



November 19, 2025

VIA ELECTRONIC MAIL

Washington Prescription Drug Affordability Board
Washington Health Care Authority
PO Box 42716
Olympia, Washington 98504-2716
HCA_WA_PDAB@hca.wa.gov

Re: Inclusion of HUMIRA® on Affordability Review Shortlist

Dear Members of the Washington Prescription Drug Affordability Board:

AbbVie is a biopharmaceutical company committed to discovering and delivering innovative medicines and solutions that solve serious health issues today and address the medical challenges of tomorrow. We strive to have a remarkable impact on people's lives across several key therapeutic areas including immunology, oncology, neuroscience, and eye care. AbbVie focuses on these areas to accelerate the development of innovative approaches to treat disease and respond to unmet patient needs. AbbVie has a robust pipeline of potential new medicines, with the goal of finding solutions to address complex health issues and enhance people's lives.

AbbVie submits these comments in response to the Washington Prescription Drug Affordability Board's ("PDAB" or "Board") selection of HUMIRA® for a "cost review" (or "affordability review"). HUMIRA® (adalimumab) delivers substantial value across Washington and the U.S. – both clinically and economically. As one of the most widely studied and broadly indicated immunology therapies available, HUMIRA® is FDA-approved for ten serious chronic conditions, including rheumatoid arthritis, Crohn's disease, ulcerative colitis, psoriatic arthritis, and several others – some of which carry orphan drug designation. Supported by extensive clinical and real-world evidence, HUMIRA® helps improve long-term outcomes and quality of life for a diverse population of Washington patients facing debilitating disease.

Our commitment to supporting patient access, promoting affordability, and advancing responsible stewardship of healthcare resources underpins our concerns throughout this letter. Accordingly, we urge the Board to carefully reconsider HUMIRA®'s inclusion in its affordability review. The concerns presented herein span several areas – methodological flaws in the Board's cost assessment, biosimilar competition and market evolution, statutory requirements for drug selection, dynamics of the Federal 340B Program, and the latest evidence on patient affordability.

I. Methodological Deficiencies in Calculating State Spend

A foundational concern regarding the Board's methodology for estimating HUMIRA®'s cost impact centers on its reliance upon the All-Payer Claims Database (APCD), which calculates

spending using wholesale acquisition cost (WAC) rather than actual net payment. This approach significantly inflates HUMIRA®'s actual medical expenditures in Washington, as it does not reflect the real-world pricing dynamics present across all major payer channels, including commercial insurance, Medicare, Medicaid, and state exchange plans. Specifically, the current methodology:

- Fails to account for substantial market rebates and negotiated discounts that consistently reduce actual costs across commercial, Medicare, and state exchange insurance segments.
- Ignores the effect of Medicaid statutory rebates – mandated by both federal and state programs – which regularly bring net HUMIRA® costs to the state well-below published WAC values.
- Overlooks the additional rebates and PBM price negotiations in the commercial market and the state exchanges, which further reduce the effective price paid by these plans, often resulting in a net spend level far lower than what is reported via the APCD.

As a result, reporting or acting on spend calculated from WAC rather than net payment significantly misrepresents the state's true expenditure for HUMIRA®, regardless of payer channel. This distortion can lead to inaccurate identification of affordability challenges and risks misdirecting Board efforts.

II. Substantial and Ongoing Market Erosion Due to Robust Biosimilar Competition

Since the WA PDAB relied on 2023 data to identify products for its affordability review – the year when HUMIRA®'s biosimilar competition first launched – the marketplace has considerably changed. The adalimumab market has fundamentally transformed: in just two years, there are now ten FDA-approved biosimilars for HUMIRA®, with eight officially interchangeable. This interchangeability allows pharmacists to automatically substitute biosimilars for brand HUMIRA® for most patients, giving Washingtonians broad access to these biosimilars. The availability of ten Humira biosimilars in the past two years demonstrates how the pharmaceutical innovation lifecycle works: after a period of exclusivity that encourages investment in new therapies, generics or biosimilars can enter the market, making these alternatives available from this point forward.

