VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

POLICY: Oncology (Injectable) – Sarclisa® (isatuximab-irfc injection, for intravenous use – Sanofi-Aventis)

DATE REVIEWED: 03/04/2020; selected revision 03/11/2020

OVERVIEW

Sarclisa, a CD38-directed monoclonal antibody, is indicated in combination with Pomalyst® (pomalidomide capsules) and dexamethasone for treatment of adults with multiple myeloma, for those who have received at least two previous therapies including with with Revlimid® (lenalidomide capsules) and a proteasome inhibitor.[1] In the pivotal study, the median number of prior lines of therapy was 3 lines (range, 2 to 11 prior lines of therapy). Safety and efficacy have not been established in patients < 18 years of age.

Disease Overview

Multiple myeloma is a cancer formed by malignant plasma cells which are found in the bone marrow.[2] Normally, B cells responding to an infection change into plasma cells that make antibodies to help attack and kill pathogens. In multiple myeloma, these plasma cells grow out of control and become cancerous. A monoclonal immunoglobulin (M protein) is produced by myeloma cells and may be found in the blood or excreted in the urine of patients with multiple myeloma. Beta-2 microglobulin is another protein made by myeloma cells, with high levels associated with more advanced disease. Sarclisa binds to CD38 and inhibits the growth of CD38-expressing tumor cells such as myeloma cells.

Guidelines

Sarclisa is not yet addressed in current guidelines for multiple myeloma.[3] Recently updated guidelines from the National Comprehensive Cancer Network (NCCN) [version 2.2020 – October 9, 2019] recommend various regimens as primary therapy (transplant eligible and non-transplant candidates), maintenance therapy, and previously-treated multiple myeloma. The relative efficacy and toxicity of each regimen, along with patient-specific factors (e.g., past therapies, renal disease), are considered for choice of primary and subsequent regimens.

POLICY STATEMENT

Prior authorization is recommended for prescription benefit coverage of Sarclisa. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Sarclisa as well as the monitoring required for adverse events and long-term efficacy, approval requires Sarclisa to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Sarclisa is recommended in those who meet the following criteria:

FDA-Approved Indications

1. **Multiple Myeloma**. Approve for 1 year if the patient meets ALL of the following (A, B, C, D, E and F):
   - **A)** The patient is ≥ 18 years of age; AND
   - **B)** The agent will be used in combination with Pomalyst (pomalidomide capsules)and dexamethasone; AND
   - **C)** The patient has tried at least TWO prior regimens for multiple myeloma.
     Note: Examples include Velcade (bortezomib injection)/Revlimid (lenalidomide capsules) /dexamethasone, Kyprolis (carfilzomib infusion)/Revlimid/dexamethasone, Darzalex (daratumumab injection)/Velcade/melphalan/prednisone, Ninlaro (ixazomib capsules)/Revlimid/dexamethasone, and Darzalex/Revlimid/dexamethasone; AND
   - **D)** A proteasome inhibitor was a component of at least one previous regimen.
     Note: Examples of proteasome inhibitors include Velcade (bortezomib injection), Kyprolis (carfilzomib infusion), Ninlaro (ixazomib capsules); AND
   - **E)** Revlimid (lenalidomide capsules) was a component of at least one previous regimen; AND
   - **F)** The agent is prescribed by or in consultation with an oncologist.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Sarclisa has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions.

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Sarclisa® injection [prescribing information]. Bridgewater, NJ: Sanofi-Aventis; March 2020.
2. The NCCN Drugs and Biologics Compendium. © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on March 2, 2020. Search term: isatuximab.
3. The NCCN Multiple Myeloma Clinical Practice Guidelines in Oncology (Version 2.2020 – October 9, 2019). © 2019 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on March 2, 2020.