Drug and Biologic Coverage Policy

Effective Date 2/1/2025
Coverage Policy Number IP0542
Policy Title.....Faricimab

Faricimab

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Related Coverage Resources

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment and have discretion in making individual coverage determinations. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This policy supports medical necessity review for faricimab-svoa intravitreal injection (**Vabysmo™**).

Medical Necessity Criteria

Faricimab (Vabysmo) is considered medically necessary when ONE of the following is met:

1. **Diabetic Macular Edema (DME).** Individual meets **ALL** of the following criteria:
    A. Medication is administered by, or under the supervision of, an ophthalmologist
    B. Preferred product criteria is met for the product as listed in the below table

    Dosing. The requested dose of faricimab (Vabysmo) meets the following:
        1. 6 mg administered by intravitreal injection for each eye being treated
        2. The dosing interval is not more frequent than once every 4 weeks for each eye being treated

2. **Macular Edema Following Retinal Vein Occlusion.** Individual meets **ALL** of the following criteria:
    A. Medication is administered by, or under the supervision of, an ophthalmologist
    B. Preferred product criteria is met for the product as listed in the below table

    Dosing. The requested dose of faricimab (Vabysmo) meets the following:
        1. 6 mg administered by intravitreal injection for each eye being treated
        2. The dosing interval is not more frequent than once every 4 weeks for each eye being treated

3. **Neovascular (Wet) Age-Related Macular Degeneration.** Individual meets **ALL** of the following criteria:
    A. Medication is administered by, or under the supervision of, an ophthalmologist
    B. Preferred product criteria is met for the product as listed in the below table

    Dosing. The requested dose of faricimab (Vabysmo) meets the following:
        1. 6 mg administered by intravitreal injection for each eye being treated
        2. The dosing interval is not more frequent than once every 4 weeks for each eye being treated

Employer Plans:

Product	Criteria
Vabysmo (faricimab-svoa intravitreal injection)	Documentation of **ONE** of the following: 1. Currently receiving Vabysmo 2. **ONE** of the following: a. According to the prescriber, patient has diabetic macular edema and a baseline Early Treatment Diabetic Retinopathy Study (ETDRS) best-corrected visual acuity (BCVA) of 20/50 or worse (< 69 ETDRS letters) b. Documentation of failure, contraindication, or intolerance to repackaged bevacizumab c. If, in the professional opinion of the prescriber, the safety of using the repackaged bevacizumab or the supplier of the repackaged bevacizumab is of significant concern

Individual and Family Plans:

Product	Criteria
Vabysmo (faricimab-svoa intravitreal injection)	Documentation of **ONE** of the following: 1. Currently receiving Vabysmo 2. **ONE** of the following: a. According to the prescriber, patient has diabetic macular edema and a baseline Early Treatment Diabetic Retinopathy Study (ETDRS) best-corrected visual acuity (BCVA) of 20/50 or worse (< 69 ETDRS letters) b. Documentation of failure, contraindication, or intolerance to repackaged bevacizumab c. If, in the professional opinion of the prescriber, the safety of using the repackaged bevacizumab or the supplier of the repackaged bevacizumab is of significant concern

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Reauthorization Criteria

Continuation of faricimab (Vabysmo) is considered medically necessary for **ALL** covered diagnoses when the above medical necessity criteria are met AND there is documentation of beneficial response.

Authorization Duration

Initial approval duration:

1. Diabetic Macular Edema (DME): up to 12 months
2. Macular Edema Following Retinal Vein Occlusion: up to 6 months
3. Neovascular (Wet) Age-Related Macular Degeneration: up to 12 months

Reauthorization approval duration:

1. Diabetic Macular Edema (DME): up to 12 months
2. Macular Edema Following Retinal Vein Occlusion: up to 6 months
3. Neovascular (Wet) Age-Related Macular Degeneration: up to 12 months

Conditions Not Covered

Any other use is considered experimental, investigational or unproven.

Coding Information

Note: 1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPCS Codes	Description
J2777	Injection, faricimab-svoa, 0.1 mg

Background

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) thereafter; 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.

References

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

Revision Details

Type of Revision	Summary of Changes	Date
Selected Revision	**Dosing:** **Updated** dosing **from** "6 mg administered by intravitreal injection not more frequent than once every 4 weeks for each eye being treated" **to** "The requested dose of faricimab (Vabysmo) meets the following: 1. 6 mg administered by intravitreal injection for each eye being treated; 2. The dosing interval is not more frequent than once every 4 weeks for each eye being treated" for all indications. **Preferred Product Table:** **Added** criteria "Documentation of ONE of the following: 1. Currently receiving Vabysmo; 2. ONE of the following: a. Documentation of failure, contraindication, or intolerance to repackaged bevacizumab; b. If, in the professional opinion of the prescriber, the safety of using the repackaged bevacizumab or the supplier of the repackaged bevacizumab is of significant concern" for all indications for both employer plans and individual and family plans. **Added** new exclusion criterion: According to the prescriber, patient has diabetic macular edema and a baseline ETDRS BCVA of 20/50 or worse (< 69 ETDRS letters).	12/1/2024
Annual Revision	**No criteria changes**	2/15/2025

The policy effective date is in force until updated or retired.