

Beovu® (brolucizumab)



Pharmacy Coverage Policy

Effective Date: July 27, 2022

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Line of Business: Medicare, Commercial, Medicaid - Humana, Medicaid - Ohio

Policy Type: Prior Authorization

Page: 1 of 5

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Disclaimer Description Coverage Determination	Background Medical Terms References
Disclaimer	<p>State and federal law, as well as contract language, including definitions and specific inclusions/exclusions, take precedence over clinical policy and must be considered first in determining eligibility for coverage. Coverage may also differ for our Medicare and/or Medicaid members based on any applicable Centers for Medicare & Medicaid Services (CMS) coverage statements including National Coverage Determinations (NCD), Local Medical Review Policies (LMRP) and/or Local Coverage Determinations. See the CMS website at http://www.cms.hhs.gov/. The member's health plan benefits in effect on the date services are rendered must be used. Clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Clinical technology is constantly evolving, and we reserve the right to review and update this policy periodically. No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any shape or form or by any means, electronic, mechanical, photocopying or otherwise without permission from Humana.</p>
Description	<p>Beovu (brolucizumab) is a human vascular endothelial growth factor (VEGF) inhibitor that binds to the 3 major isoforms of VEGF-A.</p> <p>VEGF is a signaling protein and is involved in new blood vessel formation and microcirculation integrity, specifically in the retina. Beovu (brolucizumab), by preventing VEGF-A from interacting with receptors, suppresses endothelial cell proliferation, neovascularization, and vascular permeability.</p> <p>Beovu (brolucizumab) is indicated for the treatment of neovascular (Wet) age related macular degeneration, and Diabetic Macular Edema (DME).</p> <p>Brolucizumab solution for intravitreal injection is available as Beovu 6 mg/0.05 mL single-dose vial, and 6 mg/0.05 mL intravitreal syringe.</p>
Coverage Determination	<p>Please note the following regarding medically accepted indications:</p> <p>All reasonable efforts have been made to ensure consideration of medically accepted indications in this policy. Medically accepted indications are defined by CMS as those uses of a covered Part D drug that are approved under the federal Food, Drug and</p>

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Cosmetic Act, or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in section 1927(g)(1)(B)(i) of the Act. These compendia guide review of off-label and off-evidence prescribing and are subject to minimum evidence standards for each compendium. Currently, this review includes the following references when applicable and may be subject to change per CMS:

- American Hospital Formulary Service-Drug Information (AHFS-DI)
- National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
- Truven Health Analytics Micromedex DrugDEX
- Elsevier/Gold Standard Clinical Pharmacology
- Wolters Kluwer Lexi-Drugs

Beovu (brolucizumab) will require prior authorization. This agent may be considered medically necessary when the following criteria are met:

Neovascular (Wet) Age Related Macular Degeneration

- The member is diagnosed with neovascular (wet) age-related macular degeneration **AND**
- Has a contraindication, or intolerance to bevacizumab.* **OR**
- Has had prior therapy with bevacizumab* and provider attests that the member has NOT demonstrated a positive clinical response to bevacizumab (e.g., improvement or maintenance in best corrected visual acuity [BCVA] or visual field, or a reduction in the rate of vision decline or the risk of more severe vision loss).

*For Medicare Part B requests, the step therapy requirement does not apply if the request is a continuation of prior therapy within the past 365 days.

Diabetic Macular Edema (DME)

- Diagnosed with Diabetic Macular Edema **AND**
- Has a contraindication, or intolerance to bevacizumab.* **OR**
- Has had prior therapy with bevacizumab* and provider attests that the member has

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NOT demonstrated a positive clinical response to bevacizumab (e.g., improvement or maintenance in best corrected visual acuity [BCVA] or visual field, or a reduction in the rate of vision decline or the risk of more severe vision loss).

- *For Medicare Part B requests, the step therapy requirement does not apply if the request is a continuation of prior therapy within the past 365 days.

Beovu (brolucizumab) will be approved in plan year durations or as determined through clinical review.

Coverage Limitations

Beovu (brolucizumab) therapy is not considered medically necessary for members with the following concomitant conditions:

- Ocular or periocular infections
- Active intraocular inflammation
- Experimental/Investigational Use – Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

Background

This is a prior authorization policy about Beovu (brolucizumab)

VEGF is a naturally occurring substance in the body responsible for the growth of new blood vessels (neovascularization). In the retina however, VEGF may stimulate growth of abnormally fragile vessels prone to leakage. This leakage causes scarring in the macula and eventually leads to loss of central vision.

Age-related macular degeneration (AMD) is a major cause of painless central vision loss and is a leading cause of blindness in people over 60.

AMD occurs in two forms: dry and wet.

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Dry AMD is associated with atrophic cell death of the central retina or macula, which is required for fine vision used for activities such as reading, driving or recognizing faces. Approximately 10-20% of patients with dry AMD eventually progress to wet AMD.

Wet AMD is associated with growth of abnormal blood vessels under the macula. These new blood vessels tend to be very fragile and often leak blood and fluid and cause scar tissue that destroys the central retina. The blood and fluid raise the macula from its normal place at the back of the eye. Damage to the macula occurs rapidly and results in a deterioration of sight over a period of months to years. Between 80% to 90% of AMD is dry, yet more than 80% of the visual loss attributable to AMD is caused by the wet form.

The natural history of AMD is variable, with clinical manifestations dependent on disease type, extent, and whether one or both eyes are affected. Principle risk factors include age, smoking, family history, Caucasian ethnicity, contralateral eye disease, diabetes, and cataract surgery. Genetics play a particularly strong role, with a single polymorphism estimated responsible for as much as 43% of disease occurrence.

Diabetic Macular Edema (DME) is the consequence of retinal microvascular changes from poorly controlled diabetes and diabetic retinopathy. DME is associated with thickening of the basement membrane and reduction of pericytes which are believed to increase permeability of the retinal vasculature. This compromises the blood-retinal barrier causing a leakage of plasma constituents and subsequent retinal edema and hypoxia, all of which stimulates the production of vascular endothelial growth factor (VEGF). DME damages the central retina, which impairs color and pinpoint vision, leading to blurry, washed-out vision. DME can be classified as either focal or diffuse types. In both cases, the predominant labeled treatment for DME is macular focal/grid laser photocoagulation (cauterization of ocular blood vessels). Intravitreal steroids and anti-VEGF agents are also used off-label. (Non-diabetic causes of macular edema include: AMD, uveitis, RVO, and certain genetic disorders.)

The safety and efficacy have not been established in pediatrics.

Provider

For medically billed requests, please visit www.humana.com/PAL. Select applicable

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Claims Codes	Preauthorization and Notification List(s) for medical and procedural coding information.
Medical Terms	Beovu; brolucizumab; neovascular (wet) age-related macular degeneration; diabetic macular edema; intravitreal injection; pharmacy
References	<ol style="list-style-type: none">1. American Academy of Ophthalmology. Preferred Practice Pattern Age-Related Macular Degeneration. Available at http://www.aao.org/education/library/ppp/upload/Age-Related_Macular_Degeneration.pdf.2. Beovu (brolucizumab) [package insert]. Novartis Pharmaceuticals Corporation. East Hanover, NJ; revised May 2022.3. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; . http://www.clinicalpharmacology.com. Updated Periodically.4. Micromedex [database online]. New York, NY: Thomson Reuters, Inc.; . http://www.thomsonhc.com/micromede2/librarian/. Updated Periodically.