Effective Date: 08/01/2017
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Next Review Due By: 10/2022
Policy Number: C11251-A

Global J Code Criteria

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 Exceptions criteria (step therapy, non- formulary, quantity limit, new-to-market, medical necessity, age limit, 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:
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

A. FOR ALL FDA LABELEDINDICATIONS
   1. Documentation of the following:
      (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 byinformation from the appropriate compendia of current literature (e.g., AHFS, Micromedex, current accepted guidelines, etc.) and recognized as a covered benefit bythe applicable health plan's program
AND

2. 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)
AND
3. IF REQUESTED AGENT IS AN INFUSED PRODUCT WITH AN ORAL OR SELF-ADMINISTERED DOSAGE FORM AVAILABLE: Documentation that the member is unableto switch to oral dosage form, or self- administered
AND
4. 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. Documentation member is demonstrating benefit from drug product and does not demonstrate toxicity

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:

No requirement

AGE RESTRICTIONS:

Per drug FDA label

QUANTITY:

Per FDA label for a maximum of course of therapy or 30 days whichever is shorter or per J-code billing limits

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.
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. For informationon site of care, see
Specialty Medication Administration Site of Care Coverage Criteria (molinamarketplace.com)

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Variable per drug

DRUG CLASS:
Variable per drug

FDA-APPROVED USES:
See drug FDA approved label

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

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 least12 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:
None

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
Per drug FDA label

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
Various	See PhysicianAdministered Medication List

AVAILABLE DOSAGE FORMS:
See drug FDA approved label

REFERENCES

NA