The Medical Letter®

on Drugs and Therapeutics

Volume 66 July 22, 2024

ISSUE No. 1707

IN THIS ISSUE

The Medical Letter®
on Drugs and Therapeutics

Volume 66 (Issue 1707) July 22, 2024

Take CME Exams

IN BRIEF

Wezlana — An Ustekinumab Biosimilar Interchangeable with *Stelara*

The FDA has approved ustekinumab-auub (*Wezlana* – Amgen), an interchangeable biosimilar product similar to the interleukin-12 and -23 antagonist *Stelara*, for treatment of the same indications as *Stelara* (see Table 1). *Wezlana* is the first *Stelara* biosimilar to be approved in the US.

Pronunciation Key

Ustekinumab-auub: us" te kin' ue mab

***Wezlana*:** wez lah' nah

The four-letter suffix -auub has no pronunciation or meaning; such suffixes are now added to biologic drugs to distinguish reference products from their biosimilars.

A biosimilar is a biologic product that is highly similar in composition, potency, and biologic properties to and has no clinically meaningful differences in safety, purity, and potency from the FDA-approved reference product. For a biosimilar to be approved as an interchangeable product, the manufacturer generally conducts clinical trials to prove that the results will be the same if the patient switches between the reference product and the biosimilar. In clinical studies, there were no clinically significant differences in efficacy and safety between *Wezlana* and *Stelara* for treatment of moderate to severe plaque psoriasis. The FDA extrapolated approval of *Wezlana* to psoriatic arthritis, Crohn's disease, and ulcerative colitis based on available data.[1-3]

According to federal law, an interchangeable product can be substituted for the reference product by the pharmacist without permission from the prescriber. Some states require the pharmacist to notify the prescriber and/or patient before making the substitution; currently four states (AL, IN, SC, and WA) restrict interchangeability entirely.[4]

Table 1. FDA-Approved Indications of *Stelara* and *Wezlana*

- Treatment of moderate to severe plaque psoriasis in patients ≥6 years old who are candidates for phototherapy or systemic therapy
- Treatment of active psoriatic arthritis in patients ≥6 years old
- Treatment of moderately to severely active Crohn's disease in adults
- Treatment of moderately to severely active ulcerative colitis in adults

Wezlana will be launched in early 2025 when *Stelara's* patent exclusivity expires. The cost of the drug is not yet available, but will presumably be less expensive than *Stelara*. The wholesale acquisition cost (WAC) for a 12-week supply of *Stelara* for treatment of plaque psoriasis for a 75-kg patient is about $13,300 and for treatment of Crohn's disease or ulcerative colitis is about $26,500.[5] ■

1. V Chow et al. Pharmacokinetic similarity of ABP 654, an ustekinumab biosimilar candidate: results from a randomized, double-blind study in healthy subjects. Clin Pharmacol Drug Dev 2023; 12:863.
2. G Cantin et al. Analytical and functional similarity of the biosimilar candidate ABP 654 to ustekinumab reference product. Drugs R D 2023; 23:421.
3. NIH. A study to investigate ABP 654 for the treatment of participants with moderate to severe plaque psoriasis. Available at: https://clinicaltrials.gov/study/NCT04607980. Accessed June 19, 2024.
4. S Humphreys. Understanding interchangeable biosimilars at the federal and state levels. Am J Manag Care 2023; 29:SP545.
5. Approximate WAC. WAC = wholesaler acquisition cost or manufacturer's published price to wholesalers; WAC represents a published catalogue or list price and may not represent an actual transactional price. Source: AnalySource® Monthly. June 5, 2024. Reprinted with permission by First Databank, Inc. All rights reserved. ©2024. www.fdbhealth.com/policies/drug-pricing-policy.

Subscription Services

Address:
The Medical Letter, Inc.
145 Huguenot St. Ste. 312
New Rochelle, NY 10801-7537
www.medicalletter.org

Customer Service:
Call: 800-211-2769 or 914-235-0500
Fax: 914-632-1733
E-mail: custserv@medicalletter.org

Permissions:
To reproduce any portion of this issue, please e-mail your request to:
permissions@medicalletter.org

Subscriptions (US):
1 year - $159; 2 years - $298;
3 years - $398. $65 per year
for students, interns, residents,
and fellows in the US and Canada.
Reprints - $45 per issue or article

Site License Inquiries:
E-mail: SubQuote@medicalletter.org
Call: 800-211-2769
Special rates available for bulk subscriptions.

Get Connected:

Copyright 2024. ISSN 1523-2859