Sarclisa Escena™ (isatuximab-irfc)
(Subcutaneous)

Document Number: IC-0874

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I. Length of Authorization [1]

- Initial: Prior authorization validity will be provided initially for 6 months (180 days).
- Renewal: Prior authorization validity may be renewed every 6 months (180 days) thereafter.

II. Dosing Limits

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

- 1400 mg every 7 days for 4 doses, then 2800 mg every 28 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 concomitantly with intravenous isatuximab; **AND**
- Therapy will not be used in combination with other anti-CD38 therapies; **AND**

Multiple Myeloma † Φ [1-3]

- Used for previously treated multiple myeloma for relapsed or refractory disease; **AND**
  - Used in combination with pomalidomide and dexamethasone after prior therapy with lenalidomide and a proteasome inhibitor (e.g., bortezomib, carfilzomib, ixazomib, etc.); **OR**
  - Used in combination with carfilzomib and dexamethasone after 1 to 3 prior lines of therapy; **OR**
- Used in the treatment of newly diagnosed disease in members not eligible for autologous stem cell transplant (ASCT); **AND**
  - Used in combination with bortezomib, lenalidomide, and dexamethasone

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

IV. Renewal Criteria [1,5]

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

- Member continues to meet the universal and other 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 or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: hypersensitivity and other administration-related reactions, severe infections, neutropenia, secondary primary malignancies, etc.

V. Dosage/Administration [1-3]

Indication	Dose
Multiple Myeloma	
	Combination therapy with bortezomib, lenalidomide, and dexamethasone: Administer 1,400 mg subcutaneously with the CirCLIQ™ On-Body delivery System (OBDS) or with a syringe and infusion set for manual administration – Weekly Cycle 1: Days 1, 8, 15, 22 – Every 2 weeks Cycle 2 to 12: Days 1 and 15 – Every 4 weeks Cycles 13 and beyond: Day 1 ** Each treatment cycle consists of a 28-day period. Treat until disease progression or unacceptable toxicity.*
	Combination therapy with carfilzomib and dexamethasone OR with pomalidomide and dexamethasone Administer 1,400 mg subcutaneously with the CirCLIQ™ On-Body delivery System (OBDS) or with a syringe and infusion set for manual administration – Weekly Cycle 1: Days 1, 8, 15, 22 – Every 2 weeks Cycle 2 and beyond: Days 1 and 15 ** Each treatment cycle consists of a 28-day period. Treat until disease progression or unacceptable toxicity.*
**Keep refrigerated. Sarclisa Escena should only be administered subcutaneously by a healthcare professional. Do NOT administer Sarclisa Escena intravenously.*	
Note: Refer to the PI for pre-medication therapies.	

VI. Billing Code/Availability Information

HCPCS Code:

- J9999 – Not otherwise classified, antineoplastic drugs
- C9399 – Unclassified drugs or biologicals (*Hospital Outpatient Use*)

NDC(s):

- Sarclisa Escena 1,400 mg/10 mL single-dose vial: 00024-0674-xx

VII. References

1. Sarclisa Escena [package insert]. Morristown, NJ; Sanofi-Aventis US, LLC; July 2026. Accessed July 2026.
2. Ailawadhi S, Spicka I, Spencer A, et al. Isatuximab Subcutaneous by On-Body Injector Versus Isatuximab Intravenous Plus Pomalidomide and Dexamethasone in Relapsed/Refractory Multiple Myeloma: Phase III IRAKLIA Study. J Clin Oncol. 2025 Aug;43(22):2527-2537. doi: 10.1200/JCO-25-00744. Epub 2025 Jun 3.
3. Parmar G, Capra M, Seguro F, et.al. Efficacy and safety of isatuximab subcutaneous plus carfilzomib and dexamethasone in patients with relapsed/refractory multiple myeloma: results of the Phase 2 study IZALCO. Blood Cancer J. 2025 Dec 27;16(1):16. doi: 10.1038/s41408-025-01436-0. PMID: 41455697; PMCID: PMC12811394.

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