MASSACHUSETTS

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Pharmacy Medical Policy
Drugs for Macular Degeneration and Diabetic Eye Disease

Table of Contents

Policy Number: 092

BCBSA Reference Number: N/A

Related Policies

- N/A

Prior Authorization Information

Policy	☒ Prior Authorization ☐ Step Therapy ☐ Quantity Limit	Reviewing Department	**Pharmacy Operations:** Tel: 1-800-366-7778 Fax: 1-800-583-6289
		Policy Effective Date	**3/2024**
Pharmacy (Rx) or Medical (MED) benefit coverage	☐ Rx ☒ MED	**To request for coverage:** Providers may call, fax, or mail the attached form (Formulary Exception/Prior Authorization form) to the address below. **Blue Cross Blue Shield of Massachusetts** **Pharmacy Operations Department** 25 Technology Place Hingham, MA 02043 Tel: 1-800-366-7778 Fax: 1-800-583-6289 **Individual Consideration for the atypical patient:** Policy for requests that do not meet clinical criteria of this policy, see section labeled Individual Consideration	
Policy applies to Commercial Members: • Managed Care (HMO and POS), • PPO and Indemnity • MEDEX with Rx plan • Managed Major Medical with Custom BCBSMA Formulary • Comprehensive Managed Major Medical with Custom BCBSMA Formulary • Managed Blue for Seniors with Custom BCBSMA Formulary **Policy does NOT apply to**: • Medicare Advantage			

Summary

This policy covers coverage requirements for non-oncologic indications of Vascular Endothelial Growth Factor (VEGF) Inhibitors and other miscellaneous ophthalmic agents used for macular degeneration/diabetic eye disease.

Drug	*AMD (wet)	*DME	*RVO	*DR	*ROP	*mCNV	*GA
†Avastin	✓	✓		✓			
Beovu (brolucizumab)	✓	✓					
Eylea (aflibercept)	✓	✓	✓	✓	✓		
Lucentis (ranibizumab)	✓	✓	✓	✓		✓	

Byooviz (ranibizumab nuna)	✓		✓			✓	
Cimerli (ranibizumab eqrn)	✓	✓	✓	✓		✓	
Izervay							✓
Susvimo (ranibizumab)	✓						
Syfovre							✓
Vabysmo (faricimab)	✓	✓	✓				
***AMD** – Age-related Macular Edema; **DME** – Diabetic Macular Edema; **RVO** – Macular Edema following Retinal Vein Occlusion; **mCNV** – Myopic Choroidal Neovascularization; **DR** – Diabetic Retinopathy; **ROP** – Retinopathy of Prematurity; **GA** – Geographic Atrophy [+]Avastin – Off-label repackaged Avastin has more than 50% use in the VEGF group for AMD, DR, and DME.							

Safety and Efficacy of Repackaged Avastin: In 2015, a comparing Avastin injections (N = 296,000) to Lucentis (N=87,000) found that repackaged Avastin was not linked to a higher risk of eye infection (endophthalmitis) versus those treated with Lucentis. Another study in 2022 study published in the New England Journal of Medicine also found that patients starting on therapy with bevacizumab that were subsequently switched to Eylea (if necessary) fared as well over the 2-year study period as patients who were initially started on Eylea.

Policy – VEGF Inhibitors for Macular Degeneration and other Diabetic Eye Disease

Length of Approval	12 months
Formulary Status	All requests must meet the Prior Authorization criteria. See section on individual consideration for more information if you require an exception to any of these criteria requirements for an atypical patient.

Coverage options and requirements of VEGF inhibitors for Macular Degeneration and other Diabetic eye diseases:

Drug	Formulary Status (BCBSMA Commercial Plan)	Requirement
Bevacizumab ™	* Covered under Medical Benefit Only, PA	Prior Authorization required
Beovu ® (brolucizumab)	* Covered under Medical Benefit Only, PA	Prior Authorization required
Byooviz ™ (ranibizumab nuna)	* Covered under Medical Benefit Only, PA	Prior Authorization required
Cimerli ™ (ranibizumab eqrn)	* Covered under Medical Benefit Only, PA	Prior Authorization required
Eylea	* Covered under Medical Benefit Only, PA	Prior Authorization required
Eylea HD	* Covered under Medical Benefit Only, PA	Prior Authorization required
Lucentis ® (ranibizumab)	* Covered under Medical Benefit Only, PA	Prior Authorization required
Susvimo (ranibizumab)	* Covered under Medical Benefit Only, PA	Prior Authorization required
Vabysmo ™ (faricimab)	* Covered under Medical Benefit Only, PA	Prior Authorization required

