BlueCross BlueShield Federal Employee Program

PROLIA (denosumab)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Prolia is used to treat osteoporosis in women after menopause who are at high risk for fracture (broken bone) and cannot use another osteoporosis medicine or other osteoporosis medicines did not work well. Prolia may also be used to increase bone mass in men with osteoporosis who are at high risk for fracture; treat bone loss in men who are at high risk for fracture receiving certain treatments for prostate cancer that has not spread to other parts of the body; and treat bone loss in women who are at high risk for fracture receiving certain treatments for breast cancer that has not spread to other parts of the body. Additionally, Prolia is used to treat glucocorticoid-induced osteoporosis in men and women at high risk for fracture (1).

Regulatory Status

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

- Treatment of postmenopausal women with osteoporosis at high risk for fracture
- Treatment to increase bone mass in men with osteoporosis at high risk for fracture
- Treatment of glucocorticoid-induced osteoporosis in men and women at high risk for fracture
- Treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for non-metastatic prostate cancer
- Treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer

Prolia carries a boxed warning for severe hypocalcemia in patients with advanced kidney disease. The presence of chronic kidney disease-mineral bone disorder (CKD-MBD) markedly increases the risk of hypocalcemia. Prior to initiation of treatment, the presence of CKD-MBD should be determined and treatment should be supervised by a healthcare professional with expertise in the diagnosis and management of CKD-MBD (1).

Pre-existing hypocalcemia must be corrected prior to initiating therapy with Prolia and patients must adequately supplement with calcium and vitamin D (1).

Prolia may cause fetal harm when administered to a pregnant woman. Prolia is contraindicated in women who are pregnant. If this drug is used during pregnancy, or if the patient becomes pregnant

while taking this drug, the patient should be apprised of the potential hazard to a fetus (1).

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

The safety and effectiveness of Prolia in pediatric patients has not been established (1).

Summary

Prolia is an osteoclast inhibitor used to treat osteoporosis, breast cancer in female patients receiving aromatase-inhibitor therapy, or non-metastatic prostate cancer in male patients receiving androgen deprivation therapy and who are at high risk of bone fractures and not receiving Xgeva. It may increase risks for osteonecrosis of the jaw, hypocalcemia, and atypical femoral fracture. The safety and effectiveness of Prolia in pediatric patients has not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Prolia while maintaining optimal therapeutic outcomes.

References

1. Prolia [package insert]. Thousand Oaks, CA: Amgen Inc.; March 2024.