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AHC Brolucizumab

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MCG Health
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28th Edition

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Clinical Indications

- Brolucizumab may be indicated when **ALL** of the following are present(1)(2) :
 - Age 18 years or older
 - Clinical diagnosis of **1 or more** of the following
 - Diabetic macular edema [A] (4)
 - Neovascular (wet, or exudative) age-related macular degeneration [B] (6)
 - No active intraocular inflammation
 - No concurrent ocular or periocular infection
 - Patient not breast-feeding

Evidence Summary

Background

Brolucizumab is a recombinant human monoclonal antibody that acts as an antagonist to vascular endothelial growth factor, inhibiting endothelial cell growth, angiogenesis, and vascular permeability.(7)(8)(9) (**EG 2**)

Criteria

For neovascular (wet, or exudative) age-related macular degeneration, Two phase III noninferiority trials randomized 1817 patients with neovascular age-related macular degeneration to treatment with brolucizumab at 2 doses or aflibercept and found, at 48-week follow-up, that brolucizumab at either dose was noninferior to aflibercept in change from baseline mean best-corrected visual acuity. At 16-week and 48-week follow-up, brolucizumab 6 mg was associated with greater central subfield thickness reduction from baseline, and brolucizumab at either dose was associated with less intraretinal or subretinal fluid compared with aflibercept. Ocular adverse effects occurred at similar rates in patients treated with brolucizumab and aflibercept.(10) (**EG 1**) An extension of these studies found, at 96-week follow-up, that the best-corrected visual acuity gains were maintained in the brolucizumab group, and that brolucizumab was associated with greater central subfield thickness reductions compared with aflibercept. Ocular adverse events occurred at similar rates across treatment groups, with the exception of combined intraocular inflammation (iritis and uveitis), which occurred more frequently in the high-dose brolucizumab group.(11) (**EG 1**)

For diabetic macular edema, Two phase III randomized trials including 926 patients with diabetic macular edema without proliferative diabetic retinopathy compared treatment with either intravitreal brolucizumab at one of two doses (3 mg or 6 mg) or aflibercept and found, at 52-week follow-up, that brolucizumab 6 mg was noninferior to aflibercept for mean change in best-corrected visual acuity from baseline; both doses of brolucizumab resulted in greater reduction in central subfield thickness and fewer participants with intraretinal or subretinal fluid compared with aflibercept. Similar rates of ocular adverse events were reported for the 2 agents. (12)

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.

Policy Revision History

- 5/28/2022: Creation date
- 05/24/2023, 12/05/2023: Revision
- 11/05/2024: Annual review, Applicable state updated, Florida removed. Diabetic macula edema added as clinical indication

Committee Approval

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

References

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2. Brolucizumab (Beovu) for age-related macular degeneration. Medical Letter on Drugs and Therapeutics 2020;62(1591):23-24. [Context Link 1]
3. Brown DM, et al. KESTREL and KITE: 52-week results from two phase III pivotal trials of brolucizumab for diabetic macular edema. American Journal of Ophthalmology 2022;238:157-172. DOI: 10.1016/j.ajo.2022.01.004. [Context Link 1]
4. Dugel PU, et al. HAWK and HARRIER: phase 3, multicenter, randomized, double-masked trials of brolucizumab for neovascular age-related macular degeneration. Ophthalmology 2020;127(1):72-84. DOI: 10.1016/j.ophtha.2019.04.017. [Context Link 1]
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6. Nguyen QD, et al. Brolucizumab: evolution through preclinical and clinical studies and the implications for the management of Neovascular Age-Related Macular Degeneration. Ophthalmology 2020;127(7):963-976. DOI: 10.1016/j.ophtha.2019.12.031. [Context Link 1]
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9. Brown DM, et al. KESTREL and KITE: 52-week results from two phase III pivotal trials of brolucizumab for diabetic macular edema. American Journal of Ophthalmology 2022;238:157-172. DOI: 10.1016/j.ajo.2022.01.004 [Context Link 1]

Footnotes

[A] For diabetic macular edema, brolucizumab is administered by intravitreal injection every 6 weeks for 5 doses, then every 8 to 12 weeks.(3) [A in Context Link 1]

[B] For neovascular age-related macular degeneration, brolucizumab is administered by intravitreal injection monthly for 3 doses, then every 8 to 12 weeks(5) [B in Context Link 1]

Codes

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