

PHARMACY POLICY STATEMENT

North Carolina Marketplace

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| 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 $\geq 20\%$ for major osteoporotic fracture or $\geq 3\%$ 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. Chart notes have been provided showing positive clinical response such as stable or increased BMD or no evidence of new fractures or vertebral fracture progression; AND
2. Duration of treatment does NOT exceed 24 months.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

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 \geq 20% or 10-yr risk of hip fracture \geq 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 12 months.

For **reauthorization**:

1. Chart notes have been provided showing positive clinical response such as stable or increased BMD or no evidence of new fractures or vertebral fracture progression.
2. Duration of treatment does NOT exceed 24 months.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

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). |
| 05/20/2024 | For men, changed initial auth duration from 24 months to 12 months. Created renewal criteria. |

References:

1. Tymlos [prescribing information]. Waltham, MA: Radius Health, Inc.; 2023.
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3. Leder BZ. Optimizing Sequential and Combined Anabolic and Antiresorptive Osteoporosis Therapy. *JBMR Plus*. 2018;2(2):62-68. Published 2018 Feb 27.
4. 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. *Endocr Pract*. 2020 May;26(5):564-570.
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. 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
7. 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
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

Effective date: 10/01/2024

Revised date: 05/20/2024