BlueCross BlueShield
Federal Employee Program

# PARATHYROID HORMONE ANALOGS

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

Tymlos (abaloparatide)

*Prior authorization for this product applies only to formulary exceptions due to being a non-covered medication

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

## RATIONALE FOR INCLUSION IN PA PROGRAM

### 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

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**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, Forteo, Teriparatide, 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 Tymlos for more than 24 months during a patient's lifetime is not recommended. Bonsity, Forteo, and Teriparatide dosing is no longer limited to 24 months of lifetime use. Use of Bonsity, Forteo, or Teriparatide 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).

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## 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]. Morristown, NJ: Alvogen, Inc.; November 2023.
2. Forteo [package insert]. Indianapolis, IN: Eli Lilly and Company; April 2021.
3. Teriparatide [package insert]. Morristown, NJ: Alvogen Inc.; November 2023.
4. Tymlos [package insert]. Waltham, MA: Radius Health, Inc.; December 2023.