



# Louisiana

## Parenteral Therapy for Osteoporosis

Policy # 00239

Original Effective Date: 01/01/2010

Current Effective Date: 10/17/2018

*Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.*

*Note: oledronic Acid (Zometa<sup>®</sup>, Reclast<sup>®</sup>)<sup>†</sup> is considered separately in medical policy 00191.*

### BONIVA<sup>®</sup> Injectable

#### When Services May Be Eligible for Coverage

*Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:*

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

#### Postmenopausal Women with Osteoporosis

Based on review of available data, the Company may consider the use of injectable ibandronate sodium (Boniva) for the treatment of osteoporosis in postmenopausal women to be **eligible for coverage**.

#### Patient Selection Criteria

Coverage eligibility will be considered for the treatment of osteoporosis with injectable ibandronate sodium (Boniva) when the following criteria are met:

- The patient is a postmenopausal woman who has central dual x-ray absorptiometry (DXA) bone mineral density (BMD) T-score less than or equal to -2.5, confirming osteoporosis, OR a fragility fracture [defined as a major osteoporotic fracture, sustained as a result of a low-level trauma (e.g., a fall from standing height or less) that is associated with low BMD, including vertebral (spine), hip, forearm (wrist/distal radius), and proximal humerus (shoulder) fractures]; AND
- The patient has or has had one of the following:
  - o An inability to take oral bisphosphonates; OR
  - o A 12-month trial of oral bisphosphonates without documented improvement  
*(Note: This criterion is a Company coverage eligibility requirement. When this criterion is not met the denial reason is not medically necessary\*\*).*

#### When Services Are Considered Investigational

*Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.*

Based on review of available data, the Company considers the use of injectable ibandronate sodium (Boniva) when patient selection criteria are not met, to be **investigational\*** (except in the absence of a 12-month trial of oral bisphosphonates which will be denied as **not medically necessary\*\***).

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Based on review of available data, the Company considers the use of injectable ibandronate sodium (Boniva) when used for indications other than those approved by the U.S. Food and Drug Administration (FDA) to be **investigational**.\*

### **When Services Are Considered Not Medically Necessary**

Based on review of available data, the Company considers the use of injectable ibandronate sodium (Boniva) in the absence of a 12-month trial of oral bisphosphonates to be **not medically necessary**\*\*.

### **FORTEO<sup>®†</sup>**

#### **When Services May Be Eligible for Coverage**

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- Benefits are available in the member's contract/certificate, and
- Medical necessity criteria and guidelines are met.

#### **Postmenopausal Women with Osteoporosis**

Based on review of available data, the Company may consider the use of teriparatide (Forteo) for the treatment of osteoporosis in postmenopausal women to be **eligible for coverage**.

#### **Patient Selection Criteria**

Coverage eligibility will be considered for the treatment of osteoporosis in postmenopausal women with teriparatide (Forteo) when all of the following criteria are met:

- The patient is a postmenopausal woman who has central DXA BMD T-score less than or equal to -2.5, confirming osteoporosis, OR a fragility fracture [defined as a major osteoporotic fracture, sustained as a result of a low-level trauma (e.g., a fall from standing height or less) that is associated with low BMD, including vertebral (spine), hip, forearm (wrist/distal radius), and proximal humerus (shoulder) fractures]; AND
- Patient has not been on Forteo (or another parathyroid hormone product, e.g., abaloparatide [Tymlos<sup>™†</sup>]) for more than 2 years of cumulative therapy; AND
- The patient has or has had one of the following:
  - Inability to take oral bisphosphonates; OR
  - A 12-month trial of oral bisphosphonates without documented improvement  
(Note: This criterion is a Company coverage eligibility requirement. When this criterion is not met the denial reason is not medically necessary\*\*).

#### **Men with Primary or Hypogonadal Osteoporosis**

Based on review of available data, the Company may consider the use of teriparatide (Forteo) for the treatment of men with primary or hypogonadal osteoporosis to be **eligible for coverage**.

#### **Patient Selection Criteria**

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Coverage eligibility will be considered for the treatment of men with primary or hypogonadal osteoporosis with teriparatide (Forteo) when the following criteria are met:

- The patient is a male who has central DXA BMD T-score less than or equal to -2.5, confirming osteoporosis, OR a fragility fracture [defined as a major osteoporotic fracture, sustained as a result of a low-level trauma (e.g., a fall from standing height or less) that is associated with low BMD, including vertebral (spine), hip, forearm (wrist/distal radius), and proximal humerus (shoulder) fractures]; AND
- Patient has not been on Forteo (or another parathyroid hormone product, e.g., abaloparatide [Tymlos]) for more than 2 years of cumulative therapy

### Glucocorticoid Induced Osteoporosis

Based on review of available data, the Company may consider the use of teriparatide (Forteo) for the treatment of men and women with glucocorticoid induced osteoporosis to be **eligible for coverage**.

