**Prior Authorization Review Panel**  
**MCO Policy Submission**

A separate copy of this form must accompany each policy submitted for review. Policies submitted without this form will not be considered for review.

<table>
<thead>
<tr>
<th>Plan: Aetna Better Health</th>
<th>Submission Date: 11/01/2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Policy Number: 0490</td>
<td>Effective Date:</td>
</tr>
<tr>
<td></td>
<td>Revision Date:</td>
</tr>
<tr>
<td>Policy Name: Transpupillary Thermal Therapy</td>
<td></td>
</tr>
<tr>
<td>Type of Submission – Check all that apply:</td>
<td></td>
</tr>
<tr>
<td>☑ New Policy*</td>
<td>☐ Revised Policy</td>
</tr>
<tr>
<td>☐ Annual Review – No Revisions</td>
<td></td>
</tr>
</tbody>
</table>

*All revisions to the policy must be highlighted using track changes throughout the document. Please provide any clarifying information for the policy below:

**CPB 0490 Transpupillary Thermal Therapy**

Policy is new to Aetna Better Health of Pennsylvania.

Name of Authorized Individual (Please type or print):  
Dr. Bernard Lewin, M.D.

Signature of Authorized Individual: 

[Signature]
Transpupillary Thermal Therapy

I. Aetna considers transpupillary thermotherapy (thermal therapy) medically necessary for either of the following indications:

A. Retinoblastoma involving less than 50% of the retina, and without associated vitreal or subretinal seeds at the time of thermotherapy; or

B. Small (2 to 3 mm) choroidal melanomas located posterior in the globe.

II. Aetna considers transpupillary thermotherapy experimental and investigational for the following indications and all other indications other than those listed above because of the lack of prospective, controlled clinical studies supporting its effectiveness for these indications:

- Central serous chorioretinopathy
- Choroidal indeterminate melanocytic lesions
- Choroidal metastases

Policy History

Last Review: 08/30/2018
Effective: 01/08/2002
Next Review: 05/09/2019

Definitions

Additional Information

Clinical Policy Bulletin
Notes
• Choroidal neovascularization associated with age-related macular degeneration
• Circumscribed choroidal hemangioma
• Polypoidal choroidal vasculopathy
• Retinopathy of prematurity.

**Background**

Transpupillary thermal therapy (TTT) is a method of delivering heat through the dilated pupil into the posterior segment of the eye. This method, using infrared radiation as the heat source, is employed to treat certain intraocular tumors including retinoblastoma and choroidal melanoma. Transpupillary thermal therapy is typically performed in the office under local anesthesia.

**Transpupillary Thermal Therapy for Retinoblastoma**

Transpupillary thermal therapy 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 retention of vision.

Retinoblastoma is the most frequent intraocular tumor in children, affecting more than 1 child in 20,000. It is rapidly fatal if not promptly diagnosed and treated. Nonetheless, survival is over 90% due to the sensitivity of tumor cells to radiation and chemotherapy.

In past years, the only acceptable management of retinoblastoma was enucleation of the affected eyes. The introduction of external beam radiation, with doses ranging from 3,500 to 4,600 cGy, has permitted many affected eyes to be salvaged, often with retention of satisfactory vision. However, external beam radiation is associated with numerous
secondary problems, mainly, poor cosmetic results in the face and ocular region, and a 6 to 30 % risk of secondary neoplasms in the field of irradiation.

Chemotherapy has been used to reduce tumor size, thus reducing the necessary doses of external radiation, and in many cases, allowing for focal treatments. Chemo-therapeutic protocols typically employ vincristine, etoposide, carboplatinum or cisplatinum.

Focal treatments, such as laser photocoagulation, cryotherapy, and episcleral plaque brachytherapy, have been used to destroy small retinoblastomas, often with retention of good vision, without the need for enucleation or external beam radiation. However, these treatment methods frequently cause chorioretinal scarring that is larger than the original tumor.

Transpupillary thermotherapy (TTT) allows the destruction of most small and some medium-sized retinoblastomas with less retinal destruction than standard laser photocoagulation, and without exposure to any form of ionizing radiation. Thermotherapy can also be used on many medium-sized and some large retinoblastomas that have been reduced in size by chemotherapy. Scars induced by TTT are usually no larger than the original tumor. However, there are no reports of the long-term success of TTT for retinoblastoma.

