

PHARMACY POLICY STATEMENT

Indiana Medicaid

DRUG NAME	Tymlos (abaloparatide)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) Alternative preferred products include alendronate, risedronate, ibandronate tablet, and zoledronic acid QUANTITY LIMIT— 1 pen per 30 days
LIST OF DIAGNOSES CONSIDERED NOT MEDICALLY NECESSARY	Click Here

Tymlos (abaloparatide) is a **non-preferred** product and will only be considered for coverage under the **pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

OSTEOPOROSIS

For **initial** authorization:

1. Member is a postmenopausal woman with osteoporosis, 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
2. Member meets **one** of the following drug trials:
 - a) Member has had an inadequate response to at least 12 months of an oral bisphosphonate (e.g., alendronate, risedronate);
 - b) If oral bisphosphonate is not tolerated or contraindicated or if member has very high risk for fracture, must have a trial with an IV bisphosphonate (e.g., zoledronic acid (Reclast), ibandronate (prior authorization required)); AND

Note: very high fracture risk is defined as having multiple fractures, T score -3.5 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^{2,7}.
3. The total length of treatment for parathyroid hormone analogs (abaloparatide, teriparatide) has not exceeded 24 months in the member's lifetime.
4. **Dosage allowed:** 80 mcg subcutaneously once daily.

If member meets all the requirements listed above, 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 stable or 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 the diseases that are not listed in this document.

DATE	ACTION/DESCRIPTION
08/07/2020	New policy for Tymlos created.

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.

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