

Policies Repository



Policy Title Teriparatide (Forteo™) (rDNA origin) Injection

Policy Number FS.CLIN.19

Application of Pharmacy Policy is determined by benefits and contracts. Benefits may vary based on product line, group or contract. Some medications may be subject to precertification, age, gender or quantity edits. Individual member benefits must be verified.

This Pharmacy Policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety or FDA approval may have changed. If the Medical/Pharmacy Reviewer is aware of any new information on the subject of this document, please provide it promptly to the Medical/Pharmacy Policy Department. This information may include new FDA approved indications, withdrawals or other FDA alerts. This type of information is relevant not only when considering whether this Policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Policy

Teriparatide (Forteo®) is indicated 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. Forteo is also indicated to increase bone mass in men with primary or hypogonadal osteoporosis who are at high risk for 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.

The use of teriparatide (Forteo®) requires prior authorization (ie, clinical pharmacy and/or Medical director review).

Policy Description

Teriparatide (Forteo) contains recombinant human parathyroid hormone (PTH). PTH is the primary regulator of calcium and phosphate metabolism in the bone and kidneys. It regulates bone metabolism, renal tubular reabsorption of calcium and phosphate, and intestinal absorption of calcium. The biological actions of PTH and teriparatide (Forteo) are mediated through binding to specific high-affinity cell-surface receptors. Teriparatide (Forteo) and the amino acids of PTH bind to these receptors with the same affinity and have the same physiological effects on the bones and kidneys. Daily usage has been shown to stimulate new bone formation on trabecular and cortical bone surfaces by preferentially stimulating osteoblastic activity over osteoclastic activity. The anabolic effect (promoting growth) seen in humans includes increased skeletal mass and increased markers of bone formation and resorption, as well as increased bone strength.

Policy Guideline Inclusion

Teriparatide (Forteo®) is approved when **all** of the following inclusion criteria are met:

- Documented diagnosis of primary (postmenopausal) or hypogonadal osteoporosis

- Patients 18 years of age or older
- Failure or intolerance with at least one of the following osteoporosis therapies
 - Bisphosphonates
 - Hormone replacement therapy
 - Selective-estrogen receptor modulators (SERM's)
 - Calcitonin-salmon (miacalcin)
- No documentation of a contraindication to Forteo
- ONE of the following:
 - Osteoporotic fractures or a history of osteoporotic fractures
 - Multiple risk factors for a fracture

Policy Guideline Exclusion

Teriparatide (Forteo®) is denied when **any** of the following exclusion criteria are present:

- No documentation of primary (postmenopausal) or hypogonadal osteoporosis
- Age less than 18
- No documentation of failure or intolerance with at least one of the following
 - Bisphosphonates
 - Hormone replacement therapy
 - Selective-estrogen receptor modulators (SERM'S)
 - Calcitonin-salmon (miacalcin)
- No documentation of osteoporotic fractures, a history of osteoporotic fractures, or multiple risk factors for fractures
- Documentation of a contraindication to Forteo

Policy List of Applicable Drugs

Brand Name	Generic Name
Forteo	teriparatide

Dosing and Administration

Refer to the specific manufacturer's prescribing information for administration and dosage details, contraindications, and Black Box warnings.

Policy References

American Hospital Formulary Service (AHFS). Drug Information 2008. Teriparatide (Forteo™). [STAT!Ref Web site]. 03/20/08. Available at: <http://online.statref.com/Document/Document.aspx?DocId=1005&FxlId=1&Scroll=1&Index=0&SessionId=C03EB0PZKIPGEHEK> [via subscription only]. Accessed October 15, 2008.

Highmark Medicare Services. Drugs & Biologicals: Self-Administered Drug Exclusions. [Highmark Medicare Services Web site]. Available at: <http://www.highmarkmedicare.com/drug-bio/drug-self.html>. Accessed October 15, 2008.

Micromedex® Healthcare Series [online through STAT! Ref]. Greenwood Village, CO: Thomson Micromedex. Teriparatide. Available at: <http://www.thomsonhc.com>. Accessed October 15, 2008.

National Osteoporosis Foundation (NOF). Fast Facts. [NOF Web site]. Available at: <http://www.nof.org/osteoporosis/diseasefacts.htm>. Accessed October 15, 2008.

National Osteoporosis Foundation (NOF). NOF's New Clinician's Guide to Prevention and Treatment of Osteoporosis. [NOF Web site]. 2008. Available at: http://www.nof.org/professionals/Clinicians_Guide.htm. Accessed October 15, 2008.

US Food and Drug Administration (FDA). Center for Drug Evaluation and Research. 505(b)

Approval Letter: Forteo™ [teriparatide (rDNA origin)] Injection. [FDA Web site]. 11/26/02. Available at: <http://www.fda.gov/cder/foi/appletter/2002/21318.pdf>. Accessed October 15, 2008.

US Food and Drug Administration (FDA). Center for Drug Evaluation and Research. 505(b) Supplemental New Drug Application: Forteo™ [teriparatide (rDNA origin)] Injection. [FDA Web site]. 09/03/04. Available at: <http://www.fda.gov/cder/foi/appletter/2004/21318s004ltr.pdf>. Accessed October 15, 2008.

US Food and Drug Administration (FDA). Center for Drug Evaluation and Research. Labeling: Forteo™ [teriparatide (rDNA origin)] Injection. [FDA Web site]. 02/16/04. Available at: <http://www.fda.gov/cder/foi/label/2004/21318s004lbl.pdf>. Accessed October 15, 2008.

World Health Organization (WHO). Assessment of fracture risk and its application to screening for postmenopausal osteoporosis: Report of a WHO study group. WHO Technical Report Series 843. Geneva, Switzerland: WHO; 1994. Available at: http://whqlibdoc.who.int/trs/WHO_TRS_843.pdf. Accessed October 15, 2008.

Policy Link to Related Policies

Printed

11/11/2008 15:30:13

The Policy Bulletins on this web site were developed to assist Independence Blue Cross and its subsidiaries ("IBC") in administering the provisions of the respective benefit programs, and do not constitute a contract. If you are an IBC member, please refer to your specific benefit program for the terms, conditions, limitations and exclusions of your coverage. IBC does not provide health care services, medical advice or treatment, or guarantee the outcome or results of any medical services/treatments. The facility and professional providers are responsible for providing medical advice and treatment. Facility and professional providers are independent contractors and are not employees or agents of IBC. If you have a specific medical condition, please consult with your doctor. IBC reserves the right at any time to change or update its Policy Bulletins. © 2008 Independence Blue Cross. All Rights Reserved. Current Procedural Terminology © 2008 American Medical Association. All Rights Reserved.

|