The entry of nine adalimumab biosimilars by the end of 2023 has introduced a level of direct competition unlike any other biologic to date. This increased competition, characterized by the adoption of lower-cost alternatives by both payers and providers – particularly with many biosimilars being interchangeable at the pharmacy level – was anticipated to impact HUMIRA®. According to AbbVie's Q3 2025 financial results, this has led to a substantial decline in HUMIRA® global net revenues. Specifically, for the nine months ended September 30, 2025, HUMIRA® global net revenues totaled \$3.294 billion, representing a 55.0% decrease compared to the prior year period, with U.S. net revenues declining 63.3% and international net revenues declining 20.2%. These decreases follow previous annual declines of 35% in 2023 and 41% in 2024. As noted in AbbVie's public filings, these results reflect the broader transformation of the adalimumab landscape due to the rapid uptake of biosimilar alternatives.¹

¹ AbbVie Reports Third-Quarter 2025 Financial Results, <https://news.abbvie.com/2025-10-31-AbbVie-Reports-Third-Quarter-2025-Financial-Results>

Given these naturally evolving, market-driven trends, it is expected that by the time the PDAB completes its review, and certainly before a UPL could go into effect in 2027, Washington’s spending on HUMIRA® will be minimal and continuing to decline. Further intervention at this stage risks disrupting a competitive landscape already generating substantial value. Therefore, continuing to focus on HUMIRA® would not represent the most effective or prudent use of Board or taxpayer resources.

A. The Board Acknowledged but Disregarded Statutory Review Obligations in Selecting HUMIRA®

Per RCW 70.405.040, the PDAB must consider both the class of a prescription drug as well as the availability of therapeutically equivalent alternatives, alongside the average patient’s out-of-pocket cost, in determining whether to initiate an affordability review.² Yet, in selecting HUMIRA® for review, it appears the Board did not put sufficient weight on these required statutory factors, particularly considering recent and significant marketplace changes.

Notwithstanding our separate concerns with each respective state’s PDAB regime, it’s notable that of the Boards that have identified products for affordability review to date – i.e., Colorado, Maryland, Oregon, and Washington State – WA PDAB is the only Board to select HUMIRA® for review. In contrast, states such as Colorado have explicitly cited the robust presence of biosimilars as the reason for declining further review of HUMIRA®. Indeed, a Board member raised this issue during the WA PDAB’s May 21, 2025 Board meeting, but rather than addressing the basis as to why other PDABs, with similar frameworks and standards, have declined to review HUMIRA®, the discrepancy by the WA PDAB was chalked up to “different selection criteria” without further inquiry.³ Another Board member surmised that other Boards had not selected HUMIRA® because “Medicare had already done an evaluation” of the drug, i.e., in the context of the Inflation Reduction Act “Medicare Drug Price Negotiation Program”.⁴ Indeed, Section 1192 of the Social Security Act (the Act or SSA)—added by the Inflation Reduction Act—makes drugs with multisource competition ineligible for price-setting in Medicare.⁵ Notably, multiple Washington PDAB members themselves articulated reservations regarding the value of continuing with HUMIRA®’s review, given developments in the adalimumab market:⁶

- Donna Sullivan observed, “Specifically the Humira, there’s been a flood of biosimilars come to market that are considerably cheaper than Humira, and the population is shifting to that biosimilar utilization. So I’m not sure if you review Humira you’re going to get the impact that you anticipate.”

² RCW 70.405.040(1).

³ *Id.* at 11-12.

⁴ *Id.* at 12.

⁵ See SSA §§ 1192(e)(1)(A)(iii) & (e)(1)(B)(iii).

⁶ Washington State Health Care Authority, Transcript of the May 21, 2025 Washington Prescription Drug Affordability Board Meeting, at 24, at <https://www.hca.wa.gov/assets/program/pdab-meeting-transcript-january-15-2025.pdf> (last visited November 14, 2025).

- Dr. Douglas Barthold acknowledged, “A good point. Yeah. I mean – and I think part of the review will include, you know, what are the therapeutic alternatives? And so, yeah, it’s a good point.”
- Greg Gipson provided further context: “Humira used to have 96% of the market share like a couple of years ago, and all these biosimilars came in... they still have 70%, I think, as of like January of 2025. But yeah, it’s sliding, right? Where it may be – I don’t know. It may be a self-resolving problem.”
- Hung Truong added, “Yeah, it’s going to slide quick because many of the PBMs or the benefit pharmacy managers... are adding biosimilars to their formulary, and many as a requirement.”

These remarks reflect broad agreement among Board members that the market is actively and rapidly responding to biosimilar entry. Importantly, the Board did not fully recognize that ten approved biosimilar alternatives are now available for HUMIRA® – with most interchangeable at the pharmacy level – directly addressing statutory requirements for evaluating therapeutic alternatives and average patient costs.

In summary, despite Board members’ clear acknowledgments of these dynamics and concerns regarding the necessity and value of a HUMIRA® affordability review, the WA PDAB continues to pursue this path. This approach not only departs from statutory guidance and precedents set by peer states but also risks redirecting resources away from areas where meaningful value and impact for Washingtonians can be achieved. This situation underscores the importance of a disciplined, evidence-based assessment, particularly when considering HUMIRA®’s value and impact for patients and the broader healthcare system. Considering these observations, we respectfully urge the Board to reconsider HUMIRA®’s inclusion in the affordability review. If Board members are interested in “exploring generics or alternative availability” as was suggested by Hung Truong in the July 15, 2025 Board meeting, the Federal 340B Program offers an excellent case study.⁷

While national HUMIRA® utilization has declined substantially in response to expanded biosimilar competition, Humira’s utilization through the Federal 340B Program has followed a different pattern. Despite significant reductions in HUMIRA® usage across most channels, our data indicates that sales within Washington State’s 340B-eligible hospitals and clinics have remained unchanged. For context, the Federal 340B Program enables eligible healthcare entities – known as “covered entities” – to purchase outpatient drugs at significantly reduced prices and was originally intended to provide low-income and vulnerable patients access to lower-cost prescription drugs and more-comprehensive healthcare services. However, perverse incentives within the Federal 340B Program can significantly influence medication selection and utilization patterns. These incentives often lead to financial arbitrage, whereby covered entities purchase medications at deeply discounted rates and then resell them at substantially higher prices, frequently sharing revenue with

⁷ Washington State Health Care Authority, Transcript of July 15, 2025 Washington Prescription Drug Affordability Board Meeting, at 37, at <https://www.hca.wa.gov/assets/program/pdab-meeting-transcript-july-15-2025.pdf> (last visited November 14, 2025).

for-profit intermediaries, while the patients do not reap the benefit of the discounted medicine. This practice ultimately results in considerable financial losses for the state.

Additional findings indicate that adalimumab biosimilar uptake in 340B institutions is 23% lower compared to non-340B sites.⁸ This discrepancy stems from systemic abuse inherent to Federal 340B policy, rather than product pricing or affordability. Therefore, as the state assesses biosimilar utilization rates, it is essential to recognize the influence of the Federal 340B program on prescribing behavior. These program dynamics – not HUMIRA® cost or competition alone – are the primary reasons biosimilar up-take may be less robust in these select settings. As such, further review of HUMIRA® in this context is unlikely to impact the underlying challenges affecting biosimilar adoption.

III. Affordability to Washington Patients

Out of pocket (OOP) costs for Washington patients taking HUMIRA® continue to fall. Current data show the average OOP cost was \$26.23 in 2023, declining by over 50% to \$12.90 in 2024, and further to \$11.57 in 2025 year-to-date, as noted in Table 1. Median OOP dropped to \$0.00 in 2024 and remains at \$0.00 in 2025. This is due to robust, ongoing manufacturer copay support for commercially insured patients, which lowers OOP costs for patients.

Table 1 Year over Year Average and Median Out-of-Pocket Cost Per Fill for HUMIRA® Across Commercial and Medicaid

Year over Year Average and Median Out-of-Pocket Cost			
Statistical Parameter	Year		
	2023	2024	2025-YTD
Average	\$26.23	\$12.90	\$11.57
Median	\$5.00	\$0.00	\$0.00

Patient affordability is an important consideration for decision-making. However, despite low patient OOP costs, the Board’s assessment during its selection of HUMIRA® has not fully captured these developments. In fact, one Board member noted during the July 15, 2025 Board meeting that the selection process did not appear to account for key factors that reduce patient financial burden – such as copay support and assistance programs – which play a significant role in minimizing out-of-pocket expenses for those patients who continue to have access to HUMIRA® (See footnotes #9 and #10 in the appendix). Additionally, many health plans have already taken steps that limit or remove coverage for HUMIRA® for certain patient populations – not necessarily in pursuit of affordability, but as part of their own formulary management with so many adalimumab biosimilars now on market.

