

Sarclisa® (isatuximab-irfc) (Intravenous)

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I. Length of Authorization ^{5,7}

- Initial: Prior authorization validity will be provided initially for 6 months (180 days), unless otherwise specified.
 - Primary therapy in Multiple Myeloma for transplant candidates in combination with bortezomib, lenalidomide, dexamethasone: Prior authorization validity will be provided for up to a maximum of 18 weeks of therapy (11 doses).
- Renewal: Prior authorization validity may be renewed every 6 months (180 days) thereafter, unless otherwise specified.
 - Primary therapy in Multiple Myeloma for transplant candidates in combination with bortezomib, lenalidomide, dexamethasone: Prior authorization validity may NOT be renewed.
 - Primary therapy in Multiple Myeloma for transplant candidates in combination with carfilzomib, lenalidomide, dexamethasone: Prior authorization validity may be renewed for up to a maximum of 48 weeks of therapy (26 doses).
 - Maintenance therapy in Multiple Myeloma for transplant candidates in combination with lenalidomide and carfilzomib: Prior authorization validity may be renewed for up to a maximum of 104 weeks of therapy (52 doses).

II. Dosing Limits

Max Units (per dose and over time) [HCPCS Unit]:

- 120 billable units weekly x 5 doses, then 720 billable units every 84 days

III. Initial Approval Criteria ¹

Prior authorization validity is provided in the following conditions:

- Member is at least 18 years of age; **AND**

Universal Criteria

- Therapy will not be used in combination with other anti-CD38 therapies; **AND**

Multiple Myeloma † ‡ Φ ^{1-9,4e}

- Used as primary therapy for symptomatic disease; **AND**
 - Used in combination with bortezomib, lenalidomide, and dexamethasone; **AND**
 - Member is ≤80 years of age (*NON-transplant candidates ONLY*); **OR**
 - Used in combination with lenalidomide and dexamethasone for non-transplant candidates or if transplant is deferred; **AND**

- Use of isatuximab will be restricted to members with a contraindication or intolerance to bortezomib/lenalidomide/dexamethasone; **OR**
 - Used in combination with carfilzomib, lenalidomide, and dexamethasone followed by maintenance therapy in combination with carfilzomib and lenalidomide (*transplant candidates ONLY*); **AND**

- Use of isatuximab will be restricted to members with a contraindication or intolerance to one of the following regimens:
 - Isatuximab/bortezomib/lenalidomide/dexamethasone
 - Bortezomib/lenalidomide/dexamethasone; **OR**
- Used for previously treated multiple myeloma for relapsed, refractory, or progressive disease; **AND**
 - Used in combination with pomalidomide and dexamethasone after at least two prior therapies including lenalidomide and a proteasome inhibitor (e.g., bortezomib, carfilzomib, ixazomib, etc.); **OR**
 - Used in combination with carfilzomib and dexamethasone

Preferred therapies and recommendations are determined by review of clinical evidence. NCCN category of recommendation is taken into account as a component of this review. Regimens deemed equally efficacious (i.e., those having the same NCCN categorization) are considered to be therapeutically equivalent.

Enhanced Oncology Value (EOV) Program – Redacted indications

Uses not listed above have inadequate data to support efficacy and are excluded from prior authorization validity.

Other treatment options including, but are not limited to, the following may be appropriate: radiation therapy, surgery, traditional chemotherapy (e.g., platinum, taxane), compassionate use/expanded access programs, clinical trials, supportive care, integrative and complementary therapies.

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Ⓢ Orphan Drug

IV. Renewal Criteria ^{1,5}

Prior authorization validity may be renewed based upon the following criteria:

- Member continues to meet the indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Duration of authorization has not been exceeded (*refer to Section I*); **AND**
- Disease response with treatment as defined by stabilization of disease and decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe infusion-related reactions, severe infections, neutropenia, secondary primary malignancies, etc.

