TRANSUPILLARY THERMOTHERAPY

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INSTRUCTIONS FOR USE

This Medical Policy provides assistance in interpreting UnitedHealthcare benefit plans. When deciding coverage, the enrollee specific document must be referenced. The terms of an enrollee’s document (e.g., Certificate of Coverage (COC) or Summary Plan Description (SPD) and Medicaid State Contracts) may differ greatly from the standard benefit plans upon which this Medical Policy is based. In the event of a conflict, the enrollee’s specific benefit document supersedes this Medical Policy. All reviewers must first identify enrollee eligibility, any federal or state regulatory requirements and the enrollee specific plan benefit coverage prior to use of this Medical Policy. Other Policies and Coverage Determination Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

COVERAGE RATIONALE

Transpupillary thermotherapy is proven and medically necessary for the treatment of retinoblastoma and choroidal melanomas.

Transpupillary thermotherapy is unproven and not medically necessary for the treatment of choroidal neovascularization or macular degeneration.

Results of studies evaluating the use of transpupillary thermotherapy for the prevention or control of choroidal neovascularization lesions in patients with age-related macular degeneration (AMD) do not provide sufficient evidence to conclude that transpupillary thermotherapy improves loss of vision due to AMD.

APPLICABLE CODES

The Current Procedural Terminology (CPT®) codes and Healthcare Common Procedure Coding System (HCPCS) codes listed in this policy are for reference purposes only. Listing of a service code in this policy does not imply that the service described by this code is a covered or non-
Transpupillary thermotherapy (TTT) of CNV lesions due to age-related macular degeneration
involves prolonged application of low-energy, infrared laser to areas of neovascularization
due to CNV lesions, thereby causing photocoagulation. The goal of TTT is to stop the growth and leakage of the new
blood vessels, thereby preserving vision. Transpupillary thermotherapy has also been proposed
to treat ocular tumors such as choroidal melanoma and retinoblastoma. The goal of TTT is to
ablate cancerous masses by heating them to temperatures as high as 60 degrees Celsius.
Healthy ocular tissue may also be damaged, but generally the damage is limited to the site of
treatment.

CLINICAL EVIDENCE

Transpupillary Thermotherapy for Choroidal Melanomas
Chojniak et al. (2011) evaluated the efficacy of transpupillary thermotherapy (TTT) for the
treatment of small choroidal melanomas. The study was a prospective nonrandomized study of
transpupillary thermotherapy for small (thickness ≤ 4.0 mm and basal diameter ≤ 12 mm)
pigmented choroidal melanomas presenting either growth or risk factors for growth and
metastasis. Ophthalmoscopic aspect, tumor control, visual acuity and complications were
evaluated. Twenty-seven patients were treated; mean age 61 years; mean tumor thickness
before treatment was 2.7 mm and base was 8.52 mm. After a mean of three treatment sessions
and 45-month follow-up, mean tumor thickness decreased significantly to 1.34 mm and mean
tumor base to 5.48 mm. Complications were observed in 12 patients (44%) and included retinal
vascular occlusion, optic disc atrophy, retinal traction, vitreous hemorrhage, rhegmatogenous
retinal detachment, and maculopathy. Lesions touching the optic disc were associated with a
significantly higher rate of disc atrophy after treatment (60% vs. 40%). Visual acuity remained the
same in nine eyes (33%), improved in five (19%) and decreased during the first 6 months after
treatment in 13 eyes (48%). Complete tumor control without recurrence was observed in 25
patients (93%). Recurrence at tumor margin was detected in two (7%). All eyes were preserved.
One patient had tumor-related death. According to the investigators, TTT is an effective treatment
in the management of selected small choroidal melanoma. Decrease in visual acuity occurred
early after treatment, mainly as a complication of subfoveal and perifoveal tumor treatment.

