Pregnancy
  - Hepatic impairment

CLINICAL CRITERIA FOR RENEWAL

AUSTEDO

- Disease response with improvement of symptoms with respective condition (e.g., tardive dyskinesia or Huntington's chorea); **AND**
- Absence of unacceptable toxicity from the drug (i.e., increased depression or suicidality in patients with Huntington's disease, clinical worsening of Huntington's disease, significant QTc prolongation, neuroleptic malignant syndrome [NMS], significant hyperprolactinemia, severe akathisia, etc.).

XENAZINE

- Disease response as indicated by improvement of symptoms per one of the following: Total Chorea Score, Unified Huntington's Disease Rating Scale (UHDRS) or Physician-rated Clinical Global Impression (CGI); **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include neuroleptic malignant syndrome, restlessness, agitation, akathisia, parkinsonism, sedation/somnolence and QT prolongation, suicidal thinking and behaviors, and symptomatic hyperprolactinemia, etc.

HYDROXYUREA (SIKLOS)

Length of Authorization:	6 months
Initiative:	MNC: Non-Formulary Product (IE 50698 / MR – GSN PatOverride)

CLINICAL CRITERIA FOR INITIAL APPROVAL

- Patient is 2 to 17 years of age; **AND**
- Patient has a diagnosis of sickle cell anemia, with recurrent moderate to severe painful crises; **AND**
- Prescriber attests that blood counts will be monitored throughout treatment for dose adjustments and monitoring for myelosuppression; **AND**
  - *Note: Blood counts within an acceptable range are defined as follows: neutrophil count at least 2,000 cells/mm^3, platelet count at least 80,000 cells/mm^3, hemoglobin concentration more than 5.3 g/dL, and a reticulocyte count at least 80,000 cells/mm^3 if the hemoglobin concentration is less than 9 g/dL*
- Females of reproductive potential and males with partners of reproductive potential must use effective contraception during treatment and for at least 6 months after treatment

CLINICAL CRITERIA FOR RENEWAL

- Decrease in number of painful crises; **AND**
- Documentation or attestation that patient's blood counts have been monitored and doses have been adjusted when appropriate; **AND**
- Absence of unacceptable toxicity from the drug

HYPOGLYCEMICS: AMYLIN ANALOG

Length of Authorization:	1 Year
Initiative:	MNC: Hypoglycemics (IE 2462 / NCPDP 75 – HICL)

SYMLINPEN INITIAL CRITERIA

- The patient has a diagnosis of type 1 or type 2 diabetes mellitus; **AND**
- The patient has been receiving Symlin for at least 3 months AND has demonstrated a reduction in A1c since starting therapy; **OR**
- The patient does NOT have any of the following:
  - Gastroparesis
  - Hypoglycemia unawareness (i.e., inability to detect and act upon the signs or symptoms of hypoglycemia)

SYMLINPEN RENEWAL CRITERIA

- The patient is stable on medication; **AND**
- Patient still meets initial criteria

HYPOGLYCEMICS: DIPEPTIDYL PEPTIDASE IV (DPP4) INHIBITORS

Length of Authorization:	Initial: 6 months, Renewal: 1 year
Initiative:	MNC: Hypoglycemics (IE 2462 / NCPDP 75 – HICL)

CLINICAL CRITERIA

Diagnosis of Type 2 Diabetes

- Patient has failed to achieve adequate glycemic control with metformin or metformin ER; **OR**
- Patient has failed to achieve adequate glycemic control with glipizide/metformin or glyburide/metformin; **OR**
- Patient has failed to achieve adequate glycemic control with pioglitazone/metformin

COVERED – PA Required
Janumet® (*sitagliptin/metformin*)
Janumet XR® (*sitagliptin/metformin*)
Januvia® (*sitagliptin*)
Jentadueto® (*linagliptin/metformin*)
Kombiglyze XR® 2.5-1,000 mg, 5-1,000 mg, 5-500 mg (*saxagliptin/metformin*)
Onglyza® (*saxagliptin*)
Tradjenta® (*linagliptin*)

HYPOGLYCEMICS: INCRETIN MIMETICS

Length of Authorization:	1 Year
Initiative:	MNC: Hypoglycemics (IE 2462 / NCPDP 75 – HICL)

CLINICAL CRITERIA

Diagnosis of Type 2 Diabetes

- Patient has failed to achieve adequate glycemic control with metformin, metformin ER, glipizide/metformin, glyburide/metformin, or pioglitazone/metformin

COVERED- PA REQUIRED
Bydureon® pen (*exenatide*): Bydureon PEN has been discontinued by the manufacturer
Byetta® (*exenatide*)
Victoza® (*liraglutide*)
Trulicity® (dulaglutide)

HYPOGLYCEMICS: SODIUM GLUCOSE CO-TRANSPORTER 2 (SGLT2) INHIBITOR

Length of Authorization:	Initial: 6 months, Renewal: 1 year
Initiative:	MNC: Hypoglycemics (IE 2462 / NCPDP 75 – HICL)

CRITERIA FOR INITIAL APPROVAL

Diagnosis of Diabetes Mellitus type 2

- Must be ≥ 18 years of age; **AND**
- Patient has failed to achieve adequate glycemic control with metformin, metformin ER, glipizide/metformin, glyburide/metformin, or pioglitazone/metformin**; AND**
- Patient does not have moderate to severe renal impairment, end-stage renal disease, and is not on dialysis .

CLINICAL CRITERIA FOR RENEWAL

- Patient continues to meet criteria identified above (patient must have failed preferred agents); **AND**
- Disease response; **AND**
- Patient has appropriate kidney function; **AND**
- Absence of unacceptable toxicity from the drug

COVERED- PA REQUIRED
Glyxambi® (*empagliflozin/linagliptin*)
Jardiance® (*empagliflozin*)
Invokana® *(canagliflozin)*
Invokamet® *(canagliflozin/metformin)*
Farxiga® (Dapagliflozin)
Synjardy® (*empagliflozin/metformin*)
Trijardy XR® (*empagliflozin/linagliptin/metformin ER)*
Xigduo XR® (*dapagliflozin/metformin ER*)

ICLUSIG® (PONATINIB)

Length of Authorization:	6 months; may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75 – HICL, 50081 and 2193)

CLINICAL CRITERIA

Diagnosis of **Chronic myeloid leukemia (CML)**

- Patient is at least 18 years of age; **AND**
- *BCR-ABL1* positive laboratory test result; **AND**
- **Chronic or accelerated or blast phase disease**
  - Patient's disease is T315I mutation positive; **OR**
  - Patient is resistant, or intolerant, or had an inadequate response to prior tyrosine kinase inhibitor (TKI) therapies, consisting of a 3-month trial or longer, with any of the following: omacetaxine, imatinib, dasatinib, bosutinib, nilotinib, etc.
- **Primary Treatment**
  - Used as a single agent for myeloid blast phase or accelerated phase disease; **OR**
  - In combination with steroids for lymphoid blast phase disease; **OR**
  - In combination with induction chemotherapy for lymphoid or myeloid blast phase disease
- **Post-allogeneic hematopoietic stem cell transplant (HCT)**
  - Used in patients with a completed cytogenetic response (CCyR) for accelerated or blast phase disease; **OR**
  - Used in patients with molecular relapse (BCR-ABL1 transcript positive) following CCyR; **OR**
  - Used in patients with relapse or those who are not in CCyR; **AND**
- Patient tried and failed Gleevec® (*imatinib*) or Tasigna (nilotinib); **AND**
- Patient tried and failed Bosulif (bosutinib); **OR**
- Patient is continuing with Iclusig

Diagnosis of **Philadelphia chromosome positive acute lymphoblastic leukemia (Ph + ALL)**

- Patient is at least 15 years old; **AND**
- Patient's disease is confirmed by either a Philadelphia chromosome-positive (Ph+) or BCR-ABL1 positive laboratory test result; **AND**
- Disease is T315I mutation positive; **OR**
- Patient has failed tyrosine kinase inhibitors (TKI); **OR**
- Used as part of induction/consolidation therapy in combination with Hyper-CVAD (hyper-fractionated cyclophosphamide, vincristine, doxorubicin, and dexamethasone, alternating with high-dose methotrexate and cytarabine); **OR**
- Used as maintenance therapy; **AND**
  - In combination with vincristine and prednisone; **OR**
  - Post stem-cell transplant
  - Absence of unacceptable toxicity from the drug (i.e., thromboembolism and vascular occlusion; hepatotoxicity; ocular toxicity; hypertensive crisis; serious congestive heart failure; pancreatitis; serious or severe hemorrhage; fluid retention (peripheral edema, pleural effusion, and pericardial effusion); cardiac arrhythmia; Grade 3 or 4 myelosuppression; tumor lysis syndrome; gastrointestinal perforation; poor wound healing); **AND**

RENEWAL CRITERIA

- **Acute lymphoblastic leukemia (ALL) only**:
  - Treatment response or stabilization of disease as indicated by CBC, bone marrow cytogenic analysis, QPCR, or FISH
- **Chronic Myelogenous Leukemia (CML) only:**
  - Treatment response as indicated by one of the following *BCR-ALB1* (IS) transcript levels:
    - ≤10 % at 3 months; **OR**
    - ≤ 10% at 6 months; **OR**
    - <1% at 12 months; **OR**
    - <0.1% beyond 12 months
    - BCR-ABL 1

  Note: cytogenetic assessment of response may be used if quantitative PT=PCR (QPCR) using International Scale (IS) for *BCR-ABL1* is not available

IMBRUVICA® (IBRUTINIB)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75 – HICL, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

For Imbruvica 140 mg TABLETS for all diagnoses, the patient must have a trial of Imbruvica 140 mg CAPSULES

Diagnosis of **Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL)**

- Patient is at least 18 years of age; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with voriconazole, posaconazole, and moderate CYP3A inhibitors (e.g., aprepitant, ciprofloxacin, diltiazem, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with other strong CYP3A inhibitors (e.g., clarithromycin, ketoconazole, nefazodone, grapefruit, Seville oranges, etc.); **AND**
  - Coadministration with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.); **AND**
- Patient does not have severe hepatic impairment (Child-Pugh Class C); **AND**
- Used as a single agent; **OR**
- Used in combination with rituximab and bendamustine for relapsed or refractory disease; **OR**
- Used in combination with rituximab or obinutuzumab as initial therapy

Diagnosis of **Waldenström's Macroglobulinemia/Lymphoplasmacytic Lymphoma**

- Patient is at least 18 years of age; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with voriconazole, posaconazole, and moderate CYP3A inhibitors (e.g., aprepitant, ciprofloxacin, diltiazem, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with other strong CYP3A inhibitors (e.g., clarithromycin, ketoconazole, nefazodone, grapefruit, Seville oranges, etc.); **AND**
  - Coadministration with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.); **AND**
- Patient does not have severe hepatic impairment (Child-Pugh Class C); **AND**
- Used as a single agent or in combination with rituximab

Diagnosis of **Chronic Graft versus Host Disease (cGvHD)**

- Patient is at least 18 years of age; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with voriconazole, posaconazole, and moderate CYP3A inhibitors (e.g., aprepitant, ciprofloxacin, diltiazem, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with other strong CYP3A inhibitors (e.g., clarithromycin, ketoconazole, nefazodone, grapefruit, Seville oranges, etc.); **AND**
  - Coadministration with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.); **AND**
- Patient does not have severe hepatic impairment (Child-Pugh Class C); **AND**
- Used as a single agent or in conjunction with systemic steroids; **AND**
- Patient is post-allogeneic stem cell transplant (generally 3 or more months); **AND**
- Patient has failed one or more previous lines of systemic therapy for the treatment of cGvHD (i.e., corticosteroids or immunosuppressants such as cyclosporine)

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **B-Cell Lymphomas**

- Patient is at least 18 years of age; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with voriconazole, posaconazole, and moderate CYP3A inhibitors (e.g., aprepitant, ciprofloxacin, diltiazem, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with other strong CYP3A inhibitors (e.g., clarithromycin, ketoconazole, nefazodone, grapefruit, Seville oranges, etc.); **AND**
  - Coadministration with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.); **AND**
- Patient does not have severe hepatic impairment (Child-Pugh Class C); **AND**
- Used as a single agent for recurrent/refractory or progressive disease as subsequent therapy for one of the following:
  - Marginal zone lymphoma (MZL) (including Nodal and Splenic)
  - Follicular lymphoma
  - Nongastric MALT lymphoma
  - Gastric MALT lymphoma
- AIDS-related B-cell lymphoma
  - Patient is at least 18 years of age; **AND**
  - Patient will avoid concomitant therapy with all of the following:
    - Coadministration with voriconazole, posaconazole, and moderate CYP3A inhibitors (e.g., aprepitant, ciprofloxacin, diltiazem, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
    - Coadministration with other strong CYP3A inhibitors (e.g., clarithromycin, ketoconazole, nefazodone, grapefruit, Seville oranges, etc.); **AND**
    - Coadministration with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.); **AND**
  - Patient does not have severe hepatic impairment (Child-Pugh Class C); **AND**
  - Patient has AIDS-related non-germinal center diffuse large B-Cell lymphoma; **AND**
  - Used as single agent, subsequent therapy for relapsed disease; **AND**
  - Patient is not a candidate for transplant
- Diffuse large B-cell lymphoma
  - Patient is at least 18 years of age; **AND**
  - Patient will avoid concomitant therapy with all of the following:
    - Coadministration with voriconazole, posaconazole, and moderate CYP3A inhibitors (e.g., aprepitant, ciprofloxacin, diltiazem, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
    - Coadministration with other strong CYP3A inhibitors (e.g., clarithromycin, ketoconazole, nefazodone, grapefruit, Seville oranges, etc.); **AND**
    - Coadministration with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.); **AND**
  - Patient does not have severe hepatic impairment (Child-Pugh Class C); **AND**
  - Used as a single agent in patients with histologic transformation of FL or MZL to non-germinal center Diffuse Large B-cell Lymphoma as subsequent therapy after multiple lines of chemoimmunotherapy for indolent or transformed disease ; **OR**
  - Used as a single agent as subsequent therapy for partial response, no response, relapsed, progressive, or refractory non-germinal center disease in non-candidates for transplant

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

- High-Grade B-Cell Lymphoma
  - Patient is at least 18 years of age; **AND**
  - Patient will avoid concomitant therapy with all of the following:
    - Coadministration with voriconazole, posaconazole, and moderate CYP3A inhibitors (e.g., aprepitant, ciprofloxacin, diltiazem, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
    - Coadministration with other strong CYP3A inhibitors (e.g., clarithromycin, ketoconazole, nefazodone, grapefruit, Seville oranges, etc.); **AND**
    - Coadministration with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.); **AND**
  - Patient does not have severe hepatic impairment (Child-Pugh Class C); **AND**
  - Used as a single agent as subsequent therapy for partial response, no response, relapsed, progressive, or refractory disease in noncandidates for transplant
- Mantle Cell Lymphoma (MCL)
  - Patient is at least 18 years of age; **AND**
  - Patient will avoid concomitant therapy with all of the following:
    - Coadministration with voriconazole, posaconazole, and moderate CYP3A inhibitors (e.g., aprepitant, ciprofloxacin, diltiazem, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
    - Coadministration with other strong CYP3A inhibitors (e.g., clarithromycin, ketoconazole, nefazodone, grapefruit, Seville oranges, etc.); **AND**
    - Coadministration with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.); **AND**
  - Patient does not have severe hepatic impairment (Child-Pugh Class C); **AND**
  - Used as subsequent therapy as a single agent or in combination with rituximab; **OR**
  - Used in combination with rituximab as pre-treatment to limit the number of aggressive induction therapy cycles with RHyperCVAD (rituximab, cyclophosphamide, vincristine, doxorubicin, and dexamethasone) regimen
- Post-Transplant Lymphoproliferative Disorders (PTLD)
  - Patient is at least 18 years of age; **AND**
  - Patient will avoid concomitant therapy with all of the following:
    - Coadministration with voriconazole, posaconazole, and moderate CYP3A inhibitors (e.g., aprepitant, ciprofloxacin, diltiazem, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
    - Coadministration with other strong CYP3A inhibitors (e.g., clarithromycin, ketoconazole, nefazodone, grapefruit, Seville oranges, etc.); **AND**
    - Coadministration with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.); **AND**
  - Patient does not have severe hepatic impairment (Child-Pugh Class C); **AND**
  - Used as subsequent therapy; **AND**
  - Used as a single agent for patients with partial response, persistent or progressive disease after receiving first-line chemo-immunotherapy for monomorphic PTLD (non-germinal center B-cell type disease).

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Primary CNS Lymphoma**

- Patient is at least 18 years of age; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with voriconazole, posaconazole, and moderate CYP3A inhibitors (e.g., aprepitant, ciprofloxacin, diltiazem, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with other strong CYP3A inhibitors (e.g., clarithromycin, ketoconazole, nefazodone, grapefruit, Seville oranges, etc.); **AND**
  - Coadministration with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.); **AND**
- Patient does not have severe hepatic impairment (Child-Pugh Class C); **AND**
- Used for relapsed or refractory disease; **AND**
  - Used as a single agent; **AND**
    - Patient has received previous whole brain radiation therapy; **OR**
    - Used in combination with radiation therapy in patients who had either no response or a short response (< 12 month duration) to a high-dose methotrexate-based regimen without previous radiation therapy; **OR**
    - Patient had a long response (≥ 12 months) to prior high-dose methotrexate-based regimen without prior radiation therapy OR to prior high-dose chemotherapy with stem cell rescue; **OR**
  - Used in combination with high-dose methotrexate and rituximab; **AND**
    - Patient has received previous whole brain radiation therapy; **OR**
    - Patient had a long response (≥ 12 months) to prior high-dose methotrexate-based regimen without prior radiation therapy; **OR**
- Used as induction therapy as a single agent; **AND**
  - Patient is unsuitable for or intolerant to high-dose methotrexate

Diagnosis of **Hairy Cell Leukemia**

- Patient is at least 18 years of age; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with voriconazole, posaconazole, and moderate CYP3A inhibitors (e.g., aprepitant, ciprofloxacin, diltiazem, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with other strong CYP3A inhibitors (e.g., clarithromycin, ketoconazole, nefazodone, grapefruit, Seville oranges, etc.); **AND**
  - Coadministration with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.); **AND**
- Patient does not have severe hepatic impairment (Child-Pugh Class C); **AND**
- Used as a single agent or in combination with rituximab

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug (e.g., hemorrhage, severe infections, myelosuppression [neutropenia, thrombocytopenia, and anemia], ventricular tachyarrhythmia, atrial fibrillation/flutter, tumor lysis syndrome, hypertension, and second primary malignancies); **AND**
- Oncology indications: Disease response with treatment defined as stabilization of disease or decrease in size of tumor or tumor spread
- cGvHD:
  - Response to therapy with an improvement in one or more of the following:
    - Clinical assessments (e.g., NIH Skin Score, Upper GI Response Score, NIH Lung Symptom Score); **OR**
    - Patient-reported symptoms (e.g., Lee Symptoms Scale).

IMMUNE GLOBULINS

Length of Authorization:	Initial: 6 months (unless noted otherwise), Renewal: 1 year (unless noted otherwise)
Initiative:	SPC: Immune Globulins (IE 2462 / NCPDP 75 – GSN MNC: Non-Formulary Product (IE 50698 / MR – GSN PatOverride)

CLINICAL CRITERIA FOR INITIAL APPROVAL OF SCIG

IMMUNE GLOBULIN SQ (SCIG): HIZENTRA®, GAMMAGARD LIQUID®, GAMUNEX®-C, GAMMAKED®, HYQVIA®, CUVITRU®, CUTAQUIG®, XEMBIFY®

Diagnosis of **Primary immunodeficiency (PID)/Wiskott-Aldrich syndrome**

Note: For SQ administered IMMUNE GLOBULIN: Hyqvia®, Cuvitru®, Cutaquig®, Xembify® are non-formulary drugs and will require trial and failure, contraindication, or intolerance to ALL formulary drugs (i.e., Hizentra®, Gammagard liquid®, Gamunex®, Gammaked®)

Note: Examples of PID include x-linked agammaglobulinemia, common variable immunodeficiency, transient hypogammaglobulinemia of infancy, IgG subclass deficiency with or without IgA deficiency, antibody deficiency with near normal immunoglobulin levels and combined deficiencies (severe combined immunodeficiencies, ataxia-telangiectasia, x-linked lymphoproliferative syndrome). This list is not all inclusive.

- Baseline values for BUN and serum creatinine obtained within 30 days of request; **AND**
- Patient is ≥ 2 years old (Exception: Cutaquig® – patient must be ≥ 17 years old, HyQvia – patient must be ≥ 18 years old
- Patient's IgG level is < 200 **or both** of the following:
  - Patient has a history of multiple hard to treat infections as indicated by at least **one** of the following:
    - Four or more ear infections within 1 year
    - Two or more serious sinus infections within 1 year
    - Two or more months of antibiotics with little effect
    - Two or more pneumonias within 1 year
    - Recurrent or deep skin abscesses
    - Need for intravenous antibiotics to clear infections
    - Two or more deep-seated infections including septicemia; **AND**
  - The patient has a deficiency in producing antibodies in response to vaccination; **AND**
    - Titers were drawn before challenging with vaccination; **AND**
    - Titers were drawn between 4 and 8 weeks of vaccination.

Note: Initial authorization is valid for 6 months; Subsequent authorizations will be approved for 1 year

RENEWAL

Coverage can be renewed for 1 year based upon the following criteria:

- Absence of unacceptable toxicity from the drug (e.g., acute kidney injury, thrombosis, hemolysis, hypersensitivity, pulmonary adverse reactions, volume overload); **AND**
- BUN and serum creatinine obtained within the last 6 months and the concentration and rate of infusion adjusted accordingly; **AND**
- Disease response as evidenced by one or more of the following:
  - Decrease in the frequency or infection
  - Decrease in the severity of infection

CLINICAL CRITERIA FOR INITIAL APPROVAL OF SCIG *(CONTINUED)*

Diagnosis of **chronic inflammatory demyelinating polyneuropathy (CIDP)—Hizentra® only**

- Baseline values for BUN and serum creatinine obtained within 30 days of request; **AND**
- Patient must be ≥ 18 years old; **AND**
- Physician has assessed baseline disease severity utilizing an objective measure/tool (e.g., INCAT, Medical Research Council (MRC) muscle strength, 6-MWT, Rankin, Modified Rankin, etc.); **AND**
  - Used as initial maintenance therapy for prevention of disease relapses after treatment and stabilization with intravenous immunoglobulin (IVIG); **OR**
  - Used for re-initiation of maintenance therapy after experiencing a relapse and requiring re-induction therapy with IVIG (see clinical criteria for renewal)

RENEWAL

Coverage can be renewed for 1 year based upon the following criteria:

- Absence of unacceptable toxicity from the drug (e.g., acute kidney injury, thrombosis, hemolysis, hypersensitivity, pulmonary adverse reactions, volume overload); **AND**
- BUN and serum creatinine obtained within the last 6 months and the concentration and rate of infusion adjusted accordingly; **AND**
  - Renewals will be authorized for patients that have demonstrated a clinical response to therapy based on an objective clinical measuring tool (e.g., INCAT, Medical Research Council (MRC) muscle strength,6 MWT, Rankin, Modified Rankin, etc.); **OR**
  - Patient is re-initiating maintenance therapy after experiencing a relapse while on Hizentra**; AND**
- Patient improved and stabilized on IVIG treatment: **AND**
- Patient was **not** receiving maximum dosing of Hizentra prior to relapse

CLINICAL CRITERIA FOR INITIAL APPROVAL OF IVIG

IMMUNE GLOBLULINS (INTRAVENOUS) (IVIG): FLEBOGAMMA DIF®, GAMMAGARD LIQUID®, GAMMAGARD S-D®, GAMMAKED®, GAMUNEX-C®, PRIVIGEN®, OCTAGAM®, ASCENIV®, GAMMAPLEX®, PANZYGA®

Note: For IV administered IMMUNE GLOBULIN: Octagam, Asceniv, Gammaplex, Panzyga are non-formulary drugs and will require trial and failure, contraindication, or intolerance to ALL formulary drugs (i.e., Flebogamma DIF, Gammagard liquid, Gammagard S-D, Gammaked, Gamunex-C, Privigen)

Diagnosis of **Primary immunodeficiency (PID)/Wiskott-Aldrich syndrome**

- Such as: x-linked agammaglobulinemia, common variable immunodeficiency, transient hypogammaglobulinemia of infancy, IgG subclass deficiency with or without IgA deficiency, antibody deficiency with near normal immunoglobulin levels) and combined deficiencies (severe combined immunodeficiencies, ataxia-telangiectasia, x-linked lymphoproliferative syndrome) [list not all inclusive]
- Baseline values for BUN and serum creatinine obtained within 30 days of request; **AND**
- Patient's IgG level is < 200 **or both** of the following:
  - Patient has a history of multiple hard to treat infections as indicated by at least **one** of the following:
    - Four or more ear infections within 1 year
    - Two or more serious sinus infections within 1 year
    - Two or more months of antibiotics with little effect
    - Two or more pneumonias within 1 year
    - Recurrent or deep skin abscesses
    - Need for intravenous antibiotics to clear infections
    - Two or more deep-seated infections including septicemia; **AND**
  - The patient has a deficiency in producing antibodies in response to vaccination; **AND**
    - Titers were drawn before challenging with vaccination; **AND**
    - Titers were drawn between 4 and 8 weeks of vaccination.

  Note: Initial authorization is valid for 6 months, Subsequent authorizations will be approved for 1 year

Diagnosis of **Immune thrombocytopenia/Idiopathic thrombocytopenia purpura (ITP):**

- For acute disease state:
  - Baseline values for BUN and serum creatinine obtained within 30 days of request; **AND**
  - To manage acute bleeding due to severe thrombocytopenia (platelet counts less than 30 X 10^9/L); **OR**
  - To increase platelet counts prior to invasive surgical procedures such as splenectomy. (Platelets less than 100 X 10^9/L); **OR**
  - Patient has severe thrombocytopenia (platelet counts $\leq$ 20 X 10^9/L)
  - Authorization is valid for 1 month only and cannot be renewed
- For chronic disease state (Chronic Immune Thrombocytopenia- CIT):
  - Baseline values for BUN and serum creatinine obtained within 30 days of request; **AND**
  - The patient is at increased risk for bleeding as indicated by a platelet count $\leq$ 30 X 10^9/L; **AND**
  - History of failure, contraindication, or intolerance with corticosteroids; **AND**
  - Duration of illness > 6 months

CLINICAL CRITERIA FOR INITIAL APPROVAL OF IVIG *(CONTINUED)*

Diagnosis of **Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)**

- Baseline values for BUN and serum creatinine obtained within 30 days of request; **AND**
- Patient's disease course is progressive or relapsing and remitting for ≥ 2 months; **AND**
- Patient has abnormal or absent deep tendon reflexes in upper or lower limbs; **AND**
- Electrodiagnostic testing indicating demyelination:
  - Partial motor conduction block in at least 2 motor nerves or in 1 nerve plus one other demyelination criterion listed here in at least 1 other nerve; **OR**
  - Distal CMAP duration increase in at least 1 nerve plus one other demyelination criterion listed here in at least 1 other nerve; **OR**
  - Abnormal temporal dispersion conduction must be present in at least 2 motor nerves; **OR**
  - Reduced motor conduction velocity in at least 2 motor nerves; **OR**
  - Prolonged distal motor latency in at least 2 motor nerves; **OR**
  - Absent F wave in at least 2 motor nerves plus one other demyelination criterion listed here in at least 1 other nerve; **OR**
  - Prolonged F wave latency in at least 2 motor nerves; **AND**
- Patient is refractory or intolerant to corticosteroids (e.g., prednisolone, prednisone) given in therapeutic doses over at least three months; **AND**
- Baseline in strength/weakness has been documented using an objective clinical measuring tool (e.g., INCAT, Medical Research Council [MRC] muscle strength, 6-MWT, Rankin, Modified Rankin)

  Note: Initial authorization is valid for 3 months, Subsequent authorizations will be approved for 1 year

Diagnosis of **Guillain-Barre Syndrome (Acute inflammatory polyneuropathy)**

- Baseline values for BUN and serum creatinine obtained within 30 days of request; **AND**
- Patient has severe disease (i.e., patient requires assistance to ambulate); **AND**
- Onset of symptoms are recent (less than 1 month); **AND**
- Patient has abnormal or absent deep tendon reflexes in upper or lower limbs**; AND**
- Patient diagnosis is confirmed using a cerebrospinal fluid (CSF) analysis; **AND**
- Approval will be granted for a maximum of 2 rounds of therapy within 6 weeks on onset; **AND**
- Authorization is valid for 2 months only and cannot be renewed

CLINICAL CRITERIA FOR INITIAL APPROVAL OF IVIG *(CONTINUED)*

Diagnosis of **Multifocal Motor Neuropathy**

- Baseline values for BUN and serum creatinine obtained within 30 days of request; **AND**
- Patient has progressive focal, asymmetric limb weakness (without sensory symptoms) for > 1 month; **OR**
- Patient has complete or partial conduction block or abnormal temporal dispersion conduction in at least 2 motor nerves; **AND**
- Patient has normal sensory nerve conduction on all nerves tested; **AND**
- Baseline in strength/weakness has been documented using objective clinical measuring tool (e.g., INCAT, Medical Research Council (MRC) muscle strength, 6 MWT, Rankin, Modified Rankin) and renewals will require current results; AND
- Initial authorization length is valid for 3 months
- Renewals will be authorized for patients that have demonstrated an improvement of 1 or better on the INCAT scale; **AND**
- Improvement over baseline in strength/weakness

Diagnosis of **HIV infected children: bacterial control or prevention**

- Baseline values for BUN and serum creatinine obtained within 30 days of request; **AND**
- Patient age does not exceed 13 years of age; **AND**
- Patient's IgG level is < 400 mg/dL

Diagnosis of **Myasthenia Gravis**

- Baseline values for BUN and serum creatinine obtained within 30 days of request; **AND**
- Patient has a positive serologic test for anti-acetylcholine receptor (AChR) antibodies; **AND**
- Patient has an acute exacerbation resulting in impending myasthenic crisis (i.e., respiratory compromise, acute respiratory failure, and/or bulbar compromise); **AND**
- Patient is failing on conventional immunosuppressant therapy alone (e.g., corticosteroids, azathioprine, cyclosporine, mycophenolate, methotrexate, tacrolimus, cyclophosphamide, etc.); **AND**
- Patient will be on combination therapy with corticosteroids or other immunosuppressant (e.g., azathioprine, mycophenolate, cyclosporine, methotrexate, tacrolimus, cyclophosphamide, etc.)

Note: Authorization length is 1 course (1 month) and cannot be renewed

CLINICAL CRITERIA FOR INITIAL APPROVAL IVIG *(CONTINUED)*

Diagnosis of **Dermatomyositis or Polymyositis**

- Baseline values for BUN and serum creatinine obtained within 30 days of request; **AND**
- Patient has severe active disease; **AND**
- Patient has proximal weakness in all upper and/or lower limbs; **AND**
- Diagnosis has been confirmed by muscle biopsy; **AND**
- Patient has failed a trial of corticosteroids (e.g., prednisone); **AND**
- Patient has failed a trial of immunosuppressants (e.g., MTX, azathioprine, etc.); **AND**
- Must be used as part of combination therapy with other agents; **AND**
- Patient has a documented baseline physical exam and muscular strength/function; **AND**
- Initial approval will be valid for 3 months; **AND**
- Renewals will require current CPK lab and physical exam

Diagnosis of **complications of transplanted organ (kidney, liver, lung, heart, pancreas) and bone marrow transplant**

- Baseline values for BUN and serum creatinine obtained within 30 days of request; **AND**
- Coverage is provided for one or more of the following (list not all-inclusive):
- Suppression of panel-reactive anti-HLA antibodies prior to transplantation; **OR**
- Treatment of antibody mediated rejection of solid organ transplantation; **OR**
- Prevention or treatment of viral infections (e.g., cytomegalovirus, Parvo B-19 virus, and Polyoma BK virus)

Diagnosis of **Stiff person syndrome**

- Baseline values for BUN and serum creatinine obtained within 30 days of request; **AND**
- Patient has anti-glutamic acid decarboxylase (GAD) antibodies; **AND**
- Patient has failed at least 2 of the following treatments: benzodiazepines, baclofen, gabapentin, valproate, tiagabine, or levetiracetam; **AND**
- Patient has a documented baseline on physical exam

Diagnosis of **Allogeneic Bone Marrow Transplant Or stem cell transplant**

- Baseline values for BUN and serum creatinine obtained within 30 days of request; **AND**
- Used for prevention of acute Graft-Versus-Host-Disease (aGvHD) or infection; **AND**
- Patient's bone marrow (BMT) or hematopoietic stem cell (HSCT) transplant was allogeneic; **AND**
- Patient's IgG level is less than 400 mg/dL

Note: Initial authorization is valid for 3 months

Diagnosis of **Kawasaki's disease (pediatric)**

- Baseline values for BUN and serum creatinine obtained within 30 days of request; **AND**

Note: Authorization is valid for 1 course (1 month) only and cannot be renewed

CLINICAL CRITERIA FOR INITIAL APPROVAL OF IVIG *(CONTINUED)*

Diagnosis of **Fetal Alloimmune Thrombocytopenia (FAIT)**

- Baseline values for BUN and serum creatinine obtained within 30 days of request; **AND**
- Patient has a history of one or more of the following:
  - Previous FAIT pregnancy
  - Family history of the disease
  - Screening reveals platelet alloantibodies

Note: Authorization is valid through the delivery date only and cannot be renewed

Diagnosis of **Neonatal Alloimmune Thrombocytopenia (NAIT)**

- Baseline values for BUN and serum creatinine obtained within 30 days of request

Note: Authorization is valid for 1 course (1 month) only and cannot be renewed

Diagnosis of **Auto-immune Mucocutaneous Blistering Diseases**

- Baseline values for BUN and serum creatinine obtained within 30 days of request; **AND**
- Patient has been diagnosed with one of the following:
  - Pemphigus vulgaris
  - Pemphigus foliaceus
  - Bullous Pemphigoid
  - Mucous Membrane Pemphigoid (AKA Cicatricial Pemphigoid)
  - Epidermolysis bullosa acquisita
  - Pemphigus gestationis (Herpes gestationis)
  - Linear IgA dermatosis; **AND**
- Patient has severe disease that is extensive and debilitating; **AND**
- Diagnosis has been confirmed by biopsy; **AND**
- Patient's disease is progressive; **AND**
- Disease is refractory to a trial of conventional therapy with corticosteroids and concurrent immunosuppressive treatment (e.g., azathioprine, cyclophosphamide, mycophenolate mofetil, etc.); **AND**
- Patient has a documented baseline on physical exam

CLINICAL CRITERIA FOR INITIAL APPROVAL *OF IVIG (CONTINUED)*

Diagnosis of **Acquired Immune Deficiency secondary to Chronic Lymphocytic Leukemia † or Multiple Myeloma**

- Baseline values for BUN and serum creatinine obtained within 30 days of request; **AND**
- Patients IgG level is < 200 **OR BOTH** of the following:
  - Patient has a history of multiple hard to treat infections as indicated by at least **ONE** of the following:
    - Four or more ear infections within 1 year
    - Two or more serious sinus infections within 1 year
    - Two or more months of antibiotics with little effect
    - Two or more pneumonias within 1 year
    - Recurrent or deep skin abscesses
    - Need for intravenous antibiotics to clear infections
    - Two or more deep-seated infections including septicemia; **AND**
  - The patient has a deficiency in producing antibodies in response to vaccination; **AND**
    - Titers were drawn before challenging with vaccination; **AND**
    - Titers were drawn between 4 and 8 weeks of vaccination.

Note: Other secondary immunodeficiencies resulting in hypogammaglobulinemia and/or B-cell aplasia will be evaluated on a case-by-case basis

Diagnosis of **Acquired Immune Deficiency** secondary to Acute Lymphoblastic Leukemia (ALL)

- Baseline values for BUN and serum creatinine obtained within 30 days of request; **AND**
- Used for prevention of infection; **AND**
- Patient age is less than 18 years old; **AND**
- Patient's IgG level is less than 400 mg/dL

Diagnosis of **Toxic Shock Syndrome**

- Baseline values for BUN and serum creatinine obtained within 30 days of request; **AND**
- Authorization is valid for 1 course (1 month) only and cannot be renewed.

CLINICAL CRITERIA FOR INITIAL APPROVAL OF IVIG *(CONTINUED)*

Diagnosis of **Management of Immune Checkpoint Inhibitor-Related Toxicity**

- Baseline values for BUN and serum creatinine obtained within 30 days of request; **AND**
- Patient has been receiving therapy with an immune checkpoint inhibitor (e.g., nivolumab, pembrolizumab, atezolizumab, avelumab, durvalumab, etc.); **AND**
- Patient has one of the following toxicities related to their immunotherapy:
  - Severe or life-threatening bullous dermatitis
  - Stevens-Johnson syndrome (SJS)
  - Toxic epidermal necrolysis (TEN)
  - Severe myasthenia gravis
  - Transverse myelitis
  - Severe or life-threatening myocarditis, pericarditis, arrhythmias, impaired ventricular function, or conduction abnormalities refractory to 24 hours of pulse-dose methylprednisolone therapy
  - Moderate or severe Guillain-Barre Syndrome or severe peripheral neuropathy toxicity used in combination with pulse-dose methylprednisolone
  - Severe pneumonitis refractory to 48 hours of methylprednisolone therapy
  - Encephalitis used in combination with pulse-dose methylprednisolone for severe or progressing symptoms or if oligoclonal bands are present
  - Severe inflammatory arthritis refractory to 14 days of high-dose corticosteroid therapy
  - Moderate, severe, or life-threatening steroid-refractory myalgias or myositis

Note: May **not** be renewed.

CLINICAL CRITERIA FOR RENEWAL OF IVIG

Note: Unless otherwise specified, the renewal authorization is provided for 1 year

Coverage can be renewed based on the following criteria:

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: renal dysfunction and acute kidney renal failure, thrombosis, hemolysis, severe hypersensitivity reactions, pulmonary adverse reactions, hyperproteinemia, increased serum viscosity, hyponatremia, aseptic meningitis syndrome, hypertension, volume overload, etc.; **AND**
- BUN and serum creatinine obtained within the last 6 months and the concentration and rate of infusion adjusted accordingly; **AND**
- Patient meets the disease-specific criteria identified below:

Primary immunodeficiency (PID)/Wiskott-Aldrich syndrome

- Disease response as evidenced by one or more of the following:
  - Decrease in the frequency or infection
  - Decrease in the severity of infection

CLINICAL CRITERIA FOR RENEWAL (*CONTINUED*)

Chronic Immune Thrombocytopenia/ITP

- Disease response as indicated by the achievement and maintenance of a platelet count of ≥ 30 X 10^9/L and at least doubling the baseline platelet count

Chronic Inflammatory Demyelinating Polyneuropathy

- Renewals will be authorized for patients who have demonstrated a clinical response to therapy based on an objective clinical measuring tool (e.g., INCAT, Medical Research Council (MRC) muscle strength, 6 MWT, Rankin, Modified Rankin, etc.)

Guillain-Barre Syndrome (Acute inflammatory polyneuropathy)

- May not be renewed.

Multifocal Motor Neuropathy

- Renewals will be authorized for patients who have demonstrated a clinical response to therapy based on an objective clinical measuring tool (e.g., INCAT, Medical Research Council (MRC) muscle strength, 6 MWT, Rankin, Modified Rankin, etc.)

HIV-infected children: Bacterial control or prevention

- Disease response as evidenced by one or more of the following:
  - Decrease in the frequency of infection
  - Decrease in the severity of infection; **AND**
- Patient continues to be at an increased risk of infection necessitating continued therapy, as evidenced by an IgG level < 400 mg/dL

Myasthenia Gravis

- May not be renewed

Dermatomyositis/polymyositis

- Patient had an improvement from baseline on physical exam and/or muscular strength and function

Note: Renewal authorization is for 6 months

Complications of transplanted solid organ (kidney, liver, lung, heart, pancreas) and bone marrow transplant

- Disease response as evidenced by one or more of the following:
  - Decrease in the frequency of infection
  - Decrease in the severity of infection; **AND**
- Patient is at a decreased risk of infection as a result of treatment necessitating continued therapy.

CLINICAL CRITERIA FOR RENEWAL *(CONTINUED)*

Stiff person disease

- Documented improvement over baseline per physical exam

Allogeneic Bone Marrow or Stem Cell Transplant

- Patient's IgG is less than or equal to 400 mg/dL; **AND**

Note: Renewal authorizations are provided for 3 months

Kawasaki's Disease

- May not be renewed.

Fetal Alloimmune Thrombocytopenia (FAIT)

- Authorization is valid through the delivery date only and cannot be renewed

Neonatal Alloimmune Thrombocytopenia

- May not be renewed.

Autoimmune mucocutaneous blistering diseases

- Documented improvement over baseline per physical exam

Note: Renewals will be approved for 6 months

Acquired Immune Deficiency secondary to Acute Lymphoblastic Leukemia (ALL), Chronic Lymphocytic Leukemia (CLL), or Multiple Myeloma

- Disease response as evidenced by one or more of the following:
  - Decrease in the frequency of infection
  - Decrease in the severity of infection; **AND**
- Patient is at a decreased risk of infection as a result of treatment necessitating continued therapy

Toxic Shock Syndrome

- May not be renewed.

Management of Immune Checkpoint Inhibitor-related Toxicity

- May not be renewed.

IMMUNOMODULATORS

Length of Authorization:	Varies: See specific criteria below
Initiative:	SPC: Immunomodulators: Systemic (IE 2462 / NCPDP 75 – HICL) – Humira, Enbrel, Xeljanz, Otezla, Renflexis MNC: Non-Formulary Product (IE 50698 / MR – GSN PatOverride) – Non-formulary drugs **NOTE: FOR INITIAL START THE PATIENT MUST MEET SCREENING QUESTIONS, INITIAL APPROVAL CRITERIA AND DRUG SPECIFIC CRITERIA. FOR RENEWALS, THE PATIENT ONLY NEEDS TO MEET RENEWAL CRITERIA.**

SCREENING QUESTIONS FOR ALL AGENTS [UNLESS NOTED]

- Patient has been evaluated and screened to rule out the presence of latent TB infection prior to initiating treatment; **(except Otezla®)**; **AND**
- Patient has been evaluated for the presence of hepatitis B virus (HBV) prior to initiating treatment **(for Enbrel®, Cimzia®, Humira®, Orencia®, Simponi®, Stelara®, Cosentyx®, Rituxan, and infliximab)**; **AND**
- Patient does not have an active infection, including clinically important localized infections **(except Otezla®)**; **AND**
- Patient will not receive any live vaccines while on therapy **(except Otezla®)**; **AND**
- Patient is not on concurrent treatment with another TNF inhibitor or biological DMARD (e.g., Orencia®, Kineret®, Actemra®, Remicade®, Rituxan®, Xeljanz®); **AND**
- Physician has assessed baseline disease severity utilizing an objective measure/tool.

Note: patient use of free goods or samples does not qualify as an established patient or guarantee coverage. All policy criteria must be met in order to obtain coverage.

HUMIRA® (ADALIMUMAB)

HUMIRA® (ADALIMUMAB) INDICATIONS (NOTE SPECIFIC POPULATIONS APPROVED)

- **Rheumatoid arthritis (RA):** Indicated for reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage and improving physical function in adult patients with moderately to severe active rheumatoid arthritis (RA). Humira can be used alone or in combination with methotrexate (MTX) or other non-biologic disease-modifying antirheumatic drugs (DMARDs).
- **Juvenile idiopathic arthritis (JIA):** Indicated for reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis in patients ages 2 years of age and older. Humira can be used alone or in combination with MTX.
- **Psoriatic arthritis (PsA):** Indicated for reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active psoriatic arthritis. Humira can be used alone or in combination with non-biologic DMARDs.
- **Ankylosing spondylitis (AS):** Indicated for reducing signs and symptoms in adult patients with active ankylosing spondylitis.
- **Adult Crohn's disease (CD):** Indicated for reducing signs and symptoms and inducing and maintaining clinical remission in adult patients with moderately to severely active Crohn's disease who have had an inadequate response to conventional therapy.
- **Pediatric Crohn's disease:** Indicated for reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients 6 years of age and older with moderately to severely active Crohn's disease who have had an inadequate response to corticosteroids or immunomodulators such as azathioprine, 6-mercaptopurine, or methotrexate.

HUMIRA® (ADALIMUMAB) *(CONTINUED)*

HUMIRA® (ADALIMUMAB) INDICATIONS (NOTE SPECIFIC POPULATIONS APPROVED) *(CONTINUED)*

- **Ulcerative colitis:** Indicated for inducing and sustaining clinical remission in adult patients with moderately to severely active ulcerative colitis who have had an inadequate response to immunosuppressants such as corticosteroids, azathioprine or 6-mercaptopurine (6-MP). The effectiveness of Humira® has not been established in patients who have lost response to or were intolerant to TNF blockers.
- **Plaque psoriasis:** Indicated for the treatment of adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate. Humira® should only be administered to patients who will be closely monitored and have regular follow-up visits with a physician.
- **Hidradenitis suppurativa:** Indicated for the treatment of moderate to severe hidradenitis suppurativa.
- **Uveitis (UV):** Indicated for the treatment of non-infectious intermediate, posterior and panuveitis in adult patients.

Drug Name:	Humira® (adalimumab)
Diagnosis:	Rheumatoid arthritis (RA)
Approval Length:	24 months

Initial Criteria:

- Diagnosis of moderately to severely active RA; **AND**
- Prescribed by or in consultation with a rheumatologist; **AND**
- Trial and failure, contraindication, or intolerance to one non-biologic disease-modifying antirheumatic drug (DMARD) (e.g., methotrexate [Rheumatrex®/Trexall®], Arava® [leflunomide], Azulfidine® [sulfasalazine])

Renewal Criteria:

- Documentation of positive clinical response to Humira® therapy

Drug Name:	Humira® (adalimumab)
Diagnosis:	Juvenile idiopathic arthritis (JIA)
Approval Length:	24 months

Initial Criteria:

- Diagnosis of moderate to severely active polyarticular JIA; **AND**
- Prescribed by or in consultation with a rheumatologist; **AND**
- Trial and failure, contraindication, or intolerance to one of the following non-biologic disease-modifying antirheumatic drugs (DMARDs):
  - Arava® (leflunomide)
  - methotrexate (Rheumatrex®/Trexall®)

Renewal Criteria:

- Documentation of positive clinical response to Humira® therapy

HUMIRA® (ADALIMUMAB) *(CONTINUED)*

Drug Name:	Humira® (adalimumab)
Diagnosis:	Psoriatic arthritis (PsA)
Approval Length:	24 months

Initial Criteria:

- Diagnosis of active PsA; **AND**
- Prescribed by or in consultation with one of the following:
  - Dermatologist
  - Rheumatologist

Renewal Criteria:

- Documentation of positive clinical response to Humira® therapy

Drug Name:	Humira® (adalimumab)
Diagnosis:	Plaque psoriasis
Approval Length:	24 months

Initial Criteria:

- Diagnosis of moderate to severe chronic plaque psoriasis; **AND**

  Note: Patients who are candidates for systemic/and or phototherapy have significant disease, typically affecting 5% or more of the body surface area (BSA). Some of these candidates may also have less than 5% BSA affected but have psoriasis in vulnerable areas such as the face, genitals, hands, or feet (palmer-plantar), nails, scalp, or intertriginous areas.
- Prescribed by or in consultation with a dermatologist

Renewal Criteria:

- Documentation of positive clinical response to therapy as evidenced by **one** of the following:
  - Reduction in the body surface area (BSA) involvement from baseline; **OR**
  - Improvement in symptoms (e.g., pruritus, inflammation) from baseline

Drug Name:	Humira® (adalimumab)
Diagnosis:	Ankylosing spondylitis
Approval Length:	24 months

Initial Criteria:

- Diagnosis of active ankylosing spondylitis; **AND**
- Prescribed by or in consultation with a rheumatologist; **AND**
- Trial and failure, contraindication, or intolerance to two NSAIDs (e.g., diclofenac, ibuprofen, indomethacin, meloxicam, naproxen)

Renewal Criteria:

- Documentation of positive clinical response to Humira® therapy

HUMIRA® (ADALIMUMAB) *(CONTINUED)*

Drug Name:	Humira® (adalimumab)
Diagnosis:	Crohn's disease
Approval Length:	24 months

Initial Criteria:

- Diagnosis of moderately to severely active Crohn's disease (In the CLASSIC-I trial, moderate to severe Crohn's disease was defined as a Crohn's Disease Activity Index [CDAI] score between 220 and 450, inclusive); **AND**
- **One** of the following:
  - Trial and failure, contraindication, or intolerance to one of the following conventional therapies:
    - 6-mercaptopurine (Purinethol®)
    - Azathioprine (Imuran®)
    - Corticosteroids (e.g., prednisone, methylprednisolone)
    - Methotrexate (Rheumatrex®, Trexall®); **AND**
- Prescribed by or in consultation with a gastroenterologist

Renewal Criteria:

- Documentation of positive clinical response to Humira® therapy

Drug Name:	Humira® (adalimumab)
Diagnosis:	Ulcerative colitis
Approval Length:	Initial: 12 weeks; Renewal: 24 months

Initial Criteria:

- Diagnosis of moderately to severely active ulcerative colitis; **AND**
- Trial and failure, contraindication, or intolerance to one of the following conventional therapies:
  - 6-mercaptopurine (Purinethol®)
  - Aminosalicylate (e.g., mesalamine [Asacol®, Pentasa®, Rowasa®], olsalazine [Dipentum®], sulfasalazine [Azulfidine®, Sulfazine®])
  - Azathioprine (Imuran®)
  - Corticosteroids (e.g., prednisone, methylprednisolone); **AND**
- Prescribed by or in consultation with a gastroenterologist

Renewal Criteria:

- Documentation of **one** of the following:
  - For patients who initiated Humira therapy within the past 12 weeks: Documentation of clinical remission or significant clinical benefit by eight weeks (Day 57) of therapy; **OR**
  - For patients who have been maintained on Humira® therapy for longer than 12 weeks: Documentation of positive clinical response to Humira® therapy

HUMIRA® (ADALIMUMAB) *(CONTINUED)*

Drug Name:	Humira® (adalimumab)
Diagnosis:	Hidradenitis suppurativa
Approval Length:	24 months

Initial Criteria:

- Diagnosis of moderate to severe hidradenitis suppurativa (i.e., Hurley stage II or III); **AND**
- Prescribed by or in consultation with a dermatologist

Renewal Criteria:

- Documentation of positive clinical response to Humira® therapy

Drug Name:	Humira® (adalimumab)
Diagnosis:	Uveitis (UV)
Approval Length:	24 months

Initial Criteria:

- Diagnosis of non-infectious uveitis; **AND**
- Uveitis is classified as one of the following:
  - Intermediate
  - Posterior
  - Panuveitis**; AND**
- Prescribed by or in consultation with one of the following:
  - Ophthalmologist
  - Rheumatologist

Renewal Criteria:

- Documentation of positive clinical response to Humira® therapy

ENBREL® (ETANERCEPT)

ENBREL® (ETANERCEPT) INDICATIONS (NOTE SPECIFIC POPULATIONS APPROVED)

- **Rheumatoid arthritis (RA):** Indicated for reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active rheumatoid arthritis. Enbrel can be initiated in combination with methotrexate (MTX) or used alone.
- **Polyarticular juvenile idiopathic arthritis (PJIA):** Indicated for reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis in patients ages 2 and older.
- **Psoriatic arthritis (PsA):** Indicated for reducing signs and symptoms, inhibiting the progression of structural damage of active arthritis, and improving physical function in patients with psoriatic arthritis. Enbrel® can be used with or without MTX.
- **Ankylosing spondylitis (AS):** Indicated for reducing signs and symptoms in patients with active ankylosing spondylitis.
- **Plaque psoriasis (PsO):** Indicated for the treatment of patients 4 years of age and older with chronic moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

ENBREL® (ETANERCEPT) *(CONTINUED)*

Drug Name:	Enbrel® (etanercept)
Diagnosis:	Rheumatoid arthritis (RA)
Approval Length:	24 months

Initial Criteria:

- Diagnosis of moderately to severely active rheumatoid arthritis; **AND**
- Prescribed by or in consultation with a rheumatologist; **AND**
- Trial and failure, contraindication, or intolerance to one nonbiologic disease-modifying antirheumatic drug (DMARD) (e.g., methotrexate [Rheumatrex®/Trexall®], Arava® [leflunomide], Azulfidine® [sulfasalazine])

Renewal Criteria:

- Documentation of positive clinical response to Enbrel® therapy

Drug Name:	Enbrel® (etanercept)
Diagnosis:	Polyarticular juvenile idiopathic arthritis (PJIA)
Approval Length:	24 months

Initial Criteria:

- Diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis; **AND**
- Prescribed by or in consultation with a rheumatologist; **AND**
- Trial and failure, contraindication, or intolerance to one of the following nonbiologic disease-modifying antirheumatic drugs (DMARDs):
  - Arava® (leflunomide)
  - methotrexate (Rheumatrex®/Trexall®)

Renewal Criteria:

- Documentation of positive clinical response to Enbrel® therapy

Drug Name:	Enbrel® (etanercept)
Diagnosis:	Psoriatic arthritis (PsA)
Approval Length:	24 months

Initial Criteria:

- Diagnosis of active psoriatic arthritis; **AND**
- Prescribed by or in consultation with one of the following:
  - Dermatologist
  - Rheumatologist

Renewal Criteria:

- Documentation of positive clinical response to Enbrel® therapy

ENBREL® (ETANERCEPT) *(CONTINUED)*

Drug Name:	Enbrel® (etanercept)
Diagnosis:	Plaque psoriasis
Approval Length:	24 months

Initial Criteria:

- Diagnosis of moderate to severe chronic plaque psoriasis; **AND**
- Prescribed by or in consultation with a dermatologist

Renewal Criteria:

- Documentation of positive clinical response to Enbrel® therapy as evidenced by **one** of the following:
  - Reduction the body surface area (BSA) involvement from baseline; **OR**
  - Improvement in symptoms (e.g., pruritus, inflammation) from baseline

Drug Name:	Enbrel (etanercept)
Diagnosis:	Ankylosing Spondylitis (AS)
Approval Length:	24 months

Initial Criteria:

- Diagnosis of active ankylosing spondylitis; **AND**
- Prescribed by or in consultation with a rheumatologist; **AND**
- Trial and failure, contraindication, or intolerance to two NSAIDs (e.g., diclofenac, ibuprofen, indomethacin, meloxicam, naproxen)

Renewal Criteria:

- Documentation of positive clinical response to Enbrel® therapy

OTEZLA® (APREMILAST)

OTEZLA® (APREMILAST) INDICATIONS (NOTE SPECIFIC POPULATIONS APPROVED)

- **Psoriatic arthritis (PsA):** Indicated for the treatment of adult patients with active psoriatic arthritis.
- **Plaque psoriasis:** Indicated for the treatment of patients with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy.
- **Oral ulcers associated with Behcet's disease:** Indicated for the treatment of adult patients with oral ulcers associated with Behcet's disease.

OTEZLA® (APREMILAST) *(CONTINUED)*

Drug Name:	Otezla® (apremilast)
Diagnosis:	Psoriatic arthritis (PsA)
Approval Length:	24 months

Initial Criteria:

- Diagnosis of active psoriatic arthritis; **AND**
- Prescribed by or in consultation with one of the following:
  - Dermatologist
  - Rheumatologist

Renewal Criteria:

- Documentation of positive clinical response to Otezla® therapy (e.g., improvement in number of swollen/tender joints, pain, or stiffness).

Drug Name:	Otezla® (apremilast)
Diagnosis:	Plaque psoriasis
Approval Length:	24 months

Initial Criteria:

- Diagnosis of moderate-to-severe plaque psoriasis; **AND**
- Prescribed by or in consultation with a dermatologist; **AND**
- **One** of the following:
  - Greater than 10% body surface area involvement
  - Palmoplantar involvement
  - Severe scalp psoriasis.

Renewal Criteria:

- Documentation of positive clinical response to Otezla® therapy (e.g., improvement in body surface area involvement or Psoriasis Area and Severity Index [PASI] 75 scoring).

Drug Name:	Otezla® (apremilast)
Diagnosis:	Oral ulcers associated with Behcet's disease
Approval Length:	24 months

Initial Criteria:

- Diagnosis of Behcet's disease; **AND**
- Patient has active oral ulcers

Renewal Criteria:

- Documentation of positive clinical response to Otezla® therapy (e.g., reduction in pain from oral ulcers or reduction in number of oral ulcers).

XELJANZ® (TOFACITINIB)

XELJANZ® (TOFACITINIB) INDICATIONS (NOTE SPECIFIC POPULATIONS APPROVED)

- **Rheumatoid arthritis:** Indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to methotrexate. It may be used as monotherapy or in combination with methotrexate or other nonbiologic disease-modifying antirheumatic drugs (DMARDs). Limitations of Use: Use of Xeljanz® in combination with biologic DMARDs or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended.
- **Psoriatic arthritis:** Indicated for the treatment of adult patients with active psoriatic arthritis who have had an inadequate response or intolerance to methotrexate or other disease-modifying antirheumatic drugs (DMARDs). Limitations of Use: Use of Xeljanz® in combination with biologic DMARDs or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended.
- **Ulcerative colitis:** Indicated for the treatment of adult patients with moderately to severely active ulcerative colitis (UC). Limitations of Use: Use of Xeljanz® in combination with biological therapies for UC or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended.

Product Name:	Xeljanz® (tofacitinib)
Diagnosis:	Rheumatoid arthritis
Approval Length:	24 months

Initial Criteria:

- Diagnosis of moderately to severely active rheumatoid arthritis; **AND**
- Prescribed by or in consultation with a rheumatologist; **AND**
- Trial and failure, contraindication, or intolerance to **one** nonbiologic disease-modifying antirheumatic drug (DMARD) (e.g., methotrexate [Rheumatrex®/Trexall®], Arava® [leflunomide], Azulfidine® [sulfasalazine]); **AND**
- Patient is not receiving Xeljanz in combination with a potent immunosuppressant (e.g., azathioprine or cyclosporine).

Renewal Criteria:

- Documentation of positive clinical response to Xeljanz® therapy; **AND**
- Patient is not receiving Xeljanz® in combination with a potent immunosuppressant (e.g., azathioprine or cyclosporine).

Product Name:	Xeljanz® (tofacitinib)
Diagnosis:	Psoriatic arthritis
Approval Length:	24 months

Initial Criteria:

- Diagnosis of active psoriatic arthritis (PsA); **AND**
- Prescribed by or in consultation with one of the following:
  - Dermatologist
  - Rheumatologist; **AND**
- Trial and failure, contraindication, or intolerance to **one** nonbiologic disease modifying anti-rheumatic drug (DMARD) (e.g., methotrexate [Rheumatrex®/Trexall®], Arava® [leflunomide], Azulfidine® [sulfasalazine]); **AND**
- Patient is not receiving Xeljanz® in combination with a potent immunosuppressant (e.g., azathioprine or cyclosporine).

Renewal Criteria:

- Documentation of positive clinical response to Xeljanz® therapy; **AND**
- Patient is not receiving Xeljanz® in combination with a potent immunosuppressant (e.g., azathioprine or cyclosporine).

XELJANZ® (TOFACITINIB) *(CONTINUED)*

Product Name:	Xeljanz® (tofacitinib)
Diagnosis:	Ulcerative colitis
Approval Length:	Initial: 4 months; Renewal: 24 months

Initial Criteria:

- Diagnosis of moderately to severely active ulcerative colitis; **AND**
- Trial and failure, contraindication, or intolerance to **one** of the following conventional therapies:
  - 6-mercaptopurine (Purinethol®)
  - Aminosalicylate (e.g., mesalamine [Asacol®, Pentasa®, Rowasa®], olsalazine [Dipentum®], sulfasalazine [Azulfidine®, Sulfazine®])
  - Azathioprine (Imuran®)
  - Corticosteroids (e.g., prednisone, methylprednisolone)**; AND**
- Prescribed by or in consultation with a gastroenterologist; **AND**
- Patient is not receiving Xeljanz® in combination with a potent immunosuppressant (e.g., azathioprine or cyclosporine).

NOTE: Initial approval length of 4 months based on dosing recommendation provided in the labeling of 10 mg twice daily for at least 8 weeks, followed by 5 mg or 10 mg twice daily depending on therapeutic response. Xeljanz® should be discontinued after 16 weeks (4 months) of treatment with 10 mg twice daily if adequate therapeutic benefit is not achieved.

Renewal Criteria:

- Documentation of positive clinical response to Xeljanz® therapy; **AND**
- Patient is not receiving Xeljanz® in combination with a potent immunosuppressant (e.g., azathioprine or cyclosporine).

RENFLEXIS® (INFLIXIMAB-ABDA)

INFLIXIMAB INDICATIONS (NOTE SPECIFIC POPULATIONS APPROVED)

- **Crohn's Disease** Indicated for reducing signs and symptoms and inducing and maintaining clinical remission in adult patients with moderately to severely active Crohn's disease who have had an inadequate response to conventional therapy. Also, indicated for reducing the number of draining enterocutaneous and rectovaginal fistulas and maintaining fistula closure in adult patients with fistulizing Crohn's disease.
- **Pediatric Crohn's Disease** Indicated for reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients 6 years of age and older with moderately to severely active Crohn's disease who have had an inadequate response to conventional therapy.
- **Ulcerative Colitis** Indicated for reducing signs and symptoms, inducing and maintaining clinical remission and mucosal healing, and eliminating corticosteroid use in adult patients with moderately to severely active ulcerative colitis who have had an inadequate response to conventional therapy.
- **Pediatric Ulcerative Colitis** Indicated for reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients 6 years of age and older with moderately to severely active ulcerative colitis who have had an inadequate response to conventional therapy.
- **Rheumatoid Arthritis** Indicated in combination with methotrexate, for reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active rheumatoid arthritis.
- **Ankylosing Spondylitis** Indicated for reducing signs and symptoms in patients with active ankylosing spondylitis

RENFLEXIS® (INFLIXIMAB-ABDA) *(CONTINUED)*

INFLIXIMAB INDICATIONS (NOTE SPECIFIC POPULATIONS APPROVED) *(CONTINUED)*

- **Psoriatic Arthritis** Indicated for reducing signs and symptoms of active arthritis, inhibiting the progression of structural damage, and improving physical function in patients with psoriatic arthritis.
- **Plaque Psoriasis** Indicated for the treatment of adult patients with chronic severe (i.e., extensive and/or disabling) plaque psoriasis who are candidates for systemic therapy and when other systemic therapies are medically less appropriate. Therapy should only be administered to patients who will be closely monitored and have regular follow-up visits with a physician.
- Off Label Uses: **Sarcoidosis** (Has been used for the treatment of refractory sarcoidosis).

Drug Name:	Renflexis® (Infliximab-abda)
Diagnosis:	Crohn's Disease or Fistulizing Crohn's Disease
Approval Length:	24 months

Initial Criteria:

- **One** of the following diagnoses:
  - Moderately to severely active Crohn's disease
  - Fistulizing Crohn's disease; **AND**
- Prescribed by or in consultation with a gastroenterologist; **AND**
- Trial and failure, contraindication, or intolerance to one of the following conventional therapies:
  - 6-mercaptopurine (Purinethol)
  - Azathioprine (Imuran)
  - Corticosteroids (e.g., prednisone, methylprednisolone)
  - Methotrexate (Rheumatrex, Trexall)

Renewal Criteria:

- Documentation of positive clinical response to infliximab therapy.

Drug Name:	Renflexis® (Infliximab-abda)
Diagnosis:	Ulcerative Colitis
Approval Length:	24 months

Initial Criteria:

- Diagnosis of moderately to severely active ulcerative colitis; **AND**
- Prescribed by or in consultation with a gastroenterologist; **AND**
- Trial and failure, contraindication, or intolerance to one of the following conventional therapies: [3]
  - 6-mercaptopurine (Purinethol®)
  - Aminosalicylate (e.g., mesalamine [Asacol®, Pentasa®, Rowasa®], olsalazine [Dipentum®], sulfasalazine [Azulfidine®, sulfazine])
  - Azathioprine (Imuran®)
  - Corticosteroids (e.g., prednisone, methylprednisolone

Renewal Criteria:

- Documentation of positive clinical response to infliximab therapy.

RENFLEXIS® (INFLIXIMAB-ABDA) *(CONTINUED)*

Drug Name:	Renflexis® (Infliximab-abda)
Diagnosis:	Rheumatoid Arthritis (RA)
Approval Length:	24 months

Initial Criteria:

- Diagnosis of moderately to severely active RA; **AND**
- Prescribed by or in consultation with a rheumatologist; **AND**
- **One** of the following:
  - Patient is receiving concurrent therapy with methotrexate (Rheumatrex®, Trexall®); **OR**
  - Trial and failure, contraindication, or intolerance to methotrexate (Rheumatrex®, Trexall®)

Renewal Criteria:

- Documentation of positive clinical response to infliximab therapy.

Drug Name:	Renflexis® (Infliximab-abda)
Diagnosis:	Ankylosing Spondylitis (AS)
Approval Length:	24 months

Initial Criteria:

- Diagnosis of active ankylosing spondylitis; **AND**
- Prescribed by or in consultation with a rheumatologist; **AND**
- Trial and failure, contraindication, or intolerance to two NSAIDs (e.g., diclofenac, ibuprofen, indomethacin, meloxicam, naproxen)

Renewal Criteria:

- Documentation of positive clinical response to infliximab therapy

Drug Name:	Renflexis® (Infliximab-abda)
Diagnosis:	Psoriatic Arthritis (PsA)
Approval Length:	24 months

Initial Criteria:

- Diagnosis of active PsA; **AND**
- Prescribed by or in consultation with **one** of the following:
  - Dermatologist
  - Rheumatologist

Renewal Criteria:

- Documentation of positive clinical response to infliximab therapy

RENFLEXIS® (INFLIXIMAB-ABDA) *(CONTINUED)*

Drug Name:	Renflexis® (Infliximab-abda)
Diagnosis:	Plaque Psoriasis
Approval Length:	24 months

Initial Criteria:

- Diagnosis of chronic severe (i.e., extensive and/or disabling) plaque psoriasis; **AND**
- Prescribed by or in consultation with a dermatologist

Renewal Criteria:

- Documentation of positive clinical response to infliximab therapy as evidenced by **one** of the following:
  - Reduction the body surface area (BSA) involvement from baseline
  - Improvement in symptoms (e.g., pruritus, inflammation) from baseline

Drug Name:	Renflexis® (Infliximab-abda)
Diagnosis:	Sarcoidosis [Off-label]
Approval Length:	24 months
Therapy Stage:	Initial Authorization

Initial Criteria:

- Diagnosis of sarcoidosis; **AND**
- Prescribed by or in consultation with one of the following:
  - Pulmonologist
  - Dermatologist
  - Ophthalmologist
- Trial and failure, contraindication, or intolerance to one corticosteroid (e.g., prednisone); **AND**
- Prescribed by or in consultation with a pulmonologist; **AND**
- Trial and failure, contraindication, or intolerance to one immunosuppressant [e.g., methotrexate (Rheumatrex, Trexall), Cytoxan (cyclophosphamide), or Imuran (azathioprine)]

Renewal Criteria:

- Documentation of positive clinical response to infliximab therapy.

CIMZIA® (CERTOLIZUMAB PEGOL)

CIMZIA®(CERTOLIZUMAB PEGOL) INDICATIONS (NOTE SPECIFIC POPULATIONS APPROVED)

- **Crohn's disease:** Indicated for reducing signs and symptoms of Crohn's disease (CD) and maintaining clinical response in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy.
- **Rheumatoid arthritis:** Indicated for the treatment of adults with moderately to severely active rheumatoid arthritis.
- **Psoriatic arthritis:** Indicated for the treatment of adult patients with active psoriatic arthritis (PsA).
- **Ankylosing spondylitis:** Indicated for the treatment of adults with active ankylosing spondylitis.
- **Plaque psoriasis:** Indicated for the treatment of adults with moderate-to-severe plaque psoriasis (PsO) who are candidates for systemic therapy or phototherapy.
- **Non-radiographic axial spondyloarthritis:** Indicated for the treatment of adults with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation.

CIMZIA® (CERTOLIZUMAB PEGOL) *(CONTINUED)*

CIMZIA® (CERTOLIZUMAB PEGOL) INDICATIONS (NOTE SPECIFIC POPULATIONS APPROVED) *(CONTINUED)*

Drug Name:	Cimzia® (certolizumab pegol)
Diagnosis:	Crohn's disease
Approval Length:	Initial: 16 weeks; Renewal: 12 months

Initial Criteria:

- Diagnosis of moderately to severely active Crohn's disease; **AND**
- Trial and failure, contraindication, or intolerance to **one** of the following conventional therapies:
  - 6-mercaptopurine (Purinethol®)
  - Azathioprine (Imuran®)
  - Corticosteroids (e.g., prednisone, methylprednisolone)
  - Methotrexate (Rheumatrex®, Trexall®); **AND**
- Trial and failure, contraindication, or intolerance to Humira; **AND**
- Prescribed by or in consultation with a gastroenterologist

NOTE: The recommended initial adult dose of Cimzia® is 400 mg (given as two subcutaneous injections of 200 mg) initially, and at Weeks 2 and 4. In patients who obtain a clinical response, the recommended maintenance regimen is 400 mg every four weeks.

Renewal Criteria:

- Documentation of positive clinical response to Cimzia® therapy

Drug Name:	Cimzia® (certolizumab pegol)
Diagnosis:	Rheumatoid arthritis (RA)
Approval Length:	Initial: 12 months; Renewal: 12 months

Initial Criteria:

- Diagnosis of moderately to severely active RA; **AND**
- Prescribed by or in consultation with a rheumatologist; **AND**
- Trial and failure, contraindication or intolerance to **one** non-biologic DMARDs [e.g., Rheumatrex®/Trexall® (methotrexate), Arava® (leflunomide), Azulfidine® (sulfasalazine)]; **AND**
- Trial and failure, contraindication or intolerance to Humira® **and** Enbrel® **and** Xeljanz®

Renewal Criteria:

- Documentation of positive clinical response to Cimzia® therapy

CIMZIA® (CERTOLIZUMAB PEGOL) *(CONTINUED)*

CIMZIA® (CERTOLIZUMAB PEGOL) INDICATIONS (NOTE SPECIFIC POPULATIONS APPROVED) *(CONTINUED)*

Drug Name:	Cimzia® (certolizumab pegol)
Diagnosis:	Psoriatic arthritis
Approval Length:	Initial: 12 months; Renewal: 12 months

Initial Criteria:

- Diagnosis of active psoriatic arthritis; **AND**
- Trial and failure, contraindication or intolerance to Humira® **and** Enbrel® **and** Xeljanz® **and** Otezla®; **AND**
- Prescribed by or in consultation with one of the following:
  - Dermatologist
  - Rheumatologist

Renewal Criteria:

- Documentation of positive clinical response to Cimzia® therapy

Drug Name:	Cimzia® (certolizumab pegol)
Diagnosis:	Ankylosing spondylitis
Approval Length:	Initial: 12 months; Renewal: 12 months

Initial Criteria:

- Diagnosis of active ankylosing spondylitis; **AND**
- Prescribed by or in consultation with a rheumatologist; **AND**
- Trial and failure, contraindication, or intolerance to two NSAIDs; **AND**
- Trial and failure, contraindication, or intolerance to Humira® **and** Enbrel®

Renewal Criteria:

- Documentation of positive clinical response to Cimzia® therapy

Drug Name:	Cimzia® (certolizumab pegol)
Diagnosis:	Plaque psoriasis
Approval Length:	Initial: 12 months; Renewal: 12 months

Initial Criteria:

- Diagnosis of moderate to severe plaque psoriasis; **AND**
- Prescribed by or in consultation with a dermatologist; **AND**
- Trial and failure, contraindication, or intolerance to Humira **and** Enbrel® **and** Otezla®

Renewal Criteria:

- Documentation of positive clinical response to Cimzia® therapy as evidenced by **one** of the following:
  - Reduction the body surface area (BSA) involvement from baseline
  - Improvement in symptoms (e.g., pruritus, inflammation) from baseline

CIMZIA® (CERTOLIZUMAB PEGOL) *(CONTINUED)*

CIMZIA® (CERTOLIZUMAB PEGOL) INDICATIONS (NOTE SPECIFIC POPULATIONS APPROVED) *(CONTINUED)*

Drug Name:	Cimzia® (certolizumab pegol)
Diagnosis:	Non-radiographic axial spondyloarthritis
Approval Length:	Initial: 12 months; Renewal: 12 months

Initial Criteria:

- Diagnosis of non-radiographic axial spondyloarthritis; **AND**
- Patient has objective signs of inflammation (e.g., C-reactive protein [CRP] levels above the upper limit of normal and/or sacroiliitis on magnetic resonance imaging [MRI], indicative of inflammatory disease, but without definitive radiographic evidence of structural damage on sacroiliac joints.); **AND**
- Prescribed by or in consultation with a rheumatologist; **AND**
- Trial and failure, contraindication, or intolerance to two NSAIDs

Renewal Criteria:

- Documentation of positive clinical response to Cimzia® therapy

COSENTYX® (SECUKINUMAB)

COSENTYX® (SECUKINUMAB) INDICATIONS (NOTE SPECIFIC POPULATIONS APPROVED)

- **Plaque psoriasis:** Indicated for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy.
- **Psoriatic arthritis:** Indicated for the treatment of adult patients with active psoriatic arthritis.
- **Ankylosing spondylitis:** Indicated for the treatment of adult patients with active ankylosing spondylitis.

Drug Name:	Cosentyx® (secukinumab)
Diagnosis:	Plaque psoriasis
Approval Length:	Initial: 12 months; Renewal: 12 months

Initial Criteria:

- Diagnosis of moderate to severe plaque psoriasis; **AND**
- Prescribed by or in consultation with a dermatologist; **AND**
- Trial and failure, contraindication, or intolerance to Humira® **and** Enbrel® **and** Otezla®

Renewal Criteria:

- Documentation of positive clinical response to Cosentyx® therapy

COSENTYX® (SECUKINUMAB) *(CONTINUED)*

COSENTYX® (SECUKINUMAB) INDICATIONS (NOTE SPECIFIC POPULATIONS APPROVED) *(CONTINUED)*

Drug Name:	Cosentyx® (secukinumab)
Diagnosis:	Ankylosing spondylitis
Approval Length:	Initial: 12 months; Renewal: 12 months

Initial Criteria:

- Diagnosis of active ankylosing spondylitis; **AND**
- Prescribed by or in consultation with a rheumatologist; **AND**
- Trial and failure, contraindication, or intolerance to **two** non-steroidal anti-inflammatory drugs (NSAIDs) (e.g., diclofenac, ibuprofen, indomethacin, meloxicam, naproxen); **AND**
- Trial and failure, contraindication, or intolerance to Humira® **and** Enbrel®

Renewal Criteria:

- Documentation of positive clinical response to Cosentyx® therapy

Drug Name:	Cosentyx® (secukinumab)
Diagnosis:	Psoriatic arthritis
Approval Length:	Initial: 12 months; Renewal: 12 months

Initial Criteria:

- Diagnosis of active psoriatic arthritis; **AND**
- Prescribed by or in consultation with one of the following:
  - Dermatologist
  - Rheumatologist**; AND**
- Trial and failure, contraindication or intolerance to Humira® **and** Enbrel® **and** Xeljanz® **and** Otezla®

Renewal Criteria:

- Documentation of positive clinical response to Cosentyx® therapy.

RITUXAN (RITUXIMAB)

RITUXAN (RITUXIMAB) INDICATIONS (NOTE SPECIFIC POPULATIONS APPROVED)

Indications:

- **Non-Hodgkin Lymphoma (NHL)** Indicated for the treatment of patients with: a. Relapsed or refractory, low-grade or follicular, CD20-positive, B-cell non-Hodgkin's lymphoma as a single agent. b. Previously untreated diffuse large B-cell, CD20-positive non-Hodgkin's lymphoma in combination with CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) or other anthracycline-based chemotherapy regimens. c. Previously untreated follicular, CD20-positive, B-cell non-Hodgkin's lymphoma in combination with first-line chemotherapy and, in patients achieving a complete or partial response to Rituxan in combination with chemotherapy, as a single-agent maintenance therapy. d. Non-progressing (including stable disease) low-grade, CD20-positive, B-cell non-Hodgkin's lymphoma, as a single agent, after first-line CVP (cyclophosphamide, vincristine, and prednisone) chemotherapy. Limitations of Use: Rituxan is not recommended for use in patients with severe, active infections.
- **Rheumatoid Arthritis (RA)** In combination with methotrexate, is indicated for the treatment of adult patients with moderately- to severely-active rheumatoid arthritis who have had an inadequate response to one or more TNF antagonist therapies. Limitation of Use: Rituxan is not recommended for use in patients with severe, active infections.

RITUXAN (RITUXIMAB) *(CONTINUED)*

RITUXAN (RITUXIMAB) INDICATIONS (NOTE SPECIFIC POPULATIONS APPROVED) (CONTINUED)

- **Chronic Lymphocytic Leukemia (CLL)** Indicated for the treatment of patients with previously untreated and previously treated CD20-positive CLL in combination fludarabine and cyclophosphamide (FC). Limitations of Use: Rituxan is not recommended for use in patients with severe, active infections.
- **Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA)** Indicated for the treatment of adult patients with Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA) in combination with glucocorticoids. Limitations of Use: Rituxan is not recommended for use in patients with severe, active infections.
- **Pemphigus Vulgaris** Indicated for the treatment of moderate to severe Pemphigus Vulgaris (PV) in adult patients.

Off Label Uses:

- **Immune Thrombocytopenic Purpura (ITP)** Has been used for the treatment of immune or idiopathic thrombocytopenic purpura. [1,2] Overall response rates of 35% to 52% in patients with refractory idiopathic thrombocytopenic purpura. [3,4]
- **Waldenström's Macroglobulinemia** Has been used for the treatment of relapsed/refractory Waldenström's macroglobulinemia. Rituximab monotherapy (1 to 8 cycles) has shown efficacy in limited studies.

Drug Name:	Rituxan (rituximab)
Diagnosis:	Rheumatoid Arthritis (RA)
Approval Length:	Initial: 1 month; Renewal: 1 month

Initial Criteria:

- Diagnosis of moderately- to severely-active rheumatoid arthritis; **AND**
- **ONE** of the following:
  - Patient is concurrently on methotrexate; **OR**
  - History of contraindication or intolerance to methotrexate**; AND**
- Trial and failure, contraindication, or intolerance to **TWO** of the following: Humira®, Enbrel®, Xeljanz®; **AND**
- For new starts only, patient must have a documented failure, contraindication, intolerance, or ineffective response to a trial of Truxima; **AND**
- Prescribed by or in consultation with a rheumatologist

Renewal Criteria:

- Documentation of positive clinical response to Rituxan therapy; **AND**
- At least 16 weeks have elapsed since last course of therapy

RITUXAN (RITUXIMAB) *(CONTINUED)*

Drug Name:	Rituxan (rituximab)
Diagnosis:	Non-Hodgkin Lymphoma
Approval Length:	Initial: 12 months; Renewal: 12 months

Criteria:

1. **ONE** of the following:

- **BOTH** of the following:
  - Diagnosis of diffuse large B-cell, CD20-positive, non-Hodgkin's lymphoma
  - Used as first-line treatment in combination with CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) or other anthracycline-based chemotherapy regimens**; OR**
- **BOTH** of the following:
  - Diagnosis of follicular, CD20-positive, B-cell non-Hodgkin's lymphoma
  - Used as first-line treatment in combination with chemotherapy**; OR**
- **ALL** of the following:
  - Diagnosis of follicular, CD20-positive, B-cell non-Hodgkin's lymphoma
  - Patient achieved a complete or partial response to Rituxan in combination with chemotherapy
  - Followed by Rituxan used as monotherapy for maintenance therapy**; OR**
- **BOTH** of the following:
  - Diagnosis of low-grade, CD20-positive, B-cell non-Hodgkin's lymphoma; **AND**
  - **ONE** of the following:
    - Patient has stable disease following first-line treatment with CVP (cyclophosphamide, vincristine, prednisolone/ prednisone) chemotherapy
    - Patient achieved a partial or complete response following first-line treatment with CVP (cyclophosphamide, vincristine, prednisolone/ prednisone) chemotherapy**; OR**
- Diagnosis of relapsed or refractory, low grade or follicular CD20-positive, B-cell non-Hodgkin's lymphoma; **AND**

2. Prescribed by or in consultation with an oncologist/hematologist; **AND**
3. For new starts only, patient must have a documented failure, contraindication, intolerance, or ineffective response to a trial of Truxima

Drug Name:	Rituxan (rituximab)
Diagnosis:	Chronic Lymphocytic Leukemia
Approval Length:	Initial: 12 months; Renewal: 12 months

Criteria:

- Diagnosis of chronic lymphocytic leukemia; **AND**
- Used in combination with fludarabine and cyclophosphamide; **AND**
- Prescribed by or in consultation with an oncologist/hematologist; **AND**
- For new starts only, patient must have a documented failure, contraindication, intolerance, or ineffective response to a trial of Truxima

RITUXAN (RITUXIMAB) *(CONTINUED)*

Drug Name:	Rituxan (rituximab)
Diagnosis:	Immune or Idiopathic Thrombocytopenic Purpura (Off-Label)
Approval Length:	Initial: 12 months; Renewal: 12 months

Criteria:

- Diagnosis of immune or idiopathic thrombocytopenic purpura (off-label); **AND**
- Prescribed by or in consultation with a hematologist/oncologist; **AND**
- Trial and failure, contraindication, or intolerance to at least **ONE** of the following:
  - Glucocorticoids (e.g., prednisone, methylprednisolone)
  - Immunoglobulins (e.g., IVIG)
  - Splenectomy**; AND**
- Documented platelet count of less than 50 x 10^9/L
- For new starts only, patient must have a documented failure, contraindication, intolerance, or ineffective response to a trial of Truxima

Drug Name:	Rituxan (rituximab)
Diagnosis:	Pemphigus Vulgaris
Approval Length:	Initial: 12 months; Renewal: 12 months

Initial Criteria:

- Diagnosis of moderate to severe pemphigus vulgaris; **AND**
- Prescribed by or in consultation with a dermatologist.
- For new starts only, patient must have a documented failure, contraindication, intolerance, or ineffective response to a trial of Truxima

Renewal Criteria:

- Documentation of positive clinical response to Rituxan therapy

Drug Name:	Rituxan (rituximab)
Diagnosis:	Waldenström's Macroglobulinemia
Approval Length:	Initial: 12 months; Renewal: 12 months

Criteria:

- Diagnosis of relapsed/refractory Waldenström's macroglobulinemia (off-label); **AND**
- For new starts only, patient must have a documented failure, contraindication, intolerance, or ineffective response to a trial of Truxima

RITUXAN (RITUXIMAB) *(CONTINUED)*

Drug Name:	Rituxan (rituximab)
Diagnosis:	Wegener's Granulomatosis and Microscopic Polyangiitis
Approval Length:	Initial: 3 months; Renewal: 3 months

Criteria:

- One of the following diagnoses:
  - Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis)
  - Microscopic Polyangiitis**; AND**
- One of the following:
  - Patient is concurrently on glucocorticoids (e.g., prednisone) **; OR**
  - History of contraindication or intolerance to glucocorticoids (e.g., prednisone) **; AND**
- Prescribed by or in consultation with one of the following:
  - Nephrologist
  - Pulmonologist
  - Rheumatologist
- For new starts only, patient must have a documented failure, contraindication, intolerance, or ineffective response to a trial of Truxima.

PREFERRED – PA REQUIRED
Enbrel® SRCLK, Enbrel® syringe, Enbrel® mini cartridge (etanercept)
Humira® Ped Crohn's
Humira® pen (adalimumab)
Humira® pen Psoriasis-Uveitis
Humira® syringe (adalimumab)
Otezla® (apremilast)
Renflexis® (Infliximab-abda)
Xeljanz® tablet (tofacitinib)

IMMUNOSUPPRESSANTS

Length of Authorization:	1 Year
Initiative:	SPC: Miscellaneous PA required (IE 2462 / NCPDP 75 – HICL) MNC: Non-Formulary Product (IE 50698 / MR – GSN PatOverride) – Purixan and Zortress

ZORTRESS

- Prophylaxis of organ rejection in adult patients at low-moderate immunologic risk receiving a kidney transplant, administered in combination with basiliximab induction and concurrently with reduced doses of cyclosporine and corticosteroids. Therapeutic drug monitoring of everolimus and cyclosporine is recommended for all patients.
- Prophylaxis of allograft rejection in adult patients receiving a liver transplant, administered no earlier than 30 days post-transplant concurrently in combination with reduced doses of tacrolimus and with corticosteroids. Therapeutic drug monitoring of everolimus and tacrolimus is recommended for all patients receiving these products.

PURIXAN* (6-MERCAPTOPURINE)

Initial Criteria (Purixan):

- Diagnosis of acute lymphatic leukemia (ALL); **OR**
- If requesting for Off-label use, use oncology off-label guidelines; **AND**
- ONE of the following:
  - History of contraindication or intolerance to generic mercaptopurine tablets; **OR**
  - Patient is unable to swallow tablets.

Renewal Criteria (Purixan):

- Patient does not show evidence of progressive disease while on Purixan therapy
- Approval length: 12 months

ASTAGRAF XL

- Diagnosis of prophylaxis of organ rejection in kidney transplant patients in combination with other immunosuppressants; **AND**
- Must have tried tacrolimus immediate release formulations

PREFRRED – PA REQUIRED
Astagraf XL® (tacrolimus)
Mercaptopurine tablets

INCRELEX® (MECASERMIN)

Length of Authorization:	12 Months
Initiative:	SPC: Growth Hormone (IE 2462 / NCPDP 75 – HICL)

CLINICAL CRITERIA FOR INITIAL APPROVAL

- Diagnosis of **Growth Failure with Primary IGFD**
  - Patient has severe primary insulin-like growth factor-1 deficiency; **AND**
  - Height standard deviation score less than or equal to -3.0; **AND**
  - Basal IGF-1 standard deviation score is less than or equal to -3.0; **AND**
  - Other secondary causes of IGFD have been excluded (e.g., under-nutrition, hepatic disease, GHD, etc.); **AND**
  - Normal or elevated growth hormone (stimulated: greater than 10 ng/Ml; unstimulated: greater than 5 ng/Ml); **AND**
  - Patient's age is between 2 and 18 years; **AND**
  - Patient's bone epiphyses are NOT closed
- Diagnosis of **Growth Failure with GH gene deletion**
  - Patient has growth hormone gene deletion and has developed neutralized antibodies to growth hormone; **AND**
  - Patient's age is between 2 and 18 years; **AND**
  - Patient's bone epiphyses are NOT closed

CLINICAL CRITERIA FOR RENEWAL

- Disease response with improvement in patient's symptoms; **AND**
- Absence of unacceptable toxicity from the drug.
  Examples include hypersensitivity/allergic reactions, intracranial hypertension, lymphoid tissue hypertrophy, progression of scoliosis, Slipped Capital Femoral Epiphysis (new onset limp, hip/knee pain), uncontrolled hyperglycemia

INHALED BETA AGONISTS COMBINATIONS

Length of Authorization:	1 Year
Initiative:	MNC: Beta-Adrenergic Agents (IE 2462 / NCPDP 75 – HICL)

STEP CRITERIA NO GRANDFATHERING – SYMBICORT®, ADVAIR® HFA (AGES 4 – 12 YEARS OLD ONLY), AND ADVAIR DISKUS®

Patient must have a trial of **one** steroid inhaler first.

The preferred steroid inhalers are:

- Pulmicort Flexhaler® (budesonide)
- Flovent HFA® (fluticasone propionate)
- Flovent Diskus® (fluticasone propionate)
- Asmanex Twisthaler (Mometasone)

ADDITIONAL INFORMATION TO AID IN THE FINAL DECISION

Auto PA coding will look back 2 years and allow claim to pay if history of one steroid inhaler.

- Trial of any steroid inhaler (whether it is preferred or non-preferred) will satisfy the step criteria.
- It is acceptable to use paid claims history to see if the member has previous paid claims for a steroid inhaler in the past. If there is a paid claim, this will satisfy the step criteria (claim will automatically pay if there is a paid claim of a steroid inhaler within the past 180 days).

PREFERRED (STEP CRITERIA APPLIES)
Dulera® **(See step criteria above)**
Symbicort® **(See step criteria above)**
Advair Diskus® **(See step criteria above)**
Advair® HFA (age limit of 4–12 years old) **(See step criteria above)**

INLYTA® (AXITINIB)

Length of Authorization:	6 Months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75 – HICL, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Renal Cell Carcinoma**

- Patient is at least 18 years of age; **AND**
- Patient will avoid concomitant use with STRONG CYP3A4/5 inducers (e.g., rifampin, carbamazepine, St. John's Wort); **AND**
- Patient will avoid concomitant use with MODERATE CYP3A4/5 inducers (e.g., bosentan, efavirenz, etravirine, modafinil, nafcillin), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **AND**
- Patient will avoid concomitant use with strong CYP3A4/5 inhibitors (e.g., itraconazole, ketoconazole, clarithromycin, grapefruit, grapefruit juice), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **AND**
- Patient has advanced disease; **AND**
  - Used as first-line therapy in combination with avelumab **or** pembrolizumab ; **AND**
  - Used as second-line therapy after failure of one prior systemic therapy ; **AND**
    - Used as single-agent therapy; **OR**
- Patient has relapsed or stage IV disease; **AND**
  - Used for non-clear cell histology; **AND**
    - Used as single-agent therapy; **OR**
  - Used for clear-cell histology; **AND**
    - Used as a single-agent as subsequent therapy; **OR**
    - Used in combination with pembrolizumab; **OR**
    - Used in combination with avelumab as first-line therapy

Diagnosis of **Thyroid Carcinoma (Follicular Carcinoma/Hurthle Cell Carcinoma/Papillary Carcinoma)**

- Patient is at least 18 years of age; **AND**
- Patient will avoid concomitant use with STRONG CYP3A4/5 inducers (e.g., rifampin, carbamazepine, St. John's Wort); **AND**
- Patient will avoid concomitant use with MODERATE CYP3A4/5 inducers (e.g., bosentan, efavirenz, etravirine, modafinil, nafcillin), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **AND**
- Patient will avoid concomitant use with strong CYP3A4/5 inhibitors (e.g., itraconazole, ketoconazole, clarithromycin, grapefruit, grapefruit juice), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **AND**
- Patient has unresectable recurrent, persistent, or distant metastatic disease; **AND**
- Patient has progressive and/or symptomatic disease that is not susceptible to radioactive iodine (RAI) therapy; **AND**
- Other systemic therapies are not available or appropriate

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug (e.g., arterial and venous thromboembolic events, hemorrhage, hypertension/hypertensive crisis, cardiac failure, gastrointestinal perforation and fistula formation, impaired wound healing, hepatic impairment/hepatotoxicity, thyroid dysfunction, reversible posterior leukoencephalopathy syndrome [RPLS], proteinuria, major adverse cardiovascular events [MACE])

INTERFERONS

Length of Authorization:	1 Year
Initiative:	SPC: Miscellaneous PA required (IE 2462 / NCPDP 75 – HICL)

CRITERIA

- Patients > 1 year of age: Chronic hepatitis; **OR**
- Patients > 18 years of age: Condyloma acuminata, hairy cell leukemia, malignant melanoma, AIDS-related Kaposi's sarcoma, follicular non-Hodgkin's lymphoma

COVERED – PA REQUIRED
Alferon N® (interferon alfa-n3)

INTERLEUKIN-5 ANTAGONIST MONOCLONAL ANTIBODIES (NUCALA® [MEPOLIZUMAB], FASENRA® [BENRALIZUMAB], CINQAIR® [RESLIZUMAB])

Length of Authorization:	6 months initial and is eligible for renewal
Initiative:	SPC: Respiratory Anti-inflammatory Agents: (IE 2462 / NCPDP 75 – GSN) – For Nucala auto-injector and syringe MNC: Non-Formulary Product (IE 50698 / MR – GSN PatOverride) – For Fasenra, Cinqair, Nucala vial

Note for Fasenra, Cinqair, Nucala vial: Patient must have a failure, contraindication, or intolerance to a trial of Nucala® auto-injector or syringe.

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Severe Asthma:**

- Patient must be at least
  - 6 years of age (Nucala®) (12 years of age for subcutaneous self-administered)
  - 12 years of age (Fasenra®); **OR**
  - 18 years of age (Cinqair®); **AND**
- Patient must have severe* disease; **AND**
- Patient must have asthma with eosinophilic phenotype defined as blood eosinophils
  - ≥ 300 cells/µL within previous 12 months or ≥ 150 cells/µL within 6 weeks of dosing (Nucala®);
  - ≥ 150 cells/µL within 6 weeks of dosing (Fasenra®)
  - ≥ 400 cells/µL within 4 weeks of dosing (Cinqair®)
- Must not be used in combination with another monoclonal antibody (e.g., reslizumab, benralizumab, mepolizumab, omalizumab); **AND**
- Must be used for add-on maintenance treatment in patients **regularly** receiving **both** of the following:
  - Medium to high-dose inhaled corticosteroids; **AND**
  - An additional controller medication (e.g., long-acting beta agonist, leukotriene modifiers); **AND**
- Will not be used for treatment acute bronchospasm or status asthmaticus; **AND**
- **For Fasenra and Cinqair only:** Must **not** be used for treatment of other eosinophilic conditions (e.g., allergic bronchopulmonary aspergillosis/mycosis, Churg-Strauss syndrome, hypereosinophilic syndrome, etc.)
- Patient must have two or more exacerbations in the previous year requiring daily oral corticosteroids for at least 3 days (in addition to the regular maintenance therapy defined above); **AND**
- Baseline measurement of at least one of the following for assessment of clinical status:
  - Use of systemic corticosteroids
  - Use of inhaled corticosteroids
  - Number of hospitalizations, ER visits, or unscheduled visits to healthcare provider due to condition
  - Forced expiratory volume in 1 second (FEV_1)

***Components of severity for classifying asthma as severe may include any of the following (not all inclusive):**
• Symptoms throughout the day • Nighttime awakenings, often 7x/week • SABA use for symptom control occurs several times per day • Extremely limited normal activities • Lung function (percent predicted FEV_1) <60% • Exacerbations requiring oral systemic corticosteroids are generally more frequent and intense relative to moderate asthma

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Eosinophilic Granulomatosis with Polyangiitis (EGPA)/Churg-Strauss Syndrome: (Nucala® only)**

- Patient must be at least 18 years of age; **AND**
- Must not be used in combination with another monoclonal antibody (e.g., reslizumab, benralizumab, mepolizumab, omalizumab); **AND**
- Patient has a confirmed diagnosis of EGPA (aka Churg-Strauss syndrome); **AND**
- Patient must have blood eosinophils ≥ 150 cells/µL within 6 weeks of dosing; **AND**
- Patient has been on stable doses of concomitant oral corticosteroid therapy for at least 4 weeks (i.e., prednisone or prednisolone at a dose of 7.5 mg/day); **AND**
- Physician has assessed baseline disease severity utilizing an objective measure/tool (e.g., Birmingham Vasculitis Activity Score [BVAS], history of asthma symptoms and/or exacerbations, duration of remission, rate of relapses).

Eosinophilic granulomatosis polyangiitis (EGPA) defined as all of the following:
• History or presence of asthma • Blood eosinophil level ≥ 10% or an absolute eosinophil count > 1,000 cells/mm^3 • Two or more of the following criteria: – Histopathologic evidence of eosinophilic vasculitis, perivascular eosinophilic infiltration or eosinophil rich granulomatous inflammation – Neuropathy – Pulmonary infiltrates – Sinonasal abnormalities – Cardiomyopathy – Glomerulonephritis – Alveolar hemorrhage – Palpable purpura – Antineutrophil Cytoplasmic Antibody (ANCA) positivity

Diagnosis of **Hypereosinophilic Syndrome (HES): (Nucala® only)**

- Patient is at least 12 years of age; **AND**
- Must not be used in combination with another monoclonal antibody (e.g., benralizumab, mepolizumab, omalizumab); **AND**
- Patient has been diagnosed with HES for at least 6 months prior to starting treatment; **AND**
- Patient does NOT have non-hematologic secondary HES (e.g., drug hypersensitivity, parasitic helminth infection, HIV infection, non-hematologic malignancy) or FIP1L1-PDGFRα kinase-positive HES; **AND**
- Patient has a history of 2 or more HES flares within the previous 12 months (e.g., documented HES-related worsening of clinical symptoms or blood eosinophil counts requiring an escalation in therapy); **AND**
- Patient must have blood eosinophils ≥ 1000 cells/µL within 4 weeks of dosing; **AND**
- Used in combination with stable doses of at least one other HES therapy (e.g., oral corticosteroids, immunosuppressive agents, cytotoxic therapy, etc.).