V. Dosage/Administration ^{1,5,7-9}

Indication	Dose
Multiple Myeloma	<u>Combination therapy with bortezomib, lenalidomide, and dexamethasone:</u>
	Transplant Candidates
	▪ Administer 10 mg/kg of actual body weight given as an intravenous infusion: – Weekly Cycle 1 (five doses total; Days 1, 8, 15, 22, & 29) – Every two weeks Cycle 2 and 3 (three doses per cycle; Days 1, 15, & 29)
	<i>*Each treatment cycle consists of a 42-day period.</i>
	Non-Transplant Candidates
	▪ Administer 10 mg/kg of actual body weight given as an intravenous infusion: – Weekly Cycle 1 (five doses total; Days 1, 8, 15, 22, & 29) – Every two weeks Cycle 2 to 4 (three doses per cycle; Days 1, 15, & 29)
	<i>*Treatment cycles 1 to 4 consist of a 42-day period.</i>
	– Every two weeks Cycle 5 to 17 (two doses per cycle; Days 1 & 15) – Every four weeks Cycle 18 and beyond (one dose per cycle; Day 1)
	<i>*Treatment cycle 5 and beyond consists of a 28-day period. Treat until disease progression or unacceptable toxicity.</i>
	<u>Combination therapy with carfilzomib, lenalidomide, and dexamethasone:</u>
	Transplant Candidates
	▪ Administer 10 mg/kg of actual body weight given as an intravenous infusion: ○ Induction (in combination with carfilzomib, lenalidomide, and dexamethasone) for up to 8 cycles: – Weekly Cycle 1 (four doses total; Days 1, 8, 15, & 22)

	– Every two weeks Cycle 2 to 8 (two doses per cycle; Days 1 & 15) ○ <i>Consolidation (in combination with carfilzomib, lenalidomide, and dexamethasone):</i> – Every two weeks Cycle 9 to 12 (two doses per cycle; Days 1 & 15) ○ <i>Maintenance (in combination with carfilzomib and lenalidomide):</i> – Every two weeks for 26 cycles until disease progression or unacceptable toxicity (two doses per cycle; Days 1 & 15) <i>*Each treatment cycle consists of a 28-day period.</i> <u>Combination therapy with lenalidomide and dexamethasone:</u> <u>Non-Transplant Candidates</u> ▪ Administer 10 mg/kg of actual body weight given as an intravenous infusion: – Weekly Cycle 1 (four doses total; Days 1, 8, 15, & 22) – Every two weeks Cycle 2 to 12 (two doses per cycle; Days 1 & 15) – Every four weeks Cycle 13 and beyond (1 dose per cycle; Day 1) <i>*Each treatment cycle consists of a 28-day period. Treatment is repeated until disease progression or unacceptable toxicity.</i> <u>Combination therapy with pomalidomide and dexamethasone OR carfilzomib and dexamethasone:</u> ▪ Administer 10 mg/kg of actual body weight given as an intravenous infusion: – Weekly Cycle 1 (four doses total; Days 1, 8, 15, & 22) – Every two weeks Cycles 2 and beyond (two doses per cycle; Days 1 & 15) <i>*Each treatment cycle consists of a 28-day period. Treatment is repeated until disease progression or unacceptable toxicity.</i>
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VI. Billing Code/Availability Information

HCPCS Code:

- J9227 – Injection, isatuximab-irfc, 10 mg; 1 billable unit=10 mg

NDC(s):

- Sarclisa 100 mg/5 mL single-dose vial: 00024-0654-xx
- Sarclisa 500 mg/25 mL single-dose vial: 00024-0656-xx

VII. References (STANDARD)

1. Sarclisa [package insert]. Morristown, NJ; Sanofi-Aventis US, LLC; June 2025. Accessed April 2026.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for isatuximab-irfc. National Comprehensive Cancer Network, 2026. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the

National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed April 2026.

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VIII. References (ENHANCED)

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- 3e. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) Multiple Myeloma Version 5.2026. National Comprehensive Cancer Network, 2026. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the NCCN Guidelines, go online to NCCN.org. Accessed April 2026.
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Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

Factor	Conclusion
Indication	Yes: Consider for PA
Safety and efficacy	No: PA not a priority
Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C90.00	Multiple myeloma not having achieved remission
C90.02	Multiple myeloma, in relapse
C90.10	Plasma cell leukemia not having achieved remission
C90.12	Plasma cell leukemia in relapse
C90.20	Extramedullary plasmacytoma not having achieved remission
C90.22	Extramedullary plasmacytoma in relapse
C90.30	Solitary plasmacytoma not having achieved remission
C90.32	Solitary plasmacytoma in relapse
Z85.79	Personal history of other malignant neoplasms of lymphoid, hematopoietic and related tissues

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: <https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC