JOHNS HOPKINS MEDICINE / JOHNS HOPKINS HEALTHCARE	Johns Hopkins HealthCare LLC **Pharmacy Public** **Medical Management Drug Policies**	*Policy Number*	MMDP017
		Effective Date	01/01/2019
		Review Date	04/19/2023
	Subject **Ophthalmic Vascular Endothelial Growth Factor (VEGF) Inhibitors: Lucentis, Byooviz, Cimerli, Beovu**	*Revision Date*	04/19/2023
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This document applies to the following Participating Organizations:

US Family Health Plan

Keywords: Beovu, Lucentis

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I. POLICY

Lucentis (ranibizumab), Byooviz (ranibizumab-nuna), Cimerli(ranibizumab-eqrn), and Beovu (brolucizumab-dbll, for Priority Partners only) will require prior authorization for medical benefit coverage to ensure appropriate use. The process for initiating a prior authorization request can be found in policy PHARM 20.

II. POLICY CRITERIA

A. **Byooviz** may be approved for patients meeting the following:
   1. Patient is 18 years of age or older
   2. Documentation has been submitted showing the patient has one of the following diagnoses:
      a. Neovascular (wet) age-related macular degeneration (AWD)
      b. Macular edema following retinal vein occlusion (RVO)
      c. Myopic choroidal neovascularization (mCNV)
   3. Prescriber is, or in consultation with, an ophthalmologist

B. **Cimerli** may be approved for patients meeting the following:
   1. Patient is 18 years of age or older
   2. Documentation has been submitted showing the patient has one of the following diagnoses:
      a. Neovascular (wet) age-related macular degeneration
      b. Macular edema following retinal vein occlusion
      c. Myopic choroidal neovascularization
      d. Diabetic macular edema (DME)
      e. Diabetic retinopathy (DR)
   3. Prescriber is, or in consultation with, an ophthalmologist

C. **Lucentis** may be approved for patient meeting the following:
   1. For a diagnosis of AMD, RVO, or mCNV:

a. Patinet is 18 years of age or older
b. Documentation has been submitted showing the following:
I. Patient has a confirmed diagnosis of AMD, RVO, or mCNV
II. Patient has had trial and inadequate response to Byooviz or Cimerli

2. For a diagnosis of DME or DR:
a. Patient is 18 years of age or older
b. Documentation has been submitted showing the following:
I. Patient has a confirmed diagnosis of DME or DR
II. Patient has had trial and inadequate response to Cimerli

3. Prescriber is, or in consultation with, an ophthalmologist

D. **Beovu** may be approved for patients who meet the following:
1. Patient is 18 years of age or older
2. Documentation has been submitted showing one of the following diagnoses:
a. Neovascular (wet) age-related macular degeneration
b. Diabetic macular edema
3. Prescriber is, or in consultation with, an ophthalmologist

III. AUTHORIZATION PERIOD/LIMITATIONS

A. Initial approval may be given for 6 months of therapy
B. Continuation of therapy for AMD, RVO, DME, or DR may be approved in 12- month intervals with documentation showing a beneficial response to treatment, evidence by at least one of the following:
1. Detained neovascularization
2. Improvement or stabilization in visual acuity
3. Maintenance of corrected visual acuity from prior treatment
4. Supportive findings from optical coherence tomography or fluorescein angiography

C. Continuation of therapy for mCNV may be approved in 12-month intervals with documentation showing the medical necessity based on disease activity, such as the presence of intra-/sub- retinal fluid or active leakage, visual symptoms, or worsening of vision
D. Approval dosages will be restricted to the FDA-approved dosing regimens that demonstrated efficacy. Requests for dosage increases that have not been found to provide additional efficacy will not be considered for approval.

IV. EXCLUSIONS

A. Lucentis, Byooviz, Cimerli, and Beovu will not be covered for the following:
1. Pediatric patients
2. Patients with ocular or peri-ocular infections
3. Patients with active intraocular inflammation
4. Concomitant use with other anti-vascular endothelial growth factor (VEGF) agents
5. Any indications that are not FDA-approved, or clinical guideline-supported

V. RECOMMENDED DOSAGE

Please refer to the FDA-approved prescribing information for indication-specific dosing details.

VI. CODES

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Note: The following CPT/HCPCS codes are included below for informational purposes. Inclusion or exclusion of a CPT/HCPCS code(s) below does not signify or imply member coverage or provider reimbursement. The member's specific benefit plan determines coverage.

Medication	HCPCS/CPT Code
Lucentis 0.3 MG/0.05ML SOLN Injection, ranibizumab, 0.1 mg	J2778
Lucentis 0.5 MG/0.05ML SOLN Injection, ranibizumab, 0.1 mg	J2778
Beovu 6MG/0.05ML SOLN Injection, brolucizumab-dbll, 1 mg	J0179
Injection, ranibizumab-nuna, biosimilar, (byooviz), 0.1 mg	Q5124
Injection, ranibizumab-eqrn (cimerli), biosimilar, 0.1 mg	Q5128

VII. REFERENCES

1. Lucentis [Prescribing Information]. South San Francisco, CA: Genetech, Inc.; 2018 March
2. Beovu [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; 2022 December
3. Byooviz [prescribing information]. Cambridge, MA: Biogen Inc; 2022 June.
4. Cimerli [prescribing information]. Redwood City, CA: Coherus BioSciences Inc;2022 August .
5. Wells JA, Glassman AR, Ayala AR, et al. Aflibercept, bevacizumab, or ranibizumab for diabetic macular edema. N Engl J Med. 2015 Mar 26;372(13):1193-203. doi: 10.1056/NEJMoa1414264
6. American Academy of Ophthalmology Retina/Vitreous Panel. Preferred Practice Pattern®
7. Guidelines. Age-Related Macular Degeneration. San Francisco, CA: American Academy of Ophthalmology; January 2015. Available at www.aao.org/ppp. Accessed November 30, 2018.
8. American Academy of Ophthalmology Retina/Vitreous Panel. Preferred Practice Pattern® Guidelines. Retinal Vein Occlusions. San Francisco, CA: American Academy of Ophthalmology; November 2015. Available at www.aao.org/ppp. Accessed November 30, 2018.
9. American Academy of Ophthalmology Retina/Vitreous Panel. Preferred Practice Pattern® Guidelines. Diabetic Retinopathy. San Francisco, CA: American Academy of Ophthalmology; December 2017. Available at www.aao.org/ppp. Accessed November 30, 2018.
10. Wang E & Chen Y: Intravitreal anti-vascular endothelial growth factor for choroidal neovascularization secondary to pathologic myopia: systematic review and meta-analysis. Retina 2013; 33(7):1375-1392.

VIII. APPROVALS

Signature on file at JHHC

DATE OF REVISION	SUMMARY OF CHANGE

12/19/2018	Policy Creation
6/5/2019	Removed Avastin step therapy requirement
01/15/2020	Adding criteria for Beovu and presented policy for USFHP adoption effective 3/1/2020
11/10/2021	Removed Priority Partners as an applicable LOB
04/19/2023	add Byooviz and Cimerli; revised criteria

Review Date: 12/19/2018, 1/15/2020, 04/19/2023

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