In the largest published study of TTT for retinoblastoma, Shields et al (1999) reported on the results of TTT in 188 retinoblastomas in 80 eyes of 58 patients. Smaller tumors were managed by thermotherapy alone, and larger tumors were managed by chemoreduction, followed by tumor consolidation with thermotherapy. Complete tumor regression was achieved in 161 tumors (85.6 %), and 27 tumors (14.4 %) developed recurrence. Complications of TTT included focal iris atrophy in 29 eyes (36 %), peripheral focal lens opacity in 19 eyes (24 %), retinal traction in 4 eyes (5 %), retinal vascular
obstruction in 2 eyes (2 %), and transient localized serous retinal detachment in 2 eyes (2 %). There were no cases of corneal scarring, central lens opacity, iris or retinal neovascularization, or rhegmatogenous retinal detachment. All eyes with focal lens opacity demonstrated adjacent focal iris atrophy. The investigators found that larger tumors require more intense treatment than smaller tumors and are at greatest risk for ocular complications such as focal iris atrophy and focal paraxial lens opacity.

The authors explained that there is little or no role for TTT alone for retinoblastomas that have produced significant vitreal or subretinal tumor seeds. Such tumors are generally best managed by chemoreduction, followed by plaque brachytherapy or external beam irradiation. However, supplemental TTT can often be employed in such cases if vitreal or subretinal seeds have resolved following irradiation.

The treatment parameters for TTT of retinoblastoma are different than the treatment parameters for choroidal melanoma (see below). Retinoblastoma is less pigmented than choroidal melanoma, and the treatment technique often employs chemotherapy so that treatment parameters are designed to disturb tumor cell integrity, to allow chemotherapy penetration, and to prevent DNA repair. Treatment parameters for choroidal melanoma are more aggressively designed to be directly cytotoxic in order to induce cell necrosis. With retinoblastoma, infrared radiation is delivered alone or in combination with chemotherapy for approximately 10 to 40 mins to the center of the tumor. Often 2 or 3 sessions of treatment are necessary for full thickness tumor destruction.

Transpupillary Thermal Therapy for Choroidal Melanomas

Transpupillary thermal therapy has been used as an alternative to laser photocoagulation for small (2 to 3 mm) melanomas located posterior in the globe. The technique
uses a near infrared diode laser to essentially burn the tumor. Heat is delivered over the entire surface of the tumor using large, overlapping treatment spots of 1-min duration each, accumulating a total treatment time of 20 to 30 mins. The treatment is repeated at 3-month intervals, usually in 3 sessions.

The evidence supporting the use of TTT for choroidal melanoma is based on the results of short-term uncontrolled case series. Transpupillary thermotherapy has been reported to cause tumor necrosis in choroidal melanomas up to 4 mm in thickness. Shields et al (1998) reported the results of the largest published case series of TTT for choroidal melanoma. After a mean of 3 treatment sessions and 14 months of follow-up, tumor control was successful in 94 % of patients. The 6 eyes (6 %) classified as treatment failures included 4 eyes with tumors that showed partial or no response to TTT, thus requiring plaque radiotherapy or enucleation, and 2 eyes with recurrence, subsequently controlled with additional thermotherapy. In 58 % of patients, visual acuity was the same (within 1 line) or better than before treatment, depending primarily on tumor location. Complications are generally limited to the site of treatment. The most common complications of TTT for choroidal melanoma were retinal vascular obstruction (5 %), retinal traction (10 %), and optic disc edema (1 %). Tumors located temporal to the fovea demonstrated a statistically higher risk for retinal traction than those located in other quadrants.

