

Writing Letters of Appeal for STOBOCLO[®]

Your medical opinion matters

When health insurers deny coverage or prior authorization, there are options. Patients, advocates, or healthcare providers can appeal these decisions.

Two types of appeals¹

✓ **Internal appeals** request an insurance company to conduct a full and fair review of its decision. *The insurance company must speed up its process for urgent cases.*

✓ **External review appeals** request a review by an independent third party. External review means the insurance company will not have the final say about paying the claim.

Learn how the process differs for each type of appeal at [healthcare.gov/appeal-insurance-company-decision](https://www.healthcare.gov/appeal-insurance-company-decision)



Tools to empower your appeals

The following pages offer advice for writing a Letter of Appeal for STOBOCLO and provide a letter template to help ensure your clinical input is taken into consideration.

NOTE: Utilizing the information provided here does not guarantee a plan will provide reimbursement for STOBOCLO. 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
- Access issues
- Prior authorizations
- Financial support

Call
1-877-81CONN

(1-877-812-6662),

Monday–Friday

between 8 AM–8 PM ET, or visit

www.celltrionconnect.com

to learn more.

FRM, field reimbursement manager.

Reference: 1. How to appeal an insurance company decision. Healthcare.gov. Accessed January 15, 2025.
<https://www.healthcare.gov/appeal-insurance-company-decision/>

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

Advice for Writing Letters of Appeal for STOBOCLO[®]

Information you will need to complete your Letter of Appeal

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

Additional guidance for writing your Letter of Appeal

- **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 STOBOCLO is the most appropriate treatment option
- **Offer clinical rationale** to support STOBOCLO 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 STOBOCLO (eg, Section 12 [Clinical Pharmacology] and Section 14 [Clinical Studies] from the full Prescribing Information for STOBOCLO)¹

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

Keeping insurer timing and processes in mind

- **Review the procedure** for submitting your appeal letter to ensure you meet insurer and state requirements
 - This includes mode of submission (eg, fax, phone, email, insurer website)
- **Internal appeals** need to be submitted within 6 months (180 days) of receiving a claim denial notice²
- **External review appeals** need to be submitted within 4 months (120 days) of receiving a claim denial notice³
- **Keep track** of your appeal/request status and follow up with the insurer as needed

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

References: 1. STOBOCLO [prescribing information]. Jersey City, NJ. Celltrion Inc; 2025. 2. Internal appeals. Healthcare.gov. Accessed January 15, 2025. <https://www.healthcare.gov/appeal-insurance-company-decision/internal-appeals/> 3. External review. Healthcare.gov. Accessed January 15, 2025. <https://www.healthcare.gov/appeal-insurance-company-decision/external-review/>

Please see Important Safety Information on page 4 and full Prescribing Information, including Boxed Warning.

Template for Letters of Appeal for STOBOCLO[®]

Helping you organize your response

Pictured below is a template for writing your Letters of Appeal for STOBOCLO 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.

[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: Request for Reconsideration of STOBOCLO[®] (denosumab-bmwo) Coverage for [Patient Name]

To whom it may concern:

My name is [Physician Name], and I am a [board-certified medical specialty] [NPI]. This letter serves as my [first/second] appeal for approval of STOBOCLO (denosumab-bmwo), which was originally denied to [Patient Name] on [Date]. I am writing this letter to provide additional information to support my request to treat [Patient Name], who has been diagnosed with [condition], [ICD code(s)], with STOBOCLO, a product indicated for the treatment of [relevant condition].

In brief, treating [Patient Name] with STOBOCLO [subcutaneously] [intravenously] [list dosing regimen] is medically appropriate and necessary and should be covered and reimbursed. [Health Plan Name] determined STOBOCLO was not covered for [Patient Name] because [reasons for denial]. This letter provides my clinical rationale and relevant information about the patient’s medical history and treatment to support my appeal.

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 STOBOCLO]
- [Supporting letters from other specialist(s) who currently treat or previously treated the patient]

My rationale for prescribing STOBOCLO 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 STOBOCLO 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 STOBOCLO]. [Consider mentioning experts in the field who also support the treatment].

Summary

Considering my patient’s condition and medical history, as well as my experience treating patients with [relevant condition], I feel treatment with STOBOCLO is warranted, appropriate, and medically necessary. The accompanying package insert provides the approved clinical information for STOBOCLO. I have also attached relevant lab test analyses and medical records to support my decision.

I am requesting an expedited review of this appeal, the enclosed documents, and the supporting evidence provided by my office and by a board-certified and specialty-matched physician who can render a decision based upon the information shared above. If you have any further questions about this matter, please contact me at [Healthcare Provider Phone Number], via email at [Healthcare Provider Email], or by fax at [Healthcare Provider Fax Number]. I look forward to receiving your timely response and approval of this claim.

Once my patient is approved for treatment with STOBOCLO, I will discontinue the treatment/prescription of [alternate BRAND (generic) name (if applicable)].

If you do not feel the information provided has established medical necessity, 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 applicable medical specialty.

Sincerely,

[Physician Name]
[Physician Signature]

Enclosures

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

References

[Include other relevant references and publications regarding STOBOCLO]
 [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 STOBOCLO® (denosumab-bmwo) injection

INDICATION

STOBOCLO® (denosumab-bmwo) is a RANK ligand (RANKL) inhibitor indicated for treatment:

- of **postmenopausal women** with osteoporosis at high risk for fracture
- to **increase bone mass in men** with osteoporosis at high risk for fracture or in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer
- of **glucocorticoid-induced osteoporosis** in men and women at high risk for fracture
- to **increase bone mass in women** at high risk for fracture receiving a adjuvant aromatase inhibitor therapy for breast cancer

IMPORTANT SAFETY INFORMATION

WARNING: SEVERE HYPOCALCEMIA IN PATIENTS WITH ADVANCED KIDNEY DISEASE

Patients with advanced chronic kidney disease (eGFR < 30 mL/min/1.73 m²), including dialysis-dependent patients, are at greater risk of severe hypocalcemia following denosumab products administration. Severe hypocalcemia resulting in hospitalization, life-threatening events and fatal cases have been reported

The presence of chronic kidney disease-mineral bone disorder (CKD-MBD) markedly increases the risk of hypocalcemia in these patients

Prior to initiating STOBOCLO in patients with advanced chronic kidney disease, evaluate for the presence of CKD-MBD. Treatment with STOBOCLO in these patients should be supervised by a healthcare provider with expertise in the diagnosis and management of CKD-MBD

Contraindications:

- Hypocalcemia: Pre-existing hypocalcemia must be corrected before initiating therapy.
- Pregnancy: Denosumab products may cause fetal harm when administered to a pregnant woman.
- Hypersensitivity: Known hypersensitivity to denosumab products

Severe Hypocalcemia and Mineral Metabolism Changes. Severe hypocalcemia can occur. Ensure adequate calcium and vitamin D supplementation.

Drug Products with Same Active Ingredient. Patients receiving Stoboclo 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 STOBOCLO.

Osteonecrosis of the Jaw (ONJ). ONJ can occur in patients on STOBOCLO, particularly after tooth extraction and/or local infection with delayed healing. A routine oral exam is recommended before starting STOBOCLO, with a dental evaluation and preventive care for high-risk patients. Good oral hygiene should be maintained, and ONJ-risk drugs may heighten ONJ likelihood, especially with extended STOBOCLO exposure. For invasive dental procedures, individualize treatment based on clinical judgment. If ONJ develops, consult a dentist or oral surgeon, as extensive surgery may worsen ONJ; consider discontinuing STOBOCLO based on benefit-risk assessment.

Atypical Subtrochanteric and Diaphyseal Femoral Fracture. Atypical low energy or low trauma fractures of the shaft have been reported in patients receiving denosumab products. During STOBOCLO 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 STOBOCLO therapy should be considered, pending a benefit-risk assessment, on an individual basis.

Multiple Vertebral Fractures (MVF) Following Discontinuation of Treatment. Following discontinuation of denosumab treatment, fracture risk increases, including the risk of multiple vertebral fractures. Prior vertebral fracture was a predictor of multiple vertebral fractures after denosumab discontinuation. Evaluate an individual's benefit-risk before initiating treatment with STOBOCLO. If STOBOCLO treatment is discontinued, patients should be transitioned to an alternative antiresorptive therapy.

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 Stoboclo discontinuation.

Serious Infections. In a trial of women with postmenopausal osteoporosis, serious infections were more frequent with denosumab than placebo, including skin, abdominal, urinary, ear infections, and endocarditis. Overall infection rates were similar between groups. Advise patients to seek medical attention for severe infection symptoms like cellulitis. Those on immunosuppressants or with weakened immune systems may face higher risks. Assess the benefit-risk profile before starting STOBOCLO, and reconsider its use if serious infections develop.

