

SPECIALTY GUIDELINE MANAGEMENT

SARCLISA (isatuximab-irfc)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications

1. Treatment of multiple myeloma, in combination with pomalidomide and dexamethasone, for adult patients who have received at least two prior therapies including lenalidomide and a proteasome inhibitor.
2. Treatment of relapsed or refractory multiple myeloma, in combination with carfilzomib and dexamethasone, for adult patients who have received one to three prior lines of therapy.

All other indications are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR INITIAL APPROVAL

Multiple Myeloma

Authorization of 12 months may be granted for treatment of multiple myeloma in either of the following settings:

1. The requested medication will be used in combination with pomalidomide and dexamethasone and the member has previously received at least two prior therapies for multiple myeloma, including lenalidomide and a proteasome inhibitor
2. The requested medication will be used in combination with carfilzomib and dexamethasone and the member has previously received at least one prior line of therapy for multiple myeloma

III. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section II when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

IV. REFERENCES

1. Sarclisa [package insert]. Bridgewater, NJ: Sanofi-aventis; March 2021.
2. U.S. National Library of Medicine. ClinicalTrials.gov. Multinational clinical study comparing isatuximab, pomalidomide and dexamethasone to pomalidomide and dexamethasone in refractory or relapsed and refractory multiple myeloma patients (ICARIA-MM). <https://clinicaltrials.gov/ct2/show/study/NCT02990338>. Accessed 10/02/2020.
3. The NCCN Drugs & Biologics Compendium® © 2021 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed April 6, 2021.