

Amgen Inc.: Pricing Amjevita for the U.S. Humira market

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*A strategy case for MBA students and working professionals
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The decision

Amgen had a date for entering the U.S. market with Amjevita, its biosimilar to AbbVie's Humira, but no public launch price or payer-contracting offer. The agreed U.S. license date was 31 January 2023, four months away. The commercial question was how to make the product accessible when the party choosing a formulary position, the party prescribing treatment, and the patient paying at the pharmacy counter may respond to different parts of a drug's price.

Assume you advise a **hypothetical Amgen launch team**. Recommend an initial U.S. price and contracting architecture for Amjevita. Should Amgen emphasize a visible reduction in wholesale acquisition cost (WAC), use confidential rebates to pursue preferred coverage, or make more than one offer available to plans? Your recommendation should explain how it could reach patients and prescribers, what evidence supports its logic, and what additional information Amgen would need before committing. This is a classroom decision frame; it does not describe a disclosed Amgen meeting or plan.

An approved product, a delayed market entry

The FDA approved Amjevita on 23 September 2016 as a biosimilar to Humira for seven eligible inflammatory-disease indications. Approval established that the product met the FDA's biosimilar standard. It did not make Amjevita interchangeable with Humira, assure pharmacy substitution, or guarantee payer coverage or patient savings. In September 2017, Amgen and AbbVie announced a settlement of patent litigation. Both companies' releases stated that the agreed U.S. entry date was 31 January 2023; the public announcements did not disclose the full settlement terms. [1-3]

The long interval between approval and U.S. entry gave Amgen time to prepare, but also left important commercial questions unanswered in public. Public sources reviewed by the information cutoff did not disclose a U.S. WAC, rebate level, payer bid, expected share, or Amjevita-specific contribution margin. The public record therefore could not identify one mathematically optimal price.

A large incumbent and a pipeline of approved competitors

AbbVie reported U.S. Humira net revenue of \$17.330 billion in 2021, up 7.6% from 2020. The same filing reported that international Humira revenue declined 9.6%, primarily because of biosimilar competition. The contrast showed that biosimilar competition was commercially real outside the United States, but the two settings differed in market structure, access rules, pricing and launch timing. AbbVie also reported \$33.9 billion in company-wide rebate and chargeback provisions for 2021. That figure covered its portfolio; it did not disclose Humira's rebates or any individual payer's net price. Accounting net revenue likewise is not a list price or an estimate of the market Amjevita could capture. [4]

By September 2022, FDA had approved seven Humira biosimilars. FDA testimony in February 2022 said none was yet on the U.S. market at that time, identified Cyltezo as the only interchangeable product in the group, and noted that some products could enter in 2023. Contemporaneous company disclosures set expected U.S. license or entry dates across 2023: Amjevita on 31 January; Hadlima on 30 June; Cyltezo on 1 July; Hulio on 31 July; Hyrimoz on 30 September; and Yusimry on or after 1 July. Pfizer's Abrilada disclosures differed: its agreement named 20 November 2023, while a later company forecast said launch could occur as early as 1 July 2023. These were announced dates, not evidence of launches that had occurred. The expected sequence suggested a crowded pipeline, but not simultaneous entry. [2, 5-7]

Who captures a discount?

Amjevita is self-administered. For this case, treat pharmacy-benefit contracting as a working premise to test the price architecture, not as a documented Amgen U.S. channel plan; coverage may vary by plan and benefit design. Under that premise, the route from manufacturer price to coverage and patient cost sharing is central to the decision. A visible WAC reduction might be legible to patients and may reduce out-of-pocket spending where a plan's deductible or coinsurance is linked to list price. A confidential rebate could improve a plan's net economics or help secure preferred formulary status. But a lower net price to a plan does not necessarily lower what a patient pays at the counter, and a lower WAC does not itself secure coverage.

The available evidence made adoption uncertain. In a survey, 73% of responding U.S. rheumatologists said they were likely to start a biosimilar for a biologic-naïve rheumatoid-arthritis patient, compared with 35% likely to switch a stable patient from the reference product. Those were stated intentions from 320 respondents, not observed prescribing. A randomized study published in 2022 found similar pharmacokinetic outcomes after protocolized repeated switching between Humira and a different biosimilar, BI 695501, among selected psoriasis patients. It did not test Amjevita's interchangeability, commercial formulary access or real-world uptake. [8-9]

Prior U.S. market evidence also cautioned against assuming that low price automatically produces share. A Medicare claims study of infused infliximab found greater biosimilar use among new than returning patients; another analysis found widely varying uptake across physician-administered biosimilars. These findings suggest that starting treatment and switching a stable patient may be different adoption challenges. Their Part B reimbursement and clinical settings differ from self-injected adalimumab on pharmacy benefits, so their market-share levels cannot be used as an Amjevita forecast. [10-11]

Three possible architectures

Amgen could make a single offer with a substantial, visible WAC discount. This would give the affordability proposition a simple reference point and could benefit patients whose cost sharing is list-linked. It might, however, be less attractive to a plan evaluating net cost after rebates, and it would surrender price flexibility if some payers valued rebate terms more than list-price reductions.

