Medical Coverage Policy

Denosumab for Preservation of Bone Health in Patients with Certain Malignancies-PREAUTH

☐ Device/Equipment  ☒ Drug  ☐ Medical  ☐ Surgery  ☐ Test  ☐ Other

Effective Date:  5/23/2011  Policy Last Updated:  2/7/2012

☒ Prospective review is recommended/required. Please check the member agreement for preauthorization guidelines.

☐ Prospective review is not required.

Note: The following policy addresses the use of denosumab to increase bone mass in individuals with breast and prostate cancer who are at high risk for fracture and to prevent skeletal related events in members with bone metastases. Denosumab used in the treatment of postmenopausal women with osteoporosis at high risk for fractures see Denosumab (Prolia) for Postmenopausal Osteoporosis policy.

Description:

Denosumab (Xgeva, Prolia) is a RANK ligand (RANKL) inhibitor that decreases bone resorption and increases bone mineral density (BMD). It is indicated for the prevention of skeletal related events (SREs) in patients with breast cancer, prostate cancer and other solid tumors. Denosumab is not indicated for the prevention of SREs in patients with multiple myeloma.

Denosumab can cause severe hypocalcemia. Prior to denosumab treatment pre-existing hypocalcemia should be corrected. Calcium levels should be monitored and calcium, magnesium, and vitamin D should be administered as necessary. Levels should be monitored more frequently when denosumab is administered with other drugs that can also lower calcium levels. Patients should contact a healthcare professional for symptoms of hypocalcemia. Calcium and vitamin D should be administered as necessary to treat or prevent hypocalcemia.

Osteonecrosis of the jaw (ONJ) can occur in patients receiving denosumab, manifesting as jaw pain, osteomyelitis, osteitis, bone erosion, tooth or periodontal infection, toothache, gingival ulceration, or gingival erosion. Persistent pain or slow healing of the mouth or jaw following dental surgery may also be manifestations of ONJ. It is recommended that an oral examination and appropriate preventive dentistry prior to the initiation of denosumab be performed and periodically during denosumab therapy. Patient should be advised regarding oral hygiene practices. Invasive dental procedures should be avoided during treatment with denosumab. Individuals who are suspected of having or who develop ONJ while on denosumab should receive care by a dentist or an oral surgeon. In these patients, extensive dental surgery to treat ONJ may exacerbate the condition.
Medical Criteria:

All BCBSRI Products

- Denosumab is considered medically necessary for patients with bone metastases from a solid tumor cancer when the criteria below is met:
  - Does not have multiple myeloma; **AND**
  - Does not have pre-existing hypocalcemia; **OR**
  - Will have hypocalcemia corrected prior to starting Xgeva; **AND**
  - Will receive calcium and vitamin D as needed to prevent hypocalcemia.

- Denosumab is considered medically necessary for the following medical conditions:

  **Women diagnosed with breast cancer; AND**
  - At high risk of fracture defined as a history of osteoporotic fracture or multiple risk factors for fracture; **AND**
  - Are receiving adjuvant aromatase inhibitor therapy; **OR**

  **Men diagnosed with nonmetastatic prostate cancer; AND**
  - At high risk of fracture defined as a history of osteoporotic fracture or multiple risk factors for fracture; **AND**
  - Are receiving androgen deprivation therapy.

**AND**

The following additional requirements must be met for patients with breast cancer or prostate cancer:

- Do not have multiple myeloma; **AND**
- Do not have uncorrected hypocalcemia; **OR**
- Will receive calcium and vitamin D as needed to prevent hypocalcemia; **AND**
- Have tried an oral or intravenous bisphosphonate; **AND**
- Have been diagnosed with an esophageal stricture, achalasia, or other severe esophageal dysmotility condition; **OR**
- Are unable to stand or sit upright for 60 minutes; **OR**
- Have a history of severe malabsorption making the use of oral bisphosphonates ineffective; **OR**
- Have renal impairment with CrCL <30mL/min; **OR**
- Have an inadequate response to at least one oral bisphosphonate while being compliant with oral bisphosphonate therapy for at least 1 year and has received adequate calcium and vitamin D supplementation while on an oral bisphosphonate who:
  - Had an osteoporosis related fracture while on an oral bisphosphonate; **OR**
  - Have a significant decline in bone mineral density (BMD) while on an oral bisphosphonate.

The recommended dosage for Xgeva for bone metastases is 120 mg every 4 weeks given as a subcutaneous injection. The recommended dosage for Prolia for osteoporosis and breast cancer or prostate cancer is 60mg every 6 months.
Policy:

Preauthorization is required for BlueCHIP for Medicare and recommended for all other BCBSRI products.

Treatment with denosumab is considered medically necessary when the medical criteria have been met.

Coverage:

Benefits may vary between groups/contracts. Please refer to the appropriate Evidence of Coverage or Subscriber Agreement for the applicable Specialty Pharmacy guidelines.

Coding:

J0897 injection, denosumab

Related topics:

Denosumab (Prolia) for Postmenopausal Osteoporosis

Published:

Provider Update, August 2011
Provider Update, April 2012

References:

Caremark, Specialty Guideline Management: Prolia (denosumab)

CMS Manual System, Pub 100-04 Medicare Claims Processing, Transmittal 2378, Date: December 29, 2011

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