



CLINICAL MEDICAL POLICY	
Policy Name:	Age-Related Macular Degeneration Procedures
Policy Number:	MP-060-MD-DE
Responsible Department(s):	Medical Management
Provider Notice Date:	08/15/2019; 08/15/2018; 09/01/2017
Issue Date:	09/16/2019
Effective Date:	09/16/2019; 11/15/2018; 10/01/2017
Annual Approval Date:	07/16/2020
Revision Date:	07/16/2019; 09/11/2018
Products:	Highmark Health Options Medicaid
Application:	All participating hospitals and providers
Page Number(s):	1 of 13

DISCLAIMER

Highmark Health Options medical policy is intended to serve only as a general reference resource regarding coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

POLICY STATEMENT

Highmark Health Options may provide coverage under the medical surgical benefits of the Company's Medicaid products for medically necessary treatments of wet age-related macular degeneration and advanced, end-stage age-related macular degeneration.

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

The qualifications of the policy will meet the standards of the National Committee for Quality Assurance (NCQA) and the Delaware Department of Health and Social Services (DHSS) and all applicable state and federal regulations.

DEFINITIONS

Wet Age-related Macular Degeneration (Wet AMD) – A rapid, chronic eye disease that causes blurred vision or central vision loss over a period of weeks to months. It is caused by abnormal blood vessels (known as choroidal neovascularization) that grow under the retina and macula. The blood vessels may bleed or leak fluid, causing the macula to bulge or lift up from its normal flat position.

Choroidal Neovascularization (CNV) – The growth of new blood vessels that originate from the choroid through a break in the Bruch membrane into the subretinal pigment epithelium or subretinal space. CNV is a major cause of vision loss.

- **Classic CNV** is characterized as a well-demarcated hyperfluorescence in early phases on a fluorescein angiography and late leakage that obscures the boundaries of the lesion.

Late-stage Age-related Macular Degeneration (Dry AMD) – Large drusen, pigment changes in the retina, or both, with accompanying vision loss due to choroidal neovascularization, geographic atrophy, or both. There is moderate to profound vision impairment due to bilateral central scotomas resulting from geographic atrophy, disciform scar, or both.

Vascular Endothelial Growth Factor (VEGF) Drug Therapy – A periodic intravitreal injection of a chemical called an anti-VEGF. In a normal body, VEGF is a healthy molecule which supports the growth of new blood vessels. In the case of macular health, VEGF is unhealthy, and it promotes the growth of new, weak blood vessels in the choroid layer behind the retina, and those vessels leak blood, lipids, and serum into the retinal layers.

- **Macugen (pegaptanib sodium)** – A stable oligonucleotide fragment (aptamer) which functions like antibodies. The drug was designed to bind and soak up the VEGF so it could not bind to its receptors, so neovascularization could be arrested.
- **Avastin (bevacizumab)** – A recombinant, humanized, monoclonal immunoglobulin antibody that binds all biologically active forms of VEGF.
- **Lucentis (ranibizumab)** – A recombinant human monoclonal antibody which antagonizes vascular endothelial growth factor to inhibit angiogenesis and vascular permeability.
- **Eylea (afibercept)** – A vascular endothelial growth factor inhibitor which acts as a soluble decoy receptor that binds VEGF and thereby can inhibit the binding and activation of VEGF receptors.

Photodynamic Therapy (PDT) – A photosensitizing dye (verteporfin) is intravenously injected into the patient's eye and a photo-activating laser is applied through the eye with a specific contact lens. The activated dye forms reactive free radicals that damage the vascular endothelium and result in thrombosis of the neovascular tissue, which retains larger amounts of dye than normal vessels.

Implantable Miniature Telescope (IMT) – A compound telescope system that consists of a glass cylinder housing wide-angle micro-optics. The device is surgically implanted in the posterior chamber of the eye after removal of the eye's lens. The device is only implanted in one eye. The implanted eye provides central vision, while the non-implanted eye is used for peripheral vision.

