BlueCross BlueShield
Federal Employee Program
Blue Cross Blue Shield Association
750 9th St NW, Suite 900
Washington, D.C. 20001
1-800-624-5060
Fax 1-877-378-4727

5.21.141

| | | | |
|---|---|---|---|
| **Section:** | Prescription Drugs | **Effective Date:** | April 1, 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)

**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).

**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
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**: 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. 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; October 2024.
2. 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 |

## Keywords

**This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 6, 2026 and is effective on April 1, 2026.**