⁸ Bond, A. M., Emma Boswell Dean, & Desai, S. (2023). The Role Of Financial Incentives In Biosimilar Uptake In Medicare: Evidence From The 340B Program. *Health Affairs*, 42(5), 632–641. <https://doi.org/10.1377/hlthaff.2022.00812>

In summary, given the evolving market realities, diminished financial impact, and low patient OOP cost, the case for continuing an affordability review of HUMIRA® in Washington has grown increasingly tenuous. We urge the Board to recognize these substantive shifts and to adhere to a disciplined, evidence-based approach that fully reflects actual cost dynamics, patient experience, and the unique nuances of market competition and policy programs like the Federal 340B Program. By reconsidering HUMIRA®'s inclusion, the Board can better direct its resources towards interventions that truly advance healthcare for Washington's most vulnerable patients.

Sincerely,

A handwritten signature in black ink that reads "Helen Kim Fitzpatrick". The signature is written in a cursive, flowing style.

Helen Kim Fitzpatrick

Vice President, State Government Affairs

Government Affairs

On behalf of AbbVie Inc

Appendix

- **During the May 21, 2025 Board Meeting:**⁹

Donna Sullivan: Yeah. I mean, specifically the Humira, there's been a flood of biosimilars come to market that are considerably cheaper than Humira, and the population is shifting to that biosimilar utilization. So I'm not sure if you review Humira you're going to get the impact that you anticipate.

Doug Barthold: A good point. Yeah. I mean -- and I think part of the review will include, you know, what are the therapeutic alternatives? And so, yeah, it's a good point.

Greg Gipson: You know, I was actually just looking at that yesterday, that like Humira used to have 96% of the market share like a couple of years ago, and all these biosimilars came in. I mean they still have 70%, I think, as of like January of 2025. But yeah, it's sliding, right? Where it may be -- I don't know. It may be a self-resolving problem.

Hung Truong: Yeah, it's going to slide quick because many of the PBMs or the benefit pharmacy managers, obviously, benefit managers, are adding biosimilars to their formulary, and many as a requirement.

⁹ Washington State Health Care Authority, Transcript of the May 21, 2025 Washington Prescription Drug Affordability Board Meeting, at 24, at <https://www.hca.wa.gov/assets/program/pdab-meeting-transcript-january-15-2025.pdf> (last visited November 14, 2025).

- **During the July 15, 2025 Board Meeting:**¹⁰

Marina Suzuki: [Cross-talk] Just to chime in here though. For the prioritized list, I remember you selected a few factors you want to consider, and these are the ranked list. But two things that are not in the rank is the availability of biosimilar or generic drugs and also the number of this list hold that met from the legislation. So that's not really considered into this ranked list, so when you go down the list, if you feel like one drug has a biosimilar already approved or generic drug already approved, you want to stick that. I think that's something the discussion you need to have because those are the two things previously mentioned that we want to consider, but it's not really in this ranking, just to give you a head's up.

Hung Truong: Yeah, I concur. I mean, Humira, there are at least 10 biosimilars if not more out there right now, and obviously, that's going to affect many of the other drugs and not just Humira, just because people would start using those over Enbrel and so forth. So it is a complex question -- complicated question. And then, you know, many of these drugs, too, will have biosimilars coming out soon. Um, and, you know, what is that timeline that we are willing to evaluate or take into consideration. Is it six months from now? Is it a year from now? And so if it's within a year, do we, you know, say yes, no? But yeah, that would be a significant variable.

Greg Gipson: I've been quiet. I think I also agree that we should stick to our methodology, and I think if -- you know, I also agree that whether we merge the list or not, it's kind of a wash. It's very similar information. So I think I like the idea of taking the Top 4 and focusing on the Top 2 to start with. I do kind of, as Hung mentioned, the, like, plethora of biologic -- biosimilars to adalimumab there out. I do wonder about the utility of that. I don't know if we have any forecast or if anyone has a better idea. I know kind of, looking at some other utilization, it sort of dropped off over time, so I wonder if we're trying to solve a problem that in that regard is already being solved with time. And I think I looked up Enbrel. It loses their exclusivity in the United States in 2027, so I think there is probably some time, and there is probably going to be some litigation, and my guess drag that out because that still seems like a good target. So I think I like the idea of Top 4, focusing on the Top 2, and then, yeah, kind of, anyone has any input about Humira or thoughts about pursuing that or if it's a good use of our resources or not. It is a huge clue. It's a huge driver of [cross-talk]

¹⁰ Washington State Health Care Authority, Transcript of the July 15, 2025 Washington Prescription Drug Affordability Board Meeting, at 14, 16-18, at <https://www.hca.wa.gov/assets/program/pdab-meeting-transcript-july-15-2025.pdf> (last visited November 14, 2025).