#### Patient Selection Criteria:

Coverage eligibility will be considered for the treatment of patients with glucocorticoid induced osteoporosis with teriparatide (Forteo) when the following criteria are met:

- The patient has been on chronic systemic glucocorticoid therapy for at least 12 months; AND
- The patient has central DXA BMD T-score less than or equal to -2.5, confirming osteoporosis, OR a fragility fracture [defined as a major osteoporotic fracture, sustained as a result of a low-level trauma (e.g., a fall from standing height or less) that is associated with low BMD, including vertebral (spine), hip, forearm (wrist/distal radius), and proximal humerus (shoulder) fractures]; AND
- Patient has not been on Forteo (or another parathyroid hormone product, e.g., abaloparatide [Tymlos]) for more than 2 years of cumulative therapy.

### **When Services Are Considered Investigational**

*Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.*

Based on review of available data, the Company considers the use of teriparatide (Forteo) when patient selection criteria are not met, to be **investigational\*** (**except** in the absence of a 12-month trial of bisphosphonates for postmenopausal women with osteoporosis which will be denied as **not medically necessary\*\***).

Based on review of available data, the Company considers the use of teriparatide (Forteo) when used for indications other than those approved by the U.S. FDA to be **investigational.\***

### **When Services Are Considered Not Medically Necessary**

Based on review of available data, the Company considers the use of teriparatide (Forteo) in the absence of a 12-month trial of oral bisphosphonates in postmenopausal women with osteoporosis to be **not medically necessary.\*\***

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### **Background/Overview**

Ibandronate (Boniva) inhibits osteoclast activity and reduces bone resorption and turnover. In postmenopausal women, it reduces the elevated rate of bone turnover, leading to, on average, a net gain in bone mass. Teriparatide (Forteo) contains recombinant human parathyroid hormone. Parathyroid hormone regulates bone metabolism, renal tubular reabsorption of calcium and phosphate, and intestinal calcium absorption. These actions stimulate new bone formation on trabecular and cortical bone surfaces by preferential stimulation of osteoblastic activity over osteoclastic activity.

Osteoporosis is characterized by decreased bone mass and increased fracture risk, most commonly at the spine, hip and wrist. DXA scans of patients with osteoporosis reveal a T-score less than or equal to -2.5. In addition to those patients with a DXA score representing osteoporosis, treatment should be considered in those patients with a fragility fracture. A fragility fracture is a major osteoporotic fracture, sustained as a result of a low-level trauma (e.g., a fall from standing height or less) that is associated with low BMD, including vertebral (spine), hip, forearm (wrist/distal radius), and proximal humerus (shoulder) fractures. While osteoporosis occurs in both men and women, it is most common among women following menopause. In healthy humans, bone formation and resorption are closely linked; old bone is resorbed and replaced by newly formed bone. In postmenopausal osteoporosis, bone resorption exceeds bone formation, leading to bone loss and increased risk of fracture. After menopause, the risk of fractures of the spine and hip increases; approximately 40% of 50-year old women will experience an osteoporosis-related fracture during their remaining lifetimes.

### **FDA or Other Governmental Regulatory Approval**

#### **U.S. Food and Drug Administration**

Boniva was approved to treat postmenopausal osteoporosis in early 2006. Forteo was approved for the treatment of postmenopausal osteoporosis and for men with primary or hypogonadal osteoporosis in late 2002. Forteo gained approval for the treatment of glucocorticoid induced osteoporosis in mid-2009.

Osteonecrosis, primarily in the jaw, has been reported in patients treated with bisphosphonates. Most cases have been in cancer patients undergoing dental procedures, but some have occurred in patients with postmenopausal osteoporosis or other diagnoses. Known risk factors for osteonecrosis include a diagnosis of cancer, concomitant therapies (e.g., chemotherapy, radiotherapy, corticosteroids), and co-morbid disorders (e.g., anemia, coagulopathy, infection, pre-existing dental disease). Most reported cases have been in patients treated with bisphosphonates intravenously but some have been in patients treated orally.

For patients who develop osteonecrosis of the jaw (ONJ) while on bisphosphonate therapy, dental surgery may exacerbate the condition. For patients requiring dental procedures, there are no data available to suggest whether discontinuation of bisphosphonate treatment reduces the risk of ONJ. Clinical judgement of the treating physician should guide the management plan of each patient based on individual benefit/risk assessment.

