## 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. CRITERIA FOR INITIAL APPROVAL

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

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. Sylvant 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. Sylvant will be used as a replacement for the second dose of tocilizumab when supplies are limited or unavailable.

## **III. 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.

## B. Cytokine release syndrome

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

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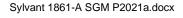


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Reference number 1861-A

## **IV. REFERENCES**

- 1. Sylvant [package insert]. Hemel Hempstead, Hertfordshire, U.K.: EUSA Pharma, LTD; December 2019.
- 2. The NCCN Drugs & Biologics Compendium® © 2021 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed October 1, 2021.



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