

## Teriparatide (Forteo)

### Criteria for Use: Osteoporosis

### January 2012

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

*The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information 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 THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.*

*The Product Information should be consulted for detailed prescribing information.*

*See the VA National PBM-MAP-VPE Monograph on this drug at [www.pbm.va.gov](http://www.pbm.va.gov) or <http://vaww.pbm.va.gov> for further information.*

**Exclusion Criteria** *If ANY item below is met, then the patient should NOT receive teriparatide.*

- Patient does not have a diagnosis of osteoporosis or is not at risk for surgical/drug-induced osteoporosis
- Patient has a history of a hypersensitivity reaction or contraindication to teriparatide including Paget's disease, hyper or hypocalcemia, bone cancer, bone metastases, radiation treatment to the skeleton, and hyperparathyroidism with a creatinine clearance <30 mL/min.

**For treatment of osteoporosis only (do not apply to prevention or patient's previously treated with teriparatide for less than 24 months):**

- Patient has been on a bisphosphonate for <2 years without an osteoporotic fracture
- Patient's bone mineral density has remained stable without clinically significant loss (a decrease of >3%) at the same anatomical site DXA compared to baseline after being on a bisphosphonate for  $\geq 2$  years in the absence of an osteoporotic fracture. (See [Injectable Alternatives to Oral Bisphosphonates Algorithm #2](#))

#### Inclusion Criteria

**NOTE: Teriparatide should generally be prescribed to patients who cannot take or have not responded to a bisphosphonate or denosumab, or who have severe osteoporosis (T-score <-3.5) or who have experienced multiple osteoporotic fractures.**

#### General Inclusion Criteria (all must be met)

- Patient's total daily dietary and supplemental calcium intake is 1000 to 1500 mg/day.
- Patient has a 25-hydroxyvitamin D concentration  $\geq 20$  ng/mL AND an active prescription for cholecalciferol (Vitamin D<sub>3</sub>) or ergocalciferol (Vitamin D<sub>2</sub>) to prevent deficiency. For example, cholecalciferol  $\geq 800$  IU per day.

#### PLUS ONE OF THE FOLLOWING INDICATIONS:

- Patient has experienced an osteoporotic fracture while taking an oral bisphosphonate

**OR**

- Patient has been on an oral bisphosphonate  $\geq 2$  years with a >3% decrease in bone mineral density on same anatomical site DXA compared to baseline. (See [Injectable Alternatives to Oral Bisphosphonates Algorithm #3](#))

**OR**

- Patient has a relative or absolute contraindication to a bisphosphonate such as a history of upper GI injury or intolerance to an oral bisphosphonate, an increased risk for upper GI injury due to a co-morbid condition (e.g., esophageal motility disorder or Barrett's esophagus), physical condition (e.g., cannot sit-up for the required time period following oral dosing), a nonfunctional GI tract (e.g., enteral feedings via gastric or jejunostomy tube), or acute renal impairment.

**OR**

- Patient is treatment naive with a T-score <-3.5 on DXA at the lumbar spine or hip

**OR**

- Patient is premenopausal and of child-bearing potential with a diagnosis of osteoporosis or at risk for drug-induced osteoporosis (See below and Issues for Consideration)

**OR**

#### **Treatment and prevention of surgical/drug-induced osteoporosis (see issues for consideration)**

- Patient has a relative or absolute contraindication to a bisphosphonate such as a history of upper GI injury or intolerance to an oral bisphosphonate, an increased risk for upper GI injury due to a co-morbid condition (e.g., esophageal motility disorder or Barrett's esophagus), physical condition (e.g., cannot sit-up for the required time period following oral dosing), a nonfunctional GI tract (e.g., enteral feedings via gastric or jejunostomy tube), or acute renal impairment.

#### PLUS ONE OF THE FOLLOWING

- Patient has been or is expected to be treated with prednisone 5 mg/day (or its equivalent) for  $\geq 3$  months

**OR**

- Patient has been or is expected to be treated with antiepileptic drugs for >2 years

January 2012

Updated versions may be found at <http://www.pbm.va.gov> or <http://vaww.pbm.va.gov>

---

\*For safety these criteria should be reviewed prior to each infusion.  
DXA = Dual-energy x-ray absorptiometry

---

**Dosage and Administration**

---

- Patient or caregiver must be assessed for ability to use and administer dosage formulation
- Treatment duration is limited to 24 months. Alternative treatment, if appropriate, should be initiated after teriparatide.

---

**Issues for Consideration**

---

- Patient's with a 25-hydroxyvitamin D concentration <20 ng/mL should receive vitamin D repletion.
- AEDs associated with osteoporosis: Phenytoin, carbamazepine/oxcarbazepine, phenobarbital/primidone, valproic acid/valproate
- Use in premenopausal women of childbearing potential: All bisphosphonates, denosumab and teriparatide are FDA Pregnancy Category C and should be used during pregnancy only if benefits outweigh risks. Based on animal data, bisphosphonates, denosumab, or teriparatide may cause fetal harm if administered during pregnancy. Bisphosphonates long terminal half-lives, storage in bone, and recirculation during bone remodeling after their discontinuation has raised concern about their use even before pregnancy. Consider the potential for future pregnancy when prescribing osteoporosis treatment to women of childbearing potential.

---

**Prepared: January 2012. Contact: Todd Semla, MS, Pharm.D., BCPS, VA Pharmacy Benefits Management Services**