Reference number(s)
3643-A

Specialty Guideline Management Sarclisa

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Sarclisa	isatuximab-irfc
Sarclisa Escena	isatuximab-irfc

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications[1,2]

- Sarclisa is indicated, in combination with pomalidomide and dexamethasone, for the treatment of adult patients with multiple myeloma who have received at least two prior therapies including lenalidomide and a proteasome inhibitor.
- Sarclisa Escena is indicated, in combination with pomalidomide and dexamethasone, for the treatment of adult patients with multiple myeloma who have received at least one prior therapy including lenalidomide and a proteasome inhibitor.
- Sarclisa and Sarclisa Escena are indicated, in combination with carfilzomib and dexamethasone, for the treatment of adult patients with relapsed or refractory multiple myeloma who have received one to three prior lines of therapy.
- Sarclisa and Sarclisa Escena are indicated, 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).

Compendial Uses (Sarclisa only)[3,4]

- Multiple myeloma
- Polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, skin changes (POEMS)
- Plasma cell-related monoclonal immunoglobulin deposition disease (MIDD)
- Plasma cell-related monoclonal gammopathy of renal significance (MGRS)

All other indications are considered experimental/investigational and not medically necessary.

Coverage Criteria

Multiple Myeloma (Sarclisa only)[1,3,4]

Authorization of 12 months may be granted for treatment of multiple myeloma when any of the following criteria are met:

- The requested medication will be used in combination with pomalidomide and dexamethasone and the member has previously received at least two prior therapies for multiple myeloma, including lenalidomide and a proteasome inhibitor if lenalidomide- or bortezomib-refractory.
- The requested medication will be used in combination with carfilzomib and dexamethasone and the member has previously received at least one prior line of therapy for multiple myeloma, if lenalidomide- or bortezomib-refractory.
- The requested medication will be used in combination with bortezomib, lenalidomide, and dexamethasone as primary therapy.
- The requested medication will be used in combination with carfilzomib, lenalidomide, and dexamethasone as primary therapy for members who are transplant candidates.
- The requested medication will be used in combination with lenalidomide and dexamethasone as primary therapy for members who are deferred or ineligible for transplant.

Multiple Myeloma (Sarclisa Escena only)[2]

Authorization of 12 months may be granted for treatment of multiple myeloma when any of the following criteria are met:

- The requested medication will be used in combination with pomalidomide and dexamethasone and the member has previously received at least one prior line of therapy including lenalidomide and a proteasome inhibitor.
- The requested medication will be used in combination with carfilzomib and dexamethasone and the member has previously received one to three prior lines of therapy.
- The requested medication will be used in combination with bortezomib, lenalidomide, and dexamethasone, in members with newly diagnosed multiple myeloma who are not eligible for transplant.

POEMS, MIDD, and MGRS (Sarclisa only)[1,3,4]

Authorization of 12 months may be granted for treatment of POEMS, plasma cell-related MIDD, or plasma cell-related MGRS.

Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria section when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

References

1. Sarclisa [package insert]. Bridgewater, NJ: Sanofi-Aventis U.S. LLC; June 2026.
2. Sarclisa Escena [package insert]. Bridgewater, NJ: Sanofi-Aventis U.S. LLC; July 2026.
3. The NCCN Drugs & Biologics Compendium® © 2026 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed October 16, 2025.
4. NCCN Clinical Practice Guidelines in Oncology Multiple Myeloma (Version 2.2026) 2025 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed October 16, 2025.