

FDA approves new treatment for diabetic eye disease

By ACSH Staff — February 10, 2015

Diabetic retinopathy a complication of diabetes caused by degeneration of the blood vessels in the retina is the most common diabetic eye disease, and a leading cause of blindness in American adults (after age-related macular degeneration). According to the



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degeneration of the blood vessels in the retina is the most common diabetic eye disease, and a leading cause of blindness in American adults (after age-related macular degeneration). [According to the CDC](#) [2], almost one-third of adults over age 40 with diabetes have diabetic retinopathy. In some cases, blood vessels may swell and leak fluid, a complication known as diabetic macular edema (DME). The FDA [has just expanded the use of ranibizumab](#) [3] injections (Lucentis, Genentech, Inc.) to treat diabetic retinopathy in patients with DME. It was previously approved in 2012 for the treatment of DME.

This is the first significant therapy to treat this vision-impairing complication, says Dr. Edward Cox, director of the Office of Antimicrobial Products in the FDA's Center for Drug Evaluation and Research. Although this treatment is just receiving FDA approval, [prior studies have suggested](#) [4] its effectiveness in treating diabetic retinopathy.

Specifically, the FDA approved the use of Lucentis injections following two clinical studies of almost 800 subjects who were treated for these two conditions using the injections. Subjects were followed for three years and compared to a control group, and those individuals who received treatment demonstrated significant improvements in severity of diabetic retinopathy. The FDA expedited the review of Lucentis for diabetic retinopathy because of the overwhelming evidence suggesting its benefit.

According to Dr. Pravin Dugel, a retinal specialist at Retinal Consultants of Arizona and an investigator in the medication's two clinical trials, "It truly is disease-modifying. In certain patients, if you treat up front, you can actually modify the disease in the eye." He explains that the drug works

by inhibiting leakage of blood vessels and deterring the growth of blood vessels into the retina of the eye.

Previously, to treat this condition, lasers were used to burn away tissues at the edge of the retina, but this often resulted in the loss of peripheral vision.

Side effects of Lucentis included bleeding of the conjunctiva, eye pain, floaters (small moving spots that appear in your field of vision), and increased intraocular pressure. More serious side effects included endophthalmitis (swelling within the eyeball) and retinal detachment.

However, Dr. Dugel says that this drug has the potential to be revolutionary in managing diabetes. In my world, it really has the potential to change the way we practice medicine. It has the potential to benefit hundreds of thousands of patients."

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[1] <https://www.nei.nih.gov/health/diabetic/retinopathy>

[2] <http://www.cdc.gov/visionhealth/pdf/factsheet.pdf>

[3] <http://health.usnews.com/health-news/articles/2015/02/06/fda-approves-1st-drug-for-diabetic-retinopathy>

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