Checklist:

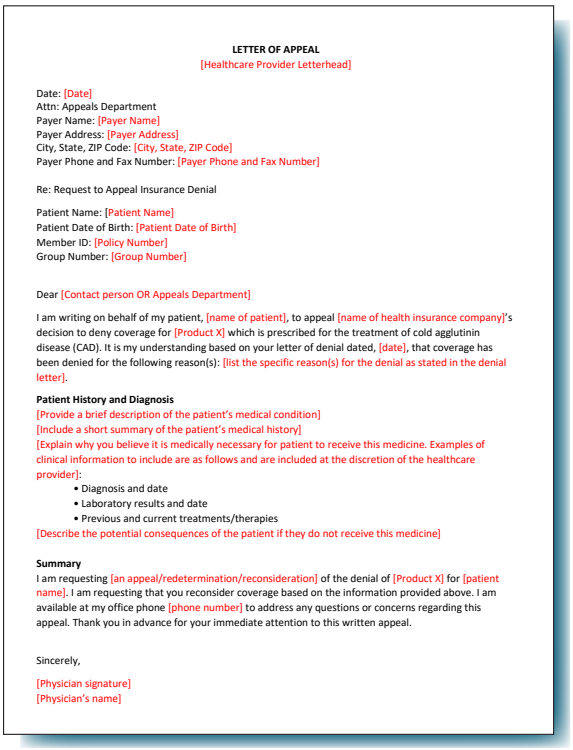
Appeal process for ENJAYMO® (sutimlimab-jome)

When medications are approved by the FDA for the treatment of rare conditions—such as ENJAYMO to treat hemolysis in adults with cold agglutinin disease (CAD)—prescribers may encounter denials from insurers or pharmacy benefit managers (PBMs).

If a patient's coverage is denied, healthcare providers may consider the following:

- ✓ Revisit the insurer's submission requirements
- ✓ Confirm the initial claim was submitted correctly
- ✓ Review the insurer's appeal process and deadlines
- ✓ Complete an appeal form (usually found on the insurer's website)
- ✓ Prepare a Letter of Medical Necessity to include with the appeal form

Letter of Appeal



LETTER OF APPEAL
[Healthcare Provider Letterhead]

Date: [Date]
Attn: Appeals Department
Payer Name: [Payer Name]
Payer Address: [Payer Address]
City, State, ZIP Code: [City, State, ZIP Code]
Payer Phone and Fax Number: [Payer Phone and Fax Number]

Re: Request to Appeal Insurance Denial

Patient Name: [Patient Name]
Patient Date of Birth: [Patient Date of Birth]
Member ID: [Policy Number]
Group Number: [Group Number]

Dear [Contact person OR Appeals Department]

I am writing on behalf of my patient, [name of patient], to appeal [name of health insurance company]'s decision to deny coverage for [Product X] which is prescribed for the treatment of cold agglutinin disease (CAD). It is my understanding based on your letter of denial dated, [date], that coverage has been denied for the following reason(s): [list the specific reason(s) for the denial as stated in the denial letter].

Patient History and Diagnosis
[Provide a brief description of the patient's medical condition]
[Include a short summary of the patient's medical history]
[Explain why you believe it is medically necessary for patient to receive this medicine. Examples of clinical information to include are as follows and are included at the discretion of the healthcare provider]:
- Diagnosis and date
- Laboratory results and date
- Previous and current treatments/therapies

[Describe the potential consequences of the patient if they do not receive this medicine]

Summary
I am requesting [an appeal/redetermination/reconsideration] of the denial of [Product X] for [patient name]. I am requesting that you reconsider coverage based on the information provided above. I am available at my office phone [phone number] to address any questions or concerns regarding this appeal. Thank you in advance for your immediate attention to this written appeal.

Sincerely,

[Physician signature]
[Physician's name]

Most insurer websites will provide appeal forms for online submission or download. If a particular insurer does not offer such a form, it may be necessary to write and submit a Letter of Appeal.

