Sarclisa® (isatuximab)	
MEDICAL POLICY NUMBER	Med_Clin_Ops_073
CURRENT VERSION EFFECTIVE DATE	January 1, 2024
APPLICABLE PRODUCT AND MARKET	*Individual Family Plan:* All Plans *Small Group*: All Plans *Medicare Advantage:* All Plans

PURPOSE

To promote consistency between reviewers in clinical coverage decision-making by providing the criteria that generally determine the medical necessity of **Sarclisa®** (isatuximab) therapy.

POLICY/CRITERIA

Prior Authorization and Medical Review is required.

Coverage for Sarclisa will be provided for 12 months and may be renewed.

1. Patient is 18 years of age or older; **AND**
2. Sarclisa is prescribed by, or in consultation with, an oncologist; **AND**
3. Patient has a documented diagnosis of multiple myeloma; **AND**
4. Patient has relapsed or refractory disease; **AND**
5. Patient has received **at least two** prior lines of systemic chemotherapy including **both** lenalidomide and a proteasome inhibitor (e.g., Velcade [bortezomib], Kyprolis [carfilzomib], Ninlaro [ixazomib]); **AND**
6. Sarclisa will be administered in combination with Pomalyst (pomalidomide) and dexamethasone; **OR**
7. Patient has received **at least one to three (1-3)** lines of therapy; **AND**
8. Sarclisa will be administered in combination with Kyprolis (carfilzomib) and dexamethasone.

LIMITATIONS/EXCLUSIONS

1. Any indication other than those listed above due to insufficient evidence of therapeutic value

BACKGROUND

Isatuximab-irfc is an IgG1-derived monoclonal antibody that binds to CD38 expressed on the surface of hematopoietic and tumor cells, including multiple myeloma cells. Isatuximab-irfc induces apoptosis of tumor cells and activation of immune effector mechanisms including antibody-dependent cell-mediated cytotoxicity (ADCC), antibody-dependent cellular phagocytosis (ADCP), and complement dependent cytotoxicity (CDC). Isatuximab-irfc inhibits the ADP-ribosyl cyclase activity of CD38. Isatuximab-irfc can activate natural killer (NK) cells in the absence of CD38-positive target tumor cells and suppresses CD38- positive T-regulatory cells. The combination of isatuximab-irfc and pomalidomide enhanced ADCC activity and direct tumor cell killing compared to that of isatuximab-irfc alone in vitro, and enhanced antitumor activity compared to the activity of isatuximab-irfc or pomalidomide alone in a human multiple myeloma xenograft model.

DEFINITIONS

1. SARCLISA (isatuximab-irfc) injection, for intravenous use. Initial U.S. Approval: 2020
2. SARCLISA (isatuximab-irfc) injection is a clear to slightly opalescent, colorless to slightly yellow solution, essentially free of visible particulates, supplied as follows:
    a. One 100 mg/5 mL single-dose vial in a carton: NDC 0024-0654-01
    b. One 500 mg/25 mL single-dose vial in a carton: NDC 0024-0656-01

CODING

Applicable NDC Codes	
00024-0654-01	Sarclisa® (isatuximab) 100 mg/5 mL single-dose vial
00024-0656-01	Sarclisa® (isatuximab) 500 mg/25 mL single-dose vial

Applicable Procedure Code	
J9227	Injection, isatuximab-irfc, 10 mg

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

EVIDENCE BASED REFERENCES

1. Product Information: SARCLISA(R) intravenous injection, isatuximab-irfc intravenous injection. sanofi-aventis US LLC (per FDA), Bridgewater, NJ, 2021.

POLICY HISTORY

Revision History	Month Day, Year	Updates
Original Effective Date	July 19, 2021	
Revision	• October 4, 2021 Added J-Code (J9227): Injection, isatuximab- irfc, 10 mg. Effective date: 10/01/2020 • February 2, 2022: Annual review – no changes made. • February 28, 2023 – Annual Review and approval (no policy revisions made) • March 1, 2023 – Adopted by MA UM Committee (no policy revisions made) • January 1, 2024 - Updated to Brand New Day/Central Health Medicare Plan (no policy revisions made)	
Approved by Pharmacy and Therapeutics Committee on 2/28/2023		