RXADVANCE
2 Park Central Drive
Southborough, MA 01772

Clinical Policy Title:	siltuximab
Policy Number:	RxA.473
Drug(s) Applied:	Sylvant®
Original Policy Date:	03/06/2020
Last Review Date:	12/07/2020
Line of Business Policy Applies to:	All lines of business

Background

Siltuximab (Sylvant®) is an interleukin-6 (IL-6) antagonist. It is indicated for the treatment of patients with multicentric Castleman's disease (MCD) who are human immunodeficiency virus (HIV) negative and human herpesvirus-8 (HHV-8) negative.

Limitation(s) of use: Sylvant® was not studied in patients with MCD who are HIV positive or HHV-8 positive because Sylvant® did not bind to virally produced IL-6 in a nonclinical study.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
siltuximab (Sylvant®)	Castleman's disease	11 mg/kg over 1 hour IV every 3 weeks	11 mg/kg

Dosage Forms

- Lyophilized powder in a single-use vial: 100 mg and 400 mg

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.

I. Initial Approval Criteria

A. Castleman's Disease (must meet all):

1. Diagnosis of Castleman's disease* (CD, angiofollicular lymph node hyperplasia) confirmed by biopsy of involved tissue (usually a lymph node);
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Meets one of the following (a or b):
   a. FDA-approved use for treatment of multicentric** Castleman's disease (MCD);
   b. NCCN-recommended use for second-line, single-agent treatment of relapsed or refractory unicentric** Castleman's disease (UCD);
5. Meets all of the following parameters prior to treatment (a, b, c, d, and e):
   a. Human immunodeficiency virus (HIV) negative;

b. Human herpesvirus-8 (HHV-8) negative;
c. Absolute neutrophil count: ≥ 1.0 x 10^9/L;
d. Platelet count ≥ 75 x 10^9/L;
e. Hemoglobin < 17 g/dL;

6. Request meets one of the following (a or b):
   a. Dose does not exceed 11 mg/kg every 3 weeks.
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

Approval duration
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy

A. Castleman's Disease (must meet all):

1. Currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. Meets the following laboratory parameters:
   a. Absolute neutrophil count: ≥ 1.0 x 10^9/L;
   b. Platelet count ≥ 50 x 10^9/L;
   c. Hemoglobin < 17 g/dL;
4. If request is for a dose increase, new dose does not exceed (a or b):
   a. 11 mg/kg every 3 weeks;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

Approval duration
Commercial: 12 months
Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
CD: Castleman's disease
HIV: human immunodeficiency virus
FDA: Food and Drug Administration
MCD: multicentric Castleman's disease
HHV-8: negative and human hperesvirus-8
UCD: unicentric Castleman's disease

APPENDIX B: Therapeutic Alternatives
Not applicable

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - Severe hypersensitivity reaction to siltuximab or any of the excipients in Sylvant®.
- Boxed warning(s):
  - None reported

APPENDIX D: General Information

*Group of lymphoproliferative disorders (classified under non-Hodgkin B-cell lymphomas) that share common histologic features

**MCD (systemic disease with symptoms that may include generalized peripheral lymphadenopathy, hepatosplenomegaly, frequent fevers, night sweats); UCD (localized disease that generally is asymptomatic)

References

1. Sylvant® Prescribing Information. Horsham, PA: Janssen Biotech, Inc.; December 2019. Available at www.sylvant.com . Accessed September 01, 2020.
2. Siltuximab. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at www.NCCN.org. Accessed October 03, 2020.
3. B-Cell Lymphomas (Version 4.2020). In: National Comprehensive Cancer Network Guidelines. Available at www.NCCN.org. Accessed September 01, 2020.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed 1. Clinical policy title was updated 2. Line of business policy applies to was updated to All lines of business 3. Background updated for “Limitation of use” 4. Continued Therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance..." 5. References were reviewed and updated.	09/01/2020	12/07/2020