BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

EVIDENCE-BASED CRITERIA	
SECTION: MEDICARE ADVANTAGE PART B DRUGS	
ORIGINAL EFFECTIVE DATE:	**01/01/23**
LAST REVIEW DATE:	**08/18/22**
CURRENT EFFECTIVE DATE:	**06/01/23**
LAST CRITERIA REVISION DATE:	**05/18/23**
NEXT REVIEW DATE: 4TH QTR 2023	
ARCHIVE DATE:	

MEDICARE ADVANTAGE PART B STEP THERAPY PROGRAMS

Non-Discrimination Statement and Multi-Language Interpreter Services information are located at the end of this document.

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Evidence-Based Criteria must be read in its entirety to determine coverage eligibility, if any.

This Evidence-Based Criteria provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Evidence-Based Criteria are subject to change as new information becomes available.

For purposes of this Evidence-Based Criteria, the terms "experimental" and "investigational" are considered to be interchangeable.

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This Policy provides assistance in administering health benefits. All reviewers must first identify member eligibility, any federal or state regulatory requirements, Centers for Medicare and Medicaid Services (CMS) policy, the member specific benefit plan coverage, and individual provider contracts prior to use of this Policy.

Criteria:

Refer to FDA website for current indications and dosage.

- A Step Therapy Medication is considered ***medically necessary*** and will be approved when **ANY** of the following criteria are met:

  1. Individual has failure, contraindication or intolerance to **ALL** drugs/products listed in the **Step 1 Drug/Product** column, **OR**

  2. Individual has been on the drug/product in the **Step 2 Drug/Product** column in the last 365 days.

This policy applies step therapy for the following drugs/products:

Drug Class	Step 2 Drug/Product	Applicable Diagnosis	Step 1 Drug/Product	Effective Date
Intravitreal Vascular Endothelial Growth Factor (VEGF) Inhibitors	**Byooviz** (ranibizumab-nuna)	• Neovascular (wet) age-related macular degeneration (AMD)	Avastin (bevacizumab)	01/01/2023
		• Macular edema following retinal vein occlusion (RVO) • Myopic choroidal neovascularization (mCNV)	Does not apply	01/01/2023
	Lucentis (ranibizumab)	• Neovascular (wet) age-related macular degeneration (AMD) • Diabetic macular edema (DME) • Diabetic Retinopathy (DR)	Avastin (bevacizumab)	01/01/2023
		• Macular edema following retinal vein occlusion (RVO) • Myopic choroidal neovascularization (mCNV)	Does not apply	
	Eylea (aflibercept)	• Neovascular (wet) age-related macular degeneration (AMD) • Diabetic macular edema (DME) • Diabetic Retinopathy (DR)	Avastin (bevacizumab) **AND** Lucentis (ranibizumab)	01/01/2023
		• Macular edema following retinal vein occlusion (RVO)	Lucentis (ranibizumab)	
	Beovu (brolucizumab-dbll)	• Neovascular (wet) age-related macular degeneration (AMD)	Avastin (bevacizumab) **AND** Lucentis (ranibizumab) **AND** Eylea (aflibercept)	01/01/2023

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	Vabysmo (faricimab-svoa)	• Neovascular (wet) age-related macular degeneration (AMD)	Avastin (bevacizumab) **AND** Lucentis (ranibizumab) **AND** Eylea (aflibercept)	06/01/2023
		• Diabetic macular edema (DME)	Avastin (bevacizumab) **AND** Lucentis (ranibizumab) **AND** Eylea (aflibercept)	

History:	**Date:**	**Activity:**
Pharmacy and Therapeutics Committee	05/18/23	Reviewed and approved policy with revisions
Medicare Advantage Clinical Pharmacist	04/25/23	Reviewed with revision
Pharmacy and Therapeutics Committee	08/18/22	Approved policy
Medicare Advantage Clinical Pharmacist	08/01/22	Development

Description:

Step Therapy is the practice of beginning a drug for a medical condition with a preferred drug before progressing to another therapy. It requires trying a Step Therapy Drug/Product 1 before getting Step Therapy Drug/Product 2. Step therapy guidelines are developed and reviewed by a panel of practicing physicians and pharmacists.
A beneficiary is not required under this policy to change a current drug/product. For the purposes of this policy, a current drug/product means the member has a paid claim for the drug/product within the past 365 days.

Angiogenesis inhibitors bind to and inhibit vascular endothelial growth factor (VEGF) to prevent the formation of new blood vessels. VEGF inhibitors are also referred to as anti-vascular endothelial growth factors (anti-VEGF) or angiogenesis inhibitors.

Beovu (brolucizumab-dbll) is indicated for the treatment of Neovascular (Wet) Age-Related Macular Degeneration (AMD).

Byooviz (ranibizumab-nuna), is biosimilar to Lucentis (ranibizumab) and is indicated for Neovascular (Wet) Age-Related Macular Degeneration (AMD); Macular Edema Following Retinal Vein Occlusion (RVO); and Myopic Choroidal Neovascularization (mCNV).

