VENTURA COUNTY
HEALTH CARE PLAN

UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Oncology (Injectable) – Sarclisa Utilization Management Medical Policy
- Sarclisa® (isatuximab-irfc intravenous infusion – Sanofi-Aventis)

REVIEW DATE: 04/12/2023

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 3.2023 – December 8, 2022] include Sarclisa/Kyprolis/dexamethasone and Sarclisa/Pomalyst/dexamethasone (after two prior therapies, including lenalidomide and a proteasome inhibitor) among the preferred regimens (both combinations are category 1) for previously treated multiple myeloma, for early relapses (one to three prior therapies), in bortezomib- and lenalidomide-refractory disease.

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Sarclisa. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indication. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). 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

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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 intravenous infusion)/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, Ninlaro.

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 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.

Dosing. Approve the following dosing regimens:

A) The dose is 10 mg/kg intravenously; AND

B) During the initial cycle, up to four infusions are given with at least 7 days separating each dose; AND

C) For subsequent cycles, the patient receives a maximum of two infusions over a 28-day period.

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; July 2022.
2. The NCCN Drugs and Biologics Compendium. © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on April 10, 2023. Search term: isatuximab.
3. The NCCN Multiple Myeloma Clinical Practice Guidelines in Oncology (version 3.2023 – December 8, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on April 10, 2023.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	04/06/2022
Annual Revision	No criteria changes.	04/12/2023