Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	May 11, 2023 January 24, 2024

Tymlos® (abaloparatide)

LENGTH OF AUTHORIZATION: Up to one year; Lifetime maximum of 2 years

REVIEW CRITERIA:

- Patient must be ≥ 18 years of age; **AND**
- Prescribed by or in consultation with a specialist (endocrinologist, rheumatologist, or obstetrician/gynecologist); **AND**
- Patient must be female with a diagnosis of post-menopausal osteoporosis OR male with a diagnosis of osteoporosis indicated by at least one of the following:
  - DXA hip (femoral neck) or spine T-score ≤ -2.5 (dated within the past 2 years); OR
  - History of a fracture of the spine or hip (must be confirmed in medical records); OR
  - History of T-score between -1.0 and -2.5 if FRAX (WHO Fracture Risk Assessment Tool) major osteoporotic fracture probability is ≥ 20% or hip fracture probability is 3% (must be confirmed in medical records; **AND**
- Confirmation patient is receiving calcium and vitamin D supplementation if dietary intake is inadequate; **AND**
- Patient must have documented treatment failure or an inadequate response to ≥ 12 month trial of the following unless intolerant or contraindicated:
  - Injectable bone resorption inhibitors (i.e., pamindronate or zoledronic Acid); AND
  - Oral bisphosphonate (i.e., alendronate)

    NOTE: Treatment failure is defined by progression of bone loss as documented by bone density measurements (BMD) after at least 12 months of therapy OR occurrence of an osteoporotic fracture after having been compliant on at least 12 months of therapy.

CONTINUATION OF THERAPY

- Patient met initial review criteria.
- Documentation of improved clinical response (e.g., disease response, absence of fractures).
- Absence of unacceptable toxicity from the drug (e.g., osteosarcoma, orthostatic hypotension, hypercalcemia, hypercalcuria and urolithiasis, etc.).
- Dosing is appropriate as per labeling or is supported by compendia.
- Total length of therapy has not exceeded 2 years.

DOSING AND ADMINISTRATION:

- Refer to product labeling at https://www.accessdata.fda.gov/scripts/cder/daf/
- Available as 3,120 mcg/1.56 mL (2,000 mcg/mL) prefilled pen.