

Clinical Policy: Teriparatide (Forteo)

Reference Number: IL.PHAR.188

Effective Date: 1.1.20

Last Review Date: 9.8.22

Line of Business: Medicaid

[Coding Implications](#)

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

Teriparatide (Forteo[®]) is a recombinant human parathyroid hormone (PTH) analog.

FDA Approved Indication(s)

Forteo is indicated:

- **Postmenopausal osteoporosis (PMO):** For the treatment of postmenopausal women with osteoporosis at high risk for fracture.* In postmenopausal women with osteoporosis, Forteo reduces the risk of vertebral and nonvertebral fractures.
- **Male osteoporosis:** To increase bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture.*
- **Glucocorticoid-induced osteoporosis (GIO):** For the treatment of men and women with osteoporosis associated with sustained systemic glucocorticoid therapy (daily dosage equivalent to 5 mg or greater of prednisone) at high risk for fracture.*

**High risk of fracture is defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy.*

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation[®] that Forteo is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Osteoporosis (must meet all):

1. Diagnosis of PMO, GIO or male osteoporosis and (a or b):
 - a. Member is at very high risk for fracture (i or ii):
 - i. BMD T-score at hip or spine ≤ -3.5 ;
 - ii. BMD T-score at hip or spine ≤ 2.5 AND major osteoporotic fracture (i.e., hip, spine, forearm, wrist, humerus);
 - b. Member has completed a 3-year trial of bisphosphonate therapy (*alendronate is preferred*) at up to maximally indicated doses unless one of the following (i-v):
 - i. All bisphosphonates are contraindicated;
 - ii. Clinically significant adverse effects are experienced to both IV and PO formulations (see Appendix E)

- iii. Member has experienced a loss of BMD while receiving bisphosphonate therapy;
- iv. Member has experienced a lack of BMD increase after ≥ 12 months of bisphosphonate therapy;
- v. Member experienced an osteoporotic fracture or fragility fracture while receiving bisphosphonate therapy;

**Prior authorization may be required for bisphosphonates*

- 2. Age ≥ 18 years or documentation of closed epiphyses on x-ray;
- 3. One of the following (a or b):
 - a. For PMO, failure of Prolia[®] or Tymlos[®] at up to maximally indicated doses unless clinically significant adverse effects are experienced or both are contraindicated;
 - b. If request is for continuation of cumulative PTH analog therapy beyond 2 years, provider attestation that member remains at or has returned to having a high risk for fracture (e.g., history of osteoporotic fracture or multiple risk factors for fracture, see Appendix D) and that the risk versus benefit of continued therapy has been reviewed with the member;

**Prior authorization may be required for Prolia and Tymlos*

- 4. Dose does not exceed 20 mcg per day (1 pen every 28 days).

Approval duration:

Medicaid – 6 months

B. Other diagnoses/indications

- 1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Osteoporosis (must meet all):

- 1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
- 2. Member is responding positively to therapy;
- 3. If request is for continuation of cumulative PTH analog therapy beyond 2 years, provider attestation that member remains at or has returned to having a high risk for fracture (e.g., history of osteoporotic fracture or multiple risk factors for fracture, see Appendix D) and that the risk versus benefit of continued therapy has been reviewed with the member;
- 4. If request is for a dose increase, new dose does not exceed 20 mcg per day (1 pen every 28 days).

Approval duration:

Medicaid – 12 months

B. Other diagnoses/indications (must meet 1 or 2):

- 1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	Treatment: Paget disease Atelvia: Treatment: PMO <i>See prescribing information for dose.</i>	
ibandronate (Boniva)	Treatment/prevention: PMO <i>See prescribing information for dose.</i>	

Therapeutic alternatives are listed as Brand name[®] (generic) when the drug is available by brand name only and generic (Brand name[®]) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): hypersensitivity
- Boxed warning(s): none reported

Appendix D: General Information

- The FRAX tool is readily available and incorporates multiple clinical risk factors that predict fracture risk, largely independent of BMD. Clinical risk factors in FRAX include age, sex, body mass index (BMI), smoking, alcohol use, prior fracture, parental history of hip fracture, use of glucocorticoids, rheumatoid arthritis, secondary osteoporosis, and femoral neck BMD, when available. FRAX predicts the 10-year probability of hip fracture and major osteoporotic fracture (hip, clinical spine, humerus, or forearm). FRAX designation of high risk of fracture is defined as 10-year major osteoporotic fracture probability $\geq 20\%$ or hip fracture probability $\geq 3\%$.
- The 2019 Endocrine Society clinical practice guidelines include patient profiles representing examples of high and very high fracture risk:
 - High risk: T-score of minus 2.5 or below, or prior hip or vertebral fracture, or high fracture probability by the fracture risk assessment tool (FRAX) (10-year probability of major osteoporotic fracture $\geq 20\%$, or 10-year probability of hip fracture $\geq 3\%$)
 - Very high risk: T-score of minus 2.5 or below and 1 or more fractures, or multiple vertebral fractures, or severe vertebral fracture.

