

Clinical Policy: Teriparatide (Forteo)

Reference Number: LA.PHAR.188

Effective Date:

Last Review Date: 01.21

Line of Business: Medicaid

[Coding Implications](#)

[Revision Log](#)

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Teriparatide (Forteo®) is a recombinant human parathyroid hormone (PTH) analog.

FDA Approved Indication(s)

Forteo is indicated:

- Postmenopausal osteoporosis (PMO): 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.
- Male osteoporosis: To increase bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture.*
- Glucocorticoid-induced osteoporosis (GIO): 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.*

**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

Prior authorization is required. Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of Louisiana Healthcare Connections that Forteo is medically necessary when the following criteria are met:

I. Initial Approval Criteria

A. Osteoporosis (must meet all):

1. Diagnosis of PMO, GIO or male osteoporosis and (a or b):
 - a. Member is at very high risk for fracture (i or ii):
 - i. BMD T-score at hip or spine < -3.5;
 - ii. BMD T-score at hip or spine ≤ 2.5 AND major osteoporotic fracture (i.e., hip, spine, forearm, wrist, humerus);
 - b. Member has completed a 3-year trial of bisphosphonate therapy at up to maximally indicated doses unless all are contraindicated or clinically significant adverse effects are experienced to both IV and PO formulations (see Appendix D);

**Prior authorization may be required for bisphosphonates*

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2. **Age ≥ 18 years or documentation of closed epiphyses on x-ray;**
3. **For PMO, failure of Tymlos® at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced;**
**Prior authorization may be required for Tymlos*
4. **Member has not received ≥ 2 years cumulative PTH analog therapy (e.g., Forteo, Tymlos);**
5. **Dose does not exceed 20 mcg per day (1 pen every 28 days).**

Approval duration:

Medicaid – 6 months (2 years cumulative PTH analog use lifetime)

B. Other diagnoses/indications

1. **Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized):**
LA.PMN.53 for Medicaid.

II. Continued Therapy

A. Osteoporosis (must meet all):

1. **Currently receiving medication via Louisiana Healthcare Connections benefit or member has previously met initial approval criteria;**
2. **Member is responding positively to therapy;**
3. **Member has not received ≥ 2 years cumulative PTH analog therapy (e.g., Forteo, Tymlos);**
4. **If request is for a dose increase, new dose does not exceed 20 mcg per day (1 pen every 28 days).**

Approval duration:

Medicaid – 12 months (2 years cumulative PTH analog use lifetime)

B. Other diagnoses/indications (must meet 1 or 2):

1. **Currently receiving medication via Louisiana Healthcare Connections benefit and documentation supports positive response to therapy.**
Approval duration: Duration of request or 6 months (whichever is less); or
2. **Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized):**
LA.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

- A. **Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy –LA.PMN.53 for Medicaid or evidence of coverage documents.**

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

BMD: bone mineral density

FDA: Food and Drug Administration

GIO: glucocorticoid-induced

osteoporosis

PMO: postmenopausal osteoporosis

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PTH: parathyroid hormone

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may require prior authorization.

<u>Drug Name</u>	<u>Dosing Regimen</u>	<u>Dose Limit/ Maximum Dose</u>
<u>PTH analog therapy</u>		
<u>Tymlos</u> (abaloparatide)	<u>Treatment:PMO</u> <u>80 mcg SC QD</u>	<u>80 mcg/day - 2 yr total lifetime</u>
<u>IV bisphosphonates</u>		
<u>ibandronate</u> (Boniva®)	<u>Treatment: PMO</u> <i>See prescribing information for dose.</i>	<u>Varies</u>
<u>zoledronic acid</u> (Reclast®)	<u>Treatment/prevention: PMO, GIO</u> <u>Treatment: male osteoporosis</u> <u>Treatment: Paget disease</u> <i>See prescribing information for dose.</i>	
<u>Oral bisphosphonates</u>		
<u>alendronate</u> (Fosamax®)	<u>Treatment/prevention: PMO</u> <u>Treatment: GIO, male osteoporosis</u> <u>Treatment: Paget disease</u> <i>See prescribing information for dose.</i>	<u>Varies</u>
<u>Fosamax® Plus D</u> (alendronate / cholecalciferol)	<u>Treatment: PMO, male osteoporosis</u> <i>See prescribing information for dose.</i>	
<u>risedronate</u> (Actonel®, Atelvia®)	<u>Actonel:</u> <u>Treatment/prevention: PMO, GIO</u> <u>Treatment: male osteoporosis</u> <u>Treatment: Paget disease</u> <u>Atelvia:</u> <u>Treatment: PMO</u> <i>See prescribing information for dose.</i>	
<u>ibandronate (Boniva)</u>	<u>Treatment/prevention: PMO</u> <i>See prescribing information for dose.</i>	

