Clinical Policy: Teriparatide (Forteo, Bonsity)

Reference Number: CP.PHAR.188
Effective Date: 11.15.17
Last Review Date: 02.25
Line of Business: Commercial, HIM, Medicaid

Coding Implications
Revision Log

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

Description

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

FDA Approved Indication(s)

Forteo and Bonsity are indicated:

- Postmenopausal osteoporosis (PMO): For the treatment of postmenopausal women with osteoporosis at high risk for fracture* or who have failed or are intolerant to other available osteoporosis therapy. In postmenopausal women with osteoporosis, Forteo and Bonsity reduce 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* or who have failed or are intolerant to other available osteoporosis therapy.
- 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* or who have failed or are intolerant to other available osteoporosis therapy.

**High risk of fracture is defined as a history of osteoporotic fracture, multiple risk factors for fracture.*

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.

It is the policy of health plans affiliated with Centene Corporation® that teriparatide 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 *(see Appendix D)*;
      iii. BMD T-score at hip or spine ≤ -2.5 AND major osteoporotic fracture (i.e., hip, spine, forearm, wrist, humerus) *(see Appendix D)*;

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 brand Forteo or Bonsity, member must use teriparatide (generic Forteo), unless contraindicated or clinically significant adverse effects are experienced;
4. One of the following (a or b):
   a. For PMO, failure of Prolia® or Tymlos® at up to maximally indicated doses, unless clinically significant adverse effects are experienced or both are contraindicated*;
      **Prior authorization may be required for Prolia and Tymlos*
   b. 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;
5. Dose does not exceed both of the following (a and b):
   a. 20 mcg per day;
   b. 1 pen every 28 days.

Approval duration:
Medicaid/HIM – 6 months
Commercial – 6 months or to the member's renewal date, whichever is longer

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business:

CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

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

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
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 brand Forteo or Bonsity, member must use teriparatide (generic Forteo), unless contraindicated or clinically significant adverse effects are experienced;
5. If request is for a dose increase, new dose does not exceed both of the following (a and b):
   a. 20 mcg per day;
   b. 1 pen every 28 days.

Approval duration:
Medicaid/HIM – 12 months
Commercial – 6 months or to the member's renewal date, whichever is longer

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

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.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 policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.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
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
PTH analog therapy		
Tymlos (abaloparatide)	Treatment: PMO 80 mcg SC QD	80 mcg/day - 2 year total lifetime
Receptor activator of nuclear factor kappa-B (RANK) ligand inhibitor		
Prolia (denosumab)	Treatment: PMO, GIO, male osteoporosis 60 mg SC once every 6 months	60 mg/dose
IV bisphosphonates		
ibandronate (Boniva®)	Treatment: PMO 3 mg IV every 3 months	3 mg /3 months
zoledronic acid (Reclast®)	Treatment: PMO, GIO, male osteoporosis 5 mg IV once a year	5 mg/year
Oral bisphosphonates		
alendronate (Fosamax®)	Treatment: PMO, GIO, male osteoporosis 10 mg PO QD or 70 mg PO once	70 mg/week
Fosamax® Plus D (alendronate / cholecalciferol)	Treatment: PMO, male osteoporosis 70 mg alendronate /2800 IU vitamin D3 or 70 mg alendronate /5600 IU vitamin D3 PO once weekly	70 mg / 5600 IU/ week

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
risedronate (Actonel®, Atelvia®)	Actonel: Treatment: PMO, GIO, male osteoporosis Atelvia: Treatment: PMO *See prescribing information for dose.*	Varies
ibandronate (Boniva)	Treatment: PMO 150 mg PO once monthly	150 mg/month

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%.
- Bone Mineral Density (BMD) T-score was established by the World Health Organization (WHO) as the operational definition for post-menopausal osteoporosis. The T-score is the standard deviation of an individual's BMD from the mean value for young normal women. A normal T-score is considered -1.0 or above.
- The 2020 American Association of Clinical Endocrinologists/American College of Endocrinology Clinical Practice Guidelines use the T-score to diagnosis postmenopausal women with osteoporosis. When an individual's T-score is -2.5 or below, the individual is considered to have osteoporosis or severe osteoporosis in the presence of a fragility fracture (i.e., a fracture sustained from force similar to a fall from a standing position or less that would not have occurred in healthy bone).

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

Bisphosphonates	Oral Formulations	IV Formulations
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
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

Drug Name	Availability
Teriparatide (Forteo)	Multi-dose prefilled pen (containing 28 daily doses of 20 mcg): 600 mcg/2.4 mL, 560 mcg/2.24 mL
Teriparatide (Bonsity)	Multi-dose prefilled pen (containing 28 daily doses of 20 mcg): 620 mcg/2.48 mL

VII. References

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Male Osteoporosis
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Glucocorticoid-Induced Osteoporosis
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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.

HCPCS Codes	Description
J3110	Injection, teriparatide, 10 mcg
J3490	Unclassified drugs
C9399	Unclassified drugs or biologicals

Reviews, Revisions, and Approvals	Date	P&T Approval Date
1Q 2021 annual review: removal of osteosarcoma black box warning per package insert update; references to HIM.PHAR.21 revised to HIM.PA.154; references reviewed and updated.	12.03.20	02.21
Per June SDC and prior clinical guidance, added Prolia in addition to Tymlos as redirect options for PMO; retire CP.CPA.199 as strategy aligns for Commercial Exchange and non-Exchange plans.	06.02.21	08.21
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; WCG.CP.PHAR.188 retired.	02.07.22	05.22
Template changes applied to other diagnoses/indications and continued therapy section.	10.03.22	
1Q 2023 annual review: no significant changes; references reviewed and updated.	11.01.22	02.23
1Q 2024 annual review: RT4: added Bonsity and revised FDA Approved Indication(s) section to align with current labeling language for both Forteo and Bonsity; added generic Forteo (620 mcg/2.4 mL formulation); added generic Bonsity (620 mcg/2.48 mL formulation); added redirection to generic Forteo for all brand requests per SDC; clarified dosage regimen in Appendix B per PI; added HCPC codes [C9399, J3490]; references reviewed and updated.	10.23.23	02.24
1Q 2025 annual review: no significant changes; references reviewed and updated.	10.22.24	02.25

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. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. 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. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.