Teriparatide (Forteo)

Policy Number: MM.04.032
Line(s) of Business: HMO; PPO
Section: Prescription Drugs
Place(s) of Service: Home

I. Description

Teriparatide (Forteo) is the first anabolic agent approved for the treatment of osteoporosis. It is a self-administered injection, delivered daily into the thigh or abdomen by way of a disposable pen-like device that can be used for up to 28 days. Teriparatide contains recombinant human parathyroid hormone (PTH), which has an identical sequence to the 34 N terminal amino acids of the 84-amino acid human parathyroid hormone. Human parathyroid hormone is the primary regulator of calcium and phosphate metabolism in bones.

Teriparatide is FDA approved for the treatment of postmenopausal women with osteoporosis who are at high risk for fracture. These include women with a history of osteoporotic fracture, or who have multiple risk factors for fracture, or who have failed or are intolerant of previous osteoporosis therapy, based upon physician assessment.

Teriparatide is FDA approved to increase bone mass in men with primary or hypogonadal osteoporosis who are at high risk of fracture. These include men with a history of osteoporotic fracture, or who have multiple risk factors for fracture, or who have failed or are intolerant to previous osteoporosis therapy, based upon physician assessment.

Teriparatide is FDA approved 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, based upon physician assessment.
II. Criteria/Guidelines

A. Teriparatide is covered (subject to Limitations/Exclusions and Administrative Guidelines) for the treatment of postmenopausal women and for the treatment of men age 50 and older when criterion 1, 2, or 3 AND criterion 4 or 5 AND 6 are met:

1. Patient has had a vertebral or hip fracture. OR
2. Patient has bone mass T-score of less than or equal to -2.5 at the femoral neck, total hip or lumbar spine by dual-energy x-ray absorptiometry (DEXA) scan. OR
3. Patient has bone mass T-score between -1 and -2.5 at the femoral neck, total hip or lumbar spine by DEXA scan and
   a. Low impact/fragility fracture, i.e., fracture occurring spontaneously or from a fall at a height no greater than the patient's standing height (excluding fingers and toes); OR
   b. Ten-year probability of hip fracture greater than or equal to three percent or a ten-year probability of any major osteoporosis-related fracture greater than or equal to 20 percent based on the U.S.-adapted World Health Organization (WHO) fracture risk assessment algorithm (it is important to note that this algorithm can only be applied to previously untreated patients); AND
4. The patient is unresponsive to treatment with at least one bisphosphonate. Unresponsiveness is defined as one of the following:
   a. A decrease in bone mineral density (BMD) of greater than or equal to 5 percent demonstrated by comparable DEXA study results in a patient who is compliant with bisphosphonate treatment and has been on treatment for at least two years.
   b. One or more vertebral, hip or low impact/fragility fractures in a patient who is compliant with bisphosphonate treatment and has been on treatment for at least one year. OR
5. The patient is intolerant to bisphosphonates or treatment with bisphosphonates is contraindicated.
   a. Intolerance is defined as having a recognized and reproducible or repeated adverse reaction that is clearly associated with taking the medication.
   b. If intolerance is secondary to gastrointestinal side effects, the use of intravenously administered bisphosphonate has been considered and ruled out. AND
6. The use of denosumab (Prolia) has been considered and ruled out.

B. Teriparatide is covered (subject to Limitations/Exclusions and Administrative Guidelines) for the treatment of patients on glucocorticoid therapy at a mean daily dose of five milligrams or more of prednisone or its equivalent for at least three consecutive months immediately prior to the request for teriparatide who meet one of the following criteria:

1. Bone mass T-score at the femoral neck, total hip, or lumbar spine is less than or equal to -2.0; OR
2. Bone mass T-score at the femoral neck, total hip, or lumbar spine is less than or equal to -1.0 and patient has had a low impact/fragility fracture during treatment with glucocorticoids.
III. Limitations/Exclusions

HMSA will not cover treatment exceeding two years. The FDA-approved package insert recommends treatment with teriparatide be limited to two years or less.

IV. Administrative Guidelines

A. Precertification is required. To precertify, complete HMSA's Drug Review Request and mail or fax the form as indicated. If approved, precertification will be given for two years.

B. The following medical record documentation, as applicable to the patient, must be submitted with the precertification request:

1. Imaging studies supporting fracture for criteria II.A.1, II.A.3.a, II.A.4.b and II.B.2.
2. Recent BMD study by DEXA for criteria II.A.2, II.A.3 and II.B. and comparable BMD studies by DEXA for criterion II.A.4.a.
3. Ten-year probability of hip or other osteoporosis-related fracture based on WHO fracture risk assessment algorithm for criterion II.A.3.b.
4. Documentation indicating duration of and supporting compliance with bisphosphonate use for criteria II.4.a and b.
5. Documentation supporting intolerance to bisphosphonate for criterion II.5.a.
6. Documentation indicating that the use of intravenously administered bisphosphonate has been considered and ruled out and the reason why use is not an option for criterion II.5.b.
7. Documentation indicating that the use of denosumab (Prolia) has been considered and ruled out and the reason why use is not an option for criterion II.6.
8. Documentation supporting that the patient has been treated with glucocorticoid therapy at a mean daily dose of five milligrams or more of prednisone or its equivalent for at least three consecutive months immediately prior to the request for teriparatide.

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<tr>
<th>HCPCS Code</th>
<th>Description</th>
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<tr>
<td>J3110</td>
<td>Injection, teriparatide, 10 mcg</td>
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V. Important Reminder

The purpose of this Medical Policy is to provide a guide to coverage. This Medical Policy is not intended to dictate to providers how to practice medicine. Nothing in this Medical Policy is intended to discourage or prohibit providing other medical advice or treatment deemed appropriate by the treating physician.

Benefit determinations are subject to applicable member contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

This Medical Policy has been developed through consideration of the medical necessity criteria under Hawaii's Patients' Bill of Rights and Responsibilities Act (Hawaii Revised Statutes §432E-1.4), generally accepted standards of medical practice and review of medical literature and government
approval status. HMSA determined that services not covered under this Medical Policy will not be medically necessary under Hawaii law in most cases. If a treating physician disagrees with HMSA's determination as to medical necessity in a given case, the physician may request that HMSA consider the application of this Medical Policy to the case at issue.

VI. References