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First Humira Biosimilar Now Available

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Insights on the first Humira biosimilar and the 2023 pipeline

On January 31, 2023, Amgen launched Amjevita (adalimumab-atto) into the marketplace as the first biosimilar for Humira. Amjevita is available in 20mg/0.4mL as a prefilled syringe only and in 40mg/0.8mL prefilled syringe and SureClick® autoinjector. The two list prices for this launch are both below Humira's current wholesale acquisition cost (WAC).

Background

Biosimilars are highly similar in structure and function to the reference biologic product. However, unlike small molecule drugs which are produced from chemicals, biosimilars are produced from living organisms and/or tissues and are, therefore, not an exact copy of the reference product.

Although the FDA defines a biosimilar to have "no clinically meaningful differences" from its reference product, some prescribers have shown hesitancy to prescribe biosimilars. Formulary status and familiarity with the FDA approval process for biosimilars were some factors influencing the hesitancy. As such, there may be a gradual uptake of Amjevita and other adalimumab biosimilars as clinicians gain experience and familiarity with these new products.

Pricing

Humira is a blockbuster drug for inflammatory diseases with over $20 billion in sales in 2021 and an annual cost of approximately $90,000, based on its WAC.

In September 2016, Amjevita became the first biosimilar for Humira to be approved by the U.S. Food & Drug Administration (FDA). It was launched with distinct National Drug Codes (NDCs) carrying two different WAC prices. One version is priced with a WAC that is 5% less than branded Humira which equates to an annual list price of approximately $85,000. The other version is priced with a WAC that is 55% less than Humira with an annual list price of approximately $40,000. Despite the differing list prices, the net price for the two products is expected to be similar once the effect of rebates is incorporated.

The bifurcated pricing approach is similar to the strategy employed by Mylan with its market launch of Semglee®, the biosimilar for Lantus®. The higher priced version is designed for payers preferring to pay more upfront to meet rebate guarantees. The lower list price product is marketed to payers and plan designs that seek lower upfront costs.

Interchangeable Status

Its lack of interchangeable status may be another factor that contributes to a slow update of Amjevita. A pharmacist may substitute an interchangeable biosimilar for the reference product without the intervention of the prescriber's approval in most jurisdictions. Since Amjevita is **not** an interchangeable biosimilar, a pharmacist needs approval from the prescribing doctor to substitute Amjevita for Humira. Cyltezo® is expected to be the first interchangeable biosimilar for Humira with an expected launch date of July 1, 2023.

Indications

Although Amjevita is a biosimilar for Humira, it does not have FDA approval for all the same indications as Humira.

Approved Indications

Below is a table that illustrates the differences in approved indications for these products.

Indication	Humira	Amjevita
Rheumatoid Arthritis	Adults	Adults
Juvenile Idiopathic Arthritis	Patients 2 years of age and older	Patients 2 years of age and older
Psoriatic Arthritis	Adults	Adults
Ankylosing Spondylitis	Adults	Adults
Crohn's Disease	Patients 6 years of age and older	Patients 6 years of age and older
Ulcerative Colitis	Adults	Adults
Plaque Psoriasis	Adults	Adults
Hidradentis Suppurativa	Patients 12 years of age and older	Not an approved indication
Uveitis	Patients 2 years of age and older	Not an approved indication

Humira Biosimilars and Interchangeable Biosimilars

The following is a table of current and pipeline biosimilar and interchangeable biosimilar products for Humira as of January 2023.

