Effective Date: 04/27/2022
Last Approval/Version: 05/2024
Next Review Due By: 10/2024
Policy Number: C22913-A

Medical Necessity Review – IL Medicaid Only

PRODUCTS AFFECTED

Non-Formulary Products, Non-Preferred Formulary Products requiring a medical necessity review, Preferred Products with prior authorization, age limit, or quantity limit and New to Market 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:
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.

A. REQUEST FOR A NON-PREFERRED DRUG LISTED ON THE FORMULARY (PDL):
Molina Reviewer Note: This criterion should only be used in the absence of drug/drug class specific IL Medicaid Only Policy, Molina Healthcare Inc. Prior Authorization Criteria, or Medical Clinical Policy.

1. Documentation or prescriber attestation that a maximum of 3 unrestricted alternative formulary agents matching the same indication 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.
   AND
2. Requested drug therapy is consistent with the diagnosis and treatment of a condition, the standards of good medical practice and required for other than convenience
   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.)

B. REQUEST FOR PREFERRED DRUG WITH PRIOR AUTHORIZATION:

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. This criterion should only be used in the absence of drug/drug class specific Molina Healthcare Inc. Prior Authorization Criteria or Medical Clinical Policy.

1. (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 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 recognized as a covered benefit by the applicable health plan's program
   AND
2. Requested dose is supported by information from the appropriate compendia of current literature (e.g. AHFS, Micromedex, current accepted guidelines, etc.) for the members age and if applicable, weight.

C. REQUEST FOR COVERAGE OF A DRUG NOT ON THE FORMULARY (PDL):

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. This criterion should only be used in the absence of drug/drug class specific Molina Healthcare Inc. Prior Authorization Criteria or Medical Clinical Policy.

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.)

AND

3. The requested Non-Formulary drug is not excluded from coverage (e.g., drugs for weight loss, drugs for erectile dysfunction) ***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. (a) Documentation [medication(s) tried, dates of trials, and reason for treatment failure(s)] that member has demonstrated a failure of or intolerance to the majority (not more than 3) of the PDL alternatives for a given diagnosis.
   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 for 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

D. FOR A NEW TO MARKET PRODUCT (LAUNCHED WITHIN LAST 180 DAYS): Medications being considered for a formulary exception must meet any applicable utilization management requirements if they are in the same therapeutic class as formulary medications that require such authorization.

1. Documentation [medication(s) tried, dates of trials, and reason for treatment failure(s)] that member has demonstrated a failure of or intolerance to the majority (not more than 3) of the PDL alternatives for a given diagnosis.
   OR
2. Member requires use of a specific dosage form (e.g. suspension, solution, injection) that is not available as the formulary alternatives
   OR
3. Member has a clinical condition for which the listed formulary alternatives are not recommended based on published guidelines or clinical literature
   OR
4. Member had an adverse reaction to OR would be reasonably expected to have anadverse reaction to the listed formulary alternatives
   OR
5. Member has an FDA labeled contraindication to the listed formulary alternatives

E. DOSE LIMIT OR QUANTITY LIMIT:

An exception may be granted for increased quantity of a drug on the formulary or the number of doses available under a dose restriction for the prescription formulary drug if:

1. The maximum allowed dose or frequency has been ineffective in the treatment of the member's disease or medical condition
   AND
2. The requested dose and/or dosing frequency cannot be made with a higher strength

and fewer dosages per day.
OR

3. Prescriber attests that the member requires a higher quantity with a lower dose for titration, therapy adjustments, dose alternating schedules, or to accommodate member swallowing issues. [treatment plan must be provided for titration/dosage adjustment needs]
   OR
4. The prescriber attest that the toxicity risk is not greater than the probable benefit, and there is a specific lab measurement showing inadequate dosing, or there is reasonable clinical rationale to suggest inadequate absorption, or there is reasonable clinical rationale to suggest more rapid metabolism of the drug.
   AND
5. If the dose and/or frequency of dosing being request is greater than the FDA labeled indicated or compendia supported dosage, please refer to the MOLINA OFF-LABEL POLICY for review.

F. BRAND EXCLUSION/GENERIC REQUIREMENT:

The requested therapy is for a non-preferred BRAND product with a generic or authorized generic available and where neither of the brand or generic are listed on the preferred drug list.

1. 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
2. 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 has the prescriber submitted a completed FDA MedWatch form (DOCUMENTATION REQUIRED)
   OR
3. Drug requested is a Narrow Therapeutic Index medication
   AND
   (a) 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
   (b) Requested drug is being used for an FDA-approved indication
   OR
   (c) 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.)

G. 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
   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

3. Requested drug is FDA-approved for the treatment of the submitted and/or comorbid diagnoses for the member's age OR is supported by information from the appropriate compendia of current literature
AND
4. Requested dose is supported by information from the appropriate compendia of current literature (e.g. AHFS, Micromedex, current accepted guidelines, etc.) for the members age and if applicable, weight.
AND
5. If the member age and indication being request is not found in the FDA label or appropriate compendia of current literature (e.g., AHFS, Micromedex, current accepted guidelines, etc.) compendia, please refer to the MOLINA OFF-LABEL POLICY for review.
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.

H. STEP EDIT 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 enrollee, 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.

