

Clinical Policy: Siltuximab (Sylvant)

Reference Number: LA.PHAR.329

Effective Date: 11.04.23

Last Review Date: ~~04.30.24~~ 04.17.25

Line of Business: Medicaid

[Coding Implications](#)

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

****Please note: This policy is for medical benefit****

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 Louisiana Healthcare Connections 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) (a B-cell lymphoma subtype) confirmed by biopsy of involved tissue (usually a lymph node);
2. Prescribed by or in consultation with an oncologist;
3. Age \geq 18 years;
4. Sylvant is prescribed in one of the following ways (a or b):
 - a. As single-agent therapy for MCD;
 - b. As single-agent therapy for relapsed or refractory unicentric CD (UCD) (off-label);
5. Documented negative tests for ~~human immunodeficiency virus (HIV)~~ and ~~human herpesvirus-8 (HHV-8)~~;
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*).

**Prescribed regimen must be FDA-approved or recommended by NCCN.*

Approval duration: 6 months

B. Cytokine Release Syndrome (off-label) (must meet all):

1. Member has a scheduled chimeric antigen receptor (CAR) T cell therapy (e.g., Kymriah[®], Yescarta[®], Abecma[®], Tecartus[®], Breyanzi[®], Carvykti[®]);
2. Sylvant is prescribed in one of the following ways (a or b):
 - a. For the management of grade 4 cytokine release syndrome (CRS) that is refractory to high-dose corticosteroids and anti-IL-6 therapy;
 - b. As a replacement for the second dose of Actemra[®] ~~or~~ Tofidence[™], or Tyenne[®] when supplies are limited or unavailable for CRS or immunotherapy related neurotoxicity;
3. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: Up to 4 doses total

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

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: LA.PMN.53 for Medicaid.

II. Continued Therapy

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

1. Currently receiving medication via Louisiana Healthcare Connections benefit, or documentation supports that member is currently receiving Sylvant for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a or b):*
 - a. New dose does not exceed 11 mg/kg every 3 weeks;
 - b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN.*

Approval duration: 12 months

B. Cytokine Release Syndrome (off-label) (must meet all):

1. Documentation supports that member is currently receiving Sylvant for CAR T cell-induced CRS and member has not yet received 4 doses total;
2. Member is responding positively to therapy;
3. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: Up to 4 doses total

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

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: LA.PMN.53 for Medicaid.

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 – LA.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

CAR: chimeric antigen receptor	HHV-8: negative and human herpesvirus-8
CD: Castleman’s disease	HIV: human immunodeficiency virus
CRS: cytokine release syndrome	MCD: multicentric Castleman’s disease
FDA: Food and Drug Administration	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

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
CD	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.; December 2019. Available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/125496s018lbl.pdf. Accessed October ~~27, 2023~~ 25, 2024.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at www.nccn.org. Accessed ~~October 27, 2023~~ November 4, 2024.
3. ~~B-Cell Lymphomas~~ Castleman Disease Version ~~6.2023~~ 1.2024. National Comprehensive Cancer Network Guidelines. Available at https://www.nccn.org/professionals/physician_gls/pdf/b-cellcastleman.pdf. Accessed ~~October 27, 2023~~ November 4, 2024.

4. Management of Immunotherapy-Related Toxicities Version ~~3-2023~~ 2024. National Comprehensive Cancer Network Guidelines. Available at https://www.nccn.org/professionals/physician_gls/pdf/immunotherapy.pdf. Accessed ~~October 27, 2023~~ November 4, 2024.

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	LDH Approval Date
Converted corporate to local policy.	06.19.23	10.05.23
Annual review: in CRS initial criteria, added Sylvant <u>Sylvant</u> may be used to replace the second dose of Actemra OR Tofidence per NCCN; references reviewed and updated.	04.30.24	<u>08.20.24</u>
<u>Added that Sylvant may be used to replace the second dose of Tyenne per NCCN; added Carvykti as an additional example of a CAR-T therapy; references reviewed and updated.</u>	<u>04.17.25</u>	

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. LHCC 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.

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