

09-J0000-47

Original Effective Date: 01/01/05

Reviewed: 01/10/24

Revised: 02/15/24

Subject: Teriparatide (Forteo®), Teriparatide Injection)

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.

Dosage/ Administration	Position Statement	Billing/Coding	Reimbursement	Program Exceptions	Definitions
Related Guidelines	Other	References	Updates		

DESCRIPTION:

Teriparatide (Forteo, Teriparatide injection) 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), abaloparatide, denosumab, romosozumab, teriparatide, and zoledronic acid are appropriate initial therapy for patients at very high risk of fracture. The 2019/2020 Endocrine Society guideline recommends initial treatment with bisphosphonates (alendronate, risedronate, zoledronic acid, ibandronate) to reduce fracture risk in postmenopausal women at high risk of fractures and denosumab is an alternative initial treatment. Teriparatide is recommended in postmenopausal women at very high risk of fracture, such as those with severe or multiple vertebral fractures for up to two years for the reduction of vertebral and nonvertebral fractures. Very high risk of fracture is further defined as those with multiple spine fractures and a BMD T-score at the hip or spine of -2.5 or below.

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, teriparatide injection) **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^[a]
 - ii. Member has a history of osteoporotic hip or spine fracture
 - iii. Member has a BMD T-score between -1.0 and -2.5^[a] and **ONE** of the following:
 1. FRAX^[b] 10-year probability of major osteoporotic fracture $\geq 20\%$
 2. FRAX^[b] 10-year probability of hip fracture $\geq 3\%$
 3. Fragility fracture of the proximal humerus, pelvis, or distal forearm
 - b. The dose does not exceed 20 mcg daily
 - c. The cumulative duration of teriparatide (Forteo, teriparatide injection) and abaloparatide (Tymlos) has not exceeded a total of 2 years in the member's lifetime
 - d. Teriparatide will not be used in combination with other anabolic or antiresorptive agents (e.g., bisphosphonates, denosumab, other parathyroid hormone analogs, or romosozumab)
 - e. **ONE** of the following – documentation must be submitted:
 - i. Member has an inadequate response^[c], intolerance, or contraindication^[d] to a bisphosphonate^[e]
 - ii. Member has an inadequate response^[c], intolerance, or contraindication to denosumab (Prolia)^[e]
 - iii. Member has a BMD T-score of -2.5 or lower^[a] **AND** a history of osteoporotic fracture
 - iv. Member has a history of multiple osteoporotic vertebral fractures

- v. Member had osteoporotic fractures while receiving a FDA approved treatment for osteoporosis
- vi. Member had osteoporotic fractures while on long-term therapy with a medication known to cause skeletal harm (e.g., glucocorticoids)
- vii. Member has a history of osteoporotic fracture in the past 12 months
- viii. Member is at high risk of falls or has a history of falls
- ix. Member has a BMD T-score of -3.0 or lower^[a]
- x. FRAX^[b] 10-year probability of major osteoporotic fracture \geq 30%
- xi. FRAX^[b] 10-year probability of hip fracture \geq 4.5%

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^[a]
 - ii. Member has a history of osteoporotic hip or spine fracture
 - iii. Member has a BMD T-score between -1.0 and -2.5^[a] and **ONE** of the following:
 - 1. FRAX^[b] 10-year probability of major osteoporotic fracture \geq 20%
 - 2. FRAX^[b] 10-year probability of hip fracture \geq 3%
 - 3. Fragility fracture of the proximal humerus, pelvis, or distal forearm
- 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 not be used in combination with other anabolic or antiresorptive agents (e.g., bisphosphonates, denosumab, other parathyroid hormone analogs, or romosozumab)
- f. **EITHER** of the following:
 - i. Member has an inadequate response^[c] to bisphosphonate therapy (oral **OR** intravenous [IV])
 - ii. Member has a contraindication to **BOTH** oral^[d] and IV bisphosphonate therapy

3. **Glucocorticoid-induced Osteoporosis** when **ALL** of the following criteria are met:

- a. History of prednisone or its equivalent at a dose of 2.5 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^[a]
 - ii. Member has a history of osteoporotic hip or spine fracture

