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## AHC Faricimab-svoa

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**MCG Health**  
Ambulatory Care  
28th Edition

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## Clinical Indications

- Faricimab-svoa may be indicated when **ALL** of the following are present(1)(2)(3):
  - Age 18 years or older
  - Eye condition appropriate for faricimab-svoa treatment, as indicated by **1 or more** of the following:
    - Diabetic macular edema [A]
    - Neovascular (wet, or exudative) age-related macular degeneration [B]
    - Macular Edema Following Retinal Vein Occlusion [C] (4)
  - No active intraocular inflammation
  - No concurrent ocular or periocular infection
  - Dosage does not exceed 6g to eye every 4 weeks (28 days)

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## Evidence Summary

### Background

Faricimab-svoa is a humanized monoclonal antibody that acts as an antagonist of vascular endothelial growth factor A (VEGF-A), inhibiting endothelial cell proliferation, angiogenesis, and vascular permeability. Faricimab-svoa also inhibits angiopoietin-2 (Ang-2), promoting vascular stability by desensitizing blood vessels to VEGF-A.(1)(3) (**EG 2**)

### Criteria

For diabetic macular edema, Two randomized controlled noninferiority trials including 1891 patients with vision loss due to central diabetic macular edema compared treatment with either intravitreal faricimab at 1 of 2 dosing regimens or aflibercept and found, at 1-year follow-up, that both faricimab dosing regimens were noninferior to aflibercept for mean best-corrected visual acuity from baseline. The authors noted that the relatively short follow-up period limited the results, and longer-term results are planned.(2) (**EG 1**)

For neovascular age-related macular degeneration, Two randomized controlled noninferiority trials including 1329 patients with treatment-naïve neovascular age-related macular degeneration compared treatment with either intravitreal faricimab or aflibercept and

found, at 48-week follow-up, that faricimab was noninferior to aflibercept for mean best-corrected visual acuity from baseline. The authors noted that the relatively short follow-up period limited the results, and longer-term results are planned.(3) (EG 1)

The efficacy of faricimab-svoa were evaluated in two randomized, double-masked studies (BALATON – in patients with macular edema following branch retinal vein occlusion, and COMINO – in patients with macular edema following central retinal vein occlusion/hemiretinal vein occlusion). A total of 1,282 newly diagnosed, treatment-naive patients were enrolled in these studies. In both studies, patients were randomized to either faricimab-svoa 6 mg administered every 4 weeks or the control arm receiving aflibercept 2 mg administered every 4 weeks. In both studies, faricimab-svoa demonstrated non-inferiority to Eylea for best-corrected visual acuity from baseline at 24 weeks. (5)

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## Committee Approval

- 01/09/2024, 02/20/2025

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## Application

- This policy applies to the following states: Arizona, California, Nevada, North Carolina, and Texas.
- Please refer to the CMS website for the most current applicable National Coverage Determination (NCD)/ Local Coverage Determination (LCD)/Local Coverage Article (LCA)/CMS Online Manual System/Transmittals.

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## Policy Revision History

- 5/12/2023: Creation date
- 12/08/2023: Revision
- 11/12/2024: Florida removed as applicable state, Clinical indications updated to include Macular Edema Following Retinal Vein Occlusion

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## References

1. Vabysmo™ (faricimab-svoa) injection, for intravitreal use. Physician prescribing information [Internet] Genentech. 2022 Jan Accessed at: <https://www.vabysmo.com/>. [created 2022; accessed 2022 Nov 13] [ Context Link 1, 2, 3, 4 ]
2. Wykoff CC, et al. Efficacy, durability, and safety of intravitreal faricimab with extended dosing up to every 16 weeks in patients with diabetic macular oedema (YOSEMITE and RHINE): two randomised, double-masked, phase 3 trials. Lancet 2022;399(10326):741-755. DOI: 10.1016/S0140-6736(22)00018-6. [ Context Link 1, 2, 3 ]
3. Heier JS, et al. Efficacy, durability, and safety of intravitreal faricimab up to every 16 weeks for neovascular age-related macular degeneration (TENAYA and LUCERNE): two randomised, double-masked, phase 3, non-inferiority trials. Lancet 2022;399(10326):729-740. DOI: 10.1016/S0140-6736(22)00010-1. [ Context Link 1, 2, 3, 4 ]
4. Tadayoni R, Paris LP, Danzig CJ, Abreu F, Khanani AM, Brittain C, Lai TYY, Haskova Z, Sakamoto T, Kotecha A, Schlottmann PG, Liu Y, Seres A, Retiere AC, Willis JR, Yoon YH; BALATON and COMINO Investigators. Efficacy and Safety of Faricimab for Macular Edema due to Retinal Vein Occlusion: 24-Week Results from the BALATON and COMINO Trials. Ophthalmology. 2024 Aug;131(8):950-960. doi: 10.1016/j.ophtha.2024.01.029. Epub 2024 Jan 26. PMID: 38280653. [ Context Link 1 ]
5. Tadayoni R, Paris LP, Danzig CJ, Abreu F, Khanani AM, Brittain C, Lai TYY, Haskova Z, Sakamoto T, Kotecha A, Schlottmann PG, Liu Y, Seres A, Retiere AC, Willis JR, Yoon YH; BALATON and COMINO Investigators. Efficacy and Safety of Faricimab for Macular Edema due to Retinal Vein Occlusion: 24-Week Results from the BALATON and COMINO Trials. Ophthalmology. 2024 Aug;131(8):950-960. doi: 10.1016/j.ophtha.2024.01.029. Epub 2024 Jan 26. PMID: 38280653. [ Context Link 1 ]

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## Footnotes

[A] For diabetic macular edema, faricimab-svoa is administered by intravitreal injection every 4 weeks for 4 doses, followed by repeat injections every 4 to 8 weeks, dependent upon results of central subfield thickness of the macula measured by optical coherence tomography after the initial injections. Intravitreal injection should be followed by careful monitoring for signs of increased ocular pressure, endophthalmitis, or retinal detachment.(1)(2) [ A in Context Link 1 ]

[B] For neovascular (wet, or exudative) age-related macular degeneration, faricimab-svoa is administered by intravitreal injection every 4 weeks for 4 doses, with the timing of repeat injections dependent upon results of optical coherence tomography and visual acuity evaluation after the initial injections. Intravitreal injection should be followed by careful monitoring for signs of increased ocular pressure, endophthalmitis, or retinal detachment.(1)(3) [ B in Context Link 1 ]

[C] For Macular Edema Following Retinal Vein Occlusion, faricimab-svoa is administered by intravitreal injection every 4 weeks (approximately every 28 ± 7 days, monthly) for 6 months  
[ C in Context Link 1 ]

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## Codes

