09-J0000-47

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Reviewed: 03/13/19

Revised: 04/15/19

Subject: Teriparatide (Forteo®)

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

DESCRIPTION:

Teriparatide (Forteo) is recombinant parathyroid hormone (PTH) and is identical to the 34 N-terminal amino acids of endogenous PTH. Similar to other osteoporosis treatments (e.g., bisphosphonates), teriparatide reduces bone turnover. Additionally, teriparatide stimulates the formation of new bone and increases bone mass. Teriparatide was initially approved by the US Food and Drug Administration in November 2002 for the treatment of postmenopausal women with osteoporosis; the FDA-approved indication was expanded to include treatment of men and women with osteoporosis secondary to sustained glucocorticoid therapy at high risk for fracture and to increase bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture.

According to evidence based guidelines (e.g., American Academy of Clinical Endocrinologists/American College of Endocrinology guidelines for treatment of postmenopausal women with osteoporosis and Endocrine Society for treatment of osteoporosis in men), teriparatide is not considered first line therapy for the majority of individuals. Oral bisphosphonate therapy, zoledronic acid, or denosumab are appropriate for most patients at high risk of fracture due to the broad spectrum antifracture efficacy.

POSITION STATEMENT:

Certificate of Medical Necessity

Submit a completed Certificate of Medical Necessity (CMN) along with your request to expedite the medical review process.

1. Click the link Teriparatide (Forteo®) under Certificates of Medical Necessity in the side navigation of this page to access the form.
2. Complete all fields on the form thoroughly.
3. Print and submit a copy of the form with your request.

Note: Florida Blue regularly updates CMNs. Ensure you are using the most current copy of a CMN before submitting to Florida Blue.

I. The initiation of teriparatide (Forteo®) **meets the definition of medical necessity** for the following indications:

1. **Postmenopausal Osteoporosis** when **ALL** of the following criteria are met
   a. Member meets **ONE** of the following:
      i. Diagnosed with osteoporosis defined as a pre-treatment bone mineral density (BMD) T-score of -2.5 or lower*
      ii. Member has a history of osteoporotic hip or vertebral fracture
   b. The dose does not exceed 20 mcg daily
   c. The cumulative duration of teriparatide (Forteo®) and abaloparatide (Tymlos®) has not exceeded a total of 2 years in the member's lifetime
   d. Teriparatide will be used as a single agent
   e. Member has an inadequate response or contraindication to abaloparatide (Tymlos®)
   f. **ONE** of the following:
      i. Member has an inadequate response† to at least one injectable antiresorptive therapy [zoledronic acid (Reclast®) OR denosumab (Prolia®)]
      ii. Member has a contraindication to **BOTH** zoledronic acid and denosumab
2. **Primary or Hypogonadal Osteoporosis** when **ALL** of the following criteria are met
   a. Member is a biological male
   b. Member meets **ONE** of the following:
      i. Diagnosed with osteoporosis defined as a pre-treatment bone mineral density (BMD) T-score of -2.5 or lower*
      ii. Member has a history of osteoporotic hip or vertebral fracture
   c. The dose does not exceed 20 mcg daily
   d. The cumulative duration of teriparatide and abaloparatide has not exceeded a total of 2 years in the member's lifetime

e. Teriparatide will be used as a single agent

f. **EITHER** of the following:

i. Member has an inadequate response† to bisphosphonate therapy (oral **OR** intravenous [IV])

ii. Member has a contraindication to **BOTH** oral‡ and IV bisphosphonate therapy

3. **Sustained Systemic Glucocorticoid Osteoporosis** when **ALL** of the following criteria are met:

a. History of prednisone or its equivalent at a dose of 5 mg/day or greater for 3 months or more

b. Member meets ONE of the following:

i. Diagnosed with osteoporosis defined as a pre-treatment bone mineral density (BMD) T-score of -2.5 or lower*

ii. Member has a history of osteoporotic hip or vertebral fracture

c. The dose does not exceed 20 mcg daily

d. The cumulative duration of teriparatide and abaloparatide has not exceeded a total of 2 years in the member's lifetime

e. Teriparatide will be used as a single agent

f. **EITHER** of the following:

i. Member has an inadequate response† to bisphosphonate therapy (oral **OR** intravenous [IV])

ii. Member has a contraindication to **BOTH** oral‡ and IV bisphosphonate therapy

4. Teriparatide meets the definition of medical necessity when used as a single agent for the following designated Orphan Drug indications (http://www.fda.gov/orphan/designat/list.htm):

1. Treatment of hypoparathyroidism

Approval duration: 1 year (maximum lifetime duration is 2 consecutive years) (all indications)

I. Continuation of teriparatide therapy **meets the definition of medical necessity** for the treatment of postmenopausal osteoporosis, primary or hypogonadal osteoporosis, sustained systemic glucocorticoid osteoporosis and orphan indications when **ALL** of the following criteria are met:

1. Member has demonstrated a beneficial response to therapy
2. Authorization/reauthorization for teriparatide has been previously approved by Florida Blue in the past 2 years, **OR** the member currently meets all indication-specific initiation criteria
3. The cumulative duration of teriparatide and abaloparatide has not exceeded a total of 2 years in the member's lifetime
4. Teriparatide will be used as a single agent
5. The dose does not exceed 20 mcg daily

Approval duration: 1 year (maximum lifetime duration is 2 consecutive years) (all indications)

*Measured at the femoral neck, total hip, lumbar spine, or 33% radius

† Inadequate response is defined as a new fracture in a compliant member or significant loss of bone mineral density on follow-up scans.

‡ **NOTE:** gastroesophageal reflux disease (GERD) is **NOT** a labeled contraindication for oral bisphosphonate therapy.

DOSAGE/ADMINISTRATION:

THIS INFORMATION IS PROVIDED FOR INFORMATIONAL PURPOSES ONLY AND SHOULD NOT BE USED AS A SOURCE FOR MAKING PRESCRIBING OR OTHER MEDICAL DETERMINATIONS. PROVIDERS SHOULD REFER TO THE MANUFACTURER'S FULL PRESCRIBING INFORMATION FOR DOSAGE GUIDELINES AND OTHER INFORMATION RELATED TO THIS MEDICATION BEFORE MAKING ANY CLINICAL DECISIONS REGARDING ITS USAGE.

FDA-approved: teriparatide is indicated for

- Treatment of postmenopausal women with osteoporosis at high risk for fracture
- Increase of 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 at high risk for fracture

The recommended dosage is 20 mcg once a day. Teriparatide should be administered as a subcutaneous injection into the thigh or abdominal wall. Initially, teriparatide should be administered under circumstances in which the member can sit or lie down if symptoms of orthostatic hypotension occur.

The safety and efficacy of teriparatide injection have not been evaluated beyond 2 years of treatment. Consequently, use of the drug for more than 2 years is not recommended.

Drug Availability: teriparatide is supplied as a multi-dose prefilled delivery device (pen) containing 28 doses of 20 mcg.

PRECAUTIONS:

Boxed Warning

- In rats, teriparatide caused an increase in the incidence of osteosarcoma, a malignant bone tumor.
- Because of the uncertain relevance of the rat osteosarcoma finding to humans, teriparatide should only be prescribed for members for whom potential benefits outweigh potential risk.
- Teriparatide should not be prescribed for persons at increased baseline risk for osteosarcoma (e.g., those with Paget's disease of bone or unexplained elevations of alkaline phosphatase, pediatric and young adult patients with open epiphyses, or prior external beam or implant radiation therapy involving the skeleton.)

Warnings/Precautions

• Patients with Paget's disease of bone, pediatric and young adult patients with open epiphyses, or prior external beam or implant radiation therapy involving the skeleton should not be treated with teriparatide.

• Treatment duration: Use of teriparatide for more than 2 years during a person's lifetime is not recommended.

