Forteo Step Therapy

To Initiate a Coverage Review, Call 1 800 753-2851

Medication Impacted

Teriparatide Injection (*Forteo*®)

What It Does and How It's Used

> Osteoporosis is a disorder of bone remodeling (decrease in bone formation and increase in bone removal), characterized by a decrease in bone mass together with a deterioration of the skeleton. Osteoporosis results in increased risk of fractures and debilitating conditions.

> Osteoporosis presents with no warning signs or symptoms. Fractures affecting weakened bones are often the first signs of osteoporosis. Furthermore, fragile osteoporotic bones can collapse on their own without external injury.

> It is estimated that 28 million Americans have osteoporosis, and about 18 million are at risk due to low bone mass. Even though the majority (80%) of those suffering from osteoporosis are elderly Caucasian and Asian women, this disease touches people of all ages, gender and ethnicity. Additionally, 2 million men are afflicted with osteoporosis, and about 1 million have low bone mass.

> Osteoporosis represents a major healthcare financial burden. It is estimated that it causes 1.5 million fractures/year incurring ~$13.8 billion in related healthcare costs. Added healthcare costs stem from the psychological impact that osteoporotic patients suffer from. Depression and anxiety are usually prevalent because of chronic pain, kyphosis (spine curvature) leading to loss in height and loss of mobility and independence.

> Osteoporosis can be classified as primary or secondary. Primary osteoporosis occurs mainly in postmenopausal women. Secondary osteoporosis can occur as a result of certain medical conditions (e.g., malignancies, rheumatoid arthritis, and chronic renal disease), chronic medications use (e.g., steroids, thyroid replacement therapy, anti-seizure drugs), and lifestyle and nutritional issues.

> Osteoporosis in men is secondary to many risk factors such as, alcoholism, smoking, previous chemotherapy for prostate cancer, and hypogonadism.

> Adolescent male and females are at risk for osteoporosis due to many lifestyle and nutritional risk factors. Female adolescent athletes are most at risk, because of potential problems with eating disorders, inadequate dairy and calcium-rich food intake, and amenorrhea. Adolescent boys taking performance-enhancing drugs (e.g., anabolic steroids) are also at high risk of developing osteoporosis later in life.

> There are many factors involved in the bone remodeling process, such as hormones (estrogens), growth factors, parathyroid hormones, and vitamin D. Age-related decrease in estrogen is responsible for increase in osteoclastic activity (bone removal) and accelerated bone loss in postmenopausal women. Parathyroid hormone (PTH) works by stimulating both bone resorption and formation, to maintain normal bone mass. However, age-related PTH changes can lead to cortical bone loss or hip fractures.

> Bone mineral density (BMD), which determines the mineral content of the bone, is the method of choice for the diagnosis of osteoporosis. Since bone mass represent about 80% of bone strength variability, BMD is a strong predictor of fracture risk. The most critical sites to be measured are the spine and most particularly the hip.

> The World Health Organization standardized BMD results to be reported as either T or Z scores. The T-score is reported as the number of standard deviations (SD) away from the average BMD value of young healthy white women. A T-score of at least –2.5 SD confirms a diagnosis of osteoporosis. A Z-score is defined as the number of SD away from the mean BMD value for age- and gender-matched controls.

> The management of osteoporosis includes appropriate calcium and vitamin D intake and adequate physical activity with weight-bearing exercise.

> Bisphosphonates, such as alendronate (*Fosamax*®) and risedronate (*Actonel*®), work to reduce bone resorption and increase BMD at the spine and hip level. They are indicated for the prevention and treatment of osteoporosis and have been shown to reduce the risk of fractures by 30-50%.

> Selective estrogen receptor modulators (SERMs), represented by raloxifene (*Evista*®) work by maximizing the beneficial effect of estrogen on the bone (preserving BMD), without the usual harmful effect of estrogen on other tissues of the body. Raloxifene is indicated for the prevention and treatment of osteoporosis in postmenopausal women.

> Teriparatide (*Forteo*®) is the first human recombinant parathyroid hormone to be indicated for the treatment of osteoporosis in postmenopausal women, as well as men with primary or hypogonadal osteoporosis at high risk for fractures, those with existing osteoporotic fractures, or who have failed other treatment modalities.

> Teriparatide possesses the same beneficial effect on the bone and kidney as the native parathyroid hormone. It works by stimulating bone formation, therefore increasing bone mass and density.

> *Forteo*® is administered as a daily subcutaneous injection into the thigh or abdomen, and to date as per clinical trials, treatment beyond two years is not recommended.

Rationale for Coverage Authorization

To reduce the cost associated with teriparatide therapy when the use of other agents (i.e., bisphosphonates) may be warranted.

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Benefit Design
Coverage for the teriparatide is provided immediately (without generating a coverage authorization process) in situations where there is a prescription for a bisphosphonate in claim history during the 18 months. The prescription for the bisphosphonate need not be an active claim. In situations where a bisphosphonate does not exist in claim history, coverage for teriparatide is provided in accord with the following criteria. *Please note that this rule logic infers a diagnosis of osteoporosis from the presence of a bisphosphonate in claim history. Claim history after 18 months will no longer include the bisphosphonate, so an initial prior authorization will be generated following 18 months of treatment with teriparatide if this rule logic is used.*

Coverage Authorization Criteria References
This prescription benefit provides coverage in accord with the following criteria: 1. Coverage provided for the treatment of osteoporosis in postmenopausal women or men > 35 years of age in the following situations: the patient has previously failed treatment with a bisphosphonate OR the patient is unable to receive treatment with a bisphosphonate AND 2. Coverage is not provided in the presence of concurrent treatment with a bisphosphonate AND 3. Coverage is not provided in the presence of any of the following conditions: • Hypercalcemia • Paget's disease • Pediatric patients or young adults with open epiphyses • Prior radiation therapy involving the skeleton • Bone metastases or history of skeletal malignancies • Metabolic bone disease other than osteoporosis Coverage duration: 12 months for a quantity not to exceed 20 mcg daily (administered by SC injection). Renewable one time for 12 more months.

Black DM, Greenspan SL, Ensrud KE, et al. The effects of parathyroid hormone and alendronate alone or in combination in postmenopausal osteoporosis. *N Eng J Med*. 2003:349:1207-1215. *Study used full-length (84-amino acid parathyroid hormone) and not Forteo® (34-amino acid parathyroid hormone.*

Body JJ et al. A randomized double-blind trial to compare the efficacy of teriparatide [recombinant human parathyroid hormone (1-34)] with alendronate in postmenopausal women with osteoporosis. *J Clin Endocrinol Metab*. 2002;87(10):4528-4535.

National Institute of Health Consensus Statement: Osteoporosis prevention. NIH Consensus Development Conference Statement, March 27-29, 2002;17(1):1-28.

Neer RM et al. Effect of parathyroid hormone (1-34) on fractures and bone mineral density in postmenopausal women with osteoporosis. *N Eng J Med.* 2001;344(19):1434-1441.

North American Menopause Society (NAMS). Management of postmenopausal osteoporosis: Position Statement of the North American Menopause Society. *Menopause: The Journal of the NAMS*. 2002;9(2):84-101.

Orwoll ES et al. The effect of teriparatide [human parathyroid hormone (1-34)] therapy on bone density in men with osteoporosis. *J Bone Miner Res*. 2003;18:9-17.

Product Information : teriparatide (*Forteo®* - Lilly) 2004.

 April 2010