Dermatologic Adverse Reactions. Epidermal and dermal adverse events such as dermatitis, eczema, and rashes have been reported in patients treated with denosumab. Consider discontinuing STOBOCLO if severe symptoms develop.

Musculoskeletal Pain. In postmarketing experience, severe and occasionally incapacitating bone, joint, and/or muscle pain has been reported in patients taking denosumab products. Consider discontinuing use if severe symptoms develop.

Suppression of Bone Turnover. In clinical trials in women with postmenopausal osteoporosis, denosumab significantly suppressed bone remodeling, with unknown long-term effects that may lead to osteonecrosis of the jaw, atypical fractures, or delayed fracture healing; patients should be monitored for these outcomes.

Hypercalcemia in Pediatric Patients with Osteogenesis Imperfecta. STOBOCLO is not indicated for use in pediatric patients. Hypercalcemia has been reported in pediatric patients with osteogenesis imperfecta treated with denosumab products. Some cases required hospitalization.

Adverse Reactions:

- **Postmenopausal osteoporosis:** Most common adverse reactions (> 5%) were: back pain, pain in extremity, hypercholesterolemia, musculoskeletal pain, and cystitis. Pancreatitis has been reported in clinical trials.
- **Male osteoporosis:** Most common adverse reactions (> 5%) were: back pain, arthralgia, and nasopharyngitis.
- **Glucocorticoid-induced osteoporosis:** Most common adverse reactions (> 3%) were: back pain, hypertension, bronchitis, and headache.
- **Bone loss due to hormone ablation for cancer:** Most common adverse reactions (≥ 10%) were: arthralgia and back pain. Pain in extremity and musculoskeletal pain have also been reported in clinical trials.

For more information about Stoboclo, please see full [Prescribing Information](#), including Boxed Warning.

[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: Request for Reconsideration of STOBOCLO® (denosumab-bmwo) Coverage for [Patient Name]

To whom it may concern:

My name is [Physician Name], and I am a [board-certified medical specialty] [NPI]. This letter serves as my [first/second] appeal for approval of STOBOCLO (denosumab-bmwo), which was originally denied to [Patient Name] on [Date]. I am writing this letter to provide additional information to support my request to treat [Patient Name], who has been diagnosed with [condition], [ICD code(s)], with STOBOCLO, a product indicated for the treatment of [relevant condition].

In brief, treating [Patient Name] with STOBOCLO [subcutaneously] [intravenously] [list dosing regimen] is medically appropriate and necessary and should be covered and reimbursed. [Health Plan Name] determined STOBOCLO was not covered for [Patient Name] because [reason(s) for denial]. This letter provides my clinical rationale and relevant information about the patient's medical history and treatment to support my appeal.

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 and (utilizing 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 STOBOCLO]
- [Supporting letters from other specialist(s) who currently treat or previously treated the patient]

My rationale for prescribing STOBOCLO 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 STOBOCLO 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 STOBOCLO]**. **[Consider mentioning experts in the field who also support the treatment]**.

Summary

Considering my patient's condition and medical history, as well as my experience treating patients with **[relevant condition]**, I feel treatment with STOBOCLO is warranted, appropriate, and medically necessary. The accompanying package insert provides the approved clinical information for STOBOCLO. I have also attached relevant lab test analyses and medical records to support my decision.

I am requesting an expedited review of this appeal, the enclosed documents, and the supporting evidence provided by my office and by a board-certified and specialty-matched physician who can render a decision based upon the information shared above. If you have any further questions about this matter, please contact me at **[Healthcare Provider Phone Number]**, via email at **[Healthcare Provider Email]**, or by fax at **[Healthcare Provider Fax Number]**. I look forward to receiving your timely response and approval of this claim.

Once my patient is approved for treatment with STOBOCLO, I will discontinue the treatment/prescription of **[alternate BRAND (generic) name (if applicable)]**.

If you do not feel the information provided has established medical necessity, 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 applicable medical specialty.

Sincerely,

[Physician Name]

[Physician Signature]

Enclosures

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

References

[Include other relevant references and publications regarding STOBOCLO]
[Copy of patient denial letter]
[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 Appeal