Drafting a Formulary Exception 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).

A formulary exception is a type of coverage determination. It is used when a drug is not included on a health plan’s formulary or is subject to a National Drug Code (NDC) block.

This resource, Drafting a Formulary Exception Request Letter, provides information to healthcare provider (HCPs) when drafting a Formulary Exception Request Letter. A checklist is included below on what to include in the letter. Sample letters are attached to this document and contain useful information that many health plans require to process the request. Typically, the patient’s medical records and a Letter of Medical Necessity (LMN) are submitted with the letter. The Formulary Exception Request Letter may originate from the patient, HCP, or legal representative.* Both the prescribing HCP and patient should sign the letter.

Plans frequently provide specific formulary exception request templates that must be used when making the request. 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.

FORMULARY EXCEPTION REQUEST LETTER CONSIDERATIONS

- Include the patient’s full name, plan identification number, and date of birth
- Add the prescribing HCP’s name, relationship to the requestor, National Provider Identifier (NPI) number, specialty, address, telephone number/fax number, and date of submission
- Record the patient’s current diagnosis
- Provide a copy of the patient’s records with the following details:
  - Patient’s history, diagnosis and specific International Classification of Diseases (ICD) code(s), and present-day condition and symptoms
  - 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 treatments and the date when they were tried
  - Describe the rationale for why each treatment was discontinued
- List the main reasons for requesting a formulary exception for FORTEO, including strength, frequency, expected length of therapy, quantity, days of supply, and route of administration
- Explain and attest to why the plan’s preferred formulary agents are not appropriate for the patient (eg, medications have been or will be ineffective, not as effective, or adverse effects)
  - List dates of trial of preferred agents
- If this letter serves as an appeal, include the case number from the denial letter, a copy of the denial letter, and a response to the denial
- Include an LMN

*Please note for Medicare Part D subscribers: Under the Medicare Part D prescription drug benefit program, a Part D plan enrollee, the enrollee’s representative, or the enrollee’s doctor or other prescriber can request a coverage determination, including a request for a tiering or formulary exception. A request for a coverage determination can be made orally or in writing. An enrollee, the enrollee’s representative, or the enrollee’s prescriber may submit a written request for a coverage determination in any format.

†Please note that the Centers for Medicare & Medicaid Services (CMS) has developed “REQUEST FOR MEDICARE PRESCRIPTION DRUG COVERAGE DETERMINATION” model forms that are posted on their website. For more information, visit https://www.cms.gov/medicare/appeals-and-grievances/medprescriptdrugappgriev/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:

My name is [HCP’s name], and I am a [board-certified medical specialty] [NPI]. I am writing to request a formulary exception for my patient, [patient’s name], who is currently a member of [name of health plan]. The request is for FORTEO® (teriparatide [rDNA origin] 20mcg daily injection). Treatment with FORTEO [dose, frequency] is medically appropriate and necessary for this patient, who has been diagnosed with osteoporosis at high risk for fracture, [ICD code]. Therefore, I am requesting that the plan removes any relevant NDC blocks, so FORTEO can be made available to my patient as a preferred medication.

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

Bone mineral density T-score at the femoral neck, total hip, or lumbar spine as measured by DEXA scan _____

Fracture Site(s) ______________________________________________________________________________
_____________________________________________________________________________________________

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

[Include the main reasons for requesting this formulary exception.]

A Letter of Medical Necessity and pertinent medical records are enclosed, which offer additional support for the formulary exception request for FORTEO.

Please contact me, [HCP’s name], at [HCP’s telephone number] for a peer-to-peer review. I would be pleased to speak to why a FORTEO formulary exception is necessary for [patient’s name]’s treatment of osteoporosis at high risk for fracture.

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, clinical trial information, Letter of Medical Necessity

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

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 Formulary Exception Request Letters

A Formulary Exception Request Letter is used when FORTEO® (teriparatide [rDNA origin] 20mcg daily injection) is not included on a health plan’s formulary or is subject to an NDC block. This step may require the HCP to submit an LMN with the Formulary Exception Request Letter.

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

[Date]  
[Formulary director]  
[Name of health plan]  
[Mailing address]  
Re: [Patient’s name]  
[Plan identification number]  
[Date of birth]  
[Case identification]

To whom it may concern:

My name is [HCP’s name], and I am a [board-certified medical specialty] [(NPI)]. I am writing to request a formulary exception for my patient, [patient’s name], who is currently a member of [name of health plan]. The request is for FORTEO® (teriparatide [rDNA origin] 20mcg daily injection). The patient was receiving treatment with FORTEO [dose, frequency], which is medically appropriate and necessary for this patient, who has been diagnosed with osteoporosis, [ICD code]. However, FORTEO is no longer included on your plan’s formulary list. Therefore, I am requesting that the plan removes any relevant NDC blocks, so FORTEO can be made available to my patient as a preferred medication.

In this section, the HCP should describe the severity of osteoporosis at the time that patient was first treated with FORTEO. The patient’s corresponding medical records and progress notes must be included, and therapeutic outcomes should be noted.

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] ______________________________________________________________________________
_____________________________________________________________________________________________

The HCP should insert rationale for prescribing FORTEO here, including his or her professional opinion of the patient’s likely prognosis or disease progression without treatment with FORTEO.

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

A Letter of Medical Necessity and my patient’s medical records are enclosed, which offer additional support for the formulary exception request for FORTEO.

Please contact me, [HCP’s name], at [HCP’s telephone number] for a peer-to-peer review. I would be pleased to speak to why a FORTEO formulary exception is necessary for [patient’s name]’s treatment of osteoporosis.

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, clinical trial information, Letter of Medical Necessity

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

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.
Formulary Exception Appeal

If this Formulary Exception Request Letter is an appeal, sample copy should include the following:

This is a formulary exception appeal. I have included a copy of the original denial letter and medical notes in response to the denial.

For appeals,* include the following:
• A copy of the denial letter
• Medical notes, written by the prescribing physician, in response to the denial letter

**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.

**WARNINGS AND PRECAUTIONS**

**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 (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 20 mcg 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).

**ADVERSE REACTIONS**

The most common adverse reactions in clinical trials include: arthralgia (10.1% FORTEO vs. 8.4% placebo), pain (21.3% FORTEO vs. 17.3% 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.

*An external review board or hearing may apply in some situations.


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