

# Medical Policy Bulletin

## Title:

Intravitreal Injection of Vascular Endothelial Growth Factor (VEGF) Antagonists and Related Biosimilars

## Policy #:

MA08.073t

The Company makes decisions on coverage based on the Centers for Medicare and Medicaid Services (CMS) regulations and guidance, benefit plan documents and contracts, and the member's medical history and condition. If CMS does not have a position addressing a service, the Company makes decisions based on Company Policy Bulletins. Benefits may vary based on contract, and individual member benefits must be verified. The Company determines medical necessity only if the benefit exists and no contract exclusions are applicable. Although the Medicare Advantage Policy Bulletin is consistent with Medicare's regulations and guidance, the Company's payment methodology may differ from Medicare.

When services can be administered in various settings, the Company reserves the right to reimburse only those services that are furnished in the most appropriate and cost-effective setting that is appropriate to the member's medical needs and condition. This decision is based on the member's current medical condition and any required monitoring or additional services that may coincide with the delivery of this service.

This Policy Bulletin document describes the status of CMS coverage, medical terminology, and/or benefit plan documents and contracts at the time the document was developed. This Policy Bulletin will be reviewed regularly and be updated as Medicare changes their regulations and guidance, scientific and medical literature becomes available, and/or the benefit plan documents and/or contracts are changed.

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## Policy

**Coverage is subject to the terms, conditions, and limitations of the member's Evidence of Coverage.**

**The Company reserves the right to reimburse only those services that are furnished in the most appropriate and cost-effective setting that is appropriate to the member's medical needs and condition.**

### MEDICALLY NECESSARY

#### COMPANY-DESIGNATED PREFERRED PRODUCTS

Although there are many brands of vascular endothelial growth factor (VEGF) antagonists and VEGF/Angiopoietin-2 (Ang-2) inhibitors on the market for the treatment of vascular diseases of the eye, there is no reliable evidence of the superiority of any one brand of VEGF antagonist compared with other brands. The company has designated the following as its preferred product for members who are treatment-naïve:

- First line:
  - Any bevacizumab product
- Second line:
  - Ranibizumab (Lucentis®)
  - Ranibizumab-nuna (Byooviz™)
  - Ranibizumab-eqrn (Cimerli®)

These products are less costly and at least as likely to produce equivalent therapeutic results as the non-preferred products, which include, but are not limited to, Beovu®, Eylea®, Eylea® High Dose (HD), Susvimo®, Vabysmo®, and related biosimilars.

#### NON-PREFERRED PRODUCTS\*

For individuals who meet the medical necessity criteria below, use of non-preferred products (which include Beovu, Eylea, Eylea HD, Susvimo, Vabysmo, and any biosimilars to nonpreferred products) is considered medically necessary and, therefore, covered when the individual has a documented contraindication, or documented nonresponse, to any bevacizumab product and at least one other preferred product.

\*The use of non-preferred products that do not meet either of these instances are considered not medically necessary and, therefore, not covered.

**NOTE:** Use of non-preferred product samples administered by the professional provider will not meet coverage criteria for the exception. Additional clinical information demonstrating medical necessity of the desired medication must be submitted by the requesting provider for review.

### **Initial Therapy**

#### **AFLIBERCEPT (EYLEA) AND RELATED BIOSIMILARS**

The intravitreal injection of VEGF antagonist aflibercept (Eylea) and related biosimilars is considered medically necessary and, therefore, covered for individuals who have the following conditions and meet the requirements listed in the COMPANY-DESIGNATED PREFERRED PRODUCTS and NON-PREFERRED PRODUCTS sections above:

- Neovascular (wet or exudative) age-related macular degeneration (AMD)
- Macular edema following retinal vein occlusion (RVO)
- Diabetic macular edema (DME)
- Diabetic retinopathy (DR)
- Retinopathy of prematurity (ROP)

#### **AFLIBERCEPT HD (EYLEA HD) AND RELATED BIOSIMILARS**

The intravitreal injection of VEGF antagonist aflibercept HD (Eylea HD) and related biosimilars are considered medically necessary and, therefore, covered for individuals who have the following conditions and meet the requirements listed in the COMPANY-DESIGNATED PREFERRED PRODUCTS and NON-PREFERRED PRODUCTS sections above:

- Neovascular (wet or exudative) AMD
- DME
- DR

#### **BEVACIZUMAB (AVASTIN) AND RELATED BIOSIMILARS**

The intravitreal injection of VEGF antagonist bevacizumab (Avastin) and related biosimilars are considered medically necessary and, therefore, covered for vascular diseases of the eye including, but not limited to, the following:

- Choroidal neovascularization due to angioid streaks, central serous chorioretinopathy, choroidal rupture or trauma, idiopathic choroidal neovascularization, multifocal choroiditis, pathologic myopia, presumed ocular histoplasmosis syndrome, uveitis
- DME
- DR
- Macular edema following RVO
- Neovascular (wet) AMD
- Neovascular glaucoma
- ROP

#### **BROLUCIZUMAB-DBLL (BEOVU) AND RELATED BIOSIMILARS**

The intravitreal injection of VEGF antagonist brolocizumab-dbl (Beovu) and related biosimilars are considered medically necessary and, therefore, covered for individuals who have the following conditions and meet the requirements listed in the COMPANY-DESIGNATED PREFERRED PRODUCTS and NON-PREFERRED PRODUCTS sections above:

- Neovascular (wet or exudative) AMD
- DME

#### **FARICIMAB-SVOA (VABYSMO) AND RELATED BIOSIMILARS**

The intravitreal injection of faricimab-svoa (Vabysmo) and related biosimilars are considered medically necessary and, therefore, covered for individuals who have the following conditions and meet the requirements listed in the COMPANY-DESIGNATED PREFERRED PRODUCTS and NON-PREFERRED PRODUCTS sections above:

- Neovascular (wet or exudative) AMD
- DME
- Macular edema following RVO

## RANIBIZUMAB (LUCENTIS) AND RELATED BIOSIMILARS

The intravitreal injection of VEGF antagonist ranibizumab (Lucentis) and related biosimilars are considered medically necessary and, therefore, covered for individuals who have the following conditions and meet the requirements listed in the COMPANY-DESIGNATED PREFERRED PRODUCTS and NON-PREFERRED PRODUCTS sections above:

