PHARMACY POLICY STATEMENT
Michigan Medicaid

DRUG NAME	Vabysmo (faricimab-svoa)
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 or prefilled syringe 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.

HAP 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.
11/08/2024	Added prefilled syringe form.

References:

1. Vabysmo [prescribing information]. Genentech, Inc.; 2024.
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: 04/01/2025
Revised date: 11/08/2024