This policy applies to the following:

	Standard Opt-in		**PDPD**		**Marketplace**		**Medical Benefit**	✓	**Medicare Part B**
	Standard Opt-out		**ACSF**		**MMT**		**Medical Benefit: Biosimilars First**		**Medicare Part B: Biosimilars First**
	VF		**Balanced**		**Medical Benefit: Managed Medicaid**		**Medical Benefit: Add-on**		**Medicare Part B: Add-on**

Reference #
4272-D

POLICY Document for LUCENTIS

The overall objective of this policy is to support the appropriate and cost effective use of the medication, specific to use of preferred medication options, lower cost site of care and overall clinically appropriate use. This document provides specific information to each section of the overall policy.

Section 1: Preferred Product
- Policy information specific to preferred medications

Section 2: Clinical Criteria
- Policy information specific to the clinical appropriateness for the medication

Section 1: Preferred Product

EXCEPTIONS CRITERIA
OCULAR DISORDERS

PREFERRED PRODUCTS: AVASTIN

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 ocular disorder products specified in this policy. Coverage for targeted 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 targeted product for the first time.

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

Table. Ocular Disorder Products

	Product(s)
Preferred	• **Avastin** (bevacizumab)
Targeted	• **Eylea** (aflibercept) • **Lucentis** (ranibizumab) • **Macugen** (pegaptanib sodium) • **Visudyne** (verteporfin)

II. EXCEPTION CRITERIA

This policy applies to the following:

	Standard Opt-in		**PDPD**		**Marketplace**		**Medical Benefit**	✓	**Medicare Part B**
	Standard Opt-out		**ACSF**		**MMT**		**Medical Benefit: Biosimilars First**		**Medicare Part B: Biosimilars First**
	VF		**Balanced**		**Medical Benefit: Managed Medicaid**		**Medical Benefit: Add-on**		**Medicare Part B: Add-on**

Reference #
4272-D

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

A. Member has received treatment with the targeted product in the past 365 days.
B. Member has a documented inadequate response or intolerable adverse event with the preferred product.

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REFERENCES

1. Eylea [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals; August 2019.
2. Lucentis [package insert]. South San Francisco, CA: Genentech, Inc.; March 2018.
3. Macugen [package insert]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; July 2016.
4. Visudyne [package insert]. Charleston, SC: Alcami Carolinas Corporation; February 2017.

Section 2: Clinical Criteria

STANDARD MEDICARE PART B MANAGEMENT

LUCENTIS (ranibizumab)

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.

A. FDA-Approved Indications
   1. Neovascular (wet) age-related macular degeneration
   2. Macular edema following retinal vein occlusion
   3. Diabetic macular edema
   4. Diabetic retinopathy
   5. Myopic choroidal neovascularization

This policy applies to the following:

	Standard Opt-in		**PDPD**		**Marketplace**		**Medical Benefit**	✓	**Medicare Part B**
	Standard Opt-out		**ACSF**		**MMT**		**Medical Benefit: Biosimilars First**		**Medicare Part B: Biosimilars First**
	VF		**Balanced**		**Medical Benefit: Managed Medicaid**		**Medical Benefit: Add-on**		**Medicare Part B: Add-on**

Reference #
4272-D

B. Compendial Uses
Retinopathy of prematurity

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

A. Neovascular (wet) age-related macular degeneration
Authorization of 24 months may be granted for treatment of neovascular age-related macular degeneration.

B. Macular edema following retinal vein occlusion
Authorization of 24 months may be granted for treatment of macular edema following retinal vein occlusion.

C. Diabetic macular edema
Authorization of 24 months may be granted for the treatment of diabetic macular edema.

D. Diabetic retinopathy
Authorization of 24 months may be granted for the treatment of diabetic retinopathy.

E. Myopic choroidal neovascularization
Authorization of 24 months may be granted for the treatment of myopic choroidal neovascularization.

F. Retinopathy of prematurity
Authorization of 24 months may be granted for the treatment of retinopathy of prematurity.

III. CONTINUATION OF THERAPY

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

This policy applies to the following:

	Standard Opt-in		**PDPD**		**Marketplace**		**Medical Benefit**	✓	**Medicare Part B**
	Standard Opt-out		**ACSF**		**MMT**		**Medical Benefit: Biosimilars First**		**Medicare Part B: Biosimilars First**
	VF		**Balanced**		**Medical Benefit: Managed Medicaid**		**Medical Benefit: Add-on**		**Medicare Part B: Add-on**

Reference #
4272-D

Authorization of 24 months may be granted when ALL of the following criteria are met:

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

REFERENCES:

SECTION 1

1. Eylea [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals; August 2019.
2. Lucentis [package insert]. South San Francisco, CA: Genentech, Inc.; March 2018.
3. Macugen [package insert]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; July 2016.
4. Visudyne [package insert]. Charleston, SC: Alcami Carolinas Corporation; February 2017.

SECTION 2

1. Lucentis [package insert]. South San Francisco, CA: Genentech, Inc.; March 2018.
2. Micromedex Solutions [database online]. Truven Health Analytics, Greenwood Village, Colorado, USA. Available at: Accessed February 25, 2020.