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**QUESTION:** What is photobiomodulation (PBM) of the retina?

**ANSWER:** PBM is the use of low levels of light to stimulate cellular activity to provide beneficial effects. The Valeda Light Delivery System is a medical device that uses PBM to improve vision. The [Valeda](#) from LumiThera delivers low-intensity, non-coherent, multi-wavelengths of light at 590, 660, and 850 nanometers to the retinal tissue stimulating mitochondrial metabolic activity, increasing available energy for the cells, reducing oxidative stress and inflammation, to improve vision in eyes with early- and intermediate-stage nonexudative (dry) age-related macular degeneration (AMD).<sup>1</sup> It was authorized by the FDA in November 2024.<sup>2</sup>

2

**QUESTION:** What are the indications for PBM in the retina?

**ANSWER:** The Valeda Light Delivery System is intended to provide improved visual acuity in patients with best corrected visual acuity of 20/32 through 20/70 and who have dry age-related macular degeneration (AMD) characterized by:

- The presence of at least 3 medium drusen (> 63 µm and ≤ 125 µm in diameter), or large drusen (> 125 µm in diameter), or non-central geographic atrophy, AND
- The absence of neovascular maculopathy or center-involving geographic atrophy.

After about two years, the Valeda Light Delivery System treatment provides improved mean visual acuity of approximately one line of visual acuity (ETDRS) compared to those not receiving the treatment.<sup>3</sup>

3

**QUESTION:** How often is PBM therapy administered?

**ANSWER:** In the LIGHTSITE III clinical trial,<sup>4</sup> subjects received PBM treatment with the Valeda in nine (9) sessions over three (3) to five (5) weeks every four (4) months, over twenty-four (24) months. 64 subjects and 91 eyes received PBM treatment.

4

**QUESTION:** What diagnosis code(s) is used on a claim?

**ANSWER:** Use an ICD-10-CM code in the H35.31- series to report nonexudative age-related macular degeneration. Use the sixth digit to identify the eye(s) and the seventh digit to identify the stage of the disease. The number 1 in the seventh digit means early stage and the number 2 means intermediate stage dry AMD.

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**QUESTION:** What CPT code is used to report PBM?

**ANSWER:** Use Category III CPT code 0936T (*Photobiomodulation therapy of retina, single session*). A session occurs on a single day. This code was inaugurated January 1, 2025.

January 23, 2025

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**QUESTION:** Will Medicare cover PBM?

**ANSWER:** Maybe. PBM is the first treatment shown to improve vision loss associated with dry AMD. There is compelling evidence to support coverage of PBM in an office setting for qualifying patients.<sup>4</sup> For comparison, Medicare covers pegcetacoplan (Syfovre®) and avacincaptad pegol (Izervay™) to treat geographic atrophy, an advanced form of dry AMD but studies have shown that there is no vision improvement. The CMS final rule for 2025 may cover 0936T in an office setting but not in an outpatient surgery setting.

7

**QUESTION:** What is the Medicare payment for PBM?

**ANSWER:** Since 0936T is a Category III code, each Medicare Administrative Contractor (MAC) determines the payment rate for 0936T; CMS did not establish a rate in the CY 2025 Medicare Physician Fee Schedule.

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**QUESTION:** What chart documentation supports 0936T?

**ANSWER:** PBM is a minor procedure, not a major surgery, that is supported by an operative report in the medical record. The essential elements of the note include: date of service, patient name, diagnosis, proceduralist's name, title of procedure, indication for the procedure, description of the procedure, discharge instructions, and signature.

9

**QUESTION:** If coverage of PBM is unlikely or uncertain, how should we proceed?

**ANSWER:** Explain to the patient why you feel the procedure is necessary, and that Medicare or other third-party payor will likely deny the claim. Ask the patient to assume financial responsibility for the charge. A financial waiver can take several forms, depending on insurance.

- An [Advance Beneficiary Notice of Noncoverage \(ABN\)](#) is required for services where Part B Medicare coverage is ambiguous or doubtful, and may be useful where a service is never covered. You may collect your fee from the patient at the time of service or wait for a Medicare denial. If both the patient and Medicare pay, promptly refund the patient or show why Medicare paid in error.
- For Part C Medicare (Medicare Advantage), determination of benefits is required to identify beneficiary financial responsibility prior to performing noncovered services; MA Plans have their own waiver forms and processes.
- For commercial insurance beneficiaries, a [Notice of Exclusion from Health Plan Benefits \(NEHB\)](#) is an alternative to an ABN.

- <sup>1</sup> LumiThera website [Link here](#). Accessed 12/20/24
- <sup>2</sup> FDA. De novo 510(k) authorization DEN230083. November 4, 2024. [Link here](#). Accessed 12/20/24
- <sup>3</sup> LumiThera. How Valeda works. [Link here](#). Accessed 12/20/24
- <sup>4</sup> Boyer D, Hu A, Warrow D, et al. LIGHTSITE III 13-Month Efficacy and Safety Evaluation of Multiwavelength Photobiomodulation in Nonexudative (Dry) Age-Related Macular Degeneration Using the LumiThera Valeda Light Delivery System. *Retina* 2023 Nov 7;44(3):487-497. [Link here](#). Accessed 12/20/24

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