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: August 2019
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:

Effective for dates of service on or after July 1, 2005:

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 thermal therapy (TTT) is a method of delivering heat through the dilated pupil into the posterior segment of the eye. This method uses an infrared radiation as the heat source. TTT is designed to gently heat subfoveal choroidal lesions while limiting damage to the overlying retinal pigment epithelium. Transpupillary thermal therapy is typically is performed in the office under local anesthesia.

Age-related Macular Degeneration (AMD)

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, 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 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.

Other Treatments for CNV Secondary to 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. Photocoagulation of macular drusen is addressed in BCBSAL policy #197, Photocoagulation of Macular Drusen.

Photodynamic therapy (see BCBSAL policy #047, Photodynamic Therapy) has 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. Photodynamic therapy, as a treatment of CNV, uses a nonthermal laser designed to activate verteporfin, the photosensitizing agent.

Central Serous Chorioretinopathy (CSC*)*
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 three 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. Photodynamic therapy is not a standard treatment for CSC due to complications that may include CNV, although low-fluence PDT is being evaluated.

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.

KEY POINTS:
This policy has been updated periodically with searches of the MEDLINE database. The most recent literature update was performed through July 30, 2019.

Summary of Evidence:
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 PDT 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.

Practice Guidelines and Position Statements:
American Academy of Opthalmology
The AAO preferred practice pattern document for age-related macular degeneration does not address transpupillary thermal therapy (AAO, 2015).

KEY WORDS:
Transpupillary thermotherapy (TTT), choroidal neovascularization (CNV), age-related macular degeneration (ARMD)

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. See the following website for more information: www.accessdata.fda.gov/cdrh_docs/pdf4/K040209.pdf.
- Nidex DC - 3000 laser diode photocoagulator (Nidek, Inc.) 510(k) (K903639) approval received 08/13/1990. See the following website for more information: www.accessdata.fda.gov/cdrh_docs/pdf/K013760.pdf.

A listing of all devices in the same product classification as those above is available on the following FDA website: www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm.

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

CURRENT CODING:

CPT codes:

67299	Unlisted procedure, posterior segment

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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

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.