AETNA BETTER HEALTH® Coverage Policy/Guideline					
Name:	Tymlos			Page:	1 of 3
Effective Date:	4/7/2024			Last Review Date:	4/2024
Applies to:	☒Illinois ☒New Jersey ☐Virginia	☐Florida ☒Maryland		☒Kentucky PRMD ☒Pennsylvania Kids ☒Florida Kids	

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Tymlos under the patient's prescription drug benefit.

Description:

FDA-Approved Indications

A. 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.
B. 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.

Drug List:

Tymlos

Policy/Guideline:

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

- Supporting chart notes or medical record indicating a history of fractures, T-score, and FRAX fracture probability as applicable below:

A. Postmenopausal osteoporosis

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

1. Member has a history of fragility fractures
2. 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:
    i. 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)
    ii. Member has failed prior treatment with or is intolerant to previous injectable osteoporosis therapy

iii. 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)

B. Osteoporosis in men

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

1. Member has a history of an osteoporotic vertebral or hip fracture
2. Member meets BOTH of the following criteria:
   i. 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)
   ii. 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

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.

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

Approval Duration and Quantity Restrictions:

Approval: Initial and Renewal: 12 months

Quantity Level Limit: 1 prefilled pen (3120 mcg) per 30 days
Reference Formulary for drug specific quanitity level limits

References:

1. Tymlos [package insert]. Boston, MA: Radius Health, Inc.; June 2023.
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://www.shef.ac.uk/FRAX. Accessed October 5, 2023.
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.