

Policy Name	Policy Number	Scope
Isatuximab (Sarclisa®)	MP-RX-FP-81-23	<input checked="" type="checkbox"/> MMM MA <input checked="" type="checkbox"/> MMM Multihealth

Service Category

- | | |
|--|---|
| <input type="checkbox"/> Anesthesia | <input type="checkbox"/> Medicine Services and Procedures |
| <input type="checkbox"/> Surgery | <input type="checkbox"/> Evaluation and Management Services |
| <input type="checkbox"/> Radiology Procedures | <input type="checkbox"/> DME/Prosthetics or Supplies |
| <input type="checkbox"/> Pathology and Laboratory Procedures | <input checked="" type="checkbox"/> Part B DRUG |

Service Description

This document addresses the use of Sarclisa® (isatuximab-irfc), a human anti-CD38 monoclonal antibody approved by the FDA for treatment of certain patients with Multiple Myeloma.

Background Information

Sarclisa is approved for the treatment of adult patients with multiple myeloma who have received at least two prior therapies including lenalidomide and a proteasome inhibitor; and is approved for use in combination with pomalidomide and dexamethasone. It is also approved for relapsed or refractory MM in combination with carfilzomib and dexamethasone. Darzalex (daratumumab) is also approved for these uses, in addition to other indications in refractory and newly diagnosed MM. The National Comprehensive Cancer Network® (NCCN) recommendations for Sarclisa reflect its FDA approved use.

Definitions and Measures

- Line of Therapy:
 - First-line therapy:
 - The first or primary treatment for the diagnosis, which may include surgery, chemotherapy, radiation therapy or a combination of these therapies.
- Second-line therapy:
 - Treatment given when initial treatment (first-line therapy) is not effective or there is disease progression.
- Third-line therapy:
 - Treatment given when both initial (first-line therapy) and subsequent treatment (second-line therapy) are not effective or there is disease progression.
- Multiple myeloma:
 - A type of cancer that begins in plasma cells (white blood cells that produce antibodies).
- Proteasome inhibitors:
 - A class of drugs used to treat multiple myeloma that work by blocking the action of proteasomes which are cellular complexes that break down proteins. Examples include bortezomib, carfilzomib and ixazomib.

Policy Name	Policy Number	Scope
Isatuximab (Sarclisa®)	MP-RX-FP-81-23	<input checked="" type="checkbox"/> MMM MA <input checked="" type="checkbox"/> MMM Multihealth

- Refractory Disease:
 - Illness or disease that does not respond to treatment.
- Relapse or recurrence:
 - After a period of improvement, during which time a disease (for example, cancer) could not be detected, the return of signs and symptoms of illness or disease. For cancer, it may come back to the same place as the original (primary) tumor or to another place in the body.

Approved Indications

See Background section above.

Other Uses

See Background section above.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

HCPCS	Description
J9227	Injection, isatuximab-irfc, 10 mg (Effective 10/1/2020)

ICD-10	Description
C90.00-C90.02	Multiple myeloma

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Medical Necessity Guidelines

When a drug is being reviewed for coverage under a member’s medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

isatuximab-irfc (Sarclisa®)

A. Criteria For Initial Approval (*Provider must submit documentation [such as office chart notes, lab results, pathology reports, imaging studies, and any other pertinent clinical information] supporting the patient’s diagnosis for the drug and confirming that the patient has met **all** approval criteria.*)

- i. Individual has a diagnosis of multiple myeloma; **AND**
- ii. Individual has relapsed or refractory disease following treatment with at least two prior lines of therapy including lenalidomide and a proteasome inhibitor (for example, bortezomib, carfilzomib, or ixazomib); **AND**
- iii. Sarclisa is used in combination with pomalidomide and dexamethasone;

OR

- iv. Individual has a diagnosis of multiple myeloma; **AND**
- v. Sarclisa is used in combination with carfilzomib and dexamethasone; **AND**
- vi. Individual has relapsed or refractory disease following treatment with one to three prior lines of therapy.

B. Criteria For Continuation of Therapy

- i. MMM considers continuation of *isatuximab-irfc (Sarclisa®)* therapy medically necessary in members requesting reauthorization for an indication listed in Section A above (Criteria for Initial Approval) when there is no evidence of an unacceptable toxicity or disease progression while on the current regimen, and the recommended duration of therapy has not been exceeded. The following information should be submitted for reauthorization:
 - A. A current oncology note documenting the patient’s response to treatment showing no progression of disease.
 - B. Current imaging studies and other objective measures, as appropriate for condition, showing no progression of disease when compared with previous results.

C. Authorization Duration

- i. Initial Approval Duration: Up to 6 months
- ii. Reauthorization Approval Duration: Up to 6 months

D. Conditions Not Covered

Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive):

Medical Policy

Healthcare Services Department

Policy Name Isatuximab (Sarclisa®)	Policy Number MP-RX-FP-81-23	Scope <input checked="" type="checkbox"/> MMM MA <input checked="" type="checkbox"/> MMM Multihealth
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- i. Requests for Sarclisa (isatuximab-irfc) may not be approved when the above criteria are not met and for all other indications.

Limits or Restrictions

A. Quantity Limitations

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines. The chart below includes dosing recommendations as per the FDA-approved prescribing information.

Drug	Limit	Dosing schedule	Treatment Duration
Sarclisa	Cycle 1 (28 days)	Days 1, 8, 15, and 22 (weekly)	Until disease progression or unacceptable toxicity.
	Cycle 2 and beyond (28 days)	Days 1, 15 (every 2 weeks)	Until disease progression or unacceptable toxicity
Exceptions			
None			

Reference Information

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: January 17, 2023.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.
4. NCCN Clinical Practice Guidelines in Oncology™. © 2023 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed January 17, 2023.
 - a. Multiple Myeloma. V5.2022. Revised March 9, 2022.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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Medical Policy

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Policy Name Isatuximab (Sarclisa®)	Policy Number MP-RX-FP-81-23	Scope <input checked="" type="checkbox"/> MMM MA <input checked="" type="checkbox"/> MMM Multihealth
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Policy History

Revision Type	Summary of Changes	P&T Approval Date	MPCC Approval Date
Policy Inception	Elevance Health’s Medical Policy adoption.	N/A	11/30/2023
Select Review	Update statement for criteria for initial approval: Provider must submit documentation [such as office chart notes, lab results, pathology reports, imaging studies, and any other pertinent clinical information] supporting the patient’s diagnosis for the drug and confirming that the patient has met all approval criteria.	3/25/2024	5/9/2024

Revised: 11/09/2023