

Writing Letters of Medical Necessity and Letters of Medical Exception for OSENVELT[®] Therapy

When Letters of Medical Necessity and Letters of Medical Exception may be required

- ✔ **Letters of Medical Necessity** explain a healthcare provider's reasons and clinical basis for selecting a specific treatment. They may be required:
 - Alongside a Letter of Appeal regarding a treatment coverage denial
 - Alongside a Letter of Medical Exception
 - For an insurer's prior authorization process
- ✔ **Letters of Medical Exception** may be required to explain a healthcare provider's reasons and clinical basis for requesting a coverage exception for a treatment not included on an insurer's formulary
 - May also be required to request waiving of utilization management requirements (eg, step therapy, prior authorization, quantity limits) for a formulary-listed drug



Resources to strengthen your letters

The following pages provide guidance to help you craft effective Letters of Medical Necessity and Letters of Medical Exception for OSENVELT therapy. They also provide a letter template to help ensure your clinical input is thoroughly catalogued and expressed.

NOTE: Utilizing the information provided here does not guarantee a plan will provide reimbursement for OSENVELT. Additionally, this information is not intended to replace or influence your medical judgment.



Celltrion CONNECT[®] is here to help

Celltrion CONNECT and your dedicated FRM are available to assist with:

- Benefit verifications
- Prior authorizations
- Access issues
- Financial support

FRM, field reimbursement manager.



Call
1-877-81CONNECT

(1-877-812-6662),

Monday–Friday

between 8 AM–8 PM ET, or visit

www.celltrionconnect.com

to learn more.

Advice for Writing Letters of Medical Necessity and Letters of Medical Exception for OSENVELT[®] Therapy

Information you will need to complete your letters

- | | |
|---|--|
| ✓ Full name and date of birth of the patient | ✓ List of current and previous treatments |
| ✓ Insurance policy/ID number of the patient | • Including dates for starting, stopping, and cause(s) for discontinuation |
| ✓ Case ID number | ✓ Overview of the patient's condition and symptoms |
| ✓ Condensed medical history of the patient | ✓ Clinical support for your recommendations |
| • Including diagnosis, ICD-10 codes, comorbidities, and allergies | |

Additional guidance for writing your letters

- **It is important to review the insurance plan's Explanation of Benefits**, as this will help you explain how your patient meets benefits criteria or why it makes sense to exclude your patient from certain criteria
- **Be sure to clearly state** why OSENVELT is the most appropriate treatment option
- **Offer clinical rationale** to support OSENVELT as your treatment choice
 - Include clinical data, such as patient chart notes and laboratory results
- **List any additional patient attributes and/or clinical factors** relevant to your clinical opinion
 - Consider attaching any clinical evidence you feel will support your recommendation for OSENVELT therapy (eg, Section 12 [Clinical Pharmacology] and Section 14 [Clinical Trials] from the full Prescribing Information for OSENVELT)¹

NOTE: Please exercise your medical judgment and discretion when providing a diagnosis and characterization of the patient's medical condition.

Follow the insurer's processes

- **Review the procedure** for submitting your letters to ensure you meet insurer and state requirements
 - This includes mode of submission (eg, fax, phone, email, insurer website)
- **Keep track** of your request status and follow up with the insurer as needed

ICD-10, International Classification of Diseases, Tenth Revision.

Reference: 1. OSENVELT [prescribing information]. Jersey City, NJ. Celltrion, Inc.; 2025.

Please see Important Safety Information on page 4 and full [Prescribing Information](#).

Template for Letters of Medical Necessity and Letters of Medical Exception for OSENVELT[®] Therapy

Helping you organize your response

Pictured below is a template for writing Letters of Medical Necessity and Letters of Medical Exception for OSENVELT therapy. You will find this editable content on pages 5 to 6 of this guide. The template includes helpful prompts and can be altered as needed.

To create your letters, simply edit the “live” text directly within the template pages, print, and fax or mail as needed.

You can also copy and paste the template page text into your practice’s letterhead before making needed edits and then printing, faxing, or mailing as needed.

NOTE: Letters of Medical Necessity and Letters of Medical Exception are very similar regarding the content you must include. Nuances are called out in a single template to help create either type of letter.