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### **Rationale/Source**

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, FDA approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, Blue Cross and Blue Shield Association technology assessment program (TEC) and other non-affiliated technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

The effectiveness and safety of Boniva Injection 3mg once every three months were demonstrated in a randomized, double-blind, multinational, noninferiority study (DIVA Study) in 1,358 women with postmenopausal osteoporosis (L2-L4 lumbar spine BMD, T-score below -2.5 SD at baseline). The control group received Boniva 2.5 mg daily oral tablets. The primary efficacy parameter was the relative change from baseline to one year of treatment in lumbar spine BMD, which was compared between the intravenous injection and the daily oral treatment groups. All patients received 400 IU vitamin D and 500 mg calcium supplementation per day. In the intent-to-treat (ITT) efficacy analysis, the least-squares mean increase at 1 year in lumbar spine BMD in patients (n = 429) treated with Boniva Injection 3 mg once every 3 months (4.5%) was statistically superior to that in patients (n = 434) treated with daily oral tablets (3.5%). The mean difference between groups was 1.1% (95% confidence interval: 0.5%, 1.6%;  $p < 0.001$ ). The mean increase from baseline in total hip BMD at 1 year was 2.1% in the Boniva Injection 3 mg once every 3 months group and 1.5% in the Boniva 2.5 mg daily oral tablet group. Consistently higher BMD increases at the femoral neck and trochanter were also observed following Boniva Injection 3 mg once every 3 months compared to Boniva 2.5 mg daily oral tablet.

The safety and efficacy of once-daily Forteo, median exposure of 19 months, were examined in a double-blind, multicenter, placebo-controlled clinical study of 1,637 postmenopausal women with osteoporosis (Forteo 20 mcg, n = 541). All women received 1000 mg of calcium and at least 400 IU of vitamin D per day. Baseline and endpoint spinal radiographs were evaluated using the semiquantitative scoring. Ninety percent of the women in the study had one or more radiographically diagnosed vertebral fractures at baseline. The primary efficacy endpoint was the occurrence of new radiographically diagnosed vertebral fractures defined as changes in the height of previously underformed vertebrae. Such fractures are not necessarily symptomatic. Forteo, when taken with calcium and vitamin D and compared with calcium and vitamin D alone, reduced the risk of 1 or more new vertebral fractures from 14.3% of women in the placebo group to 5.0% in the Forteo group. This difference was statistically significant ( $p < 0.001$ ); the absolute reduction in risk was 9.3% and the relative reduction was 65%. Forteo was effective in reducing the risk for vertebral fractures regardless of age, baseline rate of bone turnover, or baseline BMD. Forteo significantly reduced the risk of any nonvertebral fracture from 5.5% in the placebo group to 2.6% in the Forteo group ( $p < 0.05$ ). The absolute reduction in risk was 2.9% and the relative reduction was 53%. The incidence of new nonvertebral fractures in the Forteo group compared with the placebo group was ankle/foot (0.2%, 0.7%), hip (0.2%, 0.7%), humerus (0.4%, 0.4%), pelvis (0%, 0.6%), ribs (0.6%, 0.9%), wrist (0.4%, 1.3%), and other sites (1.1%, 1.5%), respectively. Forteo increased lumbar spine BMD in postmenopausal women with osteoporosis. Statistically significant increases were seen at 3 months and continued throughout the treatment period. Postmenopausal women with osteoporosis who were treated with Forteo had statistically significant increases in BMD from baseline to endpoint at the lumbar spine, femoral neck, total hip, and total body. Forteo treatment increased lumbar spine BMD from baseline in 96% of postmenopausal women

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treated. Seventy-two percent of patients treated with FORTEO achieved at least a 5% increase in spine BMD, and 44% gained 10% or more.

The safety and efficacy of once-daily FORTEO, median exposure of 10 months, were examined in a double-blind, multicenter, placebo-controlled clinical study of 437 men with either primary (idiopathic) or hypogonadal osteoporosis (Forteo 20 mcg, n = 151). All men received 1000 mg of calcium and at least 400 IU of vitamin D per day. The primary efficacy endpoint was change in lumbar spine BMD. Forteo increased lumbar spine BMD in men with primary or hypogonadal osteoporosis. Statistically significant increases were seen at three months and continued throughout the treatment period. Forteo was effective in increasing lumbar spine BMD regardless of age, baseline rate of bone turnover and baseline BMD. Forteo treatment for a median of ten months increased lumbar spine BMD from baseline in 94% of men treated. Fifty-three percent of patients treated with Forteo achieved at least a 5% increase in spine BMD, and 14% gained 10% or more.

