SmartHealth Ascension

Isatuximab-irfc

(Sarclisa®) J9227 (10 mg)

Covered with prior authorization

Isatuximab-irfc (Sarclisa®) may be authorized when the following criteria are met:

- Individual has a diagnosis of multiple myeloma; **AND**
- Individual has not received treatment with isatuximab or another anti-CD38 agent (such as daratumumab); **AND**
- 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**
- Sarclisa is used in combination with pomalidomide and dexamethasone.

OR

- Individual has a diagnosis of multiple myeloma; **AND**
- Individual has not received treatment with isatuximab or another anti-CD38 agent (such as daratumumab); **AND**
- Sarclisa is used in combination with carfilzomib and dexamethasone; **AND**
- Individual has relapsed or refractory disease following treatment with one to three prior lines of therapy.

Exclusion criteria:
Requests for Ibalizumab-uiyk (Trogarzo®) may not be approved for the following:

- Product use for non-FDA approved indications or indications not supported by industry-accepted guidelines
- Doses, durations, or dosing intervals that exceed FDA maximum limits for any FDA-approved indication or are not supported by industry-accepted practice guidelines or peer-reviewed literature for the relevant off-label use

Initial authorization is up to 12 months.

Annual reauthorizations will require medical chart documentation that the patient has been seen within the past 12 months and that markers of disease are improved by therapy.

Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

U.S. Food and Drug Administration:
This section is to be used for informational purposes. FDA approval alone is not a basis for coverage.

Sarclisa® is a CD38-directed cytolytic antibody indicated:

- In combination with pomalidomide and dexamethasone, for the treatment of adult patients with multiple myeloma who have received at least 2 prior therapies including lenalidomide and a proteasome inhibitor.
- In combination with carfilzomib and dexamethasone, for the treatment of adult patients with relapsed or refractory multiple myeloma who have received 1 to 3 prior lines of therapy.

References:

1. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
2. NCCN Clinical Practice Guidelines in Oncology™. © 2022 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp.
3. Sarclisa® [Prescribing Information]. Bridgewater, NJ.: Sanofi-Aventis US.., 2023.

Date	Summary of Changes
January 2023	Criteria for use summary developed by the Ascension Medical Specialty Prior Authorization Team.
February 2023	Criteria for use summary approved by the Ascension Hematology/Oncology Expert Review Panel.
March 2023	Criteria for use summary approved by the Ascension Therapeutic Affinity Group.

If you have questions, call 833-980-2352 to speak to a member of the Ascension Rx prior authorization team, or email your questions to smarthealthspecialty@ascension.org.