Alcon
Vision Suite

Valeda™
PBM

The **first and only** FDA-authorized treatment for dry AMD to improve and maintain vision for up to 2 years[1]*

*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.

LIGHTSITE III Pivotal Trial Design

Assessing the Efficacy and Safety of Valeda™ PBM

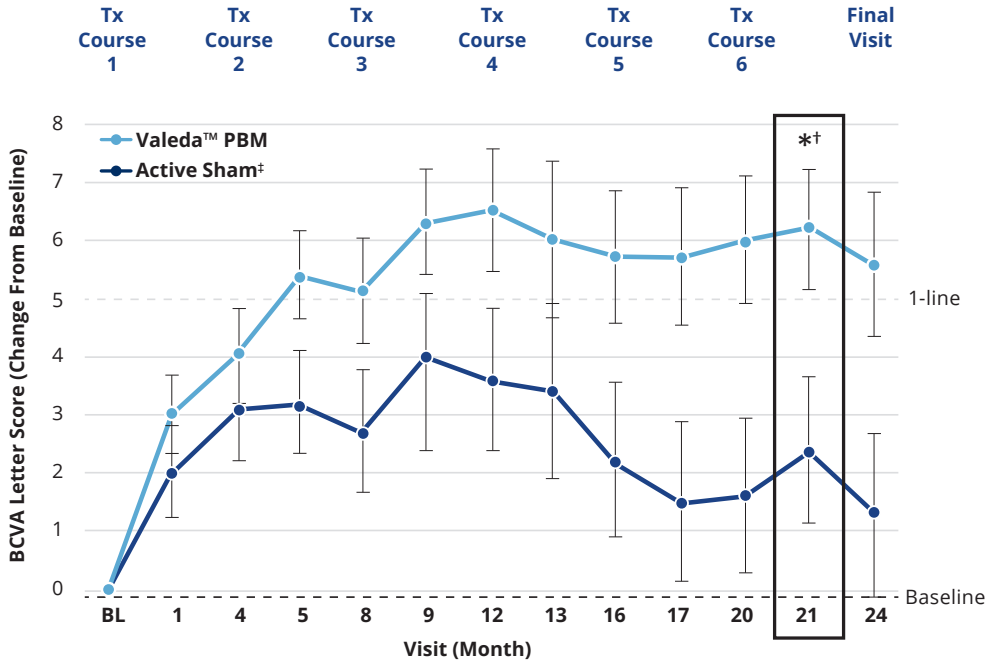
Study design
LIGHTSITE III evaluated the efficacy and safety of Valeda™ PBM in a 24-month, double-masked, Sham-controlled, parallel design, prospective, randomized, multi-center trial.[2,3]

Study population
98 patients (145 eyes) aged ≥50 years with ETDRS BCVA letter score between 50 and 75 and a diagnosis of dry AMD defined by the presence of drusen and/or nonfoveal center GA were randomized at a 2:1 ratio into 2 treatment groups.[2]

Endpoints
Primary efficacy endpoint: Mean BCVA change from baseline to Month 13 or Month 21.
Primary safety endpoint: Mean change from baseline to Month 13 or Month 24.[2]

Valeda™ PBM Improved and Maintained Vision

Valeda™ PBM demonstrated a significant benefit in BCVA[2]



Least squares (LS) mean presented with multiple imputation.
*P<0.05 between group comparison. †P<0.0001 within group comparison (PBM).
‡10x reduction of 590 nm, 100x reduction of 660 nm, and no 850 nm wavelengths.

Primary efficacy endpoint

Mean BCVA change from baseline to Month 13 or Month 21.[2]

Valeda™ PBM improved BCVA with a mean 6.2 letter gain from baseline at Month 21 (P<0.0001), which was maintained with a mean 5.9 letter gain from baseline at Month 24 (P<0.0001).[2,5]

84% of Valeda™ PBM–treated patients **maintained or improved vision** at about 2 years compared to baseline[2,4§]

More than 60% of Valeda™ PBM–treated patients experienced **≥1-line vision improvement** at about 2 years compared to baseline[2,4§]

Consistent safety in multiple clinical trials

Valeda™ PBM delivers proven efficacy in dry AMD with a **favorable safety profile**[5]

0 reports of phototoxicity in 3 LIGHTSITE trials[5]

of patients did not report eye pain[2]

Noninvasive. Dilation Free. Anesthesia Free.[2]

A smooth experience

- No drops, no speculum, no injections
- A treatment session is either unilateral or bilateral, with each eye being treated individually

1 treatment course consists of:

3 applications per week

Over **3** consecutive weeks[¶]

Repeat

3 times a year[‖]

Treatment regimen consists of 54 applications administered in 6 courses over 2 years

[¶]3-5 weeks.
[‖]For 2 years.

