Reference number(s)
4718-A

Standard Medicare Part B 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

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]

Sarclisa is indicated:

- 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).

Compendial Uses[2]

- Multiple myeloma

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

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this criteria should be accompanied by supporting evidence from Medicare approved compendia.

Coverage Criteria

Multiple Myeloma[1-3]

Authorization of 12 months may be granted for treatment of multiple myeloma when any of the following criteria is 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 or carfilzomib, lenalidomide, and dexamethasone as primary therapy.
- The requested medication will be used in combination with lenalidomide and dexamethasone as primary therapy for members who are deferred or ineligible for transplant.

POEMS, MIDD, and MGRS[2,3]

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

Continuation of Therapy

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 months may be granted when all of the following criteria are met:

- The member is currently receiving therapy with the requested medication
- The requested medication is being used to treat an indication in the coverage criteria section
- The member is receiving benefit from therapy. Benefit is defined as:

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- No evidence of unacceptable toxicity while on the current regimen AND
- No evidence of disease progression while on the current regimen.

Summary of Evidence

The contents of this policy were created after examining the following resources:

- The prescribing information for Sarclisa.
- The available compendium
  - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
  - Micromedex DrugDex
  - American Hospital Formulary Service- Drug Information (AHFS-DI)
  - Lexi-Drugs
  - Clinical Pharmacology
- NCCN Guideline: Multiple Myeloma

Explanation of Rationale

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

Support for using Sarclisa to treat multiple myeloma, POEMS, plasma-cell related MIDD, and plasma-cell related MGRS in combination with agents not listed in the prescribing information can be found in the NCCN Drugs and Biologics Compendium. Use of information in the NCCN Drugs and Biologics Compendium for off-label use of drugs and biologicals in an anti-cancer chemotherapeutic regimen is supported by the Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 (Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen).

References

1. Sarclisa [package insert]. Bridgewater, NJ: Sanofi-Aventis U.S. LLC; June 2025.
2. The NCCN Drugs & Biologics Compendium® ©2025 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed October 16, 2025.
3. 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.

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