# 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 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 (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.
2. 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.
3. Treatment of men and women with glucocorticoid-induced osteoporosis at high risk for fracture or who have failed or are intolerant to other available osteoporosis therapy.

## 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 Approval.

Criteria for Approval

**A. Postmenopausal osteoporosis**

Authorization for teriparatide of an initial total of 12 months 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**

3. 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 (e.g., zoledronic acid [Reclast], denosumab [Prolia], abaloparatide [Tymlos])
   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 for teriparatide of an initial total of 12 months may be granted to male members with primary or hypogonadal 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 an osteoporotic vertebral or hip fracture

   **OR**

3. Member meets 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 for teriparatide 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 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 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.

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 and the risk versus benefit of cumulative use of parathyroid hormone analogs over 24 months has been reviewed with the patient.

Appendix

**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 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.

## 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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## POLICY HISTORY

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