Sample letter of medical necessity for ENJAYMO® (sutimlimab-jome)

Overview
The following letter is intended to serve as a sample for your consideration. It may not include all of the information necessary to support a prior authorization request or letter of appeal. Please note that supplying the information below does not guarantee a health plan will provide reimbursement for ENJAYMO. The sample letter is provided for your guidance only; it is not intended to influence or substitute for your independent medical judgment. The requesting provider is always responsible for ensuring the accuracy, adequacy, and supportability of all information provided.

Some key reminders
- Consider including a letter of medical necessity like this with a prior authorization (PA) request to emphasize the medical necessity for ENJAYMO, or in addition to an appeal letter, as needed
- Letters of medical necessity should be drafted and signed by the physician **only**
- Be sure to populate with the updated *International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM)* code. Note that the ICD-10-CM code for cold agglutinin disease was updated in 2020 to D59.12.

Some health plans require supporting documentation along with a letter of medical necessity, such as:
- Patient's medical records
- Peer-reviewed literature
- Supporting clinical studies
- Prescribing Information
- Clinic notes and laboratory results

To avoid any delays in reimbursement, it is recommended to provide as much documentation as possible.

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, e.g., *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.

IMPORTANT SAFETY INFORMATION (cont'd)
WARNINGS AND PRECAUTIONS (cont'd)
Serious Infections Including Those Caused by Encapsulated Bacteria (cont'd)

- 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.

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.

IMPORTANT SAFETY INFORMATION (cont'd)
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 accompanying full Prescribing Information.

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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 ENJAYMO® (sutimlimab-jome) to treat hemolysis in this CAD patient.

I have included a detailed explanation of the severity of <<Patient's First Name>>'s disease, information about their medical history, a statement summarizing my treatment rationale, and a copy of the Prescribing Information for ENJAYMO, 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 ENJAYMO 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>>