



Prior Authorization Approval Criteria

Forteo (teriparatide)

Generic name:	teriparatide
Brand name:	Forteo
Medication class:	Parathyroid hormone
FDA-approved uses:	Post menopausal women with a high risk for fracture To increase bone mass in men with primary or hypogonadal osteoporosis who are at high risk for fracture
Usual dose:	20 mcg daily for up to 24 months
Duration of therapy:	Up to 24 months

Criteria for use (*bullet points below are all inclusive unless otherwise noted*):

- Postmenopausal women who are at a high risk for fracture
- Or**
- Men with primary or hypogonadal osteoporosis who are at a high risk for fracture.
High risk for fracture defined as:
 - History of osteoporosis-related fracture
 - Low bone density less than 2.5SD below normalAnd one or more of the following:
 - failed two oral bisphosphonates and one injectable bisphosphonate.
- Or**
- intolerant to one oral bisphosphonate and one injectable bisphosphonate.

Contraindications: hypersensitivity to teriparatide or to any of its excipients.

Not indicated if:

- Patient has risk for osteosarcoma
- Patient has Paget's disease
- Patient has unexplained elevations of alkaline phosphatase
- Child
- Growing adults
- Patient has had prior bone radiation
- Patient has bone metastases or a history of skeletal malignancies
- Patient has metabolic bone diseases other than osteoporosis
- Patient has high levels of calcium
- Patient has used product for 24 months

Special information:

- In a 2-year rat study, there was an increase in the incidence of osteosarcoma, which was dependent upon dose and duration of product.
- It is not known at this time whether humans will be at risk for bone cancer.
- It should only be prescribed if benefit outweighs risk.

FCHP Pharmacy and Therapeutics Committee approval: _____

Date: _____

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Updated: 12/08/10