



CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all plans administered by CIGNA Companies including plans administered by Great-West Healthcare, which is now a part of CIGNA.

Subject Transpupillary Thermal Therapy (TTT)

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Coverage Policy

CIGNA covers transpupillary thermal therapy (TTT) as medically necessary for EITHER of the following conditions:

- retinoblastoma involving less than 50% of the retina, without associated vitreal or subretinal seeds at the time of thermotherapy
- small choroidal melanomas located posterior to the globe

CIGNA does not cover TTT for the treatment of choroidal neovascularization (CNV) associated with age-related macular degeneration (ARMD), central serous chorioretinopathy (CSC), or any other indication because such treatment is considered experimental, investigational or unproven.

General Background

Transpupillary thermotherapy (TTT) is a method of delivering heat through the dilated pupil into the posterior segment of the eye. This method employs infrared radiation as the heat source and is used to treat certain intraocular tumors, including retinoblastoma and choroidal melanoma. This laser technique differs from the laser used in standard photocoagulation therapy in that thermotherapy applies a lower-power laser for more

prolonged periods. It is designed to heat the lesion gently, limiting damage to the surrounding structures of the eye. TTT has been evaluated as a treatment for retinoblastoma, choroidal melanoma, choroidal neovascularization (CNV), and has also been proposed as a treatment option for central serous chorioretinopathy (CSC).

U.S. Food and Drug Administration (FDA)

U.S. FDA-approved ophthalmic lasers that can be used for TTT include the IRIS Medical® Oculight® SLx (IRIDEX Corp., Mountain View, CA); the Nidek DC-3000 (Nidek, Inc., Fremont, CA); and the GaAIAs diode laser (Candela USA, Wayland, MA) (FDA, 2002).

TTT for Retinoblastoma

TTT has been proposed as an alternative to laser photocoagulation for posteriorly located retinoblastomas involving less than 50% of the retinal surface, where there is a clinically significant chance of retaining vision.

In the past, the standard treatment for retinoblastoma was enucleation (i.e., removal of the affected eye). Other treatments that have been developed for use with retinoblastomas include external beam radiation, chemotherapy, laser photocoagulation, cryotherapy and plaque brachytherapy. TTT allows the destruction of most small and some medium-sized retinoblastomas with less destruction of the retina than standard laser photocoagulation and without exposure to ionizing radiation. Thermotherapy can also be used on many medium-sized and some large retinoblastomas that have been reduced by chemotherapy. Scars caused by TTT are usually no larger than the original tumor.

Literature Review: The available evidence investigating the use of TTT with retinoblastomas is limited. Studies supporting TTT for retinoblastoma have been in the form of retrospective and prospective case series with sample sizes ranging from 24–58 (Abramson and Scheffler, 2004; Shields, et al., 1999). Despite the lack of robust evidence, TTT has become a standard of care in the treatment of subset of retinoblastoma patients. Laser therapy, including TTT is most appropriate for small intraretinal extramacular and extrapapillary tumors and is not applicable to tumors associated with intravitreal or subretinal tumor seeds or retinal detachment (Augsburger, et al., 2008).

TTT for Choroidal Melanoma

TTT has also been used as an alternative to laser photocoagulation for small (i.e., 2–3 mm) choroidal melanomas located posterior to the globe. Treatment modalities for choroidal melanoma include plaque radiotherapy, local resection, and enucleation.

Literature Review: The evidence supporting TTT for choroidal melanoma comes from the results of short-term, uncontrolled case series with patient populations ranging from 20–256 (Pan, et al., 2008; Aaberg, et al., 2008; Win, et al., 2006; Shields, et al., 2002; Shields, et al., 1998). Results of these studies indicate that TTT is safe and effective for the treatment of small choroidal melanomas. As a standard of care, TTT is usually reserved for tumors ≤ 10mm in diameter with limited or no associated retinal detachment that are located posterior to the ocular equator in eyes with clear optical media (Augsburger, et al., 2008).

TTT for Choroidal Neovascularization (CNV)

Age-related macular degeneration (ARMD) is a deterioration of the central portion of the retina. There are two forms of late ARMD: the atrophic form and the neovascular, exudative form. The atrophic form does not involve leakage of blood or serum and is therefore called "dry" ARMD. The neovascular, exudative form includes serous or hemorrhagic detachment of retinal pigment epithelium and CNV, in which new blood vessels grow across the back of the eye, leading to leakage and scarring. This form is called "wet" ARMD. In patients with untreated CNV, scar tissue may replace the normal anatomic structures of the macula, including photoreceptors, resulting in a profound loss of central vision. However, CNV can be detected before scarring and extensive leakage cause irreversible loss of vision. TTT of CNV involves prolonged application of low-energy, infrared laser to photocoagulate areas of neovascularization by increasing retinal temperatures.

Literature Review: The majority of studies of TTT for treatment of CNV reported in the peer-reviewed medical literature are retrospective analyses of uncontrolled case series (Stolba, et al., 2006; Tranos, et al., 2005) and uncontrolled, short-term pilot studies (Myint, et al., 2006; Oik, et al., 1999).

In a prospective randomized study, Odergren et al. (2008) compared the efficacy of low-dose TTT (n=46) and verteporfin photodynamic therapy (PDT) (n=52) in patients with occult neovascular ARMD. At 12 months follow-up, 75% of patients in the TTT group lost <15 letters and 73.9% of those in the PDT group (p>0.05). In the TTT group, 36.5% of patients had preserved or improved BCVA versus 23.9% of patients in the PDT group (p>0.05). There was also no significant difference between groups in the decrease of foveal thickness and change in total lesion area. Study results suggest that TTT and PDT treatments performed equally for this subset of patients. However, additional randomized clinical trials are needed to support the effectiveness of TTT as a treatment for CNV due to the conflicting nature of the available literature.

An assessment of TTT for ARMD conducted by the National Institute for Clinical Excellence (NICE) reached the following conclusion: Current evidence on the safety and efficacy of TTT for ARMD does not appear adequate for this procedure to be used without special arrangements for consent and for audit or research (NICE, 2004).

The Transpupillary Thermotherapy of Occult Subfoveal Choroidal Neovascular Membranes in Patients with Age-Related Macular Degeneration (TTT4CNV) is a multicenter RCT designed to evaluate the effectiveness of TTT for the management of occult CNV. The study enrolled 303 patients age 50 and older with ARMD who have visual acuity between 20/50 and 20/400 (Macular Degeneration Foundation [MDF], 2002). Published results of the TTT4CNV trial remain pending.

TTT for Central Serous Chorioretinopathy

TTT is being investigated as a treatment for central serous chorioretinopathy (CSC). CSC is characterized by serous detachment of the neurosensory retina due to one or more focal lesions of the retinal pigment epithelium (RPE). Symptoms of CSC include blurred vision, usually in one eye only. Normal vision often recurs spontaneously within a few months. Treatment is generally considered for acute CSC that has not resolved within three months and chronic CSC. Resolution of detachment can usually be achieved by photocoagulation of leaking RPE lesions in acute CSC or by photodynamic therapy in chronic CSC. Chronic CSC may be difficult to differentiate from occult CNV secondary to CSC (Wang, et al, 2008).

Literature Review: There is a paucity of studies including several case reports and case series (Shukla, et al., 2008) in the published peer-reviewed medical literature evaluating the use of TTT as a treatment for CSC. There is insufficient evidence to support the safety and effectiveness of TTT for this indication.

Professional Societies/Organizations

According to the NCI, treatment of retinoblastoma should be planned after the extent of the tumor within and outside the eye is known. Treatment options consider both cure and preservation of sight. TTT delivered via infrared radiation may be used as an alternative to laser photocoagulation for posteriorly located tumors that are smaller than 4 DD, distinct from the optic nerve head and macula, and without large nutrient vessels or choroid involvement (NCI, 2010).

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, 2007).

The American Academy of Ophthalmology (AAO) preferred practice pattern for ARMD does not address the use of TTT as a treatment for the condition (AAO, 2008).

Summary

The overall body of evidence in the published peer-reviewed medical literature suggests that transpupillary thermotherapy (TTT) is safe and effective for the treatment of retinoblastoma and choroidal melanoma in selected patients. The available evidence indicates the need for further randomized clinical trials to determine the efficacy of TTT relative to that of photodynamic therapy for choroidal neovascularization (CNV). TTT for the treatment of age-related macular degeneration (ARMD) and central serous chorioretinopathy (CSC) is unproven at this time.

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

Covered when medically necessary:

CPT ^{®*} Codes	Description
0016T	Destruction of localized lesion of choroid (eg, choroidal neovascularization), transpupillary thermotherapy

ICD-9-CM Diagnosis Codes	Description
190.5	Malignant neoplasm of retina
190.6	Malignant neoplasm of choroid

Experimental/Investigational/Unproven/Not Covered:

ICD-9-CM Diagnosis Codes	Description
362.16	Retinal neovascularization NOS (choroidal neovascularization)
362.41	Central serous retinopathy
362.50	Macular degeneration (senile) of retina, unspecified
362.51	Nonexudative senile macular degeneration of retina
362.52	Exudative senile macular degeneration of retina
	All other codes

*Current Procedural Terminology (CPT[®]) © 2010 American Medical Association: Chicago, IL.

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Policy History

Pre-Merger Organizations	Last Review Date	Policy Number	Title
CIGNA HealthCare	10/15/2008	0191	Transpupillary Thermal Therapy (TTT) for Choroidal Tumors and Macular Degeneration

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