MEDICAL COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 06/14/10
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FORTEO® (teriparatide) INJECTION

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

Description:

Forteo® is a synthetic form of human parathyroid hormone that is the primary regulator of bone and mineral metabolism. Forteo may be used for treatment of osteoporosis in postmenopausal women, to increase bone mass in men with osteoporosis and for treatment of women and men with osteoporosis associated with sustained systemic glucocorticoid therapy. Generally, Forteo is given as a 2 year course of treatment.

FORTEO (teriparatide) INJECTION (cont.)

Criteria:

Osteoporosis:

- FDA-approved dosage of Forteo is considered ***medically necessary*** with documentation of **ALL** of the following:

1. **ONE** of the following:
   - Postmenopausal female with osteoporosis at high risk for fracture*
   - Male with primary osteoporosis **or** hypogonadal osteoporosis at high risk for fracture*
2. T-score of -2.5 or worse (e.g., -3.0, -3.5)
3. Absence of **ALL** of the following:
   - Active nephrolithiasis
   - End-stage renal disease
   - Open epiphyses
   - Osteomalacia
   - Paget's disease of bone
   - Primary or metastatic bone cancer or history of skeletal malignancies
   - Metabolic bone diseases other than osteoporosis
   - Unexplained elevation of serum calcium or alkaline phosphatase prior to initiation of therapy
   - Pre-existing hypercalcemic disorder (e.g., hyperparathyroidism)
   - History of external beam radiation involving the skeleton **or** for a soft tissue malignancy, such as breast cancer, where the radiation would likely have affected the skeleton around the area
   - History of implant radiation (e.g., brachytherapy, interstitial radiation, intracavitary radiation)
4. Not used in combination with a bisphosphonate (e.g., Actonel, Fosamax)
5. Dosage not greater than 20 mcg per day given by subcutaneous injection
6. Course of therapy is no greater than 2 years

FORTEO (teriparatide) INJECTION (cont.)

Criteria: (cont.)

Osteoporosis: (cont.)

- As Forteo is generally a 2 year course of treatment, the second year of Forteo therapy may be approved if the above criteria were met for the initial year.

- Review by the clinical pharmacist, and/or medical director(s) and/or clinical advisor(s) is required for course of therapy beyond 2 years.

* High risk for fracture is defined as **ONE** of the following:

  - Osteoporotic fracture
  - Multiple risk factors for fracture (significantly low bone mass, frequent falls, limited movement, medical conditions likely to cause bone loss, medicines that may cause bone loss, e.g., seizure medicines, blood thinners, corticosteroids, high doses of vitamins A or D)
  - Failed response (as defined by prescribing provider) to previous osteoporosis therapy
  - Intolerant to previous osteoporosis therapy

FORTEO (teriparatide) INJECTION (cont.)

Criteria: (cont.)

Glucocorticoid-Induced Osteoporosis:

- FDA-approved dosage of Forteo is considered ***medically necessary*** for treatment of osteoporosis in men or women at high risk for fracture* with documentation of **ALL** of the following:

  1. **ONE** of the following:

     - T-score of -2.0 or worse (e.g., -2.5, -3.0) at the lumbar spine or total hip
     - T-score of -1.0 or worse (e.g., -1.5, -2.0) **and** at least 1 fragility fracture** during treatment with glucocorticoids

  2. Osteoporosis is associated with sustained glucocorticoid therapy defined as daily Prednisone dosing of 5 mg or greater for a minimum of 3 months
  3. Absence of **ALL** of the following:

     - Active nephrolithiasis
     - End-stage renal disease
     - Open epiphyses
     - Osteomalacia
     - Paget's disease of bone
     - Primary or metastatic bone cancer or history of skeletal malignancies
     - Metabolic bone diseases other than osteoporosis
     - Unexplained elevation of serum calcium or alkaline phosphatase prior to initiation of therapy
     - Pre-existing hypercalcemic disorder (e.g., hyperparathyroidism)
     - History of external beam radiation involving the skeleton **or** for a soft tissue malignancy, such as breast cancer, where the radiation would likely have affected the skeleton around the area
     - History of implant radiation (e.g., brachytherapy, interstitial radiation, intracavitary radiation)

  4. Not used in combination with a bisphosphonate (e.g., Actonel, Fosamax)
  5. Dosage not greater than 20 mcg per day given by subcutaneous injection

* High risk for fracture is defined as **ONE** of the following:

- Osteoporotic fracture
- Multiple risk factors for fracture (significantly low bone mass, frequent falls, limited movement, medical conditions likely to cause bone loss, medicines that may cause bone loss, e.g., seizure medicines, blood thinners, steroids, high doses of vitamins A or D)
- Failed response (as defined by prescribing provider) to previous osteoporosis therapy
- Intolerant to previous osteoporosis therapy

** A fracture occurring spontaneously or after a minor trauma.

FORTEO (teriparatide) INJECTION (cont.)

