Clinical Policy: Teriparatide (Forteo)

Reference Number: ERX.SPA.63
Effective Date: 10.01.16
Last Review Date: 05.22
Line of Business: Commercial, Medicaid

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

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

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ 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 one of the following (a or b):
   a. Member is at very high risk for fracture as evidenced by one of the following (i, ii, or iii):
      i. Recent osteoporotic fracture (within the past 12 months;
      ii. Bone mineral density (BMD) T-score at hip or spine ≤ -3.0;
      iii. 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 *(see Appendix B; alendronate is preferred)* at up to maximally indicated doses, unless one of the following (i-v):
      i. All bisphosphonates are contraindicated;
      ii. Clinically significant adverse effects are experienced to both IV and PO formulations (*see Appendix E*)
      iii. Member has experienced a loss of BMD while receiving bisphosphonate therapy;
      iv. Member has experienced a lack of BMD increase after ≥ 12 months of bisphosphonate therapy;
      v. Member experienced an osteoporotic fracture or fragility fracture while receiving bisphosphonate therapy;

      **Prior authorization may be required for bisphosphonates*

2. Age ≥ 18 years or documentation of closed epiphyses on x-ray;
3. If request is for continuation of cumulative PTH analog therapy beyond 2 years, provider attestation that member remains at or has returned to having a high risk for fracture (e.g., history of osteoporotic fracture or multiple risk factors for fracture, *see Appendix D*) and that the risk versus benefit of continued therapy has been reviewed with the member;
4. Dose does not exceed 20 mcg per day (1 pen every 28 days).

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Osteoporosis (must meet all)**:**

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. If request is for continuation of cumulative PTH analog therapy beyond 2 years, provider attestation that member remains at or has returned to having a high risk for fracture (e.g., history of osteoporotic fracture or multiple risk factors for fracture, *see Appendix D*) and that the risk versus benefit of continued therapy has been reviewed with the member;
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

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

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 – ERX.PA.01 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
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 not be a formulary agent and may require prior authorization.

Drug name	***Dosing Regimen***	***Dose Limit Maximum Dose***
IV bisphosphonates		
ibandronate (Boniva®)	Treatment: PMO *See prescribing information for dose.*	Varies
zoledronic acid (Reclast®)	Teatment/prevention: PMO, GIO Treatment: male osteoporosis Treatment: Paget disease *See prescribing information for dose.*	

Drug name	Dosing Regimen	Dose Limit Maximum Dose
Oral bisphosphonates		
alendronate (Fosamax®)	Treatment/prevention: PMO Treatment: GIO, male osteoporosis Treatment: Paget disease *See prescribing information for dose.*	Varies
Fosamax® Plus D (alendronate / cholecalciferol)	Treatment: PMO, male osteoporosis *See prescribing information for dose.*	
risedronate (Actonel®, Atelvia®)	Actonel: Treatment/prevention: PMO, GIO Treatment: male osteoporosis Treatment: Paget disease Atelvia: Treatment: PMO *See prescribing information for dose.*	
ibandronate (Boniva)	Treatment/prevention: PMO *See prescribing information for dose.*	

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: General Information

- The FRAX tool is readily available and incorporates multiple clinical risk factors that predict fracture risk, largely independent of BMD. Clinical risk factors in FRAX include age, sex, body mass index (BMI), smoking, alcohol use, prior fracture, parental history of hip fracture, use of glucocorticoids, rheumatoid arthritis, secondary osteoporosis, and femoral neck BMD, when available. FRAX predicts the 10-year probability of hip fracture and major osteoporotic fracture (hip, clinical spine, humerus, or forearm). FRAX designation of high risk of fracture is defined as 10-year major osteoporotic fracture probability ≥ 20% or hip fracture probability ≥ 3%.
- The 2019 Endocrine Society clinical practice guidelines include patient profiles representing examples of high and very high fracture risk:
  - High risk: T-score of minus 2.5 or below, or prior hip or vertebral fracture, or high fracture probability by the fracture risk assessment tool (FRAX) (10-year probability of major osteoporotic fracture ≥ 20%, or 10-year probability of hip fracture ≥ 3%)
  - Very high risk: T-score of minus 2.5 or below and 1 or more fractures, or multiple vertebral fractures, or severe vertebral fracture.

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

Bisphosphonates	Oral Formulations	IV Formulations
Contraindications		
Hypocalcemia	X	X
Increased risk of aspiration	X	-
Hypersensitivity to product component	X	X
Inability to stand/sit upright for at least 30 minutes	X	-
Creatinine clearance < 35 mL/min or evidence of acute renal impairment	-	X
Esophagus abnormalities which delay emptying such as stricture or achalasia	X	-
Clinically significant warnings or adverse side effects		
Pregnancy	X	X

Bisphosphonates	Oral Formulations	IV Formulations
Eye inflammation	X	X
Acute renal failure	X	X
Osteonecrosis of the jaw	X	X
Atypical femoral shaft fracture	X	X
Drug interactions (product-specific)	X	X
Severe or incapacitating musculoskeletal pain	X	X

V. Dosage and Administration

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

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; April 2021. Available at http://www.forteo.com. Accessed September 16, 2021.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2020. URL: http://www.clinicalpharmacology.com.

Osteoporosis Diagnosis, Fracture Risk, and Treatment

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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.
5. Camacho PM, Petak SM, Brinkley N et al. American Association of Clinical Endocrinologists/American College of Endocrinology clinical practice guidelines for the diagnosis and treatment of postmenopausal osteoporosis—2020 update. Endocr Pract. 2020;26(1):1-46.
6. National Osteoporosis Foundation Clinician's Guide to Prevention and Treatment of Osteoporosis. Osteoporosis International 2014. Available at: https://cdn.nof.org/wp-content/uploads/2016/01/995.pdf. Accessed September 16, 2021.
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.
9. Gilsenan A, Midkiff K, Harris D, et al. Teriparatide Did Not Increase Adult Osteosarcoma Incidence in a 15-Year US Postmarketing Surveillance Study. J Bone Miner Res. 2021 Feb;36(2):244-251.

Male Osteoporosis

10. 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

11. 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.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
1Q18 annual review:	11.08.17	02.18

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Converted to new template. Removed requirements for evidence of diagnosis (T-score, history of fracture). Removed conditions of hypogonadal and glucocorticoid-induced osteoporosis from initial criteria. Modified criteria to add specialist requirement or trial and failure of a bisphosphate (alendronate is preferred). Removed definition of treatment failure. Removed requirements regarding admin of last doses of Reclast and injectable ibandronate. Changed approval duration for continuation treatment under other diagnoses/indications to 6 months for specialty drugs. Updated appendices, Therapeutic Alternatives, and Dosing and Administration.		
1Q 2019 annual review: no significant changes; added geriatrician prescriber option; revised continued therapy approval duration to 12 months; references reviewed and updated.	10.31.18	02.19
1Q 2020 annual review: very high fracture risk or 3-year bisphosphonate trial added with required contraindication to both PO/IV formulations; specialists removed; age 18 or closed epiphyses added per PI; references reviewed and updated.	11.19.19	02.20
1Q 2021 annual review: no significant changes; removed osteosarcoma black box warning per package insert update; references reviewed and updated.	12.03.20	02.21
Corrected BMD T-score to indicate “negative” 2.5 is required.	07.28.21	
1Q 2022 annual review: updated definition of very high risk for fracture per 2020 AACE/ACE PMO guidelines; references reviewed and updated.	09.16.21	02.22
Per updated prescribing information regarding length of therapy, removed criteria and approval duration requirements that limited therapy to 2 years cumulative PTH analog therapy, added requirement if request is for continuation of cumulative PTH analog therapy beyond 2 years, provider attestation that member remains at or has returned to having a high risk for fracture (e.g., history of osteoporotic fracture or multiple risk factors for fracture) and that the risk versus benefit of continued therapy has been reviewed with the member, added general information regarding fracture risk assessments; added option (in addition to contraindications or adverse effects) to bypass bisphosphonate trial if member has experienced a loss of BMD, lack of BMD increase, or has had an osteoporotic fracture or fragility fracture while receiving bisphosphonate therapy.	02.07.22	05.22

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 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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.

be bound by the foregoing terms and conditions, in addition to the Site Use Agreement for Health Plans associated with Envolve Pharmacy Solutions.