Teriparatide (Forteo®) Non-Formulary Criteria For Use

VHA Pharmacy Benefits Management Strategic Healthcare Group and Medical Advisory Panel

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The following recommendations are based on current medical evidence and expert opinion from clinicians. The content of the document is dynamic and will be revised as new clinical data becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. The clinician should utilize this guidance and interpret it in the clinical context of individual patient situations

Teriparatide in Patients at High Risk for Osteoporotic Fractures:

- ☐ Treatment of postmenopausal women with osteoporotic fracture while compliant on bisphosphonate after a minimum of 6-months of treatment

OR

- ☐ A documented adverse drug event or contraindication to bisphosphonates.

OR

- ☐ To increase bone mass in men with primary or hypogonadal osteoporosis who are at high risk for fracture, as defined as patients with a history of osteoporotic fractures (2 at baseline) **AND** who have multiple risk factors for fracture, **AND** while compliant on bisphosphonate after a minimum of 6-months if treatment, OR have a documented adverse drug event or contraindication to bisphosphonates.

  - ❑ Risk assessment must be performed on each patient and documented in the Non-formulary Request.
    - Document BMD scores in HIP or LUMBAR SPINE
    - Monitoring plan for patient once PTH is initiated. **[Baseline and 6- month BMD measurements must be assessed for monitoring requirements]**
    - Documentation of patient's risk profile
  - ❑ Assessment of Baseline Fracture History must be performed on each patient and documented in the Non-formulary Request
  - ❑ Assessment of treatment response or contraindications/ADRs to standard therapies
    - Document treatment duration with bisphosphonates and Calcium + Vitamin D supplementation
    - Documentation of adherence to regimen
    - Documentation of Adverse Drug Events to standard treatments where applicable.
    - Patient must be assessed for ability to use dosage formulation. If patient meets criteria for initiation of therapy, a 28-day supply is a maximum quantity for dispensing to assess patient tolerability and ability to self-administer daily injection. Initial prescriptions will be for 28-day with 5 refills.
    - Serum calcium levels at baseline and follow-up as indicated
  - ❑ Initial approval restricted to 6 months of therapy requiring follow-up approvals for future prescriptions up to 2 years of treatment. All follow-up information will be reviewed to determine if patient qualifies for continued therapy.
  - ❑

Dosage and Administration

Inject 20 mcg once daily for up to 2 years. Teriparatide is administered subcutaneously in the thigh or abdominal wall. Teriparatide should initially be administered under circumstances where the patient can sit or lie down if symptoms of orthostatic hypotension occur. Visually inspect teriparatide injection solution for particulate matter and discoloration prior to administration. Do not use injection solutions, which are cloudy or colored. Each Forteo™ Pen can be used for up to 28 days after the first injection. After a 28-day use period, the pen should be discarded, even if it still contains unused solution. The Forteo™ Pen administration device should not be shared. The Forteo™ Pen requires refrigeration for storage.

CONTRAINDICATIONS TO BISPHOSPHONATE THERAPY:

- Esophageal abnormalities
- Hypersensitivity to bisphosphonates
- Hypocalcemia
- Inability to sit or stand upright for at least 30 minutes

Risk Factor Assessment for Fractures

- Identification of Low Bone Mass through BMD measurement
  - Low BMD in patients with or without fractures

    WHO Diagnostic Criteria for Women Without Fragility Fractures:

    Normal: T score within 1 SD of the young adult mean

    Osteopenia: T score between –1 and - 2.5 SD of the average young adult mean

    Osteoporosis: T score is ≥ - 2.5 SD of the average young adult mean
- Prior Low trauma fracture as an adult
- Identification of Hip Fracture Risks
  - History of hip fracture in a first degree relative
  - Weight Loss and low body weight
  - Increased likelihood of falling*
  - Tallness
  - High bone turnover – as measured by serum blood levels or urine levels
  - Advancing age
  - Cigarette Smoking
- Consideration of secondary causes of osteoporosis: i.e. drug induced, hypogonadism, disorders of collagen metabolism, nutritional conditions, etc.
- Risk of Falling*
  - Frailty and associated deconditioning
  - Cognitive dysfunction
  - Poor visual acuity
  - Impaired Hearing
  - Medications with associated fall risks (neurologic effects, hypotension, etc.)

Criteria developed by: Melissa DeLattre, Pharm.D & Leonard J. Deftos, M.D., VA San Diego Healthcare System
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