UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2023 P 1222-9
Program	Prior Authorization/Notification
Medication	Tymlos® (abaloparatide)
P&T Approval Date	7/2017, 11/2017, 11/2018, 11/2019, 11/2020, 11/2021, 11/2022, 2/2023, 10/2023
Effective Date	1/1/2024

1. Background:

Tymlos is a human parathyroid hormone analog indicated for the treatment of postmenopausal women with osteoporosis at high risk for fracture or patients who have failed or are intolerant to other available osteoporosis therapy. Tymlos is also indicated to increase bone density in men with osteoporosis at high risk for fracture or patients who have failed or are intolerant to other available osteoporosis therapy.[1]

The American Association of Clinical Endocrinologists/American College of Endocrinology recommend the use of Tymlos in patients unable to use oral therapy and as initial therapy for patients at very high fracture risk defined as the following: patients with a recent fracture (e.g., within the past 12 months), fractures while on approved osteoporosis therapy, multiple fractures, fractures while on drugs causing skeletal harm (e.g., long-term glucocorticoids), very low T-score (e.g., less than −3.0), high risk for falls or history of injurious falls, and very high fracture probability by FRAX® (fracture risk assessment tool) (e.g., major osteoporosis fracture >30%, hip fracture >4.5%) or other validated fracture risk algorithm to be at very high fracture risk.[2]

The safety and efficacy of Tymlos have not been evaluated beyond 2 years of treatment. Cumulative use of Tymlos and other parathyroid hormone analogs (e.g., Forteo, Teriparatide Injection) for more than 2 years during a patient's lifetime is not recommended.[1-2]

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

2. Coverage Criteria[a]:

A. Osteoporosis

1. **Tymlos** will be approved based on **all** of the following criteria:
   a. **One** of the following:
      (1) **Both** of the following:
         (a) Patient is female

-AND-

         (b) Diagnosis of postmenopausal osteoporosis

-OR-

(2) **Both** of the following:

(a) Patient is male

-AND-

(b) Diagnosis of osteoporosis

-AND-

b. **One** of the following:

(1) Patient is at high risk of fracture [e.g., recent fracture (e.g., within the past 12 months), fractures while on approved osteoporosis therapy, multiple fractures, fractures while on drugs causing skeletal harm (e.g., long-term glucocorticoids), very low T-score (e.g., less than −3.0), high risk for falls or history of injurious falls, and very high fracture probability by FRAX® (fracture risk assessment tool) (e.g., major osteoporosis fracture >30%, hip fracture >4.5%)]

-OR-

(2) Patient has a history of failure, intolerance or contraindication to other available osteoporosis therapy (e.g., alendronate, denosumab, risedronate, zoledronate)

-AND-

c. Treatment duration has not exceeded a total of 24 months of cumulative use of parathyroid hormone analogs (e.g., Teriparatide Injection, Forteo, Tymlos) during the patient's lifetime

Authorization will be issued for up to 24 months. (Duration of coverage will be limited to 24 months of cumulative parathyroid hormone analog therapy (e.g., Teriparatide Injection, Forteo, Tymlos) in the member's lifetime.)

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

4. References:

1. Tymlos [package insert]. Boston, MA: Radius Health, Inc.; June 2023.

2. American Association of Clinical Endocrinologists/American College of Endocrinology Clinical Practice Guidelines for the Diagnosis and Treatment of Postmenopausal Osteoporosis - 2020 Update. Endocr Pract. 2020;26(Suppl 1):1-46. doi:10.4158/GL-2020-0524SUPPL

Program	Prior Authorization/Notification – Tymlos (abaloparatide)
Change Control	
7/2017	New program.
11/2017	Added requirement for BMD T-score submission and previous medication trial documentation. Added physician attestation criterion.
11/2018	Annual review with no changes to clinical criteria. Updated references.
11/2019	Annual review with no changes to clinical criteria. Updated references.
11/2020	Annual review. Updated diagnosis criteria according to label. Minor revision to coverage criteria to align with other parathyroid programs. Updated background and references.
11/2021	Annual review with no changes to clinical criteria. Updated references.
11/2022	Annual review. Added state mandate. Updated references.
2/2023	Added new indication for use in men with osteoporosis to background and coverage criteria. Updated criteria confirming osteoporosis diagnosis and high fracture risk to align with current treatment guidelines. Updated references.
10/2023	Annual review. Updated background and coverage criteria to align with the label and treatment guidelines. Removed “routine audit” language from criteria. Updated references.