Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 213.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Sarclisa (isatuximab-irfc)

I. Policy:
Sarclisa (isatuximab-irfc)

II. Purpose/Objective:
To provide a policy of coverage regarding Sarclisa (isatuximab-irfc).

III. Responsibility:
A. Medical Directors
B. Medical Management
C. Pharmacy Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than
3. the department requiring/authoring the policy.
4. Devised – the date the policy was implemented.
5. Revised – the date of every revision to the policy, including typographical and grammatical changes.
6. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Medicaid Business Segment
Medically Necessary — A service, item, procedure, or level of care compensable under the Medical Assistance program that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

i. Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
ii. Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
iii. Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

DESCRIPTION:
Sarclisa (isatuximab-irfc) is a CD38-directed monoclonal antibody that binds to CD38 expressed on the surface of hematopoietic and tumor cells (including multiple myeloma cells). After binding, Sarclisa induces apoptosis the cells and activates immune effector mechanisms via antibody-dependent cell-mediated cytotoxicity (ADCC), antibody-dependent cellular phagocytosis (ADCP), and complement dependent cytotoxicity (CDC). The combination of Sarclisa and pomalidomide enhanced ADCC activity and direct tumor cell killing compared to that of Sarclisa alone in vitro, and enhanced antitumor activity compared to the activity of Sarclisa or pomalidomide alone in human multiple myeloma xenograft model.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Sarclisa (isatuximab-irfc) will be considered medically necessary for all lines of business when ALL of the following criteria are met:

- Medical record documentation that Sarclisa is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of one of the following:
    - Medical record documentation of diagnosis of multiple myeloma **AND** both of the following:
        - Medical record documentation that Sarclisa will be used in combination with pomalidomide (Pomalyst) and dexamethasone **AND**
        - Medical record documentation of prior treatment with at least two lines of therapy, which included lenalidomide (Revlimid) AND a proteasome inhibitor (including but not limited to Velcade (bortezomib)*, Kyprolis (carfilzomib)*, or Ninlaro (ixazomib))

    OR
    - Medical record documentation of diagnosis of relapsed or refractory multiple myeloma **AND** both of the following:
        - Medical record documentation that Sarclisa will be used in combination with carfilzomib (Kyprolis)* and dexamethasone **AND**
        - Medical record documentation of prior treatment with one to three lines of therapy

*Prior authorization required

AUTHORIZATION DURATION: Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if the member experiences unacceptable toxicity or worsening of disease.

Note: For Medicaid (GHP Family), any requests for services that do not meet criteria set in the PARP will be evaluated on a case-by-case basis.

LINE OF BUSINESS:
Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

REFERENCES:
1. Sarclisa [prescribing information]. Bridgewater, NJ: Sanofi-Aventis US LLC; November 2023.

This policy will be revised as necessary and reviewed no less than annually.

Devised: 5/19/20

Revised: 5/18/21 (relapsed/refractory), 3/31/23 (LOB carve out, Medicaid business segment), 12/28/23 (references added)

Reviewed: 5/2/22 (Medicaid PARP statement), 3/18/24

MA UM Committee approval: 12/31/23