VALEDA® Light Delivery System Coding and Billing Guide

Overview

VALEDA® Light Delivery System is the first and only Food and Drug Administration (FDA) authorized treatment for dry aged-related macular degeneration (AMD).

Indications & Use

The Valeda® Light Delivery System was authorized by the FDA in 2024. It is intended to provide improved visual acuity in patients with best corrected visual acuity of 20/32 through 20/70 and who have dry AMD characterized by:

- The presence of at least 3 medium drusen (>63 um and <125 um in diameter), or large drusen (>125 um 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 provides improved mean visual acuity of approximately one line of visual acuity Early Treatment Diabetic Retinopathy Study (ETDRS) compared to those not receiving the treatment.

Procedure Coding

The procedure can be reported with a Current Procedural Terminology (CPT®) code:

CPT® Code	Description
0936T	Photobiomodulation Therapy of Retina, single session

Modifiers	Description
RT/LT	Right/Left Eye
50	Report Bilateral Procedures
GA	Report when an Advanced Beneficiary Notice (ABN) is on file

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Diagnosis Coding

The diagnosis code is determined by the patient's medical condition. The following are International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) codes commonly used when a patient has been diagnosed with dry AMD. It is the provider responsibility to report the ICD-10-CM diagnosis code that accurately describes the patient's condition. Common diagnosis codes include:

ICD-10-CM	Description
H35.3112	Nonexudative age-related macular degeneration, right eye, intermediate dry stage
H35.3113	Nonexudative age-related macular degeneration, right eye, advanced atrophic without subfoveal involvement
H35.3122	Nonexudative age-related macular degeneration, left eye, intermediate dry stage
H35.3123	Nonexudative age-related macular degeneration, left eye, advanced atrophic without subfoveal involvement
H35.3132	Nonexudative age-related macular degeneration, bilateral, intermediate dry stage
H35.3133	Nonexudative age-related macular degeneration, bilateral, eye, advanced atrophic without subfoveal involvement

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Documentation for Prior Authorization (PA), Additional Documentation Request, or Claim Appeal

The following documentation may be used to support a PA request or claim appeal:

- Clear and concise letter of medical necessity
- Patient records or narrative of the patient's medical history
- Any other information required by the health plan's medical policy

Support - Alcon is here to help

An experienced team of Field Reimbursement Experts are available to support billing, coding, coverage, and reimbursement questions for your local area. Billing and coding information is also available online at: www.myalcon.com/professional/resources/reimbursement-services

DESCRIPTION AND CHARACTERISTICS

The Valeda® Light Delivery System is a benchtop instrument emitting non-coherent light in the wavelengths of 590 nm (amber), 660 nm (red), and 850 nm (near infrared, i.e., NIR) from three light emitting diodes (LEDs), respectively. The system projects a beam spot with a diameter of approximately 30 mm at the corneal plane of the patient for each of the three wavelengths.

Intended Users:

The system is to be used by qualified health professionals (QHP) to treat a certain population of patients with dry AMD as defined in the Indications for Use (IFU).

Contraindications:

As a precaution, patients who have not been tested should not be treated with Valeda® Light Delivery System if there is known photosensitivity to yellow light or red light, near-infrared radiation (NIR) or there is a history of light activated central nervous system disorders (e.g., epilepsy, migraine). In addition, patients should not receive treatment within 30 days of using photosensitizing agents (e.g., topicals, injectables) that are affected by 590, 660, and/or 850 nm light before consulting with their physician.

Precautions:

Safety and effectiveness in patient populations and/or conditions excluded from the clinical study has not been established. This includes the following:

- Patients under the age of 50
- Pregnant or nursing women
- Current or history of neovascular maculopathy
- Presence of center involving geographic atrophy (GA) within the central 1 mm diameter
- Media opacities, including cataracts, which might interfere with visual acuity or imaging in the eye
- Posterior capsule opacification, which might interfere with visual acuity or imaging in the eye
- Ocular disorder or disease that partially or completely obstructs the pupil
- Any visually significant disease in any ocular structure apart from dry AMD

There is limited safety and effectiveness in patients with best-corrected visual acuity (BCVA) worse than 20/70 or better than 20/32 and have been excluded from the Indications for Use. If the eyecare practitioner wishes to treat these patients who are not considered in the intended population, he/she should consider that the safety and effectiveness have not been demonstrated in these groups.

No non-white subjects received treatment with the device in the study and the clinical performance of the device in non-white patients is unknown. There is limited safety and effectiveness data in subjects of Hispanic or Latino origin. The eye care practitioner should consider the benefit/risk of treating patients outside of the study population.

An analysis of the primary effectiveness endpoint (mean BCVA change from baseline for the PBM arm – the mean BCVA change in the Sham arm) showed the following differences between arms for the subgroup of pivotal study patients with early AMD (Beckman Clinical Category Classification): o At Month 13: +1.90 letters; o At Month 21: -0.10 letters; o At Month 24: +0.29 letters. The eyecare practitioner should consider the observed benefit/risk profile for this subpopulation, when contemplating treatment of patients with this classification of Early AMD.

It is possible that treatment benefit may not persist significantly after treatment is stopped. The eyecare practitioner should inform patients of this potential.

The clinical study provided no significant data concerning the safety and effectiveness of the device should treatments be applied more frequently than described in this manual, or if more than 54 total treatments are delivered per eye. The eyecare practitioner should inform patients of this information.

Twelve (12) eyes (12.9%) in the PBM group and 4 eyes (7.3%) in the sham group had a fellow eye that had neovascular AMD (nAMD). Of these 5 (41.7%) of 12 eyes in the PBM-treated group converted to nAMD, and 1 (25.0%) of the 4 eyes in the Sham group converted to nAMD. The eye care practitioner should consider the benefit/risk profile in this sub-population and should closely monitor patients whose fellow eye has nAMD.

PLEASE REFER TO THE LABELING FOR A MORE COMPLETE LIST OF WARNINGS, PRECAUTIONS AND CONTRAINDICATIONS.

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Valeda™ PBM