The letter should include:

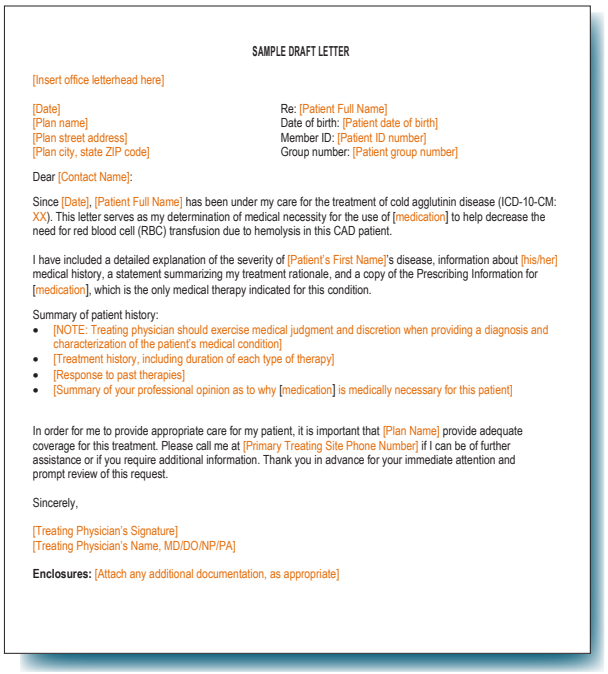
- ✓ Patient information, such as name, date of birth, employer/health plan sponsor, case number, insurance ID number, group number, etc
- ✓ Healthcare provider name, facility name, office address, phone and fax numbers, etc
- ✓ Amount billed
- ✓ A statement of rationale for treatment
- ✓ Dosing and administration information per the medication label
- ✓ Clinical trial data supporting FDA approval for the medication

Please see complete Important Safety Information on pages 3-4, as well as full Prescribing Information.

Enjaymo®
sutimlimab-jome
Injection for intravenous use
1100 mg/22 mL

Letter of Medical Necessity

Including a Letter of Medical Necessity with an appeal can help explain the rationale and clinical decision-making behind the choice of a specific therapy.



SAMPLE DRAFT LETTER

[Insert office letterhead here]

[Date]
[Plan name]
[Plan street address]
[Plan city, state ZIP code]

Re: [Patient Full Name]
Date of birth: [Patient date of birth]
Member ID: [Patient ID number]
Group number: [Patient group number]

Dear [Contact Name]:

Since [Date], [Patient Full Name] has been under my care for the treatment of cold agglutinin disease (ICD-10-CM: XX). This letter serves as my determination of medical necessity for the use of [medication] to help decrease the need for red blood cell (RBC) transfusion due to hemolysis in this CAD patient.

I have included a detailed explanation of the severity of [Patient's First Name]'s disease, information about [his/her] medical history, a statement summarizing my treatment rationale, and a copy of the Prescribing Information for [medication], which is the only medical therapy indicated for this condition.

Summary of patient history:

- [NOTE: Treating physician should exercise medical judgment and discretion when providing a diagnosis and characterization of the patient's medical condition]
- [Treatment history, including duration of each type of therapy]
- [Response to past therapies]
- [Summary of your professional opinion as to why [medication] is medically necessary for this patient]

In order for me to provide appropriate care for my patient, it is important that [Plan Name] provide adequate coverage for this treatment. Please call me at [Primary Treating Site Phone Number] if I can be of further assistance or if you require additional information. Thank you in advance for your immediate attention and prompt review of this request.

Sincerely,

[Treating Physician's Signature]
[Treating Physician's Name, MD/DO/NP/PA]

Enclosures: [Attach any additional documentation, as appropriate]

The letter should include:

- ✓ A timeline for onset of symptoms
- ✓ Prior treatments, procedures, and medications
- ✓ Patient response to prior interventions
- ✓ Current symptoms
- ✓ Prescriber notes about the patient's disease state and progression
- ✓ ICD-10-CM diagnosis code and any other codes as requested by the insurer
- ✓ Patient medical records and test results
- ✓ Patient comorbidities, intolerance to other therapies, and/or unavailability of other approved medications

Note: *Letters of medical necessity must be* ***signed by the prescribing physician only.***

Further Considerations

- To expedite an appeal, provide the information necessary to support the urgent nature of the request
- If an appeal is denied, request that a relevant specialist at the insurer or PBM conduct a peer-to-peer claim review
- Should additional challenges arise when appealing a denial of coverage, please contact your Recordati Rare Disease Account Manager

These recommendations are guidelines only and do not guarantee authorization or reimbursement, nor should they be construed as medical advice. This letter is not intended to be a substitute for or influence on the independent medical judgment of the physician. Insurers/PBMs may require additional information for authorization or reimbursement.

