

# INFUSION GUIDE

## ENJAYMO, the first and only approved treatment for Cold Agglutinin Disease<sup>1</sup>

ENJAYMO is indicated for the treatment of hemolysis in adults with Cold Agglutinin Disease.

### IMPORTANT SAFETY INFORMATION CONTRAINDICATIONS

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

**Please see Important Safety Information on pages 9-10 and full [Prescribing Information](#).**

GET TO  
KNOW CAD

HOW  
TO START

DOSING

INFUSION RATE  
REFERENCE

INFUSION  
PROCESS

PATIENT  
SUPPORT

FINANCIAL  
ASSISTANCE

IMPORTANT SAFETY  
INFORMATION

# CAD is a chronic condition characterized by complement-mediated destruction of red blood cells, causing unpredictable and potentially severe anemia<sup>2</sup>

## Epidemiology<sup>3</sup>

- Up to 16 people per 1,000,000 are impacted by CAD
- Average age of onset is ≈60 years, but CAD has been seen in some patients as young as 30 years

## Common symptoms<sup>4-8</sup>



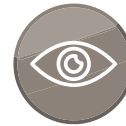
Anemia



Hemoglobinuria



Shortness of breath



Jaundice



Chronic hemolysis  
(destruction of RBCs)



Livedo reticularis (rarely)



Circulatory symptoms  
(acrocyanosis, Raynaud's phenomenon)



Profound fatigue

CAD=Cold Agglutinin Disease; RBC=red blood cell.

# ENJAYMO administration information<sup>1</sup>



Patients can receive an infusion 3 ways, subject to coverage requirements and physician determination: **in office, at an infusion center, or at home.**

## BEFORE INITIATION



Complete or update vaccination against encapsulated bacteria, including *Streptococcus pneumoniae* and *Neisseria meningitidis* (serogroups A, C, W, Y and B), according to current ACIP recommendations for patients receiving complement inhibitors at least 2 weeks prior to initiation of ENJAYMO.

If urgent ENJAYMO therapy is indicated in a patient who is not up to date with vaccines for *Streptococcus pneumoniae* and *Neisseria meningitidis* administer these vaccines as soon as possible.

Vaccination does not eliminate the risk of serious encapsulated bacterial infections.

ACIP=Advisory Committee on Immunization Practices.

## DURING INFUSION



Monitor for infusion-related reactions like shortness of breath, rapid heartbeat, nausea, flushing, headache, hypotension, chest discomfort, pruritus, rash, injection-site reaction, and dizziness.

Slow or stop the infusion if an infusion reaction occurs and institute appropriate supportive measures if signs of hypersensitivity reactions occur.

## AFTER INFUSION



Following initial infusion, monitor for 2 hours for signs or symptoms of an infusion and/or hypersensitivity reaction.

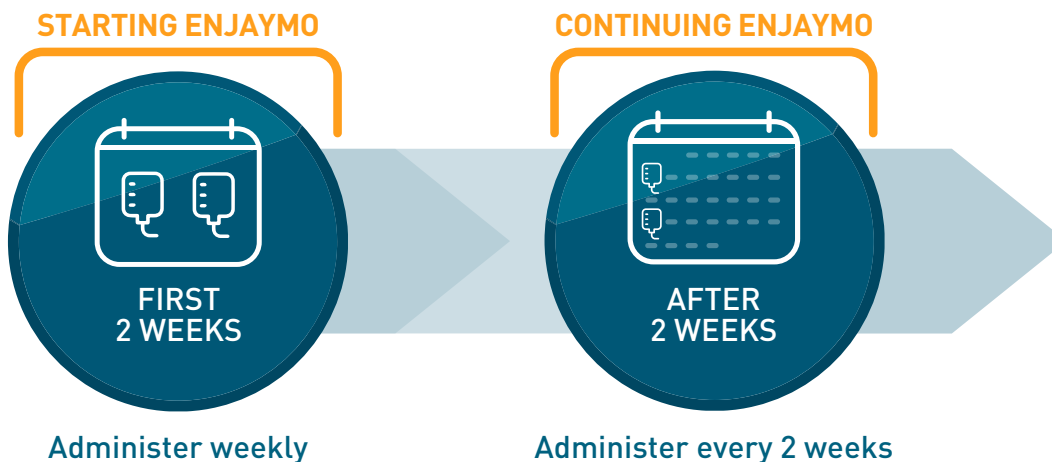
For subsequent ENJAYMO infusions, monitor for 1 hour for signs of an infusion reaction.

