Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

teriparatide (Bonsity, Forteo)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	2 years

Medications	Quantity Limit
Bonsity (teriparatide) Injection pen Forteo (teriparatide) Injection pen	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Bonsity (teriparatide) or Forteo (teriparatide) may be approved for the following:

I. Individual has one of the following:
   A. Individual is a postmenopausal female with a diagnosis of osteoporosis (defined as bone mineral density (BMD) T-score in the spine, femoral neck, total hip or distal 1/3 of the radius of less than or equal to -2.5 as compared to young-adult reference population OR a clinical diagnosis based on history of a low trauma fracture (fragility fracture))at high risk for fracture[1]; **OR**

   B. Individual is a male diagnosed with primary or hypogonadal osteoporosis (defined as BMD T-score in the spine, femoral neck, total hip or distal 1/3 of the radius of less than or equal to -2.5 as compared to young-adult reference population OR a clinical diagnosis based on a history of a low trauma fracture (fragility fracture)) at high risk for fracture[1] using to increase bone mass; **OR**

   C. Individual has a diagnosis of osteoporosis (defined as BMD T-score in the spine, femoral neck, total hip or distal 1/3 of the radius of less than or equal to -2.5 as compared to young-adult reference population OR a clinical diagnosis based on history of low trauma fracture (fragility fracture)) associated with sustained systemic glucocorticoid therapy (daily dosage equivalent to 5 mg or greater of prednisone for at least 3 months) at high risk for fracture[1];

AND

II. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or intolerance to one preferred oral bisphosphonate;

   Preferred agents: Alendronate tablet (generic Fosamax), alendronate oral solution (generic Fosamax oral solution

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

OR

III. The preferred agents is not FDA-approved and does not have an accepted off-label use per the off-label policy for the prescribed indication and the requested non-preferred agent does;

OR

IV. Individual meets one of the following:
   A. The individual has been refractory to a prior trial of a bisphosphonate;
      OR
   B. The individual is intolerant to or has a contraindication to a bisphosphonate as defined by:
      1. Hypersensitivity to TWO bisphosphonates (one of which must be alendronate); **OR**
      2. Inability to stand or sit upright for at least 30 minutes; **OR**
      3. Pre-existing gastrointestinal disorders (Barrett's esophagus, hypersecretory disorders, delayed esophageal emptying, atrophic gastritis, etc.); **OR**
      4. Uncorrected hypocalcemia; **OR**
      5. Severe renal insufficiency as defined by creatinine clearance less than 35 mL/min for alendronate agents and zoledronic acid or creatinine clearance less than 30 mL/min for risedronate and ibandronate;

AND

V. Individual is not using Bonsity (teriparatide) or Forteo (teriparatide) in combination with any of the following:
   A. Prolia (denosumab); **OR**
   B. Bisphosphonates; **OR**
   C. Evista (raloxifene); **OR**
   D. Miacalcin/Fortical (calcitonin nasal spray); **OR**
   E. Reclast (zoledronic acid); **OR**
   F. Tymlos (abaloparatide); **OR**
   G. Evenity (romosozumab-aqqg);
   H. Another teriparatide agent;

AND

VI. Individual has utilized Bonsity (teriparatide) AND Forteo (teriparatide) AND Tymlos (abaloparatide) for a combined total duration of less than 24 months in their lifetime.

Requests for Bonsity (teriparatide), Forteo (teriparatide) may not be approved when the above criteria are not met and for all other indications.

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

Notes:

1. High risk for fracture is defined as the following:
   a. History of osteoporotic fracture; or
   b. Multiple risk factors for fractures including but not limited to: Prior low-trauma fracture as an adult, advanced age, gender, ethnicity , low bone mineral density, low body weight, family history of osteoporosis, use of glucocorticoids (daily dosage equivalent to 5mg per day or greater prednisone for at least 3 months), cigarette smoking, excessive alcohol consumption (3 or more drinks/day), secondary osteoporosis (such as, rheumatoid arthritis), early menopause, height loss or kyphosis, fall risk and low calcium intake; ; or
   c. Failure or intolerance to other osteoporosis therapies.
2. A failure of other osteoporosis therapies, otherwise known as refractory disease, may be defined as a decline in BMD while on therapy (≥5%) or a fragility fracture while on therapy.
3. Requests to continue therapy beyond 24 months (2 years) should NOT be approved. [The safety and efficacy of Forteo have not been evaluated beyond 2 years of treatment. The use of the drug for more than 2 years during a patient's lifetime is NOT recommended.
4. Bonsity (teriparatide), Forteo (teriparatide) has a black box warning for potential risk of osteosarcoma. In rates, an increase in the incidence of osteosarcoma (malignant bone tumor dependent on dose and treatment duration has been identified with uncertain relevance to humans. Forteo should not be prescribed for individuals who are at increased baseline risk for osteosarcoma (including hose with Paget's disease of bon or unexplained elevations of alkaline phosphatase, pediatric and young adults with open epiphyses, or prior external beam or implant radiation therapy involving the skeleton).

Key References:

1. Camacho PM, Petak SM, Binkley N, et al. American Association of Clinical Endocrinologists and American College of Endocrinology Clinical Practice Guidelines for the Diagnosis and Treatment of Postmenopausal Osteoporosis – 2016. *Endocrine Practice*. 2016;22(4):1-42.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2019. URL: http://www.clinicalpharmacology.com. Updated periodically.
3. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: June 28, 2019.
4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. Drug Facts and Comparisons. Facts and Comparisons [database online]. St. Louis, MO: Wolters Kluwer Health, Inc; 2019. Updated periodically.
6. Eastell R, Rose CJ, Black DM, et al. Pharmacological Management of Osteoporosis in Postmenopausal Women: An Endocrine Society Clinical Practice Guideline, The Journal of Clinical Endocrinology & Metabolism, Volume 104, Issue 5, May 2019, Pages 1595–1622, https://doi.org/10.1210/jc.2019-00221.
7. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.