MEDICAL MUTUAL®

Drug Policy

Policy:	Tymlos (abaloparatide)	Annual Review Date: 08/24/2023 Last Revised Date: 08/24/2023

OVERVIEW

Tymlos, a human parathyroid hormone related peptide analog, is indicated for the following uses:[1]

- **Osteoporosis, treatment of postmenopausal women**, at high risk for fracture.
- **Osteoporosis, treatment to increase bone density in men**, at high risk for fracture.

Patients at high risk for fracture are defined as those with a history of osteoporotic fracture, have multiple risk factors for fracture, or have failed or are intolerant to other osteoporosis therapy.

POLICY STATEMENT

This policy involves the use of Tymlos. Prior authorization is recommended for pharmacy benefit coverage of Tymlos. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Tymlos as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Tymlos be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

Automation: Smart Coverage Review uses patient claim history to answer Prior Authorization questions regarding medication history of Boniva® (ibandronate intravenous injection) or Reclast® (zoledronic acid intravenous infusion). A 2-year look back period will be used to check claim history and automate for use of either agent (Boniva intravenous injection or Reclast). If not in claims, medication history can be obtained through Prior Authorization criteria. For all reviews, other Prior Authorization criteria listed below will also be applied.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Tymlos is recommended in those who meet the following criteria:

1. **Osteoporosis Treatment for a Postmenopausal Patient**
   Criteria. Approve for 1 year if the following criteria are met (A, B, and C)
   A) Patient meets ONE of the following conditions (i, ii, or iii):

i. Patient has had a T-score (current or at any time in the past) at or below -2.5 at the lumbar spine, femoral neck, total hip and/or 33% (one-third) radius (wrist); OR
ii. Patient has had an osteoporotic fracture or a fragility fracture; OR
iii. The patient meets both of the following (a and b):
a) Patient has low bone mass; AND
Note: An example of low bone mass includes a T-score (current or at any time in the past) between -1.0 and -2.5 at the lumbar spine, femoral neck, total hip, and/or 33% (one-third) radius (wrist).
b) Prescriber determines the patient is at high risk for fracture; AND

B) Patient meets ONE of the following (i, ii, iii, or iv):
i. Patient has tried ibandronate intravenous injection (Boniva) or zoledronic acid intravenous infusion (Reclast); OR
ii. Patient has tried at least one oral bisphosphonate or oral bisphosphonate-containing product and meets one of the following (a, b, or c):
Note: Examples of oral bisphosphonate products include Fosamax® (alendronate tablets and oral solution), Fosamax® Plus D (alendronate/cholecalciferol tablets), Actonel® (risedronate tablets), Atelvia® (risedronate delayed-release tablets), and Boniva® (ibandronate tablets).
a) Patient has experienced inadequate efficacy to oral bisphosphonate therapy after a trial duration of 12 months as determined by the prescriber; OR
Note: An example of an inadequate efficacy is ongoing and significant loss of bone mineral density (BMD) or a lack or a BMD increase.
b) Patient has had an osteoporotic fracture or fragility fracture while receiving oral bisphosphonate therapy; OR
c) Patient has experienced significant intolerance to an oral bisphosphonate; OR
Note: Examples of significant intolerance include severe gastrointestinal related adverse events, severe musculoskeletal related adverse events, or a femoral fracture.
iii. The patient cannot take an oral bisphosphonate due to one of the following circumstances (a, b, or c):
a) Patient cannot swallow or has difficulty swallowing; OR
b) Patient cannot remain in an upright position post oral bisphosphonate administration; OR
c) Patient has a pre-existing gastrointestinal medical condition; OR
Note: Examples of pre-existing gastrointestinal medical conditions include esophageal lesions, esophageal ulcers, or abnormalities of the esophagus that delay esophageal emptying (stricture, achalasia).
iv. Patient meets one of the following conditions (a, b, or c):
a) Severe renal impairment; OR
Note: An example of severe renal impairment is a creatinine clearance < 35 mL/min.
b) Chronic kidney disease (CKD); OR
c) Patient has had an osteoporotic fracture or a fragility fracture; AND

C) Use of Tymlos and/or teriparatide injection for subcutaneous use (Forteo/Bonsity) does not exceed 2 years during a patient's lifetime.

