Isatuximab-irfc (Sarclisa®)

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

POLICY

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

- Treatment of multiple myeloma, in combination with pomalidomide and dexamethasone, for adult patients who have received at least two prior therapies including lenalidomide and a proteasome inhibitor.
- Treatment of relapsed or refractory multiple myeloma, in combination with carfilzomib and dexamethasone, for adult patients who have received one to three prior lines of therapy.
- Treatment of newly diagnosed multiple myeloma, in combination with bortezomib, lenalidomide and dexamethasone, for adult patients who are not eligible for autologous stem cell transplant (ASCT).

Compendial Uses

- 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

Authorization of 12 months may be granted for treatment of multiple myeloma in any of the following settings:

- 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.

POEMS, MIDD, and MGRS

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.

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

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. 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.

EFFECTIVE DATE 7/31/2026

ID_CHS_2025