

Medical Drug Clinical Criteria

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| Subject: | Sylvant (siltuximab) | | |
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Overview

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. It is 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.

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. NCCN guidelines for management of immunotherapy-related toxicities to include the use of siltuximab as an option for chimeric antigen receptor (CAR) T-cell related cytokine release syndrome refractory to high-dose corticosteroids and anti-IL-6 therapy.

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.

Clinical Criteria

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.

Sylvant (siltuximab)

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~~

- OR**
- V. Individual has a diagnosis of relapsed/refractory unicentric Castleman Disease (NCCN 2A); **AND**
 - VI. Sylvant (siltuximab) used as a single agent; **AND**
 - VII. Individual is Human immunodeficiency virus negative; **AND**
 - VIII. Individual is Human herpes-8 negative; **AND**

- OR**
- IX. Individual has a diagnosis of Grade 4 chimeric antigen receptor (CAR) T cell-induced CRS (NCCN 2A); **AND**
 - X. ~~CRS is refractory to high-dose corticosteroids and other anti-IL-6 therapy.~~

Requests for Sylvant (siltuximab) may not be approved for the following:

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- I. Individual has a current severe infection: **OR**
II. #When the above criteria are not met and for all other indications.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS

J2860 Injection, siltuximab, 10 mg [Sylvant]

ICD-10 Diagnosis

D47.Z2 Castleman disease

Document History

Revised: 02/23/2024

Document History:

- 02/23/2024 – Annual Review: Include use in immunotherapy-related toxicity and unicentric Castleman disease per NCCN; update multicentric Castleman disease per NCCN. Coding Reviewed: No changes.
- 02/24/2023 – Annual Review: No changes. Coding Reviewed: No changes.
- 02/24/2022 – Annual Review: No changes. Coding Reviewed: No changes.
- 02/25/2022 – Annual Review: No changes. Coding Reviewed: No changes.
- 02/19/2021 – Annual Review: No changes. Coding Reviewed: No changes.
- 02/21/2020 – Annual Review: Wording and formatting changes. Coding Reviewed: No changes.
- 05/17/2019 – Select Review: Update Sylvant criteria to specify use as single agent for consistency and in alignment with NCCN guideline recommendations. Coding Reviewed: No changes.

References

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 8, 2024.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2024; Updated periodically.
4. NCCN Clinical Practice Guidelines in Oncology™. © 2024 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on January 8, 2024.
 - a. B-Cell Lymphomas. V6.2023. Revised October 10, 2023.
 - b. Management of Immunotherapy-related toxicities. V1.2024. Revised December 7, 2023.

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

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