Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 02/01/2020**
Policy Number: PA.CP.PHAR.329	**Effective Date: 01/01/2018** **Revision Date: 01/15/2020**
Policy Name: Siltuximab (Sylvant)	

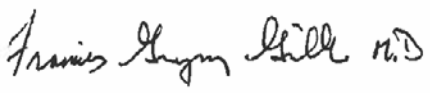
Type of Submission – Check all that apply:

- ☐ **New Policy**
- ✓ **Revised Policy***
- ☐ **Annual Review - No Revisions**
- ☐ **Statewide PDL -** *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

References reviewed and updated.

Name of Authorized Individual (Please type or print): **Francis G. Grillo, MD**	**Signature of Authorized Individual:** 

Clinical Policy: Siltuximab (Sylvant)

Reference Number: PA.CP.PHAR.329
Effective Date: 01/18
Last Review Date: 01/20

Coding Implications
Revision Log

Description
Siltuximab (Sylvant®) is an interleukin-6 (IL-6) antagonist.

FDA Approved Indication(s)
Sylvant 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.

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 Pennsylvania Health and Wellness® that Sylvant is **medically necessary** when the following criteria are met:

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*).

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

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

Approval duration: 6 months

B. Other diagnoses/indications: Refer to PA.CP.PMN.53

II. Continued Approval

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

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. Meets the following laboratory parameters:
   a. Absolute neutrophil count: $\geq 1.0 \times 10^9$/L;
   b. Platelet count $\geq 50 \times 10^9$/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: 12 months

B. Other diagnoses/indications (must meet 1 or 2):

1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to PA.CP.PMN.53

III. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

CD: Castleman's disease
FDA: Food and Drug Administration
HHV-8: negative and human hperesvirus-8
HIV: human immunodeficiency virus
MCD: multicentric Castleman's disease
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)

IV. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Castleman's disease	11 mg/kg over 1 hour IV every 3 weeks	11 mg/kg

V. Product Availability

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

VI. References

1. Sylvant Prescribing Information. Horsham, PA: Janssen Biotech, Inc.; May 2018. Available at www.sylvant.com. Accessed October 26, 2019.
2. Siltuximab. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at www.NCCN.org. Accessed October 26, 2019.
3. B-Cell Lymphomas (Version 5.2018). In: National Comprehensive Cancer Network Guidelines. Available at www.NCCN.org. Accessed October 26, 2019.

Coding Implications

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.

HCPCS Codes	Description
J2860	Injection, siltuximab, 10 mg

Reviews, Revisions, and Approvals	Date	Approval Date
Age added. Dose parameters delineated. References reviewed and updated.	02/18	
1Q 2019 annual review: added prescriber requirement; allowed COC for continued approval; added option for off-label dosing as supported by guidelines or literature; references reviewed and updated.	01/19	
1Q 2020 annual review: references reviewed and updated.	01/2020	