

Market Applicability														
Market	DC	FL & FHK	FL MMA	FL LTC	GA	KS	KY	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	X

\*FHK- Florida Healthy Kids

## Prolia (denosumab)

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

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;

**AND**

III. Individual has a diagnosis of osteoporosis (defined as a T score -2.5 or less);

**OR**

IV. Individual has glucocorticoid-induced osteoporosis (defined as a T score -2.5 or less 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**

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

**OR**

VI. Individual has two or more risk factors for osteoporotic fracture;

**OR**

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

**OR**

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

**OR**

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

**AND**

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	X

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- X. Individual has had at least one osteoporotic (minimal trauma) fracture;  
**OR**  
XI. Individual has one or more additional risk factors for osteoporotic fracture.

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

**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.: 2018. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
3. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. [http://dailymed.nlm.nih.gov/daily\\_med/about.cfm](http://dailymed.nlm.nih.gov/daily_med/about.cfm). Accessed: June 18, 2018.
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.
6. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2018; Updated periodically.

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