

Ebglyss, a New Biologic Treatment for Atopic Dermatitis, Gets FDA Approval

Every Day Health

People with moderate-to-severe atopic dermatitis, the most common form of eczema, don't always get adequate relief from topical treatments like steroid creams and ointments. **Now they have a new option:** The U.S. Food and Drug Administration (FDA) just approved Ebglyss (lebrikizumab-lb-kz), a biologic treatment for adults and children ages 12 years and older.

This once-a-month injectable drug belongs to a class of medicines called targeted interleukin-13 (IL-13) inhibitors, and offers a new systemic option to combat the underlying inflammation in people living with atopic dermatitis, clearing skin and alleviating itch.

The approval of Ebglyss has been highly anticipated because the data on the phase 3 studies is so strong, says Amy McMichael, MD, a dermatologist who specializes in treating people of color with dermatologic conditions at Atrium Health Wake Forest Baptist in Winston Salem, North Carolina. (Dr. McMichael was not involved in any of this research.) One study that focused exclusively on people of color determined that the medication provided consistent results no matter an individual's skin tone.

"People can have a reduction in signs of their disease, relief from itch, and are able to reimagine what they can do with their lives now that they can function better," says Mark Genovese, MD, senior vice president of immunology development at Eli Lilly, the drug's manufacturer.

Nearly 40 Percent of People Achieved Clear Skin in 16 Weeks The approval of Ebglyss is based on three pivotal phase 3 trials, ADvocate 1, ADvocate 2, and ADhere, which included a total of over 1,000 participants ages 12 and older with moderate-to-severe eczema who were unable to control their symptoms with topical prescription medications.

Long-Term Efficacy Of the people who experienced cleared skin,

77 percent maintained it at one year with once-monthly dosing.

Additionally, 48 percent of those who were switched to placebo at week 16 maintained their improvement at one year.

Itch Relief Significant itch relief at 16 weeks was experienced by 43 percent of participants, with some people reporting relief as soon as two weeks into treatment.

Side Effects The most common side effects of Ebglyss included eye and eyelid inflammation, such as redness, swelling, and itching; injection site reactions; and shingles (herpes zoster).

Ebglyss Proves Effective in People of Color

In a first-of-its-kind study, Ebglyss showed improvement in skin clearance and itch relief in a small trial of 50 people with darker skin tones, which included Black, Asian, Hispanic/Latinx, and American Indian or Alaska Native people. The results have yet to be published in a peer-reviewed journal.

Results at 16 weeks were consistent and similar with earlier trials, with most people experiencing significant improvement, and close to 40 percent achieving clear or almost-clear skin.[2] People of color are disproportionately affected by atopic dermatitis, often experiencing more severe symptoms, a delay in diagnosis, and a lengthier time frame to find appropriate treatment, according to lead author Andrew Alexis, MD, MPH, a professor of clinical dermatology at Weill Cornell Medicine and a dermatologist at NewYork-Presbyterian/Weill Cornell Medical Center, both in New York City.[2] A recent national health survey found that about 19 percent of Black children have atopic dermatitis, compared with about 16 percent of white children and 8 percent of Asian children. Another study found that Black children are 1.7 times more likely to develop atopic dermatitis than white children.[3] "They also have been histori-

cally underrepresented in clinical trials, which means we have lacked data pertaining to the treatment of patients with skin of color," said Dr. Alexis.

Because most dermatologic trials often don't include people of color, providers have to assume medications work in all races and ethnicities — even without the data, says McMichael.

"This trial in patients of color shows that this drug is unequivocally effective in patients with skin of color," she says.

How Much Will Ebglyss Cost?

According to the Lilly press release, a patient's out-of-pocket cost will depend on multiple factors, including the type of in-

urance coverage they have on their current phase of coverage. Lilly is working to ensure broad patient access through collaborations with insurers and health systems, alongside providing support programs such as copay assistance for eligible patients, said a company spokesperson. Covered patients may pay as little as \$5 per month.

The list price in the United States for Ebglyss is \$3,500 per pen, according to a Lilly spokesperson.

Without insurance, that means a person on a typical dosing schedule would spend \$38,500 by week 16.

Ebglyss will be available in the United States in the coming weeks, according to the company press release.

Saving Strokes Event Scheduled for October 2nd

The Annual Saving Strokes event will be held at Legacy Golf Course on October 2nd.

This annual event sponsored by the **American Heart & Stroke Association and Encompass Rehabilitation Hospitals** provides an opportunity for Stroke Survivors to engage in therapy and fun at the same time!

The event starts at 10:00 am. There are explanations on golf and even a brief warmup before starting the golf.

The participants are able to begin their fun and therapy with

3 different activities.
Putting on the green

Chipping to the green

Driving range

Volunteers from Encompass Rehabilitation Hospital, Touro University and Golf Professionals from the PGA and others will be on hand to assist everyone!

Caregivers can attend and a **free lunch will be provided.**

Attend this fun, recreational and therapeutic event!

The Challenger is published monthly in Nevada. Nevada's only independent Health/Rehab/Seniors/People With Disabilities, newspaper.

Vol. 28 No. 10 PO Box 530005, Henderson, NV 89053-0005. Phone: 702-496-8198.

E-mail: Challengerrehab@aol.com

Web: www.thechallengernewspaper.com

Lee & Toni Brasted, Publishers

Note: Editorial material does not necessarily reflect the views of The Challenger newspaper. Unsolicited material will be considered for publication, but The Challenger cannot be responsible for loss or damages to items submitted. Submissions are the author's warranty that the material is not an infringement on the rights of others and that the material may be published without further approval. The Challenger newspaper is not responsible for any of the advertising copy in this publication. No part of this publication may be reprinted without the permission of the publishers.

Celebrating 28 years !