CLINICAL CRITERIA FOR RENEWAL

- Must not be used in combination with another monoclonal antibody (e.g., benralizumab, mepolizumab, omalizumab); **AND**
- Absence of unacceptable toxicity from the drug (e.g., parasitic [helminth] infection, herpes zoster infection, severe hypersensitivity reactions); **AND**
- Severe asthma:
  - Improvement in asthma symptoms or asthma exacerbations as evidenced by decrease in one or more of the following:
    - Use of systemic corticosteroids
    - Two-fold or greater decrease in inhaled corticosteroid use for at least 3 days
    - Hospitalizations
    - ER visits
    - Unscheduled visits to healthcare provider; **OR**
  - Improvement from baseline in forced expiratory volume in 1 second (FEV_1)
- **Eosinophilic granulomatosis with polyangiitis/ Churg-Strauss Syndrome: (Nucala® only)**
  - Disease response as indicated by improvement in signs and symptoms compared to baseline as evidenced in one or more of the following:
    - Patient is in remission [defined as a Birmingham Vasculitis Activity Score (BVAS) score = 0 and a prednisone/prednisolone daily dose of ≤ 7.5 mg]
    - Decrease in maintenance dose of systemic corticosteroids
    - Improvement in BVAS score compared to baseline
    - Improvement in asthma symptoms or asthma exacerbations
    - Improvement in duration of remission or decrease in the rate of relapses
- **Hypereosinophilic Syndrome (HES): (Nucala® only)**
  - Disease response as indicated by a decrease in HES flares from baseline (**Note:** An HES flare is defined as worsening of clinical signs and symptoms of HES or increasing eosinophils (on at least 2 occasions), resulting in the need to increase oral corticosteroids or increase/add cytotoxic or immunosuppressive HES therapy)

INTRA-ARTICULAR OSTEOARTHRITIS AGENTS (INTRA-ARTICULAR HYALURONIC ACIDS)

Length of Authorization:	6 months and may be renewed
Initiative:	MNC: Drug Exclusion (IE 2211/NCPDP 70 – HICL) – For Euflexxa, Durolane, Gelsyn-3 MNC: Non-Formulary Product (IE 50698 / MR – GSN PatOverride) and MNC: Drug Exclusion (IE 2211/NCPDP 70 – HICL) – For the non-formulary agents

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Osteoarthritis** of the knee:

- Documented symptomatic osteoarthritis of the knee; **AND**
- The patient has had a trial and failure to BOTH of the following conservative methods that have not resulted in functional improvement after at least three months:
  - Non-Pharmacologic Approach (e.g., physical, psychosocial, or mind-body [e.g., exercise-land based or aquatic, physical therapy, tai chi, yoga, weight management, cognitive behavioral therapy, knee brace or cane, etc.]); **AND**
  - Pharmacologic approach (e.g., topical NSAIDs, oral NSAIDs with or without oral proton pump inhibitors, COX-2 inhibitors, topical capsaicin, acetaminophen, tramadol, duloxetine, etc.); **AND**
- The patient has failed to adequately respond to aspiration and injection of intra-articular steroids; **AND**
- Patient has not received therapy with intra-articular long-acting corticosteroid type drugs (i.e., Zilretta, etc.) within the previous 6 months of therapy; **AND**
- The patient reports pain that interferes with functional activities (e.g., ambulation, prolonged standing); **AND**
- Patient does not have any conditions that would preclude intra-articular injections (e.g., active joint infection, unstable joint, bleeding disorders, etc.); **AND**
- Patient must have a documented failure, contraindication, intolerance, or ineffective response of at least **TWO** of the following:
  - Euflexxa; **AND**
  - Durolane **OR** Gelsyn

CLINICAL CRITERIA FOR RENEWAL

- The patient shows disease response, as indicated by improvement in signs and symptoms of pain and a stabilization or improvement in functional capacity during the 6-month period following the previous series of injections as evidenced by objective measures; **AND**
- Absence of unacceptable toxicity from the previous injections (e.g., severe joint swelling and pain, severe infections, and anaphylactic or anaphylactoid reactions).

FORMULARY AGENTS (PA REQUIRED)	NON-FORMULARY AGENTS (PA REQUIRED)
Durolane	Gel-One
Euflexxa	GenVisc
Gelsyn-3	Hyalgan
	Hymovis
	Monovisc
	Orthovisc
	Supartz
	Synvisc
	Synvisc-One
	Trivisc
	Visco-3

INTRON-A (INTERFERON ALFA 2B)

Length of Authorization:	6 months, may be renewed (except Hepatitis B: adults HBeAg positive: up to 16 weeks ONLY; HBeAg negative: up to 48 weeks ONLY; Hepatitis B: Pediatrics (children 1-17 years) up to 24 weeks ONLY; Hepatitis C: 16 weeks initially and may be renewed every 16 weeks up to a total of 96 weeks)
Initiative:	SPC: Miscellaneous PA required (IE 2462 / NCPDP 75 – HICL)

CLINICAL CRITERIA

Hairy cell leukemia

- Adult patient (18 years or older)

Malignant Melanoma

- Adult patient (18 years or older); **AND**
- Must be used as single agent for adjuvant treatment; **OR**
- Therapy for metastatic or unresectable disease; **AND**
  - Used in combination with interleukin-2, and dacarbazine or temozolomide, and cisplatin or carboplatin; **AND**
  - Used as second-line or subsequent therapy for disease progression or after maximum clinical benefit from BRAF targeted therapy; **AND**
  - Patient has a performance status (PS) score of 0-2

Follicular Non-Hodgkin's lymphoma

- Adult patient (18 years or older); **AND**
- Must be used for initial treatment of clinically aggressive disease; **AND**
- Must be used in conjunction with anthracycline-containing chemotherapy

Condylomata acuminate

- Adult patient (18 years or older); **AND**
- Must be used intralesionally; **AND**
- Involves external surfaces of the genital and perianal areas; **AND**
- Prior failure to all of the following topical agents: Condylox (podofilox), Veregen (sinecatechins), Aldara (imiquimod), and trichloroacetic acid (TCA)

AIDS-Related Kaposi Sarcoma

- Adult patient (18 years or older)

Chronic Hepatitis B

- Patient must be at least 1 year of age; **AND**
- Patient must have been HBsAg positive for at least 6 months; **AND**
- Patient must not have decompensated cirrhosis; **AND**

Patients without cirrhosis

- Patient has elevated serum ALT > 2 times Upper Limit of Normal (ULN); **OR**
- Patient has evidence of significant histologic disease (e.g., significant inflammation and/or fibrosis) plus one of the following:
  - HBV DNA > 2,000 IU/Ml (HBeAg negative); **OR**
  - HBV DNA > 20,000 IU/Ml (HBeAg positive)

Patients with compensated cirrhosis

- HBV DNA > 2,000 IU/Ml; **OR**
- Patient has elevated serum ALT > 2 times Upper Limit of Normal (ULN)

CLINICAL CRITERIA *(CONTINUED)*

Bone Cancer – Giant Cell Tumor of the Bone

- Must be used as a single agent or combined with denosumab or radiation therapy for localized disease; **OR**
- Must be used as a single agent for metastatic disease

Renal cell carcinoma

- Must be used in combination with bevacizumab (Avastin®) as first-line therapy**; AND**
- Patient's disease must be relapsed or surgically unresectable stage IV disease; **AND**
- Patient's disease has predominant clear cell histology

Desmoid Tumors (Aggressive Fibromatosis)

- Must be used as low-dose single agent for primary, recurrent, or progressive disease

Mycosis Fungoides (MF)/Sezary Syndrome (SS)

Adult T-Cell Leukemia/Lymphoma

- Adult patient (18 years or older); **AND**
- Used in combination with zidovudine (Retrovir®) for chronic, smoldering, or acute disease; **OR**
- Used in combination with arsenic trioxide as one of the following:
  - As second line therapy in non-responders to first-line therapy; **OR**
  - Used in lymphoma; **OR**
  - Used as subsequent after high dose therapy/autologous stem cell rescue (HDT/ASCR)

Myelofibrosis

- Patient must have myelofibrosis that is: primary, post –polycythemia vera, or post-essential thrombocythemia; **AND**
- Patient must have symptomatic low-risk disease

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: elevated triglycerides; exacerbation of psoriasis and sarcoidosis; peripheral neuropathy; development of autoimmune disorders (thrombocytopenia, vasculitis, Raynaud's phenomenon, rheumatoid arthritis, lupus erythematosus, and rhabdomyolysis); pulmonary function impairment; liver function abnormalities; thyroid abnormalities; ocular symptoms; severe decreases in neutrophil (less than 0.5 x 10^9/L) or platelet counts (less than 25 x 10^9/L); **AND**
- Disease response with stabilization of disease or decrease in size of tumor/lesion or tumor/lesion spread; **OR**
- **Hepatitis B**: May not be renewed; **OR**
- **Myelofibrosis**: Treatment response with a decrease in spleen size or improvements in other myelofibrosis symptoms (such as fatigue, bone pain, frequent infections, fever, night sweats, easy bruising/bleeding, etc.)

IRESSA® (GEFITINIB)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75 – HICL, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Non-small cell lung cancer**

- Patient is at least 18 years old; **AND**
- Patient's tumor has EGFR exon 19 deletions or exon 21 (L858R) substitution mutations confirmed by an FDA-approved or CLIA-compliant test; **AND**
- Used as a single agent; **AND**
- Patient will avoid concomitant therapy with any of the following:
  - Coadministration with acid-reducing agents (i.e. proton pump inhibitors), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **OR**
  - Coadministration with CYP3A4 inhibitors (e.g., fluconazole, itraconazole), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **OR**
  - Coadministration with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, phenytoin, St. John's Wort), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **OR**
- Patient has advanced, metastatic, or recurrent disease (excluding locoregional recurrence or symptomatic local disease with no evidence of disseminated disease) or mediastinal lymph node recurrence with prior radiation therapy; **AND**
  - Used as first-line therapy; **OR**
  - Used as continuation therapy in patients with disease progression while on gefitinib for asymptomatic disease, symptomatic brain lesions, or isolated symptomatic systemic lesions

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug (e.g., interstitial lung disease, hepatotoxicity, gastrointestinal perforation, severe/persistent diarrhea, ocular disorders including keratitis, and bullous and exfoliative skin disorders)

IRON CHELATORS

Length of Authorization:	6 Months
Initiative:	MNC: Non-Formulary Product (IE 50698 / MR – GSN PatOverride)

CLINICAL CRITERIA FOR APPROVAL

SYPRINE® (TRIENTENE)

Diagnosis of **Wilson's Disease**

- Must be intolerant to penicillamine (1st line); **OR**
- Diagnosis of manganism (orphan designation)

DEFERASIROX (JADENU®, JADENU SPRINKLES®, EXJADE®)

INITIAL CRITERIA

Diagnosis of **Chronic Iron Overload Due to Blood Transfusions Demonstrated by Transfusion of at Least 100 mL/kg of Packed Red Blood Cells and a Serum Ferritin Consistently Greater than 1,000 mcg/L**

- Patient is over 2 years of age; **AND**
- Patient must have serum creatinine less than two times the age appropriate upper limit of normal or creatinine clearance ≥ 40 mL/min; **AND**
- Patient must have platelet counts ≥ 50 x 10^9/L

Diagnosis of **Chronic Iron Overload in Patients with Non-transfusion-dependent Thalassemia (NTDT) Syndromes**

- Patient is over 10 years of age; **AND**
- Liver iron concentration of at least 5 mg iron per gram of dry weight; **AND**
- Serum ferritin greater than 300 mcg/L; **AND**
- Patient must have serum creatinine less than two times the age appropriate upper limit of normal or creatinine clearance ≥ 40 mL/min; **AND**
- Patient must have platelet counts ≥ 50 x 10^9/L

RENEWAL CRITERIA

For **Transfusional Iron Overload**

- Patient has demonstrated clinical improvement in response to treatment; **AND**
- Patient has not developed any contraindications or other exclusions to its continued use; **AND**
- Serum ferritin levels must be >500 mcg/L

For **Non-Transfusion-Dependent Thalassemia**

- Patient has demonstrated clinical improvement in response to treatment; **AND**
- Patient has not developed any contraindications or other exclusions to its continued use; **AND**
- Serum ferritin levels must be > 300 mcg/L

CLINICAL CRITERIA FOR APPROVAL *(CONTINUED)*

FERRIPROX®

INITIAL CRITERIA

Diagnosis of **Transfusional Iron Overload Due to a Thalassemia Syndrome**

- Not to be approved in other diagnoses associated with chronic anemia (e.g., sickle cell anemia, aplastic anemia)
- Failure of Exjade®/Jadenu®/deferasirox (after a minimum of three months of therapy) as demonstrated by serum ferritin consistently > 500 mcg/L despite maximization of Exjade® dosage at 40 mg/kg/day.

RENEWAL CRITERIA

- Serum ferritin must have been measured within 30 days of continuation of therapy request (copy of lab results must be submitted); **AND**
- Ferritin levels must be > 500 mcg/L; **AND**
- Dose must not exceed 99 mg/kg/day.

JAKAFI® (RUXOLITINIB)

Length of Authorization:	6 Months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75 – HICL, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Myelofibrosis (MF) (including primary, post-polycythemia vera and post-essential thrombocythemia MF)**

- Patient is at least 18 years of age; **AND**
- Patient does not have an active infection, including clinically important localized infections; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with fluconazole, or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A4 inhibitors (e.g., clarithromycin, ketoconazole, nefazodone, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient has symptomatic low- to intermediate-1-risk disease; **OR**
- Patient has intermediate-2 or high-risk disease; **AND**
  - Starting platelet count (< 30 days old) is ≥ 50 X 10^9/L; **OR**
- Patient has accelerated phase or blast phase/acute myeloid leukemia.

Diagnosis of **Polycythemia Vera**

- Patient is at least 18 years of age; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with fluconazole, or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A4 inhibitors (e.g., clarithromycin, ketoconazole, nefazodone, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient does not have an active infection, including clinically important localized infections; **AND**
- Patient has had an inadequate response to (or cannot tolerate) a 3 month or longer trial of hydroxyurea or interferon therapy; **AND**
  - Patient has symptomatic low risk disease with indications for cytoreductive therapy; **OR**
  - Patient has high risk disease.

Diagnosis of **Essential Thrombocythemia**

- Patient is at least 18 years of age; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with fluconazole, or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A4 inhibitors (e.g., clarithromycin, ketoconazole, nefazodone, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient does not have an active infection, including clinically important localized infections; **AND**
- Patient has had an inadequate response or loss of response to hydroxyurea, interferon therapy, or anagrelide.

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Graft Versus Host Disease (GvHD)**

- Patient is at least 18 years of age (unless noted); **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with fluconazole, or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A4 inhibitors (e.g., clarithromycin, ketoconazole, nefazodone, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient does not have an active infection, including clinically important localized infections; **AND**
- Used for disease related to allogeneic hematopoietic stem cell transplantation; **AND**
- Used in combination with systemic corticosteroids for steroid-refractory disease; **AND**
  - Patient has acute graft versus host disease (aGVHD); **AND**
    - Patient is at least 12 years of age; **OR**
  - Patient has chronic graft versus host disease (cGvHD).

Diagnosis of **Myelodysplastic/Myeloproliferative Overlap Neoplasms (MDS/MPN)**

- Patient is at least 18 years of age; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with fluconazole, or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A4 inhibitors (e.g., clarithromycin, ketoconazole, nefazodone, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient does not have an active infection, including clinically important localized infections; **AND**
- Used in combination with a hypomethylating agent (e.g., decitabine, azacitidine, etc.) for chronic myelomonocytic leukemia (CMML)-2; **OR**
- Used as a single agent or in combination with a hypomethylating agent (e.g., decitabine, azacitidine, etc.) for BCR-ABL negative atypical chronic myeloid leukemia (aCML).

Diagnosis of **Myeloid/Lymphoid Neoplasms with Eosinophilia**

- Patient is at least 18 years of age; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with fluconazole, or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A4 inhibitors (e.g., clarithromycin, ketoconazole, nefazodone, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient does not have an active infection, including clinically important localized infections; **AND**
- Used in combination with ALL- or AML-type induction chemotherapy followed by allogeneic HCT (if eligible); **AND**
  - Patient has lymphoid, myeloid, or mixed lineage neoplasm; **AND**
  - Patient has JAK2 rearrangement in blast phase; **OR**
- Patient has myeloid or lymphoid neoplasms; **AND**
  - Patient has JAK2 rearrangement in chronic phase.

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Pediatric Acute Lymphoblastic Leukemia (ALL)**

- Patient is at least 1 year of age; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with fluconazole, or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A4 inhibitors (e.g., clarithromycin, ketoconazole, nefazodone, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient does not have an active infection, including clinically important localized infections; **AND**
- Patient has Ph-like B-ALL; **AND**
  - Used as induction therapy in combination with Total Therapy XVII regimen (prednisone, vincristine, daunorubicin, pegaspargase, cyclophosphamide, cytarabine, 6-MP, intrathecal [IT] therapy [methotrexate OR cytarabine OR methotrexate, cytarabine, and corticosteroid]); **AND**
    - Patient has disease with mutations associated with JAK-STAT pathway activation; **OR**
  - Used as consolidation therapy in combination with COG AALL1521 regimen (cyclophosphamide, cytarabine, 6-MP, vincristine, pegaspargase, IT methotrexate); **AND**
    - Patient has CRLF2+ or CRLF2- with JAK2 fusions, EPOR rearrangements, SH2B3 alterations, IL7R insertions/deletions; **OR**
  - Used as consolidation therapy in combination with the standard risk/high risk (SR/HR) arm of the Total Therapy XVII regimen (high-dose methotrexate, pegaspargase, 6-MP, intrathecal [IT] therapy [methotrexate OR cytarabine OR methotrexate, cytarabine, and corticosteroid]); **AND**
    - Patient has with mutations associated with JAK-STAT pathway activation.

CLINICAL CRITERIA FOR RENEWAL

Absence of unacceptable toxicity from the drug (e.g., serious infections [bacterial, mycobacterial, fungal, and viral], severe hematologic toxicity[(neutropenia, thrombocytopenia, and anemia], non-melanoma skin cancer, lipid elevations [including total cholesterol, LDL, and triglycerides]); **AND**

Myelofibrosis:

- Treatment response with a decrease in spleen size or improvements in other myelofibrosis symptoms (such as fatigue, bone pain, frequent infections, fever, night sweats, easy bruising/bleeding).

Polycythemia Vera:

- Treatment response such as hematocrit control and/or spleen volume reduction.

Essential Thrombocythemia:

- Disease response as evidenced by at least one of the following:
  - Decrease in spleen size or improvements in other myelofibrosis symptoms (such as fatigue, bone pain, frequent infections, fever, night sweats, easy bruising/bleeding, etc.)
  - Platelet count ≤ 400 x 10^9/L, WBC count < 10 x 10^9/L, absence of leukoerythroblastosis
  - Absence of any signs of progressive disease or hemorrhagic or thrombotic events

aGVHD:

- Treatment response such as stabilization or improvement in disease; **AND**
- In patients who have had a response and have discontinued therapeutic doses of corticosteroids, tapering of Jakafi® should be considered.

cGvHD:

- Treatment response as evidenced by stabilization or improvement in disease

Myelodysplastic/Myeloproliferative Overlap Neoplasms (MDS/MPN):

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread.

Myeloid/Lymphoid Neoplasms with Eosinophilia:

- Disease response as evidenced by at least one of the following:
  - Decrease in spleen size or improvements in other myelofibrosis symptoms (such as fatigue, bone pain, frequent infections, fever, night sweats, easy bruising/bleeding, etc.)
  - Stabilization or improvement as evidenced by a complete response (CR) (i.e. morphologic, cytogenetic or molecular complete response CR), complete hematologic response or a partial response by CBC, bone marrow cytogenic analysis, QPCR, or FISH.

Pediatric Acute Lymphoblastic Leukemia (ALL):

- Treatment response or stabilization of disease as indicated by CBC, bone marrow cytogenic analysis, QPCR, or FISH.

JUXTAPID® (LOMITAPIDE)

Length of Authorization:	6 Months – May be renewed
Initiative:	MNC: Non-Formulary Product (IE 50698 / MR – GSN PatOverride)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Homozygous familial hypercholesterolemia (HoFH)**

- Patient at least 18 years old; **AND**
- Prescriber and patient must be enrolled in and meet the conditions of the Juxtapid REMS program; **AND**
- Must not be concurrently taking strong or moderate CYP3A4 inhibitors (e.g., clarithromycin, itraconazole, ritonavir, aprepitant, ciprofloxacin, diltiazem, grapefruit juice, etc.); **AND**
- Diagnoses of HoFH must be confirmed by the presence of at least one of the following:
  - Documented DNA test for functional mutation(s) in both LDL receptor alleles and alleles known to affect LDL receptor functionality; **OR**
  - Untreated total cholesterol (TC) >500 mg/dL; **AND**
    - Cutaneous or tendon xanthoma before age 10 years; **OR**
    - Untreated LDL-C in both parents consistent with HeFH; **AND**
- Must be used as an adjunct to a low-fat diet supplying < 20% of energy from fat; **AND**
- Baseline alanine and aspartate aminotransferases (ALT, AST), alkaline phosphatase, and total bilirubin lab values must be obtained prior to initiating treatment; **AND**
- Baseline low-density lipoprotein cholesterol (LDL-C), total cholesterol (TC), apolipoprotein B (apo B), and non-high-density lipoprotein cholesterol (non-HDL-C) labs must be obtained prior to initiating treatment and required for renewal; **AND**
- Patient tried and failed at least a 3-month trial of adherent therapy with: ezetimibe (Zetia) used in combination with the highest available (or maximally tolerated*) dose of atorvastatin (Lipitor) or rosuvastatin (Crestor), unless contraindicated; **AND**
- Patient tried and failed at least a 3-month trial of adherent therapy with:
  - Combination therapy consisting of the highest available (or maximally tolerated*) dose of atorvastatin or rosuvastatin, ezetimibe AND a PCSK9 inhibitor indicated for HoFH (e.g., evolocumab, etc.) unless contraindicated; **AND**
  - Despite the pharmacological treatment with PCSK9, statin and ezetimibe, patient's LDL cholesterol ≥ 100 mg/dL (or ≥70 mg/dL for patients with clinical atherosclerotic cardiovascular disease (ASCVD)); **AND**
  - FEMALE PATIENTS ONLY: Obtain a negative pregnancy test in females of reproductive potential

NOTE: *If the patient is not able to use a maximum dose of atorvastatin or rosuvastatin due to muscle symptoms, documentation of a causal relationship must be established between statin use and muscle symptoms.

- Documentation must demonstrate that the patient experienced pain, tenderness, stiffness, cramping, weakness, and/or fatigue and all the following:
  - Muscle symptoms resolve after discontinuation of statin; **AND**
  - Muscle symptoms occurred when rechallenged at a lower dose of the same statin; **AND**
  - Muscle symptoms occurred after switching to an alternative statin; **AND**
  - Documentation ruling out non-statin causes of muscle symptoms (e.g., hypothyroidism, reduced renal function, reduced hepatic function, rheumatologic disorders, such as polymyalgia rheumatica, steroid myopathy, vitamin D deficiency, or primary muscle disease); **OR**
  - The patient has been diagnosed with rhabdomyolysis associated with statin use
  - The diagnosis should be supported by acute neuromuscular illness or dark urine AND an acute elevation in creatine kinase (usually > 5,000 IU/L or 5 times the upper limit of normal [ULN])

CLINICAL CRITERIA FOR RENEWAL

- Documented reduction of low-density lipoprotein cholesterol (LDL-C), total cholesterol (TC), apolipoprotein B (apo B), and non-high-density lipoprotein cholesterol (non-HDL-C) from pre-lomitapide baseline; **AND**
- Documentation of dosage adjustment if ALT or AST is ≥ 3 times the upper limit of normal (ULN); **AND**
- FEMALE PATIENTS ONLY: Obtain a negative pregnancy test in females of reproductive potential; **AND**
- Patient has demonstrated continued adherence to lipid-lowering therapy with rosuvastatin/atorvastatin, ezetimibe, PCSK9-I plus lomitapide; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: elevations in transaminases (ALT, AST), hepatic steatosis, and severe diarrhea, severe vomiting.

KALYDECO® (IVACAFTOR)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Respiratory Agents (IE 2462 / NCPDP 75 – GSN)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Cystic Fibrosis**

- Patient is at least 4 months old; **AND**
- Patient has a baseline percent predicted FEV_1 (reported measurements may be used on renewal); **AND**
- Confirmation the patient is not receiving concurrent treatment with any other CFTR-targeted therapy containing one or more of the following: ivacaftor, lumacaftor, tezacaftor, elexacaftor; **AND**
- Patient will avoid concomitant therapy with any of the following:
  - Patient will avoid concomitant use with strong CYP3A inducers (e.g., rifampin, rifabutin, phenobarbital, carbamazepine, phenytoin, and St. John's wort, etc.); **AND**
  - Patient will avoid concomitant use with strong or moderate CYP3A inhibitors (e.g., fluconazole, erythromycin, grapefruit juice, etc.), if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented *(Note: Concomitant use of moderate or strong CYP3A inhibitors is not recommended in patients below 6 months of age)*; **AND**
- *Patients aged 4 months to less than 6 months*: Patient does not have severe hepatic impairment (Child-Pugh Class C); **AND**
- Pediatric patients have had a baseline ophthalmological test obtained prior to initiation of therapy and will continue to have follow-up ophthalmological examinations periodically thereafter; **AND**
- Patient has one mutation in the *CFTR* gene, as confirmed by an FDA-cleared or CLIA-compliant CF mutation test, that is responsive to ivacaftor based on clinical and/or in vitro assay data*****; **AND**
- Therapy is not indicated in patients whose mutations in the *CFTR* gene are unresponsive to ivacaftor potentiation (e.g., homozygous for the *F508del* mutation, etc.)

  *****_CFTR_ Gene Mutations that produce CFTR Protein and are responsive to ivacaftor:

E56K	*G178R*	*S549R*	*K1060T*	*G1244E*
P67L	*E193K*	*G551D*	*A1067T*	*S1251N*
R74W	*L206W*	*G551S*	*G1069R*	*S1255P*
D110E	*R347H*	*D579G*	*R1070Q*	*D1270N*
D110H	*R352Q*	*S945L*	*R1070W*	*G1349D*
R117C	*A455E*	*S977F*	*F1074L*	*711+3A→G*
R117H	*S549N*	*F1052V*	*D1152H*	*E831X*
2789+5G→A	*3272-26A→G*	*3849+10kbC→T*		

Table may not be all-inclusive; verify gene mutations responsive to ivacaftor in the current prescribing information

CLINICAL CRITERIA FOR RENEWAL

- Disease response as indicated by one or more of the following:
  - Decreased pulmonary exacerbations compared to pretreatment baseline;
  - Improvement or stabilization of lung function (measured by percent predicted FEV_1 within previous 30 days) compared to baseline;
  - Decrease in decline of lung function (measured by percent predicted FEV_1 within previous 30 days) compared to baseline;
  - Improvement in quality of life (e.g., Cystic Fibrosis Questionnaire-Revised [CFQ-R] score), weight gain, or growth; **AND**
- Patient has not received a lung transplant; **AND**
- Absence of unacceptable toxicity from the drug (e.g., elevated transaminases [ALT or AST], development of cataracts or lens opacities).

KENALOG (TRIAMCINOLONE ACETONIDE INJECTION)

Length of Authorization:	12 months
Initiative:	MNC: Miscellaneous: PA Required (IE 2462 / NCPDP 75 – GSN)

CLINICAL CRITERIA FOR INITIAL APPROVAL

- **For intramuscular use:**
  - Patient must have an FDA labeled indication and dosage; **AND**
  - Patient does not have any of the following contraindications:
    - Hypersensitivity to any components of the product
    - Intramuscular injection in those with idiopathic thrombocytopenic purpura
- **For intra-articular use:**
  - Use as adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in acute gouty arthritis, acute and subacute bursitis, acute nonspecific tenosynovitis, epicondylitis, rheumatoid arthritis, synovitis of osteoarthritis; **AND**
  - Patient does not have any of the following contraindications:
    - Hypersensitivity to any components of the product

CLINICAL CRITERIA FOR RENEWAL

- Patient must continue to meet above criteria; **AND**
- Absence of unacceptable toxicity from the drug

KORLYM® (MIFEPRISTONE)

Length of Authorization:	6 Months
Initiative:	MNC: Hormone Agents (IE 2462 / NCPDP 75 – HICL)

CLINICAL CRITERIA FOR INITIAL APPROVAL

- Diagnosis of endogenous Cushing's syndrome with secondary hyperglycemia; **OR**
- Diagnosis of type 2 diabetes mellitus (DM);
- Patient must have failed or not be candidate for pituitary surgery

KOSELUGO® (SELUMETINIB)

Length of Authorization:	6 Months, may be renewed
Initiative:	MNC: Non-Formulary Product (IE 50698 / MR – GSN PatOverride)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Neurofibromatosis Type-1 (NF1)**

- Patient is at least 2 years or older; **AND**
- Left ventricular ejection fraction (LVEF) is within normal limits prior to initiating therapy and will be assessed at regular intervals during treatment; **AND**
- Patient will avoid any of the following potential drug-drug interactions:
  - Coadministration with strong or moderate CYP3A4-Inducers (e.g., rifampin, carbamazepine, St. John's Wort); **OR**
  - Coadministration with strong or moderate CYP3A4 inhibitors (e.g., fluconazole, itraconazole) if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **OR**
  - Patient will not receive vitamin E supplementation greater than 100% of the daily recommended dose; **AND**
- Patient does not have severe hepatic impairment (i.e., Child-Pugh C); **AND**
- Patient will have a comprehensive ophthalmic exam prior to initiating therapy and at regular intervals during treatment, and for new or worsening visual changes; **AND**
- Patient serum creatinine phosphokinase (CPK) will be measured at baseline and periodically during treatment as clinically indicated; **AND**
- Will not be used in combination with other MEK inhibitors (e.g., binimetinib, cobimetinib, trametinib); **AND**
- Patient has a confirmed diagnosis of NF1 as defined by either of the following:
  - Patient has positive genetic testing for NF1 as evidenced by heterozygous pathogenic variants in *NF1*-gene; **OR**
  - Patient at least one of the below diagnostic criteria for NF1 listed below:
    - Six or more cafe-au-lait macules (≥ 0.5cm in pre-pubertal subjects or ≥ 1.5 cm in post-pubertal subjects)
    - Freckling in axilla or groin
    - Optic glioma
    - Two or more Lisch nodules
    - A distinctive bony lesion (dysplasia of the sphenoid bone or dysplasia or thinning of long bone cortex)
    - A first-degree relative with NF1; **AND**
- Patient has symptomatic plexiform neurofibromas (PN) (e.g., lesions causing significant morbidity defined by, but not limited to, head and neck lesions that could compromise the airway or great vessels, paraspinal lesions that can cause myelopathy brachial or lumbar plexus lesions that could cause nerve compression and loss of function, lesions that could result in major deformity [e.g., orbital lesions] or are significantly disfiguring, lesions of the extremity that cause limb hypertrophy or loss of function, and painful lesions); **AND**
- Patient PN are inoperable (i.e., PN could not be completely removed without risk for substantial morbidity due to encasement of, or close proximity to, vital structures, invasiveness, or high vascularity of the PN).

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug (e.g., cardiomyopathy, ocular toxicities [e.g., retinal vein occlusion or retinal pigment epithelial detachment], severe diarrhea, severe skin rashes, rhabdomyolysis, bleeding); **AND**
- Left ventricular ejection fraction (LVEF) has not had an **absolute** decrease from baseline ≥ 10% and is not below the lower limit of normal (LLN).

KUVAN® (SAPROPTERIN)

Length of Authorization:	1 Year
Initiative:	MNC: Non-Formulary Product (IE 50698 / MR – GSN PatOverride)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of phenylketonuria (PKU)

- Physician must be a metabolic specialist; **AND**
- Patient must be on a Phenylalanine (Phe) restricted diet; **AND**
- Confirm that Phe levels cannot be maintained within recommended range with dietary intervention alone; **AND**
- Document baseline Phe level. Baseline level should be greater than 600 µmol/L.

INITIAL RENEWAL

Technicians: Document current Phe level. Pharmacist: After initial 2-month approval confirm that patient has had at least a 30% reduction in baseline.

RENEWAL AFTER 1 YEAR

Technicians: Document current Phe level.

Pharmacists: Once responsiveness is established, dose should be adjusted within the range of 5-20 mg/kg PO once daily. Maximum dosing is 20 mg/kg/day. Phe levels below should be maintained.

- Neonates thru 12 – 120-360 µmol/dL (2–6 mg/dL)
- Greater than 12 – 120-960 µmol/dL (2–15 mg/dL)
- During pregnancy – 120-360 µmol/dL (2–6 mg/dL)

LEUCOVORIN CALCIUM TABLETS

Length of Authorization:	12 months
Initiative:	MNC: Miscellaneous: PA Required (IE 2462 / NCPDP 75 – GSN)

CLINICAL CRITERIA FOR INITIAL APPROVAL

- The medication will be used to diminish the toxicity and counteract the effects of impaired methotrexate elimination and of inadvertent overdosages of folic acid antagonists; **AND**
- There are no contraindications to therapy:
  - Pernicious anemia and other megaloblastic anemias secondary to the lack of vitamin B12.

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug

LEUPROLIDE PRODUCTS

Length of Authorization:	Varies by product and diagnosis, see specific criteria below
Initiative:	SPC: Hormonal Agents (IE 2462 / NCPDP 75 – GSN)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Endometriosis [Lupron Depot, Trelstar, Zoladex]**

- Patient older than 18; **AND**
- Diagnosis has been confirmed by a workup/evaluation (vs. presumptive treatment); **AND**
- Patient has not received prior-treatment with a gonadotropin releasing hormone (GnRH) agonist for this indication within a 6-month prior period.

Length of Authorization:	6 months, eligible for renewal one time

Diagnosis of **Uterine leiomyomata (fibroids): [Lupron Depot, Trelstar]**

- Patient older than 18; **AND**
- Diagnosis has been confirmed by a workup/evaluation (vs. presumptive treatment); **AND**
- Documentation patient is receiving iron therapy.

Length of Authorization:	3 months **not** eligible for renewal.

Diagnosis of **Dysfunctional uterine bleeding (Endometrial thinning) [Zoladex]**

- Patient is at least 18 years old**; AND**
- Used prior to endometrial ablation.

Length of Authorization:	Coverage will be provided for 2 doses only (given 4 weeks apart) and medication is NOT eligible for renewal

Diagnosis of **Breast Cancer [Eligard, Lupron Depot, Zoladex]**

- Patient is 18 years or older**; AND**
- Patient is pre-menopausal or peri-menopausal woman; or is a male with suppression of testicular steroidogenesis; **AND**
- Patient's disease is hormone receptor positive; **AND**
  - Used in combination with adjuvant endocrine therapy; **OR**
  - Endocrine therapy for recurrent or metastatic disease; **OR**
  - Used as palliative treatment for advanced disease (Zoladex only).

Diagnosis of **Ovarian cancer (Eligard, Lupron Depot)**

- Patient is 18 years or older**; AND**
- Used as single agent; **AND**
- Patient has a diagnosis of stage II-IV granulosa cell tumors of the ovary; **AND**
  - Patient's disease has relapsed; **OR**
- Patient has a diagnosis of Epithelial Ovarian Cancer or Fallopian Tube Cancer or Primary Peritoneal cancer; **AND**
  - Patient's disease is persistent or recurrent (excluding immediate treatment of biochemical relapse).

Length of Authorization:	1 year, eligible for renewal(s)

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Head and Neck Cancer [Lupron Depot]:**

- Patient is 18 years or older**; AND**
- Patient has a diagnosis of androgen receptor-positive recurrent salivary gland tumor; **AND**
  - Patient has distant metastases with a performance status score of 0–3; **OR**
  - Patient has unresectable locoregional recurrence or second primary with prior radiation therapy.

Length of Authorization: 1 year, eligible for renewal(s)

Diagnosis of **Central Precocious Puberty (CPP) [Leuprolide acetate, Lupron Depot-Ped®, Supprelin LA, Trelstar, Triptodur]**

- Patient is less than 13 years old (between the ages of 2 and 13 years for Triptodur); **AND**
- Onset of secondary sexual characteristics earlier than age 8 for girls and 9 for boys associated with pubertal pituitary gonadotropin activation; **AND**
- Diagnosis is confirmed by a pubertal gonadal sex steroid levels and a pubertal LH response to stimulation by native GnRH; **AND**
- Bone age advanced greater than 2 standard deviations (SD) beyond chronological age; **AND**
- Tumor has been ruled out by lab tests such as diagnostic imaging of the brain (to rule out intracranial tumor), pelvic/testicular/adrenal ultrasound (to rule out steroid secreting tumors), and human chorionic gonadotropin levels (to rule out a chorionic gonadotropin secreting tumor); **AND**
- Will not be used in combination with growth hormone.

Length of Authorization: 1 year, eligible for renewal(s)

Diagnosis of **Prostate Cancer; [Leuprolide (all formulations), Eligard, Trelstar, Vantas and Zoladex]**

- Patient is 18 years or older.

Length of Authorization: 1 year, eligible for renewal(s)

CLINICAL CRITERIA FOR RENEWAL

Diagnosis of **Central Precocious Puberty**

- Disease response as indicated by lack of progression or stabilization of secondary sexual characteristics, decrease in growth velocity and bone age advancement, and improvement in final height prediction; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: severe QT/QTc interval prolongation, severe hyperglycemia and diabetes, cardiovascular toxicity, hypercalcemia, severe injection site reactions, tumor flare phenomenon, severe hypersensitivity reactions, etc.

Diagnosis of **Prostate Cancer; Breast/Ovarian Cancer; Head and neck cancer**

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: severe QT/QTc interval prolongation, severe hyperglycemia and diabetes, cardiovascular toxicity, hypercalcemia, severe injection site reactions, tumor flare phenomenon, severe hypersensitivity reactions, etc.

Diagnosis of **Oncology Indications (Zoladex only)**

- Tumor response with stabilization of disease or decrease in size of tumor; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: severe QT/QTc interval prolongation, severe hyperglycemia and diabetes, cardiovascular toxicity, hypercalcemia, severe injection site reactions, tumor flare phenomenon, severe hypersensitivity reactions, etc.

CLINICAL CRITERIA FOR RENEWAL *(CONTINUED)*

Diagnosis of **Non-Oncology Indications (except Endometriosis) (Zoladex only)**

- Disease response; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: severe QT/QTc interval prolongation, severe hyperglycemia and diabetes, cardiovascular toxicity, hypercalcemia, severe injection site reactions, tumor flare phenomenon, severe hypersensitivity reactions, etc.

Diagnosis of **Endometriosis**

- Patient has not received a total of 12 months of therapy of a GnRH-agonist (i.e., leuprolide acetate, etc.); **AND**
- Patient continues to have symptoms of endometriosis or symptoms recur after the initial 6-month course of therapy; **AND**
- Patient will have bone density assessment prior to retreatment; **AND**
- Patient will use in combination with add-back therapy in combination with norethindrone; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: severe QT/QTc interval prolongation, severe hyperglycemia and diabetes, cardiovascular toxicity, hypercalcemia, severe injection site reactions, tumor flare phenomenon, severe hypersensitivity reactions, etc.

Diagnosis of **Uterine leiomyomata (fibroids)**

- May not be renewed.

Diagnosis of **Endometrial Bleeding**

- May not be renewed.

ADDITIONAL INFORMATION TO AID IN THE FINAL DECISION

- Examples of secondary sexual characteristics:
  - In ***females***: growth of pubic and underarm hair, enlargement of breasts, and menstruation.
  - In ***males***: growth of abdominal, chest, pubic, and underarm hair; enlargement of larynx (Adam's apple); deepening of voice, enlargement (growth) of the penis.

COVERED – PA REQUIRED
Eligard® *(leuprolide)*
Leuprolide (generic Lupron Depot®)
Lupron Depot® and Lupron Depot-Ped® *(leuprolide)*

L-GLUTAMINE (ENDARI)

Length of Authorization:	1 year
Initiative:	MNC: Non-Formulary Product (IE 50698 / MR – GSN PatOverride)

CLINICAL CRITERIA

- Diagnosis of sickle cell disease; **AND**
- Patient is over ≥ 5; **AND**
- Patient is not pregnant or lactating.

CLINICAL CRITERIA FOR RENEWAL

- The patient continued to meet initial criteria; **AND**
- The patient has had disease improvement with the medication.

LIDOCAINE

Length of Authorization:	1 Year, eligible for renewal
Initiative:	MNC: Miscellaneous: PA Required (IE 2462 / NCPDP 75 – GSN)

CLINICAL CRITERIA FOR LIDOZION LOTION

- Patient must have a diagnosis of one of the following:
  - Need for the relief of pruritus, pruritic eczemas, abrasions, minor burns, insect bites, pain, soreness and discomfort due to pruritus ani, pruritus vulvae, hemorrhoids, anal fissures, OR similar conditions of the skin and mucous membranes.

CLINICAL CRITERIA FOR LIDOCAINE 5% OINTMENT

- Patient must have a diagnosis of one of the following:
  - Need for anesthesia of accessible mucous membranes of the oropharynx, **OR**
  - Need for temporary relief of pain associated with minor burns, including sunburn, abrasions of the skin, and insect bites.

CLINICAL CRITERIA FOR LIDOCAINE 5% PATCH

- Patient is 18 years of age or older; **AND**
- Patient must have a diagnosis of post-herpetic neuralgia; **AND**
- Patient must have an inadequate response, contraindication, or intolerance to at least one agent from one of the following classes:
  - Tricyclic antidepressant (e.g., amitriptyline, desipramine, or nortriptyline); **OR**
  - Gabapentinoid (e.g., gabapentin or pregabalin).

LINZESS® (LINCLOTIDE)

Length of Authorization:	1 Year, eligible for renewal
Initiative:	MNC: Gastrointestinals: IBS Agents (IE 2462 / NCPDP 75 – HICL)

CLINICAL CRITERIA

- Patient is 18 years of age or older (contraindicated in patient <6 years of age and avoid use in patients 6 to <18 years of age); **AND**
- Patient does not have a known or suspected mechanical gastrointestinal obstruction; **AND**
- Patient must have a diagnosis of one of the following:
  - Chronic idiopathic constipation (CIC)
  - Irritable bowel syndrome with constipation (IBS-C); **AND**
- For patients with CIC or IBS-C, patient must have had an inadequate response, contraindication, or intolerance to at least one agent from two of the following classes:
  - Osmotic Laxatives (e.g., lactulose, polyethylene glycol (PEG))
  - Bulk Forming Laxatives (e.g., Metamucil® – psyllium, Citrucel® – methylcellulose)
  - Stimulant Laxatives (e.g., bisacodyl, senna)

LONSURF® (TRIFLURIDINE AND TIPIRACIL)

Length of Authorization:	6 months, may be renewed
Initiative:	MNC: Non-Formulary Product (IE 50698 / MR – GSN PatOverride)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Colorectal Cancer**

- Patient is at least 18 years of age; **AND**
- Must be used as a single agent; **AND**
- Patient has advanced or metastatic disease; **AND**
- Patient has been previously treated with ALL the following: fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy regimens (e.g., FOLFOX, FOLFIRI, FOLFIRINOX); **AND**
- Patient has been previously treated with an anti-VEGF biological therapy (e.g., bevacizumab), **AND**
- Patient has been previously treated with an anti-EGFR therapy (if RAS wild-type) (e.g., panitumumab, cetuximab)

Diagnosis of **Gastric and Gastro-Esophageal Junction Adenocarcinoma**

- Patient is at least 18 years of age; **AND**
- Must be used as a single agent; **AND**
- Patient has recurrent, metastatic, or unresectable locally advanced disease OR patient is not a surgical candidate; **AND**
- Patient has received at least two (2) prior lines of chemotherapy that included: a fluoropyrimidine-, a platinum, and either a taxane or irinotecan; **AND**
- Patient has been previously treated with HER2/neu-targeted therapy (if HER2 positive disease) (e.g., trastuzumab)

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug (e.g., severe myelosuppression)

LYRICA® (PREGABALIN)

Length of Authorization:	1 Year, eligible for renewal
Initiative:	MNC: Neuropathic Pain Agents (IE 2462 / NCPDP 75 – HICL) MNC: Anticonvulsants (IE 2462 / NCPDP 75)

CLINICAL CRITERIA

- Patient is 1 month of age or older **AND** has a diagnosis of partial onset seizures, **OR**
- Patient is 18 years of age or older **AND** has a diagnosis of one of the following**:**
  - Diabetic peripheral neuropathy (DPN)
  - Postherpetic neuralgia (PHN)
    - For patients with postherpetic neuralgia (PHN), patient has an inadequate response, contraindication or intolerance, or has failed at least one of these first-line agents:
      - Tricyclic antidepressant (e.g., amitriptyline, desipramine, nortriptyline, etc.)
      - Gabapentin
      - Generic SNRI (e.g., duloxetine, venlafaxine)
  - Neuropathic pain associated with spinal cord injury
  - Fibromyalgia
    - For patients with fibromyalgia, patient has an inadequate response, contraindication, or intolerance to at least one of these first-line agents:
      - Tricyclic antidepressant (e.g., amitriptyline, desipramine, nortriptyline)
      - Cyclobenzaprine
      - Duloxetine

MAKENA® (HYDROXYPROGESTERONE CAPROATE)

Length of Authorization:	Up to 6 months per singleton pregnancy
Initiative:	SPC: Injectable Progestin (IE 2462 / NCPDP 75 – HICL)

CLINICAL CRITERIA

- Prevention of preterm birth (delivery at less than 37 weeks, 0 days gestation)
  - Patient is currently pregnant with a singleton pregnancy; **AND**
  - Patient must have history of a prior spontaneous singleton preterm birth due to spontaneous preterm labor or premature rupture of membranes; **AND**
  - Confirmation that patient does not have any of the following contraindications:
    - Current or history of thrombosis or thromboembolic disorders; **OR**
    - Known or suspected breast cancer, other hormone-sensitive cancer, or history of these conditions; **OR**
    - Undiagnosed abnormal vaginal bleeding unrelated to pregnancy; **OR**
    - Cholestatic jaundice of pregnancy; **OR**
    - Liver tumors, benign or malignant, or active liver disease; **OR**
    - Uncontrolled hypertension; **AND**
  - Therapy must be initiated between 16 weeks, 0 days and 20 weeks, 6 days of gestation and will continue through 36 weeks, 6 days' gestation or delivery, whichever occurs first.

PA REQUIRED
Makena® and Makena Auto-injector (*hydroxyprogesterone caproate*)

DISTRIBUTION INFORMATION

- Makena is a limited distribution product and is not available at retail pharmacies
- The prescription process for Makena is managed through the Makena Care Connection® support program.
- Members and their Doctors must submit a Makena Referral/Prescription Form to the Makena Care Connection; (1-800-847-3413)

MIFEPREX® (MIFEPRISTONE)

Length of Authorization:	1 time
Initiative:	MNC: Non-Formulary Product (IE 50698 / MR – GSN PatOverride)

CLINICAL CRITERIA FOR INITIAL APPROVAL

If Under the Pharmacy Benefit: Abortifacients Prior Authorization:

- Must have:
  - Intrauterine pregnancy
  - Must be ≤ 70 days' gestation
- Must **not** have
  - A suspected or confirmed ectopic pregnancy (not effective)

FYI - Mifeprex is only available through a restricted program under a REMS called MIFEPREX REMS Program because of the risks of serious complications

- Requirements of the program:
  - Prescribers must be certified with the program by completing the Prescriber Agreement Form
  - Patients must sign a Patient Agreement Form
  - Mifeprex must be dispensed to patients only in certain healthcare settings, specifically clinics, medical offices and hospitals by or under the supervision of a certified prescriber
  - Further information is available at 1-877-4 Early Option (1-877-432-7596)

MODAFINIL (PROVIGIL)

Length of Authorization:	1 Year
Initiative:	MNC: Non-Formulary Product (IE 50698 / MR – GSN PatOverride)

CLINICAL CRITERIA

- Diagnosis of Narcolepsy; **OR**
- Diagnosis of Obstructive Sleep Apnea- with CPAP; **OR**
- Diagnosis of Shift Work Disorder; **OR**
- Diagnosis of Hypersomnia, **OR**
- Diagnosis of fatigue related to cancer; **OR**
- Diagnosis of Fatigue related to multiple sclerosis
  - Tried and failed amantadine within the past year; **AND**
  - Tried and failed a stimulant; **AND**
  - Documented compliance with current therapy

MULTIPLE SCLEROSIS THERAPY

Length of Authorization:	1 year; Lemtrada limited to 2 courses total
Initiative:	SPC: Multiple Sclerosis Therapy (IE 2462 / NCPDP 75 – GSN) MNC: Non-Formulary Product (IE 50698 / MR – GSN PatOverride)

CLINICAL CRITERIA FOR INITIAL APPROVAL OF ALL MEDICATIONS

Diagnosis of **Relapsing Form of Multiple Sclerosis** (i.e., Relapsing-Remitting Disease [RRMS], Active Secondary Progressive Disease [SPMS], or Clinically Isolated Syndrome)

- Patient is 18 years or older (unless specified elsewhere); **AND**
- Diagnosis confirmed by laboratory report (i.e., MRI); **AND**
- Must be used as single agent therapy.

DRUG SPECIFIC CRITERIA IN ADDITION TO CRITERIA ABOVE

BETASERON®, REBIF®

In addition to the criteria under initial approval:

- Patient must have a **documented** failure, contraindication, intolerance, or ineffective response with a minimum of **3-month** trial of Avonex®, Copaxone®, Gilenya®, or Glatopa®; **AND**
- Patient is continuing treatment with requested medication.

GILENYA®

In addition to the criteria under initial approval:

- Patient is 10 years of age or older; **AND**
- Patient must not have any of the following contraindications to Gilenya®:
  - Recent myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure with hospitalization, or Class III/IV heart failure
  - History of second- or third-degree atrioventricular block or sick sinus syndrome (unless treated with a pacemaker)
  - Prolonged QTc interval at baseline (≥ 500 msec)
  - Cardiac arrhythmias requiring treatment with Class Ia (e.g., quinidine, procainamide, disopyramide) or Class III (e.g. amiodarone, dronedarone, sotalol, dofetilide, ibutilide) anti-arrhythmic drugs; **AND**
- Gilenya® must not be administered concurrently with live vaccines and at least 2 months after treatment; **AND**
- Patient has been tested for antibodies to the varicella zoster virus (VZV) or has received immunization for VCV 1 month prior to beginning therapy; **AND**
- Patient does not have an active infection, including clinically important localized infections.

