COMMUNICATION

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PLEASE REVIEW

Drug Information

PharmPix Clinical Department

PharmPix is committed to the health and wellness of our members.

The clinical team wants to communicate the latest up-to-date drug information requested.

Drug Information:

Remember that medical literature is dynamic and is continuously changing as new scientific knowledge is developed. We exhort the frequent revision of treatment guidelines to assure that your recommendations are consistent with the most updated information.

It is our priority to offer high-quality services and support practices for health promotion and disease prevention. If you have any questions or wish to have more information regarding this document, you can call us directly or view PharmPix communications online.

QUESTIONS

Call us at 787-522-5252, ext. 219.

Access our recent communications at our providers' portal: https://www.pharmpix.com/providers/.

FDA Approves First Interchangeable Biosimilars to Eylea™

The Food and Drug Administration (FDA) has approved two biosimilars that are interchangeable with Eylea™ (aflibercept). Biocon Biologic's Yesafili™ (aflibercept-jbvf) and Samsung Bioepis' Opuviz™ (aflibercept-yszy) are approved to treat neovascular (wet) age-related macular degeneration, macular edema following retinal vein occlusion, diabetic macular edema and diabetic retinopathy.

Background:

Aflibercept works by inhibiting vascular endothelial growth factor (VEGF), which prevents abnormal blood vessel growth within the eye. By blocking VEGF, aflibercept products can slow down or reduce damage to the retina and help preserve vision.

The dosages of Opuviz and Yesafili are identical to Eylea at 2 mg administered every 4 to 12 weeks, depending on the indication.

Data from Clinical Trials:

According to the FDA, both approvals were based on "a comprehensive review of scientific evidence demonstrating that each product is highly similar to Eylea, respectively, and that they have no clinically meaningful differences from Eylea." Clinical data used to support the approval of Yesafili and Opuviz indicated that there were no clinically meaningful differences from Eylea regarding efficacy, safety, or immunogenicity.

Of note, both Yesafili and Opuviz lack Eylea's indication for retinopathy of prematurity (ROP), which is protected by Orphan Drug Exclusivity (ODE) until February 8, 2030. An additional 6 months of pediatric exclusivity extends protection until August 8, 2030.

In order to compete with new products available in the category, including other biosimilars, Yesafili and Opuviz will need to be priced at a significant discount (35% to 45%) to brand Eylea.

If you have any questions or wish to have more information regarding this document, you can call us at 787-522-5252-ext 219. Our pharmacists will help you. In addition, know that you can access our recent communications at our providers' portal: https://www.pharmpix.com/providers/.

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REFERENCES:

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2. Center for Drug Evaluation and Research. (2024). FDA approves first interchangeable biosimilars to Eylea to treat macular degeneration and other eye conditions. U.S. Food and Drug Administration. https://www.fda.gov/drugs/news-events-human-drugs/fda-approves-first-interchangeable-biosimilars-eylea-treat-macular-degeneration-and-other-eye
3. Rx Brief: Ophthalmology. (2024, May 28). First Eylea Biosimilars FDA-Approved. IPD Analytics. https://secure.ipdanalytics.com/User/Pharma/RxStrategy/Recent/Reports

urac ACCREDITED Pharmacy Benefit Management Expires 12/01/2025

2 Street 1, Suite 500
Guaynabo, PR 00968

Tel. 787.522.5252
Fax 866.912.2830

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