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Next Review Due By: 10/2024
Policy Number: C15447-A

Olumiant (baricitinib)

PRODUCTS AFFECTED

Olumiant (baricitinib)

COVERAGE POLICY

Coverage for services, procedures, medical devices, and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Rheumatoid Arthritis, Alopecia areata

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. MODERATE TO SEVERE RHEUMATOID ARTHRITIS:
1. (a) Prescriber attests, or clinical reviewer has found, member has had a negative TB screening* or TB test (if indicated)** result within the last 12 months for initial and continuation of therapy requests
*MOLINA REVIEWER NOTE: TB SCREENING assesses patient for future or ongoing TB exposure or risk

and includes reviewing if they have been exposed to tuberculosis, if they have resided or traveled to areas of endemic tuberculosis, if patient resides or works in a congregate setting (e.g., correctional facilities, long-term care facilities, homeless shelters), etc.
**MOLINA REVIEWER NOTE: TB SKIN TEST (TST, PPD) AND TB BLOOD TEST (QuantiFERON TB Gold, T-Spot) are not required or recommended in those without risk factors for tuberculosis
*MOLINA REVIEWER NOTE: TB SCREENING assesses patient for future or ongoing TB exposure or risk and includes reviewing if they have been exposed to tuberculosis, if they have resided or traveled to areas of endemic tuberculosis, if patient resides or works in a congregate setting (e.g., correctional facilities, long-term care facilities, homeless shelters), etc.
**MOLINA REVIEWER NOTE: TB SKIN TEST (TST, PPD) AND TB BLOOD TEST (QuantiFERON TB Gold, T-Spot) are not required or recommended in those without risk factors for tuberculosis
OR
(b) For members who have a positive test for latent TB, provider documents member has completed a treatment course (a negative chest x-ray is also required every 12 months) OR that member has been cleared by an infectious disease specialist to begin treatment
AND

2. Member is not on concurrent treatment or will not be used in combination with TNF- inhibitor, biologic response modifier or other biologic DMARDs, Janus kinase Inhibitors, or Phosphodiesterase 4 inhibitor (i.e., apremilast, tofacitinib, upadacitinib) as verified by prescriber attestation, member medication fill history, or submitted documentation
AND
3. Prescriber attests member does not have an active infection, including clinically important localized infections
AND
4. Documentation of moderate to severe rheumatoid arthritis diagnosis
AND
5. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal [DOCUMENTATION REQUIRED]
AND
6. Prescriber attests that member does NOT have an absolute lymphocyte count (ALC) less than 500/mm3, absolute neutrophil count (ANC) less than 1000 cells/mm3, or hemoglobin less than 8 g/dL
AND
7. (a) Member is currently receiving maximally tolerated dose of methotrexate and is not at goal disease activity
OR
(b) Member has an FDA labeled contraindication or serious side effects to methotrexate, as determined by the prescribing physician AND Member has tried one additional disease- modifying antirheumatic drug (DMARD) (brand or generic; oral or injectable) for at least 3 months
(NOTE: An exception to the requirement for a trial of one conventional synthetic DMARD can be made if the member has already had a 3-month trial of at least one biologic. These members who have already tried a biologic for RA are not required to "step back" and try a conventional synthetic DMARD.)
AND
8. Documentation of treatment failure or serious side effects to a trial (> 3 months) of ONE FORMULARY OR PREFERRED TNF-inhibitor
AND
9. Prescriber attests to (or the clinical reviewer has found that) the member not having any FDA labeled contraindications that haven't been addressed by the prescriber within the documentation submitted for review [Contraindications to Olumiant (baricitinib) include: patients with active, serious, or opportunistic infection, including localized infections, patients with hemoglobin less than 8 g/dL., absolute lymphocyte counts less than 500 cells/mm3, absolute neutrophil count (ANC) less than 1000 cells/mm3, severe hepatic impairment (Child Pugh class C), severe renal impairment (eGFR < 30 mL/minute/1.73m2).]
AND
10. IF THIS IS A NON-FORMULARY/NON-PREFERRED PRODUCT: Documentation of trial/failure of or intolerance to a majority (not more than 2) of the preferred formulary/PDL alternatives for the given diagnosis. Submit documentation including medication(s) tried, dates of trial(s) and reason for

treatment failure(s) [DOCUMENTATION REQUIRED]

