Reference number(s)
6936-D

This document applies to the following:

Product	Applies
Medicare Part B	☑
Medicare Part B: Advanced Biosimilars First	☑

Medicare Part B Step Therapy Retinal Disorders

Indications

This document informs prescribers of preferred products and provides an exception process for non-preferred products through prior authorization.

These criteria were developed to align with the following: Medicare Part B.

Plan Design Summary

This program applies to the retinal disorders prodcuts specified in this document. Coverage for non-preferred products is provided based on clinical circumstances that would exclude the use of the preferred product and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to members who are new to treatment with a non-preferred product for the first time.

Step therapy is applied in addition to any applicable National Coverage Determination (NCD), Local Coverage Determination (LCD), and Medicare Part B utilization management (UM) programs implemented for the client.

Table. Retinal Disorders Products

Medications considered formulary or preferred on your plan may still require a clinical prior authorization review.

	Products
Primary Preferred	• Avastin (bevacizumab)
Secondary Preferred	• Eylea (aflibercept) or Eylea HD (aflibercept) • Lucentis (ranibizumab) • Pavblu (aflibercept-ayyh)
Non-preferred	• Beovu (brolucizumab-dbll) • Byooviz (ranibizumab-nuna) • Cimerli (ranibizumab-eqrn) • Susvimo (ranibizumab injection) • Vabysmo (faricimab-svoa)

Step Therapy Criteria

Coverage for a non-preferred product is provided when any of the following criteria are met:

- Member has received treatment with the non-preferred product in the past 365 days.
- The requested product is Eylea or Pavblu and either of the following criteria are met:
    - Member has a diagnosis of retinopathy of prematurity.
    - Member has had a documented inadequate response or intolerable adverse event with the primary preferred product, Avastin.
- The requested product is Eylea HD or Lucentis and member has had a documented inadequate response or intolerable adverse event with the primary preferred product, Avastin.
- The requested product is Beovu or Vabysmo and both of the following criteria are met:
    - Member has had a documented inadequate response or intolerable adverse event with the primary preferred product, Avastin.
    - Member has had a documented inadequate response or intolerable adverse event with any of the secondary preferred products: Eylea, Eylea HD, Lucentis, or Pavblu.
- The requested product is Byooviz or Cimerli and either of the following criteria are met:
    - Member has a diagnosis of myopic choroidal neovascularization (mCNV) and both of the following criteria are met:
        - Member has a documented inadequate response or intolerable adverse event with the primary preferred product, Avastin.
        - Member has had a documented intolerable adverse event to the secondary preferred product, Lucentis, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the reference product and biosimilar product).
    - Member has a diagnosis other than myopic choroidal neovascularization (mCNV) and both of the following criteria are met:

    - Member has had a documented inadequate response or intolerable adverse event with the primary preferred product, Avastin.
    - Member has had a documented intolerable adverse event to the secondary preferred product, Lucentis, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the reference product and biosimilar product) OR member has had a documented inadequate response or intolerable adverse event with any of the secondary preferred products: Eylea, Eylea HD, or Pavblu.
- The requested product is Susvimo and both of the following criteria are met:
    - Member has had a documented inadequate response or intolerable adverse event with the primary preferred product, Avastin.
    - Member has had a documented intolerable adverse event to the secondary preferred products, Lucentis and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the reference product and biosimilar product) OR member has had a documented inadequate response or intolerable adverse event with any of the secondary preferred products: Eylea, Eylea HD, Pavblu.

References

1. Avastin [package insert]. South San Francisco, CA: Genentech, Inc.; September 2022.
2. Beovu [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2024.
3. Byooviz [package insert]. Cambridge, MA: Biogen, Inc.; October 2023.
4. Cimerli [package insert]. Redwood City, CA: Coherus BioSciences, Inc.; June 2024.
5. Eylea [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; December 2023.
6. Eylea HD [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; December 2023.
7. Lucentis [package insert]. San Francisco, CA: Genentech, Inc.; February 2024.
8. Pavblu [package insert]. Thousand Oaks, CA: Amgen, Inc.; August 2024.
9. Susvimo [package insert]. San Francisco, CA: Genentech, Inc.; February 2025.
10. Vabysmo [package insert]. San Francisco, CA: Genentech, Inc.; July 2024.