Parathyroid Hormone Analogs

Description

Forteo (teriparatide), Tymlos (abaloparatide)

Background

Forteo (teriparatide) is used to treat osteoporosis in women after menopause who are at high risk for fracture (broken bone) and cannot use another osteoporosis medicine or other osteoporosis medicines did not work well. Forteo may also be used to increase bone mass in men with primary or hypogonadal osteoporosis; and treat men and women with osteoporosis associated with sustained systemic glucocorticoid therapy (1).

Tymlos (abaloparatide) is indicated for the treatment of postmenopausal women with osteoporosis at high risk for fracture defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy. In postmenopausal women with osteoporosis, Tymlos reduces the risk of vertebral fractures and nonvertebral fractures (2).

Regulatory Status
FDA-approved indications:

Forteo

Forteo is recombinant human parathyroid hormone analog (1-34), [rhPTH(1-34)] indicated for:

1. Treatment of postmenopausal women with osteoporosis at high risk for fracture
2. Increase of bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture
3. Treatment of men and women with osteoporosis associated with sustained systemic
Tymlos
Tymlos is a human parathyroid hormone related peptide [PTHrP(1-34)] analog indicated for: (2)

1. Treatment of postmenopausal women with osteoporosis at high risk for fracture

The Forteo and Tymlos labels includes a boxed warning citing the risk of osteosarcoma dependent on dose and treatment duration. Forteo and Tymlos should not be prescribed for patients who are at increased baseline risk for osteosarcoma including those with Paget’s disease of bone or unexplained elevations of alkaline phosphatase, pediatric and young adult patients with open epiphyses, or prior external beam or implant radiation therapy involving the skeleton (1-2).

Because of the unknown relevance of the rodent osteosarcoma findings to humans, cumulative use of parathyroid hormone analogs including Forteo (teriparatide) and Tymlos (abaloparatide) for more than 2 years during a patient’s lifetime is not recommended (1-2).

Caution should be used in prescribing Forteo in patients with severe renal impairment. In 5 patients with severe renal impairment (CrCl <30 mL/min), the AUC and T1/2 of teriparatide were increased by 73% and 77%, respectively (1).

The safety and effectiveness of Forteo and Tymlos in pediatric patients has not been established (1-2).

Related policies
Prolia, Xgeva

Policy
This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Forteo may be considered medically necessary in patients 18 years of age and older to treat postmenopausal women with osteoporosis, primary or hypogonadal osteoporosis or osteoporosis associated with sustained systemic glucocorticoid therapy if the conditions indicated below are met.

Tymlos may be considered medically necessary for patients 18 years of age or older to treat postmenopausal women with osteoporosis if the conditions below are met
Forteo and Tymlos may be considered *investigational* for patients less than 18 years of age and for all other indications.

**Prior-Approval Requirements**

**Age**

18 years of age or older

**Diagnoses**

Patient must have **ONE** of the following:

**Forteo and Tymlos**

1. Postmenopausal women with osteoporosis

   **AND ONE** of the following:
   a. History of an osteoporotic low trauma fracture of the spine, hip, proximal humerus, pelvis, or distal forearm
   b. Inadequate response, intolerance or contraindication to oral or injectable bisphosphonate

**Forteo ONLY**

1. Primary or hypogonadal osteoporosis in men

   **AND ONE** of the following:
   a. History of an osteoporotic low trauma fracture of the spine, hip, proximal humerus, pelvis, or distal forearm
   b. Inadequate response, intolerance or contraindication to oral or injectable bisphosphonate

2. Osteoporosis associated with sustained systemic glucocorticoid therapy

   **AND ONE** of the following:
   a. History of an osteoporotic low trauma fracture of the spine, hip, proximal humerus, pelvis, or distal forearm
   b. Inadequate response, intolerance or contraindication to oral or injectable bisphosphonate **AND** the following:
      i. Currently receiving or will be initiating glucocorticoid therapy
AND NONE of the following:
   a. Risk for osteosarcoma
   b. Paget's disease
   c. Unexplained elevations of alkaline phosphatase
   d. Prior bone radiation
   e. Bone metastases or a history of skeletal malignancies
   f. Metabolic bone diseases other than osteoporosis
   g. High levels of calcium
   h. Patient has used any parathyroid hormone analogs including Forteo (teriparatide) or Tymlos (abaloparatide) cumulatively for longer than 24 months
   i. Dual therapy with other human parathyroid hormone related peptide analogs

Prior – Approval Renewal Requirements

Age
18 years of age or older

Diagnoses

Patient must have ONE of the following:

Forteo and Tymlos

1. Postmenopausal women with osteoporosis

Forteo ONLY

1. Primary or hypogonadal osteoporosis in men
2. Osteoporosis associated with sustained systemic glucocorticoid therapy

AND NONE of the following:
   a. Risk for osteosarcoma
   b. Paget's disease
   c. Unexplained elevations of alkaline phosphatase
   d. Prior bone radiation
   e. Bone metastases or a history of skeletal malignancies
   f. Metabolic bone diseases other than osteoporosis
   g. High levels of calcium
   h. Patient has used any parathyroid hormone analogs including Forteo (teriparatide) or Tymlos (abaloparatide) cumulatively for longer than 24 months
i. Dual therapy with other human parathyroid hormone related peptide analogs

### Policy Guidelines

#### Pre - PA Allowance

None

#### Prior - Approval Limits

**Forteo**

- **Quantity**: 3 multi-dose prefilled pens per 84 days
- **Duration**: 12 months

**Tymlos**

- **Quantity**: 3 multi-dose prefilled pens per 90 days
- **Duration**: 12 months

#### Prior – Approval *Renewal* Limits

**Forteo**

- **Quantity**: 3 multi-dose prefilled pens per 84 days
- **Duration**: 12 months (*Only ONE renewal*)

**Tymlos**

- **Quantity**: 3 multi-dose prefilled pens per 90 days
- **Duration**: 12 months (*Only ONE renewal*)

### Rationale

#### Summary

Forteo (teriparatide) is used to treat osteoporosis in women after menopause who are at high risk for fracture (broken bone) and may also be used to increase bone mass in men with primary or hypogonadal osteoporosis; and treat men and women with osteoporosis associated with sustained systemic glucocorticoid therapy. Tymlos (abaloparatide) is indicated for the treatment
of postmenopausal women with osteoporosis at high risk for fracture defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy. These agents should not be prescribed for patients who are at increased baseline risk for osteosarcoma including those with Paget's disease of bone or unexplained elevations of alkaline phosphatase, pediatric and young adult patients with open epiphyses, or prior external beam or implant radiation therapy involving the skeleton. The safety and effectiveness of Forteo and Tymlos in pediatric patients has not been established (1-2).

Prior authorization is required to ensure the safe, clinically appropriate and cost effective use of Forteo and Tymlos while maintaining optimal therapeutic outcomes.

References

Policy History

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<thead>
<tr>
<th>Date</th>
<th>Action</th>
<th>Reason</th>
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<tbody>
<tr>
<td>February 2017</td>
<td>Addition to PA</td>
<td></td>
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<tr>
<td>May 2017</td>
<td>Change in policy name from Forteo To Parathyroid Hormone Analogs</td>
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<td></td>
<td>Addition of Tymlos (abaloparatide) to policy and no dual therapy with other human parathyroid hormone related peptide analogs</td>
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<tr>
<td>June 2017</td>
<td>Annual review</td>
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<tr>
<td>September 2017</td>
<td>Annual review</td>
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Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 15, 2017 and is effective on October 1, 2017.