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
- Prevention or treatment of osteoporosis during androgen deprivation therapy for patients with high fracture risk

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 an osteoporotic vertebral or hip fracture
ii. Member has a pre-treatment T-score of $<-2.5$
iii. Member has a pre-treatment T-score of $<-1$ but $>-2.5$ AND either of the following:
   1) Pre-treatment FRAX score of $\geq 20\%$ for any major osteoporosis-related fracture
   2) Pre-treatment FRAX score of $\geq 3\%$ 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 an osteoporotic vertebral or hip fracture
      ii. Member has a pre-treatment T-score of $<-2.5$
      iii. Member has a pre-treatment T-score of $<-1$ but $>-2.5$ AND either of the following:
          1) Pre-treatment FRAX score of $\geq 20\%$ for any major fracture
          2) Pre-treatment FRAX score of $\geq 3\%$ 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.

   For breast or prostate cancer, all members (including new members) 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
   - Inability to take at least 30 to 60 minutes before first food, drink, or medication of the day
   - 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

G. 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.

H. REFERENCES
   medical guidelines for clinical practice for the diagnosis and treatment of postmenopausal
   2014.
8. Treatment to prevent osteoporotic fractures: an update. Department of Health and Human Services,
   Agency for Healthcare Research and Quality. 2012; Publication No. 12-EHC023-EF. Available at
10. 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.

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