STATE OF IOWA DEPARTMENT OF
Health AND Human
SERVICES

Sarclisa (isatuximab-irfc)
PAM–015

Iowa Medicaid Program:	Prior Authorization	**Effective Date:**	07/01/2021
Revision Number:	3	**Last Rev Date:**	07/21/2023
Reviewed By:	Medicaid Medical Director	**Next Rev Date:**	07/19/2024
Approved By:	Medicaid Clinical Advisory Committee	**Approved Date:**	07/16/2021

Overview

Medication: [1]	isatuximab-irfc
Brand Name:	Sarclisa®
Pharmacologic Category:	CD38-directed cytolytic antibody; chimeric immunoglobulin G1 (IgG1) monoclonal antibody
FDA-Approved Indication(s):	1. In combination with pomalidomide and dexamethasone: treatment of adult patients with multiple myeloma who have received at least 2 prior therapies including lenalidomide and a proteasome inhibitor. 2. In combination with carfilzomib and dexamethasone: treatment of adult patients with relapsed or refractory multiple myeloma who have received 1 to 3 prior lines of therapy.
How Supplied:	Single-dose vial, either 100 mg/5 mL or 500 mg/25 mL
Dosage and Administration:	Intravenous (IV) infusion, in combination with either: a) pomalidomide and dexamethasone; or b) carfilzomib and dexamethasone, as follows: Cycle 1: 10 mg/kg on days 1, 8, 15, and 22 (weekly) Cycle 2 and beyond: 10 mg/kg on days 1, 15 (every 2 weeks) * Should be administered by a healthcare professional, with immediate access to emergency equipment and appropriate medical support to manage infusion-related reactions if they occur.
Benefit Category:	Medical

Descriptive Narrative

Multiple myeloma (MM) is a malignant hematological disorder characterized by the neoplastic proliferation of plasma cells producing a monoclonal immunoglobulin. The plasma cells proliferate in the bone marrow and can result in extensive skeletal destruction with osteolytic lesions, osteopenia, and/or pathologic fractures. Clinical manifestations of multiple myeloma may include bone pain, increased total serum protein concentration, anemia, hypercalcemia, and acute kidney failure.[2]

Data from the US Surveillance, Epidemiology, and End Results (SEER) registry estimates 34,470 new cases of MM and 12,640 deaths from MM in the United States in 2022 (representing 1.8%

of all new cancer cases and 2.1% of all cancer deaths). This correlates with an annual incidence of 7.1 per 100,000 men and women per year, and a death rate of 3.2 per 100,000 men and women per year.

Most patients with multiple myeloma will have an initial response to treatment. However, conventional therapy is not curative, and MM will ultimately relapse. In addition, a minority will have primary refractory disease that does not respond to initial treatment. Relative survival is an estimate of the percentage of patients who would be expected to survive the effects of their cancer. It excludes the risk of dying from other causes. The introduction of proteasome inhibitors, immunomodulatory agents, monoclonal antibodies, and stem cell transplantation has extended median survival. The 5-year relative survival of MM varies depends on the stage at diagnosis. Localized myeloma (confined to the primary site) has a 78.5% 5-year survival rate, while distant (metastasized) myeloma has a 57% 5-year survival rate [compared to an approximately 25% 5-year relative survival rate in 1975 (SEER 8)].

Multiple myeloma primarily affects older individuals and is most frequently diagnosed among people ages 65 to 74, with a median age at diagnosis of 69 years. The percent of myeloma deaths is highest among people aged 75 to 84, with a median age at death of 75. It is more prevalent in men than in women (8.8/100,000 men and 5.9/100,000 women for all races and ethnicities combined). While MM affects all races, it is much more prevalent among individuals of African American descent (17.0/100,000 for non-Hispanic black males and 12.9/100,000 for non-Hispanic black females).[3]

Guidelines

As new and emerging therapies are rapidly coming to market, oncology treatment recommendations and guidelines are constantly changing. To keep up with these changes, the National Comprehensive Cancer Network (NCCN) publishes guidelines which are developed and updated by 60 individual panels, comprising over 1,660 clinicians and oncology researchers from the 31 NCCN Member Institutions.[4]

The NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) are a work in progress that may be refined as often as new significant data becomes available. To view the most recent and complete version of the guidelines, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.

