Medical Policy

Section
Miscellaneous Policies

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Description

Photocoagulation describes the use of focused laser energy to treat disease. Laser photocoagulation of macular drusen has been evaluated as a method of slowing progression to advanced age-related macular degeneration (AMD).

Age-related macular degeneration (AMD) is a painless, insidious process. In its earliest stages, it is characterized by minimal visual impairment and the presence of large or "soft" drusen, i.e., subretinal accumulations of cellular debris adjacent to the basement membrane of the retinal pigment epithelium.

Large drusen appear as large, pale yellow or pale gray domed elevations and result in thickening of the space between the retinal pigment epithelium and its blood supply, the choriocapillaris. Clinical and epidemiologic studies have shown that the presence of large and/or numerous soft drusen is associated with an increased risk of the development of choroidal neovascularization (CNV) in eyes with AMD. For example, in patients with bilateral drusen, the 3-year risk of developing CNV is estimated to be 13%, rising to 18% for those over the age of 65 years. The emergence of CNV greatly increases the risk of subsequent irreversible loss of vision.

Two different kinds of low energy laser therapies, argon and infrared laser, have been investigated as techniques to eliminate drusen by photocoagulation in an effort to prevent the evolution to CNV, ultimately leading to improved preservation of vision. The lasers used are those that are widely used for standard photocoagulation of extrafoveal CNV. Therefore, the treatment of macular drusen represents an additional indication for an existing laser approved by the U.S. Food and Drug Administration (FDA).

Policy

Destruction of macular drusen with laser therapy is considered not medically necessary.
Policy Guidelines

During 2002-2010, there was a CPT category III code that specifically identified laser therapy of macular drusen:

0017T: Destruction of macular drusen, photocoagulation

Code 0017T was discontinued at the end of 2010. CPT instructs that the unlisted code 67299 should now be used for this procedure.

Rationale

While studies have shown that laser therapy can induce regression of drusen, not only at the treatment site, but also at sites remote from the laser, (1-3) outcomes of greatest interest are preventing vision loss from atrophy and choroidal neovascularization (CNV). Unfortunately, the biologic rationale has not translated into patient benefit, as demonstrated in multiple trials.

Following initially optimistic results (1) Figueroa and colleagues updated follow-up in 46 patients with confluent soft drusen. (4) A total of 30 patients with bilateral drusen were randomized to receive argon green laser therapy in 1 eye. The remaining 16 patients had CNV in one eye and laser therapy performed on the other eye. Although laser therapy resulted in resolution of the drusen, after 3 years there was no difference between the groups regarding development of CNV.

The Choroidal Neovascular Prevention Trial (CNVPT) randomized eyes with exudative AMD in 1 eye and 10 or more large drusen in the other (Fellow Eye Study, 120 patients, 120 study eyes) or bilateral large drusen without exudative AMD (Bilateral Drusen Study, 156 patients, 312 study eyes) to receive argon green laser therapy or observation. (5) Due to an increased incidence of CNV in laser-treated eyes enrollment and treatment was suspended in December 1996. An earlier report excluding eyes developing CNV found eyes with 50% or more drusen reduction at 1 year had more increases in visual acuity compared to the control group. (6) An updated report from the Fellow Eye Study found no significant differences in visual acuity between photocoagulation or observation eyes during a 4-year follow-up. (7) In addition, the authors noted an increased risk of CNV in treated eyes treated early during follow-up (23% treated eyes vs. 5% observed at 1 year) but diminished over time (33% and 32% at 30 months, respectively. Higher intensity laser treatment was associated with greater risk of developing CNV.

