MACULAR DEGENERATION TREATMENT PROCEDURES

Protocol: OPT015
Effective Date: August 1, 2016

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INSTRUCTIONS FOR USE

This protocol provides assistance in interpreting UnitedHealthcare benefit plans. When deciding coverage, the enrollee specific document must be referenced. The terms of an enrollee's document (e.g., Certificate of Coverage (COC) or Evidence of Coverage (EOC)) may differ greatly. In the event of a conflict, the enrollee's specific benefit document supersedes this protocol. All reviewers must first identify enrollee eligibility, any federal or state regulatory requirements and the plan benefit coverage prior to use of this protocol. Other Protocols, Policies and Coverage Determination Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, to modify its Protocols, Policies and Guidelines as necessary. This protocol is provided for informational purposes. It does not constitute medical advice. This policy does not govern Medicare Group Retiree members.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

COMMERCIAL, MEDICARE & MEDICAID COVERAGE RATIONALE

Implantable Miniature Telescope (IMT)
The implantable miniature telescope is medically necessary when used according to U.S. Food and Drug Administration (FDA) labeled indications for treating patients with end-stage, age-related macular degeneration. See the FDA section of this policy for a complete list of FDA indications and contraindications for IMT.

Conjunctival Incision with Placement of a Pharmacologic Agent
Conjunctival incision with posterior extrascleral placement of a pharmacologic agent is not medically necessary for treating ocular disorders including age-related macular degeneration. 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.

**Epiretinal Radiation Therapy**
Epiretinal radiation therapy is not medically necessary for treating ocular disorders including age-related macular degeneration. The evidence does not support the use of epiretinal radiation therapy. Controlled trials with larger patient populations are needed to demonstrate the effectiveness of this procedure.

**Laser Photocoagulation**
Laser photocoagulation is not medically necessary for treating macular drusen. Results of available studies lead to the conclusion that current prophylactic laser treatment does not benefit patients who have macular drusen.

Medicare does not have a National Coverage Determination for the implantable miniature telescope used in the treatment of end-stage, age related macular degeneration, conjunctival incision with placement of a pharmacologic agent. Epiretinal radiation therapy or laser photocoagulation used for treatment of macular drusen. Local Coverage Determinations (LCDs) for Nevada do not exist at this time (Accessed June 2016).

Medicare does recognize the use of lasers for many medical indications. In the absence of a specific non-coverage instruction, and where a laser has been approved for marketing by the Food and Drug Administration, contractor discretion may be used to determine whether a procedure performed with a laser is reasonable and necessary and, therefore, covered. The determination of coverage for a procedure performed using a laser is made on the basis that the use of lasers to alter, revise, or destroy tissue is a surgical procedure. Therefore, coverage of laser procedures is restricted to practitioners with training in the surgical management of the disease or condition being treated. Refer to the National Coverage Determination (NCD) for Laser Procedures (140.5) (Accessed June 2016).

**Laser Procedures (140.5)**
**Indications and Limitations of Coverage**
Medicare recognizes the use of lasers for many medical indications. Procedures performed with lasers are sometimes used in place of more conventional techniques. In the absence of a specific non-coverage instruction, and where a laser has been approved for marketing by the Food and Drug Administration, contractor discretion may be used to determine whether a procedure performed with a laser is reasonable and necessary and, therefore, covered.

The determination of coverage for a procedure performed using a laser is made on the basis that the use of lasers to alter, revise, or destroy tissue is a surgical procedure. Therefore, coverage of laser procedures is restricted to practitioners with training in the surgical management of the disease or condition being treated.

**For Medicare and Medicaid Determinations Related to States Outside of Nevada:**
Please review Local Coverage Determinations that apply to other states outside of Nevada.
http://www.cms.hhs.gov/mcd/search
**Important Note:** Please also review local carrier web sites in addition to the Medicare Coverage database on the Centers for Medicare and Medicaid Services’ Website.

**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 patients 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 or corneal transplant, the patient 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 juxtascleral 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 juxtascleral placement of a pharmacologic agent 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).

The 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. The NeoVista device has not been approved for use in the United States; however, it is undergoing clinical trials.

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.
**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 BDCVA. 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.

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.

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).
Conjunctival Incision with Placement of a Pharmacologic Agent

Gelzer 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 acetonide anecortave acetate with placebo, a second trial compared triamcinolone acetonide versus placebo, and the third trial compared 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 acetonide, all compared to placebo and 1.08 with anecortave acetate compared with PDT. The authors found no evidence that antiangiogenic steroids prevent visual loss in patients with neovascular AMD. The authors concluded that it is unclear what role steroids have in treating patients with neovascular AMD.

