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 AVASTIN

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 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)

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

II. EXCEPTION CRITERIA

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.

.

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

B. Compendial Uses

Retinopathy of prematurity

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

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.

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.

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

EYLEA (aflibercept)

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

A. Neovascular (wet) age-related macular degeneration

B. Macular edema following retinal vein occlusion

C. Diabetic macular edema

D. Diabetic retinopathy

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 (wet) 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.

III. CONTINUATION OF THERAPY

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

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

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

A. The member is currently receiving therapy with Eylea.

B. Eylea is being used to treat an indication enumerated in Section II.

C. The medication has been effective for treating the diagnosis or condition.

VISUDYNE (verteporfin)

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

Predominantly classic subfoveal choroidal neovascularization due to age-related macular degeneration, pathologic myopia, or presumed ocular histoplasmosis.

B. Compendial Uses

Non-melanoma skin cancer

C. Nationally Covered Indication

CMS covers Visudyne for age-related macular degeneration in specific circumstances. See Section III for more information.

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. EXCLUSIONS

A. The following exclusion applies to all requests for Visudyne

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

Use of Visudyne is excluded when it is not used in conjunction with ocular photodynamic therapy or not administered intravenously

B. The following exclusions apply to requests for Visudyne for age-related macular degeneration (AMD)

1. Treatment of juxtafoveal or extrafoveal CNV lesions (lesions outside the fovea)

2. Inability to obtain a fluorescein angiogram

3. Atrophic or “dry” AMD

III. 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 when any of the following criteria are/is met:

1. The member has predominately classic subfoveal choroidal neovascularization (CNV) lesions, where the area of classic CNV occupies at least 50% of the area of the entire lesion, at the initial visit as determined by a fluorescein angiogram.

2. The member has subfoveal occult with no classic CNV associated with AMD and meets both criteria below:

i. The lesions are small (4 disk areas or less in size) at the time of initial treatment or within the 3 months prior to initial treatment.

ii. The lesions have shown evidence of progression within the 3 months prior to initial treatment. Evidence of progression must be documented by deterioration of visual acuity (at least 5 letters on a standard eye examination chart), lesion growth (an increase in at least 1 disk area), or the appearance of blood associated with the lesion.

3. The member has subfoveal minimally classic CNV, where the area occupies less than 50% of the area of the entire lesion, associated with AMD and meets both criteria below:

i. The lesions are small (4 disk areas or less in size) at the time of initial treatment or within the 3 months prior to initial treatment.

ii. The lesions have shown evidence of progression within the 3 months prior to initial treatment. Evidence of progression must be documented by deterioration of visual acuity (at least 5 letters on a standard eye examination chart), lesion growth (an increase in at least 1 disk area), or the appearance of blood associated with the lesion.

B. Pathologic myopia associated with classic subfoveal 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

Authorization of 24 months may be granted for treatment of pathologic myopia associated with classic subfoveal choroidal neovascularization.

C. Presumed ocular histoplasmosis associated with classic subfoveal choroidal neovascularization

Authorization of 24 months may be granted for the treatment of presumed ocular histoplasmosis associated with classic subfoveal choroidal neovascularization.

D. Non-melanoma skin cancer

Authorization of 24 months may be granted for the treatment of non-melanoma skin cancer.

IV. CONTINUATION OF THERAPY

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

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

A. The member is currently receiving therapy with Visudyne.

B. None of the exclusions delineated in section II are met.

C. Visudyne is being used to treat an indication enumerated in Section III.

D. The medication has been effective for treating the diagnosis or condition.

UNIVERSAL CRITERIA

POLICY

The Specialty Universal Med B Criteria ensure appropriate utilization of Specialty medications and confirm that selection elements established in the FDA-approved product labeling and relevant compendia are followed. The criteria may be applied in situations where specific criteria are pending development.

Authorization of 12 months may be granted for a requested medication when clinically appropriate

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

IV. REFERENCE

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: http://www.micromedexsolutions.com/. Accessed February 25, 2020.

1. Visudyne [package insert]. Charleston, SC: Alcami Carolinas Corporation; February 2017.

2. Micromedex Solutions [database online]. Truven Health Analytics, Greenwood Village, Colorado, USA. Available at: http://www.micromedexsolutions.com/. Accessed February 12, 2020.

3. National Coverage Determination (NCD) for Verteporfin (80.3.1). Version 2. https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=350&ncdver=2&DocID=80.3.1&SearchType=Advanced&bc=EAAAAAgAAAAA& Accessed February 25, 2020.

4. American Academy of Ophthalmology Retinal/Vitreous Panel. Preferred Practice Pattern® Guidelines. Age-Related Macular Degeneration. San Francisco, CA: American Academy of Ophthalmology; 2019. Available at: https://www.aao.org/preferred-practice-pattern/age-related-macular-degeneration-ppp.