# Teriparatide

## NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

## BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

## DESCRIPTION

The intent of the Teriparatide policy is to ensure appropriate selection of patients for therapy based on product labeling, clinical guidelines and clinical studies while steering utilization to the most cost-effective medication within the therapeutic class. The criteria will require the use of the health plan's preferred product, Teriparatide, before the use of Forteo, unless there are clinical circumstances that exclude the use of the preferred product and may be based on previous use of a product. The preferred product, Teriparatide, is the follow-on biologic product to Forteo. Forteo is not a preferred product.

The indications below including FDA-approved indications and compendial uses for both Forteo and Teriparatide 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. Treatment of postmenopausal women with osteoporosis at high risk for fracture
2. Increase of bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture
3. Treatment of men and women with glucocorticoid-induced osteoporosis at high risk for fracture

## POLICY

Required 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 to Criteria for Initial Approval.

Criteria for Initial Approval

**A. Postmenopausal osteoporosis**

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

1. Member meets any of the following exception criteria for non-preferred product, Forteo (if applicable)
   a. Member has had a documented inadequate response to the preferred product Teriparatide
   b. Member has experienced a documented intolerable adverse event with the preferred product Teriparatide

   **AND**
2. Member has a history of fragility fractures

   **OR**

   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 higher fracture risk (e.g., advanced age, frailty, glucocorticoid use, very low T-scores [less than or equal to -3.5], or increased fall risk)
   b. Member has failed prior treatment with or is intolerant to previous injectable osteoporosis therapy (e.g., zoledronic acid [Reclast], denosumab [Prolia])
   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 for Forteo and Teriparatide may be granted to male members with primary or hypogonadal osteoporosis when ANY of the following criteria are met:

1. Member meets any of the following exception criteria for non-preferred product, Forteo (if applicable)
   a. Member has had a documented inadequate response to the preferred product Teriparatide
   b. Member has experienced a documented intolerable adverse event with the preferred product Teriparatide
2. Member has a history of an osteoporotic vertebral or hip fracture
3. Member meets BOTH of the following criteria:
   a. Member has a pre-treatment T-score of 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 for Forteo and Teriparatide may be granted for members with glucocorticoid-induced osteoporosis when ALL of the following criteria are met:

1. Member meets any of the following exception criteria for non-preferred product, Forteo (if applicable)
   a. Member has had a documented inadequate response to the preferred product Teriparatide
   b. Member has experienced a documented intolerable adverse event with the preferred product Teriparatide
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
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 of 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

All members (including new members) requesting authorization for continuation of therapy must be currently receiving the requested medication through a paid pharmacy or medical benefit AND have received less than 24 months of total lifetime therapy with parathyroid hormone analogs (e.g., abaloparatide or teriparatide).

Appendix

**Appendix A. Clinical reasons to avoid oral bisphosphonate therapy**

- Esophageal abnormality that delays emptying such as stricture or achalasia
- Active upper gastrointestinal problem (e.g., dysphagia, gastritis, duodenitis, erosive esophagitis, ulcers)
- Inability to stand or sit upright for at least 30 to 60 minutes
- Inability to take 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 and 1.2 for hip fracture if glucocorticoid treatment is greater than 7.5 mg (prednisone equivalent) per day.

## PROCEDURES AND BILLING CODES

**To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.**

- N/A

## REFERENCES


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- 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.
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## POLICY HISTORY

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