Utilization Review Policy 285A

POLICY: Ophthalmology – Vascular Endothelial Growth Factor Inhibitors – Vabysmo Utilization Management Medical Policy

- Vabysmo™ (faricimab-svoa intravitreal injection – Genentech/Roche)

EFFECTIVE DATE: 6/1/2022
LAST REVISION DATE: 11/15/2023

COVERAGE CRITERIA FOR: UCare Medicaid and Exchange Plans Only (PMAP, Connect, MSC+, MnCare, all Individual and Family Plans)

OVERVIEW

Vabysmo, a vascular endothelial growth factor (VEGF) and angiopoietin-2 (Ang-2) inhibitor, is indicated for the following uses:[1]

- **Diabetic macular edema** (DME).
- **Macular edema following retinal vein occlusion** (RVO).
- **Neovascular (wet) age-related macular degeneration** (nAMD).

For the indication of macular edema following RVO, Vabysmo is recommended for use for 6 months.[1] The prescribing information does not note a duration of treatment for DME or nAMD.

Dosing Information

The recommended dosing for each indication is as follows[1]:

- DME: There are two recommended dosage regimens: 1) 6 mg administered by intravitreal injection every 4 weeks (approximately every 28 ± 7 days) for at least four doses and then depending on clinical evaluation, dosing interval may be modified by extensions of up to 4 week interval increments or reductions of up to 8 week interval increments; or 2) 6 mg administered by intravitreal injection every 4 weeks (approximately every 28 ± 7 days) for the first six doses and then the dosing frequency is every 8 weeks (2 months); some patients may require dosing every 4 weeks after the first four doses.
- Macular edema following RVO: The recommended dose is 6 mg administered by intravitreal injection every 4 weeks (approximately every 28 ± 7 days) for 6 months.
- nAMD: The recommended dose is 6 mg administered by intravitreal injection every 4 weeks (approximately every 28 ± 7 days) for the first four doses. Thereafter, depending on clinical evaluation, dosing frequency can range from every 4 weeks to every 16 weeks.

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Vabysmo. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indications. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. Because of the specialized skills required for evaluation and diagnosis of patients treated with Vabysmo as well as the monitoring required for adverse events and long-term efficacy, approval requires Vabysmo to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Vabysmo is recommended for requests meeting both the step therapy requirements and indication requirements:

Step Therapy Requirements (New Starts Only)

Criteria. *The patient must meet the following criteria (A or B):*

A) For patients new to Vabysmo therapy only, must have a trial of repackaged Avastin prior to approval of Vabysmo. New starts to therapy defined as no use of Vabysmo within the past 180 days for Medicaid and Commercial patients and includes use in either eye.

B) Patient has a contraindication or other clinical reason why repackaged Avastin cannot be tried before Vabysmo.

Note: Step therapy only required for indications FDA-Approved for both Vabysmo and Avastin.

FDA-Approved Indications

---

1. **Diabetic Macular Edema.** Approve for 1 year if administered by or under the supervision of an ophthalmologist.

   Dosing. Approve if the requested dosing meets the following (A and B):
   A) The dose is 6 mg administered by intravitreal injection for each eye being treated; AND
   B) The dosing interval is not more frequent than once every 4 weeks for each eye being treated.

---

2. **Macular Edema Following Retinal Vein Occlusion.** Approve for 6 months if administered by or under the supervision of an ophthalmologist.

   Dosing. Approve if the requested dosing meets the following (A and B):
   A) The dose is 6 mg administered by intravitreal injection for each eye being treated; AND
   B) The dosing interval is not more frequent than once every 4 weeks for each eye being treated.

---

3. **Neovascular (Wet) Age-Related Macular Degeneration.** Approve for 1 year if administered by or under the supervision of an ophthalmologist.

   Dosing. Approve if the requested dosing meets the following (A and B):
   A) The dose is 6 mg administered by intravitreal injection for each eye being treated; AND
   B) The dosing interval is not more frequent than once every 4 weeks for each eye being treated.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Vabysmo is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Vabysmo™ intravitreal injection [prescribing information]. South San Francisco, CA: Genentech; October 2023.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	02/09/2022
Early Annual Revision	**Neovascular (Wet) Age-Related Macular Degeneration:** The dosing interval was changed to not more frequent than once every 4 weeks.	11/16/2022
Annual Revision	**Macular Edema Following Retinal Vein Occlusion:** This condition and criteria for approval was added to the policy.	11/15/2023