**** Not available for retail Pharmacy Billing***

Bevacizumab, Byooviz, Cimerli, Lucentis, Susvimo, and Vabysmo

The above VEGF inhibitors may be considered **MEDICALLY NECESSARY** and covered when **ALL** of the following criteria are met:

1. Age 18 years and older; **AND**
2. Treatment failure or contraindication to Avastin ® (bevacizumab) **AND**
3. Confirmed diagnosis of one (1) of the following:
   a. Neovascular (Wet) Age-Related Macular Degeneration (AMD)
   b. Macular Edema Following Retinal Vein Occlusion (RVO)
   c. Diabetic Macular Edema (DME)
   d. Diabetic Retinopathy (DR)
   e. Myopic Choroidal Neovascularization (mCNV)

Eylea or Eylea HD

Eylea or Eylea HD may be considered **MEDICALLY NECESSARY** and covered when **ALL** of the following criteria are met:

1. Age 18 years and older; **AND**
2. Treatment failure or contraindication to Avastin ® (bevacizumab) **AND**
3. Documented Dose and Frequency must be submitted and must be within the FDA approved Dosing and Frequency, **AND**
4. Confirmed diagnosis of one (1) of the following:
   a. Neovascular (Wet) Age-Related Macular Degeneration (AMD)
   b. Macular Edema Following Retinal Vein Occlusion (RVO)
   c. Diabetic Macular Edema (DME)
   d. Diabetic Retinopathy (DR)
   e. Retinopathy of Prematurity (ROP)

Complement Inhibitors for Geographic Atrophy

Length of Approval	12 months
Formulary Status	All requests must meet the Prior Authorization criteria. See section on individual consideration for more information if you require an exception to any of these criteria requirements for an atypical patient.

Coverage options and requirements of complement inhibitors for the treatment of Geographic Atrophy (GA):

Drug	Formulary Status (BCBSMA Commercial Plan)	Requirement
Syfovre ™ (pegcetacoplan)	* Covered under Medical Benefit Only, PA	Prior Authorization required

Not available for retail Pharmacy Billing

Izervay or Syfovre

Izervay (avacincaptad) or **Syfovre** (pegcetacoplan) may be considered **MEDICALLY NECESSARY** and covered when **ALL** of the following criteria are met:

1. Age 18 years and older; **AND**
2. Confirmed diagnosis of Geographic Atrophy (GA); **AND**
3. Absence of Choroidal Neovascularization (CNV) in both eyes **AND**
4. Secondary to Age-Related Macular Degeneration (AMD)

Provider Documentation Requirements

Documentation from the provider to support a reason preventing trial of formulary alternative(s) must include the name and strength of alternatives tried and failed (if alternatives were tried, including dates if available) and specifics regarding the treatment failure. Documentation to support clinical basis preventing switch to formulary alternative should also provide specifics around clinical reason.

Individual Consideration (For Atypical Patients)

Our medical policies are written for most people with a given condition. Each policy is based on peer reviewed clinical evidence. We also take into consideration the needs of atypical patient populations and diagnoses.

If the coverage criteria outlined is unlikely to be clinically effective for the prescribed purpose, the health care provider may request an exception to cover the requested medication based on an individual's unique clinical circumstances. This is also referred to as "individual consideration" or an "exception request."

Some reasons why you may need us to make an exception include: therapeutic contraindications; history of adverse effects; expected to be ineffective or likely to cause harm (physical, mental, or adverse reaction).

To facilitate a thorough and prompt review of an exception request, we encourage the provider to include additional supporting clinical documentation with their request. This may include:

- Clinical notes or supporting clinical statements;
- The name and strength of formulary alternatives tried and failed (if alternatives were tried) and specifics regarding the treatment failure, if applicable;
- Clinical literature from reputable peer reviewed journals;
- References from nationally recognized and approved drug compendia such as American Hospital Formulary Service® Drug Information (AHFS-DI), Lexi-Drug, Clinical Pharmacology, Micromedex or Drugdex®; and
- References from consensus documents and/or nationally sanctioned guidelines.