Eylea (aflibercept) is indicated for the treatment of patients with: neovascular (Wet) age-related macular degeneration (AMD); macular edema following retinal vein occlusion (RVO); diabetic macular edema (DME); and diabetic retinopathy (DR).

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Lucentis (ranibizumab) is indicated for the treatment of patients with: Neovascular (Wet) Age-Related Macular Degeneration (AMD); Macular Edema Following Retinal Vein Occlusion (RVO); Diabetic Macular Edema (DME); Diabetic Retinopathy (DR); and Myopic Choroidal Neovascularization (mCNV).

Vabysmo is a VEGF and angiopoietin-2 (Ang-2) inhibitor indicated for the treatment of patients with Neovascular (Wet) Age-Related Macular Degeneration (nAMD) and Diabetic Macular Edema (DME).

Avastin (bevacizumab) is approved for the treatment of metastatic cancers including colorectal and lung cancer. Avastin is the full-length monoclonal antibody from which the Lucentis fragment is derived. Avastin is commonly used ***off label*** in the treatment of age-related macular degeneration, macular edema from diabetes, diabetic retinopathy, retinal vein occlusions, and choroidal and retinal neovascularization. The American Academy of Ophthalmology (AAO) Preferred Practice Patterns for AMD, RVO, and DR review literature for bevacizumab and its efficacy and safety and demonstrated benefit for improved vision.

Definitions:

Age-Related Macular Degeneration (AMD):
Gradual painless loss of central vision due to a breakdown of a portion of the retina known as the macula. The neovascular form (also known as wet, exudative. or disciform) is characterized by choroidal neovascularization, the proliferation of fine blood vessels at the back of the eye that begin to leak or exude fluid, causing hemorrhage, swelling, and scar tissue which may result in permanent central vision loss within days or weeks. The non-neovascular form (also known as dry, non-exudative, or atrophic) is more common and progresses slowly, characterized by the accumulation of small, yellowish deposits called drusen that form within the layers of the retina. Non-neovascular AMD may suddenly develop into neovascular AMD.

Choroidal Neovascularization (CNV):
The proliferative growth of abnormal new blood vessels, called neovascular membranes, originating from the choroid (between the retina and the sclera) that begin to leak or exude fluid, causing hemorrhage, swelling and scar tissue which can lead to rapid irreversible loss of vision.

Diabetic Retinopathy:
At its earliest stage (nonproliferative retinopathy), microaneurysms occur. With disruption of the blood-retinal barrier, macular retinal vessels become permeable, leading to exudation of serous fluid and lipids into the macula (macular edema). As the disease progresses, blood vessels that provide nourishment to the retina are blocked, triggering the growth of new and fragile blood vessels (proliferative retinopathy). Severe vision loss with proliferative retinopathy arises from vitreous hemorrhage. Moderate vision loss can also arise from macular edema (fluid accumulating in the center of the macula) during the proliferative or nonproliferative stages of the disease. Although proliferative disease is the main blinding complication of diabetic retinopathy, macular edema is more frequent and is the leading cause of moderate vision loss in people with diabetes.

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Central and Branch Retinal Vein Occlusions:
Retinal vein occlusions are classified by whether there is a central retinal vein occlusion (CRVO) or branch retinal vein occlusion (BRVO). CRVO is also categorized as ischemic or non-ischemic. Ischemic CRVO is associated with a poor visual prognosis, with macular edema and permanent macular dysfunction occurring in virtually all individuals. Non-ischemic CRVO has a better visual prognosis, but many individuals will have macular edema, and it may convert to the ischemic type within 3 years. Most of the vision loss associated with CRVO results from the main complications, macular edema and intraocular neovascularization. BRVO is a common retinal vascular disorder in adults between 60 and 70 years of age and occurs approximately 3 times more commonly than CRVOs. Macular edema is the most significant cause of central visual loss in BRVO.

Retinopathy of Prematurity:
This is a neovascular retinal disorder that primarily affects premature infants of low birth weight. It is one of the most common causes of childhood blindness in the United States. Typically, retinal vascularization begins at the optic nerve when the eye begins to develop (16 weeks' gestation) and reaches the edge of the retina at 40 weeks' gestation. If an infant is born prematurely, normal vessel growth may stop, followed by neovascularization at the interface between the vascular and avascular retinal areas.

Other Retinal Vascular Conditions:
Other retinal vascular conditions that have been investigated for treatment with VEGF inhibitors are cystoid macular edema resulting from vasculitis, Coats disease, Eales disease, idiopathic macular telangiectasia type II, neovascularization of the iris/neovascularization of the angle/neovascular glaucoma, pseudoxanthoma elasticum, radiation retinopathy, retinal neovascularization, rubeosis, Von Hippel- Lindau and vitreous hemorrhage secondary to retinal neovascularization.

Biosimilar:
Biological product is approved based on data demonstrating that it is highly similar to an FDA-approved biological product, known as a reference product, and that there are no clinically meaningful differences between the biosimilar product and the reference product.