The information referenced at the time of this policy writing/revision is from:

- NCCN Guidelines® for Multiple Myeloma (Version 3.2023 – December 8, 2022).[5]

NCCN Guidelines® Recommendation(s) for isatuximab-irfc (Sarclisa®) in multiple myeloma (MM)
(1) Previously treated MM, refractory to bortezomib A. Early relapses (1 – 3 prior therapies) i. Sarclisa + carfilzomib + dexamethasone: Category 1, preferred regimen B. After 2 prior therapies including lenalidomide and a PI i. Sarclisa + pomalidomide + dexamethasone: Category 1, preferred regimen

NCCN Guidelines® Recommendation(s) for isatuximab-irfc (Sarclisa®) in multiple myeloma (MM)
(2) Previously treated MM, refractory to lenalidomide A. Early relapses (1 – 3 therapies) i. Sarclisa + carfilzomib + dexamethasone: 1, preferred regimen B. After 2 prior therapies including lenalidomide and a PI i. Sarclisa + pomalidomide + dexamethasone: Category 1, preferred regimen

NCCN Categories of Evidence and Consensus (all recommendations are category 2A unless otherwise indicated)	
Category 1	Based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
Category 2A	Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
Category 2B	Based upon lower-level evidence, there is NCCN consensus that the intervention is appropriate.
Category 3	Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate.

NCCN Categories of Preference (all recommendations are considered appropriate)	
Preferred intervention	Interventions that are based on superior efficacy, safety, and evidence; and, when appropriate, affordability.
Other recommended intervention	Other interventions that may be somewhat less efficacious, more toxic, or based on less mature data; or significantly less affordable for similar outcomes.
Useful in certain circumstances	Other interventions that may be used for select patient populations (defined with recommendation).

Criteria

Prior authorization is required.

Sarclisa® is considered medically necessary when **ALL** of the following are met:

1. Diagnosis of multiple myeloma; **AND**
2. Member is 18 years of age or older; **AND**
3. Member meets **ONE** of the following:
   a. Has relapsed or refractory multiple myeloma after receiving at least two prior therapies including lenalidomide (Revlimid®) and a proteosome inhibitor [e.g., bortezomib (Velcade® or generic), carfilzomib (Kyprolis®), or ixazomib (Ninlaro®)] and is prescribed Sarclisa® in combination with pomalidomide (Pomalyst®) and dexamethasone; ‡ **OR**
   b. Has relapsed or refractory multiple myeloma after receiving one to three prior lines of therapy and is prescribed Sarclisa® in combination with carfilzomib and dexamethasone; **AND**
4. Prescribed by, or in consultation with, an oncologist; **AND**
5. The regimen prescribed is within the FDA-approved labeling. If dose or schedule exceeds the FDA-approved labeling, therapy regimen (including dosage) must be supported by clinical practice guidelines (i.e., must be recommended in the NCCN Clinical Practice Guidelines®). Supporting clinical documentation must be provided with any request for which the regimen or dosage prescribed does not align with FDA-approved labeling.

Sarclisa® is considered medically necessary for continuation of therapy when **ALL** of the following are met:

1. Member is currently receiving medication through the Iowa Medicaid benefit or has previously met initial approval criteria; **AND**
2. Documentation of positive clinical response to therapy, as demonstrated by tumor response or lack of disease progression, and an acceptable toxicity profile; **AND**
3. Prescribed by, or in consultation with, an oncologist; **AND**
4. The regimen prescribed is within the FDA-approved labeling. If dose or schedule exceeds the FDA-approved labeling, therapy regimen (including dosage) must be supported by clinical practice guidelines (i.e., must be recommended in the NCCN Clinical Practice Guidelines®). Supporting clinical documentation must be provided with any request for which the regimen or dosage prescribed does not align with FDA-approved labeling.

‡ Ninlaro®, Pomalyst®, and Revlimid® may require a separate pharmacy prior authorization. See Iowa Medicaid Preferred Drug List (PDL) for details.