Available studies show that there appear to be fewer adverse effects on visual acuity with TTT compared to laser photocoagulation. However, there are no reported results of the long-term success of this procedure in terms of complications and incidence of metastases. Under established guidelines, enucleation remains the standard of care for large choroidal melanomas with a high-risk of metastases.
In a retrospective review, Gunduz and associates (2010) evaluated the results of ruthenium-106 (Ru-106) plaque radiotherapy alone (group A) or in combination with TTT (group B) in the management of choroidal melanoma with tumor thickness (height) less than 8 mm. The tumors in each group were subclassified as those with thickness less than or equal to 5 mm versus those with thickness of greater than 5 and less than 8 mm. The main outcome measures were globe conservation rate, the rate of a reduction of at least 50% in tumor thickness, treatment complications, visual acuity (VA) change, and metastasis. Kaplan-Meier curves for prediction of decrease in tumor thickness of at least 50% over time were constructed. A total of 54 patients (24 in group A and 30 in group B) were included in this study. The groups were matched with respect to patient age, tumor base diameter, tumor thickness, tumor distance to optic disc, tumor distance to foveola, and baseline VA. The mean follow-up was 24.6 months in group A and 44.9 months in group B. Globe conservation was achieved in 21 (87.5%) eyes in group A and in 26 (86.7%) eyes in group B. The globe conservation rates did not differ significantly between groups A and B or between tumors less than or equal to 5 mm in thickness and those greater than 5 to less than 8 mm in thickness in each group (p > 0.05). There was no statistical difference between groups A and B in the rate of tumor thickness reduction of at least 50% (p > 0.05). There was a significant decrease in final VA compared to baseline VA in group B (p = 0.007) but not in group A. Radiation complications were similar in groups A and B. Liver metastasis occurred in 2 patients in group A and in 1 patient in group B. Statistical analysis could not be carried out for the latter 2 variables because of the small number of affected patients. The authors concluded that compared to Ru-106 plaque radiotherapy alone, Ru-106 plaque radiotherapy combined with TTT did not result in a significant change in the globe conservation rate or the rate of at least 50% reduction in tumor thickness in choroidal melanomas less than 8 mm in thickness. Although Ru-106 plaque radiotherapy is mainly used for choroidal melanomas greater than or equal
to 5 mm thick, it can also be considered in selected tumors with thickness between 5 and 8 mm with comparable tumor control.

Transpupillary Thermal Therapy for Choroidal Neovascularization

Age-related macular degeneration (AMD), a deterioration of the central portion of the retina, is the chief cause of severe and irreversible loss of vision in the United States. The risk of AMD increases with age, and usually affects people 60 years of age and older. Because the macula is the central portion of the retina, advanced AMD often leads to irreversible loss of the ability to read, recognize faces, and drive.

There are 2 forms of late AMD: (i) the atrophic form and (ii) the neovascular, exudative form. The atrophic form does not involve leakage of blood or serum; hence, it is called “dry” AMD. The neovascular, exudative form includes serous or hemorrhagic detachment of retinal pigment epithelium and choroidal neovascularization, which lead to leakage and scarring; hence it is called “wet” AMD.

Patients with untreated choroidal neovascularization may have scar tissue replace the normal anatomic structures of the macula, including photoreceptors, resulting in a profound loss of central vision. However, choroidal neovascularization can be detected before scarring and extensive leakage cause irreversible loss of vision.

Prospective controlled clinical trials have demonstrated the effectiveness of laser photocoagulation and of photodynamic therapy with Visudyne for treatment of selected patients with choroidal neovascularization due to AMD.

Transpupillary thermal therapy of choroidal neovascularization involves prolonged application of low-energy, infrared laser to photocoagulate areas of neovascularization by increasing
retinal temperatures. Studies of TTT for treatment of choroidal neovascularization reported in the peer-reviewed medical literature are limited to retrospective analysis of uncontrolled case series and small, uncontrolled, short-term pilot studies. The authors (Newsom et al, 2001) of the most recent published study, reported in the British Journal of Ophthalmology, noted that results of TTT appeared promising, but concluded that “further trials of TTT are needed to compare this intervention to the natural history and other treatment modalities.” A controlled, multi-center study is planned to examine the possible indications, the efficacy, and side effects of TTT.

Subramanian and Reichel (2003) stated that a prospective, randomized, sham-controlled multi-center clinical trial is currently underway to evaluate the effectiveness of TTT for the management of choroidal neovascularization secondary to AMD. An assessment of TTT for AMD conducted by the National Institute for Clinical Excellence (2004) reached the following conclusion: “Current evidence on the safety and efficacy of transpupillary thermotherapy for age-related macular degeneration does not appear adequate for this procedure to be used without special arrangements for consent and for audit or research.” Furthermore, the European guidance on the medical management of neovascular AMD (Chakravarthy et al, 2006) did not recommend TTT in the management of patients with this condition.

