Preparing a Coverage Authorization Appeals Letter

The following information is presented for informational purposes only and is not intended to provide reimbursement or legal advice. Laws, regulations, and policies concerning reimbursement are complex and are updated frequently. While we have made an effort to be current as of the issue date of this document, the information may not be as current or comprehensive when you view it. Providers are encouraged to contact third-party payers for specific information on their coverage policies. For more information, please call 1-866-4-FORTEO (1-866-436-7836).

If the Coverage Authorization Request Letter from Drafting a Coverage Authorization Request Letter is denied by the patient’s health plan, the payer may require a Coverage Authorization Appeals Letter. Depending on the plan, there may be varying levels of appeals. If you are uncertain about a plan’s appeal levels or specific procedures, always refer to the plan’s appeal guidelines.

This resource, Preparing a Coverage Authorization Appeals Letter, provides information to healthcare providers (HCPs) when appealing a coverage authorization for a patient’s plan. A checklist is included below that can be followed when creating a Coverage Authorization Appeals Letter. In addition, 2 sample letters are attached to this document and feature information that many plans require to process a coverage authorization appeal. Follow the patient’s plan requirements when requesting FORTEO® (teriparatide [rDNA origin] 20mcg daily injection), otherwise treatment may be delayed.

A Coverage Authorization Appeals Letter originates from the patient and the prescribing HCP.* It should be submitted with 2 additional items: the patient’s medical records and a Letter of Medical Necessity (LMN).

**COVERAGE AUTHORIZATION: APPEALS CONSIDERATIONS**

- Include the patient’s full name, plan identification number, and date of birth
- Add the prescribing HCP’s National Provider Identifier (NPI) number and specialty
- Disclose that you are familiar with the plan’s policy. Clearly document the basis for the plan’s denial within the letter, along with case identification number from the initial denial letter
- Provide a copy of the patient’s records with the following details:
  - The patient’s history, diagnosis and International Classification of Diseases (ICD) code[s], and present-day condition and symptoms
  - The patient’s recent history of infection[s], along with any allergies and existing comorbidities
- Note the fracture site[s] and dates
- Supply the bone mineral density T-score at the femoral neck, total hip, or lumbar spine as measured by DXA scan
- Document prior osteoporosis treatments and the duration of each
  - Describe the rationale for why each treatment was discontinued
- Explain why the plan’s preferred formulary agents are not appropriate for the patient
  - List the dates of trial of the preferred agents
- Provide the clinical rationale for treatment; this information may be found in the FORTEO prescribing information and/or clinical peer-reviewed literature
- Summarize your recommendation at the end of the letter
- Include an LMN

*For Medicare beneficiaries, there are specific requirements that need to be met for the HCP to be considered a legal representative of the patient in an appeal. For additional information, please visit https://www.cms.gov/medicare/appeals-and-grievances/medprescripdrugapplgriev/coveragedeterminationsandexceptions.html.

Please see Important Safety Information on page 4. Please click to access full Prescribing Information, including Boxed Warning about osteosarcoma, and Medication Guide. Please see User Manual included with the device.
To whom it may concern:

We have reviewed and recognize your guidelines for the responsible management of medications within this class. We are requesting that you reassess your recent denial of FORTEO® (teriparatide [rDNA origin] 20mcg daily injection) coverage. We understand that the reason for your denial is [copy reason verbatim from the plan’s denial letter]. However, we believe that FORTEO [dose, frequency] is the appropriate treatment for the patient. In support of our recommendation for FORTEO treatment, we have provided an overview of the patient’s relevant clinical history below.

Patient’s history, diagnosis, condition, and symptoms*:
Bone mineral density T-score at the femoral neck, total hip, or lumbar spine as measured by DXA scan ____
Fracture Site [s] ______________________________________________________________________________
_____________________________________________________________________________________________
Past Treatment[s]†   Start/Stop Dates Reason[s] for Discontinuing
[Provide clinical rationale for this treatment; this information may be found in the FORTEO prescribing information and/or clinical peer-reviewed literature.]
[Insert your recommendation summary here, including your professional opinion of the patient’s likely prognosis or disease progression without treatment with FORTEO.]

Please feel free to contact me, [HCP name] at [office phone number] or [patient’s name] at [phone number] for any additional information you may require. We look forward to receiving your timely response and approval of this claim.

Sincerely,

[Physician’s name and signature] [Physician’s medical specialty] [Physician’s NPI] [Physician’s practice name] [Phone #] [Fax #]

Encl: Medical records and clinical notes, clinical trial information, Letter of Medical Necessity, original denial letter

*Include patient’s medical records and supporting documentation.
†Identify drug name, strength, dosage form, and therapeutic outcome.

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We have reviewed and recognize your guidelines for the responsible management of medications in this class. We are requesting that you reassess your recent denial of FORTEO® (teriparatide [rDNA origin] 20mcg daily injection) coverage. We understand that the reason for your denial is [copy reason verbatim from the plan’s denial letter]. However, we believe that FORTEO [dose, frequency] is the appropriate treatment for the patient. In support of our recommendation for FORTEO treatment, we have provided an overview of the patient’s relevant clinical history below.

[In this section, include a summary of the patient’s clinical response to FORTEO. It may be necessary to review past medical records to gather this information.]

Patient’s history, diagnosis, condition, and symptoms*:

Bone mineral density T-score at the femoral neck, total hip, or lumbar spine as measured by DXA scan ____
Fracture Site (s) ______________________________________________________________________________
_____________________________________________________________________________________________

Past Treatment(s)†   Start/Stop Dates   Reason(s) for Discontinuing

[Provide clinical rationale for this treatment; this information may be found in the FORTEO prescribing information and/or clinical peer-reviewed literature.]

[Insert your recommendation summary here, including your professional opinion of the patient’s likely prognosis or disease progression without treatment with FORTEO.]

Please feel free to contact me, [HCP name], at [office phone number] or [patient’s name] at [phone number] for any additional information you may require. We look forward to receiving your timely response and approval of this claim.

Sincerely,

[Physician’s name and signature]         [Patient’s name and signature]
[Physician’s medical specialty]        [Physician’s NPI]
[Physician’s practice name]            [Phone #]
[Phone #]

Encl: Medical records and clinical notes, clinical trial information, Letter of Medical Necessity, original denial letter

*Include patient’s medical records and supporting documentation.
†Identify drug name, strength, dosage form, and therapeutic outcome.

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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 categorizes 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 hypercalcemia 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. 8.4% 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.

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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.