

Sylvant® (siltuximab)
Effective 05/01/2023

Plan	<input checked="" type="checkbox"/> MassHealth UPPL <input type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Benefit	<input type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit (NLX)		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	Specialty Medications		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	N/A		

Overview

Sylvant® (siltuximab) is an interleukin-6 (IL-6) antagonist indicated for the treatment of patients with multicentric Castleman’s disease (MCD) who are human herpesvirus-8 (HHV-8) negative and human immunodeficiency virus (HIV) negative. It is a monoclonal antibody injection for intravenous infusion that works by blocking IL-6, a protein that stimulates abnormal growth of immune cells.

No PA	Drugs that require PA
	Sylvant® (siltuximab) ^{MB}

MB This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. The plan does not pay for this drug to be dispensed through the retail pharmacy.

Coverage Guidelines

Authorization may be reviewed on a case by case basis for members who are new to the plan currently receiving treatment with requested medication excluding when the product is obtained as samples or via manufacturer’s patient assistance programs.

OR

Authorization may be granted for members when all the following criteria are met, and documentation is provided:

1. Diagnosis of multicentric Castleman’s disease (MCD)
2. Member is HIV negative and HHV-8 negative
3. Member is ≥ 18 years of age
4. Member’s current weight
5. Results from hematological laboratory tests at baseline showing **ALL** of the following:
 - a. Absolute neutrophil count: ≥ 1.0 × 10⁹/L

- b. Platelet count: $\geq 75 \times 10^9/L$
- c. Hemoglobin: $< 17 \text{ g/dL}$

Continuation of Therapy

For initial reauthorization, physician must provide results from hematological laboratory tests showing **ALL** of the following:

- 1. Absolute neutrophil count: $\geq 1.0 \times 10^9/L$
- 2. Platelet count: $\geq 50 \times 10^9/L$
- 3. Hemoglobin: $< 17 \text{ g/dL}$

Subsequent reauthorizations will infer a positive response to therapy *without documentation* of hematological laboratory tests.

Limitations

- 1. Initial approvals will be granted for 3 weeks.
- 2. Reauthorizations will be granted for 12 months.
- 3. Members who have already started treatment on Sylvant® may be approved for any FDA-approved indication.

References

- 1. Sylvant® [package insert]. Hertfordshire, UK: EUSA Pharma (UK), Ltd.; 2019 Dec.
- 2. Casper C. The aetiology and management of Castleman disease at 50 years: translating pathophysiology to patient care. *Br J Haematol.* 2005;129(1):3-17.
- 3. Dispenzieri A, Armitage JO, Loe MJ, et al. The clinical spectrum of Castleman's disease. *Am J Hematol.* 2012;87(11):997-1002.
- 4. Waterston A, Bower M. Fifty years of multicentric Castleman's disease. *Acta Oncol.* 2004;43(8):698-704.
- 5. Fajgenbaum DC. HHV-8-negative/idiopathic multicentric Castleman disease. In: Basow DS (Ed). UpToDate [database on the internet]. Waltham (MA): UpToDate; 2021 [cited 2021 Jul 17]. Available from: <http://www.uptodate.com/utd/index.do>
- 6. Sylvant® (siltuximab) formulary dossier. Janssen Biotech, Inc., Data on file.
- 7. van Rhee F, Voorhees P, Dispenzieri A, Fossa A, Srkalovic G, Ide M et al. International, evidence-based consensus treatment guidelines for idiopathic multicentric Castleman disease. *Blood.* 2018 Nov 15;132(20):2115-2124.
- 8. First-ever Treatment Guidelines for Idiopathic Multicentric Castleman Disease! Paso Robles (CA): Castleman Disease Collaborative Network; 2018 Sep 28 [cited 2021 Jul 17]. Available from: <https://www.cdcn.org/news-events/first-ever-treatment-guidelines-for-idiopathic-multicentric-castleman-disease>.
- 9. Yao S. FDA approves Sylvant for rare Castleman's disease. Paso Robles (CA): Castleman Disease Collaborative Network; 2014 Apr 24 [cited 2021 Jul 17]. Available from: <https://www.cdcn.org/news-events/fda-approves-sylvant-for-rare-castlemans-disease>.

Review History

01/11/23 - Reviewed and created for Jan P&T; matched MH UPPL. Created criteria to be in compliance with Masshealth unified formulary requirements. Effective 4/1/23.

04/12/23 – Reviewed and updated for P&T. Admin: updated benefit coverage to align with coding. No clinical changes. Effective 5/1/23.

