CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all health benefit plans administered by CIGNA Companies including plans formerly administered by Great-West Healthcare, which is now a part of CIGNA.

Subject **Photocoagulation Laser Treatment of Macular Drusen**

Effective Date 4/15/2011
Next Review Date 4/15/2012
Coverage Policy Number 0319

Table of Contents

Hyperlink to Related Coverage Policies

Artificial Retinal Devices
Bevacizumab (Avastin®)
Photodynamic Therapy for Ocular Conditions
Proton Beam Therapy for Ocular Melanoma, Ocular Hemangiomas and Macular Degeneration
Transpupillary Thermal Therapy (TTT)

INSTRUCTIONS FOR USE

*Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement (GSA), Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document **always supercedes** the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines.*

Coverage Policy

CIGNA does not cover photocoagulation laser therapy for the destruction of macular drusen because it is considered experimental, investigational or unproven.

General Background

Age-related macular degeneration (ARMD) is one of the leading causes of visual impairment and blindness in the United States. There are two forms of macular degeneration: dry and wet. Most cases of ARMD are the dry or non-exudative form, distinguished by yellowish deposits of debris called "drusen" in the retina. "Hard" drusen are found in aging eyes and do not necessarily lead to ARMD. Irregular and ill-defined "soft" drusen, however, have been associated with progression of the disease. Approximately 10–15% of ARMD cases are the wet, or exudative, form; however, this form accounts for the majority of cases with severe vision loss. Wet ARMD, also known as choroidal neovascularization (CNV), is considered advanced ARMD. It is characterized by the development of abnormal blood vessels called choroidal neovascular membranes, which leak serum and blood under the retina. It is thought that an increase in the size or number of drusen increases the risk of developing either advanced or wet ARMD (National Eye Institute [NEI], 2008).

The vascular endothelial growth factor (VEGF) inhibitors have become the first-line therapy for treating neovascular ARMD (American Academy of Ophthalmology [AAO], 2008). Other treatments for advanced ARMD

include antioxidant and zinc formulations, photodynamic therapy (PDT), transpupillary thermotherapy (TTT) and laser photocoagulation.

Laser photocoagulation utilizes a concentrated, high-intensity laser beam that destroys the abnormal blood vessels to prevent further vision loss. Argon and infrared lasers have been used in the treatment of ARMD. Laser photocoagulation is the preferred treatment method for extra-foveal CNV. Although laser therapy is known to damage the macula and cause some loss of vision, this treatment usually results in better outcomes for patients with extra-foveal CNV than if no treatment were administered.

Due to the correlation between larger drusen and advanced ARMD, a focus of investigators has been to find an effective prophylactic treatment that could prevent the progression of dry ARMD. Laser photocoagulation has been proposed for the treatment of macular drusen.

Literature Review: In a Cochrane review and meta-analysis of nine randomized controlled trials (RCTs) (n=2216), Parodi et al. (2009) examined the effectiveness and adverse effects of laser photocoagulation of drusen in ARMD. Laser treatment was compared to no intervention or sham treatment. Although two of the studies reported significant drusen disappearance at two years, photocoagulation did not appear to affect the development of CNV at two years follow up (Parodi, et al., 2009).

Evidence evaluating the safety and efficacy of laser photocoagulation used to treat macular drusen exists in the form of RCTs (n=50─1052) and a meta-analysis (Parodi, et al., 2009; Friberg, et al. 2006; Complications of AMD Prevention Trial [CAPT] Research Group, 2006; Owens, et al., 2006; Choroidal Neovascularization Prevention Trial [CNVPT] Research Group, 2003; Rodanant, et al., 2002). Some RCTs have reported drusen reduction of approximately 50% after laser treatment (Friberg, et al. 2006; CAPT Research Group, 2006; Rodanant, et al., 2002). Improvement in visual acuity with laser photocoagulation of drusen has also been reported (Olk, et al., 1999). However, studies have failed to demonstrate that these outcomes result in risk-reduction for the development of ARMD. In addition, some study results suggest that laser treatment may accelerate the onset of CNV.

Professional Societies/Organizations
According to the NEI, laser surgery may be used to destroy the fragile, leaky blood vessels associated with wet AMD in a small percentage of individuals. However, laser treatment may also destroy some surrounding healthy tissue and some vision. Laser therapy is not discussed as a treatment for macular drusen that would prevent the progression from dry or intermediate stages to wet ARMD (NEI, 2010).