In a retrospective, non-randomized study, Tsai et al (2007) assessed the therapeutic outcome and the recurrence of choroidal neovascularization (CNV) secondary to AMD after TTT in light-brown retinas (n = 58 eyes in 55 patients). Power settings were set about half the value for Caucasian eyes. The outcome was assessed with best-corrected visual acuity (BCVA), fluorescein angiography, indocyanine green angiography, and fundoscopic examination. A total of 44 membranes were occult, 6 classic, and 8 mixed. Mean follow-
Membranes closed in 46 eyes. Iatrogenic complications included 3 subretinal hemorrhage, 2 retinal pigment epithelium tears, and 2 macular area cystic changes. In eyes with occult CNV, VA improved in 6 (13.6 %), 14 (31.8 %) remained unchanged, and 24 (54.6 %) deteriorated. For various CNV, average logMAR changes from baseline at last follow-up were 0.30 in occult, -0.08 in classic, and 0.59 in mixed (p < 0.01). A total of 30 eyes experienced recurrence within 9.2 +/- 6.2 months (range of 2 to 22). Cumulative recurrence rate was 45 % at 12 months and 71 % at 22 months, with no significant difference between occult and non-occult type CNV. The authors concluded that TTT does not cure CNV secondary to AMD. High recurrence was found independent of CNV type. Most improved vision was found mostly in classic CNV. Complications associated with high energy level should be considered in light-brown retinas.

Ozdek and co-workers (2007) examined the effect of TTT on CNV secondary to angioid streaks. A total of 6 eyes of 5 patients with an average age of 61 years were diagnosed to have subfoveal CNV secondary to angioid streaks. Four of the CNVs were predominantly classic and 2 were occult with no classic. Visual acuity measurement, ophthalmoscopic and fluorescein angiographic examination, and optic coherence tomography (OCT) were carried out before TTT treatment and at each follow-up visit. Activity scores (AS) based on clinical, angiographic, and OCT findings were also recorded. The mean follow-up was 12 months. The VA initially ranged from counting fingers to 20/100 and remained stable in all patients. The mean greatest lesion diameter increased significantly from 2,221 microm to 3,109 microm at last follow-up (p = 0.046). The mean AS decreased significantly from 6.5 to 4.8 at the 3rd month (p = 0.039), but tended to increase thereafter. Re-treatment with TTT was applied to 5 eyes after a mean of 7.8 months but did not decrease CNV activity as effectively as the 1st treatments. A fibrotic scar developed in 1 eye after the 1st treatment. The authors concluded that TTT may decrease the
activity of CNVs secondary to angioid streaks in the short-
term, but re-treatment may be necessary with unfavorable
results. Transpupillary thermal therapy appears to stabilize VA
but not lesion size in this group of patients, which may be the
natural history rather than a treatment effect.

In a pilot study, Tewari and colleagues (2007) compared the
visual outcomes of photodynamic therapy (PDT) with
verteporfin and TTT for classic subfoveal choroidal
neovascularization (CNVM) secondary to AMD. Patients with
subfoveal classic CNVM caused by AMD attending vitreo-
retinal services at a tertiary care setup were included in this
non-randomized, open label, prospective, clinical, comparative
pilot trial. Standardized refraction, VA testing, evaluation of
fundus and serial color photography and fundus fluorescein
angiography were carried out to evaluate the effects of
treatment in 32 eyes each undergoing either PDT or TTT.
Follow-up was carried out at 4 weeks, 12 weeks and 6
months. Re-treatment, if indicated, was carried out 3 months
post-treatment. Stabilization or improvement occurred in 69 %
of patients undergoing PDT and 50 % patients undergoing
TTT at 6-month follow-up. Among patients with a pre-
treatment VA greater than or equal to 20/63, only 1 out of 6
patients who underwent PDT had a drop of VA greater than 2
lines as compared to 4 patients (100 %) who underwent TTT
(p = 0.0476, 2-tailed Fisher's exact test). The authors
concluded that for short-term preservation of vision in patients
of classic CNVM due to AMD, PDT seems to be better than
TTT if the pre-laser BCVA is greater than 20/63 but both are
equally effective if pre-laser BCVA is less than 20/63.

