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Policy Number: C29961-A

## Physician Administered Drugs Nevada Medicaid ONLY

### PRODUCTS AFFECTED

See Individual STATE/LINE OF BUSINESS HCPCS (PHYSICIAN ADMINISTERED DRUG) Matrix for applicable products

FOR ALL ONCOLOGY AGENTS: See Product specific criteria or use Standard Oncology Criteria

FOR PHARMACY FORMULARY EXCEPTIONS: See Standard PDL Exception Criteria (non-formulary, new-to-market, medical necessity, ALL oral products, etc.)

### 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:**

Per FDA label or compendia support for the requested product

#### **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/>

### B. FOR ALL FDA LABELED INDICATIONS:

*Molina Reviewer Note: This criteria should only be used in the absence of MSM criteria or drug-specific policies.*

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.)

NOTE: Requests for off-label use will be reviewed using the Off-Label Use of Drugs and Biologic Agents policy

AND

3. Documentation that the drug being requested is prescribed within the manufacturer's published dosing guidelines or falls within dosing guidelines found in the compendia of current literature (e.g., package insert, AHFS, Micromedex, current accepted guidelines, etc.). Documentation to include quantity, strength, directions, and duration requested.

NOTE: If the dose and/or frequency of dosing being requested is greater than the FDA labeled or compendia supported dosage, please refer to the Off-Label Use of Drugs and Biologic Agents policy for review.

AND

4. IF REQUESTED AGENT IS AN INFUSED PRODUCT WITH AN ORAL OR SELF- ADMINISTERED DOSAGE FORM AVAILABLE: Documentation that the member is unable to switch to oral dosage form, or self- administer  
AND

5. Documentation that the drug being requested is planned to be administered in the appropriate site of care- See Appendix for excerpt of the Molina Healthcare Site of Care Policy

## CONTINUATION OF THERAPY:

### A. ALL INDICATIONS:

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 as demonstrated by low disease activity and/or improvements in the condition's signs and symptoms  
AND
3. 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: Up to 6 months OR up to the limit of the appropriate FDA labeled course of treatment

Continuation of therapy: Up to 12 months OR up to the limit of the appropriate FDA labeled course of treatment

## Drug and Biologic Coverage Criteria

### 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, for a maximum of course of therapy or 30 days whichever is shorter or per J-code billing limits

### PLACE OF ADMINISTRATION:

**Note:** Site of Care Utilization Management Policy may apply. For information on site of care, see [Specialty Medication Administration Site of Care Coverage Criteria \(molinamarketplace.com\)](http://molinamarketplace.com)

## DRUG INFORMATION

### ROUTE OF ADMINISTRATION:

NA

### DRUG CLASS:

NA

### FDA-APPROVED USES:

NA

### COMPENDIAL APPROVED OFF-LABELED USES:

NA

## APPENDIX

### APPENDIX 1:

Molina Healthcare, Inc. covers injectable/infused treatment in a hospital outpatient setting or at a hospital-affiliated infusion suite\* when the level of care is determined to be medically necessary. Considerations used to determine if an alternative level of care is not suitable may include the following findings:

1. The member is clinically unstable based on documented medical history and susceptible to complication with drug administration (e.g., cardiopulmonary, or renal dysfunction, risk for fluid overload)
2. The requested medication is administered as part of a chemotherapy regimen (e.g., anti-neoplastic agent, colony stimulating factor, erythropoiesis-stimulating agent, anti-emetic) for treatment of cancer or with dialysis
3. The member exhibits physical or cognitive impairment, and a capable caregiver is not available to assist with safe administration of prescribed medication in the home
4. It is the member's first dose of the medication or it is being re-initiated after at least 12 months\*
5. The member has experienced adverse events with past administration of the drug and cannot be managed by premedication or resources available at a non-hospital facility- based location (NHFBL)
6. Documented history of difficulty establishing and maintaining patent vascular access, or is not a candidate for a mode of long-term vascular access during the duration of prescribed treatment

*Note: a hospital outpatient setting, or a hospital-affiliated infusion suite is expected to have immediate access to specific services of a medical center/hospital setting, including having emergency resuscitation equipment and personnel (ACLS protocol), emergency services, and inpatient admission or intensive care, if necessary.*

## BACKGROUND AND OTHER CONSIDERATIONS

### BACKGROUND:

### 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 drug FDA approved label

## REFERENCES

NA

SUMMARY OF REVIEW/REVISIONS	DATE
NEW CRITERIA CREATION	Q4 2025