Policy Number	**OTH903.043**
Policy Effective Date	**02/01/2025**
Policy End Date	**12/31/2025**

Brolucizumab-dbll

Table of Contents

Related Policies (if applicable)
OTH903.015: Photodynamic Therapy for Choroidal Neovascularization
OTH903.027: Aflibercept
OTH903.041: Ranibizumab Injections, Implants and Biosimilars
OTH903.044 Faricimab-svoa

Disclaimer

Medical policies are a set of written guidelines that support current standards of practice. They are based on current peer-reviewed scientific literature. A requested therapy must be proven effective for the relevant diagnosis or procedure. For drug therapy, the proposed dose, frequency and duration of therapy must be consistent with recommendations in at least one authoritative source. This medical policy is supported by FDA-approved labeling and/or nationally recognized authoritative references to major drug compendia, peer reviewed scientific literature and acceptable standards of medical practice. These references include, but are not limited to: MCG care guidelines, DrugDex (IIa level of evidence or higher), NCCN Guidelines (IIb level of evidence or higher), NCCN Compendia (IIb level of evidence or higher), professional society guidelines, and CMS coverage policy.

Carefully check state regulations and/or the member contract.

Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Legislative Mandates

EXCEPTION: For HCSC members residing in the state of Ohio, § 3923.60 requires any group or individual policy (Small, Mid-Market, Large Groups, Municipalities/Counties/Schools, State Employees, Fully-Insured, PPO, HMO, POS, EPO) that covers prescription drugs to provide for the coverage of any drug approved by the U. S. Food and Drug Administration (FDA) when it is prescribed for a use recognized as safe and effective for the treatment of a given indication in one or more of the standard medical reference compendia adopted by the United States Department of Health and Human Services or in medical literature even if the FDA has not approved the drug for that indication. Medical literature support is only satisfied when safety and efficacy has been confirmed in two articles from major peer-reviewed professional medical journals that present data supporting the proposed off-label use or uses as generally safe and effective. Examples of accepted journals include, but are not limited to, Journal of

American Medical Association (JAMA), New England Journal of Medicine (NEJM), and Lancet. Accepted study designs may include, but are not limited to, randomized, double blind, placebo controlled clinical trials. Evidence limited to case studies or case series is not sufficient to meet the standard of this criterion. Coverage is never required where the FDA has recognized a use to be contraindicated and coverage is not required for non-formulary drugs.

Coverage

NOTE 1: This policy does not address:

- Verteporfin (Visudyne™) - see OTH903.015 Photodynamic Therapy for Choroidal Neovascularization
- Aflibercept (Eylea® and Eylea® HD) – see OTH903.027 Aflibercept
- Ranibizumab (Lucentis®) – see OTH903.041 Ranibizumab Injections, Implants and Biosimilars
- Faricimab-svoa (Vabysmo®) – see OTH903.044 Faricimab-svoa

Continuation Therapy

Continuation of brolucizumab-dbll (Beovu®) therapy **may be considered medically necessary** for all members (including new members):

- Who are currently receiving the requested medication; AND
- Who are experiencing benefit from therapy as evidenced by disease stability or disease improvement; AND
- When dosing is in accordance with an authoritative source.

Initial Therapy

Intravitreal injections of brolucizumab-dbll (Beovu®) **may be considered medically necessary** contingent on the following coverage criteria:

- Individual has tried and failed, or has a clinical reason to avoid, or there is a documented drug shortage or recalls from a wholesaler, manufacturer, the ASHP (American Hospital of Health-System Pharmacist) Drug Shortage web page or the US Food and Drug Administration of intravitreal injection(s) of bevacizumab (Avastin™) as an anti-VEGF (vascular endothelial growth factor) therapy for the following indications:
  - Diabetic Macular Edema (DME);
  - Treatment of neovascular (wet) age-related macular degeneration (AMD or ARMD);
  - Treatment of choroidal neovascularization (CNV; includes myopic CNV or mCNV) due to:
    - Angioid streaks,
    - Central serous chorioretinopathy,
    - Choroidal retinal neovascularization, secondary to pathologic myopia,
    - Choroidal retinal neovascularization, degenerative progressive high myopia,
    - Choroidal rupture or trauma,
    - Idiopathic choroidal neovascularization,
    - Multifocal choroiditis,
    - Pathologic myopia,
    - Presumed ocular histoplasmosis syndrome, and

- Uveitis.

Intravitreal injections of brolucizumab-dbll (Beovu®) as an anti-VEGF (vascular endothelial growth factor) therapy **are considered experimental, investigational and/or unproven** for all other ophthalmological indications.

Policy Guidelines

None.

Description

NOTE 2: Several different anti-VEGF (vascular endothelial growth factor) agents are mentioned throughout the policy. However, the focus of this policy is specific to the use of brolucizumab-dbll (Beovu®) rather than the other agents that may be mentioned. Please refer to other policies for information on those agents as listed in NOTE 1 above.

Angiogenesis inhibitors (e.g., ranibizumab, bevacizumab, pegaptanib, aflibercept, brolucizumab-dbll) are being evaluated for the treatment of disorders of choroidal circulation. Ophthalmic disorders affecting the choroidal circulation include age-related macular degeneration (ARMD), central serous chorioretinopathy (CSC), pathologic myopia, presumed ocular histoplasmosis syndrome, angioid streaks, idiopathic choroidal neovascularization (CNV), uveitis, choroidal rupture or trauma, and chorioretinal scars.

Background
Vascular endothelial growth factor (VEGF) has been implicated in the pathogenesis of a variety of ocular vascular conditions characterized by CNV and macular edema. The macula, with the fovea at its center, has the highest photoreceptor concentration and is where visual detail is discerned. VEGF has been implicated in the pathogenesis of a variety of ocular vascular conditions characterized by neovascularization (including CNV) and macular edema. Anti-VEGF agents are also being evaluated for the treatment of disorders of retinal circulation (e.g., diabetic retinopathy, retinal vein occlusion, and retinopathy of prematurity). Other therapeutic options may include photodynamic therapy (PDT), antioxidants, and thermal laser photocoagulation. The safety and efficacy of each treatment depends on the form and location of the neovascularization. Angiostatic agents block some stage in the pathway leading to new blood vessel formation (angiogenesis). In contrast to palliative treatments for CNV (e.g., thermal photocoagulation and PDT), they are potentially disease modifying by inhibiting the development of newly formed vessels.

For the treatment of ocular disorders, these agents are given by intravitreal injection every 1 to 2 months. The distinct pharmacologic properties of available VEGF inhibitors suggest that safety and efficacy data from one agent cannot be extrapolated to another. These agents may vary by penetration, potency, half-life, localization to the retina, and initiation of the immune system.

Bevacizumab is a full-length anti-VEGF antibody derived from the same murine monoclonal antibody precursor as ranibizumab and inhibits all isoforms of VEGF-A.

Diabetic Macular Edema (DME)

One of the most serious complications for vision in patients with diabetes is diabetic macular edema (DME). At its earliest stage, microaneurysms occur. With disruption of the blood-retinal barrier, macular retinal vessels become permeable, leading to exudation of serous fluid and lipids into the macula (macular edema). Moderate vision loss can arise from macular edema (fluid accumulating in the center of the macula) during the proliferative or non-proliferative stages of the disease. Although proliferative disease is the main blinding complication of diabetic retinopathy (DR), macular edema is more frequent and is the leading cause of moderate vision loss in people with diabetes.

Focal macular edema (characterized by leakage from discrete microaneurysms on fluorescein angiography) may be treated with focal laser photocoagulation, while diffuse macular edema (characterized by generalized macular edema on fluorescein angiography) may be treated with grid laser photocoagulation. Corticosteroids may reduce vascular permeability and inhibit VEGF production but are associated with serious adverse effects including cataracts and glaucoma with damage to the optic nerve. Corticosteroids can also worsen diabetes control. VEGF inhibitors (e.g., ranibizumab, bevacizumab, aflibercept, pegaptanib), which reduce permeability and block the pathway leading to new blood vessel formation (angiogenesis) are being evaluated for the treatment of DME and proliferative DR. For DME, outcomes of interest include macular thickness and visual acuity.

Age-Related Macular Degeneration (AMD or ARMD)

Neovascular AMD is characterized by CNV, which is the growth of abnormal choroidal blood vessels beneath the macula, which causes severe loss of vision and is responsible for most of the loss of vision caused by AMD. In its earliest stages, AMD is characterized by minimal visual impairment and the presence of large drusen and other pigmentary abnormalities on ophthalmoscopic examination. As AMD progresses, 2 distinctively different forms of degeneration may be observed. The first, called the atrophic or areolar or dry form, evolves slowly. Atrophic AMD is the most common form of degeneration and is often a precursor of the second form, the more devastating exudative neovascular form, also referred to as disciform or wet degeneration. The wet form is distinguished from the atrophic form by serous or hemorrhagic detachment of the retinal pigment epithelium and the development of CNV, sometimes called neovascular membranes. Risk of developing severe irreversible loss of vision is greatly increased by the presence of CNV. The pattern of CNV, as revealed by fluorescein or indocyanine angiography, is further categorized as classic or occult. For example, classic CNV appears as an initial lacy pattern of hyperfluorescence followed by more irregular patterns as the dye leaks into the subretinal space. Occult CNV lacks the characteristic angiographic pattern, either due to the opacity of coexisting subretinal hemorrhage or, especially in CNV associated with AMD, by a tendency for epithelial cells to proliferate and partially or completely surround the new vessels. Interestingly, lesions consisting only of classic CNV carry a worse

visual prognosis than those made up of only occult CNV, suggesting that the proliferative response that obscures new vessels may also favorably alter the clinical course of AMD.

