Reference number(s)
2390-A

STANDARD MEDICARE PART B 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 of men and women with glucocorticoid-induced osteoporosis at high risk for fracture
4. Treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer
5. Treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer

B. Compendial Uses
1. Prevention of osteoporosis in osteopenic postmenopausal women
2. Prevention or treatment of osteoporosis during androgen deprivation therapy for prostate cancer in patients with high fracture risk
3. Consider in postmenopausal (natural or induced) patients receiving adjuvant endocrine therapy along with calcium and vitamin D supplementation to maintain or improve bone mineral density and reduce risk of fractures

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. CRITERIA FOR INITIAL APPROVAL

A. Osteoporosis treatment
Authorization of 12 months may be granted for the treatment of osteoporosis in men or postmenopausal women at high risk for fracture.

B. Osteoporosis prevention
Authorization of 12 months may be granted for the prevention of osteoporosis in osteopenic postmenopausal women.

C. Increasing bone mass in prostate cancer

Authorization of 12 months may be granted to increase bone mass in men at high risk for fracture who are receiving androgen deprivation therapy for prostate cancer.

D. Increasing bone mass in breast cancer
Authorization of 12 months may be granted to increase bone mass in women at high risk for fracture who are receiving endocrine therapy for breast cancer.

E. Treatment of men and women with glucocorticoid-induced osteoporosis at high risk for fracture
Authorization of 12 months may be granted to increase bone mass in men and women with glucocorticoid-induced osteoporosis at high risk for fracture.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 months may be granted when all of the following criteria are met:
A. The member is currently receiving therapy with Prolia
B. The member is receiving the requested medication for an indication listed in Section II
C. The medication has been effective for treating the diagnosis or condition

IV. REFERENCES

1. Prolia [package insert]. Thousand Oaks, CA: Amgen Inc.; March 2020.
2. Micromedex® (electronic version). IBM Watson Health, Greenwood Village, Colorado. Available at https://www.micromedexsolutions.com Accessed October 19, 2020.
3. The NCCN Drugs & Biologics Compendium™ © 2020 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed October 19, 2020.