

This policy applies to the following:

Standard Control (SF)	Managed Medicaid Template (MMT)	ACSF Chart (ACSFC)	✓	Medical Benefit	Medicare Part B
Standard Control – Choice (SCCF)	Marketplace (MF)	SF Chart (SFC)	✓	Medical: Advanced Biosimilars First	Medicare Part B: Biosimilars First
Preferred Drug Plan Design (PDPD)	Aetna Health Exchange (AHE)	VF Chart (VFC)		Medical Benefit: Managed Medicaid	Medicare Part B: Advanced Biosimilars First
Advanced Control Specialty (ACSF)	IVL	New to Market (NTM)		Medical Benefit: Add-on	
Advanced Control Specialty – Choice (ACSCF)	Value (VF)				

Reference #
5057-D

EXCEPTIONS CRITERIA RETINAL DISORDERS

PRIMARY PREFERRED PRODUCT: AVASTIN

SECONDARY PREFERRED PRODUCTS: BYOOVIZ, CIMERLI

POLICY

This policy informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

I. PLAN DESIGN SUMMARY

This program applies to the retinal disorder products specified in this policy. Coverage for targeted products is provided based on clinical circumstances that would exclude the use of the preferred products 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 all members requesting treatment with Lucentis who have not tried a secondary preferred product. This program applies to members who are new to treatment with Byooviz, Cimerli, Eylea, and Vabysmo for the first time.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. Retinal Disorder products

	Product(s)
Primary Preferred*	<ul style="list-style-type: none"> • Avastin (bevacizumab)
Secondary Preferred*	<ul style="list-style-type: none"> • Byooviz (ranibizumab-nuna) • Cimerli (ranibizumab-eqrn)
Targeted	<ul style="list-style-type: none"> • Eylea (afibercept) • Lucentis (ranibizumab) • Vabysmo (faricimab-svoa)

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

II. EXCEPTION CRITERIA

A. Byooviz, Cimerli

Coverage for the targeted products is provided when any of the following criteria are met:

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	Advanced Control Specialty – Choice (ACSCF)	Value (VF)					

1. Member is currently receiving treatment with a targeted product, Byooviz or Cimerli, excluding when the requested targeted product is obtained via samples or via manufacturer’s patient assistance programs.
2. Member has had a documented inadequate response or intolerable adverse event with the primary preferred product, Avastin.

B. Eylea

Coverage for the targeted product is provided when any of the following criteria are met:

1. Member is currently receiving treatment with the targeted product, Eylea, excluding when the requested targeted product is obtained via samples or via manufacturer’s patient assistance programs.
2. Member has a diagnosis of retinopathy of prematurity.
3. Member has a documented inadequate response or intolerable adverse event with the primary preferred product, Avastin, and at least one of the secondary preferred products, Byooviz or Cimerli.

C. Lucentis

Coverage for the targeted product is provided when all of the following criteria are met:

1. Member meets either of the following criteria:
 - A. Member is currently receiving treatment with the targeted product, Lucentis, excluding when the requested targeted product is obtained via samples or via manufacturer’s patient assistance programs.
 - B. Member has had a documented inadequate response or intolerable adverse event with the primary preferred product, Avastin.
2. Member has a documented intolerable adverse event to both of the secondary preferred products, Byooviz and Cimerli, 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 products).

D. Vabysmo

Coverage for the targeted product is provided when any of the following criteria are met:

1. Member is currently receiving treatment with the targeted product, Vabysmo, excluding when the requested targeted product is obtained as samples or via manufacturer’s patient assistance programs.
2. Member has a documented inadequate response or intolerable adverse event with the primary preferred product, Avastin, and at least one of the secondary preferred products, Byooviz or Cimerli.

REFERENCES

1. Avastin [package insert]. South San Francisco, CA: Genentech, Inc.; December 2020.
2. Byooviz (ranibizumab) [package insert]. Cambridge, MA: Biogen Inc; June 2022.
3. Cimerli [package insert]. Redwood City, CA: Coherus BioSciences, Inc.; November 2022.
4. Eylea [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; August 2022.

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Advanced Control Specialty – Choice (ACSCF)	Value (VF)				

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5. Lucentis [package insert]. San Francisco, CA: Genentech, Inc.; March 2018.
6. Vabysmo [package insert]. San Francisco, CA: Genentech, Inc.; January 2023.