Writing a Tiering 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 tiering exception is a type of coverage determination. This type of exception is used when a medication is on a plan’s formulary, but it is placed in a non-preferred tier that has a higher co-pay or co-insurance. Plans may make a tier exception when the drug is demonstrated to be medically necessary. The healthcare provider (HCP) submits a Tiering Exception Request Letter to request that the medication be offered at a lower co-pay that is usually reserved for preferred drugs. A Tiering Exception Request Letter can help make medication more affordable for patients covered through Medicare or TRICARE who may not be eligible to participate in savings programs.

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

Plans often have specific Tiering Request Forms that must be used. 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.

TIERING 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 osteoporosis treatments and the duration of each treatment
  - Describe the rationale for why each treatment was discontinued
- List the main reasons for requesting a tiering exception for FORTEO
- Explain and attest to why the plan’s preferred formulary agents are not appropriate for the patient (e.g., 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
- Include a statement of financial hardship, written by the patient

*Requests may originate from subscriber, HCP, or legal representative. 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 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/medprescriptdrugapplicable/covereddeterminationsandexceptions.html.

Please see Important Safety Information on page 6. Please click to access full Prescribing Information, including Boxed Warning about osteosarcoma, and Medication Guide. Please see User Manual included with the device.
Sample Tiering Exception Request Letter

A Tiering Exception Request Letter is used when FORTEO® (teriparatide [rDNA origin] 20mcg daily injection) 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.

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

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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 tiering 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), which is medically appropriate and necessary for this patient who has been diagnosed with osteoporosis at high risk for fracture, [ICD codes]. I am requesting that FORTEO be made available to my patient as a preferred medication.

In the past, [patient’s name] has attempted other treatments for osteoporosis, but those trials have failed due to either inadequate efficacy or lack of tolerability.

<table>
<thead>
<tr>
<th>Past Treatment(s)*</th>
<th>Start/Stop Dates</th>
<th>Reason(s) for Discontinuing</th>
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</tbody>
</table>

The patient’s present treatment[s] are as follows:

<table>
<thead>
<tr>
<th>Current Treatment(s)*</th>
<th>Start/Stop Dates</th>
<th>Outcome(s)</th>
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</table>

Currently, [patient’s name] has the following unresolved symptoms:

* [Symptom 1]
* [Symptom 2]

Along with this letter, I have enclosed a copy of the patient’s medical records and a Letter of Medical Necessity. The letter describes why FORTEO is medically necessary for my patient’s care over the preferred drugs listed in the plan’s formulary. [Explain why lower-tiered formulary drugs would not be as effective as FORTEO.]

The reason I am requesting a tiering exception is because the cost associated with FORTEO’s assigned tier would present a financial burden to [patient’s name]. Furthermore, it prevents my patient from utilizing a medication that will help treat osteoporosis.

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†Identify drug name, strength, dosage form, and therapeutic outcome.

Please see Important Safety Information on page 6. Please click to access full Prescribing Information, including Boxed Warning about osteosarcoma, and Medication Guide. Please see User Manual included with the device.
To summarize, I consider FORTEO to be the best option in successfully treating [patient’s name]’s osteoporosis. Please contact me, [physician’s name], at [physician’s telephone number] for a peer-to-peer review or to answer any pending questions.

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, Letter of Medical Necessity, statement of financial hardship from [patient’s name], previous denial letter (if this is an appeal), medical notes in response to the denial (if this is an appeal)
Sample Tiering Exception Request Letter

A Tiering Exception Request Letter is used when FORTEO® (teriparatide [rDNA origin] 20mcg daily injection) 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.

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

<table>
<thead>
<tr>
<th>[Date]</th>
<th>[Formulary director]</th>
<th>Re: [Patient's name]</th>
</tr>
</thead>
<tbody>
<tr>
<td>[Name of health plan]</td>
<td>[Plan identification number]</td>
<td>[Plan identification number]</td>
</tr>
<tr>
<td>[Mailing address]</td>
<td>[Date of birth]</td>
<td>[Case identification]</td>
</tr>
</tbody>
</table>

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 tiering 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], which is medically appropriate and necessary for this patient who has been diagnosed with osteoporosis, [ICD code(s)]. The patient was receiving treatment with FORTEO [dose, frequency] but had to discontinue treatment due to [HCP to list reason (e.g., change in plan’s formulary list or patient changed health plans during the past year)]. Therefore, I am requesting that FORTEO be made available to my patient as a preferred medication.

In the past, [patient’s name] has attempted other treatments for osteoporosis, but those trials have failed due to either inadequate efficacy or lack of tolerability.

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Along with this letter, I have enclosed a copy of [patient’s name]’s medical records [include medical records dating back to the initial FORTEO prescription] and a Letter of Medical Necessity. The letter describes why FORTEO is medically necessary for my patient’s care over the preferred drugs listed in the plan’s formulary. [Explain why lower-tiered formulary drugs would not be as effective as FORTEO. If the patient is currently being treated with FORTEO, explain the benefits they have experienced since starting FORTEO and the expected outcomes if FORTEO were to be discontinued.]

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*Identify drug name, strength, dosage form, and therapeutic outcome.

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Sample Tiering Exception Request Letter

HCPs can follow this format for patients who HAVE been treated with FORTEO® (teriparatide [rDNA origin] 20mcg daily injection), and have had treatment interruptions

When comparing [patient’s name]’s osteoporosis before and after starting FORTEO for [enter length of time on FORTEO], the results confirm that FORTEO is medically necessary for managing the disease. The reason I am requesting a tiering exception for my patient is because the cost associated with FORTEO’s assigned tier has presented a financial hardship for [patient’s name].

To summarize, I consider FORTEO to be the best option in successfully treating my patient’s osteoporosis. Please contact me, [physician’s name], at [physician’s telephone number] for a peer-to-peer review or to answer any pending questions.

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, Letter of Medical Necessity, statement of financial hardship from [patient’s name], previous denial letter (if this is an appeal), medical notes in response to the denial (if this is an appeal)
An external review board or hearing may apply in some situations. Cases of bone tumor and osteosarcoma have been reported on registery.rti.org. Patients who have taken FORTEO. Enrollment information can be found on the FORTEO Patient Registry, which is designed to collect data on patients taking FORTEO: Paget's disease of bone, pediatric populations and young adults with open epiphyses, or prior external beam or implant radiation therapy.

**WARNINGS AND PRECAUTIONS**

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.

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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.