Conjunctival incision with posterior Juxtасcleral placement of a pharmacologic agent – Is a proposed procedure to treat ocular disorders such as age-related macular degeneration. During this procedure a small incision into the superior temporal quadrant of the orbit is made posterior to the limbus between the superior and lateral rectus muscle insertions. A blunt tipped, curved cannula is inserted into the

posterior area of the globe through the Tenon's space and positioned with the tip near the macula. The medication is injected and the cannula is removed.

Epi-Rad90™ Ophthalmic System (NeoVista, Inc.) - is an epiretinal radiation delivery device developed to treat wet age-related macular degeneration. The Epi-Rad90 Ophthalmic System delivers radiation (strontium 90) directly to the neovascular lesion in a single treatment therapy session.

AREDS2 (Age-Related Eye Disease Study 2) – Researchers in the Age-Related Eye Disease Study developed a clinically effective vitamin formula tested by the National Eye Institute (NEI) to reduce risk of developing AMD. A supplement was developed and combines vitamin C, vitamin E, zinc, copper, lutein, zeaxanthin, omega-3 fatty acids, and zinc.

PROCEDURES

1. Medical Necessity Guidelines

- A. PDT therapy with light-activated Visudyne (verteporfin) may be considered medically necessary for wet AMD when the following criteria are met:
- 1) The patient is 18 years of age and older; AND
 - 2) The therapy must be prescribed and managed by an Ophthalmologist; AND
 - 3) There is an existing contraindication to anti-VEGF therapy; OR
 - 4) The patient has failed to respond to one anti-VEGF therapies; AND
 - 5) The patient must have predominately classic, subfoveal CNV lesions.

Note: There are no requirements regarding visual acuity, lesion size, and number of re-treatments.

Note: This policy only identifies and addresses the use of PDT therapy with Visudyne for wet Age-related Macular Degeneration (AMD). This policy does not address any other diagnosis, including but not limited to pathologic myopia and presumed ocular histoplasmosis. For all indications other indications, please see applicable pharmacy policy regarding medical necessity for Visudyne (verteporfin).

Note: *Please refer to applicable pharmacy policy regarding medical necessity for the Visudyne Injections which is done with the PDT therapy:*

<https://highmarkhealthoptions.com/sites/default/files/Visudyne.pdf>

- B. An implantable miniature telescope (IMT) may be considered medically necessary for advanced AMD when the following criteria are met:
- 1) The patient must be aged 65 or older; AND
 - 2) The patient is diagnosed with bilateral, untreatable advanced, non-exudative AMD (*see Attachment E*); AND
 - 3) The patient must have stable severe to profound vision impairment (best corrected distance visual acuity 20/160 to 20/800); AND
 - 4) The patient has retinal findings of geographic atrophy, or disciform scar with foveal involvement determined by fluorescein angiography; AND
 - 5) The patient must have evidence of cataract at a grade 2 or higher; AND
 - 6) The patient has adequate peripheral vision in the eye not scheduled for surgery; AND

- 7) The patient has achieved at least 5-letter improvement on the ETDRS chart with an external telescope during the pre-implant evaluation; AND
- 8) The patient has agreed to participate in pre-implant and post-implant visual rehabilitation programs with an ophthalmologist specializing in low vision.

Note: Please refer to applicable pharmacy policy regarding medical necessity for the intravitreal injection of vascular endothelial growth factor (VEGF) drug therapies:

https://highmarkhealthoptions.com/sites/default/files/IVIG_SCIG.pdf

2. Contraindications

PDT therapy for wet AMD is contraindicated in patients with:

- A. Porphyria; OR
- B. Hypersensitivity to Visudyne or any component of the PDT therapy formula

IMT surgical procedure for end-stage AMD is contraindicated in patients with:

- A. Actively wet AMD; OR
- B. Central anterior chamber depth (ACD) < 3.0 mm; measurement of the ACD should be taken from the posterior surface of the cornea (endothelium) to the anterior surface of the crystalline lens; OR
- C. Presence of corneal guttata; OR
- D. Evidence of active CNV on fluorescein angiography or treatment for CNV within the past six months; OR
- E. Previous intraocular or cornea surgery of any kind in the operative eye, including any type of surgery for either refractive or therapeutic purposes; OR
- F. Diabetic retinopathy, untreated retinal tears, a retinal vascular disease, history of retinal detachment, and retinitis pigmentosa in the operative eye; OR
- G. Known sensitivity to post-operative medications

3. The treatments for wet AMD that are not covered

For conditions other than those listed above, scientific evidence has not been established. Examples are included but not limited to:

- A. Thermal laser photocoagulation; OR
- B. Macular translocation surgery; OR
- C. Cell Penetrating Peptide (CPP) eye drops

4. Post-payment Audit Statement

The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Highmark Health Options at any time pursuant to the terms of your provider agreement.