Appendix E: IV/PO Bisphosphonates: Examples of Contraindications and Adverse Effects

Bisphosphonates	Oral Formulations	IV Formulations
Contraindications		
Hypocalcemia	X	X
Increased risk of aspiration	X	-
Hypersensitivity to product component	X	X
Inability to stand/sit upright for at least 30 minutes	X	-
Creatinine clearance < 35 mL/min or evidence of acute renal impairment	-	X

Bisphosphonates	Oral Formulations	IV Formulations
Esophagus abnormalities which delay emptying such as stricture or achalasia	X	-
<i>Clinically significant warnings or adverse side effects</i>		
Pregnancy	X	X
Eye inflammation	X	X
Acute renal failure	X	X
Osteonecrosis of the jaw	X	X
Atypical femoral shaft fracture	X	X
Drug interactions (product-specific)	X	X
Severe or incapacitating musculoskeletal pain	X	X

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
PMO, GIO, male osteoporosis	20 mcg SC QD	20 mcg/day up to 2 years cumulative PTH analog use lifetime

VI. Product Availability

Multi-dose prefilled pen (2.4 mL): 28 daily doses of 20 mcg

VII. References

1. Forteo Prescribing Information. Indianapolis, IN: Eli Lilly and Company; April 2021. Available at <http://www.forteo.com>. Accessed September 16, 2021.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2020. URL: <http://www.clinicalpharmacology.com>.

Osteoporosis Diagnosis, Fracture Risk, and Treatment

3. Shoback D, Rosen CJ, Black DM, et al. Pharmacological management of osteoporosis in postmenopausal women: an endocrine society guideline update. J Clin Endocrinol Metab; March 2020, 105(3): 587-594.
4. Eastell R, Rosen CJ, Black DM, et al. Pharmacological management of osteoporosis in postmenopausal women: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab; 2019, 104: 1595–1622.
5. Camacho PM, Petak SM, Brinkley N et al. AACE/ACE Guidelines- American Association of Clinical Endocrinologists and American College of Endocrinology Clinical Practice Guidelines for Diagnosis and Treatment of Postmenopausal Osteoporosis. Endocrine Practice Vol 22 (suppl 4) September 2016.
6. National Osteoporosis Foundation Clinician’s Guide to Prevention and Treatment of Osteoporosis. Osteoporosis International 2014. Available at: <http://nof.org/files/nof/public/content/file/2791/upload/919.pdf>. Accessed October 31, 2018.
7. Siris ES, Adler R, Bilezikian J, et al. The clinical diagnosis of osteoporosis: a position statement from the National Bone Health Alliance Working Group. Osteoporos Int (2014) 25:1439–1443. DOI 10.1007/s00198-014-2655-z.
8. Hodsman AB, Bauder DC, Dempster DW, et al. Parathyroid hormone and teriparatide for the treatment of osteoporosis: a review of the evidence and suggested guidelines for its use. Endocr Rev. 2005 Aug;26(5):688-703. Epub 2005 Mar 15.

Male Osteoporosis

9. Watts NB, Adler RA, Bilezikian JP, et al. Osteoporosis in men: an Endocrine Society clinical practice guidelines. J Clin Endocrinol Metab 2012;97(6):1802-1822.

Glucocorticoid-Induced Osteoporosis

10. Buckley L, Guyatt G, Fink HA, et al. 2017 American College of Rheumatology guideline for the prevention and treatment of glucocorticoid-induced osteoporosis. Arthritis Rheumatol. 2017; 69(8): 1521-1537.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J3110	Injection, teriparatide, 10 mcg

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created, adapted from CP.PHAR.188 Teriparatide (Forteo) for migration to HFS PDL.	12.31.19	1.7.19
1Q 2021 annual review: removal of osteosarcoma black box warning per package insert update; references reviewed and updated.	3.11.2021	
Changes: added Prolia in addition to Tymlos as redirect options for PMO;	9.2.21	
3Q2022 annual review: updated definition of very high risk for fracture per 2020 AACE/ACE PMO guidelines; Per updated prescribing information regarding length of therapy, removed criteria and approval duration requirements that limited therapy to 2 years cumulative PTH analog therapy, added requirement if request is for continuation of cumulative PTH analog therapy beyond 2 years, provider attestation that member remains at or has returned to having a high risk for fracture (e.g., history of osteoporotic fracture or multiple risk factors for fracture) and that the risk versus benefit of continued therapy has been reviewed with the member, added general information regarding fracture risk assessments; added option (in addition to contraindications or adverse effects) to bypass bisphosphonate trial if member has experienced a loss of BMD, lack of BMD increase, or has had an osteoporotic fracture or fragility fracture while receiving bisphosphonate therapy; references reviewed and updated	9.8.22	

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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Note:

For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

For Health Insurance Marketplace members, when applicable, this policy applies only when the prescribed agent is on your health plan approved formulary. Request for non-formulary drugs must be reviewed using the formulary exception policy: HIM.PA.103.

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