Isatuximab-irfc inj,soln (SARCLISA®)

Criteria for Use

January 2025

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. **THE CLINICIAN SHOULD UTILIZE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.**

The Product Information should be consulted for detailed prescribing information.

See the VA National PBM-MAP-VPE Monograph on this drug at www.pbm.va.gov or http://vaww.pbm.va.gov for further information.

Exclusion Criteria *If the answer to ANY item below is met, then the patient should NOT receive isatuximab*

- ☐ Unable to be observed in clinic for an extended period following the first dose
- ☐ Absolute neutrophil count (ANC) < 1000/mm^3
- ☐ Hemoglobin < 8 g/dL; Must transfuse to hemoglobin above 8 g/dL prior to therapy initiation
- ☐ Platelet count < 50,000/mm^3 (<30,000/mm^3 if myeloma involvement in bone barrow >50%)
- ☐ Active or uncontrolled infection
- ☐ Known pregnancy
- ☐ Lactating

Inclusion Criteria *The answers to one of the following must be met:*

- ☐ Previously treated multiple myeloma, as part of a pomalidomide- or carfilzomib-based regimen
- ☐ Newly diagnosed multiple myeloma, in combination with bortezomib, lenalidomide and dexamethasone, in transplant ineligible patients

Additional Inclusion Criteria *ALL of the following must be selected:*

- ☐ Care is provided by a VA or VA Community Care hematology/oncology provider
- ☐ Goals of care and role of Palliative Care consult has been discussed and documented
- ☐ Eastern Cooperative Oncology Group (ECOG) performance status 0-2
- ☐ Type and screen patients for Red Blood Cell antibodies PRIOR to starting therapy
- ☐ Provider has informed Blood Bank that patient will be starting isatuximab

Additional Inclusion Criteria *Select if applicable:*

- ☐ Female patients of child-bearing potential: counseling provided on potential risks vs. benefits of treatment and the use of effective contraception during therapy and for 5 months after stopping treatment
- ☐ Male patients with female partners of child-bearing potential: counseling provided on potential risks vs. benefits of treatment and the use of effective contraception during therapy and for 5 months after stopping treatment

Other Justification*:*

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Prepared: July 2021; Revised Jan 2025.
Contact: B, Heron, Pharm.D., BCOP, National Clinical Pharmacy Program Manager,
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