5. Place of Service

- A. The place of service for PDT therapy with Visudyne is an outpatient setting.
- B. The place of service for the implantable miniature telescope is an outpatient surgery setting.

GOVERNING BODIES APPROVAL

The Epi-Rad90™ System (NeoVista) is accepted by the UFDA under the provisions of an Investigational Device Exemption (IDE) which allows the investigational device to be used in order to collect safety and effectiveness data required to provide data for a device application to the FDA.

PDT therapy with Visudyne injections was approved by the FDA in 2000 for the treatment of predominately classic subfoveal choroidal neovascularization due to age-related macular degeneration, pathologic myopia, and presumed ocular histoplasmosis. The label notes that there is insufficient evidence for verteporfin use in predominately occult subfoveal CNV, and it is contraindicated in patients with porphyria.

On July 6, 2010, the FDA approved the implantable miniature telescope (IMT) developed by VisionCare Ophthalmic Technologies, Inc. for patients aged 75 years and older diagnosed with end-stage AMD. In October 2014, the FDA expanded approval of IMT to patients 65 years of age or older.

CODING REQUIREMENTS

Procedure Codes

CPT/HCPCS Codes	Description
PDT Therapy	
67221	Destruction of localized lesion of choroid (e.g., choroidal neovascularization); photodynamic therapy (includes intravenous infusion)
67225	Destruction of localized lesion of choroid (e.g., choroidal neovascularization); photodynamic therapy, second eye, at single session (Use in conjunction with 67221)
96570	Photodynamic therapy by endoscopic application of light to ablate abnormal tissue via activation of photosensitive drug(s); first 30 minutes (list separately in addition to code for endoscopy or bronchoscopy procedures of lung and esophagus)
96571	Photodynamic therapy by endoscopic application of light to ablate abnormal tissue via activation of photosensitive drug(s); each additional 15 minutes (list separately in addition to code for endoscopy or bronchoscopy procedures of lung and esophagus)
Implantable Miniature Telescope	
0308T	Insertion of Ocular Telescope Prosthesis including Removal of Crystalline Lens or Intraocular Lens Prosthesis
C1840	Lens, Intraocular (Telescopic)

Non-covered Procedure Codes

CPT/HCPCS Codes	Description
Laser Photocoagulation	
67220	Destruction of localized lesion of choroid (e.g., choroidal neovascularization); photocoagulation (eg, laser), 1 or more sessions
Proton Beam Radiation Therapy	
77385	Intensity modulated radiation treatment delivery (IMRT), includes guidance and tracking, when performed; simple

77386	Intensity modulated radiation treatment delivery (IMRT), includes guidance and tracking, when performed; complex
77387	Guidance for localization of target volume for delivery of radiation treatment delivery, includes intrafraction tracking, when performed
77520	Proton treatment delivery; simple, without compensation
77522	Proton treatment delivery; simple, with compensation
77523	Proton treatment delivery; intermediate
77525	Proton treatment delivery; complex
G6015	Intensity modulated treatment delivery, single or multiple fields/arcs, via narrow spatially and temporally modulated beams, binary, dynamic MLC, per treatment session
G6016	Compensator-based beam modulation treatment delivery of inverse planned treatment using 3 or more high resolution (milled or cast) compensator, convergent beam modulated fields, per treatment session
G6017	Intra-fraction localization and tracking of target or patient motion during delivery of radiation therapy (e.g., 3D positional tracking, gating, 3D surface tracking), each fraction of treatment
Transpupillary Thermal Therapy	
<i>There is no specific procedure code listed for this procedure</i>	
Epiretinal Radiation Therapy	
0190T	Placement of intraocular radiation source applicator
67036	Vitrectomy, mechanical, pars plana approach

Diagnosis Codes

ICD-10 Codes	Description
Wet, Neovascular Age-Related Macular Degeneration	
H35.3210	Exudative age-related macular degeneration, wet age-related macular degeneration, right eye, stage unspecified
H35.3211	Exudative age-related macular degeneration, wet age-related macular degeneration, right eye, with active choroidal neovascularization
H35.3212	Exudative age-related macular degeneration, wet age-related macular degeneration, right eye, with inactive choroidal neovascularization with involuted or regressed neovascularization
H35.3213	Exudative age-related macular degeneration, wet age-related macular degeneration, right eye, with inactive scar
H35.3220	Exudative age-related macular degeneration, wet age-related macular degeneration, left eye, stage unspecified
H35.3221	Exudative age-related macular degeneration, wet age-related macular degeneration, left eye, with active choroidal neovascularization
H35.3222	Exudative age-related macular degeneration, wet age-related macular degeneration, left eye, with inactive choroidal neovascularization with involuted or regressed neovascularization
H35.3223	Exudative age-related macular degeneration, wet age-related macular degeneration, left eye, with inactive scar
H35.3230	Exudative age-related macular degeneration, wet age-related macular degeneration, bilateral, stage unspecified

H35.3231	Exudative age-related macular degeneration, wet age-related macular degeneration, bilateral, with active choroidal neovascularization
H35.3232	Exudative age-related macular degeneration, wet age-related macular degeneration, bilateral, with inactive choroidal neovascularization with involuted or regressed neovascularization
H35.3233	Exudative age-related macular degeneration, wet age-related macular degeneration, bilateral, with inactive scar
H35.3290	Exudative age-related macular degeneration, wet age-related macular degeneration, unspecified eye, stage unspecified
H35.3291	Exudative age-related macular degeneration, wet age-related macular degeneration, unspecified eye, with active choroidal neovascularization
H35.3292	Exudative age-related macular degeneration, wet age-related macular degeneration, unspecified eye, with inactive choroidal neovascularization with involuted or regressed neovascularization
H35.3293	Exudative age-related macular degeneration, wet age-related macular degeneration, unspecified eye, with inactive scar
Advanced, End-stage Age-related Macular Degeneration	
H35.3113	Nonexudative age-related macular degeneration, right eye, advanced atrophic without subfoveal involvement
H35.3114	Nonexudative age-related macular degeneration, right eye, advanced atrophic with subfoveal involvement
H35.3123	Nonexudative age-related macular degeneration, left eye, advanced atrophic without subfoveal involvement
H35.3124	Nonexudative age-related macular degeneration, left eye, advanced atrophic with subfoveal involvement
H35.3133	Nonexudative age-related macular degeneration, bilateral, advanced atrophic without subfoveal involvement
H35.3134	Nonexudative age-related macular degeneration, bilateral, advanced atrophic with subfoveal involvement

ICD-10/CPT Coding Criteria

	Policy Section	Condition Category	Applicable ICD-10 Codes	Applicable HCPCS/CPT Codes
PDT Therapy	<i>See Procedure Section A</i>	Wet AMD with CNV	H35.3211, H35.3221, H35.3231, H35.3291	67221, 67225, 96570, 96571, J3396
Implantable Miniature Telescope	<i>See Procedure Section B</i>	Advanced, End-stage AMD	H35.3113, H35.3114, H35.3123, H35.3124, H35.3133, H35.3134	0308T, C1840

REIMBURSEMENT

Participating facilities will be reimbursed per their Highmark Health Options contract.

SUMMARY OF LITERATURE

Age-related macular degeneration (AMD) is a degenerative disease of the central portion of the retina (the macula) that results in loss of central vision (Arroyo, 2017). AMD is the leading cause of vision loss, affecting more than 16 million Americans, more than cataracts and glaucoma combined (AMDF). Epidemiology data suggests that the prevalence of AMD has only been found in people at the age of 55 and older (Arroyo, 2017). With an aging population and high prevalence in developed countries, the disease is forecasted to affect 25 million people worldwide by 2020 (Syed, 2012).