- iii. Member has a BMD T-score between -1.0 and -2.5^[a] and **ONE** of the following:
 - 1. FRAX^[b] 10-year probability of major osteoporotic fracture \geq 20%
 - 2. FRAX^[b] 10-year probability of hip fracture \geq 3%
 - 3. Fragility fracture of the proximal humerus, pelvis, or distal forearm
- 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 not be used in combination with other anabolic or antiresorptive agents (e.g., bisphosphonates, denosumab, other parathyroid hormone analogs, or romosozumab)
- f. **ONE** of the following:
 - i. Member has an inadequate response^[c] to bisphosphonate therapy (oral **OR** intravenous [IV])
 - ii. Member has a contraindication to **BOTH** oral^[d] and IV bisphosphonate therapy
 - iii. Member has an inadequate response^[c] or contraindication to denosumab [Prolia]^[e]
 - iv. Member has a history of a fragility fracture
 - v. Member is at high risk of falls or has a history of falls
 - vi. Member has a BMD T-score of -2.5 or lower^[a]
 - vii. FRAX^[b] 10-year probability of major osteoporotic fracture \geq 20%
 - viii. FRAX^[b] 10-year probability of hip fracture \geq 3%
 - ix. High dose glucocorticoid use with prednisone equivalent of greater than or equal to 30 mg/day for 30 days or cumulative doses of greater than or equal to 5 grams per year.
- 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>):
 - a. Treatment of hypoparathyroidism when **ALL** of the following criteria are met:
 - i. The dose does not exceed 20 mcg daily
 - ii. The cumulative duration of teriparatide and abaloparatide has not exceeded a total of 2 years in the member's lifetime
 - iii. Teriparatide will not be used in combination with other anabolic or antiresorptive agents (e.g., bisphosphonates, denosumab, other parathyroid hormone analogs, or romosozumab)

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, glucocorticoid-induced 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 not be used in combination with other anabolic or antiresorptive agents (e.g., bisphosphonates, denosumab, other parathyroid hormone analogs, or romosozumab)
5. The dose does not exceed 20 mcg daily

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

[a] Measured at the femoral neck, total hip, lumbar spine, or 33% radius

[b] FRAX[®] Fracture Risk Assessment Tool. <https://www.sheffield.ac.uk/FRAX/index.aspx>

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

[d] NOTE: gastroesophageal reflux disease (GERD) is NOT a labeled contraindication for oral bisphosphonate therapy.

[e] Exception: Not required if the member previously received treatment with abaloparatide (Tymlos™) – documentation must be submitted

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 or patients who have failed or are intolerant to other available osteoporosis therapy
- Increase of bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture or patients who have failed or are intolerant to other available osteoporosis therapy
- Treatment of men and women with osteoporosis associated with sustained systemic glucocorticoid therapy at high risk for fracture or patients who have failed or are intolerant to other available osteoporosis therapy

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.

Use for more than 2 years during a patient's lifetime should only be considered if a patient remains at or has returned to having a high risk for fracture.

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

PRECAUTIONS:

Contraindications

- Patients with hypersensitivity to teriparatide or to any of its excipients. Angioedema and anaphylaxis has occurred.

Warnings/Precautions

- Teriparatide caused an increase in the incidence of osteosarcoma, a malignant bone tumor in rats. Osteosarcoma has been reported in humans in the post marketing setting. There is limited data assessing the risk of osteosarcoma beyond 2 years of teriparatide. Teriparatide should not be prescribed for persons at increased baseline risk for osteosarcoma (e.g., those with metabolic bone diseases other than osteoporosis including Paget's disease of bone, pediatric and young adult patients with open epiphyses, bone metastases or history of skeletal malignancies, hereditary disorders predisposing to osteosarcoma, or prior external beam or implant radiation therapy involving the skeleton.)
- Patients with hypercalcemic disorders, such as primary hyperparathyroidism, should not be treated with teriparatide.
- Serious reports of calciphylaxis and worsening of previously stable cutaneous calcification have been reported in the post-marketing setting. Risk factors include underlying auto-immune disease, kidney failure, and concomitant warfarin or systemic corticosteroid use. Discontinue teriparatide in patients who develop calciphylaxis or worsening of previously stable cutaneous calcification.
- 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.
- Risk of Digoxin toxicity: Hypercalcemia may predispose patients to digitalis toxicity.

BILLING/CODING INFORMATION:

HCPSC Coding:

J3110	Injection, teriparatide, 10 mcg
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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 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 M80.0AXA – M80.0AXS M80.0B1A – M80.0B1S M80.0B2A – M80.0B2S M80.0B9A – M80.0B9S	Age-related osteoporosis with current pathological fracture
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	Other osteoporosis with current pathological fracture

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	
M80.8AXA – M80.8AXS	
M80.8B1A – M80.8B1S	
M80.8B2A – M80.8B2S	
M80.8B9A – M80.8B9S	
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](#)

[Romosozumab-aqqg \(Evenity\), 09-J3000-03](#)

OTHER:

None applicable.

REFERENCES:

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Pharmacy Policy Committee on 01/10/24.

GUIDELINE UPDATE INFORMATION:

01/01/05	New Medical Coverage Guideline.
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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.
04/15/20	Review and revision to guideline; consisting of updating the description, position statement and references.
10/01/20	Revision to ICD-10 coding.

02/15/21	Review and revision to guideline; consisting of updating the description, position statement and references.
08/15/21	Review and revision to guideline; consisting of updating the position statement and references.
02/15/22	Review and revision to guideline; consisting of updating the warnings and references.
02/15/23	Review and revision to guideline; consisting of updating the references.
10/01/23	ICD-10 additions.
02/15/24	Review and revision to guideline; consisting of updating glucocorticoid-induced osteoporosis and updating the references.