OncoHealth

Xgeva (denosumab)

Effective Date: 8/1/2022
Revision Date(s): 10/04/2021
Review Date: 05/02/2022
Policy type: Medical Necessity

Approval Criteria

Authorizations are for 12 months, after which time they may be reviewed for efficacy, safety, and tolerability.

Coverage is provided for the following conditions:

Universal Criteria Applied to All Requests

- Administration and monitoring of calcium and vitamin D as needed to treat or prevent hypocalcemia.
- Denosumab may not be administered concurrently with bisphosphonate therapy.
- Dose and frequency should be consistent with FDA labeling, NCCN, or indication specific peer-reviewed literature

Indication Specific Criteria

Bone metastases from solid tumors

Prevention of skeletal-related events in patients with Multiple Myeloma

Giant cell tumor of bone

Hypercalcemia of malignancy

- The patient has hypercalcemia of malignancy, defined as an albumin-corrected[1] calcium level of greater than 12.5 mg/dL **AND**
- Prior therapy refractory treatment to bisphosphonate therapy, unless not tolerated or contraindicated.

Systemic Mastocytosis

- Osteopenia or osteoporosis with documented bone pain

[1] Albumin corrected calcium level = serum calcium + 0.8 * (4 - serum albumin)

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Billing

Drug Name	HCPCS Code	Description
Xgeva	J0897	inj., denosumab, 120 mg

References

1. Xgeva® [package insert]. Amgen, Inc., Thousand Oaks, CA. Available at: https://www.pi.amgen.com/~/media/amgen/repositorysites/pi-amgen-com/xgeva/xgeva_pi.pdf
2. Denosumab (Xgeva®). NCCN Drugs & Biologics Compendium. Available at: https://www.nccn.org/professionals/drug_compendium/content/
3. NCCN Clinical Practice Guidelines in Oncology. Available at: https://www.nccn.org/professionals/physician_gls/default.aspx
4. Fizazi K, Carducci M, Smith M, et al. Denosumab versus zoledronic acid for treatment of bone metastases in men with castration-resistant prostate cancer: A randomised, double-blind study. Lancet. 2011 Mar;377(9768):813-822. doi: 10.1016/s0140-6736(10)62344-6.
5. Henry DH, Costa L, Goldwasser F, et al. Randomized, double-blind study of denosumab versus zoledronic acid in the treatment of bone metastases in patients with advanced cancer (excluding breast and prostate cancer) or multiple myeloma. J Clin Oncol. 2011;29:1125-1132. doi: 10.1200/jco.2010.31.3304.
6. Hu MI, Glezerman IG, Leboulleux S, et al. Denosumab for treatment of hypercalcemia of malignancy. J Clin Endocrinol Metab. 2014 Sep;99(9):3144–3152. doi: 10.1210/jc.2014-1001.
7. Raje N, Terpos E, Willenbacher W, et al. Denosumab versus zoledronic acid in bone disease treatment of newly diagnosed multiple myeloma: an international, double-blind, double-dummy, randomised, controlled, phase 3 study. Lancet Oncol. 2018 Mar;19:370–381. doi: 10.1016/s1470-2045(18)30072-x.
8. Stopeck AT, Lipton A, Body JJ, et al. Denosumab compared with zoledronic acid for the treatment of bone metastases in patients with advanced breast cancer: A randomized, double-blind study. J Clin Oncol. 2010;28(35):5132-5139. doi: 10.1200/jco.2010.29.7101.
9. Thomas D, Henshaw R, Skubitz K, et al. Denosumab in patients with giant-cell tumour of bone: an open-label, phase 2 study. Lancet Oncol. 2010 Mar;11:275-80. doi: 10.1016/s1470-2045(10)70010-3.

Disclaimer

Consideration of medically necessary indications are based upon U.S. Food and Drug Administration (FDA) indications, recommended uses within the Centers of Medicare & Medicaid Services (CMS) five recognized compendia, including the National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium (Category 1 or 2A recommendations), and peer-reviewed scientific literature eligible for coverage according to the CMS, Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 titled, "Off-Label Use of Anti-Cancer Drugs and Biologics." This policy evaluates whether the drug therapy is proven to be effective based on published evidence-based medicine. OncoHealth reserves the right to request medical documentation as needed to validate medical necessity determinations.

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