BlueCross BlueShield Federal Employee Program

SYLVANT
(siltuximab)

RATIONALE FOR INCLUSION IN PA PROGRAM

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).

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).

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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 2024. National Comprehensive Cancer Network, Inc. Accessed on July 18, 2024.