Parathyroid Hormone Analogs

Description

Bonsity (teriparatide), Forteo (teriparatide), Tymlos (abaloparatide)

Background

Bonsity and Forteo (teriparatide) are 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. Bonsity and 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 (1-2).

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 (3).

Regulatory Status

FDA-approved indications:

Bonsity and Forteo

Bonsity and Forteo are recombinant human parathyroid hormone analogs (1-34), [rhPTH(1-34)] indicated for: (1-2)

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
glucocorticoid therapy at high risk for fracture

**Tymlos**

Tymlos is a human parathyroid hormone related peptide [PTHrP(1-34)] analog indicated for: (3)

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

The Bonsity, 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 (1-3).

Because of the unknown relevance of the rodent osteosarcoma findings to humans, cumulative use of parathyroid hormone analogs including Bonsity (teriparatide), Forteo (teriparatide), and Tymlos (abaloparatide) for more than 2 years during a patient’s lifetime is not recommended (1-3).

Caution should be used in prescribing Bonsity and 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 (1-2).

The safety and effectiveness of Bonsity, Forteo, and Tymlos in pediatric patients has not been established (1-3).

**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.*

Bonsity and 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 indicated below are met.

Bonsity, 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:

**Bonsity, 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

**Bonsity and 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. Concurrent therapy with other human parathyroid hormone related peptide analogs (see Appendix 1)
   j. Concurrent therapy with another Prior Authorization (PA) medication for osteoporosis (see Appendix 2)

Prior – Approval Renewal Requirements

Age 18 years of age or older

Diagnoses

Patient must have ONE of the following:

Bonsity, Forteo, and Tymlos

1. Postmenopausal women with osteoporosis

Bonsity and 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. Concurrent therapy with other human parathyroid hormone related peptide analogs (see Appendix 1)
j. Concurrent therapy with another Prior Authorization (PA) medication for osteoporosis (see Appendix 2)

Policy Guidelines

Pre - PA Allowance
None

Prior - Approval Limits

Bonsity and 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

Bonsity and 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
Bonsity (teriparatide) and Forteo (teriparatide) are 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 Bonsity, Forteo, and Tymlos in pediatric patients have not been established (1-3).

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

References

Policy History

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<td>Addition to PA</td>
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<tr>
<td>May 2017</td>
<td>Change in policy name from Forteo To Parathyroid Hormone Analogs 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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### 5.30.36

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<td>February 17, 2017</td>
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<tr>
<td>November 2018</td>
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<td>April 2019</td>
<td>Addition of requirement of no concurrent therapy with another PA osteoporosis medication and addition of Appendices 1 and 2</td>
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**Keywords**

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 6, 2019 and is effective January 1, 2020.
### Appendix 1 - List of human parathyroid hormone related peptide analogs

<table>
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<tr>
<th>Generic Name</th>
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<tr>
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### Appendix 2 - List of PA Osteoporosis Medications

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