Macular Degeneration Treatment Procedures (for North Carolina Only)

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Instructions for Use

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Related Policies

- Outpatient Surgical Procedures – Site of Service (for North Carolina Only)
- Transpupillary Thermotherapy

Application

This Medical Policy only applies to the state of North Carolina.

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 individuals 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
- Laser photocoagulation for treating macular drusen
- Radiation therapy for AMD (i.e., epimacular and/or epiretinal brachytherapy and stereotactic radiotherapy and/or radiosurgery)

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 federal, state, or contractual requirements 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

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 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).

Ocular home monitoring devices are devices intended to be used as an aid in detecting, monitoring progression and characterizing lesions in individuals with AMD.

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.

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 AMD. The Vidion System delivers radiation (strontium 90) directly to the neovascular lesion in a single treatment therapy session.

Stereotactic radiotherapy is a nonsurgical procedure performed in an office setting. It uses a robotically controlled device to deliver radiation beams through the inferior sclera to overlap at the macula.

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 (Hudson et al. 2018). 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 three lines of BCVA compared with 13 in the control eyes. 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.

Clinical Practice Guidelines

American Academy of Ophthalmology (AAO)

The 2019 AAO Preferred Practice Patterns guidelines on AMD 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.

National Institute for Health and Care Excellence (NICE)

A National Institute for Health and Care Excellence (NICE) guidance for miniature lens system implantation for advanced age-related macular degeneration (AMD) states that evidence on the efficacy of miniature lens system implantation for advanced 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).

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 acetonide anecortave acetate with placebo, a second trial compared juxtascleral placement of triamcinolone acetonide versus placebo, and the third trial compared juxtascleral 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 three 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. Overall, the review found limited evidence regarding the benefits of posterior juxtascleral placement of steroids for treating neovascular AMD.

Laser Photocoagulation for Macular Drusen

Results of available studies suggest that laser photocoagulation treatment does not show benefits in 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 2,159 participants (3,580 eyes) and followed them up to two years, of which six studies (1,454 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. The CAPT Trial Research Group (2016) included in this review, indicated that 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. 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 AMD and 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 results of three additional randomized controlled trials (Friberg, 2006; Maguire, 2003; Owens, 2006) suggest that current prophylactic laser treatment protocols do not benefit patients who have macular drusen.

Clinical Practice Guidelines

National Institute for Health and Care Excellence (NICE)

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).

Radiation Therapy

There is insufficient evidence to support the use of radiation therapy including epiretinal/epimacular brachytherapy and stereotactic radiotherapy for age-related macular degeneration (AMD). Controlled trials with larger populations are needed to establish safety, efficacy, and long-term outcomes of this procedure.

Evans et al. (2020) examined the effects of radiotherapy on neovascular AMD in a Cochrane review. The authors searched Central, MEDLINE, Embase, Lilacs and three trial registers thru May 4, 2020. They included all randomized controlled trials that compared radiotherapy to another treatment, sham, low dose radiation or no treatment at all in people with choroidal neovascularization (CNV) secondary to AMD. There were 18 studies included, three of these studies investigated brachytherapy (plaque and epimacular), the rest were studies of external beam radiotherapy (EBM) including one trial of stereotactic radiotherapy. Four studies compared radiotherapy combined with anti-vascular endothelial growth factor (anti-VEGF) with anti-VEGF alone. Eleven studies gave no radiotherapy treatment to the control group; five studies used sham irradiation; and one study used very low-dose irradiation (1 Gy). One study used a mixture of sham irradiation and no treatment. Results notes that there may be little or no difference in loss of three lines of vision at 12 months in eyes treated with radiotherapy compared with no radiotherapy [risk ratio (RR) 0.82, 95% confidence interval (CI) 0.64 to 1.04, 811 eyes, eight studies, I2 = 66%, low-certainty evidence]. Low-certainty evidence suggests a small benefit in change in visual acuity [mean difference (MD) -0.10 logMAR, 95% CI -0.17 to -0.03; eyes = 883; studies = 10] and average contrast sensitivity at 12 months (MD 0.15 log units, 95% CI 0.05 to 0.25; eyes = 267; studies = 2). Growth of new vessels (largely change in CNV size) was variably reported and It was not possible to produce a summary estimate of this outcome. The studies were small with imprecise estimates and there was no consistent pattern to the study results (very low-certainty evidence). Quality of life was only reported in one study of 199 people; there was no clear difference between treatment and control groups (low-certainty evidence). Low-certainty evidence was available on adverse effects from eight of 14 studies. Seven studies reported on radiation retinopathy and/or neuropathy. Five of these studies reported no radiation-associated adverse effects. One study of 88 eyes reported one case of possible radiation retinopathy. One study of 74 eyes graded retinal abnormalities in some detail and found that 72% of participants who had radiation compared with 71% of participants in the control group had retinal abnormalities resembling radiation retinopathy or choroidopathy. Four studies reported cataract surgery or progression: events were generally few with no consistent evidence of any increased occurrence in the radiation group. One study noted transient disturbance of the precorneal tear film but there was no evidence from the other two studies that reported dry eye of any increased risk with radiation therapy. None of the participants received anti-VEGF injections. Radiotherapy combined with anti-VEGF versus anti-VEGF alone: People receiving radiotherapy/anti-VEGF were probably more likely to lose three or more lines of BCVA at 12 months compared with anti-VEGF alone (RR 2.11, 95% CI 1.40 to 3.17, 1,050 eyes, three studies, moderate-certainty). Most of the data for this outcome come from two studies of epimacular brachytherapy (114 events) compared with 20 events from the one trial of EBM. Data on change in BCVA were heterogenous (I2 = 82%). Individual study results ranged from a small difference of -0.03 logMAR in favor of radiotherapy/anti-VEGF to a difference of 0.13 logMAR in favor of anti-VEGF alone (low-certainty evidence). The effect differed depending on how the radiotherapy was delivered (test for interaction p = 0.0007). Epimacular brachytherapy was associated with worse visual outcomes (MD 0.10 logMAR, 95% CI 0.05 to 0.15, 820 eyes, two studies) compared with EBM (MD -0.03 logMAR, 95% CI -0.09 to 0.03, 252 eyes, two studies). None of the included studies reported contrast sensitivity or quality of life. Growth of new vessels (largely change in CNV size) was variably reported in three studies (803 eyes). It was not possible to produce a summary estimate and there was no consistent pattern to the study results (very low-certainty evidence). For adverse outcomes, variable results were reported in the four studies. In three studies reports of adverse events were low and no radiation-associated adverse events were reported. In one study of epimacular brachytherapy there was a higher proportion of ocular adverse events (54%) compared to the anti-VEGF alone (18%). The majority of these adverse events were cataract. Overall, 5% of the treatment group had radiation device-related adverse events

