Original Effective Date: 12/1/2015
Current Effective Date: 08/30/2023
Last P&T Approval/Version: 07/26/2023
Next Review Due By: 07/2024
Policy Number: C8523-A

Forteo (teriparatide)

PRODUCTS AFFECTED

Forteo (teriparatide), Teriparatide

COVERAGE POLICY

Coverage for services, procedures, medical devices, and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.
This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Treatment of postmenopausal women with osteoporosis at high risk for fracture, increase of bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture, treatment of osteoporosis associated with sustained systemic glucocorticoid therapy at high risk for fracture

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review.

A. OSTEOPOROSIS:
1. Documented diagnosis of postmenopausal osteoporosis in women who are at a high risk

of fracture, OR hypogonadal osteoporosis in men, OR glucocorticoid-induced osteoporosis (Note: Glucocorticoid-induced osteoporosis typically occurs following prednisone use [or its equivalent] at a dose of > 5 mg/day for > 3 months)
AND

2. (a) The member has had a T-score (current or at any time in the past) at or below -2.5 at the lumbar spine, femoral neck, total hip, and/or 33% (one-third) radius (wrist)
   OR
   (b) The member has had an osteoporotic fracture or a fragility fracture of the spine, hip, proximal humerus, pelvis, or distal forearm
   OR
   (c) The member has low bone mass (T-score [current or at any time in the past] between - 1.0 and -2.5 at the lumbar spine, femoral neck, total hip and/or 33% [one-third] radius [wrist]) and the prescriber determines the member is at high risk for fracture
   OR
   (d) FOR GLUCOCORTICOID-INDUCED OSTEOPOROSIS ONLY: Fracture Risk Assessment Tool (FRAX) (GC-adjusted) 10-year risk of major osteoporotic fracture score of 20% or greater OR FRAX (GC-adjusted) 10-year risk of hip fracture score of 3% or greater indicating member is at high risk for fracture
   AND
3. Prescriber attests that member has been counseled to concurrently take calcium (1000 mg) and vitamin D (400-1200 international units) supplements in conjunction with Forteo (teriparatide)
   AND
4. Prescriber attests to (or the clinical reviewer has found that) the member not having any FDA labeled contraindications that haven't been addressed by the prescriber within the documentation submitted for review [Contraindications to Forteo (teriparatide) include: Hypersensitivity to teriparatide or to any of its excipients, patients with increased risk of osteosarcoma including patients with open epiphyses, metabolic bone diseases including Paget's disease, bone metastases or history of skeletal malignancies, prior external beam or implant radiation therapy involving the skeleton, and hereditary disorders predisposing to osteosarcoma, patients known to have an underlying hypercalcemic disorder]
   AND
5. Documentation of failure (12-month trial), contraindication, or serious side effects to oral AND IV bisphosphonate therapy (Document drug, date, and duration of trial)
   NOTE: Treatment failure is defined by progression of bone loss as documented by bone density measurements (BMD) after at least 12 months of therapy OR occurrence of an osteoporotic fracture after having been compliant on at least 12 months of therapy on an oral bisphosphonate
   AND
6. POSTMENOPAUSAL OSTEOPORSIS INDICATION ONLY: Documentation of trial and failure or labeled contraindication to Prolia (denosumab) or Tymlos (abaloparatide) (Document drug, date, and duration of trial)
   NOTE: Treatment failure is defined by progression of bone loss as documented by bone density measurements (BMD) after at least 12 months of therapy OR Occurrence of an osteoporotic fracture after having been compliant on at least 12 months of therapy on Prolia (denosumab) or Tymlos (abaloparatide).
   AND
7. Prescriber attests (or medical records support) that the treatment duration has not exceeded a total of 24 months of cumulative use of parathyroid hormone analogs (e.g., Forteo, Tymlos) during the member's lifetime.
   AND
8. Prescriber attests that Forteo will not be used concurrently with bisphosphonates, RANKL inhibitor (e.g., denosumab), parathyroid hormone analog (e.g., Tymlos), or other anabolic agent (e.g., Evenity)

CONTINUATION OF THERAPY:
N/A

DURATION OF APPROVAL:
Authorization will be issued for up to 24 months. (Duration of coverage will be limited to 24 months of cumulative parathyroid hormone analog therapy (e.g., Forteo, Tymlos) in the member's lifetime.)

PRESCRIBER REQUIREMENTS:
No requirement

AGE RESTRICTIONS:
18 years of age and older

QUANTITY:
20 mcg subcutaneously once a day
Maximum Quantity Limits –1 PEN (2.4ML or 2.48ML) every 28 days

PLACE OF ADMINISTRATION:
The recommendation is that injectable medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Subcutaneous

DRUG CLASS:
Parathyroid Hormone And Derivatives

FDA-APPROVED USES:
Indicated for treatment of postmenopausal women with osteoporosis at high risk for fracture, increase of bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture and 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.
"High risk for fracture" is defined as a history of osteoporotic fracture or multiple risk factors for fracture.

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:
Clinical reasons to avoid oral bisphosphonate therapy

- Esophageal abnormality that delays emptying such as stricture of achalasia
- Active upper gastrointestinal problem (e.g., dysphagia, gastritis, duodenitis, erosive esophagitis, ulcers)
- Inability to stand or sit upright for at least 30 to 60 minutes
- Inability to take at least 30 to 60 minutes before first food, drink, or medication of the day
- Renal insufficiency (creatinine clearance <30 mL/min) WHO Fracture Risk Assessment Tool10- year probability of major osteoporotic fracture; calculation tool available at: http://www.shef.ac.uk/FRAX/tool.jsp

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:

Teriparatide (Forteo®) is a recombinant human parathyroid hormone. Parathyroid hormone stimulates the formation and resorption of bone. Forteo® is indicated for the treatment of osteoporosis in postmenopausal women who are at high risk for fracture and to increase bone mass in men with primary or hypogonadal osteoporosis who are at high risk for fracture. High risk includes those with a history of osteoporotic fracture, those with multiple risk factors for fracture, or who have failed or are intolerant of previous osteoporosis therapy. Forteo® is indicated for the treatment of glucocorticoid-induced osteoporosis. Forteo® has not been studied in pediatric patients or as replacement therapy in patients with primary hypoparathyroidism.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

All other uses of Forteo (teriparatide) are considered experimental/investigational and therefore, will follow Molina's Off-Label policy. Contraindications to Forteo (teriparatide) include: Hypersensitivity to teriparatide or to any of its excipients, patients with increased risk of osteosarcoma including patients with open epiphyses, metabolic bone diseases including Paget's disease, bone metastases or history of skeletal malignancies, prior external beam or implant radiation therapy involving the skeleton, and hereditary disorders predisposing to osteosarcoma, patients known to have an underlying hypercalcemic disorder.

OTHER SPECIAL CONSIDERATIONS:

Cumulative lifetime duration of teriparatide and any other parathyroid hormone therapy (e.g., abaloparatide) should not exceed 2 years.

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
N/A	

AVAILABLE DOSAGE FORMS:

Forteo 620 mcg/2.48 ML package size 2.4ML
Teriparatide (Recombinant) SOPN 620MCG/2.48ML package size 2.480 ML

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SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Products Affected Required Medical Information Drug Class FDA-Approved Uses References	Q3 2023
REVISION- Notable revisions: Required Medical Information Quantity Contraindications/Exclusions/Discontinuation Other Special Considerations References	Q3 2022
Q2 2022 Established tracking in new format	Historical changes on file