Intravitreal triamcinolone acetonide is one of the first pharmacologic compounds evaluated for the treatment of CNV secondary to AMD. The most important effects of this treatment consist of the stabilization of the blood-retinal barrier and the down-regulation of inflammation. Triamcinolone acetonide also has antiangiogenic and anti-fibrotic properties and remains active for months after intravitreal injection. However, cataracts are a common adverse effect, and steroid-related pressure elevation occurs in approximately one third of patients, with some requiring filtration surgery.

Photodynamic therapy (PDT) is a treatment modality designed to selectively occlude ocular choroidal neovascular tissue. The therapy is a 2-step process, consisting initially of an injection of the photosensitizer verteporfin, followed 15 minutes later by laser treatment to the targeted sites of neovascularization in the retina. The laser treatment selectively damages the vascular endothelium. Patients may be retreated if leakage from CNV persists. Combination therapy with PDT and VEGF antagonists is being investigated. Refer to OTH903.015, Photodynamic Therapy for Choroidal Neovascularization, for coverage information.

Before the availability of angiostatic agents and PDT, CNV was treated with photocoagulation using either argon, green, or infrared lasers. This conventional photocoagulation was limited to extrafoveal lesions due to the risk of retinal burns. Introduction of a scotoma or enlargement of a pre-existing scotoma, with or without visual acuity loss, is an immediate and permanent effect of photocoagulation surgery. Because of the loss of vision associated with laser photocoagulation, photocoagulation is no longer recommended as the initial treatment of subfovealeovascularization.

Polypoidal Choroidal Vasculopathy (PCV)

PCV is characterized by the presence of a branching vascular network with terminal, polyp-like aneurismal dilations. Some investigators consider PCV to be a subtype of AMD, while others suggest that the lesions, when sub-macular, can be mistaken for AMD. PCV is more common in Asian compared with white populations. Both PDT and ranibizumab have been used to treat PCV; although the optimal treatment for PCV may differ from that for AMD.

Central Serous Chorioretinopathy (CSC)

CSC is the fourth most common retinopathy after AMD, diabetic retinopathy, and branch retinal vein occlusion. CSC refers to an idiopathic disease in which there is a serious detachment of the macula due to leakage of fluid from the choriocapillaris through the retinal pigment epithelium. CSC can be divided into acute, recurrent, and chronic conditions. Usually, serous retinal detachments have spontaneous resolution with recovery of visual function; however, a subset of patients may experience permanent deterioration of visual function attributable to chronic CSC or multiple recurrences of CSC. The pathogenesis of CSC is believed to be ischemia and inflammation, which lead to abnormal permeability of the inner choroid and elevation of the retinal pigment epithelium, causing serous epithelial detachments. The separated retinal

pigment epithelium can then undergo tiny rips (blowouts) with a break in continuity. The change in permeability of the retinal pigment epithelium results in focal leakage and retinal detachment. Neovascularization can occur as a secondary complication. In about 90% of cases, CSC resolves spontaneously with detachment resolution within 3 months. The traditional management of acute CSC is observation. Recurring or chronic CSC can be treated with focal laser photocoagulation if the leaks are extrafoveal. Although laser may shorten the duration of symptoms, it does not have any impact on the final vision or the recurrence rate of CSC. In addition, laser photocoagulation causes collateral damage creating symptomatic scotomas and a risk of triggering secondary CNV. PDT is not a standard treatment for CSC due to complications that may include CNV, although low-fluence PDT is being evaluated.

Other Causes of CNV

Other causes of CNV include pathologic myopia, presumed ocular histoplasmosis syndrome, angioid streaks, idiopathic CNV, uveitis, choroidal rupture or trauma, and chorioretinal scars. Treatments that have been evaluated for CNV not related to AMD include sub-macular surgery, laser photocoagulation, and PDT. Efficacy of these treatment modalities is limited.

Other Retinal Vascular Conditions

Other retinal vascular conditions that are being evaluated for treatment with VEGF inhibitors are cystoid macular edema resulting from vasculitis, Coats disease, Eales disease, idiopathic macular telangiectasia type II, neovascularization of the iris/neovascularization of the angle/neovascular glaucoma, pseudoxanthoma elasticum, radiation retinopathy, retinal neovascularization, rubeosis, von Hippel-Lindau, and vitreous hemorrhage secondary to retinal neovascularization.

