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Section:	Prescription Drugs	**Effective Date:**	July 1, 2024
Subsection:	Antineoplastic Agents	**Original Policy Date:**	March 27, 2020
Subject:	Sarclisa	**Page:**	1 of 4

Last Review Date: June 13, 2024

Sarclisa

Description

Sarclisa (isatuximab-irfc)

Background
Sarclisa (isatuximab-irfc) is a CD38 monoclonal antibody indicated for the treatment of multiple myeloma in patients who have received prior therapy. 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.

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 is contraindicated in pregnant women because pomalidomide 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).

Related Policies
Darzalex, Darzalex Faspro

Policy

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

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

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

Prior-Approval Requirements

Age 18 years of age and older

Diagnoses

Patient must have **ONE** of the following:

1. Multiple myeloma (MM)
    a. Used in combination with pomalidomide and dexamethasone
    b. Patient has received at least two prior therapies including the following:
        i. Proteasome inhibitor (PI)
        ii. Lenalidomide (Revlimid)
2. Relapsed or refractory multiple myeloma (MM)
    a. Used in combination with carfilzomib and dexamethasone
    b. Patient has received one to three prior lines of therapy

AND ALL of the following for **ALL** diagnoses:

1. Prescriber agrees to monitor complete blood counts (CBC)
2. Females of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Sarclisa and for 5 months after the final dose

Prior – Approval *Renewal* Requirements

Age 18 years of age and older

Diagnosis

Patient must have the following:

Multiple myeloma (MM)

AND ALL of the following:

1. **NO** disease progression or unacceptable toxicity
2. Prescriber agrees to monitor complete blood counts (CBC)
3. Females of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Sarclisa and for 5 months after the final dose

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Sarclisa (isatuximab-irfc) is a CD38 monoclonal antibody indicated for the treatment of multiple myeloma in patients who have received prior therapy. 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; November 2023.
2. NCCN Drugs & Biologics Compendium® Isatuximab-irfc 2024. National Comprehensive Cancer Network, Inc. Accessed on April 24, 2024.

Policy History

Date	Action
March 2020	Addition to PA
June 2020	Annual review
September 2020	Annual review
December 2020	Annual review
April 2021	Addition of indication: relapsed or refractory multiple myeloma. Added contraception requirement for female patients of reproductive potential to align with product label.
June 2021	Annual review and reference update
June 2022	Annual review and reference update
March 2023	Annual review and reference update
December 2023	Annual review and reference update
June 2024	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 13, 2024 and is effective on July 1, 2024.