Summary
The role of laser therapy as a prophylactic treatment to prevent the progression of age-related macular degeneration (ARMD) is unclear at present. The currently available data show photocoagulation laser to be effective in reducing drusen and there is some indication that short-term visual improvement may occur after prophylactic treatment. However, questions remain regarding the long-term impact of this therapy on vision function and the development of choroidal neovascularization (CNV). Based on the lack of supportive evidence in the scientific literature, photocoagulation laser treatment of macular drusen remains unproven at this time.

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

Experimental/Investigational/Unproven/Not Covered:

CPT* Codes	Description
67299	Unlisted procedure, posterior segment
0017T	Destruction of macular drusen, photocoagulation (code deleted 1/1/2011)

ICD-9-CM Diagnosis Codes	Description

362.57	Drusen (degenerative) of retina

References

1. American Academy of Ophthalmology (AAO). Preferred Practice Pattern® (PPP) guidelines. Age-Related Macular Degeneration. Sep 2008. Accessed Mar 2, 2010. Available at URL address: http://one.aao.org/asset.axd?id=29a3f5f4-afa1-41ea-bbc5-0bb01ff1fc9c

2. Bylsma GW, Guymer RH. Treatment of age-related macular degeneration. Clin Exp Optom. 2005 Sep;88(5):322-34.

3. Choroidal Neovascularization Prevention Trial Research Group. Laser treatment in fellow eyes with large drusen: updated findings from a pilot randomized clinical trial. Ophthalmology. 2003 May;110(5):971-8.

4. Complications of Age-Related Macular Degeneration Prevention Trial Research Group. Laser treatment in patients with bilateral large drusen: the complications of age-related macular degeneration prevention trial. Ophthalmology. 2006 Nov;113(11):1974-86.

5. Friberg TR, Musch DC, Lim JI, Morse L, Freeman W, Sinclair S; et al. Prophylactic treatment of age-related macular degeneration report number 1: 810-nanometer laser to eyes with drusen. Unilaterally eligible patients. Ophthalmology. 2006 Apr;113(4):622.e1.

6. Jager RD, Mieler WF, Miller JW. Age-related macular degeneration. N Engl J Med. 2008 Jun 12;358(24):2606-17.

7. National Eye Institute (NEI). Complications of Age-Related Macular Degeneration Prevention Trial (CAPT). Clinical studies database. Accessed Mar 3, 2005. Available at URL address: http://www.nei.nih.gov/neitrials/viewStudyWeb.aspx?id=70

8. National Eye Institute (NEI). Facts About Age-Related Macular Degeneration. Modified 2010 Aug. Accessed Mar 2, 2011. Available at URL address: http://www.nei.nih.gov/health/maculardegen/armd_facts.asp

9. Owens SL, Bunce C, Brannon AJ, Xing W, Chisholm IH, Gross M, et al. Prophylactic laser treatment hastens choroidal neovascularization in unilateral age-related maculopathy: final results of the drusen laser study. Am J Ophthalmol. 2006 Feb;141(2):276-81.

10. Owens SL, Bunce C, Brannon AJ, Wormald R, Bird AC; Drusen Laser Study Group. Prophylactic laser treatment appears to promote choroidal neovascularisation in high-risk ARM: results of an interim analysis. Eye. 2003 Jul;17(5):623-7.

11. Parodi MB, Virgili G, Evans JR. Laser treatment of drusen to prevent progression to advanced age-related macular degeneration. Cochrane Database Syst Rev. 2009 Jul 8;(3):CD006537

12. Rodanant N, Friberg TR, Cheng L, Aurora A, Bartsch D, Toyoguchi M, et al. Predictors of drusen reduction after subthreshold infrared (810 nm) diode laser macular grid photocoagulation for nonexudative age-related macular degeneration. Am J Ophthalmol. 2002 Oct;134(4):577-85.

13. Virgili G, Bini A. Laser photocoagulation for neovascular age-related macular degeneration. Cochrane Database Syst Rev. 2007 Jul 18;(3):CD004763.

Policy History

Pre-Merger Organizations	Last Review Date	Policy Number	Title
CIGNA HealthCare	4/15/2008	0319	Photocoagulation Laser Treatment of Macular Drusen