CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Tymlos (abaloparatide)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Tymlos was initially approved by the FDA in 2017 for the treatment of postmenopausal women with osteoporosis at high risk for fracture. In 2022 it was also approved to treat osteoporosis in men with high fracture risk. Tymlos is a parathyroid hormone (PTH) analog and is classified as an anabolic agent. PTH regulates calcium homeostasis.
Osteoporosis can be diagnosed by occurrence of a fragility fracture, or by low bone mineral density (BMD) as measured by dual-energy x-ray absorptiometry (DXA) with results scored as standard deviations and reported as T scores. Femoral neck is the preferred site of measure.

Tymlos (abaloparatide) will be considered for coverage when the following criteria are met:

Osteoporosis in Postmenopausal Women

For **initial** authorization:
1. Member is a postmenopausal woman; AND
2. Member has a diagnosis of osteoporosis with high fracture risk as evidenced by one of the following:
   a) Bone mineral density (BMD) T-score –2.5 or below in the lumbar spine, femoral neck, total proximal femur, or 1/3 radius;
   b) Low-trauma spine or hip fracture (regardless of BMD);
   c) Osteopenia (T-score between –1 and –2.5) with a fragility fracture of proximal humerus, pelvis, or distal forearm;
   d) Osteopenia (T-score between –1 and –2.5) with FRAX fracture probability of ≥ 20% for major osteoporotic fracture or ≥ 3% for hip fracture; AND
3. Member meets one of the following:
   a) Member has had an inadequate response to at least 12 months of an oral bisphosphonate (e.g., alendronate, risedronate) or an IV bisphosphonate (e.g., zoledronic acid (Reclast), ibandronate) OR
   b) Member has very high risk for fracture (e.g., having multiple fractures, very low T score (-3.0 or below), T-score -2.5 or below plus fractures, fractures while taking osteoporosis drug, FRAX > 30% for major osteoporosis fracture or 4.5% for hip fracture); AND
4. The total length of treatment for parathyroid hormone analogs (abaloparatide, teriparatide) has not exceeded 24 months in the member's lifetime.
5. **Dosage allowed/Quantity limit:** 80 mcg subQ once daily. (1 pen per 30 days)

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:
1. Treatment beyond 24 months will not be authorized.

Osteoporosis in Men

For **initial** authorization:

1. Member is a male and at least 18 years of age; AND
2. Member has a diagnosis of osteoporosis with high fracture risk as evidenced by one of the following:
   a) Hip or vertebral fracture without major trauma
   b) BMD of the spine, femoral neck, and/or total hip is 2.5 SD or more below the mean of normal young white males (T-score -2.5 or less)
   c) T-score between −1.0 and −2.5 in the spine, femoral neck, or total hip plus a 10-yr risk of experiencing any fracture ≥ 20% or 10-yr risk of hip fracture ≥ 3% using FRAX; AND
3. Member has had an inadequate response to at least 12 months of an oral bisphosphonate (e.g., alendronate, risedronate) or an IV bisphosphonate (e.g., zoledronic acid (Reclast)) unless not tolerated or contraindicated; AND
4. The total length of treatment for parathyroid hormone analogs (abaloparatide, teriparatide) has not exceeded 24 months in the member's lifetime.
5. **Dosage allowed/Quantity limit:** 80 mcg subQ once daily. (1 pen per 30 days)

If all the above requirements are met, the medication will be approved for up to 24 months.

For **reauthorization**:

1. Treatment beyond 24 months will not be authorized.

CareSource considers Tymlos (abaloparatide) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
08/07/2020	New policy for Tymlos created
04/26/2022	Transferred to new template. Added new reference. Removed "stable" from renewal; BMD should increase. Removed ibandronate for very high risk. Corrected very low T score from -3.5 to -3.0.
01/03/2023	Updated references. Removed zoledronic acid trial for very high risk postmenopausal women; Removed renewal criteria and changed initial approval duration to total 24 months. Added section for osteoporosis in men (new indication).

References:

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3. Miller PD, Hattersley G, Riis BJ, et al. Effect of Abaloparatide vs Placebo on New Vertebral Fractures in Postmenopausal Women With Osteoporosis: A Randomized Clinical Trial [published correction appears in JAMA. 2017 Jan 24;317(4):442]. *JAMA*. 2016;316(7):722-733. doi:10.1001/jama.2016.11136
4. Leder BZ. Optimizing Sequential and Combined Anabolic and Antiresorptive Osteoporosis Therapy. *JBMR Plus*. 2018;2(2):62-68. Published 2018 Feb 27.
5. Shoback D, Rosen CJ, Black DM, Cheung AM, Murad MH, Eastell R. Pharmacological Management of Osteoporosis in Postmenopausal Women: An Endocrine Society Guideline Update. *J Clin Endocrinol Metab*. 2020;105(3):dgaa048.
6. Gregson CL, Armstrong DJ, Bowden J, et al. UK clinical guideline for the prevention and treatment of osteoporosis. *Arch Osteoporos*. 2022;17(1):58. Published 2022 Apr 5. doi:10.1007/s11657-022-01061-5
7. Watts NB, Adler RA, Bilezikian JP, et al. Osteoporosis in men: an Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2012;97(6):1802-1822. doi:10.1210/jc.2011-3045

8. LeBoff MS, Greenspan SL, Insogna KL, et al. The clinician's guide to prevention and treatment of osteoporosis [published correction appears in Osteoporos Int. 2022 Jul 28;:]. *Osteoporos Int*. 2022;33(10):2049-2102. doi:10.1007/s00198-021-05900-y

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