

Macular Degeneration Treatment Procedures

Guideline Number: MMG076.K
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[Instructions for Use](#)

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<p>Related Medical Management Guidelines</p> <ul style="list-style-type: none"> Proton Beam Radiation Therapy Transpupillary Thermotherapy
<p>Related UnitedHealthcare Drug Policy</p> <ul style="list-style-type: none"> Ophthalmologic Policy: Vascular Endothelial Growth Factor (VEGF) Inhibitors

Coverage Rationale

The following is proven and medically necessary:

- The Implantable Miniature Telescope (IMT) when used according to [U.S. Food and Drug Administration \(FDA\) labeled indications, contraindications, warnings and precautions](#) for treating members with end-stage, age-related macular degeneration.

The following are unproven and not medically necessary due to insufficient evidence of efficacy:

- Conjunctival incision with posterior extrascleral placement of a pharmacologic agent for treating ocular disorders including age-related macular degeneration.
- Epiretinal radiation therapy for treating ocular disorders including age-related macular degeneration.
- Laser photocoagulation for treating macular drusen.

Documentation Requirements

Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The documentation requirements outlined below are used to assess whether the member meets the clinical criteria for coverage but do not guarantee coverage of the service requested.

Required Clinical Information
<p>Macular Degeneration Treatment Procedures</p> <p>Medical notes documenting all of the following:</p> <ul style="list-style-type: none"> History Physical examination, including patient weight and co-morbidities Surgical plan Physician privileging information related to the need for the use of the hospital outpatient department American Society of Anesthesiologists (ASA) score, as applicable

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this guideline does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

CPT Code	Description
0308T	Insertion of ocular telescope prosthesis including removal of crystalline lens or intraocular lens prosthesis
67036	Vitrectomy, mechanical, pars plana approach;
67299	Unlisted procedure, posterior segment
92499	Unlisted ophthalmological service or procedure

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Description of Services

Age-related macular degeneration (AMD) is caused by deterioration of retinal photoreceptors in the central portion of the retina. As AMD progresses, it develops into a "dry" form or a "wet" form. Wet AMD is characterized by the growth of new blood vessels across the posterior of the eye, a process known as choroidal neovascularization (CNV). These blood vessels are fragile and often leak blood and serum, damaging the macular area of the retina and interfering with central vision.

The Implantable Miniature Telescope (IMT) (VisionCare Ophthalmic Technologies, Inc.) is a device used for individuals who are age 65 years or older who suffer from end-stage AMD. During the short outpatient procedure, a surgeon inserts the device into the posterior chamber of only one eye. Although the device eliminates peripheral vision in the affected eye, the untreated eye allows for peripheral vision. Due to the risk of corneal endothelial cell loss which may lead to the need for corneal transplant, an individual must meet specific criteria, including adequate peripheral vision before surgery and willingness to enroll in a visual training or rehabilitation program. The IMT is the only telescope system that is FDA approved for treatment of macular degeneration.

Conjunctival incision with posterior juxtasclear placement of a pharmacologic agent has been proposed 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. Advantages to the posterior juxtasclear placement of a pharmacologic agent may include reduced risk for retinal detachment and other safety issues associated with repeated intravitreal injections (a common route of administration for pharmaceutical agents in the treatment of ocular disorders).

Epiretinal radiation therapy also known as epiretinal brachytherapy or epimacular brachytherapy is the intraocular placement or administration of radioactive material to vessels in the retina. The Vidion Anti-Neovascular Epimacular Brachytherapy (EMBT) System formally known as the Epi-Rad90 Ophthalmic System™ (NeoVista, Inc.) is an epiretinal radiation delivery device developed to treat wet age-related macular degeneration. The Vidio System delivers radiation (strontium 90) directly to the neovascular lesion in a single treatment therapy session.

A common early sign of dry AMD is macular drusen, yellow deposits under the retina. Although drusen do not usually cause vision loss directly, the presence of many or large drusen is associated with elevated risk of progression to advanced dry or wet AMD. Based on this association, some investigators believed that destroying drusen with low-intensity laser light, a treatment known as photocoagulation, would slow the development of AMD and/or prevent the progression from dry AMD to wet AMD. Subthreshold laser therapy is a type of laser photocoagulation that uses a segmented low duty cycle pulse instead of a continuous wave.

Implantable Miniature Telescope

Boyer et al. (2015) evaluated the long-term results of an implantable miniature telescope (IMT) in patients with bilateral, end-stage, age-related macular degeneration (AMD). This prospective, open-label, multicenter clinical trial with fellow eye controls enrolled 217 patients (mean age 76 years) with AMD and moderate-to-profound bilateral central visual acuity loss (20/80-20/800) resulting from untreatable geographic atrophy, disciform scars, or both. A subgroup analysis was performed with stratification for age (patient age 65 to <75 years [group 1; n=70] and patient age ≥75 years [group 2; n=127]), with a comparative evaluation of change in best-corrected distance visual acuity (BCDVA), quality of life, ocular complications from surgery, adverse events, and endothelial cell density (ECD). Follow-up in an extension study was 60 months. Long-term results show substantial retention of improvement in BCDVA. Chronic ECD loss was consistent with that reported for conventional intraocular lenses. The IMT performed as well in group 1 (the younger group) as it did in group 2 through month 60. Younger patients retained more vision than their older counterparts and had fewer adverse events.

At two years, data from the IMT-002 clinical trial that included 174 available patients were analyzed. Overall, 103 (59.5%) of 173 telescope-implanted eyes gained three lines or more of BCVA compared with 18 (10.3%) of 174 fellow control eyes. One telescope-implanted eye lost 3 lines of BCVA compared with 13 in the control group. Mean endothelial cell density (ECD) stabilized through two years, with 2.4% mean cell loss occurring from one to two years. There was no significant change in coefficient of variation or percentage of hexagonal endothelial cells from within six months to two years after surgery. The most common complication was inflammatory deposits. The authors concluded that long-term results of the IMT prosthesis show the substantial BCVA improvement at one year is maintained at two years. Key indicators of corneal health demonstrate ECD change that reflects remodeling of the endothelium associated with the implantation procedure. The authors state that ECD stabilizes over time, and there is no evidence of any ongoing endothelial trauma (Hudson et al. 2008).

In a prospective open-label clinical trial, called the IMT-002 clinical trial, Hudson et al. (2006) evaluated the safety and efficacy of an implantable visual prosthetic device (IMT; VisionCare Ophthalmic Technologies) in patients with bilateral, end-stage age-related macular degeneration (AMD). A total of 217 patients (mean age, 76 years) with AMD and moderate to profound bilateral central visual acuity loss (20/80 - 20/800) resulting from bilateral untreatable geographic atrophy, disciform scars, or both were implanted with the IMT device. Fellow eyes were not implanted to provide peripheral vision and served as controls. At 1 year, 67% of implanted eyes achieved a 3-line or more improvement in best-corrected distance visual acuity (BCDVA) versus 13% of fellow eye controls. Fifty-three percent of implanted eyes achieved a 3-line or more improvement in both BCDVA and best-corrected near visual acuity (BCNVA) versus 10% of fellow eyes. Eleven eyes did not receive the device because of an aborted procedure. Endothelial cell density (ECD) was reduced by 20% at 3 months and 25% at 1 year. The decrease in ECD was correlated with postsurgical edema, and there was no evidence that endothelial cell loss is accelerated by ongoing endothelial trauma after implantation. The authors concluded that the IMT visual prosthesis can improve visual acuity and quality of life in patients with moderate to profound visual impairment caused by bilateral, end-stage AMD.

A National Institute for Health and Care Excellence (NICE) guidance for miniature lens system implantation for advanced age-related macular degeneration states that evidence on the efficacy of miniature lens system implantation for advanced age-related macular degeneration (AMD) shows that the procedure can improve both vision and quality of life in the short term. Data on short-term safety are available for limited numbers of patients. According to NICE, there is currently insufficient long-term evidence on both efficacy and safety. NICE guidance states that this procedure should only be used with special arrangements for clinical governance, consent and audit or research (NICE 2016).

