CVS Caremark®

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| 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 Indications1

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 Uses2

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

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

## 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 Criteria1,2

### Castleman’s disease1,2

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 syndrome2

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.

### 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.