

<b>POLICY TITLE</b>	<b>TRANSPUPILLARY THERMOTHERAPY FOR THE TREATMENT OF CHOROIDAL NEOVASCULAR CONDITIONS</b>
<b>POLICY NUMBER</b>	<b>MP- 4.023</b>

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**I. POLICY**

Transpupillary thermotherapy is considered **investigational** as a treatment of choroidal neovascularization secondary to ocular conditions, including but not limited to age-related macular degeneration, as there is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

***Cross-references***

- MP-2.128 Bevacizumab (Avastin™)
- MP-2.028 Eye Care
- MP-2.149 Aqueous Shunts and Devices for Glaucoma
- MP-2.159 Intravitreal Corticosteroid Implants
- MP 2.163 Intravitreal Angiogenesis Inhibitors for Choroidal Vascular Conditions
- MP-2.164 Intravitreal Angiogenesis Inhibitors for Retinal Vascular Conditions
- MP-4.008 Photodynamic Therapy for Choroidal Neovascularization
- MP 4.032 Suprachoroidal Delivery of Pharmacologic Agents

**II. PRODUCT VARIATIONS**

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*[N] = No product variation, policy applies as stated*

*[Y] = Standard product coverage varies from application of this policy, see below*

- |                          |                 |
|--------------------------|-----------------|
| [N] Capital Cares 4 Kids | [N] Indemnity   |
| [N] PPO                  | [N] SpecialCare |
| [N] HMO                  | [N] POS         |
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\* Refer to FEP Medical Policy Manual MP-9.03.10 Transpupillary Thermotherapy for Treatment of Choroidal Neovascularization. The FEP Medical Policy manual can be found at: [www.fepblue.org](http://www.fepblue.org)

**III. DESCRIPTION/BACKGROUND**

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Transpupillary thermotherapy (TTT) is a technique in which low-level heat is delivered through the pupil using a modified diode laser. TTT is designed to gently heat subfoveal choroidal lesions while limiting damage to the overlying retinal pigment epithelium.

Age-related Macular Degeneration

Choroidal neovascularization (CNV) is a common cause of adult-onset blindness, most commonly associated with age-related macular degeneration (AMD). In its earliest stages, AMD is characterized by minimal visual impairment and the presence of large drusen and other pigmentary abnormalities on ophthalmoscopic examination. As AMD progresses, 2 distinctively different forms of degeneration may be observed. The first, called the atrophic, areolar or dry form, evolves slowly. Atrophic AMD is the most common form of degeneration and is often a precursor of the second form, the more devastating exudative neovascular form, also referred to as disciform or wet degeneration. The wet form is distinguished from the atrophic form by serous or hemorrhagic detachment of the retinal pigment epithelium and the development of choroidal neovascularization (CNV), sometimes called neovascular membranes. Risk of developing severe irreversible loss of vision is greatly increased by the presence of CNV.

The pattern of CNV, as revealed by fluorescein or indocyanine angiography, is further categorized as classic or occult. For example, classic CNV appears as an initial lacy pattern of hyperfluorescence followed by more irregular patterns as the dye leaks into the subretinal space. Occult CNV lacks the characteristic angiographic pattern, either due to the opacity of coexisting subretinal hemorrhage or, especially in CNV associated with AMD, by a tendency for epithelial cells to proliferate and partially or completely surround the new vessels. Interestingly, lesions consisting only of classic CNV carry a worse visual prognosis than those composed of only occult CNV, suggesting that the proliferative response that obscures new vessels may also favorably alter the clinical course of AMD.

There is ongoing research interest in the use of TTT to treat subfoveal choroidal neovascularization with an “occult” angiographic pattern. TTT is a technique in which heat is delivered to the choroid and retinal pigment epithelium through the pupil using a modified diode laser. This laser technique contrasts with the laser used in standard photocoagulation therapy in that TTT uses a lower power laser for more prolonged periods of time and is designed to gently heat the choroidal lesion, thus limiting damage to the overlying retinal pigment epithelium.