There are two types of AMD, including dry (atrophic or non-exudative) and wet (neovascular or exudative). Dry AMD is the most common type and is associated with drusen (small, yellow deposits) in the macula. Drusen cause the macula to lose its function and result in blurred central vision that slowly worsens (Arroyo, 2017). Dry AMD progresses slowly over time and can lead to end-stage (advanced) AMD or neovascular (wet) AMD. Advanced, end-stage AMD patients will develop irreversible retinal damage, including large atrophic areas or macula scarring (Chan, 2013) (*please see Attachment E*). In wet AMD, choroidal neovascularization (CNV) forms under the retina and macula. Wet-AMD subcategories exist based upon the pattern of the choroidal neovascularization seen on the fluorescein angiography, including classic, occult, or fibrous lesions (Arroyo, 2017). Lesions that are predominately classic typically progress more rapidly (Arroyo, 2017). The formation leads to the leakage of blood and fluid, causing the macula to bulge and destroy the central vision, rapidly leading to blindness (Ambati, 2003). Although wet AMD accounts for only 10-15% of patients, more than 80% of severe vision loss or legally blind patient cases are due to wet AMD (Arroyo, 2017).

Before AMD treatments are emphasized, it is important to note the purpose of treatment is to slow down or stop the progression of the disease. Early detection is important because vision loss becomes irreversible with a delayed diagnosis and treatment (Schmidt-Erfurth, 2014). There are no treatment options available to prevent AMD from occurring or to cure AMD. There are various effective treatment options for patients with wet AMD, including intravitreal injections of VEGF inhibitors, implantable miniature telescopes, and photodynamic therapy (PDT).

PDT therapy is a wet-AMD treatment that was developed and FDA-approved in 2000. A pharmaceutical (Visudyne) is injected into the bloodstream, which binds abnormal retinal blood vessels. A nonthermal laser then activates the drug that damages the neovascular endothelium, resulting in vessel occlusion. In recent years, there has been a decrease in utilization due to lack of vision-improvement outcomes and the development of a new class of drugs called intravitreal anti-VEGF injection therapy (Science of AMD). Currently, PDT therapy with Visudyne is only proven to be suitable as an alternative for patients who have contraindications to the current standard treatment of VEGF drug therapy or for patients with chronic exudative lesions who have preserved vision in one eye and are unlikely to achieve reading vision in the second eye (Arroyo, 2017). According to an UpToDate review, PDT therapy was associated with a lower rate of vision loss at one year, and vision remained relatively stable in the three year follow-up (Arroyo, 2019). The FDA labeling also notes a contraindication in patients with porphyria.

When the patient does not respond to Anti-VEGF therapy, PDT therapy can be a successful option for patients who already have significant vision loss because it can inactivate the lesion (Kent, 2016). The combination of Anti-VEGF therapy and PDT therapy have been presented as an alternative, but there is little evidence and no clinical trials to support the treatment method (Schmidt-Erfurth, 2014).

There are no current FDA-approved drug therapies or technologies available for dry AMD. In recent years, a surgical procedure was developed and FDA-approved to treat end-stage, advanced (dry) AMD and is called the implantable miniature telescope or IMT. Advanced AMD results in central vision loss which has a significant impact on the activities of daily life (ADL), including reading, recognizing faces, and driving (*please see Attachment E*). The IMT is an intraocular visual prosthetic device that replaces the natural lens in one eye of a patient with bilateral, advanced AMD in order to enlarge the retinal image to a degree that is visualized outside of vision-impairing central scotomas (CMS, 2016). The power of the IMT magnifies images two to three times their original size to improve the central vision in one eye, while allowing the fellow eye to compensate for peripheral vision (Chan, 2013). Clinical trials prove visual acuity gains and significant increases in quality of life (Boyer, 2015). Several CMS local carriers and FDA recommendations have determined patient criteria and limitations which are utilized within this policy. Many of the IMT contraindications are identified by patient exclusions from manufacturer clinical trials, institutional clinical trials, and FDA product labeling. Identified exclusions include active wet AMD, CNV treatment within the previous six months, retinal vascular disease for the planned operative eye, and previous intraocular or corneal surgery (Haller, 2010).

