Premier Health Plan

POLICY AND PROCEDURE

POLICY TITLE: **Forteo (teriparatide) and Tymlos (abaloparatide) Step Therapy**
DEPARTMENT: **Clinical Pharmacy Services- Utilization Management**
ORIGINAL DATE: ***May 2003***

Last P & T Committee Approval Date: *February 2018*

Product Applicability: *mark all applicable products below:*

COMMERCIAL	[ ] HMO [ ] PPO *Products*: [ ] Small [ ] Indiv. [ ] Large *Exchange*: [ ] Shop [ ] Indiv. [x] All
OTHER	[x] Self-funded/ASO

PURPOSE

The purpose of this policy is to define the prior authorization process for Forteo (teriparatide) and Tymlos (abaloparatide).

DEFINITIONS

N/A

POLICY

It is the policy of the 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 & Therapeutics Committee of the criteria for prior authorization, as described in RX.003-Prior Authorization Process.

The drugs, Forteo (teriparatide) and Tymlos (abaloparatide), are subject to the prior authorization process.

PROCEDURE

Forteo (teriparatide) is a recombinant human parathyroid hormone agent 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
- Treatment of men and women with glucocorticoid-induced osteoporosis at high risk for fracture

Tymlos (abaloparatide) is a synthetic analog of human parathyroid hormone related peptide indicated for the treatment of postmenopausal women with osteoporosis at high risk for fracture.

Initial Authorization Criteria:

Must meet all of the criteria listed under the respective diagnosis:

For All Diagnoses:

- Must have a documented pharmacy claim history of either one bisphosphonate or raloxifene (Evista®) in the 3 months prior to filling teriparatide
- For members without a documented pharmacy claim history of a bisphosphonate or raloxifene (Evista), a medical necessity review is completed, and the following criterion must be met:
    - For Tymlos:
        - Must be female sex assigned at birth
        - Must be used for the treatment of postmenopausal osteoporosis at high risk for fracture.
    - For Forteo:
        - Must be used for one of the following:
            - 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 men and women with glucocorticoid-induced osteoporosis at high risk for fracture
    - Must have chart documentation which shows the member has failed or has an intolerance or contraindication to one bisphosphonate or raloxifene (Evista)
    - Must not have used Forteo (teriparatide) or Tymlos (abaloparatide) either separately or in sequence for greater than 2 years
    - Must not be at an increased risk for osteosarcoma (ie Paget's disease of bone, unexplained elevations of alkaline phosphatase, open epiphyses or

lack of epiphyseal closure, or prior external beam of implant radiation therapy involving the skeleton)

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 2 years
Reauthorization	N/A – no reauthorizations granted after 2 years
Quantity Level Limit	
Forteo & Tymlos	• 1 pen per 28 days • Maximum of 2 years of therapy per lifetime cumulative of either Forteo and/or Tymlos or a combination of the two products.

If the established criteria are not met, the request is referred to a Medical Director for review.

REFERENCES

1. Forteo [package insert]. Eli Lilly and Company; Indianapolis, IN: January 2010.
2. Evista [package insert]. Indianapolis, IN: Eli Lilly and Co; January 2011.
3. Tymlos [package insert]. Waltham, MA: Radium Health, Inc; 2017.

RECORD RETENTION

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual Review	*02/16, 02/17, 02/18*
Addition of Tymlos	*07/17*