Sylvant

Description

Sylvant (situximab)

Background
Sylvant is used to treat patients with multicentric Castleman’s disease (MCD), a rare disorder 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 labeled 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

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**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 in patients 18 years of age and older for the treatment multicentric Castleman’s disease and if the conditions indicated below are met.

Sylvant is considered investigational for patients less than 18 years of age and 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

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**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

Policy History

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<td>September 2014</td>
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<td>October 2014</td>
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Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 6, 2019 and is effective on January 1, 2020.