Clinical Policy Title:	sutimlimab
Policy Number:	RxA.753
Drug(s) Applied:	Enjaymo™
Original Policy Date:	04/18/2022
Last Review Date:	04/18/2022
Line of Business Policy Applies to:	All lines of business

Background

Enjaymo™ (sutimlimab-jome) is indicated to decrease the need for red blood cell (RBC) transfusion due to hemolysis in adults with cold agglutinin disease (CAD).

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
sutimlimab (Enjaymo™)	Cold agglutinin disease	Weight-based dosage weekly for two weeks then every two weeks: • For patients weighing 39 kg to less than 75 kg: 6,500 mg by intravenous infusion. • For patients weighing 75 kg or more: 7,500 mg by intravenous infusion.	• Weighing 75 kg or more: 7,500 mg/dose intravenous. • Weighing 39 to 74 kg: 6,500 mg/dose intravenous.

Dosage Forms

- Injection: 1,100 mg/22 mL (50 mg/mL) in a single-dose vial.

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

I. Initial Approval Criteria

A. Cold agglutinin disease (CAD) (must meet all):

1. Diagnosis of Primary Cold agglutinin disease confirmed by all of the followings (a, b, c, d, e and f);
   a. Chronic hemolysis;
   b. Polyspecific direct antiglobulin test (DAT) positive;
   c. Monospecific DAT strongly positive for C3d;
   d. Cold agglutinin titer >= 64 at 4-degree celsius;

e. Immunoglobulin G (IgG) DAT less than or equal to (<=) 1+;
f. No overt malignant disease;
2. Member age ≥ 18;
3. Prescribed by or in consultation with a hematologist;
4. Member has history of at least one documented blood transfusion within 6 months of starting Enjaymo™;
5. Hemoglobin level ≤ 10.0 g/dL;
6. Bilirubin level above normal reference range, including patients with Gilbert's syndrome;
7. Prescence of one or more symptoms associated with CAD (a, b, c, d, e or f);
   a. Symptomatic anemia
   b. Acrocyanosis
   c. Raynaud's phenomenon
   d. Hemoglobinuria
   e. Disabling circulatory symptoms
   f. Major adverse vascular event
8. Dose does not exceed one of the following (a, or b):
   a. Weighing 75 kg or more: 7,500 mg/dose intravenous.
   b. Weighing 39 to 74 kg: 6,500 mg/dose intravenous

Approval Duration
Commercial: 26 weeks
Medicaid: 26 weeks

II. Continued Therapy Approval

A. Cold agglutinin disease (CAD) (must meet all):
1. Member is currently receiving medication that has been authorized by RxAdvance or member has met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed one of the following (a or b)
   a. Weighing 75 kg or more: 7,500 mg/dose intravenous.
   b. Weighing 39 to 74 kg: 6,500 mg/dose intravenous

Approval Duration
Commercial: 12 months
Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
CAD: Cold agglutinin disease
DAT: Direct antiglobulin test

APPENDIX B: Therapeutic Alternatives
N/A

APPENDIX C: Contraindications/Boxed Warnings
- Contraindication(s):
  - Enjaymo™ is contraindicated in patients with known hypersensitivity to sutimlimab-jome or any of the inactive ingredients.
    *Contraindications listed reflect direct statements made in the manufacturer's package insert; for additional uses, warnings, and precautions, please refer to clinical guidelines.

- Boxed Warning(s):
  - None.

APPENDIX D: General Information

- Serious Infections: Ensure patients are vaccinated against encapsulated bacteria. Monitor patients for early signs and symptoms of infections.
- Infusion-Related Reactions: Monitor patients for infusion-related reactions, interrupt if reaction occurs, and institute appropriate medical management as needed.
- Risk of Autoimmune Disease: Monitor patients for signs and symptoms and manage medically.
- Recurrent Hemolysis After Enjaymo™ Discontinuation: Monitor patients for signs and symptoms of hemolysis if treatment with Enjaymo™ is interrupted.

References

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2. Sutimlimab, Lexi-Drug. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Available at: https://online.lexi.com/lco/action/doc/retrieve/docid/patch_f/7195539?cesid=a9ERIXS0xWm&searchUrl=%2Flco%2Faction%2Fsearch%3Fq%3Denjaymo%26t%3Dname%26va%3Denjaymo#. Accessed March 09, 2022.
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5. IPD Analytics IPD Analytics_RxInsights_New Drug Review_Enjaymo_03 2022. Available at: https://secure.ipdanalytics.com/User/Pharma/RxStrategy/Search?q=Enjaymo. Accessed March 09, 2022.
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7. Bioverativ, a Sanofi company. A Phase 3, Pivotal, Open-Label, Multicenter Study to Assess the Efficacy and Safety of Sutimlimab in Patients with Primary Cold Agglutinin Disease Who Have a Recent History of Blood Transfusion. clinicaltrials.gov; 2021. Available at: https://www.clinicaltrials.gov/ct2/show/NCT03347396. Accessed March 09, 2022.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	03/09/2022	04/18/2022