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Section:	Prescription Drugs	**Effective Date:**	July 31, 2026
Subsection:	Antineoplastic Agents	**Original Policy Date:**	March 27, 2020
Subject:	Sarclisa	**Page:**	1 of 5

Last Review Date: March 6, 2026

Sarclisa

Description

Sarclisa (isatuximab-irfc)

Sarclisa Escena (isatuximab-irfc)

Background
Sarclisa and Sarclisa Escena (isatuximab-irfc) are CD38 monoclonal antibodies 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 and Sarclisa Escena bind to the CD38 receptors and inhibit the growth of tumor cells by inducing cell death (1-2).

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.

Sarclisa Escena is a CD38-directed cytolytic antibody indicated: (2)

- in combination with pomalidomide and dexamethasone, for the treatment of adult patients with multiple myeloma who have received at least 1 prior therapy including lenalidomide and a proteasome inhibitor.

Sarclisa and Sarclisa Escena are both also indicated: (1-2)

- 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 and Sarclisa Escena 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 (1-2).

Sarclisa and Sarclisa Escena 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 or Sarclisa Escena, and for at least 5 months or 7 months after the last dose, respectively. The combination of Sarclisa or Sarclisa Escena with pomalidomide or lenalidomide is contraindicated in pregnant women because pomalidomide or lenalidomide may cause birth defects and death of the unborn child (1-2).

The safety and effectiveness of Sarclisa and Sarclisa Escena in pediatric patients less than 18 years of age have not been established (1-2).

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

Sarclisa and Sarclisa Escena 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. Sarclisa **only**: Patient has received at least two prior therapies including a proteasome inhibitor (PI) and lenalidomide (Revlimid)
    c. Sarclisa Escena **only**: Patient has received at least one prior therapy including a proteasome inhibitor (PI) and 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
3. Newly diagnosed multiple myeloma (MM)
    a. Used in combination with bortezomib, lenalidomide, and dexamethasone
    b. Patient is not eligible for autologous stem cell transplant (ASCT)

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

1. Prescriber agrees to monitor complete blood counts (CBC)
2. Females of reproductive potential **only**:
    a. Sarclisa **only**: patient will be advised to use effective contraception during treatment with Sarclisa and for 5 months after the last dose
    b. Sarclisa Escena **only**: patient will be advised to use effective contraception during treatment with Sarclisa Escena and for 7 months after the last 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**:
    a. Sarclisa **only**: patient will be advised to use effective contraception during treatment with Sarclisa and for 5 months after the last dose
    b. Sarclisa Escena **only**: patient will be advised to use effective contraception during treatment with Sarclisa Escena and for 7 months after the last dose

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Sarclisa and Sarclisa Escena (isatuximab-irfc) are CD38 monoclonal antibodies 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 and Sarclisa Escena bind to the CD38 receptors and inhibit the growth of tumor cells by inducing cell death. Sarclisa and Sarclisa Escena can cause fetal harm when administered to a pregnant woman. The safety and effectiveness of Sarclisa and Sarclisa Escena have not been established in pediatric patients (1-2).

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

References

1. Sarclisa [package insert]. Morristown, NJ: Sanofi-aventis U.S. LLC; October 2024.
2. Sarclisa Escena [package insert]. Morristown, NJ: Sanofi-aventis U.S. LLC; July 2026.
3. NCCN Drugs & Biologics Compendium® Isatuximab-irfc 2026. National Comprehensive Cancer Network, Inc. Accessed on January 15, 2026.

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
October 2024	Per PI update, added indication of newly diagnosed multiple myeloma
December 2024	Annual review and reference update
June 2025	Annual review and reference update
March 2026	Annual review and reference update
July 2026	Addition of Sarclisa Escena to policy

Keywords

This policy was effective with interim approval on July 31, 2026 and will be reviewed by the FEP® Pharmacy and Medical Policy Committee on December 11, 2026.