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 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-IL-6 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.

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.

Requests for Sylvant (siltuximab) may not be approved if 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

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Document History:

- 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. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2022. URL: http://www.clinicalpharmacology.com. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: January 14, 2022.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
5. 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 14, 2022.
    a. B-Cell Lymphomas. V5.2021. Revised September 22, 2021.
    b. Management of Immunotherapy-related toxicities. V4.2021. Revised September 27, 2021.

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.