- Neovascular (wet or exudative) AMD
- Macular edema following RVO
- DME
- DR
- ROP
- Choroidal neovascularization due to angioid streaks, central serous chorioretinopathy, choroidal rupture or trauma, idiopathic choroidal neovascularization, multifocal choroiditis, pathologic myopia, presumed ocular histoplasmosis syndrome, uveitis

## RANIBIZUMAB (SUSVIMO) OCULAR IMPLANT

The intravitreal ocular implant ranibizumab (Susvimo) is considered medically necessary and, therefore, covered for individuals who meet all of the following criteria and meet the requirements listed in the COMPANY-DESIGNATED

PREFERRED PRODUCTS and NON-PREFERRED PRODUCTS sections above:

- Diagnosed with neovascular (wet or exudative) AMD and requires VEGF antagonist treatment every month
- Documented response to at least two intravitreal injections of a non-preferred product (e.g., Beovu, Eylea, Eylea HD, Vabysmo, and related biosimilars) within the last 6 months

## Continuation Therapy

VEGF antagonists and VEGF/Ang-2 inhibitors are considered medically necessary and, therefore, covered for the continuation therapy when the individual meets **all** of the following:

- Individual has met the medical necessity criteria for initial therapy
- Medical Records show **both** of the following:
  - Documented improvement or stabilization in visual acuity
  - The professional provider orders continued treatment with the requested drug

## NOT MEDICALLY NECESSARY

For individuals receiving their first course of VEGF antagonists, use of non-preferred products is considered not medically necessary and, therefore, not covered unless the individual has a documented contraindication or non-response to a preferred bevacizumab product first, then a ranibizumab product second, because more cost-effective alternatives are available.

## EXPERIMENTAL/INVESTIGATIONAL

All other uses of aflibercept (Eylea), aflibercept HD (Eylea HD), bevacizumab (Avastin), brolicizumab-dbl (Beovu), faricimab-svoa (Vabysmo), ranibizumab (Lucentis, Susvimo), and related biosimilars are considered experimental/investigational and, therefore, not covered unless the indication is supported as an accepted off-label use, as defined in the medical policy on off-label coverage for prescription drugs and biologics.

## REQUIRED DOCUMENTATION

The individual's medical record must reflect the medical necessity for the care provided. These medical records may include, but are not limited to: records from the professional provider's office, hospital, nursing home, home health agencies, therapies, and test reports.

The Company may conduct reviews and audits of services to our members, regardless of the participation status of the provider. All documentation is to be available to the Company upon request. Failure to produce the requested information may result in a denial for the drug.

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## Guidelines

There is no Medicare coverage determination addressing intravitreal injection of vascular endothelial growth factor (VEGF) antagonists, VEGF biosimilars, and combination VEGF/Angiopoietin-2 (Ang-2) inhibitors; therefore, the Company policy is applicable.

### **BLACK BOX WARNINGS**

Refer to the specific manufacturer's prescribing information for any applicable Black Box Warnings for ranibizumab (Susvimo).

### **BENEFIT APPLICATION**

Subject to the terms and conditions of the applicable Evidence of Coverage, the intravitreal injection of aflibercept (Eylea), bevacizumab (Avastin), brolocizumab-dbl (Beovu), faricimab-svoa (Vabysmo), ranibizumab (Lucentis, Susvimo), and related biosimilars are covered under the medical benefits of the Company's Medicare Advantage products when the medical necessity criteria listed in the medical policy are met.

Certain drugs are available through either the member's medical benefit (Part B benefit) or pharmacy benefit (Part D benefit), depending on how the drug is prescribed, dispensed, or administered. This medical policy only addresses instances when aflibercept (Eylea), aflibercept high dose (HD) (Eylea HD), bevacizumab (Avastin), brolocizumab-dbl (Beovu), faricimab-svoa (Vabysmo), ranibizumab (Lucentis, Susvimo), and related biosimilars are covered under a member's medical benefit (Part B benefit). It does not address instances when aflibercept (Eylea), bevacizumab (Avastin), brolocizumab-dbl (Beovu), faricimab-svoa (Vabysmo), ranibizumab (Lucentis, Susvimo), and related biosimilars are covered under a member's pharmacy benefit (Part D benefit).

However, drugs that are identified in this policy as not medically necessary are not eligible for coverage or reimbursement by the Company.

### **ADMINISTRATION GUIDELINES FROM THE PRODUCTS' PACKAGE INSERTS**

#### **AFLIBERCEPT (EYLEA)**

Aflibercept (Eylea) is supplied as a single-dose vial or single-dose prefilled syringe and is administered only by ophthalmic intravitreal injection as follows:

- Wet age-related macular degeneration (AMD): 2 mg every 4 weeks (monthly) for the first 3 months, followed by one intravitreal injection every 8 weeks. Additional efficacy was not demonstrated in most individuals when dosing every 4 weeks compared to every 8 weeks; however, some individuals may need dosing every 4 weeks after the first 3 months. Although not as effective as the recommended every-8-week dosing regimen, individuals may also be treated with one dose every 12 weeks after 1 year of effective therapy. Individuals should be evaluated regularly.
- Diabetic macular edema and diabetic retinopathy in individuals with diabetic macular edema: every 4 weeks (monthly) for the first 5 months, followed by one intravitreal injection every 8 weeks. Additional efficacy was not demonstrated in most individuals when dosing every 4 weeks compared to every 8 weeks; however, some individuals may need dosing every 4 weeks after the first 20 weeks (5 months).
- Macular edema following retinal vein occlusion (RVO): every 4 weeks
- Retinopathy of prematurity: treatment is initiated with a single injection per eligible eye and may be given bilaterally on the same day. Injections may be repeated in each eye but should be at least 10 days after the previous injection.

#### **AFLIBERCEPT HD (EYLEA HD) AND RELATED BIOSIMILARS**

Aflibercept (Eylea) is supplied as a single-dose vial and is administered only by ophthalmic intravitreal injection as follows:

- Wet AMD: 8 mg every 4 weeks (monthly) for the first 3 months, followed by one intravitreal injection every 8 to 16 weeks.
- Diabetic macular edema: 8 mg every 4 weeks (monthly) for the first 3 months, followed by one intravitreal injection once every 8 to 16 weeks.
- Diabetic retinopathy: 8 mg every 4 weeks (monthly) for the first 3 months, followed by one intravitreal injection once every 8 to 12 weeks.

### BROLUCIZUMAB-DBLL (BEOVU)

Brolucizumab-dbl (Beovu) is supplied as a single-dose vial or single-dose prefilled syringe and is administered only by ophthalmic intravitreal injection as follows:

- Wet AMD: once monthly (approximately every 25–31 days) for the first three doses, followed by one injection every 8 to 12 weeks thereafter.
- Diabetic macular edema: every 6 weeks (approximately every 39–45 days) for the first five doses, followed by one injection every 8 to 12 weeks thereafter.

### FARICIMAB-SVOA (VABYSMO)

Faricimab-svoa (Vabysmo) is supplied as a single-dose vial and is administered only by ophthalmic intravitreal injection, as follows:

- Wet AMD:
  - 6 mg every 4 weeks (monthly) for the first 4 months, followed by optical coherence tomography and visual acuity evaluations 8 and 12 weeks later to inform whether to give a 6-mg dose on one of the following three regimens:
    - Weeks 28 and 44
    - Weeks 24, 36, and 48
    - Weeks 20, 28, 36, and 44
  - Additional efficacy was not demonstrated in most individuals when dosing every 4 weeks compared to every 8 weeks; however, some individuals may need dosing every 4 weeks after the first four doses.
- Diabetic macular edema:
  - One of the following regimens:
    - 1) 6 mg every 4 weeks (monthly) for at least four doses. If after at least four doses, resolution of edema based on the central subfield thickness (CST) of the macula as measured by optical coherence tomography is achieved, then modify the interval by extensions of up to 4-week interval increments or reductions of up to 8-week interval increments based on CST and visual acuity evaluations.
    - 2) 6 mg every 4 weeks for the first six doses, followed by intervals of every 8 weeks.
  - Additional efficacy was not demonstrated in most individuals when dosing every 4 weeks compared to every 8 weeks; however, some individuals may need dosing every 4 weeks after the first 4 months.
- Macular edema following RVO: 6 mg administered every 4 weeks for 6 months (after 6 months, the frequency is individualized based on clinical response, but would not be administered more frequently than every 4 weeks).

### RANIBIZUMAB (LUCENTIS) AND RELATED BIOSIMILARS

Ranibizumab (Lucentis) is supplied in a single-dose vial or single-dose prefilled syringe and is administered only by ophthalmic intravitreal injection, no more than once monthly per affected eye for treatment of wet AMD, macular edema following RVO, diabetic macular edema, and diabetic retinopathy, and myopic choroidal neovascularization (mCNV).

Although less effective, treatment for AMD may begin with three monthly doses followed by less-frequent dosing. In the 9 months after the three initial monthly doses, less frequent dosing with four to five doses on average is expected to maintain visual acuity, while monthly dosing may be expected to result in an additional average one- to two-letter gain of visual acuity. Individuals should be evaluated regularly.

Although less effective, treatment for AMD may be reduced to one injection every 3 months after the first four injections if monthly injections are not feasible. Compared to continued monthly dosing, dosing every 3 months over the next 9 months will lead to an approximate five-letter (one-line) loss of visual acuity benefit, on average. Individuals should be evaluated regularly.

Monthly dosing for up to 3 months is the recommendation for the treatment of mCNV; although individuals may be retreated, if needed.

### RANIBIZUMAB (SUSVIMO) OCULAR IMPLANT

Ranibizumab (Susvimo) is a surgically placed intravitreal ocular implant that is filled with ranibizumab. It is designed to continuously deliver ranibizumab 2 mg via the ocular implant over 24 weeks (approximately 6 months), then a refill procedure is performed every 24 weeks. Supplemental treatment with 0.5-mg intravitreal ranibizumab injection may be administered in the affected eye while the Susvimo implant is in place and if clinically necessary.

## US FOOD AND DRUG ADMINISTRATION (FDA) STATUS

Aflibercept (Eylea) was approved by the FDA on November 18, 2011, for treatment of neovascular (wet) AMD. Supplemental approvals for aflibercept (Eylea) have since been issued by the FDA.

Aflibercept HD (Eylea HD) was approved by the FDA on August 18, 2023, for the treatment of individuals with neovascular (wet) AMD (nAMD), diabetic macular edema (DME), and diabetic retinopathy (DR).

The initial approval for the use of bevacizumab (Avastin) was granted by the FDA on February 26, 2004. Supplemental approvals have since been issued by the FDA. The FDA has issued subsequent approvals for biosimilar products.

Brolucizumab-dbl (Beovu) was approved by the FDA on October 7, 2019, for the treatment of neovascular (wet) AMD. Supplemental approvals for brolucizumab-dbl (Beovu) have since been issued by the FDA.

Faricimab-svoa (Vabysmo) was approved by the FDA on January 28, 2022, for the treatment of neovascular (wet) AMD and diabetic macular edema. Supplemental approvals for faricimab-svoa (Vabysmo) have since been issued by the FDA.

Ranibizumab (Lucentis) was approved by the FDA on June 30, 2006, for the treatment of neovascular (wet) AMD. Supplemental approvals for ranibizumab (Lucentis) have since been issued by the FDA. The FDA has issued subsequent approvals for biosimilar products.

Ranibizumab (Susvimo) was approved by the FDA on October 22, 2021, for the neovascular (wet) AMD who have previously responded to at least two intravitreal injections of a VEGF inhibitor.

### PEDIATRIC USE

The safety and effectiveness of aflibercept (Eylea) have been demonstrated in two clinical studies of pre-term infants with ROP.

The safety and effectiveness of aflibercept HD (Eylea HD) have not been established in the pediatric population.

The safety and effectiveness of bevacizumab (Avastin), brolucizumab-dbl (Beovu), faricimab-svoa (Vabysmo), ranibizumab (Lucentis, Susvimo), and related biosimilars have not been established in the pediatric population.

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## Description

Vascular endothelial growth factor (VEGF) is a secreted protein that selectively binds and activates its receptors, which are located primarily on the surface of vascular endothelial cells. VEGF stimulates new blood vessel formation. Overexpression of VEGF can induce abnormal neovascularization and increase vascular permeability and inflammation.

Neovascularization results in the growth of abnormal blood vessels behind the retina and contributes to the progression of neovascular (wet) age-related macular degeneration (AMD), also known as exudative AMD. Wet AMD occurs when the abnormal blood vessels under the macula leak blood and fluid, leading to vision loss.

Other ocular conditions where VEGF plays a role includes retinal vein occlusion (RVO) where the normal blood flow through a retinal vein becomes blocked, causing edema and hemorrhaging in the retina that can lead to vision loss. RVO is classified according to whether the central retinal vein (CRVO) or one of its branches is obstructed. Diabetic macular edema (DME) is a condition associated with diabetes and causes blurred vision, severe vision loss, and sometimes blindness. Diabetic retinopathy may occur with or without DME and is classified as nonproliferative or proliferative, depending on the severity of the disease. Choroidal neovascularization occurs when abnormal blood vessels begin growing in the choroid (the area beneath the retina) and move into subretinal space and leak blood and fluid, leading to vision loss.

Aflibercept (Eylea) is a VEGF antagonist administered via ophthalmic intravitreal injection that received US Food and Drug Administration (FDA) approval in 2011 for the treatment of neovascular (wet) AMD. Aflibercept (Eylea) Since that time, multiple related biosimilars have also received FDA approval. Aflibercept (Eylea) and related

biosimilars act as a soluble decoy receptor that binds VEGF-A and placental growth factor (PlGF), a second growth factor that initiates the formation of new blood vessels. Aflibercept (Eylea) received supplemental approvals from the FDA in September 2012 for use in the treatment of macular edema following central retinal vein occlusion (CRVO), in July 2014 for use in the treatment of DME, in October 2014 for use in the treatment of macular edema following branch retinal vein occlusion, and in March 2015 and May 2019 for expanded use in the treatment of diabetic retinopathy. In February 2023, the FDA approved its use for retinopathy of prematurity (ROP).

Aflibercept high dose (HD) (Eylea HD) is a VEGF inhibitor administered via ophthalmic intravitreal injection that received FDA approval in 2023 for the treatment of neovascular (wet) AMD, DME, and diabetic retinopathy. The high-dose formulation contains 8 mg of active ingredient while the low-dose formulation contains 2 mg of active ingredient. The high-dose formulation has the same mechanism of action as the low-dose formulation. After the first three doses, the interval of administration can be increased depending on the response to the injection.

Bevacizumab (Avastin) and related biosimilars are a recombinant humanized monoclonal immunoglobulin G1 (IgG1) antibody derived from the same monoclonal antibody as ranibizumab (Lucentis) that binds to and inhibits the biologic activity of human VEGF. Bevacizumab (Avastin) and related biosimilars are administered via ophthalmic intravitreal injection.

Brolucizumab-dbl (Beovu) is a recombinant humanized VEGF inhibitor that binds to the three major isoforms of VEGF-A, thereby preventing interaction with receptors VEGFR-1 and VEGFR-2. By inhibiting VEGF-A, brolucizumab suppresses endothelial cell proliferation, neovascularization, and vascular permeability. Brolucizumab-dbl (Beovu) is administered via ophthalmic intravitreal injection. Brolucizumab-dbl (Beovu) received FDA approval on October 7, 2019, for the treatment of neovascular (wet) AMD. In May 2022, brolucizumab-dbl (Beovu) received FDA approval for the treatment of DME.

Faricimab-svoa (Vabysmo) is administered via ophthalmic intravitreal injection. Faricimab-svoa (Vabysmo) is a humanized bispecific IgG1 antibody that binds both VEGF A and angiopoietin-2 (Ang-2). By inhibiting VEGF-A, the drug suppresses endothelial cell proliferation, neovascularization, and vascular permeability. By inhibiting Ang-2, the drug is thought to promote vascular stability and desensitize blood vessels to the effects of VEGF-A. Faricimab-svoa (Vabysmo) was approved by the FDA on January 28, 2022, for the treatment of neovascular (wet) AMD and DME. Faricimab-svoa (Vabysmo) was approved by the FDA on October 26, 2023, for the treatment of macular edema following RVO.

Ranibizumab (Lucentis) and related biosimilars are VEGF-A antagonists. Ranibizumab (Lucentis) and related biosimilars work by binding to and inhibiting the action of VEGF-A, a substance that binds to certain cells to stimulate new blood vessel formation and growth (e.g., angiogenesis, neovascularization). When VEGF-A binds to ranibizumab (Lucentis), it cannot stimulate neovascularization.

- Ranibizumab (Lucentis) is also administered via ophthalmic intravitreal injection. Ranibizumab (Lucentis) received FDA approval in 2006 for the treatment of neovascular (wet) AMD. Ranibizumab (Lucentis) received supplemental approvals from the FDA in June 2010 for use in the treatment of macular edema following retinal vein occlusion (RVO) and in August 2012 for use in the treatment of DME. In February 2015, ranibizumab (Lucentis) received FDA approval for use in the treatment of diabetic retinopathy in individuals with DME; in April 2017, the approval was modified to include those without DME. Also, in January 2017, ranibizumab (Lucentis) was FDA approved for the treatment of myopic choroidal neovascularization (mCNV). Multiple biosimilars have also received FDA approval.
- Ranibizumab (Susvimo) is also administered via ophthalmic intravitreal injection. Ranibizumab (Susvimo) was approved by the FDA on October 22, 2021, for the neovascular (wet) AMD who have previously responded to at least two intravitreal injections of a VEGF inhibitor.

## **OFF-LABEL INDICATIONS**

There may be additional indications contained in the Policy section of this document due to evaluation of criteria highlighted in the Company's off-label policy, and/or review of clinical guidelines issued by leading professional organizations and government entities.

