CARECONTINUUM™

UTILIZATION MANAGEMENT MEDICAL POLICY

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

REVIEW DATE: 04/24/2024; selected revision 10/16/2024

OVERVIEW

Sarclisa, a CD38-directed monoclonal antibody, is indicated for **multiple myeloma** in adults, in the following situations:[1]

- in combination with bortezomib, lenalidomide, and dexamethasone for the treatment of newly diagnosed multiple myeloma in adult patients who are not eligible for autologous stem cell transplant (ASCT).
- 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

Multiple Myeloma: Guidelines from the National Comprehensive Cancer Network (NCCN) [version 1.2025 – September 17, 2024] recommend Sarclisa/lenalidomide/bortezomib/dexamethasone as one of the "Other Recommended Regimens" (category 2A) for primary therapy in transplant candidates.[2,3] Sarclisa/Kyprolis/lenalidomide/dexamethasone is recommended under "Useful in Certain Circumstances" (category 2A) in this setting (transplant; primary therapy). For non-transplant candidates, Sarclisa/bortezomib/lenalidomde/dexamethasone is recommended as one of the "Preferred Regimens" for primary therapy in patients < 80 years of age who are not frail (category 1). Sarclisa/Kyprolis/lenalidomide/dexamethasone is listed as "Useful in Certain Circumstances" (category 2B) in this setting (non-transplant; primary therapy). The guidelines 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, ii, or iii):
  - **i.** The medication will be used as primary therapy in ONE of the following combinations (a or b):
    - **a)** The medication will be used in combination with bortezomib, lenalidomide, and dexamethasone; OR
    - **b)** The medication will be used in combination with Kyprolis (carfilzomib intravenous infusion), lenalidomide, and dexamethasone; OR
  - **ii.** 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 /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
  - **iii.** 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, B, and C):
- **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; September 2024.
2. The NCCN Drugs and Biologics Compendium. © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on April 17, 2024. Search term: isatuximab.
3. The NCCN Multiple Myeloma Clinical Practice Guidelines in Oncology (version 1.2025 – September 17, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on October 14, 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	04/12/2023
Annual Revision	**Multiple Myeloma:** Added criterion that Sarclisa can be used as primary therapy in combination with lenalidomide, bortezomib, and dexamethasone.	04/24/2024
Selected Revision	**Multiple Myeloma:** Added criterion for primary therapy that the medication is used in combination with Kyprolis, lenalidomide, and dexamethasone.	10/16/2024