Prolia (denosumab)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Prolia (denosumab)	May be subject to quantity limit

APPROVAL CRITERIA

Initial requests for Prolia (denosumab) may be approved when the following criteria are met:

I. Individual is 18 years of age or older;

AND

II. Individual is a male or postmenopausal female with a diagnosis of osteoporosis (defined as a bone mineral density (BMD) T-score in the spine, femoral neck, total hip or distal 1/3 of the radius of less than or equal to -2.5 as compared to a young-adult reference population OR a clinical diagnosis based on history of a low trauma fracture (fragility fracture)); **AND**

III. Individual has had at least one osteoporotic (minimal trauma) fracture; **OR**

IV. Individual has two or more risk factors for osteoporotic fracture; **OR**

V. Individual has failed, is intolerant to or has a medical contraindication to other available osteoporosis therapies (for example, bisphosphonates);

OR

VI. Individual has glucocorticoid-induced osteoporosis (defined as a bone mineral density (BMD) T-score in the spine, femoral neck, total hip or distal 1/3 of the radius of less than or equal to -2.5 as compared to a young-adult reference population OR a clinical diagnosis based on history of a low trauma fracture (fragility fracture)) and is initiating or continuing systemic glucocorticoids in a daily dosage equivalent to 7.5mg or greater of prednisone and expected to remain on glucocorticoids for at least 6 months;
AND

VII. Individual has had at least one osteoporotic (minimal trauma) fracture; **OR**

VIII. Individual has two or more risk factors for osteoporotic fracture; **OR**

IX. Individual has failed, is intolerant to or has a medical contraindication other available osteoporosis therapies (e.g. bisphosphonates);

OR

X. Individual is a postmenopausal (natural or induced) female receiving adjuvant aromatase inhibitor therapy for treatment of breast cancer;

OR

XI. Individual is a male receiving androgen deprivation therapy for non-metastatic prostate cancer; **AND**

XII. Individual has had at least one osteoporotic (minimal trauma) fracture;
OR

XIII. Individual has one or more additional risk factors for osteoporotic fracture.

Continuation Request for Prolia (denosumab) may be approved if the following criterion is met:

I. There is confirmation of clinically significant response to therapy (including but not limited to confirmation of no new fractures or reduction of fractures, or no worsening vertebral fractures, or no clinically significant adverse reaction); **AND**
II. If individual has been on therapy ≥ 24 months of treatment, a repeat BMD demonstrates a stable or increase in BMD.

Request for Prolia may not be approved when the above criteria are not met and for all other indications.

Key References:

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4. Drug Facts and Comparisons. Facts and Comparisons [database online]. St. Louis, MO: Wolters Kluwer Health, Inc; 2020. Updated periodically.
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7. Fizazi K, et al. Denosumab versus zoledronic acid for treatment of bone metastases in men with castration-resistant prostate cancer: a randomized, double-blind study. Lancet. 2011;377:813-22.
8. Henry DH, Costa L, Goldwasser F, et al. Randomized, Double-Blind Study of Denosumab Versus Zoledronic Acid in the Treatment of Bone Metastases in Patients With Advanced Cancer (Excluding Breast and Prostate Cancer) or Multiple Myeloma. J Clin Oncol 2011 ;29: 1125-1132.
9. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2021; Updated periodically.
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