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Last P&T Approval/Version: NA
Last Reviewed Date: 09/2023
Policy Number: C25040-A

Nebraska Medicaid Medical Necessity Review

PRODUCTS AFFECTED

Non-Preferred Products, Non-Formulary Products, Formulary Products requiring a medical necessity review, step therapy, age limit, or quantity limit and New to Market Launched drugs

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:
NA

REQUIRED MEDICAL INFORMATION:
NOTE: PRIOR TO ANY REVIEW FOR EXCEPTION, REVIEWER SHOULD VERIFY THERAPY ELIGIBILITY FOR BENEFIT EXCLUSION OR CARVE OUT STATUS
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.

A. REQUEST FOR COVERAGE OF DRUG PRODUCT REQUIRING A MEDICAL NECESSITY REVIEW:

Molina Reviewer Note: This criterion should only be used for drug reviews that are directed by state agencies to only be reviewed for medical necessity. Please verify and potentially use MHI or drug class/drug specific criteria, if required by State PDL.

1. The requested agent is being used to treat a medical condition/disease state that is not otherwise excluded from coverage (i.e., recognized as a covered benefit by the applicable health plan's program)
   AND
2. (a) Requested drug is being used for an FDA-approved indication
   OR
   (b) Requested drug is being used for a medically accepted indication that is supported by information from the appropriate compendia of current literature (e.g., AHFS, Micromedex, current accepted guidelines, etc.)
   NOTE: Requests for off-label use will be reviewed using the Off-Label Use of Drugs and Biologic Agents policy
   AND
3. The requested Non-Formulary drug is not excluded from coverage (e.g., drugs for erectile dysfunction, cosmetic) ***SSA Section 1927d (2) List of Drugs subject to restriction
   AND
4. The requested Non-Formulary drug is prescribed for a medically accepted indication as defined in Sec. 1927 of the Social Security Act: Permissible Restrictions
   AND
5. Requested dose is supported by information from the appropriate compendia of current literature (e.g., AHFS, Micromedex, current accepted guidelines, etc.) for the member's age and, if applicable, weight.
   NOTE: Requests for off-label use will be reviewed using the Off-Label Use of Drugs and Biologic Agents policy
   AND
6. FOR NEW TO MARKET PRODUCT (LAUNCHED WITHIN LAST 180 DAYS): Medications being considered for a formulary exception must be found on the Nebraska Preferred Drug List (PDL). Medications included on the PDL must meet any applicable utilization management requirements if they are in the same therapeutic class as formulary medications that require such authorization. NOTE: Additional information on Nebraska Preferred Drug List (PDL) available in Appendix.
   AND
7. IF THIS IS A NON-PREFERRED/NON-FORMULARY PRODUCT:
   a. Documentation member has 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, doses of trial(s), dates of trial(s) and reason for treatment failure(s).
      OR
   b. Member requires use of a specific dosage form (e.g., suspension, solution, injection) that is not available as the formulary alternatives
      OR
   c. Member has a clinical condition which the listed formulary alternatives are not recommended based on published guidelines or clinical literature
      OR
   d. Member had an adverse reaction to OR would be reasonably expected to have an adverse reaction to the listed formulary alternatives
      OR
   e. Member has an FDA labeled contraindication to the listed formulary alternatives

B. DOSE LIMIT/QUANTITY LIMIT:
   MOLINA REVIEWER NOTE: Please refer to the Quantity Limit or High Dose Override Nebraska Medicaid, C25041-A policy for review.

C. STEP THERAPY FOR FORMULARY DRUGS WITHOUT STATE DESIGNATED STEP THERAPY CRITERIA:
   1. Documentation or prescriber attestation that the step one agent(s) (i.e., preferred products) have

been ineffective in the treatment of the member's disease or medical condition OR based on both sound clinical evidence and medical and scientific evidence, the known relevant physical or mental characteristics of the member, and known characteristics of the drug regimen, is likely to be ineffective or adversely affect the drug's effectiveness or member compliance.
OR

2. Documentation or prescriber attestation that the preferred product has caused or, based on sound clinical evidence and medical and scientific evidence, is likely to cause a clinically significant adverse reaction or other harm to the member and which the requested drug is not as likely to cause.

D. BRAND EXCLUSION/GENERIC REQUIREMENT FOR DRUGS NOT LISTED ON THE PREFERRED DRUG LIST:

1. The requested therapy is a BRAND product with a generic or authorized generic available and where neither the Brand or generic product are listed on the preferred drug list
AND

2. (a) Documentation that the member has been re-challenged on a maximum of three available generically manufactured products OR, if three generic manufacturers are not available, other generically available products within the same therapeutic class (three total generic products)
OR

(b) Documentation the member experiences a documented adverse drug reaction with the generic agent re-challenge (examples: rash, anaphylaxis) that is NOT a known side effect of the medication and/or the prescriber has submitted a completed FDA MedWatch form [DOCUMENTATION REQUIRED]
OR

(c) Drug requested is a Narrow Therapeutic Index medication

E. AGE LIMIT:
MOLINA REVIEWER NOTE: Verify all age edits with formulary documents.

1. The requested agent is being used to treat a medical condition/disease state that is not otherwise excluded from coverage (i.e., recognized as a covered benefit by the applicable health plan's program)
AND
2. (a) Requested drug is being used for an FDA-approved indication and recognized as a covered benefit by the applicable health plan's program
OR

(b) Requested drug being used for a medically accepted indication that is supported by information from the appropriate compendia of current literature (e.g., AHFS, Micromedex, current accepted guidelines, etc.) and recognized as a covered benefit by the applicable health plan's program
NOTE: Requests for off-label use will be reviewed using the Off-Label Use of Drugs and Biologic Agents policy

AND
3. Use for the member's age for the requested indication is FDA labeled or supported by the appropriate compendia of current literature (e.g., AHFS, Micromedex, current accepted guidelines, etc.)
AND
4. If the member's age and indication being requested is not found in the FDA label or appropriate compendia of current literature (e.g., AHFS, Micromedex, current accepted guidelines, etc.), please refer to the Off-Label Use of Drugs and Biologic Agents policy for review.
AND
5. Requested dose is supported by information from the appropriate compendia of current literature (e.g., AHFS, Micromedex, current accepted guidelines, etc.) for the member's age and, if applicable, weight.
NOTE: Requests for off-label use will be reviewed using the Off-Label Use of Drugs and Biologic Agents policy

AND

6. FOR LIQUID DOSAGE FORM REQUESTS: Documentation member is unable to ingest preferred solid dosage form (i.e., tablet or capsule) due to ONE of the following: age, oral/motor difficulties, dysphagia, or member utilizes a feeding tube for medical administration.

F. CONTINUITY OF CARE OF MAINTENANCE MEDICATIONS FOR MEMBERS NEWLY ENROLLED WITH PLAN:
MOLINA REVIEWER NOTE: Please refer to MHI PHARM 008.1 Medication Prior Authorization Nebraska Addendum
NOTE: (https://nebraskalegislature.gov/FloorDocs/106/PDF/Slip/LB1052.pdf)
apply to antidepressant, antipsychotic, anticonvulsant, human immunodeficiency virus, multiple sclerosis, epilepsy, cancer, or immunosuppressant therapy medications. For these drug classes, if the member has had a claim in the preceding 90-day period, they must be allowed to continue the medication without prior authorization.

CONTINUATION OF THERAPY:

A. RENEWAL OF A PREVIOUS MOLINA AUTHORIZATION FOR ANY FORMULARY EXCEPTION TYPE (Excludes step therapy):

1. If this initial review was done for a new to market product that has since been P&T reviewed, please check for updated drug specific criteria
   AND
2. Documentation within chart notes of member disease stabilization or improvement from baseline since starting therapy
   AND
3. FOR THERAPIES TO TREAT CHRONIC CONDITIONS: Prescriber attests that member has been compliant to therapy OR through verification of member medication fill history
   AND
4. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity

DURATION OF APPROVAL:

Initial authorization: 12 months**;** New to Market Drug (launched within last 180 days): 3 months
Continuation of Therapy: 12 months

PRESCRIBER REQUIREMENTS:

None

AGE RESTRICTIONS:

Must be prescribed within FDA labeled or compendia supported age maximums or minimums

QUANTITY:

Must be prescribed within FDA labeled, compendia supported, or guideline recommended dosing maximums
MOLINA REVIEWER NOTE: Additional daily quantity limits may apply per formulary allowance

PLACE OF ADMINISTRATION:

N/A

DRUG INFORMATION

ROUTE OF ADMINISTRATION:

NA

DRUG CLASS:
NA

FDA-APPROVED USES:
NA

COMPENDIAL APPROVED OFF-LABELED USES:
NA

APPENDIX

APPENDIX:
New to Market Drugs:
Per the Nebraska Department of Health and Human Services (DHHS) Medicaid Provider Manual, Pharmacy Chapter, Section 18 (Version date: August 14, 2023), newly approved drug products will not normally be placed on the formulary during their first six months on the market. During this period, access to these medications will be considered through the prior authorization process.

