BlueCross BlueShield
Federal Employee Program

SARCLISA
(isatuximab-irfc)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Sarclisa (isatuximab-irfc) is a CD38 monoclonal antibody indicated for the treatment of multiple myeloma. Multiple myeloma is a cancer that forms in a type of white blood cells called plasma cells. CD38 is a transmembrane protein found on the surface of hematopoietic cells (cells that give rise to all other blood cells), including multiple myeloma and other cell types. Sarclisa binds to the CD38 receptors and inhibits the growth of tumor cells by inducing cell death (1).

Regulatory Status

FDA-approved indications: Sarclisa is a CD38-directed cytolytic antibody indicated: (1)

- in combination with pomalidomide and dexamethasone, for the treatment of adult patients with multiple myeloma who have received at least 2 prior therapies including lenalidomide and a proteasome inhibitor.
- in combination with carfilzomib and dexamethasone, for the treatment of adult patients with relapsed or refractory multiple myeloma who have received 1 to 3 prior lines of therapy.
- in combination with bortezomib, lenalidomide and dexamethasone, for the treatment of adult patients with newly diagnosed multiple myeloma who are not eligible for autologous stem cell transplant (ASCT).

Sarclisa may cause infusion-related reactions, second primary malignancies, laboratory test interference and neutropenia. Complete blood counts should be monitored periodically during treatment. Patients with neutropenia should be monitored for signs of infection. The use of antibiotics and antiviral prophylaxis during treatment should be considered (1).

Sarclisa can cause fetal harm when administered to a pregnant woman. Female patients of reproductive potential should be advised to use an effective method of contraception during treatment with Sarclisa and for at least 5 months after the last dose. The combination of Sarclisa with pomalidomide or lenalidomide is contraindicated in pregnant women because pomalidomide or lenalidomide may cause birth defects and death of the unborn child (1).

The safety and effectiveness of Sarclisa in pediatric patients less than 18 years of age have not been established (1).

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Summary

Sarclisa (isatuximab-irfc) is a CD38 monoclonal antibody indicated for the treatment of multiple myeloma. Multiple myeloma is a cancer that forms in a type of white blood cells called plasma cells. CD38 is a transmembrane protein found on the surface of hematopoietic cells (cells that give rise to all other blood cells), including multiple myeloma and other cell types. Sarclisa binds to the CD38 receptors and inhibits the growth of tumor cells by inducing cell death. Sarclisa can cause fetal harm when administered to a pregnant woman. The safety and effectiveness of Sarclisa have not been established in pediatric patients (1).

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

References

1. Sarclisa [package insert]. Bridgewater, NJ: Sanofi-aventis U.S. LLC; September 2024.
2. NCCN Drugs & Biologics Compendium® Isatuximab-irfc 2024. National Comprehensive Cancer Network, Inc. Accessed on November 8, 2024.