

Reference number(s) 1861-A

# Specialty Guideline Management Sylvant

# **Products Referenced by this Document**

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated

Brand Name	Generic Name
Sylvant	siltuximab

## **Indications**

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

## FDA-approved Indications<sup>1</sup>

Sylvant is indicated for the treatment of patients with multicentric Castleman's disease who are human immunodeficiency virus (HIV) negative and human herpesvirus-8 (HHV-8) negative.

#### Compendial Uses<sup>2</sup>

- Castleman's disease
- CAR T-cell related toxicities Cytokine release syndrome (CRS)

All other indications are considered experimental/investigational and not medically necessary.

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#### **Documentation**

Submission of the following information is necessary to initiate the prior authorization review: medical record documentation of HIV and HHV-8 status (where applicable)

# Coverage Criteria<sup>1,2</sup>

#### Castleman's disease<sup>1,2</sup>

Authorization of 12 months may be granted for treatment of Castleman's disease (CD) as a single agent when either of the following criteria are met:

- Member has multicentric CD and any of the following:
  - Active idiopathic disease with no organ failure that is human immunodeficiency virus-1 (HIV-1) negative and human herpesvirus-8 (HHV-8) negative and the requested drug will be used as first-line therapy
  - Relapsed/refractory or progressive disease that is HHV-8 negative
  - Fulminant/severe disease that is HHV-8 negative
- Member has relapsed/refractory or progressive unresectable unicentric CD that is HIV-1 negative and HHV-8 negative

### Cytokine release syndrome<sup>2</sup>

Authorization of 1 month may be granted for treatment of chimeric antigen receptor (CAR) T cell-induced cytokine release syndrome when either of the following criteria are met:

- Grade 4 cytokine release syndrome is refractory to high-dose corticosteroids and anti-IL-6 therapy.
- The requested medication will be used as a replacement for the second dose of tocilizumab when supplies are limited or unavailable.

# **Continuation of Therapy**

#### Castleman's disease

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for multicentric and relapsed/refractory or progressive unresectable unicentric Castleman's disease when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

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## Cytokine release syndrome

All members (including new members) requesting authorization for continuation of therapy must meet all requirements in the coverage criteria section.

#### References

- 1. Sylvant [package insert]. Bridgewater, NJ: Recordati Rare Diseases, Inc.; June 2024.
- 2. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed January 21, 2025.