BlueCross BlueShield of Alabama

**Name of Blue Advantage Policy:**

# Transpupillary Thermotherapy (TTT) for Treatment of Choroidal Neovascular Conditions

Policy #: 079
Category: Surgery

Latest Review Date: March 2021
Policy Grade: **Effective 1/1/2015: Active Policy but no longer scheduled for regular literature reviews and updates.**

## BACKGROUND:

***Blue Advantage*** *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
    - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
    - *Furnished in a setting appropriate to the patient's medical needs and condition;*
    - *Ordered and furnished by qualified personnel;*
    - *One that meets, but does not exceed, the patient's medical need; and*
    - *At least as beneficial as an existing and available medically appropriate alternative.*

**Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare*** *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

## POLICY:

**Blue Advantage** will treat **transpupillary thermotherapy (TTT)** as a **non-covered** benefit for the treatment of choroidal neovascularization secondary to ocular conditions, including but not limited to age-related macular degeneration and as **investigational.**

*Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.*

## DESCRIPTION OF PROCEDURE OR SERVICE:

Transpupillary thermotherapy (TTT) of Choroidal Neovascularization (CNV) lesions involves prolonged application of low-energy, infrared laser to areas of neovascularization thereby causing photocoagulation through the dilated pupil into the posterior segment of the eye. Infrared radiation creates a heat source. TTT is designed to gently heat subfoveal choroidal lesions while limited damage to the overlying retinal pigment epithelium. Healthy ocular tissue may be damaged, but generally the damage is limited to the site of treatment. The goal of TTT is to stop the growth and leakage of the new blood vessels, thereby preserving vision, as well as ablating cancerous masses by heating them to temperatures as high as 60 degrees Celsius. TTT is typically is performed in the office under local anesthesia.

**Age-related Macular Degeneration (AMD)**

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, two 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 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.

**Other Treatments for Choroidal Neovascularization (CNV) Secondary to Age-related Macular Degeneration (AMD)**
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.

Photodynamic therapy has been used with success in treating subfoveal CNV. This treatment has shown the greatest success in treating patients with classic CNV. Photodynamic therapy, as a treatment of CNV, uses a nonthermal laser designed to activate verteporfin, the photosensitizing agent.

## KEY POINTS:

This policy has been updated periodically with the most recent literature update performed through March 18, 2021.

**Summary of Evidence**
In a 24-month, double-masked, randomized, active-controlled clinical trial, Söderberg et al. (2012) compared the effect of combined low-dose transpupillary thermotherapy (TTT) and intravitreal ranibizumab with sham TTT and intravitreal ranibizumab in patients with neovascular age-related macular degeneration (AMD). A total of 100 patients were randomly assigned (1:1) to receive intravitreal ranibizumab and sham TTT or intravitreal ranibizumab and low-dose TTT. Patients in the TTT group required fewer treatments with ranibizumab compared to those in the sham TTT group. The mean number of ranibizumab injections was 8.0 in the sham TTT group versus 6.3 in the TTT group over two years. There was no statistically significant difference in best corrected visual acuity (BCVA), central retinal thickness (CRT) or lesion area between the treatment groups at the final examination. The results of the intent-to-treat population (92 patients) were similar to the per-protocol (PP) population. The authors concluded that treatment with low-dose TTT significantly reduced the number or intravitreal injections of ranibizumab over 24 months. According to the authors, these results suggest that low-dose TTT can serve as an adjuvant in combination with intravitreal ranibizumab for neovascular AMD. Further research with a larger number of patients is needed to confirm these results and further assess the impact on vision outcomes.

In a prospective, interventional, comparative case series, Nowak et al. (2012) compared the efficacy of verteporfin photodynamic therapy (PDT), intravitreal injections of bevacizumab (IVB), and transpupillary thermotherapy (TTT) in patients with neovascular age-related macular degeneration (AMD). The study included 426 eyes of 426 consecutive patients presenting with neovascular AMD. Patients presented with subfoveal CNV predominantly classic, minimally classic, and occult with no classic component; lesion size less than 5000 μm in the greatest linear dimension, and the area of hemorrhages ≤ 1/3 were randomized to receive either PDT (group I) or IVB (group II) in a 1:1 ratio. Other patients with CNV were included into the group III and received TTT. One hundred eyes were treated with PDT. Mean baseline logMAR BCVA was 0.62 and final visual acuity decreased to 0.74; 104 eyes were treated with IVB. Mean baseline BCVA was 0.82 and final visual acuity increased to 0.79; 222 patients were treated with TTT. Mean baseline BCVA was 1.10 and final visual acuity decreased to 1.15. Among all eyes the average number of treatment sessions was 2.34. The authors concluded that IVB injections had the best efficacy in the improvement of final BCVA. However, both IVB and TTT demonstrated

good stabilization of vision. The lack of a control group limits the validity of the results of this study.

Results of studies evaluating the use of transpupillary thermotherapy for the prevention or control of choroidal neovascularization lesions in individuals with age-related macular degeneration (AMD) do not provide sufficient evidence to conclude that transpupillary thermotherapy improves loss of vision due to AMD. The evidence is insufficient to prove that the technology results in an improvement in the net health outcome.

Based on limited studies, small sample sizes, and weak study designs, there is insufficient evidence to conclude that transpupillary thermotherapy is safe and/or effective for treating other conditions. The evidence is insufficient to prove that the technology results in an improvement in the net health outcome.

**Practice Guidelines and Position Statements**

**American Academy of Ophthalmology**

The American Academy of Ophthalmology (2019) preferred practice pattern document for age-related macular degeneration states that thermal laser photocoagulation surgery is no longer recommended for subfoveal choroidal neovascularization (CNV) treatment.

**The National Institute for Health and Care Excellence**

The National Institute for Health and Care Excellence (2004) concluded that clinical evidence on the safety and efficacy of TTT for age-related macular degeneration was inadequate for TTT to be used without special arrangement for consent and for audit or research.

## KEY WORDS:

Transpupillary thermotherapy (TTT), choroidal neovascularization (CNV), age-related macular degeneration (ARMD), AMD

## APPROVED BY GOVERNING BODIES:

Ophthalmic lasers are regulated by the FDA as Class II devices and many lasers have been approved via the 510(k) approval process. Ophthalmic diode laser systems that have received 510(k) marketing clearance for transpupillary thermotherapy include but are not limited to:

- IRIS Medical IQ 810 laser photocoagulator (IRIDEX Corp.) 510(k) approval (K040209) received 1/30/2004.
- Nidex DC - 3000 laser diode photocoagulator (Nidek, Inc.) 510(k) (K903639) approval received 08/13/1990.

Product Code: HQF and GEX

## BENEFIT APPLICATION:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

## CURRENT CODING:

**CPT codes:**

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| **67299** | Unlisted procedure, posterior segment. |

## REFERENCES:


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## POLICY HISTORY:

Adopted for Blue Advantage, March 2005
Available for comment May 1-June 14, 2005
Medical Policy Group, November 2007

Medical Policy Group, February 2009
Medical Policy Group, February 2010
Medical Policy Group, December 2010
Medical Policy Group, June 2011
Medical Policy Group, February 2012
Medical Policy Group, February 2013
Medical Policy Group, February 2014
Medical Policy Group, June 2018
Medical Policy Group, August 2019
Medical Policy Group, March 2021

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