Original Effective Date: 01/01/2026
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Policy Number: C29936-A

Standard PDL Exception Nevada Medicaid ONLY

PRODUCTS AFFECTED

Non-Formulary Products, Preferred drugs on or off the PDL, Non-preferred drugs, and New to Market Launched drugs (for which there is new clinical evidence supporting its inclusion on the PDL)

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.

Drug and Biologic Coverage Criteria

A. REQUEST FOR COVERAGE OF DRUG PRODUCT WITH CLINICAL CRITERIA WITHIN MSM CHAPTER 1200:

1. Request meets all criteria for approval in the most current MSM Chapter 1200
   [NOTE: Refer to the MSM Chapter 1200 at: https://dhcfp.nv.gov/Resources/AdminSupport/Manuals/MSM/C1200/Chapter1200/]
   AND
2. Request meets all PDL criteria per below as applicable
   [NOTE: Refer to the PDL at: https://nv.primetherapeutics.com/provider/documents]

B. REQUEST FOR COVERAGE OF DRUG PRODUCT REQUIRING A MEDICAL NECESSITY REVIEW, NEW TO MARKET DRUGS:

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. 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. Age of the member is within FDA labeling limits, compendia supported age range, and/or guideline recommendations for the diagnosis
   AND
4. Prescriber attests that member has no contraindications for use of the requested product, based on contraindications specified in FDA labeling
   AND
5. 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
6. IF THIS IS A NON-PREFERRED/NON-FORMULARY PRODUCT: Documentation of ONE of the following:
   (a) Member has tried and failed:
   - Two preferred medications within the same class
     OR
   - One preferred medication if there are not two preferred medications within the same class
     OR
   - For atypical or typical antipsychotic, anticonvulsant, and antidiabetic medications: one preferred medication

   (b) Member has an allergy to all preferred medications within the same class
   (c) Member has a contraindication to or drug-to-drug interaction with all preferred medications within the same class
   (d) Member has a history of unacceptable/toxic side effects to all preferred medications within the same class

   (e) An indication which is unique to a non-preferred agent, and is supported by peer-reviewed literature or an FDA-approved indication

C. CONTINUITY OF CARE OF PSYCHOTROPIC AND/OR ANTIDEPRESSANT MEDICATIONS:
1. For members discharged from an institution on non-preferred psychotropic and/or non-preferred anti-depressant medication(s), their drugs will continue to be covered by Medicaid for up to six months to allow the member time to establish outpatient mental health services

D. REQUEST FOR COVERAGE OF DRUG PRODUCT BEING PRESCRIBED FOR A PSYCHIATRIC CONDITION:
NOTE: For the purposes of this section, "psychiatric condition" means a mental disorder for which criteria are prescribed in the current version of the Diagnostic and Statistical Manual of Mental Disorders (DSM), published by the American Psychiatric Association (APA).
1. (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
2. Prescriber provides supportive clinical documentation demonstrating the approved diagnosis or evidence for use
AND
3. Prescriber of the drug is ONE of the following:
   i. A psychiatrist
   OR
   ii. A physician assistant under the supervision of a psychiatrist
   OR
   iii. An APRN who has the psychiatric training and experience prescribed by the State Board of Nursing pursuant to NRS 632.120
   OR
   iv. A primary care provider that is providing care to an insured in consultation with a practitioner listed in subparagraph a., b., or c., if the closest practitioner listed in subparagraph a., b., or c., who participates in the network plan of the insurer is located 60 miles or more from the residence of the insured

AND
4. Prescriber believes based on the medical history of the insured or reasonably expects each preferred drug within the same class to be ineffective at treating the psychiatric condition and the prescriber provides supportive clinical documentation demonstrating the reasoning for use of the drug

CONTINUATION OF THERAPY:

A. RECERTIFICATION OF A PREVIOUS MOLINA AUTHORIZATION FOR MEDICAL NECESSITY:
1. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity
AND
2. Documentation of positive clinical response to requested therapy
AND
3. 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.
AND
4. Request meets all criteria for approval in the most current MSM Chapter 1200
[NOTE: Refer to the MSM Chapter 1200 at:
https://dhcfp.nv.gov/Resources/AdminSupport/Manuals/MSM/C1200/Chapter1200/]

DURATION OF APPROVAL:

Initial authorization: 12 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:
New to Market Drugs:
Per the Medicaid Services Manual (MSM) Chapter 1200, new pharmaceutical products not within reviewed PDL drug classes and not excluded under the state plan or by NRS are covered without a Standard PDL Exception PA until, or if, the SSSB adds the drug class to the PDL and reviews the product or evidence. New FDA approved drugs, or existing pharmaceutical products within reviewed PDL drug classes, for which there is new clinical evidence supporting its inclusion on the PDL and are not excluded under state plan or by NRS, are covered with an approved Standard PDL Exception prior authorization until SSSB can review the new evidence or drug.

Exclusions:
Per the Medicaid Services Manual (MSM) Chapter 1200, the following drug categories are NOT COVERED as a benefit:

- Agents used for weight management.
- Agents used to promote fertility.
- Agents used for cosmetic purposes or hair growth.
- Yohimbine.
- Drug Efficacy Study Implementation (DESI) list “Less than Effective Drugs”: In accordance with current policy, federal financial participation is not allowed for any drug on the Federal Upper Limit (FUL) listing for which the FDA has issued a notice of an opportunity for a hearing as a result of the DESI program which has been found to be a less than effective or is identical, related or similar to the DESI drug. The DESI drug is identified by the FDA or reported by the drug manufacturer for purposes of the MDRP. This listing is available on the CMS website. This includes pharmaceuticals designated “ineffective” or “less than

effective" (including identical, related, or similar drugs) by the FDA as to substance or diagnosis for which prescribed.
- Pharmaceuticals considered "experimental" as to substance or diagnosis for which prescribed. Pharmaceuticals manufactured by companies not participating in the federal MDRP unless rated "1-A" by the FDA.
- Agents used for impotence/erectile dysfunction.
- Prescription dietary supplements/vitamins/minerals (other than prescription prenatal vitamins or fluoride) without an FDA-approved indication.

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

1. Nevada Medicaid Services Manual (MSM) Chapter MSM 1200 – Prescribed Drugs. Revised: August 4, 2025. Available at: https://dhcfp.nv.gov/Resources/AdminSupport/Manuals/MSM/C1200/Chapter1200/.

SUMMARY OF REVIEW/REVISIONS	DATE
NEW CRITERIA CREATION	Q4 2025