Clinical Policy: Sutimlimab
Reference Number: CP.PHAR.503
Effective Date: FDA Approval Date
Last Review Date: 08.21
Line of Business: Commercial, HIM, Medicaid

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Sutimlimab is a monoclonal antibody that targets complement-mediated hemolysis.

FDA Approved Indication(s) [Pending]
Sutimlimab is indicated for the treatment of hemolysis in adult patients with primary, transfusion-dependent cold agglutinin disease (CAD).

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that sutimlimab is medically necessary when the following criteria are met:

I. Initial Approval Criteria*
   *Criteria will mirror the clinical information from the prescribing information once FDA-approved

A. Cold Agglutinin Disease (must meet all):
   1. Diagnosis of primary CAD,*
   2. Prescribed by or in consultation with a hematologist or oncologist;*
   3. Age ≥ 18 years;*
   4. Secondary CAD has been ruled out (i.e., cold agglutinin syndrome secondary to infection, rheumatologic disease, or active hematologic malignancy);*
   5. Member meets all of the following (a, b, c, and d):*  
      a. Active hemolysis as evidenced by elevated total bilirubin; 
      b. Polyspecific direct antiglobulin test (DAT) (i.e., Coombs test) is positive; 
      c. Monospecific DAT shows both of the following (i and ii):
         i. C3d DAT: strongly positive; 
         ii. IgG DAT: negative or weakly positive; 
      d. Cold agglutinin titer ≥ 64 at 4 degrees Celsius; 
   6. Hemoglobin ≤ 10 g/dL;*
   7. History of at least one documented blood transfusion within 6 months prior to initiating sutimlimab therapy;*
   8. Request meets all of the following (a, b, and c):*  
      a. Dose does not exceed one intravenous infusion on Day 0, Day 7, then once every other week;
b. For body weight < 75 kg, dose does not exceed 6.5 g;
c. For body weight ≥ 75 kg, dose does not exceed 7.5 g.

**Approval duration: 6 months**

**B. Other diagnoses/indications**
1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

**II. Continued Therapy***

*Criteria will mirror the clinical information from the prescribing information once FDA-approved*

**A. Cold Agglutinin Disease** (must meet all):
1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy as evidenced by both of the following since initiation of sutimlimab therapy (a and b):*
   a. Increase in hemoglobin > 2 g/dL or hemoglobin level > 11 g/dL;
   b. Transfusion free or decreased number of transfusions/blood units;
3. If request is for a dose increase, request meets all of the following (a, b, and c):*
   a. New dose does not exceed one intravenous infusion on Day 0, Day 7, then once every other week;
   b. For body weight < 75 kg, new dose does not exceed 6.5 g;
   c. For body weight ≥ 75 kg, new dose does not exceed 7.5 g.

**Approval duration: 12 months**

**B. Other diagnoses/indications**
1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

**III. Diagnoses/Indications for which coverage is NOT authorized:**

**A.** Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid or evidence of coverage documents.

**IV. Appendices/General Information**

*Appendix A: Abbreviation/Acronym Key*

- CAD: cold agglutinin disease
- DAT: direct antiglobulin test
- FDA: Food and Drug Administration

*Appendix B: Therapeutic Alternatives*

Not applicable
Appendix C: Contraindications/Boxed Warnings [Pending]
- Contraindication(s): pending
- Boxed warning(s): pending

Appendix D: Cold Agglutinins
- During passage through acral parts of the body, cooling of the blood allows cold agglutinins (CA) to bind to erythrocytes and cause agglutination.
- The antigen-IgM complex binds complement protein 1q (C1q) on the cell surface and initiates the classical complement pathway.
- C1 esterase activates C2 and C4, generating C3 convertase which results in the cleavage of C3 to C3a and C3b.
- Upon warming to 37°C in the central circulation, the CA detach from the cells, allowing agglutinated erythrocytes to separate, while C3b remains bound.
- C3b-opsonized cells are prone to phagocytosis by the mononuclear phagocytic system, mainly in the liver, a process known as extravascular hemolysis.
- On the surface of the surviving erythrocytes, C3b is cleaved, leaving high numbers of C3d molecules that can be detected by the DAT.


V. Dosage and Administration [Pending]

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<thead>
<tr>
<th>Indication</th>
<th>Dosing Regimen</th>
<th>Maximum Dose</th>
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<tbody>
<tr>
<td>CAD*</td>
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<td>Pending</td>
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VI. Product Availability [Pending]
 Pending

VII. References

**Coding Implications [Pending]**

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

<table>
<thead>
<tr>
<th>HCPCS Codes</th>
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<tr>
<th>Reviews, Revisions, and Approvals</th>
<th>Date</th>
<th>P&amp;T Approval Date</th>
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<tr>
<td>Policy created pre-emptively</td>
<td>07.07.20</td>
<td>08.20</td>
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<tr>
<td>3Q 2021 annual review: no significant changes as drug is not yet FDA-approved; references to HIM.PHAR.21 revised to HIM.PA.154; references reviewed and updated.</td>
<td>03.23.21</td>
<td>08.21</td>
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**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering
benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage
decisions and the administration of benefits are subject to all terms, conditions, exclusions and
limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy,
contract of insurance, etc.), as well as to state and federal requirements and applicable Health
Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting
may not be the effective date of this clinical policy. This clinical policy may be subject to
applicable legal and regulatory requirements relating to provider notification. If there is a
discrepancy between the effective date of this clinical policy and any applicable legal or
regulatory requirement, the requirements of law and regulation shall govern. The Health Plan
retains the right to change, amend or withdraw this clinical policy, and additional clinical
policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is
not intended to dictate to providers how to practice medicine. Providers are expected to exercise
professional medical judgment in providing the most appropriate care, and are solely responsible
for the medical advice and treatment of members. This clinical policy is not intended to
recommend treatment for members. Members should consult with their treating physician in
connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent
judgment and over whom the Health Plan has no control or right of control. Providers are not
agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and
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Providers, members and their representatives are bound to the terms and conditions expressed
herein through the terms of their contracts. Where no such contract exists, providers, members
and their representatives agree to be bound by such terms and conditions by providing services to
members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage
provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please
refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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