Valeda™ PBM Uses the Power of Light

Valeda™ PBM applies 3 science-backed wavelengths to upregulate cellular energy production[3]

590 nm

Increases nitric oxide synthesis and vasodilation which can improve local oxygenation and nutrient delivery[6]

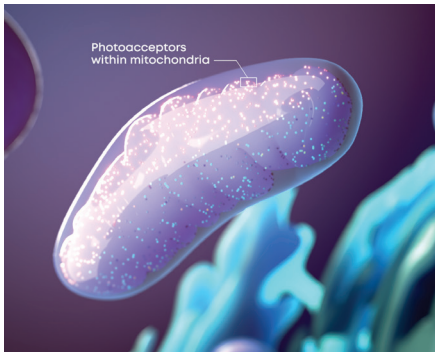
660 nm

Promotes O^2 binding (Cu_B), stimulates metabolic activity (ATP), and inhibits inflammation and cell death[7]

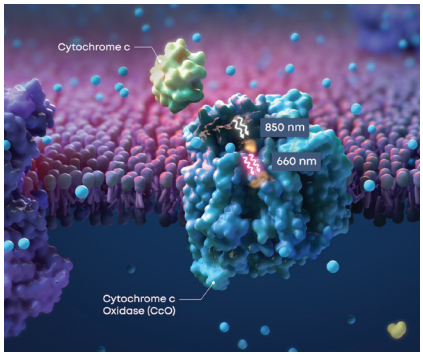
850 nm

Drives electron transfer (Cu_A), stimulates metabolic activity (ATP), and inhibits inflammation and cell death[7]

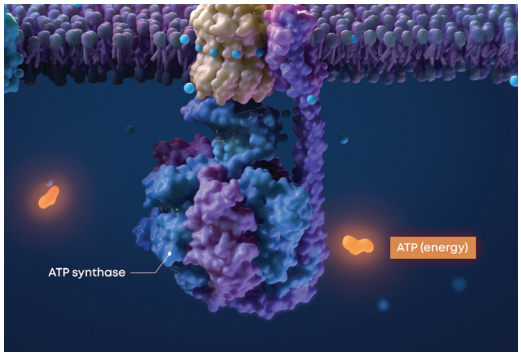
Valeda™ PBM's unique mechanism of action works to restore cellular energy production and improve retinal cellular health[3]



The retina is rich in mitochondria, and mitochondrial dysfunction is a known cause of vision loss in dry AMD.



Cytochrome c oxidase (CcO) is a key photoacceptor in the mitochondrial electron transport chain.



Valeda™ PBM wavelengths activate CcO, enhancing electron transport and mitochondrial adenosine triphosphate (ATP) production, the cell's major source of energy.

See Valeda™ PBM in action

[§]n=98 subjects and 145 eyes.

AMD, age-related macular degeneration; BCVA, best-corrected visual acuity; BL, baseline; ETDRS, Early Treatment of Diabetic Retinopathy Study; GA, geographic atrophy; PBM, photobiomodulation.

Valeda™ PBM

Valeda™ PBM

Alcon Vision Suite

No More Watch and Wait

Treat With Valeda™ PBM

The first and only

Valeda™ PBM is the first and only FDA-authorized treatment for early and intermediate dry AMD[1]

Improve and maintain vision

84% of Valeda™ PBM–treated patients improved or maintained vision at ~2 years compared to baseline[2,4]*

A noninvasive and smooth patient experience

Dilation free, speculum free, anesthesia free, and injection free[2]

*n=98 subjects and 145 eyes.

Hear firsthand from Valeda™ PBM patients

Discover more at **MyValeda.com**

Important Product Information

Indications for Use

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 central-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.

Contraindications for Use

As a precaution, patients have not been tested and should not be treated with Valeda if they have any known photosensitivity to yellow light, red light, or near-infrared radiation (NIR), or if they have 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 1mm 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.

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):

- At Month 13: +1.90 letters
- At Month 21: -0.10 letters
- At Month 24: +0.29 letters

The eyecare practitioner should consider the observed benefit/risk profile for this sub-population, 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 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.

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.

References: 1. Valeda US Instructions for Use. **2.** Valeda US User Manual 2025. **3.** Boyer D, Hu A, Warrow D, et al. 13-Month efficacy and safety evaluation of multiwavelength photobiomodulation in nonexudative (dry) age-related macular degeneration using the Lumithera Valeda Light Delivery System. *Retina*. 2024;44(3):487-497. doi:10.1097/IAE.0000000000003980 **4.** Valeda US LIGHTSITE III Exhibit Data. **5.** Valeda Clinical Study Report. 2023. **6.** Ball KA, Castello PR, Poyton RO. Low intensity light stimulates nitrite-dependent nitric oxide synthesis but not oxygen consumption by cytochrome c oxidase: implications for phototherapy. *J Photochem Photobiol B*. 2011;102(3):182-191. doi:10.1016/j.jphotobiol.2010.12.002 **7.** Wong-Riley MT, Liang HL, Eells JT, et al. Photobiomodulation directly benefits primary neurons functionally inactivated by toxins: role of cytochrome c oxidase. *J Biol Chem*. 2005;280(6):4761-4771. doi:10.1074/jbc.M409650200