(17 cases); ten of these cases were radiation retinopathy. There were differences in average number of injections given between the four studies (1,072 eyes). In three of the four studies, the anti-VEGF alone group on average received more injections (moderate-certainty evidence). In conclusion, the author indicates that the evidence is uncertain around the use of radiotherapy for neovascular AMD. Overall vision with epimacular brachytherapy is likely to be worse, with an increased risk of adverse events, probably related to vitrectomy. The role of stereotactic radiotherapy combined with anti-VEGF is currently uncertain. Further research on radiotherapy for neovascular AMD is needed. [CABERNET (Jackson, 2013, Dugel 2013), INTREPID (Jackson 2015) and MERLOT (Jackson 2016) which were previously cited in this policy are included in this Cochrane review].

Freiberg et al. (2019) assessed the features of retinal microvascular abnormalities (MVAs) occurring secondary to stereotactic radiotherapy (SRT) analyzing data from a randomized double-masked sham-controlled clinical trial at 21 European sites (INTREPID Trail). The study included 230 participants with neovascular AMD treated with at least three intravitreal antivascular endothelial growth factor (anti-VEGF) injections prior to enrolment and demonstrating a continuing need for re-treatment. Interventions included 16 Gy, 24 Gy or sham SRT. All three groups received as needed anti-VEGF injections if the lesion was judged to be active at review visits. Color fundus images from baseline and 6 months and fluorescein angiograms from baseline and annual visits were graded for measures of morphological outcome and safety using a prespecified protocol with accompanying definitions to distinguish RT-related MVA from non-specific retinal vessel abnormalities that are known to occur in neovascular AMD. The main outcome measure was MVA detected by months 12, 24, and 36 after enrollment. The frequency of MVAs in the combined SRT arms was 0% in year one, 13.1% in year two and 30.3% in year three. The area of MVA was small and the mean change in visual acuity in year two was similar in a subset of SRT eyes with MVAs, versus those without MVAs. MVA was considered to have possibly contributed to vision loss in two of 18 cases with MVA in year two, and five of 37 cases in year three. The authors concluded that SRT is associated with development of subtle MVAs that have little or no impact on visual outcome and that these findings can help clinicians recognize that retinal MVAs can occur in response to SRT. Additional studies are needed to further evaluate microvascular abnormalities following SRT therapy related to AMD treatment.

Zur et al. (2015) evaluated the clinical feasibility, safety, and efficacy of epiretinal strontium-90 brachytherapy in sub foveal choroidal neovascularization (CNV) due to 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.

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 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 two than year one, 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 includes a lack of controls and a small sample size.

Clinical Practice Guidelines

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.

National Institute for Health and Care Excellence (NICE)

A National Institute for Health and Care Excellence (NICE) guidance for epiretinal brachytherapy for wet AMD states that evidence on the efficacy of epiretinal brachytherapy for wet AMD is inadequate and limited to small numbers of patients. Regarding 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).

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. Refer to the following website for more information: http://www.accessdata.fda.gov/cdrh_docs/pdf5/P050034a.pdf. (Accessed August 2, 2023)

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

Refer to the following website for more information: http://www.accessdata.fda.gov/cdrh_docs/pdf5/P050034b.pdf. (Accessed August 2, 2023)

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.

Home Visual Field Monitoring

In 2009, the FDA granted 510(k) premarket approval for the ForeseeHome™ device (Notal Vision Ltd.) (K091579). The device is intended for use in the detection and characterization of central and paracentral metamorphopsia (visual distortion) in patients with age-related macular degeneration as an aid in monitoring progression of disease factors causing metamorphopsia including, but not limited to choroidal neovascularization (CNV). It is intended to be used at home for patients with stable fixation. Product code: HPT. Refer to the following website for more information at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K091579. (Accessed August 2, 2023).

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. Refer to the following website for more information (use product codes HQB or HQF): https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed August 2, 2023)

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Policy History/Revision Information

Date	Summary of Changes
01/01/2024	**Supporting Information** • Updated *Description of Services*, *Clinical Evidence*, and *FDA* sections to reflect the most current information • Archived previous policy version CSNCT0404.02

Instructions for Use

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