Clinical Policy: Siltuximab (Sylvant)

Reference Number: PA.CP.PHAR.329
Effective Date: 01/18
Last Review Date: 07/18

Coding Implications
Revision Log

Description
The intent of these criteria is to ensure that patients follow selection elements established by Pennsylvania Health and Wellness® clinical policy for siltuximab (Sylvant™).

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
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. Age ≥ 18 years;
3. Meets 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);
4. Meets the following parameters prior to treatment:
   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.
5. Dose does not exceed 11 mg/kg.
   a.

**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. No disease progression or unacceptable toxicity;
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 11 mg/kg.
   a.

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

Background

Description/Mechanism of Action:

Sylvant (siltuximab) is a human-mouse chimeric monoclonal antibody that binds human interleukin-6 (IL-6). Siltuximab binds human IL-6 and prevents the binding of IL-6 to both soluble and membrane bound IL-6 receptors. IL-6 has been shown to be involved in diverse normal physiologic processes such as induction of immunoglobulin secretion. Overproduction of IL-6 has been linked to systemic manifestations in patients with multicentric Castleman's disease (MCD).

Formulations:

Sylvant is packaged as a lyophilized powder for reconstitution in 100 mg or 400 mg single-use vials (reconstituted with Sterile Water for Injection to 20 mg/mL).

FDA Approved Indications:

Appendices

Appendix A: Abbreviation Key

CD: Castleman's disease
HHV-8: negative and human hperesvirus-8
HIV: human immunodeficiency virus
MCD: multicentric Castleman's disease
UCD: unicentric Castleman's disease

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	

References

i. Sylvant Prescribing Information. Horsham, PA: Janssen Biotech, Inc.; November 2015. Available at https://www.janssenmd.com/pdf/sylvant/SYLVANT-PI.pdf. Accessed November 20, 2017.
ii. Siltuximab. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at www.NCCN.org. Accessed August 20, 2017.
iii. Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (Version 2.2017). In: National Comprehensive Cancer Network Guidelines. Available at www.NCCN.org. Accessed August 20, 2017.