

# Writing Letters of Medical Necessity and Letters of Medical Exception for STEQEYMA 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 STEQEYMA<sup>®</sup> 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 STEQEYMA. 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.



# Advice for Writing Letters of Medical Necessity and Letters of Medical Exception for STEQEYMA 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 STEQEYMA is the most appropriate treatment option
- **Offer clinical rationale** to support STEQEYMA 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 STEQEYMA therapy (eg, Section 12 (Clinical Pharmacology) and Section 14 (Clinical Studies) from the full Prescribing Information for STEQEYMA)<sup>1</sup>

**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

Reference: 1. STEQEYMA (ustekinumab-stba) Prescribing Information. CELLTRION, Inc.; 2024.

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

# Templates for Letters of Medical Necessity and Letters of Medical Exception for STEQEYMA Therapy

## Helping you organize your response

Pictured below is a template for writing Letters of Medical Necessity and Letters of Medical Exception for STEQEYMA therapy. You will find this editable content on pages 5-6 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: [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 STEQEYMA<sup>®</sup> (ustekinumab-stba) 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 STEQEYMA (ustekinumab-stba) 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 STEQEYMA, 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 STEQEYMA 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 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 table below 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 STEQEYMA and/or why a medical formulary exception should be made]
- [Supporting letters from other specialist(s) that currently treat or previously treated the patient]

My rationale for prescribing STEQEYMA 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] (Please list the reasons for discontinuing)
- [Drug name] [start date MM/YY] – [stop date MM/YY] (Please list the reasons for discontinuing)
- [Drug name] [start date MM/YY] – [stop date MM/YY] (Please list the reasons for discontinuing)
- [Drug name] [start date MM/YY] – [stop date MM/YY] (Please list the reasons for discontinuing)

**Treatment Plan**

On December 17, 2024, the FDA approved STEQEYMA 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 STEQEYMA]. [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 STEQEYMA is medically appropriate in this case. I further attest [include physician expectations regarding clinical outcomes for 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 STEQEYMA is medically necessary [a formulary exception for STEQEYMA 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 STEQEYMA.

Sincerely,  
 [Physician Name]  
 [Physician Signature]

**Enclosures**

[List enclosures, which may include medical records/clinical notes for STEQEYMA, STEQEYMA 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 STEQEYMA]  
 [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.

# Indications and Important Safety Information for STEQEYMA (ustekinumab-stba) injection

## INDICATIONS

STEQEYMA (ustekinumab-stba) is a human interleukin-12 and -23 antagonist indicated for the treatment of:

- **Plaque Psoriasis (PsO)** in adults and pediatric patients 6 years of age and older with moderate to severe PsO who are candidates for phototherapy or systemic therapy.
- **Psoriatic Arthritis (PsA)** in adults and pediatric patients 6 years of age and older with active PsA.
- **Crohn's Disease (CD)** in adult patients with moderately to severely active CD.
- **Ulcerative Colitis (UC)** in adult patients with moderately to severely active UC.

## CONTRAINDICATIONS

STEQEYMA is contraindicated in patients with clinically significant hypersensitivity to ustekinumab products or to any of the excipients in STEQEYMA.

## IMPORTANT SAFETY INFORMATION

**Infections.** Ustekinumab products, including STEQEYMA, may increase the risk of infections and reactivation of latent infections, including serious bacterial, mycobacterial, fungal, and viral infections requiring hospitalization. Reported infections include pneumonia, gastroenteritis, cellulitis, sepsis, cholecystitis, anal abscess, listeria meningitis, and ophthalmic herpes zoster. Avoid starting STEQEYMA in patients with active infections until resolved, and assess risks in those with chronic or recurrent infections. Advise patients to seek medical care for signs of infection. Discontinue STEQEYMA for serious infections until treated or resolved.

**Theoretical Risk for Particular Infections.** Genetic IL-12/IL-23 deficiencies are linked to disseminated infections (e.g., mycobacteria, salmonella, and BCG). It is unknown whether IL-12/IL-23 blockade from ustekinumab products may cause similar susceptibility. Consider diagnostic testing, such as tissue or stool cultures, based on clinical circumstances.

