FDA Authorizes Light Therapy for Dry AMD

Imagine a special light that could protect vision in people with dry age-related macular degeneration (dry AMD) without eye injections. That's what a new treatment aims to do.

Dry AMD affects mostly adults over 55, and it's a leading cause of vision loss. Right now, only specific types of dry AMD can be treated — and the treatment involves eye injections that may slow the disease without improving vision. Some patients with dry AMD may also benefit from special vitamins.

The new light therapy — called photobiomodulation — could be a big breakthrough. It's the first non-invasive treatment authorized by the FDA for use in treating dry AMD, which means no needles are needed.

Many ophthalmologists are excited about this new option, but want to see more information to make sure it's safe and works well before recommending it to patients.

"Photobiomodulation certainly holds promise," says ophthalmologist Nieraj Jain, M.D., a specialist in retinal diseases. "But we look forward to seeing more data. We don't know how these outcomes will hold up in the real world."

How Does Light Therapy for AMD Work?

Dry AMD causes the light-sensitive cells of the retina to slowly break down and die. These cells are essential for central vision and seeing details.

Light therapy exposes cells in the retina to different wavelengths of light. This is thought to slow disease progression.

Light therapy is not new. It has been used to treat skin conditions and musculoskeletal disorders, and provide pain relief. It has also been studied in other eye conditions such as diabetic eye disease, childhood myopia, and retinitis pigmentosa. Light therapy was previously approved in Europe and some parts of Latin America for the treatment of dry AMD.

Real-World Benefits of Light Therapy Not Yet Known

Light therapy technology has been **authorized** (cleared) by the FDA for use in treating dry AMD:

- FDA **authorization** means the treatment can be advertised to patients based on early evidence that it is safe and works as intended. It's possible that some insurance providers won't cover the treatment if they view it as experimental or investigational.

- Some ophthalmologists would like additional long-term evidence to confirm the real-world effectiveness of treatment.

The FDA authorized light therapy for dry AMD based on results from a small study of 100 people in the early stages of the disease, treating some with LumiThera's Valeda Light Delivery System in nine short sessions over 3 to 5 weeks. This was repeated every four months, for a total of 2 years.

Patients who received the treatment could see an average of 5 more letters on an eye chart after 13 months of treatment, compared with their previous ability. Participants who received a placebo (fake, or sham) treatment could see about 3 more letters, on average.

The treated patients were also less likely to develop geographic atrophy — a particularly debilitating stage of AMD that steals central vision — compared with study participants who did not receive the treatment.

The light therapy appeared to be generally safe, though slightly more patients developed wet AMD after receiving the treatment versus a placebo. Additionally, the study was relatively small and not all of the participants actually finished the study.

It remains unclear what the long-term benefits and drawbacks of light therapy will be for patients in the real world, outside of clinical studies.

When Will Light Therapy be Available for Patients With Dry AMD?

Light therapy may become available in some ophthalmology offices later this

year. The out-of-pocket cost to patients is not yet known.

A downside of the treatment is that patients would need to travel to the clinic for frequent therapy sessions, says Dr. Jain, adding, “That being said, having a new tool in the box to treat the leading cause of blindness among older American adults would be a welcome and much needed development."