Pilotto et al. (2009) compared long-term choroidal vascular changes after iodine-125
brachytherapy (IBT) versus transpupillary thermotherapy (TTT) used as primary treatment. A total
of 95 small choroidal melanomas were randomized: 49 eyes with TTT and 46 eyes with IBT
alone. Mean follow-up was 56.2 months. Tumor regressed in 45 (92%) TTT-treated vs 45 (98%)
IBT-treated eyes. Four TTT-treated and one IBT-treated tumor recurred. Closure of medium and
large choroidal vessels was observed in 17 (35%) TTT-treated vs 44 (96%) IBT-treated eyes.
Choroidal vascular remodeling was detected in 20 (41%) TTT-treated and 16 (35%) IBT-treated
eyes. Retinochoroidal anastomosis was present in 4 of the 37 (11%) TTT-treated eyes with
patency of medium and large choroidal vessels, but never observed in the IBT-treated eyes, and
was associated with tumor recurrence. Among IBT-treated eyes, segments of choroidal vascular
wall ICG staining and choroidal aneurysmal changes were detected in 30 (65%) and 7 (15%),
respectively. These changes were never detected in TTT-treated cases. The investigators
concluded that the pattern of tumor choroidal vascular changes following IBT and TTT differs.
TTT is less effective in closing all tumor vasculature. The role of long-term choroidal vascular remodeling observed after these two treatments needs longer follow-up.

Desjardins et al. (2006) conducted a randomized study to determine whether systematic TTT after proton beam radiotherapy could have a beneficial effect in 151 patients with uveal melanomas. One half of the patients received proton beam radiotherapy alone (and the other half received the same dose of proton beam radiotherapy followed by TTT at 1, 6 and 12 months. The median follow-up was 38 months. The patients treated with TTT showed a greater reduction of tumor thickness, less retinal detachment at the latest follow-up and a lower secondaryenucleation rate. Further studies are needed to determine whether TTT could be beneficial to smaller tumors and to define its optimal dose.

Parrozzani et al. (2008) prospectively evaluated the clinical outcomes of TTT as the primary treatment of choroidal melanoma in 77 eyes. Follow-up was longer than 36 months. Thirteen (76%) parapapillary tumors and 55 (92%) non-parapapillary tumors regressed. Nine tumors recurred.

Shields et al. (2002a) conducted a prospective non-comparative interventional case series to evaluate tumor control and treatment complications following plaque radiotherapy combined with transpupillary thermotherapy for choroidal melanoma. A total of 270 patients received treatment for choroidal melanoma using plaque radiotherapy followed by 3 sessions of transpupillary thermotherapy provided at plaque removal and at 4-month intervals. Prior to treatment, the median base of the tumor was 11 mm (range, 4-21 mm) and the median thickness was 4 mm (range, 2-9 mm). The tumor decreased in thickness to a median of 2.3 mm by 1 year and 2.1 mm by 2 years' follow-up with stable findings thereafter. Using Kaplan-Meier estimates, tumor recurrence was 2% at 2 years and 3% at 5 years. Risk factors for tumor recurrence included macular location of the tumor epicenter, diffuse tumor configuration, and tumor margin extending underneath the foveola. Using Kaplan-Meier estimates, treatment-related complications at 5 years included maculopathy in 18% of the participants, papillopathy in 38%, macular retinal vascular obstruction in 18%, vitreous hemorrhage in 18%, rhegmatogenous retinal detachment in 2%, cataract in 6%, and neovascular glaucoma in 7%. Enucleation for radiation complications was necessary in 3 cases (1%). The investigators concluded that plaque radiotherapy combined with transpupillary thermotherapy provides excellent local tumor control with only 3% recurrence at 5 years’ follow-up.

Sagoo et al. (2010) evaluated treatment of juxtapapillary choroidal melanoma with plaque radiotherapy and investigated the role of supplemental transpupillary thermotherapy (TTT) in a retrospective, comparative case series of 650 consecutive eyes with juxtapapillary choroidal melanoma within 1 mm of the optic disc. Eyes receiving plaque radiotherapy over a 31-year period from October 1974 to November 2005 were included in the study. The TTT (n=242) and no TTT (n=307) groups were analyzed separately and compared. Kaplan-Meier estimates for tumor recurrence, metastasis, and death were 14%, 11%, and 4% at 5 years and 21%, 24%, and 9% at 10 years, respectively. Eyes treated with additional TTT showed slight (statistically nonsignificant) reduction in recurrence and metastasis. Using multivariable analysis, factors predictive of tumor recurrence included foveolar tumor requiring TTT and greater tumor thickness. Factors predictive of metastasis included greater tumor base and increasing intraocular pressure. The investigators concluded that plaque radiotherapy for juxtapapillary melanoma provides local tumor control in approximately 80% of eyes at 10 years. In patients who received TTT, there was slight but nonsignificant improved local tumor control and lower metastatic rate. According to the investigators, further randomized, prospective analysis could assist in evaluating the true benefit of adjunctive TTT in juxtapapillary choroidal melanoma.

