Medical Drug Clinical Criteria

Subject:	Sarclisa (isatuximab-irfc)		
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Overview

This document addresses the use of Sarclisa (isatuximab-irfc). Sarclisa is the second human anti-CD38 monoclonal antibody approved by the FDA for treatment of multiple myeloma (MM), following Darzalex (daratumumab).

Sarclisa is approved for the treatment of adult patients with multiple myeloma who have received at least two prior therapies including lenalidomide and a proteasome inhibitor; and is approved for use in combination with pomalidomide and dexamethasone. It is also approved for relapsed or refractory MM in combination with carfilzomib and dexamethasone. Darzalex is also approved for these uses, in addition to other indications in refractory and newly diagnosed MM. The National Comprehensive Cancer Network® (NCCN) recommendations for Sarclisa reflect its FDA approved use.

Definitions and Measures

Line of Therapy:

- First-line therapy: The first or primary treatment for the diagnosis, which may include surgery, chemotherapy, radiation therapy or a combination of these therapies.
- Second-line therapy: Treatment given when initial treatment (first-line therapy) is not effective or there is disease progression.
- Third-line therapy: Treatment given when both initial (first-line therapy) and subsequent treatment (second-line therapy) are not effective or there is disease progression.

Multiple myeloma: A type of cancer that begins in plasma cells (white blood cells that produce antibodies).

Proteasome inhibitors: A class of drugs used to treat multiple myeloma that work by blocking the action of proteasomes which are cellular complexes that break down proteins. Examples include bortezomib, carfilzomib and ixazomib.

Refractory Disease: Illness or disease that does not respond to treatment.

Relapse or recurrence: After a period of improvement, during which time a disease (for example, cancer) could not be detected, the return of signs and symptoms of illness or disease. For cancer, it may come back to the same place as the original (primary) tumor or to another place in the body.

Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Sarclisa (isatuximab-irfc)

Requests for Sarclisa (isatuximab-irfc) may be approved if the following criteria are met:

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

OR

~~V.~~IV. Individual has a diagnosis of multiple myeloma; **AND**

~~VI. Individual has not received treatment with isatuximab or another anti-CD38 agent (such as daratumumab); **AND**~~

~~VII.~~V. Sarclisa is used in combination with carfilzomib and dexamethasone; **AND**

~~VIII.~~VI. Individual has relapsed or refractory disease following treatment with one to three prior lines of therapy.

Requests for Sarclisa (isatuximab-irfc) may not be approved when the above criteria are not met and for all other indications.

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Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS

J9227	Injection, isatuximab-irfc, 10 mg (Effective 10/1/2020)

ICD-10 Diagnosis

C90.00-C90.02	Multiple myeloma

Document History

Reviewed: 02/24/2023

Document History:

- 02/24/2023 – Annual Review: Remove language excluding prior use of anti-CD38 agents. Coding Reviewed: No changes.
- 05/20/2022 – Annual Review: No changes. Coding Reviewed: No changes.
- 05/21/2021 – Annual Review: Update criteria to include new indication in combination with carfilzomib and dexamethasone. Coding Reviewed: No changes.
- 05/15/2020 – Annual Review: No changes. Coding Review: No changes. Effective 10/1/2020 Added HCPCS J9227, Added ICD-10-CM C90.00-C90.02, Delete 9/30/2020-C9399, J3490, J3590, J9999.
- 03/16/2020 – Select Review: Add clinical criteria document for new FDA approval Sarclisa (isatuximab-irfc). Coding reviewed: Added C9399, J3490, J3590, J9999. All diagnosis.

References

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: January 17, 2023.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.
4. NCCN Clinical Practice Guidelines in Oncology™. © 2023 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed January 17, 2023.
    a. Multiple Myeloma. V5.2022. Revised March 9, 2022.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.