RXADVANCE
2 Park Central Drive
Southborough, MA 01772

Clinical Policy Title:	isatuximab-irfc
Policy Number:	RxA.640
Drug(s) Applied:	Sarclisa®
Original Policy Date:	7/5/2020
Line of Business Policy Applies to:	All lines of business

Background

SARCLISA is a CD38-directed cytolytic antibody indicated, in combination with pomalidomide and dexamethasone, for the treatment of adult patients with multiple myeloma who have received at least two prior therapies including lenalidomide and a proteasome inhibitor.

Dosing Information

Drug Name	Dosing Regimen	Maximum Dose
isatuximab-irfc (Sarclisa®)	**Cycle 1:** 10 mg/kg on days 1, 8, 15, and 22 of a 28-day cycle (in combination with pomalidomide and dexamethasone). **Cycle 2 and beyond:** 10 mg/kg on days 1 and 15 of a 28-day cycle (in combination with pomalidomide and dexamethasone), continue until disease progression or unacceptable toxicity.	No max dose, but has max infusion rates: • First infusion = 150mL/hr • Second and subsequent infusions = 200mL/hr

Dosage Forms

- Injection: 100 mg/5 mL (20 mg/mL), 500 mg/25 mL (20 mg/mL) in a single-dose vial

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

I. Initial Approval Criteria

A. Multiple Myeloma (must meet all):

1. Diagnosis of multiple myeloma;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Must be prescribed in combination with Pomalyst and dexamethasone;
5. Patient must have failed at least two prior therapies including Revlimid and a proteasome inhibitor such as Velcade, Kyprolis, Ninlaro.
6. Dose does not exceed 10 mg/kg IV weekly.

Approval Duration:

Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

A. All Indications in Section I (must meet all):

1. Currently receiving medication that has been authorized by RxAdvance, or documentation supports that member is currently receiving Sarclisa® for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy.
3. Dose does not exceed 10 mg/kg IV weekly.

Approval Duration:
Commercial: 12 months
Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
Not applicable.

APPENDIX B: Therapeutic Alternatives
There are multiple regimens and medications that can be used for RRMM. The following is a short list out of many regimens provided in the National Comprehensive Care Network (NCCN) 2020 guidelines.

- Velcade/Revlimid/dexamethasone
- Kyprolis/dexamethasone
- Kyprolis/Revlimid/dexamethasone
- Darzalex/Velcade/dexamethasone
- Darzalex/Revlimid/dexamethasone
- Empliciti/Revlimid/dexamethasone
- Ninlaro/Revlimid/dexamethasone
- Bendamustine/Velcade/dexamethasone
- Cyclophosphamide/Revlimid/dexamethasone

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - None.

- Boxed Warning(s):
  - None.

References

1. Sarclisa Prescribing Information. Bridgewater, NJ: Sanofi Aventis US, LLC; March 2020. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/761113s000lbl.pdf. Accessed July 2, 2020.
2. National Comprehensive Cancer Network Guidelines. Multiple Myeloma Version 4.2020. Available at: https://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf. Published May 8, 2020. Accessed July 2, 2020.
3. Attal M, Richardson PG, Rajkumar SV, et al. Isatuximab plus pomalidomide and low-dose dexamethasone versus pomalidomide and low-dose dexamethasone in patients with relapsed and refractory multiple myeloma (ICARIA-MM):

a randomised, multicentre, open-label, phase 3 study [published correction appears in Lancet. 2019 Dec 7;394(10214):2072]. *Lancet*. 2019;394(10214):2096-2107. doi:10.1016/S0140-6736(19)32556-5. Accessed July 2, 2020.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	07/05/2020	09/14/2020