Clinical Policy: Siltuximab (Sylvant)

Reference Number: CP. PHAR.329
Effective Date: 03.01.17
Last Review Date: 02.18
Line of Business: Medicaid

Coding Implications
Revision Log

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

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 (which may include office chart notes and lab results) supporting that member has met all approval 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. Age ≥ 18 years;
3. 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);
4. 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;
5. Dose does not exceed 11 mg/kg.

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

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

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
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 11 mg/kg.

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.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – CP.PMN.53 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym 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

Appendix B: Therapeutic Alternatives

Not applicable

Appendix C: 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)*

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose

Castleman's disease	11 mg/kg over 1 hour IV every 3 weeks	11 mg/kg

VI. Product Availability

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

VII. References

1. 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.
2. Siltuximab. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at www.NCCN.org. Accessed August 20, 2017.
3. Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (Version 2.2017). In: National Comprehensive Cancer Network Guidelines. Available at www.NCCN.org. Accessed August 20, 2017.

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	P&T Approval Date
Policy split from CP.PHAR.183 Excellus Other Specialty Pharmacy.	02.01.17	03.17
Updated references and template.	08.20.17	11.17
1Q18 annual review: - No significant changes - References reviewed and updated.	11.20.17	02.18

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and 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.