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Other Treatments for CNV Secondary to AMD

Other available therapeutic options for CNV not addressed in this policy include photodynamic therapy (PDT) (Policy No. 9.03.08) and vascular endothelial growth factor antagonists or angiostatics (Policy No. 9.03.24). These may be administered alone or in combination. Angiostatic agents target various points in the pathway leading to new blood vessel formation (angiogenesis): messenger RNA, vascular endothelial growth factors, and endothelial cell proliferation, migration, and proteolysis. Pegaptanib (Macugen®, Eyetech and Pfizer), ranibizumab (Lucentis™, Genentech) and aflibercept (Eylea™, Regeneron) are approved by the U.S. Food and Drug Administration (FDA) for use in AMD. Bevacizumab (Avastin, Genentech) has been used off label to treat AMD. It is derived from the same murine monoclonal antibody precursor as ranibizumab and is approved by the FDA for the treatment of metastatic cancer of the colon or rectum. PDT has also been used with success in treating subfoveal CNV; the treatment has shown the greatest success in treating patients with classic CNV (as opposed to occult CNV), as defined angiographically. PDT as a treatment of CNV uses a nonthermal laser designed to activate verteporfin, the photosensitizing agent. Laser photocoagulation has been used to treat CNV; however, patients with subfoveal lesions are generally not candidates for this treatment due to the risk of an immediate reduction in central vision, outweighing any treatment advantage.

Central Serous Chorioretinopathy

Central serous chorioretinopathy (CSC) is the fourth most common retinopathy after AMD, diabetic retinopathy, and branch retinal vein occlusion. CSC refers to an idiopathic disease in which there is a serous detachment of the macula due to leakage of fluid from the choriocapillaris through the retinal pigment epithelium. CSC can be divided into acute, recurrent, and chronic conditions. Usually, serous retinal detachments have spontaneous resolution with recovery of visual function; however, a subset of patients may experience permanent deterioration of visual function attributable to chronic CSC or multiple recurrences of CSC. The pathogenesis of CSC is believed to be ischemia and inflammation, which lead to abnormal permeability of the inner choroid and elevation of the retinal pigment epithelium, causing serous epithelial detachments. The separated retinal pigment epithelium can then undergo tiny rips (blowouts) with a break in continuity. The change in permeability of the retinal pigment epithelium results in focal leakage and retinal detachment. Neovascularization can occur as a secondary complication. In about 90% of cases, CSC resolves spontaneously with detachment resolution within 3 months. The traditional management of acute CSC is observation. Recurring or chronic CSC can be treated with focal laser photocoagulation if the leaks are extrafoveal. Although laser may shorten the duration of symptoms, it does not have any impact on the final vision or the recurrence rate of CSC. In addition, laser photocoagulation causes collateral damage creating symptomatic scotomas and a risk of triggering secondary CNV. PDT is not a standard treatment for CSC due to complications that may include CNV, although low-fluence PDT is being evaluated.

**MEDICAL POLICY**

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Other Choroidal Neovascular Conditions

Other choroidal neovascular conditions include pathologic myopia, presumed ocular histoplasmosis syndrome, angioid streaks, idiopathic CNV, uveitis, choroidal rupture or trauma, and chorioretinal scars. Treatments that have been evaluated for CNV not related to AMD include submacular surgery, laser photocoagulation, and PDT. Efficacy of these treatment modalities is limited.

**IV. RATIONALE**[TOP](#)**Transpupillary Thermotherapy versus Sham**

In a presentation at the American Academy of Ophthalmology meeting in October 2004, in New Orleans, Iridex Corporation announced preliminary results of the TTT4 choroidal neovascularization (CNV) study. The TTT4 CNV study is a nationwide study involving 22 centers that began in March 2000. A total of 336 patients with symptomatic occult CNV that show signs of exudation were to be recruited. Two-thirds of eyes would be treated and one third would receive sham treatment. Patients would be followed up for 2 years. Iridex-reported preliminary results did not show TTT for CNV resulted in significant benefit over sham treatment. Forty-seven percent of 303 patients who received TTT for CNV had modest or severe visual loss after 2 years, compared with 43% in those who received sham treatment. To date, results of this trial have not been published.

Two small randomized trials (28 and 25 patients) from 2005 and 2006 reported no benefit of TTT in preventing further visual loss in patients with occult CNV who were not candidates for photodynamic therapy (PDT).(4,5)

**TTT versus PDT**

The largest published controlled trial randomly assigned 98 patients with occult CNV to TTT (136 mW/mm) with sham PDT (n=52), or to PDT with sham TTT (n=46). (6) Retreatment was given if leakage was documented by fluorescein angiography (follow-up of 6, 12, 18, 24, 36, and 48 weeks). With a mean of 3.0 treatments in the TTT group and 2.3 treatments in the PDT group, a similar percentage of patients had lost fewer than 15 letters at 12 months (75% for TTT and 74% for PDT). There were nonsignificant trends for a larger percentage of patients to have preserved or improved best corrected visual acuity in the TTT group (37%) than in the PDT group (24%) and to have less of a decrease in foveal thickness (15% vs 24%). Patient-reported visual function from this trial was reported in 2010.(7) Outcomes on the National Eye Institute Visual Function Questionnaire 25 were similar in patients treated with TTT (change, +1.2) or PDT (change, +0.7) at 12 months, but the study was underpowered to detect differences in this outcome measure.

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In a controlled trial from Asia, patients chose PDT or TTT after an explanation of the costs, benefits, and risks of each treatment.(8) Sixteen patients (16 eyes) selected PDT, and 14 patients (16 eyes) selected TTT; treatments were repeated if dye leakage was evident at follow-up. The average pretreatment visual acuity was similar in the 2 groups. At 6-month follow-up, loss of visual acuity was 15 letters or less in 14 (87%) eyes treated with TTT and in 13 (81%) eyes treated with PDT; however, more patients with good initial visual acuity (20/63 or greater) had a loss of 2 or more lines following TTT (4 of 4), than following PDT (1 of 6). Although the authors concluded that patients with good initial visual acuity should be treated with PDT, the study is limited by selection bias and small subject number. The authors of this study and another report from Asia indicated that the rationale for using TTT was the lower cost of this treatment in comparison with PDT. (8, 9)

In 2012, Nowak et al reported on 222 eyes with AMD treated with TTT, 100 eyes treated with PDT, and 104 eyes treated with intravitreal bevacizumab.(10) Assignment into the 3 groups was based on the angiographic appearance of CNV, and patients who did not meet criteria for the randomized comparison of bevacizumab and PDT were treated with TTT. Following treatment with TTT, there was a mean decline of visual acuity 0.05 log MAR, compared with a decline of 0.12 log MAR following PDT and improvement of 0.03 logMAR following treatment with intravitreal bevacizumab. Out of the 222 eyes treated with TTT, visual acuity improved in 14.9%, remained unchanged in 64.4%, and was reduced in 20.7%. This study is limited by selection bias and differences in baseline visual acuity in the 3 groups.

**TTT Combined with Intravitreal Ranibizumab**

In a 2012 report, Soderberg et al randomized 100 patients with neovascular AMD to low-dose TTT and intravitreal ranibizumab or to sham TTT and intravitreal ranibizumab. (11) At 24-month follow-up (78 patients), quarterly TTT was found to decrease the mean number of ranibizumab injections from 8.0 to 6.3 with no significant difference between the sham and active TTT groups in best corrected visual acuity (+4.0 vs +0.9, respectively). Thus, 7 quarterly treatments with TTT resulted in a mean reduction of 1.7 ranibizumab injections. It was not described whether the investigator who determined if the patient met retreatment criteria was masked to treatment allocation. Masked evaluation found no significant difference between the sham and active TTT groups in central retinal thickness (-49.9% vs -36.4%) or lesion area (-0.3% vs -10.6%, both respectively).

**Other**

One randomized (not masked) study of 26 patients from 2005 did not find a statistically significant improvement for combination treatment with triamcinolone and TTT in comparison with TTT alone. (12)

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Four nonrandomized studies of TTT in eyes with CNV related to AMD were identified from 2003 and 2004. (13-16) The largest series is from Nagpal et al, who reported on TTT for CNV in 160 eyes (99 classic and 61 occult) of patients of Indian descent.(13) The authors reported that in eyes with classic CNV, 29.3% improved, 39.4% stabilized, and 31.3% deteriorated at 12-month follow-up. In occult CNV, 19.6% improved, 57.4% stabilized, and 22.9% deteriorated. Nagpal et al concluded that there was effectiveness with TTT in Indian eyes, which responded to lower energy levels than did Caucasian eyes in their experience.

In 2011, Peyman et al reported treatment of a small series of patients (n=4) with peripapillary CNV that was recalcitrant to other treatments, including intravitreal angiostatic agents.(17) These investigators used a variation of TTT with indocyanine green dye as a thermal enhancing agent, which permitted use of a lower energy level (oscillatory thermotherapy). The photodynamic treatment was combined with bevacizumab and intravitreal dexamethasone, and visual acuity was found to remain stable (1 of 4 improved visual acuity) at a mean 12-month follow-up.

Small case series from Asia describe the use of TTT for central serous chorioretinopathy and choroidal hemangioma. (18, 19)

**Adverse Events**

A case series reported macular burn as a complication of TTT in 8.6% of 35 patients available for follow-up. (20)

Questions have been raised about the potential harms of this treatment if given at higher intensity, while Peyman et al note that a major limitation of TTT is the inability to titrate the energy level and subsequently control both the rate and the total amount of temperature rise during the procedure. (17, 21)

**Summary**

Transpupillary thermotherapy (TTT) is a technique in which low-level heat is delivered through the pupil using a modified diode laser. TTT is designed to gently heat subfoveal choroidal lesions while limiting damage to the overlying retinal pigment epithelium. Evidence on TTT is limited. The available studies comparing TTT with sham have not shown a benefit of this procedure. Although trials comparing TTT to photodynamic therapy show similar outcomes for the 2 treatments, there may be an increase in adverse events with TTT. TTT has not been compared with angiogenesis inhibitors. Evidence is insufficient to determine whether TTT is as beneficial as the established alternative; this procedure is considered investigational.

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**Practice Guidelines and Position Statements**

Recent practice guidelines on treatment of age-related macular degeneration from the American academy of Ophthalmology (AAO) do not mention TTT. In the 2006 Preferred Practice Patterns the AAO indicated that there was insufficient evidence to guide treatment recommendations for TTT. Preferred Practice Patterns from 2008 and 2011 and the AAO’s 2013 Summary Benchmark do not describe TTT as a treatment option. (22)

**Medicare National Coverage**

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers

**V. DEFINITIONS**

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**ANGIOGENESIS** refers to the development of blood vessels.

**CHOROID** is the thin, highly vascular membrane covering the posterior five sixths of the eye between the retina and the sclera.

**CHOROIDAL NEOVASCULARIZATION** refers to the abnormal formation of new blood vessels usually on or under the retina, usually seen in diabetic retinopathy, blockages of central retinal vision and macular degeneration.

**EXUDATION** refers to the pathological oozing of fluids, usually the result of inflammation.

**MACULAR DEGENERATION** refers to loss of pigmentation in the macular region of the retina, usually affecting persons over age fifty (50); a common disease of unknown etiology that produces central visual field loss and is the leading cause of permanent blindness in the United States.

**OCULAR** refers to the eye or vision.

**PHOTODYNAMIC** refers to the effects of light on biological, chemical, or physical systems.

**VI. BENEFIT VARIATIONS**

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The existence of this medical policy does not mean that this service is a covered benefit under the member's contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member’s individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and

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providers should consult the member’s benefit information or contact Capital for benefit information.

**VII. DISCLAIMER**

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*Capital’s medical policies are developed to assist in administering a member’s benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member’s benefit information, the benefit information will govern. Capital considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.*

**VIII. CODING INFORMATION**

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**Note:** This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

The following codes are **INVESTIGATIONAL** and therefore not covered

CPT Codes®							
67299							

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\*If applicable, please see Medicare LCD or NCD for additional covered diagnoses.

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**X. POLICY HISTORY**

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<b>MP 4.023</b>	<b>CAC 10/28/12</b> Adopting BCBSA. <ul style="list-style-type: none"> <li>• Extracted information regarding Transpupillary Thermotherapy from MP 4.008 - Ocular Therapy and this new policy created.</li> <li>• Changed FEP variation to reference FEP Medical Policy Manual MP 9.03.10 Transpupillary Therapy for Treatment of Choroidal Neovascularization.</li> <li>• No change to policy statement, remains investigational.</li> <li>• Codes reviewed 9/19/12 klr</li> </ul>
	<b>CAC 11/26/13</b> Consensus review. Title changed to Transpupillary Thermotherapy for Treatment of Choroidal Neovascular Conditions. Policy expanded to include other choroidal vascular conditions; remains investigational. Rationale added, Background updated.
	<b>CAC 5/20/14</b> Consensus review. Rationale and references update. No changes to the policy statements. Codes reviewed. Admin title update

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