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## Coding

**Inclusion of a code in this table does not imply reimbursement. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.**

**The codes listed below are updated on a regular basis, in accordance with nationally accepted coding guidelines. Therefore, this policy applies to any and all future applicable coding changes, revisions, or updates.**

**In order to ensure optimal reimbursement, all health care services, devices, and pharmaceuticals should be reported using the billing codes and modifiers that most accurately represent the services rendered, unless otherwise directed by the Company.**

**The Coding Table lists any CPT, ICD-10, and HCPCS billing codes related only to the specific policy in which they appear.**

CPT Procedure Code Number(s)

N/A

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ICD - 10 Procedure Code Number(s)

N/A

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ICD - 10 Diagnosis Code Number(s)

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HCPCS Level II Code Number(s)

**MEDICALLY NECESSARY**

C9257 Injection, bevacizumab, 0.25 mg  
J0177 Injection, aflibercept hd, 1 mg  
J0178 Injection, aflibercept, 1 mg  
J0179 Injection, brolocizumab-dbl, 1 mg  
J2777 Injection, faricimab-svoa, 0.1 mg  
J2778 Injection, ranibizumab, 0.1 mg  
J2779 Injection, ranibizumab, via intravitreal implant (susvimo), 0.1 mg  
J9035 Injection, bevacizumab, 10 mg  
Q5107 Injection, bevacizumab-awwb, biosimilar, (mvasi), 10 mg  
Q5118 Injection, bevacizumab-bvzr, biosimilar, (zirabev), 10 mg  
Q5124 Injection, ranibizumab-nuna, biosimilar, (byooviz), 0.1 mg  
Q5126 Injection, bevacizumab-maly, biosimilar, (alymys), 10 mg  
Q5128 Injection, ranibizumab-eqrn (cimerli), biosimilar, 0.1 mg  
Q5129 Injection, bevacizumab-adcd (vezgelma), biosimilar, 10 mg  
Q5147 Injection, aflibercept-ayyh (pavblu), biosimilar, 1 mg  
Q5149 Injection, aflibercept-abzv (enzeevu), biosimilar, 1 mg  
Q5150 Injection, aflibercept-mrbb (ahzantive), biosimilar, 1 mg  
Q5153 Injection, aflibercept-yszy (opuviz), biosimilar, 1 mg  
Q5155 Injection, aflibercept-jbvf (yesafili), biosimilar, 1 mg  
THE FOLLOWING CODES ARE USED TO REPRESENT AFLIBERCEPT-JBVF (YESAFILI™), AFLIBERCEPT-YSZY (OPUVIZ™), AND BEVACIZUMAB-TNJV (AVZIVI®)  
C9399 Unclassified drugs or biologics  
J3590 Unclassified biologics

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Revenue Code Number(s)

N/A

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Policy History

**Revisions From MA08.073t**

12/15/2025	This version of the policy will become effective 12/15/2025.  Inclusion of a policy in a Code Update memo does not imply that a full review of the policy was completed at this time.  The following HCPCS code has been added to this policy: Q5155 Injection, aflibercept-jbvf (yesafili), biosimilar, 1 mg
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**Revisions From MA08.073s**

09/16/2025	<p>This version of the policy will become effective 09/16/2025. Inclusion of a policy in a Code Update memo does not imply that a full review of the policy was completed at this time.</p> <p>The following HCPCS code has been added to this policy: Q5153 Injection, aflibercept-yszy (opuviz), biosimilar, 1 mg</p>
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**Revisions From MA08.073r:**

06/13/2025	<p>This version of the policy will become effective 06/13/2025. Inclusion of a policy in a Code Update memo does not imply that a full review of the policy was completed at this time.</p> <p>The following HCPCS codes have been added to this policy: Q5147 Injection, aflibercept-ayyh (pavblu), biosimilar, 1 mg Q5149 Injection, aflibercept-abzv (enzeevu), biosimilar, 1 mg Q5150 Injection, aflibercept-mrbb (ahzantive), biosimilar, 1 mg</p>
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**Revisions From MA08.073q:**

03/28/2025	<p>This version of the policy will become effective 03/28/2025.</p> <p>First line and second line Company-Designated Preferred Products were added to the policy:</p> <ul style="list-style-type: none"> <li>• First line: <ul style="list-style-type: none"> <li>○ Any bevacizumab product</li> </ul> </li> <li>• Second line: <ul style="list-style-type: none"> <li>○ Ranibizumab (Lucentis®)</li> <li>○ Ranibizumab-nuna (Byooviz™)</li> <li>○ Ranibizumab-eqrn (Cimerli®)</li> </ul> </li> </ul> <p>Ranibizumab (Lucentis) was removed from the list of Non-Preferred Products.</p> <p>The following drugs have been added to the policy in accordance with the US Food and Drug Administration (FDA):</p> <p>Aflibercept-abzy (Enzeevu™) 08/07/2024 Aflibercept-ayyh (Pavblu™) 08/23/2024 Aflibercept-jbvf (Yesafili™) 05/20/2024 Aflibercept-mrbb (Ahzantive™) 06/28/2024 Aflibercept-yszy (Opuviz™) 05/20/2024</p>
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**Revisions From MA08.073p:**

05/07/2024	<p>This version of the policy will become effective 05/07/2024.</p> <p>The following drug has been <b>added</b> to the policy in accordance with the US Food and Drug Administration (FDA) (12/06/2023): Bevacizumab-tjnj (Avzivi)</p> <p>The following HCPCS codes were <b>added</b> to the policy: C9399 Unclassified drugs or biologicals to represent bevacizumab-tjnj (Avzivi) J3590 unclassified biologics to represent bevacizumab-tjnj (Avzivi) J0177 Injection, aflibercept hd, 1 mg</p> <p>The following HCPCS code has been <b>termed</b> (no longer valid codes) and <b>removed</b> from the policy: C9161 Injection, aflibercept hd, 1 mg</p>
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**Revisions From MA08.073o:**

02/26/2024	This version of the policy will become effective 02/26/2024.
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	<p>The following indication for faricimab-svoa (Vabysmo) has been <b>added</b> to this policy in accordance with the US Food and Drug Administration (FDA) (10/26/2023):</p> <p>Macular edema following retinal vein occlusion (RVO)</p>
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**Revisions From MA08.073n:**

