



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/medprescriptdrugapplgriev/coveragedeterminationsandexceptions.html>.

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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 are **NOT** currently receiving treatment with FORTEO

[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). 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.

If this appeal has been previously denied by the plan, sample wording from page 4 of this document can be placed after the second sentence of this paragraph.

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.

[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]

[Physician's medical specialty]

[Physician's NPI]

[Physician's practice name]

[Phone #]

[Fax #]

[Patient's name and signature]

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.

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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
<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>

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]

[Physician's medical specialty]

[Physician's NPI]

[Physician's practice name]

[Phone #]

[Fax #]

[Patient's name and signature]

Encl: Medical records, clinical trial information, Letter of Medical Necessity

If this appeal has been previously denied by the plan, sample wording from page 4 of this document can be placed after the second sentence of this paragraph.

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

*Include patient's medical records and supporting documentation.

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

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