National Cancer Institute (NCI): The NCI states that transpupillary thermotherapy (TTT) has important limitations that confine its use to very restricted circumstances. The limited ability of TTT to penetrate thick tumors with sufficient energy restricts its use to small melanomas or tumors of a size that some ophthalmologists recommend for follow-up without any initial therapy.
When used as the primary therapy, there are relatively high rates of local recurrence and retinal vascular damage. Recurrence rates are particularly high when the tumor abuts the optic nerve and overhangs the optic disc. The NCI also states that combined therapy, with ablative laser coagulation or transpupillary thermotherapy to supplement plaque treatment may be used for medium-sized choroidal melanomas (NCI, Intraocular (Uveal) Melanoma 2012).

Transpupillary Thermotherapy for Retinoblastomas
Shields et al. (2005) evaluated the effectiveness of chemoreduction alone and chemoreduction with thermotherapy for macular retinoblastoma in a prospective, nonrandomized, single-center case series. There were 68 macular retinoblastomas in 62 eyes of 49 patients managed with chemoreduction. All patients received 6 cycles of intravenous chemoreduction using vincristine, etoposide, and carboplatin. The patients were then treated according to 1 of 2 approaches: chemoreduction alone with no adjuvant focal therapy (group A) or chemoreduction combined with adjuvant foveal-sparing thermotherapy to each macular retinoblastoma (group B). The main outcome measure was tumor recurrence. Of the 68 tumors, 28 were in group A and 40 were in group B. A comparison of both groups revealed that the tumors were similar with regard to clinical features. Following treatment, Kaplan-Meier estimates revealed that group A tumors showed recurrence in 25% by 1 year and 35% by 4 years whereas those in group B showed recurrence in 17% by 1 year and 17% by 4 years. By multivariate analysis, the most important factors predictive of tumor recurrence were smaller macular tumor size (judged by percentage of the macula occupied by the tumor), absence of subretinal or vitreous seeds, and unilateral disease. Tumors most destined for recurrence are small tumors. According to the investigators, treatment of macular retinoblastoma with chemoreduction plus adjuvant foveal-sparing thermotherapy provides tumor control of 83% by 4 years, and this is slightly more favorable than chemoreduction alone, which provides control of 65% by 4 years.

Shields et al. (1999) reported on the results of TTT in 188 retinoblastomas in 80 eyes of 58 patients in a prospective study. Smaller tumors were managed by thermotherapy alone; larger tumors were managed by chemoreduction, followed by tumor consolidation with thermotherapy. Complete tumor regression was achieved in 161 tumors (85.6%). A total of 27 tumors (14.4%) developed recurrence. The investigators concluded that thermotherapy is effective for relatively small retinoblastomas without associated vitreous or subretinal seeds. Such tumors are generally best managed by chemoreduction, followed by plaque brachytherapy or external beam irradiation. However, supplemental thermotherapy can often be employed in such cases if vitreal or subretinal seeds have resolved following irradiation. The study also concluded that larger tumors require more intense treatment than smaller tumors and are at greater risk of ocular complications, such as focal iris atrophy and focal paraxial lens opacity.

Abramson and Schefler (2004) evaluated 91 retinoblastoma tumors in 22 eyes of 24 patients with TTT as the primary treatment modality. In this case series, the outcome measures included local tumor recurrence and failure of TTT, requiring the use of salvage therapies. The mean follow-up from the time of the first TTT treatment was 21 months. Tumors were defined as cured when no regrowth had been observed for six months after treatment. A total of 84 tumors (92%) were cured with TTT alone and seven tumors (8%) required salvage treatments. All seven tumors requiring salvage treatment were cured without enucleation. The mean number of treatment sessions required for cure was 1.7, with 64% of the tumors requiring only one session. According to the investigators, retinoblastoma tumors less than 1.5 DD in base diameter can be successfully treated with TTT alone.

National Cancer Institute (NCI): According to the NCI, laser therapy (thermotherapy) may be used as primary therapy for small retinoblastoma tumors or in combination with chemotherapy for larger retinoblastoma tumors. Traditional photocoagulation, in which the laser was applied around the tumor, has given way to thermotherapy. Thermotherapy is delivered directly to the tumor surface via infrared wavelengths of light. (NCI, Retinoblastoma 2013).
Transpupillary Thermotherapy for Choroidal Neovascularization (CNV) Associated With Age-Related Macular Degeneration (AMD)

The clinical evidence was reviewed on February 14, 2014 with no additional information identified that would change the unproven conclusion for conjunctival incision with placement of a pharmacologic agent.

