Clinical Policy:Teriparatide (Forteo)

Reference Number: CP.PHAR.188
Effective Date: 03/16
Last Review Date: 03/17

Coding Implications
Revision Log

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

Description
The intent of the criteria is to ensure that patients follow selection elements established by Centene® clinical policy for teriparatide (Forteo®).

Policy/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. Age ≥ 18 years or documentation of closed epiphyses;
2. Member meets one of the following (a, b, c, or d):
   a. Postmenopausal woman with osteoporosis;
   b. Male with primary osteoporosis;
   c. Male with hypogonadal osteoporosis who is receiving testosterone but remains at high risk for fracture or who has a contraindication to testosterone;
   d. Osteoporosis associated with sustained systemic glucocorticoid therapy (daily dosage equivalent to ≥ 5 mg of prednisone);
3. Diagnosis of osteoporosis is evidenced by one of the following (a or b):
   a. T-score ≤ -2.5 (DXA) at the femoral neck, spine, or total hip;
   b. History of osteoporotic fracture confirmed by radiographic imaging;
4. Failure (decline in BMD of ≥ 5% or continued fractures) of both of the following (a and b), each trialed for one year unless contraindicated or clinically significant adverse effects are experienced:
   a. An oral bisphosphonate (e.g., alendronate, risedronate);
   b. Reclast* (zoledronic acid);
5. If member has received Reclast, it has been at least one year since the last administration of Reclast;
6. Prescribed dose of Forteo does not exceed 20 mcg per day (1 pen every 28 days).

**Requires prior authorization*

Approval duration: 6 months (limited to 2 years lifetime use)

B. Other diagnoses/indications: Refer to CP.PHAR.57 - Global Biopharm Policy

II. Continued Approval

A. Osteoporosis (must meet all)**:**

1. Currently receiving medication via Centene benefit or member has previously met all initial approval criteria;

2. Documentation of positive response to therapy;
3. Prescribed dose does not exceed 20 mcg per day (1 pen every 28 days);
4. Member has not used Forteo for ≥ 2 years.

Approval duration: 6 months (limited to 2 years lifetime use)

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy; or
2. Refer to CP.PHAR.57 - Global Biopharm Policy**.**

Background

Description/Mechanism of Action:

Forteo (teriparatide [rDNA origin] injection) contains recombinant human parathyroid hormone and is also called rhPTH. Teriparatide (rDNA origin) is manufactured using a strain of *Escherichia coli* modified by recombinant DNA technology.

Parathyroid hormone (PTH) is the primary regulator of calcium and phosphate metabolism in bone and kidney. Physiological actions of PTH include regulation of bone metabolism, renal tubular reabsorption of calcium and phosphate, and intestinal calcium absorption. The biological actions of PTH and teriparatide are mediated through binding to specific high-affinity cell-surface receptors. Teriparatide and the 34 N-terminal amino acids of PTH bind to these receptors with the same affinity and have the same physiological actions on bone and kidney. Teriparatide is not expected to accumulate in bone or other tissues. The skeletal effects of teriparatide depend upon the pattern of systemic exposure. Once-daily administration of teriparatide stimulates new bone formation on trabecular and cortical (periosteal and/or endosteal) bone surfaces by preferential stimulation of osteoblastic activity over osteoclastic activity. In humans, the anabolic effects of teriparatide manifest as an increase in skeletal mass, an increase in markers of bone formation and resorption, and an increase in bone strength. By contrast, continuous excess of endogenous PTH, as occurs in hyperparathyroidism, may be detrimental to the skeleton because bone resorption may be stimulated more than bone formation.

Two studies have found that increases in hip and spine bone mineral density (BMD) decline after discontinuation of PTH (Rosen, PTH for osteoporosis). For this reason, treatment with an antiresporptive agent after PTH is recommended to preserve gains in BMD.

Formulations:
Forteo is supplied as a multi-dose prefilled delivery device (pen) containing 28 daily doses of 20 mcg.

FDA Approved Indications:

Forteo is a recombinant human parathyroid hormone analog/subcutaneous injectable solution indicated for:

- 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.

- Increasing bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture*.
- 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*.

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**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.*

Appendices
Appendix A: Abbreviation Key
BMD: bone mineral density
DXA: dual energy X-ray absorptiometry
PTH: parathyroid hormone
rhPTH: recombinant human parathyroid hormone

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	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
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	02/17	03/17

Reviews, Revisions, and Approvals	Date	Approval Date
administration of calcium/vitamin D. Removed conditions representing potential contraindications to therapy. Added dose to continued therapy Added requirement for positive response to therapy.		

References

1. Forteo Prescribing Information. Indianapolis, IN: Eli Lilly and Company; October 2013. Available at http://www.forteo.com. Accessed February 9, 2017.
2. Cosman F, de Beur SJ, LeBoff MS, et al. Position paper: clinician's guide to prevention and treatment of osteoporosis. Osteoporosis Int. 2014; 25(10): 2359-2381.
3. Camacho PM, Petak SM, Binkley N, et al. American Association of Clinical Endocrinologists and American College of Endocrinology practice guidelines for the diagnosis and treatment of postmenopausal osteoporosis – 2016. Endocrin Pract. 2016; 22(Suppl 4).
4. Watts NB, Adler RA, Bilezikian JP, et al. Osteoporosis in men: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab. 2012; 97(6): 1802-1822.

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.

Note: For Medicare members, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.