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Section:	Prescription Drugs	**Effective Date:**	April 1, 2023
Subsection:	Endocrine and Metabolic Drugs	**Original Policy Date:**	February 17, 2017
Subject:	Parathyroid Hormone Analogs	**Page:**	1 of 10

Last Review Date: March 10, 2023

Parathyroid Hormone Analogs

Description

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

Tymlos (abaloparatide)

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

Background
Bonsity (teriparatide), Forteo (teriparatide) and Teriparatide (teriparatide) are synthetic forms of human parathyroid hormone (PTH), which is the primary regulator of bone and mineral metabolism. The pharmacologic activity of teriparatide, which is similar to the physiologic activity of PTH, includes stimulating osteoblast function, increasing gastrointestinal calcium absorption, and increasing renal tubular reabsorption of calcium. Treatment with teriparatide results in increased bone mineral density, bone mass, and strength. In postmenopausal females, teriparatide has been shown to decrease osteoporosis-related fractures (1-3).

Teriparatide (teriparatide) manufactured by Alvogen is not considered a true generic of Forteo. It is a follow-on teriparatide product approved under the 505 (b) (2) regulatory pathway, with Forteo as the reference drug (3).

Tymlos (abaloparatide) is an analog of human parathyroid hormone related protein (PTHrP[1-34]), which acts as an agonist at the PTH1 receptor (PTH1R). This results in stimulation of osteoblast function and increased bone mass (4).

Regulatory Status
FDA-approved indications:

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 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 or patients who have failed or are intolerant to other available osteoporosis therapy
2. Treatment to increase bone density in men with osteoporosis at high risk for fracture or patients who have failed or are intolerant to other available osteoporosis therapy

Bonsity and Teriparatide include a boxed warning citing the risk of osteosarcoma dependent on dose and treatment duration. Forteo and Tymlos no longer carry a boxed warning about the risk of osteosarcoma, however it is still listed as a warning and precaution. Bonsity, Forteo, 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 (1-4).

Because of the unknown relevance of the rodent osteosarcoma findings to humans, cumulative use of parathyroid hormone analogs including Bonsity, Teriparatide, and Tymlos for more than 24 months during a patient's lifetime is not recommended. Forteo dosing is no longer limited to 24 months of lifetime use. Use of Forteo for more than 24 months during a patient's lifetime should only be considered if a patient remains at or has returned to having a high risk for fracture (1-4).

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

Evenity, 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 for the treatment of postmenopausal women with osteoporosis, primary or hypogonadal osteoporosis in men or osteoporosis associated with sustained systemic glucocorticoid therapy; and if the conditions indicated below are met.

Tymlos may be considered **medically necessary** for patients 18 years of age or older for the treatment of postmenopausal women or in men with osteoporosis and 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

Tymlos ONLY

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

1. Postmenopausal women with osteoporosis
2. Men 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 treatment response, intolerance, or contraindication to oral or injectable bisphosphonate

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. Cumulative lifetime therapy with parathyroid hormone analogs exceeds 24 months (see Appendix 1)
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)

Bonsity, Forteo, and Teriparatide ONLY

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

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 treatment response, intolerance, or contraindication to oral or injectable bisphosphonate

2. 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 treatment response, intolerance, or contraindication to oral or injectable bisphosphonate

3. 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 treatment response, intolerance, or contraindication to oral or injectable bisphosphonate **AND** the following:

i. Currently receiving or will be initiating glucocorticoid therapy

AND ONE of the following for all indications:

a. Cumulative lifetime therapy with parathyroid hormone analogs does not exceed 24 months (see Appendix 1)
b. Forteo **only**: patient remains at or has returned to having high risk for fracture despite a total of 24 months of use of parathyroid hormones

AND NONE of the following for all indications:

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. Concurrent therapy with other human parathyroid hormone related peptide analogs (see Appendix 1)
i. 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

Tymlos ONLY

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

1. Postmenopausal women with osteoporosis
2. Men with osteoporosis

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. Cumulative lifetime therapy with parathyroid hormone analogs exceeds 24 months (see Appendix 1)
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)

Bonsity, Forteo, and Teriparatide ONLY

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

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

AND ONE of the following for all indications:

a. Cumulative lifetime therapy with parathyroid hormones does not exceed 24 months
b. Forteo **only**: patient remains at or has returned to having high risk for fracture despite a total of 24 months of use of parathyroid hormones

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

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Tymlos

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

Bonsity, Forteo, and Teriparatide

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

Prior – Approval *Renewal* Limits

Tymlos

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

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

Rationale

Summary

Bonsity (teriparatide), Forteo (teriparatide), and Teriparatide (teriparatide) are used in the treatment of postmenopausal women with osteoporosis, primary or hypogonadal osteoporosis in men and osteoporosis associated with sustained systemic glucocorticoid therapy. Tymlos (abaloparatide) is used in the treatment of postmenopausal women or in men with osteoporosis. 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; April 2021.
3. Teriparatide [package insert]. Morristown, NJ: Alvogen Inc.; November 2019.
4. Tymlos [package insert]. Waltham, MA: Radius Health, Inc.; December 2022.

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	
September 2021	Annual review and reference update	
October 2021	Rearranged and reworded criteria requirements to clarify that cumulative use of parathyroid hormone analogs, other than Forteo, should not exceed 24 months. Revised background, regulatory and summary sections	
December 2021	Annual review	
January 2022	Regulatory section updated with the removal of Tymlos boxed warning for osteosarcoma	

March 2022	Annual review and reference update
December 2022	Annual review. Changed policy number to 5.30.036
January 2023	Per PI update, added Tymlos indication of men with osteoporosis
March 2023	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 10, 2023 and is effective on April 1, 2023.

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