Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

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

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;

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

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.

Request for denosumab agents (Prolia, Xgeva) may not be approved when the above criteria are not met and for all other indications.

Key References:

1. Camacho PM, Petak SM, Binkley N, et al. American Association of Clinical Endocrinologists and American College of Endocrinology Clinical Practice Guidelines for the Diagnosis and Treatment of Postmenopausal Osteoporosis – 2016. *Endocrine Practice*. 2016;22(4):1-42.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2019. URL: http://www.clinicalpharmacology.com. Updated periodically.
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4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. Drug Facts and Comparisons. Facts and Comparisons [database online]. St. Louis, MO: Wolters Kluwer Health, Inc; 2018. Updated periodically.
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7. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.