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Subject: Photocoagulation of Macular Drusen

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Position Statement	Billing/Coding	Reimbursement	Program Exceptions	Definitions	Related Guidelines
Other	References	Updates			

DESCRIPTION:

Drusen are yellow deposits under the retina, composed of lipids and proteins. Small drusen may not cause vision problems for a long time, if at all. Larger drusen increase the risk for advanced AMD, which can result in vision loss.

Drusen can also occur in the optic nerve. These drusen are composed of protein and calcium salts and generally appear in both eyes. Unlike the drusen associated with AMD, optic nerve drusen (also known as optic disc drusen) are not related to aging and often appear in children. Optic nerve drusen usually do not affect vision, but some of those with these drusen may lose peripheral vision.

Summary and Analysis of Evidence: Virgili et al (2015) examined the effectiveness and adverse effects of laser photocoagulation of drusen in ARMD. The authors conducted a literature search through August 2015. Selection criteria included randomised controlled trials (RCTs) of laser treatment of drusen in AMD in which laser treatment had been compared with no intervention or sham treatment. Two types of trials were included. Some trials studied one eye of each participant (unilateral studies); other studies recruited participants with bilateral drusen and randomised one eye to photocoagulation or control and the fellow eye to the other group. Photocoagulation did not reduce the development of CNV at two years' follow-up. This estimate means that, given an overall occurrence of CNV of 8.3% in the control group, the authors estimated an absolute risk reduction by no more than 1.4% in the laser group, according to the lower CI limit. Only two studies investigated the effect on the development of geographic atrophy and could not show a difference, but estimates were imprecise. Among secondary outcomes, photocoagulation led to drusen reduction but was not shown to limit loss of 3 or more lines of visual acuity. In a subgroup analysis, no difference could be shown for conventional visible (eight studies) versus subthreshold invisible (four studies) photocoagulation for the primary outcomes. The effect in the subthreshold group did not suggest a relevant benefit. No study used micropulse

subthreshold photocoagulation. No other adverse effects (apart from development of CNV, geographic atrophy or visual loss) were reported. The authors concluded their review confirmed “the clinical observation that laser photocoagulation of drusen leads to their disappearance. However, treatment does not result in a reduction in the risk of developing CNV, and was not shown to limit the occurrence of geographic atrophy or visual acuity loss. Ongoing studies are being conducted to assess whether the use of extremely short laser pulses (i.e. nanosecond laser treatment) cannot only lead to drusen regression but also prevent neovascular AMD.” Lenassi et al (2013) conducted a prospective, interventional case series to assess whether laser treatment to the retinal pigment epithelium anterior to drusen in eyes of patients with EFEMP1-related maculopathy affects visual acuity, deposit volume, and retinal sensitivity. In 11 patients with autosomal dominant drusen and confirmed disease-causing EFEMP1 mutation, the worse-seeing eye was treated with Argon green laser. Patients were examined before treatment as well as 1, 3, 6, and 12 months after the procedure. Clinical assessment included visual acuity, fundus-controlled perimetry, spectral-domain optical coherence tomography, and autofluorescence imaging. Custom-made software allowed for coregistration of fundus-controlled perimetry and spectral-domain optical coherence tomography data sets. The main outcome measures were change in visual acuity, retinal sensitivity, and drusen volume. The untreated eyes lost an average of 0.8 letters, whereas the treated eyes gained an average of 4.9 letters. For fundus-controlled perimetry, locus-by-locus differences in sensitivity were calculated between pretreatment and posttreatment assessments; subsequently, the overall difference in the treated and untreated eye was compared. Five patients showed significant improvement in retinal sensitivity, 5 patients showed no change, and 1 patient showed significant deterioration. An increase in mean drusen thickness was observed in the untreated eyes, but not in the treated eyes. The thickness of the drusen correlated with retinal sensitivity. Safety was demonstrated and no adverse events were observed. The authors concluded “low-energy laser treatment is safe and may be effective in the treatment of autosomal dominant drusen. Further evaluation with long-term assessment is required to confirm the benefits.” Huang et al (2011) prospectively evaluated the efficacy and safety of prophylactic laser treatment in Chinese patients with bilateral soft drusen, examining the structure and function of the macula 8 years after treatment. Ten patients with more than 10 soft drusen ($> 125 \mu\text{m}$) and best corrected visual acuity $\geq 20/25$ in each eye participated in the study. One eye, with relatively more drusen, was exposed to an argon laser (514 nm) to achieve a barely visible retinal lesion. The contralateral eye was used as a control. Fluorescein angiography, Amsler tests, Fourier-domain optical coherence tomography and visual evoked potential tests were carried out 8 years later. No choroidal neovascularization was seen in the laser-treated eyes or control eyes. There were no significant differences in visual acuity or P100 latency and amplitude between the laser treated eyes and contralateral eyes. The thickness of the retinal pigment epithelium of the treated eyes was less than that of the contralateral eyes. The full retinal thickness in treated eyes was slightly, but insignificantly, reduced relative to contralateral eyes. The authors concluded “the treatment was associated with a reduction in retinal pigment epithelium thickness elevation compared with the contralateral eyes. Macular function was not impaired.” Mojana et al (2011) studied the long-term effect of subthreshold diode laser treatment for drusen in patients with nonexudative age-related macular degeneration with spectral domain optical coherence tomography combined with simultaneous scanning laser ophthalmoscope. Eight eyes of four consecutive age-related macular degeneration patients with bilateral drusen previously treated with subthreshold diode laser were imaged with spectral domain optical coherence tomography/scanning laser ophthalmoscope. Abnormalities in the outer retinal layers' reflectivity as seen with spectral domain