ADDITIONAL INFORMATION ON MS DIAGNOSIS CRITERIA

Definitive diagnosis of MS with a relapsing-remitting course is based upon BOTH dissemination in time and space. Unless contraindicated, MRI should be obtained (even if criteria are met).	
Dissemination in time (*Development/appearance of new CNS lesions over time*)	**Dissemination in space** (*Development of lesions in distinct anatomical locations within the CNS; multifocal*)
• ≥ 2 clinical attacks; **OR** • 1 clinical attack **and** one of the following: – MRI indicating simultaneous presence of gadolinium-enhancing and non-enhancing lesions at any time or by a new T2-hyperintense or gadolinium-enhancing lesion on follow-up MRI compared to baseline scan – CSF-specific oligoclonal bands	• ≥ 2 lesions; **OR** • 1 lesion **and** one of the following: – Clear-cut historical evidence of a previous attack involving a lesion in a distinct anatomical location – MRI indicating ≥ 1 T2-hyperintense lesions characteristic of MS in ≥ 2 of 4 areas of the CNS (periventricular, cortical or juxtacortical, infratentorial, or spinal cord)

Active secondary progressive MS (SPMS) is defined as the following:
• Expanded Disability Status Scale (EDSS) score > 3.0; **AND** • Disease is progressive ≥ 3 months following an initial relapsing-remitting course (i.e., EDSS score increase by 1.0 in patients with EDSS ≤ 5.5 or increase by 0.5 in patients with EDSS ≥ 6); **AND** – ≥ 1 relapse within the previous 2 years; **OR** – Patient has gadolinium-enhancing activity or new or unequivocally enlarging T2 contrast-enhancing lesions as evidenced by MRI
Definitive diagnosis of MS with a primary progressive course is based upon the following:
• 1 year of disability progression independent of clinical relapse; **AND** • **Two** of the following: – ≥ 1 T2-hyperintense lesion characteristic of MS in one or more of the following regions of the CNS (periventricular, cortical or juxtacortical, or infratentorial) – ≥ 2 T2-hyperintense lesions in the spinal cord – Presence of CSF-specific oligoclonal bands
Definitive diagnosis of CIS is based upon all of the following:
• A monophasic clinical episode with patient-reported symptoms and objective findings reflecting a focal or multifocal inflammatory demyelinating event in the CNS • Neurologic symptom duration of at least 24 hours, with or without recovery • Absence of fever or infection • Resembles a typical MS relapse (attack and exacerbation) but occurs in a patient not known to have MS

CLINICAL CRITERIA FOR RENEWAL

- Patient continues to meet criteria identified above; **AND**
- Continuous monitoring of response to therapy (Manifestations of MS disease activity include, but are not limited to increase in annualized relapse rate [ARR], development of new/worsening T2 hyperintensities or enhancing lesions on brain/spinal MRI, and progression of sustained impairment as evidenced by expanded disability status scale [EDSS], timed 25-foot walk [T25-FW], 9-hole peg test [9-HPT])
  - Inadequate response to therapy, in those who have been adherent and receiving therapy for sufficient time to realize the full treatment effect, is defined as ≥ 1 relapse, ≥ 2 unequivocally new MRI-detected lesions, or increased disability on examination over a one-year period; **AND**
- Absence of unacceptable toxicity from the drug
  - Examples for Aubagio®: increase in serum transaminases (ALT) or severe hepatic injury
  - Examples for Gilenya®: macular edema; severe hepatic injury; bradyarrhythmia; atrioventricular (AV) blocks; active serious infection; decreased respiratory function; progressive multifocal leukoencephalopathy (PML); posterior reversible encephalopathy syndrome (PRES); basal cell carcinoma; lymphomas, uncontrolled hypertension
  - Examples for Lemtrada®: signs or symptoms of autoimmune mediated conditions (thyroid disorders, immune thrombocytopenia, and anti-glomerular basement membrane disease); infusion reactions; anaphylactic hypersensitivity reactions; malignancies (thyroid cancer, melanoma, lymphoproliferative disorders, lymphoma); neutropenia, hemolytic anemia, pancytopenia, hepatoxicity; development of severe infections (including appendicitis, gastroenteritis, pneumonia, herpes; hepatitis B or C); pneumonitis
  - Examples for Tecfidera®: anaphylaxis and angioedema, prolonged (more than 6 months) lymphopenia (< 0.5 x 10^9/L), serious flushing reactions, progressive multifocal leukoencephalopathy (PML), liver injury, herpes zoster or other serious infections
  - Examples for Avonex®, Betaseron®, Copaxone®, Extavia®, glatiramer acetate, Glatopa®, Plegridy®, Rebif®, and Tysabri®: increase in serum transaminases (ALT) or severe hepatic injury; decreased blood counts (e.g., leukopenia, anemia, thrombocytopenia, pancytopenia); depression and suicide ideation; or seizures
  - Examples for Zinbryta®: nasopharyngitis, upper respiratory tract infection, rash, influenza, dermatitis, oropharyngeal pain, bronchitis, eczema, and lymphadenopathy compared with Avonex®; upper respiratory tract infection, depression, rash, pharyngitis, and increased alanine aminotransferase (ALT) compared with placebo

COVERED – PA REQUIRED
Avonex® (*interferon beta-1a*)
Betaseron®, Extavia® (*interferon beta-1b*)
Copaxone® 20 mg (*glatiramer acetate*)
Gilenya® (*fingolimod*)
Glatopa® 40 mg (*glatiramer acetate*)
Rebif®, Rebif Rebidose® (*interferon beta-1a*)

NAMENDA/NAMENDA ER (MEMANTINE/MEMANTINE ER)

Length of Authorization:	1 Year, eligible for renewal
Initiative:	MNC: Miscellaneous: PA Required (IE 2462 / NCPDP 75 – GSN)

CLINICAL CRITERIA FOR INITIAL THERAPY

- Diagnosis of moderate to severe dementia of the Alzheimer's type; **AND**
- For the oral solution, unable to swallow solid dosage forms of medication

CLINICAL CRITERIA FOR RENEWAL

- Patient must continue to meet above criteria**; AND**
- Patient has not experienced any treatment-restricting adverse effects

NAYZILAM® (MIDAZOLAM NASAL SPRAY)

Length of Authorization:	12 months
Initiative:	MNC: Non-Formulary Product (IE 50698 / MR – GSN PatOverride)

CLINICAL CRITERIA FOR INITIAL APPROVAL

- Patient is 12 years of age or older; **AND**
- Patient has a diagnosis of epilepsy and therapy is being used for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern; **AND**
- Patient does not have any of the following contraindications:
  - Known hypersensitivity to midazolam; **OR**
  - Acute narrow-angle glaucoma

CLINICAL CRITERIA FOR RENEWAL

- Patient must continue to meet above criteria; **AND**
- Absence of unacceptable toxicity from the drug

NEUROPATHIC PAIN AGENTS

Length of Authorization:	1 year
Initiative:	MNC: Neuropathic Pain Agents (IE 2462 / NCPDP 75 – HICL)

STEP CRITERIA

GRALISE®

Diagnosis of **Neuropathic Pain**

- Patient must have a trial and failure of gabapentin

CLINICAL CRITERIA

HORIZANT®

Diagnosis of **Chronic Persistent Restless Leg Syndrome or Postherpetic Neuralgia** (Must Have Had PHN for at Least 3 Months)

- Patient is 18 years of age or older; **AND**
- Provider attests to informing patients and caregivers to monitor for emergence of worsening of depression, suicidal thoughts or behavior, and/or any unusual changes in mood or behavior and that medication may cause significant driving impairment, somnolence/sedation and dizziness and alcohol should be avoided; **AND**
- Patient must **not** have iron deficiency anemia **or** renal failure; **AND**
- Must have a history of failure, contraindication or intolerance to **or** is not successfully managed with gabapentin for PHN; **OR**
- For chronic persistent RLS, must have a history of failure, contraindications, or intolerance to pramipexole (IR) or ropinirole (IR) **and** gabapentin (IR)

RENEWAL CRITERIA

- Patient has had benefit from therapy; **AND**
- Patients condition has not progressed or worsened while on therapy; **AND**
- Patient has not developed any contraindications or other exclusions to its continued use (i.e., emergence or worsening of depression, suicidal thoughts or behavior, and/or unusual changes in mood or behavior)

COVERED – PA REQUIRED
Gralise® (*gabapentin*)
Horizant® (gabapentin)

NEXAVAR® (SORAFENIB)

Length of Authorization:	6 Months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75 – HICL, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Renal Cell Cancer**

- Patient is at least 18 years of age; **AND**
- Patient will avoid concomitant use with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **AND**
- Used as a single agent; **AND**
- Patient has advanced disease

Diagnosis of **Hepatocellular Cancer (HCC)**

- Patient is at least 18 years of age; **AND**
- Patient will avoid concomitant use with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **AND**
- Used as single-agent therapy; **AND**
  - Patient has unresectable disease; **OR**
  - Patient has Child-Pugh Class A or B7 disease only; **AND**
    - Patient has metastatic disease or extensive liver tumor burden; **OR**
    - Patient is inoperable by performance status or comorbidity with local disease or local disease with minimal extrahepatic disease only

Diagnosis of **Angiosarcoma**

- Patient is at least 18 years of age; **AND**
- Patient will avoid concomitant use with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **AND**
- Used as a single agent

Diagnosis of **Desmoid Tumors (Aggressive Fibromatosis)**

- Patient is at least 18 years of age; **AND**
- Patient will avoid concomitant use with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **AND**
- Used as a single agent; **AND**
- Timeframe for a treatment response is more critical; **AND**
  - Used as an alternative therapy for disease progression on primary therapy if not already used for primary treatment; **OR**
  - Used as primary treatment in one of the following treatment settings
    - Progressive disease; **OR**
    - Gross residual disease (R2 resection); **OR**
    - Patient has no documented progression, but there are concerns for morbidity or significant symptoms

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Gastrointestinal Stromal Tumors (GIST)**

- Patient is at least 18 years of age; **AND**
- Patient will avoid concomitant use with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **AND**
- Patient has unresectable or metastatic disease; **AND**
- Used as fourth-line therapy as a single agent; **AND**
- Disease has progressed after single-agent treatment with each of the following: imatinib, sunitinib and regorafenib

Diagnosis of **Solitary Fibrous Tumor**

- Patient is at least 18 years of age; **AND**
- Patient will avoid concomitant use with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **AND**
- Used as a single agent

Diagnosis of **Thyroid Carcinoma – Medullary**

- Patient is at least 18 years of age; **AND**
- Patient will avoid concomitant use with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **AND**
- Used as a single agent; **AND**
- Patient has recurrent or persistent metastatic disease; **AND**
- Patient has progressive or symptomatic disease; **AND**
  - Treatment with clinical trials, vandetanib, or cabozantinib are not available or appropriate; **OR**
  - Disease has progressed on vandetanib or cabozantinib

Diagnosis of **Thyroid Carcinoma – Differentiated (Follicular Carcinoma/Hürthle Cell Carcinoma/Papillary Carcinoma)**

- Patient is at least 18 years of age; **AND**
- Patient will avoid concomitant use with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **AND**
- Used as a single agent; **AND**
- Patient has recurrent, persistent, or metastatic disease; **AND**
  - Patient is refractory to radioactive iodine; **OR**
  - Patient has progressive and/or symptomatic disease that is not susceptible to radioactive iodine (RAI) therapy

Diagnosis of **Chordoma**

- Patient is at least 18 years of age; **AND**
- Patient will avoid concomitant use with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **AND**
- Used as a single agent for recurrent disease

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Osteosarcoma**

- Patient is at least 18 years of age; **AND**
- Patient will avoid concomitant use with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **AND**
- Patient has relapsed, refractory, or metastatic disease; **AND**
- Used as a single agent; **AND**
- Used as second line therapy

Diagnosis of **Ovarian Cancer (Epithelial, Fallopian Tube, or Primary Peritoneal)**

- Patient is at least 18 years of age; **AND**
- Patient will avoid concomitant use with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **AND**
- Patient has recurrent or persistent disease; **AND**
- Used in combination with topotecan; **AND**
- Patient has platinum-resistant disease; **AND**
- Patient is not experiencing an immediate biochemical relapse (i.e., rising CA-125 without radiographic evidence of disease)

Diagnosis of **Acute Myeloid Leukemia (AML)**

- Patient is at least 18 years of age; **AND**
- Patient will avoid concomitant use with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **AND**
- Patient has FLT3-ITD mutation-positive disease; **AND**
  - Used in combination with azacitidine or decitabine; **AND**
    - Patient has relapsed or refractory disease; **OR**
    - Used as induction therapy in patients ≥ 60 years of age who are not candidates for or decline intensive therapy; **OR**
    - Used as post-induction therapy following response to previous lower intensity therapy with the same regimen in patients ≥ 60 years of age; **OR**
  - Used as a component of repeating the initial successful induction regimen for relapsed or refractory disease in patients experiencing a late relapse (≥ 12 months after induction regimen); **AND**
    - Treatment has not been administered continuously; **AND**
    - Treatment was not previously stopped due to development of clinical resistance.

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug (e.g., cardiac ischemia and/or infarction, hemorrhage, severe hypertension, transaminase elevations leading to hepatitis, severe dermatologic toxicity [Stevens-Johnson syndrome (SJS), toxic epidermal necrosis (TEN)], gastrointestinal perforation, QT-prolongation, risk of impaired wound healing, impairment of thyroid stimulating hormone suppression in differentiated thyroid carcinoma).

NINLARO® (IXAZOMIB)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75 – HICL, 50081 and 2193) MNC: Non-Formulary Product (IE 50698 / MR – GSN PatOverride)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Multiple Myeloma**

- Patient is at least 18 years of age; **AND**
- Patient will avoid concomitant use with strong CYP3A inducers (e.g., rifampin, phenytoin, carbamazepine, St. John's Wort, etc.); **AND**
- Used as initial therapy; **AND**
  - Used in combination with lenalidomide and dexamethasone in patients who are not transplant candidates; **OR**
  - Used in combination with cyclophosphamide and dexamethasone in patients who are transplant candidates; **OR**
- Used as maintenance therapy; **AND**
  - Used as single agent therapy in patients who are transplant candidates; **AND**
    - Patient is symptomatic after response to primary myeloma therapy; **OR**
    - Patient has a response or stable disease following autologous stem cell transplant; **OR**
- Used for relapsed or progressive disease; **AND**
  - Dexamethasone with or without lenalidomide or cyclophosphamide after failure of at least one prior therapy; **OR**
  - Dexamethasone and pomalidomide after disease progression following at least two prior therapies, including an immunomodulatory agent (i.e. lenalidomide or thalidomide) and proteasome inhibitor (i.e. bortezomib, carfilzomib, etc.), on or within 60 days of completion of the last therapy.

Diagnosis of **Systemic Light Chain Amyloidosis**

- Patient is at least 18 years of age; **AND**
- Patient will avoid concomitant use with strong CYP3A inducers (e.g., rifampin, phenytoin, carbamazepine, St. John's Wort, etc.); **AND**
- Used for relapsed or refractory disease; **AND**
- Used as a single agent or in combination with dexamethasone.

Diagnosis of **Waldenström macroglobulinemia**

- Patient is at least 18 years of age; **AND**
- Patient will avoid concomitant use with strong CYP3A inducers (e.g., rifampin, phenytoin, carbamazepine, St. John's Wort, etc.); **AND**
- Used in combination with rituximab and dexamethasone; **AND**
  - Used as primary therapy; **OR**
  - Used for relapsed disease if previously used as primary therapy that was well tolerated and elicited a prolonged response.

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug (e.g., gastrointestinal toxicities [e.g., diarrhea, constipation, nausea, vomiting], thrombocytopenia, peripheral neuropathy, peripheral edema, hepatotoxicity, severe rash, thrombotic microangiopathy including thrombotic thrombocytopenic purpura/hemolytic uremic syndrome [TTP/HUS]); **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
  - Waldenström Macroglobulinemia: Patient has not exceeded the maximum of six 8-week cycles of maintenance therapy
  - Systemic Light Chain Amyloidosis: Patient has not exceeded the maximum of twelve 4-week cycles.

ONDANSETRON TABLETS 24 MG

Length of Authorization:	For requested duration, up to 6 months
Initiative:	MNC: Antiemetics (IE 2462 / NCPDP 75 – HICL)

CLINICAL CRITERIA FOR INITIAL APPROVAL

- Patient is at least 4 years of age; **AND**
- Medication will be used for one of the following indications:
  - Prevention of nausea and vomiting associated with highly emetogenic cancer chemotherapy, including cisplatin ≥ 50 mg/m^2; **OR**
  - Prevention of nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy; **OR**
  - Prevention of nausea and vomiting associated with radiotherapy in patients receiving either total body irradiation, single high-dose fraction to the abdomen, or daily fractions to the abdomen; **OR**
  - Prevention of postoperative nausea and/or vomiting.

CLINICAL CRITERIA FOR RENEWAL

- Patient continues to meet initial criteria; **AND**
- Absence of unacceptable toxicity from the drug

ORFADIN® (NITISINONE)

Length of Authorization:	1 year
Initiative:	MNC: Non-Formulary Product (IE 50698 / MR – GSN PatOverride)

CLINICAL CRITERIA

- Diagnosis of hereditary tyrosinemia type 1 (HT-1); **AND**
- Patient is on a tyrosine and phenylalanine restricted diet

ORKAMBI® (LUMACAFTOR/IVACAFTOR

Length of Authorization:	6 months, may be renewed
Initiative:	MNC: Non-Formulary Product (IE 50698 / MR – GSN PatOverride)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Cystic Fibrosis**

- Patient is at least 2 years old; **AND**
- Confirmation the patient is not receiving concurrent treatment with other CFTR-targeted therapy (e.g., single agent ivacaftor, tezacaftor/ivacaftor); **AND**
- Patient is homozygous (mutation is present on both alleles) for the *F508del* mutation in the CFTR gene as confirmed by an FDA-cleared CF mutation test; **AND**
- Baseline percent predicted FEV_1 (reported measurements may be used on renewal).

CLINICAL CRITERIA FOR RENEWAL

Authorizations can be renewed based on the following criteria:

- Disease response as indicated by one or more of the following:
  - Decreased pulmonary exacerbations compared to pretreatment baseline
  - Improvement or stabilization of lung function (measured by percent predicted FEV_1 within previous 30 days) compared to baseline
  - Decrease in decline of lung function (measured by percent predicted FEV_1 within previous 30 days) compared to baseline
  - Improvement in quality of life (e.g., Cystic Fibrosis Questionnaire-Revised [CFQ-R] score), weight gain, or growth; **AND**
- Patient has not received a lung transplant; **AND**
- Absence of unacceptable toxicity from the drug (e.g., severe hepatotoxicity [e.g., elevated ALT, AST, or bilirubin], respiratory events [e.g., chest discomfort, dyspnea, and abnormal respiration], malignant hypertension, development of cataracts or lens opacities)

OXBRYTA® (VOXELOTOR)

Length of Authorization:	Initial: 6 months, Renewal: 12 months
Initiative:	MNC: Non-Formulary Product (IE 50698 / MR – GSN PatOverride)

CLINICAL CRITERIA FOR APPROVAL

Diagnosis of **Sickle Cell Disease**

- Patient must be 12 years or older; **AND**
- Hemoglobin (Hb) lab values are obtained within 30 days of the date of administration (unless otherwise indicated); **AND**
- Will not to be used in combination with crizanlizumab (Adakveo) or L-glutamine (Endari); **AND**
- Patient will avoid concomitant therapy with ALL of the following:
  - Coadministration with fluconazole or strong CYP3A4 inhibitors (e.g., ketoconazole, clarithromycin, grapefruit juice, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong or moderate CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort, phenobarbital, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient has a confirmed diagnosis of sickle-cell disease, of any genotype (e.g., HbSS, HbSC, HbS/beta0-thalassemia, HbS/beta+-thalassemia, and others) as determined by one of the following:
  - Identification of significant quantities of HbS with or without an additional abnormal β-globin chain variant by hemoglobin assay; **OR**
  - Identification of biallelic *HBB* pathogenic variants where at least one allele is the p.Glu6Val pathogenic variant on molecular genetic testing; **AND**
- Patient had an insufficient response to a minimum 3-month trial of hydroxyurea (unless contraindicated or intolerant); **AND**
- Patient has symptomatic anemia with a baseline hemoglobin (Hb) between ≥ 5.5 g/dL to ≤ 10.5 g/dL prior to start of therapy; **AND**
- Other causes of anemia (e.g., hemolysis not attributed to SCD, bleeding, vitamin deficiency, etc.) have been ruled out.

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug (e.g., severe hypersensitivity reactions); **AND**
- Disease response as evidenced by an increase in hemoglobin of > 1 g/dL from baseline.

PIQRAY® (ALPELISIB)

Length of Authorization:	6 months, may be renewed
Initiative:	MNC: Non-Formulary Product (IE 50698 / MR – GSN PatOverride)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Breast Cancer**:

- Patient is at least 18 years of age; **AND**
- Patient has not received prior treatment with other PI3K inhibitors (e.g., idelalisib, duvelisib, copanlisib); **AND**
- Patient has not received prior treatment with a mammalian target of rapamycin (mTOR) inhibitor (e.g., everolimus); **AND**
- Patient has not received prior chemotherapy for advanced breast cancer; **AND**
- Patient has not previously been treated with fulvestrant; **AND**
- Patient will avoid concomitant use with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort); **AND**
- Patient will avoid concomitant use with BCRP inhibitors (e.g., ritonavir, imatinib, cyclosporin A), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **AND**
- Patient has a baseline fasting plasma glucose, HbA1c, and does not have diabetes mellitus Type 1 or uncontrolled Type 2; **AND**
- Patient does not have a history of acute pancreatitis within 1 year of therapy or a past medical history of chronic pancreatitis; **AND**
- Patient has the presence of one or more PIK3CA-mutations in tumor tissue or plasma specimens, as detected by an FDA-approved test or CLIA-compliant test; **AND**
- Patient does **not** have inflammatory breast cancer; **AND**
- Patient has human epidermal growth factor receptor 2 (HER2)-negative disease; **AND**
- Patient has hormone receptor (HR)-positive disease; **AND**
- Used in combination with fulvestrant; **AND**
  - Patient has advanced, recurrent, or metastatic disease; **AND**
    - Used as second-line therapy or beyond; **AND**
    - Patient has no visceral crisis; **AND**
      - Patient is male or a post-menopausal female; **OR**
      - Patient is a pre-menopausal female treated with ovarian ablation/suppression

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug (e.g., severe hypersensitivity, severe cutaneous reactions [≥ Grade 3 rash], severe hyperglycemia [>250 mg/dL], severe pneumonitis/interstitial-lung-disease, severe diarrhea [≥ Grade 2], severe pancreatitis [≥ Grade 2]).

POMALYST® (POMALIDOMIDE)

Length of Authorization:	6 Months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75 – HICL, 50081 and 2193) MNC: Non-Formulary Product (IE 50698 / MR – GSN PatOverride)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Multiple Myeloma**

- Patient is at least 18 years of age; **AND**
- Females of reproductive potential must have 2 negative pregnancy tests before initiation of therapy and use 2 contraception methods starting 4 weeks prior to initiation, during, and at least 4-weeks after discontinuing therapy; **AND**
- Prescriber and patient must be enrolled in and meet the conditions of the POMALYST REMS program; **AND**
- Patient will not receive in combination with PD-1 or PD-L1 targeted therapy (e.g., avelumab, durvalumab, atezolizumab, pembrolizumab, nivolumab, cemiplimab); **AND**
- Patient will avoid coadministration with strong CYP1A2 inhibitors (e.g., ciprofloxacin, fluvoxamine); if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **AND**
- Patient will receive thromboprophylaxis, unless contraindicated; **AND**
- Patient has relapsed or progressive disease and received at least 2 prior therapies, including an immunomodulatory agent (e.g., lenalidomide or thalidomide) and a proteasome inhibitor (e.g., bortezomib); **AND**
  - Patient has demonstrated disease progression on or within 60 days of completion of last therapy; **AND**
    - Used in combination with dexamethasone with or without one of the following: bortezomib, carfilzomib, ixazomib, or cyclophosphamide; **OR**
    - Used as a single agent if patient is steroid-intolerant; **OR**
  - Used in combination with dexamethasone and either daratumumab, elotuzumab, or isatuximab
- Patient has POEMS (polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, skin changes) syndrome; **AND**
  - Used in combination with dexamethasone; **AND**
    - Used as induction therapy for transplant eligible patients; **OR**
    - Used for transplant ineligible patients

Diagnosis of **Primary CNS Lymphoma**

- Patient is at least 18 years of age; **AND**
- Females of reproductive potential must have 2 negative pregnancy tests before initiation of therapy and use 2 contraception methods starting 4 weeks prior to initiation, during, and at least 4-weeks after discontinuing therapy; **AND**
- Prescriber and patient must be enrolled in and meet the conditions of the POMALYST REMS program; **AND**
- Patient will not receive in combination with PD-1 or PD-L1 targeted therapy (e.g., avelumab, durvalumab, atezolizumab, pembrolizumab, nivolumab, cemiplimab); **AND**
- Patient will avoid coadministration with strong CYP1A2 inhibitors (e.g., ciprofloxacin, fluvoxamine, etc.); if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **AND**
- Patient will receive thromboprophylaxis, unless contraindicated; **AND**
- Used as single agent therapy for relapsed or refractory disease; **AND**
  - Patient has failed prior methotrexate-based regimen without prior radiation therapy; **OR**
  - Patient has received prior whole brain radiation therapy; **OR**
  - Patient has received prior high-dose chemotherapy with stem cell rescue; **OR**
- Used as induction therapy as a single agent; **AND**
  - Patient is unsuitable for or intolerant to high-dose methotrexate.

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Systemic Light Chain Amyloidosis**

- Patient is at least 18 years of age; **AND**
- Females of reproductive potential must have 2 negative pregnancy tests before initiation of therapy and use 2 contraception methods starting 4 weeks prior to initiation, during, and at least 4-weeks after discontinuing therapy; **AND**
- Prescriber and patient must be enrolled in and meet the conditions of the POMALYST REMS program; **AND**
- Patient will not receive in combination with PD-1 or PD-L1 targeted therapy (e.g., avelumab, durvalumab, atezolizumab, pembrolizumab, nivolumab, cemiplimab); **AND**
- Patient will avoid coadministration with strong CYP1A2 inhibitors (e.g., ciprofloxacin, fluvoxamine); if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **AND**
- Patient will receive thromboprophylaxis, unless contraindicated; **AND**
- Patient has relapsed or refractory disease; **AND**
- Used in combination with dexamethasone.

Diagnosis of **Kaposi Sarcoma**

- Patient is at least 18 years of age; **AND**
- Females of reproductive potential must have 2 negative pregnancy tests before initiation of therapy and use 2 contraception methods starting 4 weeks prior to initiation, during, and at least 4-weeks after discontinuing therapy; **AND**
- Prescriber and patient must be enrolled in and meet the conditions of the POMALYST REMS program; **AND**
- Patient will not receive in combination with PD-1 or PD-L1 targeted therapy (e.g., avelumab, durvalumab, atezolizumab, pembrolizumab, nivolumab, cemiplimab); **AND**
- Patient will avoid coadministration with strong CYP1A2 inhibitors (e.g., ciprofloxacin, fluvoxamine); if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **AND**
- Patient will receive thromboprophylaxis, unless contraindicated; **AND**
- Patient has AIDS-related Kaposi sarcoma; **AND**
  - Used in combination with highly active antiretroviral therapy (HAART); **AND**
    - Patient has failed on at least one month of HAART; **AND**
      - Patient does not have symptomatic pulmonary Kaposi sarcoma or symptomatic visceral Kaposi sarcoma (except for non-ulcerating disease restricted to the oral cavity); **OR**
    - Patient has relapsed or refractory advanced cutaneous, oral, visceral, or nodal disease ; **AND**
      - Used as subsequent therapy after failure on two lines of prior systemic therapy**; OR**
- Patient is HIV-negative; **AND**
  - Patient does not have symptomatic pulmonary Kaposi sarcoma or symptomatic visceral Kaposi sarcoma (except for non-ulcerating disease restricted to the oral cavity)

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug (e.g., hematologic toxicity [anemia, neutropenia, or thrombocytopenia], hepatotoxicity, venous or arterial thromboembolism, severe cutaneous reactions, dizziness/confusional state, neuropathy, development of second primary malignancy, tumor lysis syndrome, severe hypersensitivity [including angioedema, anaphylaxis, and anaphylactic reactions]).

PREMARIN CREAM (CONJUGATED ESTROGENS)

Length of Authorization:	1 Year, eligible for renewal
Initiative:	MNC: Estrogens (IE 2462 / NCPDP 75 – HICL)

CLINICAL CRITERIA

- Patient is 18 years of age or older; **AND**
- Patient must have a diagnosis of one of the following; **AND**
  - Atrophic Vaginitis and Kraurosis Vulvae, **OR**
  - Moderate to Severe Dyspareunia, a Symptom of Vulvar and Vaginal Atrophy, due to Menopause
- Patient must have an inadequate response, contraindication, or intolerance to generic estradiol 0.01% cream or 10 mcg vaginal tablet

Contraindications:

- Known or suspected estrogen-dependent neoplasia
- Active DVT, PE, or a history of these conditions
- Active arterial thromboembolic disease (for example, stroke and MI), or a history of these conditions
- Known liver dysfunction or disease
- Known protein C, protein S, or anti-thrombin deficiency or other known thrombophilic disorders
- Known or suspected pregnancy

PREVYMIS® (LETERMOVIR)

Length of Authorization:	100 days, may not be renewed
Initiative:	MNC: Non-Formulary Product (IE 50698 / MR – GSN PatOverride)

CLINICAL CRITERIA FOR APPROVAL

- Patient is at least 18 years old; **AND**
- Allogeneic hematopoietic stem cell transplant (HSCT) recipient; **AND**
- Seropositive for CMV within 1 year before or < 100 days after HSCT; **AND**
- Patient is not receiving concurrent therapy with any of the following:
  - Pimozide
  - Ergot alkaloids
  - Cyclosporine in conjunction with either pitavastatin or simvastatin

CLINICAL CRITERIA FOR RENEWAL

- Coverage cannot be renewed

PROLEUKIN® (ALDESLEUKIN, IL-2)

Length of Authorization:	2 Months, may be renewed
Initiative:	MNC: Non-Formulary Product (IE 50698 / MR – GSN PatOverride)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Renal Cell carcinoma:**

- Patient must be at least 18 years old; **AND**
- Patient must have normal cardiac function (i.e., Normal ejection fraction and unimpaired wall motion) determined by thallium stress testing; **AND**
- Patient must have normal pulmonary function determined by formal pulmonary function testing (i.e., FEV 1 >2 liters or ≥75% of predicted for height and age) prior to initiating therapy; **AND**
- Patient must have serum creatinine of ≤1.5 mg/dL; **AND**
- Patient has a performance status (ECOG of 0-1); **AND**
- Proleukin should be administered in a hospital setting under close supervision of a qualified physician; **AND**
- Pre-existing bacterial infections should be adequately treated prior to initiation of therapy; **AND**
- Patient must not have an organ allograft; **AND**
- Patient must not have untreated or active CNS metastases; **AND**
- Patient must have relapsed or metastatic disease; **AND**
- Must be used as a single agent; **AND**
- Must be used as first-line therapy; **AND**
- Patient's cancer is predominantly clear cell histology

Diagnosis of **Melanoma:**

- Patient must be at least 18 years old; **AND**
- Patient must have normal cardiac function (i.e., normal ejection fraction and unimpaired wall motion) determined by thallium stress testing; **AND**
- Patient must have normal pulmonary function determined by formal pulmonary function testing (i.e., FEV 1 >2 liters or ≥75% of predicted for height and age) prior to initiating therapy; **AND**
- Patient must have serum creatinine of ≤1.5 mg/dL; **AND**
- Patient has a performance status (ECOG of 0-1); **AND**
- Proleukin should be administered in a hospital setting under close supervision of a qualified physician; **AND**
- Pre-existing bacterial infections should be adequately treated prior to initiation of therapy; **AND**
- Patient must not have an organ allograft; **AND**
- Patient must not have untreated or active CNS metastases; **AND**
- Patient must have unresectable or metastatic disease; **AND**
- Must be used as a single agent: **AND**
  - Used as first line therapy ; **OR**
  - Used as second line or subsequent therapy; **AND**
    - Patient has disease progression or used after maximum clinical benefit from BRAF targeted therapy; **AND**
    - Patient must not have active or untreated brain metastases or inadequate organ reserves

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Hematopoietic Cell Transplantation:**

- Patient must be at least 18 years old; **AND**
- Patient must have normal cardiac function (i.e., Normal ejection fraction and unimpaired wall motion) determined by thallium stress testing; **AND**
- Patient must have normal pulmonary function determined by formal pulmonary function testing (i.e., FEV 1 >2 liters or ≥75% of predicted for height and age) prior to initiating therapy; **AND**
- Patient must have serum creatinine of ≤1.5 mg/dL; **AND**
- Patient has a performance status (ECOG of 0-1); **AND**
- Proleukin should be administered in a hospital setting under close supervision of a qualified physician; **AND**
- Pre-existing bacterial infections should be adequately treated prior to initiation of therapy; **AND**
- Patient must not have an organ allograft; **AND**
- Patient must not have untreated or active CNS metastases; **AND**
- For chronic graft-versus-host disease (GVHD) as additional therapy in conjunction with systemic corticosteroids following no response (steroid-refractory disease) to first-line therapy options

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: capillary leak syndrome (CLS); sustained ventricular tachycardia (≥ 5 beats); cardiac arrhythmias not controlled or unresponsive to management; chest pain with ECG changes, consistent with angina or myocardial infarction; cardiac tamponade; intubation for >72 hours; renal failure requiring dialysis > 72 hours; coma or toxic psychosis lasting > 48 hours; repetitive or difficult to control seizures; bowel ischemia/perforation; GI bleeding requiring surgery, etc.; **AND**
- Patient must not have developed moderate to severe lethargy or somnolence

PROLIA® (DENOSUMAB)

Length of Authorization:	1 year- May be renewed
Initiative:	SPC: Osteoporosis Agents (IE 2462 / NCPDP 75 – GSN)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Osteoporosis in men and women:**

- Patient must be supplementing with 1,000 mg of calcium and at least 400 IU of vitamin D daily; **AND**
- Patient must be 18 years of age or older; **AND**
- Patient must not have hypocalcemia; **AND**
- Patient must be at a high risk of fracture; **AND**
- Pregnancy must be ruled out prior to starting therapy in women of child-bearing potential; **AND**
- Women only: Patient must be post-menopausal; **AND**
- Patient has a documented diagnosis of osteoporosis indicated by one or more of the following:
  - Hip DXA (femoral neck or total hip) or lumbar spine T-score ≤ -2.5 and/or forearm DXA 33% (one-third) radius; **OR**
  - T-score ≤-1 or low bone mass **and** a history of fragility fracture to the hip or spine; **OR**
  - T-score between -1 and -2.5 with a FRAX 10-year probability for major fracture ≥ 20% or hip fracture ≥ 3%; **AND**
- Documented treatment failure or ineffective response to a minimum 12-month trial on previous therapy with bisphosphonates (oral) such as alendronate or ibandronate; **OR**
- Patient has a documented contraindication* or intolerance to oral bisphosphonates such as alendronate or ibandronate.

Diagnosis of **Glucocorticoid-Induced Osteoporosis:**

- Patient must be supplementing with 1,000 mg of calcium and at least 400 IU of vitamin D daily; **AND**
- Patient is at least 18 years of age; **AND**
- Pregnancy must be ruled out prior to starting therapy in women of child-bearing potential; **AND**
- Patient must not have hypocalcemia; **AND**
- Patient must be at a high risk of fracture; **AND**
- Patient will be initiating or is continuing systemic glucocorticoid therapy at a daily dosage equivalent to ≥ 7.5 mg of prednisone and is expected to remain on glucocorticoid therapy for at least 6 months; **AND**
  - Documented treatment failure or ineffective response to a minimum 12-month trial on previous therapy with bisphosphonates (oral or IV) such as alendronate, risedronate, ibandronate, or zoledronic acid; **OR**
  - Patient has a documented contraindication or intolerance to BOTH oral bisphosphonates AND intravenous (IV) bisphosphonates such as alendronate, risedronate, ibandronate, or zoledronic acid

Diagnosis of **Osteoporosis treatment and prevention in prostate cancer patients:**

- Patient must be supplementing with 1,000 mg of calcium and at least 400 IU of vitamin D daily; **AND**
- Patient must be 18 years of age or older; **AND**
- Patient must not have hypocalcemia; **AND**
- Patient must be at a high risk of fracture; **AND**
- Documented hip DXA (femoral neck or total hip) or lumbar spine T-score ≤-1 (or patient meets the diagnostic criteria for osteoporosis above); **AND**
- Patient must be receiving androgen deprivation therapy for non-metastatic prostate cancer

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Osteoporosis treatment and prevention in breast cancer patients:**

- Patient must be supplementing with 1,000mg of calcium and at least 400 IU of vitamin D daily; **AND**
- Patient must be 18 years of age or older; **AND**
- Pregnancy must be ruled out prior to starting therapy in women of child-bearing potential; **AND**
- Patient must not have hypocalcemia; **AND**
- Patient must be at a high risk of fracture; **AND**
- Patient must be receiving adjuvant aromatase inhibitor therapy for breast cancer

ADDITIONAL INFORMATION TO AID IN THE FINAL DECISION

- Ineffective response is defined as one or more of the following:
  - Decrease in T-score in comparison with baseline T-score from DXA scam
  - Patient has a new fracture while on bisphosphonate therapy
- High risk for fractures include, but are not limited to, one or more of the following:
  - History of an osteoporotic fracture as an adult
  - Parental history of hip fracture
  - Low BMI
  - Rheumatoid arthritis
  - Alcohol intake (3 or more drinks per day)
  - Current smoking
  - History of oral glucocorticoids ≥ 5 mg per day of prednisone for > 3 months (ever)
- Examples of contraindications to oral bisphosphonate therapy include the following:
  - Documented inability to sit or stand upright for at least 30 minutes
  - Documented pre-existing gastrointestinal disorder such as inability to swallow, Barrett's esophagus, esophageal stricture, dysmotility, or achalasia

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: severe symptomatic hypocalcemia, osteonecrosis of the jaw, atypical femoral fractures, dermatological adverse reactions, severe infection, severe hypersensitivity/anaphylaxis, musculoskeletal pain, etc.; **AND**
- Disease response as indicated by one or more of the following:
  - Absence of fractures
  - Increase in bone mineral density compared to pretreatment base

Osteoporosis in men and women ONLY:

- After 5 years of treatment, patient will have a repeat DXA performed; **AND**
  - Patients with low to moderate risk disease will have therapy changed to an oral or IV bisphosphonate unless there is a contraindication or intolerance to both dosage forms

PROMACTA® (ELTROMBOPAG)

Length of Authorization:	3 Months, may be renewed
Initiative:	SPC: Blood Modifiers (IE 2462 / NCPDP 75 – HICL)

CLINICAL CRITERIA FOR INITIAL APPROVAL

- Diagnosis of **Chronic immune (idiopathic) thrombocytopenia (ITP)**
  - Patient is age 1 or older; **AND**
  - Patient has failed any of the following treatments for ITP:
    - Patient has failed previous therapy with corticosteroids; **OR**
    - Patient has failed previous therapy with immunoglobulins; **OR**
    - Patient has had splenectomy or is not a surgery candidate; **AND**
  - The patient is at increased risk for bleeding as indicated by platelet count is less than 30 x 10^9/L (30,000/mm^3); **AND**
  - Promacta is not being used to attempt to normalize platelet count
- Diagnosis of **Chronic Hepatitis C-associated thrombocytopenia**
  - Patient is 18 years of age or older; **AND**
  - Patient will be initiating and/or continuing interferon-based therapy to treat Hepatitis C; **AND**
  - Patient is diagnosed with thrombocytopenia as indicated by platelet count is less than 60x10^9/L (60,000/mm^3)
- Diagnosis of **Severe Aplastic Anemia**
  - Patient is 18 years of age or older; **AND**
    - Patient has bone marrow (BM) cellularity < 25%; **OR**
    - Patient has bone marrow (BM) cellularity < 50% if < 30% of BM is hematopoietic cells: **AND**
  - Patient is diagnosed with severe aplastic anemia and has at least two of the following:
    - Peripheral blood neutrophil count < 0.5 x10^9/L
    - Peripheral blood platelet count < 20x10^9/L
    - Peripheral blood reticulocyte count < 20x10^9/L; **AND**
  - Patient has had at least a 3-month trial and failure of previous therapy with **one** immunosuppressive therapy such as antithymocyte globulin (ATGAM, Thymoglobulin), cyclosporine (Sandimmune, Neoral), or cyclophosphamide (Cytoxan)

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include hepatotoxicity (abnormal liver enzymes) and thrombotic/thromboembolic complications (blood clots); **AND**
- **Thrombocytopenia**: Disease response indicated by the achievement and maintenance of a platelet count of at least 50 × 10^9/L as necessary to reduce the risk for bleeding; **OR**
- **Aplastic Anemia**: Disease response as indicated by one or more of the following:
  - Platelet count increases to 20x10^9/L above baseline, or stable platelet counts with transfusion independence for a minimum of 8 weeks;
  - Hemoglobin increase by greater than 1.5g/dL, or a reduction in greater than or equal to 4 units of RBC transfusions for 8 consecutive weeks;
  - ANC increase of 100% or an ANC increase greater than 0.5 x 10^9/L

PROPROTEIN CONVERTASE SUBTILISIN/KEXIN TYPE 9 INHIBITOR (PCSK9)

Length of Authorization:	Initial: 3 months, Renewal: 12months
Initiative:	MNC: Non-Formulary Product (IE 50698 / MR – GSN PatOverride)

CLINICAL CRITERIA FOR INITIAL APPROVAL

PRALUENT

Diagnosis of **Primary Hyperlipidemia/Heterozygous Familial Hypercholesterolemia (HeFH) and Prevention of Cardiovascular Events**

- Patient is 18 years or older; **AND**
- Patient is not on other concomitant PCSK9-inhibitors (e.g., evolocumab); **AND**
- Patient is not on combination therapy with a microsomal triglyceride transfer protein (MTP) inhibitor (e.g., lomitapide); **AND**
- Must be prescribed by, or in consultation with, a specialist in cardiology, lipidology, or endocrinology; **AND**
- Therapy will be used in conjunction with diet alone or in conjunction with other lipid-lowering therapies unless the patient is unable to tolerate (e.g., statins, ezetimibe); **AND**
- Patient has a diagnosis of atherosclerotic cardiovascular disease (ASCVD) (i.e. myocardial infarction, non-hemorrhagic stroke, or peripheral arterial disease) or ASCVD risk; **AND**
  - Patient can be classified into **one** of the following risk factor groups:
    - Extremely high risk ASCVD (defined as extensive burden of or active ASCVD, or ASCVD with extremely high burden of adverse poorly controlled risk cardiometabolic risk factors including HeFH or severe hypercholesterolemia (SH) with untreated LDL-C ≥ 220 mg/dL) with LDL-C ≥ 70 mg/dL
    - Very high risk ASCVD (defined as less extensive ASCVD and poorly controlled cardiometabolic risk factors) with LDL-C ≥ 100 mg/dL
    - High risk ASCVD with LDL-C ≥ 130 mg/dL; **AND**
      - Less extensive ASCVD and well-controlled risk factors; **OR**
      - SH with untreated LDL-C ≥ 220 mg/dL with poorly controlled risk factors; **AND**
  - Prior treatment history with highest available dose or maximally-tolerated dose of high intensity HMG-CoA reductase inhibitors (i.e., 'statin' therapy: atorvastatin 40 mg or 80 mg daily, rosuvastatin 20 mg or 40 mg daily, or simvastatin 80 mg daily* [*if already on this dose for more than 1 year]), unless one of the following:
    - Patient is not able to use a maximum dose of statin therapy due to muscle symptoms and statin re-challenge has been completed; **OR**
    - Patient has been diagnosed with rhabdomyolysis associated with statin use by acute neuromuscular illness or dark urine **and** an acute elevation in creatine kinase (usually > 5,000 IU/L or 5 times the upper limit of normal); **AND**
  - Patient has failed to reach a target LDL-C despite physician attestation that the patient is adherent to maximally-tolerated doses of statins prior to the lipid panel demonstrating suboptimal reduction; **OR**

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

PRALUENT *(CONTINUED)*

Diagnosis of **Primary Hyperlipidemia/Heterozygous Familial Hypercholesterolemia (HeFH) and Prevention of Cardiovascular Events *(Continued)***

- Patient has a diagnosis of Heterozygous Familial Hypercholesterolemia (HeFH) as confirmed by genotyping OR by patient having a first-degree relative similarly affected or with premature coronary artery disease (CAD) or with positive genetic testing for an LDL-C raising gene defect (LDL receptor, ApoB, or PCSK9); **AND**
  - Patient is currently undergoing LDL apheresis therapy; **OR**
  - Patient has prior treatment history with highest available dose or maximally-tolerated dose of high intensity HMG-CoA reductase inhibitors (i.e., 'statin' therapy: atorvastatin 40 mg or 80 mg daily, rosuvastatin 20 mg or 40 mg daily, or simvastatin 80 mg daily* [*if already on this dose for more than 1 year]), unless one of the following:
    - Patient is not able to use a maximum dose of statin therapy due to muscle symptoms and statin re-challenge has been completed; **OR**
    - Patient has been diagnosed with rhabdomyolysis associated with statin use by acute neuromuscular illness or dark urine AND an acute elevation in creatine kinase (usually > 5,000 IU/L or 5 times the upper limit of normal); **AND**
  - Patient has failed to reach a target LDL-C despite physician attestation that the patient is adherent to maximally-tolerated doses of statins prior to the lipid panel demonstrating suboptimal reduction; **AND**
  - Used as one of the following:
    - For primary prevention (i.e., patients without ASCVD) and LDL-C ≥100 mg/dL; **OR**
    - For secondary prevention (i.e., patients with ASCVD) and LDL-C ≥70 mg/dL

REPATHA

Diagnosis of **Hyperlipidemia (including Heterozygous Familial Hypercholesterolemia [HeFH]) and Prevention of Cardiovascular Events**.

- Patient aged 18 years and older; **AND**
- Patient is not on other concomitant PCSK9-inhibitor(i.e., alirocumab) therapy; **AND**
- Patient is not on combination therapy with a microsomal triglyceride transfer protein (MTP) inhibitor (i.e., lomitapide); **AND**
- Must be prescribed by, or in consultation with, a specialist in cardiology, lipidology, or endocrinology; **AND**
- Therapy will be used in conjunction with diet alone or in conjunction with other lipid-lowering therapies unless the patient is unable to tolerate (e.g., statins, ezetimibe); **AND**

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

REPATHA *(CONTINUED)*

Diagnosis of **Hyperlipidemia (including Heterozygous Familial Hypercholesterolemia [HeFH]) and Prevention of Cardiovascular Events *(Continued)***

- Patient has a diagnosis of atherosclerotic cardiovascular disease (ASCVD) (i.e. myocardial infarction, non-hemorrhagic stroke, or peripheral arterial disease) or ASCVD risk; **AND**
  - Patient can be classified into **one** of the following risk factor groups:
    - Extremely high risk ASCVD (defined as extensive burden of or active ASCVD, or ASCVD with extremely high burden of adverse poorly controlled risk cardiometabolic risk factors including HeFH or severe hypercholesterolemia (SH) with untreated LDL-C ≥ 220 mg/dL) with LDL-C ≥ 70 mg/dL
    - Very high risk ASCVD (defined as less extensive ASCVD and poorly controlled cardiometabolic risk factors) with LDL-C ≥ 100 mg/dL
    - High risk ASCVD with LDL-C ≥ 130 mg/dL; **AND**
      - Less extensive ASCVD and well-controlled risk factors; OR
      - SH with untreated LDL-C ≥ 220 mg/dL with poorly controlled risk factors; **AND**
  - Prior treatment history with highest available dose or maximally-tolerated dose of high intensity HMG-CoA reductase inhibitors (i.e., 'statin' therapy: atorvastatin 40 mg or 80 mg daily, rosuvastatin 20 mg or 40 mg daily, or simvastatin 80 mg daily* [*if already on this dose for more than 1 year]), unless one of the following:
    - Patient is not able to use a maximum dose of statin therapy due to muscle symptoms and statin re-challenge has been completed; **OR**
    - Patient has been diagnosed with rhabdomyolysis associated with statin use by acute neuromuscular illness or dark urine **and** an acute elevation in creatine kinase (usually > 5,000 IU/L or 5 times the upper limit of normal); **AND**
  - Patient has failed to reach a target LDL-C despite physician attestation that the patient is adherent to maximally-tolerated doses of statins prior to the lipid panel demonstrating suboptimal reduction; **OR**
- Patient has a diagnosis of Heterozygous Familial Hypercholesterolemia (HeFH) as confirmed by genotyping OR by patient having a first-degree relative similarly affected or with premature coronary artery disease (CAD) or with positive genetic testing for an LDL-C raising gene defect (LDL receptor, ApoB, or PCSK9); **AND**
  - Patient has prior treatment history with highest available dose or maximally-tolerated dose of high intensity HMG-CoA reductase inhibitors (i.e., 'statin' therapy: atorvastatin 40 mg or 80 mg daily, rosuvastatin 20 mg or 40 mg daily, or simvastatin 80 mg daily* [*if already on this dose for more than 1 year]), unless one of the following:
    - Patient is not able to use a maximum dose of statin therapy due to muscle symptoms and statin re-challenge has been completed; **OR**
    - Patient has been diagnosed with rhabdomyolysis associated with statin use by acute neuromuscular illness or dark urine AND an acute elevation in creatine kinase (usually > 5,000 IU/L or 5 times the upper limit of normal); **AND**
  - Patient has failed to reach a target LDL-C despite physician attestation that the patient is adherent to maximally-tolerated doses of statins prior to the lipid panel demonstrating suboptimal reduction; **AND**
  - Used as one of the following:
    - For primary prevention (i.e., patients without ASCVD) and LDL-C ≥ 100 mg/dL; **OR**
    - For secondary prevention (i.e., patients with ASCVD) and LDL-C ≥ 70 mg/dL

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

REPATHA *(CONTINUED)*

Diagnosis of **Homozygous Familial Hypercholesterolemia (HoFH)**.