B. ALOPECIA AREATA:
REVIEWER NOTE: PLEASE FIRST REFER TO STATE AND LINE OF BUSINESS EXPLANATION OF BENEFITS TO DETERMINE IF HAIR LOSS/COSMETIC INDICATIONS ARE A COVERED BENEFIT.
Olumiant (baricitinib) is excluded from coverage for alopecia areata per Social Security 1927(d)(2)(A)
A State may exclude or otherwise restrict coverage of a covered outpatient drug if the drug is contained in the list:

- Agents when used for anorexia, weight loss, or weight gain.
- Agents when used to promote fertility.
- **Agents when used for cosmetic purposes or hair growth.**
- Agents when used for the symptomatic relief of cough and colds.
- Agents when used to promote smoking cessation.
- Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations.
- Nonprescription drugs, except, in the case of pregnant women when recommended in accordance with the Guideline referred to in section 1905(bb)(2)(A), agents approved by the Food and Drug
  Administration under the over-the-counter monograph process for purposes of promoting, and when used to promote, tobacco cessation.
- Covered outpatient drugs which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee.
- Barbiturates.
- Benzodiazepines.
- Agents when used for the treatment of sexual or erectile dysfunction, unless such agents are used to treat a condition, other than sexual or erectile dysfunction, for which the agents have been approved by the Food and Drug Administration.

CONTINUATION OF THERAPY:
A. RHEUMATOID ARTHRITIS:

1. Adherence to therapy at least 85% of the time as verified by the prescriber or member medication fill history OR adherence less than 85% of the time due to the need for surgery or treatment of an infection, causing temporary discontinuation
   AND
2. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity
   AND
3. Documentation of positive clinical response as demonstrated by low disease activity and/or improvements in the condition's signs and symptoms. [DOCUMENTATION REQUIRED]
   AND
4. (a) Prescriber attests, or clinical reviewer has found, member has had a negative TB screening* or TB test (if indicated)** result within the last 12 months for initial and continuation of therapy requests
   *MOLINA REVIEWER NOTE: TB SCREENING assesses patient for future or ongoing TB exposure or risk and includes reviewing if they have been exposed to tuberculosis, if they have resided or traveled to areas of endemic tuberculosis, if patient resides or works in a congregate setting (e.g., correctional facilities, long-term care facilities, homeless shelters), etc.
   **MOLINA REVIEWER NOTE: TB SKIN TEST (TST, PPD) AND TB BLOOD TEST (QuantiFERON TB Gold, T-Spot) are not required or recommended in those without risk factors for tuberculosis
   OR
   (b) For members who have a positive test for latent TB, provider documents member has completed a treatment course (a negative chest x-ray is also required every 12 months) OR that member has been cleared by an infectious disease specialist to begin treatment

B. ALOPECIA AREATA: N/A

DURATION OF APPROVAL:
Initial authorization: 6 months, Continuation of Therapy: 12 months

PRESCRIBER REQUIREMENTS:
Prescribed by or in consultation with a board-certified rheumatologist. [If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

AGE RESTRICTIONS:
18 years of age and older

QUANTITY:
RHEUMATOID ARTHRITIS: 2mg once daily

PLACE OF ADMINISTRATION:
The recommendation is that oral medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Oral

DRUG CLASS:
Antirheumatic-Janus Kinase Inhibitors

FDA-APPROVED USES:
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 blockers.

Limitations of Use: Not recommended for use in combination with other JAK inhibitors, biologic DMARDs, or with potent immunosuppressants such as azathioprine and cyclosporine.

- The treatment of COVID-19 in hospitalized adults requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or ECMO.
- The treatment of adult patients with severe alopecia areata.

Limitations of Use: Not recommended for use in combination with other JAK inhibitors, biologic immunomodulators, cyclosporine or other potent immunosuppressants

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:
None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
Olumiant (baricitinib) is the second oral JAK inhibitor approved in the US to treat moderate-to-severe RA. Xeljanz was the first JAK inhibitor approved in November 2012 for RA. Olumiant inhibits JAK1 and JAK2, while Xeljanz targets JAK1 and JAK3. The relevance of specific JAK inhibition to therapeutic effectiveness is not known. Olumiant has a black box warning for the risk of serious infections, malignancies, and

thrombosis. Serious infections leading to hospitalizations or death, including tuberculosis and bacterial, invasive fungal, viral, and other opportunistic infections, have occurred.

