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Last Review Date: September 8, 2023

Sylvant

Description

Sylvant (siltuximab)

Background
Sylvant (siltuximab) is used to treat patients with multicentric Castleman's disease (MCD), which is a rare disorder that is similar to lymphoma (cancer of the lymph nodes). MCD causes an abnormal overgrowth of immune cells in lymph nodes and related tissues in the body. The disease usually affects adults who often suffer from fever, night sweats, weight loss and weakness or fatigue because their body's immune system is weakened and cannot fight infections. Sylvant is an injection that works by blocking a protein that stimulates abnormal growth of immune cells (1).

Regulatory Status
FDA-approved indication: Sylvant is an interleukin-6 (IL-6) antagonist indicated for the treatment of patients with multicentric Castleman's disease (MCD) who are human immunodeficiency virus (HIV) negative and human herpesvirus-8 (HHV-8) negative (1).

Limitations of Use: (1)
Sylvant was not studied in patients with MCD who are HIV positive or HHV-8 positive because Sylvant did not bind to virally produced IL-6 in a nonclinical study.

Severe hypersensitivity reactions to Sylvant or any of the excipients have occurred in patients during and after infusion. Physician should stop the infusion if patient develops signs of anaphylaxis (1).

Sylvant should not be administered to patients with severe infections until the infection resolves (1).

Safety and effectiveness of Sylvant in pediatric patients have not been established (1).

Related policies
Actemra, Revlimid

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Sylvant may be considered **medically necessary** if the conditions indicated below are met.

Sylvant may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Multicentric Castleman's disease (MCD)

AND ALL of the following:
1. Human immunodeficiency virus (HIV) negative
2. Human herpesvirus-8 (HHV-8) negative

Prior – Approval *Renewal* Requirements

Same as Above

Policy Guidelines

Pre - PA Allowance

None

Prior – Approval

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Sylvant is the first FDA-approved drug to treat patients with MCD. Sylvant is used for the treatment multicentric Castleman's disease who are human immunodeficiency virus (HIV) negative and human herpesvirus-8 (HHV-8) negative (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Sylvant while maintaining optimal therapeutic outcomes.

References

1. Sylvant [package insert]. Hemel Hempstead, Hertfordshire: EUSA Pharma, Ltd.; December 2019.
2. NCCN Drugs & Biologics Compendium® Siltuximab 2023. National Comprehensive Cancer Network, Inc. Accessed on July 28, 2023.

Policy History

Date	Action
September 2014	PMPC review
October 2014	New addition to PA
December 2016	Annual editorial review and reference update. Policy number changed from 5.18.10 to 5.20.10.
December 2017	Annual editorial review
November 2018	Annual review and reference update
December 2019	Annual review
December 2020	Annual review and reference update
September 2021	Annual review and reference update
September 2022	Annual review and reference update
September 2023	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 8, 2023 and is effective on October 1, 2023.