Reference number(s)
1826-A

Specialty Guideline Management
Tymlos

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Tymlos	abaloparatide

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications[1]

- Treatment of postmenopausal women with osteoporosis at high risk for fracture (defined as history of osteoporotic fracture or multiple risk factors for fracture), or patients who have failed or are intolerant to other available osteoporosis therapy.
- Treatment to increase bone density in men with osteoporosis at high risk for fracture (defined as a history of osteoporotic fracture or multiple risk factors for fracture), or patients who have failed or are intolerant to other available osteoporosis therapy.

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

- Chart notes or medical record documentation indicating a history of fractures, T-score, and

Fracture Risk Assessment Tool (FRAX) probability as applicable to the coverage criteria section.

- Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy.

Coverage Criteria

Postmenopausal Osteoporosis[1-7]

Authorization of an initial total of 12 months may be granted to postmenopausal members with osteoporosis when EITHER of the following criteria is met:

- Member has a history of fragility fractures (e.g., low trauma fracture from force similar to a fall from standing position).
- Member has a pre-treatment T-score ≤ -2.5 OR member has osteopenia (i.e., pre-treatment T-score score between -1 and -2.5) with a high pre-treatment FRAX probability (see Appendix) and meets ANY of the following criteria:
    - Member has indicators of very high fracture risk (e.g., advanced age, frailty, glucocorticoid use, very low T-scores [≤ -3], or increased fall risk)
    - Member has had an inadequate response or intolerance to previous injectable osteoporosis therapy (e.g., zoledronic acid [Reclast], a denosumab product [e.g. Prolia and biosimilars], teriparatide [Forteo])
    - Member has had an inadequate response or intolerance to previous oral bisphosphonate therapy

Osteoporosis in Men[1,7,8]

Authorization of an initial total of 12 months may be granted to male members with osteoporosis when any of the following criteria is met:

- Member has a history of an osteoporotic vertebral or hip fracture
- Member has a pre-treatment T-score ≤ -2.5 OR member has osteopenia (i.e., pre-treatment T-score between -1 and -2.5) with a high pre-treatment FRAX probability (see Appendix)
- Member has had an inadequate response or intolerance to previous bisphosphonate therapy

Continuation of Therapy[1]

Authorization of 12 months may be granted for all members (including new members) who are currently receiving the requested medication through a previously authorized pharmacy or medical benefit, who have not experienced clinically significant adverse events during therapy.

Other

The cumulative duration of parathyroid hormone analogs (teriparatide and abaloparatide) will not exceed a total of 24 months in the member's lifetime.

Appendix

FRAX Fracture Risk Assessment Tool[4]

- FRAX© (fracture risk assessment tool) available at: https://fraxplus.org
- High FRAX probability: 10-year major osteoporotic fracture probability ≥ 20% or hip fracture probability ≥ 3%
- FRAX Glucocorticoid correction: If glucocorticoid dose is greater than 7.5 mg (prednisone equivalent) per day, the estimated risk score generated with FRAX should be multiplied by 1.15 for major osteoporotic fracture (including fractures of the spine [clinical], hip, wrist, or humerus) and 1.2 for hip fracture.

References

1. Tymlos [package insert]. Boston, MA: Radius Health, Inc.; April 2025.
2. Miller PD, Hattersley G, Riis BJ, et al. Effect of Abalaoparatide Vs Placebo on New Vertebral Fractures in Postmenopausal Women with Osteoporosis: A Randomized Clinical Trial. JAMA. 2016; 316 (7): 722:733.
3. Camacho PM, Petak SM, Binkley N, et al. 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.
4. FRAX® Fracture Risk Assessment Tool. © Osteoporosis Research Ltd, UK. Available online: https://fraxplus.org. Accessed September 5, 2025.
5. Ensrud KE, Crandall CJ. Osteoporosis. Ann Intern Med. 2024;177(1):ITC1-ITC16
6. Shoback D, Rosen CJ, Black DM, et al. Pharmacological Management of Osteoporosis in Postmenopausal Women: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2020;105(3):587-594.
7. Carey JJ. What is a 'failure' of bisphosphonate therapy for osteoporosis? Cleve Clin J of Med. 2005;72(11):1033-1039.
8. Watts NB, Adler RA, Bilezikian JP, et al. Osteoporosis in men: an Endocrine Society clinical practice guideline. J Clin Endocr Metab. 2012;97(6):1802-1822.