Criteria: (cont.)

Other:

- Forteo for all other indications not previously listed or if above criteria not met is considered ***experimental or investigational*** based upon:

  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome.

Resources:

1. FDA Approves Teriparatide To Treat Osteoporosis. *FDA Talk Paper.* 11/26/2002.

2. American College of Physicians, Qaseem, A, et al. Screening for Osteoporosis in Men: A Clinical Practice Guideline from the American College of Physicians. 2008;148:680-684.

3. American College of Rheumatology, Gluck, O, Maricic, M. Teriparatide (Forteo) for the Treatment of Osteoporosis. *HOTLINE.* 01/2003.

4. Black, D, Greenspan, S, al e. The Effects of Parathyroid Hormone and Alendronate Alone or in Combination in Postmenopausal Osteoporosis. *The New England Journal of Medicine.* 09/25/2003;349(No. 13):1207-1215.

5. Brunader, R, Shelton, D. Radiologic Bone Assessment in the Evaluation of Osteoporosis. *American Family Physician.* 04/01/2002.

6. CenterWatch Clinical Trials Listing Service ™. Drugs Approved by the FDA Drug Name: Forteo (teriparatide). 12/30/2002.

7. External Consultant Review. Clinical Pharmacy. 05/13/2008.

8. Finkelstein, J, Hayes, A, al e. The Effects of Parathyroid Hormone, Alendronate, or Both in Men With Osteoporosis. *The New England Journal of Medicine.* 09/25/2003;349(No. 13):1216-1226.

9. Forteo. Package Insert. Accessed 10/09/2013.

FORTEO (teriparatide) INJECTION (cont.)

Resources: (cont.)

10. Hodsman, A, Bauer, D, et, al. Parathyroid Hormone and Teriparatide for the Treatment of Osteoporosis: A Review of the Evidence and Suggested Guidelines for Its Use. *Endocrine Reviews.* 2005;26(5):688-703.

11. International Society for Clinical Densitometry. 2007 Official Positions.

12. Khosla, S. Parathyroid Hormone Plus Alendronate A Combination That Does Not Add Up. *The New England Journal of Medicine.* 09/25/2003;349(No. 13):1277-1279.

13. Liu, H, Paige, N, et, al. Screening for Osteoporosis in Men: A Systematic Review for an American College of Physicians Guideline. *Annals of Internal Medicine.* 05/2008;148(9).

14. MacLean, C, Newberry, S, et, al. Systematic Review: Comparative Effectiveness of Treatments to Prevent Fractures in Men and Women with Low Bone Density or Osteoporosis. *Annals of Internal Medicine.* 2008.

15. Migliaccio, S, Brama, M, Malavolta, N. Management of Glucocorticoids-induced Osteoporosis: Role of Teriparatide. *Therapeutics and Clinical Risk Management.* 2009;5:305-310.

16. National Institutes of Health Osteoporosis and Related Bone Diseases National Resource Center. Osteoporosis in Men. 05/2009.

17. Saag, K, Shane, E, et, al. Teriparatide or Alendronate in Glucocorticoid-Induced Osteoporosis. *N Engl J Med.* 2007;357:2028-2039.

18. Summey, B, Yosipovitch, G. Glucocorticoid-Induced Bone Loss in Dermatologic Patients: An Update. *Arch Dermatol.* 2006;142:82-90.

FORTEO (teriparatide) INJECTION (cont.)

Resources: (cont.)

FDA Product Approval Information for Forteo:

- FDA-approved indication: For the treatment of postmenopausal women with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, multiple risk factors for fracture or patients who have failed or are intolerant to other available osteoporosis therapy.

  To increase bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, multiple risk factors for fracture or patients who have failed or are intolerant to other available osteoporosis therapy.

  For the treatment of men and women with osteoporosis associated with sustained systemic glucocorticoid therapy (daily dosage equivalent to 5 mg or greater of prednisone) at high risk for fracture, defined as a history of osteoporotic fracture, multiple risk factors for fracture or patients who have failed or are intolerant to other available osteoporosis therapy.

FDA Product Approval Information for Forteo: (cont.)

- FDA-approved dosage: Treatment of postmenopausal women with osteoporosis at high risk for fracture: The recommended dosage is 20 mcg subcutaneously once a day.

  Treatment of bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture: The recommended dosage is 20 mcg subcutaneously once a day.

  Treatment of men and women with glucocorticoid-induced osteoporosis at high risk for fracture: The recommended dosage is 20 mcg subcutaneously once a day.