Coverage Authorization Guide for Healthcare Providers

This resource will walk you through the coverage authorization and appeals processes when requesting approval for **FORTEO® (teriparatide [rDNA origin] 20mcg daily injection)**. This guide serves as a general roadmap for you to follow; sample letters and checklists contain information that health plans may require when requesting authorizations for biologic treatments. Use this information to assist you when completing and submitting your patients' coverage authorization requests. See below for the detailed information required at each step.

Most of your patients' health plans will have specific coverage authorization forms that must be used when requesting FORTEO; these forms can be found on each plan's website. Follow the plan's requirements when requesting FORTEO, otherwise treatment may be delayed.

Drafting a Coverage Authorization Request Letter

- Most health plans require a coverage authorization request and supporting documentation to cover a claim for FORTEO. This resource, Drafting a Coverage Authorization Request Letter, provides guidance to healthcare providers (HCPs) when drafting the necessary letter
- For Medicare coverage authorization guidance or to download coverage authorization request forms, visit www.cms.gov/medicare/appeals-and-grievances/medprescriptdrugapplgriev/coveragedeterminationsandexceptions.html

Preparing a Coverage Authorization Appeals Letter

- If the Coverage Authorization Request Letter is denied by the patient's health plan, it is necessary to proceed to Preparing a Coverage Authorization Appeals Letter. Some plans may require a Letter of Medical Necessity (LMN) to accompany the appeals letter

Composing a Letter of Medical Necessity

- The purpose of an LMN is to explain the prescribing HCP's rationale and clinical decision when choosing FORTEO for a patient. LMNs are often required by plans when submitting a Coverage Authorization Appeals Letter, Formulary Exception Request Letter, and Tiering Exception Request Letter

Drafting a Formulary Exception Request Letter

- A Formulary Exception Request Letter is used when FORTEO is not included on a health plan's formulary or is subject to a National Drug Code block. This step may require the HCP to submit an LMN with the Formulary Exception Request Letter

Writing a Tiering Exception Request Letter

- A Tiering Exception Request Letter is used when FORTEO is on a health plan's formulary but is placed in a non-preferred tier that has a higher co-pay or co-insurance. This step may require the HCP to submit an LMN with the Tiering Exception Request Letter

For further questions, contact your FORTEO Field Reimbursement Manager.

Please see Important Safety Information on page 2. Please click to access full Prescribing Information, including Boxed Warning about osteosarcoma, and Medication Guide. Please see User Manual included with the device.

IMPORTANT SAFETY INFORMATION

INDICATIONS AND USAGE

FORTEO is indicated for the treatment of postmenopausal women with osteoporosis at high risk for fracture, to increase bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture, and 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

High risk for fracture is 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

FORTEO is administered as a 20-microgram once-daily dose and is available in a 2.4-mL prefilled delivery device for subcutaneous injection over 28 days.

WARNING: POTENTIAL RISK OF OSTEOSARCOMA

In male and female rats, teriparatide caused an increase in the incidence of osteosarcoma (a malignant bone tumor) that was dependent on dose and treatment duration. The effect was observed at systemic exposures to teriparatide ranging from 3 to 60 times the exposure in humans given a 20mcg dose. Because of the uncertain relevance of the rat osteosarcoma finding to humans, prescribe FORTEO® (teriparatide [rDNA origin] injection) only for patients for whom the potential benefits are considered to outweigh the potential risk. FORTEO should not be prescribed for patients who are at increased baseline risk for osteosarcoma (including those with Paget's disease of bone or unexplained elevations of alkaline phosphatase, pediatric and young adult patients with open epiphyses, or prior external beam or implant radiation therapy involving the skeleton).

CONTRAINDICATIONS

Hypersensitivity to teriparatide or to any of its excipients. Reactions have included angioedema and anaphylaxis.

WARNINGS AND PRECAUTIONS

The following categories of patients have increased baseline risk of osteosarcoma and therefore should not be treated with FORTEO: Paget's disease of bone, pediatric populations and young adults with open epiphyses, or prior external beam or implant radiation therapy.

Patients should be encouraged to enroll in the voluntary FORTEO Patient Registry, which is designed to collect information about any potential risk of osteosarcoma in patients who have taken FORTEO. Enrollment information can be obtained by calling 1-866-382-6813, or by visiting www.forteoregistry.rti.org.

Cases of bone tumor and osteosarcoma have been reported rarely in people taking FORTEO in the post-marketing period. The causality to FORTEO use is unclear.

The safety and efficacy of FORTEO have not been evaluated beyond 2 years of treatment. The use of FORTEO for more than 2 years during a patient's lifetime is, therefore, not recommended.

Patients with the following conditions also should not receive FORTEO: bone metastases or a history of skeletal malignancies, metabolic bone diseases other than osteoporosis, or hypercalcemic disorders.

FORTEO may increase serum calcium, urinary calcium, and serum uric acid.

Use with caution in patients with active or recent urolithiasis because of risk of exacerbation. If active urolithiasis or pre-existing hypercalciuria are suspected, measurement of urinary calcium excretion should be considered.

Transient orthostatic hypotension may occur with initial doses of FORTEO. In short-term clinical pharmacology studies, transient episodes of symptomatic orthostatic hypotension were observed in 5% of patients. FORTEO should be administered initially under circumstances where the patient can sit or lie down if symptoms of orthostatic hypotension occur.

Patients receiving digoxin should use FORTEO with caution because FORTEO may transiently increase serum calcium and hypercalcemia may predispose patients to digitalis toxicity.

ADVERSE REACTIONS

The most common adverse reactions in clinical trials include: arthralgia (10.1% FORTEO vs. 8.4% placebo), pain (21.3% FORTEO vs. 20.5% placebo), and nausea (8.5% FORTEO vs. 6.7% placebo). Other adverse reactions include: dizziness, leg cramps, joint aches, and injection site reactions.

USE IN PREGNANCY/NURSING MOTHERS

FORTEO should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Based on animal studies, FORTEO may cause fetal harm.

It is not known whether teriparatide is excreted in human milk. Breastfeeding mothers should discontinue nursing or FORTEO, taking into account the importance of treatment to the mother.

INSTRUCTIONS FOR FORTEO USE

FORTEO is provided as a fixed-dose, prefilled delivery device that can be used for up to 28 days, including the first injection. The delivery device contains 28 daily doses of 20 mcg each. Do not transfer the contents of the delivery device into a syringe. The FORTEO Delivery Device should be stored under refrigeration at 36° to 46° F (2° to 8° C) at all times. Do not use FORTEO if it has been frozen.

TE HCP ISI 24SEP2012

For more safety information, please see Medication Guide and Full Prescribing Information, including Boxed Warning regarding osteosarcoma. See Full User Manual that accompanies the delivery device.

Sources: 1. Centers for Medicare & Medicaid Services. Part D enrollee grievances, coverage determinations, and appeals. In: Prescription Drug Benefit Manual. Baltimore, MD: Centers for Medicare & Medicaid Services; 2014. https://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/Downloads/Chapter18.zip. Accessed January 26, 2017. **2.** FORTEO [package insert]. Indianapolis, IN: Eli Lilly and Company; 2017.