Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 253.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Vabysmo (faricimab)

I. Policy:
Vabysmo (faricimab)

II. Purpose/Objective:
To provide a policy of coverage regarding Vabysmo (faricimab).

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:
Faricimab is a recombinant humanized bispecific antibody that inhibits vascular endothelial growth factor A (VEGF-A), resulting in suppression of endothelial cell proliferation, neovascularization, and vascular permeability. Faricimab also inhibits angiopoietin-2 (Ang-2), which promotes vascular stability and desensitizes blood vessels to effects of VEGF-A.

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

Vabysmo (faricimab) will be considered medically necessary for the commercial, exchange, and CHIP lines of business when all of the following criteria are met:

- Medical record documentation of a diagnosis of neovascular age-related macular degeneration **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to intravitreal bevacizumab (Avastin) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to two (2) additional intravitreal VEGF inhibitors (e.g. Eylea, Beovu, or Lucentis)

OR

- Medical record documentation of a diagnosis of diabetic macular edema **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to intravitreal bevacizumab (Avastin) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to two (2) additional intravitreal VEGF inhibitors (e.g. Eylea and Lucentis)

NOTE: Indicators of intravitreal bevacizumab (Avastin) failure may include:

- Worse or unchanged intraretinal or subretinal fluid.
- Persistent subretinal or intraretinal fluid.
- Recurrent intraretinal or subretinal fluid at current interval or extended interval.
- New subretinal hemorrhage
- In the absence of subretinal fluid, intraretinal fluid, or subretinal hemorrhage a failure documented as evidence of growth of the neovascular membrane on clinical exam or multimodal imaging.
- Any ocular or systemic adverse event thought related to the use of intravitreal bevacizumab.

AUTHORIZATION DURATION: Approvals will be given for a lifetime duration.

QUANTITY LIMIT: 0.1mL (12mg) per 21 days (6mg per eye per 21 days)

Vabysmo (faricimab) will be considered medically necessary for the Medicare line of business when all of the following criteria are met:

- Medical record documentation of a diagnosis of neovascular age-related macular degeneration **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to intravitreal bevacizumab (Avastin) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to one (1) additional intravitreal VEGF inhibitor (e.g. Eylea, Beovu, or Lucentis)

OR

- Medical record documentation of a diagnosis of diabetic macular edema **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to intravitreal bevacizumab (Avastin) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to one (1) additional intravitreal VEGF inhibitor (e.g. Eylea or Lucentis)

NOTE: Indicators of intravitreal bevacizumab (Avastin) failure may include:

- Worse or unchanged intraretinal or subretinal fluid.
- Persistent subretinal or intraretinal fluid.
- Recurrent intraretinal or subretinal fluid at current interval or extended interval.
- New subretinal hemorrhage
- In the absence of subretinal fluid, intraretinal fluid, or subretinal hemorrhage a failure documented as evidence of growth of the neovascular membrane on clinical exam or multimodal imaging.
- Any ocular or systemic adverse event thought related to the use of intravitreal bevacizumab.

AUTHORIZATION DURATION: Approvals will be given for a lifetime duration.

QUANTITY LIMIT: 0.1mL (12mg) per 21 days (6mg per eye per 21 days)

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: 3/15/22

Revised: 5/17/22 (added QL), 10/25/22 (QL update, LOB carve out), 10/12/23 (Medicare business segment)

Reviewed: