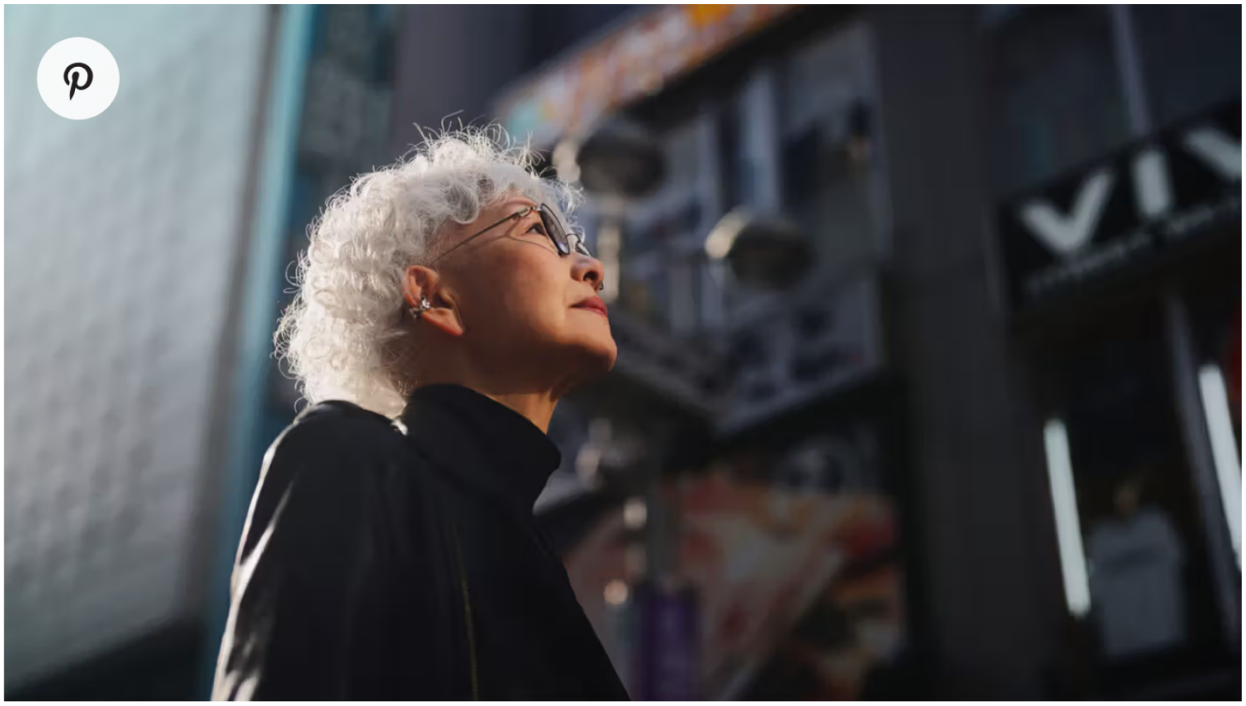
healthline

HEALTH NEWS ✓ Fact Checked

FDA Approves Biosimilars for Macular Degeneration Treatment



The FDA has approved biosimilars for macular degeneration treatment. recep-bg/Getty Images

- **The FDA approved two biosimilars for Eylea (aflibercept), a drug used to treat age-related macular degeneration, diabetic retinopathy and other eye conditions.**
- **Biosimilars Yesafili and Opuviz work the same way, and have similar safety and efficacy, as Eylea.**
- **The biosimilars' manufacturers have not yet revealed the launch date and list prices for the drugs.**

The Food and Drug Administration approved two interchangeable biosimilars to Eylea (aflibercept), a brand name drug used to treat age-related macular degeneration, diabetic retinopathy and other eye conditions.

Biosimilars are generic copies of name-brand biologic drugs and get their name from their similarity in structure and function to their counterparts.

Biosimilars Yesafili (aflibercept-jbvf, from Biocon Biologics) and Opuviz (aflibercept-yszy, from Biogen and Samsung Bioepis) work the same way as Eylea — by inhibiting a protein called vascular endothelial growth factor. This prevents abnormal blood vessel growth in the eye.

This can help preserve vision by slowing down or reducing damage to the retina.

Yesafili and Opuviz, which are injected into the eye, are now approved to treat the following conditions:

- neovascular (wet) age-related macular degeneration
- macular edema following retinal vein occlusion
- diabetic macular edema
- diabetic retinopathy

The approval of these biosimilars "is very reassuring, since we are always looking to find more treatment options for age-related macular degeneration and diabetic eye diseases," said Asadolah Movahedan, MD, assistant professor of ophthalmology at the George Washington University School of Medicine.

