Siltuximab (Sylvant™)

NDC CODE(S) 73090-0420-XX - SYLVANT 100MG Solution Reconstituted (EUSA PHARMA (US), LLC)
73090-0421-XX - SYLVANT 400MG Solution Reconstituted (EUSA PHARMA (US), LLC)

DESCRIPTION

Siltuximab is a monoclonal antibody that binds the cytokine interleukin-6 (IL-6). This prevents IL-6 from binding to both soluble and membrane-bound IL-6 receptors. IL-6 is involved in diverse physiological processes, including coordination of the immune response to infection. When IL-6 is overproduced by cells within the lymph nodes it contributes to overgrowth of lymphatic cells and other systemic symptoms

POLICY

- Siltuximab for the treatment of Castleman's disease is considered ***medically necessary*** if the medical appropriateness criteria are met. **(See Medical Appropriateness below.)**
- Siltuximab for the treatment of other conditions/diseases is considered ***investigational.***

MEDICAL APPROPRIATENESS

INITIAL APPROVAL CRITERIA

- Patient is at least 18 years of age; **AND**

Universal Criteria
- Patient is human immunodeficiency virus (HIV) negative**; AND**
- Patient is human herpes virus-8 (HHV-8) negative**; AND**
- Patient is currently free of all clinically significant active infections; **AND**
- Patient will **NOT** receive any live vaccines during treatment with siltuximab; **AND**
- Must be used as a single agent; **AND**

Multicentric Castleman's Disease (MCD)

Unicentric Castleman's Disease (UCD)
- Must be used second-line therapy for relapsed or refractory disease; **AND**
- Patient has plasmacytic/mixed histology

RENEWAL CRITERIA

- Patient continues to meet universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in initial approval criteria; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: gastrointestinal perforation, severe infusion related reactions and severe hypersensitivity, etc.

DOSAGE/ADMINISTRATION

INDICATION	DOSE

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All indications	Administer 11 mg/kg intravenously every 21 days until treatment failure

LENGTH OF AUTHORIZATION

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

DOSAGE LIMITS

Max Units (per dose and over time) [HCPCS Unit]:

- 130 billable units every 21 days

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.

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, the express terms of the health plan will govern.

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).

SOURCES

1. Sylvant [package insert]. Hemel Hempstead, Hertfordshire, U.K.; EUSA Pharma (UK), Ltd; December 2019. Accessed December 2020.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for siltuximab. National Comprehensive Cancer Network, 2020. 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 December 2020.
3. van Rhee F, Wong RS, Munshi N, et al. Siltuximab for multicentric Castleman's disease: a randomised, double-blind, placebo-controlled trial. Lancet Oncol. 2014 Aug;15(9):966-74. doi: 10.1016/S1470-2045(14)70319-5. Epub 2014 Jul 17.
4. Kurzrock R, Voorhees PM, Casper C, et al. A phase I, open-label study of siltuximab, an anti-IL-6 monoclonal antibody, in patients with B-cell non-Hodgkin lymphoma, multiple myeloma, or Castleman disease. Clin Cancer Res. 2013 Jul 1;19(13):3659-70. doi: 10.1158/1078-0432.CCR-12-3349. Epub 2013 May 9.

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5. Lexicomp Online. (2020, March). AHFS DI. Siltuximab. Retrieved January 20, 2021 from Lexicomp Online with AHFS.
6. MICROMEDEX Healthcare Series. Drugdex Evaluations. (2020, December). Siltuximab. Retrieved January 20, 2021 from MICROMEDEX Healthcare Series.

EFFECTIVE DATE 6/2/2021

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