Xgeva® (denosumab)

Humana

Pharmacy Coverage Policy

Effective Date: January 01, 2024
Revision Date: September 25, 2024
Review Date: September 18, 2024
Line of Business: Medicaid - Louisiana
Policy Type: Prior Authorization

Products Affected
Xgeva subcutaneous solution

Listed Indications
Hypercalcemia of malignancy
Osteolytic Bone Metastases of Solid Tumors
Multiple Myeloma
Giant Cell Tumor of Bone

Hypercalcemia of malignancy	
Does the member meet all of the following criteria?	
Criteria #1	The member has hypercalcemia of malignancy, defined as an albumin-corrected calcium of greater than 12.5 mg/dL
Criteria #2	The member has had prior therapy, intolerance, or contraindication to intravenous bisphosphonate therapy (e.g., pamidronate or zoledronic acid)
Does the member have any of the following exclusions? If yes, approval may not be appropriate. NOTE: Experimental/Investigational Use – Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.	
Exclusion #1	Concurrent use of bisphosphonate therapy (e.g., zoledronic acid, pamidronate)
Approval Duration	
Initial	plan year duration
Renewal	plan year duration

Back to top

Osteolytic Bone Metastases of Solid Tumors	
Does the member meet all of the following criteria?	
Criteria #1	The member has a diagnosis of solid tumor cancer (such as breast cancer, prostate cancer, or other solid tumor)
Criteria #2	The member must have documented bone metastases
Criteria #3	The member has experienced disease progression, intolerance, or contraindication following treatment with pamidronate or zoledronic acid (disease progression, intolerance, or contraindication following treatment with pamidronate or zoledronic acid does not apply for prostate cancer requests)
Does the member have any of the following exclusions? If yes, approval may not be appropriate. NOTE: Experimental/Investigational Use – Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.	
Exclusion #1	Concurrent use of bisphosphonate therapy (e.g., zoledronic acid, pamidronate)
Approval Duration	
Initial	plan year duration
Renewal	plan year duration

Back to top

Multiple Myeloma

Does the member meet all of the following criteria?	
Criteria #1	The member has a diagnosis of multiple myeloma
Criteria #2	The member has experienced disease progression, intolerance, or contraindication following treatment with pamidronate or zoledronic acid
Does the member have any of the following exclusions? If yes, approval may not be appropriate. NOTE: Experimental/Investigational Use – Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.	
Exclusion #1	Concurrent use of bisphosphonate therapy (e.g., zoledronic acid, pamidronate)
Approval Duration	
Initial	plan year duration
Renewal	plan year duration

Back to top

Giant Cell Tumor of Bone

Does the member meet all of the following criteria?	
Criteria #1	The member has a diagnosis of giant cell tumor of bone
Does the member have any of the following exclusions? If yes, approval may not be appropriate. NOTE: Experimental/Investigational Use – Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.	
Exclusion #1	Concurrent use of bisphosphonate therapy (e.g., zoledronic acid, pamidronate)
Approval Duration	
Initial	plan year duration
Renewal	plan year duration

Back to top

Background

This is a prior authorization policy about Xgeva (denosumab).

Xgeva (denosumab) is a RANK ligand (RANKL) inhibitor. Denosumab (AMG-162) is a novel, fully human, highly specific, monoclonal antibody to receptor activator of nuclear factor kappa-beta ligand (RANKL). The antibody is produced in genetically engineered mammalian (Chinese hamster ovary) cells. Use blocks osteoclast activation, thereby resulting in a decreased bone resorption (less bone breakdown).

Contraindications:

- Hypocalcemia. Pre-existing hypocalcemia must be corrected prior to initiating therapy with Xgeva.

See prescribing information for full list of warnings and precautions.

Xgeva (denosumab) has been FDA approved for the prevention of skeletal-related events in members with multiple myeloma and bone metastases from solid tumors; 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; and the treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy.

Xgeva (denosumab) is available as a single-use vial containing 120 mg in 1.7 mL of solution.

Provider Claim Codes

For medically billed requests, please visit www.humana.com/PAL. Select applicable Preauthorization and Notification List(s) for medical and procedural coding information.

Medical Terms

Xgeva; denosumab; bone metastasis; solid tumors; hypercalcemia of malignancy; multiple myeloma; subcutaneous; pharmacy.

References

1. Clinical Pharmacology powered by ClinicalKey [database online]. Elsevier, Philadelphia, PA. Available at: http://www.clinicalkey.com. (Updated Periodically).
2. Lexi-Comp [database online]. Hudson, OH Lexi-comp, Inc.: URL http://online.lexi.com Updated periodically.
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5. Xgeva (denosumab) [package insert]. Amgen Inc. Thousand Oaks, CA. June 2020.

Disclaimer	State and federal law, as well as contract language, including definitions and specific inclusions/exclusions, take precedence over clinical policy and must be considered first in determining eligibility for coverage. Coverage may also differ for our Medicare and/or Medicaid members based on any applicable Centers for Medicare & Medicaid Services (CMS) coverage statements including National Coverage Determinations (NCD), Local Medical Review Policies (LMRP) and/or Local Coverage Determinations. See the CMS website at http://www.cms.hhs.gov/. The member's health plan benefits in effect on the date services are rendered must be used. Clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Clinical technology is constantly evolving, and we reserve the right to review and update this policy periodically.