

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

## Tymlos (abaloparatide)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	2 years

Medications	Quantity Limit
Tymlos (abaloparatide)	May be subject to quantity limit

### APPROVAL CRITERIA

Requests for Tymlos (abaloparatide) may be approved for the following:

- I. Individual is a postmenopausal female with the following:
  - A. 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 an osteoporotic low trauma fracture (fragility fracture) at high risk for additional fractures;

#### **AND**

- II. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or intolerance to one preferred oral bisphosphonate;

Preferred agents: Alendronate tablet (generic Fosamax), alendronate oral solution (generic Fosamax oral solution)

#### **OR**

- III. The preferred agents is not FDA-approved and does not have an accepted off-label use per the off-label policy for the prescribed indication and the requested non-preferred agent does;

#### **OR**

- IV. Individual meets one of the following:
  - A. The individual has been refractory to a prior trial of a preferred oral bisphosphonate;
  - OR**
  - B. The individual is intolerant to or has a contraindication to an oral bisphosphonate therapy as defined by:

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New Program Date 05/05/2017

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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1. Hypersensitivity to TWO oral bisphosphonates (one of which must be generic alendronate); **OR**
2. Inability to stand or sit upright for at least 30 minutes; **OR**
3. Pre-existing gastrointestinal disorders (Barrett's esophagus, hypersecretory disorders, delayed esophageal emptying, atrophic gastritis, etc.); **OR**
4. Uncorrected hypocalcemia; **OR**
5. Severe renal insufficiency as defined by creatinine clearance less than 35 mL/min for alendronate agents or creatinine clearance less than 30 mL/min for risedronate and ibandronate;

**AND**

V. Individual is not using abaloparatide in combination with **any** of the following:

1. Prolia (denosumab); **OR**
2. Bisphosphonates; **OR**
3. Evista (raloxifene); **OR**
4. Miacalcin/Fortical (calcitonin nasal spray); **OR**
5. Reclast (zoledronic acid); **OR**
6. Forteo (teriparatide);

**AND**

VI. Individual has utilized Tymlos (abaloparatide) injection AND Forteo (teriparatide) for a combined total duration of less than 24 months in the individual's lifetime.

**Note:**

Tymlos (abaloparatide) has a black box warnings for potential risk of osteosarcoma. In rats, an increase in the incidence of osteosarcoma (malignant bone tumor) dependent on dose and treatment duration has been identified with uncertain relevance to humans.

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.

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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/dailymed/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.  
Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2018; Updated periodically.

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