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): hypersensitivity
- Boxed warning(s): none reported

Appendix D: IV/PO Bisphosphonates: Examples of Contraindications and Adverse Effects

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<u>Bisphosphonates</u>	<u>Oral Formulations</u>	<u>IV Formulations</u>
<u><i>Contraindications</i></u>		
<u>Hypocalcemia</u>	X	X
<u>Increased risk of aspiration</u>	X	-
<u>Hypersensitivity to product component</u>	X	X
<u>Inability to stand/sit upright for at least 30 minutes</u>	X	-
<u>Creatinine clearance < 35 mL/min or evidence of acute renal impairment</u>	-	X
<u>Esophagus abnormalities which delay emptying such as stricture or achalasia</u>	X	-
<u><i>Clinically significant warnings or adverse side effects</i></u>		
<u>Pregnancy</u>	X	X
<u>Eye inflammation</u>	X	X
<u>Acute renal failure</u>	X	X
<u>Osteonecrosis of the jaw</u>	X	X
<u>Atypical femoral shaft fracture</u>	X	X
<u>Drug interactions (product-specific)</u>	X	X
<u>Severe or incapacitating musculoskeletal pain</u>	X	X

V. Dosage and Administration

<u>Indication</u>	<u>Dosing Regimen</u>	<u>Maximum Dose</u>
<u>PMO, GIO, male osteoporosis</u>	<u>20 mcg SC QD</u>	<u>20 mcg/day up to 2 years cumulative PTH analog use lifetime</u>

VI. Product Availability

Multi-dose prefilled pen (2.4 mL): 28 daily doses of 20 mcg

VII. References

1. Forteo Prescribing Information. Indianapolis, IN: Eli Lilly and Company; November 2020. Available at <http://www.forteo.com>. Accessed December 3, 2020.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2020. URL: <http://www.clinicalpharmacology.com>.
3. Shoback D, Rosen CJ, Black DM, et al. Pharmacological management of osteoporosis in postmenopausal women: an endocrine society guideline update. J Clin Endocrinol Metab; March 2020, 105(3): 587-594.
4. Eastell R, Rosen CJ, Black DM, et al. Pharmacological management of osteoporosis in postmenopausal women: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab; 2019, 104: 1595-1622.

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6. National Osteoporosis Foundation Clinician's Guide to Prevention and Treatment of Osteoporosis. Osteoporosis International 2014. Available at: <http://nof.org/files/nof/public/content/file/2791/upload/919.pdf>. Accessed October 31, 2018.
7. Siris ES, Adler R, Bilezikian J, et al. The clinical diagnosis of osteoporosis: a position statement from the National Bone Health Alliance Working Group. Osteoporos Int (2014) 25:1439–1443. DOI 10.1007/s00198-014-2655-z.
8. Hodsman AB, Bauder DC, Dempster DW, et al. Parathyroid hormone and teriparatide for the treatment of osteoporosis: a review of the evidence and suggested guidelines for its use. Endocr Rev. 2005 Aug;26(5):688-703. Epub 2005 Mar 15.

Male Osteoporosis

9. 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.

Glucocorticoid-Induced Osteoporosis

10. 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.

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.

<u>HCPCS Codes</u>	<u>Description</u>
<u>J3110</u>	<u>Injection, teriparatide, 10 mcg</u>

<u>Reviews, Revisions, and Approvals</u>	<u>Date</u>
<u>Converted corporate to local policy.</u>	<u>01.21</u>

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government

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agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.
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