Regulatory Status

Brolucizumab-dbll (Beovu®) is a human VEGF inhibitor and was approved by the U. S. Food and Drug Administration (FDA) in 2019 for the treatment of neovascular (wet) age-related macular degeneration (AMD). In 2022, the FDA approved brolucizumab for diabetic macular edema. (1)

Rationale

This policy was developed in April 2022 and is based on the clinical studies provided to the U.S. Food and Drug Administration (FDA) for consideration of approval.

Brolucizumab-dbll (Beovu®) (1, 2)

Neovascular (Wet) Age-Related Macular Degeneration (AMD)

The safety and efficacy of Beovu were assessed in two randomized, multi-center, double-masked, active-controlled studies (HAWK - NCT02307682 and HARRIER - NCT02434328) in patients with neovascular AMD. (12) A total of 1817 patients were treated in these studies for two years (1088 on brolucizumab and 729 on control). Patient ages ranged from 50 to 97 years with a mean of 76 years.

In the HAWK study, patients were randomized in a 1:1:1 ratio to the following dosing regimens: 1) brolucizumab 3 mg administered every 8 or 12 weeks after the first 3 monthly doses, 2) brolucizumab 6 mg administered every 8 or 12 weeks after the first 3 monthly doses, 3) aflibercept 2 mg administered every 8 weeks after the first 3 monthly doses.

In the HARRIER study, patients were randomized in a 1:1 ratio to the following dosing regimens: 1) brolucizumab 6 mg administered every 8 or 12 weeks after the first 3 monthly doses, 2) aflibercept 2 mg administered every 8 weeks after the first 3 monthly doses.

In both studies, after three initial monthly doses (Week 0, 4, and 8), treating physicians decided whether to treat each individual patient on a every 8 week or 12-week dosing interval guided by visual and anatomical measures of disease activity, although the utility of these measures has not been established. Patients on 12-week dosing intervals could be changed based on the same measures to an 8-week schedule after subsequent treatment visits. Any patient placed on an 8-week schedule, remained on the 8-week dosing interval until the end of the study. Protocol-specified visits in the initial three months occurred every 28 ± 3 days followed by every 28 ± 7 days for the remainder of the studies. Baseline anatomical measures may have contributed to the regimen selection because the majority of patients on the 12-week dosing schedule at the end of the trial had less baseline macular edema and/or smaller baseline lesions.

Both studies demonstrated efficacy in the primary endpoint defined as the change from baseline in Best Corrected Visual Acuity (BCVA) at Week 48, measured by the Early Treatment Diabetic Retinopathy Study (ETDRS) Letter Score. In both studies, Beovu treated patients had a similar mean change from baseline in BCVA as the patients treated with aflibercept 2 mg (fixed every 8 weeks). Detailed results of both studies are shown in Table 1 and figures 1 and 2 below.

Table 1. Efficacy Outcomes at Week 48 and 96 in Phase 3 HAWK and HARRIER Studies

		HAWK			HARRIER		
Efficacy outcome	**At Week**	**Beovu (n=360)**	**Aflibercept 2mg (n=360)**	**Difference (95% CI) brolucizumab aflibercept**	**Beovu (n=370)**	**Aflib-ercept 2 mg (n=369)**	**Difference (95% CI) brolucizumab aflibercept**
Mean (SD) BCVA at Baseline	---	60.8 (13.7)	60.0 (13.9)	---	61.5 (12.6)	60.8 (12.9)	---
Mean (SE) change from baseline in	48	6.6 (0.71)	6.8 (0.71)	-0.2 (-2.1, 1.8)	6.9 (0.61)	7.6 (0.61)	-0.7 (-2.4, 1.0)
	96		5.3 (0.78)				

BCVA (measured by ETDRS letters score)		5.9 (0.78)		+0.5 (-1.6, 2.7)	6.1 (0.73)	6.6 (0.73)	-0.4 (-2.5, 1.6)
Proportion of patients who gained visual acuity (%) (> 15 letters of BCVA)	48	33.6	25.4	8.2 (2.2, 5.0)	29.3	29.9	-0.6 (-7.1, 5.8)
	96	34.2	27	7.2 (1.4, 3.8)	29.1	31.5	-2.4 (-8.8, 4.1)
Proportion of patients who lost visual acuity (%) (> 15 letters of BCVA)	48	6.4	5.5	0.9 (-2.7, 4.3)	3.8	4.8	-1.0 (-3.9, 2.2)
	96	8.1	7.4	0.7 (-3.6, 4.6)	7.1	7.5	-0.4 (-3.8, 3.3)

Abbreviations - BCVA: Best Corrected Visual Acuity; missing data are imputed using last observation carried forward (LOCF) method, ETDRS: Early Treatment Diabetic Retinopathy Study, SE: standard error, WK: week, CI: confidence interval.

Figure 1. Mean Change in Visual Acuity From Baseline to Week 96 in HAWK

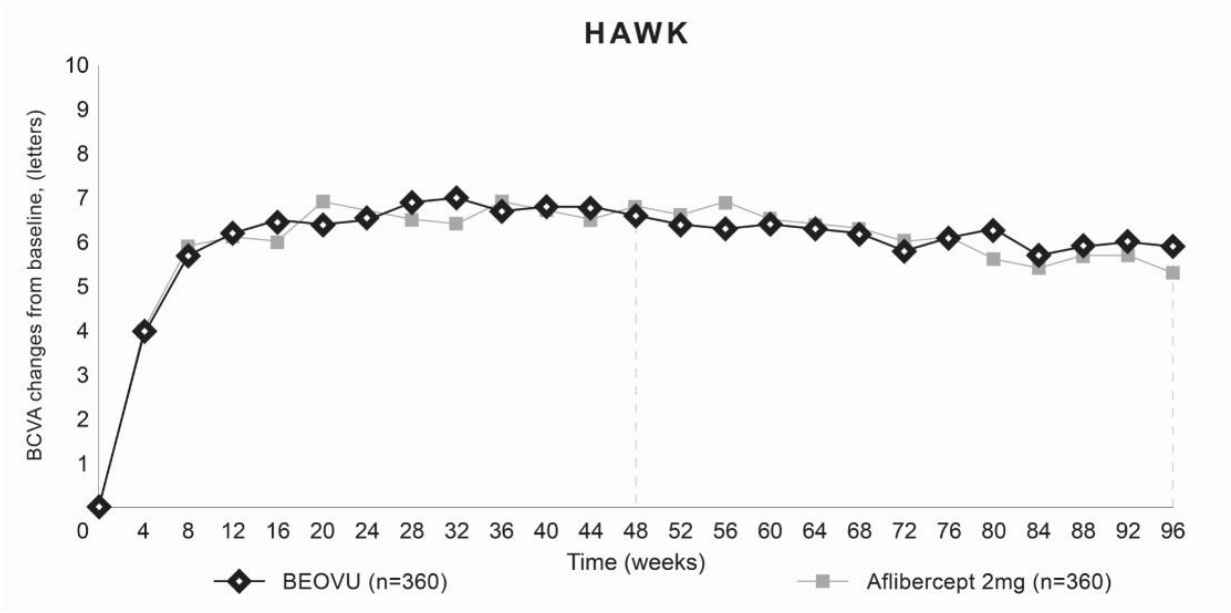
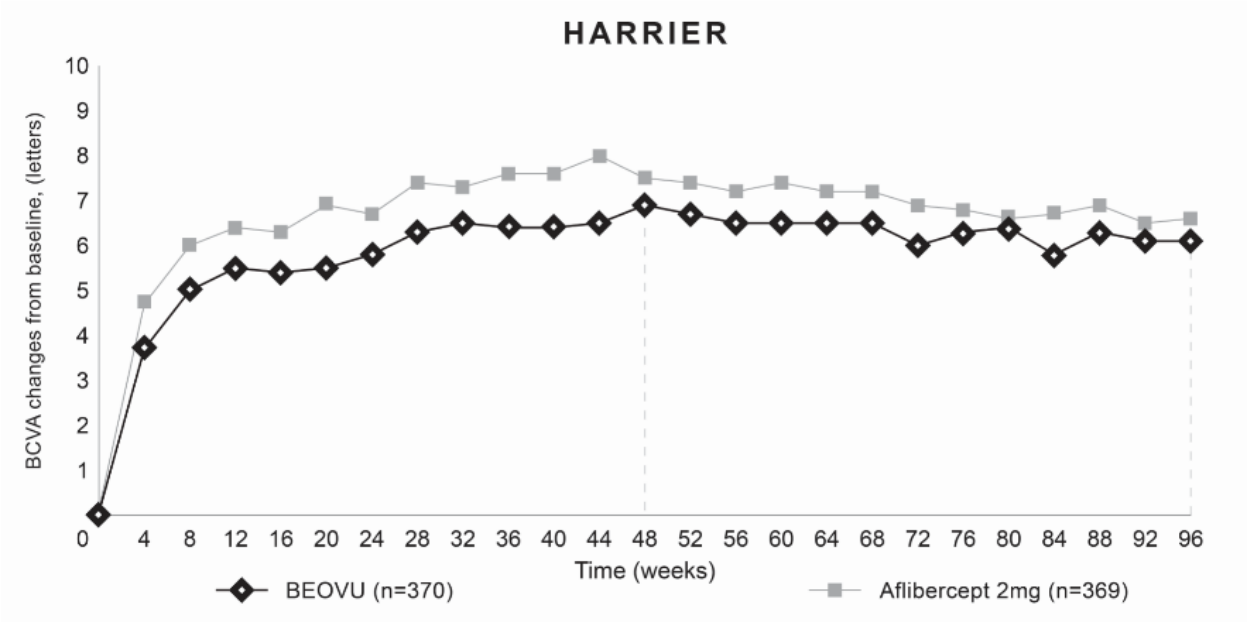


Figure 2. Mean Change in Visual Acuity From Baseline to Week 96 in HARRIER



Through Week 48, 56% (HAWK) and 51% (HARRIER) of patients remained on Beovu every 12 weeks. The proportion of patients who were maintained on every 12-week dosing through Week 96 was 45% and 39% in HAWK and HARRIER, respectively. The probability of remaining on every 12-week dosing from Week 20 to Week 48 was 85% and 82%, and from Week 48 to Week 96 was 82% and 75% in HAWK and HARRIER, respectively. Treatment effects in evaluable subgroups (e.g., age, gender, race, baseline visual acuity) in each study were generally consistent with the results in the overall populations.

Diabetic Macular Edema (DME)

The safety and efficacy of Beovu were assessed in two randomized, multi-center, double-masked, active controlled studies (KESTREL – NCT03481634 and KITE - NCT03481660) in patients with DME. A total of 926 patients were treated in these studies for 1 year (558 on brolucizumab and 368 on aflibercept 2 mg). Patient ages ranged from 23 to 87 years with a mean of 63 years.

In KESTREL, patients were randomized in a 1:1:1 ratio to the following dosing regimens:

1) brolucizumab 6 mg administered once every 6 weeks for first 5 doses, followed by brolucizumab 6 mg every 8 or 12 weeks;
2) brolucizumab 3 mg administered once every 6 weeks for first 5 doses, followed by brolucizumab 3 mg every 8 or 12 weeks;
3) aflibercept 2 mg administered once every 4 weeks for first 5 doses, followed by aflibercept 2 mg every 8 weeks.

In KITE, patients were randomized in a 1:1 ratio to the following dosing regimens:

1) brolucizumab 6 mg administered once every 6 weeks for first 5 doses, followed by brolucizumab 6 mg every 8 or 12 weeks;
2) aflibercept 2 mg administered once every 4 weeks for first 5 doses, followed by aflibercept 2 mg every 8 weeks.

In both studies, after the first five doses (Weeks 0, 6, 12, 18 and 24), brolucizumab patients were treated every 12 weeks, with the option of adjusting to an every 8 week dosing interval based on disease activity. Disease activity was assessed by changes in visual acuity and/or anatomical parameters, including central retinal subfield thickness (CST) and/or presence of intraretinal fluid (IRF)/subretinal fluid (SRF) although the utility of the specific action parameters used has not been established. Disease activity was assessed by a physician during the first 12-week interval (at Weeks 32 and 36) and at each subsequent scheduled 12-week treatment visit. Patients who showed disease activity at any of these visits were adjusted to an every 8 week treatment interval. The comparator aflibercept was administered every 8 weeks after the first 5 monthly doses.

The primary efficacy endpoint for both studies was the change from baseline to Week 52 in Best Corrected Visual Acuity (BCVA) as measured by the Early Treatment Diabetic Retinopathy Study (ETDRS) Letter Score with the primary objective being to demonstrate non-inferiority of Beovu vs. aflibercept 2 mg. In both studies, Beovu was non-inferior to aflibercept 2 mg for the change in BCVA from baseline to Week 52 and the change from baseline over the period Week 40 through Week 52.

After 5 initial q6w loading doses, the patients in the Beovu arm could have received between the minimum of 2 and maximum of 3 additional injections through Week 52. At Week 52, the median number of injections given over 12 months was 7 in patients treated with Beovu.

Through Week 52, 55% (KESTREL) and 50% (KITE) of patients remained on Beovu every 12 weeks. The probability of remaining on every 12-week dosing from Week 36 to Week 52 was 88% and 95% in KESTREL and KITE, respectively. Results of both studies are shown in Table 2 and figures 3 and 4 below.

