Reference number(s)
4718-A

STANDARD MEDICARE PART B MANAGEMENT

SARCLISA (isatuximab-irfc)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications
Sarclisa is indicated:
A. in combination with pomalidomide and dexamethasone, for the treatment of adult patients with multiple myeloma who have received at least 2 prior therapies including lenalidomide and a proteasome inhibitor.
B. in combination with carfilzomib and dexamethasone, for the treatment of adult patients with relapsed or refractory multiple myeloma who have received 1 to 3 prior lines of therapy.

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. CRITERIA FOR INITIAL APPROVAL

Multiple myeloma
Authorization of 12 months may be granted for treatment of multiple myeloma when either of the following criteria is met:
A. The requested medication will be used in combination with pomalidomide and dexamethasone and the member has previously received at least two prior therapies for multiple myeloma, including lenalidomide and a proteasome inhibitor.
B. The requested medication will be used in combination with carfilzomib and dexamethasone and the member has previously received at least one prior line of therapy for multiple myeloma

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 months may be granted when all of the following criteria are met:
A. The member is currently receiving therapy with the requested medication
B. The requested medication is being used to treat an indication enumerated in Section II
C. The member is receiving benefit from therapy. Benefit is defined as:
    1. No evidence of unacceptable toxicity while on the current regimen AND

2. No evidence of disease progression while on the current regimen

IV. SUMMARY OF EVIDENCE

The contents of this policy were created after examining the following resources:

1. The prescribing information for Sarclisa.
2. The available compendium
    a. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    b. Micromedex DrugDex
    c. American Hospital Formulary Service- Drug Information (AHFS-DI)
    d. Lexi-Drugs
    e. Clinical Pharmacology
3. NCCN Guideline: Multiple myeloma

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Sarclisa are covered.

V. EXPLANATION OF RATIONALE

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

VI. REFERENCES

1. Sarclisa [package insert]. Bridgewater, NJ: sanofi-aventis U.S. LLC; July 2022
2. The NCCN Drugs & Biologics Compendium® ©2022 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed October 4, 2022.