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Next Review Due By: 5/01/2023
Policy Number: C29913-A

Illinois Medicaid Medical Necessity Review

PRODUCTS AFFECTED

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

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 Illinois Department of Healthcare and Family Services (HFS)MEDICAID PREFERRED DRUG LIST

Drug and Biologic Coverage Criteria

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. (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
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.

B. REQUEST FOR COVERAGE OF A DRUG NOT ON THE FORMULARY

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 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
2. (a) 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
(b) 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
3. IF 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.
AND

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4. (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 a contraindication to the listed formulary alternatives

5. DOSE LIMIT/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:
 - a. The maximum allowed dose or frequency has been ineffective in the treatment of the member's disease or medical condition
AND
 - b. (a) The requested dose and/or dosing frequency cannot be made with a higher strength and fewer dosages per day.
OR
(b) 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
(c) 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
 - c. 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.
AND
 - d. FOR TOPICAL DOSAGE FORMS: Documentation of area and/or size of application site and application frequency (see appendix).

6. BRAND EXCLUSION/GENERIC REQUIREMENT:
 - a. 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.
AND
 - b. (a) Documentation that the member has been re-challenged on a maximum of three available generically manufactured products OR, if three generic

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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 has the prescriber submitted a completed FDA MedWatch form (DOCUMENTATION REQUIRED)

OR

(c) Drug requested is a Narrow Therapeutic Index medication

AND

c. (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

7. AGE LIMIT:

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

a. (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

AND

b. 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

c. 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

d. 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

e. 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.

8. STEP EDIT THERAPY FOR FORMULARY DRUGS WITHOUT STATE DESIGNATED STEP THERAPY CRITERIA:

a. Documentation or prescriber attestation that the step one agent(s) (i.e., preferred products) have been ineffective in the treatment of the member

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'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

- b. 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 or Initial Controlled Substances: 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.

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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:Topical Dosage Forms:

A finger-tip unit (FTU) is the amount of topical cream or ointment that is from the distal skin-crease to the tip of the index finger. As an estimate, one FTU is an approximate amount needed to treat an area of skin twice the size of the flat of an adult's hand.

Additional reference: <https://www.pennine-gp-training.co.uk/res/Eczema%20finger%20tip%20units.pdf>

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 nonpreferred 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.

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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

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- Unkept appointments
- Visits with persons other than a patient, such as family members or long term care facility staff

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:

A prescribing provider on behalf of the member, may make a request to obtain a medication that is not on the health plan's formulary. The plan will review the medical necessity of this request and respond back to the prescribing provider and the member per regulatory and/or accreditation standards.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

All FDA labeled contraindications are exclusions to any therapy.

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. 2022. *Medicaid Preferred Drug List | HFS*. [online] Available at: <<https://www2.illinois.gov/hfs/MedicalProviders/Pharmacy/preferred/Pages/default.aspx>> [Accessed 22 February 2022].
2. Long CC, Finlay AY. The finger-tip unit--a new practical measure. *Clin Exp Dermatol*. 1991 Nov;16 (6):444-7. doi: 10.1111/j.1365-2230.1991.tb01232.x. PMID: 1806320
3. www2.illinois.gov. 2022. *Provider Handbooks | HFS*. [online] Available at: <<https://www2.illinois.gov/hfs/MedicalProviders/Handbooks/Pages/default.aspx>> [Accessed 22 February 2022].

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SUMMARY OF REVIEW/REVISIONS	DATE

IL Medicaid Only