Slakter et al. (2006) compared 1-year safety and efficacy of anecortave acetate with photodynamic therapy (PDT) in a prospective, masked, randomized, multicenter, parallel group, active controlled clinical trial (the Anecortave Acetate Clinical Study). Five hundred thirty patients with age-related macular degeneration were randomized to treatment with either anecortave acetate 15 mg or PDT. In the anecortave acetate group, the drug was administered under the Tenon's capsule as a periocular posterior juxtascleral depot (PJD) at the beginning of the study and at month 6. Percent responders (patients losing less than 3 lines of vision) in the anecortave acetate and PDT groups were 45% and 49%, respectively. The confidence interval (CI) for the difference ranged from -13.2% favoring PDT to +5.6% favoring anecortave acetate. The month 12 clinical outcome for anecortave acetate was improved in patients for whom reflux was controlled and who were treated within the 6-month treatment window (57% vs. 49%; 95% CI, -4.3% favoring PDT to +21.7% favoring anecortave acetate). No serious adverse events related to the study drug were reported in either treatment group. According to the investigators, the safety and efficacy outcomes in this study demonstrate that the benefits of anecortave acetate for the treatment of choroidal neovascularization outweigh the risks associated with either the drug or the PJD administration procedure. In July 2008, Alcon, Inc. announced that it has terminated the development program designed to evaluate the benefit of anecortave acetate treatment on the risk for developing sight-threatening choroidal neovascularization secondary to age-related macular degeneration. The decision followed a planned interim analysis of studies C-02-60 A and B that was performed after 2,546 patients had completed the 24 month time point. In this analysis, anecortave acetate showed no effect on the primary or secondary endpoints. See the following Web site for more information: http://www.medicalnewstoday.com/articles/114883.php

The clinical evidence was reviewed in March 2016 with no additional information identified that would change the conclusion for conjunctival incision with placement of a pharmacologic agent.

Epiretinal Radiation 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 nonsignificant 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.

Avila et al. (2012) evaluated the long-term safety and visual acuity outcomes associated with epimacular strontium 90 brachytherapy combined with intravitreal bevacizumab for the treatment of subfoveal choroidal neovascularization because of age-related macular degeneration. Thirty-four treatment-naïve patients with predominantly classic, minimally classic, and occult subfoveal choroidal neovascularization lesions participated in this prospective, 2-year, nonrandomized multicenter study. Based on the results of the study, the authors concluded that epimacular brachytherapy shows promise as a therapeutic option for subfoveal neovascular age-related macular degeneration. The procedure was safe and well tolerated, with a reasonable risk-benefit profile that warrants further study in larger subject populations.
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.

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).

A phase IV randomized controlled trial comparing macular epiretinal brachytherapy versus ranibizumab (Lucentis®) only treatment (MERLOT) sponsored by NeoVista is being conducted in the United Kingdom. The projected study completion date is 2015. See the following for more information: http://clinicaltrials.gov/ct2/show/NCT01006538. Accessed June 2016.

**Professional Societies**

**American Academy of Ophthalmology (AAO)**

The 2015 AAO Preferred Practice Patterns guidelines on age-related macular degeneration state that radiation therapy is not recommended for extrafoveal and peripapillary choroidal neovascularization (CNV) lesions.
Laser Photocoagulation for Macular Drusen
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 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.

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

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 Web site for more information: [http://www.accessdata.fda.gov/cdrh_docs/pdf5/P050034a.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf5/P050034a.pdf). Accessed June 2016.

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

See the following web sites for more information:

Epirental Radiation Therapy
The NeoVista Epi-Rad90™ System is accepted by the U.S. Food and Drug Administration (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 support a premarket approval application or a 510(k) submission to the FDA. See the following for more information:

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. An example of an ophthalmic laser used for photocoagulation of macular drusen is the Iris Medical OcuLight (Iridex Corp.) (Product Code HQF). This device was approved by the FDA on August 27, 2003.
See the following Web site for more information:
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 policy 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 Coverage Determination Guidelines may apply. This list of codes may not be all inclusive.

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REFERENCES


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


**PROTOCOL HISTORY/REVISION INFORMATION**

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The foregoing Health Plan of Nevada/Sierra Health & Life Health Operations protocol has been adopted from an existing UnitedHealthcare coverage determination guideline that was researched, developed and approved by the UnitedHealthcare Coverage Determination Committee.