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Section:	Prescription Drugs	**Effective Date:**	April 1, 2021
Subsection:	Endocrine and Metabolic Drugs	**Original Policy Date:**	February 17, 2017
Subject:	Parathyroid Hormone Analogs	**Page:**	1 of 8

Last Review Date: March 12, 2021

Parathyroid Hormone Analogs

Description

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

*This medication is included in this policy but is not available in the market as of yet

Background
Bonsity, Forteo, and 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. They 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 (1-3).

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 (4).

Regulatory Status
FDA-approved indications:

Bonsity, Forteo, and Teriparatide

Bonsity, Forteo, and Teriparatide are recombinant human parathyroid hormone analogs (1-34), [rhPTH(1-34)] indicated for: (1-3)

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: (4)

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

The Bonsity, Teriparatide, and Tymlos labels include a boxed warning citing the risk of osteosarcoma dependent on dose and treatment duration. Bonsity, Teriparatide, 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, 3-4).

Because of the unknown relevance of the rodent osteosarcoma findings to humans, cumulative use of parathyroid hormone analogs including Bonsity (teriparatide), Teriparatide, and Tymlos (abaloparatide) for more than 2 years during a patient's lifetime is not recommended (1, 3-4).

Use of Forteo for more than 2 years during a patient's lifetime should only be considered if a patient remains at or has returned to having a high risk for fracture (2).

Caution should be used in prescribing Bonsity, Forteo, or Teriparatide 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 (1-3).

The safety and effectiveness of Bonsity, Forteo, Teriparatide, and Tymlos in pediatric patients has not been established (1-4).

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, Forteo, and Teriparatide 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, Teriparatide, 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, Teriparatide, 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, Forteo, and Teriparatide 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. Bonsity, Teriparatide, and Tymlos **only:** Patient has used any parathyroid hormone analogs (see Appendix 1) 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, Teriparatide, and Tymlos

1. Postmenopausal women with osteoporosis

Bonsity, Forteo, and Teriparatide ONLY

1. Primary or hypogonadal osteoporosis in men

2. Osteoporosis associated with sustained systemic glucocorticoid therapy

AND the following for Forteo treatment beyond 2 years only:

a. Patient remains at high risk for fracture or has returned to having a high risk for fracture

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. Bonsity, Teriparatide, and Tymlos **only:** Patient has used any parathyroid hormone analogs (see Appendix 1) 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, Forteo, and Teriparatide

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 Teriparatide

Quantity 3 multi-dose prefilled pens per 84 days

Duration 12 months (**Only ONE renewal**)

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 (**Only ONE renewal**)

Rationale

Summary
Bonsity, Forteo, and Teriparatide are used to treat osteoporosis in women after menopause who are at high risk for fracture (broken bone), 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, Teriparatide, and Tymlos in pediatric patients have not been established (1-4).

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

References

1. Bonsity [package insert]. San Diego, CA: Pfenex, Inc.; October 2019.
2. Forteo [package insert]. Indianapolis, IN: Eli Lilly and Company; November 2020.
3. Teriparatide [package insert]. Morristown, NJ: Alvogen Inc.; November 2019.
4. Tymlos [package insert]. Waltham, MA: Radius Health, Inc.; October 2018.

Policy History

Date	Action	Reason
February 2017	Addition to PA	
May 2017	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	
June 2017	Annual review	
September 2017	Annual review	
December 2017	Annual review	
November 2018	Annual review and reference update	
April 2019	Addition of requirement of no concurrent therapy with another PA osteoporosis medication and addition of Appendices 1 and 2	
June 2019	Annual review	
November 2019	Addition of Bonsity	
December 2019	Annual review	
August 2020	Addition of Teriparatide (biosimilar)	
September 2020	Annual review and reference update	
January 2021	Forteo boxed warning for osteosarcoma removed. Treatment for Forteo can now extend beyond 24 months if the patient remains at high risk for fracture or returns to having high risk for fracture	
March 2021	Annual review	

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 12, 2021 and is effective on April 1, 2021.

Appendix 1 - List of human parathyroid hormone related peptide analogs

Generic Name	Brand Name
abaloparatide	Tymlos
teriparatide	Bonsity
teriparatide	Forteo
teriparatide	Teriparatide

Appendix 2 - List of PA Osteoporosis Medications

Generic Name	Brand Name
abaloparatide	Tymlos
denosumab	Prolia
romosuzumab-aqqg	Evenity
teriparatide	Bonsity
teriparatide	Forteo
teriparatide	Teriparatide