**Pre-treatment Evaluation for Tuberculosis (TB).** Evaluate patients for TB prior to starting STEQEYMA. Avoid using STEQEYMA in patients with active tuberculosis. Treat latent TB before starting STEQEYMA and consider TB therapy for patients with unclear treatment history. Monitor for signs of active TB during and after treatment.

**Malignancies.** Ustekinumab products are immunosuppressants that may increase the risk of malignancy. Malignancies occurred in clinical trials, and IL-12/IL-23 inhibition increased malignancy

risk in rodent models. The safety in patients with a history of malignancy is unknown. Post-marketing reports include rapid onset of multiple cutaneous squamous cell carcinomas in patients with risk factors for non-melanoma skin cancer. Monitor all patients, especially those over 60, with prolonged immunosuppressant use, or a history of PUVA treatment.

**Hypersensitivity Reactions.** If an anaphylactic or other clinically significant hypersensitivity reaction occurs, institute appropriate therapy and discontinue STEQEYMA.

### Posterior Reversible Encephalopathy Syndrome (PRES).

Cases of PRES have been reported in clinical trials and postmarketing, with symptoms like headache, seizures, confusion, visual disturbances, and imaging changes. Onset ranged from days to over a year after starting ustekinumab. Patients recovered after discontinuation and supportive care. Monitor for PRES symptoms, and if suspected, treat promptly and discontinue STEQEYMA.

**Immunizations.** Ensure patients receive all age-appropriate immunizations before starting STEQEYMA. Avoid live vaccines during treatment and for one year before and after discontinuation. Do not administer BCG vaccines during this time. Use caution with live vaccines for household contacts due to the risk of shedding and transmission. Non-live vaccines may have a reduced immune response during STEQEYMA treatment.

**Noninfectious Pneumonia.** Noninfectious pneumonia, including interstitial, eosinophilic, and cryptogenic organizing pneumonia, has been reported with ustekinumab, presenting as cough, dyspnea, and interstitial infiltrates after 1–3 doses. Serious cases included respiratory failure and prolonged hospitalization. Patients improved with discontinuation and corticosteroids. Discontinue STEQEYMA and treat if confirmed.

### Adverse Reactions

The most common adverse reactions ( $\geq 3\%$ ) reported in patients receiving ustekinumab were:

**Psoriasis:** nasopharyngitis, upper respiratory tract infection, headache, and fatigue.

**CD induction:** vomiting

**CD maintenance:** nasopharyngitis, injection site erythema, vulvovaginal candidiasis/mycotic infection, bronchitis, pruritus, urinary tract infection, and sinusitis.

**UC induction:** nasopharyngitis

**UC maintenance:** nasopharyngitis, headache, abdominal pain, influenza, fever, diarrhea, sinusitis, fatigue, and nausea.

[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: [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 STEQEYMA® (ustekinumab-stba) 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 STEQEYMA (ustekinumab-stba) 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 STEQEYMA, 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 STEQEYMA 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 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 table below 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 STEQEYMA and/or why a medical formulary exception should be made]
- [Supporting letters from other specialist(s) that currently treat or previously treated the patient]

My rationale for prescribing STEQEYMA 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] [Please list the reasons for discontinuing]
- [Drug name] [start date MM/YY] – [stop date MM/YY] [Please list the reasons for discontinuing]
- [Drug name] [start date MM/YY] – [stop date MM/YY] [Please list the reasons for discontinuing]
- [Drug name] [start date MM/YY] – [stop date MM/YY] [Please list the reasons for discontinuing]

## Treatment Plan

On December 17, 2024, the FDA approved STEQEYMA 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 STEQEYMA]. [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 STEQEYMA is medically appropriate in this case. I further attest *[include physician expectations regarding clinical outcomes for 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 [STEQEYMA is medically necessary] [a formulary exception for STEQEYMA 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 STEQEYMA.

Sincerely,  
[Physician Name]  
[Physician Signature]

## Enclosures

*[List enclosures, which may include medical records/clinical notes for STEQEYMA, STEQEYMA 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 STEQEYMA]*  
*[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)]*