

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

Brand New Day/Central Health Medicare Plan develops policies and makes coverage determinations using credible scientific evidence including but not limited to MCG™ Health Guidelines, the ASAM Criteria™, and other third party sources, such as peer-reviewed medical literature generally recognized by the relevant medical community, physician specialty society recommendations, and expert opinion as relevant to supplement those sources. Brand New Day/Central Health Medicare Plan Medical Policies, MCG™ Guidelines, and the ASAM Criteria™ are not intended to be used without the independent clinical judgment of a qualified health care provider considering the individual circumstances of each member's case. The treating health care providers are solely responsible for diagnosis, treatment, and medical advice. Members may contact Brand New Day/Central Health Medicare Plan Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Brand New Day/Central Health Medicare Plan Medical Policy may contact the Health Plan. Brand New Day/Central Health Medicare Plan policies and practices are compliant with federal and state requirements, including mental health parity laws.

If there is a difference between this policy and the member specific plan document, the member benefit plan document will govern. For Medicare Advantage members, Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), govern. Refer to the CMS website at <http://www.cms.gov> for additional information.

Brand New Day/Central Health Medicare Plan medical policies address technology assessment of new and emerging treatments, devices, drugs, etc. They are developed to assist in administering plan benefits and do not constitute an offer of coverage nor medical advice. Brand New Day/Central Health Medicare Plan medical policies contain only a partial, general description of plan or program benefits and do not constitute a contract. Brand New Day/Central Health Medicare Plan does not provide health care services and, therefore, cannot guarantee any results or outcomes. Treating providers are solely responsible for medical advice and treatment of members. Our medical policies are updated based on changes in the evidence and healthcare coding and therefore are subject to change without notice. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). MCG™ and Care Guidelines® are trademarks of MCG Health, LLC (MCG).

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	<ul style="list-style-type: none"> 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		