Professional Societies

American Academy of Ophthalmology (AAO)

The 2019 AAO Preferred Practice Patterns guidelines on age-related macular degeneration state that an implantable miniature telescope (IMT) is an FDA-approved device that may be effective for screened, phakic, motivated patients with end-stage AMD.

Conjunctival Incision with Placement of a Pharmacologic Agent

Conjunctival incision with posterior extrascleral placement of a pharmacologic agent has not been demonstrated to be as effective as standard therapy for ocular disorders including macular degeneration. Further studies with larger sample sizes are needed to demonstrate the efficacy of this treatment.

Geltzer et al. (2013) conducted a Cochrane review to examine the effects of steroids with antiangiogenic properties in the treatment of neovascular AMD. The authors searched electronic databases for randomized controlled clinical trials of intra- and peri-ocular antiangiogenic steroids in people diagnosed with neovascular AMD. Three trials with a total of 809 participants met review specifications and were included in the review. One trial compared different doses of acetate anecortave acetate with placebo, a second trial compared juxtasclear placement of triamcinolone acetate versus placebo, and the third trial compared juxtasclear placement of anecortave acetate against photodynamic therapy (PDT). A meta-analysis was not conducted owing to heterogeneity of interventions and comparisons. The risk ratio for loss of 3 or more lines of vision at 12 months follow-up was 0.8 with 3 mg anecortave acetate, 0.45 with 15 mg anecortave acetate, 0.91 with 30 mg anecortave acetate, 0.97 with triamcinolone acetate, all compared to placebo and 1.08 with anecortave acetate compared with PDT. Overall, the review found limited evidence regarding the benefits of posterior juxtasclear placement of steroids for treating neovascular AMD.

Epiretinal Radiation Therapy

The evidence does not support the use of epiretinal radiation therapy. Controlled trials with larger populations are needed to demonstrate the effectiveness of this procedure.

In a Phase 3 randomized controlled trial, Jackson et al. (2016) assessed the safety and efficacy of epimacular brachytherapy (EMB) for patients with chronic, active, neovascular age-related macular degeneration (AMD). The trial included 363 patients with neovascular AMD already receiving intravitreal ranibizumab injections. Patients underwent either pars plana vitrectomy with 24-gray EMB and ongoing pro re nata (PRN) ranibizumab (n = 224) or ongoing PRN ranibizumab monotherapy (n = 119). The co-primary outcomes, at 12 months, were the number of PRN ranibizumab injections and Early Treatment of Diabetic Retinopathy Study (ETDRS) best-corrected visual acuity (VA). Secondary outcomes included the proportion of participants losing fewer than 15 ETDRS letters, angiographic total lesion size, choroidal neovascularization (CNV) size, and optical coherence tomography (OCT) foveal thickness. The mean number of PRN ranibizumab injections was 4.8 in the EMB arm and 4.1 in the ranibizumab monotherapy arm. The mean VA change was -4.8 letters in the EMB arm and -0.9 letters in the ranibizumab arm. The proportion of participants losing fewer than 15 letters was 84% in the EMB arm and 92% in the ranibizumab arm. In the EMB arm, the mean total lesion size increased by 1.2 mm² versus 0.4 mm² in the ranibizumab arm. The CNV size decreased by 0.5 mm² in the EMB arm and by 1.3 mm² in the ranibizumab arm. The OCT foveal thickness decreased by 1.0 μm in the EMB arm and by 15.7 μm in the ranibizumab arm. Most subgroups favored ranibizumab monotherapy, some significantly so. One participant showed retinal vascular abnormality attributed to radiation, but otherwise safety was acceptable. According to the authors, these results do not support the use of EMB for chronic, active, neovascular AMD. The authors did not identify any subgroup of patients who responded well to EMB or who warranted further study. The authors indicated that three years of safety follow-up is planned because radiation retinopathy can occur beyond the current 12-month milestone.

