



RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Xgeva is indicated for the prevention of skeletal-related events in patients with multiple myeloma and in patients with bone metastases from solid tumors and for treatment of giant cell tumor of bone. Xgeva binds to the protein essential for the formation, function, and survival of osteoclasts, the cells responsible for bone resorption. Increased osteoclast activity is a mediator of solid tumor bone metastases. Similarly, giant cell tumors of bone and osteoclast-like giant cells contribute to osteolysis and [bone] tumor growth. Xgeva prevents activation of osteoclasts, their precursors, and osteoclast-like giant cells (1).

Regulatory Status

FDA-approved indications: Xgeva is a RANK ligand (RANKL) inhibitor indicated for: (1)

- 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
- Hypercalcemia of malignancy refractory to bisphosphonate therapy

Xgeva is contraindicated in patients with hypocalcemia. Pre-existing hypocalcemia must be corrected prior to initiating therapy with Xgeva (1).

Xgeva may increase risks for osteonecrosis of the jaw, hypocalcemia, and atypical femoral fracture (1).

Summary

Xgeva an osteoclast inhibitor is used to treat complications of bone metastases in patients with multiple myeloma and in patients with solid tumor cancers, for treatment of giant cell tumor of bone and for hypercalcemia of malignancy refractory to bisphosphonate therapy. Xgeva may increase risks for osteonecrosis of the jaw, hypocalcemia, and atypical femoral fracture. The safety and efficacy of Xgeva have not been established in pediatric patients except in skeletally mature adolescents with giant cell tumor of bone (1).

Prior authorization is required to ensure the safe, clinically appropriate and cost-effective use of



**BlueCross.
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Federal Employee Program.

XGEVA
(denosumab)

Xgeva while maintaining optimal therapeutic outcomes.

References

1. Xgeva [package insert]. Thousand Oaks, CA: Amgen Inc.; June 2020.