optical coherence tomography/scanning laser ophthalmoscope were retrospectively analyzed and compared with color fundus pictures, and autofluorescence images were acquired immediately before and after the laser treatment. The authors found a focal discrete disruption in the reflectivity of the outer retinal layers in 29% of the laser lesions. The junction in between the inner and outer segment of the photoreceptor was more frequently affected, with associated focal damage of the outer nuclear layer. Defects of the retinal pigment epithelium were occasionally detected. These changes did not correspond to threshold burns on color fundus photography but corresponded to focal areas of increased autofluorescence in the majority of the cases. The authors concluded “(s)ubthreshold diode laser treatment causes long-term disruption of the retinal photoreceptor layer as analyzed by spectral domain optical coherence tomography/scanning laser ophthalmoscope. The concept that subthreshold laser treatment can achieve a selected retinal pigment epithelium effect without damage to rods and cones may be flawed.”

POSITION STATEMENT:

Laser photocoagulation of macular drusen for the prevention or treatment of age-related macular degeneration is considered **experimental or investigational**. Data in published medical literature are inadequate to permit scientific conclusions on long-term and net health outcomes.

BILLING/CODING INFORMATION:

There is no specific CPT or HCPCS code to report photocoagulation of macular drusen.

REIMBURSEMENT INFORMATION:

Refer to section entitled [POSITION STATEMENT](#).

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage products: No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) were found at the time of the last guideline review date.

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at [Coverage Protocol Exemption Request](#).

DEFINITIONS:

No guideline specific definitions apply.

RELATED GUIDELINES:

[Verteporfin \(Visudyne™\) Injection, 09-J1000-72](#)

OTHER:

None applicable.

REFERENCES:

1. American Academy of Ophthalmology. EyeSmart®: What are Drusen? Accessed at <https://www.aao.org/eye-health/diseases/what-are-drusen>.
2. Blue Cross Blue Shield Association Evidence Positioning System®. 9.03.11 - Photocoagulation of Macular Drusen (ARCHIVED 05/11).
3. Blue Cross Blue Shield TEC Special Report: Current and Evolving Strategies in the Treatment of Age-Related Macular Degeneration, Vol. 20 No. 11, 01/06.
4. ClinicalTrials.gov. Complications of Age-Related Macular Degeneration Prevention Trial (CAPT), 2006.
5. 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; 113(11): 1974-1986.
6. Findlay Q, Jobling AI, et al. Prophylactic laser in age-related macular degeneration: the past, the present and the future. *Eye (Lond)*. 2018 May;32(5):972-980. doi: 10.1038/s41433-018-0035-1. Epub 2018 Mar 9.
7. First Coast Service Options, Inc. (FCSO) Local Coverage Determination Noncovered Services (L29288), 02/02/09. (Retired 09/30/15).
8. First Coast Service Options, Inc. (FCSO). Local Coverage Determination (LCD): Noncovered Services (L33777) (10/01/15) (Retired 07/01/20).
9. Folk JC, Russell SR. Can Laser Photocoagulation of Eyes with High-Risk Drusen Prevent Vision Loss From Age-Related Macular Degeneration? *Ophthalmology* 1999; 106(7): 1241-1242 [Editorial].
10. Food & Drug Administration, Health & Human Services News Release, FDA Approves Treatment For Wet Macular Degeneration, 04/13/00.
11. Friberg TR. Prophylactic Treatment of Drusen in AMD. *Review of Ophthalmology*: October 2001. Accessed 02/06/07.
12. Guymer RH, Wu Z, Hodgson LAB, et al. Laser Intervention in Early Stages of Age-Related Macular Degeneration Study Group. Subthreshold Nanosecond Laser Intervention in Age-Related Macular Degeneration: The LEAD Randomized Controlled Clinical Trial. *Ophthalmology*. 2019 Jun;126(6):829-838. doi: 10.1016/j.ophtha.2018.09.015. Epub 2018 Sep 20.
13. Hayes Technology Brief. Laser Photocoagulation of Macular Drusen as a Prophylaxis Against Progression of Age-Related Macular Degeneration (12/31/07).
14. Huang YX, Xiang LN, Wang YL, Li MM, Hu YX. Long-term effect of prophylactic laser treatment for bilateral soft drusen. *Chin Med J (Engl)*. 2011 Feb;124(4):541-5.
15. Jobling AI, Guymer RH, et al. Nanosecond laser therapy reverses pathologic and molecular changes in age-related macular degeneration without retinal damage. *FASEB J*. 2015 Feb;29(2):696-710. doi: 10.1096/fj.14-262444. Epub 2014 Nov 12. PMID: 25392267 DOI: 10.1096/fj.14-262444.
16. Kim MS, Ryoo NK, Park KH. Laser and anti-vascular endothelial growth factor treatment for drusenoid pigment epithelial detachment in age-related macular degeneration. *Sci Rep*. 2020 Sep 1;10(1):14370. doi: 10.1038/s41598-020-71401-3.
17. Laser Treatment in Fellow Eyes with Large Drusen: Updated Findings from a Pilot Randomized Clinical Trial. *Ophthalmology*. 2003; 110 (5): 971-978.

