Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 94.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Eylea/Eylea HD (aflibercept)

I. Policy:
Eylea/Eylea HD (aflibercept)

II. Purpose/Objective:
To provide a policy of coverage regarding Eylea/Eylea HD (aflibercept)

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:
Eylea (aflibercept) is a recombinant fusion protein that acts as a decoy receptor for vascular endothelial growth factor-A (VEGF-A) and placental growth factor (PLGF). Aflibercept binds to VEGF-A and PLGF and inhibits binding and activating of endothelial cell receptors, thereby suppressing neovascularization and slowing vision loss.

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

Eylea (aflibercept) will be considered medically necessary for commercial, exchange, CHIP and Medicare 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).

OR

- Medical record documentation of a diagnosis of diabetic retinopathy with or without macular edema **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to intravitreal bevacizumab (Avastin) **OR** medical record documentation of baseline best-corrected visual acuity 20/50 or worse.

OR

- Medical record documentation of a diagnosis of macular edema following retinal vein occlusion.

OR

- Medical record documentation of a diagnosis of retinopathy of prematurity (ROP)

NOTES:
- Indicators of 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.
- In clinical trials, prematurity was defined as a maximum gestational age at birth of 32 weeks or a maximum birth weight of 1500 grams [3.3 lbs].

AUTHORIZATION DURATION
- **Retinopathy of Prematurity (ROP):** 12 months
- **All other indications:** Approvals will be given for a lifetime duration.

QUANTITY LIMIT: 0.1mL (4mg) per 25 days (2mg per eye per 25 days) (Enter by GPI 14)

Eylea HD (aflibercept) will be considered medically necessary for 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 one (1) of the following: Eylea*, Beovu*, Lucentis*, Byooviz*, or Cimerli* **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Vabysmo*

OR

- Medical record documentation of a diagnosis of diabetic retinopathy with or without 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) of the following: Eylea*, Beovu*, Lucentis*, Byooviz*, or Cimerli* **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Vabysmo*

*Prior authorization required

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

QUANTITY LIMIT: 0.14mL (16mg) per 21 days (8mg per eye per 21 days)

Eylea HD (aflibercept) 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 one (1) of the following: Eylea*, Beovu*, Lucentis*, Byooviz*, or Cimerli* **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Vabysmo*

OR

- Medical record documentation of a diagnosis of diabetic retinopathy with or without macular edema **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to one (1) of the following: Eylea*, Beovu*, Lucentis*, Byooviz*, or Cimerli* **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Vabysmo*

*Prior authorization required

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

QUANTITY LIMIT: 0.14mL (16mg) per 21 days (8mg per eye per 21 days)

NOTE (for all LOB): Indicators of intravitreal VEGF 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.

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. Eylea [prescribing information]. Tarrytown, NY: Regeneron Pharmaceuticals Inc; March 2023.
2. Eylea HD [prescribing information]. Tarrytown, NY: Regeneron Pharmaceuticals Inc; August 2023.

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

Devised: 3/14/12

Revised: 11/2012 (added indication); 1/2014 revised indications, 1/20/15 (policy retired), 9/15/20 (policy and prior auth reinstated), 5/7/22 (added QL), 7/19/22 (“best-corrected” VA), 10/25/22 (QL update, LOB carve out), 6/23/23 (added ROP, Medicaid Business Segment), 11/21/23 (added Eylea HD), 12/31/23 (references added)

Reviewed: 11/2/2013, 9/8/21 (clarified intravitreal bevacizumab)

MA UM Committee approval: 12/31/23