Coding:

HCPCS: C9097, J0178, J0179, J2778, J3590, Q5124

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Resources:

Literature reviewed 08/18/22. We do not include marketing materials, poster boards and non-published literature in our review.

1. American Academy of Ophthalmology Retina/Vitreous Panel. Preferred Practice Pattern® Guidelines. Age-related macular degeneration. San Francisco, CA: American Academy of Ophthalmology; 2019. Available at: https://www.aao.org/preferred-practice-pattern/age-related-macular-degeneration-ppp. Accessed August 1, 2022.

2. American Academy of Ophthalmology Retina/Vitreous Panel. Preferred Practice Pattern® Guidelines. Diabetic retinopathy. San Francisco, CA: American Academy of Ophthalmology; 2019. Available at: https://www.aao.org/preferred-practice-pattern/diabetic-retinopathy-ppp. Accessed August 1, 2022.

3. American Academy of Ophthalmology Retina/Vitreous Panel. Preferred Practice Pattern® Guidelines. Retinal Vein Occlusions. San Francisco, CA: American Academy of Ophthalmology; 2019. Available at: https://www.aao.org/preferred-practice-pattern/retinal-vein-occlusions-ppp. Accessed August 1, 2022.

4. Beovu. Prescribing Information. Novartis Pharmaceuticals Corporation; March 2022. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed August 1, 2022.

5. Byooviz. Prescribing Information. Biogen, Inc; April 2022. DailyMed http://dailymed.nlm.nih.gov. Accessed July 13, 2022.

6. CMS Chapter 15 – Covered Medical and Other Health Services. Chapter 15- Drugs and Biologicals. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf. Access August 10, 2022.

7. CMS Local Coverage Article (LCA) A53009 Intraocular Bevacizumab Coding/Billing Guidelines. https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=53009&DocID=A53009. Access August 10, 2022.

8. CMS Memorandum titled Off-label Use of Drugs in Medicare Advantage Step Therapy Programs, dated November 5, 2021. https://www.cms.gov/files/document/hpmssteptherapymemo.pdf. Access August 10, 2022.

9. CMS Memorandum titled Prior Authorization and Step Therapy for Part B Drugs in Medicare Advantage, dated August 7, 2018; see: https://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/Downloads/MA_Step_Therapy_HPMS_Memo_8_7_2018.pdf?source=your_stories_page. Access August 10, 2022.

10. Eylea Prescribing Information. Regeneron Pharmaceuticals, Inc; June 2021. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed August 1, 2022.

11. Fraser CE, D'Amico DJ. Diabetic retinopathy: Classification and clinical features. In: UpToDate, Nathan DM, Trobe J, Mulder JE. (Eds). UpToDate, Waltham, MA. Available at http://uptodate.com. Topic last updated October 26, 2020. Accessed August 1, 2022.

12. Fraser CE, D'Amico DJ, Shah AR. Diabetic retinopathy: Prevention and treatment. In: UpToDate, Nathan DM, Trobe J, Mulder JE. (Eds). UpToDate, Waltham, MA. Available at http://uptodate.com. Topic last updated October 29, 2019. Accessed August 1, 2022.

13. Han DP, Ahmad B. Retinal vein occlusion: Epidemiology, clinical manifestations, and diagnosis. In: UpToDate, Trobe J, Givens J (Eds). UpToDate, Waltham, MA. Available at http://uptodate.com. Topic last updated December 1, 2021. Accessed August 1, 2022.

14. Han DP, Ahmad B. Retinal vein occlusion: Treatment. In: UpToDate, Trobe J, Givens J (Eds). UpToDate, Waltham, MA. Available at http://uptodate.com. Topic last updated November 16, 2021. Accessed August 1, 2022.

15. Lucentis Prescribing Information.Genentech, Inc; March 2018. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed August 1, 2022.

16. Vabysmo Prescribing Information. Genentech, Inc; January 2022. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed August 1, 2022.

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Non-Discrimination Statement:

Blue Cross Blue Shield of Arizona (BCBSAZ) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability or sex. BCBSAZ provides appropriate free aids and services, such as qualified interpreters and written information in other formats, to people with disabilities to communicate effectively with us. BCBSAZ also provides free language services to people whose primary language is not English, such as qualified interpreters and information written in other languages. If you need these services, call (602) 864-4884 for Spanish and (877) 475-4799 for all other languages and other aids and services.

If you believe that BCBSAZ has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability or sex, you can file a grievance with: BCBSAZ's Civil Rights Coordinator, Attn: Civil Rights Coordinator, Blue Cross Blue Shield of Arizona, P.O. Box 13466, Phoenix, AZ 85002-3466, (602) 864-2288, TTY/TDD (602) 864-4823, crc@azblue.com. You can file a grievance in person or by mail or email. If you need help filing a grievance BCBSAZ's Civil Rights Coordinator is available to help you. You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 509F, HHH Building, Washington, DC 20201, 1–800–368–1019, 800–537–7697 (TDD). Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html