Tymlos (abaloparatide)

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

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

APPROVAL CRITERIA

Initial requests for Tymlos (abaloparatide) may be approved for the following:

I. Individual has one of the following:
   A. Individual is a 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 diagnosis based on history of an osteoporotic low trauma fracture (fragility fracture) at high risk for additional fracture; **OR**
   B. Individual is a male with a diagnosis of osteoporosis (defined as 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 young-adult reference population OR a clinical diagnosis based on history of a low trauma fracture (fragility fracture)) at high risk for fracture using to increase bone mass;

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; **OR**

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

OR

III. The preferred agent 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. Individual is at very high risk for fracture as defined by one or more of the following (AACE/ACE 2020):
      1. Recent fracture (within the past 12 months); **OR**
      2. Fractures while on approved osteoporosis therapy; **OR**
      3. Multiple fractures; **OR**

4. Fractures while on drugs causing skeletal harm (e.g. long-term glucocorticoids); **OR**
5. Very low T-score (less than -3.0); **OR**
6. High risk for falls or history of injurious falls; **OR**
7. Very high fracture probability by FRAX (fracture risk assessment tool) (e.g. major osteoporosis fracture >30%, hip fracture >4.5%) or other validated fracture risk algorithm;

OR

C. Individual has been refractory to a prior trial of a bisphosphonate;

OR

D. Individual is intolerant to or has a contraindication to a bisphosphonate therapy as defined:
   1. Hypersensitivity to TWO 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 and Zoledronic acide or creatinine clearance less than 30 mL/min for risedronate and ibandronate;

AND

V. The individual is not using Tymlos (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):

Continuation of therapy with Tymlos (abaloparatide) may be approved if the following criteria are 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; **AND**
III. Individual is not using Tymlos (abaloparatide) in combination with any of the following:
   A. Prolia (denosumab);
   B. Bisphosphonates;
   C. Evista (raloxifene);
   D. Miacalcin/Fortical (calcitonin nasal spray);
   E. Reclast (zoledronic acid);
   F. Forteo (teriparatide) or Bonsity (teriparatide);

G. Evenity (romosozumab-aqqg).

Requests for Tymlos (abaloparatide) 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 – 2020 Update. *Endocrine Practice*. 2020;26(1):1-46.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2023. 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: January 10, 2022.
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; 2022. Updated periodically.
6. Eastell R, Rosen 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. Gilsenan A, Midkiff K, Harris D, et al. Assessing the incidence of osteosarcoma among teriparatide users based on Medicare Part D and US State Cancer Registry Data. Pharmacoepidemiol Drug Saf. 2020 Dec;29(12):1616-1626. Available at: https://onlinelibrary.wiley.com/doi/10.1002/pds.5103 Accessed July 8, 2021.
8. Gilsenan A, Midkiff K, Harris D, et al. Teriparatide Did Not Increase Adult Osteosarcoma Incidence in a 15-Year US Postmarketing Surveillance Study. J Bone Miner Res. 2021 Feb;36(2):244-251. Available at: https://asbmr.onlinelibrary.wiley.com/doi/10.1002/jbmr.4188 Accessed July 8, 2021.
9. Shoback D, Rosen CJ, Black DM, et al. Pharmacological Management of Osteoporosis in Postmenopausal Women: An Endocrine Society Guideline Update, The Journal of Clinical Endocrinology & Metabolism, Volume 105, Issue 3, March 2020, Pages 587-594.
10. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.