***Effective November 1, 2023, refer to CMS Manual 100-02, Chapter 16-General Exclusions from Coverage for services included in this policy.***

BlueCross BlueShield of Alabama

**Name of Blue Advantage Policy:**

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

Policy #: 079
Latest Review Date: April 2023
Category: Vision
**ARCHIVED EFFECTIVE 11/1/2023**

## 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** for the treatment of choroidal neovascularization secondary to ocular conditions, including but not limited to age-related macular degeneration, as a **non-covered benefit** 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 uses infrared laser light administered by a modified diode laser to photocoagulate choroidal neovascularization tissue in patients with wet age-related macular degeneration. When compared to light laser photocoagulation treatment, the lower light intensity of the infrared laser enables light administration over a broader area, for a longer period of time, with less temperature elevation. This gentler heating of the choroidal lesion is intended to limit damage to overlying retinal pigment epithelium, and as such is suggested as an alternative to standard focal laser photocoagulation. Healthy ocular tissue may be damaged, but generally the damage is limited to the site of treatment. The goal of transpupillary thermotherapy 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. Transpupillary thermotherapy is typically performed in the office or clinical outpatient setting under local anesthesia.

### Age-Related Macular Degeneration

Age-related macular degeneration is one of the most frequent causes of blindness among people over the age of 60. There are two different forms of macular degeneration that may develop.

- Wet macular degeneration is the more severe of the two forms of macular degeneration. Wet macular degeneration results when new blood vessels grow over the posterior of the eye and results in blood and serum leaking into the retina.
- Chronic, dry macular degeneration (also known as atrophic or areolar macular degeneration) is the most common form of macular degeneration. It is characterized by slower formation of vascular structures without classic leakage into surrounding tissue.

### Choroidal Neovascularization

Choroidal Neovascularization, also known as CNV, involves the growth of new blood vessels that originate from the choroid through a break in the Bruch membrane into the sub-retinal pigment epithelium or sub retinal space. Choroidal neovascularization is a major cause of visual loss. The symptoms of choroidal neovascularization include a distortion or waviness of central vision or a gray/black/void spot in the central vision. The condition is typically painless. The

standard treatment of choroidal neovascularization is anti–vascular endothelial growth factor therapy.

**Other Treatments for Choroidal Neovascularization Secondary to Age-Related Macular Degeneration**
Laser photocoagulation has been used to treat choroidal neovascularization, 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 choroidal neovascularization. This treatment has shown the greatest success in treating patients with classic choroidal neovascularization. Photodynamic therapy, as a treatment of choroidal neovascularization, uses a nonthermal laser designed to activate verteporfin, the photosensitizing agent.

## KEY POINTS:

This policy has been updated regularly with the most recent literature update performed through April 19, 2023.

**Summary of Evidence**
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 do not provide sufficient evidence to conclude that transpupillary thermotherapy improves loss of vision due to age-related macular degeneration. Based on the identified study weaknesses, lack of a control group and small sample size, the evidence is insufficient to prove that the technology results in an improvement in net health outcomes. Further study is needed using well-designed randomized control trials.

Evidence on transpupillary thermotherapy is limited. The available studies comparing transpupillary thermotherapy with sham have not shown benefit of this procedure. Although trials comparing transpupillary thermotherapy to photodynamic therapy show similar outcomes, there may be an increase in adverse events with transpupillary thermotherapy. Based on weak study designs, there is insufficient evidence to conclude that transpupillary thermotherapy is safe and/or effective for treating other conditions. Further study is needed using well-designed randomized control trials. The evidence is insufficient to prove that the technology results in an improvement in net health outcomes

**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**
In 2016, the National Institute for Health and Care Excellence concluded that clinical evidence on the safety and efficacy of transpupillary thermotherapy for age-related macular degeneration was inadequate for transpupillary thermotherapy 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 laser systems that have received 510(k) marketing clearance for transpupillary thermotherapy include, but are not limited to:

- IRIS Medical® OcuLight® SLx (IREDIEX Corp., Mountainview CA)
- Nidek DC-3000 (Nidek, Inc., Fremont CA)
- GaAIAs diode laser (Candela USA, Wayland MA).

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: Reviewed by consensus. No new published peer-reviewed literature available that would alter the coverage statement in this policy.
Medical Policy Group, April 2022
Medical Policy Group, April 2023: No new published peer-reviewed literature available that would alter the coverage statement in this policy.
Medical Policy Group, November 2023: Archived effective 11/1/2023.

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