Geisinger Health Plan

POLICIES AND PROCEDURE MANUAL

Policy: MBP 212.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Adakveo (crizanlizumab-tmca)

I. Policy:
Adakveo (crizanlizumab-tmca)

II. Purpose/Objective:
To provide a policy of coverage regarding Adakveo (crizanlizumab-tmca)

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
Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance Program and if it meets any one of the following standards:

(i) the service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.

(ii) the service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability.

(iii) the service or benefit 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:

Adakveo (crizanlizumab-tmca) is a humanized monoclonal antibody, which binds to P-selectin and blocks interaction with ligands, including P-selectin glycoprotein ligand 1. Normally, the translocation of P-selectin to the activated endothelial cell surface results in adhesion of sickle erythrocytes to vessels and the development of vascular occlusion. By binding to P-selectin, Adakveo inhibits interactions between endothelial cells, platelets, red blood cells, and leukocytes, which results in decreased platelet aggregation, maintenance of blood flow, and minimized sickle cell-related crises.

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

Adakveo (crizanlizumab-tmca) will be considered medically necessary when ALL of the following criteria are met:

- Prescription written by or in consultation with a hematologist **AND**
- Medical record documentation of the member being greater than or equal to 16 years of age **AND**
- Medical record documentation of diagnosis of sickle cell disease **AND**
- Medical record documentation of number of vasoocclusive crises in the previous 12 months **AND**
- Medical record documentation of intolerance to, or contraindication to, or therapeutic failure on a minimum 3-month trial of generic hydroxyurea **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Endari

AUTHORIZATION DURATION: Each treatment period is defined as 12 months. Re-review will occur every 12 months. The following criteria is required for reauthorization:

- Medical record documentation of continued or sustained improvement in the acute complications of sickle cell disease (i.e. number of vasoocclusive crises, hospitalizations, and number of ACS occurrences)

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.

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

Devised: 5/19/20

Revised:

Reviewed: 4/30/21