Zur et al. (2015) evaluated the clinical feasibility, safety, and efficacy of epiretinal strontium-90 brachytherapy in subfoveal choroidal neovascularization (CNV) due to age-related macular degeneration (AMD) in eyes unresponsive to repeated anti-Vascular Endothelial Growth Factor (VEGF) injections. Twenty-two patients were treated, and 20 completed 12 months of follow-up. Ten patients maintained stable vision, eight gained vision, and two lost more than three Snellen lines. The mean best corrected visual acuity change from baseline was -8 ± 5.7 letters. A mean of 5.5 ± 4.4 anti-VEGF injections were administered throughout 12 months. The authors found that while some patients benefit from the treatment and need significantly fewer as-needed injections, others appear not to react to irradiation treatment after 1 year of follow-up. According to the authors, larger numbers of patients are needed to evaluate therapeutic efficacy and to determine which patients can benefit from combined radiation and anti-VEGF therapy.

Jackson et al. (2013) reported the results of an active-controlled, randomized clinical trial of epimacular brachytherapy (EMBT) used for the treatment of neovascular age-related macular degeneration (AMD). A total of 494 participants with classic, minimally classic, and occult lesions were randomized to receive (a) EMBT and 2 mandated monthly ranibizumab injections followed by pro re nata (PRN) ranibizumab or (b) 3 mandated monthly ranibizumab injections followed by mandated quarterly plus PRN ranibizumab. Participants underwent fluorescein angiography (FA) at screening and at months 1, 6, 12, 18, and 24. Optical coherence tomography (OCT) scans were undertaken monthly for 24 months. Based on the results of the study, the authors concluded that both FA and OCT suggest that EMBT with PRN ranibizumab results in an inferior structural outcome than quarterly plus PRN ranibizumab. Some subgroup analyses suggest that classic lesions may be more responsive than occult lesions, although generally both subgroups are inferior to ranibizumab.

Dugel et al. (2013) evaluated the safety and efficacy of epimacular brachytherapy (EMBT) for the treatment of neovascular age-related macular degeneration (AMD) in a multicenter, randomized, active-controlled, phase III clinical trial. Four hundred ninety-four participants with classic, minimally classic, and occult lesions were randomized in a 2:1 ratio to EMBT or a ranibizumab monotherapy control arm. The EMBT arm received 2 mandated, monthly loading injections of 0.5 mg ranibizumab. The control arm received 3 mandated, monthly loading injections of ranibizumab then quarterly injections. Both arms also received monthly as needed (pro re nata) retreatment. At 24 months, 77% of the EMBT group and 90% of the control group lost fewer than 15 letters. The EMBT did not meet the superiority end point for the proportion of participants gaining more than 15 letters (16% for the EMBT group vs. 26% for the control group): this difference was statistically significant (favoring controls) for occult lesions, but not for predominantly classic and minimally classic lesions. The authors concluded that the 2-year efficacy data do not support the routine use of EMBT for treatment-naïve wet AMD, despite an acceptable safety profile.

Twelve- and 24-month results have been reported from the multicenter macular epiretinal brachytherapy in treated age-related macular degeneration (MERITAGE) study which is a prospective, interventional, non-controlled clinical trial. The results of this study were reported in 2013 and 2014. Petrarca et al. (2013) reported the optical coherence tomography (OCT) and fundus fluorescein angiography (FFA) results of 53 eyes of 53 participants with chronic, active neovascular age-related macular degeneration (AMD). Participants underwent pars plana vitrectomy with a single 24-gray dose of epimacular brachytherapy (EMB). The main outcome measures for the study were change in OCT center-point thickness and angiographic lesion size 12 months after EMB. Based on the results of the study, the authors concluded that in chronic, active, neovascular AMD, EMB is associated with non-significant changes in center-point thickness and FFA total lesion size over 12 months. Petrarca et al. (2014) reported that over 24 months, 68.1% lost less than 15 letters with a mean of 8.7 ranibizumab retreatments. The authors concluded that the apparent reduction in ranibizumab retreatment was less evident in Year 2 than Year 1, with the moderate reduction in visual acuity extending into the second year. Although radiation retinopathy occurred in one case, it was not vision threatening and safety remained acceptable. Limitations of the MERITAGE study include a lack of controls and a small sample size.

A Cochrane systematic evidence review examined the effects of radiotherapy on neovascular age-related macular degeneration (AMD). All randomized controlled trials in which radiotherapy was compared to another treatment, sham treatment, low dosage irradiation or no treatment in people with choroidal neovascularization secondary to AMD were included. Thirteen trials (n=1154) investigated external beam radiotherapy with dosages ranging from 7.5 to 24 Gy; one additional trial (n=88) used plaque brachytherapy (15Gy at 1.75mm for 54 minutes/12.6 Gy at 4mm for 11 minutes). Most studies found effects (not always significant) that favored treatment. Overall there was a small statistically significant reduction in risk of visual acuity loss in the treatment group. There was considerable inconsistency between trials and the trials were considered to be at risk of bias, in particular because of the lack of masking of treatment group. Subgroup analyses did not reveal any significant interactions; however, there were small numbers of trials in each subgroup (range three to five). There was some indication that trials with no sham irradiation in the control group reported a greater effect of treatment. According to the authors, the review did not provide convincing evidence that radiotherapy is an effective treatment for neovascular AMD. If further trials are to be considered to evaluate radiotherapy in AMD then adequate masking of the control group must be considered (Evans et al. 2010).

A National Institute for Health and Care Excellence (NICE) guidance for epiretinal brachytherapy for wet age-related macular degeneration states that current evidence on the efficacy of epiretinal brachytherapy for wet age related macular degeneration (AMD) is inadequate and limited to small numbers of patients. With regard to safety, vitrectomy has well-recognized complications and there is a possibility of subsequent radiation retinopathy. NICE guidance states that this procedure should only be used in the context of research (NICE 2011).

Professional Societies

American Academy of Ophthalmology (AAO)

The 2019 AAO Preferred Practice Patterns guidelines on age-related macular degeneration indicate that there is insufficient data to demonstrate the clinical efficacy of radiation therapy for treating age-related macular degeneration. Therefore, radiation therapy is not recommended for treating this condition.

Laser Photocoagulation for Macular Drusen

Results of available studies lead to the conclusion that current prophylactic laser treatment does not benefit individuals who have macular drusen.

Eng et al. (2019) evaluated the published literature on subthreshold retinal laser therapy as prophylactic treatment of nonexudative AMD. Studies were analyzed based upon study design, laser parameters, drusen reduction, changes in visual acuity (VA), and the development of choroidal neovascularization (CNV) and/or geographic atrophy (GA). Twelve studies involving 2,481 eyes treated with subthreshold retinal laser therapy were included in the review. Treatment led to increased drusen reduction, and studies with significant VA improvement were associated with significant drusen reduction. There was no significant change in the risk of developing CNV or GA. The investigators concluded that subthreshold retinal laser therapy is effective for reducing drusen and potentially improving vision in patients with nonexudative AMD. This therapy does not show benefits in reducing development of CNV or GA. Thus, its long-term efficacy to prevent progression to advanced AMD cannot yet be recommended.

A Cochrane review examined the effectiveness and adverse effects of laser photocoagulation of drusen in age-related macular degeneration (AMD). The review included 11 studies that randomized 2159 participants (3580 eyes) and followed them up to two years, of which six studies (1454 participants) included people with one eye randomized to treatment and one to control. Overall, the risk of bias in the included studies was low, particularly for the larger studies and for the primary outcome development of choroidal neovascularization (CNV). Photocoagulation did not reduce the development of CNV at two years' follow-up (high quality evidence). This estimate means that, given an overall occurrence of CNV of 8.3% in the control group, an absolute risk reduction by no more than 1.4% was estimated in the laser group. Only two studies investigated the effect on the development of geographic atrophy and could not show a difference, but estimates were imprecise. Among secondary outcomes, photocoagulation led to drusen reduction but was not shown to limit loss of 3 or more lines of visual acuity (moderate quality evidence). In a subgroup analysis, no difference could be shown for conventional visible (eight studies) versus subthreshold invisible (four studies) photocoagulation for the primary outcomes. The effect in the subthreshold group did not suggest a relevant benefit. No other adverse effects (apart from development of CNV, geographic atrophy or visual loss) were reported. According to the authors, the trials included in this review confirm the clinical observation that laser photocoagulation of drusen leads to their disappearance. However, treatment does not result in a reduction in the risk of developing CNV, and was not shown to limit the occurrence of geographic atrophy or visual acuity loss. The authors indicated that ongoing studies are being conducted to assess whether the use of extremely short laser pulses (i.e., nanosecond laser treatment) can not only lead to drusen regression but also prevent neovascular AMD (Virgili et al. 2015).

Mojana et al. (2011) evaluated the long-term effect of subthreshold diode laser treatment for drusen. Eight eyes of four consecutive age-related macular degeneration patients with bilateral drusen previously treated with subthreshold diode laser were imaged with spectral domain optical coherence tomography/scanning laser ophthalmoscope. Based on the study results, the investigators concluded that subthreshold diode laser treatment causes long-term disruption of the retinal photoreceptor layer. They state further that the concept that subthreshold laser treatment can achieve a selected retinal pigment epithelium effect without damage to rods and cones may be flawed.

The largest available randomized controlled trial (RCT) of laser treatment for macular drusen is the Complications of Age-Related Macular Degeneration Prevention Trial (CAPT). This study enrolled 1052 patients who had large bilateral drusen and randomized one eye to laser treatment and the other eye to observation. An argon green laser was preferred but lasers with other wavelengths could be used if an argon green laser was not available. At randomization, the treatment eye received 60 laser burns of 100-diameter and 100-millisecond duration in a grid pattern between 1500 and 2500 from the foveal center. Lesions were designed to be barely visible and drusen were not targeted specifically. If significant reduction of drusen was not apparent after 12 months, a second treatment of 30 burns specifically targeting drusen was administered in the treatment eye. Of the 1042 patients available 1 year after the initial treatment, 856 (82%) underwent a second laser treatment. At 2 years follow-up, 50% or greater drusen reduction was seen in 34% of treated eyes versus 9% of untreated eyes. Despite the influence of laser therapy on drusen, at 5 years follow-up, there were no statistically significant differences between treated and untreated eyes in visual acuity (VA), CNV, geographic atrophy, contrast threshold, or critical print size. The CAPT Research Group concluded that preventative laser treatment was neither harmful nor beneficial (Complications of Age-Related Macular Degeneration Prevention Trial (CAPT) Research Group, 2006).

The results of three additional randomized controlled trials (Friberg, 2006; Maguire, 2003; Owens, 2006) provide strong evidence that current prophylactic laser treatment protocols do not benefit patients who have macular drusen. None of the reviewed studies found that laser treatment provided a statistically or clinically significant benefit. Furthermore, these studies concluded that laser therapy accelerated onset of CNV in patients who have drusen in one eye and CNV or retinal detachment in the other eye.

A National Institute for Health and Care Excellence (NICE) guidance for age-related macular degeneration recommends that thermal laser therapy (for example, argon, diode) should not be offered for treating drusen in people with early AMD. According to NICE, the evidence presented demonstrated that laser treatment reduces drusen size; however there was no evidence of an associated effect on AMD progression or vision and that noted that patient-relevant benefits have never been demonstrated (NICE 2018).

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Implantable Miniature Telescope

The Implantable Miniature Telescope (IMT) received FDA approval, effective July 1, 2010. This device is indicated for monocular implantation to improve vision in patients greater than or equal to 75 years of age with stable severe to profound vision impairment (best corrected distance visual acuity 20/160 to 20/800) caused by bilateral central scotomas associated with end-stage age-related macular degeneration. In October 2014, the FDA expanded the age limit for IMT to 65 years of age or older.

