

# UPMC Health Plan POLICY AND PROCEDURE MANUAL

**POLICY NUMBER: RX.PA.026**  
**REVISION DATE: 04/2008**  
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**PAGE NUMBER: 1 of 4**

**SUBJECT:** Teriparatide (Forteo®)  
**INDEX TITLE:** Clinical Pharmacy Services  
**ORIGINAL DATE:** 5/1/03

**This policy applies to the following lines of business: (Check those that apply.)**

<b>Commercial:</b>					
HMO ( )	POS ( )	PPO ( )	OOA/DOC ( )		
Fully Insured ( )	Self-funded/ASO ( )	HSA ( )	All ( X )		
Medicare Select ( )	Medicare Supplement ( )				
<b>DPW-MA:</b>					
Health Choices ( )		Voluntary ( )		All ( X )	
<b>CMS-MA:</b>					
HMO ( )	PPO ( )	Specialty Needs Plan ( )	Part D ( )	PFFS ( )	All ( )
<b>PID-CHIP:</b>					
Free ( )		Sub ( )		All ( X )	

## **I. POLICY**

It is the policy of UPMC Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, as defined in CRM.015-Medical Necessity, and approval by the Pharmacy and Therapeutics Committee of the criteria for prior authorization, as described in RX.003-Prior Authorization Process.

The drug Teriparatide (Forteo) is subject to the prior authorization process.

## **II. DEFINITIONS**

N/A

## **III. PURPOSE**

The purpose of this policy is to define the Prior Authorization process for Teriparatide (Forteo).

## **IV. SCOPE**

This policy applies to the Pharmacy Services Department.

## V. PROCEDURE

Forteo is a recombinant human parathyroid hormone agent indicated for the treatment of osteoporosis in postmenopausal women and is indicated for use in men to increase bone mass with primary or hypogonadal osteoporosis. It should be used in these members when they are considered high risk for fracture and have failed conventional treatment options.

### Criteria for Teriparatide

Forteo will only be covered for members who meet all the following criteria:

- Member has a T score of -2.5 or below or has clinical osteoporosis (fragility/fracture(s))
- Member has tried and failed (failure meaning a break while on the therapy or a decline in T scores) one osteoporotic treatment, including:
  - a bisphosphonate (Actonel or Fosamax); or
  - a selective estrogen receptor modulator (Evista); or
  - hormone replacement therapy; or
  - Miacalcin; or
  - calcitonin; or
- Member has a documented contraindication/intolerance to two (2) of the conventional therapies listed above; or
- Member has a contraindication/intolerance to one of the conventional therapies listed above followed by a subsequent failure of one (1) of the conventional therapies listed above
- Member does not have a history of any of the following conditions:
  - Paget's Disease
  - Prior radiation therapy
  - Bone metastases
  - History of skeletal malignancies
  - Metabolic bone disease other than osteoporosis

If a member meets the above criteria, approvals will be granted for up to two (2) years. No reauthorization will be granted after this period of coverage.

### Limitations:

If a member does not meet the above approval criteria, the request will be referred to a UPMC Health Plan Medical Director for review.

**V. BIBLIOGRAPHY**

1. Donaldson LJ, Cook A, Thomson RG. Incidence of fractures in a geographically defined population. *J Epidemiol Commun Health.* 1990; 44:241-5.
2. Neer RM, Arnaud CD, Zanchetta JR, et al. Effect of parathyroid hormone (1-34) on fractures and bone mineral density in postmenopausal women with osteoporosis. *NEJM.* 2001; 344(19):1434-41.
3. Forteo Product Information. Eli Lilly and Company. Indianapolis, IN. November 2002.
4. Body JJ, et al. A randomized double-blind trial to compare the efficacy of teriparatide [recombinant human parathyroid hormone (1-34)] with alendronate in postmenopausal women with osteoporosis. *J Clin Endocrin Metab.* 2002;87:4528-35.
5. Deal C, Gideon J. Recombinant human PTH 1-34 (Forteo): An anabolic drug for osteoporosis. *Cleveland Clinic Journal of Medicine* 2003;70(7):585-601.