Name of Policy:
Photocoagulation of Macular Drusen

Policy #: 197
Category: Surgery
Latest Review Date: May 2011
Policy Grade: Active Policy but no longer scheduled for regular literature reviews and updates.

Background/Definitions:
As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:
1. The technology must have final approval from the appropriate government regulatory bodies;
2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;
3. The technology must improve the net health outcome;
4. The technology must be as beneficial as any established alternatives;
5. The improvement must be attainable outside the investigational setting.

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. In accordance with generally accepted standards of medical practice; and
2. Clinically appropriate in terms of type, frequency, extent and duration and considered effective for the patient’s illness, injury or disease; and
3. Not primarily for the convenience of the patient, physician or other health care provider; and
4. Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient’s illness, injury or disease.
**Description of Procedure or Service:**
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 increase the 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. 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 choroidal neovascularization. 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 does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered not medically necessary.

*Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the members' contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.*

**Key Points:**
A variety of 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. However, the results of existing trials regarding the outcome of greatest interest, severe vision loss from atrophy and CNV, are still inconclusive. Figueroa and colleagues reported on a group of 46 patients with confluent soft drusen. A total of 30 patients with bilateral drusen were randomized to receive argon green laser therapy in 1 eye. The remaining 16 patients had choroidal neovascularization in 1 eye and laser therapy was 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) consisted of a randomized trial of 351 eyes with unilateral or bilateral drusen that were randomized to receive green argon laser therapy or observation. Laser-treated eyes with 50% or more drusen reduction at 1 year had more increases in visual acuity compared to the control group. However, short-term visual acuity is an intermediate outcome. A subsequent analysis suggested that there was an increased incidence of CNV development in the laser-treated eyes in patients with CNV in the fellow eye.

Subsequently, these patients were excluded from the trial. The trial continued, renamed as the Complications of AMD Prevention Trial (CAPT), and enrolled only those patients with bilateral drusen; 1 eye is assigned to laser treatment and the other receives no treatment. The recruitment of 1,052 patients at 23 clinical centers across the United States has been completed. Patients will be followed up for 5 years, focusing on changes in visual acuity and complications of AMD. (CAPT Web site available at http://www.vitreoussociety.org/capt/frames/homefr.htm or http://www.nei.nih.gov/neitrials/static/study70.htm.)

An initial randomized pilot study of infrared laser therapy enrolled 152 patients (229 eyes) who had either bilateral drusen or unilateral drusen if CNV was detected in the fellow eye. The eyes were randomized to receive infrared 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 choroidal neovascularization. The ongoing Prophylactic Treatment of AMD trial (PTAMD), based on the results of the initial pilot study, is designed to determine whether infrared laser therapy can decrease or at least delay the development of CNV and the associated severe visual loss. The PTAMD trial is in its third year of recruitment and will follow up study patients for 5 years. (PTAMD Web site available at http://www.eyesight.org/Research/Research-PTAMD/research-ptamd.html).

Definitive data regarding the role of laser therapy as a prophylactic treatment to prevent progression to CNV must await the completion of the cited trials. While the currently available results suggest some short-term improvement in visual acuity, the outcome of greatest interest is the reduction of severe vision loss from atrophy and CNV. Long-term results are also important to evaluate safety issues. Laser therapy can damage the retinal pigment epithelium and photoreceptors, and it is unknown whether the short-term improvement in visual acuity may be counterbalanced by a more rapid progression of visual loss if and when CNV occurs.

**August 2008 Update**

Preferred Practice Patterns 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. 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.” The literature indicates that photocoagulation of macular drusen procedure is not clinically appropriate; the policy statement is unchanged.
August 2010 Update
As a follow-up to 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. 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 of high risk for AMD. 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 three-year outcomes from 639 participants (1278 eyes). 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 three 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. 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.

Based on the above information, the policy statement remains unchanged.

Key Words:
Age-related macular degeneration (AMD), drusen, photocoagulation,

Approved by Governing Bodies:
The treatment of macular drusen represents an additional indication for an existing laser approved by the U.S. Food and Drug Administration (FDA). The lasers used are those that are
widely used for standard photocoagulation of extrafoveal choroidal neovascularization, the argon and infrared lasers.

**Benefit Application:**
Coverage is subject to member’s specific benefits. Group specific policy will supersede this policy when applicable.

ITS: Home Policy provisions apply
FEP contracts: FEP does not consider investigational. Will be reviewed for medical necessity
Pre-certification/Pre-determination requirements: Not applicable

**CURRENT Coding:**
**Effective for dates of service on or after January 1, 2011:**

67299 Unlisted procedure, posterior segment.

**PREVIOUS Coding:**
HCPCS: 0017T Destruction of macular drusen, photocoagulation

**References:**

**Policy History:**
Medical Policy Group, August 2004 (4)
Medical Policy Administration Committee, August 2004
Available for comment August 24-October 7, 2004
Medical Policy Group, August 2006 (1)
Medical Policy Group, August 2008 (1)
Medical Policy Group, August 2010 (1) Key Points updated, Changed policy statement to “not medically necessary” previously investigational.
Medical Policy Administration Committee, July 2010
Medical Policy Group, December 2010; 2011 Code updates
Medical Policy Panel, May 2011
Medical Policy Group, May 2011 (2) Key Points updated
Medical Policy Group, May 31, 2011: Active Policy but no longer scheduled for regular literature reviews and updates.

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member’s plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield’s administration of plan contracts.