Original Effective Date: 12/01/2020
Current Effective Date: 12/28/2025
Last P&T Approval/Version: 10/29/2025
Next Review Due By: 10/2026
Policy Number: C20326-A

Medical Necessity Review

PRODUCTS AFFECTED

Non-Formulary Products, Formulary Products requiring a medical necessity review, Non-preferred products

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

Molina Reviewer Note: These criteria 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. Requested drug has been approved by the U.S. Food and Drug Administration (FDA) for at least ONE indication
   AND
2. Prescriber must submit member's medical records and other relevant documentation as deemed necessary by Molina Healthcare to determine if a medical necessity use is reasonable and necessary for treatment of a member's condition or disease.
   AND
3. 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
4. (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.)
   AND
5. Age of the member is within FDA labeling limits, compendia supported age range, and/or guideline recommendations for the diagnosis
   AND
6. Prescriber attests that member has no contraindications for use of the requested product, based on contraindications specified in FDA labeling
   AND
7. Requested dosing is consistent with the FDA labeling or compendia supported dosing for both individual dose and requested frequency AND does not exceed the maximum recommended dosing of the FDA label or compendia.
   AND
8. IF THIS IS A NON-PREFERRED/NON-FORMULARY PRODUCT: Documentation of ONE of the following:
   (a) Member has tried, failed, or was intolerant to the specified number of preferred products within the same class
   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

CONTINUATION OF THERAPY:

A. RENEWAL OF A PREVIOUS MOLINA AUTHORIZATION FOR MEDICAL NECESSITY:

1. Requested drug does not have drug or class specific criteria to reference
   AND
2. FOR CHRONIC CONDITIONS: 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

3. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity
   AND
4. Documentation of positive clinical response as demonstrated by low disease activity, stable disease activity and/or improvements in the condition's signs and symptoms.
   AND
5. If the preferred status on the preferred drug list (PDL) has changed, and not granted specific grandfather status, the drug must meet initial criteria for continuation of coverage.

DURATION OF APPROVAL:
Initial authorization: 6 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:
N/A

DRUG CLASS:
N/A

FDA-APPROVED USES:
N/A

COMPENDIAL APPROVED OFF-LABELED USES:
NA

APPENDIX

APPENDIX:
None

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

CODING DISCLAIMER. *Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.*

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:
N/A

REFERENCES

SUMMARY OF REVIEW/REVISIONS	DATE
ANNUAL REVIEW COMPLETED- No coverage criteria changes with this annual review	Q4 2025
REVISION- Notable revisions: Coding/Billing Information Template Update ANNUAL REVIEW COMPLETED- No coverage criteria changes with this annual review.	Q4 2024
ANNUAL REVIEW COMPLETED- No coverage criteria changes with this annual review.	Q4 2023
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Duration of Approval Compendial Approved Off-Labeled Uses Background	Q4 2022
Q2 2022 Established tracking in new format	Historical changes on file