Clinical Policy Title:	isatuximab-irfc
Policy Number:	RxA.640
Drug(s) Applied:	Sarclisa®
Original Policy Date:	07/05/2020
Last Review Date:	10/19/2023
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Multiple Myeloma (must meet all):

1. Diagnosis of MM (Multiple Myeloma);
2. Prescribed by or in consultation with an oncologist or hematologist;
3. Age ≥ 18 years;
4. Request is for one of the following (a or b):
   a. For progressive multiple myeloma, prescribed in combination with pomalidomide and dexamethasone after failure of at least two prior therapies including Revlimid® and a proteasome inhibitor such as Velcade®, Kyprolis®, Ninlaro®;
   b. For relapsed or refractory multiple myeloma, prescribed in combination with carfilzomib and dexamethasone in patients who have received 1 to 3 prior lines therapy;
5. Request meets one of the following (a or b):*
   a. Dose does not exceed 10 mg/kg intravenous weekly for the first 4 weeks, then every 2 weeks thereafter;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

*Prescribed regimen must be FDA-approved or recommended by NCCN

Approval Duration
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

A. Multiple Myeloma (must meet all):

1. Member is 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. If request is for a dose increase, request meets one of the following (a or b):*
   a. Dose does not exceed 10 mg/kg intravenous every 2 weeks;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).
   *Prescribed regimen must be FDA-approved or recommended by NCCN

Approval Duration

Commercial: 12 months
Medicaid: 12 months

References

1. National Comprehensive Cancer Network Guidelines. Multiple Myeloma Version 3.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf. Accessed May 1, 2023.
2. 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. Available at https://pubmed.ncbi.nlm.nih.gov/31735560/. Accessed May 1, 2023.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	07/05/2020	09/14/2020
Policy was reviewed: 1. Initial Approval Criteria I.A.1 was updated to include "…relapsed, refractory, or progressive…". 2. Initial Approval Criteria I.A.4 was updated to include "Request is for one of the following (a or b)…". 3. Initial Approval Criteria I.A.4.a was updated to include "For progressive multiple myeloma, prescribed in combination with pomalidomide…". 4. Initial Approval Criteria I.A.4.b was updated to include "For relapsed or refractory multiple myeloma, prescribed in combination…". 5. Continued Therapy Approval Criteria II.A was updated from "All Indications in Section I" to "Multiple Myeloma". 6. Continued Therapy Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 7. References were reviewed and updated.	07/05/2021	09/14/2021
Policy was reviewed: 1. References were reviewed and updated.	04/07/2022	07/18/2022
Policy was reviewed: 1. Initial Approval Criteria, I.A.1: Updated diagnosis criteria from Diagnosis of relapsed, refractory, or progressive multiple myeloma to Diagnosis of MM (Multiple Myeloma). 2. References were reviewed and updated.	05/01/2023	07/13/2023
Policy was reviewed.	10/19/2023	10/19/2023