The NEI-sponsored Complications of AMD Prevention Trial (CAPT) enrolled patients with bilateral large drusen (n = 1,052);1 eye assigned to low-intensity laser treatment and the other to observation. After 5 years, there were no differences between treated and observed eyes in worsening visual acuity (20.5% in both groups lost ≥ 3 ETDRS [Early Treatment of Diabetic Retinopathy Study] lines), development of CNV (13.3% in both groups) or geographic atrophy. (8)

A pilot study of infrared laser therapy (810 nm) enrolled 152 patients (229 eyes) who had either bilateral drusen or unilateral drusen if CNV was detected in the fellow eye. (9) Eyes were randomized to receive laser therapy or observation. While laser therapy was associated with resolution of drusen and improved visual acuity, the study was not powered to detect an effect
on progression to CNV. Based on these results the prophylactic treatment of AMD trial (PTAMD) followed 244 patients with CNV or advanced AMD in 1 eye and ≥ 5 drusen and no CNV in the fellow eye. (10) Treatment consisted of an extrafoveal grid of subthreshold 810-nm laser spots. Enrollment was halted after 47 months due to an excess of CNV in treated eyes. CNV occurred more often in treated eyes (15.8% vs. 1.4% at 1 year); there were no differences in moderate ( ≥ 3 ETDRS lines) visual loss after 6 months, with or without treatment.

The drusen laser study randomized patients with eyes at high risk for AMD. (11) Follow-up was completed over 3 years. A unilateral group (n =177) in the trial included patients with drusen in the study eye and CNV in the fellow eye; the bilateral group (n =105) had drusen in both eyes. The treatment protocol was revised and recruitment ultimately halted after 23 months due to concerns over laser-induced CNV in interim analyses. In the unilateral group, prophylactic laser treatment hastened the onset of CNV (29.7% vs. 17.7% observed, p =0.06) and was associated with worsening visual acuity. In the bilateral group, 3-year CNV incidence was 11.6% in laser-treated eyes versus 6.8% without treatment (p =0.22). In both groups, visual loss paralleled development of CNV.

In 2009, Friberg and colleagues from the Prophylactic Treatment of AMD study group reported 3-year outcomes from 639 participants (1,278 eyes). (12) Treatment consisted of the placement of an annular grid of 48 extrafoveal, subthreshold laser applications in one eye of each participant. Subthreshold laser treatment did not decrease the incidence of CNV in comparison with the other (fellow) eye. A very slight benefit in visual acuity (1.5 letter difference) was found at 24 months, but this effect was not sustained at 3 years. The authors concluded that a single subthreshold 810-nanometer laser treatment to eyes of participants with drusen is not an effective prophylactic strategy against CNV.

A Cochrane review on laser treatment of drusen to prevent progression to advanced AMD was published in 2009. (13) Nine randomized studies with a total of 2,216 patients were included in the systematic review. Two of the studies reported significant drusen disappearance at 2 years, but photocoagulation did not appear to affect the development of CNV at 2 years' follow-up. The authors concluded that the trials confirmed the clinical observation that laser photocoagulation of drusen leads to their disappearance. However, there is no evidence that this reduces the risk of developing CNV, geographic atrophy, or visual acuity loss.

Summary

Evidence from multiple trials indicates that drusen ablation does not prevent visual loss, CNV, or AMD. Furthermore, the evidence from trials indicates that drusen ablation may be accompanied by harm. The literature indicates that photocoagulation of macular drusen procedure is not clinically appropriate; this approach is considered not medically necessary.

Technology Assessments, Guidelines and Position Statements

Preferred Practice Patterns (practice guidelines) on photodynamic therapy from the American Academy of Ophthalmology (AAO) recommend regular dilated eye exams for the early detection of the intermediate stage of AMD and possible treatment with antioxidants and minerals for patients who have progressed to intermediate or advanced AMD in 1 eye. (14) No recommendations were made regarding photocoagulation of macular drusen. The guidelines state that “patients with intermediate AMD who are at increased risk of visual loss or of progression to advanced AMD should be educated about methods of detecting new symptoms
of CNV and about the need for prompt notification to an ophthalmologist who can confirm if the new symptoms are from CNV and who can begin treatment if indicated."

**Medicare National Coverage**
No national coverage determination

**References:**


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<th>Codes</th>
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</tbody>
</table>

Type of Service: Vision  
Place of Service: Outpatient

Index

Drusen, Laser Therapy  
Laser Therapy, Macular Drusen  
Macular Drusen Destruction  
Photocoagulation, Macular Drusen