(Physician Name, address, phone number, and tax ID number)

(Date)

Patient Name: (Patient Name)
 Patient Date of Birth: (Patient Date of Birth)
 Insurance Plan: (Name of Insurance Plan)
 Member ID: (Member ID #)
 Group Number: (Group Number)
 Insurance Plan Address: (Address of Insurance Plan)
 Claim or Explanation of Benefit #: (Claim/Explanation of Benefit #)

Re: Action Requested: (Letter of Medical Necessity) (Letter of Medical Exception)—Coverage Request for OSENVELT[®] (denosumab-bmwo) for (Patient Name)

To whom it may concern:

My name is (Physician Name), and I am a (board-certified medical specialty) (NP). I am writing on behalf of my patient (Patient Name) to document the (medical necessity) (medical need for formulary exception) for OSENVELT (denosumab-bmwo) for (subcutaneous) (intravenous) use (list dosing regimen) for my patient, a current member of (Health Plan Name). This letter provides information about the patient's medical history and diagnosis and a statement summarizing my treatment rationale.

I have prescribed OSENVELT, which is medically appropriate and necessary for this patient who has been diagnosed with (condition), (ICD-10 code(s)). Therefore, I am requesting that (Health Plan Name) remove any medical policy or guideline requirements in this case so that OSENVELT can be made available to my patient as a covered medication.

Patient's Clinical History and Treatment Rationale

(Patient Name) is (a/an) (age)-year-old (male/female) patient who has been diagnosed with (condition), (ICD-10 code(s)) as of (date of diagnosis). (He/she) has been in my care since (date).

(Elaborate on the patient's clinical/medical history, condition, and symptoms)

(The following items are important):

- (Previous treatments, including drug names, duration of treatment(s), and responses to those treatments (utilizing and referring to the Past Treatment section on the next page can help condense your explanation))
- (Relevant laboratory results at key points in the treatment journey)
- (Acute and chronic complications)
- (Why you believe it is medically necessary for the patient to receive OSENVELT and/or why a medical formulary exception should be made)
- (Supporting letters from other specialist(s) who currently treat or previously treated the patient)

My rationale for prescribing OSENVELT is based on (the patient's) disease course, including history of disease, laboratory results, symptoms, and previous treatments. (Include medical reasoning for choosing to bypass any alternative medications covered by the health plan (eg, infectious diseases due to multiple infusions, potential for patient inability to comply with labeled dosing requirements of covered/preferred products over an extended period of time, and any applicable treatment guidelines)).

Continued

Past Treatment

- (Drug name) (start date MM/YY) – (stop date MM/YY) (List the reasons for discontinuing)
- (Drug name) (start date MM/YY) – (stop date MM/YY) (List the reasons for discontinuing)
- (Drug name) (start date MM/YY) – (stop date MM/YY) (List the reasons for discontinuing)
- (Drug name) (start date MM/YY) – (stop date MM/YY) (List the reasons for discontinuing)

Treatment Plan

On February 28, 2025, the U.S. Food & Drug Administration (FDA) approved OSENVELT for the treatment of (relevant condition). (Include plan of treatment (dosage, length of treatment, number of doses for which an exception may be needed—if applicable) and clinical practice guidelines that support the use of OSENVELT). (Consider mentioning experts in the field who also support the treatment).

Summary

Based on the patient's condition and medical history, as well as my experience treating patients with (relevant condition), I have concluded that treatment with OSENVELT is medically appropriate in this case. I further attest (Include physician expectations regarding clinical outcomes for the patient).

I am requesting an expedited review of this request by a board-certified and specialty-matched physician who can render a decision based upon the information included above and the supporting documentation I am enclosing. If you have any questions, please contact me at (physician phone number) for a peer-to-peer discussion. I would be pleased to speak to you in more detail about why (OSENVELT is medically necessary) (a formulary exception for OSENVELT is needed) for (Patient Name) for the treatment of (relevant condition).

If you do not feel that the information provided has established (medical necessity) (a medical reason for formulary exception), please provide me with your detailed rationale based upon the standards of care, the specialty of the physician who reviewed this case, and whether they are board certified in an appropriate medical specialty.

I look forward to receiving your timely response and approval of OSENVELT.

Sincerely,

(Physician Name)
(Physician Signature)

Enclosures

(List enclosures, which may include medical records/clinical notes for OSENVELT, OSENVELT Prescribing Information, Letter of Medical Necessity (if applicable), and other supporting documentation)
(Include full Prescribing Information, including Medication Guide)

References

(Include other relevant references and publications regarding OSENVELT)
(Copy of patient denial letter (if applicable))
(Clinical progress notes)
(Patient's lab results)
(Documentation of hospitalization/emergency room visits and/or unscheduled office visits)
(List of medications provided (including dosages, dates used, and if samples were given))

This template is for informational purposes only and provides an outline of the types of information that may be required or helpful when responding to a patient’s insurer. Use of this information does not constitute medical or legal advice and does not guarantee reimbursement for coverage. It is not a substitute for, or to be considered an influence on, the clinical decision of the prescribing healthcare professional. Celltrion makes no representations or warranties about the template or its fitness for any specific use. Celltrion is not responsible for any changes made to the template document. All billing and coding decisions are the responsibility of the relevant physician.