2. Osteoporosis – Treatment in Men*
Criteria. Approve for 1 year if the following criteria are met (A, B, and C)

A) Patient meets ONE of the following conditions (i, ii, or iii):
- **i.** Patient has had a T-score (current or at any time in the past) at or below -2.5 at the lumbar spine, femoral neck, total hip and/or 33% (one-third) radius (wrist); OR
- **ii.** Patient has had an osteoporotic fracture or a fragility fracture; OR
- **iii.** The patient meets both of the following (a and b):
  - **a)** Patient has low bone mass; AND
    Note: An example of low bone mass includes a T-score (current or at any time in the past) between -1.0 and -2.5 at the lumbar spine, femoral neck, total hip, and/or 33% (one-third) radius (wrist).
  - **b)** Prescriber determines the patient is at high risk for fracture; AND

B) Patient meets ONE of the following (i, ii, iii, or iv):
- **i.** Patient has tried zoledronic acid intravenous infusion (Reclast); OR
- **ii.** Patient has tried at least one oral bisphosphonate or oral bisphosphonate-containing product and meets one of the following (a, b, or c):
  Note: Examples of oral bisphosphonate products include Fosamax (alendronate tablets and oral solution), Fosamax Plus D (alendronate/cholecalciferol tablets), Actonel (risedronate tablets), Atelvia (risedronate delayed-release tablets), and Boniva (ibandronate tablets).
  - **a)** Patient has experienced inadequate efficacy to oral bisphosphonate therapy after a trial duration of 12 months as determined by the prescriber; OR
    Note: An example of an inadequate efficacy is ongoing and significant loss of bone mineral density (BMD) or a lack or a BMD increase.
  - **b)** Patient has had an osteoporotic fracture or fragility fracture while receiving oral bisphosphonate therapy; OR
  - **c)** Patient has experienced significant intolerance to an oral bisphosphonate; OR
    Note: Examples of significant intolerance include severe gastrointestinal related adverse events, severe musculoskeletal related adverse events, or a femoral fracture.
- **iii.** Patient cannot take an oral bisphosphonate due to one of the following circumstances (a, b, or c):
  - **a)** Patient cannot swallow or has difficulty swallowing; OR
  - **b)** Patient cannot remain in an upright position post oral bisphosphonate administration; OR
  - **c)** Patient has a pre-existing gastrointestinal medical condition; OR
    Note: Examples of pre-existing gastrointestinal medical conditions include esophageal lesions, esophageal ulcers, or abnormalities of the esophagus that delay esophageal emptying (stricture, achalasia).
- **iv.** Patient meets one of the following conditions (a, b, or c):
  - **a)** Severe renal impairment; OR
    Note: An example of severe renal impairment is a creatinine clearance < 35 mL/min.
  - **b)** Chronic kidney disease; OR
  - **c)** Patient has had an osteoporotic fracture or a fragility fracture.

C) Use of Tymlos and/or teriparatide injection for subcutaneous use (Forteo/Bonsity) does not exceed 2 years during a patient's lifetime.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Tymlos has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. **Concurrent Use with Other Medications for Osetoporosis.**
   Note: Examples of medications for osteoporosis that Tymlos should not be given with include Prolia (denosumab subcutaneous injection), oral bisphosphonates (alendronate, risedronate, ibandronate), intravenous bisphosphonates (zoledronic acid intravenous infusion [Reclast], ibandronate intravenous injection), calcitonin nasal spray (Miacalcin/Fortical), teriparatide subcutaneous injection (Forteo), and Evenity (romosozumab-aqqg subcutaneous injection). However, this does NOT exclude use of calcium and/or vitamin D supplements in combination with Tymlos.

2. **Osteoporosis Prevention.** Tymlos has not been studied in this patient population. The benefits and risks of building bone with Tymlos in a condition in which substantial bone loss has not occurred have not been investigated.[1]

3. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Tymlos® injection for subcutaneous use [prescribing information]. Waltham, MA: Radius Health; April 2021.
2. Eastell R, Rosen CJ, Black DM, et al. Pharmacological management of osteoporosis in postmenopausal women: an Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2019;104(5):1595-1622.
3. 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 update. *Endocrin Pract*. 2020;26(Suppl 1):1-46.