

<b>POLICY NAME</b>	Enjaymo (sutimlimab)	<b>POLICY #</b>	<b>3169P</b>
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## Criteria

### Cold Agglutinin Disease

- ☐ **1.1** Diagnosis of primary cold agglutinin disease (CAD) as evidenced by the following:
  - Evidence of hemolysis (eg, high reticulocyte count, high lactate dehydrogenase [LDH], low haptoglobin)
  - Positive direct antiglobulin (Coombs) test for C3
  - Cold agglutinin titer of  $\geq 64$  at 4°C
- ☐ **1.2** Age 18 years or older
- ☐ **1.3** Hemoglobin level  $\leq 10.0$  g/dL
- ☐ **1.4** Bilirubin level above normal reference range
- ☐ **1.5** Prescribed by or in consultation with a hematologist (doctor of blood disorders) or other CAD specialist
- ☐ **1.6** Presence of one or more symptoms associated with CAD: symptomatic anemia, acrocyanosis, Raynaud's phenomenon, hemoglobinuria, disabling circulatory symptoms, or a major adverse vascular event
- ☐ **1.7** Documented trial of cold avoidance efforts (utilizing warm clothing when outdoors, avoiding cold rooms or environments, cold liquids, etc)
- ☐ **1.8** Documented trial and failure or contraindication to rituximab with or without bendamustine
- ☐ **1.9** Documentation of vaccination against encapsulated bacteria, including *Streptococcus pneumoniae* and *Neisseria meningitidis* OR will receive vaccine at least 2 weeks prior to first dose (unless treatment cannot be delayed)

### Exclusion Criteria – Any of the following prevents coverage

- ☐ **2.1** Secondary cold agglutinin syndrome such as autoimmune hemolytic anemia related to underlying viral infection, autoimmune disorder or lymphoid malignancy
- ☐ **2.2** Use in combination with rituximab and/or bendamustine