



AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name: Forteo, Teriparatide

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Effective Date: 9/16/2024

Last Review Date: 8/2024

Applies to:	<input checked="" type="checkbox"/> Illinois	<input type="checkbox"/> Florida	<input type="checkbox"/> Michigan
	<input type="checkbox"/> New Jersey	<input type="checkbox"/> Maryland	<input type="checkbox"/> Florida Kids
	<input type="checkbox"/> Pennsylvania Kids	<input type="checkbox"/> Virginia	<input type="checkbox"/> Kentucky PRMD

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.

Applicable Drug List:

Forteo
Teriparatide

Policy/Guideline:

DOCUMENTATION

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:

CRITERIA FOR INITIAL APPROVAL

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



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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:
 - 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 has a history of an osteoporotic vertebral or hip fracture
2. Member 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 the following criteria are met:

1. 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)
2. Member is currently receiving or will be initiating glucocorticoid therapy at an equivalent prednisone dose of ≥ 2.5 mg/day for ≥ 3 months.
3. 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



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

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 Limits:

- Forteo (teriparatide) 600 mcg/2.4 mL (250 mcg/mL) single-use prefilled pen: 1 pen per 28 days
- Forteo (teriparatide) 560 mcg/2.24 mL (250 mcg/mL) single-use prefilled pen: 1 pen per 28 days
- Teriparatide 620 mcg/2.48 mL (250 mcg/mL) single-use pen: 1 pen per 28 days

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)



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- History of intolerance to an oral bisphosphonate

Appendix B. WHO Fractures Risk Assessment Tool

- High FRAX fracture probability: 10 year major osteoporotic fracture risk \geq 20% or hip fracture risk \geq 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:

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