Approval Duration and Quantity Limits

	Initial Authorization	Subsequent Authorization(s)
Approval Duration	6 months	12 months
Quantity Limits	Cycle 1: 10 mg/kg weekly for 4 weeks Cycle 2 and beyond: 10 mg/kg every 2 weeks	10 mg/kg every 2 weeks

Coding and Product Information

The following list(s) of codes and product information are provided for reference purposes only and may not be all inclusive. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment, nor does the exclusion of a code imply that its association to the HCPCS code is inappropriate.

HCPCS	Description
J9227	Injection, isatuximab-irfc, 10 mg

ICD-10	Description
C90.0	Multiple myeloma
C90.00	Multiple myeloma not having achieved remission
C90.01	Multiple myeloma in remission
C90.02	Multiple myeloma in relapse

NDC	Labeler	Dosage	Pkg Size	Pkg Qty	Units/Pkg
00024-0654-01	Sanofi-Aventis	10 mg	5	1	10
00024-0656-01	Sanofi-Aventis	10 mg	25	1	50

Compliance

1. Should conflict exist between this policy and applicable statute, the applicable statute shall supersede.
2. Federal and State law, as well as contract language, including definitions and specific contract provisions or exclusions, take precedence over medical policy and must be considered first in determining eligibility for coverage.
3. Medical technology is constantly evolving, and Iowa Medicaid reserves the right to review and update medical policy on an annual or as-needed basis.

Medical necessity guidelines have been developed for determining coverage for member benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. Medical necessity guidelines are developed for selected physician-administered medications found to be safe and proven to be effective in a limited, defined population or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. Criteria are revised and updated annually, or more frequently if new evidence becomes available that suggests needed revisions.

References

[1] Sarclisa prescribing information (07/2022). Sanofi-aventis U.S. LLC: Bridgewater, NJ. Available online at www.sarclisahcp.com. Accessed July 10, 2023.

[2] Laubach JP. Multiple myeloma: Clinical features, laboratory manifestations, and diagnosis. Connor RF, ed. UpToDate. Waltham, MA: UpToDate Inc. www.uptodate.com. Accessed July 12, 2023.

[3] SEER Cancer Stat Facts: Myeloma. National Cancer Institute. Bethesda, MD. Available online at seer.cancer.gov/statfacts/html/mulmy.html. Accessed May 10, 2022.

[4] National Comprehensive Cancer Network (NCCN). Development and Update of Guidelines. Available online at www.nccn.org. Accessed January 19, 2023.

[5] Referenced from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Multiple Myeloma V.3.2023 – December 8, 2022. Accessed July 12, 2023. The NCCN Guidelines are a work in progress that may be refined as often as new significant data becomes available. To view the most recent and complete version of the guideline, go online to NCCN.org.

Development of utilization management criteria may also involve research into other state Medicaid programs, other payer policies, consultation with experts and review by the Medicaid Clinical Advisory Committee (CAC). These sources may not be referenced individually unless they are specifically published and are otherwise applicable to the criteria at issue.

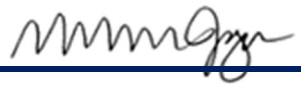
Criteria Change History

Change Date	Changed By	Description of Change	Version
	CAC		
Signature			

Change Date	Changed By	Description of Change	Version
	CAC		
Signature			

Change Date	Changed By	Description of Change	Version
07/21/2023	CAC	Annual review. Updated NCCN recommendations.	3
Signature William (Bill) Jagiello, DO			

Change Date	Changed By	Description of Change	Version
07/15/2022	CAC	Updated Descriptive Narrative with multiple myeloma disease information and 2022 estimates for disease incidence. Updated Guidelines section (NCCN recommends Sarclisa® (with carfilzomib and dexamethasone) as a **category 1**, **preferred** treatment option for relapsed or refractory multiple myeloma after 1 to 3 prior therapies (previously category 2A, "other recommended regimen").	2
Signature William (Bill) Jagiello, DO			

Change Date	Changed By	Description of Change	Version
07/16/2021	CAC	Criteria implementation.	1
Signature William (Bill) Jagiello, DO			

CAC = Medicaid Clinical Advisory Committee