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

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

VACCINATION GUIDE

Getting patients started on ENJAYMO begins with completing or updating required vaccinations against encapsulated bacteria prior to treatment, including:

- **Streptococcus pneumoniae (pneumococcal)**
- **Neisseria meningitidis (meningococcal): serogroups A, C, W, Y, and B**

According to current Advisory Committee on Immunization Practices (ACIP) recommendations for patients receiving complement inhibitors, immunization should be administered at least 2 weeks prior to initiation of first dose of ENJAYMO.

If urgent ENJAYMO therapy is indicated in a patient who is not up to date on their vaccines, administer vaccine(s) as soon as possible.

Use this vaccination guide to help you manage onboarding your patients to treatment with ENJAYMO.

This guide is for educational purposes only and is not intended to replace the full prescribing information for any vaccine. Healthcare providers should refer to the FDA-approved prescribing information for the most complete and up-to-date details, including contraindications, warnings, and precautions for individual vaccines.

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.
- 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*.

Please see additional Important Safety Information throughout and accompanying full Prescribing Information.

ACIP RECOMMENDATIONS: PNEUMOCOCCAL VACCINATIONS (2025)[1-4]

PNEUMOCOCCAL VACCINE TIMING FOR ADULTS WITH SPECIFIED IMMUNOCOMPROMISING CONDITIONS

Adults ≥ 19 years old with specified immunocompromising conditions: Complete pneumococcal vaccine schedules

PCV = Pneumococcal Conjugate Vaccine; PPSV = Pneumococcal Polysaccharide Vaccine

PRIOR VACCINES	OPTION A	OPTION B
None*	**PCV20** OR **PCV21**	**PCV15** ≥8 weeks **PPSV23†**
PCV15 only at any age	≥8 weeks **PPSV23‡**	NO OPTION B
PCV15 & PPSV23 OR **PCV20** OR **PCV21** at any age	**No vaccines** recommended at this time	
PPSV23 only at any age	≥1 year **PCV20** OR **PCV21**	≥1 year **PCV15**
PCV13 only at any age	≥1 year **PCV20** OR **PCV21**	NO OPTION B
PCV13 and **1 dose of PPSV23** at any age	≥5 years **PCV20** OR **PCV21**	
PCV13 and **2 doses of PPSV23** at any age	≥5 years **PCV20** OR **PCV21**	
Immunocompromising conditions	Chronic renal failure, congenital or acquired asplenia, congenital or acquired immunodeficiency,‡ generalized malignancy, HIV infection, Hodgkin disease, iatrogenic immunosuppression,§ leukemia, lymphoma, multiple myeloma, nephrotic syndrome, sickle cell disease/ other hemoglobinopathies, solid organ transplant.	

*Also applies to people who have received PCV7 at any age and no other pneumococcal vaccines.
†If PPSV23 is not available, PCV20 or PCV21 may be used.
‡Include B- (humoral) or T-lymphocyte deficiency, complement deficiencies (particularly C1, C2, C3, and C4 deficiencies), and phagocytic disorders (excluding chronic granulomatous disease).
§Includes diseases requiring treatment with immunosuppressive drugs, including long-term systemic corticosteroids and radiation therapy.

HCP should refer to the most up-to-date ACIP recommendations for the most current and complete information for pneumococcal/meningococcal vaccine recommendations. ACIP recommends an administration schedule in patients receiving complement inhibitors that differs from the administration schedule in the vaccine prescribing information.