- Patient aged 13 years and older; **AND**
- Patient is not on other concomitant PCSK9-inhibitor(i.e., alirocumab) therapy; **AND**
- Patient is not on combination therapy with a microsomal triglyceride transfer protein (MTP) inhibitor (i.e., lomitapide); **AND**
- Must be prescribed by, or in consultation with, a specialist in cardiology, lipidology, or endocrinology; **AND**
- Patient has a confirmed diagnosis of Homozygous Familial Hypercholesterolemia (HoFH) by any of the following:
  - Documented DNA test for functional mutation(s) in LDL receptor alleles or alleles known to affect LDL receptor functionality; **OR**
  - Untreated LDL-C > 500 mg/dL or treated LDL-C ≥ 300 mg/dL; **AND**
    - Cutaneous or tendon xanthoma before age 10 years; **OR**
    - Untreated LDL-C levels consistent with HeFH in both parents consistent with HeFH; **AND**
- Patient has been receiving stable lipid lowering therapy for at least 4 weeks; **AND**
- Therapy will be used in conjunction with diet and other LDL-lowering therapies (e.g., statins, ezetimibe, LDL apheresis)

CLINICAL CRITERIA FOR RENEWAL (MAY BE REQUESTED BY PRIMARY CARE PROVIDER)

- Absence of unacceptable toxicity from therapy. Examples of unacceptable toxicity include the following: severe hypersensitivity, etc.; **AND**
- Physician attests that patient has had a reduction in LDL-C when compared to the baseline labs (prior to initiating alirocumab or evolocumab); **AND**
- Patient continues to adhere to diet and/or lipid lowering therapy established prior to the original alirocumab approval; **AND**
- For Praluent: Dose escalation (up to the maximum dose and frequency specified below)- requests based on clinical and laboratory parameters being interpreted as an unsatisfactory response are defined as at least **one** of the following:
  - Patient has failed to achieve an LDL-C goal of <100 mg/dL (or non-HDL-C <130 mg/dL) if HeFH without ASCVD
  - Patient has failed to achieve an LDL-C goal of <70 mg/dL (or non-HDL-C <100 mg/dL) if ASCVD or HeFH with ASCVD

PULMONARY ARTERIAL HYPERTENSION AGENTS

Length of Authorization:	1 Year
Initiative:	SPC: Pulmonary Hypertension (IE 2462 / NCPDP 75 – HICL, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Pulmonary Arterial Hypertension (PAH)**

- Patient is at least 18 years old (≥ 17 for Remodulin or ≥ 3 for Tracleer); **AND**
  Note: Clinical review for use in pediatric patients, unless specified above, will occur on a case by case basis
- Patients of reproductive potential have had a negative pregnancy test prior to start of therapy and are enrolled in the manufacturer's REMS program (Opsumit, Letairis, Tracleer and Adempas only); **AND**
- Diagnosis confirmed by documented right heart catheterization with ALL of the following:
  - Mean pulmonary artery pressure (mPAP) > 20 mmHg; **AND**
  - Pulmonary arterial wedge pressure (PAWP) ≤ 15 mmHg; **AND**
  - Pulmonary vascular resistance (PVR) ≥ 3 wood units (240 dynes-sec/cm^5); **AND**
- Baseline assessment of 6-minute walk distance (6MWD) and/or B-type natriuretic peptide plasma levels (NT-proBNP); **AND**
- Patient does not have any of the following:
  - Patient is **not** concurrently on organic nitrates (i.e., isosorbide mononitrate, isosorbide dinitrate, nitroglycerin) or riociguat (For Revatio, Adcirca and Adempas **only**); **AND**
  - Patient does not have heart failure with reduced ejection fraction (**Flolan® only)**
  - Patient does not have congestive heart failure due to severe left ventricular systolic dysfunction **or** pulmonary edema (**Veletri® only**)
- Diagnosed with pulmonary arterial hypertension and classified as WHO Group 1 (See below for description of WHO classification for pulmonary hypertension); **AND**
- Pediatric patients are diagnosed with idiopathic or congenital pulmonary arterial hypertension (**Tracleer only**); **AND**
- Designated as New York Heart Association (NYHA) or World Health Organization (WHO) functional class II-IV (See below for description of functional classes):
- Patient is treatment-naïve to PAH-specific pharmacotherapy §; **AND**
  - Patient is Functional Class II or Functional Class III without evidence of rapid disease progression or poor prognosis; **AND**
    - Patient had an inadequate response to calcium channel blocker therapy or is not a candidate for treatment with a calcium channel blocker (i.e., negative results for acute vasoreactivity, right ventricular failure, or contraindication to calcium channel blocker); **AND**
      - Patient will be treated with a combination of Letairis and Adcirca; **OR**
      - Patient is unwilling or unable to tolerate combination therapy; **AND**
        - Patient will be treated with Revatio monotherapy; **OR**
      - Patient is unwilling or unable to tolerate combination therapy and will receive monotherapy with an endothelial-receptor antagonist (ERA) **§**, phosphodiesterase-5 inhibitor (PDE5i) **§**, or Adempas; **OR**
  - Patient is Functional Class III with evidence of rapid progression of their disease, or other markers of a poor clinical prognosis; **AND**
    - Patient will be treated with continuous IV Flolan or Veletri; **OR**
    - Patient will be treated with IV or SC Remodulin; **OR**

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Pulmonary Arterial Hypertension (PAH)** ***(Continued)***

- Patient is Functional Class IV; **AND**
  - Patient will be treated with continuous IV Flolan, or Veletri; **OR**
  - Patient will be treated with IV or SC Remodulin; **OR**
  - Patient is unwilling or unable to manage intravenous or subcutaneous prostacyclin analog therapy **§**; **AND**
  - Patient will be treated with an inhaled prostacyclin analog in combination with an oral PDE5i and an ERA **§**; **OR**
- Patient is Functional Class III or IV and had an inadequate clinical response (see criteria below) to monotherapy and will be adding a second class of PAH therapy as one of the following (see PAH pharmacotherapy table below)
  - Adding Revatio to an intravenous epoprostenol; **OR**
  - Initiating an up-titration of the patient's current dose of IV Flolan or Veletri; **OR**
  - Adding an inhaled prostacyclin analog to an ERA or a PDE5i; **OR**
  - Adding Revatio to an intravenous epoprostenol; **OR**
  - Adding Adempas to Tracleer, Letairis, or an inhaled prostacyclin analog; **OR**
  - Adding Opsumit to a PDE5i or an inhaled prostacyclin analog; **OR**
- Patient is Functional Class III or IV with an inadequate clinical response (see criteria below) to two classes of PAH pharmacotherapy and will be adding a third class of PAH therapy (see PAH pharmacotherapy table below **§**;); **OR**
- Patient is currently on Letairis with stable or symptomatic disease and will add Adcirca; **OR**
- Patient is transitioning from Remodulin to Orenitram and using Remodulin (treprostinil) and Orenitram (treprostinil) concurrently

Pulmonary Hypertension Pharmacotherapy §		
Class	**Drug**	**Route of Administration**
Phosphodiesterase-5 inhibitors (PDE5i)	Revatio (Sildenafil) Adcirca (Tadalafil)	IV, Oral Oral
Prostacyclin analogs	Flolan, Veletri (Epoprostenol) Orenitram, Remodulin, Tyvaso (Treprostinil) Ventavis (Iloprost)	IV Oral, IV/SC, Inhaled Inhaled
Endothelial-receptor antagonists (ERA)	Tracleer (Bosentan) Letairis (Ambrisentan) Opsumit (Macitentan)	Oral Oral Oral
Soluble guanylate cyclase stimulators	Adempas (riociguat) Must **not** be used in combination with PDE5i (e.g., Revatio, Adcirca) or intravenous prostacyclin analogs (e.g., Flolan, Veletri, Remodulin) *Subcutaneous administration of Remodulin is allowable with Adempas*	Oral
Prostacyclin receptor agonists	Uptravi (selexipag)	Oral

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

ADEMPAS

Diagnosis of **Pulmonary Arterial Hypertension (PAH)**

- Follow criteria above

Diagnosis of **Chronic-Thromboembolic Pulmonary Hypertension (Adempas only)**

- Patient is at least 18 years old; **AND**
- Patients of reproductive potential have had a negative pregnancy test prior to start of therapy and are enrolled in the manufacturer's REMS program; **AND**
- Baseline 6-minute walk test (6MWD) performed; **AND**
- Patient is **not** concurrently on organic nitrates (for example, isosorbide mononitrate, isosorbide dinitrate, nitroglycerin); **AND**
- Must not be used in combination with phosphodiesterase-5 inhibitors (PDE5i), prostacyclin analogs, or endothelial-receptor antagonists (ERAs) ; **AND**
- Patient does not have left heart disease or lung disease (e.g., COPD, interstitial lung disease, combined pulmonary fibrosis and emphysema [CPFE], etc.); **AND**
- Diagnosis of chronic pulmonary thromboembolic hypertension (CTEPH) confirmed after at least 3 months of effective anticoagulation with ALL of the following:
  - Mean pulmonary arterial pressure (mPAP) ≥ 25 mmHg
  - Pulmonary arterial wedge pressure (PAWP) ≤ 15 mmHg
  - Mismatch perfusion defects and/or specific diagnostic signs for CTEPH as seen on at least two of the following imaging methods: ventilation–perfusion (V/Q) scanning, pulmonary angiography, spiral computed tomography, or magnetic resonance angiography; **AND**
- Diagnosed with CTEPH and classified as WHO Group 4 (See below for description of WHO classification for pulmonary hypertension); **AND**
  - Patient is inoperable for surgery (i.e., pulmonary thromboendarterectomy); **AND**
    - Patient's pulmonary vascular resistance (PVR) > 300 dyn*sec*cm^{-5} measured at least 90 days after the start of full anticoagulation; **AND**
  - Patient has recurrent or persisting pulmonary hypertension with pulmonary vascular resistance (PVR) > 300 dyn*sec*cm^{-5} measured at least 180 days following pulmonary thromboendarterectomy.

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Inadequate Clinical Response Criteria
Inadequate clinical response for patients who were initially in WHO Functional Class II or III: • Resulting clinical status defined as stable and not satisfactory; **OR** • Resulting clinical status defined as unstable and deteriorating Inadequate clinical response for patients who were initially in WHO Functional Class IV: • No rapid improvement to WHO Functional Class III or better; **OR** • Resulting clinical status defined as stable and not satisfactory
Reference charts
WHO classification of pulmonary hypertension (PH): • Group 1 PAH: Pulmonary arterial hypertension (PAH) • Group 2 PH: Pulmonary hypertension owing to left heart disease • Group 3 PH: Pulmonary hypertension owing to lung diseases and/or hypoxia • Group 4 PH: Chronic thromboembolic pulmonary hypertension (CTEPH) • Group 5 PH: Pulmonary hypertension with unclear multifactorial mechanisms **New York Heart Association (NYHA) Functional Classification** • Class I: No symptoms with ordinary physical activity. • Class II: Symptoms with ordinary activity. Slight limitation of activity. • Class III: Symptoms with less than ordinary activity. Marked limitation of activity. • Class IV: Symptoms with any activity or even at rest. **World Health Organization (WHO) Functional Assessment Classification** • Class I: Patients with PH but without resulting limitation of physical activity. Ordinary physical activity does not cause undue dyspnea or fatigue, chest pain, or near syncope. • Class II: Patients with PH resulting in slight limitation of physical activity. They are comfortable at rest. Ordinary physical activity causes undue dyspnea or fatigue, chest pain, or near syncope. • Class III: Patients with PH resulting in marked limitation of physical activity. They are comfortable at rest. Less than ordinary activity causes undue dyspnea or fatigue, chest pain, or near syncope. • Class IV: Patients with PH with inability to carry out any physical activity without symptoms. These patients manifest signs of right-heart failure. Dyspnea and/or fatigue may even be present at rest. Discomfort is increased by any physical activity.

CLINICAL CRITERIA FOR RENEWAL

- Disease response as determined by one or more of the following:
  - Progress towards an improvement in WHO functional class status
  - Improvement in right ventricular function (based on echocardiogram or cardiac MRI)
  - Improvement (from baseline) on the 6-minute walk distance
  - Improvement in B-type natriuretic peptide plasma levels
  - Increase in time to first clinical worsening event (e.g., hospitalization due to worsening of PAH, initiation of inhaled/infused prostacyclin, disease progression [≥ 15% decrease in 6-minute walk distance and increase in functional class or worsening heart failure, or unsatisfactory long-term clinical response) (**Orenitram ONLY**); **AND**
- Absence of unacceptable toxicity from the drug.

CLINICAL CRITERIA FOR RENEWAL *(CONTINUED)*

REVATIO™ AND ADCIRCA®

- Absence of unacceptable toxicity from the drug (e.g., pulmonary edema, worsening of pulmonary veno-occlusive disease [PVOD], hearing loss, visual loss, hypotension; epistaxis; priapism)

FLOLAN®, VELETRI®

- Absence of unacceptable toxicity from the drug (e.g., anticoagulation abnormalities/risk of bleeding, pulmonary edema, vasodilation reactions [hypotension, flushing, nausea, vomiting, dizziness, or headache])

REMODULIN®

- Absence of unacceptable toxicity from the drug (e.g., catheter-blood stream infections [BSI], sepsis, severe infusion site reactions, symptomatic hypotension; anticoagulation abnormalities/risk of bleeding)

ORENITRAM™

- Absence of unacceptable toxicity from the drug (e.g., anticoagulation abnormalities [bleeding])

REMODULIN®

- Absence of unacceptable toxicity from the drug (e.g., blood stream infections [BSI]; sepsis; infusion site reactions; symptomatic hypotension; anticoagulation abnormalities [bleeding])

TYVASO®

- Absence of unacceptable toxicity from the drug (e.g., symptomatic hypotension; anticoagulation abnormalities [bleeding])

VENTAVIS®

- Absence of unacceptable toxicity from the drug (e.g., hypotension [systolic BP < 85 mmHg]; pulmonary edema)

TRACLEER®, LETAIRIS™, AND OPSUMIT®

- Absence of unacceptable toxicity from the drug (e.g., hepatic impairment; fluid retention; pulmonary edema/pulmonary veno-occlusive disease [PVOD]; decreased hemoglobin and hematocrit)

ADEMPAS

- Absence of unacceptable toxicity from the drug (e.g., symptomatic hypotension, bleeding, and pulmonary edema/pulmonary veno-occlusive disease [PVOD])

UPTRAVI

- Absence of unacceptable toxicity from the drug (e.g., pulmonary edema/pulmonary veno-occlusive disease [PVOD])

PULMONARY ARTERIAL HYPERTENSION AGENTS (CONTINUED)

Table below includes the preferred pulmonary arterial hypertension agents **(for non-formulary drugs, both clinical criteria and non-formulary drug criteria apply)**.

PREFERRED: PA REQUIRED (except for Revatio suspension for patients 12y.o or less)
Endothelin Receptor Antagonists
Letairis® (*ambrisentan*)
Tracleer® (*bosentan*)
Prostacyclin Analogue
Veletri (Epoprostenol)
PDE5 Inhibitors
Adcirca® (*tadalafil*)
Revatio® susp (*sildenafil*) No PA required: **Max age limit of 12 years old**
Sildenafil **20 mg** (generic for Revatio®)
Guanylate Cyclase Stimulator
Adcirca®(*tadalafil*)

PULMOZYME® (DORNASE ALFA)

Length of Authorization:	1 year
Initiative:	SPC: Respiratory Agents (IE 2462 / NCPDP 75 – HICL)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Cystic fibrosis (CF)**

- Patient is at least 5 years old; **AND**
- Patient has baseline forced vital capacity (FVC) greater than or equal to 40% predicted; **AND**
- Patient has concurrent use of at least one standard of therapy treatment. Standard cystic fibrosis treatments include: oral, inhaled and/or parenteral antibiotics (examples: tobramycin, aztreonam, azithromycin), cystic fibrosis transmembrane conductance regulator (CFTR) potentiators (examples: lumacaftor/ivacaftor, ivacaftor, etc.), bronchodilators (examples: albuterol solution/HFA, pirbuterol MDI , levalbuterol solution/HFA), enzyme supplements (example: pancrelipase), vitamins, oral or inhaled corticosteroids (examples: budesonide, budesonide/formoterol, prednisone) and analgesics

CLINICAL CRITERIA FOR RENEWAL

- Disease response as indicated by absence of respiratory tract infection, improved pulmonary function, etc.; **AND**
- Absence of unacceptable toxicity from the drug (e.g., hypersensitivity/allergic reaction)

RANEXA® (RANOLAZINE)

Length of Authorization:	1 Year, eligible for renewal
Initiative:	MNC: Antianginal Agents (IE 2462 / NCPDP 75 – HICL)

CLINICAL CRITERIA

- Patient is 18 years of age or older; **AND**
- Patient must have a diagnosis of chronic angina; **AND**
- Patient has an inadequate response, contraindication, or intolerance to beta blocker therapy; **AND**
- Patient does not have any of the following exclusion criteria; **AND**
  - QT interval prolongation
  - Concomitant use of strong CYP3A inhibitors (e.g., ketoconazole, clarithromycin, nelfinavir)
  - Concomitant use of strong CYP3A inducers (e.g., rifampin, phenobarbital, St. John's wort)
  - Liver cirrhosis
- Patient has been evaluated for potential clinically significant drug interactions, including the following:
  - Moderate CYP3A inhibitors (e.g., diltiazem, verapamil, erythromycin): **Limit Ranexa to 500 mg twice daily**.
  - P-gp inhibitors (e.g., cyclosporine): Ranolazine exposure increased. **Titrate Ranexa based on clinical response.**
  - CYP3A substrates: **Limit simvastatin to 20 mg when used with Ranexa**. Doses of other sensitive CYP3A substrates (e.g., lovastatin) and CYP3A substrates with narrow therapeutic range (e.g., cyclosporine, tacrolimus, sirolimus) may need to be reduced with Ranexa.
  - OCT2 substrates: **Limit the dose of metformin to 1700 mg daily when used with Ranexa 1000 mg twice daily.** Doses of other OCT2 substrates may require adjusted doses.
  - Drugs transported by P-gp (e.g., digoxin), or drugs metabolized by CYP2D6 (e.g., tricyclic antidepressants) may need reduced doses when used with Ranexa.

RAZADYNE® ER/IR (GALANTAMINE ER/IR)

Length of Authorization:	12 months
Initiative:	MNC: Miscellaneous: PA Required (IE 2462 / NCPDP 75 – GSN)

CLINICAL CRITERIA FOR INITIAL APPROVAL

- Diagnosis of mild to moderate dementia of the Alzheimer's type; **AND**
- Patient does not have any of the following contraindications:
  - Known hypersensitivity to galantamine hydrobromide or to any excipients used in the formulation

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug

RESTASIS® (CYCLOSPORINE)

Length of Authorization:	Initial approval: 3 months, Renewal: 6 months
Initiative:	MNC: Ophthalmics (IE 2462 / NCPDP 75 – HICL)

CLINICAL CRITERIA FOR INITIAL APPROVAL

- Patient is 16 years of age or older; **AND**
- Diagnosis of Sjögren's Disease (approve, no additional criteria below needs to be met); **OR**
- Diagnosis of moderate to severe **Keratoconjunctivitis Sicca (KCS) or Chronic Dry Eye disease (DED)- due to KCS; AND**
- Prescribed by an ophthalmologist, optometrist, or rheumatologist; **AND**
- Patient has one of the following:
  - Corneal fluorescein staining score of > 2 points in any field on a 0 to 4-point scale; **OR**
  - Schirmer test (STT) of 1 to 10 mm in 5 minutes; **OR**
  - Tear break up time (TBUT) positive for dry eye; **AND**
- Patient has tried and failed any one of the following therapies
  - Lubricating artificial tear drops or ointments (e.g., Refresh Tears®, any polyvinyl alcohol-based drops or ointments, any carboxymethylcellulose based drops or ointments, etc.) administered at least 4 times per day (recommended lipid-based eye drops Systane Balance, Refresh Optive Advance, Soothe XP, Retaine MGD); **OR**
  - Punctal plugs; **OR**
- Diagnosis of severe Atopic Keratoconjunctivitis; **AND**
  - Patient has tried and failed at least two ophthalmic steroids; or patient has a contraindication or intolerance to ophthalmic steroids; **AND**
  - Prescribed by an ophthalmologist, optometrist or rheumatologist

CLINICAL CRITERIA FOR RENEWAL

- Diagnosis of Sjögren's disease (approve, no additional criteria needs to be met); **OR**
- For other diagnoses: Patient has attested to using medicine without break in therapy. If there was a break in therapy, refer to initial approval criteria; **AND**
- Have improvement in signs of DED as measured by one of the following:
  - Decrease in corneal fluorescein staining score; **OR**
  - Increase in number of mm per 5 minutes using Schirmer tear test; **OR**
  - Improvement in Tear break up time (TBUT); **AND**
- Decrease in conjunctival redness; **AND**
- Improvement in ocular discomfort.

REVLIMID® (LENALIDOMIDE)

Length of Authorization:	6 Months, may be renewed Previously untreated Follicular lymphoma may be renewed for up to 18 cycles Previously treated Follicular lymphoma and Marginal zone lymphoma may be renewed for up to 12 cycles.
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75 – HICL, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Myelodysplastic Syndrome (MDS)**

- Both patient **and** prescriber are enrolled in the Revlimid REMS™ program; **AND**
- Patient has symptomatic or transfusion-dependent anemia (i.e., has had 2 or more units of red blood cells in the previous 8 weeks) with del(5q) ; **AND**
  - Used as a single agent in patients with lower risk disease (defined as IPSS-R [Very Low, Low, Intermediate], IPSS [Low/Intermediate-1], WPSS [Very Low, Low, Intermediate]); **OR**
- Patient has myelodysplastic/myeloproliferative neoplasms with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T) overlap disease; **AND**
  - Used as a single agent or in combination with a hypomethylating agent (e.g., azacitidine, decitabine); **OR**
- Patient has symptomatic anemia without del(5q); **AND**
  - Patient has lower risk disease (defined as IPSS-R [Very Low, Low, Intermediate], IPSS [Low/Intermediate-1], WPSS [Very Low, Low, Intermediate]); **AND**
    - Patient has serum erythropoietin (EPO) levels (within 28 days preceding request) of ≤ 500 mU/mL; **AND**
      - Patient has ring sideroblasts < 15%; **AND**
    - Used in combination with an erythropoiesis-stimulating agent [ESA] (i.e., epoetin alfa, darbepoetin alfa) following no response or loss of response to an ESA alone; **OR**
      - Patient has ring sideroblasts ≥15%; **AND**
    - Patient failed therapy with an ESA and a granulocyte-colony stimulating factor [G-CSF] (i.e., filgrastim, pegfilgrastim, etc.) agent**; OR**
    - Patient has serum EPO levels (within 28 days preceding request) > 500 mU/mL; **AND**
      - Patient had no response or an intolerance to immunosuppressive therapy (i.e., antithymocyte globulin [ATG] ± cyclosporine).

Diagnosis of **Multiple Myeloma**

- Both patient and prescriber are enrolled in the Revlimid REMS™ program; **AND**
- Used as primary therapy for newly diagnosed disease in combination with dexamethasone (excludes combination with dexamethasone and ixazomib in transplant candidates); **OR**
- Used as maintenance therapy after response to primary myeloma therapy or following autologous hematopoietic stem cell transplant (auto-HSCT) as a single agent or in combination with bortezomib; **OR**
- Used for previously treated multiple myeloma for relapsed or progressive disease in combination with dexamethasone or as a single agent if patient is steroid-intolerant

Diagnosis of **Systemic light chain amyloidosis**

- Both patient **and** prescriber are enrolled in the Revlimid REMS™ program; **AND**
- Used in combination with dexamethasone; **AND**
- Used for newly diagnosed or relapsed or refractory disease.

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Hodgkin Lymphoma (HL)**

- Used as a single agent; **AND**
- Used as third-line or greater therapy for relapsed or refractory disease; **AND**
- Both patient **and** prescriber are enrolled in the Revlimid REMS™ program.

Diagnosis of **Non-Hodgkin Lymphoma (NHL)**

- Both patient **and** prescriber are enrolled in the Revlimid REMS™ program; **AND**
- Mantle Cell lymphoma
  - Used as initial/induction therapy in combination with rituximab; **OR**
  - Used as a single agent after two prior therapies, one of which included bortezomib; **OR**
  - Used as a single agent or in combination with rituximab (excluding use in combination with ibrutinib and rituximab); **AND**
    - Used as second-line therapy; **OR**
    - Used to achieve a complete response after partial response to induction therapy; **OR**
    - Used for relapsed or progressive disease following a short response duration to prior chemoimmunotherapy.
  - Follicular Lymphoma
    - Used as first-line therapy in combination with rituximab for treatment of stage III or IV disease; **OR**
    - Used as subsequent therapy in patients with refractory or progressive disease.
  - AIDS-Related Cell Lymphoma
    - Used as subsequent therapy for relapsed non-germinal diffuse large B-cell lymphoma in patients who are not transplant candidates.
  - Diffuse Large B-Cell Lymphoma (DLBCL)
    - Used as subsequent therapy; **AND**
      - Treatment of non-germinal center DLBCL indolent or transformed disease in patients who had a histologic transformation from marginal zone or follicular lymphoma; **OR**
      - Treatment of non-germinal center DLBCL disease that is relapsed, progressive, refractory, partial or no response and patient is not a transplant candidate (includes primary cutaneous, leg-type disease).
  - High-Grade B-Cell Lymphoma (DLBCLC)
    - Used as subsequent therapy in patients with a partial response, no response, relapsed, progressive, or refractory disease and is not a transplant candidate.
  - Gastric MALT Lymphoma
    - Used as subsequent therapy for recurrent or progressive disease.
  - Non-gastric MALT Lymphoma
    - Used as subsequent therapy as a single agent or in combination with rituximab for refractory or progressive disease.
  - Nodal Marginal Zone lymphoma
    - Used as subsequent therapy for refractory or progressive disease.
  - Peripheral T-Cell Lymphoma (includes all of the following: peripheral T-cell lymphoma not otherwise specified, angioimmunoblastic T-cell lymphoma, enteropathy-associated T-cell lymphoma, monomorphic epitheliotropic intestinal T-cell lymphoma, nodal peripheral T-cell lymphoma with TFH phenotype, or follicular T-cell lymphoma):
    - Used as a single agent subsequent therapy for relapsed or refractory disease.

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Non-Hodgkin Lymphoma (NHL)** ***(Continued)***

- Splenic Marginal Zone Lymphoma
  - Used as subsequent therapy for previously treated or recurrent disease.
- Adult T-cell Leukemia/Lymphoma
  - Used as a single agent subsequent therapy for non-responders to first-line treatment for acute or lymphoma subtypes.
- Hepatosplenic gamma-Delta T-Cell Lymphoma
  - Used as a single agent subsequent therapy for refractory disease after two prior primary treatment regimens.
- Multicentric Castleman's Disease
  - Both patient **and** prescriber are enrolled in the Revlimid REMS™ program; **AND**
  - Used as subsequent therapy for disease that has progressed following treatment of relapsed/refractory or progressive disease.
- Mycosis Fungoides (MF)/Sezary Syndrome (SS)
  - Used as primary systemic therapy; **AND**
    - Patient has stage IV non-Sezary or visceral disease; **OR**
    - Patient has large cell transformation (LCT) with generalized cutaneous or extracutaneous lesions; **OR**
  - Used as systemic therapy for relapsed, refractory, or persistent disease.
- Post-Transplant Lymphoproliferative Disorders (PTLD)
  - Used as subsequent therapy in patients with persistent, progressive or partial response to first-line therapy; **AND**
  - Patient has monomorphic non-germinal center disease (B-cell type).
- Primary Cutaneous CD30+ T-Cell Lymphoproliferative Disorders
  - Used as a single agent for relapsed or refractory disease; **AND**
    - Patient has primary cutaneous anaplastic large cell lymphoma (ALCL) with multifocal lesions; **OR**
    - Patient has cutaneous ALCL with regional nodes (excludes systemic ALCL).
- Multicentric Castleman's Disease
  - Used as subsequent therapy for disease that has progressed following treatment of relapsed/refractory or progressive disease.
- Mycosis Fungoides (MF)/Sezary Syndrome (SS)
  - Used as primary systemic therapy; **AND**
    - Patient has stage IV non-Sezary or visceral disease; **OR**
    - Patient has large cell transformation (LCT) with generalized cutaneous or extracutaneous lesions; **OR**
  - Used as systemic therapy for relapsed, refractory, or persistent disease.
- Post-Transplant Lymphoproliferative Disorders (PTLD)
  - Used as subsequent therapy in patients with persistent, progressive or partial response to first-line therapy; **AND**
  - Patient has monomorphic non-germinal center disease (B-cell type)
- Primary Cutaneous CD30+ T-Cell Lymphoproliferative Disorders
  - Used as a single agent for relapsed or refractory disease; **AND**
    - Patient has primary cutaneous anaplastic large cell lymphoma (ALCL) with multifocal lesions; **OR**
    - Patient has cutaneous ALCL with regional nodes (excludes systemic ALCL)

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Primary CNS Lymphoma**

- Both patient and prescriber are enrolled in the Revlimid REMS™ program; **AND**
- Used as a single-agent or in combination with rituximab for relapsed or refractory disease; **AND**
  - Patient previously received whole brain radiation therapy; **OR**
  - Patient previously received high-dose methotrexate based regimen; **OR**
  - Patient received prior high-dose chemotherapy with stem cell rescue (HDT/ASCR)

Diagnosis of **Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL)**

- Both patient **and** prescriber are enrolled in the Revlimid REMS™ program; **AND**
- Used for relapsed or refractory disease; **OR**
- Used as maintenance therapy following a complete or partial response to second-line therapy in patients without del(17p)TP53 mutation; **OR**
- Used as maintenance therapy after first-line therapy in patients without del(17p)TP53 mutation; **AND**
  - Patient has high-risk minimal residual disease (MRD) $\geq 10^{-2}$ or $\geq 10^{-4}$ and $< 10^{-2}$ with unmutated immunoglobulin heavy-chain variable region gene (IGHV)

Diagnosis of **Myelofibrosis**

- Both patient **and** prescriber are enrolled in the Revlimid REMS™ program; **AND**
- Must be used as a single agent or in combination with prednisone for management of myelofibrosis-associated anemia; **AND**
  - Patient has a serum EPO ≥ 500 mU/mL; **OR**
  - Patient has a serum EPO < 500 mU/mL and no response or loss of response to erythropoietic stimulating agents.

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment defined as stabilization or disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: secondary primary malignancies, pulmonary embolism; deep vein thrombosis, hematologic toxicity (neutropenia, thrombocytopenia), tumor lysis syndrome, hepatic failure, severe cutaneous reactions, severe hypersensitivity reactions, etc.

RIVASTIGMINE (EXELON)

Length of Authorization:	12 months
Initiative:	MNC: Miscellaneous: PA Required (IE 2462 / NCPDP 75 – GSN)

CLINICAL CRITERIA FOR INITIAL APPROVAL

- Patient has a diagnosis of mild to moderate dementia of the Alzheimer's type; **OR**
- Patient has a diagnosis of mild to moderate dementia associated with Parkinson's disease
- For Rivastigmine Patch: The patient must have trialed and failed oral Rivastigmine

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug

RSV PROPHYLAXIS- SYNAGIS®

Length of Authorization:	November through April
Initiative:	SPC: RSV Prophylaxis (IE 2462 / NCPDP 75 – HICL)

INFORMATION ON RSV SEASON AND PATIENT POPULATIONS

- There is variability in the onset and offset of RSV season. Generally, it runs from November to April within the continental US. A maximum of 5 doses during RSV season provides 6 months of RSV prophylaxis.
- A total of 5 monthly doses beginning in November will provide protection for most infants through April and is recommended for most areas in the US.
- Native American Indian infants:
  - There is limited information about the burden of RSV infection among American Indian populations. Prophylaxis can be considered for Navajo and White Mountain Apache infants in the first year of life.
- Despite differences in onset and offset of RSV infection in some states or regions, only a maximum of 5 doses will be approved during RSV season. If prophylaxis is initiated later in the RSV season, the infant or child will receive less than 5 doses. For example, if prophylaxis is initiated in January, the fourth and final dose will be administered in April. For eligible infants born during RSV season, fewer than 5 monthly doses may be needed.

CLINICAL CRITERIA FOR APPROVAL

- **Technicians**: Do not approve. You may obtain the requested criteria information listed and escalate to pharmacist for review.
- **Pharmacists**: Approve the correct strength based on patient weight (15 mg/kg).

Synagis may be approved in the following scenarios:

Infant/Child Age at Start of RSV Season	Criteria
< 12 months (1st year of life)	• GA < 29 wks, 0 d (otherwise healthy); **OR** • Profoundly immunocompromised
≤ 12 months (1st year of life)	• CHD (hemodynamically *significant*) with *acyanotic* HD on CHF medications and will require cardiac surgery or with moderate to severe PH. For *cyanotic* heart defects consult a pediatric cardiologist; **OR** • CLD of prematurity (GA < 32 wks, 0 d and > 21% O2 x first 28 d after birth); **OR** • Anatomic pulmonary abnormalities, or neuromuscular disorder, or congenital anomaly that impairs the ability to clear upper airway secretions ; **OR** • CF with CLD and/or nutritional compromise
> 12 months (2nd year of life)	• CLD of prematurity (GA < 32 wks, 0 d and > 21% O2 x first 28 d after birth) and medical support (chronic steroids, diuretic therapy, or supplemental O2) within 6 months before start of 2nd RSV season; **OR** • CF with severe lung disease* or weight for length < 10th percentile
< 24 months (2nd year of life)	• Cardiac transplant during RSV season; **OR** • Already on prophylaxis and eligible: give post-op dose after cardiac bypass or after ECMO; **OR** • Profoundly immunocompromised

GA=gestational age; d=day; CF=cystic fibrosis; CHD=congenital heart disease; CHF=congestive heart failure; CLD=chronic lung disease; ECMO=extracorporeal membrane oxygenation; HD=heart disease; O_2=oxygen; PH=pulmonary hypertension; wks=weeks

*Examples of severe lung disease: previous hospitalization for pulmonary exacerbation in the first year of life, abnormalities on chest radiography (chest X-ray), or chest computed tomography (chest CT) that persist when stable.

*Examples of profoundly immunocompromised: HIV, Cancer - receiving chemotherapy, organ transplant receiving immunosuppressant therapy.

ADDITIONAL INFORMATION TO AID IN THE FINAL DETERMINATION

Synagis will **not** be approved in the following scenarios:

Infant/Child Age at Start of RSV Season	Deny
> 12 months (2nd year of life)	• Based on prematurity alone • CLD *without* medical support (chronic systemic steroids, diuretic therapy, or supplemental O2) • CHD • Otherwise healthy children in 2nd year of life
Any age	• Outpatient RSV infection or breakthrough RSV hospitalization** • Hemodynamically *insignificant* CHD*** • CHD lesions corrected by surgery (unless on CHF meds) • CHD and mild cardiomyopathy not on medical therapy • CHD in 2nd year of life
No specific age defined	• GA ≥ 29 wks, 0 d (otherwise healthy) • Asthma prevention • Reduce wheezing episodes • Down Syndrome • CF (otherwise healthy) • Healthcare-associated RSV disease****

CLD=chronic lung disease; CHD=congenital heart disease; CHF=congestive heart failure; GA=gestational age; CF=cystic fibrosis

**If any infant or child is receiving palivizumab prophylaxis and experiences an outpatient RSV infection of breakthrough RSV hospitalization, discontinue palivizumab, because the likelihood of a second RSV hospitalization in the same season is extremely low.

***Examples of hemodynamically *insignificant* CHD: secundum atrial septal defect, small ventricular septal defect, pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, patent ductus arteriosus.

**** No rigorous data exist to support palivizumab use in controlling outbreaks of health care-associated disease; palivizumab use is not recommended for this purpose.

RUFINAMIDE (BANZEL®)

Length of Authorization:	1 year
Initiative:	MNC: Anticonvulsants (IE 2462 / NCPDP 75 – HICL, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

- Patient is 1 year of age or older; **AND**
- Diagnosis of adjunctive therapy for Lennox-Gastaut syndrome when used in combination with at least one other anticonvulsant

RUXIENCE (RITUXIMAB-PVVR)

Length of Authorization:	6 months (12 months initially for pemphigus vulgaris; see below for RA), may be renewed (see exceptions below) • Rheumatoid arthritis (RA) – Initial: 1 month; Renewal: 1 month • Maintenance therapy for oncology indications (excluding acute lymphoblastic leukemia [ALL], mantle cell lymphoma, and hairy cell leukemia) may be renewed for up to a maximum of 2 years – Mantle cell lymphoma may be renewed until disease progression or intolerable toxicity – ALL and hairy cell leukemia may not be renewed • Relapse therapy for pemphigus vulgaris must be at least 16 weeks past a prior infusion
Initiative:	MNC: Non-Formulary Product (IE 50698 / MR – GSN PatOverride)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Acute lymphoblastic leukemia (ALL)**

For new starts only, patient must have a documented failure, contraindication, intolerance, or ineffective response to a trial of Truxima®.

- Patient age is 18 years or older (for relapsed/refractory treatment) or 15 years of older (for induction/consolidation treatment); **AND**
- Patient does not have a severe, active infection; **AND**
- Patient has been screened for the presence of hepatitis B (HBV) infection (i.e., HBsAg and anti-HBc) prior to initiating therapy and patients with evidence of current or prior HBV infection will be monitored for HBV reactivation during treatment; **AND**
- Patient has not received a live vaccine within 28 days prior to starting treatment and live vaccines will not be administered concurrently while on treatment; **AND**
- Patient CD20 antigen expression is positive; **AND**
- For induction/consolidation treatment:
  - Patient has Philadelphia chromosome-negative (Ph-) disease; **AND**
    - Patient is 15 years or older; **AND**
      - Used in combination with an anthracycline, cyclophosphamide, and vincristine-based regimen; **OR**
- For relapsed/refractory treatment:
  - Patient has Philadelphia chromosome-negative (Ph-) disease **or** tyrosine kinase inhibitor (TKI) refractory Philadelphia chromosome-positive (Ph+) disease; **AND**
    - Used in combination with MOpAD regimen (methotrexate, vincristine, pegaspargase, dexamethasone)

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL)**

For new starts only, patient must have a documented failure, contraindication, intolerance, or ineffective response to a trial of Truxima®.

- Patient age is 18 years or older; **AND**
- Patient does not have a severe, active infection; **AND**
- Patient has been screened for the presence of hepatitis B (HBV) infection (i.e., HBsAg and anti-HBc) prior to initiating therapy and patients with evidence of current or prior HBV infection will be monitored for HBV reactivation during treatment; **AND**
- Patient has not received a live vaccine within 28 days prior to starting treatment and live vaccines will not be administered concurrently while on treatment; **AND**
- Patient CD20 antigen expression is positive; **AND**
- Used in combination with fludarabine and cyclophosphamide (FC); **OR**
- Patient has disease that is ***without*** del(17p)/TP53 mutation; **AND**
  - Used as first-line therapy in **one** of the following settings or in combination with:
    - Bendamustine (patients ≥ 65 years, or younger patients with or without significant comorbidities)
    - Fludarabine (patient is without del(11q) and is <65 years without significant comorbidities); **OR**
  - Used for relapsed or refractory disease in combination with **one** of the following:
    - Alemtuzumab
    - Bendamustine (patients ≥ 65 years or younger patients with significant comorbidities)
    - Chlorambucil (patients ≥ 65 years or younger patients with significant comorbidities)
    - High-dose methylprednisolone
    - Idelalisib
    - Lenalidomide
    - Venetoclax
    - PCR (pentostatin, cyclophosphamide, and rituximab); **OR**
- Patient has disease **with** del(17p)/TP53 mutation; **AND**
  - Used as first-line therapy in one of the following settings or in combination with:
    - Alemtuzumab
    - High-dose Methylprednisolone; **OR**
  - Used for relapsed or refractory disease in one of the following settings or in combination with:
    - Alemtuzumab
    - High-dose Methylprednisolone
    - Idelalisib
    - Lenalidomide
    - Venetoclax; **OR**
- Used as first line therapy for histologic (Richter's) transformation to diffuse large B-cell lymphoma in combination with cyclophosphamide, doxorubicin, and vincristine- based regimens or as a component of OFAR (oxaliplatin, fludarabine, cytarabine, and rituximab).

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Non-Hodgkin lymphomas (NHL)**

For new starts only, patient must have a documented failure, contraindication, intolerance, or ineffective response to a trial of Truxima®.

- Patient age is 18 years or older; **AND**
- Patient does not have a severe, active infection; **AND**
- Patient has been screened for the presence of hepatitis B (HBV) infection (i.e., HBsAg and anti-HBc) prior to initiating therapy and patients with evidence of current or prior HBV infection will be monitored for HBV reactivation during treatment; **AND**
- Patient has not received a live vaccine within 28 days prior to starting treatment and live vaccines will not be administered concurrently while on treatment; **AND**
- Patient CD20 antigen expression is positive; **AND**
- Diagnosis of **Non-Hodgkin lymphomas (NHL) including, but not limited to, the following:**
  - AIDS-related B-cell lymphoma
    - Disease is related to Burkitt lymphoma or diffuse large B-cell lymphoma (including HHV-8 DLBCL, not otherwise specified)
  - Burkitt lymphoma
    - Used in combination with other chemotherapy
  - Castleman's disease
    - Patient has multicentric disease; **OR**
    - Patient has unicentric disease; **AND**
      - Used as second-line therapy for relapsed or refractory disease; **OR**
      - Used for patients with symptoms after resection or unresectable disease
  - Diffuse large B-cell lymphoma
  - Low-grade or follicular lymphoma
  - Gastric and non-gastric MALT lymphoma
  - High grade B-cell lymphoma
  - Mantle cell lymphoma
  - Nodal and splenic marginal zone lymphoma
  - Histologic transformation of follicular or nodal marginal zone lymphoma to diffuse large B-cell lymphoma
  - Post-transplant lymphoproliferative disorder (PTLD) (B-cell type)
    - Patient has had solid organ transplant or allogeneic hematopoietic stem cell transplantation
  - Pediatric aggressive mature B-cell lymphomas
    - Used in combination with chemotherapy
  - Primary cutaneous B-cell lymphomas
  - Hairy cell leukemia
    - Used in combination with cladribine as initial therapy; **OR**
    - Used for relapsed or refractory disease or in patients with a less than complete response (CR) to initial therapy

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Waldenström's Macroglobulinemia/Lymphoplasmacytic Lymphoma**

For new starts only, patient must have a documented failure, contraindication, intolerance, or ineffective response to a trial of Truxima®.

- Patient age is 18 years or older; **AND**
- Patient does not have a severe, active infection; **AND**
- Patient has been screened for the presence of hepatitis B (HBV) infection (i.e., HBsAg and anti-HBc) prior to initiating therapy and patients with evidence of current or prior HBV infection will be monitored for HBV reactivation during treatment; **AND**
- Patient has not received a live vaccine within 28 days prior to starting treatment and live vaccines will not be administered concurrently while on treatment; **AND**
- Patient CD20 antigen expression is positive.

Diagnosis of **Granulomatosis with Polyangiitis (GPA) (Wegener's granulomatosis) and Microscopic Polyangiitis (MPA)**

For new starts only, patient must have a documented failure, contraindication, intolerance, or ineffective response to a trial of Truxima®.

- Patient is at least 2 years of age; **AND**
- Patient does not have a severe, active infection; **AND**
- Patient has been screened for the presence of hepatitis B (HBV) infection (i.e., HBsAg and anti-HBc) prior to initiating therapy and patients with evidence of current or prior HBV infection will be monitored for HBV reactivation during treatment; **AND**
- Patient has not received a live vaccine within 28 days prior to starting treatment and live vaccines will not be administered concurrently while on treatment; **AND**
- Used in combination with glucocorticoids (e.g., prednisone, methylprednisolone)

Diagnosis of **Pemphigus Vulgaris**

For new starts only, patient must have a documented failure, contraindication, intolerance, or ineffective response to a trial of Truxima®.

- Patient age is 18 years or older; **AND**
- Patient does not have a severe, active infection; **AND**
- Patient has been screened for the presence of hepatitis B (HBV) infection (i.e., HBsAg and anti-HBc) prior to initiating therapy and patients with evidence of current or prior HBV infection will be monitored for HBV reactivation during treatment; **AND**
- Patient has not received a live vaccine within 28 days prior to starting treatment and live vaccines will not be administered concurrently while on treatment; **AND**
- Patient has a diagnosis of pemphigus vulgaris as determined by the following:
  - One or more of the following clinical features:
    - Appearance of lesions, erosions and/or blisters
    - Nikolsky sign (induction of blistering via mechanical pressure at the edge of a blister or on normal skin)
    - Characteristic scarring and lesion distribution; **AND**
  - Histopathologic confirmation by skin/mucous membrane biopsy; **AND**
  - Presence of autoantibodies as detected by indirect immunofluorescence or enzyme linked immunosorbent assay (ELISA); **AND**
- Patient has moderate to severe disease as assessed utilizing an objective measure/tool (i.e., PDAI, PSS, ABSIS); **AND**
- Patient is on combination glucocorticoid therapy; **AND**
- Other causes of blistering or erosive skin and mucous membrane diseases have been ruled out

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Rheumatoid Arthritis**

For new starts only, patient must have a documented failure, contraindication, intolerance, or ineffective response to a trial of Truxima®.

- Diagnosis of **moderately- to severely-active rheumatoid arthritis**; **AND**
- **One** of the following:
  - Patient is concurrently on methotrexate; **OR**
  - History of contraindication or intolerance to methotrexate**; AND**
- Trial and failure, contraindication, or intolerance to **two** of the following: Humira®, Enbrel®, or Xeljanz®; **AND**
- Prescribed by or in consultation with a rheumatologist

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug (e.g., severe infusion-related reactions, tumor lysis syndrome [TLS], severe mucocutaneous reactions, progressive multifocal leukoencephalopathy [PML], hepatitis B virus reactivation, serious bacterial, fungal, or viral infections, cardiac arrhythmias, renal toxicity, bowel obstruction or perforation); **AND**
- **For Oncology indications:** Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread
- **For Granulomatosis with Polyangiitis (GPA) (Wegener's granulomatosis) and Microscopic Polyangiitis (MPA):**
  - Disease response as indicated by disease control and improvement in signs and symptoms of condition compared to baseline; **AND**
  - A decrease frequency in the occurrence of major relapses (defined by the reappearance of clinical and/or laboratory signs of vasculitis activity that could lead to organ failure or damage, or could be life threatening)
- **For all other non-oncology indications:** Documentation of positive clinical response to Ruxience therapy

SAMSCA® (TOLVAPTAN)

Length of Authorization:	30 days; may be renewed
Initiative:	MNC: Non-Formulary Product (IE 50698 / MR – GSN PatOverride)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **hyponatremia**:

- Patient is at least 18 years of age; **AND**
- Documentation the medication was initiated or re-initiated in a hospital; **AND**
- Confirmation the patient does not have liver disease (including cirrhosis); **AND**
- Patient will not use strong CYP3A–inhibitors (e.g., ketoconazole, nefazodone, clarithromycin) concomitantly with therapy; **AND**
- Patient is able to sense or respond to thirst; **AND**
- Patient does not have hypovolemia or hypovolemic hyponatremia; **AND**
- Patient does not have anuria; **AND**
- Confirmation the patient has not been on continuous therapy which exceeds 30 consecutive days; **AND**
- Confirmation the patient has clinically significant hypervolemic or euvolemic hyponatremia as evidenced by one of the following:
  - Serum sodium < 125 mEq/L; **OR**
  - Patient is symptomatic (dizziness, gait disturbances, forgetfulness, confusion, lethargy, seizures, impaired mental status, or coma) and resisted correction with fluid restriction

CLINICAL CRITERIA FOR RENEWAL

- Patient has responded to therapy (achieved the desired level of serum sodium); **AND**
- Confirmation the patient has not been on continuous therapy which exceeds 30 consecutive days**; AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include osmotic demyelination, liver injury or ALT/AST ever exceeded 3 times the ULN during treatment, dehydration, hypovolemia, etc.

SEDATIVE HYPNOTIC AGENTS

Length of Authorization:	Length of the prescription (up to 6 months)
Initiative:	MNC: Sedative Hypnotics (IE 2462 / NCPDP 75) MNC: Sedative/Anxiolytic QL Override (IE 7008/NCPDP 75)

ROZEREM® (BRAND ONLY)

STEP CRITERIA (NO GRANDFATHERING)

- Patient must have tried:
  - Temazepam; **AND**
  - Zolpidem
- Patient must be at least 6 years old

PRIOR AUTHORIZATION REQUIRED WHEN MEMBER IS CONCURRENTLY TAKING > 1 HYPNOTIC DRUG WITHIN A 30 DAY OVERLAP TIME PERIOD

To include the following HSNS: 001592, 007842, 026791

The clinical pharmacist will use professional judgment whether to approve or escalate to MRIOA for denial.

COVERED – NO PA REQUIRED
Temazepam 15 mg and 30 mg capsules
Zolpidem tartrate 5 mg and 10 mg tablets
Eszopiclone

SENSIPAR® (CINACALCET)

Length of Authorization:	3 months initial, 1 year for renewals
Initiative:	SPC: Miscellaneous: PA required (IE 2462/ NCPDP 75-HICL)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of Secondary Hyperparathyroidism (HPT):

- Patient is at least 18 years of age; **AND**
- Patient has a diagnosis of chronic kidney disease (CKD); **AND**
- Patient is currently undergoing dialysis; **AND**
- Baseline (pre-treatment) intact parathyroid hormone (iPTH) > 300 pg/mL **OR** bio-intact parathyroid hormone (biPTH) > 160 pg/mL; **AND**
- Baseline serum calcium (Ca) > 8.4 mg/Dl (corrected for albumin); **AND**
- Documented failure, contraindication, or ineffective response at maximum tolerated doses to a minimum 3-month trial on previous therapy with calcitriol; **AND**
- Documented failure, contraindication, or ineffective response at maximum tolerated doses to a minimum 3-month trial on previous therapy with ONE of the following phosphate binders: calcium carbonate, calcium acetate, sevelamer carbonate; **AND**
- Must be prescribed by a nephrologist or endocrinologist, or by nephrology or endocrinology consult.

Diagnosis of Parathyroid Carcinoma (PC):

- Patient is at least 18 years of age; **AND**
- Confirmation the patient has a diagnosis of Parathyroid Carcinoma; **AND**
- Confirmation the patient has hypercalcemia as defined by baseline serum calcium (Ca) > 10 mg/Dl (corrected for albumin); **AND**
- Must be prescribed by an oncologist, nephrologist or endocrinologist, or by oncology, nephrology, or endocrinology consult.

Diagnosis of Primary Hyperparathyroidism (HPT):

- Patient is at least 18 years of age; **AND**
- Confirmation the patient has severe hypercalcemia as defined by baseline (pre-treatment) serum calcium (Ca) > 12 mg/Dl (corrected for albumin); **AND**
- Confirmation the parathyroidectomy is indicated but patient is unable to undergo parathyroidectomy; **AND**
- Must be prescribed by a nephrologist or endocrinologist, or by nephrology or endocrinology consult.

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: hypocalcemia, seizures, hypotension, worsening heart failure, arrhythmia, adynamic bone disease; **AND**
- Current serum calcium (Ca) >8.4 mg/Dl; **AND**

Secondary Hyperparathyroidism (HPT)

- Adequate documentation of disease response as indicated by improvement of intact parathyroid hormone (iPTH) levels from baseline; **AND**
- Current intact parathyroid hormone (iPTH) >150 pg/mL

Parathyroid Carcinoma (PC)

- Adequate documentation of disease response as indicated by improvement of serum calcium (Ca) from baseline.

Primary Hyperparathyroidism (HPT)

- Adequate documentation of disease response as indicated by improvement of serum calcium (Ca) from baseline.

SEREVENT DISKUS (SALMETEROL XINAFOATE)

Length of Authorization:	12 months
Initiative:	MNC: Beta-Adrenergic Agents (IE 2462 / NCPDP 75 – HICL)

CLINICAL CRITERIA FOR INITIAL APPROVAL

- Patient is 4 years of age or older; **AND**
- Medication will be used for one of the following indications:
  - Treatment of asthma AND is uncontrolled on ICS monotherapy; **OR**
  - Prevention of exercise induced bronchospasms (Note: may be used as monotherapy in absence of persistent asthma); **OR**
  - Maintenance Treatment of Chronic Obstructive Pulmonary Disease (COPD); **AND**
- There are no contraindications to therapy:
  - Use of Serevent for treatment of asthma without concomitant use of an ICS; **AND**
  - Use of Serevent in the following conditions:
    - Primary treatment of status asthmaticus or other acute episodes of asthma or COPD where intensive measures are required
    - Severe hypersensitivity to milk proteins or demonstrated hypersensitivity to salmeterol or any of the excipients

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug

SMOKING CESSATION – AHCCCS-MANDATED CRITERIA

Length of Authorization:	12 weeks in a 6-month time period
Initiative:	MNC: Smoking Cessation (IE 2462 / NCPDP 75 – HICL) MNC: Smoking Cessation QL Override (IE 7008/NCPDP 75) MNC: MNC: Quantity Limit (IE 7003/NCPDP 76)

CLINICAL CRITERIA

The smoking cessation agents provided in chart below are covered with no PA required.

The following guidelines apply:

- Members are encouraged to enroll in a tobacco cessation program through Arizona Department of Health Services (ADHS). To enroll in an ADHS cessation program the member must call 1-800-556-6222.
- Members must contact their Primary Care Provider (PCP) to obtain a prescription for a tobacco cessation product. The PCP will identify an appropriate tobacco cessation product. In order to be covered by AHCCCS, all tobacco use medications require a prescription. This includes all tobacco cessation products, including those that are available over the counter.
- Members must be 18 years of age or older.
- Indication must be for smoking cessation.
- Doses should be within the FDA Maximum Allowable doses (see chart below).
- Coverage cannot be authorized for combination treatment with more than one smoking cessation agent (see smoking cessation agents provided in chart below).
  - Claims for smoking cessation therapies overlapping within a 30-day period will reject at POS for IE 7008/NCPDP 75
- The maximum supply a member may receive of a tobacco cessation product is a 12-week supply in a six-month period. The six-month period begins the date the first prescription is filled for the tobacco cessation product.
  - Claims for smoking cessation agents exceeding 12-week supply in a six-month period (with one agent or with multiple agents) will reject at POS for IE 7003/NCPDP 76

COVERAGE FOR DUAL ELIGIBLES:

- Medications that are available by prescription only and bear the federal legend, Federal Law Prohibits Dispensing Without a Prescription, are to be obtained from and covered by the Medicare Part D Plan.
- Medications that are available over the counter are to be covered by the AHCCCS Contracted Health Plans and ordered in accordance with Section B, Guidelines for Approval.

SMOKING CESSATION THERAPY: AHCCCS MANDATED CRITERIA (CONTINUED)

SMOKING CESSATION PRODUCT	DOSING REGIMEN	MAXIMUM DAILY DOSE
NICOTINE NASAL SPRAY (Nicotrol® NS)	2-4 sprays per hour Minimum effective dose is 16 sprays per day	40 mg 80 sprays per day 80 sprays = ½ bottle
NICOTINE INHALER (Nicotrol® Inhaler)	6-16 cartridges a day individualized dosing as needed.	16 cartridges per day
NICOTINE PATCH (NicoDerm® CQ, Nicotrol®, Habitrol®)	7 mg / 24 hours 14 mg / 24 hours 21 mg / 24 hours	21 mg per 24 hours
NICOTINE GUM (Nicorette®), OR Lozenge (Commit®)	1 piece every 1-2 hours weeks 1-6, then 1 piece every 2-4 hours weeks 7-9, then 1 piece every 4-8 hours weeks 10-12.	24 pieces of gum or lozenges per day
BUPROPION HCL SR (Zyban®/ Wellbutrin SR®)	150 mg orally every day for the first 3 days, may increase to 150 mg twice a day if tolerated.	300 mg per day
VERENICLINE (Chantix®)	Titration Schedule: 0.5 mg orally daily for 3 days, then 0.5 mg twice daily for 4 days, then 1 mg twice daily to complete the 12-week course of therapy	2 mg per day

SOLIRIS® (ECULIZUMAB)

Length of Authorization:	6 months, may be renewed
Initiative:	MNC: Non-Formulary Product (IE 50698 / MR – GSN PatOverride)

CLINICAL CRITERIA FOR INITIAL APPROVAL

- Diagnosis of **Paroxysmal nocturnal hemoglobinuria (PNH)**
  - Patient is 18 years of age or older; **AND**
  - Patient does not have a systemic infection; **AND**
  - Patient must be administered a meningococcal vaccine at least two weeks prior to initiation of therapy and revaccinated according to current medical guidelines; **AND**
  - Prescriber is enrolled in the Soliris Risk Evaluation and Mitigation Strategy (REMS); **AND**
  - Documented baseline values for one or more of the following (necessary for renewal): serum lactate dehydrogenase (LDH), hemoglobin level, and packed RBC transfusion requirement; **AND**
  - Diagnosis must be accompanied by detection of PNH clones by flow cytometry diagnostic test; **AND**
    - Demonstrate the presence of at least 2 different glycosylphosphatidylinositol (GPI) protein deficiencies (e.g. CD55, CD59, etc.) within at least 2 different cell lines (granulocytes, monocytes, erythrocytes); **AND**
  - Patient has one of the following indications for therapy:
    - Presence of a thrombotic event
    - Presence of organ damage secondary to chronic hemolysis
    - Patient is pregnant and potential benefit outweighs potential fetal risk
    - Patient is transfusion dependent
    - Patient has high LDH activity (defined as $\geq$ 1.5 x ULN) with clinical symptoms
- Diagnosis of **Atypical Hemolytic uremic syndrome (aHUS)**;
  - Patient is 2 months or older; **AND**
  - Thrombotic Thrombocytopenic Purpura (TTP) has been ruled out by evaluating ADAMTS-13 level (ADAMTS-13 activity level > 10%); **AND**
  - Shiga toxin *E. coli* related hemolytic uremic syndrome (STEC-HUS) has been ruled out; **AND**
  - Other causes have been ruled out, such as coexisting diseases or conditions (e.g., bone marrow transplantation, solid organ transplantation, malignancy, autoimmune disorder, drug-induced, malignant hypertension, HIV infection, etc.), *Streptococcus pneumoniae* or Influenza A (H1N1) infection, or cobalamin deficiency; **AND**
  - Documented baseline values for one or more of the following (necessary for renewal): serum lactate dehydrogenase (LDH); serum creatinine/eGFR, platelet count and plasma exchange/infusion requirement; **AND**
  - Patient does not have a systemic infection; **AND**
  - Patient must be administered a meningococcal vaccine at least two weeks prior to initiation of therapy and revaccinated according to current medical guidelines; **AND**
  - Prescriber is enrolled in the Soliris Risk Evaluation and Mitigation Strategy (REMS)

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

- Diagnosis of **Generalized Myasthenia Gravis(gMG)**
  - Patient is 18 years or older; **AND**
  - Patient has Myasthenia Gravis Foundation of America (MGFA) Clinical Classification of Class II to IV disease; **AND**
  - Patient has a positive serologic test for anti-acetylcholine receptor (AChR) antibodies; **AND**
  - Physician has assessed the baseline Quantitative Myasthenia Gravis (QMG) score; **AND**
  - Patient has a MG-activities of Daily Living (MG-ADL) total score of $\geq$ 6; **AND**
  - Patient has failed treatment over at least 1 year with at least 2 immunosuppressive therapies (i.e., azathioprine, cyclosporine, mycophenolate, etc.), or has failed at least 1 immunosuppressive therapy and required chronic plasmapheresis or plasma exchange (PE) or intravenous immunoglobulin (IVIG); **AND**
  - Patient does not have a systemic infection; **AND**
  - Patient must be administered a meningococcal vaccine at least two weeks prior to initiation of therapy and revaccinated according to current medical guidelines; **AND**
  - Prescriber is enrolled in the Soliris Risk Evaluation and Mitigation Strategy (REMS)

CLINICAL CRITERIA FOR RENEWAL

- Disease response as indicated by one or more of the following:
  - For PNH: decrease in serum LDH from pretreatment baseline, stabilization/improvement in hemoglobin level from pretreatment baseline or decrease in packed RBC transfusion requirement from pretreatment baseline
  - For aHUS: decrease in serum LDH from pretreatment baseline, stabilization/improvement in serum creatinine/eGFR from pretreatment baseline, increase in platelet count from pretreatment baseline or decrease in plasma exchange/infusion requirement from pretreatment baseline
  - For gMG: Improvement of at least 3-points from baseline in the Myasthenia Gravis-Specific Activities of Daily Living scale (MG-ADL) total score or improvement of at least 5-points from baseline in the Quantitative Myasthenia Gravis (QMG) total score; **AND**
- Absence of unacceptable toxicity from the drug
  Examples include: serious meningococcal infections (septicemia and/or meningitis), infusion reactions, serious infections, thrombotic microangiopathy complications (TMA), etc.

SPINRAZA® (NUSINERSEN)

Length of Authorization:	1 year, may be renewed
Initiative:	MNC: Non-Formulary Product (IE 50698 / MR – GSN PatOverride)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Spinal Muscular Atrophy (SMA)**

- Patient must have the following laboratory tests at baseline and prior to each administration **(Laboratory tests should be obtained within several days prior to administration)**: platelet count, prothrombin time; activated partial thromboplastin time, and quantitative spot urine protein testing; **AND**
- Patient retains meaningful voluntary motor function (e.g. manipulate objects using upper extremities, ambulate, etc.); **AND**
- Patient must have a diagnosis of 5q spinal muscular atrophy confirmed by either homozygous deletion of the *SMN1* gene or dysfunctional mutation of the *SMN1* gene; **AND**
- Patient must have one of the following SMA phenotypes; **AND**
  - SMA I
  - SMA II with symptomatic disease (i.e. impaired motor function and/or delayed motor milestones)
  - SMA III with symptomatic disease (i.e. impaired motor function and/or delayed motor milestones)
- Baseline documentation of one or more of the following:
  - Motor function/milestones, including but not limited to, the following validated scales: Hammersmith Infant Neurologic Exam (HINE), Hammersmith Functional Motor Scale Expanded (HFMSE), 6-minute walk test (6MWT), upper limb module (ULM), etc.
  - Respiratory function tests [e.g., forced vital capacity (FVC), etc.]
  - Exacerbations necessitating hospitalization and/or antibiotic therapy for respiratory infection in the preceding year/timeframe
  - Patient weight (for patients without a gastrostomy tube)

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity which would preclude safe administration of the drug. Examples of unacceptable toxicity include the following: significant renal toxicity, thrombocytopenia, coagulation abnormalities, etc.; **AND**
- Patient has responded to therapy compared to pretreatment baseline in one or more of the following:
  - Stability or improvement in net motor function/milestones, including but not limited to, the following validated scales: Hammersmith Infant Neurologic Exam (HINE), Hammersmith Functional Motor Scale Expanded (HFMSE), 6-minute walk test (6MWT), upper limb module (ULM), etc.
  - Stability or improvement in respiratory function tests [e.g., forced vital capacity (FVC), etc.]
  - Reduction in exacerbations necessitating hospitalization and/or antibiotic therapy for respiratory infection in the preceding year/timeframe
  - Stable or increased patient weight (for patients without a gastrostomy tube)
  - Slowed rate of decline in the aforementioned measures

SPRAVATO® (ESKETAMINE) – AHCCCS-MANDATED CRITERIA

Length of Authorization:	Initial: 3 months, Renewal: 6 months **Quantity limit: for induction phase (weeks 1-4): 24 devices/month, For maintenance phase: 12 devices/month**
Initiative:	MNC: Non-Formulary Product (IE 50698 / MR – GSN PatOverride)

CLINICAL CRITERIA FOR INITIAL APPROVAL

- Member has a confirmed diagnosis of major depressive disorder as defined by the DSM-V criteria and is treatment resistant**; AND**
- Member is 18 years of age or older**; AND**
- Spravato® is prescribed by or in consultation with a psychiatric provider; **AND**
- One of the following:
  - Member does not have an active substance use disorder (SUD); **OR**
  - Both of the following:
    - Member has an active substance use disorder
    - Member is currently receiving treatment; **AND**
- One of the following:
  - Member has experienced an inadequate response during the current depressive episode with each of the following therapies:
    - Two antidepressants from at least two different classes (must include one of each AHCCCS preferred agents: SSRI, SNRI, or bupropion) having different mechanisms of action at the maximally tolerated labeled dose, each used for at least 4-6 weeks; **AND**
    - At least two augmentation therapies below for at least 4 weeks:
      - SSRI or SNRI, and a second-generation antipsychotic used concomitantly (aripiprazole, quetiapine, risperidone, olanzapine)
      - SSRI or SNRI, and lithium used concomitantly
      - SSRI or SNRI, and liothyronine (T3) used concomitantly
      - SSRI or SNRI, and mirtazapine
      - SSRI and bupropion and buspirone

    OR
  - Member has active suicidal ideation and urgent symptom control is necessary; **AND**
- Esketamine is used in combination with an oral antidepressant (e.g., duloxetine, escitalopram, sertraline, venlafaxine); **AND**
- Esketamine is administered under the direct supervision of a healthcare provider; **AND**
- Provider is certified in the Spravato REMS program; **AND**
- Member must be monitored by a health care provider for at least 2 hours after administration.

CLINICAL CRITERIA FOR RENEWAL

- Provider attests that the member has documented improvement or sustained improvement in depressive symptoms from baseline; **AND**
- Member use of esketamine is in combination with an oral antidepressant; **AND**
- Member administers esketamine under the direct supervision of a healthcare provider; **AND**
- Provider is certified in the Spravato REMS Program; **AND**
- Member must continue to be monitored by a health care provider certified by the Spravato REMS Program for at least 2 hours after administration.

SPRYCEL® (DASATINIB)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75 – HICL, 50081 and 2193) MNC: Non-Formulary Product (IE 50698 / MR – GSN PatOverride)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Chronic Myelogenous Leukemia**

- For CML: For new starts only, patient must have a documented failure, contraindication, intolerance, or ineffective response to a trial of generic imatinib
- Patient is at least 18 years of age (unless otherwise noted); **AND**
- Patient will avoid concomitant use with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **AND**
- Patient will avoid concomitant use strong CYP3A inhibitors (e.g., itraconazole, ketoconazole, clarithromycin), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient will avoid concomitant use with acid-reducing agents (i.e., proton pump inhibitors), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient's disease is confirmed by either a Philadelphia chromosome-positive (Ph+) or BCR-ABL1 positive laboratory test result; **AND**
- Patient does not have any of the following BCR-ABL1 mutations: T315I/A, F317L/V/I/C, or V299L (****Note**: This does not apply to patients receiving first-line or continued therapy); **AND**
  - Patient has chronic phase disease and is 1 year of age or older ; **OR**
  - Patient is resistant, intolerant, or had an inadequate response to prior tyrosine kinase inhibitor (TKI) therapies, consisting of a 3 month trial or longer, with omacetaxine or a tyrosine kinase inhibitor (e.g., imatinib, bosutinib, ponatinib, nilotinib); **AND**
    - Patient has chronic, accelerated, or blast phase disease; **OR**
  - Used as primary treatment; **AND**
    - Used as single agent for newly diagnosed chronic or accelerated or myeloid blast phase disease; **OR**
    - Used in combination with corticosteroids for lymphoid blast phase disease; **OR**
    - Used in combination with induction chemotherapy for disease in lymphoid blast phase or myeloid blast phase; **OR**
  - Used as switch therapy; **AND**
    - Patient received initial therapy with one of the following: imatinib, bosutinib or nilotinib; **AND**
    - Patient has *BCR-ABL1* transcript levels:
      - > 1% to 10% at 12 months; **OR**
      - > 1% to 10% at ≥15 months; **OR**
      - > 10% at any response milestone; **OR**
  - Used as continued therapy ; **AND**
    - Patient has *BCR-ABL1* transcript levels:
      - ≤ 1% at any response milestone; **OR**
      - > 1% to 10% at 3, 6, or 12 months; **OR**
      - > 10% at 3 months; **OR**

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Chronic Myelogenous Leukemia** *(Continued)*

- Used post-allogeneic hematopoietic stem cell transplant (HCT); **AND**
  - Used for at least one year in patients with prior complete cytogenetic response (CCyR) for accelerated or blast phase disease; **OR**
  - Used as follow-up therapy in patients with molecular relapse (BCR-ABL1 transcript positive) following CCyR; **OR**
  - Used as follow-up therapy in patients with relapse or those who are not in CCyR

Diagnosis of **Acute Lymphoblastic Leukemia (ALL)**

- Patient is at least 18 years of age (unless otherwise noted); **AND**
- Patient will avoid concomitant use with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **AND**
- Patient will avoid concomitant use strong CYP3A inhibitors (e.g., itraconazole, ketoconazole, clarithromycin), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient will avoid concomitant use with acid-reducing agents (i.e., proton pump inhibitors), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patients disease is Philadelphia chromosome-positive (Ph+); **AND**
  - Used for newly diagnosed disease in patients aged 1 year and older in combination with chemotherapy ✝; **OR**
  - Patient has relapsed/refractory disease; **AND**
    - Patient does not have any of the following *BCR-ABL1* mutations: T315I/A, F317L/V/I/C, or V299L; **AND**
      - Patient is resistant, or intolerant, or had an inadequate response to prior therapy, consisting of a 3 month trial or longer, with any of the following: imatinib, bosutinib, ponatinib, nilotinib, etc. ; **OR**
      - Used as a single agent therapy ; **OR**
      - Used in combination with an induction therapy not previously used; **OR**
  - Used as maintenance therapy; **AND**
    - Used in combination with vincristine and prednisone with or without methotrexate and mercaptopurine; **OR**
    - Used post-hematopoietic stem cell transplant; **OR**
  - Patient is at least 15 years of age and < 65 years of age; **AND**
    - Used in a multiagent chemotherapy regimen for induction or consolidation therapy; **OR**
    - Used in combination with a corticosteroid for induction therapy; **OR**
    - Used in combination with vincristine and dexamethasone for induction therapy; **OR**
  - Patient is ≥ 65 years of age; **AND**
    - Used as induction therapy as part of one of the following regimens:
      - As a single agent or in combination with a corticosteroid; **OR**
      - In combination with vincristine and dexamethasone; **OR**
      - In combination with a multiagent chemotherapy regimen; **OR**
  - Patient is < 18 years of age; **AND**
    - Used as part of a cytotoxic chemotherapy regimen for B-cell ALL as induction or consolidation therapy or for relapsed/refractory disease; **OR**
    - Used as part of a TKI-based regimen for relapsed/refractory T-cell ALL with ABL-class translocations

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Gastrointestinal stromal tumors (GIST)**

- Patient is 18 years old or older; **AND**
- Patient will avoid concomitant use with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **AND**
- Patient will avoid concomitant use strong CYP3A inhibitors (e.g., itraconazole, ketoconazole, clarithromycin), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient will avoid concomitant use with acid-reducing agents (i.e., proton pump inhibitors), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient has unresectable or metastatic disease; **AND**
- Patient's BCR-ABL KD mutational analysis contains the PDGFRA D842V mutation; **AND**
- Used as fourth-line therapy as a single agent; **AND**
- Disease has progressed after single-agent treatment with each of the following: imatinib, sunitinib and regorafenib

Diagnosis of **Bone Cancer (Chondrosarcoma and Chordoma)**

- Patient is 18 years old or older; **AND**
- Patient will avoid concomitant use with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **AND**
- Patient will avoid concomitant use strong CYP3A inhibitors (e.g., itraconazole, ketoconazole, clarithromycin), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient will avoid concomitant use with acid-reducing agents (i.e., proton pump inhibitors), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Used as single agent; **AND**
  - Patient has chondrosarcoma and widespread metastatic disease: **OR**
  - Patient has chordoma and recurrent disease

CLINICAL CRITERIA FOR RENEWAL

- Patient has been adherent to therapy; **AND**
- Absence of unacceptable toxicity from the drug (e.g., pulmonary arterial hypertension, severe myelosuppression [neutropenia, anemia, thrombocytopenia], fluid retention, cardiovascular events [ischemia, conduction system abnormalities, arrhythmia/palpitations], cardiac dysfunction, QT prolongation, severe dermatologic reactions, tumor lysis syndrome); **AND**
- Acute lymphoblastic leukemia (ALL) only:
  - Treatment response or stabilization of disease as indicated by CBC, bone marrow cytogenic analysis, QPCR, or FISH
- Chronic myelogenous leukemia (CML) only:
  - Treatment response as indicated by one of the following *BCR-ABL1* transcript levels:
    - ≤ 10% at 3 months; **OR**
    - ≤ 10% at 6 months; **OR**
    - < 1% at 12 months and beyond

    Note: cytogenetic assessment of response may be used if quantitative RT-PCR (QPCR) using International Scale (IS) for BCR-ABL1 is not available
- Gastrointestinal stromal tumors (GIST) only:
  - Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread
- Bone cancer (chondrosarcoma and chordoma) only:
  - Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread

STIMATE (DESMOPRESSIN ACETATE)

Length of Authorization:	6 months
Initiative:	MNC: Miscellaneous: PA Required (IE 2462 / NCPDP 75 – GSN)

CLINICAL CRITERIA FOR INITIAL APPROVAL

- Diagnosis of hemophilia A with Factor VIII coagulant activity levels greater than 5%; **OR**
- Diagnosis of von Willebrand's Disease (Type I)

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug

STIOLTO RESPIMAT (TIOTROPIUM BROMIDE AND OLODATEROL)

Length of Authorization:	12 months
Initiative:	MNC: Miscellaneous: PA Required (IE 2462 / NCPDP 75 – GSN)

CLINICAL CRITERIA FOR INITIAL APPROVAL

- Patient has a diagnosis of COPD; **AND**
- There are no contraindications to therapy:
  - Use for treatment of asthma
  - Hypersensitivity to tiotropium, ipratropium, olodaterol, or any component of this product

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug

SUCRAID (SACROSIDASE)

Length of Authorization:	12 months; may be renewed
Initiative:	SPC: Enzyme Deficiency (IE 2462 / NCPDP 75 – HICL)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Congenital Sucrase-Isomaltase Deficiency (CSID)**

- Patient is at least 5 months of age; **AND**
- Patient has a diagnosis of symptomatic genetic or congenital SI deficiency that has been confirmed by one of the following:
  - Patient has a positive result on a ^{13}C-sucrose breath test defined as an expressed coefficient of glucose oxidation (CDO) is less than or equal to 79%; **OR**
  - Disaccharidase assay (i.e., lactase, sucrase, isomaltase (palatinase), and maltase activity) of a small intestinal biopsy; **AND**
- Other causes of chronic diarrhea (e.g., diarrhea predominant IBS, malabsorption disorders, infectious, etc.) as well as congenital anatomic anomalies of the intestine have been ruled out; **AND**
- Patient is adhering to a reduced starch and/or sugar diet.

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: severe allergic and anaphylactic reactions, severe wheezing, etc.; **AND**
- Patient has demonstrated a beneficial response to therapy compared to pretreatment baseline as evidenced by fewer total stools and a greater number of hard/formed stools; **AND**
- Patient re-evaluated to confirm symptomatic starch/sugar intolerance still persists; **AND**
- Patient is adhering to a reduced starch and/or sugar diet.

SUTENT® (SUNITINIB)

Length of Authorization:	6 months, may be renewed Adjuvant RCC may be renewed up to 9 cycles of therapy Adjuvant GIST may be renewed up to 3 years of therapy
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75 – HICL 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Renal cell carcinoma (RCC)**

- Patient is at least 18 years of age; **AND**
- Patient will avoid concomitant use with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort), if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient will avoid concomitant use with strong CYP3A4 inhibitors (e.g., clarithromycin, itraconazole, indinavir, nefazodone), if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Must be used as a single agent; **AND**
  - Patient has advanced disease; **OR**
  - Used as adjuvant treatment for high-risk of recurrence, in patients with clear cell histology, following nephrectomy; **OR**
  - Used for relapse or stage IV disease ; **AND**
    - Used as first-line or subsequent therapy for predominant clear cell histology; **OR**
    - Used as systemic therapy for non-clear cell histology

Diagnosis of **Gastrointestinal Stromal Tumors (GIST)**

- Patient is at least 18 years of age; **AND**
- Patient will avoid concomitant use with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort), if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient will avoid concomitant use with strong CYP3A4 inhibitors (e.g., clarithromycin, itraconazole, indinavir, nefazodone), if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Used for disease progression, on or intolerance to, imatinib**; OR**
- Used as fourth-line therapy for unresectable or metastatic disease, in combination with everolimus for progression after monotherapy with imatinib, sunitinib and regorafenib; **OR**
- Used as adjuvant alternative therapy to imatinib due to life-threatening side-effects; **AND**
  - Used following resection of primary disease with an intermediate or high-risk of re-occurrence and imatinib was not used pre-operatively; **OR**
  - Used for persistent microscopic or gross residual disease

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Pancreatic Neuroendocrine Tumors (pNET)**

- Patient is at least 18 years of age; **AND**
- Patient will avoid concomitant use with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort), if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient will avoid concomitant use with strong CYP3A4 inhibitors (e.g., clarithromycin, itraconazole, indinavir, nefazodone), if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient has unresectable locally advanced or metastatic disease; **AND**
- Must be used as single agent**; AND**
- Patient has progressive disease, significant tumor burden, or is symptomatic

Diagnosis of **Soft Tissue Sarcoma**

- Patient is at least 18 years of age; **AND**
- Patient will avoid concomitant use with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort), if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient will avoid concomitant use with strong CYP3A4 inhibitors (e.g., clarithromycin, itraconazole, indinavir, nefazodone), if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Used as a single agent; **AND**
- Patient has one of the following subtypes of disease:
  - Alveolar Soft Part Sarcoma (ASPS)
  - Angiosarcoma
  - Solitary Fibrous Tumor

Diagnosis of **Thymic Carcinomas**

- Patient is at least 18 years of age; **AND**
- Patient will avoid concomitant use with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort), if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient will avoid concomitant use with strong CYP3A4 inhibitors (e.g., clarithromycin, itraconazole, indinavir, nefazodone), if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Must be used as single agent for second- line therapy; **AND**
- Patient has unresectable or metastatic disease

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Thyroid Carcinoma**

- Patient is at least 18 years of age; **AND**
- Patient will avoid concomitant use with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort), if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient will avoid concomitant use with strong CYP3A4 inhibitors (e.g., clarithromycin, itraconazole, indinavir, nefazodone), if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient has follicular, Hürthle cell, or papillary carcinoma; **AND**
  - Patient has unresectable, recurrent, persistent, or metastatic disease; **AND**
  - Treatment with clinical trials or other systemic therapies are not available or appropriate **AND**
  - Patient has progressive and/or symptomatic disease that is not susceptible to radioactive iodine (RAI) therapy; **OR**
- Patient has Medullary carcinoma; **AND**
  - Patient has recurrent or persistent metastatic disease; **AND**
  - Disease is symptomatic or progressive; **AND**
    - Treatment with clinical trials, vandetanib, or cabozantinib are not available or appropriate; **OR**
    - Patient has progressed on vandetanib or cabozantinib

Diagnosis of **Bone Cancer**- **Chordoma**

- Patient is at least 18 years of age; **AND**
- Patient will avoid concomitant use with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort), if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient will avoid concomitant use with strong CYP3A4 inhibitors (e.g., clarithromycin, itraconazole, indinavir, nefazodone), if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient has recurrent disease; **AND**
- Must be used as a single agent

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug (e.g., hepatotoxicity, cardiotoxicity [heart failure, cardiomyopathy, myocardial ischemia/infarction, QT prolongation, Torsades de Pointes], hypertension, tumor lysis syndrome [TLS], thrombotic microangiopathy [TMA], dermatologic toxicity [erythema multiforme (MF), Stevens-Johnsons syndrome (SJS), toxic epidermal necrolysis (TEN)], hypoglycemia, osteonecrosis of the jaw, impaired wound healing)
- **Adjuvant renal cell carcinoma (RCC)**: may be renewed up to nine 6-week cycles of therapy
- **Adjuvant Gastrointestinal Stromal Tumors (GIST)**: may be renewed up to 3 years of therapy

SYLATRON® (PEGINTERFERON ALFA-2B)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75 – HICL, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

- **Diagnosis of Melanoma**; **AND**
  - Patient is 18 years old or greater; **AND**
  - Used as adjuvant therapy; **AND**
  - Used as single agent
- **Diagnosis of Myeloproliferative Neoplasms-Primary; Post-polycythemia Vera; Post-Essential Thrombocythemia (Primary MF/Post-PV MF/Post-ET MF)**; **AND**
  - Patient is 18 years old or greater; **AND**
  - Patient is symptomatic; **AND**
  - Patient is low-risk

CLINICAL CRITERIA FOR RENEWAL

- Tumor response with stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug (e.g., Persistent or worsening severe neuropsychiatric disorders, grade 4 non-hematologic toxicity, new or worsening retinopathy, new onset of ventricular arrhythmia, or cardiovascular decompensation); **AND**
- Total length of therapy does not exceed 5 years

SYMDEKO® (TEZACAFTOR/IVACAFTOR AND IVACAFTOR)

Length of Authorization:	6 months, may be renewed
Initiative:	MNC: Non-Formulary Product (IE 50698 / MR – GSN PatOverride)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Cystic fibrosis**

- Patient is at least 6 years old; **AND**
- Patient has a documented diagnosis of cystic fibrosis; **AND**
- Confirmation the patient is not receiving concurrent treatment with other CFTR-targeted therapy (e.g., single agent ivacaftor, lumacaftor/ivacaftor); **AND**
- Patient is homozygous (mutation is present on both alleles) for the *F508del* mutation or has at least one mutation in the *CFTR* gene, as confirmed by an FDA-cleared CF mutation test, that is responsive to tezacaftor/ivacaftor based on clinical and/or in vitro assay data*****; **AND**
- Patient has a baseline percent predicted FEV1 (reported measurements may be used on renewal).

List of CFTR Gene Mutations that Produce CFTR Protein and are Responsive to Symdeko				
E56K	*R117C*	*A455E*	*S945L*	*R1070W*
P67L	*E193K*	*F508del**	*S977F*	*F1074L*
R74W	*L206W*	*D579G*	*F1052V*	*D1152H*
D110E	*R347H*	*711+3A→G*	*K1060T*	*D1270N*
D110H	*R352Q*	*E831X*	*A1067T*	*2789+5G→A*
3272-26A→G	*3849+10kbC→T*			

**A patient must have two copies of the F508del mutation.*

Table may not be all-inclusive; verify gene mutations responsive to tezacaftor/ivacaftor in the current prescribing information

CLINICAL CRITERIA FOR RENEWAL

- Disease response as indicated by **one** or more of the following:
  - Decreased pulmonary exacerbations compared to pretreatment baseline
  - Decrease in decline of lung function as measured by FEV_1 within previous 30 days compared to baseline
  - Improvement or stabilization of lung function as measured by FEV_1 within previous 30 days compared to baseline
  - Improvement in quality of life (e.g., Cystic Fibrosis Questionnaire-Revised [CFQ-R] score, etc.), weight gain, or growth; **AND**
- Patient has not received a lung transplant; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include elevated transaminases (ALT or AST), development of cataracts or lens opacities, etc.

SYNAREL® (NAFARELIN ACETATE)

Length of Authorization:	Varies by diagnosis, see specific criteria below
Initiative:	SPC: Hormonal Agents (IE 2462 / NCPDP 75 – HICL)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Endometriosis**

- Patient is 18 years of age or older; **AND**
- Female patients do not have undiagnosed abnormal vaginal bleeding; **AND**
- Patient does not have a hypersensitivity to GnRH or GnRH agonist analog type medications; **AND**
- Women of child-bearing age must have a negative pregnancy test; **AND**
- Diagnosis has been confirmed by a workup/evaluation (vs. presumptive treatment); **AND**
- Patient has not previously used Synarel® for endometriosis

Length of Authorization:	6 months, **not eligible for renewal**. Escalate renewal request to a pharmacist.

Diagnosis of **Central Precocious Puberty**

- Patient is less than 13 years old; **AND**
- Female patients do not have undiagnosed abnormal vaginal bleeding; **AND**
- Patient does not have a hypersensitivity to GnRH or GnRH agonist analog type medications; **AND**
- Onset of secondary sexual characteristics earlier than age 8 for girls and 9 for boys associated with pubertal pituitary gonadotropin activation; **AND**
- Diagnosis is confirmed by a pubertal gonadal sex steroid levels and a pubertal LH response to stimulation by native GnRH; **AND**
- Bone age advanced greater than 2 standard deviations (SD) beyond chronological age; **AND**
- Tumor has been ruled out by lab tests such as diagnostic imaging of the brain (to rule out intracranial tumor), pelvic/testicular/adrenal ultrasound (to rule out steroid secreting tumors), and human chorionic gonadotropin levels (to rule out a chorionic gonadotropin secreting tumor).

Length of Authorization:	1 year

CLINICAL CRITERIA FOR RENEWAL

Diagnosis of **Central Precocious Puberty**

- Disease response with treatment as indicated by lack of progression of secondary sexual characteristics, decrease in height velocity, and improvement in final height prediction; **AND**
- Absence of unacceptable toxicity from the drug (e.g., convulsions/seizures, development of ovarian cysts, psychiatric events, cerebrovascular disorder)

TABLOID (THIOGUANINE)

Length of Authorization:	12 months
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75 – HICL, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

- Diagnosis of Acute Myeloid Leukemia; **AND**
- Patient is currently NOT pregnant; **AND**
- Patient does not have the following contraindication:
  - Prior resistance to thioguanine or mercaptopurine

CLINICAL CRITERIA FOR RENEWAL

- Patient must continue to meet above criteria; **AND**
- Absence of unacceptable toxicity from the drug

TAGRISSO (OSIMERTINIB)

Length of Authorization:	3 months, may be renewed
Initiative:	MNC: Non-Formulary Product (IE 50698 / MR – GSN PatOverride)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Non-small cell lung cancer**:

- Patient is at least 18 years or older; **AND**
- Must be used as a single agent; **AND**
- Patient's tumor is epidermal growth factor receptor (EGFR) mutation-positive, confirmed by an FDA-approved test; **AND**
- Patient's disease is metastatic; **AND**
  - Used as subsequent therapy, for T790M mutation-positive disease, after progression on or after EGFR tyrosine kinase inhibitor therapy (e.g., erlotinib, gefitinib, afatinib, dacomitinib, etc.); **OR**
  - Used as first-line therapy; **OR**
  - Continuation of therapy following disease progression on osimertinib for asymptomatic disease, symptomatic brain lesions, or isolated symptomatic systemic lesions; **OR**
  - Used for the treatment of progressive leptomeningeal disease following progression on EGFR tyrosine kinase inhibitor therapy (e.g., erlotinib, gefitinib, afatinib, dacomitinib, etc.)

Diagnosis of **Brain Metastases/Leptomeningeal metastases from NSCLC**:

- Patient is at least 18 years or older; **AND**
- Must be used as a single agent; **AND**
- Patient's tumor is epidermal growth factor receptor (EGFR) mutation-positive, confirmed by an FDA-approved test; **AND**
- Patient has recurrent limited brain metastases; **OR**
- Patient has stable systemic disease or reasonable treatment options; **AND**
  - Patient has recurrent brain metastases that are T790M mutation-positive; **OR**
  - Patient has newly diagnosed brain metastases in patients with small asymptomatic brain metastases; **OR**
- Patient's has leptomeningeal metastases; **AND**
  - Used as primary treatment for patients with good risk status; **OR**
  - Used for maintenance treatment in patients with negative cerebrospinal fluid (CSF) cytology or in clinically stable patients with persistently positive CSF cytology; **OR**
  - Used as systemic treatment in patients with positive CSF cytology that have progressed after receiving prior treatment

CLINICAL CRITERIA FOR RENEWAL

- Tumor response with stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: interstitial lung disease (ILD), QTc prolongation, cardiomyopathy (cardiac failure, congestive heart failure, pulmonary edema or decreased ejection fraction), keratitis, etc.

TARCEVA® (ERLOTINIB)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75 – HICL, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

- Diagnosis of **Pancreatic Cancer**
  - Patient is at least 18 years old; **AND**
  - Cancer is locally advanced, unresectable or metastatic; **AND**
  - Administered in combination with Gemzar® (*gemcitabine*); **AND**
  - Patient must have a good performance status (ECOGPS 0-2); **AND**
  - May not be used in platinum-based chemotherapy regimens
- Diagnosis of **Non–small cell lung cancer**
  - Patient is at least 18 years old; **AND**
  - Cancer is recurrent, or metastatic; **AND**
  - May not be used in platinum-based chemotherapy regimens; **AND**
  - Used as a single agent; **AND**
  - Patient's disease has a known sensitizing EGFR mutation (i.e., exon 19 deletions or exon 21 (L858R) substitution mutation) detected by FDA-approved test; **AND**
    - For 1st line treatment; **OR**
    - Maintenance treatment; **OR**
    - Subsequent treatment following disease progression on one or more chemotherapy regimens or on erlotinib
- Diagnosis of **Bone Cancer –Chordoma**
  - Patient is at least 18 years of age; **AND**
  - May not be used in platinum-based chemotherapy regimens; **AND**
  - Patient's disease is recurrent; **AND**
  - Must be used as a single-agent therapy
- Diagnosis of **Renal Cell Carcinoma**
  - Patient is at least 18 years old; **AND**
  - May not be used in platinum-based chemotherapy regimens; **AND**
  - Patients disease must be relapsed or unresectable stage IV; **AND**
  - Must be used as a single agent; **AND**
  - Patient's disease has predominantly non-clear cell histology

CLINICAL CRITERIA FOR RENEWAL

- Tumor response with stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug
  Examples of unacceptable toxicity include the following: acute onset of new or progressive unexplained pulmonary symptoms (such as dyspnea, cough and fever); acute renal failure; hepatotoxicity (severe changes in liver function); gastrointestinal perforations; bullous and exfoliative skin disorders; corneal perforation and ulceration.

TARGRETIN® (BEXAROTENE) ORAL FORMULATION

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75 – HICL, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

- Diagnosis of **Cutaneous T-cell lymphoma (CTCL)**
  - Patient is 18 years of age or older; **AND**
  - Diagnosis of cutaneous manifestations of cutaneous T-cell lymphoma (e.g., Mycosis fungoides/Sezary Syndrome); **AND**
  - Patient has stage III disease with blood involvement; **OR**
  - Patient has evidence of folliculotropic, large cell transformed, limited extent, or generalized extent disease, **OR**
  - Patient has refractory or progressive stage I-III disease following other therapies; **OR**
  - Used after chemotherapy for stage IV non-Sezary or visceral disease
- Diagnosis of **Cutaneous T-cell lymphoproliferative Disorders**
  - Patient is 18 years of age or older; **AND**
  - Patient is CD30-positive; **AND**
  - Patient has cutaneous manifestation of disease; **AND**
  - Must be used as a single agent; **AND**
  - Used as primary therapy for relapsed or refractory disease; **AND**
  - Patient has a diagnosis of primary cutaneous anaplastic large cell lymphoma (ALCL); **OR**
  - Patient has a diagnosis of lymphomatoid papulosis (LyP); **AND**
    - Patient is symptomatic or has extensive lesions
    - **NOTE:** For topical Targretin please see the DERMATOLOGICS: TOPICAL ANTINEOPLASTICS section

CLINICAL CRITERIA FOR RENEWAL

- Tumor response with stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug
  - Examples include: pancreatitis, leukopenia, and neutropenia, more than 3 times the upper limit of normal values for SGOT/AST, SGPT/ALT, or bilirubin.

TASIGNA® (NILOTINIB)

Length of Authorization:	6 months, may renewed Patients with Ph+ CML-CP who have achieved a sustained molecular response should be evaluated for discontinuation after taking nilotinib for a minimum of 3 years
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75 – HICL, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Chronic Myelogenous Leukemia (CML)**

For CML: For new starts only, patient must have a documented failure, contraindication, intolerance, or ineffective response to a trial of generic imatinib

- Patient is at least 18 years old; **AND**
- Patient has a baseline QTc interval of ≤ 480 ms AND does not have a history of long QT-syndrome; **AND**
- Patient does not have hypokalemia or hypomagnesemia; **AND**
- Patient will avoid concomitant use with strong CYP3A inhibitors (e.g., itraconazole, ketoconazole, clarithromycin), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient will avoid concomitant use with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort); **AND**
- Patient will avoid concomitant use with acid-reducing agents (i.e., proton pump inhibitors), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient's disease is confirmed by either Philadelphia chromosome-positive (Ph+) or BCR-ABL1 positive laboratory test result; **AND**
- Patient does not have any of the following *BCR-ABL1* mutations: T315I, Y253H, E255K/V, F359V/C/I or G250E (****Note:** This does not apply to patients receiving first-line or continued therapy); **AND**
  - Patient is resistant, intolerant, or had an inadequate response to prior tyrosine kinase inhibitor (TKI) therapies, consisting of a 3 month trial or longer, with omacetaxine or a tyrosine kinase inhibitor (e.g., imatinib, bosutinib, ponatinib, dasatinib); **AND**
    - Used as a single agent for accelerated phase disease; **OR**
    - Patient is at least 1 year old and used as a single agent for chronic phase disease; **OR**
  - Used as primary treatment; **AND**
    - Used as single agent for newly diagnosed chronic phase disease in patients at least 1 year old; **OR**
    - Used as a single agent for accelerated or myeloid blast phase disease; **OR**
    - Used in combination with corticosteroids for lymphoid blast phase disease; **OR**
    - Used in combination with induction chemotherapy for disease in lymphoid blast phase or myeloid blast phase; **OR**
  - Used as switch therapy; **AND**
    - Patient received initial therapy with one of the following: imatinib, bosutinib, or dasatinib; **AND**
    - Patient has *BCR-ALB1* transcript levels:
      - > 1% to 10% at 12 months; **OR**
      - > 1% to 10% at ≥15 months; **OR**
      - > 10% at any response milestone; **OR**

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Chronic Myelogenous Leukemia (CML)** *(Continued)*

- Used as continued therapy; **AND**
  - Patient has *BCR-ALB1* transcript levels:
    - ≤ 1% at any response milestone; **OR**
    - 1% to 10% at 3,6, or 12 months; **OR**
    - > 10% at 3 months; **OR**
- Used post-allogeneic hematopoietic stem cell transplant (HCT); **AND**
  - Used for at least one year in patients with prior complete cytogenetic response (CCyR) for accelerated or blast phase disease; **OR**
  - Used as follow-up therapy in patients with molecular relapse (BCR-ABL1 transcript positive) following CCyR; **OR**
  - Used as follow-up therapy in patients with relapse or those who are not in CCyR; **OR**
- Re-initiation of treatment**; AND**
  - Patient lost molecular response (MMR or MR4.0) after discontinuation of therapy with nilotinib

Diagnosis of **Acute Lymphoblastic Leukemia (ALL)**

- Patient is at least 18 years old unless otherwise specified; **AND**
- Patient has a baseline QTc interval of ≤ 480 ms AND does not have a history of long QT-syndrome; **AND**
- Patient does not have hypokalemia or hypomagnesemia; **AND**
- Patient will avoid concomitant use with strong CYP3A inhibitors (e.g., itraconazole, ketoconazole, clarithromycin), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient will avoid concomitant use with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort); **AND**
- Patient will avoid concomitant use with acid-reducing agents (i.e., proton pump inhibitors), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patients disease is Philadelphia chromosome positive (Ph+) disease; **AND**
  - Used for relapsed or refractory disease; **AND**
    - Patient does not have any of the following *BCR-ABL1* mutations: T315I, Y253H, E255K/V, F359V/C/I or G250E; **AND**
      - Used as a single agent; **OR**
      - Used in combination with an induction therapy not previously used; **OR**
  - Used as maintenance therapy; **AND**
    - Used in combination with vincristine and prednisone with or without methotrexate and mercaptopurine; **OR**
    - Used post-hematopoietic stem cell transplant; **OR**
  - Patient is at least 15 years of age and < 65 years of age; **AND**
    - Used in a multiagent chemotherapy regimen for induction or consolidation therapy; **OR**
    - Used in combination with a corticosteroid for induction therapy; **OR**
    - Used in combination with vincristine and dexamethasone for induction therapy; **OR**
  - Patient is ≥ 65 years of age; **AND**
    - Used as induction therapy as part of one of the following regimens:
      - As a single agent or in combination with a corticosteroid; **OR**
      - In combination with vincristine and dexamethasone; **OR**
      - In combination with a multiagent chemotherapy regimen

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Gastrointestinal Stromal Tumors (GIST)**

- Patient is at least 18 years old; **AND**
- Patient has a baseline QTc interval of ≤ 480 ms **and** does not have a history of long QT-syndrome; **AND**
- Patient does not have hypokalemia or hypomagnesemia; **AND**
- Patient will avoid concomitant use with strong CYP3A inhibitors (e.g., itraconazole, ketoconazole, clarithromycin), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient will avoid concomitant use with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort); **AND**
- Patient will avoid concomitant use with acid-reducing agents (i.e., proton pump inhibitors), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient had unresectable or metastatic disease; **AND**
- Used as fourth-line therapy as a single agent; **AND**
- Disease has progressed after single-agent treatment with each of the following: imatinib, regorafenib, and sunitinib

CLINICAL CRITERIA FOR RENEWAL

- Patient adherent to therapy; **AND**
- Absence of unacceptable toxicity from the drug (e.g., electrolyte abnormalities [hypophosphatemia, hypokalemia, hyperkalemia, hypocalcemia, hyponatremia], myelosuppression [neutropenia, thrombocytopenia, anemia], QT prolongation, cardiac and arterial vascular occlusive events, pancreatitis and elevated serum lipase, hepatotoxicity [severe changes in liver function tests], tumor lysis syndrome, hemorrhage, fluid retention, growth retardation in pediatric patients); **AND**
- **Acute lymphoblastic leukemia (ALL) only**:
  - Treatment response or stabilization of disease as indicated by CBC, bone marrow cytogenic analysis, QPCR, or FISH
- **Chronic myelogenous leukemia (CML) only**:
  - Re-initiation of treatment:
    - Patient lost molecular response (MMR or MR4.0) after discontinuation of therapy with nilotinib; **OR**
  - Treatment response as indicated by one of the following *BCR-ABL1* (IS) transcript levels:
    - ≤ 10% at 3 months; **OR**
    - ≤ 10% at 6 months; **OR**
    - < 1 % at 12 months and beyond

    Note: cytogenetic assessment of response may be used if quantitative PT-PCR (QPCR) using international scale (IS) for *BCR-ABL1* is not available
- **Gastrointestinal Stromal Tumors (GIST) only**:
  - Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread

TEMODAR® (TEMOZOLOMIDE): IV FORMULATION

Length of Authorization:	6 months, may be renewed
Initiative:	MNC: Non-Formulary Product (IE 50698 / MR – GSN PatOverride)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Bone Cancer**

- Documented diagnosis of Ewing's sarcoma; **AND**
- Used in combination with Camptosar® (*irinotecan*); **AND**
  - Used for progressive disease following primary treatment; **OR**
  - Used as second-line therapy for metastatic disease; **OR**
  - Used for relapsed disease

Diagnosis of **CNS Cancer – Glioblastoma multiforme (GBM)**

- Used concomitantly with radiotherapy and then as a single agent as maintenance treatment for newly diagnosed disease; **OR**
- Used adjuvantly following surgery; **AND**
  - Used concurrently with radiotherapy and then as a single agent for patients with Karnofsky Performance Status (KPS) ≥ 60 (i.e., ECOG 0-2); **OR**
  - Used concurrently with or after radiotherapy for patients ≤ 70 years old with KPS < 60 (i.e., ECOG ≥ 3); **OR**
  - Used as single agent chemotherapy for patients > 70 years old or with KPS < 60 (i.e., ECOG ≥ 3); **AND**
    - Tumor is O6-methylguanine-DNA methyltransferase (MGMT) promoter methylated; **OR**
- Patient has recurrent disease and used as a single agent or in combination with bevacizumab

Diagnosis of **CNS Cancer – Astrocytoma/Oligodendroglioma- Low-grade (WHO Grade II) Infiltrative Supratentorial**

- Used with concurrent radiation followed by adjuvant treatment as a single agent

Diagnosis of **CNS Cancer – Adult Intracranial and Spinal Ependymoma**

- Used as single agent for progressive disease; **AND**
- Patient does **not** have subependymoma

Diagnosis of **CNS Cancer – Adult medulloblastoma**

- Used as a single agent in patients who have received prior chemotherapy

Diagnosis of **CNS Cancer – anaplastic Gliomas (Anaplastic Astrocytoma, Anaplastic Oligoastrocytoma, Anaplastic oligodendroglioma–1p19p codeleted)**

- Patient has recurrent disease and used as a single agent or in combination with bevacizumab; **OR**
- Used for patients with KPS ≥60 (i.e., ECOG 0-2) as adjuvant treatment as a single agent; **OR**
- Patient has an Anaplastic Astrocytoma and used as a single agent for disease progression on nitrosourea and procarbazine

Diagnosis of **CNS Cancer – CNS metastases**

- Used as a single agent therapy for recurrent disease; **AND**
- Temodar is active against the patient's primary tumor; **AND**
- Patient has stable disease or reasonable systemic treatment options

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Primary CNS Lymphoma

- Used in combination with rituximab and high-dose methotrexate; **AND**
  - Used as induction therapy; **OR**
- Used as consolidation therapy in patients who have had a complete response to induction therapy; **OR**
- Used as a single agent or in combination with rituximab for patients with relapsed or refractory disease who previously received high-dose chemotherapy with stem cell rescue or high-dose methotrexate or who received prior whole-brain radiation therapy

Diagnosis of **Melanoma**

- Used as a single agent therapy; **AND**
- Patient has unresectable or metastatic disease; **AND**
  - Used as subsequent therapy in patients who have had disease progression (or maximum clinical benefit achieved) from BRAF targeted therapies; **OR**
  - Patient has uveal melanoma

Diagnosis of **Neuroendocrine Tumors (NET)**

- Patient has documented pancreatic neuroendocrine tumors; **AND**
  - Used as a single agent or in combination with capecitabine; **AND**
  - Patient has locally advanced or metastatic disease ; **AND**
  - Patient has symptomatic or bulky (i.e., clinically significant tumor burden) or progressive disease; **OR**
- Patient has documented Pheochromocytoma/Paraganglioma; **AND**
  - Used as a single agent as primary treatment for distant metastases; **OR**
- Patient has disease in the lung/thymus with carcinoid syndrome that is poorly controlled; **AND**
  - Used as a single agent or in combination with capecitabine; **AND**
  - Used in combination with octreotide LAR, lanreotide or telotristat for persistent symptoms (e.g., diarrhea, etc.); **OR**
- Patient has bronchopulmonary or thymic disease; **AND**
  - Will **not** be used for adjuvant therapy; **AND**
  - Used as a single agent or in combination with capecitabine; **AND**
    - Patient has distant metastatic disease; **AND**
      - Patient has clinically significant tumor burden and low grade (typical) histology, evidence of progression, or intermediate grade (atypical) histology; **OR**
      - Patient has locally advanced unresectable disease; **OR**
  - Patient has Poorly differentiated (i.e., high-grade) neuroendocrine carcinoma or Large or small cell carcinoma (other than lung); **AND**
    - Used as a single agent or in combination with capecitabine; **AND**
      - Used for locally advanced unresectable or metastatic disease; **OR**
      - Used as neoadjuvant or adjuvant therapy or as chemotherapy alone for resectable disease

Diagnosis of **Mycosis fungoides/Sezary syndrome**

- Patient does not have relapsed or persistent stage IA-IIA mycosis fungoides with B1 blood involvement

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Primary Cutaneous CD30+ T-Cell Lymphoproliferative Disorders**

- Patient has primary cutaneous anaplastic large cell lymphoma (ALCL) with multifocal lesions or cutaneous ALCL with regional nodes (excludes systemic ALCL); **AND**
- Used as a single agent for relapsed or refractory disease with CNS involvement

Diagnosis of **Small Cell Lung Cancer**

- Used as subsequent therapy as a single agent for disease progression or relapse; **AND**
- Patient has a performance status 0-2

Diagnosis of Soft Tissue Sarcoma

- Used as palliative therapy as a single agent; **AND**
  - Patient is diagnosed with angiosarcoma; **OR**
  - Patient has retroperitoneal or intra-abdominal disease; **AND**
    - Disease is unresectable and/or progressive; **OR**
  - Patient has pleomorphic rhabdomyosarcoma; **OR**
  - Patient has recurrent or disseminated metastatic sarcoma of the extremities, superficial trunk or head/neck; **OR**
- Used in combination with vincristine and irinotecan for non-pleomorphic rhabdomyosarcoma; **OR**
- Patient has Solitary Fibrous Tumor or Hemangiopericytoma; **AND**
  - Used in combination with bevacizumab

Diagnosis of **Uterine Sarcoma**

- Used as a single agent for recurrent or metastatic disease which has progressed following prior cytotoxic chemotherapy; **AND**
- Patient has Stage II, III or IV disease

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: myelosuppression (neutropenia, thrombocytopenia, leukopenia, lymphopenia), aplastic anemia, myelodysplastic syndrome or secondary malignancy, pneumocystis pneumonia, severe hepatotoxicity, etc.

TEMODAR® (TEMOZOLOMIDE): ORAL FORMULATION

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75 – HICL, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Coverage is provided in the following conditions:

- Bone Cancer – Ewing's Sarcoma
- CNS Cancer
  - Glioblastoma multiforme (GBM)
  - Astrocytoma/Oligodendroglioma- Low-grade (WHO Grade II) Infiltrative, Supratentorial
  - Adult Intracranial and Spinal Ependymoma (excluding Subependymoma)
  - Adult medulloblastoma
  - Anaplastic Gliomas (Anaplastic Astrocytoma, Anaplastic Oligoastrocytoma, Anaplastic oligodendroglioma–1p19p codeleted)
  - CNS Metastases (when active against the primary tumor)
- Primary CNS Lymphoma
- Melanoma and Uveal Melanoma
- Neuroendocrine Tumors (NET)
  - Lung and Thymus neuroendocrine tumors
  - Carcinoid Tumors (lung or thymus)
  - Pancreatic neuroendocrine tumors
  - Pheochromocytoma/Paraganglioma
  - Poorly differentiated high grade disease/Large or Small Cell Carcinoma (other than lung)
- Mycosis fungoides/Sezary syndrome
- Primary Cutaneous CD30+ T-Cell Lymphoproliferative Disorders
- Small Cell Lung Cancer
- Soft Tissue Sarcoma
  - Angiosarcoma
  - Retroperitoneal or intra-abdominal disease
  - Rhabdomyosarcoma
  - Recurrent or metastatic sarcoma of the extremities, superficial trunk or head/neck
  - Solitary Fibrous Tumor/Hemangiopericytoma
- Uterine Sarcoma (Stage II-IV disease)

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: myelosuppression (neutropenia, thrombocytopenia, leukopenia, lymphopenia), aplastic anemia, myelodysplastic syndrome or secondary malignancy, pneumocystis pneumonia, severe hepatotoxicity, etc.

THALOMID®

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75 – HICL, 50081 and 2193) MNC: Non-Formulary Product (IE 50698 / MR – GSN PatOverride)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Multiple Myeloma (MM)**

- Prescriber and patient must be enrolled in Thalomid REMS program; **AND**
- Women of child-bearing age must be using two forms of contraception; **AND**
- Patient is 18 years of age or older; **AND**
- Used as primary chemotherapy for active (symptomatic) disease; **AND**
  - Used in combination with dexamethasone; **OR**
  - Used in combination with dexamethasone and bortezomib, with or without daratumumab, in transplant candidates; **OR**
  - Used as part of a VTD-PACE (bortezomib, dexamethasone, thalidomide, cisplatin, doxorubicin, cyclophosphamide, and etoposide) regimen in transplant candidates; **OR**
- Used for disease relapse that occurred after 6 months following primary therapy with the same regimen; **AND**
  - Used as part of VTD-PACE regimen in transplant candidates; **OR**
- Used for previously treated disease that is progressive or relapsed; **AND**
  - Used as part of DT-PACE (dexamethasone, thalidomide, cisplatin, doxorubicin, cyclophosphamide, and etoposide) regimen; **OR**
  - Used as part of VTD-PACE regimen; **OR**
  - Used in combination with carfilzomib, cyclophosphamide and dexamethasone.

Diagnosis of **Erythema nodosum leprosum (ENL)**

- Prescriber and patient must be enrolled in Thalomid REMS program; **AND**
- Women of child-bearing age must be using two forms of contraception; **AND**
- Patient is 18 years of age or older; **AND**
- Used as acute treatment of cutaneous manifestations of ENL in patient with moderate to severe disease; **AND**
  - Will not be used as monotherapy for patients with moderate to severe neuritis; **OR**
  - Used as maintenance therapy for prevention and suppression of the cutaneous manifestations of ENL recurrence

Diagnosis of **Castleman's Disease (CD)**

- Prescriber and patient must be enrolled in Thalomid REMS program; **AND**
- Women of child-bearing age must be using two forms of contraception; **AND**
- Patient is 18 years of age or older; **AND**
- Used as subsequent therapy for multicentric disease that has progressed following treatment of relapsed/refractory or progressive disease

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Myelofibrosis**

- Prescriber and patient must be enrolled in Thalomid REMS program; **AND**
- Women of child-bearing age must be using two forms of contraception; **AND**
- Patient is 18 years of age or older; **AND**
- Must be used as a single agent or in combination with prednisone for management of myelofibrosis-associated anemia; **AND**
  - With serum EPO ≥ 500 mU/mL; **OR**
  - With serum EPO < 500 mU/mL and no response or loss of response to erythropoietic stimulating agents.

Diagnosis of **AIDS-Related Kaposi Sarcoma**

- Prescriber and patient must be enrolled in Thalomid REMS program; **AND**
- Women of child-bearing age must be using two forms of contraception; **AND**
- Patient is 18 years of age or older; **AND**
- Used in combination with antiretroviral therapy (ART); **AND**
- Used as subsequent systemic therapy for relapsed or refractory advanced disease that has progressed or not responded to first-line and alternate first-line systemic therapy for one of the following disease types:
  - Cutaneous disease
  - Oral disease
  - Visceral disease
  - Nodal disease

CLINICAL CRITERIA FOR RENEWAL:

Authorizations can be renewed based on the following criteria:

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: hematologic toxicity (neutropenia, thrombocytopenia), ischemic heart disease (including myocardial infarction and stroke), pulmonary embolism, deep vein thrombosis, peripheral neuropathy, severe bradycardia/syncope, severe cutaneous reactions, seizures, tumor lysis syndrome, bradycardia, etc.; **AND**
- Oncology Indications:
  - Disease response with treatment as defined as stabilization or disease or decrease in size of tumor or tumor spread
- Erythema nodosum leprosum:
  - Disease response as evidenced by a decrease/reduction in the total steroid dosage and/or a decrease in disease relapse

THYROID PRODUCTS

All of the following thyroid products now reject for DESI and/or no rebate (excluded from coverage): NP thyroid, WP thyroid, Armour thyroid, Thyroid, Nature-Throid. Covered thyroid drugs include Levoxyl, Unithroid, Levothyroxine, Tirosint, Levo-T, Liothyronine.

TOBRAMYCIN

Length of Authorization:	1 YEAR
Initiative:	SPC: Respiratory Agents (IE 2462 / NCPDP 75 – HICL)

CLINICAL CRITERIA

- Diagnosis of cystic fibrosis; **AND**
- Patient is 6 years or older; **AND**
- Patient is **not** colonized with *Burkholderia cepacia*; **AND**
- Confirmation the patient has been colonized with *Pseudomonas aeruginosa* per positive sputum culture; **AND**
- Confirmation the patient is not receiving treatment with other inhaled antibiotics and/or anti-infective agents, including alternating treatment schedules; **AND**
- Baseline percent predicted FEV1.

Requesting Bethkis® Solution:

- All Items above; **AND**
- Patient has a FEV1 > 40% and < 80% predicted

Requesting Kitabis® Solution:

- All items above; **AND**
- Patient has a FEV1 > 25% and < 75% predicted

COVERED – PA REQUIRED
Bethkis® (*tobramycin*)
Kitabis® Pak (*tobramycin*)

TRAVATAN Z® (TRAVOPROST)

Length of Authorization:	1 Year, eligible for renewal
Initiative:	MNC: Glaucoma Agents (IE 2462 / NCPDP 75 – HICL)

CLINICAL CRITERIA

- Patient is 16 years of age or older; **AND**
- Patient must have a diagnosis of elevated intraocular pressure with open-angle glaucoma **or** ocular hypertension; **AND**
- Patient has an inadequate response, contraindication, or intolerance to latanoprost

TRIKAFTA® (ELEXACAFTOR/TEZACAFTOR/IVACAFTOR)

Length of Authorization:	6 months, may be renewed
Initiative:	MNC: Non-Formulary Product (IE 50698 / MR – GSN PatOverride)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Cystic Fibrosis**

- Patient is at least 12 years old; **AND**
- Patient has a documented diagnosis of cystic fibrosis; **AND**
- Confirmation the patient is not receiving concurrent treatment with any other CFTR-targeted therapy containing one or more of the following: ivacaftor, lumacaftor, tezacaftor, elexacaftor; **AND**
- Patient does not have severe hepatic impairment (Child-Pugh class C); **AND**
- Patient will avoid concomitant use with strong CYP3A Inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.); **AND**
- Patient has at least one F508del mutation, as confirmed by an FDA-cleared or CLIA-compliant CF mutation test; **AND**
- Patient has a baseline percent predicted FEV1 (reported measurements may be used on renewal)

CLINICAL CRITERIA FOR RENEWAL

Authorizations can be renewed based on the following criteria:

- Disease response as indicated by one or more of the following:
  - Decreased pulmonary exacerbations compared to pretreatment baseline
  - Decrease in decline of lung function as measured by FEV_1 within previous 30 days compared to baseline
  - Improvement or stabilization of lung function as measured by FEV_1 within previous 30 days compared to baseline
  - Improvement in quality of life (e.g., Cystic Fibrosis Questionnaire-Revised [CFQ-R] score, etc.), weight gain, or growth; **AND**
- Patient has not received a lung transplant; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include elevated transaminases (ALT or AST), development of cataracts or lens opacities, etc.

TRUXIMA® (RITUXIMAB-ABBS)

Length of Authorization:	6 months (12 months initially for pemphigus vulgaris; see below for RA), may be renewed (see exceptions below) • Rheumatoid arthritis (RA) – Initial: 1 month; Renewal: 1 month • Maintenance therapy for oncology indications (excluding acute lymphoblastic leukemia [ALL], mantle cell lymphoma, hairy cell leukemia) may be renewed for up to a maximum of 2 years – Mantle cell lymphoma may be renewed until disease progression or intolerable toxicity – ALL and Hairy cell leukemia may not be renewed • Relapse therapy for pemphigus vulgaris must be at least 16 weeks past a prior infusion
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Acute lymphoblastic leukemia (ALL)**

- Patient age is 18 years or older (for relapsed/refractory treatment) or 15 years of older (for induction/consolidation treatment); **AND**
- Patient does not have a severe, active infection; **AND**
- Patient has been screened for the presence of hepatitis B (HBV) infection (i.e., HBsAg and anti-HBc) prior to initiating therapy and patients with evidence of current or prior HBV infection will be monitored for HBV reactivation during treatment; **AND**
- Patient has not received a live vaccine within 28 days prior to starting treatment and live vaccines will not be administered concurrently while on treatment; **AND**
- Patient CD20 antigen expression is positive; **AND**
- For induction/consolidation treatment:
  - Patient has Philadelphia chromosome-negative (Ph-) disease; **AND**
    - Patient is 15 years or older; **AND**
      - Used in combination with an anthracycline, cyclophosphamide, and vincristine-based regimen; **OR**
- For relapsed/refractory treatment:
  - Patient has Philadelphia chromosome-negative (Ph-) disease **or** tyrosine kinase inhibitor (TKI) refractory Philadelphia chromosome-positive (Ph+) disease; **AND**
    - Used in combination with MOpAD regimen (methotrexate, vincristine, pegaspargase, dexamethasone)

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL)**

- Patient age is 18 years or older; **AND**
- Patient does not have a severe, active infection; **AND**
- Patient has been screened for the presence of hepatitis B (HBV) infection (i.e., HBsAg and anti-HBc) prior to initiating therapy and patients with evidence of current or prior HBV infection will be monitored for HBV reactivation during treatment; **AND**
- Patient has not received a live vaccine within 28 days prior to starting treatment and live vaccines will not be administered concurrently while on treatment; **AND**
- Patient CD20 antigen expression is positive; **AND**
- Used in combination with fludarabine and cyclophosphamide (FC); **OR**
- Patient has disease that is ***without*** del(17p)/TP53 mutation; **AND**
  - Used as first-line therapy in **ONE** of the following settings or in combination with:
    - Bendamustine (patients ≥ 65 years, or younger patients with or without significant comorbidities)
    - Fludarabine (patient is without del(11q) and is <65 years without significant comorbidities); **OR**
  - Used for relapsed or refractory disease in combination with **ONE** of the following:
    - Alemtuzumab
    - Bendamustine (patients ≥ 65 years or younger patients with significant comorbidities)
    - Chlorambucil (patients ≥ 65 years or younger patients with significant comorbidities)
    - High-dose Methylprednisolone
    - Idelalisib
    - Lenalidomide
    - Venetoclax
    - PCR (pentostatin, cyclophosphamide, and rituximab); **OR**
- Patient has disease ***with*** del(17p)/TP53 mutation; **AND**
  - Used as first-line therapy in one of the following settings or in combination with:
    - Alemtuzumab
    - High-dose Methylprednisolone; **OR**
  - Used for relapsed or refractory disease in one of the following settings or in combination with:
    - Alemtuzumab
    - High-dose Methylprednisolone
    - Idelalisib
    - Lenalidomide
    - Venetoclax; **OR**
- Used as first line therapy for histologic (Richter's) transformation to diffuse large B-cell lymphoma in combination with cyclophosphamide, doxorubicin, and vincristine- based regimens or as a component of OFAR (oxaliplatin, fludarabine, cytarabine, and rituximab).

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Non-Hodgkin lymphomas (NHL)**

- Patient age is 18 years or older; **AND**
- Patient does not have a severe, active infection; **AND**
- Patient has been screened for the presence of hepatitis B (HBV) infection (i.e., HBsAg and anti-HBc) prior to initiating therapy and patients with evidence of current or prior HBV infection will be monitored for HBV reactivation during treatment; **AND**
- Patient has not received a live vaccine within 28 days prior to starting treatment and live vaccines will not be administered concurrently while on treatment; **AND**
- Patient CD20 antigen expression is positive; **AND**
- Diagnosis of **Non-Hodgkin lymphomas (NHL) including, but not limited to, the following:**
  - AIDS-related B-Cell Lymphoma
    - Disease is related to Burkitt Lymphoma or diffuse large B-cell lymphoma *(including HHV-8 DLBCL, not otherwise specified)*
  - Burkitt Lymphoma
    - Used in combination with other chemotherapy
  - Castleman's Disease
    - Patient has multicentric disease; **OR**
    - Patient has unicentric disease; **AND**
      - Used as second-line therapy for relapsed or refractory disease; **OR**
      - Used for patients with symptoms after resection or unresectable disease
  - Diffuse Large B-Cell Lymphoma
  - Low-grade or Follicular Lymphoma
  - Gastric & Non-Gastric MALT Lymphoma
  - High Grade B-Cell Lymphoma
  - Mantle Cell Lymphoma
  - Nodal & Splenic Marginal Zone Lymphoma
  - Histologic transformation of Follicular or Nodal Marginal Zone Lymphoma to Diffuse Large B-Cell Lymphoma
  - Post-transplant lymphoproliferative disorder (PTLD) (B-cell type)
    - Patient has had solid organ transplant or allogeneic hematopoietic stem cell transplantation
  - Pediatric Aggressive Mature B-Cell Lymphomas
    - Used in combination with chemotherapy
  - Primary Cutaneous B-Cell Lymphomas
  - Hairy Cell Leukemia
    - Used in combination with cladribine as initial therapy; **OR**
    - Used for relapsed or refractory disease or in patients with a less than complete response (CR) to initial therapy.

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Waldenström's Macroglobulinemia/Lymphoplasmacytic Lymphoma**

- Patient age is 18 years or older; **AND**
- Patient does not have a severe, active infection; **AND**
- Patient has been screened for the presence of hepatitis B (HBV) infection (i.e., HBsAg and anti-HBc) prior to initiating therapy and patients with evidence of current or prior HBV infection will be monitored for HBV reactivation during treatment; **AND**
- Patient has not received a live vaccine within 28 days prior to starting treatment and live vaccines will not be administered concurrently while on treatment; **AND**
- Patient CD20 antigen expression is positive

Diagnosis of **Granulomatosis with Polyangiitis (GPA) (Wegener's granulomatosis) and Microscopic Polyangiitis (MPA)**

- Patient is at least 2 years of age; **AND**
- Patient does not have a severe, active infection; **AND**
- Patient has been screened for the presence of hepatitis B (HBV) infection (i.e., HBsAg and anti-HBc) prior to initiating therapy and patients with evidence of current or prior HBV infection will be monitored for HBV reactivation during treatment; **AND**
- Patient has not received a live vaccine within 28 days prior to starting treatment and live vaccines will not be administered concurrently while on treatment; **AND**
- Used in combination with glucocorticoids (e.g., prednisone, methylprednisolone)

Diagnosis of **Pemphigus Vulgaris**

- Patient age is 18 years or older; **AND**
- Patient does not have a severe, active infection; **AND**
- Patient has been screened for the presence of hepatitis B (HBV) infection (i.e., HBsAg and anti-HBc) prior to initiating therapy and patients with evidence of current or prior HBV infection will be monitored for HBV reactivation during treatment; **AND**
- Patient has not received a live vaccine within 28 days prior to starting treatment and live vaccines will not be administered concurrently while on treatment; **AND**
- Patient has a diagnosis of pemphigus vulgaris as determined by the following:
  - One or more of the following clinical features:
    - Appearance of lesions, erosions and/or blisters
    - Nikolsky sign (induction of blistering via mechanical pressure at the edge of a blister or on normal skin)
    - Characteristic scarring and lesion distribution; **AND**
  - Histopathologic confirmation by skin/mucous membrane biopsy; **AND**
  - Presence of autoantibodies as detected by indirect immunofluorescence or enzyme-linked immunosorbent assay (ELISA); **AND**
- Patient has moderate to severe disease as assessed utilizing an objective measure/tool (i.e., PDAI, PSS, ABSIS); **AND**
- Patient is on combination glucocorticoid therapy; **AND**
- Other causes of blistering or erosive skin and mucous membrane diseases have been ruled out

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Rheumatoid Arthritis**

- Diagnosis of **moderately- to severely-active rheumatoid arthritis**; **AND**
- **One** of the following:
  - Patient is concurrently on methotrexate; **OR**
  - History of contraindication or intolerance to methotrexate**; AND**
- Trial and failure, contraindication, or intolerance to **two** of the following: Humira®, Enbrel®, Xeljanz®; **AND**
- Prescribed by or in consultation with a rheumatologist

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug (e.g., severe infusion-related reactions, tumor lysis syndrome [TLS], severe mucocutaneous reactions, progressive multifocal leukoencephalopathy [PML], hepatitis B virus reactivation, serious bacterial, fungal, or viral infections, cardiac arrhythmias, renal toxicity, bowel obstruction or perforation); **AND**
- **For oncology indications:** Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread
- **For granulomatosis with polyangiitis (GPA) (Wegener's granulomatosis) and microscopic polyangiitis (MPA):**
  - Disease response as indicated by disease control and improvement in signs and symptoms of condition compared to baseline; **AND**
  - A decrease frequency in the occurrence of major relapses (defined by the reappearance of clinical and/or laboratory signs of vasculitis activity that could lead to organ failure or damage, or could be life threatening)
- **For all other non-oncology indications:** Documentation of positive clinical response to Truxima therapy

TYKERB® (LAPATINIB)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75 – HICL, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

- Diagnosis of **Breast Cancer**
  - Patient is at least 18 years old; **AND**
  - Patient's disease is human epidermal growth factor receptor positive (HER2+)*; **AND**
  - Baseline left ventricular ejection fraction (LVEF); **AND**
  - Patient's disease is metastatic **OR** recurrent; **AND**
    - Used as subsequent therapy in combination with Herceptin® (*trastuzumab*) or Xeloda (capecitabine); **AND**
      - Patient was previously treated with Herceptin® (*trastuzumab*); **AND**
      - Patient has symptomatic visceral disease or visceral crisis; **OR**
      - Patient's disease is hormone receptor negative; **OR**
      - Patient's disease is hormone receptor positive and is refractory to endocrine therapy; **OR**
    - Used in combination with an aromatase inhibitor (i.e., letrozole, etc.); **AND**
      - Patient's disease must be estrogen receptor positive; **AND**
      - Patient is a male receiving concomitant androgen deprivation therapy; **OR**
      - Patient is a postmenopausal female
- Diagnosis of **Breast Cancer (Brain Metastases)**
  - Patient is at least 18 years old; **AND**
  - Patient's disease is human epidermal growth factor receptor positive (HER2+)*; **AND**
  - Baseline left ventricular ejection fraction (LVEF); **AND**
  - Patient has brain metastases; **AND**
  - Patient's disease is recurrent; **AND**
  - Must be used in combination with Xeloda (capecitabine); **AND**
  - Tykerb is active against primary breast tumor

***HER2 over expression must be confirmed as followed:**

- Immunohistochemistry (IHC) assay 3+; **OR**
- Fluorescence in situ hybridization (FISH) Assay > 2.0 (HER2/CEP17 ratio); **OR**
- Average HER2 copy number ≥ 6 singles/cell

CLINICAL CRITERIA FOR RENEWAL

- Tumor response with stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Left ventricular ejection fraction (LVEF) has decreased no more than 15% from baseline and is within normal limits; **AND**
- Absence of unacceptable toxicity from the drug
  Examples include: acute onset of new or progressive unexplained shortness of breath, cough, or fever; severe changes in liver function tests, QT prolongation, decreased LVEF

VALCYTE® (VALGANCICLOVIR)

Length of Authorization:	1 Year, eligible for renewal
Initiative:	MNC: Antivirals (IE 2462 / NCPDP 75 – HICL)

CLINICAL CRITERIA

- Patient must have a diagnosis of one of the following:
  - Adult Patients (for ages 16 years and older):
    - CMV retinitis in patients with acquired immunodeficiency syndrome (AIDS)
    - Need for prophylaxis of CMV disease in kidney, heart, and kidney-pancreas transplant patients at high risk
  - Pediatric Patients (for ages 1 month to 16 years of age):
    - Need for prophylaxis of CMV disease in kidney and heart transplant patients at high risk
- For the oral solution:
  - Adult patients should use valganciclovir tablets, not valganciclovir for oral solution.
  - Patient must have difficulty swallowing, cannot swallow tablets, or the dosage needed is not available in tablet formulation.

VALTOCO® (DIAZEPAM SPRAY)

Length of Authorization:	12 months
Initiative:	MNC: Non-Formulary Product (IE 50698 / MR – GSN PatOverride)

CLINICAL CRITERIA FOR INITIAL APPROVAL

- Patient is 6 years of age or older; **AND**
- Patient has a diagnosis of epilepsy; **AND**
- Therapy is being used for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern; **AND**
- Patient does not have any of the following contraindications:
  - Known hypersensitivity to midazolam; **OR**
  - Acute narrow-angle glaucoma

CLINICAL CRITERIA FOR RENEWAL

- Patient must continue to meet above criteria; **AND**
- Absence of unacceptable toxicity from the drug

VENCLEXTA® (VENETOCLAX)

Length of Authorization:	6 months, may be renewed When used for CLL/SLL in combination with rituximab, coverage may be renewed up to a total of 24 months of therapy (from day 1 of cycle 1 of rituximab) When used for CLL/SLL in combination with obinutuzumab, coverage may be renewed up until the end of 12 cycles of obinutuzumab therapy (Venetoclax therapy begins on day 22 of cycle 1 of obinutuzumab)
Initiative:	MNC: Non-Formulary Product (IE 50698 / MR – GSN PatOverride) SPC: Oncology Agents (IE 2462 / NCPDP 75 – HICL, 50081 and 2193)

Grandfathered drug: Grandfathering criteria applies

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL)**

- Patient is 18 years of age or older; **AND**
- Patient must not have a concurrent diagnosis of multiple myeloma; **AND**
- Patient must not receive live attenuated vaccines prior to, during, or after venetoclax treatment until B-cell recovery occurs; **AND**
- Patient will not be on concomitant therapy with moderate or strong CYP3A-inducers (e.g., rifampin, carbamazepine, phenytoin, St. John's Wort); **AND**
- Patient must not be on strong CYP3A-inhibitors (e.g., posaconazole, nefazodone, ritonavir, grapefruit juice) during initiation and ramp-up phase.

Diagnosis of **Acute Myeloid Leukemia (AML)**

- Patient must not have a concurrent diagnosis of multiple myeloma; **AND**
- Patient must not receive live attenuated vaccines prior to, during, or after venetoclax treatment until B-cell recovery occurs; **AND**
- Patient will not be on concomitant therapy with moderate or strong CYP3A-inducers (e.g., rifampin, carbamazepine, phenytoin, St. John's Wort)**; AND**
- Patient is at least 60 years old or is unable to receive intensive induction therapy due to comorbidities (e.g., PS > 2, moderate hepatic impairment, severe cardiac or pulmonary disease, CLCR < 45 mL/min); **AND**
  - Used in combination with azacitidine, decitabine, or low-dose cytarabine; **AND**
    - Patient has newly-diagnosed disease; **OR**
    - Used as post-induction therapy following response to previous lower intensity therapy with the same regimen; **OR**
- Patient has relapsed/refractory disease; **AND**
  - Used in combination with the initial successful induction regimen in patients with late relapse (≥ 12 months) if not administered continuously and not stopped due to development of clinical resistance; **OR**
  - Used in combination with azacitidine, decitabine, or low-dose cytarabine

Diagnosis of **Blastic Plasmacytoid Dendritic Cell Neoplasm (BPDCN)**

- Patient is 18 years of age or older; **AND**
- Patient must not have a concurrent diagnosis of multiple myeloma; **AND**
- Patient must not receive live attenuated vaccines prior to, during, or after venetoclax treatment until B-cell recovery occurs; **AND**
- Patient will not be on concomitant therapy with moderate or strong CYP3A-inducers (e.g., rifampin, carbamazepine, phenytoin, St. John's Wort)**; AND**
- Patient has relapsed/refractory disease; **AND**
- Used in combination with azacitidine, decitabine, or low-dose cytarabine

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Mantle Cell Lymphoma**

- Patient is 18 years of age or older; **AND**
- Patient must not have a concurrent diagnosis of multiple myeloma; **AND**
- Patient must not receive live attenuated vaccines prior to, during, or after venetoclax treatment until B-cell recovery occurs; **AND**
- Patient will not be on concomitant therapy with moderate or strong CYP3A-inducers (e.g., rifampin, carbamazepine, phenytoin, St. John's Wort)**; AND**
- Used as second line therapy; **AND**
- Used as a single agent.

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug (e.g., tumor lysis syndrome, severe neutropenia, severe infection); **AND**
- **Acute Myeloid Leukemia (AML)**
  - Disease stabilization or improvement as evidenced by a complete response [CR] (i.e., morphologic, cytogenetic or molecular complete response CR), complete hematologic response or a partial response by CBC, bone marrow cytogenic analysis, QPCR, or FISH.
- **Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL)**
  - Venetoclax/rituximab regimen: Patient has not received more than 24 months of therapy; **OR**
  - Venetoclax/obinutuzumab regimen: Patient has not received more than 12 cycles of therapy.
- **All other indications**
  - Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread.

VERZENIO® (ABEMACICLIB)

Length of Authorization:	6 months, may be renewed
Initiative:	MNC: Non-Formulary Product (IE 50698 / MR – GSN PatOverride)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Breast cancer**

- Patient is at least 18 years of age; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Patient will avoid concomitant use with strong and moderate CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.); **AND**
  - Patient will avoid concomitant use with strong and CYP3A inhibitors (e.g., fluconazole, clarithromycin, erythromycin, grapefruit, grapefruit juice, etc.). If therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Patient will avoid concomitant use with ketoconazole; **AND**
- Patient has hormone receptor (HR)-positive disease; **AND**
- Patient has human epidermal growth factor receptor 2 (HER2)-negative disease; **AND**
- Patient has advanced, recurrent or metastatic disease; **AND**
- Patient does not have visceral crisis; **AND**
  - Patient is a male and receiving androgen deprivation therapy (ADT); **OR**
  - Patient is a postmenopausal woman; **OR**
  - Patient is a premenopausal woman receiving ovarian ablation/suppression (e.g., surgical ablation, suppression with a gonadotropin-releasing hormone agonist, etc.); **AND**
- Therapy is being use as one of the following:
  - As initial endocrine based therapy in combination with an aromatase inhibitor (e.g., letrozole); **OR**
  - Used in combination with fulvestrant as initial endocrine based therapy OR as subsequent therapy after disease progression on or after endocrine therapy; **OR**
  - Used as a single agent after progression on endocrine therapy and chemotherapy in the metastatic setting

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: Grade 3 or 4 diarrhea, neutropenia, hepatotoxicity, venous thromboembolism, severe interstitial lung disease/pneumonitis, etc.

VIIBRYD® (VILAZODONE)

Length of Authorization:	1 Year, eligible for renewal
Initiative:	MNC: Non-Formulary Product (IE 50698 / MR – GSN PatOverride) MNC: Antidepressants (IE 2462 / NCPDP 75 – HICL)

CLINICAL CRITERIA

- Patient is 18 years of age or older; **AND**
- Patient must have a diagnosis of major depressive disorder (MDD); **AND**
- Patient has a history of failure of at least 4 weeks of therapy with, contraindication to, or intolerance to one generic antidepressant; **AND**
- Patient must not be on concomitant therapy with an MAOI or within 14 days of stopping an MAOI; **AND**
- Patient has been evaluated for potential clinically significant drug interactions, including the following:
  - Strong CYP3A4 Inhibitors: The Viibryd dose **should not exceed 20 mg once daily** when co-administered with strong CYP3A4 inhibitors (e.g., itraconazole, clarithromycin, voriconazole)
  - Strong CYP3A4 Inducers: **Consider increasing VIIBRYD dosage** by 2-fold, up to 80 mg once-daily over 1 to 2 weeks when used concomitantly with strong CYP3A4 inducers s (e.g., carbamazepine, phenytoin, rifampin) for greater than 14 days.

VILTEPSO (VILTOLARSEN)

Length of Authorization:	12 months
Initiative:	MNC: Non-Formulary Product (IE 50698 / MR – GSN PatOverride)

CLINICAL CRITERIA FOR INITIAL APPROVAL

- Patient is not on concomitant therapy with other DMD-directed antisense oligonucleotides (e.g., eteplirsen, golodirsen, etc.); **AND**
- Patient does not have symptomatic cardiomyopathy; **AND**
- Patient serum cystatin C, urine dipstick, and urine protein-to-creatinine ratio will be measured prior to start of therapy and during treatment (monthly urine dipstick with serum cystatin C and urine protein-to-creatinine ratio every three months); **AND**
- Patient has a diagnosis of Duchenne muscular dystrophy (DMD); **AND**
- Patient must have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping; **AND**
- Patient has been on a stable dose of corticosteroids, unless contraindicated or intolerance, for at least 3 months; **AND**
- Patient retains meaningful voluntary motor function (e.g., patient is able to speak, manipulate objects using upper extremities, ambulate, etc.); **AND**
- Patient should be receiving physical and/or occupational therapy; **AND**
- Baseline documentation of one or more of the following:
  - Dystrophin level
  - 6-minute walk test (6MWT) or other timed function tests (e.g., time to stand
  - [TTSTAND], time to run/walk 10 meters [TTRW], time to climb 4 stairs [TTCLIMB])
  - Upper limb function (ULM) test
  - North Star Ambulatory Assessment (NSAA)
  - Forced Vital Capacity (FVC) percent predicted

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug

VIMPAT® (LACOSAMIDE)

Length of Authorization:	1 Year, eligible for renewal
Initiative:	MNC: Anticonvulsants (IE 2462 / NCPDP 75 – HICL, 50081 and 2193)

CLINICAL CRITERIA TABLETS, SOLUTION

- Patient is 4 years of age or older; **AND**
- Patient is stable on lacosamide therapy OR patient has a diagnosis of partial-onset seizures OR other seizure disorder; **AND**
- In patients with known cardiac conduction problems, severe cardiac disease, or taking medications known to induce PR interval prolongation, confirm that an ECG was obtained prior to beginning and after titration to steady-state maintenance; **AND**
- For the oral solution, patient must have difficulty swallowing, cannot swallow tablets, or the dosage needed is not available in tablet formulation.

VISTIDE (CIDOFOVIR)

Length of Authorization:	6 months
Initiative:	MNC: Antivirals (IE 2462 / NCPDP 75 – HICL)

CLINICAL CRITERIA FOR INITIAL APPROVAL

- Patient is 18 years of age or older; **AND**
- Diagnosis of CMV retinitis in patients with acquired immunodeficiency syndrome (AIDS); **AND**
- Patient does not have any of the following contraindications:
  - A serum creatinine > 1.5 mg/dL, a calculated creatinine clearance ≤ 55 mL/min, or a urine protein ≥ 100 mg/dL (equivalent to ≥ 2+ proteinuria); **OR**
  - Patient is receiving any agents with nephrotoxic potential (e.g., tobramycin, gentamicin, amikacin, amphotericin B, foscarnet, IV pentamidine, vancomycin, and NSAIDs). Such agents must be discontinued at least seven days prior to starting therapy; **OR**
  - Hypersensitivity to cidofovir; **OR**
  - History of clinically severe hypersensitivity to probenecid or other sulfa-containing medications; **OR**
  - If medication will be used for direct intraocular injection

Note: Direct injection of cidofovir has been associated with iritis, ocular hypotony, and permanent impairment of vision.

CLINICAL CRITERIA FOR RENEWAL

- Patient must continue to meet above criteria; **AND**
- Absence of unacceptable toxicity from the drug

VITRAKVI® (LAROTRECTINIB)

Length of Authorization:	3 months, may be renewed
Initiative:	MNC: Non-Formulary Product (IE 50698 / MR – GSN PatOverride)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Solid Tumors with NTRK gene fusion**

- Patient is at least 1 month of age; **AND**
- The healthcare provider must attest that they will comply with the requirements of the Vitrakvi® Commitment Program, including the following:
  - Complete the attestation form for patients who stop taking Vitrakvi due to a lack of clinical benefit within 90 days of treatment initiation; **AND**
  - Submit the attestation form within 120 days of last prescription fulfilled within the program eligibility period; **AND**
- Patient will avoid concomitant use with strong CYP3A4 Inducers (e.g., rifampin, carbamazepine, St. John's Wort), if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient will avoid concomitant use with strong CYP3A4 Inhibitors (e.g., itraconazole, indinavir, nefazodone, grapefruit juice), if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient will avoid concomitant use with sensitive CYP3A4 Substrates (e.g., alprazolam, amlodipine, aripiprazole, eszopiclone, mirtazapine, simvastatin), if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient has one of the following solid tumors: infantile fibrosarcoma or gastrointestinal stromal tumors; AND
  - Tumor has a neurotrophic receptor tyrosine kinase (NTRK) gene fusion or fusion partner in ETV6-NTRK3 or TPM3-NTRK1 without any known acquired resistance mutations; **AND**
  - Patient has metastatic disease or locally advanced disease and is not a candidate for surgery due to the potential of causing severe morbidity; **AND**
  - Patient has no satisfactory alternative treatments or disease has progressed following treatment

  OR
- Patient has a neurotrophic receptor tyrosine kinase (NTRK) gene fusion or fusion partner positive tumor without any known acquired resistance mutations; **AND**
- Used as single agent therapy; **AND**
- Patient has one of the following solid tumors:
  - **Breast cancer**
    - Patient has locally advanced disease and is not a candidate for surgery due to the potential of causing severe morbidity **or** has recurrent or metastatic disease; **AND**
    - Patient has no satisfactory alternative treatments or disease has progressed following treatment
  - **Central nervous system cancers**
    - Patient has brain metastases from NTRK-gene fusion positive tumors; **AND**
      - Used as initial treatment in patients with small, asymptomatic brain lesions; **OR**
      - Used for relapsed disease in patients with limited brain metastases and stable systemic disease or reasonable systemic treatment options; **OR**
      - Patient has recurrent limited brain metastases; **OR**
      - Used for recurrent disease in patients with extensive brain metastases and stable systemic disease or reasonable systemic treatment options

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

- **Colorectal adenocarcinoma**
  - Used as subsequent therapy for progression of metastatic disease
- **Cutaneous melanoma**
  - Used for unresectable or metastatic disease**; AND**
  - Used as subsequent therapy for progression or after maximum clinical benefit from BRAF targeted therapy
- **Gastric adenocarcinoma or esophageal/esophago-gastric junction (GEJ) adenocarcinoma/squamous cell carcinoma**
  - Used palliatively as subsequent therapy; **AND**
  - Patient has unresectable (or are not surgical candidates) locally advanced, recurrent, or metastatic disease; **AND**
  - Patient has a Karnofsky performance score ≥ 60% or ECOG score ≤ 2
- **Head and neck cancer**
  - Patient has salivary gland tumors; **AND**
  - Patient has unresectable (or are not surgical candidates) locally advanced, recurrent, or metastatic disease
- **Liver cancer**
  - Patient has unresectable or metastatic disease; **AND**
    - Patient has gallbladder cancer or cholangiocarcinoma (intra-/extra-hepatic); **OR**
    - Patient has hepatocellular carcinoma; **AND**
      - Used as subsequent treatment for progressive disease
- **Non-small cell lung cancer**
  - Used for recurrent, advanced, or metastatic disease (excluding locoregional recurrence or symptomatic local disease without evidence of disseminated disease) or mediastinal lymph node recurrence with prior radiation therapy; **AND**
  - Used as first line therapy **or** as subsequent therapy following progression on first-line systemic therapy in patients who did not receive an NTRK-inhibitor in a previous line of therapy
- **Ovarian cancer**
  - Patient is not experiencing an immediate biochemical relapse (i.e., rising CA-125 without radiographic evidence of disease); **AND**
  - Patient has persistent, relapsed, or recurrent disease
- **Pancreatic adenocarcinoma**
  - Used as subsequent therapy
- **Small bowel adenocarcinoma**
  - Used as first line therapy in metastatic disease in patients with poor performance status (PS < 2); **OR**
  - Used as subsequent therapy for metastatic disease
- **Soft tissue sarcoma**
  - Will not be used as pre-operative or adjuvant therapy for non-metastatic disease; **AND**
    - Used for solitary fibrous tumors; **OR**
    - Used for undifferentiated pleomorphic sarcoma (UPS); **OR**
    - Used as first-line therapy for one of the following:
      - Locally advanced, unresectable, recurrent, or metastatic disease of the extremity/body wall/head-neck
      - Locally advanced, unresectable, metastatic disease or post-operatively for sarcoma of the retroperitoneal or intra-abdominal area

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

- **Thyroid carcinoma**
  - Patient has Follicular, Hürthle Cell, or Papillary carcinoma; **AND**
    - Patient has unresectable recurrent or persistent locally advanced or metastatic disease; **AND**
    - Disease is not susceptible to radioactive iodine (RAI) therapy; **OR**
  - Patient Anaplastic carcinoma; **AND**
    - Patient has metastatic disease

*****An FDA-approved test for the detection of NTRK gene fusion is not currently available. NTRK gene fusions can be identified by means of the following testing methodologies: next-generation sequencing (NGS), fluorescence in situ hybridization (FISH), or reverse transcription-polymerase chain reactions (RT-PCR), etc.