Macular degeneration treatment is safe and effective

The FDA approval was based on a review of scientific evidence showing that both drugs are "highly similar" to Regeneron Pharmaceuticals' Eylea, and that they have "no clinically meaningful differences from Eylea," the agency wrote May 20 in a press release.

This analysis included comparing multiple lots of the drugs with Eylea across a range of product quality characteristics, the agency said. Clinical studies also showed that there are no clinically meaningful differences in efficacy or safety between the two biosimilars and Eylea.

According to the FDA, the most common side effects of Yesafili and Opuviz are consistent with those observed with Eylea, and include:

- conjunctival hemorrhage (bleeding)
- eye pain
- cataract
- vitreous detachment

- vitreous floaters
- increased pressure inside the eye

Both biosimilar drugs carry the following warnings and precautions:

- Hypersensitivity to the drug
- Inflammation in parts of the eye that can lead to retinal detachments.
- inflammation of arteries in the retina
- Increase in pressure in side the eye
- Blood clots

“I am interested to see what the rate of real-world intraocular inflammation is after these meds become available,” Movahedan told Healthline. The FDA continues to monitor the safety of approved drugs after they enter the market.

Will new biosimilars mean cheaper macular degeneration treatment?

As with generic drugs, biosimilars can sometimes offer a more affordable — but similarly safe and effective — alternative to an existing medication.

“Biosimilars are typically less expensive than the original biologic, making treatment more affordable for a broader range of patients,” said James Kelly, MD, an ophthalmologist and refractive surgeon specialist in New York City. “Insurance companies may also offer better coverage, reducing out-of-pocket expenses for patients.”

Lower costs can help patients stick to their treatment regimen, he told Healthline, “leading to better management of the disease and potentially better outcomes.”

In addition, “more affordable options can help bridge the gap between different socioeconomic groups, ensuring that all patients receive the care they need,” he said.

Drugmakers, though, have not yet released the list prices for these medications. Healthline reached out to Biocon Biologics and Biogen, but the companies declined to comment on pricing at this time.

So there is not a guarantee of a significantly lower price for the biosimilars.

“Despite all promises [of affordability], biosimilars are still very expensive and there may not be a huge difference in terms of patient out-of-pocket costs, even if the [biosimilar] is $1000 instead of $1800,” said Movahedan. “Particularly when there are off-label medications which have a reasonably good list price.”

So there’s a long way to go before these medications are really affordable, he said. However, “more biosimilars will be available in the near future, and hopefully this will lower the price, so that more patients can benefit from these drugs,” he added.

Even if prices of this class of drugs don’t come down right away, Kelly thinks “the introduction of biosimilars creates competition, which … could ultimately lead to to improvements in drug formulations and delivery methods.”

Also, “[having] multiple suppliers reduces the risk of drug shortages,” he said, “ensuring a more consistent supply of the medication for patients in need.”

When will these drugs be available in the U.S.?

It is not clear when these drugs will hit the market in the United States.

Yesafili is already approved as a biosimilar in Europe and the United Kingdom, and is approved in Canada and is expected to launch there by July 2025, Biocon Biologics said in a press release.

The company has not announced a U.S. launch date of Yesafili, but a spokesperson said, “We remain committed to bringing the product to the market at the earliest to meet the needs of our customers and patients.”

In an email, a Biogen spokesperson told Healthline that “at this time we are unable to disclose the potential launch timeline for Opuviz in the U.S., and will share more information when appropriate.”

Takeaway

The FDA approved two interchangeable biosimilars for Regeneron Pharmaceuticals’ eye drug Eylea — Yesafili and Opuviz.

The biosimilars work the same way as Eylea, by inhibiting vascular endothelial growth factor, which prevents abnormal blood vessel growth in the eye, and helps preserve vision. Clinical trials also showed the drugs have similar safety and efficacy as Eylea.

These drugs are approved to treat neovascular (wet) age-related macular degeneration, macular edema following retinal vein occlusion, diabetic macular edema and diabetic retinopathy.

How we reviewed this article:

HISTORY

Our experts continually monitor the health and wellness space, and we update our articles when new information becomes available.

Current Version

May 22, 2024

Written By

Shawn Radcliffe

Edited By

Gillian Mohney

Fact Checked By

Kevin Cyr, MD

Link to Coverage: https://bit.ly/3wDdbAv
UVM: 96,028,063