A second route would keep WAC closer to the incumbent's list price and use confidential rebates to compete for preferred access. That could suit plans focused on net economics. The counterargument is that rebate value may not reach patients and that list-linked cost sharing could remain high. AbbVie's company-wide rebate disclosures show that rebates were material in its commercial model, but they do not establish Humira-specific terms or prove that every payer would favor a rebate-led Amjevita offer.

A third route would offer plans more than one price structure—for example, a lower-WAC option and a higher-WAC option with a larger rebate. This could let different plans select according to their benefit design and contracting preferences. It could also add contracting, distribution, communication and inventory complexity. The public evidence available at the cutoff did not show whether such segmentation would improve access, volume or returns for Amjevita.

Each choice leaves questions about clinical confidence and operational execution. New-patient starts may be easier to win than conversion of stable patients. Education and support could address questions, but evidence does not show how much they would change prescribing. Pricing cannot substitute for a credible supply and access plan; the case evidence does not establish a differentiated Amjevita service or supply advantage.

Assignment

1. Recommend one architecture, or a staged/segmented approach. State what outcome the strategy is designed to improve: preferred coverage, new starts, stable-patient switching, patient affordability, or another defined objective.
2. Map the consequences for a plan/PBM, a prescriber, a patient with list-linked cost sharing, and a patient whose cost sharing is not list-linked. Identify who receives each concession and where the public evidence is silent.
3. Explain how you would manage the distinct challenges of new starts and switching stable patients. Use the clinical and adoption evidence without treating another product or benefit channel as a direct forecast.
4. Name the two or three pieces of internal or payer evidence that could change your recommendation. State a decision guardrail or trigger without inventing Amgen's costs, prices, elasticity or contract terms.

Sources and evidence notes

All facts and expectations in this case are limited to material public by 30 September 2022. Dates for future competitor entry are contemporaneous license/forecast disclosures, not actual launch outcomes. Academic findings are summarized with their transfer limits.

1. FDA, "FDA approves Amjevita, a biosimilar to Humira," 23 Sep 2016, opening and indication paragraphs. [FDA release](#).

2. Amgen, "Amgen and AbbVie Agree to Settlement Allowing Commercialization of AMGEVITA," 28 Sep 2017; AbbVie, "Global Resolution of HUMIRA Patent Disputes with Amgen," same date. [Amgen release](#); [AbbVie release](#). Both identify 31 Jan 2023 as the U.S. entry date.
3. FDA release cited in note 1; biosimilar approval is distinct from interchangeability and substitution.
4. AbbVie, 2021 Form 10-K, filed 18 Feb 2022, Item 7 product revenue table (printed p. 37), Humira discussion (p. 39), rebates/chargebacks (p. 44), rebate accruals (p. 59). [SEC filing](#).
5. FDA, "Timeline of Biosimilar and Interchangeable Biosimilar Approvals," 7 Dec 2021, adalimumab approval timeline; FDA congressional testimony, 3 Feb 2022, adalimumab passage. [FDA timeline](#); [FDA testimony](#).
6. Contemporaneous primary entry-date disclosures: AbbVie/Samsung Bioepis, 5 Apr 2018, [Hadlima settlement](#); Boehringer Ingelheim, 14 May 2019, [Cyltezo settlement](#); AbbVie, Q2 2018, [Hulio license-date disclosure](#); AbbVie/Sandoz, 11 Oct 2018, [Hyrimoz settlement](#); Coherus, 29 Mar 2022, [Yusimry anticipated launch](#). These dates are expected/license dates only, not actual launch outcomes.
7. Pfizer, 30 Nov 2018 license announcement and 2021 Q3 results release, each discussing Abrilada timing. [License release](#); [Q3 2021 results](#).
8. Gibofsky A, McCabe D. "US rheumatologists' beliefs and knowledge about biosimilars: a survey." *Rheumatology* 60(2), 896-901 (2021), Methods pp. 897-898; Results pp. 898-899, Tables 1-3; Discussion pp. 899-900. [Full text](#). Survey intentions; 320/9,050 invited.
9. Gerdes S, et al. "Switching Between Adalimumab Reference Product and BI 695501... (VOLTAIRE-X)." *American Journal of Clinical Dermatology* 23, 719-728 (2022), published 7 Aug 2022; Methods §§2.3-2.8; Results §§3.1-3.5, Table 2 and Figs. 2-3. [Full text](#). BI 695501 is not Amjevita; study sponsor participated in the research.
10. Chen AJ, et al. "Uptake of Infliximab Biosimilars Among the Medicare Population." *JAMA Internal Medicine* 180(9), 1255-56 (2020), Methods, Figs. 1-2 and limitations. [Full text](#). Descriptive Part B infliximab claims; corresponding author disclosed Amgen fees outside the work.
11. Kozlowski S, et al. "Uptake and Competition Among Biosimilar Biological Products in the US Medicare Fee-for-Service Population." *Journal of General Internal Medicine* 37, 4292-94 (2022), pp. 4292-94, Figs. 1-2. [Full text](#). Short descriptive Part B analysis; not an Amjevita uptake estimate.