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Next Review Due By: 10/2024
Policy Number: C11251-A

Physician Administered Drugs

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 Global Formulary Exception Criteria (step therapy, non-formulary, quantity limit, new-to-market, medical necessity, age limit, ALL oral products, etc.) OR State specific exception criteria

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.

A. FOR ALL FDA LABELED INDICATIONS:

Molina Reviewer Note: This criteria should only be used in the absence of Molina Healthcare Inc. Prior Authorization Criteria or Molina Clinical Policy (MCP) 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. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal
   AND
5. 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
6. 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. IF DRUG USED FOR CHRONIC CONDITION: Adherence to therapy at least 85% of the time as verified by Prescriber and member's medication fill history (review Rx history for compliance)
   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: 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

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)

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
NA

DRUG CLASS:
NA

FDA-APPROVED USES:
NA

COMPENDIAL APPROVED OFF-LABELED USES:
NA

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
Texas (Source: Texas Statutes, Insurance Code)
"Sec. 1369.654. PROHIBITION ON MULTIPLE PRIOR AUTHORIZATIONS.
(a) A health benefit plan issuer that provides prescription drug benefits *may not require an enrollee to receive more than one prior authorization annually* of the prescription drug benefit for *a prescription drug prescribed to treat an autoimmune disease, hemophilia, or Von Willebrand disease*.
(b) This section does not apply to:
(1) opioids, benzodiazepines, barbiturates, or carisoprodol;
(2) prescription drugs that have a typical treatment period of less than 12 months;
(3) drugs that:
(A) have a boxed warning assigned by the United States Food and Drug Administration for use; and
(B) must have specific provider assessment; or
(4) the use of a drug approved for use by the United States Food and Drug Administration in a manner other than the approved use."

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

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	NA

AVAILABLE DOSAGE FORMS:
See drug FDA approved label

REFERENCES

NA

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Diagnosis Required Medical Information Place of Administration	Q4 2023
REVISION- Notable revisions: Title Products Affected Route of Administration Drug Class FDA-Approved Uses Contraindications/Exclusions/Discontinuation	Q4 2022
Q2 2022 Established tracking in new format	Historical changes on file