Teriparatide (Forteo®)

Place of Service

Self-Administration - *May be covered under the pharmacy benefit*

HCPCS: **J3110** per 10 mcg

Condition(s) listed in policy (*see criteria for details*)

- Osteoporosis

AHFS therapeutic class: Parathyroid Agents

Mechanism of action: Teriparatide, a biosynthetic (rDNA origin) peptide fragment of human parathyroid hormone (PTH), is a regulator of bone metabolism.

(1) Special Instructions and Pertinent Information

This drug is managed under the outpatient Pharmacy Benefit for self-administration. Please contact the member's Pharmacy Benefit for information on how to obtain this drug.

To submit a request to the Medical Benefit, please submit clinical information for prior authorization review and include medical rationale why the patient cannot self-administer this drug in the home.

For plans with self-injectables only covered under the Medical Benefit, please submit clinical information for prior authorization review.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for Forteo® (teriparatide) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Treatment or prevention of osteoporosis

1. One of the following:
    a. Provider attestation of one or more non-traumatic fractures, OR
    b. T-score less than or equal to -2.5 SD, OR
    c. T-score is between -1.0 and -2.5 and patient is at high risk for fracture
    [e.g. multiple risk factors or 10-year hip fracture probability ≥ 3% or a 10-year major osteoporosis-related fracture probability ≥ 20% based on USA-adapted absolute fracture risk model (FRAX® risk assessment)]

AND

2. One of the following:
    a. Intolerable side effect to bisphosphonate (oral and IV) therapy or Prolia, or contraindication to bisphosphonate (oral and IV) therapy and Prolia, OR
    b. Inadequate response, as evidenced by documented worsening BMD, following at least two years therapy with a bisphosphonate or Prolia, OR
    c. Patient is initiating or continuing long-term glucocorticoid treatment (≥3 months), OR
    d. Patient is at very high risk of fracture by meeting at least one of the following:
        I. Fracture while on bisphosphonate therapy or Prolia, or

II. Provider attestation that patient has experienced a recent fracture (within the past 12 months) or history of multiple fractures, or

III. Provider attestation that patient experienced a fracture while on long-term glucocorticoid therapy, or

IV. T-score less than −3.0, or

V. Provider attestation that patient is at high risk for falls, or

VI. 10-year hip fracture probability of > 4.5% based on FRAX® score, or

VII. 10-year major osteoporosis-related fracture probability > 30% based on FRAX® score

AND

3. Patient had intolerance or is not able to use Tymlos, **AND**
4. Not used in combination with other osteoporosis therapy (i.e., Tymlos, Prolia)

Covered Doses
Up to 20 mcg SC once daily

Coverage Period
Initial: 2 years
Reauthorization: Yearly with provider attestation that patient remains at or has returned to having a high risk for fracture.

ICD-10:
M81.0-M81.9

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for Forteo® (teriparatide) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)

Blue Shield's research indicates there is inadequate clinical evidence to support off-label use of this drug for the following conditions (Health and Safety Code 1367.21): -

- Gonadotropin releasing hormone analog induced estrogen deficiency

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication**.**

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How supplied:
Multi-dose prefilled delivery device (pen) containing 28 daily doses of 20 mcg

Table 1. Clinical Risk Factors for Osteoporosis-Related Fractures in POSTMENOPAUSAL WOMEN

Risk Factor
Prior low-trauma fracture as an adult
Advanced age (>/= 65yrs)
Low body weight [<57.6 kg(127lb)]
Family history of osteoporosis or fractures
Use of corticosteroids
Cigarette smoking

Excessive alcohol consumption (≥ 3 drinks per day)
Secondary osteoporosis (e.g. rheumatoid arthritis)
Early menopause

https://www.aace.com/files/postmenopausal-guidelines.pdf

FRAX tool: FRAX is a tool developed by the World Health Organization (WHO) to predict a patient's risk of having an osteoporosis-related fracture in the next 10 years. Generally, it is used for people not already being treated for osteoporosis. The calculation tool can be found at this link: http://www.shef.ac.uk/FRAX/

(6) References

- AHFS®. Available by subscription at http://www.lexi.com
- Camacho PM, Petak SM, Blinkley N, et al. American Association of Clinical Endocrinologists and 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.
- Cosman F, de Beur SJ, LeBoff MS, et al. Clinician's Guide to Prevention and Treatment of Osteoporosis. Osteoporos Int. 2014;25(10):2359-2381. doi:10.1007/s00198-014-2794-2
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com
- Forteo® (teriparatide) [Prescribing information]. Indianapolis, IN: Eli Lilly. 11/2022.
- Qaseem A, Forciea MA, McLean RM, Denberg TD, Clinical Guidelines Committee of the American College of Physicians. Treatment of Low Bone Density or Osteoporosis to Prevent Fractures in Men and Women: A Clinical Practice Guideline Update From the American College of Physicians. Ann Intern Med. 2017;166(11):818-839. doi:10.7326/M15-1361
- Shoback D, Rosen CJ, Black DM, et al. Pharmacological management of osteoporosis in postmenopausal women: an Endocrine Society guideline update. J Clin Endocrinol Metab 2020; 105:587-594.

(7) Policy Update

Date of last review: 4Q2022
Date of next review: 4Q2023
Changes from previous policy version:

- No clinical change to policy following routine annual review.

BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee