Drafting a Coverage Authorization Request 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).

Most health plans require a coverage authorization request and supporting documentation to process and cover a claim for biologic treatments. A coverage authorization allows the payer to review the reason for the requested treatment and determine its medical appropriateness.

This resource, Drafting a Coverage Authorization Request Letter, provides information to healthcare providers (HCPs) when drafting a Coverage Authorization Request Letter. A list of sample payer requirements and a checklist are included below and outline what to include in the letter. Sample letters are attached to this document and include information that many health plans require to process the coverage authorization request.

Plans often have specific Coverage Authorization Request Forms that must be used for requests. These forms may be downloaded from each plan’s website. Follow the plan’s requirements when requesting FORTEO® (teriparatide [rDNA origin] 20mcg daily injection). Otherwise treatment may be delayed.

COVERAGE AUTHORIZATION REQUESTS: GUIDANCE AND RECOMMENDATIONS

1. Your FORTEO Field Reimbursement Manager (FRM) may be able to provide you with coverage authorization requirements for specific plans and pharmacy benefit managers. Insurance investigation verifications performed by the FORTEO Connect Hub and/or specialty pharmacies can assist with identifying coverage authorizations, form requirements, and step edit therapies.

2. All FORTEO Coverage Authorization Request Forms should be completed and submitted to the plan by the HCP’s office.

3. Fax the completed Coverage Authorization Request Form to the health plan.

4. Fax the FORTEO Connect Enrollment Form to FORTEO Connect at 1-866-436-7830.

5. If the HCP expects that a plan-specified step edit therapy will not be well tolerated by the patient, an appeal may be submitted to the plan to bypass this requirement. For more information, refer to Composing a Letter of Medical Necessity.

6. Plans will usually allow up to 3 levels of appeal for coverage authorization denials. The third appeal may include a review by an external review board or hearing. Refer to Preparing a Coverage Authorization Appeals Letter.

COVERAGE AUTHORIZATION CONSIDERATIONS

- Verify and record that all of the coverage authorization requirements for the plan have been met.
- If applicable, provide evidence that all step edit therapy prerequisites have been met. For step edit therapy exception requests, when medically appropriate, include wording explaining why a particular step edit therapy as required by the plan is not medically appropriate for the patient.
- Review the attached sample letters as examples.
- If required, use the health plan’s Coverage Authorization Request Form that can be found on the plan’s website. Your FORTEO FRM may also be able to assist you in locating the plan-specific form.

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.
Sample Coverage Authorization Request Letters

Most health plans require a coverage authorization request and supporting documentation to cover a claim for FORTEO® (teriparatide [rDNA origin] 20mcg daily injection). This resource, Drafting a Coverage Authorization Request Letter, provides guidance to HCPs when drafting the necessary letter.

HCPs can follow this format for patients who are NOT currently receiving treatment with FORTEO

To whom it may concern:

This letter serves as a coverage authorization request for FORTEO® (teriparatide [rDNA origin] 20mcg daily injection) for [patient’s name, plan identification, and group number] for the treatment of [diagnosis and ICD code].

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

[Insert rationale for prescribing FORTEO here, including your professional opinion of the patient’s likely prognosis or disease progression without FORTEO treatment.]

Provide supporting references for your recommendation:

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

Physician contact information:

The ordering physician is [physician name, NPI #]. The coverage authorization decision may be faxed to [fax #] or mailed to [physician office mailing address]. Please send a copy of the coverage determination decision to [patient’s name, street address, state, ZIP].

Sincerely,

[Physician’s name and signature] [Patient’s name and signature]

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

Encl: Medical records, supporting documentation, clinical trial information

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

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Sample Coverage Authorization Request Letters

Most health plans require a coverage authorization request and supporting documentation to cover a claim for FORTEO® (teriparatide [rDNA origin] 20mcg daily injection). This resource, Drafting a Coverage Authorization Request Letter, provides guidance to HCPs when drafting the necessary letter.

HCPs can follow this format for patients who HAVE been treated with FORTEO and have had treatment interruptions

[date]
[payer department]
[name of health plan]
[mailing address]

To whom it may concern:

This letter serves as a coverage authorization request for FORTEO® (teriparatide [rDNA origin] 20mcg daily injection) for [patient’s name, plan identification, and group number] for the treatment of [diagnosis and ICD code]. This authorization is being requested for [insert date] to [insert future date].

[In this section, describe the severity of osteoporosis at the time when the patient was first treated with FORTEO. It may be necessary to review past medical records.]

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

Please detail all that apply and add additional lines as necessary.

[Insert rationale for prescribing FORTEO here, including your professional opinion of the patient’s likely prognosis or disease progression without FORTEO treatment.]

Provide supporting references for your recommendation:
[In this section, provide clinical evidence that supports continued treatment with FORTEO. Supplying clinical trial data from the FORTEO prescribing information is helpful.]

Physician contact information:
The ordering physician is [physician name, NPI #]. The coverage authorization decision may be faxed to [fax #] or mailed to [physician office mailing address]. Please send a copy of the coverage determination decision to [patient’s name, street address, state, ZIP].

Sincerely,

[Physician’s name and signature] [Patient’s name and signature]

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

Encl: Medical records, supporting documentation, clinical trial information

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

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Step Edit Therapy Information

If this Coverage Authorization Request Letter is intended to appeal a plan’s step edit therapy requirement, sample copy should include the following:

This plan currently lists [insert required step edit therapies] to be attempted prior to treatment with FORTEO. These step edit therapies are not viable for this patient. We are requesting that the step edit therapy requirement be bypassed.

[Please provide statement(s) indicating why these step edit therapy requirements are inappropriate for this patient. Include examples of previous trials and failures with other therapies, due to lack of response or intolerance to the drug.]

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.

FORTEO is provided as a fixed-dose, prefilled delivery device that contains 28 daily doses of 20 mcg each. Do not transfer the contents of the delivery device into a syringe. The delivery device contains 28 daily doses of 20 mcg each. Do not use FORTEO if it has been frozen. 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.

INSTRUCTIONS FOR FORTEO USE
Breastfeeding mothers should discontinue nursing or FORTEO, as it is not known whether teriparatide is excreted in human milk.

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.

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

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).

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. 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.

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.

FORTEO® is a registered trademark of Eli Lilly and Company. FORTEO Connect™ is a trademark of Eli Lilly and Company.

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