

PHARMACY POLICY STATEMENT

Indiana Medicaid

DRUG NAME	Tymlos (abaloparatide)
BILLING CODE	Must use valid NDC
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
STATUS	Prior Authorization Required

Tymlos (abaloparatide) was initially approved by the FDA in 2017 for the treatment of postmenopausal women with osteoporosis at high risk for fracture. Tymlos is a parathyroid hormone analog.

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

Osteoporosis

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^{2,4}) AND has had a trial of zoledronic acid; 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 length has not exceeded 24 months in lifetime; AND
2. Chart notes have been provided that show increase in bone mineral density, with no evidence of new fractures or vertebral fracture progression.

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.

References:

1. Tymlos [prescribing information]. Waltham, MA: Radius Health, Inc.; October, 2018.
2. 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.
3. ClinicalTrials.gov. Identifier: NCT01343004. Study to Evaluate the Safety and Efficacy of BA058 (Abaloparatide) for Prevention of Fracture in Postmenopausal Women (ACTIVE). Available at: <https://www.clinicaltrials.gov/ct2/show/NCT01343004>.
4. Cosman, F., de Beur, S.J., LeBoff, M.S. et al. Clinician’s Guide to Prevention and Treatment of Osteoporosis. *Osteoporos Int* 25, 2359–2381 (2014).
5. Compston J, Cooper A, Cooper C, et al. UK clinical guideline for the prevention and treatment of osteoporosis. *Arch Osteoporos.* 2017;12(1):43. doi:10.1007/s11657-017-0324-5.
6. Leder BZ. Optimizing Sequential and Combined Anabolic and Antiresorptive Osteoporosis Therapy. *JBMR Plus.* 2018;2(2):62-68. Published 2018 Feb 27.
7. 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.
8. 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

Effective date: 10/01/2022

Revised date: 4/26/2022