

Amjevita™



First biosimilar for Humira® now available

Availability of **Amjevita™, the first biosimilar for Humira®**, rocked the headlines on January 31, 2023. Amjevita™ (adalimumab-atto), a citrate-free biosimilar to Humira® (adalimumab), is now available in the U.S.¹

Similar to the Humira, Amjevita carries all the same indications for:²

- Rheumatoid arthritis (RA)
- Juvenile idiopathic arthritis (JIA)
- Psoriatic arthritis (PsA)
- Ankylosing spondylitis (AS)
- Crohn disease (CD)
- Ulcerative colitis (UC): moderately to severely active UC in adult patients
- Plaque psoriasis (PsO)

The FDA originally approved Amjevita in September 2016 based on studies demonstrating that Amjevita and the reference product were highly similar, with no clinically meaningful differences between the agents.³ Although Amjevita is not interchangeable with Humira, the biosimilar presents a viable treatment alternative for Humira, which for over two decades has dominated the charts as the top selling prescription drug in the U.S., reaping estimated annual sales of over \$20 billion.

As observed with other first-time biosimilar entrants on the market, embracing Amjevita will not be as easy due to pharmaceutical contracting dynamics, and the still limited competition with only one biosimilar competitor. In order to make Amjevita broadly accessible, Amgen is making Amjevita available at two list prices.² Amjevita is supplied in a 40mg/0.8mL single-dose prefilled SureClick autoinjector, and in 20mg/0.4mL and 40mg/0.8mL single-dose prefilled syringes which will be available at two list price options that are about 5% or 55% less than Humira's list price of \$6,922 per month. This means a typical annual cost for Amjevita 40mg every 2 weeks could be \$40,500 or as much as \$85,500. Payers will be able to select the pricing option based on their pharmaceutical contracting arrangements with the manufacturer. For the time being, patients may be less likely to see immediate benefit from the more significant discount. What the patient pays will be dependent on their health insurance benefit.

Some health plan payers and prescription benefit managers (PBMs) may continue to maintain Humira in a preferred position (because of substantive rebates, current contracted discounts and challenges in switching patients to a biosimilar), or add the biosimilar as a formulary option (but as a result may sacrifice some loss of their contracted discounts). Payers may also vary in their decisions to adopt the higher list price for Amjevita, as this higher price will also likely have higher discounts. Of note, here are some of the decisions made by the PBMs which have been released. CVS Health has stated it will keep originator Humira and include the biosimilar Amjevita as co-preferred on some formularies. ESI and Optum have both stated they will add Amjevita as a co-preferred agent.

Bottom Line:

Uptake of Amjevita will take time. Much will come down to timing and introduction of seven more biosimilars for Humira that are anticipated to be available by the end of this year (made by Boehringer Ingelheim, Novartis' Sandoz, Organon, Pfizer, Mylan, Coherus, and Fresenius Kabi). Increasing the number of biosimilars in the market space and having potential interchangeability with Humira will lend to greater competition, prices to fall,

and likewise greater uptake and switching to biosimilars. According to one analytic study, they believe the first-year capture by biosimilar should be up to 5 percent with up to a **maximum market share of 20 or 25% by 2026**.⁶ Also, Amjevita is only the first up to 12 total biosimilars expected to come to market in the coming year.

Who is PayerAlly?

PayerAlly's mission is to provide cutting-edge support for our clients as they look to better manage their medication costs. We offer best-in-class clinical, financial, and consultative solutions to help better manage costs and improve performance.

References:

1. Amjevita, first biosimilar to Humira, now available in the United States. Amgen. January 31, 2023. Found at: <https://www.amgen.com/newsroom/press-releases/2023/01/amjevita-adalimumabatto-first-biosimilar-to-humira-now-available-in-the-united-states>. Accessed 2/3/2023.
2. AMJEVITA U.S. prescribing information. Available at: https://www.pi.amgen.com/-/media/Project/Amgen/Repository/pi-amgen-com/Amjevita/amjevita_pi_hcp_english.pdf [Last accessed: January 2023]. Accessed 02/3/2023.
3. Food and Drug Administration. FDA approves Amjevita, a biosimilar to Humira. Available at: <https://www.fda.gov/news-events/press-announcements/fda-approves-amjevita-biosimilar-humira>. Last accessed 2/3.2023.
4. Nash P, et al. Randomized Crossover Comparison of Injection Site Pain with 40 mg/0.4 or 0.8 mL Formulations of Adalimumab in Patients with Rheumatoid Arthritis. *Rheumatol Ther*. 2016 Dec; 3 (2): 257-270.
5. Access to medications. Amgen's approach to responsible pricing. Amgen. Inc. Found at <https://wwwext.amgen.com/responsibility/healthy-people/access-to-medicines/our-approach-to-pricing-access-and-affordability/access-approaches-treatment-and-collaborations/responsible-approach-to-pricing/pricing>. Accessed 2/2/2023.
6. GoodRoot – Biosimilar Whitepaper. Found at: https://info.goodrootinc.com/hubfs/Goodroot/Humira_Biosimilars_Whitepaper.pdf?utm_campaign=Goodroot%20Biosimilars%20Campaign%202023&utm_source=form&utm_medium=LP%20Finsights%20gated%20form%20for%20download&utm_content=Biosimilars%20Whitepaper%20Gated