VENTURA COUNTY HEALTH CARE PLAN

Prior Authorization DRUG Guidelines

TYMLOS (abaloparatide)

Effective Date: 10/24/17

Date Developed: 10/24/17 by Catherine R. Sanders, MD and ESI P&T

Date Approved by P&T Committee: 10/24/17, 1/23/18, 1/22/19

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Tymlos is a human parathyroid hormone related peptide (PTHrP[1-34]) analog. Tymlos is given as a SC injection.

Pre-Authorization Criteria:
Patient meets A and B below:

A. Treatment of osteoporosis for a postmenopausal patient meeting ONE of the following criteria (1, 2, or 3):
   1. T-score at or below -2.5 at the lumbar spine, femoral neck, total hip and/or wrist, OR
   2. Presence of an osteoporotic fracture or a fragility fracture, OR
   3. Osteopenia with T-score between -1.0 and -2.5 at the lumbar spine, femoral neck, total hip and/or wrist and the physician determines the patient is at high risk for fracture AND

B. Additionally meets ONE of the following criteria (1, 2, or 3):
   1. Has tried one oral bisphosphonate and has had an inadequate response after 12 month trial, or had an osteoporotic fracture or fragility fracture while on oral bisphosphonate therapy, or has intolerance with severe GI related adverse effects, OR
   2. Unable to take an oral bisphosphonate as has difficulty swallowing, or cannot remain in an upright position post administration, or has a pre-existing GI condition such as esophageal lesions, ulcers, stricture, achalasia, OR
   3. Has tried ibandronate (Boniva) or zoledronic acid (Reclast) [PA required] OR
   4. Has severe renal impairment with creatinine clearance <35mL/min, or chronic kidney disease.

Restrictions: The prescribing information for Tymlos states that cumulative use of Tymlos and parathyroid hormone analogs (e.g. Forteo) collectively for >2 years during a patient's lifetime is not recommended. This is related to the risk of osteosarcoma.

Note: Tymlos will not be approved for osteoporosis prevention, previous use of tymlos and/or Forteo for a combined total of > 2 years lifetime duration, or during concurrent use with other medication for osteoporosis.

Dosing Forms: Solution Pen-Injector, Subcutaneous: 3120 mcg/1.56 mL

Dosing: 80 mcg SC once daily

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