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) fracture probability as applicable to the coverage criteria section.

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 less than or equal to -2.5 OR member has osteopenia (i.e., pre-treatment T-score greater than -2.5 and less than -1) with a high pre-treatment FRAX fracture probability (see Appendix B) 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 [less than or equal to -3], or increased fall risk)
    - Member has failed prior treatment with or is intolerant to previous injectable osteoporosis therapy (e.g., zoledronic acid [Reclast], a denosumab product [Prolia, Jubbonti, Ospomyv, Stoboclo], teriparatide [Forteo])
    - Member has had an oral bisphosphonate trial of at least 1-year duration or there is a clinical reason to avoid treatment with an oral bisphosphonate (see Appendix A)

Osteoporosis in Men[1,7,8]

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

- Member has a history of an osteoporotic vertebral or hip fracture
- Member meets BOTH of the following criteria:
    - Member has a pre-treatment T-score less than or equal to -2.5 OR member has osteopenia (i.e., pre-treatment T-score greater than -2.5 and less than -1) with a high pre-treatment FRAX fracture probability (see Appendix B)
    - Member has had an oral or injectable bisphosphonate trial of at least 1-year duration OR there is a clinical reason to avoid treatment with a bisphosphonate (see Appendix A)

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

Appendix A. Clinical Reasons to Avoid Oral Bisphosphonate Therapy[3]

- Presence of anatomic or functional esophageal abnormalities that might delay transit of the tablet (e.g., achalasia, stricture, or dysmotility)
- Active upper gastrointestinal problem (e.g., dysphagia, gastritis, duodenitis, erosive esophagitis, ulcers)
- Presence of documented or potential gastrointestinal malabsorption (e.g., gastric bypass procedures, celiac disease, Crohn's disease, infiltrative disorders, etc.)
- Inability to stand or sit upright for at least 30 to 60 minutes
- Inability to take oral bisphosphonate at least 30 to 60 minutes before first food, drink, or medication of the day
- Renal insufficiency (creatinine clearance < 35 mL/min)
- History of intolerance to an oral bisphosphonate

Appendix B. FRAX Fracture Risk Assessment Tool[4]

- High FRAX fracture probability: 10-year major osteoporosis-related fracture risk ≥ 20% or hip fracture risk ≥ 3%
- 10-year probability; calculation tool available at: https://frax.shef.ac.uk/FRAX
- 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 if glucocorticoid treatment is greater than 7.5 mg (prednisone equivalent) per day

References

1. Tymlos [package insert]. Boston, MA: Radius Health, Inc.; February 2024.
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. © Centre for Metabolic Bone Diseases, University of Sheffield, UK. Available at: https://frax.shef.ac.uk/FRAX. Accessed October 12, 2024.
5. Ensrud KE, Crandall CJ. Osteoporosis. Ann Intern Med. 2017;167(03): ITC17–ITC32.
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.