Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 312.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Veopoz (pozelimab-bbfg)

I. Policy:
Veopoz (pozelimab-bbfg)

II. Purpose/Objective:
To provide a policy of coverage regarding Veopoz (pozelimab-bbfg).

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:
Pozelimab-bbfg is a human, monoclonal immunoglobulin G4P (IgG4P) antibody directed against the terminal complement protein C5 that inhibits terminal complement activation by blocking cleavage of C5 into C5a (anaphylatoxin) and C5b, thereby blocking the formation of the membrane-attack complex (C5b-C9, a structure mediating cell lysis).

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

Veopoz (pozelimab-bbfg) will be considered medically necessary for all lines of business when ALL of the following criteria are met:

- Medical record documentation of CD55-deficient protein losing enteropathy (CHAPLE disease) with a confirmed genotype of biallelic CD55 loss-of-function mutation **AND**
- Medical record documentation of age ≥ 1 year **AND**
- Prescribed by or in consultation with a hematologist, gastroenterologist, or a provider specialized in rare genetic hematologic diseases **AND**
- Medical record documentation that the patient is vaccinated with the meningococcal vaccine **AND**
- Medical record documentation that Veopoz will not be used in combination with Soliris (eculizumab) **AND**
- Medical record documentation of a prescribed dose and administration that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature

AUTHORIZATION DURATION: Initial approval will be for 6 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for 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 (i.e., improvement or no worsening of clinical symptoms, increase in or stabilization of albumin and IgG concentration)

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. Veopoz [prescribing information]. Tarrytown, New York: Regeneron Pharmaceuticals, Inc.; August 2023. Accessed 12/2023.

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

Devised: 1/16/24

Revised:

Reviewed:

MA UM Committee approval: Pending