01/02/2024	<p>The policy will become effective 01/02/2024. Inclusion of a policy in a Code Update memo does not imply that a full review of the policy was completed at this time.</p> <p>The following HCPCS code has been <b>added</b> to this policy: C9161 Injection, aflibercept hd, 1 mg</p> <p>The following HCPCS code has been <b>removed</b> from this policy: C9399 Unclassified drugs or biologicals</p>
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**Revisions From MA08.073m:**

10/16/2023	<p>This version of the policy will become effective 10/16/2023</p> <p>Aflibercept high dose (HD) (Eylea HD) and related biosimilars were added to the policy in accordance with US Food and Drug Administration (FDA) labeling (08/18/2023)</p> <p>The following HCPCS codes have been <b>added</b> to the policy:</p> <ul style="list-style-type: none"> <li>• C9399 Unclassified drugs or biologicals</li> <li>• J3590 Unclassified biologics</li> </ul>
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**Revisions From MA08.073l:**

09/18/2023	<p>This version of the policy will become effective 09/18/2023.</p> <p>This policy has been updated to communicate the Company's coverage position for the newly FDA-approved products: faricimab-svoa (Vabysmo) and intravitreal ocular implant ranibizumab (Susvimo).</p> <p>There was clarification that the Company has designated bevacizumab as its preferred product for members who are treatment-naïve.</p> <p>The following indication for aflibercept (Eylea) has been <b>added</b> to this policy in accordance with the US Food and Drug Administration (FDA) (02/08/2023): Retinopathy of prematurity</p> <p>The following indication for bevacizumab (Avastin) and related biosimilars and ranibizumab (Lucentis) and related biosimilars has been <b>added</b> to this policy in accordance with clinical trials and peer-reviewed literature: Retinopathy of prematurity</p> <p>Continuation Therapy criteria were <b>added</b> as a policy criterion.</p> <p>Due to the retired Novitas LCA, the following criterion was <b>removed</b> from Eylea, bevacizumab, Beovu, and Lucentis: "Other retinal diseases, including ischemic retinal vein occlusions, and for decreasing the vascularity of proliferative diabetic retinopathy prior to vitreous surgery". These indications are covered under indications from the FDA labeling.</p> <p>The following HCPCS codes have been <b>added</b> to this policy:</p> <ul style="list-style-type: none"> <li>• J2777 Injection, faricimab-svoa, 0.1 mg</li> <li>• J2779 Injection, ranibizumab, via intravitreal implant (Susvimo), 0.1 mg</li> </ul> <p>The following HCPCS code has been <b>removed</b> from this policy, since it is no longer manufactured and has been withdrawn from market :</p>
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	<ul style="list-style-type: none"> <li>J2503 Injection, pegaptanib sodium, 0.3 mg</li> </ul>
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**Revisions From MA08.073k:**

04/01/2023	<p>This version of the policy will become effective 04/01/2023</p> <p>Inclusion of a policy in a Code Update memo does not imply that a full review of the policy was completed at this time.</p> <p>The following HCPCS codes have been <b>removed</b> from this policy:  C9399 Unclassified drugs or biologicals  J3590 Unclassified biologics</p> <p>The following HCPCS codes have been <b>added</b> to this policy:  Q5128 Injection, ranibizumab-eqrn (cimerli), biosimilar, 0.1 mg  Q5129 Injection, bevacizumab-adcd (vegzelma), biosimilar, 10 mg</p>
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**Revisions From MA08.073j:**

01/01/2023	<p>This version of the policy will become effective 01/01/2023.</p> <p>This policy has been updated to communicate the Company's coverage position for the newly FDA-approved products: bevacizumab-adcd (Vegzelma), ranibizumab-eqrn (Cimerli), bevacizumab-maly (Alymsys).</p> <p>Brolucizumab-dbl (Beovu) coverage was added for a new indication for diabetic macular edema (DME), in alignment with the FDA-approval.</p> <p>The following HCPCS codes have been <b>added</b> to this policy:  Q5126 Injection, bevacizumab-maly, biosimilar, (alymsys), 10 mg  <b>THE FOLLOWING CODES ARE USED TO REPRESENT ranibizumab-eqrn (Cimerli), bevacizumab-adcd (Vegzelma):</b>  C9399 Unclassified drugs or biologicals  J3590 Unclassified biologics</p> <p>All of the ICD-10 CM codes have been <b>removed</b> from this policy, since they are informational.</p>
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**MA08.073i**

04/01/2022	<p>This version of the policy will become effective 04/01/2022.</p> <p>The following HCPCS code has been <b>added</b> to this policy:  Q5124 Injection, ranibizumab-nuna, biosimilar, (byooviz), 0.1 mg</p>
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**MA08.073h**

04/12/2021	<p>This policy has been updated to communicate the Company's coverage position for the following:</p> <p>Clarify the Medical Necessity of non-preferred products when the product was <b>initiated prior to 01/01/2020</b> and the individual is currently receiving the product or has previously received a non-preferred product for vascular diseases of the eye.</p> <p>Clarify the use of non-preferred <b>product samples</b>; additional clinical information demonstrating medical necessity of the desired medication must be submitted by the requesting provider for review.</p> <p>The following indication for <b>Beovu</b> has been added as Medically Necessary, and is in alignment with Novitas:</p>
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	<ul style="list-style-type: none"> <li>Other retinal diseases, including ischemic retinal vein occlusions, and for decreasing the vascularity of proliferative diabetic retinopathy prior to vitreous surgery</li> </ul> <p><b>Macugen</b> has been withdrawn from the market and is no longer eligible for reimbursement. The following HCPCS code has been revised from Medically Necessary to Not Eligible for Reimbursement:</p> <p>J2503 Injection, pegaptanib sodium, 0.3 mg</p> <p>The following ICD-10 DM codes have been <b>added</b> to this policy:</p> <p><b>Beovu:</b>  H35.82 Retinal ischemia  H35.89 Other specified retinal disorders</p> <p><b>Eylea:</b>  H34.8110 - H34.8190 Central retinal vein occlusion, with macular edema  H34.8111 - H34.8191 Central retinal vein occlusion, with retinal neovascularization  H34.8310 - H34.8390 Tributary (branch) retinal vein occlusion, with macular edema  H34.8311 - H34.8391 Tributary (branch) retinal vein occlusion, with retinal neovascularization  H35.82 Retinal ischemia  H35.89 Other specified retinal disorders</p> <p><b>Avastin &amp; Lucentis:</b>  H20.011 - H20.019 Primary iridocyclitis  H20.021 - H20.029 Recurrent acute iridocyclitis  H20.031 - H20.039 Secondary infectious iridocyclitis  H20.041 - H20.049 Secondary noninfectious iridocyclitis  H20.052 - H20.059 Hypopyon  H20.10 - H20.13 Chronic iridocyclitis  H20.20 - H20.23 Lens-induced iridocyclitis  H20.811 - H20.819 Fuchs' heterochromic cyclitis  H20.821 - H20.829 Vogt-Koyanagi syndrome  H35.82 Retinal ischemia  H35.89 Other specified retinal disorders</p>
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**MA08.073g**

04/27/2020	<p>This version of the policy will become effective 04/27/2020.</p> <p>This policy has been updated to communicate the Company's coverage position for brolocizumab-dbl (Beovu®) and bevacizumab-bvzr (Zirabev™), in accordance with US Food and Drug Administration (FDA) prescribing information. An additional indication has been added for Avastin® and related biosimilars in accordance with Novitas Solutions, Inc.</p> <p>The following HCPCS codes have been added to this policy:</p> <p>J0179 Injection, brolocizumab-dbl, 1 mg  Q5118 Injection, bevacizumab-bvcr, biosimilar, (Zirabev), 10 mg</p>
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**MA08.073f**

01/01/2020	<p>This version of the policy will become effective 01/01/2020. This policy was updated to:</p> <ul style="list-style-type: none"> <li>change policy title to "Intravitreal Injection of Vascular Endothelial Growth Factor (VEGF) Antagonists and Related Biosimilars"</li> <li>include Avastin® and incorporate the company's designation of Avastin® and related biosimilars as its preferred product.</li> <li>revise the 'Medically Necessary' criteria for Lucentis and Eylea to indicate both vascular endothelial growth factor (VEGF) antagonists are covered for individuals with non-proliferative and proliferative diabetic retinopathy with and without diabetic macular edema.</li> </ul>
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	<p>The following ICD10 codes have been added to the policy for Lucentis only: E08.3521, E08.3522, E08.3523, and E08.3529.</p> <p>Applicable diagnosis codes have been added to the policy due to criteria changes for Eylea and Avastin.</p>
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**MA08.073e**

10/30/2017	<p>This policy was updated to include a new FDA-labeled indication for Lucentis® for the treatment of non-proliferative and proliferative diabetic retinopathy in individuals with or without diabetic macular edema.</p> <p><b>Note:</b> on 05/03/2018 the following ICD-10 codes were removed from Attachment A for Lucentis, Eylea, and Macugen: H34.00, H34.01, H34.02, H34.03, H34.10, H34.11, H34.12, H34.13, H34.211, H34.212, H34.213, H34.219, H34.231, H34.232, H34.233, H34.239, H34.8112, H34.8122, H34.8132, H34.8192, H34.821, H34.822, H34.823, H34.829, H34.8312, H34.8322, H34.8392, H35.89, H36</p> <p><b>Note:</b> on 05/22/2018 the following ICD-10 code was removed from Attachment A for Lucentis and Eylea: H34.8332.</p>
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**MA08.073d**

10/01/2017	<p>This policy has been identified for the ICD-10 CM code update, effective 10/01/2017.</p> <p>The following ICD-10 CM codes have been <b>added</b> to this policy for <b>Lucentis® only</b>:</p> <p>H44.2A1 Degenerative myopia with choroidal neovascularization, right eye  H44.2A2 Degenerative myopia with choroidal neovascularization, left eye  H44.2A3 Degenerative myopia with choroidal neovascularization, bilateral eye  H44.2A9 Degenerative myopia with choroidal neovascularization, unspecified eye  H44.2B1 Degenerative myopia with macular hole, right eye  H44.2B2 Degenerative myopia with macular hole, left eye  H44.2B3 Degenerative myopia with macular hole, bilateral eye  H44.2B9 Degenerative myopia with macular hole, unspecified eye  H44.2C1 Degenerative myopia with retinal detachment, right eye  H44.2C2 Degenerative myopia with retinal detachment, left eye  H44.2C3 Degenerative myopia with retinal detachment, bilateral eye  H44.2C9 Degenerative myopia with retinal detachment, unspecified eye  H44.2D1 Degenerative myopia with foveoschisis, right eye  H44.2D2 Degenerative myopia with foveoschisis, left eye  H44.2D3 Degenerative myopia with foveoschisis, bilateral eye  H44.2D9 Degenerative myopia with foveoschisis, unspecified eye  H44.2E1 Degenerative myopia with other maculopathy, right eye  H44.2E2 Degenerative myopia with other maculopathy, left eye  H44.2E3 Degenerative myopia with other maculopathy, bilateral eye  H44.2E9 Degenerative myopia with other maculopathy, unspecified eye</p>
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**MA08.073c**

03/28/2017	<p>This policy has been updated to reflect the FDA-approved prescribing information for Eylea®.</p> <p>The coding table has been updated to reflect the Policy's covered indications; as such, the following codes have been removed from this policy:</p> <p><b>The following ICD-10 codes have been removed from the policy for EYLEA® &amp; MACUGEN® &amp; LUCENTIS®:</b>  E08.3521, E08.3522, E08.3523, E08.3529, E08.3531, E08.3532, E08.3533, E08.3539, E08.3541, E08.3542, E08.3543, E08.3549, E08.3551, E08.3552, E08.3553, E08.3559, E09.3521, E09.3522, E09.3523, E09.3529, E09.3531, E09.3532, E09.3533, E09.3539, E09.3541, E09.3542, E09.3543, E09.3549, E09.3551, E09.3552, E09.3553, E09.3559, E10.3521, E10.3522, E10.3523, E10.3529, E10.3531, E10.3532, E10.3533, E10.3539, E10.3541, E10.3542, E10.3543, E10.3549, E10.3551, E10.3552, E10.3553, E10.3559, E11.3521, E11.3522, E11.3523, E11.3529, E11.3531, E11.3532,</p>
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	<p>E11.3533, E11.3539, E11.3541, E11.3542, E11.3543, E11.3549, E11.3551, E11.3552, E11.3553, E11.3559, E13.3521, E13.3522, E13.3523, E13.3529, E13.3531, E13.3532, E13.3533, E13.3539, E13.3541, E13.3542, E13.3543, E13.3549, E13.3551, E13.3552, E13.3553, E13.3559, H34.11, H34.12, H34.13, H34.231, H34.232, H34.233, H34.8112, H34.8122, H34.8132, H34.8192, H34.821, H34.822, H34.823, H34.8312, H34.8322, H34.8332, H34.8392, H35.3113, H35.3114, H35.3123, H35.3124, H35.3133, H35.3134, H35.3193, H35.3194</p> <p><b>The following ICD-10 codes have been removed from the policy for LUCENTIS® only:</b> H21.1X1, H21.1X2, H21.1X3</p>
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**MA08.073b**

<p>10/01/2016</p>	<p>This policy has been identified for the ICD-10 code update, effective 10/01/2016.</p> <p>The following ICD-10 code has been <b>added</b> to this policy: H34.8110, H34.8111, H34.8112, H34.8120, H34.8121, H34.8122, H34.8130, H34.8131, H34.8132, H34.8190, H34.8191, H34.8192, H34.8310, H34.8311, H34.8312, H34.8320, H34.8321, H34.8322, H34.8330, H34.8331, H34.8332, H34.8390, H34.8391, H34.8392, H35.3113, H35.3114, H35.3123, H35.3124, H35.3133, H35.3134, H35.3193, H35.3194, H35.3210, H35.3211, H35.3212, H35.3213, H35.3220, H35.3221, H35.3222, H35.3223, H35.3230, H35.3231, H35.3232, H35.3233, H35.3290, H35.3291, H35.3292, H35.3293, E08.3211, E08.3212, E08.3213, E08.3219, E08.3311, E08.3312, E08.3313, E08.3319, E08.3411, E08.3412, E08.3413, E08.3419, E08.3511, E08.3512, E08.3513, E08.3519, E08.3521, E08.3522, E08.3523, E08.3529, E08.3531, E08.3532, E08.3533, E08.3539, E08.3541, E08.3542, E08.3543, E08.3549, E08.3551, E08.3552, E08.3553, E08.3559, E09.3211, E09.3212, E09.3213, E09.3219, E09.3311, E09.3312, E09.3313, E09.3319, E09.3411, E09.3412, E09.3413, E09.3419, E09.3511, E09.3512, E09.3513, E09.3519, E09.3521, E09.3522, E09.3523, E09.3529, E09.3531, E09.3532, E09.3533, E09.3539, E09.3541, E09.3542, E09.3543, E09.3549, E09.3551, E09.3552, E09.3553, E09.3559, E10.3211, E10.3212, E10.3213, E10.3219, E10.3311, E10.3312, E10.3313, E10.3319, E10.3411, E10.3412, E10.3413, E10.3419, E10.3511, E10.3512, E10.3513, E10.3519, E10.3521, E10.3522, E10.3523, E10.3529, E10.3531, E10.3532, E10.3533, E10.3539, E10.3541, E10.3542, E10.3543, E10.3549, E10.3551, E10.3552, E10.3553, E10.3559, E11.3211, E11.3212, E11.3213, E11.3219, E11.3311, E11.3312, E11.3313, E11.3319, E11.3411, E11.3412, E11.3413, E11.3419, E11.3511, E11.3512, E11.3513, E11.3519, E11.3521, E11.3522, E11.3523, E11.3529, E11.3531, E11.3532, E11.3533, E11.3539, E11.3541, E11.3542, E11.3543, E11.3549, E11.3551, E11.3552, E11.3553, E11.3559, E13.3211, E13.3212, E13.3213, E13.3219, E13.3311, E13.3312, E13.3313, E13.3319, E13.3411, E13.3412, E13.3413, E13.3419, E13.3511, E13.3512, E13.3513, E13.3519, E13.3521, E13.3522, E13.3523, E13.3529, E13.3531, E13.3532, E13.3533, E13.3539, E13.3541, E13.3542, E13.3543, E13.3549, E13.3551, E13.3552, E13.3553, E13.3559</p> <p>The following ICD-10 codes have been <b>deleted</b> from this policy: H34.811, H34.812, H34.813, H34.831, H34.832, H34.833, H35.31, H35.32, E08.321, E08.331, E08.341, E08.351, E09.321, E09.331, E09.341, E09.351, E10.321, E10.331, E10.341, E10.351, E11.321, E11.331, E11.341, E11.351, E13.321, E13.331, E13.341, E13.351</p>
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**MA08.073a**

<p>07/15/2015</p>	<p>This policy has been updated to communicate the Medical Necessity of the new FDA-labeled indications for aflibercept (Eylea®) for the treatment of diabetic macular edema and macular edema following branch retinal vein occlusion. The administration guidelines of aflibercept (Eylea®) were also updated.</p> <p>The Medical Necessity of a new FDA-labeled indication for ranibizumab (Lucentis®) and aflibercept (Eylea®) was included for the treatment of non-proliferative and proliferative diabetic retinopathy in individuals with diabetic macular edema.</p> <p>The Medical Necessity of an off-label indication for ranibizumab (Lucentis®) was also included.</p> <ul style="list-style-type: none"> <li>• Choroidal neovascularization due to angioid streaks, central serous chorioretinopathy, choroidal rupture or trauma, idiopathic choroidal neovascularization, multifocal choroiditis, pathologic myopia, and presumed ocular histoplasmosis syndrome, uveitis</li> </ul> <p>Language regarding off-label indications have been updated.</p>
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**MA08.073**

01/01/2015	This is a new policy.
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Version Effective Date:

09/16/2025

Version Issued Date:

09/16/2025

Version Reissued Date:

N/A