Composing a Letter of Medical Necessity

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).

Many health plans require that a Letter of Medical Necessity (LMN) accompanies a Coverage Authorization Appeals Letter. The purpose of an LMN is to explain the prescribing healthcare provider’s (HCP) rationale and clinical decision making when choosing a treatment. LMNs are often required by plans when submitting a Coverage Authorization Appeals Letter, Formulary Exception Request Letter, and Tiering Exception Request Letter.

This resource, Composing a Letter of Medical Necessity, provides information on the process of drafting an LMN. A checklist is included below that can be followed when creating an LMN. In addition, 2 sample letters are attached to this document and include information that plans often require. Note that some plans have specific Coverage Authorization Forms that must be utilized to document an LMN.

Follow the patient’s plan requirements when requesting FORTEO® (teriparatide [rDNA origin] 20mcg daily injection), otherwise treatment may be delayed.

LMN CONSIDERATIONS

- Include the patient’s full name, plan identification number, date of birth, and case identification number if a decision has already been rendered
- Provide a copy of the patient’s records with the following details:
  - The patient’s history, diagnosis with specific International Classification of Diseases (ICD) code, 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 treatments and the duration of each. It may be beneficial to include Current Procedural Terminology, 4th Edition (CPT-4) and/or J-codes to define prior services/treatments, so that the health plan can conduct research and make a timely determination request
  - Describe the rationale for why each treatment was discontinued
- Attach clinical documentation that supports your recommendation; this information may be found in the FORTEO prescribing information and/or clinical peer-reviewed literature

*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/MedPrescriptDrugApplGriev/Downloads/Chapter18.zip.
To whom it may concern:

I am writing to provide additional information to support my claim for [patient’s name]’s treatment of osteoporosis at high risk for fracture with FORTEO® (teriparatide [rDNA origin] 20mcg daily injection). In brief, treatment with FORTEO [dose, frequency] is medically appropriate and necessary for this patient. This letter outlines the patient’s medical history and previous treatments that support my recommendation for treatment with FORTEO.

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] for any additional information you may require.

Sincerely,

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

Encl: Medical records, clinical trial information

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*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.
To whom it may concern:

I am writing to provide additional information to support my claim for [patient's name]'s treatment of osteoporosis with FORTEO® (teriparatide [rDNA origin] 20mcg daily injection). In brief, continued treatment with FORTEO is medically appropriate and necessary for this patient. This letter outlines the patient’s medical history and previous treatments that support my recommendation for treatment with FORTEO.

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] ____________________________________________________________________________
_____________________________________________________________________________________________

Past Treatment[s]*

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[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] 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, clinical trial information

*Include patient’s medical records and supporting documentation, medical history and previous treatments
*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.
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 subcutaneous injection over 28 days. The delivery device contains 28 daily doses of 20 mcg each. 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. For more safety information, please see Medication Guide accompanying the delivery device. 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 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 digitalsis 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. 16.9% placebo), leg cramps (9.2% FORTEO vs. 4.7% placebo), joint aches (11.1% FORTEO vs. 5.3% placebo), and injection site reactions (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.


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