CVS Caremark®

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| 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 Indications1-5

* 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.

## 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 Osteoporosis1-10,14

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 Men1-5,10,11

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 Osteoporosis1-5,10,12

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 Therapy1-5

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 Therapy8

* 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 Tool12,13

* 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.
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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.
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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.