**Please see Important Safety Information on pages 9-10 and full Prescribing Information.**

## Dosing once every 2 weeks with ENJAYMO<sup>1</sup>

The recommended dosing regimen for adults with CAD consists of an initial dose and a dose 1 week later, followed by 1 dose every 2 weeks

Administer ENJAYMO at the recommended dosage regimen time points or within 2 days of these time points



### WEIGHT-BASED INFUSION

6500 mg FOR PATIENTS 39 kg TO <75 kg  
7500 mg FOR PATIENTS  $\geq$ 75 kg

### Interruptions in ENJAYMO treatment

- If a dose is missed, administer as soon as possible and resume dosing every 2 weeks
- If the duration after the last dose exceeds 17 days, administer weekly for 2 weeks, with administration every 2 weeks thereafter

Staying on therapy matters—stopping ENJAYMO resulted in recurrent hemolysis and anemia<sup>1</sup>

Please see Important Safety Information on pages 9-10 and full [Prescribing Information](#).

## Determine the appropriate dose and infusion rate for your patients receiving ENJAYMO<sup>1</sup>

ENJAYMO is supplied as one 1100 mg/22 mL (50 mg/mL) single-dose vial per carton. ENJAYMO can either be administered via an undiluted or diluted preparation.

**Dosing and infusion rate reference table for ENJAYMO undiluted<sup>1</sup>**

Body weight range	Dose	ENJAYMO vials needed	ENJAYMO volume	Maximum infusion rate
39 kg to <75 kg	6500 mg	6	130 mL	130 mL/hour*
≥75 kg	7500 mg	7	150 mL	150 mL/hour*

**Dosing and infusion rate reference table for ENJAYMO diluted in saline<sup>1</sup>**

Body weight range	Dose	ENJAYMO vials needed	ENJAYMO volume	NaCl diluent volume	Total volume	Maximum infusion rate
39 kg to <70 kg	6500 mg	6	130 mL	370 mL	500 mL	250 mL/hour
70 kg to <75 kg	6500 mg	6	130 mL	370 mL	500 mL	500 mL/hour*
≥75 kg	7500 mg	7	150 mL	350 mL	500 mL	500 mL/hour*

**Slow or stop the infusion in case of infusion reaction during ENJAYMO administration**

\*Patients with cardiopulmonary disease should receive the infusion over 120 minutes.

**Please see Important Safety Information on pages 9-10 and full [Prescribing Information](#).**

## 4 steps to infusing ENJAYMO<sup>1</sup>



Use aseptic technique to prepare ENJAYMO. Withdraw the calculated volume of ENJAYMO from the appropriate number of single-use vials based on the recommended dosage by weight in the dosing and infusion rate reference table.

### Key Reminders

- To minimize foaming, do not shake ENJAYMO
- ENJAYMO is a clear to slightly opalescent and colorless to slightly yellow solution. Do not administer if discolored or if foreign particulate matter is present
- If preparing ENJAYMO for undiluted administration, the appropriate amount of ENJAYMO should be added to an empty infusion bag (130 mL or 150 mL depending on the dose)
- If preparing ENJAYMO for diluted administration, dilute with 0.9% Sodium Chloride to a total volume of 500 mL
- Discard unused portion of ENJAYMO



Allow the ENJAYMO infusion solution to adjust to room temperature 59 °F to 77 °F (15 °C to 25 °C) and administer within 8 hours.

### Key Reminders

- Store ENJAYMO vials refrigerated at 36 °F to 46 °F (2 °C to 8 °C) in the original carton to protect from light. Do not freeze. Do not shake
- If the ENJAYMO infusion solution is not used immediately, store refrigerated at 36 °F to 46 °F (2 °C to 8 °C)
- Total time from the time of preparation, including refrigeration, adjustment to room temperature, and the expected infusion time, should not exceed 36 hours



Prime the infusion tubing with the dosing solution immediately before infusion and flush immediately following completion of the infusion with a sufficient quantity (approximately 20 mL) of 0.9% Sodium Chloride Injection, USP.

### Key Reminder

- In-line infusion warmers may be used, but should not exceed a temperature of 104 °F (40 °C)



Administer the ENJAYMO infusion over 1 to 2 hours (depending on the patient's body weight) and only administer through a 0.2 micron in-line filter with a polyethersulfone (PES) membrane.

### Key Reminders

- Patients with cardiopulmonary disease should receive the infusion over 2 hours regardless of body weight
- Monitor for signs of infusion and/or hypersensitivity reactions per recommendations

Please see Important Safety Information on pages 9-10 and full [Prescribing Information](#).

# ENJAYMO Patient Solutions is here to support your patients from the start and throughout treatment

Designed to increase accessibility to treatment while reducing barriers to starting and staying on therapy



## PATIENT SUPPORT SERVICES

Patient Support Services may be able to provide your patients with education services, reimbursement services, and related materials.

**Case Managers and Therapeutic Education Managers (TEMs) are available to support ENJAYMO patients.**

### Case Managers

You and your patient will be assigned a case manager to help you through the onboarding process for ENJAYMO, including getting started on treatment and insurance-related needs.

### TEMs\*

A team of educators experienced in rare blood disorders committed to educating people living with CAD, their families, and care partners. TEMs can speak with your enrolled patients about topics such as what CAD is, questions to ask, and having conversations with you and their healthcare team.

