

POLICY NAME	Enjaymo (sutimlimab)	POLICY #	3169P
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Criteria

Cold Agglutinin Disease

- ☐ 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 ≥ 64 at 4°C
- ☐ Age 18 years or older
- ☐ Hemoglobin level ≤ 10.0 g/dL
- ☐ Bilirubin level above normal reference range
- ☐ Prescribed by or in consultation with a hematologist (doctor of blood disorders) or other CAD specialist
- ☐ 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
- ☐ Documented trial of cold avoidance efforts (utilizing warm clothing when outdoors, avoiding cold rooms or environments, cold liquids, etc)
- ☐ Documented trial and failure or contraindication to rituximab with or without bendamustine
- ☐ 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

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