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.

Evidence from a large, multicenter, randomized controlled trial by Olk et al. (1999) suggests that transpupillary thermotherapy can reduce drusen levels and improve visual acuity in patients with AMD but does not decrease the incidence of choroidal neovascularization (CNV). Results also suggest that fewer complications occur when TTT is given at a low intensity that does not cause visible burns for the treatment of drusen than when used for photocoagulation of CNVs. However, this study has several methodological flaws, including a follow-up period that may not be sufficient to fully evaluate the effects of transpupillary thermotherapy. Standard periods of follow-up provided by studies of visible light laser photocoagulation therapy have been 3 to 5 years, which suggests that similar follow-up should be performed in studies of transpupillary thermotherapy for drusen. Other shortcomings of the trial by Olk et al. include lack of blinding of patients and examiners to the treatment given and the fact that the infrared laser manufacturer provided funding for this trial.

Odergren et al. (2008) compared the efficacy of low-dose transpupillary thermotherapy (TTT) and verteporfin photodynamic therapy (PDT) in patients with occult neovascular age-related macular degeneration (AMD). Patients were randomized to receive either low-dose TTT (136 mW/mm) (and sham PDT) (n = 52) or PDT (and sham TTT) (n = 46) with retreatment if leakage was documented by fluorescein angiography. The percent of patients losing fewer than 15 letters at 12 months was 75.0% in the TTT group and 73.9% in the PDT group. The percent of patients with preserved or improved best corrected visual acuity (BCVA) was 36.5% in the TTT group versus 23.9% in the PDT group. The investigators concluded that low-dose TTT and PDT appeared to be equally efficient at stabilizing visual acuity in patients with occult neovascular AMD. In the same group of patients, Odergren et al. (2010) compared the effects of low-dose TTT and verteporfin photodynamic therapy (PDT) on patient-reported visual function using the National Eye Institute Visual Function Questionnaire 25 (NEI VFQ-25) in patients with occult neovascular age-related macular degeneration (AMD). Patients were followed for 12 months with retreatment according to clinical assessment. The NEI VFQ-25 questionnaire was administered at baseline and at 12 months. Forty-two patients (80.1%) in the TTT group and 37 patients (80.0%) in the PDT group completed the questionnaire at the 12-month follow-up. The mean change in the NEI VFQ-25 composite score was +1.2 for the TTT group and +0.7 for PDT group. None of the subscale categories showed significant changes between treatment groups at 12 months. Subgroup analysis showed that NEI VFQ-25 scores were lower in patients treated in their better-seeing eye. The investigators concluded that in this randomized study on patients with occult neovascular AMD, low-dose TTT and PDT appeared to be equally effective at stabilizing patient-
reported visual function. However, the study was not powered for this measure. Also, ranibizumab is superior to PDT and low-dose TTT for all types of neovascular AMD.

Gustavsson and Agardh (2005) conducted a prospective, randomized, controlled pilot study of 28 patients with occult or minimally classic neovascularization. Nineteen patients were treated with TTT and nine received sham treatment. A total of 21 patients were available to one year follow-up, 13 in the TTT group and 8 in the sham group. Membrane diameter increased by a median of 350 microm in the TTT group and 800 microm in the sham group and there was a loss in visual acuity (VA) of more than or equal to 15 letters in 5/13 (38%) of the TTT group and 2/8 (25%) of the sham group.

Six case studies with a total n = 286 and follow-up ranging from 6 to 24 months reported improvement in visual acuity (VA) in 18%, stabilized VA in 51% and deteriorated VA in 35% of treated eyes (7,9-12). The two studies with 12-month or longer follow-up reported the VA had improved in 14%, stabilized in 42% and deteriorated in 44% of treated eyes (Algvere et al. 2001; Algver et al. 2003; Lin et al. 2002; Thach et al. 2004; Tranos et al. 2004; Verma et al. 2004).

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.