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ENJAYMO Patient Solutions help is available to you and your patients  
Monday through Friday, 8 AM to 8 PM ET, by calling 1-833-223-2428

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\*TEMs are paid to provide educational services on behalf of Recordati Rare Diseases Inc. They don't provide medical advice. Patients should always talk to you, their healthcare provider, about any healthcare needs.

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Designed to increase accessibility to treatment while reducing barriers to starting and staying on therapy



## FINANCIAL ASSISTANCE PROGRAMS

ENJAYMO Financial Assistance Programs may be able to help with the cost of treatment. Access to ENJAYMO at no cost may be available to eligible patients who are uninsured or underinsured.

Co-pay assistance of up to **[\$25,000]** US dollars per calendar year may be available for out-of-pocket co-pay or co-insurance costs related to ENJAYMO prescription costs for eligible patients.\*

The co-pay program related to the prescription is valid ONLY for patients with commercial insurance who have a valid prescription for a US Food and Drug Administration-approved indication for a qualifying Recordati Rare Diseases product. Covers co-pays and co-insurance for ENJAYMO for up to **[\$25k]** per calendar year.

For more information on ENJAYMO Patient Solutions and to download the ENJAYMO Patient Enrollment Form, visit [ENJAYMOhcp.com](https://www.enjaymo.com/ENJAYMOhcp.com)

Contact ENJAYMO Patient Solutions: 1-833-223-2428

\*The ENJAYMO Patient Solutions Co-Pay program (the "Program") is not valid for prescriptions covered by or submitted for reimbursement under Medicare, Medicaid, VA, DoD, TRICARE, or similar federal or state programs including any state pharmaceutical assistance programs. The Program is not valid where prohibited by law and savings may vary depending on patients' out-of-pocket costs. Recordati Rare Diseases reserves the right to modify or terminate the Program at any time without notice. Patients will receive all Program details upon registration. Approval is not guaranteed. Additional terms and conditions apply.

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DoD=Department of Defense; VA=Veterans Affairs.

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# Indication and Important Safety Information

## 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.
- 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.

**Please see full Prescribing Information.**

## Important Safety Information (continued)

### WARNINGS AND PRECAUTIONS (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  $\geq 18\%$ ) are rhinitis, headache, hypertension, acrocyanosis, and Raynaud's phenomenon. The most common adverse reactions in the CARDINAL trial (incidence  $\geq 25\%$ ) are urinary tract infection, respiratory tract infection, bacterial infection, dizziness, fatigue, peripheral edema, arthralgia, cough, hypertension, and nausea.

Please see full [Prescribing Information](#).

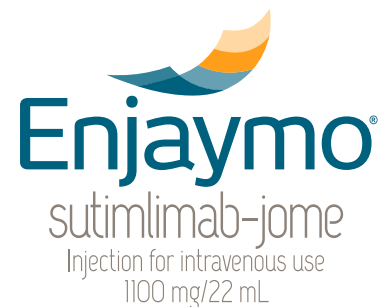
# LEARN ABOUT THE 4 SIMPLE STEPS TO GET YOUR PATIENT STARTED ON ENJAYMO AT



[ENJAYMOhcp.com](https://enjaymohcp.com)

Contact ENJAYMO Patient Solutions at 1-833-223-2428

**References:** 1. ENJAYMO. Prescribing information. 2. Berentsen S. Complement activation and inhibition in autoimmune hemolytic anemia: focus on cold agglutinin disease. *Semin Hematol.* 2018;55(3):141-149. doi:10.1053/j.seminhematol.2018.04.002 3. Berentsen S, Ulvestad E, Langholm R, et al. Primary chronic cold agglutinin disease: a population based clinical study of 86 patients. *Haematologica.* 2006;91(4):460-466. 4. Mullins M, Jiang X, Bylsma LC, et al. Cold agglutinin disease burden: a longitudinal analysis of anemia, medications, transfusions, and health care utilization. *Blood Adv.* 2017;1(13):839-848. doi:10.1182/bloodadvances.2017004390 5. Elharake M, Bors K. Cold agglutinin disease: a case report. *WV Med J.* 2017;1-4. 6. Collie JC, Lockey RF. Cold agglutinin disease clinical presentation. Updated February 7, 2022. Accessed January 6, 2023. <https://emedicine.medscape.com/article/135327-clinical> 7. Hill QA, Stamps R, Massey E, Grainger JD, Provan D, Hill A; British Society for Haematology. The diagnosis and management of primary autoimmune haemolytic anaemia. *Br J Haematol.* 2017;176(3):395-411. doi:10.1111/bjh.14478 8. Berentsen S, Röth A, Randen U, Jilma B, Tjønnfjord GE. Cold agglutinin disease: current challenges and future prospects. *J Blood Med.* 2019;10:93-103. doi:10.2147/JBM.S177621.



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