The efficacy of Forteo for treating glucocorticoid-induced osteoporosis was assessed in a randomized, double-blind, active-controlled trial of 428 patients (19% men, 81% women) aged 22 to 89 years (mean 57 years) treated with  $\geq 5$  mg/day prednisone or equivalent for a minimum of 3 months. The duration of the trial was 18 months with 214 patients exposed to Forteo. In the Forteo group, the baseline median glucocorticoid dose was 7.5 mg/day and the median duration of glucocorticoid use was 1.5 years. The mean standard deviation (SD) baseline lumbar spine BMD was  $0.85 \pm 0.13$  g/cm<sup>2</sup> and lumbar spine BMD T-score was  $-2.5 \pm 1$  (number of SDs below the mean BMD value for healthy adults). A total of 30% of patients had prevalent vertebral fracture(s) and 43% had prior non-vertebral fracture(s). The patients had chronic rheumatologic, respiratory or other diseases that required sustained glucocorticoid therapy. All patients received 1000 mg of calcium plus 800 IU of vitamin D supplementation per day. In patients with glucocorticoid-induced osteoporosis, Forteo increased lumbar spine BMD compared with baseline at 3 months through 18 months of treatment. In patients treated with Forteo, the mean percent change in BMD from baseline to endpoint was 7.2% at the lumbar spine, 3.6% at the total hip and 3.7% at the femoral neck ( $p < 0.001$  all sites). The relative treatment effects of Forteo were consistent in subgroups defined by gender, age, geographic region, body mass index, underlying disease, prevalent vertebral fracture, baseline glucocorticoid dose, prior biphosphonate use and glucocorticoid discontinuation during trial.

## References

1. Food and Drug Administration. Labeling of the Drug Boniva. February 12, 2007.
2. Food and Drug Administration. Labeling of the Drug Forteo. July 22, 2009.
3. Boniva Injection [Prescribing Information]. Nutley, NJ: Roche Laboratories Inc. April 2013.
4. Forteo [Prescribing Information]. Indianapolis, IN: Eli Lilly Company. March 2012.

## Policy History

Original Effective Date: 01/01/2010

Current Effective Date: 10/17/2018

09/03/2009 Medical Policy Committee approval.

09/16/2009 Medical Policy Implementation Committee approval. New policy.

09/09/2010 Medical Policy Committee review

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09/15/2010	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
09/01/2011	Medical Policy Committee review
09/14/2011	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
10/06/2011	Medical Policy Committee review
10/19/2011	Medical Policy Implementation Committee approval. Added a <i>Note</i> to the Boniva and Forteo criteria regarding the 12-month trial of oral bisphosphonates without documented improvement. Noted that the reason for denial will be not medically necessary if these criteria are not met. The not medically necessary denial statements for Boniva and Forteo are also incorporated into the Investigational and Not Medically Necessary coverage sections for each of these drugs.
10/11/2012	Medical Policy Committee review
10/31/2012	Medical Policy Implementation Committee approval. Policy statement updated with "oral" for clarification. Black box warning omitted.
10/03/2013	Medical Policy Committee review
10/16/2013	Medical Policy Implementation Committee approval. No change to coverage.
04/03/2014	Medical Policy Committee review
04/23/2014	Medical Policy Implementation Committee approval. Added fragility fracture as an option for treatment as an alternative for T score in treatment of osteoporosis.
04/02/2015	Medical Policy Committee review
04/20/2015	Medical Policy Implementation Committee approval. No change to coverage.
08/03/2015	Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
04/07/2016	Medical Policy Committee review
04/20/2016	Medical Policy Implementation Committee approval. No change to coverage.
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes
04/06/2017	Medical Policy Committee review
04/19/2017	Medical Policy Implementation Committee approval. No change to coverage.
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes
10/05/2017	Medical Policy Committee review
10/18/2017	Medical Policy Implementation Committee approval. Updated the definition of fragility fracture and added language to ensure that the patient has not been on any parathyroid hormone product for more than 2 years of cumulative therapy.
10/04/2018	Medical Policy Committee review
10/17/2018	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
Next Scheduled Review Date:	10/2019

### **Coding**

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CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	No codes
HCPCS	J1740, J3110
ICD-10 Diagnosis	M81.0 M81.6 M81.8

\*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
  - 1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
  - 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
  - 3. Reference to federal regulations.

\*\*Medically Necessary (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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