Siltuximab (Sylvant™)

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

The proposal is to add text/statements in red and to delete text/statements with strikethrough:

POLICY

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 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.

Compendial Uses
- ~~Relapsed/refractory unicentric~~ 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 CRITERIA ~~FOR INITIAL APPROVAL~~

~~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 (CD) as a single agent ~~with no organ failure or relapsed/refractory unicentric Castleman's disease~~ when either ~~both~~ of the following criteria are met:
- Member has multicentric CD and any of the following:
  - Active idiopathic disease with no organ failure that ~~Member~~ 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
  - ~~The requested medication is used as a single agent.~~
- Member has relapsed/refractory or progressive unresectable unicentric CD that is HIV-1 negative and HHV-8 negative

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:

- 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

~~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 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 ~~initial authorization~~ criteria section.

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

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.

EFFECTIVE DATE

ID_CHS