Isatuximab-irfc (Sarclisa®)	Place of Service Office Administration Infusion Center Administration Home Infusion Administration Outpatient Facility Administration HCPCS: **J9227** per 10 mg

Condition listed in policy (*see criteria for details*)

- Multiple myeloma – previously treated

AHFS therapeutic class: Antineoplastic agent

Mechanism of action: CD38-directed cytolytic antibody

(1) Special Instructions and pertinent Information

Covered under the medical benefit, please submit clinical information for prior authorization review via fax.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for isatuximab-irfc (Sarclisa®) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Multiple myeloma – previously treated

1. Patient has received prior treatment for multiple myeloma and meets one of the following:
    a. Patient has received at least two prior therapies, that include the use of Revlimid (lenalidomide) and a proteasome inhibitor, and being used in combination with Pomalyst (pomalidomide) and dexamethasone, OR
    b. Being used in combination with Kyprolis (carfilzomib) and dexamethasone

Covered Dose

Up to 10 mg/kg IV every week for first 4 weeks (Cycle 1) followed by every 2 weeks (Cycle 2 and beyond) in 28-day treatment cycles.

Coverage Period

Indefinite

ICD-10:

C90.00, C90.02, C90.10, C90.12, C90.20, C90.22, C90.30, C90.32, Z85.79

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for isatuximab-irfc (Sarclisa®) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How supplied:

- 100 mg/5 mL single-dose vial
- 500 mg/25 mL single-dose vial

(6) References

- AHFS®. Available by subscription at http://www.lexi.com
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
- National Comprehensive Cancer Network. Multiple Myeloma (Version 4.2023). Available at http://www.nccn.org.
- Sarclisa® (isatuximab-Irfc) [Prescribing information]. Bridgewater, NJ: Sanofi-Aventis U.S. LLC; 7/2022.

(7) Policy Update

Date of last review: 4Q2023

Date of next review: 4Q2024

Changes from previous policy version:

- No clinical change to policy following routine annual review.

BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee