August 14, 2026

VIA ELECTRONIC MAIL

Oregon Prescription Drug Affordability Board
350 Winter Street NE
Salem, OR 97309-0405
Email: pdab@dcbs.oregon.gov

Re: Comments Regarding SKYRIZI®'s Statutory Exemption from Affordability Review by the Board and Deficiencies with the Board's Affordability Review Materials for SKYRIZI®

Dear Members of the Oregon Prescription Drug Affordability Board:

AbbVie Inc. ("AbbVie" or "the Company") respectfully submits these comments regarding the Oregon Prescription Drug Affordability Board's ("Board" or "PDAB") inclusion of SKYRIZI® (risankizumab-rzaa) ("SKYRIZI") on its list of drugs selected for affordability review and its affordability review materials for SKYRIZI, including the Board's dossier and clinical review. AbbVie is a research-based biopharmaceutical company whose medicines, including SKYRIZI, are relied upon by Oregon patients every day.

AbbVie submits these comments in two parts:

- ***First***, SKYRIZI is categorically exempt from affordability review by the Board under ORS 646A.694(2), which plainly states that a drug designated by FDA as a drug for a rare disease or condition is not subject to review; and

- ***Second***, even assuming SKYRIZI was eligible for affordability review (it is not despite the Board's decision to proceed notwithstanding SKYRIZI's orphan drug designation being inconsistent with the plain language of the Oregon PDAB statute and with the Board's own prior interpretation and practice), the Board's affordability review will produce a flawed result because it relies upon materials, including the Board's SKYRIZI dossier and clinical review, that do not provide a sufficiently accurate, complete, or clinically-grounded basis for an affordability determination regarding SKYRIZI.

For the reasons set forth below and in AbbVie's May 4, 2026 and July 13, 2026 comment letters, AbbVie respectfully requests that the Board:

1. Remove SKYRIZI from the 2026 affordability review consistent with Oregon law's orphan-drug exclusion, and confirm that SKYRIZI will remain excluded from any future review cycle;

2. Repeal OAR 925-200-0020(2)(n) because it conflicts with ORS 646A.694(2) and OAR 925-200-0020(1)(m); and

3. To the extent the Board nonetheless improperly proceeds with an affordability review of SKYRIZI, refrain from making an affordability determination until, at a minimum, the Board addresses the significant methodological and clinical concerns identified herein.[1]

I. The Oregon PDAB Statute Categorically Exempts SKYRIZI from Affordability Review by the Board.

The plain language of the Oregon PDAB statute is unambiguous. ORS 646A.694(2) provides that "[a] drug that is designated by the Secretary of the United States Food and Drug Administration, under 21 U.S.C. 360bb, as a drug for a rare disease or condition is not subject to review" by the Board,[2] keying the affordability-review exemption to the *drug*—not to any particular indication, use, patient population, or claim associated with that drug. Had the Oregon Legislature intended to authorize, in relevant part, any distinction between a drug's orphan-designated indication and its non-orphan indication(s), it would have said so.

SKYRIZI fits squarely in this statutory exemption. In November 2016, the FDA granted SKYRIZI an Orphan Drug Designation for the treatment of pediatric Crohn's disease,[3] a designation that remains active today. AbbVie is currently sponsoring a Phase 3, multicenter study evaluating SKYRIZI's pharmacokinetics, efficacy, and safety in pediatric patients with moderately to severely active Crohn's disease.[4] Because SKYRIZI carries an Orphan Drug Designation, SKYRIZI is statutorily ineligible for an affordability review.

This reading is confirmed by the Board's own longstanding practice prior to 2026:

- In May 2024, the Board voted to remove SKYRIZI from its list of drugs subject to affordability review due to its orphan designation.[5]

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[1] The Board posted the SKYRIZI dossier and clinical review on August 13, 2026. The Board requires comment letters to be submitted at least 48 hours before a Board meeting to be considered for it. Given the compressed timeframe between when the materials were posted on August 13, 2026 and the deadline for AbbVie to submit comments for consideration at the upcoming August 19, 2026 Board meeting, AbbVie expressly reserves all rights to identify and raise additional issues and deficiencies beyond those identified in this letter after a fulsome and fair opportunity to comprehensively review the Board's SKYRIZI dossier and clinical review. Nothing in this letter should be construed as a waiver of AbbVie's right to raise such additional issues.