CONTINUATION OF THERAPY:

A. RENEWAL OF A PREVIOUS MOLINA AUTHORIZATION FOR ANY FORMULARY EXCEPTION TYPE:

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. Prescriber attestation 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

DURATION OF APPROVAL:

Acute treatment: Length of treatment, no greater than 3 months
All others: up to 12 months*

*Up to 12 months, dependent upon FDA label recommendation and prescriber requested duration

PRESCRIBER REQUIREMENTS:
None

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

QUANTITY:
Must be prescribed within FDA labeled or compendia supported dosing maximums

PLACE OF ADMINISTRATION:
The recommendation is that oral medications in this policy will be for pharmacy benefit coverage and patient self-administered; intranasal medications in this policy will be for pharmacy benefit coverage and patient self-administered; subcutaneous or intramuscular injectable medications in this policy will be for pharmacy or medical benefit coverage and the subcutaneous injectable products administered in a place of service that is a non-hospital facility-based location or, if appropriate, patient self-administered; injectable implant medications in this policy will be for pharmacy or medical benefit coverage and the subcutaneous injectable implant products be administered in a place of service that is a non-hospital facility-based location; infused medications in this policy will be for pharmacy or medical benefit coverage administered in a place of service that is a non-inpatient hospital facility-based location.

Note: Site of Care Utilization Management Policy may apply for drugs reviewed by this policy to channel to the prescription drug benefit for member self-administration as appropriate

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
NA

DRUG CLASS:
NA

FDA-APPROVED USES:
NA

COMPENDIAL APPROVED OFF-LABELED USES:
NA

APPENDIX

APPENDIX:

P-204.2 Preferred Drug List (PDL)

The Department maintains a Preferred Drug List (PDL) in many therapeutic classes. It is the Department's goal to ensure broad access to a variety of preferred drugs in each class. Most classes have multiple preferred products. Therefore, the Department generally expects patients to use multiple preferred products before being approved for a non-preferred product. However, if there is a clinical reason that a patient must use a non-preferred product before having tried and failed the preferred alternatives, the provider should submit a prior approval request supported with clinical justification.

Generally, preferred drugs do not require prior approval, and non-preferred drugs do require prior approval. In certain classes of drugs, both the preferred and non-preferred drugs require prior approval in order to ensure safety or appropriate utilization, e.g., growth hormones and TNF Alpha Blockers/Biological Modifiers. In these cases, if the participant meets the criteria to be approved for a drug in the class, then the Department expects the participant to use a preferred product, unless there is a clinical reason that the participant must use a non-preferred product without having tried the preferred products.

P-204.11 Ninety (90) Day Supply

The Department allows billing of a 90-day supply for certain generic, oral, nonnarcotic, maintenance medications for certain disease states including hypertension, diabetes and hypothyroidism.

P-206 Services Not Covered

P-206.3 Certain Prescription Pharmacy Items:

Prescription pharmacy items that are not covered under the Medical Assistance Program are:

- Drugs manufactured by companies that have not signed a rebate agreement with the federal government
- Weight loss drugs
- Agents to promote fertility
- Agents used for cosmetic purposes, e.g., hair growth or wrinkle-removal
- Drugs identified by the FDA as being in Drug Efficacy Study Implementation (DESI) status
- Drugs dispensed after the termination date included on the quarterly drug tape provided by the federal Centers for Medicare and Medicaid Services
- Drugs indicated only for the treatment of erectile dysfunction

104 Services Not Covered

Services for which medical necessity is not clearly established are not covered in the Department's Medical Programs, in accordance with 89 Ill. Adm. Code 140.6. Services and supplies for which payment will not be made under any of the Department's medical programs include, but are not limited to, the following:

- Abortion services, except as allowed pursuant to 89 Ill. Admin. Code 140.413(a)(1)
- Acupuncture
- Artificial insemination
- Autopsy examinations
- Diagnostic or therapeutic procedures related to primary infertility or sterility
- Experimental procedures
- Items or services for which medical necessity is not clearly established
- Medical care provided by mail or telephone, except for approved telemedicine services described in Chapter 200 handbooks for practitioners and providers of encounter clinic services. This does not prohibit the mailing of medically necessary covered items, for example, prescription drugs sent to a patient by a mail-order pharmacy
- Medical examinations required for entrance in to adult educational or vocational programs
- Medical or surgical procedures performed for cosmetic purposes

- Preparation of routine records, forms and reports
- Research oriented procedures
- Services available without charge
- Services prohibited by state or federal law
- Services provided by terminated or barred providers
- Services provided only, or primarily, for the convenience of the patient/family
- Services or supplies not personally rendered by the provider, unless specifically allowed in this handbook or in the Chapter 200 handbook or otherwise specifically authorized in writing by the Department
- Subsequent treatment for venereal disease when such services are available free of charge through state and/or local health agencies
- Unkept appointments
- Visits with persons other than a patient, such as family members or long term care facility staff

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)
- Wolters Kluwer Lexi-Drugs (Lexi Drugs)
- 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)

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:

None

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:

NA

REFERENCES

1. www2.illinois.gov. 2023. *Medicaid Preferred Drug List | HFS*. [online] Available at: <https://www2.illinois.gov/hfs/MedicalProviders/Pharmacy/preferred/Pages/default.aspx> [Accessed 13 July 2023].
2. www2.illinois.gov. 2023. *Provider Handbooks | HFS*. [online] Available at: <https://www2.illinois.gov/hfs/MedicalProviders/Handbooks/Pages/default.aspx> [Accessed 13 July 2023].

SUMMARY OF REVIEW/REVISIONS	DATE
Off-cycle Updates: Duration of Approval	05/2024
Off-cycle Updates: Required Medical Information	10/2023
Annual update and review	07/2023