I. Medication Description

Bonsity (teriparatide) is a parathyroid hormone analog (PTH 1-34). Endogenous 84-amino acid parathyroid hormone (PTH) is the primary regulator of bone metabolism, renal tubular reabsorption of calcium and phosphate, and intestinal calcium absorption. The biological actions of PTH and teriparatide are mediated through binding to specific high-affinity cell-surface receptors. Teriparatide and the 34 N-terminal amino acids of PTH bind to these receptors with the same affinity and have the same physiological actions on bone and kidney. Teriparatide is not expected to accumulate in bone or other tissues.

The skeletal effects of teriparatide depend upon the pattern of systemic exposure. Once-daily administration of teriparatide stimulates new bone formation on trabecular and cortical (periosteal and/or endosteal) bone surfaces by preferential stimulation of osteoblastic activity over osteoclastic activity. In monkey studies, teriparatide improved trabecular microarchitecture and increased bone mass and strength by stimulating new bone formation in both cancellous and cortical bone. In humans, the anabolic effects of teriparatide manifest as an increase in skeletal mass, an increase in markers of bone formation and resorption, and an increase in bone strength. By contrast, continuous excess of endogenous PTH, as occurs in hyperparathyroidism, may be detrimental to the skeleton because bone resorption may be stimulated more than bone formation.

II. Position Statement

Coverage is determined through a prior authorization process with supporting clinical documentation for every request.

III. Policy

Coverage of Bonsity is provided when the following criteria have been met:

- Bonsity is being used:
  - For the treatment of osteoporosis in postmenopausal women at high risk for fracture OR
  - For the treatment of osteoporosis in men and women with sustained systemic glucocorticoid therapy at high risk of fracture OR
  - To increase bone mass in men with primary or hypogonadal osteoporosis at high risk of fracture AND
- Member is 18 years of age or older AND
- Member must have failed therapy with a bisphosphonate (defined by a fracture while on therapy or worsening bone density) unless such a trial is shown to be inappropriate or contraindicated (e.g.,
Drug Therapy Guidelines  |  Bonsity (teriparatide)  |  Last Review Date: 12/2019

presence of severe osteoporosis [T-scores -3.0 or worse in lumbar spine, femoral neck, or total hip region], history of major osteoporotic fracture, presence of renal insufficiency, etc) AND

- Member has at least one of the following:
  - T-score equal to or worse than -2.5 in the lumbar spine, femoral neck, or total hip region OR
  - A FRAX calculator based 10-year risk of at least 20% for a major osteoporotic fracture (spine, shoulder, hip, or wrist), or a 10-year risk of at least 3% for a hip fracture OR
  - Presence or history of osteoporotic fracture.

IV. Quantity Limitations

One Bonsity pen per each 28 days will be covered (to accommodate a dose of 20mcg per day).

V. Coverage Duration

Coverage is provided for up to 2 years and cannot be renewed.

VI. Coverage Renewal Criteria

n/a

VII. Billing/Coding Information

Bonsity is available as Injection: 620 mcg/2.48 mL (250 mcg/mL) in single-patient-use pen containing 28 daily doses of 20 mcg.

VIII. Summary of Policy Changes

1/15/20: new policy

IX. References


10. Forteo [package insert]. Indianapolis, IN: Lilly USA, LLC; Revised 10/2019
12. IPD Analytics, LLC. Accessed 12/2019

The Plan fully expects that only appropriate and medically necessary services will be rendered. The Plan reserves the right to conduct pre-payment and post-payment reviews to assess the medical appropriateness of the above-referenced therapies.

The preceding policy applies only to members for whom the above named pharmacy benefit medications are included on their covered formulary. Members with closed formulary benefits are subject to trying all appropriate formulary alternatives before a coverage exception for a non-formulary medication will be considered.

The preceding policy is a guideline to allow for coverage of the pertinent medication/product, and is not meant to serve as a clinical practice guideline.