Original Effective Date: 02/01/2020
Current Effective Date: 12/28/2025
Last P&T Approval/Version: 10/29/2025
Next Review Due By: 10/2026
Policy Number: C17973-A

High-Cost Outlier Targeted Drug Exception

PRODUCTS AFFECTED

See High-Cost Outlier Targeted Drug List

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. 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. ALL DRUGS/ALL INDICATIONS:
1. The requested agent is used to treat a medical condition/disease state that is not otherwise excluded from coverage under the pharmacy benefit (i.e., recognized as a covered benefit by the applicable health plan's program)
   AND

2. 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.) or FDA-approved label
   NOTE: Requests for off-label use will be reviewed using the Off-Label Use of Drugs and Biologic Agents policy
   AND
3. Documentation of ONE of the following [DOCUMENTATION REQUIRED]:
   (i) The member has tried and failed ALL formulary/preferred alternatives AND generic NON-formulary drugs with matching member indication PRIOR to use of the requested therapy
   MOLINA REVIEWER NOTE: For Illinois Marketplace, please see Appendix.
   OR
   (ii) The member has an FDA labeled contraindication or serious side effects to ALL formulary/preferred alternatives AND generic NON-formulary drugs or they are likely to be less effective or cause harm for the member
   MOLINA REVIEWER NOTE: For Illinois Marketplace, please see Appendix.
   OR
   (iii) The member is currently receiving the requested medication and is at medical risk if therapy changes
   AND
4. 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
   AND
5. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal
   AND
6. FOR COMBINATION PRODUCT REQUESTS ONLY: Combination products and/or kits are not covered. Notify prescriber that separate products could be preferred and/or on formulary and may be covered when valid prescriptions are presented to the pharmacy.

CONTINUATION OF THERAPY:

A. ALL DRUGS/ALL INDICATIONS:

1. IF DRUG USED FOR CHRONIC CONDITION: 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

DURATION OF APPROVAL:

Initial authorization: 6 months, Continuation of therapy: 12 months

PRESCRIBER REQUIREMENTS:

None

AGE RESTRICTIONS:

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

QUANTITY:

Maximum 30-day supply per fill based on the FDA labeled or compendia recommended dosage for

PLACE OF ADMINISTRATION:
NA

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
NA

DRUG CLASS:
NA

FDA-APPROVED USES:
NA

COMPENDIAL APPROVED OFF-LABELED USES:
NA

APPENDIX

APPENDIX:
Reserved for State specific information. *Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*

State Specific Information
State Marketplace
Illinois (Source: Illinois General Assembly)
"(215 ILCS 134/45.1) Sec. 45.1. Medical exceptions procedures required. (c) An off-formulary exception request shall not be denied if: (1) the formulary prescription drug is contraindicated; (2) the patient has tried the formulary prescription drug while under the patient's current or previous health insurance or health benefit plan and the prescribing provider submits evidence of failure or intolerance; or (3) the patient is stable on a prescription drug selected by his or her health care provider for the medical condition under consideration while on a current or previous health insurance or health benefit plan. (d) Upon the granting of an exception request, the insurer, health plan, utilization review organization, or other entity shall authorize the coverage for the drug prescribed by the enrollee's treating health care provider, to the extent the prescribed drug is a covered drug under the policy or contract up to the quantity covered. (e) Any approval of a medical exception request made pursuant to this Section shall be honored for 12 months following the date of the approval or until renewal of the plan."

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
The intent of the high-cost outlier targeted drug list is to mitigate the utilization of drugs that do not have a material clinical impact over another less expensive drug or are a re-branding of one or more generic drugs into a branded/patented drug for financial gain by the manufacturer. Even though these drugs provide no clinical advantage, they are FDA approved or approved by the 510K marketing pathway with no clinical trial data and have a detrimental cost to the healthcare system.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All FDA labeled contraindications are exclusions to any therapy.

OTHER SPECIAL CONSIDERATIONS:
None

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	NA

AVAILABLE DOSAGE FORMS:
See High-Cost Outlier Targeted Drug List *(See Internal SharePoint criteria folder)*

REFERENCES

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Appendix	Q4 2025
REVISION- Notable revisions: Coding/Billing Information Template Update ANNUAL REVIEW COMPLETED- No coverage criteria changes with this annual review.	Q4 2024
REVISION- Notable revisions: Required Medical Information	Q4 2023
REVISION- Notable revisions: Diagnosis Required Medical Information Continuation of Therapy Age Restrictions Quantity Place of Administration	Q4 2022
Q2 2022 Established tracking in new format	Historical changes on file