Mitamura et al. (2009) compared the therapeutic efficacy of photodynamic therapy (PDT) to that of transpupillary thermotherapy (TTT) for polypoidal choroidal vasculopathy (PCV) a form of choroidal neovascularization. PDT or TTT was performed on 46 eyes of 46 patients with PCV; 19 eyes were treated with TTT (TTT group) and 27 eyes with PDT (PDT group). Best-corrected visual acuity (BCVA) was significantly better and the fovea was significantly thinner in the PDT group than in the TTT group after treatment.

Tewari et al. (2007) compared the visual outcomes of photodynamic therapy (PDT) with verteporfin and transpupillary thermotherapy (TTT) for classic subfoveal choroidal neovascularization (CNVM) secondary to age-related macular degeneration (ARMD) in 32 eyes. Stabilization or improvement occurred in 69% of patients undergoing PDT and 50% patients undergoing TTT at six months of follow-up. The investigators concluded that for short-term preservation of vision in patients of classic CNVM due to ARMD, PDT seems to be better than TTT if the pre-laser best corrected visual acuity is greater than 20/63 but both are equally effective if pre-laser best corrected visual acuity is less than 20/63.

Shukla et al. (2008) evaluated transpupillary thermotherapy (TTT) for the treatment of subfoveal focal leaks in central serous chorioretinopathy (CSC). The study included 39 patients (40 eyes) with CSC of whom 25 patients (25 eyes) opted for TTT for subfoveal leaks. Fourteen patients (15 eyes) were followed up without treatment. Minimum follow-up was 6 months. Within 3 months, TTT resulted in the resolution of the serous detachment in 24 (96%) eyes with a single session; one eye required a repeat treatment. Eight control eyes demonstrated persisting CSC at the last follow-up. Visual acuity improved in 23 (92%) treated and five (33%) control eyes; the difference
in outcome was statistically significant. One case developed choroidal neovascularization, which
resolved with visual recovery to 20/20 after repeat-TTT. The investigators concluded that TTT
resulted in the resolution of CSC with subfoveal angiographic leaks with significant improvement
in visual outcome, in comparison to the natural history of persistent CSC. The value of this study
is limited by the small sample size and short follow-up.

Mason et al. (2008) conducted a retrospective review of 84 consecutive patients with age-related
macular degeneration who received transpupillary thermotherapy for occult subfoveal choroidal
neovascularization. The study was conducted to determine risk factors for immediate severe
vision loss after transpupillary thermotherapy. Seven cases had severe vision loss and 77 were
controls. All patients were treated with a diode infrared laser. Follow-up was completed on all
patients 1, 3, and 6 months after treatment with transpupillary thermotherapy. Transpupillary
thermotherapy has a small but significant risk of immediate severe vision loss in patients with
age-related macular degeneration with occult subfoveal choroidal neovascularization. Statistically
significant risk factors include a subretinal hemorrhage 5 disc areas or greater in size, 9 disc
areas or greater of subretinal fluid, and a laser power greater than 550 mW.

The National Institute for Health and Care are Excellence (NICE) 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 (NICE 2004).

Professional Societies
American Academy of Ophthalmology (AAO): The AAO preferred practice pattern document
for age-related macular degeneration does not address transpupillary thermal therapy (AAO,
2008).

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

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 Web site for more information:

- Nidex DC - 3000 laser diode photocoagulator (Nidek, Inc.) 510(k) (K903639) approval
  received 08/13/1990. (See the following Web site for more information:

A listing of all devices in the same product classification as those above (Product Code HQF and
GEX) is available on the following FDA Web site

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Medicare does not have a National Coverage Determination (NCD) for transpupillary
thermotherapy for the treatment of retinoblastoma and choroidal melanomas. Local Coverage
Determinations (LCDs) do exist at this time. Refer to the LCDs for Panretinal (Scatter) Laser
Photocoagulation. (Accessed March 14, 2014)

REFERENCES

Abramson DH, Schefler AC. Transpupillary thermotherapy as initial treatment for small intraocular


POLICY HISTORY/REVISION INFORMATION

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| 07/01/2014 | • Reorganized policy content; coverage guidelines for this service previously outlined under policy titled Macular Degeneration and Ocular Tumor Treatment  
• Updated coverage rationale; added language to indicate if service is “medically necessary” or “not medically necessary” to applicable proven/unproven statement  
• Updated supporting information to reflect the most current description of services, clinical evidence, FDA and CMS information, and references  
• Archived previous policy version 2014T0404K |