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

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 bisphosphonate;
      OR
   B. The individual is intolerant to or has a contraindication to a bisphosphonate as defined by:
      1. Hypersensitivity to TWO bisphosphonates (one of which must be generic alendronate); **OR**

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

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 and zoledronic acid 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:
   A. Prolia (denosumab); **OR**
   B. Bisphosphonates; **OR**
   C. Evista (raloxifene); **OR**
   D. Miacalcin/Fortical (calcitonin nasal spray); **OR**
   E. Reclast (zoledronic acid); **OR**
   F. Forteo (teriparatide) or Bonsity (teriparatide); **OR**
   G. Evenity (romosozumab-aqqg);

AND

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

Requests for Tymlos (abaloparatide) may not be approved when the above criteria are not met and for all other indications.

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.

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.
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 28, 2019.
4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.

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.

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

5. Drug Facts and Comparisons. Facts and Comparisons [database online]. St. Louis, MO: Wolters Kluwer Health, Inc; 2019. Updated periodically.
6. Eastell R, Rose CJ, Black DM, et al. Pharmacological Management of Osteoporosis in Postmenopausal Women: An Endocrine Society Clinical Practice Guideline, The Journal of Clinical Endocrinology & Metabolism, Volume 104, Issue 5, May 2019, Pages 1595–1622, https://doi.org/10.1210/jc.2019-00221.
7. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.

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