Clinical Policy:Teriparatide (Forteo)

Reference Number: PA.CP.PHAR.188
Effective Date: 01/18
Last Review Date: 03/17

Coding Implications
Revision Log

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

Policy/Criteria
It is the policy of Pennsylvania Health and Wellness 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,b or c):
   a. T-score ≤ -2.5 (DXA) at the femoral neck, spine, or total hip;
   b. History of osteoporotic fracture confirmed by radiographic imaging;
   c. Osteopenia with a high FRAX fracture probability as defined by the National Bone Health Alliance
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 PA.CP.PHAR.57 - Global Biopharm Policy

II. Continued Approval

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

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care policy applies;
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 Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy applies; or
2. Refer to PA.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

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.