MACULAR DEGENERATION TREATMENT PROCEDURES

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Related Policies:
- Proton Beam Radiation Therapy
- Transpupillary Thermotherapy
- Ophthalmologic Policy: Vascular Endothelial Growth Factor (VEGF) Inhibitors

INSTRUCTIONS FOR USE

This Medical Policy 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 Summary Plan Description (SPD) and Medicaid State Contracts) may differ greatly from the standard benefit plans upon which this Medical Policy is based. In the event of a conflict, the enrollee's specific benefit document supersedes this Medical Policy. All reviewers must first identify enrollee eligibility, any federal or state regulatory requirements and the enrollee specific plan benefit coverage prior to use of this Medical Policy. Other Policies and Coverage Determination Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

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COVERAGE RATIONALE

Implantable Miniature Telescope (IMT)
The implantable miniature telescope is proven and medically necessary when used according to U.S. Food and Drug Administration (FDA) labeled indications for the treatment of 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 unproven and not medically necessary to treat 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.
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 75 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 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).

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.

**CLINICAL EVIDENCE**

**Implantable Miniature Telescope**

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).

The 2008 National Institute for Health and Care Excellence (NICE) guidance on implantable miniature lens systems for the treatment of AMD states that the evidence on the efficacy of implantation of miniature lens systems for advanced age-related macular degeneration shows that the procedure can improve both vision and quality of life in the short-term. Short-term safety data are available for limited numbers of patients. There is currently insufficient long-term
evidence on both efficacy and safety. Therefore this procedure should only be used with special arrangements for clinical governance, consent and audit or research (NICE 2008).

**Conjunctival Incision with Placement of a Pharmacologic Agent**

The clinical evidence was reviewed on February 14, 2014 with no additional information identified that would change the unproven conclusion for conjunctival incision with placement of a pharmacologic agent.

The studies that assessed conjunctival incision with placement of a pharmacologic agent evaluated posterior juxtascleral placement of anecortave acetate (Alcon, Inc), an angiostatic steroid that is under investigation for the prevention and treatment of ocular disease. These studies indicate that conjunctival incision with posterior juxtascleral placement of anecortave acetate depot suspension or placebo appears be promising (Veritti, 2009; Hayek, 2007; Van de Moere, 2005; Augustin, 2004; D'Amico, 2003); however, given the small sample sizes and quality of the studies, there is not enough evidence to support the use of this technique in treating age-related macular degeneration.

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 acetone 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-02-60A 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](http://www.medicalnewstoday.com/articles/114883.php). Accessed February 2014.
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.

Petrarca et al. (2013) reported the optical coherence tomography (OCT) and fundus fluorescein angiography (FFA) results of the Macular Epiretinal Brachytherapy in Treated Age-Related Macular Degeneration study which is a prospective, multicenter, interventional, non-controlled clinical trial. The trial included 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.

Avila et al. (2011) 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.

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 document for radiotherapy for age-related macular degeneration states that current evidence shows radiotherapy for age-related macular degeneration to have little efficacy. There are also concerns about its safety. It is suitable for use only within good quality research studies approved by a research ethics committee, specifying the dose of radiation used and with explicit patient consent (NICE, 2004).

A National Institute for Health and Care Excellence (NICE) guidance for epiretinal brachytherapy for wet age-related macular degeneration (AMD) 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 2014. See the following for more information: [http://clinicaltrials.gov/ct2/show/NCT01006538](http://clinicaltrials.gov/ct2/show/NCT01006538) Accessed February 2014.

**Laser Photocoagulation for Macular Drusen**

The clinical evidence was reviewed on February 14, 2014 with no additional information identified that would change the unproven conclusion for laser photoagulation 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 AMD. The selected studies for the review included randomized controlled trials (RCTs) of laser treatment of drusen in AMD in which laser treatment had been compared with no intervention or sham treatment. Nine studies which randomized 2216 people were selected: four unilateral trials, three bilateral trials and two trials that included both a unilateral and a bilateral study arm. Overall, the studies were of moderate quality. Although two (of the nine) studies reported significant drusen disappearance at two years, photocoagulation did not appear to affect the development of CNV at two years follow up or the loss of three or more lines of visual acuity. The authors concluded that the reviewed trials confirmed the clinical observation that laser photocoagulation of drusen leads to their disappearance. However, there is no evidence that this subsequently results in a reduction in the risk of developing CNV, geographic atrophy or visual acuity loss (Parodi et al. 2009).

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.

Huang et al. (2011) prospectively evaluated the efficacy and safety of prophylactic laser treatment in patients with bilateral soft drusen 8 years after treatment. The study included 10 patients with more than 10 soft drusen (> 125 mm) and best corrected visual acuity ≥ 20/25 in each eye. One eye, with relatively more drusen, was exposed to an argon laser (514 nm) to achieve a barely visible retinal lesion. The contralateral eye was used as a control. Fluorescein angiography, Amsler tests, Fourier-domain optical coherence tomography and visual evoked potential tests were carried out 8 years later. No choroidal neovascularization was seen in the laser-treated eyes or control eyes. There were no significant differences in visual acuity or P100 latency and amplitude between the laser treated eyes and contralateral eyes. The thickness of the retinal pigment epithelium of the treated eyes was less than that of the contralateral eyes. The full retinal thickness in treated eyes was slightly, but insignificantly, reduced relative to contralateral eyes. The authors concluded that laser treatment was associated with a reduction in retinal pigment epithelium thickness elevation compared with the contralateral eyes. Macular function was not impaired. According to the authors, the study was small and therefore the results should be interpreted with caution.

**U.S. FOOD AND DRUG ADMINISTRATION (FDA)**

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: [http://pbadupws.nrc.gov/docs/ML0911/ML091140370.pdf](http://pbadupws.nrc.gov/docs/ML0911/ML091140370.pdf) Accessed February 2014.

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: [http://www.accessdata.fda.gov/cdrh_docs/pdf3/K031665.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf3/K031665.pdf). Accessed February 2014.
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.

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:

According to the FDA’s Summary of Safety and Effectiveness Data, 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.
- Endothelial cell density (ECD) counts below the following minimum baseline:
  - Age 75 - 84 years with ECD below 2000 cells/mm²
  - Age 85 years or older with ECD below 1800 cells/mm²
- 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
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- 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:

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Medicare does not have a National Coverage Determination (NCD) for epiretinal radiation therapy. Local Coverage Determinations (LCDs) for epiretinal radiation therapy do not exist at this time.

Medicare does not have a NCD for conjunctival incision with placement of a pharmacologic agent. LCDs for conjunctival incision with placement of a pharmacologic agent do not exist at this time. However, there is mention of CPT code 0190T or “placement of intraocular radiation source applicator” in the following LCDs: Non-Covered Services, Category III CPT Codes, Non-Covered Category III CPT Codes, Noncovered Services and Services That Are Not Reasonable and Necessary.

Medicare does not have a NCD specifically for laser photocoagulation used for treatment of macular drusen. LCDs for laser photocoagulation do not exist at this time.

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 March 16, 2014)

REFERENCES


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


POLICY HISTORY/REVISION INFORMATION

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<th>Date</th>
<th>Action/Description</th>
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<tr>
<td>07/01/2014</td>
<td>• Reorganized and renamed policy; previously titled Macular Degeneration and Ocular Tumor Treatment</td>
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<td>• Updated coverage rationale:</td>
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<td>○ Removed and relocated content/language specific to transpupillary thermotherapy (TTT); applicable coverage guidelines for this service now outlined under separate policy titled Transpupillary Thermotherapy</td>
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<td>○ Added language to indicate if service is “medically necessary” or “not medically necessary” to applicable proven/unproven statement</td>
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