66 Hudson Boulevard East
New York, NY 10001-2192

*VIA ELECTRONIC SUBMISSION*

September 11, 2026

Washington Prescription Drug Affordability Board
ATTN: MaryAnne Lindeblad, Chair
c/o Washington State Health Care Authority
PO Box 42716
Olympia, WA 98504-2716

**RE: Request for Removal of XELJANZ® (tofacitinib) and XELJANZ® XR from Affordability Review Consideration**

Dear Chair Lindeblad and Members of the Washington Prescription Drug Affordability Board:

Pfizer Inc. ("Pfizer") is a research-based, global biopharmaceutical company that applies science and our global resources to bring therapies to people that extend and significantly improve their lives through the discovery, development, and manufacture of medicines and vaccines.

Pfizer appreciates the opportunity to submit comments to the Washington Prescription Drug Affordability Board (the "Board"). Pfizer maintains significant concerns with Wash. Rev. Code §§ 70.405.010 et seq., enacted as Second Substitute Senate Bill 5532, ch. 153, Laws of 2022, and its implementing regulations at Wash. Admin. Code §§ 182-52-0005 et seq., which we believe take a narrow view of health care costs and lacks a mechanism to impact health insurance benefit design or pharmacy benefit manager (PBM) practices that control patient access and out-of-pocket costs for medicines. Pfizer submits these comments without waiver of, and expressly reserves, all legal objections to the statute and the Board's implementation of it.

We understand that XELJANZ® (tofacitinib) and XELJANZ® XR appear on the Board's Aggregated Prioritized Ranked and Weighted List shortlist of drugs eligible for affordability review. We wish to highlight key factors impacting these medicines, including a July 2026 decision by the Centers for Medicare and Medicaid Services to remove XELJANZ® and XELJANZ® XR from the list of selected drugs subject to a Maximum Fair Price, and respectfully request that the Board remove XELJANZ® and XELJANZ® XR from affordability review consideration.

> **The 2023 claims data underlying the prioritized list predates fundamental changes in the tofacitinib market, including XELJANZ® loss of exclusivity and generic entry.**

In selecting drugs for affordability review, the Board is directed to consider "the class of the prescription drug and whether any therapeutically equivalent prescription drugs are available for sale" under Wash. Rev. Code § 70.405.040(1)(a). AB-rated generic tofacitinib is available for sale and is therapeutically equivalent to XELJANZ®.

The prioritized list relies, in part, on Washington All-Payer Claims Database (WA-APCD) data from calendar year 2023. Since 2023, the tofacitinib market has fundamentally changed in a manner that could not be reflected in the 2023 data before the Board. The basic product patent expiration for XELJANZ® occurred in December 2025 and its data exclusivity expired in June 2026. Generic market entry has already occurred, despite the Board's current

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data dashboard Aggregated Prioritized Ranked and Weighted List[1] indicating otherwise. **Thus, the 2023 data reflects a brand-only market that no longer exists for XELJANZ®.**

Further, in January 2026, the Centers for Medicare & Medicaid Services (CMS) selected XELJANZ® and XELJANZ® XR for the Medicare Drug Price Negotiation Program for Initial Price Applicability Year (IPAY) 2028 to determine a Maximum Fair Price (MFP). **However, CMS announced on July 28, 2026 (See Enclosure), that XELJANZ® and XELJANZ® XR had been removed from the selected drug list as CMS had determined that bona fide marketing of a generic version exists. Under the IPAY Final Guidance, because of the timing of CMS determination of generic entries, XELJANZ® and XELJANZ® XR will remain on the selected drug list through 2028, and no MFP will apply.**

In the U.S. health care system, loss of exclusivity for brand prescription drugs serves as a built-in cost-control mechanism that does not exist for other health care services. Even as the FDA has approved more than 800 novel medicines since 2000[2], retail prescription drugs have remained a stable share of total health care spending in the U.S., at approximately 9-10 percent.[3] When accounting for both retail and non-retail medicines, prescription drugs are estimated to represent 13-14 percent of total health care spending.[4] This reflects the exclusivity-to-competition cycle[5] functioning as intended: continued innovation adds to the body of available therapies while, over time, individual products lose exclusivity and typically face downward price pressure without external intervention.

Because generic competition has arrived and federal authorities have also accounted for the changed market dynamic, we respectfully urge the Board to consider what timely, durable impact a state affordability review of XELJANZ® could have and urge the Board to remove it from affordability review consideration.

**Patient out-of-pocket costs are determined by benefit design.**

Patients' out-of-pocket costs are set by insurance benefit design—including deductibles, copayments, and coinsurance—determined by health plans and PBMs.[6] Along with determining patients' cost-sharing requirements, PBMs and health plans determine whether patients receive the discounts and rebates they negotiate with pharmaceutical manufacturers.

In 2024, manufacturers paid an estimated $356 billion in discounts and rebates.[7] However, unlike other medical services where the patient pays less when their health plan negotiates a better price, very few, if any, patients pay less at the pharmacy counter despite billions of dollars in discounts and rebates paid to PBMs and insurers by

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[1] Washington State Health Care Authority, Prescription Drug Affordability Board 2026 Data Dashboard, "Overall Aggregated Prioritized List" (calendar year 2023 WA-APCD claims data), https://hca-tableau.watech.wa.gov/t/51/views/PDAB2026/OverallAggregatedPrioritizedList
[2] U.S. Food & Drug Administration, Center for Drug Evaluation & Research, Compilation of CDER NME and New Biologic Approvals 1985–2025, https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals (last updated May 12, 2026). Figure reflects a count of new molecular entity and new biologic approvals for calendar years 2000 through 2025 and does not include biologics reviewed by FDA's Center for Biologics Evaluation and Research.
[3] Centers for Medicare & Medicaid Services, Office of the Actuary, National Health Expenditure Data: Historical, https://www.cms.gov/data-research/statistics-trends-and-reports/national-health-expenditure-data/historical.
[4] Altarum, Projections of the Non-Retail Prescription Drug Share of National Health Expenditures (July 2022), https://drugchannelsinstitute.com/files/Projections-of-Non-Retail-Drug-Share-of-NHE-2022.pdf.
[5] Kolchinsky, P. (2020). The great American drug deal: A new prescription for innovative and affordable medicines. Evelexa Press.
[6] Kaiser Family Foundation. (2025). Navigating the maze: Patient cost-sharing complexities and consumer protections. https://www.kff.org/private-insurance/navigating-the-maze-a-look-at-patient-cost-sharing-complexities-and-consumer-protections/
[7] Fein, A. (2025, March). The 2025 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers. Drug Channels Institute. https://drugchannelsinstitute.com/files/2025-PharmacyPBM-DCI-Overview.pdf

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manufacturers.[8] Instead, most manufacturer discounts and rebates are retained by PBMs as profit or are passed to a health plan rather than the patient obtaining the medicine. Recent analyses confirm that, after accounting for rebates and discounts, net prices for brand-name prescription drugs have *declined*[9] as other supply chain actors, who do not create or manufacture medicines, retain more than half of their cost.[10]

Again, we urge the Board to consider the life cycle factors that have altered the XELJANZ® market since the Board's data was collected and what impact an affordability review could have at this stage.

Pfizer appreciates the opportunity to provide comments to the Board. We support efforts to help ensure that patients can access innovative medicines and look forward to working with Washington policymakers to find solutions that directly help patients. If you have any questions, please contact Brandy Flores, Director of Government Relations, at Brandy.Flores@pfizer.com.

Sincerely,



Tom Brownlie
Vice President
State Policy and Government Relations

**Enclosure: July 28, 2026 CMS Letter**

[8] Peterson-KFF Health System Tracker. (2021, January 13). Price transparency and variation in U.S. health services. https://www.healthsystemtracker.org/brief/price-transparency-and-variation-in-u-s-health-services/
[9] Fein, A. J. (2026, January 7). U.S. brand-name drug prices fell in 2025 as the net pricing drug channel emerges. Drug Channels Institute. https://www.drugchannels.net/2026/01/us-brand-name-drug-prices-fell-in-2025.html
[10] Berkeley Research Group (BRG). The Pharmaceutical Supply Chain, 2013–2023 (Jan. 2025), https://www.thinkbrg.com/news/more-than-half-brand-medicine-spending-goes-to-supply-chain-middlemen-other-stakeholders/

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop WB-06-05
Baltimore, Maryland 21244-1850

CENTER FOR MEDICARE

**DATE:** July 28, 2026

**TO:** Medicare Advantage & Prescription Drug Plan Sponsors

**FROM:** Lara Strawbridge, Acting Director
Medicare Drug Rebate and Negotiations Group

**SUBJECT:** Removal of Xeljanz; Xeljanz XR from the Selected Drug List Effective January 1, 2029

In accordance with section 1192(c)(2) of the Social Security Act ("the Act") and sections 60.7 and 70 of the Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair Price in 2026, 2027, and 2028 ("Final Guidance"), the following selected drug(s) will cease to be a selected drug on January 1, 2029 and no maximum fair price will apply:

- Xeljanz; Xeljanz XR

In accordance with section 70 of the Final Guidance, CMS determined that, for the selected drug(s) listed above, the totality of circumstances reveals that at least one generic drug approved under section 505(j) of the FD&C Act that identifies the selected drug as its listed drug, is being bona fide marketed pursuant to such approval.

In accordance with section 1192(c)(2) of the Act and sections 60.7 and 70 of the Final Guidance, because CMS made this determination between the date that the selected drug list for initial price applicability year 2028 was published and November 1, 2026, the selected drug listed above will remain a selected drug through 2028 and no maximum fair price will apply. The selected drug(s) will cease to be a selected drug on January 1, 2029.

For questions, please contact IRARebateandNegotiation@cms.hhs.gov.