Medical Policy:

Sylvant (siltuximab)

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.167	January 3, 2024	July 15, 2019

Definitions

Siltuximab is a human-mouse chimeric monoclonal antibody that binds interleukin-6 (IL-6) and prevents the binding of IL-6 to soluble and membrane-bound IL-6 receptors. IL-6 can induce immunoglobulin secretion, and its overproduction is associated with systemic effects in patients with multicentric Castleman's disease.

Length of Authorization

Coverage will be provided for 6 months and may be renewed.

Dosing Limits [Medical Benefit]

Max Units (per dose and over time):

130 billable units per 21 days

Guideline

I. Initial Approval Criteria

Sylvant *may be considered medically necessary in the following conditions:*

1. Patient is human immunodeficiency virus (HIV) negative; **AND**
2. Patient is human herpes virus-8 (HHV-8) negative; **AND**
3. Patient is currently free of all clinically significant infections; **AND**
4. Patient will NOT receive any live vaccines while being treated with Sylvant; **AND**
5. Must be used as a single agent; **AND**
6. Patient has a diagnosis of **Multicentric Castleman's Disease† OR**
7. Patient has a diagnosis of **Unicentric Castleman's Disease‡; AND**
    i. Must be used second-line for relapsed or refractory disease.

† FDA Approved Indication(s); **‡** Compendia Recommended Indication(s);

Limitations/Exclusions

Sylvant is not considered medically necessary for when any of the following selection criteria is met:

1. Dosing exceeds dose limit of Sylvant (Siltuximab).
2. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature may be deemed as not approvable and therefore not reimbursable.

II. Renewal Criteria

1. Patient continues to meet INITIAL APPROVAL CRITERIA.
2. Tumor response with disease stabilization or reduction of tumor size and spread.
3. Absence of unacceptable toxicity from the drug including: Severe infusion related reactions, GI perforation, etc.

Dosage/Administration

Indication	Dose
All indications	11 mg/kg intravenously every 21 days

Applicable Procedure Codes

Code	Description
J2860	Injection, siltuximab, 10 mg, 1 billable unit = 10 mg

Applicable NDCs

Code	Description
57894-0420-xx	Sylvant 100 mg single-use vial
57894-0421-xx	Sylvant 400 mg single-use vial

ICD-10 Diagnoses

Code	Description
D47.Z2	Castleman disease

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	1/3/2024	Annual Review: No criteria changes
EmblemHealth & ConnectiCare	4/26/2023	Annual Review: Added: 1. Patient has a diagnosis of Unicentric Castleman's Disease; AND i. Must be used second-line for relapsed or refractory disease. Removed "must be used second-line for relapsed or refractory disease" under Multicentric Castleman's Disease. Removed Code D36.0, R59, R59.1, R59.9
EmblemHealth & ConnectiCare	1/13/2023	Transfer to New Template
EmblemHealth & ConnectiCare	7/15/2019	New Policy

References

1. Sylvant [package insert]. Horsham, PA; Janssen Biotech; November 2015. Accessed March 2019
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for siltuximab. National Comprehensive Cancer Network, 2019. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc." To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed March 2019.