

## PHARMACY POLICY STATEMENT

### Arkansas PASSE

<b>DRUG NAME</b>	<b>Vabysmo (faricimab-svoa)</b>
BENEFIT TYPE	Medical
STATUS	Prior Authorization Required

Vabysmo, initially approved by the FDA in 2022, is a vascular endothelial growth factor (VEGF) and angiopoietin-2 (Ang-2) inhibitor indicated for the treatment of patients with Neovascular (Wet) Age-Related Macular Degeneration (nAMD), Diabetic Macular Edema (DME), or Macular Edema following Retinal Vein Occlusion (RVO). It is administered by intravitreal injection by a physician. VEGF inhibitors suppress endothelial cell proliferation, neovascularization, and vascular permeability. Inhibition of Ang-2 is thought to promote vascular stability and desensitize blood vessels to the effects of VEGF-A. Vabysmo was approved based on clinical trial results showing achievement of vision gains noninferior to Eylea.

Vabysmo (faricimab-svoa) will be considered for coverage when the following criteria are met:

#### Retinal Disease

For **initial** authorization:

1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with an ophthalmologist; AND
3. Member has a diagnosis of one of the following conditions:
  - a) Neovascular (wet) Age-Related Macular Degeneration (AMD)
  - b) Diabetic Macular Edema (DME)
  - c) Macular Edema Following Retinal Vein Occlusion (RVO); AND
4. Member has tried and failed bevacizumab intravitreal injection; AND
5. Documentation of best-corrected visual acuity (BCVA); AND
6. Member does NOT have active infection or inflammation in or around the eye(s) to be treated.
7. **Dosage allowed/Quantity limit:** See package insert for full instructions.
  - AMD: 6 mg every 4 weeks for 4 doses; adjust per clinical evaluation to an interval of every 4 to 16 weeks. *Note: For most patients, every 4-week dosing did not demonstrate additional efficacy compared to every 8 weeks.*
  - DME: 6 mg every 4 weeks for 4 to 6 doses; adjust per clinical evaluation to an interval of every 4 to 8 weeks. *Note: For most patients, every 4-week dosing did not demonstrate additional efficacy compared to every 8 weeks.*
  - RVO: 6 mg every 4 weeks for 6 months.
  - QL: 1 vial per eye per 28 days

***If all the above requirements are met, the medication will be approved for 6 months.***

For **reauthorization**:

1. Chart notes must include documentation of improved or stabilized visual acuity.

***If all the above requirements are met, the medication will be approved for an additional 12 months.***

**CareSource considers Vabysmo (faricimab-svoa) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.**

DATE	ACTION/DESCRIPTION
04/05/2022	New policy for Vabysmo created.
05/25/2023	Annual review; no updates.
11/15/2023	Added RVO as an approved indication per label expansion. Clarified dosing for AMD, DME.

References:

1. Vabysmo [prescribing information]. Genentech, Inc.; 2023.
2. Flaxel CJ, Adelman RA, Bailey ST, et al. Age-Related Macular Degeneration Preferred Practice Pattern® [published correction appears in *Ophthalmology*. 2020 Sep;127(9):1279]. *Ophthalmology*. 2020;127(1):P1-P65. doi:10.1016/j.ophtha.2019.09.024
3. Solomon SD, Lindsley K, Vedula SS, Krzystolik MG, Hawkins BS. Anti-vascular endothelial growth factor for neovascular age-related macular degeneration. *Cochrane Database Syst Rev*. 2019;3(3):CD005139. Published 2019 Mar 4. doi:10.1002/14651858.CD005139.pub4
4. Holekamp, Nanvy M. Review of Neovascular Age-Related Macular Degeneration Treatment Options. *Am J Manag Care*. July 2019; 25:-S0
5. Flaxel CJ, Adelman RA, Bailey ST, et al. Diabetic Retinopathy Preferred Practice Pattern® [published correction appears in *Ophthalmology*. 2020 Sep;127(9):1279]. *Ophthalmology*. 2020;127(1):P66-P145. doi:10.1016/j.ophtha.2019.09.025
6. Virgili G, Parravano M, Evans JR, Gordon I, Lucenteforte E. Anti-vascular endothelial growth factor for diabetic macular oedema: a network meta-analysis. *Cochrane Database Syst Rev*. 2018;10(10):CD007419. Published 2018 Oct 16. doi:10.1002/14651858.CD007419.pub6
7. Diabetic Retinopathy Clinical Research Network, Wells JA, Glassman AR, et al. Aflibercept, bevacizumab, or ranibizumab for diabetic macular edema. *N Engl J Med*. 2015;372(13):1193-1203. doi:10.1056/NEJMoa1414264
8. Flaxel CJ, Adelman RA, Bailey ST, et al. Retinal Vein Occlusions Preferred Practice Pattern® [published correction appears in *Ophthalmology*. 2020 Sep;127(9):1279]. *Ophthalmology*. 2020;127(2):P288-P320. doi:10.1016/j.ophtha.2019.09.029
9. Schmidt-Erfurth U, Garcia-Arumi J, Gerendas BS, et al. Guidelines for the Management of Retinal Vein Occlusion by the European Society of Retina Specialists (EURETINA). *Ophthalmologica*. 2019;242(3):123-162. doi:10.1159/000502041

Effective date: 04/01/2024

Revised date: 11/15/2023