18. Lenassi E, Troeger E, Wilke R, Tufail A, Hawlina M, Jeffery G, Webster AR. Laser clearance of drusen deposit in patients with autosomal dominant drusen (p.Arg345Trp in EFEMP1). *Am J Ophthalmol.* 2013 Jan;155(1):190-8. doi: 10.1016/j.ajo.2012.07.003. Epub 2012 Oct 2. PMID: 23036572.
19. Mojana F, Brar M, Cheng L, Bartsch DU, Freeman WR. Long-term SD-OCT/SLO imaging of neuroretina and retinal pigment epithelium after subthreshold infrared laser treatment of drusen. *Retina.* 2011 Feb;31(2):235-42. doi: 10.1097/IAE.0b013e3181ec80ad.
20. Nashine S. Potential Therapeutic Candidates for Age-Related Macular Degeneration (AMD). *Cells.* 2021 Sep 19;10(9):2483. doi: 10.3390/cells10092483.
21. National Eye Institute-Age-Related Macular Degeneration, 04/06. Updated 09/09.
22. National Institute for Health and Care Excellence (NICE). NICE guideline [NG82]: Age-related macular degeneration (January 2018). Accessed at <https://www.nice.org.uk/>.
23. Nguyen V, Barthelmes D, Gillies MC. Neovascular age-related macular degeneration: A review of findings from the real-world Fight Retinal Blindness! registry. *Clin Exp Ophthalmol.* 2021 Sep;49(7):652-663. doi: 10.1111/ceo.13949. Epub 2021 Jun 21.
24. Owens SL, Bunce C, Brannon AJ et al. Prophylactic Laser Treatment Hastens Choroidal Neovascularization in Unilateral Age-Related Maculopathy: Final Results of the Drusen Laser Study. *American Journal of Ophthalmology* 2006; 141(2): 276-281.
25. Querques G, Cicinelli MV, et al. Laser photocoagulation as treatment of non-exudative age-related macular degeneration: state-of-the-art and future perspectives. *Graefes Arch Clin Exp Ophthalmol.* 2018 Jan;256(1):1-9. doi: 10.1007/s00417-017-3848-x. Epub 2017 Nov 25. PMID: 29177712 DOI: 10.1007/s00417-017-3848-x.
26. UpToDate. Age-related macular degeneration: Treatment and prevention. 2024. Accessed at [uptodate.com](https://www.uptodate.com).
27. Virgili G, Michelessi M, et al. Laser treatment of drusen to prevent progression to advanced age-related macular degeneration. *Cochrane Database Syst Rev.* 2015 Oct 23;(10):CD006537. doi: 10.1002/14651858.CD006537.pub3.

COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 10/24/24.

GUIDELINE UPDATE INFORMATION:

04/15/02	New Medical Coverage Guideline.
05/15/03	Annual review.
05/15/04	Changed guideline number from 01-91000-21 to 01-92000-21.
06/15/04	Scheduled review, no changes.
03/15/05	Scheduled review, no change in coverage statement.
03/15/06	Added information regarding the treatment of macular drusen with an U.S. FDA approved laser to the description section. Added Laser Photocoagulation of Drusen to other section. Updated references.
03/15/07	Scheduled review, no change in coverage statement. Updated references.
06/15/07	Reformatted guideline.
03/15/08	Scheduled review; change in position statement. Update references.

03/15/09	Scheduled review; no change in position statement.
03/15/10	Scheduled review; no change in position statement. Update references.
12/15/10	Unscheduled review; revised position statement to reflect that photocoagulation of macular drusen (0017T) is considered experimental or investigational (versus the previous verbiage of “not medically necessary”).
01/01/11	Annual HCPCS coding update. Deleted code 0017T.
02/15/14	Revision; Program Exceptions section and references updated.
11/01/15	Revision: ICD-9 Codes deleted.
03/15/19	Scheduled review. Revised description, program exceptions, and related guidelines. Maintained position statement. Updated references.
11/15/20	Scheduled review. Revised description, maintained position statement, and updated references.
08/15/22	Scheduled review. Revised description, maintained position statement, and updated references.
05/22/23	Update to Program Exceptions section.
01/01/24	Position statements maintained.
11/15/24	Scheduled review. Revised description, maintained position statement and updated references.