

MEDICAL POLICY



SUBJECT: TRANSPUPILLARY THERMOTHERAPY	EFFECTIVE DATE: 05/16/02 REVISED DATE: 03/20/03, 01/15/04, 11/18/04, 09/15/05, 08/17/06, 07/19/07, 07/17/08, 07/16/09, 06/17/10, 06/16/11, 08/16/12, 08/15/13 ARCHIVED DATE: 07/17/14 EDITED DATE: 08/20/15, 08/18/16, 08/17/17, 08/16/18 PAGE: 1 OF: 4
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<ul style="list-style-type: none">• <i>If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.</i>• <i>If a commercial product (including an Essential Plan product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit.</i>• <i>If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.</i>	

POLICY STATEMENT:

- I. Based upon our criteria and assessment of peer-reviewed literature, transpupillary thermotherapy has been medically proven to be effective, and therefore, **medically appropriate** for the following indications:
 - A. Small choroidal melanomas located posterior to the globe that have minimal contact with the optic nerve; and
 - B. Retinoblastomas with no evidence of vitreal or subvitreal seeding at the time of the thermotherapy.
- II. Based upon our criteria and assessment of peer-reviewed literature, transpupillary thermotherapy has not been medically proven to be effective and is considered **investigational** for all other indications, including but not limited to choroidal neovascularization.

Refer to Corporate Medical Policy # 8.01.11 regarding Photodynamic Therapy for Subfoveal Choroidal Neovascularization.

Refer to Corporate Medical Policy # 11.01.03 regarding Experimental and Investigational Services.

POLICY GUIDELINES:

The Federal Employees Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

DESCRIPTION:

Transpupillary thermotherapy (TTT) is a technique in which heat is delivered through a dilated pupil to a lesion or lesions located in the posterior segment of the eye. TTT employs an infrared 810-nm diode laser as the heat source to achieve temperatures of 45–60 degrees C for a short period of time, which has a direct destructive or cytotoxic effect on tumor cells. TTT differs from hyperthermia based on the fact that hyperthermia is performed at lower temperatures (42–45 degrees C) which does not cause permanent tumor damage, but is thought to enhance the effects of radiotherapy or chemotherapy. TTT has been investigated as a treatment method for certain intraocular tumors such as choroidal melanoma and retinoblastoma and also has been proposed as a treatment method for choroidal neovascularization (CNV) associated with age-related macular degeneration.

Choroidal melanoma is an eye cancer that develops from the pigmented cells of the choroid, the sponge-like membrane that lies between the sclera and the retina. Choroidal melanoma is a primary cancer, which over time, can enlarge and cause the retina to detach. These tumors can also metastasize to other parts of the body (liver is most common site) and cause death. TTT is thought to allow for deeper heat penetration of the tumor than the photocoagulation method of treatment of choroidal melanoma, yet have fewer adverse effects on visual acuity.

Retinoblastoma is a rare, malignant glioma of the retina that occurs in infants and young children. Retinoblastoma can occur in 2 forms, a genetic, hereditary variant and a non-genetic, non-hereditary form. Approximately 40% of children with retinoblastoma have the genetic form. TTT has been proposed as an alternative to the radical treatment method of enucleation and as an alternative to external beam radiation, which is associated with poor cosmetic results of the face and ocular region.

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The wet form of age-related macular degeneration is caused by the growth of abnormal, leaky blood vessels (CNV) that eventually damage the macula, the area of the eye responsible for central vision. TTT directed at choroidal neovascularization creates blood clots that seal the leaky vessels thus preventing further leakage and subsequent damage to the macula and central vision. TTT has been proposed as an alternative to photodynamic therapy, as TTT is not associated with the high expense of a photosensitizing drug. TTT has also been proposed as an alternative to laser photocoagulation due to its ability to treat the leakage with less overlying retinal damage.

RATIONALE:

Transpupillary thermotherapy as a primary method of treating intraocular tumors has shown promising short-term results in uncontrolled case studies. While further studies are needed to determine the long-term outcomes of TTT, the available evidence demonstrates acceptable safety and efficacy in the treatment of select patients with retinoblastoma and choroidal melanoma (e.g., Abramson, et al. 2004, Shields, et al. 1999, Shields, et al. 2002, Aaberg, et al. 2008, Pilotto, et al. 2009, respectively).

According to the National Cancer Institute (NCI, March 2012), enucleation is reserved for patients with advanced unilateral disease intraocular disease with no hope for useful vision in the affected eye. Laser therapy (thermotherapy) may be used as primary therapy for small tumors or in combination with chemotherapy for larger tumors. Traditional photocoagulation has given way to thermotherapy. Systemic chemotherapy to reduce tumor volume (chemoreduction) and to avoid long-term effects of radiation therapy for patients with intraocular tumors has succeeded in rendering many eyes amenable to treatment with cryotherapy or laser therapy.

The NCI states that TTT is also used in selected cases with deeply pigmented small choroidal melanomas in the posterior pole that have minimal or no contact with the optic nerve. TTT causes substantial tumor necrosis in choroidal melanomas up to 3.5 mm in thickness and can be used as a primary treatment or as an adjunctive method to plaque radiation therapy. TTT can be used in conjunction with plaque radiation therapy for medium-sized and larger melanomas as an adjuvant treatment to enhance the effects of radiation therapy and to minimize damage to normal ocular tissue. Enucleation remains the standard therapy for most large choroidal melanomas and melanomas that cause severe glaucoma or invade the optic nerve (NCI, Dec 2007).

There is minimal published data regarding treatment of choroidal neovascularization with transpupillary thermotherapy. Studies are small and limited to retrospective analyses of uncontrolled case series. Preliminary, 2-year results from the TTT4CNV trial for occult CNV were presented at the American Academy of Ophthalmology meeting in October of 2004. 303 patients were enrolled and were either treated with TTT or a sham treatment. At 2 years, 47% of eyes in the active treatment group avoided modest or severe vision loss compared to 43% of patients in the sham group, which was not statistically significant. As with TTT for intraocular tumors, long-term follow-up is lacking and further trials of TTT are needed to compare this intervention with other treatment modalities (e.g., PDT).

CODES: Number Description

Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.

CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).

CPT: There is no specific code for transpupillary thermotherapy; 67299, unlisted procedure, posterior segment could be billed for this procedure.

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HCPCS: No specific code(s)

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ICD10: C69.20-C69.22 Malignant neoplasm of retina (code range)
C69.30-C69.32 Malignant neoplasm of choroid (code range)
H35.051-H35.059 (E/I) Retinal neovascularization (code range)

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*Key article

KEY WORDS:

Choroidal melanoma, Choroidal neovascularization, Retinoblastoma, TTT.

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

Based upon our review, transpupillary thermotherapy is not addressed in National or regional CMS coverage determinations or policies.