



Louisiana

Photocoagulation of Macular Drusen

Policy # 00096

Original Effective Date: 06/05/2002

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Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the “Company”), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers destruction of macular drusen with laser therapy to be **investigational**.*

Background/Overview

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 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 increases 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 years. The emergence of CNV greatly increases the risk of subsequent irreversible loss of vision.

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FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

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 FDA.

Centers for Medicare and Medicaid Services (CMS)

There is no national coverage determination.

Rationale/Source

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, outcomes of greatest interest are preventing vision loss from atrophy and CNV. Unfortunately, the biologic rationale has not translated into patient benefit, as demonstrated in multiple trials.

Following initially optimistic results Figueroa and colleagues updated follow-up in 46 patients with confluent soft drusen. A total of 30 patients with bilateral drusen were randomized to receive argon green laser therapy in one 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 three years there was no difference between the groups regarding development of CNV.

The Choroidal Neovascular Prevention Trial (CNVPT) randomized eyes with exudative AMD in one 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. 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 one year had more increases in visual acuity compared to the control group. An updated report from the Fellow Eye Study found no significant differences in visual acuity between photocoagulation or observation

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eyes during a 4-year follow-up. In addition, the authors noted an increased risk of CNV in eyes treated early during follow-up (23% treated eyes vs. 5% observed at one 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 National Eye Institute-sponsored Complications of AMD Prevention Trial (CAPT) enrolled patients with bilateral large drusen (n=1,052); one eye assigned to low-intensity laser treatment and the other to observation. After five 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.

A pilot study of infrared laser therapy (810nm) enrolled 152 patients (229 eyes) who had either bilateral drusen or unilateral drusen if CNV was detected in the fellow eye. 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 one 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. Choroidal neovascularization occurred more often in treated eyes (15.8% vs. 1.4% at one year); there were no differences in moderate (≥ 3 ETDRS lines) visual loss after six months, with or without treatment.

The drusen laser study randomized patients with eyes at high risk for AMD. Follow-up was completed over three 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.

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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 two years, but photocoagulation did not appear to affect the development of CNV at two 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.

Supplemental Information

In 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. Given these findings, this approach is considered to be investigational.

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Policy History

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- 05/16/2002 Medical Policy Committee review
- 06/05/2002 Managed Care Advisory Council approval
- 06/24/2002 Format revision. No substance change to policy.
- 06/01/2004 Medical Director review
- 06/15/2004 Medical Policy Committee review
- 06/28/2004 Managed Care Advisory Council approval

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06/07/2006 Medical Director review
06/21/2006 Medical Policy Committee approval. Format revision including addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged.
06/04/2008 Medical Director review
06/18/2008 Medical Policy Committee approval. No change to coverage eligibility.
06/04/2009 Medical Director review
06/17/2009 Medical Policy Committee approval. No change to coverage eligibility.
06/03/2010 Medical Policy Committee approval
06/16/2010 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/31/2010 Coding updated
06/02/2011 Medical Policy Committee review
06/15/2011 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/14/2012 Medical Policy Committee review
06/20/2012 Medical Policy Implementation Committee approval. Coverage eligibility unchanged. Archived
02/07/2019 Medical Policy Committee review
02/20/2019 Medical Policy Implementation Committee approval. Brought back to active status.
02/06/2020 Medical Policy Committee review
02/12/2020 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 02/2021

Coding

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	67220, 67225, 67299
HCPCS	No codes
ICD-10 Diagnosis	H35.361-H35.369

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or

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- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 3. Reference to federal regulations.

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