

Medical Policy:

Sylvant (siltuximab)

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

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The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as “EmblemHealth”), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

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.