According to the FDA's indications for use of the Implantable Miniature Telescope, patients must:

- Have retinal findings of geographic atrophy or disciform scar with foveal involvement, as determined by fluorescein angiography
- Have evidence of visually significant cataract (greater or equal to Grade 2)
- Agree to undergo pre-surgery training and assessment (typically 2 to 4 sessions) with low vision specialists (optometrist or occupational therapist) in the use of an external telescope sufficient for patient assessment and for the patient to make an informed decision
- Achieve at least a 5-letter improvement on the Early Treatment Diabetic Retinopathy Study (ETDRS) chart with an external telescope
- Have adequate peripheral vision in the eye not scheduled for surgery
- Agree to participate in postoperative visual training with a low vision specialist

According to the FDA approval letter, a post-approval requirement indicates that the manufacturer must 1) continue follow-up on the patients from its long-term cohort study to provide additional long-term (up to 8 years) safety data and 2) must conduct an additional study of 770 newly enrolled patients to evaluate adverse events for 5 years after implantation. See the following website for more information: http://www.accessdata.fda.gov/cdrh_docs/pdf5/P050034a.pdf (Accessed April 8, 2020)

According to the FDA's Summary of Safety and Effectiveness Data (2010), the IMT is contraindicated in patients with any of the following:

- Stargardt's macular dystrophy.
- 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.
- The presence of corneal guttata.
- The minimum age and endothelial cell density requirements are not met.
- Cognitive impairment that would interfere with the ability to understand and complete the Acceptance of Risk and Informed Decision Agreement or prevent proper visual training/rehabilitation with the device.
- Evidence of active choroidal neovascularization (CNV) on fluorescein angiography or treatment for CNV within the past six months.
- Any ophthalmic pathology that compromises the patient's peripheral vision in the fellow eye.
- Previous intraocular or cornea surgery of any kind in the operative eye, including any type of surgery for either refractive or therapeutic purposes.
- Prior or expected ophthalmic related surgery within 30 days preceding intraocular telescope implantation.
- A history of steroid-responsive rise in intraocular pressure, uncontrolled glaucoma, or preoperative intraocular pressure greater than 22 mm Hg, while on maximum medication.
- Known sensitivity to post-operative medications.
- A history of eye rubbing or an ocular condition that predisposes them to eye rubbing.

- The planned operative eye has:
 - Myopia greater than 6.0 diopters
 - Hyperopia greater than 4.0 diopters
 - Axial length less than 21 mm
 - A narrow angle (i.e., less than Schaffer grade 2)
 - Cornea stromal or endothelial dystrophies, including guttata
 - Inflammatory ocular disease
 - Zonular weakness/instability of crystalline lens, or pseudoexfoliation
 - Diabetic retinopathy
 - Untreated retinal tears
 - Retinal vascular disease
 - Optic nerve disease
 - A history of retinal detachment
 - Intraocular tumor
 - Retinitis pigmentosa

See the following website for more information: http://www.accessdata.fda.gov/cdrh_docs/pdf5/P050034b.pdf (Accessed April 8, 2020)

Epiretinal Radiation Therapy

There are no devices specifically approved by the FDA for epiretinal radiation therapy. The Epi-Rad90™ System (NeoVista) (now known as Vidion Anti-Neovascular Epimacular Brachytherapy [EMBT] System) is accepted by the FDA 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.

Laser Photocoagulation

Laser photocoagulation for macular drusen is a procedure and, as such, is not subject to regulation by the FDA. However, laser devices used to perform this therapy are regulated by the FDA. They are classified under two product codes, HQB (Ophthalmic Photocoagulator) and HQF (Ophthalmic Laser), incorporating more than 100 approved devices. See the following website for more information at (use product codes HQB or HQF): <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm> (Accessed April 8, 2020)

References

- American Academy of Ophthalmology. Preferred practice pattern Guidelines. Age-related macular degeneration. 2015. Available at: <https://www.aaopt.org/preferred-practice-pattern/age-related-macular-degeneration-ppp> . Accessed April 8, 2020.
- Boyer D, Freund KB, 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. Clin Ophthalmol. 2015 Jun 17;9:1099-107.
- Complications of Age-Related Macular Degeneration Prevention Trial (CAPT) Research Group. Laser treatment in patients with bilateral large drusen: the complications of age-related macular degeneration prevention trial; Ophthalmology. 2006. 113(11):1974-1986.
- Dugel PU, Bebhuk JD, Nau J, et al. CABERNET Study Group. Epimacular brachytherapy for neovascular age-related macular degeneration: a randomized, controlled trial (CABERNET). Ophthalmology. 2013 Feb;120(2):317-27.
- Eng VA, Wood EH, Boddu S, et al. Preventing progression in nonexudative age-related macular degeneration with subthreshold laser therapy: a systematic review. Ophthalmic Surg Lasers Imaging Retina. 2019 Mar 1;50(3):e61-e70.
- Evans JR, Sivagnanavel V, Chong V. Radiotherapy for neovascular age-related macular degeneration. Cochrane Database Syst Rev. 2010 May 12;(5):CD004004.
- Friberg TR, Musch DC, Lim JI, et al. PTAMD Study Group. Prophylactic treatment of age-related macular degeneration report number 1: 810-nanometer laser to eyes with drusen. Unilaterally eligible patients. Ophthalmology. 2006; 113(4):612.e1-622.e1.

