PRIOR AUTHORIZATION POLICY

POLICY: Oncology (Injectable) – Sarclisa Prior Authorization Policy
- Sarclisa® (isatuximab-irfc intravenous infusion – Sanofi-Aventis)

REVIEW DATE: 04/06/2022

OVERVIEW
Sarclisa, a CD38-directed monoclonal antibody, is indicated in adults with **multiple myeloma**, in the following situations:[1]
- in combination with Pomalyst® (pomalidomide capsules) and dexamethasone in patients who have received at least two prior therapies, including lenalidomide and a proteasome inhibitor.
- in combination with Kyprolis® (carilzomib intravenous infusion) and dexamethasone in patients with relapsed or refractory disease who have received one to three prior lines of therapy.

Guidelines
Guidelines from the National Comprehensive Cancer Network (NCCN) [version 5.2022 – March 9, 2022] include Sarclisa/Kyprolis/dexamethasone and Sarclisa/Pomalyst/dexamethasone (after two prior therapies, including lenalidomide and a proteasome inhibitor) among the preferred regimens for previously treated multiple myeloma, for early relapses (one to three prior therapies).

POLICY STATEMENT
Prior Authorization is recommended for prescription benefit coverage of Sarclisa. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Sarclisa as well as the monitoring required for adverse events and long-term efficacy, approval requires Sarclisa to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA
Coverage of Sarclisa is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Multiple Myeloma**. Approve for 1 year if the patient meets ALL of the following (A, B, and C):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient meets one of the following (i or ii):
     - **i.** All of the following apply (a, b, c, and d):
       - **a)** The medication will be used in combination with Pomalyst (pomalidomide capsules) and dexamethasone; AND
       - **b)** Patient has tried at least TWO prior regimens for multiple myeloma; AND
         Note: Examples include bortezomib/lenalidomide/dexamethasone, Kyprolis (carfilzomib intravenous infusion)/lenalidomide/dexamethasone, Darzalex (daratumumab injection)/bortezomib/melphalan/prednisone, Ninlaro (ixazomib capsules)/lenalidomide/dexamethasone, and Darzalex/lenalidomide/dexamethasone.

c) A proteasome inhibitor was a component of at least one previous regimen; AND
Note: Examples of proteasome inhibitors include bortezomib, Kyprolis (carfilzomib intravenous infusion), Ninlaro (ixazomib capsules).

d) Lenalidomide was a component of at least one previous regimen; OR

ii. Patient meets both of the following (a and b):

a) The medication will be used in combination with Kyprolis (carfilzomib intravenous infusion) and dexamethasone; AND

b) Patient has tried at least ONE prior regimen; AND

C) The medication is prescribed by or in consultation with an oncologist.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Sarclisa is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Sarclisa® intravenous infusion [prescribing information]. Bridgewater, NJ: Sanofi-Aventis; March 2021.
2. The NCCN Drugs and Biologics Compendium. © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on April 1, 2022. Search term: isatuximab.
3. The NCCN Multiple Myeloma Clinical Practice Guidelines in Oncology (Version 5.2022 – March 9, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on April 1, 2022.