Several procedures and therapies have been investigated for the treatment of wet AMD, such as thermal laser photocoagulation, macular translocation surgery, submacular surgery, transpupillary thermotherapy, conjunctival incision with placement of a pharmacologic agent, epiretinal radiation therapy, and proton beam radiation therapy; however, the evidence in the peer-reviewed medical literature to support the safety and efficacy of these procedures is limited, and the treatments are investigational. Please see the following evidence:

- **Thermal laser photocoagulation** was the first technology developed to treat wet AMD and is a type of laser surgery for the eyes which seals off abnormal blood vessels in the eye (Cour, 2004). Currently, thermal laser photocoagulation is rarely recommended due to the development and availability of more effective therapies, the increased risk of scotoma, increased risk of vision loss, and the high rate of disease recurrence (Arroyo, 2017). A systematic review of nine randomized trials was completed regarding the laser photocoagulation treatment for wet AMD which concluded a reduction in drusen, but there was no decrease in CNV risk, loss of vision, or development of geographic atrophy acuity (Arroyo, 2017).
- **Macular translocation surgery and Submacular surgery** move the macula to a less diseased area of the retina in patients with subfoveal choroidal neovascularization. **Submacular surgery** involves the removal of abnormal subretinal neovascularization and large submacular hemorrhages. Macular translocation and submacular surgeries are experimental due to the unsuccessful clinical trials and substantial risks, including retinal detachment, proliferative vitreoretinopathy, cystoid macular edema, macular hole, macular tear, new or recurrent CNV, epiretinal membrane, and diplopia (Arroyo, 2017).
- **Transpupillary thermal therapy (TTT)** is considered for CNV associated with AMD. TTT for CNV involves prolonged application of low-energy, infrared laser to photocoagulate areas of neovascularization by increasing retinal temperatures. There was a retrospective, non-randomized study, Tsai et al. (2007), which assessed the therapeutic outcome and recurrence of CNV with AMD after TTT. Other studies and clinical trials have been done, and most of the authors concluded that TTT does not cure CNV secondary to AMD, due to high recurrence and complications.
- **External beam radiation therapy** has been studied in patients with AMD. A meta-analysis of randomized, controlled trials concluded inconsistent evidence of benefit and unknown long-term safety (Arroyo, 2019).

- **Epiretinal radiation therapy**, also known as epiretinal brachytherapy or epimacular brachytherapy, is an intraocular placement or administration of radioactive material to vessels in the retina. There have been several clinical trials and studies that were completed to assess the feasibility, safety and effectiveness of epiretinal radiation therapy. A retrospective, single-center study evaluated the epiretinal strontium-90 brachytherapy in subfoveal CNV due to AMD in the eyes, which were unresponsive to repeated anti-VEGF therapies (Zur et al., 2015). Some of the patients benefited from the treatment, others appear not to have reacted to irradiation treatment after one year of follow-up. The authors stated there is a larger number of patients needed to evaluate the effectiveness of the treatment. Epiretinal radiation therapy is a promising treatment for wet AMD, but larger studies are needed in order to demonstrate its effectiveness.
- **Conjunctival incision with posterior juxtasceral placement of a pharmacologic agent** was proposed to treat ocular disorders, such as AMD. A small incision into the superior temporal quadrant of the orbit is made posterior to the limbus and a blunt tipped, curved cannula is inserted into the posterior area of the globe through the Tenon's space and positioned near the macula. The medication is injected, and the cannula is removed. A Cochrane review (2013) was conducted to examine the effects of steroids with antiangiogenic properties to treat neovascular AMD. The authors found three trials that met the qualifications of the study. Overall, the review found limited evidence that the treatment provided benefits in treating neovascular AMD. **Cell-penetrating peptide (CPP)** is a new treatment that utilizes eye drops that are cell-penetrating peptides, which can deliver the drug to the retina. The scientists' pending patents for the eye drops are owned by a US-based company, Macregen Inc., and a team of Birmingham researchers is working with the company to develop therapies for AMD (Kassam, 2018). The combined team is expediting proof of concept studies to confirm the validity of the therapeutic approach, then clinical trials are expected to start in spring 2019 (Kassam, 2018).

