

## PHARMACY POLICY STATEMENT

### Georgia 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 <b>NOT</b> MEDICALLY NECESSARY	<a href="#">Click Here</a>

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<sup>2,7</sup>.
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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