[2] ORS 646A.694(2); *see also* Oregon Administrative Rule (OAR) 925-200-0020(1)(m), which restates the same categorical bar, providing that "a drug for a rare disease or condition is not subject to an affordability review" by the Board.

[3] U.S. Food and Drug Administration, Orphan Drug Designations and Approvals, at https://www.accessdata.fda.gov/scripts/opdlisting/oopd/detailedIndex.cfm?cfgridkey=544716.

[4] *See, e.g.*, ClinicalTrials.gov, "A Study to Assess Adverse Events, Change in Disease Activity, and How Intravenous and Subcutaneous Risankizumab Moves Through the Body of Pediatric Participants With Moderately to Severely Active Crohn's Disease (RISE)," at https://clinicaltrials.gov/study/NCT05995353?term=skyrizi&viewType=Card&rank=8.

[5] Oregon Prescription Drug Affordability Board, Meeting Minutes (May 15, 2024), at 1, at https://dfr.oregon.gov/pdab/Documents/archive/20240515-PDAB-approved-minutes.pdf; Oregon Prescription Drug

- In June 2025, the Board removed BOTOX® (onabotulinumtoxinA), DUPIXENT® (dupilumab), HUMIRA® (adalimumab), and RINVOQ® (upadacitinib) from its eligibility list, expressly citing each product's orphan designation and confirming, in the words of Board staff, that "[a]ccording to the language in our statute, it says the Board cannot . . . select a[n] orphan drug as unaffordable due to its designation."[6]

The Board's abrupt January 2026 reversal of this long-held, correct interpretation—with no explanation, no rulemaking, and no accounting for manufacturers who relied on the prior position—is arbitrary, capricious, and inconsistent with Oregon law. The Board's authority is defined and limited by statute: ORS 646A.694 establishes both the scope of review and the explicit exclusion for orphan-designated drugs, and any effort to subject an exempted drug to review exceeds the authority the Oregon Legislature granted to the Board.

AbbVie recognizes that OAR 925-200-0020(2)(n) purports to narrow this exemption, stating that "[a] prescription drug approved by the FDA for other indications, in addition to a rare disease or condition, is not exempt from an affordability review for those other indications." That subsection directly conflicts with both ORS 646A.694(2) and OAR 925-200-0020(1)(m), and AbbVie urges the Board to repeal OAR 925-200-0020(2)(n) for that reason.

Further, the orphan exclusion reflects the Oregon Legislature's deliberate policy choice to preserve incentives for manufacturers to research and develop treatments for rare diseases. AbbVie has invested substantial resources in studying SKYRIZI for additional, and often rare, disease indications. Subjecting an orphan-designated drug to an affordability review would hinder exactly this kind of innovation, deterring manufacturers from pursuing rare disease research on drugs already approved for other indications, and would harm the very patients the orphan drug framework is designed to protect.

AbbVie urges the Board to remove SKYRIZI from the affordability review process immediately.

II. Even Assuming SKYRIZI Was Eligible for Affordability Review (It Is Not), the Board's Affordability Review Materials for SKYRIZI Contain Significant, Material Deficiencies Upon Which the Board's Reliance Would Produce a Flawed Result.

Should the Board proceed with conducting an affordability review of SKYRIZI in direct violation of the Oregon PDAB's statutory exemption for orphan designated drugs, the Board's review of SKYRIZI would produce an incomplete and fundamentally flawed result because the review would be founded upon materials—the Board's SKYRIZI dossier and clinical review—that are wholly insufficient to provide an adequate assessment of affordability.

Affordability Board, May 15, 2024 Meeting, at https://youtu.be/s3gOiI3-lfo?si=uwAVteJO093EG0LN&t=1195 (beginning at minute 00:19:54).

[6] The Board Member who proposed those removals similarly confirmed: "This is what it is. We have to take [orphan-designated drugs] out because it's in the rules that if it has a[n orphan] designation, [the Board] can't review it." Oregon Prescription Drug Affordability Board, June 18, 2025 Meeting, at https://www.youtube.com/watch?v=RP3A5s6hiwc.

SKYRIZI has redefined treatment goals, shifting the focus from symptom control to deep remission, minimal disease activity, and disease modification. Its affordability should not be compared with older or generic therapies simply because they share one or more approved indications. AbbVie believes SKYRIZI stands apart because, among other reasons, no other available therapy matches its clinical expectations, strongest efficacy endpoints, tolerability, and convenient dosing across such a broad range of indications. Affordability should instead be assessed in the context of other factors such as clinical superiority, patient value, and broader system-wide benefits. SKYRIZI has shown value as one of the most effective and well-tolerated therapies for chronic immunological conditions.

AbbVie's preliminary concerns include, but are not limited to:

- **The dossier does not provide a sufficient basis for an affordability finding, and the dossier's figures cut against affordability concerns.** Gross APAC spend, WAC trend, and broad therapeutic-alternative groupings are not reliable proxies for patient unaffordability or clinical substitutability because, among other reasons, they ignore net cost, omit direct comparative evidence, and use comparators that are not meaningfully interchangeable. In addition, the APAC data underlying the dossier's analysis is itself incomplete and unreliable—for example, by the dossier's own admission, APAC excludes self-insured plans regulated under ERISA. Despite these methodological and data deficiencies, the dossier's own figures actually cut *against* affordability concerns: for SKYRIZI, it reports a median enrollee out-of-pocket cost of $0 per claim, $0 median out-of-pocket cost for Medicaid enrollees, no step therapy requirements, universal plan coverage, and price concessions reducing gross-to-net cost. The Board should not draw an affordability conclusion on this record unless and until it incorporates, at a minimum, net-cost context, head-to-head evidence where available, clinically relevant comparators, and broader downstream value to patients and the healthcare system.

- **The review materials exclude head-to-head trials and other real-world evidence, while inviting improper comparisons.** The trial-specific tables in the clinical review expressly caution that "[t]rials are not direct head-to-head comparative trials" and that "differences in trial design, patient population, and follow-up duration preclude direct statistical comparison of the results shown." Despite this caveat, the dossier and clinical review present SKYRIZI alongside its purported therapeutic alternatives in a manner that invites exactly the kind of cross-trial comparison the clinical review itself disclaims—while omitting the head-to-head evidence that does exist showing SKYRIZI's superiority, and omitting published real-world evidence on economic benefit, including lower treatment-switching rates, treatment-pattern advantages, and healthcare-utilization and cost outcomes. A clinical review that omits important comparative evidence—including, but not limited, head-to-head trial results, pediatric indications, and current prescribing information—cannot provide an accurate or complete picture of SKYRIZI's clinical profile relative to its comparators.

- **The dossier and clinical review bear the hallmarks of a rushed process, raising concerns about the diligence behind the broader analysis.** By way of illustrative example, the dossier's Drug and FDA Information table (Table 5) lists SKYRIZI's first

FDA approval date as June 16, 2022, which is inconsistent with the dossier's own Table 1, which correctly identifies 2019 as SKYRIZI's year of approval. Further, the *SKYRIZI* dossier manages to misspell SKYRIZI as "Skyrize" in at least one instance—an error a basic spell check would have caught. If there was not adequate time or care to catch errors this basic, AbbVie has serious concerns about whether adequate time or care was used to conduct the more rigorous analytical work that a defensible affordability determination requires. AbbVie urges the Board to audit the dossier and clinical review more broadly for errors before relying on these materials for any affordability determination.

Conclusion

AbbVie renews the requests set forth at the outset of this letter, and asks that the Board act on them without further delay.

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AbbVie remains committed to engaging constructively with the Board and looks forward to continued dialogue. Please do not hesitate to contact me at hfitzpatrick@abbvie.com with any questions or to discuss these matters further.

Sincerely,

Helen Fitzpatrick

Helen Kim Fitzpatrick
Vice President, State Government Affairs
On behalf of AbbVie Inc.