Original Effective Date: 10/2012
Current Effective Date: 03/08/2025
Last P&T Approval/Version: 01/29/2025
Next Review Due By: 01/2026
Policy Number: C8849-A

Xgeva (denosumab)

PRODUCTS AFFECTED

Xgeva (denosumab)

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:
Bone metastases from solid tumors, Giant cell tumor of bone, Hypercalcemia of malignancy, Multiple myeloma

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. HYPERCALCEMIA OF MALIGNANCY:
1. Documented diagnosis of hypercalcemia of malignancy, defined as albumin-corrected serum calcium level greater than 12.5 mg/dL (3.1 mmol/L) dated within the past 30 days

AND

2. Prescriber attestation of a trial and failure or labeled contraindication of Zometa (zoledronic acid SOLN 5MG/100ML) or pamidronate
   AND
3. Prescriber attests, or clinical reviewer has found, member is not on concurrent treatment with another RANKL-inhibitor [i.e., combination use of same active ingredient (Prolia)] OR intravenous bisphosphonates

B. GIANT CELL TUMOR OF BONE:
1. Documentation that member has a diagnosis of a giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity
   AND
2. FOR MEMBERS AGES 12-17 YEARS ONLY:
   a) Member weighs at least 45kg
      AND
   b) Member has documented skeletal maturity defined by at least 1 mature long bone (e.g., closed epiphyseal growth plate of the humerus)
   AND
3. Prescriber attestation that member has been counseled to concurrently take calcium (1000 mg) and vitamin D (400-1200 international units) supplements in conjunction with Xgeva (denosumab)
   AND
4. Prescriber attests, or clinical reviewer has found, member is not on concurrent treatment with another RANKL-inhibitor [i.e., combination use of same active ingredient (Prolia)] OR intravenous bisphosphonates

C. PREVENTION OF SKELETAL- RELATED EVENTS IN PATIENTS WITH MULTIPLE MYELOMA OR BONE METASTASES FROM SOLID TUMORS:
1. (a) Diagnosis of a solid tumor primary cancer (i.e., breast, bladder, kidney, ovarian, thyroid cancer etc.) AND evidence of ONE or more metastatic bone lesions.
   OR
   (b) Diagnosis of multiple myeloma
   AND
2. Prescriber attests, or clinical reviewer has found, member is not on concurrent treatment with another RANKL-inhibitor [i.e., combination use of same active ingredient (Prolia)] OR intravenous bisphosphonates
   AND
3. Prescriber attestation that member has been counseled to concurrently take calcium (1000 mg) and vitamin D (400-1200 international units) supplements in conjunction with Xgeva (denosumab)

CONTINUATION OF THERAPY:

A. HYPERCALCEMIA OF MALIGNANCY:
1. Documentation of positive response to therapy with objective improvement in symptoms defined as albumin-corrected serum calcium level of 12.5 mg/dL or less
   AND
2. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity

B. PREVENTION OF SKELETAL- RELATED EVENTS IN PATIENTS WITH MULTIPLE MYELOMA OR BONE METASTASES FROM SOLID TUMORS AND GIANT CELL TUMOR OF BONE:
1. Documented clinically significant improvements in the disease state, stability on the medication, or lack of disease progression
   AND
2. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity

DURATION OF APPROVAL:
Hypercalcemia of Malignancy: Initial authorization: 3 months, Continuation of therapy: 12 months
Giant cell tumor of bone, Multiple Myeloma and Bone Metastases from a Solid Tumor: Initial Authorization: 12 months, Continuation of therapy: 12 months

PRESCRIBER REQUIREMENTS:
Prescribed by, or in consultation with, a board-certified endocrinologist, oncologist, or other applicable specialist. [If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

AGE RESTRICTIONS:
GIANT CELL TUMOR OF BONE: 12 years of age and older
ALL OTHER INDICATIONS: 18 years of age and older

QUANTITY:
Hypercalcemia of malignancy: 120 mg every 4 weeks; during the first month, give an additional 120mg on days 8 and 15
Giant cell tumor of bone: 120 mg once every 4 weeks; during the first month, give an additional 120mg on days 8 and 15
Bone metastases from solid tumors: 120 mg every 4 weeks
Multiple myeloma: 120 mg every 4 weeks

PLACE OF ADMINISTRATION:
The recommendation is that 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.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Subcutaneous

DRUG CLASS:
RANK Ligand (RANKL) Inhibitors

FDA-APPROVED USES:
Indicated for prevention of skeletal-related events in patients with multiple myeloma and in patients with bone metastases from solid tumors, treatment of adults and skeletally mature adolescents with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity, treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy.

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:
None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
Xgeva, a receptor activator of nuclear factor kappa-B ligand (RANKL) inhibitor, is indicated for the prevention of skeletal related events in patients with multiple myeloma and in patients with bone metastases from solid tumors. Xgeva is also indicated for the treatment of adults and skeletally mature

adolescents with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity. Xgeva is also indicated for the treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy. Another injectable formulation of denosumab is available, Prolia®, but it is not included in this policy. The prescribing information for Xgeva notes that patients receiving Xgeva should not take Prolia. Xgeva is available as a single-use vial that contains 120 mg of denosumab per 1.7 mL (70 mg/mL).

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Xgeva (denosumab) are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. Contraindications to Xgeva (denosumab) include: hypocalcemia, known clinically significant hypersensitivity to Xgeva, pregnancy.

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
J0897	Injection, denosumab,1mg

AVAILABLE DOSAGE FORMS:
Xgeva SOLN 120MG/1.7ML single- dose vial

REFERENCES

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SUMMARY OF REVIEW/REVISIONS	DATE

REVISION- Notable revisions: Required Medical Information Continuation of Therapy References	Q1 2024
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Prescriber Requirements Age Restrictions Place of Administration FDA-Approved Uses Contraindications/Exclusions/Discontinuation References	Q1 2023
Q2 2022 Established tracking in new format	Historical changes on file