Medical Policy

Healthcare Services Department

Policy Name	Policy Number	Scope
Sylvant (siltuximab)	MP-RX-FP-87-23	☒ MMM MA ☒ MMM Multihealth

Service Category

☐ Anesthesia
☐ Surgery
☐ Radiology Procedures
☐ Pathology and Laboratory Procedures
☐ Medicine Services and Procedures
☐ Evaluation and Management Services
☐ DME/Prosthetics or Supplies
☒ Part B DRUG

Service Description

This document addresses the use of Sylvant (siltuximab) , a drug approved by the Food and Drug Administration (FDA) for the treatment of multicentric Castleman's disease in individuals who are human immunodeficiency virus (HIV) negative and human herpesvirus-8 (HHV-8) negative.

Background Information

This document addresses the use of Sylvant (siltuximab). Sylvant is a monoclonal antibody which binds to interleukin-6 (IL-6) receptors and inhibits release of proinflammatory cytokines primarily used to treat multicentric Castleman's disease.

The FDA approved indications for Sylvant include treatment of multicentric Castleman's disease in individuals who are human immunodeficiency virus (HIV) negative and human herpesvirus-8 (HHV-8) negative. Sylvant has a labeled warning that it should not be administered to individuals with severe infections; and those with concurrent lymphoma were excluded from clinical trials.

Other Uses

The National Comprehensive Cancer Network® (NCCN) provides additional recommendations with a category 2A level of evidence for the use of Sylvant in relapsed or refractory, surgically unresectable unicentric Castleman's disease. However, available literature is limited to small case reports and retrospective studies. NCCN recently updated guidelines for management of immunotherapy-related toxicities to include the use of siltuximab as an option for cytokine release syndrome refractory to high-dose corticosteroids and anti-IL6 therapy or to replace tocilizumab when supplies limited. There is limited evidence to support these recommendations.

Definitions and Measures Castleman's disease (CD):

A rare, non-cancerous disorder that affects the lymph nodes and other immune-cell structures throughout the body. CD has two variants: unicentric CD and multicentric Castleman's disease, and is also known as giant lymph node hyperplasia and angiofollicular lymph node hyperplasia

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Approved Indications

A. Multicentric Castleman's disease in individuals who are human immunodeficiency virus (HIV) negative and human herpesvirus-8 (HHV-8) negative.

Other Uses

A. Relapsed or refractory, surgically unresectable unicentric Castleman's disease.

B. Cytokine release syndrome refractory to high-dose corticosteroids and anti-IL6 therapy or to replace tocilizumab when supplies are limited.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

HCPCS	Description
J2860	Injection, siltuximab, 10 mg [Sylvant]

ICD-10	Description
D47.Z2	Castleman disease

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Medical Necessity Guidelines

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Sylvant (siltuximab)

A. Criteria For Initial Approval

Requests for Sylvant (siltuximab) may be approved for the following:

i. Individual has a diagnosis of Multicentric Castleman's; **AND**
ii. Sylvant (siltuximab) is used as a single agent; **AND**
iii. Individual is human immunodeficiency virus negative; **AND**
iv. Individual is human herpesvirus-8 negative; **AND**
v. No concurrent clinically significant infection (for example, Hepatitis B or C); **AND**
vi. No concurrent lymphoma.

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Reference Information

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: January 3, 2023.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.
4. NCCN Clinical Practice Guidelines in Oncology™. © 2022 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on January 3, 2023.
   a. B-Cell Lymphomas. V5.2022. Revised July 12, 2022.
   b. Management of Immunotherapy-related toxicities. V1.2022. Revised February 28, 2022.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.

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Policy History

Revision Type	Summary of Changes	P&T Approval Date	MPCC Approval Date
Annual Review 03/24/2025	Validation of information to ensure is up to date. Word formatting, indentation alignment.	4/16/2025	5/6/2025
Policy Inception	Elevance Health's Medical Policy adoption.	N/A	11/30/2023