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

Hudson HL, Lane SS, Heier JS, et al. IMT-002 Study Group. Implantable miniature telescope for the treatment of visual acuity loss resulting from end-stage age-related macular degeneration: 1-year results. *Ophthalmology* 2006 Nov;113(11):1987-2001.

Hudson HL, Stulting RD, Heier JS, et al. IMT002 Study Group. Implantable telescope for end-stage age-related macular degeneration: long-term visual acuity and safety outcomes. *Am J Ophthalmol* 2008 Nov;146(5):664-673.

Jackson TL, Desai R, Simpson A, et al.; Macular Epiretinal Brachytherapy versus Ranibizumab (Lucentis) Only Treatment (MERLOT) Study Group. Epimacular brachytherapy for previously treated neovascular age-related macular degeneration (MERLOT): A phase 3 randomized controlled trial. *Ophthalmology.* 2016 Jun;123(6):1287-96.

Jackson TL, Dugel PU, Bechuk JD, et al. CABERNET Study Group; Epimacular brachytherapy for neovascular age-related macular degeneration (CABERNET): fluorescein angiography and optical coherence tomography. *Ophthalmology.* 2013 Aug;120(8):1597-603.

Maguire MG, Sternberg P, Aaberg TM, et al. Choroidal Neovascularization Prevention Trial (CNVPT) Research Group. Laser treatment in fellow eyes with large drusen: updated findings from a pilot randomized clinical trial. *Ophthalmology.* 2003;110(5):971-978.

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). Age-related macular degeneration: diagnosis and management. NICE interventional procedure guidance [NG82]. Publication date: January 2018.

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.

National Institute for Health and Care Excellence (NICE). Miniature lens system implantation for advanced age-related macular degeneration. NICE interventional procedure guidance 565. Publication date: September 2016.

Owens SL, Bunce C, Brannon AJ, et al. Drusen Laser Study Group. Prophylactic laser treatment hastens choroidal neovascularization in unilateral age-related maculopathy: final results of the drusen laser study. *Am J Ophthalmol.* 2006;141(2):276-281.

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.

Petrarca R, Dugel PU, Nau J, et al. Macular epiretinal brachytherapy in treated age-related macular degeneration (MERITAGE): month 12 optical coherence tomography and fluorescein angiography. *Ophthalmology.* 2013 Feb; 120(2):328-33.

Virgili G, Michelessi M, Parodi MB, et al. Laser treatment of drusen to prevent progression to advanced age-related macular degeneration. *Cochrane Database Syst Rev.* 2015 Oct 23;10:CD006537.

Zur D, Loewenstein A, Barak A. 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 Mar;46(3):338-43.

Guideline History/Revision Information

Date	Summary of Changes
01/01/2021	<p>Template Update</p> <ul style="list-style-type: none"> Reformatted policy; transferred content to new template
06/01/2020	<p>Template Update</p> <ul style="list-style-type: none"> Added <i>Documentation Requirements</i> section <p>Supporting Information</p> <ul style="list-style-type: none"> Updated <i>Description of Services</i>, <i>Clinical Evidence</i>, and <i>References</i> sections to reflect the most current information Archived previous policy version MMG076.J

Instructions for Use

This Medical Management Guideline provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this guideline, please check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Management Guideline is provided for informational purposes. It does not constitute medical advice.

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