Reference number(s)
2028-A

Specialty Guideline Management teriparatide-Forteo-Bonsity

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	Dosage Form
Forteo	teriparatide	560 mcg/2.24 ml prefilled pen
Bonsity	teriparatide	560 mcg/2.24 ml prefilled pen
Teriparatide (branded generic)	teriparatide	620 mcg/2.48 ml prefilled pen

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[1-5]

- 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.
- 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.
- 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.

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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[1-10,14]

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], denosumab-bbdz [Jubbonti], abaloparatide [Tymlos])
    - 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)

Primary or Hypogonadal Osteoporosis in Men[1-5,10,11]

Authorization of an initial total of 12 months may be granted to male members with primary or hypogonadal 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)

Glucocorticoid-Induced Osteoporosis[1-5,10,12]

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

- 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)
- Member is currently receiving or will be initiating glucocorticoid therapy at an equivalent prednisone dose of ≥ 2.5 mg/day for ≥ 3 months
- Member meets ANY of the following criteria:
    - Member has a history of a fragility fracture (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
    - 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[1-5]

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:

- Member has received less than 24 months of therapy and has not experienced clinically significant adverse events during therapy
- Member has received 24 months of therapy or more and meets both of the following:
    - Member has experienced clinical benefit (i.e., improvement or stabilization in T-score since the previous bone mass measurement)
    - Member has not experienced any adverse effects

Other

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.

Appendix

Appendix A. Clinical Reasons to Avoid Oral Bisphosphonate Therapy[8]

- 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)
- 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[12,13]

- 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. Forteo [package insert]. Indianapolis, IN: Eli Lilly and Company; July 2024.
2. Bonsity [package insert]. Morristown, NJ: Alvogen, Inc.; December 2024.
3. Teriparatide [package insert]. Parsippany, NJ: Teva Pharmaceuticals USA, Inc.; September 2024.
4. Teriparatide [package insert]. Morristown, NJ: Alvogen, Inc.; December 2024.
5. Teriparatide [package insert]. Weston, FL: Apotex Corp.; January 2023.
6. 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.
7. Jeremiah MP, Unwin BK, Greenwald MH, et al. Diagnosis and management of osteoporosis. Am Fam Physician. 2015;92(4):261-268.
8. 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.
9. 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.
10. Carey JJ. What is a 'failure' of bisphosphonate therapy for osteoporosis? Cleve Clin J of Med. 2005;72(11):1033-1039.
11. 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.
12. Humphrey MB, Russell L, Danila MI, et al. 2022 American College of Rheumatology Guideline for the Prevention and Treatment of Glucocorticoid-Induced Osteoporosis. Arthritis Rheumatol. 2023;75(12):2088-2012.

13. 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.
14. Ensrud KE, Crandall CJ. Osteoporosis. Ann Intern. Med 2017;167(03):ITC17–ITC32.