Medical Coverage Policy | Prolia® and Xgeva® (denosumab)

EFFECTIVE DATE: 07|16|2019
POLICY LAST UPDATED: 07|16|2019

OVERVIEW

Denosumab is a receptor activator of nuclear factor kappa-B ligand (RANKL) inhibitor. Binding to the transmembrane or soluble protein RANKL inhibits the formation, function, and survival of osteoclasts resulting in decreased bone resorption and increased bone mass and strength.

This policy is applicable to BlueCHiP for Medicare products only. For Commercial Products, see related policy section.

MEDICAL CRITERIA

Denosumab (Prolia®) is indicated for the treatment of individuals with any of the following:

- Postmenopausal women with osteoporosis at high risk* for fracture,
  *defined as a history of osteoporotic fracture, or multiple risk factors for fractures;
- Postmenopausal women with osteoporosis who have failed or are intolerant to other available osteoporosis therapy.
- Patients with significant renal failure where treatment with biphosphonate is not indicated, CrCl less than 35 ml/min.
- To increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer. In these patients Prolia® also reduced the incidence of vertebral fractures.
- To increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer.
- To increase bone mass in men with osteoporosis at high risk for fracture defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy.
- Glucocorticoid-induced osteoporosis in men and women at high risk of fracture who are either initiating or continuing systemic glucocorticoids in a daily dosage equivalent to 7.5 mg or greater of prednisone and expected to remain on glucocorticoids for at least 6 months

Prolia® is contraindicated in patients with hypocalcemia.

Denosumab (Xgeva®) is indicated for the treatment of individuals with any of the following:

- Bone metastases from solid tumors.
- 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
- Treatment of skeletal-related events in patients with multiple myeloma

PRIOR AUTHORIZATION

Prior authorization is required for BlueCHiP for Medicare

POLICY STATEMENT

BlueCHiP for Medicare

Prolia® and Xgeva® (denosumab) is covered when the medical criteria for each indication above are met.

COVERAGE

Benefits may vary between groups/contracts. Please refer to the Evidence of Coverage for applicable physician administered drug benefits.

BACKGROUND

Denosumab is a fully human monoclonal antibody that specifically binds to and inhibits the receptor activator of NF-kappaB ligand (RANK Ligand), the primary mediator of bone resorption. RANK Ligand is the protein responsible for activating osteoclasts, the cells that break down bone. An increased amount of the protein has been linked as the primary cause of a broad range of bone loss conditions including osteoporosis, treatment-induced bone loss, bone erosions, and bone metastases.

In June 2010 the U.S. Food and Drug Administration (FDA) approved denosumab (Prolia®) for the treatment of postmenopausal women with osteoporosis at high risk for fracture. In November 2010 the FDA approved the same drug, denosumab (Xgeva®) in a higher dose for the prevention of skeletal-related events in patients with bone metastases from solid tumors. In September 2011 the FDA also approved denosumab for the treatment of bone loss in patients with non-metastatic prostate or breast cancer. In September 2012 denosumab (Prolia®) was approved by the FDA as a treatment of bone loss in men with osteoporosis at high-risk for fracture. They were given distinct trade names in order to differentiate between their unique dosing schedules and indications for use. The two are the same drug, but they have different clinical indications for use and dosing.

Documentation Requirements:

The patient's medical record should contain documentation that fully supports the medical necessity for the administration of either formulation. Requirements specific to each formulation are as follows:

Denosumab (Prolia®)
For postmenopausal osteoporosis at high risk for fracture, documentation should include but is not limited to:

1. Menopausal status (for female beneficiaries only)
2. Patients age and sex.
3. Documentation supporting the diagnosis of osteoporosis.
4. Previous treatment of osteoporosis, agents used, outcomes and adverse reactions if any.
5. History of previous fractures, including type of fracture, cause and time since occurrence
6. Risk factors for future fracture including preventive measures.

For the treatment of cancer treatment-induced bone loss (CTIBL) due to hormone ablation such documentation should include, but is not limited to:

1. Documentation supporting the diagnosis of breast cancer or nonmetastatic prostate cancer.
2. Use of adjuvant aromatase inhibitor (AI) therapy or androgen deprivation therapy (ADT).
3. Additional diagnosed risk factors, if any.

Denosumab (Xgeva®)

Documentation should include, but is not limited to:
For treatment of bone metastasis from a solid tumor:

1. Adequate calcium levels
2. Use of Vitamin D if indicated

CODING

BlueCHiP for Medicare

The following HCPCS code is covered when the medical criteria are met:
J0897 Injection, denosumab, 1mg

RELATED POLICIES
Prior Authorization of Drugs

PUBLISHED
Provider Update, September 2019
Provider Update, June 2018
Provider Update, February 2018
Provider Update, January 2017
Provider Update, December 2015

REFERENCES
1. CMS.gov Centers for Medicare and Medicaid Services Local Coverage Article: Denosumab (Prolia ™, Xgeva ™) - Related to LCD L33394 (A52399)