Exclusions:
Per the Nebraska Department of Health and Human Services (DHHS) Medicaid Provider Manual, Pharmacy Chapter, Section 18 (Version date: August 14, 2023), the following drug categories are NOT COVERED as a benefit:

- Agents used to promote fertility
- Agents used for treatment of sexual or erectile dysfunction
- Agents used for anorexia
- Agents used for cosmetic purposes or hair growth
- Experimental or investigational drugs
- Proposed less-than-effective (LTE) drugs identified by the Drug Efficacy Study Implementation (DESI) program
- Drugs recalled by Labelers
- Drugs not FDA approved or licensed for use in the United States

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
Medications and vaccines that have not received final FDA marketing approval for any indication are considered investigational. Orphan designation is not synonymous to FDA-approval and orphan drug status has no significance in the evaluation of off-label treatments. An orphan drug is one that is used for the treatment of a rare disease or condition that either occurs in fewer than 200,000 individuals in the US or is more prevalent but for which there is no reasonable expectation that the cost of developing and marketing the drug in the US for such disease or condition would be recovered from US sales. The orphan drug designation is independent from marketing approval status and may apply to medications that are either approved or unapproved for marketing.

The following are currently the authoritative compendia for CMS approved clinical decision support tools to determine medically accepted indication of medical necessity:

- American Hospital Formulary Service-Drug Information (AHFS-DI)
- National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
- Truven Micromedex DrugDex Compendium (DrugDex) [Successor to USP-DI]
- Elsevier Gold Standard's Clinical Pharmacology Compendium (Clinical Pharmacology)
- Wolters Kluwer Lexi-Drugs (Lexi-Drugs)

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
Coverage will not be authorized for medical necessity usage unless prior authorization request

meets ALL criteria defined in the above section. Drugs are not covered when the following circumstances are applicable:

- The FDA has determined its use to be contraindicated; or
- The benefit plan excludes drug coverage; or
- The benefit plan includes drug benefit limitations based on a formulary and the off-label drug is not part of the formulary; or
- Pharmaceutical agents (and vaccines) that have not received final FDA marketing approval for any indication or has not been fully licensed or approved by the FDA are considered investigational and coverage will not be authorized; or
- Use is identified as not indicated by CMS (in the case of Medicare members) or the FDA; or
- Use is specifically identified as not indicated in at least one of the major compendia; or
- Use is determined (based on peer-reviewed literature) that the drug is not safe and effective
- Expanded Access Program (EAP) (also referred to as 'Managed Access Program (MAP), Early Access Program, or Compassionate Use Program (CUP'): A pathway for physicians and patients with an immediately life-threatening condition or serious disease or condition to gain access to pre-approval, investigational product* outside of the clinical trial setting: The investigational drug, cost of the treatment(s) or procedure(s) the clinical trial is investigating, or procedure(s) required to collect data for the study will not be authorized.
- Drugs determined to be lacking substantial evidence of effectiveness based on DESI (Drug Efficacy Study Implementation) review.

OTHER SPECIAL CONSIDERATIONS:

N/A

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:

REFERENCES

1. Nebraska Department of Health and Human Services (DHHS) Prior Authorization Criteria for Documentation of Medical Necessity. Revised: October 1, 2012. Available at: https://nebraska.fhsc.com/priorauth/paforms.asp.
2. Request for Proposal for Contractual Services: State of Nebraska Department of Health and Human Services. Release Date: April 15, 2022. Last Updated: July 1, 2019. Available at: https://dhhs.ne.gov/Pages/Grants-and-Contract-Opportunities.aspx.

3. NE Medicaid Provider Manual. Molina Healthcare of Nebraska, Inc. Last Updated: August 14, 2023. Available at: http://www.molinahealthcare.com/.
4. MHI PHARM 008.1 Medication Prior Authorization NE Addendum. Molina Healthcare of Nebraska, Inc. Last Updated: June 30, 2023.
5. Nebraska Department of Health and Human Services (DHHS) Prior Authorization Criteria for Documentation of Medical Necessity for Quantity Limit or High Dose Override. Revised: October 1, 2012. Available at: https://nebraska.fhsc.com/priorauth/paforms.asp.

SUMMARY OF REVIEW/REVISIONS	DATE
NEW CRITERIA CREATION	Q1 2023