Sutimlimab (Enjaymo) – PA Criteria

HCPC: J1302

Sutimlimab (Enjaymo) is a classical complement inhibitor indicated for the treatment of hemolysis in adults with cold agglutinin disease (CAD). It is covered by South Dakota Medicaid following prior authorization when the patient meets the following criteria:

- **Initial therapy (must meet all):**
  - Prescribed by or in consultation with a hematologist
  - Individual is ≥18 years of age
  - Individual has a confirmed diagnosis of CAD based on **all** the following:
    - Chronic hemolysis (Ex. elevated lactated dehydrogenase [LDH], decreased haptoglobin, increased indirect bilirubin, increased reticulocyte count)
    - Positive polyspecific direct antiglobulin test (DAT)
    - Positive monospecific DAT specific for C3d
    - Cold agglutinin titer greater than or equal to 64 (1:64) at 4°C
    - IgG DAT less than or equal to 1+
    - Presence of one or more symptoms associated with CAD (i.e. symptomatic anemia, acrocyanosis, Raynaud's phenomenon, hemoglobinuria, disabling circulatory symptoms, or a major adverse vascular event)
  - Documentation is submitted indicating baseline hemoglobin ≤10 g/dL
  - Individual meets one of the following in regards to indication for therapy:
    - Therapy is being utilized in the emergency setting due to hemolysis
      - ***Retrospective authorization will be accepted for this medication in the emergency setting (when all below criteria are met) in efforts to prevent delay of care***
    - Individual has a failure, contraindication or intolerance to a rituximab containing regimen
    - Individual has hemolytic anemia that is unresponsive to B cell-directed therapies
  - Therapy is not being utilized in combination with other complement inhibitors [e.g., Soliris (eculizumab), Ultomiris (ravilizumab-cwzb), Empaveli (pegcetacoplan)
  - Individual has not received rituximab within three (3) months of initiation and will not be using rituximab with sutimlimab-jome (Enjaymo)
  - Cold agglutinin disease secondary to other factors has been ruled out (e.g. infection, rheumatologic disease, systemic lupus erythematosus, or overt hematologic malignancy)
  - Approval duration: 6 months
- **Continuation of Therapy (must meet all):**
  - Individual continues to meet initial therapy
  - Documentation of positive response to therapy by hemoglobin increase of ≥ 1.5 g/dL from pre-treatment baseline OR hemoglobin level ≥12 g/dL and **one** of the following:
    - Reduction in transfusion requirement (if previously transfusion dependent) after starting sutimlimab therapy
    - Improvement in anemia related symptoms
  - Approval duration: 1 year