

SPECIALTY GUIDELINE MANAGEMENT

SYLVANT (siltuximab)

POLICY

I. 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.

A. FDA-Approved Indication

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.

B. Compendial Use

1. Relapsed/refractory unicentric Castleman's disease
2. CAR T-cell related toxicities - Cytokine release syndrome (CRS)

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

II. 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).

III. CRITERIA FOR INITIAL APPROVAL

A. **Multicentric Castleman's disease or relapsed/refractory unicentric Castleman's disease**^{1,2}

Authorization of 12 months may be granted for treatment of active multicentric Castleman's disease with no organ failure or relapsed/refractory unicentric Castleman's disease when both of the following criteria are met:

1. Member is human immunodeficiency virus (HIV) negative and human herpesvirus-8 (HHV-8) negative.
2. The requested medication is used as a single agent.

B. **Cytokine release syndrome**

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:

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

IV. CONTINUATION OF THERAPY

A. **Multicentric Castleman's disease or relapsed/refractory unicentric Castleman's disease**

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

Reference number
1861-A

B. Cytokine release syndrome

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

V. REFERENCES

1. Sylvant [package insert]. Hemel Hempstead, Hertfordshire, U.K.: EUSA Pharma, LTD; December 2019.
2. The NCCN Drugs & Biologics Compendium® © 2023 National Comprehensive Cancer Network, Inc. <https://www.nccn.org>. Accessed January 6, 2023.