Douglas Barthold: I think I have a couple of thoughts on that. First of all, it seems that Enbrel is the clear #1, so if we were going to prioritize, and we are prioritizing, maybe that should be the first one we do. Um, but then Humira, given that there are, you know, therapeutic alternatives, whatever, biosimilars, does that rule -- should we rule that out? And I'm trying to find the documentation of our -- how exactly when we're supposed to incorporate that information if it's now or if it's the affordability review. Does anyone happen to know that?

Mike Neuenschwander: So the way we were using that as a factor to help us select, um, so if you scroll all the way to the right on the -- or there we go. Yeah, keep going. There is a -- it talks about, you know, does it have an alternative or not?

Douglas Barthold: Yeah.

Mike Neuenschwander: There we go. Therapeutic equivalent and generic. Um, so that's something that can help us decide, you know, in terms of importance but not necessarily the type of consideration.

Eileen Cody: Well, I would say that we could since there is a therapeutic equivalent on that one that we drop it down in the priority list so it's not one of the Top 2 to start with. Since there -- if we have concerns that things are going to get -- are getting cheaper. Is that -- how you're -- what you were thinking, Doug?

Douglas Barthold: Something like that.

Hung Truong: Doug, I think we probably should keep it just to go through the exercise knowing that if we have four and it will prioritize two, we can perhaps Humira would not be in the Top 2, but I like the team to do some work on it and just to give us a good exercise to thinking about generics or, you know, alternative, availability, and so forth.

Douglas Barthold: Yeah, I agree, like, we obviously we don't have to, uh -- we can do the affordability review and [indistinct] we don't have to propose an upper payment limit or whatever, we [indistinct] -- we'll learn a lot from the affordability review regardless. And to your point, having it lower on the priority list I think would still align with our stated methodology, where we look at the weighted ranking, but then we also incorporate this information about whether or not there are therapeutic alternatives.

- **At the July 15, 2025 Board Meeting:**¹¹

Marina Suzuki: [Cross-talk] Yeah. I think one thing I just want to point out is that out-of-pocket costs calculation, that's all coming from our Washington State all payer data [cross-talk], so that's coming from payers, [cross-talk] not patients. So one critique, you know, we had from manufacturers is that those out-of-pocket costs are actually -- well, could be an overestimate because they are offering patient assistance programs, they can use coupons, that kind of things. So if you -- I think getting the out of pocket cost from the patients, I think that might be a more actual representative numbers, so I think that that's -- I think that's the only thing that [cross-talk] --

- **At the January 15, 2025 Board Meeting:**¹²

I also know that some of the Board Members had chosen based on out-of-pocket expenses, but I couldn't find anything in the spreadsheet that listed the patient assistance programs that are offered by most manufacturers. And although they are stated as offered to people to help with low income, they are really provided to everyone. I had a child on a very expensive drug program for many years of his life and was provided a drug assistance program, but no one every asked me to provide any financial information. As a matter of fact, it was just simply assumed that I would want it. And of course I took it because it was a very, very expensive drug, but I didn't have to provide any information. So whatever the drug said it costs per month, that was -- I paid a small fraction of that amount. So if that is a consideration for the Board on the patient out-of-pocket expense, I think that needs to be researched a bit more.

¹¹ Washington State Health Care Authority, Transcript of July 15, 2025 Washington Prescription Drug Affordability Board Meeting, at 37, at <https://www.hca.wa.gov/assets/program/pdab-meeting-transcript-july-15-2025.pdf> (last visited November 14, 2025).

¹² Washington State Health Care Authority, Transcript of January 15, 2025 Washington Prescription Drug Affordability Board Meeting, at 23-24, at <https://www.hca.wa.gov/assets/program/pdab-meeting-transcript-january-15-2025.pdf> (last visited November 14, 2025) (statement by Laura Berry).