Table 2. Efficacy Outcomes at Week 52 in Phase 3 – KESTREL and KITE Studies

		KESTREL			KITE		
Efficacy outcome	**At Week**	**Beovu (n=189)**	**Aflibercept 2 mg (n=187)**	**Difference (95% CI) Beovu-aflibercept**	**Beovu (n=179)**	**Aflibercept 2 mg (n=181)**	**Difference (95% CI) Beovu-aflibercept**
Change from baseline in BCVA (measured by ETDRS letters score) – LS mean (SE)	52	9.2 (0.57)	10.5 (0.57)	-1.3 (-2.9, 0.3)	10.6 (0.66)	9.4 (0.66)	1.2 (-0.6, 3.1)
	40-52	9.0 (0.53)	10.5 (0.53)	-1.5 (-3.0, 0.0)	10.3 (0.62)	9.4 (0.62)	0.9 (-0.9, 2.6)

BCVA: Best Corrected Visual Acuity; CI: confidence interval; ETDRS: Early Treatment Diabetic Retinopathy Study; n: number(s).
BCVA assessments after start of alternative DME treatment in the study eye were censored and replaced by the last value prior to start of this alternative treatment

Figure 3. Mean Change in Visual Acuity from Baseline to Week 52 in KESTREL

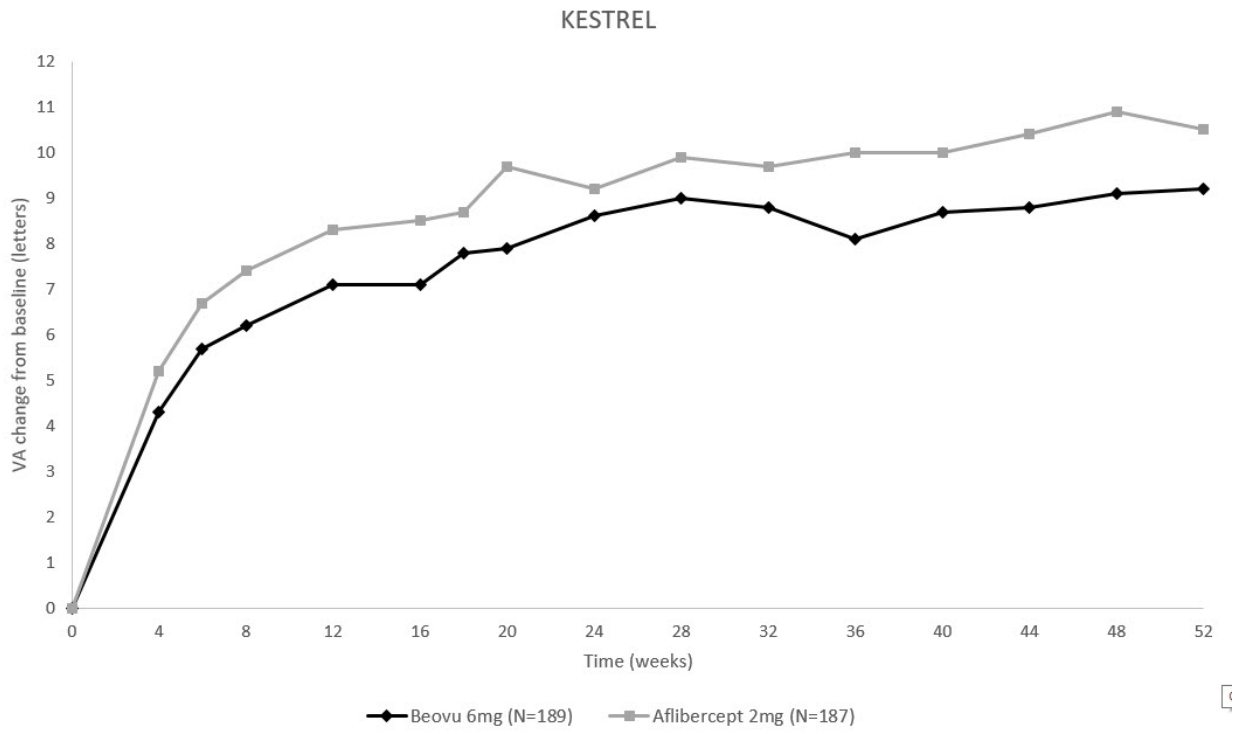
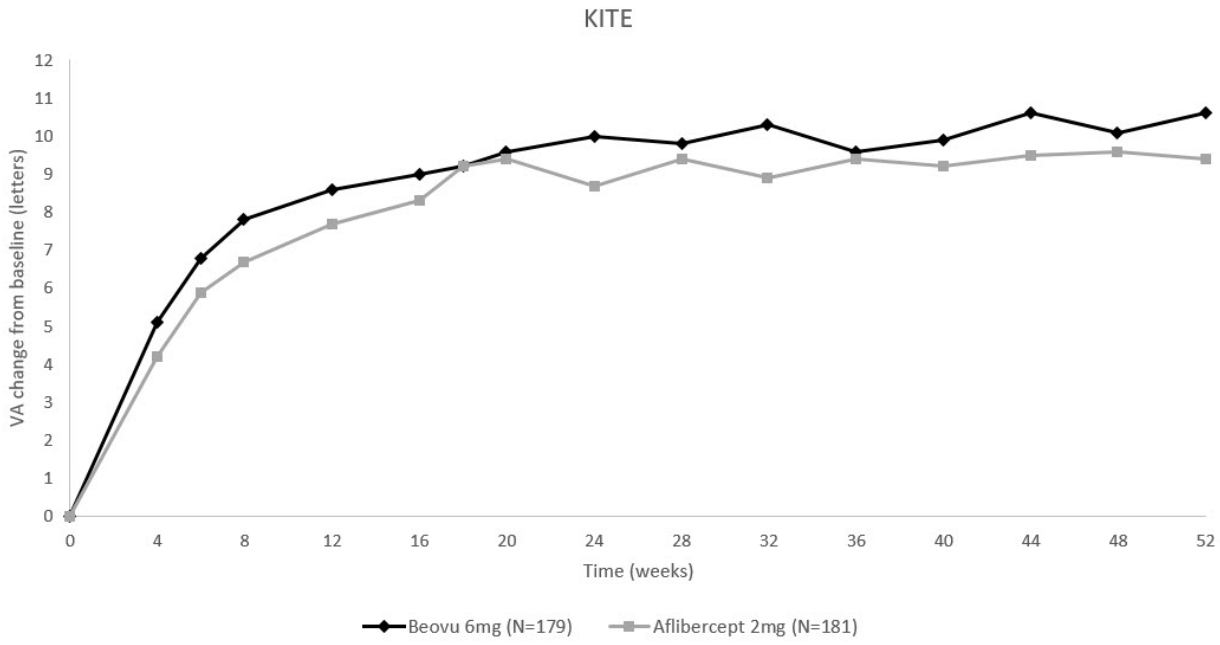


