

STANDARD MEDICARE PART B MANAGEMENT

BEOVU (brolucizumab-dbli)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

1. Neovascular (wet) age-related macular degeneration
2. Diabetic macular edema

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. CRITERIA FOR INITIAL APPROVAL

Neovascular (wet) age-related macular degeneration

Authorization of 12 months may be granted for treatment of neovascular (wet) age-related macular degeneration.

Diabetic macular edema

Authorization of 12 months may be granted for treatment of diabetic macular edema

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization of 12 months may be granted when ALL of the following criteria are met:

- A. The member is currently receiving therapy with Beovu.
- B. Beovu is being used to treat an indication enumerated in Section II.
- C. The medication has been effective for treating the diagnosis or condition.

IV. SUMMARY OF EVIDENCE

The contents of this policy were created after examining the following resources:

1. The prescribing information for Beovu.

Reference number(s)
3348-A

2. The available compendium
 - a. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
 - b. Micromedex DrugDex
 - c. American Hospital Formulary Service- Drug Information (AHFS-DI)
 - d. Lexi-Drugs
 - e. Clinical Pharmacology

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Beovu are covered.

V. EXPLANATION OF RATIONALE

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

VI. REFERENCES

1. Beovu [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; December 2022.
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. *Ophthalmology*. 2020; 127:72-84.