• Patients with bone metastases, history of skeletal malignancies, metabolic bone diseases other than osteoporosis, or hypercalcemic disorders should not be treated with teriparatide.

• Laboratory alterations: teriparatide may increase serum calcium, urinary calcium, and serum uric acid

• Urolithiasis: Use with caution in persons with active or recent urolithiasis because of risk of exacerbation

• Orthostatic hypotension: Transient orthostatic hypotension may occur with initial doses of teriparatide.

BILLING/CODING INFORMATION:

The following codes may be used with respect to teriparatide therapy:

HCPCS Coding:

J3110	Injection, teriparatide, 10 mcg

ICD-10 Diagnosis Codes That Support Medical Necessity:

E20.0	Idiopathic hypoparathyroidism
E20.8	Other hypoparathyroidism
E20.9	Hypoparathyroidism, unspecified
E28.310	Symptomatic premature menopause
E28.319	Asymptomatic premature menopause
E28.39	Other primary ovarian failure
E29.1	Testicular hypofunction
E34.50	Androgen insensitivity syndrome, unspecified
M80.00XA – M80.00XS M80.011A – M80.011S M80.012A – M80.012S M80.019A – M80.019S M80.021A – M80.021S M80.022A – M80.022S M80.029A – M80.029S M80.031A – M80.031S M80.032A – M80.032S M80.039A – M80.039S M80.041A – M80.041S M80.042A – M80.042S	Age-related osteoporosis with current pathological fracture

M80.049A – M80.049S M80.051A – M80.051S M80.052A – M80.052S M80.059A – M80.059S M80.061A – M80.061S M80.062A – M80.062S M80.069A – M80.069S M80.071A – M80.071S M80.072A – M80.072S M80.079A – M80.079S M80.08XA – M80.08XS	
M80.80XA – M80.80XS M80.811A – M80.811S M80.812A – M80.812S M80.819A – M80.819S M80.821A – M80.821S M80.822A – M80.822S M80.829A – M80.829S M80.831A – M80.831S M80.832A – M80.832S M80.839A – M80.839S M80.841A – M80.841S M80.842A – M80.842S M80.849A – M80.849S M80.851A – M80.851S M80.852A – M80.852S M80.859A – M80.859S M80.861A – M80.861S M80.862A – M80.862S M80.869A – M80.869S M80.871A – M80.871S M80.872A – M80.872S M80.879A – M80.879S M80.88XA – M80.88XS	Other osteoporosis with current pathological fracture
M81.0	Age-related osteoporosis without current pathological fracture
M81.8	Other osteoporosis without current pathological fracture
N95.1	Menopausal and female climacteric states
T38.0X5A	Adverse effect of glucocorticoids and synthetic analogues, initial encounter
T38.0X5D	Adverse effect of glucocorticoids and synthetic analogues, subsequent encounter
T38.0X5S	Adverse effect of glucocorticoids and synthetic analogues, sequela
Z78.0	Asymptomatic menopausal state

REIMBURSEMENT INFORMATION:

Refer to section entitled **POSITION STATEMENT**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage Products: No National Coverage Determination (NCD) or Local Coverage Determination (LCD) was found at the time of the last guideline reviewed date.

Medicare Part D: Florida Blue has delegated Prime Therapeutics authority to make coverage determinations for the Medicare Part D services referenced in this guideline.

DEFINITIONS:

Hypogonadal: abnormally decreased gonadal function.

Osteoporosis: reduction in the amount of bone mass, leading to fractures after minimal trauma. Osteoporosis is defined by the World Health Organization (WHO) as a bone mineral density (BMD) value for the hip, spine, or wrist of 2.5 standard deviations (SD) or more below the mean for healthy young white women, or a T-score of less than or equal to –2.5. The disease is characterized by an increased risk of fractures, which can result in pain, diminished quality of life, decreased physical mobility and independence, inability to work, and increased burden on caregivers.

Postmenopausal: occurring after menopause.

Risk Factors for Osteoporosis: For osteoporotic fractures, includes low BMD, parental history of hip fracture, low body weight, previous fracture, smoking, excess alcohol intake, glucocorticoid use, secondary osteoporosis (e.g., rheumatoid arthritis) and history of falls. These readily accessible and commonplace factors are associated with the risk of hip fracture and, in most cases, with that of vertebral and other types of fracture as well.

Sustained systemic glucocorticoid therapy: daily dosage equivalent to 5 mg or greater of prednisone.

RELATED GUIDELINES:

Abaloparatide (Tymlos™), 09-J2000-85

Bone Mineral Density Studies, 04-70000-21

Denosumab (Prolia™, Xgeva™) Injection, 09-J1000-25

Ibandronate IV (Boniva®), 09-J0000-71

Zoledronic Acid IV (Reclast®, Zometa®), 09-J0000-72

OTHER:

None applicable.

REFERENCES:

1. American Association of Clinical Endocrinologists Position Statement on IV Bisphosphonates. Accessed 11/29/12.
2. American College of Obstetricians and Gynecologists, ACOG Education Pamphlet APO48 – Osteoporosis. Accessed 05/07/07.

3. ACOG Practice Bulletin on Osteoporosis. American Family Physician. 2013; 88(4): 273 – 275.
4. Boonen S, Marin F, Mellstrom D, Xie L, Desaiah D, Krege JH, Rosen CJ. Safety and efficacy of teraparatide in elderly women with established osteoporosis: bone anabolic therapy from a geriatric perspective. J Am Geriatr Soc. 2006 May; 54(5): 782-9.
5. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.;2019. URL www.clinicalpharmacilogy-ip.com Accessed 02/22/19.
6. Camacho PM, Petak SM, Binkley N, et al. American Association of Clinical Endocrinologists and American College of Endocrinology Clinical Practice Guidelines for the Diagnosis and Treatment of Postmenopausal Osteoporosis. Endocr Pract. 2016; 22: Suppl 4;1-42.
7. Cosman F, de Beur SJ, LeBoff MS, et al. National Osteoporosis Foundation. Clinician's guide to prevention and treatment of osteoporosis. Osteoporos Int. 2014; 25 (10): 2359-81.
8. Forteo (teriparatide injection, solution). Prescribing Information. Eli Lilly and Company. Indianapolis, IN. August 2017.
9. Ingenix HCPCS Level II, Expert February 2015.
10. Ingenix ICD-9-CM for Physicians-Volumes 1 & 2, Expert 2013.
11. Ma YL, Zeng Q, Donley DW, Ste-Marie LG, Gallagher JC, Dalsky GP, Marcus R, Eriksen EF. Teriparatide increases bone formation in modeling and remodeling osteons and enhances IGF-II immunoreactivity in postmenopausal women with osteoporosis. J Bone Miner Res. 2006 Jun; 21(6): 855-64.
12. Meadows ES, Rousculp M, Sasser AC, Birnbaum HG, Moyneur E, Mallet D, Johnston JA. Actual versus predicted first-year utilization patterns of teriparatide in patients with employer-sponsored health insurance. Curr Med Res Opin. 2007 Nov 15.
13. Micromedex® Healthcare Series [Internet Database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed 02/22/19.
14. Middleton ET, Steel SA, Doherty SM. The effect of prior bisphosphonate exposure on the treatment to teriparatide in clinical practice. Calcif Tissue Int. 2007 Nov; 81(5): 335-40. Epub 2007 Oct 16.
15. North American Menopause Society (NAMS) Position Statement. Management of osteoporosis in postmenopausal women: 2010 position statement of the NAMS. Menopause. 2010; 17(1): 25-54.
16. Nevitt MC, Chen P, Kiel DP, Reginster JY, Dore RK, Zanchetta JR, Glass EV, Krege JH. Reduction in the risk of developing back pain persists at least 30 months after discontinuation of teriparatide treatment: a meta-analysis. Osteoporos Int. (2006). 17(11): 1630-7. Epub. August 08, 2006.
17. Saag KG, Shane E, Boonen S, Marin F, Donley DW, Taylor KA, Dalsky GP, Marcus R. Teraparatide or alendronate in glucocorticoid-induced osteoporosis. N Engl J Med. 2007 Nov 15; 357(20): 2028-39.
18. Teriparatide. In McEvoy GK, editor. AHFS drug information 2016 [monograph on the internet]. Bethesda (MD): American Society of Health-System Pharmacists; 2016 [cited 2016 Dec 16]. Available from http://online.statref.com Subscription required to review.)
19. Watts NB, Adler RA, Bilezikan JP, Drake MT, et al. Osteoporosis in men: an endocrine society clinical practice guideline. J Clin Endocrinol Metab 2012;97(6):1802-22.
20. Watts NB, Bilezkian JP, Camacho PM et al. American Association of Clinical Endocrinologists medical guidelines for clinical practice for the diagnosis and treatment of postmenopausal osteoporosis. Endocrine Practice. 2010; 16 (Suppl 3): 1-37.
21. WHO Scientific Group on the Assessment of Osteoporosis as Primary Health Care Level. May 2004.

COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Pharmacy Policy Committee on 03/13/19.

GUIDELINE UPDATE INFORMATION:

01/01/05	New Medical Coverage Guideline.
01/01/06	Annual HCPCS coding update: deleted expired CPT code 90782, added new code 90772.
02/15/06	Annual Review. Updated CPT coding: deleted expired code 90782 added new code 90772. Deleted unclassified code J3490. Deleted ICD-9 codes: 733.02, 733.03, 733.09, V82.81, added code 259.5. Updated references and internet links.
05/15/06	Revision to guideline; added Medicare Part D and Medicare Advantage product verbiage.
02/15/07	Annual Review. Added HCPCS code J3110 and updated ICD-9 codes. Added verbiage under Program Exceptions regarding delegation to Prime Therapeutics for Medicare Part D and updated references.
06/15/07	Reformatted guideline; updated references.
11/15/07	Revision to guideline; consisting of modifying coverage criteria under “Position Statement”.
02/15/08	Review and revision of guideline; consisting of updating “Dosage/Administration” section, added black box warning, added related guidelines, and updated references and links.
01/01/09	Annual HCPCS coding update: deleted code 90772; added code 96372.
05/15/09	Review and revision to guideline consisting of; updating the description section, reformatting and updating references.
09/15/09	Revision to guideline; consisting of removing osteoporotic fracture as coverage criteria and add new indication of sustained glucocorticoid induced osteoporosis.
12/15/10	Review and revision to guideline; consisting of updating coding and references.
12/15/11	Review and revision to guideline; consisting of updating references.
09/15/12	Revision to guideline: consisting of updating position statement.
02/15/13	Review and revision to guideline; consisting of updating position statement with additional indications and criteria.
09/15/13	Revision to guideline; consisting of administrative action to remove requirement of high risk for fracture from position statement of and that 2 years of therapy should be consecutive.
01/15/14	Revision to guideline; consisting of adding approval duration.
02/15/14	Review and revision to guideline; consisting of revising position statement, dosage/administration, precautions; updating program exceptions and references.
02/15/15	Review and revision to guideline; consisting of reformatting position statement, updating references.
11/01/15	Revision: ICD-9 Codes deleted.
02/15/16	Review and revision to guideline; consisting of revising position statement, precautions; coding and references.
12/15/16	Review and revision to guideline; consisting of updating position statement, coding and references.
02/15/17	Review and revision to guideline; consisting of updating references.
09/15/17	Review and revision to guideline; consisting of updating position statement and references.
10/15/17	Revision to guideline; consisting of updating position statement and references.
01/01/18	Revision to guideline; consisting of updating position statement.
02/15/18	Review and revision to guideline; consisting of updating references.
04/15/19	Review and revision to guideline; consisting of updating references.