

## UTILIZATION MANAGEMENT MEDICAL POLICY

**POLICY:** Oncology (Injectable – CD38-Directed Cytolytic Antibody) – Sarclisa Escena Utilization Management Medical Policy

- Sarclisa Escena™ (isatuximab-irfc subcutaneous injection – Sanofi-Aventis)

**REVIEW DATE:** 07/22/2026

### OVERVIEW

Sarclisa Escena, a CD38-directed cytolytic antibody, is indicated for **multiple myeloma** in the following situations:<sup>1</sup>

- in combination with bortezomib, lenalidomide, and dexamethasone for the treatment of newly diagnosed disease in adults who are not eligible for autologous stem cell transplant.
- in combination with pomalidomide and dexamethasone in adults who have received at least one prior therapy, including lenalidomide and a proteasome inhibitor.
- in combination with Kyprolis® (carfilzomib intravenous infusion) and dexamethasone in adults with relapsed or refractory disease who have received one to three prior lines of therapy.

### Dosing

The recommended dose of Sarclisa Escena is 1,400 mg administered as a subcutaneous (SC) injection with the CirCLIQ™ On-Body Delivery System (OBDS) or with a syringe and infusion set for manual administration. Sarclisa Escena is given in combination with pomalidomide and dexamethasone; in combination with Kyprolis and dexamethasone; or in combination with bortezomib, lenalidomide, and dexamethasone. Treatment is repeated until disease progression or unacceptable toxicity. Sarclisa Escena dosing schedules are provided in Tables 1 and 2. Patients currently receiving Sarclisa® (isatuximab-irfc intravenous [IV] infusion) may transition to Sarclisa Escena after the completion of the first cycle.

**Table 1: Sarclisa Escena Dosing Schedule In Combination with Pomalidomide and Dexamethasone or in Combination with Kyprolis (carfilzomib intravenous infusion) and Dexamethasone<sup>1</sup>**

| Cycles                             | Dosing Schedules               |
|------------------------------------|--------------------------------|
| Cycle 1 (28-day cycle)             | Days 1, 8, 15, and 22 (weekly) |
| Cycle 2 and beyond (28-day cycles) | Days 1 and 15 (every 2 weeks)  |

**Table 2: Sarclisa Escena Dosing Schedule In Combination with Bortezomib, Lenalidomide, and Dexamethasone<sup>1</sup>**

| Cycles                               | Dosing Schedules               |
|--------------------------------------|--------------------------------|
| Cycle 1 (28-day cycle)               | Days 1, 8, 15, and 22 (weekly) |
| Cycle 2 to 12 (28-day cycles)        | Days 1 and 15 (every 2 weeks)  |
| Cycles 13 and beyond (28-day cycles) | Day 1 (every 4 weeks)          |

### Guidelines

National Comprehensive Cancer Network (NCCN) multiple myeloma guidelines (version 5.2026 – January 9, 2026) recommend numerous treatment regimens across various disease settings, several of which include Sarclisa.<sup>2</sup> Sarclisa Escena is not specifically mentioned in the guidelines yet. For primary therapy for hematopoietic cell transplant (HCT) candidates, Sarclisa/bortezomib/lenalidomide/dexamethasone is listed as “Preferred” (category 1) and Sarclisa/Kyprolis/lenalidomide/dexamethasone is listed as “Other Recommended Regimen” (category 2A). For primary therapy if HCT-deferred or HCT is not indicated, Sarclisa/bortezomib/lenalidomide/dexamethasone (for patients < 80 years old who are not frail) is listed as “Preferred” (category 1), Sarclisa/lenalidomide/dexamethasone is listed as “Other Recommended Regimen” (category 2A), and Sarclisa/Kyprolis/lenalidomide/dexamethasone is listed as “Useful in Certain

Circumstances” (category 2B). For relapsed/refractory multiple myeloma after 1 to 3 prior therapies, “Preferred” therapies include Sarclisa/Kyprolis/dexamethasone (category 1) for bortezomib- and lenalidomide-refractory patients and Sarclisa/pomalidomide/dexamethasone (category 1) for patients who have received two prior therapies, including lenalidomide and a proteasome inhibitor, and are lenalidomide- or bortezomib-refractory.

## POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Sarclisa Escena. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indication. 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 Escena as well as the monitoring required for adverse events and long-term efficacy, approval requires Sarclisa Escena 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 Escena 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  $\geq 18$  years of age; AND
  - B) Patient meets ONE of the following (i or ii):
    - 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 lenalidomide and dexamethasone with or without bortezomib; OR
      - b) The medication will be used in combination with Kyprolis (carfilzomib intravenous infusion), lenalidomide, and dexamethasone; OR
    - ii. Patient meets BOTH of the following (a and b):
      - a) Patient has tried at least one prior regimen for multiple myeloma; AND  
Note: Examples include Darzalex (daratumumab intravenous infusion), or Darzalex Faspro (daratumumab and hyaluronidase-fihj subcutaneous injection), lenalidomide, bortezomib, dexamethasone; bortezomib, lenalidomide, dexamethasone; Kyprolis (carfilzomib intravenous infusion), lenalidomide, or dexamethasone.
      - b) Patient meets ONE of the following ([1] or [2]):
        - (1) Patient meets BOTH of the following (a and b):
          - a. The medication will be used in combination with pomalidomide and dexamethasone; AND
          - b. A proteasome inhibitor and lenalidomide were a component of at least one previous regimen; OR
        - Note: Examples of proteasome inhibitors include bortezomib, Kyprolis (carfilzomib intravenous infusion), and Ninlaro (ixazomib capsules).

- (2) The medication will be used in combination with Kyprolis (carfilzomib intravenous infusion) and dexamethasone; AND
- C) The medication is prescribed by or in consultation with an oncologist or hematologist.
- Dosing.** Approve the following dosing regimens (A, B, and C):
- A) The dose is 1,400 mg given subcutaneously; AND
- B) During the initial cycle, up to four injections are given with at least 7 days separating each dose;  
AND
- C) For subsequent cycles, the patient receives a maximum of two injections over a 28-day period.

#### CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Sarclisa Escena 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 Escena™ subcutaneous injection [prescribing information]. Morristown, NJ: Sanofi-Aventis; July 2026.
2. The NCCN Multiple Myeloma Clinical Practice Guidelines in Oncology (version 5.2026 – January 9, 2026). © 2026 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on July 20, 2026.

#### HISTORY

| Type of Revision | Summary of Changes | Review Date |
|------------------|--------------------|-------------|
| New Policy       | --                 | 07/22/2026  |