# Sarclisa® (isatuximab-irfc)
## (Intravenous)

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Document Number: IC-0551

**Last Review Date: 05/03/2021**
**Date of Origin:** 07/01/2020
**Dates Reviewed: 07/2020, 10/2020, 05/2021**

## I. Length of Authorization

Coverage will be provided for 6 months and may be renewed.

## II. Dosing Limits

**A. Quantity Limit (max daily dose) [NDC Unit]:**

- Cycle 1, every week x 4 doses, followed by Cycle 2, and beyond, every 2 weeks
  - Sarclisa 100 mg/5 mL single-dose vial for injection: 4 vials per dose
  - Sarclisa 500 mg/25 mL single dose vial for injection: 2 vials per dose

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

- Cycle 1 every week x 4 doses, followed by Cycle 2, and beyond, every 2 weeks
  - 110 billable units per dose

## III. Initial Approval Criteria [1,3,4]

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**
- Patient is not refractory to previous treatment with anti-CD38 therapy (i.e., daratumumab, etc.) [*Note: refractory is defined as progression on or within 60 days after the end of prior anti-CD38 treatment OR failure to achieve at least minimum response to treatment*]; **AND**

**Multiple Myeloma † Φ [1-4]**

- Patient has 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 in patients who have received 1 to 3 prior lines therapy

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

## IV. Renewal Criteria [1]

Coverage can be renewed based upon the following criteria:

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

## V. Dosage/Administration [1]

| Indication | Dose |
|---|---|
| Multiple Myeloma | Combination therapy with pomalidomide and dexamethasone OR carfilzomib and dexamethasone:<br>▪ 10 mg/kg of actual body weight given as an intravenous infusion:<br>– Weekly Cycle 1 (four doses total; Days 1, 8, 15, & 22)<br>– Every two weeks Cycles 2 and beyond (two doses per cycle; Days 1 & 15)<br>**Each treatment cycle consists of a 28-day period. Treatment is repeated until disease progression or unacceptable toxicity.* |

## 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]. Bridgewater, NJ; Sanofi-Aventis US, LLC; March 2021. Accessed April 2021.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for isatuximab-irfc. National Comprehensive Cancer Network, 2021. 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 2021.

3. Attal M, Richardson PG, Rajkumar SV, et al; ICARIA-MM study group. Isatuximab plus pomalidomide and low-dose dexamethasone versus pomalidomide and low-dose dexamethasone in patients with relapsed and refractory multiple myeloma (ICARIA-MM): a randomised, multicentre, open-label, phase 3 study. Lancet. 2019 Dec 7;394(10214):2096-2107. doi: 10.1016/S0140-6736(19)32556-5. Epub 2019 Nov 14. Erratum in: Lancet. 2019 Dec 7;394(10214):2072.
4. Moreau P, Dimopoulos M, Yong K, et al. Isatuximab plus carfilzomib/dexamethasone versus carfilzomib/dexamethasone in patients with relapsed/refractory multiple myeloma: IKEMA Phase III study design. Future Oncol. 2020 Jan;16(2):4347-4358. doi: 10.2217/fon-2019-0431. Epub 2019 Dec 13.

## VIII. References (ENHANCED)

1e. Moreau P, Dimopoulos MA, Mikhael J, et al: Isatuximab plus carfilzomib and dexamethasone vs carfilzomib and dexamethasone in relapsed/refractory multiple myeloma (IKEMA): Interim analysis of a phase III, randomized, open-label study. EHA25 Virtual Congress. Abstract LB2603.

2e. Attal M, Richardson PG, Rajkumar SV, et al. Isatuximab plus pomalidomide and low-dose dexamethasone versus pomalidomide and low-dose dexamethasone in patients with relapsed and refractory multiple myeloma (ICARIA-MM): a randomised, multicentre, open-label, phase 3 study. The Lancet. 2019 Dec 7;394(10214):2096-107.

3e. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) Multiple Myeloma Version 5.2021. National Comprehensive Cancer Network, 2021. 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 2021.

4e. Magellan Health, Magellan Rx Management. Sarclisa Clinical Literature Review Analysis. Last updated April 2021. Accessed April 2021.

## 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 |

| ICD-10 | ICD-10 Description |
|---|---|
| C90.30 | Solitary plasmacytoma not having achieved remission |
| C90.32 | Solitary plasmacytoma in relapse |
| D47.2 | Monoclonal gammopathy |
| Z85.79 | Personal history of other malignant neoplasms of lymphoid, hematopoietic and related tissues |

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

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 Determination (NCD), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx. Additional indications may be covered 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, LLC |
| M (11) | NC, SC, WV, VA (excluding below) | Palmetto GBA, LLC |
| 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 |

## Appendix 3 – CLINICAL LITERATURE REVIEW

OS = overall survival; PFS = progression-free survival; ORR = objective response rate; CR = complete response; PR = partial response; DoR = duration of response; TTP = time to progression; FFS = failure-free survival; EFS = event-free survival; PFR = progression free rate; NR = not reached

### Multiple Myeloma

| Relapsed or Progressive Disease | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Regimen** | **NCCN Category** | **FDA Approved** | **Trial Design** | **Comparator** | **Primary End-Point** | **Line of Therapy** | **Conclusion** |
| Isatuximab + carfilzomib + dexamethasone (Isa-Kd ) | N/A | Yes | IKEMA Phase 3, randomized, open label | Carfilzomib + low-dose dexamethasone (Kd) | PFS | After 1-3 prior therapies | • In relapsed or refractory multiple myeloma, isatuximab in combination with carfilzomib and dexamethasone improved PFS with a 45% reduction in the risk of disease progression compared to patients treatment with carfilzomib and dexamethasone. |
| Isatuximab + pomalidomide + low-dose dexamethasone (IPd ) | 1 preferred | Yes, in adults after at least 2 prior therapies including an lenalidomide and proteasome inhibitor | ICARIA-MM Phase 3, randomized, open label | Pomalidomide + low-dose dexamethasone (Pd) | PFS | ≥2 prior lines of therapy including Len (for ≥2 cycles) and PI (for ≥2 cycles) | • Addition of isatuximab to pomalidomide and dexamethasone improved PFS by 5 months compared to pomalidomide plus dexamethasone alone. |