Indication and Important Safety Information for OSENVELT® (denosumab-bmwo) injection

INDICATION

Osenvelt (denosumab-bmwo) is a RANK ligand (RANKL) inhibitor indicated for:

- Prevention of skeletal-related events in patients with multiple myeloma and in patients with bone metastases from solid tumors.
- Treatment of adults and skeletally mature adolescents with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity
- Treatment of hypercalcemia of malignancy refractory to bisphosphonate therap.

IMPORTANT SAFETY INFORMATION

Contraindications: Patients with hypocalcemia or with known clinically significant hypersensitivity to denosumab products.

Drug Products with Same Active Ingredient. Patients receiving OSENVELT should not receive other denosumab products concomitantly.

Hypersensitivity. Clinically significant hypersensitivity including anaphylaxis has been reported with denosumab products. If an anaphylactic or other clinically significant allergic reaction occurs, initiate appropriate therapy and discontinue further use of OSENVELT.

Hypocalcemia. Severe hypocalcemia can occur, and fatal cases have been reported. Monitor calcium levels and calcium and vitamin D intake.

Osteonecrosis of the Jaw (ONJ). ONJ can occur in patients on OSENVELT. A routine oral exam and appropriate preventive dentistry are recommended before starting and during treatment with OSENVELT. Good oral hygiene should be maintained. Avoid invasive dental procedures during treatment with OSENVELT. For invasive dental procedures, consider temporary discontinuation of OSENVELT. If ONJ develops, consult a dentist or oral surgeon, as extensive surgery may worsen ONJ; consider discontinuing OSENVELT based on benefit-risk assessment.

Atypical Subtrochanteric and Diaphyseal Femoral Fracture. Atypical femoral fracture has been reported with denosumab products. During OSENVELT treatment, patients should be advised to report new or unusual thigh, hip, or groin pain. Patients with thigh or groin pain should be evaluated for an atypical femur fracture, including assessment

for potential fractures in the contralateral limb. Interruption of OSENVELT therapy should be considered, pending a benefit-risk assessment, on an individual basis.

Hypercalcemia Following Treatment Discontinuation in Patients with Giant Cell Tumor of Bone and in Patients with Growing Skeletons. Clinically significant hypercalcemia, sometimes requiring hospitalization and complicated by acute renal injury, has occurred in denosumab-treated patients with giant cell tumor of bone and in those with growing skeletons, often within the first year after discontinuation. After treatment discontinuation, monitor for hypercalcemia symptoms, check serum calcium periodically, reassess calcium and vitamin D needs, and manage as appropriate.

Multiple Vertebral Fractures (MVF) Following Treatment Discontinuation. Following discontinuation of denosumab treatment, fracture risk increases, including the risk of multiple vertebral fractures. Evaluate the individual patient's risk for vertebral fractures after OSENVELT discontinuation.

Embryo-Fetal Toxicity. Denosumab may cause fetal harm based on animal studies and its mechanism of action. Verify pregnancy status in females of reproductive potential before starting OSENVELT, and advise them to use effective contraception during treatment and for 5 months after the last dose to prevent fetal harm.

Adverse Reactions:

- Bone Metastasis from Solid Tumors: Most common adverse reactions ($\geq 25\%$) were fatigue/asthenia, hypophosphatemia, and nausea.
- Multiple Myeloma: Most common adverse reactions ($\geq 10\%$) were diarrhea, nausea, anemia, back pain, thrombocytopenia, peripheral edema, hypocalcemia, upper respiratory tract infection, rash, and headache.
- Giant Cell Tumor of Bone: Most common adverse reactions ($\geq 10\%$) were arthralgia, headache, nausea, back pain, fatigue, and pain in extremity.
- Hypercalcemia of Malignancy: Most common adverse reactions ($> 20\%$) were nausea, dyspnea, decreased appetite, headache, peripheral edema, vomiting, anemia, constipation, and diarrhea.

For more information about OSENVELT, please see full [Prescribing Information](#).

