

Sarclisa (isatuximab-irfc)

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
Sarclisa (isatuximab-irfc)

APPROVAL CRITERIA

Requests for Sarclisa (isatuximab-irfc) may be approved if the following criteria are met:

- I. Individual has a diagnosis of multiple myeloma; **AND**
- II. Individual has relapsed or refractory disease following treatment with at least two prior lines of therapy including lenalidomide and a proteasome inhibitor (for example, bortezomib, carfilzomib, or ixazomib); **AND**
- III. Sarclisa is used in combination with pomalidomide and dexamethasone (Label, NCCN 1);

OR

- IV. Individual has a diagnosis of multiple myeloma; **AND**
- V. Individual has not received treatment with isatuximab or another anti-CD38 agent (such as daratumumab); **AND**
- VI. Individual has relapsed or refractory disease following treatment with one to three prior lines of therapy (Label, NCCN 1);

OR

- VII. Individual has a diagnosis of multiple myeloma; **AND**
- VIII. Individual is using as primary therapy; **AND**
- IX. Individual is eligible for stem cell transplant; **AND**
- X. Sarclisa is used in combination with bortezomib, lenalidomide, and dexamethasone (NCCN 2A).

Requests for Sarclisa (isatuximab-irfc) may not be approved when the above criteria are not met and for all other indications.

Key References:

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: January 9, 2024.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.

3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2024; Updated periodically.
4. NCCN Clinical Practice Guidelines in Oncology™. © 2024 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed January 9, 2024.
 - a. Multiple Myeloma. V2.2024. Revised November 1, 2023.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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