Drug	Manufacturer	Biosimilar / Interchangeable	Approval Date	Earliest Launch Date
Humira	Abbvie	Reference	January 18, 2008	N/A
Amjevita*	Amgen	Biosimilar	September 23, 2016	January 31, 2023
Cyltezo	Boehringer	Interchangeable	August 25, 2017	July 1, 2023
Hyrimoz	Novartis	Biosimilar	October 30, 2018	As early as July 2023
Hadlima*	Organon, Samsung Bioepis	Biosimilar	July 23, 2019	July 1, 2023
Abrilada*	Pfizer	Biosimilar	November 15, 2019	July 1, 2023
Hulio	Viatris/Biocon	Biosimilar	July 6, 2020	As early as July 2023
Yusimry	Coherus	Biosimilar	December 17, 2021	July 1, 2023
Idacio	Fresenium Kabi	Biosimilar	December 13, 2022	July 1, 2023

*Seeking interchangeability status from FDA

Medicaid Impact

Rebate

Medicaid programs already receive substantial federal and state supplemental rebates from AbbVie for Humira utilization. The net cost of Humira for Medicaid programs is expected to keep Humira as preferred on Medicaid's preferred drug lists (PDLs) in 2023. The expectation is that Amjevita will offer a supplemental rebate but individual states will need to review their offers to determine whether Amjevita or Humira offers the lowest price, net of rebate.

With the number of biosimilars and interchangeable biosimilars entering the market in 2023, Medicaid programs should closely monitor net costs for these products, including Humira, when making decisions for future PDL placement.

Medicaid programs sometimes receive rebate offers from manufacturers that bundle rebates for branded products, including reference biologics, with other products made by the same manufacturer to encourage continued presence of the branded product on the PDL.

Fiscal modeling will help identify the most efficient option for PDL decisions.

Considerations for Medicaid:

- Programs will need to decide whether to allow preferred access to all biosimilars, some biosimilars, or maintain Humira as the only preferred product in the drug class.
- As more adalimumab biosimilars enter the market, their manufacturers may offer different rebates that Medicaid programs should consider for manufacturer specific biosimilar placement on the PDL.

Reimbursement

In fee-for-service Medicaid (FFS), the expectation is that Amjevita will have acquisition cost-based reimbursement rates through the National Average Drug Acquisition Cost and state average acquisition cost (AAC) programs.

As was the case with Semglee, Medicaid programs should be aware of the multiple NDCs with different WAC prices for Amjevita when establishing reimbursement rates reflective of pharmacy acquisition costs. Given the number of biosimilars entering the market in 2023, another strategy for Medicaid agencies is to implement a maximum allowable cost rate to the adalimumab drug groups to incentivize the use of the most cost-effective biosimilar product.

340B Considerations

Since Medicaid programs cannot collect rebates on drugs purchased through the 340B program, there are different factors to consider for programs with significant amounts of 340B claims for adalimumab. In particular, this is the case when a uniform or statewide PDL is in place. In FFS programs or managed care programs that require the managed care organizations (MCOs) to pay for 340B dispensed claims based on AAC or the 340B ceiling price, the state can confidently select the lowest net price product as the preferred agent.

In programs where MCOs do not reimburse 340B claims at 340B acquisition cost, states may want to consider selecting the product with the lowest list price for preferred status on the PDL.

Important Next Steps for State Medicaid Programs

The introduction of biosimilars for the blockbuster drug Humira represents an important opportunity for Medicaid drug programs to plan and implement a strategy for the growing impact of biosimilars.

Medicaid programs should be prepared to:

- **Monitor uptake** of Amjevita and other adalimumab biosimilars to observe prescriber adoption of biosimilars.
- Consider **prescriber** education on biosimilars and their approval process.
- Perform **fiscal modeling** to determine most effective option for PDL placement of Humira and its biosimilars with consideration of 340B volume and managed care reimbursement policy. Any fiscal modeling should also consider the impact of bundled rebate offers.
- Consider manufacturer specific **PDL placement** for biosimilars.
- Review **reimbursement** policy for biosimilars, particularly for products that are introduced at multiple price points.

Questions for Your Specific State?

Please contact James Shin or your Mercer client leader to discuss the pipeline and implementing a strategy for your specific state program. You may also email us at mercer.government@mercer.com.

View more information at https://www.mercer-government.mercer.com