Lymphoma and other malignancies have been observed as well. Thrombosis, including deep venous thrombosis, pulmonary embolism, and arterial thrombosis, some fatal, have occurred in patients treated with Olumiant. As a result, Olumiant also requires patients have had an inadequate response to one or more TNF inhibitors. It is estimated that about two-thirds of RA patients will not reach clinical remission with their first anti-TNF, which presents an opportunity for Olumiant even with its current label. The FDA-approved dose of Olumiant (2 mg QD) was studied in four randomized, double-blind trials in patients with RA that had not responded adequately to other DMARDs. More patients achieved ACR20, ACR50, and ACR70 responses at 12 weeks with Olumiant than with placebo. Olumiant may be used as monotherapy or in combination with methotrexate or other non-biologic DMARDs.

RA-BUILD study: This confirmatory study was a 24-week trial in 684 patients with moderately to severely active rheumatoid arthritis who had an inadequate response or intolerance to conventional DMARDs (cDMARDs). Patients received Olumiant 2 mg or4 mg once daily or placebo added to existing background cDMARD treatment. From Week 16, nonresponding patients could be rescued to receive baricitinib 4 mg once daily. The primary endpoint was the proportion of patients who achieved an ACR20 response at Week 12. A-BEACON study: This randomized, double-blind, placebo-controlled study compared Olumiant 2mg, 4 mg and placebo. Patients remained on their conventional DMARDs that they were currently using. The study included 527 patients who had an inadequate response or intolerance to one or more TNF inhibitors. Patients could have had prior therapy with other DMARDs. The study results showed that the Olumiant patients had significantly higher ACR20 response rates and improvement in all individual ACR20 component scores at week 12 compared to placebo (49% versus 27%). Higher ACR20 response rates were observed as early as 1 week with Olumiant 2 mg versus placebo. The proportions of patients achieving DAS28-CRP < 2.6 who had at least 3 active joints at the end of week 24 were 18.2% and 10.5%, in the placebo and Olumiant 2 mg arms, respectively.

RA-BEAM study (Baricitinib 4mg versus Humira) – not approved in US: Baricitinib 4 mg was compared head- to-head versus adalimumab 40 mg in a 52-week, double-blind, placebo and active controlled trial with1307 patients with active RA who were receiving therapy with methotrexate.

Primary endpoint was ACR20 response. Secondary endpoints included DAS28, HAQ-DI, SDAI, as well as radiographic progression of joint damage. More patients had an ACR20 response at week 12 with baricitinib than with placebo (70% vs. 40%). All major secondary endpoints were met, including inhibition of radiographic progression of joint damage and an increased ACR20 response at week 12 with baricitinib versus adalimumab (70% vs. 61%, p=0.014).

Comments on ACR20: With the plethora of disease modifying targeted immune modulator treatment options now available for RA, perhaps the FDA bar is set too low with ACR20 as the primary endpoint for clinical trials. ACR20 has a positive outcome if 20% improvement in tender or swollen joint counts is achieved as well as a 20% improvement in at least three of the other five criteria (member assessment, physician assessment, pain scale, disability/functional questionnaire, acute phase reactant). ACR50 would require a 50% improvement and ACR70 a 70% improvement. ACR50 and ACR70 would represent a considerably stronger clinical response and should be considered the preferred endpoints for RA clinical trials going forward.

Alopecia areata (AA) is a disease characterized by hair cycle dysfunction and the presence of peribulbar and perifollicular mononuclear cell infiltrates. The diagnosis of this condition is made by observation. The majority of patients is under 40 years old and report the rapid onset of one or several defined, usually round, 1 to 4 cm areas of scalp hair loss. A common feature is the presence of “exclamation-mark” hairs that may be present at the margins of the bald patch. “Exclamation-mark” hairs are broken, short hairs that taper proximally. Some patients with alopecia areata also exhibit nail pitting. The disease may affect any hair-bearing area, but most commonly affects the scalp, eyebrows, eyelashes, and beard. Hair loss may be patchy or extensive. In extreme cases, the disease may result in total loss of scalp hair (alopecia totalis) or scalp and body hair (alopecia universalis).

