Clinical Policy: Teriparatide (Forteo)

Reference Number: CP.PHAR.188
Effective Date: 11.15.17
Last Review Date: 02.20
Line of Business: Commercial* (Exchange Plans), HIM, Medicaid

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

**If request is for Commercial Non-Exchange Plans, please use CP.CPA.199 - Teriparatide (Forteo).*

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 contraindicated or clinically significant adverse effects are experienced to both IV and PO formulations (*see Appendix D*);
      Prior authorization may be required for bisphosphonates

2. Age ≥ 18 years or documentation of closed epiphyses on x-ray;
3. For PMO, failure of Tymlos® at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced;
   **Prior authorization may be required for Tymlos*
4. Member has not received ≥ 2 years cumulative PTH analog therapy (e.g., Forteo, Tymlos);
5. Dose does not exceed 20 mcg per day (1 pen every 28 days).

Approval duration:
Medicaid/HIM – 6 months (2 years cumulative PTH analog use lifetime)
Commercial – 6 months or to the member's renewal date, whichever is longer (2 years cumulative PTH analog use lifetime)

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.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and 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. Member has not received ≥ 2 years cumulative PTH analog therapy (e.g., Forteo, Tymlos);
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/HIM – 12 months (2 years cumulative PTH analog use lifetime)
Commercial – 6 months or to the member's renewal date, whichever is longer (2 years cumulative PTH analog use lifetime)

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

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. 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.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

BMD: bone mineral density
FDA: Food and Drug Administration
GIO: glucocorticoid-induced osteoporosis
PMO: postmenopausal osteoporosis
PTH: parathyroid hormone

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
PTH analog therapy		
Tymlos (abaloparatide)	Treatment:PMO 80 mcg SC QD	80 mcg/day - 2 yr total lifetime
IV bisphosphonates		
ibandronate (Boniva®)	Treatment: PMO *See prescribing information for dose.*	Varies
zoledronic acid (Reclast®)	Teatment/prevention: PMO, GIO Treatment: male osteoporosis Treatment: Paget disease *See prescribing information for dose.*	
Oral bisphosphonates		
alendronate (Fosamax®)	Treatment/prevention: PMO Treatment: GIO, male osteoporosis Treatment: Paget disease *See prescribing information for dose.*	Varies
Fosamax® Plus D (alendronate / cholecalciferol)	Treatment: PMO, male osteoporosis *See prescribing information for dose.*	
risedronate (Actonel®, Atelvia®)	Actonel: Treatment/prevention: PMO, GIO Treatment: male osteoporosis Treatment: Paget disease Atelvia: Treatment: PMO *See prescribing information for dose.*	
ibandronate (Boniva)	Treatment/prevention: PMO *See prescribing information for dose.*	

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): risk of osteosarcoma

Appendix D: 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
Esophagus abnormalities which delay emptying such as stricture or achalasia	X	-
Clinically significant warnings or adverse side effects		
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; October 2019. Available at http://www.forteo.com. Accessed October 14, 2019.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2019. URL: http://www.clinicalpharmacology.com.

Osteoporosis Diagnosis, Fracture Risk, and Treatment

3. 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.
4. 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.
5. 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.
6. 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.
7. 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

8. 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

9. 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 split from CP.PHAR.20.Osteoporosis Injection Therapy and converted to new template. Requests for documentation removed. Criteria: For men with osteoporosis- criteria changed to require testosterone only for hypogonadal rather than primary osteoporosis, and removed required year-long testosterone therapy prior to Forteo. Removed the expected 12-month duration criteria as anti-resorptive therapy is recommended at any glucocorticoid duration; added "at femoral neck or spine" to T score. Removed requirement that must be over 50 in cases where the osteoporosis diagnosis relies on history of an osteoporotic fracture. Added definition of bisphosphonate trial failure and, if contraindication/intolerance, that it be to one of the two oral drugs listed and to Reclast. Calcium/vitamin D requirement language edited to be less specific. Shortened approval durations to 6 months.	02.16	03.16

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Age requirement modified to apply to pediatric members with open epiphyses. Added "at total hip" to T score. Added that osteoporotic fracture should be confirmed by radiographic imaging. Removed requirement for administration of calcium/vitamin D. Removed conditions representing potential contraindications to therapy. Added dose to continued therapy Added requirement for positive response to therapy.	02.17	03.17
Added preferencing for Tymlos in postmenopausal osteoporosis based on SDC decision. Added lifetime limitation criteria for parathyroid hormone analog per previously approved clinical guidance	11.01.17	
1Q18 annual review: policies combined for commercial and Medicaid; converted to new template; removed criteria for evidence of diagnosis; removed member characteristic requirements for gender and type of osteoporosis; modified age requirement; modified criteria to add specialist requirement or trial and failure of a bisphosphonate (alendronate is preferred); removed definition of treatment failure; rmoved requirement regarding admin of last dose of Reclast; modified approval duration to 6 months (initial) and 12 months (continuation); references reviewed and updated.	11.09.17	02.18
No clinical changes: line of business designation modified to apply to Commercial Exchange Plans; Commercial Non-Exchange Plans will be addressed with separate criteria per SDC.	06.26.18	
1Q 2019 annual review: no significant changes; added geriatrician prescriber option; removed previous requirement that physiatrist prescriber apply only to postmenopausal osteoporosis; modify approval duration for Commercial to "6 months or to the member's renewal date, whichever is longer"; references reviewed and updated.	10.31.18	02.19
1Q 2020 annual review: removed HIM disclaimer for HIM NF drugs; very high fracture risk or 3-year bisphosphonate trial added with required contraindication to both PO/IV formulations; specialists removed; age 18 or closed epiphyses added per PI; references reviewed and updated.	11.19.19	02.20

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.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

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.