[Physician Name, address, phone number, and tax ID number]

[Date]

Patient Name: [Patient Name]

Patient Date of Birth: [Patient Date of Birth]

Insurance Plan: [Name of Insurance Plan]

Member ID: [Member ID #]

Group Number: [Group Number]

Insurance Plan Address: [Address of Insurance Plan]

Claim or Explanation of Benefit #: [Claim/Explanation of Benefit #]

Re: Action Required: [Letter of Medical Necessity] [Letter of Medical Exception]—Coverage Request for OSENVELT® (denosumab-bmwo) for [Patient Name]

To whom it may concern:

My name is [Physician Name], and I am a [board-certified medical specialty] [NPI]. I am writing on behalf of my patient [Patient Name] to document the [medical necessity] [medical need for formulary exception] for OSENVELT (denosumab-bmwo) for [subcutaneous] [intravenous] use [list dosing regimen] for my patient, a current member of [Health Plan Name]. This letter provides information about the patient's medical history and diagnosis and a statement summarizing my treatment rationale.

I have prescribed OSENVELT, which is medically appropriate and necessary for this patient who has been diagnosed with [condition], [ICD code(s)]. Therefore, I am requesting that [Health Plan Name] remove any medical policy or guideline requirements in this case so that OSENVELT can be made available to my patient as a covered medication.

Patient's Clinical History and Treatment Rationale

[Patient Name] is [a/an] [age]-year-old [male/female] patient who has been diagnosed with [condition] [ICD-10-code(s)] as of [date of diagnosis]. [He/she] has been in my care since [date].

[Elaborate on the patient's clinical/medical history, condition, and symptoms]

[The following items are important:]

- [Previous treatments, including drug names, duration of treatment(s), and responses to those treatments (utilizing and referring to the Past Treatment section on the next page can help condense your explanation)]
- [Relevant laboratory results at key points in the treatment journey]
- [Acute and chronic complications]
- [Why you believe it is medically necessary for the patient to receive OSENVELT and/or why a medical formulary exception should be made]
- [Supporting letters from other specialist(s) who currently treat or previously treated the patient]

My rationale for prescribing OSENVELT is based on [the patient's disease course, including history of disease, laboratory results, symptoms, and previous treatments]. *[Include medical reasoning for choosing to bypass any alternative medications covered by the health plan (eg, infectious diseases due to multiple infusions, potential for patient inability to comply with labeled dosing requirements of covered/preferred products over an extended period of time, and any applicable treatment guidelines)].*

Continued

Past Treatment

- [Drug name] [start date MM/YY] – [stop date MM/YY] [List the reasons for discontinuing]
- [Drug name] [start date MM/YY] – [stop date MM/YY] [List the reasons for discontinuing]
- [Drug name] [start date MM/YY] – [stop date MM/YY] [List the reasons for discontinuing]
- [Drug name] [start date MM/YY] – [stop date MM/YY] [List the reasons for discontinuing]

Treatment Plan

On February 28, 2025, the U.S. Food & Drug Administration (FDA) approved OSENVELT for the treatment of **[relevant condition]**. *[Include plan of treatment (dosage, length of treatment, number of doses for which an exception may be needed—if applicable) and clinical practice guidelines that support the use of OSENVELT]. [Consider mentioning experts in the field who also support the treatment].*

Summary

Based on the patient's condition and medical history, as well as my experience treating patients with **[relevant condition]**, I have concluded that treatment with OSENVELT is medically appropriate in this case. I further attest *[include physician expectations regarding clinical outcomes for the patient]*.

I am requesting an expedited review of this request by a board-certified and specialty-matched physician who can render a decision based upon the information included above and the supporting documentation I am enclosing. If you have any questions, please contact me at **[physician phone number]** for a peer-to-peer discussion. I would be pleased to speak to you in more detail about why **[OSENVELT is medically necessary] [a formulary exception for OSENVELT is needed]** for **[Patient Name]** for the treatment of **[relevant condition]**.

If you do not feel that the information provided has established **[medical necessity] [a medical reason for formulary exception]**, please provide me with your detailed rationale based upon the standards of care, the specialty of the physician who reviewed this case, and whether they are board certified in an appropriate medical specialty.

I look forward to receiving your timely response and approval of OSENVELT.

Sincerely,

[Physician Name]

[Physician Signature]

Enclosures

[List enclosures, which may include medical records/clinical notes for OSENVELT, OSENVELT Prescribing Information, Letter of Medical Necessity (if applicable), and other supporting documentation]
[Include full Prescribing Information, including Medication Guide]

References

[Include other relevant references and publications regarding OSENVELT]
[Copy of patient denial letter (if applicable)]
[Clinical progress notes]
[Patient's lab results]
[Documentation of hospitalization/emergency room visits and/or unscheduled office visits]
[List of medications provided (including dosages, dates used, and if samples were given)]



Please click here to download and customize the Letter of Medical Necessity/Exception