Medical Coverage Policy

Denosumab (Prolia) for Postmenopausal Osteoporosis-PREAUTH

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

Effective Date:	12/7/2010	Policy Last Updated:	10/4/2011

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

☐ **Prospective review is not required.**

NOTE: Prolia is the same drug as Xgeva. Xgeva is used for different indications. See policy "Denosumab (XGEVA™) for Prevention of Skeletal-Related Events in Patients with Bone Metastases from Solid Tumor."

Description:

Denosumab is a fully human monoclonal antibody that specifically binds RANKL, blocks the binding of RANKL to RANK and thereby reduces the formation, function and survival of osteoclasts, which results in decreased bone resorption and increased bone density.

The US Food and Drug Administration (FDA) approved denosumab (Prolia™) for the initial treatment of postmenopausal women with osteoporosis (T-score below -2.5) 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 of other available osteoporosis therapies. The recommended dosage is a single 60 mg subcutaneous injection given once every six (6) months. The most common adverse effects reported with denosumab include back pain, high cholesterol levels, musculoskeletal pain, pain in the extremities, and urinary bladder infections. Serious adverse effects include hypocalcemia*, serious infections, including infections of the skin, as well as dermatological reactions such as dermatitis, eczema, and rashes.

* Pre-existing hypocalcemia must be corrected prior to initiating therapy with Prolia. Hypocalcemia is a serious risk in patients with severe renal impairment (creatinine clearance < 30 mL/min), or receiving dialysis. Calcium levels must be maintained with adequate calcium and vitamin D supplementation.

Medical Criteria:

Denosumab is considered medically necessary for the treatment of osteoporosis in post-menopausal women who do not have uncorrected hypocalcemia and whose vitamin D status has been evaluated and corrected while receiving an adequate intake of supplemental calcium and vitamin D that:

- 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**
- Are unable to tolerate at least 2 different oral bisphosphonates; **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.

Denosumab is considered **not medically necessary** for all other indications not listed above.

Policy:

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

Denosumab is considered medically necessary when the medical criteria listed above are 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.

Specialty Pharmacy:
For contracts with specialty drug coverage, please refer to the member agreement for benefits and preauthorization guidelines.

Coding:

Providers should file HCPCS J3490 or J9999 for unclassified drug along with the NDC#.
NDC 55513071001 [PROLIA SOL 60MG/ML - AMGEN]

Related Topics:
Denosumab (XGEVA™) for Prevention of Skeletal-Related Events in Patients with Bone Metastases from Solid Tumor

Published:
Provider Update, February 2011
Provider Update, December 2011

References:

CVS CAREMARK SPECIALTY GUIDELINE MANAGEMENT BCBSRI: Prolia™ (denosumab) 07/2011

and eligibility are determined by the member's subscriber agreement or member certificate and/or the employer agreement, and those documents will supersede the provisions of this medical policy. For information on member-specific benefits, call the provider call center. If you provide services to a member which are determined to not be medically necessary (or in some cases medically necessary services which are non-covered benefits), you may not charge the member for the services unless you have informed the member and they have agreed in writing in advance to continue with the treatment at their own expense. Please refer to your participation agreement(s) for the applicable provisions. This policy is current at the time of publication; however, medical practices, technology, and knowledge are constantly changing. BCBSRI reserves the right to review and revise this policy for any reason and at any time, with or without notice.