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. Darzalex is also approved for this use, 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. The pivotal trial leading to FDA approval excluded patients who were refractory to previous therapy with an anti-CD38 monoclonal antibody, such as Darzalex.

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. 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. Sarclisa is used in combination with pomalidomide and dexamethasone.

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

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

C9399	Unclassified drugs or biologicals when specified as (isatuximab-irfc) [Sarclisa] Hospital outpatient only
J3490	Unclassified drugs when specified as (isatuximab-irfc) [Sarclisa]
J3590	Unclassified biologics when specified as (isatuximab-irfc) [Sarclisa]
J9999	Not otherwise classified, antineoplastic drugs when specified as (isatuximab-irfc) [Sarclisa]

ICD-10 Diagnosis

	All diagnosis pend with NOC codes only

Document History

Revised: 03/16/2020
Document History:

- 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

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2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: March 12, 2020.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2020; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2019 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on March 12, 2020.
    a. Multiple Myeloma. V3.2020. Revised March 10, 2020.

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.

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