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug (e.g., severe neurotoxicity, hepatotoxicity); **AND**
- Provider attests that the patient is receiving clinical benefit from therapy (refer to the above regarding Vitrakvi® commitment program requirements)

VOTRIENT® (PAZOPANIB)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75 – HICL, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Renal Cell Carcinoma**

- Patient is at least 18 years of age; **AND**
- Baseline left ventricular ejection fraction (LVEF) is within normal limits prior to initiating therapy and will be assessed at regular intervals during treatment in patients at risk of cardiac dysfunction including prior anthracycline exposure; **AND**
- Patient has not had hemoptysis, cerebral hemorrhage, or clinically significant gastrointestinal hemorrhage within the prior 6 months; **AND**
- Patient has not had an arterial thromboembolic event within the previous 6 months; **AND**
- Patient will have an electrocardiogram (ECG) at baseline and periodically during therapy; **AND**
- Patient will avoid all of the following:
  - Coadministration with acid-reducing agents (e.g., proton-pump inhibitors, H2 receptor antagonists) or if therapy is required, consider short-acting antacids instead
  - Coadministration with strong CYP3A4 inhibitors (e.g., fluconazole, itraconazole), if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented
  - Coadministration with strong and moderate CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort)
  - Coadministration with substrates of CYP3A4 (e.g., amitriptyline, carbamazepine), CYP2D6 (e.g., codeine, propafenone, thioridazine), CYP2C8 (e.g., paclitaxel, dabrafenib, pioglitazone, repaglinide) with narrow therapeutic windows
  - Coadministration of strong P-glycoprotein (P-gp) or breast cancer resistance protein (BCRP) inhibitors (e.g., ketoconazole, imatinib, HIV protease inhibitors) or if therapy is required, an alternative product should be considered
  - Coadministration simvastatin or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Used as single-agent therapy; **AND**
- Patient has advanced disease; **OR**
- Patient has relapsed or stage IV disease; **AND**
  - Used as first line or subsequent therapy for clear cell histology; **OR**
  - Used as systemic therapy for non-clear cell histology

Diagnosis of **Ovarian Cancer (Epithelial Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer)**

- Patient is at least 18 years of age; **AND**
- Baseline left ventricular ejection fraction (LVEF) is within normal limits prior to initiating therapy and will be assessed at regular intervals during treatment in patients at risk of cardiac dysfunction including prior anthracycline exposure; **AND**
- Patient has not had hemoptysis, cerebral hemorrhage, or clinically significant gastrointestinal hemorrhage within the prior 6 months; **AND**
- Patient has not had an arterial thromboembolic event within the previous 6 months; **AND**
- Patient will have an electrocardiogram (ECG) at baseline and periodically during therapy; **AND**

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Ovarian Cancer (Epithelial Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer)** *(Continued)*

- Patient will avoid all of the following:
  - Coadministration with acid-reducing agents (e.g., proton-pump inhibitors, H2 receptor antagonists) or if therapy is required, consider short-acting antacids instead
  - Coadministration with strong CYP3A4 inhibitors (e.g., fluconazole, itraconazole), if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented
  - Coadministration with strong and moderate CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort)
  - Coadministration with substrates of CYP3A4 (e.g., amitriptyline, carbamazepine), CYP2D6 (e.g., codeine, propafenone, thioridazine), CYP2C8 (e.g., paclitaxel, dabrafenib, pioglitazone, repaglinide) with narrow therapeutic windows
  - Coadministration of strong P-glycoprotein (P-gp) or breast cancer resistance protein (BCRP) inhibitors (e.g., ketoconazole, imatinib, HIV protease inhibitors) or if therapy is required, an alternative product should be considered
  - Coadministration simvastatin or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Used as single-agent therapy; **AND**
- Patient has persistent, relapsed, or recurrent disease; **AND**
- Patient is not experiencing an immediate biochemical relapse (i.e., rising CA-125 without radiographic evidence of disease)

Diagnosis of **Soft Tissue Sarcoma**

- Patient is at least 18 years of age; **AND**
- Baseline left ventricular ejection fraction (LVEF) is within normal limits prior to initiating therapy and will be assessed at regular intervals during treatment in patients at risk of cardiac dysfunction including prior anthracycline exposure; **AND**
- Patient has not had hemoptysis, cerebral hemorrhage, or clinically significant gastrointestinal hemorrhage within the prior 6 months; **AND**
- Patient has not had an arterial thromboembolic event within the previous 6 months; **AND**
- Patient will have an electrocardiogram (ECG) at baseline and periodically during therapy; **AND**
- Patient will avoid all of the following:
  - Coadministration with acid-reducing agents (e.g., proton-pump inhibitors, H2 receptor antagonists) or if therapy is required, consider short-acting antacids instead
  - Coadministration with strong CYP3A4 inhibitors (e.g., fluconazole, itraconazole), if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented
  - Coadministration with strong and moderate CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort)
  - Coadministration with substrates of CYP3A4 (e.g., amitriptyline, carbamazepine), CYP2D6 (e.g., codeine, propafenone, thioridazine), CYP2C8 (e.g., paclitaxel, dabrafenib, pioglitazone, repaglinide) with narrow therapeutic windows
  - Coadministration of strong P-glycoprotein (P-gp) or breast cancer resistance protein (BCRP) inhibitors (e.g., ketoconazole, imatinib, HIV protease inhibitors) or if therapy is required, an alternative product should be considered
  - Coadministration simvastatin or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Used as single-agent therapy; **AND**

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Soft Tissue Sarcoma** *(Continued)*

- Patient has advanced disease; **AND**
  - Patient must have received prior chemotherapy; **AND**
  - Patient does **not** have adipocytic disease; **OR**
- Used for one of the following:
  - Angiosarcoma
  - Gastrointestinal stromal tumors (GIST)
    - Used as fourth line therapy for progressive disease after previous single-agent treatment with imatinib, sunitinib and regorafenib
  - Retroperitoneal/intra-abdominal
    - Patient has advanced, unresectable, or metastatic disease; **AND**
      - Used as first-line treatment or post-operatively in patients not eligible for intravenous therapy; **OR**
    - Patient has recurrent unresectable or metastatic disease; **AND**
      - Used palliatively as subsequent lines of therapy in patients with non-adipocytic disease
  - Rhabdomyosarcoma
    - Used for advanced or metastatic pleomorphic disease
  - Cancer of the extremity/superficial trunk, head/neck
    - Patient has advanced, metastatic, unresectable, or recurrent disease; **AND**
      - Used as first-line treatment in patients not eligible for intravenous therapy; **OR**
    - Patient has advanced or metastatic disease; **AND**
      - Used palliatively as subsequent lines of therapy in patients with non-adipocytic disease
  - Alveolar soft part sarcoma (ASPS)
  - Solitary fibrous tumor/hemangiopericytoma
  - Patient has advanced disease

Diagnosis of **Uterine Sarcoma**

- Patient is at least 18 years of age; **AND**
- Baseline left ventricular ejection fraction (LVEF) is within normal limits prior to initiating therapy and will be assessed at regular intervals during treatment in patients at risk of cardiac dysfunction including prior anthracycline exposure; **AND**
- Patient has not had hemoptysis, cerebral hemorrhage, or clinically significant gastrointestinal hemorrhage within the prior 6 months; **AND**
- Patient has not had an arterial thromboembolic event within the previous 6 months; **AND**
- Patient will have an electrocardiogram (ECG) at baseline and periodically during therapy; **AND**
- Patient will avoid all of the following:
  - Coadministration with acid-reducing agents (e.g., proton-pump inhibitors, H2 receptor antagonists) or if therapy is required, consider short-acting antacids instead
  - Coadministration with strong CYP3A4 inhibitors (e.g., fluconazole, itraconazole), if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented
  - Coadministration with strong and moderate CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort)
  - Coadministration with substrates of CYP3A4 (e.g., amitriptyline, carbamazepine), CYP2D6 (e.g., codeine, propafenone, thioridazine), CYP2C8 (e.g., paclitaxel, dabrafenib, pioglitazone, repaglinide) with narrow therapeutic windows

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Uterine Sarcoma** *(Continued)*

- Coadministration of strong P-glycoprotein (P-gp) or breast cancer resistance protein (BCRP) inhibitors (e.g., ketoconazole, imatinib, HIV protease inhibitors) or if therapy is required, an alternative product should be considered
- Coadministration simvastatin or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**

- Used as single-agent therapy; **AND**
- Patient has recurrent or metastatic disease that has progressed following prior cytotoxic chemotherapy

Diagnosis of **Thyroid Carcinoma**

- Patient is at least 18 years of age; **AND**
- Baseline left ventricular ejection fraction (LVEF) is within normal limits prior to initiating therapy and will be assessed at regular intervals during treatment in patients at risk of cardiac dysfunction including prior anthracycline exposure; **AND**
- Patient has not had hemoptysis, cerebral hemorrhage, or clinically significant gastrointestinal hemorrhage within the prior 6 months; **AND**
- Patient has not had an arterial thromboembolic event within the previous 6 months; **AND**
- Patient will have an electrocardiogram (ECG) at baseline and periodically during therapy; **AND**
- Patient will avoid all of the following:
  - Coadministration with acid-reducing agents (e.g., proton-pump inhibitors, H2 receptor antagonists) or if therapy is required, consider short-acting antacids instead
  - Coadministration with strong CYP3A4 inhibitors (e.g., fluconazole, itraconazole), if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented
  - Coadministration with strong and moderate CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort)
  - Coadministration with substrates of CYP3A4 (e.g., amitriptyline, carbamazepine), CYP2D6 (e.g., codeine, propafenone, thioridazine), CYP2C8 (e.g., paclitaxel, dabrafenib, pioglitazone, repaglinide) with narrow therapeutic windows
  - Coadministration of strong P-glycoprotein (P-gp) or breast cancer resistance protein (BCRP) inhibitors (e.g., ketoconazole, imatinib, HIV protease inhibitors) or if therapy is required, an alternative product should be considered
  - Coadministration simvastatin or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Used as single-agent therapy; **AND**
- Patient has medullary carcinoma; **AND**
  - Patient has recurrent or persistent distant metastatic disease; **AND**
  - Disease is symptomatic or progressive; **AND**
    - Treatment with clinical trials, vandetanib, or cabozantinib are not available or appropriate; **OR**
    - Disease progressed on vandetanib or cabozantinib; **OR**
- Patient has follicular, Hürthle cell, or papillary carcinoma; **AND**
  - Patient has unresectable recurrent, persistent, or metastatic disease; **AND**
  - Treatment with clinical trials or other systemic therapies are not available or appropriate; **AND**
  - Patient has progressive and/or symptomatic disease that is not susceptible to radioactive iodine (RAI) therapy

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug (e.g., hepatotoxicity [severe changes in liver function tests], cardiac toxicity [QT prolongation, decreased LVEF], hemorrhagic events, arterial thromboembolic events, venous thrombotic events [VTE, PE], thrombotic microangiopathy, gastrointestinal perforation/fistula, severe and repeated proteinuria episodes, interstitial lung disease [ILD]/pneumonitis, reversible posterior leukoencephalopathy syndrome [RPLS], hypertension, impaired wound healing, hypothyroidism, infection, tumor lysis syndrome [TLS])

VPRIV® (VELAGLUCERASE ALFA)

Length of Authorization:	12 months, may be renewed
Initiative:	SPC: Enzyme Deficiency (IE 2462 / NCPDP 75 – HICL)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Type 1 Gaucher Disease**

- Patient age is at least 4 years or older; **AND**
- Patient has a documented diagnosis of Type 1 Gaucher Disease as confirmed by beta-glucosidase leukocyte (BGL) test with significantly reduced or absent glucocerebrosidase enzyme activity; **AND**
- **Adults only criteria (patient at least 18 years or older):** Patient's disease results in one or more of the following:
  - Anemia (hemoglobin less than or equal to 11 g/dL (adult women) or 12 g/dL (adult men) not attributed to iron, folic acid or vitamin B12 deficiency**; OR**
  - Moderate to severe hepatomegaly (liver size 1.25 or more times normal) or splenomegaly (spleen size 5 or more times normal); **OR**
  - Skeletal disease (e.g., lesions, remodeling defects and/or deformity of long bones, osteopenia/osteoporosis); **OR**
  - Symptomatic disease (e.g., bone pain, fatigue, dyspnea, angina, abdominal distension, diminished quality of life); **OR**
  - Thrombocytopenia (platelet count less than or equal to 120,000/mm^3); **AND**
- Must be used as a single agent

CLINICAL CRITERIA FOR RENEWAL

- Disease response as indicated by one or more of the following (compared to pre-treatment baseline):
  - Improvement in symptoms (e.g., bone pain, fatigue, dyspnea, angina, abdominal distension, diminished quality of life)
  - Reduction in size of liver or spleen
  - Improvement in hemoglobin/anemia
  - Improvement in skeletal disease (e.g., increase in lumbar spine and/or femoral neck BMD, no bone crises or bone fractures)
  - Improvement in platelet counts; **AND**
- Absence of unacceptable toxicity from the drug (e.g., hypersensitivity reactions)

VYNDAMAX™ (TAFAMIDIS)/VYNDAQEL® (TAFAMIDIS MEGLUMINE)

Length of Authorization:	6 months, may be renewed
Initiative:	MNC: Non-Formulary Product (IE 50698 / MR – GSN PatOverride)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Cardiomyopathy of Wild Type Transthyretin-Mediated Amyloidosis (ATTR-CM)**

- Patient must be at least 18 years old; **AND**
- Must not be used in combination with other transthyretin (TTR) reducing agents (e.g., inotersen, patisiran, etc.); **AND**
- Patient has New York Heart Association (MYHA) class I or II heart failure (i.e., excludes patients with NYHA Class III and IV disease); **AND**
- Patient does not have primary (light chain) amyloidosis; **AND**
- Patient has not had a prior liver transplant; **AND**
- Patient does not have an implanted cardiac mechanical-assist device (e.g., left-ventricular assist device, etc.); **AN**D
- Patient has evidence of cardiac involvement by echocardiography with an end-diastolic interventricular septal wall thickness > 12 mm; **AND**
- Patient has a definitive diagnosis of ATTR amyloidosis as documented by amyloid deposition on tissue biopsy and identification of a pathogenic *TTR* variant and/or TTR precursor using molecular genetic testing (i.e., immunohistochemistry, scintigraphy or mass spectrometry); **AND**
  - Patient has a medical of heart failure which required at least 1 prior hospitalization; **OR**
  - Patient has clinical evidence of heart failure, without a prior history of hospitalization for disease, manifested by signs or symptoms of volume overload or elevated intracardiac pressure (e.g., elevated jugular venous pressure, shortness of breath or signs of pulmonary congestion on x-ray or auscultation, peripheral edema) which requires/required treatment with a diuretic; **AND**
- Patient has a baseline 6-minute walk-test distance exceeding 100 m

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug; **AND**
  - Disease response compared to pre-treatment baseline as evidenced by decreased frequency of cardiovascular-related hospitalizations, defined as the number of times a patient was hospitalized (i.e., admitted to a hospital) for cardiovascular-related morbidity; **OR**
  - Patient has had an improvement in the in the total distance walked during 6-Minute Walk Test (6MWT) as compared to baseline

WAKIX® (PITOLISANT)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Narcolepsy Agents (IE 50698 / MR – HICL)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of Excessive Daytime Sleepiness (EDS) in Narcolepsy

- Patient is 18 years of age or older; **AND**
- Patient must not be receiving treatment with sedative hypnotic agents (e.g., zolpidem, eszopiclone, zaleplon, benzodiazepines, barbiturates, etc.); **AND**
- Patient has daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least three months; **AND**
- Baseline daytime sleepiness as measured by a validated scale (e.g., Epworth Sleepiness Scale, Stanford Sleepiness Scale, Karolinska Sleepiness Scale, Cleveland Adolescent Sleepiness Questionnaire, or a Visual Analog Scale); **AND**
- Patient will not use drugs that prolong the QT interval (e.g., quinidine, procainamide, disopyramide; amiodarone, sotalol; ziprasidone, chlorpromazine, thioridazine; moxifloxacin, etc.) concomitantly; **AND**
- Patient will not use histamine-1 (H1) receptor antagonists (e.g., pheniramine maleate, diphenhydramine, promethazine, imipramine, clomipramine, mirtazapine, etc.) concomitantly; **AND**
- Patient does not have a history of prolonged QTc interval (i.e., QTc interval > 450 milliseconds); **AND**
- Therapy will not be used in patients with severe hepatic impairment (Child-Pugh C); **AND**
- Patient does not have end-stage renal disease (ESRD) (i.e., eGFR < 15 mL/minute/1.73 m2); **AND**
- A mean sleep latency of ≤ 8 minutes **AND** two or more sleep onset REM periods (SOREMPs) are found on a mean sleep latency test (MSLT) performed according to standard techniques. (*A SOREMP [within 15 minutes of sleep onset] on the preceding nocturnal polysomnogram may replace one of the SOREMPs on the MSLT)*; **AND**
- Either CSF hypocretin-1 concentration has not been measured **OR** CSF hypocretin-1 concentration measured by immunoreactivity is either > 110 pg/mL **OR** > 1/3 of mean values obtained in normal subjects with the same standardized assay; **AND**
- The hypersomnolence and/or MSLT findings are not better explained by other causes such as insufficient sleep, obstructive sleep apnea, delayed sleep phase disorder, or the effect of medication or substances or their withdrawal; **AND**
- One of the following:
  - Patient has had a trial and failure, contraindication or intolerance to:
    - generic amphetamine (e.g., amphetamine, dextroamphetamine) or methylphenidate based stimulant; **OR**
  - Patient has a history of or potential for a substance abuse disorder.

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug (e.g., QT interval prolongation); **AND**
- Response to therapy with a reduction in excessive daytime sleepiness from pre-treatment baseline as measured by a validated scale (e.g., Epworth Sleepiness Scale, Stanford Sleepiness Scale, Karolinska Sleepiness Scale, Cleveland Adolescent Sleepiness Questionnaire, or a Visual Analog Scale).

XALKORI® (CRIZOTINIB)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75 – HICL, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

- Diagnosis of **Non-Small Cell Lung Cancer (NSCLC)**
  - Patient is at least 18 years old; **AND**
  - Must be used as a single agent; **AND**
  - Patient's disease is metastatic or recurrent; **AND**
    - Patient's cancer is anaplastic lymphoma kinase (ALK) positive as detected by an FDA approved test; **OR**
    - Patient's cancer is ROS-1 positive; **OR**
    - Patient has high level MET amplification or MET exon 14 skipping mutation
- Diagnosis of **Inflammatory Myofibroblastic Tumor (IMT)—Soft tissue sarcoma**
  - Patient is at least 18 years old; **AND**
  - Must be used as a single agent; **AND**
  - Patient's disease has an ALK translocation as detected upon standard laboratory diagnostic tests (e.g., FISH).

CLINICAL CRITERIA FOR RENEWAL

- Tumor response with stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug
  Examples include: severe changes in liver function tests, pneumonitis, and QT prolongation.

XELODA® (CAPECITABINE)

Length of Authorization:	6 months, may be renewed
Initiative:	MNC: Non-Formulary Product (IE 50698 / MR – GSN PatOverride)

CLINICAL CRITERIA FOR INITIAL APPROVAL

- Diagnosis of **anal squamous cell carcinoma**
- Diagnosis of **breast cancer**
- Diagnosis of **central nervous system cancers** (brain metastases)
- Diagnosis of **colorectal adenocarcinoma**
- Diagnosis of **esophageal and esophagogastric junction cancers**
- Diagnosis of **gastric adenocarcinoma**
- Diagnosis of **gestational trophoblastic neoplasia**
- Diagnosis of **head and neck cancers**
- Diagnosis of **hepatobiliary adenocarcinoma** (includes gallbladder cancer, intra/extra-hepatic cholangiocarcinoma)
- Diagnosis of **carcinoid tumors** (includes GI tract, lung and thymus)
- Diagnosis of **neuroendocrine tumors** (includes pancreas and poorly differentiated/large or small cell)
- Diagnosis of **occult primary cancer**
- Diagnosis of **ovarian cancer**
- Diagnosis of **pancreatic adenocarcinoma**
- Diagnosis of **penile cancer**
- Diagnosis of **thymomas and thymic carcinomas**

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug (e.g., coagulopathy, severe diarrhea, cardiotoxicity, dihydropyridine dehydrogenase deficiency, dehydration/renal failure, severe mucocutaneous and dermatologic toxicity, hyperbilirubinemia [grade 2 or 4], hematologic [neutrophil counts < 1.5 x 10^9/L or thrombocyte counts < 100 x 10^9/L], hepatic insufficiency)

XIAFLEX® (COLLAGENASE CLOSTRIDIUM HISTOLYTICUM)

Length of Authorization:	Dupuytren's contracture: 3 months, eligible for renewal (max of 3 injections per joint) Peyronie's disease: 6 weeks, eligible for renewal (max of 4 treatment cycles for each plaque causing the curvature deformity)
Initiative:	MNC: Non-Formulary Product (IE 50698 / MR – GSN PatOverride)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Peyronie's disease**

- Patient is at least 18 years of age; **AND**
- Patient has palpable plaque on penis; **AND**
- Prescriber is enrolled in the Xiaflex REMS program; **AND**
- Patient has stable disease with penis curvature deformity of > 30 and < 90 degrees; **AND**
- Patient has intact erectile function (with or without use of medications); **AND**
- Patient does not have isolated hourglass deformity or calcified plaque; **AND**
- The plaque(s) do not involve the penile urethra; **AND**
- Will be used in combination with penile modeling procedures; **AND**
- Patient has not exceeded 4 treatment cycles for each plaque causing the curvature deformity; **AND**
- The patient has not received a collagenase injection for this condition within the past 6 weeks

Diagnosis of **Dupuytren's contracture**

- Patient is at least 18 years of age; **AND**
- Patient has a palpable cord; **AND**
- Documented flexion contracture of 20° to 100° in a metacarpophalangeal (MP) joint or 20° to 80° in a proximal interphalangeal (PIP) joint; **AND**
- Documentation of a positive "tabletop test" defined as the inability to simultaneously place the affected finger(s) and palm flat against a tabletop; **AND**
- Documentation that the flexion deformity results in functional limitations

CLINICAL CRITERIA FOR RENEWAL

Dupuytren's contracture only

- Absence of unacceptable toxicity from the drug (e.g., anaphylaxis and allergic reactions; abnormal coagulation; tendon ruptures or other serious injury to the injected extremity); **AND**
- Disease response as indicated by reduction in contracture of the selected primary joint compared to baseline; **AND**
- Patient has not exceeded 3 injections per joint/cord.

Peyronie's Disease only

- Absence of unacceptable toxicity from the drug (e.g., anaphylaxis and allergic reactions; abnormal coagulation; corporal rupture [penile fracture] or other serious injury to the penis); **AND**
- Further treatment is clinically indicated as the patient has penis curvature deformity of at least 15 degrees after the previous treatment cycle(s); **AND**
- Patient has not exceeded 4 treatment cycles for each plaque causing the curvature deformity; **AND**
- The patient has not received a collagenase injection for this condition within the past 6 weeks

XIFAXAN (RIFAXIMIN)

Length of Authorization:	Varies by diagnosis, see specific criteria below
Initiative:	MNC: Non-Formulary Product (IE 50698 / MR – GSN PatOverride)

CLINICAL CRITERIA FOR APPROVAL

- Diagnosis of Irritable bowel syndrome with diarrhea (IBS-D); **AND**
  - The patient is 18 or older
  - Length of authorization: 14 days
- Diagnosis of Hepatic Encephalopathy; **AND**
  - The patient is 18 or older
  - Length of authorization: 6 months
- Diagnosis of traveler's diarrhea caused by noninvasive strains of Escherichia coli; **AND**
  - The patient is 12 or older
  - Length of authorization: 3 days

XOLAIR ® (OMALIZUMAB)

Length of Authorization:	6 months initial, May be renewed (Management of Immune Checkpoint Inhibitor-Related Toxicity may **not** be renewed)
Initiative:	MNC: Non-Formulary Product (IE 50698 / MR – GSN PatOverride)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis Moderate-to-severe persistent allergic asthma:

- Patient must be at least 6 years of age; **AND**
- Must not be used in combination with another monoclonal antibody (e.g., benralizumab, mepolizumab, reslizumab)
- Will not be used for treatment of acute bronchospasm, status asthmaticus, or allergic conditions (other than indicated); **AND**
- Patient has a positive skin test or in vitro reactivity to a perennial allergen; **AND**
- Patient must weigh between 20 kg (44 lbs.) and 150 kg (330 lbs.); **AND**
- Patient has a serum total IgE level, measured before the start of treatment, of either:
  - ≥ 30 IU/mL and ≤ 700 IU/mL in patients age ≥ 12 years; **OR**
  - ≥ 30 IU/mL and ≤ 1300 IU/mL in patients aged 6 to < 12 years; **AND**
- Patient has documented ongoing symptoms of moderate-to-severe asthma* with a minimum (3) month trial on previous combination therapy including medium or high-dosed inhaled corticosteroids **PLUS** another controller medication (i.e., long acting beta-2 agonist, leukotriene receptor antagonist, theophylline, etc.)

***Components of severity for classifying asthma as MODERATE may include any of the following (not all inclusive):**
• Daily symptoms • Nighttime awakenings > 1x/week but not nightly • SABA use for symptom control occurs daily • Some limitation to normal activities • Lung function (percent predicted FEV_1) >60%, but <80% • Exacerbations requiring oral systemic corticosteroids are generally more frequent and intense relative to mild asthma
***Components of severity for classifying asthma as SEVERE may include any of the following (not all inclusive):**
• Symptoms throughout the day • Nighttime awakenings, often 7x/week • SABA use for symptom control occurs several times daily • Extremely limited in normal activities • Lung function (percent predicted FEV_1) < 60% • Exacerbations requiring oral systemic corticosteroids are generally more frequent and intense relative to moderate asthma

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of Chronic idiopathic urticaria:

- Patient must be at least 12 years of age or older; **AND**
- The underlying cause of the patient's condition has been ruled out and is NOT considered to be any other allergic condition(s) or other form(s) of urticaria; **AND**
- Patient is avoiding triggers (e.g., NSAIDs, etc.); **AND**
- Must not be used in combination with another monoclonal antibody (e.g., benralizumab, mepolizumab, reslizumab, etc.); **AND**
- Documented baseline score from an objective clinical evaluation tool, such as: urticaria activity score (UAS7), angioedema activity score (AAS), Dermatology Life Quality Index (DLQI), Angioedema Quality of Life (AE-QoL), or Chronic Urticaria Quality of Life Questionnaire (CU-Q_2oL); **AND**
- Patient had an inadequate response to a one, or more, month trial on previous therapy with scheduled dosing of a second-generation H1-antihistamine product**; **AND**
- Patient had an inadequate response to a one-, or more, month trial on previous therapy with scheduled dosing of at least one of the following:
  - Updosing/dose advancement (up to 4-fold) of a second generation H1-antihistamine**
  - Add-on therapy with a leukotriene antagonist (e.g., montelukast, zafirlukast)
  - Add-on therapy with another H1 antihistamine**
  - Add-on therapy with a H2-antagonist (e.g., ranitidine)
  - Add-on therapy with ciclosporin

Note: renewal will require submission of a current (within 30 days) score from an objective clinical evaluation tool (i.e., UAS7, AAS, DLQI, AE-QoL or CU-Q_2oL).

**H1 Antihistamine Products (not all inclusive)
• fexofenadine • loratadine • desloratadine • cetirizine • levocetirizine • clemastine • diphenhydramine • chlorpheniramine • hydroxyzine • cyproheptadine • brompheniramine • triprolidine • dexchlorpheniramine • carbinoxamine

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of Management of Immune Checkpoint Inhibitor-Related Toxicity:

- Patient must be at least 18 years of age; **AND**
- Must not be used in combination with another monoclonal antibody (e.g., benralizumab, mepolizumab, reslizumab)
- Patient has been receiving therapy with an immune checkpoint inhibitor (e.g., nivolumab, pembrolizumab, atezolizumab, avelumab, durvalumab, cemiplimab, ipilimumab); **AND**
- Patient has refractory and severe (i.e., grade 3: intense or widespread, constant, limiting self-care activities of daily living or sleep) pruritis; **AND**
- Patient has an increased serum IgE level above the upper limit of normal of the laboratory reference value.

Diagnosis of Systemic Mastocytosis:

- Patient must be at least 18 years of age; **AND**
- Must not be used in combination with another monoclonal antibody (e.g., benralizumab, mepolizumab, reslizumab)
- Used for the prevention of one of the following:
  - Chronic mast-cell-mediator-related cardiovascular (e.g., pre-syncope, tachycardia) or pulmonary (e.g., wheezing, throat-swelling) symptoms insufficiently controlled by conventional therapy (e.g., H1 or H2 blockers or corticosteroids); **OR**
  - Unprovoked anaphylaxis; **OR**
  - Hymenoptera or food-induced anaphylaxis in patients with a negative test for specific IgE antibodies or a negative skin test; **OR**
- Used to improve tolerance while on immunotherapy (i.e., venom immunotherapy [VIT])

CLINICAL CRITERIA FOR RENEWAL

- Must not be used in combination with another monoclonal antibody (e.g., benralizumab, mepolizumab, reslizumab); **AND**
- Absence of unacceptable toxicity from the drug (e.g., symptoms of anaphylaxis [bronchospasm, hypotension, syncope, urticaria, and/or angioedema]; malignancy; symptoms similar to serum sickness [fever, arthralgia, and rash]; eosinophilic conditions, including vasculitic rash, worsening pulmonary symptoms, cardiac complications, and/or neuropathy, especially upon reduction of oral corticosteroids); **AND**
- For Moderate-to-severe persistent allergic asthma
  - Patient must weigh between 20 kg (44 lbs.) and 150 kg (330 lbs.); **AND**
  - Treatment has resulted in clinical improvement as documented by one or more of the following:
    - Decreased utilization of rescue medications; **OR**
    - Decreased frequency of exacerbations (defined as worsening of asthma that requires increase in inhaled corticosteroid dose or treatment with systemic corticosteroids); **OR**
    - Improvement in lung function (increase in percent predicted FEV1 or PEF) from pre-treatment baseline; **OR**
    - Reduction in reported symptoms (decrease in asthma symptom score), as evidenced by decreases in frequency or magnitude of one or more of the following symptoms:
      - Asthma attacks
      - Chest tightness or heaviness
      - Coughing or clearing throat
      - Difficulty taking deep breath or difficulty breathing out
      - Shortness of breath
      - Sleep disturbance, night wakening, or symptoms upon awakening
      - Tiredness
      - Wheezing/heavy breathing/fighting for air; **AND**
    - Patient is periodically checked to reassess the need for continued therapy based upon the patient's disease severity and level of asthma control

CLINICAL CRITERIA FOR RENEWAL *(CONTINUED)*

- **For Chronic idiopathic urticaria**
  - Treatment has resulted in clinical improvement as documented by improvement from baseline using objective clinical evaluation tools such as the urticaria activity score (UAS7), angioedema activity score (AAS), Dermatology Life Quality Index (DLQI), Angioedema Quality of Life (AE-QoL), or Chronic Urticaria Quality of Life Questionnaire (CU-Q_2oL); **AND**
  - Submitted current UAS7, AAS, DLQI, AE-QoL, or Cu-Q_2oL was recorded within the past 30 days.
- Management of immune checkpoint inhibitor-related toxicity
  - May not be renewed
- **Systemic mastocytosis**
  - Disease response as indicated by improvement in signs and symptoms compared to baseline or a decreased frequency of exacerbations

XTANDI® (ENZALUTAMIDE)

Length of Authorization:	6 months, may be renewed
Initiative:	MNC: Non-Formulary Product (IE 50698 / MR – GSN PatOverride)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Prostate Cancer**

- Patient is at least 18 years old; **AND**
- Will not be used in combination with other androgen receptor inhibitors (e.g., darolutamide, apalutamide); **AND**
- Patient is receiving gonadotropin-releasing hormone (GnRH) therapy or has had prior bilateral orchiectomy
  - Patient has castration-resistant prostate cancer (CRPC); **OR**
  - Patient has metastatic castration-sensitive prostate cancer (mCSPC)
- For patients with metastatic prostate cancer, in addition to the above criteria,
  - Patient has a documented failure (minimum three-month trial), contraindication or intolerance to Zytiga; **OR**
  - Patient is continuing with Xtandi®

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug (e.g., seizures, posterior reversible encephalopathy syndrome (PRES), hypersensitivity reactions, ischemic heart disease, falls/fractures)

XYREM® (SODIUM OXYBATE)

Length of Authorization:	3 months (90 days), may be renewed
Initiative:	SPC: Narcolepsy Agents (IE 50698 / MR – HICL)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Coverage is provided for the following FDA-approved indications **only** (coverage for any other use will **not** be provided):

Diagnosis of **Cataplexy in narcolepsy**

- Patient must be 7 years of age or older; **AND**
- Patient and provider enrolled in and compliant with Xyrem REMS Programs; **AND**
- Patient must not be receiving treatment with sedative hypnotic agents (e.g., zolpidem, eszopiclone, zaleplon, benzodiazepines, barbiturates, etc.); **AND**
- Patient must not drink alcohol when using Xyrem; **AND**
- Patient must not have succinic semialdehyde dehydrogenase deficiency; **AND**
- Patient was evaluated for history of drug abuse; **AND**
- Continued monitoring for signs of misuse or abuse of sodium oxybate aka gamma-hydroxybutyrate (GHB) including, but not limited to, the following: use of increasingly large doses, increased frequency of use, drug-seeking behavior, feigned cataplexy, etc.; **AND**
- Patient has daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least three months; **AND**
- Baseline daytime sleepiness as measured by a validated scale (e.g., Epworth Sleepiness Scale, Stanford Sleepiness Scale, Karolinska Sleepiness Scale, Cleveland Adolescent Sleepiness Questionnaire, or a Visual Analog Scale); **AND**
- Patient has cataplexy (i.e., sudden loss of some or all muscle tone in which consciousness is maintained); **AND**
- Baseline frequency of attacks is documented in patient's record; **AND**
  - A mean sleep latency of ≤ 8 minutes AND two or more sleep onset REM periods (SOREMPs) on an MSLT performed according to standard techniques [A SOREMP (within 15 minutes of sleep onset) on the preceding nocturnal polysomnogram may replace one of the SOREMPs on the MSLT]; **OR**
  - CSF hypocretin-1 concentration, measured by immunoreactivity, is either ≤ 110 pg/mL OR 1/3 of mean values obtained in normal subjects with the same standardized assay

Diagnosis of **Excessive Daytime Sleepiness (EDS) in Narcolepsy**

- Patient must be 7 years of age or older; **AND**
- Patient and provider enrolled in and compliant with Xyrem REMS Programs; **AND**
- Patient must not be receiving treatment with sedative hypnotic agents (e.g., zolpidem, eszopiclone, zaleplon, benzodiazepines, barbiturates, etc.); **AND**
- Patient must not drink alcohol when using Xyrem; **AND**
- Patient must not have succinic semialdehyde dehydrogenase deficiency; **AND**
- Patient was evaluated for history of drug abuse; **AND**
- Continued monitoring for signs of misuse or abuse of sodium oxybate aka gamma-hydroxybutyrate (GHB) including, but not limited to, the following: use of increasingly large doses, increased frequency of use, drug-seeking behavior, feigned cataplexy, etc.; **AND**
- Patient has daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least three months; **AND**
- Baseline daytime sleepiness as measured by a validated scale (e.g., Epworth Sleepiness Scale, Stanford Sleepiness Scale, Karolinska Sleepiness Scale, Cleveland Adolescent Sleepiness Questionnaire, or a Visual Analog Scale); **AND**

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

- Patient does not have cataplexy; **AND**
- A mean sleep latency of < 8 minutes and two or more sleep onset REM periods (SOREMPs) are found on a MSLT performed according to standard techniques [A SOREMP (within 15 minutes of sleep onset) on the preceding nocturnal polysomnogram may replace one of the SOREMPs on the MSLT]; **AND**
- Either CSF hypocretin-1 concentration has not been measured or CSF hypocretin-1 concentration measured by immunoreactivity is either > 110 pg/mL or > 1/3 of mean values obtained in normal subjects with the same standardized assay; **AND**
- The hypersomnolence and/or MSLT findings are not better explained by other causes such as insufficient sleep, obstructive sleep apnea, delayed sleep phase disorder, or the effect of medication or substances or their withdrawal; **AND**
- Trial and failure, contraindication, or intolerance to an amphetamine (e.g., amphetamine, dextroamphetamine) or methylphenidate-based stimulant.

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include severe depression or suicidality, heart failure, impaired renal function or uncontrolled hypertension, parasomnias, life-threatening respiratory depression, parasomnias, behavior/psychiatric adverse reactions, severe impaired cognitive function or motor function, etc.; **AND**
- Nightly dose does not exceed 9 g; **AND**
- For **Excessive Daytime Sleepiness**: Response to therapy with a reduction in excessive daytime sleepiness from pre-treatment baseline as measured by a validated scale (e.g., Epworth Sleepiness Scale, Stanford Sleepiness Scale, Karolinska Sleepiness Scale, Cleveland Adolescent Sleepiness Questionnaire, or a Visual Analog Scale); **AND**
- For **Cataplexy** only- reduced frequency of cataplexy attacks from pre-treatment baseline.

ZAVESCA® (MIGLUSTAT)

Length of Authorization:	12 months and may be renewed
Initiative:	SPC: Enzyme Deficiency (IE 2462 / NCPDP 75 – HICL)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Type 1 Gaucher Disease**

- Patient is 18 years of age or older; **AND**
- Must be used as a single agent; **AND**
- Patient is not a candidate (e.g. due to allergy, hypersensitivity, or poor venous access) for enzyme replacement therapy (e.g., imiglucerase, taliglucerase alfa, velaglucerase alfa)
- Patient has a documented diagnosis of Type 1 Gaucher Disease as confirmed by a beta-glucosidase leukocyte (BGL) test with significantly reduced or absent glucocerebrosidase enzyme activity; **AND**
- Patient's disease results in one or more of the following conditions:
  - Anemia (i.e., hemoglobin less than or equal to 11 g/dL [women] or 12 g/dL [men]) not attributed to iron, folic acid or vitamin B12 deficiency; **OR**
  - Moderate to severe hepatomegaly (liver size 1.25 or more times normal) or splenomegaly (spleen size 5 or more times normal); **OR**
  - Skeletal disease (e.g., lesions, remodeling defects and/or deformity of long bones, osteopenia/osteoporosis); **OR**
  - Symptomatic disease (e.g., bone pain, fatigue, dyspnea, angina, abdominal distension, diminished quality of life); **OR**
  - Thrombocytopenia (platelet count less than or equal to 120,000/mm^3)

CLINICAL CRITERIA FOR RENEWAL

Authorizations can be renewed based on the following criteria:

- Disease response as indicated by one or more of the following:
  - Improvement in symptoms (e.g. bone pain, fatigue, dyspnea, angina, abdominal distension, diminished quality of life, peripheral neuropathy)
  - Reduction in size of liver or spleen
  - Improvement in hemoglobin/anemia
  - Improvement in skeletal disease (e.g. increase in lumbar spine and/or femoral neck BMD, no bone crises or bone fractures)
  - Improvement in platelet counts; **AND**
- Absence of unacceptable toxicity from the drug (e.g., severe diarrhea and weight loss, severe tremors, peripheral neuropathies)

ZELBORAF® (VEMURAFENIB)

Length of Authorization:	6 months, may be renewed Coverage for the adjuvant treatment of melanoma is up to a maximum of 1 year of therapy
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75 – HICL, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Cutaneous Melanoma**

- Patient is at least 18 years of age; **AND**
- Patient does not have long QT syndrome; **AND**
- Baseline electrocardiogram (ECG) QTc >500 milliseconds prior to initiating therapy and will be assessed at regular intervals during treatment; **AND**
- Patient will avoid coadministration with all of the following:
  - Strong CYP3A4 inhibitors (e.g., fluconazole, itraconazole, etc.), if therapy is unavoidable, the patient will be monitored closely for adverse reactions and/or dose modifications will be implemented
  - Strong CYP3A4 inducers (e.g., phenytoin, carbamazepine, rifampin, etc.), if therapy is unavoidable, the patient will be monitored closely for adverse reactions and/or dose modifications will be implemented
  - Drugs known to prolong the QT interval (e.g., amitriptyline, amiodarone, etc.); **AND**
- Patient has not received prior therapy with BRAF and/or MEK inhibitors (e.g., trametinib, encorafenib, dabrafenib, binimetinib, etc.) unless otherwise specified; **AND**
- Patient has BRAF V600 mutation-positive disease as detected by an FDA approved or CLIA compliant test; **AND**
  - Patient has unresectable or metastatic** disease; **AND**
    - Used in combination with atezolizumab and cobimetinib as first-line therapy; **OR**
    - Used in combination with cobimetinib OR as a single agent if BRAF/MEK inhibitor combination therapy is contraindicated; **AND**
      - Used as initial therapy or subsequent therapy; **OR**
      - Used as re-induction therapy for patients who experience disease control (i.e., complete response, partial response, or stable disease) from prior BRAF inhibitor therapy, but subsequently have disease progression/relapse > 3 months after treatment discontinuation
  - Used as adjuvant therapy in combination with cobimetinib in patients with unacceptable toxicities to dabrafenib/trametinib; **AND**
    - Patient has lymph node involvement following complete resection, complete lymph node dissection (CLND), therapeutic lymph node dissection (TLND), or nodal basin ultrasound surveillance; **OR**
    - Patient has clinical satellite/in-transit metastases or local satellite/in-transit recurrence with no evidence of disease (NED) after complete excision to clear margins

***Metastatic disease includes stage III clinical satellite/in transit metastases or local satellite/in-transit recurrence in patients with limited resectable and unresectable disease, unresectable nodal recurrence, and disseminated (unresectable) distant metastatic disease.*

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Erdheim-Chester Disease (ECD)**

- Patient is at least 18 years of age; **AND**
- Patient does not have long QT syndrome; **AND**
- Baseline electrocardiogram (ECG) QTc >500 milliseconds prior to initiating therapy and will be assessed at regular intervals during treatment; **AND**
- Patient will avoid coadministration with all of the following:
  - Strong CYP3A4 inhibitors (e.g., fluconazole, itraconazole, etc.). If therapy is unavoidable, the patient will be monitored closely for adverse reactions and/or dose modifications will be implemented
  - Strong CYP3A4 inducers (e.g., phenytoin, carbamazepine, rifampin, etc.). If therapy is unavoidable, the patient will be monitored closely for adverse reactions and/or dose modifications will be implemented
  - Drugs known to prolong the QT interval (e.g., amitriptyline, amiodarone, etc.); **AND**
- Patient has not received prior therapy with BRAF and/or MEK inhibitors (e.g., trametinib, encorafenib, dabrafenib, binimetinib, etc.); **AND**
- Must be used as a single agent; **AND**
- Patient has non-melanoma BRAF V600E mutation-positive disease.

Diagnosis of **Central Nervous System (CNS) Cancers**

- Patient is at least 18 years of age; **AND**
- Patient does not have long QT syndrome; **AND**
- Baseline electrocardiogram (ECG) QTc >500 milliseconds prior to initiating therapy and will be assessed at regular intervals during treatment; **AND**
- Patient will avoid coadministration with all of the following:
  - Strong CYP3A4 inhibitors (e.g., fluconazole, itraconazole, etc.). If therapy is unavoidable, the patient will be monitored closely for adverse reactions and/or dose modifications will be implemented
  - Strong CYP3A4 inducers (e.g., phenytoin, carbamazepine, rifampin, etc.). If therapy is unavoidable, the patient will be monitored closely for adverse reactions and/or dose modifications will be implemented
  - Drugs known to prolong the QT interval (e.g., amitriptyline, amiodarone, etc.); **AND**
- Patient has not received prior therapy with BRAF and/or MEK inhibitors (e.g., trametinib, encorafenib, dabrafenib, binimetinib, etc.); **AND**
- Patient has one of the following:
  - Pilocytic astrocytoma
  - Pleomorphic xanthoastrocytoma (PXA)
  - Ganglioglioma; **AND**
- Patient has BRAF V600E mutation-positive disease; **AND**
- Used as adjuvant treatment in combination with cobimetinib; **AND**
- Patient has incomplete resection, biopsy, or surgically inaccessible location.

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Non-Small Cell Lung Cancer (NSCLC)**

- Patient is at least 18 years of age; **AND**
- Patient does not have long QT syndrome; **AND**
- Baseline electrocardiogram (ECG) QTc >500 milliseconds prior to initiating therapy and will be assessed at regular intervals during treatment; **AND**
- Patient will avoid coadministration with all of the following:
  - Strong CYP3A4 inhibitors (e.g., fluconazole, itraconazole, etc.). If therapy is unavoidable, the patient will be monitored closely for adverse reactions and/or dose modifications will be implemented
  - Strong CYP3A4 inducers (e.g., phenytoin, carbamazepine, rifampin, etc.). If therapy is unavoidable, the patient will be monitored closely for adverse reactions and/or dose modifications will be implemented
  - Drugs known to prolong the QT interval (e.g., amitriptyline, amiodarone, etc.); **AND**
- Patient has not received prior therapy with BRAF and/or MEK inhibitors (e.g., trametinib, encorafenib, dabrafenib, binimetinib, etc.); **AND**
- Patient has BRAF V600E mutation- positive disease; **AND**
- Patient has recurrent, advanced, or metastatic disease (excluding locoregional recurrence or symptomatic local disease with no evidence of disseminated disease) or mediastinal lymph node recurrence with prior radiation therapy; **AND**
- Used as a single agent if the combination of dabrafenib plus trametinib is not tolerated: **AND**
  - Used as first line therapy; **OR**
  - Used as subsequent therapy following progression on first-line therapy with a non-BRAF-targeted regimen

Diagnosis of **Hairy Cell Leukemia**

- Patient is at least 18 years of age; **AND**
- Patient does not have long QT syndrome; **AND**
- Baseline electrocardiogram (ECG) QTc >500 milliseconds prior to initiating therapy and will be assessed at regular intervals during treatment; **AND**
- Patient will avoid coadministration with all of the following:
  - Strong CYP3A4 inhibitors (e.g., fluconazole, itraconazole, etc.). If therapy is unavoidable, the patient will be monitored closely for adverse reactions and/or dose modifications will be implemented
  - Strong CYP3A4 inducers (e.g., phenytoin, carbamazepine, rifampin, etc.). If therapy is unavoidable, the patient will be monitored closely for adverse reactions and/or dose modifications will be implemented
  - Drugs known to prolong the QT interval (e.g., amitriptyline, amiodarone, etc.); **AND**
- Patient has not received prior therapy with BRAF and/or MEK inhibitors (e.g., trametinib, encorafenib, dabrafenib, binimetinib, etc.); **AND**
- Used as a single agent; **AND**
  - Patient had a less than complete response to initial purine analog therapy (e.g., cladribine or pentostatin); **OR**
  - Patient relapsed within 2 years of a complete response; **OR**
- Used with or without rituximab for progression after therapy for relapsed or refractory disease

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Differentiated Thyroid Carcinoma (Papillary, Follicular, or Hürthle Cell)**

- Patient is at least 18 years of age; **AND**
- Patient does not have long QT syndrome; **AND**
- Baseline electrocardiogram (ECG) QTc > 500 milliseconds prior to initiating therapy and will be assessed at regular intervals during treatment; **AND**
- Patient will avoid coadministration with all of the following:
  - Strong CYP3A4 inhibitors (e.g., fluconazole, itraconazole, etc.). If therapy is unavoidable, the patient will be monitored closely for adverse reactions and/or dose modifications will be implemented
  - Strong CYP3A4 inducers (e.g., phenytoin, carbamazepine, rifampin, etc.). If therapy is unavoidable, the patient will be monitored closely for adverse reactions and/or dose modifications will be implemented
  - Drugs known to prolong the QT interval (e.g., amitriptyline, amiodarone, etc.); **AND**
- Patient has not received prior therapy with BRAF and/or MEK inhibitors (e.g., trametinib, encorafenib, dabrafenib, binimetinib, etc.); **AND**
- Patient has progressive and/or symptomatic BRAF mutation-positive disease; **AND**
- Patient has unresectable locoregional recurrent disease, persistent disease, or distant metastases; **AND**
- Disease is not susceptible to radioactive-iodine (RAI) therapy; **AND**
- Alternative therapies (e.g., clinical trial or systemic therapy) are not available or appropriate; **AND**
- Used as a single agent.

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug (e.g., new primary malignancies, uveitis, severe dermatologic reactions [e.g., Stevens-Johnson syndrome, toxic epidermal necrolysis], severe photosensitivity reactions, severe hepatotoxicity, renal failure, QTc prolongation [e.g., QTc ≤ 500 milliseconds], severe hemorrhagic events, severe radiation sensitization/recall, severe Dupuytren's Contracture and plantar fascial fibromatosis, severe hypersensitivity reactions); **AND**
- Cutaneous Melanoma (re-induction therapy)
  - Refer to initial criteria. (See *Cutaneous Melanoma* – used as re-induction therapy)

ZIOPTAN® (TAFLUPROST) SOLUTION/DROPS

Length of Authorization:	12 months
Initiative:	MNC: Glaucoma Agents (IE 2462 / NCPDP 75 – HICL)

CLINICAL CRITERIA FOR INITIAL APPROVAL

- Patient has a diagnosis of open-angle glaucoma or ocular hypertension; **AND**
- The patient has tried and failed or has a contraindication to two generic alternatives (e.g., bimatoprost and latanoprost)

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug

ZOLINZA® (VORINOSTAT)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75 – HICL, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Cutaneous T-Cell Lymphoma (Mycosis Fungoides/Sézary Syndrome)**

- Patient is at least 18 years of age; **AND**
- Patient has progressive, persistent, or recurrent disease following treatment with two systemic therapies; **OR**
- Patient has stage IB – IV disease

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug (e.g., pulmonary embolism, deep vein thrombosis, myelosuppression [e.g., thrombocytopenia, anemia], gastrointestinal toxicity, hyperglycemia, clinical chemistry abnormalities, severe thrombocytopenia with other histone deacetylase [HDAC])

ZOMIG NASAL SPRAY

Length of Authorization:	1 year
Initiative:	MNC: Antimigraine Agents (IE 2462 / NCPDP 75 – GSN)

Grandfathered drug: Grandfathering criteria applies.

STEP CRITERIA

- The patient must have had a therapeutic failure to the following:
  - Imitrex nasal spray

Note: Zomig nasal spray is grandfathered (Grandfathering criteria applies).

ZYTIGA® (ABIRATERONE ACETATE)

Length of Authorization:	6 months, may be renewed
Initiative:	Zytiga - SPC: Oncology Agents (IE 2462 / NCPDP 75 – HICL, 50081 and 2193) Yonsa - MNC: Non-Formulary Product (IE 50698 / MR – GSN PatOverride)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Zytiga®

Diagnosis of **Prostate Cancer**

- Patient aged 18 years and older; **AND**
- Patient will receive concurrent treatment with a GnRH-analog or has had a bilateral orchiectomy; **AND**
- Used in combination with prednisone or methylprednisolone; **AND**
- Patient has not progressed following previous receipt of an abiraterone-corticosteroid regimen; **AND**
  - Used as initial therapy for patients in the regional risk group (i.e., any T, N1, M0) with a life expectancy of >5 years or is symptomatic (*Zytiga® only*) ; **OR**
  - Patient has castration-sensitive/castration-naive metastatic disease (*Zytiga® only*) ; **AND**
    - Patient has high-risk disease with at least 2 of the following at baseline:
      - Total Gleason score of ≥ 8;
      - Presence of ≥ 3 lesions on bone scan;
      - Evidence of measurable visceral metastases; **OR**
- Patient has castration-resistant metastatic disease (*Zytiga® or Yonsa®*)

YONSA®

- In addition to the above clinical criteria:
  - Patient has a documented failure, contraindication, or intolerance to Zytiga®; **OR**
  - Patient has an ineffective response with a minimum three-month trial of Zytiga®; **OR**
  - Patient is continuing with Yonsa®

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug (e.g., uncontrolled hypertension, hypokalemia, fluid retention, hepatotoxicity, severe adrenocortical insufficiency)

ZYVOX® (LINEZOLID)

Length of Authorization:	28-day, or up to 8 weeks if appropriate for diagnosis
Initiative:	MNC: Antibiotics (IE 2462 / NCPDP 75 – GSN)

CLINICAL CRITERIA FOR APPROVAL

****If the patient is completing a course of therapy with Linezolid (Zyvox®) which was initiated in the hospital, approve the requested medication for the remainder of the course of therapy (no other criteria needs to be addressed).**

- **Diagnosis of Vancomycin-resistant Enterococcus faecalis (VRE) or Vancomycin-resistant Enterococcus faecium (VRE) or Methicillin-resistant *Staphylococcus aureus* (MRSA)**
  - Patient has tried and failed vancomycin; **AND**
  - Pathogen has been confirmed by culture **or** prescriber is unable to obtain specimen for culture; **OR**
- **Diagnosis of another Gram-Positive Bacteria Infection or Infection Caused by an Undetermined Pathogen**
  - Refer requests for any other identified pathogen to a clinical pharmacist for review.
    Note: **Some diagnoses require treatment for more than 28 days (e.g., VRE endocarditis, MRSA osteomyelitis). This edit allows flexibility to approve for up to 8 weeks when appropriate. Therapy beyond 8 weeks will require additional PA.