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Sutimlimab-jome (Enjaymo) for the Management of Hemolysis in Adult Patients with Cold Agglutinin Disease (CAD)

Description:

- The purpose of this document is to help guide management of patients receiving sutimlimab-jome.

Background:

- Sutimlimab-jome in an immunoglobulin G subclass 4 (IgG4) monoclonal antibody[1]
  - Inhibits the classical complement pathway
  - Inhibition of pathway at the level of complement protein component 1, s subcomponent (C1s) prevents deposition of complement opsonins on the surface of red blood cells
  - Results in inhibition of hemolysis in patients with CAD
- FDA approved for the treatment of hemolysis in adults with CAD[1]
- Most common adverse reactions (≥18-25% in two clinical trials)[1]
  - Infections: urinary tract, respiratory tract, bacterial
    - Complement inhibitors increase the patient's susceptibility to infections including those caused by encapsulated bacteria (e.g. *Neisseria meningitidis, Streptococcus pneumoniae,* and *Haemophilus influenza* type B)
  - Nervous system: headache, dizziness
  - Vascular: hypertension, acrocyanosis, Raynaud's phenomenon
  - Other: rhinitis, fatigue, peripheral edema, arthralgia, cough, nausea
- Additional safety considerations: in pooled safety data across two clinical trials (CARDINAL[2] and CADENZA[3]), infusion-related reactions were reported in approximately 29% of patients[1]

PQI Process:

- Vaccination against encapsulated bacteria should take place at least 2 weeks prior to initiation of sutimlimab-jome. If urgent therapy is indicated, administer vaccines as soon as possible[1]
- Advisory Committee on Immunization Practices (ACIP) recommendations for patients on complement inhibitor therapy (may differ from adult recommendations in vaccine package inserts):[4]
  - Meningococcal vaccine
    - MenACWY: 2 dose primary series with either Menveo or MenQuadfi at least 8 weeks apart, 1 booster dose 5 years after primary series and every 5 years if remaining on treatment
    - MenB: Bexsero or Trumenba (use same brand for all doses including booster doses)
      - Primary series: 3 doses at 0, 1-2, 6 months (if dose 2 administered at least 6 months after dose 1, dose 3 not needed; if dose 3 is administered earlier than 4 months after dose 2, a 4th dose should be administered at least 4 months after dose 3)
      - Booster doses:1 booster dose one year after primary series and every 2-3 years if remaining on treatment

        - MenACWY-TT/MenB-FHbp: May receive a single dose of Penbraya as an alternative to separate administration of MenACWY and MenB when both vaccines would be given on the same clinic day. Penbraya may be used for booster doses if at least 6 months have elapsed since most recent dose.
    - Pneumococcal vaccine
        - Not previously received a PCV13, PCV15, PCV20, or PCV21 or whose previous vaccination history is unknown: 1 dose PCV15, PCV20, or PCV21
            - If PCV15 is given, administer 1 dose PPSV23 at minimum interval of 8 weeks after the PCV15 dose
        - Previously received PCV7: same recommendation as above
        - Previously received PCV13: 1 dose PCV20 or PCV21 at least 1 year after PCV13 dose
        - Previously received PPSV23: 1 dose PCV15, PCV20, or PCV21 at least 1 year after the last PPSV23
        - Previously received PCV13 and 1 dose of PPSV23: 1 dose PCV20 or PCV21 at least 5 years after the last pneumococcal vaccine dose (if additional PPSV23 received at age 65 or older, based on shared clinical decision making can receive this booster at least 5 years after the last pneumococcal vaccine dose)
- Dosing and administration recommendations for sutimlimab-jone[1]
    - May be administered as either an undiluted or diluted preparation
    - Table 1: Dosing and infusion rates for undiluted administration

Body weight	Dose	Volume	Maximum Infusion Rate
≥39 kg to <75 kg	6,500 mg	130 mL	130 mL/hr*
≥75 kg	7,500 mg	150 mL	150 mL/hr*

    - Table 2: Dosing and infusion rates for diluted administration

Body weight	Dose	Volume of Drug	Volume of NaCl diluent	Maximum Infusion Rate
39 kg to <70 kg	6,500 mg	130 mL	370 mL	250 mL/hr
70 kg to <75 kg	6,500 mg	130 mL	370 mL	500 mL/hr*
≥75 kg	7,500 mg	150 mL	500 mL	500 mL/hr*

*Patients with cardiopulmonary disease may receive infusion over 120 minutes

    - For diluted administration:
        - Dilute with normal saline to a total volume of 500 mL
        - Administer through 0.2 micron in-filter with a polyethersulfone membrane
        - Prime tubing with medication solution immediately prior to infusion and flush immediately following completion with ~20mL of normal saline
    - Slow or stop the infusion in case of infusion reaction
    - Monitor patient for at least two hours after initial infusion for signs/symptoms of infusion and/or hypersensitivity reaction and for at least one hour after completion of subsequent infusions
    - Administer dose based on body weight weekly for the first 2 doses then every two weeks thereafter
    - If a dose is missed and the duration after the last dose is >17 days, patients should be given doses weekly for two weeks and then resume every two-week dosing schedule

- If treatment is interrupted or stopped, patients should be monitored for signs/symptoms of recurrent hemolysis and consideration for resumption of therapy given:
    - Elevated total bilirubin or lactate dehydrogenase with decrease in hemoglobin
    - Reappearance of symptoms such as fatigue, dyspnea, palpitations, or hemoglobinuria
- Polysorbate 80 is listed as an inactive ingredient – review patient allergy list for potential cross reactivity

Patient-Centered Activities:[1,5]

- Anticipate treatment times in infusion center of 2-4 hours depending on infusion rate and monitoring time (some insurance providers may require specialty pharmacy and home infusion)
- If dose is missed by >3 days of maintenance schedule, will need to go back to weekly dosing for 2 doses
- Complete vaccination schedule as laid out above (ideally at least 2 weeks prior to therapy initiation)
- Contact healthcare provider or seek emergency medical care immediately for any signs and symptoms of a serious infection including but not limited to fever, headache, confusion, neck/back stiffness, body aches, light sensitivity
- Sutimlimab-jome increases the risk for developing autoimmune diseases such as systemic lupus erythematosus. Monitor for:
    - Joint pain/swelling
    - Rash on cheeks and nose
    - Unexplained fever
- Discuss with healthcare provider before starting any other immunosuppressant medication or receiving a live vaccine
- ENJAYMO Patient Solutions – Copay assistance program and patient assistance program with access to case managers and therapeutic education managers to help patients with access to treatment and understanding CAD and treatment with sutimlimab-jome

References:

1. Enjaymo. Package insert. Recordati Rare Diseases Inc; 2024.
2. Röth A, Barcellini W, D'Sa S, et al. Sutimlimab in Cold Agglutinin Disease. *New England Journal of Medicine.* 2021;384:1323–1334. doi:10.1056/NEJMoa2027760.
3. Röth A, Berentsen S, Barcellini W, et al. Sutimlimab in patients with cold agglutinin disease: results of the randomized placebo-controlled phase 3 CADENZA trial. *Blood.* 2022;140(9):980–991. doi:10.1182/blood.2021014955.
4. Adult Immunization Schedule Notes. Centers for Disease Control and Prevention. Updated July 2, 2025. Accessed September 12, 2025. https://www.cdc.gov/vaccines/hcp/imz-schedules/adult-notes.html.
5. Enjaymo website. https://www.enjaymo.com.