Prolia (denosumab)

Line(s) of Business: HMO; PPO; QUEST Integration
Medicare Advantage

Original Effective Date: 10/01/2015
Current Effective Date: 02/01/2018

POLICY
A. INDICATIONS
The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications
- 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 to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy (ADT) for nonmetastatic prostate cancer
- Treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer

Compendial Uses
- Prostate cancer: prevention or treatment of osteoporosis during androgen deprivation therapy for patients with high fracture risk
- Breast cancer: consider in postmenopausal women (natural or induced) receiving adjuvant endocrine therapy along with calcium and vitamin D supplementation to maintain or improve bone mineral density and reduce risk of fractures

B. REQUIRED DOCUMENTATION
The following information may be necessary to initiate the prior authorization review (where applicable):
- Osteoporosis in postmenopausal women:
  - Documentation of oral bisphosphonate 1-year trial from member’s chart notes
  - Documentation of pre-treatment T-score
- Osteoporosis in men:
  - Documentation of oral bisphosphonate 1-year trial from member’s chart notes
  - Documentation of pre-treatment T-score
C. CRITERIA FOR INITIAL APPROVAL

1. Osteoporosis in Postmenopausal Women
   Indefinite authorization may be granted to postmenopausal female members who are prescribed Prolia for osteoporosis when ALL of the following criteria are met:
   a. Member has had an oral bisphosphonate trial of at least 1-year duration OR there is a clinical reason to avoid treatment with an oral bisphosphonate (See Appendix A)
   b. Member meets ANY of the following criteria:
      i. Member has a history of vertebral or hip fracture
      ii. Member has a pre-treatment T-score of < -2.5 at the femoral neck, total hip or lumbar spine by dual-energy x-ray absorptiometry (DEXA) scan
      iii. Member has a pre-treatment T-score of ≤ -1 but > -2.5 at the femoral neck, total hip or lumbar spine by dual-energy x-ray absorptiometry (DEXA) scan AND either of the following:
          1) Pre-treatment FRAX score of ≥ 20% for any major osteoporosis-related fracture
          2) Pre-treatment FRAX score of ≥ 3% for hip fracture

2. Osteoporosis in Men
   Indefinite authorization may be granted to male members who are prescribed Prolia for osteoporosis when ALL of the following criteria are met:
   a. Member has had an oral bisphosphonate trial of at least 1-year duration OR there is a clinical reason to avoid treatment with an oral bisphosphonate (See Appendix A)
   b. Member meets ANY of the following criteria:
      i. Member has a history of vertebral or hip fracture
      ii. Member has a pre-treatment T-score of ≤ -2.5 at the femoral neck, total hip or lumbar spine by dual-energy x-ray absorptiometry (DEXA) scan
      iii. Member has a pre-treatment T-score of ≤ -1 but > -2.5 at the femoral neck, total hip or lumbar spine by dual-energy x-ray absorptiometry (DEXA) scan AND either of the following:
          1) Pre-treatment FRAX score of ≥ 20% for any major fracture
          2) Pre-treatment FRAX score of ≥ 3% for hip fracture

3. Breast Cancer
   Authorization of 24 months may be granted to members who are prescribed Prolia and who are receiving adjuvant aromatase inhibitor therapy for breast cancer.

4. Prostate Cancer
   Authorization of 24 months may be granted to members who are prescribed Prolia and who are receiving androgen deprivation therapy for prostate cancer.

D. CONTINUATION OF THERAPY
   For postmenopausal women or for men with osteoporosis continuing with Prolia therapy, indefinite authorization may be granted if they meet the criteria for initial approval in section C.1.b or C.2.b.

   For breast or prostate cancer, all members (including new members and members current receiving treatment without prior authorization) continuing with Prolia therapy must meet criteria for initial approval in section C. above.
E. **DOSAGE AND ADMINISTRATION**

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

F. **APPENDIX**

Appendix A. Clinical reasons to avoid oral bisphosphonate therapy
- Esophageal abnormality that delays emptying such as stricture of achalasia
- Active upper gastrointestinal problem (eg, dysphagia, gastritis, duodenitis, erosive esophagitis, ulcers)
- Inability to stand or sit upright for at least 30 to 60 minutes
- Renal insufficiency (creatinine clearance <30 mL/min)

Appendix B. *WHO Fracture Risk Assessment Tool*
10-year probability of major osteoporotic fracture; calculation tool available at: [http://www.shef.ac.uk/FRAX/tool.jsp](http://www.shef.ac.uk/FRAX/tool.jsp)

G. **ADMINISTRATIVE GUIDELINES**

Prior authorization is required. Please refer to the [HMSA medical policy web site](http://www.hmsa.com) for the fax form.

H. **IMPORTANT REMINDER**

The purpose of this Medical Policy is to provide a guide to coverage. This Medical Policy is not intended to dictate to providers how to practice medicine. Nothing in this Medical Policy is intended to discourage or prohibit providing other medical advice or treatment deemed appropriate by the treating physician.

Benefit determinations are subject to applicable member contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

This Medical Policy has been developed through consideration of the medical necessity criteria under Hawaii’s Patients’ Bill of Rights and Responsibilities Act (Hawaii Revised Statutes §432E-1.4), generally accepted standards of medical practice and review of medical literature and government approval status. HMSA has determined that services not covered under this Medical Policy will not be medically necessary under Hawaii law in most cases. If a treating physician disagrees with HMSA’s determination as to medical necessity in a given case, the physician may request that CVS/caremark reconsider the application of the medical necessity criteria to the case at issue in light of any supporting documentation.

I. **REFERENCES**


8. FRAX® WHO fracture risk assessment tool. © World Health Organization Collaborating Centre for Metabolic Bone Diseases: University of Sheffield, UK. Available at: [http://www.shef.ac.uk/FRAX](http://www.shef.ac.uk/FRAX).

**Document History**

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