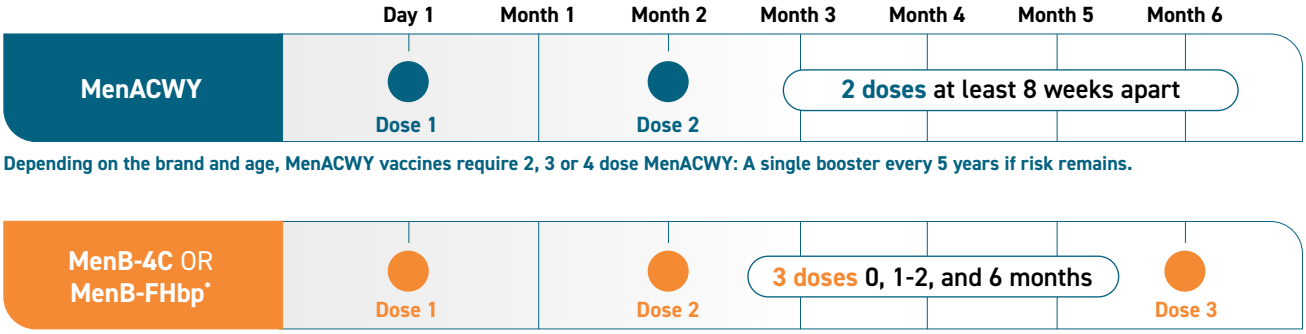
IMPORTANT SAFETY INFORMATION (CONTINUED)

- 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.

ACIP RECOMMENDATIONS: MENINGOCOCCAL VACCINATIONS A, C, W, Y AND B (2025)[2,4,5]

MENINGOCOCCAL VACCINE RECOMMENDATIONS FOR ADULTS RECEIVING A COMPLEMENT INHIBITOR

Complete meningococcal vaccine schedules



Depending on the brand and age, MenACWY vaccines require 2, 3 or 4 dose MenACWY: A single booster every 5 years if risk remains.

MenB-4C or MenB-FHbp: A single booster 1 year following completion of primary series, then every 2-3 years if risk remains.

*Individuals must receive the same MenB vaccine product for all doses.

HCP should refer to the most up-to-date ACIP recommendations for the most current and complete information for pneumococcal/meningococcal vaccine recommendations. ACIP recommends an administration schedule in patients receiving complement inhibitors that differs from the administration schedule in the vaccine prescribing information.

MenABCWY vaccination[4,5]

If a patient is receiving MenACWY and MenB vaccines at the same visit, vaccine providers have 2 options: 1. Administer the individual vaccines at different anatomical injection sites; or 2. Administer MenABCWY vaccine instead.

The minimum interval between MenABCWY doses is 6 months.

Guidance for use as a booster dose[4,5]

People with prolonged increased risk for serogroup A, C, W, or Y and B meningococcal disease need regular boosters. However, the recommended interval between doses varies by age and vaccine type. MenABCWY vaccine can be used only when both MenACWY and MenB vaccines are indicated at the same visit. Otherwise, MenACWY and MenB vaccines should be given separately as appropriate.

IMPORTANT SAFETY INFORMATION (CONTINUED)

- 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.

Please see additional Important Safety Information throughout and accompanying full Prescribing Information.

Scan QR code to download enrollment form

Fax completed form to: **1-888-241-3572**

Call: **1-833-223-2428** to enroll

Monday through Friday, 8 am to 8 pm ET

Visit enjaymohcp.com for more information

IMPORTANT SAFETY INFORMATION (CONTINUED)

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.

For additional information about ENJAYMO, including full Prescribing Information and Medication Guide, visit https://enjaymohcp.com/

Please see additional Important Safety Information throughout and accompanying full Prescribing Information.

References: 1. Kobayashi M, Leidner AJ, Gierke R, et al. Expanded Recommendations for Use of Pneumococcal Conjugate Vaccines Among Adults Aged ≥50 Years: Recommendations of the Advisory Committee on Immunization Practices - United States, 2024. *MMWR Morb Mortal Wkly Rep.* 2025 Jan 9;74(1):1-8. doi: 10.15585/mmwr.mm7401a1 **2.** Centers for Disease Control and Prevention. Accessed October 20, 2025. https://www.cdc.gov/pneumococcal/hcp/vaccine-recommendations/ **3.** Centers for Disease Control and Prevention. Accessed October 20, 2025. https://www.cdc.gov/pneumococcal/downloads/Vaccine-Timing-Adults-JobAid.pdf **4.** Centers for Disease Control and Prevention. Accessed October 20, 2025. https://www.cdc.gov/vaccines/hcp/imz-schedules/adult-age.html **5.** Centers for Disease Control and Prevention. Accessed October 20, 2025. https://www.cdc.gov/meningococcal/hcp/vaccine-recommendations/index.html

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