Clinical Policy: Teriparatide (Forteo)

Reference Number: PA.CP.PHAR.188
Effective Date: 01/18
Last Review Date: 07/18

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®).

FDA Approved Indication(s)
Forteo is indicated:

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

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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.*

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. Diagnosis of osteoporosis;
2. Age ≥ 18 years or documentation of closed epiphyses (e.g., x-ray);
3. Member meets one of the following (a or b):
   a. Prescribed by or in consultation with one of the following specialists: a gynecologist, endocrinologist, rheumatologist, orthopaedist, or physiatrist for postmenopausal osteoporosis;
   b. Failure of a 12-month trial of a bisphosphonate (*alendronate is preferred*) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
4. For postmenopausal osteoporosis, failure of Tymlos* at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced;
   **Prior authorization is required for Tymlos*

5. Member has not received cumulative therapy on parathyroid hormone (PTH) analogs (e.g., Tymlos, Forteo) that exceeds 2 years;
6. Dose does not exceed 20 mcg per day (1 pen every 28 days).

**Requires prior authorization*

Approval duration: 6 months (limited to 2 years cumulative use of PTH analogs lifetime use)

B. Other diagnoses/indications: Refer to PA.CP.PMN.53

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. Member is responding positively to therapy;
3. Member has not received cumulative therapy on parathyroid hormone (PTH) analogs (e.g., Tymlos, Forteo) that exceeds 2 years;
4. If request is for a dose increase, new dose does not exceed 20 mcg per day (1 pen every 28 days).

Approval duration: 12 months (limited to 2 years cumulative use of PTH analogs 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; **Approval duration: Duration of request or 6 months (whichever is less)**; or
2. Refer to PA.CP.PMN.53

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.

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
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.Removed requirement regarding admin of last dose of Reclast. Modified approval duration to 6 months (initial) and 12 months (continuation). References reviewed and updated.	02/18	

References

1. Forteo Prescribing Information. Indianapolis, IN: Eli Lilly and Company; October 2016. Available at http://www.forteo.com. Accessed November 8, 2017.
2. National Osteoporosis Foundation Clinician's Guide to Prevention and Treatment of Osteoporosis. Available at: http://nof.org/files/nof/public/content/file/2791/upload/919.pdf. Accessed November 9, 2017.
3. Watts NB, Bilezikian JP, Camacho PM, et al. American Association of Clinical Endocrinologists medical guidelines for clinical practice for the diagnosis and treatment of postmenopausal osteoporosis. Endocr Pract 2010;16(Suppl 3):1-37.
4. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2017. URL: http://www.clinicalpharmacology.com.
5. 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.
6. 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.

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