AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name:	Forteo and Teriparatide	Page:	1 of 4
Effective Date:	8/10/2023	Last Review Date:	6/2/2023

Applies to:	☐Illinois	☐Florida	☒Florida Kids
	☒New Jersey	☒Maryland	☐Michigan
	☒Pennsylvania Kids	☐Virginia	☐Texas

Intent:

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

Description:

FDA-Approved Indications

A. Treatment of postmenopausal women with osteoporosis at high risk for fracture (defined herein as having a history of osteoporotic fracture or multiple risk factors for fracture) or who have failed or are intolerant to other available osteoporosis therapy.
B. Increase of bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture or who have failed or are intolerant to other available osteoporosis therapy.
C. Treatment of men and women with osteoporosis associated with sustained glucocorticoid therapy (daily dosage equivalent to 5 mg or greater of prednisone) at high risk for fracture or who have failed or are intolerant to other available osteoporosis therapy.

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

Drug List:

Non-Preferred: Forteo and Teriparatide

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 is unable to take Tymlos and Prolia due to a trial and inadequate treatment response or intolerance, or a contraindication and has a history of fragility fractures
2. Member is unable to take Tymlos and Prolia due to a trial and inadequate treatment response or intolerance, or a contraindication and 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:
   a. 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)
   b. Member has failed prior treatment with or is intolerant to previous injectable osteoporosis therapy
   c. 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. Primary or hypogonadal osteoporosis in men

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

1. Member is unable to take Tymlos and Prolia due to a trial and inadequate treatment response or intolerance, or a contraindication and has a history of an osteoporotic vertebral or hip fracture
2. Member is unable to take Tymlos and Prolia due to a trial and inadequate treatment response or intolerance, or a contraindication and meets criteria BOTH of the following criteria:
   a. 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)
   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)

C. Glucocorticoid-induced Osteoporosis

Authorization of an initial total of 12 months may be granted for members with glucocorticoid-induced osteoporosis when ALL of the following criteria are met:

1. Member is unable to take Prolia due to a trial and inadequate treatment response or intolerance, or a contraindication
2. 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)
3. Member is currently receiving or will be initiating glucocorticoid therapy at an equivalent prednisone dose of ≥ 2.5 mg/day for ≥ 3 months.
4. Member meets ANY of the following criteria:
   a. Member has a history of a fragility fracture

b. Member has a pre-treatment T-score less than or equal to -2.5
c. 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)

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 meet one of the following:

A. Member has experienced clinical benefit as evidenced by a bone mass measurement showing an improvement or stabilization in T-score compared with the previous bone mass measurement and member has not experienced any adverse effects.
B. Member has experienced clinical benefit (e.g., no new fracture seen on radiography) and has not experienced clinically significant adverse events during therapy.

NOTE: The cumulative duration of parathyroid hormone analogs (e.g., teriparatide and abaloparatide) will not exceed a total of 24 months in the member's lifetime unless the member remains at or has returned to having a high risk for fracture.

Approval Duration and Quantity Restrictions:

Approval: Initial and Renewal: 12 months
NOTE: The cumulative duration of parathyroid hormone analogs (e.g., teriparatide and abaloparatide) will not exceed a total of 24 months in the member's lifetime unless the member remains at or has returned to having a high risk for fracture.

Quantity Level Limit: 1 pen per 28 days
Reference Formulary for drug specific quanitity level limits

Appendix A. Clinical reasons to avoid oral bisphosphonate therapy

- 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. WHO Fracture Risk Assessment Tool

- High FRAX fracture probability: 10 year major osteoporotic fracture risk ≥ 20% or hip fracture risk ≥ 3%.
- 10-year probability; calculation tool available at: https://www.sheffield.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. Forteo [package insert]. Indianapolis, IN: Eli Lilly and Company; September 2021.
2. Teriparatide [package insert]. San Diego, CA: Alvogen, Inc.; November 2019.
3. Bisphosphonates. *Drug Facts and Comparisons.* Facts & Comparisons [database online]. St. Louis, MO: Wolters Kluwer Health Inc; October 24, 2019. Accessed October 10, 2022.
4. Cosman F, de Beur SJ, LeBoff MS, et al. National Osteoporosis Foundation. Clinician's guide to prevention and treatment of osteoporosis. *Osteoporos Int.* 2014;25(10): 2359-2381.
5. Jeremiah MP, Unwin BK, Greenwald MH, et al. Diagnosis and management of osteoporosis. *Am Fam Physician*. 2015;92(4):261-268.
6. Camacho PM, Petak SM, Binkley N, et al. American Association of Clinical Endocrinologists and American College of Endocrinology Clinical Practice Guidelines for the Diagnosis and Treatment of Postmenopausal Osteoporosis 2020. Endocr Pract. 2020;26 (Suppl 1):1-46.
7. National Institute for Health and Care Excellence. Osteoporosis Overview. Last updated February 2018. Available at: http://pathways.nice.org.uk/pathways/osteoporosis. Accessed April 10, 2019.
8. Treatment to prevent osteoporotic fractures: an update. Department of Health and Human Services, Agency for Healthcare Research and Quality. 2012; Publication No. 12-EHC023-EF. Available at www.effectivehealthcare.ahrq.gov/lbd.cfm.
9. 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.
10. Fink HA, Gordon G, Buckley L, et al. 2017 American College of Rheumatology Guidelines for the Prevention and Treatment of Glucocorticoid-Induced Osteoporosis. *Arthritis Care Res*. 2017;69:1521-1537.
11. FRAX® Fracture Risk Assessment Tool. © Centre for Metabolic Bone Diseases, University of Sheffield, UK. Available at: https://www.shef.ac.uk/FRAX. Accessed October 10, 2022.
12. Ensrud KE, Crandall CJ. Osteoporosis. Ann Intern Med 2017;167(03):ITC17–ITC32.
13. Eastell R, Rosen CJ, Black DM, et al. Pharmacological Management of Osteoporosis in Postmenopausal Women: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2019;104:1595-1622.
14. Carey John. What is a 'failure' of bisphosphonate therapy for osteoporosis? Cleveland Clinic Journal of Medicine Nov 2005, 72 (11) 1033-1039.