Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 245.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Empaveli (pegcetacoplan)

I. Policy:
Empaveli (pegcetacoplan)

II. Purpose/Objective:
To provide a policy of coverage regarding Empaveli (pegcetacoplan).

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:
Pegcetacoplan is a pegylated pentadecapeptide that targets complement C3. In binding to complement protein C3 (and its activation fragment C3b), pegcetacoplan regulates the cleavage of C3 and the generation of downstream effectors of complement activation. Pegcetacoplan acts in the complement cascade that controls both C3b-mediated extravascular hemolysis and terminal complement-mediated intravascular hemolysis.

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

Empaveli (pegcetacoplan) will be considered medically necessary for all lines of business when all of the following criteria are met:

- Medical record documentation of a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH)
- Medical record documentation of flow cytometry confirming diagnosis **AND**
- Medical record documentation that Empaveli is prescribed by a hematologist **AND**
- Medical record documentation that member has received vaccinations against encapsulated bacteria, including *Streptococcus pneumoniae, Neisseria meningitidis,* and *Haemophilus influenzae type B* **AND**
- Medical record documentation of one of the following:
    - member is transfusion-dependent (i.e., has at least 1 transfusion in the 24 months prior to initiation of pegcetacoplan due to documented hemoglobin less than 7 g/dL in persons without anemic symptoms or less than 9 g/dL in persons with symptoms from anemia) prior to initiation of pegcetacoplan treatment; **OR**
    - there is a significant adverse impact on the insured individual's health such as end organ damage or thrombosis without other cause

AUTHORIZATION DURATION: Initial approval will be for 6 months. Subsequent authorizations will be for 6 months and will require of:

- Medical record documentation:
    - Hemolysis control measured by lactic acid dehydrogenase (LDH) level less than 1.5 times the upper limit of normal (ULN) **AND**
    - Reduced need or elimination of transfusion requirements **OR**
    - Stabilization of hemoglobin levels

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.

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

Devised: 10/27/21

Revised: 10/26/22 (Medicaid PARP statement), 10/16/23 (LOB carve out, Medicaid business segment)

Reviewed: