Utilization Review Policy 285

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: 12/11/2023

COVERAGE CRITERIA FOR: All Aspirus Medicare 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. All approvals are provided for the duration noted below.

This policy incorporates Medicare coverage guidance as set forth in National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs), as well as in companion policy articles and other guidance applicable to the relevant service areas. These documents are cited in the References section of this policy. In some cases, this guidance includes specific lists of HCPCS and ICD-10 codes to help inform the coverage determination process. The Articles that include specific lists for billing and coding purposes

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will be included in the Reference section of this policy. However, to the extent that this policy cites such lists of HCPCS and ICD-10 codes, they should be used for reference purposes only. The presence of a specific HCPCS or ICD-10 code in a chart or companion article to an LCD is not by itself sufficient to approve coverage. Similarly, the absence of such a code does not necessarily mean that the applicable condition or diagnosis is excluded from coverage.

Note: Conditions for coverage outlined in this Medicare Advantage Medical Policy may be less restrictive than those found in applicable National Coverage Determinations, Local Coverage Determinations and/or Local Coverage Articles. Examples of situations where this clinical policy may be less restrictive include, but are not limited to, coverage of additional indications supported by CMS-approved compendia and the exclusion from this policy of additional coverage criteria requirements outlined in applicable National Coverage Determinations, Local Coverage Determinations and/or Local Coverage Articles.

Indications with a ^ below are also covered (and, if applicable, further detailed/referenced) in the corresponding Commercial Care Continuum (CC) Policy. Note: Additional criteria requirements for coverage of the same indication as outlined in the Commercial CC Policy and this Medicare Advantage CC Policy may NOT be the same.

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 365 days for Medicare 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

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1. Diabetic Macular Edema. ^

Criteria. Approve for 1 year.

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.

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2. Macular Edema Following Retinal Vein Occlusion. ^

Criteria. Approve for 6 months.

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

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B) The dosing interval is not more frequent than once every 4 weeks for each eye being treated.

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3. Neovascular (Wet) Age-Related Macular Degeneration. ^

Criteria. Approve for 1 year.

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.
2. Centers for Medicare and Medicaid Services, National Government Services, Inc, Local Coverage Determination (LCD): Drugs and Biologicals, Coverage of, for Label and Off-Label Uses (L33394) [original date 10/01/2015; revision effective date 11/1/2022]. Accessed on December 11, 2023.
3. Centers for Medicare and Medicaid Services, National Government Services, Inc, Local Coverage Article (LCA): Billing and Coding: Ranibizumab, Aflibercept and Brolucizumab-dbll (A52451) [original date 10/01/2015; revision effective date 4/1/2023]. Accessed on December 11, 2023.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	05/11/2022
UCare Revision	Clarified that continuation of therapy is acceptable if the requested product has been used in either eye.	10/7/2022
Policy revision	**Neovascular (Wet) Age-Related Macular Degeneration:** The dosing interval was changed to not more frequent than once every 4 weeks.	12/13/2022
Policy revision	**Macular Edema Following Retinal Vein Occlusion:** This condition and criteria for approval was added to the policy.	12/11/2023

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