Providers may call, fax or mail relevant clinical information, including clinical references for individual patient consideration, to:

Blue Cross Blue Shield of Massachusetts
Pharmacy Operations Department
25 Technology Place
Hingham, MA 02043
Phone: 1-800-366-7778
Fax: 1-800-583-6289

We may also use prescription claims records to establish prior use of formulary alternatives or to show if step therapy criteria has been met. We will require the provider to share additional information when prescription claims data is either not available or the medication fill history fails to establish use of preferred formulary medications or that step therapy criteria has been met.

Policy History

Date	Action
3/2024	Updated to require dose and frequency for Eylea ® to coincide with the Medical claim edits.
1/2024	Updated to removed Step and to update the policy to a Prior authorization policy. Plus, to add Izervay ™ to the policy.
10/2023	Updated to move Eylea ® to step 2 and to add Eylea ®HD, Syfovre and Bevacizumab to the policy.
9/2023	Reformatted policy and updated IC to align with 118E MGL § 51A.
8/2023	Update to move Eylea ® and Beovu ® to step 3.
7/2023	Reformatted Policy
5/2023	Updated to a two-step policy prior to the August change announced in policy 999.
4/2023	Updated to add Vegzelma ® to step 1 of policy
11/2022	Updated to add Alymsys to step 1 and Cimerli to step 2.
8/2022	Updated to add Byooviz and to move Lucentis ® to step 3
3/2022	Updated new Medications Vabysmo ™ & Susvimo ™
11/2020	VEGF Inhibitors Step Therapy issued. Effective 11/2020. Policy #343 Intravitreal Angiogenesis Inhibitors for Choroidal Vascular Conditions and policy #401 Intravitreal Angiogenesis Inhibitors for Retinal Vascular Conditions were retired effective 11/2020. For coverage information, see policy #092 VEGF Inhibitors Step Therapy.

Forms

To request prior authorization using the Massachusetts Standard Form for Medication Prior Authorization Requests (eForm), click the link below:

https://www.bluecrossma.org/medical-policies/sites/g/files/csphws2091/files/acquiadam-assets/023%20E%20Form%20medication%20prior%20auth%20instruction%20prn.pdf

OR

Print and fax, Massachusetts Standard Form for Medication Prior Authorization Requests #434

References

1. Ranibizumab or Bevacizumab for Neovascular Age-Related Macular Degeneration According to the Lucentis Compared to Avastin Study Treat-and-Extend Protocol. Karina Berg, et al. Ophthalmology; 2016 Jan;123(1):51-9
2. Aflibercept Monotherapy or Bevacizumab first for Diabetic Macular Edema. Jhaveri CD, et al. N Engl J Med 2022; 387:692-703
3. Avastin ® [package insert South San Francisco, CA: Genentech, Inc.: 6/2019.
4. Beovu ® [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation: 1/2020.
5. Eylea ® [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.: 8/2019.
6. Lucentis ® [package insert]. South San Francisco, CA: Genentech, Inc.: 11/2019.
7. Macugen ® [package insert]. Bridgewater, NJ: Valeant Pharmaceuticals N. America LLC: 7/2016.

8. Susvimo ™ [package insert]. South San Francisco, CA: Genentech, Inc.: 3/2021.
9. Vabysmo ™ [package insert]. South San Francisco, CA: Genentech, Inc.: 3/2021.
10. Byooviz ™ [package insert]. Cambridge, MA: Biogen, Inc.: 4/2022.
11. Alymsys ® [package insert]. Bridgewater, NJ: Amneal Pharmaceuticals LLC: 4/2022.
12. Mvasi ™ [package insert]. Thousand Oaks, CA: Amgen, Inc.: 11/2021.
13. Zirabev ™ [package insert]. NY, NY: Pfizer, Inc.: 2/2023.
14. Vegzelma ® [package insert]. Jersey City, NJ: Celltrion USA, Inc: 4/2022.
15. Izervay ™ [package insert]. Parsippany, NJ: IVERIC bio, Inc.: 9/2023.