

POLICIES AND PROCEDURE MANUAL

Policy: MBP 47.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Lucentis (ranibizumab), Byooviz (ranibizumab-nuna), and Cimerli (ranibizumab-eqrn)

Applicable line of business:

Commercial	X	Medicaid	
Medicare	X	ACA	X
CHIP	X		

I. Policy:

Lucentis (ranibizumab), Byooviz (ranibizumab-nuna), and Cimerli (ranibizumab-eqrn)

II. Purpose/Objective:

To provide a policy of coverage regarding Lucentis (ranibizumab), Byooviz (ranibizumab-nuna), and Cimerli (ranibizumab-eqrn)

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 the department requiring/authoring the policy.
- 3. Devised the date the policy was implemented.
- 4. Revised the date of every revision to the policy, including typographical and grammatical changes.
- 5. 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

Commercial

Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Medicare

Geisinger Gold Medicare Advantage HMO, PPO, and HMO D-SNP plans are offered by Geisinger Health Plan/Geisinger Indemnity Insurance Company, health plans with a Medicare contract. Continued enrollment in Geisinger Gold depends on contract renewal. Geisinger Health Plan/Geisinger Indemnity Insurance Company are part of Geisinger, an integrated health care delivery and coverage organization.

CHIF

Geisinger Health Plan Kids (GHP Kids) is a Children's Health Insurance Program (CHIP) offered by Geisinger Health Plan in conjunction with the Pennsylvania Department of Human Services (DHS). Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

DESCRIPTION:

Ranibizumab is a recombinant humanized monoclonal antibody fragment which binds to and inhibits human vascular endothelial growth factor A (VEGF-A). Ranibizumab inhibits VEGF from binding to its receptors and thereby suppressing neovascularization and slowing vision loss.

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

Intravitreal VEGF products for Commercial, Exchange, CHIP, and Medicare lines of business			
Preferred	Non-preferred		
Avastin (bevacizumab)			
<u>Aflibercept</u>	<u>Aflibercept</u>		
Eylea (aflibercept)*	Eylea HD (aflibercept)*		
Pavblu (aflibercept-ayyh)*			
<u>Ranibizumab</u>	<u>Ranibizumab</u>		
Lucentis (ranibizumab)*	Susvimo (ranibizumab)*		
Byooviz (ranibizumab-nuna)*			
Cimerli (ranibizumab-eqrn)*			
<u>Brolucizumab</u>	<u>Brolucizumab</u>		
Beovu*			
<u>Faricimab</u>	<u>Faricimab</u>		
	Vabysmo (faricimab)*		
*prior authorization required			

Lucentis (ranibizumab), Byooviz (ranibizumab-nuna), and Cimerli (ranibizumab-eqrn) will be considered medically necessary for the 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 an adequate trial of intravitreal bevacizumab (Avastin) given at every four (4) week dosing intervals.

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 an adequate trial of intravitreal bevacizumab (Avastin) given at every four (4) week dosing intervals.

OR

 Medical record documentation of a diagnosis of macular edema following retinal vein occlusion OR myopic choroidal neovascularization

AND

Medical record documentation of therapeutic failure on, intolerance to, or contraindication to an adequate trial of intravitreal bevacizumab (Avastin) given at every four (4) week dosing intervals.

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. Initial authorization approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate. Medical record documentation of a beneficial clinical response based on objective clinical monitoring will be required for subsequent approvals. The medication will no

longer be covered if the member experiences unacceptable toxicity or worsening of disease in a manner suggestive of lack of efficacy of the medication.

QUANTITY LIMIT: 0.1mL (1mg) per 28 days (0.5mg per eye per 28 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.

REFERENCES:

- 1. Lucentis [prescribing information]. South San Francisco, CA: Genentech Inc; February 2024.
- 2. Byooviz [prescribing information]. Cambridge, MA: Biogen Inc; August 2025.
- 3. Cimerli [prescribing information]. Redwood City, CA: Coherus BioSciences Inc; May 2025.

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

Devised: 9/15/20

Revised: 5/17/22 (added QL), 10/25/22 (QL update, LOB carve out), 1/17/23 (added Byooviz and Cimerli, Medicaid Business Segment), 12/31/23 (references added), 7/16/24 (added RVO alt, LOB table, taglines), 7/10/25 (deleted Medicaid business segment), 10/17/25 (Avastin trial, auth duration, note deleted)

Reviewed: 2/15/13 (reviewed at P&T, no policy), 8/27/21 (clarified intravitreal bevacizumab), 1/8/24

MA UM Committee approval: 12/31/23, 8/30/24, 12/31/24, 9/10/25