Four Stages of Age-related Eye Disease

Category	Designation	Description
1	No ARMD	No or few small drusen (<63 µm in diameter)
2	Early	Multiple small drusen (<20), a few intermediate drusen (63-124 µm in diameter), or RPE abnormalities
3	Intermediate	Extensive intermediate drusen, ≥1 large drusen (125 µm in diameter), or geographic atrophy not involving center of fovea
4	Advanced	Geographic atrophy or neovascular maculopathy

*AREDS: Age-Related Eye Disease Study; ARMD: age-related macular degeneration; RPE: retinal pigment epithelium.
Source: Reference 6.*

POLICY SOURCE(S)

Ambati, J., Ambati, B.K., Yoo, S.H., et al. Age Related Macular Degeneration: Etiology, Pathogenesis, and Therapeutic Strategies, 2003. Survey of Ophthalmology, 48:3. Accessed on June 6, 2017.

American Academy of Ophthalmology. Age-Related Macular Degeneration, 2004. Accessed on March 26, 2019.

American Macular Degeneration Foundation (AMDF). What is Macular Degeneration? Accessed on May 22, 2017.

Arroyo, J.G. Age-related macular degeneration: Clinical presentation, etiology, and diagnosis; Treatment and prevention. UpToDate. April 2017. Accessed on June 2, 2017.

Arroyo, J.G. Age-related macular degeneration: Treatment and prevention. UpToDate. Waltham, MA; reviewed on February 2019. Accessed on March 23, 2019.

Avastin (bevacizumab) (Genentech Inc.) for Age-Related Macular Degeneration, September, 2008. Hayes: Transforming Healthcare with Evidence. Accessed on June 6, 2017.

Boyer, D., Freund, K.B., Regillo, C., et al. Long-term (60-month) results for the implantable miniature telescope: efficacy and safety outcomes stratified by age in patients with end-stage age-related macular degeneration, June 2015. *Clinical Ophthalmology*, 2015;9 1099-1107. Accessed on June 5, 2017.

Centers for Medicare & Medicaid Services (CMS), November, 2016. Local Coverage Determinations (LCD): Implantable Miniature Telescope (IMT) (L33584). Accessed on June 9, 2017.

Chan, T.I., Implantable Miniature Telescope: The first-ever technology approved for end-stage age-related macular degeneration, May/June 2013. *Advanced Ocular Care: Spotlight on Low-Vision Services*. Accessed on June 8, 2017.

Cour, M.L., Photodynamic therapy for AMD: smaller is better, December 2004. *Acta Ophthalmologica Scandinavica*, 82:6; 641-642. Accessed on June 6, 2017.

Geltzer A, Turalba A, Vedula SS. Surgical implantation of steroids with antiangiogenic characteristics for treating neovascular age-related macular generation. *Cochrane Database Syst Rev*. 2013 Jan 31; 1:CD005022. Accessed on March 26, 2019.

Haller, J.A., Heier, J.S. A new Option for End-Stage AMD: Review of Ophthalmology, December 2010. Accessed on June 8, 2017.

Kent, C. Treating Wet AMD with Anti-VEGF Drugs, August 2016. *Review of Ophthalmology*. Accessed on June 15, 2017.

Kassam, Zara. New: Revolutionary eye drops to treat age-related macular degeneration. July 20, 2018. Accessed on March 27, 2019.

Major, J.C., Wykoff, C.C. Current Management of Wet AMD: My Approach, 2013. *Intravitreal Interventions*, Issue 3. Accessed on June 15, 2017.

Martin, D.F., Maguire, M.G., Ying, G., et al. Five-Year Outcomes with Anti-Vascular Endothelial Growth Factor Treatment of Neovascular Age-Related Macular Degeneration: The Comparison of Age-Related Macular Degeneration Treatments Trials, March 2016. *American Academy of Ophthalmology*. Accessed on June 6, 2017.

Mojana F, Brar M, Cheng L, et al. Long-term SD-OCT/SLO imaging of neuroretina and retinal pigment epithelium after subthreshold infrared laser treatment of drusen. *Retina*. 2011 Feb;31(2):235-42.

National Institute for Health and Care Excellence (NICE). Epiretinal brachytherapy for wet age-related macular degeneration. NICE interventional procedure guidance 415. Publication date: December 2011.

Petrarca R, Dugel PU, Bennett M, et al. Macular epiretinal brachytherapy in treated age-related macular degeneration (MERITAGE): month 24 safety and efficacy results. *Retina*. 2014 May;34(5):874-9.

Ranibizumab and Bevacizumab for Neovascular Age-Related Macular Degeneration: The CATT Research Group, May 19, 2011. *The New England Journal of Medicine*, 364:20. Accessed on June 6, 2017.

Science of AMD. The Angiogenesis Foundation. Accessed on June 6, 2017.

Schmidt-Erfurth, U., Chong, V., Loewenstein, A., et al. Guidelines for the management of neovascular age-related macular degeneration by the European Society of Retina Specialists. *British Journal of Ophthalmology*, 2014. Accessed on June 2, 2017.

Shah, G.K., Augustin, A.J., Blinder, K.J., Syed, B.A., Bielory, L. Wet AMD market, October 2012. *Nature Reviews Drug Discovery*. Accessed on June 8, 2017.

Tsai TH, Yang CM, Yang CH, et al. Transpupillary thermotherapy for the treatment of choroidal neovascularization in age-related macular degeneration in Taiwan. *Eye*. 2007;21(6):721-726. Accessed on March 26, 2019.

U.S. Food and Drug Administration. Center for Devices and Radiological Health (CDRH). Approval Order, Summary of Safety and Effectiveness, and Labeling: Implantable Miniature Telescope™. No. P050034. Rockville, MD: FDA. Accessed on June 7, 2017.

VisionCare: Ophthalmic Technologies. News: CMS Establishes New Ambulatory Surgery Center Payment for VisionCare's Telescope Implant for Macular Degeneration. Accessed on June 8, 2017.

VisionCare: Ophthalmic Technologies. Technology: Implantable Telescope Technology. Accessed on June 8, 2017.

Yang, S., Zhao, J., Sun, X. Resistance to anti-VEGF therapy in neovascular age-related macular degeneration: a comprehensive review, October 2015. *Drug Design, Development and Therapy*, Vol 2016:10; 1857-1867. Accessed on June 15, 2017.

Zur D, Loewenstein A, Barak A, et al. One-year results from clinical practice of epimacular strontium-90 brachytherapy for the treatment of subfoveal choroidal neovascularization secondary to AMD. *Ophthalmic Surg Lasers Imaging Retina*. 2015;46(3):338-343. Accessed on March 26, 2019.

Policy History

Date	Activity
06/15/2017	Initial policy developed
09/26/2017	EHS Revisions: Updated operational guidelines; Table 1 in Attachment A is informational; Attachment E is 'informational;' Attachment D has been added to categorize ICD-10 coding with specific CPT coding.
09/27/2017	QI/UM Committee approval
11/01/2017	Provider effective date
04/20/2018	Revision: Removed the word 'Covered' from the procedure and diagnosis code tables in Attachments B & C
07/11/2018	Annual Review Revisions: Added related policies; added note for referencing related policies; #1 -Removed the VEGF drug therapies from the criteria and created a note to refer readers to pharmacy website; #2 - Removed contraindications for VEGF drug therapies; #3 - Updated language and added new non-covered indications; #5 – Removed the VEGF place of service; updated operational guidelines to reflect VEGF drug therapy removal; Governing Bodies Approval update; Attachment A – Updated summary of literature and Removed Table 1 to reflect VEGF drug therapy removal; updated the PDT therapy criteria in 1.A. to reflect the FDA guidelines.
09/11/2018	QI/UM Committee Review Approval
11/15/2018	Provider effective date
07/16/2019	Annual Review Revisions: Note added to procedure section A to direct providers to the pharmacy policy for Visudyne; Updated the summary of literature and removed specific information referring to anti-VEGF therapy; Added UpToDate literature on PDT therapy; Added literature on submacular surgery, translocation surgery, transpupillary thermotherapy, placement of a pharmacologic agent, epiretinal radiation therapy, and cell-penetrating peptides; Removed code J3396 (Visudyne) due to pharmacy active Visudyne policy; formatting revisions; Added new references
07/16/2019	QI/UM Committee Review Approval
09/16/2019	Provider Effective Date