Reference number
1861-A

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.

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.