COLORADO RETINA

Informed Consent for Valeda® Light Delivery System Treatment

You are being offered this treatment because you have dry age-related macular degeneration (AMD). This informed consent describes the treatment and procedures you will receive. If you have questions or do not understand something, please ask your treating physician to explain. This information is part of your informed consent process and is provided to help you make the best decision for yourself and your eyes.

Please review this document carefully to make an informed decision about whether you would like to receive this treatment. It may contain words that you do not understand. Take your time and feel free to ask any questions before you consent to proceed with this treatment. Discuss any questions with our medically trained staff.

BACKGROUND

AMD is a progressive disease of the retina (the part of the eye that detects visual signals and sends them to the brain). AMD is the leading cause of vision loss in people over 65 years. There are two categories of AMD: the dry form accounts for 80 to 90% of all AMD cases and the wet form accounts for 10 to 20%. The treatment you are being offered is for dry AMD.

The exact cause of AMD is not known. There is evidence to suggest that several factors are involved. These include reduced blood flow to the eye through the small blood vessels and a buildup of waste products in the cell.

There is no cure for AMD. LumiThera, Inc. developed a device called the Valeda® Light Delivery System to treat dry AMD. The device has been approved for the treatment of dry AMD in Europe since 2019. The U.S. Food & Drug Administration (FDA) authorized Valeda on November 4, 2024, for the treatment of dry AMD to improve vision.

Valeda delivers a light-based therapy called Photobiomodulation (PBM) to the retinal tissue. PBM is the application of specific wavelengths of light to the eye. Valeda uses Light Emitting Diodes (LED) which are very low powered and do not cause any heat damage to the eye. This is NOT a laser device. The FDA has approved similar wavelengths of light for use in other clinical devices for medical conditions such as wrinkles around the eyes, temporary relief of minor muscle and joint pain, arthritis and muscle spasm, and to temporarily improve blood flow in areas where it is applied.

PURPOSE

The purpose of this treatment plan is to provide you with PBM treatment using the Valeda Light Delivery System.

TREATMENT

This treatment plan includes a series of 9 treatments, approximately 3 times a week over a 3-to-5-week period. Each treatment session takes about 5 minutes per eye.

No special preparation is needed prior to the treatment. Your eyes will not be dilated. No drugs or needles are used in the treatments. You will need to remove your glasses or contact lenses. Your eye(s) that are eligible for the treatment plan will receive the PBM treatment using the Valeda Light Delivery System, which uses 3 different wavelengths: red light, near-infrared (invisible light), and yellow light. Your eye(s) will be

TREATMENT CONTINUED…

given a treatment of different wavelengths through both open and closed eyelids to stimulate the retinal tissue at the back of the eye. The Valeda looks similar to the devices you look into to test your vision.

VISIT DETAILS

Initial Consultation Visit: The purpose of this visit is to confirm that you meet all requirements to take part in the treatment plan. The following procedures may be performed during this visit:

- Review of medical history
- Detailed eye examination – this will include a routine eye exam (slit lamp exam, dilated retinal exam and intraocular pressure test), visual acuity test, optical coherence tomography (OCT) images and color retinal photographs. Other eye tests might be performed if advised.
    - Slit lamp exam: An examination of the eye using a microscope and light.
    - Dilated retinal exam: An exam performed on a dilated eye that looks at the back of the eye and retina. (If you have had a dilated retinal exam with a CRA physician within 3 months of your Valeda Consultation visit, we may waive the dilated exam during your consultation).
    - Intraocular pressure test (IOP): A simple test to measure the pressure inside of your eyes.
    - Visual acuity (vision) test: A measurement of your vision using an eye chart.
    - Optical coherence tomography (OCT): A scanning light beam takes multiple pictures of the retina (back of the eye) and produces a very detailed picture of the individual layers of the retina.
    - Retinal photography: A color photograph of the back (retina) of the eye.

Treatment Visits: You will receive nine treatments over three to five (3 to 5) weeks during each series of treatments. Each treatment takes approximately five (5) minutes for each eye treated. During the treatment, you will be told when to open your eyes and when to close your eyes. There are no eye drops used at the treatment visit. There is no discomfort during the treatment.

Follow-Up Visits: You will continue having thorough dilated exams with imaging monitoring of your disease state every 6 months.

ALTERNATIVE TREATMENTS

You do not have to agree to this treatment plan. Alternatives to this treatment include NOT having this treatment, lifestyle changes such as stopping smoking, dietary change, and the use of antioxidant vitamins are other options that may affect the progression of Dry AMD.

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 systems 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.

POTENTIAL RISKS

The Valeda Light Delivery System has been in use in Europe since 2019. There have been no significant adverse effects reported.

Potential risks for this treatment may include the development of an afterimage which is a common occurrence in the eye when staring at a specific color for too long (for example, staring at a bright light then looking away), and light sensitivity.

POTENTIAL RISKS CONTINUED…

You may experience inconveniences due to the required number of trips to our office and getting tired from taking tests and receiving multiple photographs of your eyes.

There could be possible unknown side effects that could occur.

The treating physician may withdraw you from the treatment plan if your condition worsens, if you do not follow the treating physician's instructions, or if the treating physician feels it is in your best interest. You may be withdrawn without your consent, but the treating physician will tell you why.

LIMITATIONS OF VALEDA PBM THERAPY

AMD is a progressive disease that may lead to vision loss over time. There is no guarantee that your vision will improve following Valeda treatment. Even with Valeda treatment, your dry macular degeneration could still progress to wet AMD and loss of vision.

TREATMENT PLAN COMMITMENT

Your participation in this Valeda treatment plan is completely voluntary. You can withdraw your consent to receive this treatment at any time and without any consequences for your medical care.

COSTS

The Valeda Light Delivery System is currently not covered by Medicare, Medicaid, or any private health insurance. Before beginning your treatment plan, you will be provided with a separate written form disclosing your costs associated with the treatments.

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CONSENT

I have been given enough time to read this form and to ask questions. All of my questions, if any, have been answered to my satisfaction. I freely agree to receive this Valeda treatment.

I wish to have the Valeda treatment in:

☐ **BOTH** eyes
☐ **RIGHT** eye ☐ **LEFT** eye

_____ DATE:_____ TIME:_____
Patient Name (printed)

_____
Patient Signature

_____ DATE: _____ TIME:_____
Witness Name (printed)

_____
Witness Signature

_____
Physician Signature

If the patient is unable to read: I attest that the information in this consent form and any other written information was accurately explained to and apparently understood by the patient, and informed consent was freely given by the patient.

_____ DATE: _____
Witness Name (printed)

_____
Witness Signature Patient Initials: _____

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OFF LABEL USAGE for Valeda® Light Delivery System Treatment

CONSENT

I understand that Valeda® Light Delivery System Treatment was approved by the FDA for dry macular degeneration fitting the following criteria:

- best corrected visual acuity of 20/32 through 20/70
- 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

Nevertheless, I wish to have Valeda® Light Delivery System Treatment performed on my eye and I am willing to accept the potential risks that my physician has discussed with me. I acknowledge that there may be other, unknown risks and that the long-term effects and risks of the Valeda® Light Delivery System are not known. I acknowledge that the outcomes of the clinical trials for the Valeda® Light Delivery System may not be directly applicable to my case due to off-label use of the system.

PATIENT'S ACCEPTANCE OF RISKS

Your signature on this document means:

- You have read it (or it has been read to you) and you understand this information.
- You have been offered a copy of this document.
- Your doctor has answered your questions to your satisfaction.
- You consent to Valeda® Light Delivery System

_____ _____

Patient (or person authorized to sign for patient) Date

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