ICD-10-CM, International Classification of Diseases, Tenth Revision, Clinical Modification.

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INDICATION

ENJAYMO® (sutimlimab-jome) is indicated for the treatment of hemolysis in adults with cold agglutinin disease (CAD).

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

ENJAYMO is contraindicated in patients with known hypersensitivity to sutimlimab-jome or any of the inactive ingredients.

WARNINGS AND PRECAUTIONS

Serious Infections Including Those Caused by Encapsulated Bacteria

- ENJAYMO, a proximal classical complement C1s inhibitor, increases susceptibility to serious infections, including those caused by encapsulated bacteria, eg, *Neisseria meningitidis* (any serogroup, including non-groupable strains), *Streptococcus pneumoniae*, and *Haemophilus influenzae* type B.
- Life-threatening and fatal infections with encapsulated bacteria have occurred in both vaccinated and unvaccinated patients treated with complement inhibitors.
- Serious infections (bacterial and viral) were reported in 15% (10/66) of patients receiving ENJAYMO in the two phase 3 trials. These infections included urinary tract infection with sepsis, respiratory tract infection, pneumonia, otomastoiditis, and skin infections. One patient (1.5%) died due to *Klebsiella pneumoniae*.
- Complete or update vaccination against encapsulated bacteria at least 2 weeks prior to administration of the first dose of ENJAYMO, according to the most current ACIP recommendations for patients receiving a complement inhibitor.
- If urgent ENJAYMO therapy is indicated in a patient who is not up to date on their vaccine(s), administer as soon as possible.
- Vaccination does not eliminate the risk of serious encapsulated bacterial infections. Closely monitor patients for early signs and symptoms of serious infection and evaluate patients immediately if an infection is suspected.
- If ENJAYMO treatment is administered to patients with active systemic infections, monitor closely for signs and symptoms of worsening infection. Some infections may become rapidly life-threatening or fatal if not recognized and treated promptly. Inform patients of these signs and symptoms and steps to be taken to seek immediate medical care.
    - Consider interruption of ENJAYMO treatment in patients who are undergoing treatment for serious infection.
    - Consider patients' immune status when initiating treatment with ENJAYMO.

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IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Infusion-Related Reactions

- Administration of ENJAYMO may result in infusion-related reactions. In the two phase 3 trials, 29% (19/66) of patients treated with ENJAYMO experienced infusion-related reactions. One patient permanently discontinued ENJAYMO due to an infusion-related reaction.
- Monitor patients for infusion-related reactions and interrupt if a reaction occurs.
- Discontinue ENJAYMO infusion and institute appropriate supportive measures if signs of hypersensitivity reactions, such as cardiovascular instability or respiratory compromise, occur.

Risk of Autoimmune Disease

- Based on its mechanism of action, ENJAYMO may potentially increase the risk for developing autoimmune diseases such as systemic lupus erythematosus (SLE). Development of SLE has been associated with inherited classical complement deficiency.
- In clinical trials, 4.5% (3/66) of patients developed a relapse or worsening of previously diagnosed autoimmune disease.
- Monitor ENJAYMO patients for signs and symptoms and manage medically.

Recurrent Hemolysis After ENJAYMO Discontinuation

- If treatment with ENJAYMO is interrupted, closely monitor patients for signs and symptoms of recurrent hemolysis, eg, elevated levels of total bilirubin or lactate dehydrogenase (LDH) accompanied by a decrease in hemoglobin, or reappearance of symptoms such as fatigue, dyspnea, palpitations, or hemoglobinuria. Consider restarting ENJAYMO if signs and symptoms of hemolysis occur after discontinuation.

ADVERSE REACTIONS

- The most common adverse reactions in the CADENZA trial (Part A) (incidence ≥18%) are rhinitis, headache, hypertension, acrocyanosis, and Raynaud's phenomenon. The most common adverse reactions in the CARDINAL trial (incidence ≥25%) are urinary tract infection, respiratory tract infection, bacterial infection, dizziness, fatigue, peripheral edema, arthralgia, cough, hypertension, and nausea.

Please see full Prescribing Information.

RECORDATI RARE DISEASES
Focused on the Few

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