PRIOR AUTHORIZATION POLICY

POLICY: Bone Modifiers – Tymlos Prior Authorization Policy
- Tymlos® (abaloparatide injection for subcutaneous use – Radius Health)

REVIEW DATE: 07/29/2020

OVERVIEW

Tymlos, a human parathyroid hormone related peptide (PTHrP[1-34]) analog, is indicated for the treatment of postmenopausal women with osteoporosis at high risk for fracture.[1] Patients at high risk for fracture are defined as those with a history of osteoporotic fractures, have multiple risk factors for fracture, or have failed or are intolerant to other osteoporosis therapy.

Guidelines

Guidelines for osteoporosis in postmenopausal women from the Endocrine Society (2019)[2] as well as from the American Association of Clinical Endocrinologists (AACE) and the American College of Endocrinology (ACE) [2020][3] discuss Tymlos. In general, Tymlos is one of several alternatives recommended in patients who are at high risk of fracture or in those unable to utilize oral bisphosphonate therapy.

Safety

The prescribing information for Tymlos includes a Boxed Warning regarding an increased incidence of osteosarcoma in rats at doses 4 to 28 times the exposure in humans administered as a 80 mcg dose.[1] Due to these risks, the agent should not be given to those who have an increased baseline risk for osteosarcoma. The prescribing information for Tymlos states that cumulative use of Tymlos and parathyroid hormone analogs (e.g., teriparatide injection for subcutaneous use [Forteo®/Bonsity®]) for > 2 years during a patient's lifetime is not recommended.

POLICY STATEMENT

Prior authorization is recommended for prescription benefit coverage of Tymlos. Coverage cumulative with Tymlos and teriparatide injection for subcutaneous use (Forteo/Bonsity) is recommended for up to 2 years of a patient's lifetime. All approval(s) are provided for up to 2 years in duration unless otherwise noted below.

Automation: Smart Coverage Review uses patient claim history to answer Prior Authorization questions regarding medication history of Boniva® (ibandronate injection for intravenous use) or Reclast® (zoledronic acid injection for intravenous use). A 2-year look back period will be used to check claim history and automate for use of either agent (Boniva intravenous 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:

FDA-Approved Indications

1. **Osteoporosis Treatment for a Postmenopausal Patient.** Approve for up to 2 years (total) if the patient meets the following criteria (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 (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]); AND
       - **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 injection (Boniva) or zoledronic acid injection (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 had an inadequate response to oral bisphosphonate therapy after a trial duration of 12 months as determined by the prescriber (e.g., ongoing and significant loss of bone mineral density [BMD], lack of BMD increase); OR
       - **b)** Patient has had an osteoporotic fracture or fragility fracture while receiving oral bisphosphonate therapy; OR
       - **c)** Patient has experienced intolerability to an oral bisphosphonate (e.g., severe gastrointestinal [GI]-related adverse effects, severe musculoskeletal-related side effects, a femoral fracture); OR
     - **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 (GI) medical condition (e.g., patient with esophageal lesions, esophageal ulcers, or abnormalities of the esophagus that delay esophageal emptying [stricture, achalasia]); OR
     - **iv.** Patient meets one of the following conditions (a, b, or c):
       - **a)** Severe renal impairment (creatinine clearance < 35 mL/min); OR
       - **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.

     Note: Approve the duration necessary to complete a maximum of 2 years of therapy during a patient's lifetime (e.g., a patient who has already received 3 months of treatment with Tymlos or teriparatide [Forteo/Bonsity] should be approved for a duration of 21 months. This allows for completion of a maximum of 2 years of therapy).

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Tymlos is not recommended in the following situations:

1. **Concurrent Use with Other Medications for Osteoporosis.**
   Note: Examples include Prolia® (denosumab injection for subcutaneous use), oral bisphosphonates (alendronate, risedronate, ibandronate), intravenous bisphosphonates (zoledronic acid injection [Reclast], ibandronate intravenous), calcitonin nasal spray (Miacalcin®/Fortical®), teriparatide injection for subcutaneous use (Forteo®/Bonsity), and Evenity® (romosozumab-aqqg injection for subcutaneous use). Tymlos is not indicated for use as combination therapy.

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.

REFERENCES

1. Tymlos® injection for subcutaneous use [prescribing information]. Waltham, MA: Radius Health; October 2018.
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.