UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Tymlos

Program	Prior Authorization
Medication	Tymlos™ (abaloparatide)
Issue Date	6/2017
Pharmacy and Therapeutics Approval Date	11/2017
Effective Date	1/2018

1. Background:

Tymlos is a human parathyroid hormone related peptide analog indicated for the treatment of postmenopausal patients with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy[1].

The participants of the leading study of Tymlos for the treatment of osteoporosis had baseline mean T-scores of -2.9 at the lumbar spine, -2.1 at the femoral neck, and -1.9 at the total hip. At baseline, 24% of patients had at least one prevalent vertebral fracture and 48% had at least one prior nonvertebral fracture.[1]

Current guidelines define osteoporosis as a bone mineral density (BMD) T-score of -2.5 or below, and osteopenia as a T-score between -1 and -2.5. Additionally, guidelines state that osteoporosis can also be diagnosed by the history of a low-trauma spine or hip fracture regardless of BMD, a history of a fragility fracture in osteopenic patients, or in osteopenic patients with an elevated fracture risk as defined by the FRAX® fracture assessment tool. [2] Available literature defines high risk for fracture as bone mineral density (BMD) T-scores of -3.5 or less, while it defines severe osteoporosis as T-scores of -2.5 or less with at least one fragility fracture.[2-7] The FRAX tool is designed to assist clinicians in predicting the ten-year probability of fracture with or without the addition of femoral neck bone mineral density (BMD).[8]

Because of the unknown relevance of the rodent osteosarcoma findings to humans, cumulative use of Tymlos and parathyroid hormone analogs (e.g., teriparatide) for more than 2 years during a patient's lifetime is not recommended.[1]

Coverage will be provided for members who meet the following criteria.

UnitedHealthcare Community Plan

2. Coverage Criteria:

A. <u>Postmenopausal patients with osteoporosis at high risk for fracture</u>

1. **Tymlos** will be approved based on **<u>all</u>** of the following criteria:

   a. Diagnosis of osteoporosis

   -AND-

   b. **<u>One</u>** of the following:

      (1) BMD T-score ≤ -3.5 based on BMD measurements from lumber spine (at least two vertebral bodies), hip (femoral neck, total hip), or radius (one-third radius site). [Provider must submit patient specific BMD T-score]

      -OR-

      (2) **<u>Both</u>** of the following:

         i. BMD T-score between -2.5 and -3.5 (BMD T-score greater than -3.5 and less than or equal to -2.5) based on BMD measurements from lumber spine (at least two vertebral bodies), hip (femoral neck, total hip), or radius (one-third radius site). [Provider must submit patient specific BMD T-score]

         -AND-

         ii. **<u>One</u>** of the following:

            a. History of **<u>one</u>** of the following resulting from minimal trauma:
               - Vertebral compression fracture
               - Fracture of the hip
               - Fracture of the distal radius
               - Fracture of the pelvis
               - Fracture of the proximal humerus

            -OR-

            b. History of failure, contraindication, or intolerance to **<u>one</u>** conventional osteoporosis therapy [e.g., bisphosphonate or selective estrogen receptor modulator (SERM)] (Document drug, date, and duration of trial)

-OR-

(3) **All** of the following:

(a) BMD T-score between -1 and -2.5 (BMD T-score greater than -2.5 and less than or equal to -1) based on BMD measurements from lumber spine (at least two vertebral bodies), hip (femoral neck, total hip), or radius (one-third radius site) [Provider must submit patient specific BMD T-score]

-AND-

(b) **One** of the following:

i. History of **one** of the following resulting from minimal trauma:

1. Vertebral compression fracture
2. Fracture of the hip
3. Fracture of the distal radius
4. Fracture of the pelvis
5. Fracture of the proximal humerus

-OR-

ii. **One** of the following FRAX 10-year fracture probabilities:

1. Major osteoporotic fracture at 20% or more
2. Hip fracture at 3% or more

-AND-

(c) History of failure, contraindication, or intolerance to **one** conventional osteoporosis therapy [e.g., bisphosphonate or selective estrogen receptor modulator (SERM)] (Document drug, date, and duration of trial)

-AND-

c. Treatment duration including other parathyroid hormone analogs has not exceeded a total of 24 months during the patient's lifetime

-AND-

d. Prescriber attests to the following: the information provided is true and accurate to the best of their knowledge and they understand that UnitedHealthcare may perform a routine audit and request the medical information necessary to verify the accuracy of the information provided

UnitedHealthcare Community Plan

Authorization will be issued for up to 24 months. (Duration of coverage will be limited to 24 months of cumulative parathyroid hormone analog therapy in the member's lifetime.)

3. References:

1. Tymlos [package insert]. Waltham, MA: Radius Health, Inc.; April 2017.
2. American Association of Clinical Endocrinologists Medical Guidelines for clinical practice for the prevention and treatment of postmenopausal osteoporosis. Endocrine Practice. September 2016;22(4):1-42.
3. North American Menopause Society (NAMS). Management of osteoporosis in postmenopausal women: 2010 position statement of The North American Menopause Society. Menopause 2010;17(1):25-54.
4. Cosman F, de Beur SJ, LeBoff MS, et al. National Osteoporosis Foundation. Clinician's Guide to Prevention and Treatment of Osteoporosis. Washington, DC: National Osteoporosis Foundation; 2014. Osteoporos Int. 2014 Oct;25(10):2359-81. Epub 2014 Aug. 15.
5. Hodsman AB, Bauer DC, Dempster DW, et al. Parathyroid hormone and teriparatide for the treatment of osteoporosis: a review of the evidence and suggested guidelines for its use. Endocr Rev. 2005(5):688-703.
6. Hodsman A, Papaioannou A, Cranney A. Clinical practice guidelines for the use of parathyroid hormone in the treatment of osteoporosis. CMAJ. 2006;175(1):48.
7. Florence R, Allen S, Benedict L, Compo R, Jensen A, Kalogeropoulou D, Kearns A, Larson S, Mallen E, O'Day K, Peltier A, Webb B. Diagnosis and treatment of osteoporosis. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2013 Jul. 87 p.
8. WHO FRAX tool: shef.ac.uk/FRAX. Accessed 7/5/2017.

Program	Prior Authorization –Tymlos (abaloparatide)
Change Control	
Date	Change
6/2017	New program.
11/2017	Added requirement for BMD T-score submission and previous medication trial documentation. Added physician attestation.