In a prospective study, Kuo et al (2008) carried out a safety
and effectiveness study of TTT in Chinese patients with CNV
secondary to AMD. A total of 26 patients (27 eyes) completed
greater than or equal to 6 months of follow-up were included in
this report. Fourteen eyes (52 %) had improved or stable VA
(loss of less than 3 lines) and 13 eyes (48 %) had vision loss
of greater than or equal to 3 lines. The serial mean VA initially
decreased during follow-up, then stabilized by 6 months. In the subgroup of occult or minimally classic CNV (20 eyes), 13 eyes (65 %) had improved or stable vision. The major complication of TTT included laser-related retinal pigment epithelium (RPE) atrophy in 10 eyes (37 %). Six eyes had mild RPE atrophy, 4 eyes had severe RPE-choroid atrophy (macular burn). Analysis of possible risk factors for macular burn showed that 3 eyes had to have the power amplified due to nuclear sclerosis, and 1 pseudophakic eye had regular power. The authors concluded that TTT in Chinese AMD patients with occult or minimally classic CNV prevented severe vision loss in the majority of patients, but power amplification due to medium lens opacity induced RPE atrophy or burn in some patients.

Transpupillary Thermal Therapy for Central Serous Chorioretinopathy

Sharma and Parikh (2010) described the use of TTT for juxtafoveal central serous chorioretinopathy (CSC) leak. A 45-year old man with juxtafoveal leak developed fibrinous exudate in the macular area, demonstrated on OCT. After 1 session of TTT, fibrinous exudate totally disappeared with improvement in vision to 20/40 from counting finger. Subretinal fluid got absorbed with obliteration of leak on fluorescein angiogram. The authors stated that TTT may be useful as a treatment option in juxtafoveal leak of CSC. They concluded that well-designed studies are needed to ascertain the clinical value of TTT in the treatment of juxtafoveal leak in CSC.

Other studies of TTT for CSC consist of case reports and small series. Wei and Yang (2005) reported on the results of TTT in a 40-year old man who had persistent CSC at the foveal region for 20 months. The pre-treatment BCVA was 0.3. The leaking point was close to the fovea, making the use of argon laser photocoagulation treatment unsafe. Transpupillary thermal therapy with diode laser was performed to cover the whole detached area. The subretinal fluid decreased 1 week
later. Fluorescein angiography 2 months later revealed neither further leakage nor any subretinal fluid. After 3 months of follow-up, BCVA improved to 0.4.

Shulka et al (2008) reported on an observational study of patients with CSC, comparing outcomes of those who opted for TTT (n = 25) or observation (control group, n = 14). The authors reported that, within 3 months, TTT resulted in the resolution of the serous detachment in 24 (96 %) eyes with a single session; 1 eye required a repeat treatment. Eight control eyes demonstrated persisting CSC at the last follow-up. Visual acuity improved in 23 (92 %) treated and 5 (33 %) control eyes; the difference in outcome was statistically significant (p < 0.001). One case developed choroidal neovascularization, which resolved with visual recovery to 20/20 after repeat-TTT.

Hussain et al (2006) reported on a pilot study of TTT in 14 eyes of 13 patients with CSC. These investigators reported that, following treatment, complete resolution of neurosensory detachment on OCT was seen in 9 eyes at 1 month and 11 eyes at months 2 and 3. Three eyes had persistent subretinal fluid at 3 months. Eight eyes had 3 or more lines of improvement (2 eyes: 5 lines and 6 eyes: 3 lines) at the final visit.

Giudice and colleagues (2011) reported the effect of subthreshold TTT in treating serous detachment of the neurosensory retina secondary to chronic CSC. A total of 7 eyes from 5 patients with chronic CSC, persistent serous detachment of the neurosensory retina and a clinical course of between 12 and 60 months were treated. All eyes received large-spot TTT guided by indocyanine green angiography (ICGA). Subthreshold TTT was performed using an 810-nm diode laser with a spot size of 3.0 mm (power was set at 350 mW). Treatment was applied for 60 seconds to the areas of choroidal hyper-fluorescence on ICGA. The mean number of TTT sessions was 1.4 +/- 0.5. All eyes were followed-up for at
least 6 months (mean of 9.6 +/- 3.2 standard deviation; range of 6 to 12 months). The mean logarithm of the minimum angle of resolution BCVA was significantly better compared with baseline. All TTT-treated eyes had stable or improved vision (p < 0.001). Mean OCT central foveal thickness was significantly lower in all patients (p < 0.001) compared with pre-treatment OCT, with a reduction in subretinal fluid and resolution of serous detachment associated with anatomical fovea restoration. No patient had any treatment-related side effects. The authors concluded that modified subthreshold TTT appears to have a beneficial effect in treating patients with chronic CSC and persistent neurosensory detachment. They stated that these encouraging findings and the lack of visually significant complications suggested that further investigation is warranted.

Kawamura et al (2012) evaluated the effectiveness of TTT in the management of atypical CSC. These investigators defined atypical CSC as bullous retinal detachment with diffuse or several leakages, severe leakage with fibrin formation under serous retinal detachment, or leakage within a pigment epithelium detachment. A total of 8 consecutive patients with atypical CSC underwent VA testing, ophthalmic examination, color photography, fluorescein angiography, and OCT to evaluate the results of TTT. Re-treatment of atypical CSC was based on ophthalmic examination, OCT, and fluorescein angiography. Transpupillary thermotherapy was performed on the leaking spots shown in fluorescein angiography, with a power of 50 to 250 mW, spot size of 500 to 1,200 μm, and exposure time of 13 to 60 seconds to minimize retinal damage. In 5 of 8 affected eyes, serous detachments completely resolved within 1 month after the initial TTT. One eye had persistent subretinal fluid and required a second TTT treatment. Two eyes showed no resolution of CSC and were treated by conventional photocoagulation. Initial BCVA ranged from 20/600 to 20/20 (mean of 20/40; median of 20/30). Final BCVA ranged from 20/200 to 20/20 (mean of 20/25; median of 20/20). Best-corrected visual acuity improved in all cases.
Only 2 eyes with persistent subretinal fibrin and existing retinal pigment epithelial alternations in macular area showed limited improvement of BCVA despite the absence of subretinal exudation. The presence of retinal attachment was confirmed by OCT in 6 eyes (75 %). The authors concluded that TTT seems to be effective for the treatment of atypical CSC in the short-term. Moreover, they stated that additional studies are needed to evaluate the long-term safety and effectiveness.

In a retrospective pilot study, Manayath et al (2012) the safety and effectiveness of "graded" subthreshold TTT, a novel treatment protocol for CSC and an alternative to PDT. This study included 10 eyes with chronic CSC that underwent TTT with 810-nm continuous diode laser treatment using a subthreshold power (60 % reduced from threshold) for 60 seconds. Treatment was repeated at 20 % increase in power from the baseline if submacular fluid persisted on OCT after 1 month (graded fashion). The mean chronic CSC duration was 20.3 +/- 8.3 months. Eight eyes (80 %) showed resolution of CSC on OCT. Mean number of TTT sittings required was 1.5. Although 5 eyes (50 %) had 3 or more lines of improvement in Snellen VA, 3 eyes (30 %) had up to 2 lines of improvement. None of the patients developed macular burn or scar. The authors concluded that the safety enhanced graded subthreshold TTT was beneficial in patients with chronic CSC. The findings of this small pilot study need to be validated by well-designed studies.

Transpupillary Thermal Therapy for Polypoidal Choroidal Vasculopathy

In a retrospective chart review, Anantharaman and colleagues (2010) presented the clinical, indocyanine green angiography (ICGA) features and results of treatment for polypoidal choroidal vasculopathy (PCV). A total of 45 patients with PCV underwent complete ocular examination, fluorescein angiography (FFA) and ICGA. Treatment was advised for patients with macular involvement and progressive loss of VA.
Demographical data, clinical features and results of treatment were analyzed. Mean age at presentation was 61.06 years. Mean follow-up was 18 months. The disease was more prevalent in males; 43 patients had unilateral disease. The most common location of polyps in ICGA was subfoveal (42.5%). Exudative form was seen in 34 of the 47 eyes and the remaining 13 eyes had a hemorrhagic presentation. Thirty-four eyes underwent treatment which included thermal laser (n = 11), PDT (n = 11) and TTT (n = 12). Statistical analysis was done using the Chi-square test. Subgroup analysis of visual outcome following various modalities of treatment showed that the results of PDT (p < 0.001) and thermal laser (p < 0.001) were statistically significant. The authors concluded that PCV is an important differential diagnosis in patients presenting with serosanguinous maculopathy and submacular hemorrhage. The disease was more prevalent in males and was unilateral in the Indian population. Timely intervention in cases with symptomatic polyps could achieve stabilization of VA. Thermal laser and PDT were safe and effective.

Transpupillary Thermal Therapy for Retinopathy of Prematurity

Shad et al (2011) compared structural and functional outcome and time efficiency between standard spot sized conventional pulsed mode diode laser and continuous mode large spot TTT (LS TTT) for treatment of high-risk pre-threshold retinopathy of prematurity (ROP). A total of 10 eyes of 5 preterm babies having bilateral symmetrical high-risk pre-threshold ROP were included in this study. One eye of each baby was randomized to get either standard spot sized conventional pulsed mode diode laser or continuous mode LS TTT. There was no significant difference between structural or functional outcome in either group. The mean time taken for conventional diode laser was 20.07 mins, while that for LS TTT was 12.3 mins. Large spot TTT was 40% more time efficient than the conventional laser. It may be better suited for the very small
fragile premature infants as it is quicker than the conventional laser. These preliminary findings need to be validated by well-designed studies.

Transpupillary Thermal Therapy for Circumscribed Choroidal Hemangioma

In a retrospective, interventional case series study, Kwon et al (2012) evaluated the effects of TTT and intra-vitreal bevacizumab injection on serous macular detachment and cystoid macular edema (CME) associated with circumscribed choroidal hemangioma. These investigators reviewed the records of 12 patients with circumscribed choroidal hemangioma treated with TTT and/or intra-vitreal injection of bevacizumab. They assessed changes in BCVA, central foveal thickness by OCT, and resolution of serous macular detachment and CME. Six of 8 patients treated with TTT showed complete resolution of serous macular detachment and CME and the median minimal angle of resolution (logMAR) BCVA improved from 0.85 to 0.35 (p = 0.026). Among these 6 patients, 1 had no recurrence for 86 months and 5 had sustained resolution of serous macular detachment for a mean duration of 32.8 months before recurrence. Among the 9 patients treated with bevacizumab (including 5 patients who had TTT as a primary treatment), 5 showed resolution of serous macular detachment and the median logMAR BCVA improved from 0.7 to 0.5 (p = 0.042). Among these 5 patients, 3 had sustained resolution for a mean duration of 5.7 months and 2 showed recurrent serous macular detachment after 3 and 12 months. The authors concluded that TTT and intra-vitreal bevacizumab appear effective in the management of symptomatic circumscribed choroidal hemangioma, although recurrence of serous macular detachment and CME developed after long-term follow-up of TTT, and the duration of treatment effectiveness appears to be short with bevacizumab. These preliminary findings need to be validated by well-designed studies.
Transpupillary Thermal Therapy for Choroidal Indeterminate Melanocytic Lesions

In a retrospective case series, Turcotte et al (2014) evaluated the ocular and metastatic outcomes of patients with choroidal indeterminate melanocytic lesions treated by primary TTT. A total of 8 patients presenting choroidal indeterminate melanocytic lesions treated by primary TTT were included in this study. A retrospective chart review was conducted for patients with a newly diagnosed choroidal indeterminate melanocytic lesion treated by at least 3 TTT sessions from 2002 to 2011. Best-corrected visual acuity and lesion dimensions were measured at baseline and during follow-up. Complications were recorded including lesion growth, metastasis, melanoma-related mortality, and treatment-related complications. Mean initial thickness was 2.0 ± 0.8 mm. Patients had an average of 3.0 ± 0.9 risk factors for lesion growing; 3 patients (38 %) had lesion growth, 2 patients (25 %) had severe visual loss (greater than 1.0 logMAR) directly related to TTT treatment. There were no fatalities due to metastasis. The authors concluded that despite careful patient selection and systematic treatment with at least 3 TTT sessions, the use of primary TTT to treat patients with choroidal indeterminate melanocytic lesions with greater than or equal to 1 risk factor for lesion growth yielded poor local lesion control and the possibility for severe ocular complications.

Transpupillary Thermal Therapy for Choroidal Metastases

In a retrospective, interventional, non-comparative case-series study, Lin and Tsai (2015) examined the effects of TTT and intra-vitreal bevacizumab (IVB) on choroidal metastases and reviewed the literature. A retrospective, interventional, non-comparative case series of 5 eyes in 3 patients with choroidal metastases was conducted. Fundus findings of choroidal metastases were divided into 2 types: Solitary or diffuse type. The size of the tumor was termed small (less than 10 mm
diameter), medium (10 to 15 mm diameter) or large (greater than 15 mm diameter). The primary sites of carcinomas were breasts and lungs. All eyes received 1 session of TTT followed by 3 weekly IVB injections as an adjuvant therapy. The parameters of treatment for TTT were 1.2 to 3 mm spot size, 150 to 300 mW, 60 s with the whole lesion covered conflently. The changes in pre-operative and post-operative BCVA were recorded. Serial color fundus photography and OCT were performed to measure the treatment efficacy. All 8 choroidal metastases were solitary type. The size of 6 tumors was small, the size of 1 tumor was medium, and the size of 1 tumor was large. All 5 eyes of the 3 patients had improvement of BCVA after treatment. Fundus photos revealed tumor shrinkage and the mean shrinkage percentage was 61.27 ± 21.71 %. Optical coherence tomography revealed complete resolution of serous retinal detachment. There was no recurrence after 6 months follow-up. The authors concluded that TTT combined with IVB injections brought about beneficial effects in reducing tumor size and improving vision in all 5 eyes of the 3 patients. Despite the retrospective nature of our study, the absence of control group and the size limitation that, of course, limited the statistical power, TTT combined with IVB appeared to be efficient in providing another cost-reducing and time-saving treatment option for patients with choroidal metastases. They stated that the anti-neoplastic properties of bevacizumab make it a viable adjunctive therapy; studies with more cases and a longer follow-up period are needed.

CPT Codes / HCPCS Codes / ICD-10 Codes

Information in the [brackets] below has been added for clarification purposes. Codes requiring a 7th character are represented by "+":

<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Other CPT codes related to the CPB:
<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>67039</td>
<td>Vitrectomy, mechanical, pars plana approach; with focal endolaser photocoagulation</td>
</tr>
<tr>
<td>67040</td>
<td>with endolaser panretinal photocoagulation</td>
</tr>
<tr>
<td>67210</td>
<td>Destruction of localized lesion of retina (e.g., macular edema, tumors), one or more sessions; photocoagulation</td>
</tr>
<tr>
<td>67218</td>
<td>radiation by implantation of source (includes removal of source)</td>
</tr>
<tr>
<td>67220</td>
<td>Destruction of localized lesion of choroid (e.g., choroidal neovascularization); photocoagulation (e.g., laser), one or more sessions</td>
</tr>
<tr>
<td>67227</td>
<td>Destruction of extensive or progressive retinopathy (e.g., diabetic retinopathy), cryotherapy, diathermy</td>
</tr>
<tr>
<td>67228</td>
<td>Treatment of extensive or progressive retinopathy (e.g., diabetic retinopathy), photocoagulation</td>
</tr>
<tr>
<td>67229</td>
<td>preterm infant (less than 37 weeks gestation at birth), performed from birth up to 1 year of age (e.g., retinopathy of prematurity), photocoagulation or cryotherapy</td>
</tr>
</tbody>
</table>

ICD-10 codes covered if selection criteria are met:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>C69.20 - C69.22</td>
<td>Malignant neoplasm of retina</td>
</tr>
<tr>
<td>C69.30 - C69.32</td>
<td>Malignant neoplasm of choroid</td>
</tr>
</tbody>
</table>

ICD-10 codes not covered for indications listed in the CPB (not all-inclusive):

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>C79.49</td>
<td>Secondary malignant neoplasm of other parts of nervous system [choroidal metastases]</td>
</tr>
</tbody>
</table>
The above policy is based on the following references:


5. Reichel E, Berrocal AM, Ip M, et al. Transpupillary thermotherapy of occult subfoveal choroidal neovascularization in patients with age-related...


53. Shah PK, Narendran V, Kalpana N. Large spot transpupillary thermotherapy: A quicker laser for treatment of high risk prethreshold retinopathy of...


AETNA BETTER HEALTH® OF PENNSYLVANIA

Amendment to
Aetna Clinical Policy Bulletin Number: 0490 Transpupillary Thermal Therapy

There are no amendments for Medicaid.