Figure 4. Mean Change in Visual Acuity from Baseline to Week 52 in KITE



Treatment effects in evaluable subgroups (i.e., age, gender, baseline HbA1c, baseline visual acuity, baseline central subfield thickness, DME lesion type, duration of DME since diagnosis, retinal fluid status) in each study were generally consistent with the results in the overall population.

In both studies, Beovu demonstrated a significant reduction from baseline in CST starting at Week 4 and continuing up to Week 52.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	67028
HCPCS Codes	J0179

*Current Procedural Terminology (CPT®) ©2024 American Medical Association: Chicago, IL.

References

1. FDA. Highlights of Prescribing Information Beovu® (brolucizumab-dbll). (2019) Revised 12/2022. Available at: <http://www.accessdata.fda.gov> (accessed on February 23, 2023).
2. Dugel PU, Koh A, Ogura Y, et al. HAWK and HARRIER: Phase 3, multicenter, randomized, double-masked trials of brolucizumab for neovascular age-related macular degeneration. Opthamology. Jan 2020; 127(1):72-84. PMID 30986442

Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change
02/01/2025	Document updated. The following change was made to Coverage: Added language regarding drug shortages/recalls to "Initial Therapy" criteria. No new references added.

05/15/2024	Document updated. The following change was made to Continuation Therapy in Coverage for brolucizumab-dbll (Beovu®): removed "through a previously authorized pharmacy or medical benefit" in the statement "Continuation of brolucizumab-dbll (Beovu®) therapy may be considered medically necessary for all members (including new members…" Now reads: Continuation of brolucizumab-dbll (Beovu®) therapy may be considered medically necessary for all Members (including new members): who are currently receiving the requested medication, AND who are experiencing benefit from therapy as evidenced by disease stability or disease improvement, AND when dosing is in accordance with an authoritative source." No new references added.
10/01/2023	Document updated. The following change was made to Coverage: Added preferred criteria for bevacizumab (Avastin™). No new references added.
06/01/2023	Document updated with literature review. Coverage unchanged. No new references added; one updated.
07/15/2022	New medical document. Intravitreal injections of brolucizumab-dbll (Beovu®) as an anti-VEGF (vascular endothelial growth factor) therapy, may be considered medically necessary for the following indications: Diabetic macular edema; Treatment of neovascular (wet) age-related macular degeneration (AMD); Treatment of choroidal neovascularization (CNV; includes myopic CNV or mCNV) due to: Angioid streaks, Central serous chorioretinopathy, Choroidal retinal neovascularization, secondary to pathologic myopia, Choroidal retinal neovascularization, degenerative progressive high myopia, Choroidal rupture or trauma, Idiopathic choroidal neovascularization, Multifocal choroiditis, Pathologic myopia, Presumed ocular histoplasmosis syndrome, and Uveitis. Intravitreal injections of brolucizumab-dbll (Beovu®) as an anti-VEGF (vascular endothelial growth factor) therapy are considered experimental, investigational and/or unproven for all other ophthalmological indications. Brolucizumab-dbll (Beovu®) was previously addressed on OTH903.020 Intravitreal Angiogenesis Inhibitors for Choroidal Vascular Conditions.