Although the etiology of alopecia areata is unknown, most evidence supports the hypothesis that the

disease is immunologically mediated. Circulating autoantibodies and follicular deposits of C3 and IgG have been reported. Alopecia areata usually occurs as an isolated condition, but may occur in conjunction with pernicious anemia, thyroid disease, ulcerative colitis, Addison's disease, vitiligo, lupus erythematosus, and Down syndrome.

Treatment success depends on the age of onset of the disease and the extent of hair loss. The prognosis tends to be worse in more extensive cases (alopecia totalis or universalis), or when alopecia areata begins in early childhood. In all cases, hair regrowth may occur spontaneously without treatment, even after months or years. In both mild and extensive cases of alopecia areata, topical corticosteroids of medium to very high potency are used.

The most common treatment for mild cases of alopecia areata (involving less than 50 % loss of scalp hair) is direct intradermal injection of corticosteroids (e.g., cortisone or triamcinolone acetonide) into patches of hair loss. Multiple injections are administered monthly to the skin in and around the bare patches; an average of 4 to 6 monthly injections are usually required for significant improvement. The prognosis for total permanent regrowth in cases with limited involvement is excellent. Topical glucocorticoid therapy may be used alone or in combination with other therapies, such as anthralin or injected glucocorticoids.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

All other uses of Olumiant (baricitinib) are considered experimental/investigational and therefore, will follow Molina's Off-Label policy. Contraindications to Olumiant (baricitinib) include: patients with active, serious or opportunistic infection, including localized infections, patients with hemoglobin less than 8 g/dL., absolute lymphocyte counts less than 500 cells/mm3, absolute neutrophil count (ANC) less than 1000 cells/mm3, severe hepatic impairment (Child Pugh class C), severe renal impairment (eGFR < 30 mL/minute/1.73m2). Use of Olumiant in combination with other JAK inhibitors, biologic DMARDs, or with potent immunosuppressants (such as azathioprine and cyclosporine) is not recommended.

OTHER SPECIAL CONSIDERATIONS:

Olumiant (baricitinib) has a Black Boxed Warning for serious infections, mortality, malignancy, major adverse cardiovascular events (MACE), and thrombosis.

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:

Olumiant TABS 1MG
Olumiant TABS 2MG
Olumiant TABS 4MG

REFERENCES

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3. Genovese, M., Kremer, J., Zamani, O., Ludivico, C., Krogulec, M., & Xie, L. et al. (2016). Baricitinib in Patients with Refractory Rheumatoid Arthritis. New England Journal Of Medicine, 374(13), 1243-1252. doi: 10.1056/nejmoa1507247
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5. Taylor, P., Keystone, E., van der Heijde, D., Weinblatt, M., del Carmen Morales, L., & Reyes Gonzaga, J. et al. (2017). Baricitinib versus Placebo or Adalimumab in Rheumatoid Arthritis. New England Journal Of Medicine, 376(7), 652-662. doi: 10.1056/nejmoa1608345
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7. King B, Ohyama M, Kwon O, Zlotogorski A, Ko J, Mesinkovska NA, Hordinsky M, Dutronc Y, Wu WS, McCollam J, Chiasserini C, Yu G, Stanley S, Holzwarth K, DeLozier AM, Sinclair R; BRAVE-AA Investigators. Two Phase 3 Trials of Baricitinib for Alopecia Areata. N Engl J Med. 2022 May 5;386(18):1687-1699. doi: 10.1056/NEJMoa2110343. Epub 2022 Mar 26.
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9. Fraenkel, L., Bathon, J., England, B., St. Clair, E., Arayssi, T., & Carandang, K. et al. (2021). 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care & Research, 73(7), 924-939. doi: 10.1002/acr.24596

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Quantity Available Dosage Forms	Q4 2023
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Duration of Approval Quantity Contraindications/Exclusions/Discontinuation Other Special Consideration References	Q4 2022
REVISION- Notable revisions: Diagnosis Required Medical Information Continuation of Therapy Prescriber Requirements Quantity FDA-Approved Uses Background Available Dosage Forms References	Q3 2022
Q2 2022 Established tracking in new format	Historical changes on file