Clinical Policy: Siltuximab (Sylvant)

Reference Number: CP.PHAR.329
Effective Date: 03/17
Last Review Date: 03/17

Coding Implications
Revision Log

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

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

Policy/Criteria
It is the policy of health plans affiliated with Centene Corporation® 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. 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);
3. Meets the following parameters prior to treatment:
   a. Human immunodeficiency virus (HIV) negative;
   b. Human herpesvirus-8 (HHV-8) negative;
   c. Absolute neutrophil count: $\geq 1.0 \times 10^9$/L;
   d. Platelet count $\geq 75 \times 10^9$/L;
   e. Hemoglobin < 17 g/dL.

**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 CP.PHAR.57 – Global Biopharm Policy.

II. Continued Approval

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

1. Currently receiving medication via Centene benefit or member has previously met all initial approval criteria;
2. No disease progression or unacceptable toxicity;
3. Meets the following laboratory parameters:
   a. Absolute neutrophil count: $\geq 1.0 \times 10^9$/L;

b. Platelet count ≥50 x 10^9/L;
c. Hemoglobin <17 g/dL.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2):
1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy; or
2. Refer to CP.PHAR.57 - Global Biopharm Policy.

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:

Sylvant is an interleukin-6 (IL-6) antagonist/intravenous formulation indicated for:

- Treatment of patients with multicentric Castleman's disease (MCD) who are human immunodeficiency virus (HIV) negative and human herpesvirus-8 (HHV-8) negative.

Limitation 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.

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
Policy split from CP.PHAR.183 Excellus Other Specialty Pharmacy.	02/17	03/17

References

1. Sylvant prescribing information. Horsham, PA: Janssen Biotech, Inc.; November 2015. Available at https://www.janssenmd.com/pdf/sylvant/SYLVANT-PI.pdf. Accessed February 27, 2017.
2. Siltuximab. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at www.NCCN.org. Accessed February 27, 2017.
3. Non-Hodgkin's B-cell lymphomas (Version 2.2017). In: National Comprehensive Cancer Network Guidelines. Available at NCCN.org. Accessed February 27, 2017.
4. Aster JC, Brown JR, Munshi NC. Multicentric Castleman's disease. In: UpToDate, Waltham, MA: Walters Kluwer Health; 2017. Available at www.UpToDate.com. Accessed February 27, 2017.
5. Brown JR, Aster, JC, Munshi NC. Unicentric Castleman's disease. In: UpToDate, Waltham, MA: Walters Kluwer Health; 2017. Available at www.UpToDate.com. Accessed February 27, 2017.

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 distribution of this clinical policy or any information contained herein are strictly prohibited. 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.

Note: For Medicare members, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare coverage articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.