CareFirst Family of health care plans

CVS caremark™

SPECIALTY GUIDELINE MANAGEMENT

PROLIA (denosumab)

POLICY

I. 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.

A. FDA-Approved Indications
1. Treatment of postmenopausal women with osteoporosis at high risk for fracture
2. Treatment to increase bone mass in men with osteoporosis at high risk for fracture
3. Treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy (ADT) for non-metastatic prostate cancer
4. Treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer

B. Compendial Uses
Prevention or treatment of osteoporosis during androgen deprivation therapy for patients with high fracture risk

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

A. Osteoporosis in Postmenopausal Women
Authorization of 24 months may be granted to postmenopausal female members when ANY of the following criteria are met:
1. Member has a history of fragility fractures
2. Member has a pre-treatment T-score of ≤ -2.5 OR member has osteopenia with a high pre-treatment FRAX fracture probability (See Appendix B) and meets ANY of the following criteria:
   a. Member has indicators of higher fracture risk (e.g., advanced age, frailty, glucocorticoid use, very low T-scores, or increased fall risk)
   b. Member has failed prior treatment with or is intolerant to previous injectable osteoporosis therapy (e.g., zoledronic acid [Reclast], teriparatide [Forteo])
   c. 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. Osteoporosis in Men
Authorization of 24 months may be granted to male members with osteoporosis when ANY of the following criteria are met:
1. Member has a history of an osteoporotic vertebral or hip fracture
2. Member has a pre-treatment T-score of ≤ -2.5
3. Member has osteopenia with a high pre-treatment FRAX fracture probability (See Appendix B)

C. Breast Cancer

Authorization of 24 months may be granted to members who are receiving adjuvant aromatase inhibitor therapy for breast cancer.

D. Prostate Cancer

Authorization of 24 months may be granted to members who are receiving androgen deprivation therapy for prostate cancer.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

IV. APPENDIX

Appendix A. Clinical reasons to avoid oral bisphosphonate therapy

- Esophageal abnormality that delays emptying such as stricture of achalasia
- Active upper gastrointestinal problem (e.g., 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 <35 mL/min)
- History of intolerance to an oral bisphosphonate

Appendix B. WHO Fracture Risk Assessment Tool

- High FRAX fracture probability: 10 year major osteoporotic fracture risk ≥ 20% or hip fracture risk ≥ 3%.
- 10-year probability; calculation tool available at: http://www.shef.ac.uk/FRAX/tool.jsp

V. REFERENCES

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