August 28, 2026

VIA ELECTRONIC MAIL

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

Re: Supplemental Comments Regarding 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 further comments regarding the Oregon Prescription Drug Affordability Board's ("Board" or "PDAB") affordability review materials for SKYRIZI® (risankizumab-rzaa) ("SKYRIZI")—the Board's SKYRIZI dossier and clinical review.

AbbVie is a research-based biopharmaceutical company whose medicines, including SKYRIZI, are relied upon by Oregon patients every day. Across plaque psoriasis, psoriatic arthritis, Crohn's disease ("CD"), and ulcerative colitis, SKYRIZI has helped redefine treatment goals by advancing beyond symptom control toward durable disease control, deep remission, minimal disease activity, and other meaningful clinical outcomes. Clinical studies have demonstrated substantial and sustained skin clearance and quality-of-life improvements, meaningful joint and functional outcomes, and clinically relevant rates of remission, endoscopic improvement, and steroid-free disease control in inflammatory bowel disease. Its value should be assessed in the context of clinical efficacy, durability, tolerability, convenient dosing, patient benefits, and broader system-wide considerations. These attributes support SKYRIZI as an important treatment option for appropriate patients with chronic immune-mediated conditions whose disease burden can significantly affect daily functioning and quality of life. Affordability should be assessed in the context of other factors such as clinical superiority, patient value, and broader system-wide benefits. SKYRIZI has demonstrated value as one of the most effective and well-tolerated therapies for chronic immune-mediated conditions.

At the outset, consistent with our comments submitted to the Board on May 4, 2026, July 13, 2026, and August 14, 2026, AbbVie maintains that SKYRIZI should not be subject to review. SKYRIZI's inclusion on the Board's list of drugs selected for affordability review directly violates ORS 646A.694(2), which plainly states that a drug designated by the FDA as a drug for a rare disease or condition is not subject to review—SKYRIZI has such a designation. In proceeding notwithstanding that exclusion, the Board acts in excess of the authority the Oregon Legislature conferred to the Board under the Oregon PDAB statute and contrary to the Oregon Legislature's

deliberate policy choice to preserve incentives for manufacturers to research and develop treatments for rare diseases. Nothing in these comments should be read as agreeing that the review is lawful or appropriate.

Should the Board proceed with making an affordability determination for SKYRIZI, consistent with our comments submitted on August 14, 2026 (incorporated by reference herein), the Board's review would produce an incomplete and fundamentally flawed result because, among other reasons,[1] the review is founded upon materials that are wholly insufficient to provide an adequate assessment of affordability. To support this conclusion, AbbVie submits:

- **SKYRIZI Saves: Fewer hospitalizations and treatment changes result in significant cost reductions.** Reducing the need for medical services or additional treatment is key to reducing health care costs. Medicines that reduce the need for other interventions offer a significant return on investment for payors and, importantly, ensure that patients can live healthier, more fulfilling lives. Clinical studies show that patients treated with SKYRIZI have reduced hospitalization rates, and that translates into tangible savings for payors. At least one study has shown that SKYRIZI is the most cost-effective treatment among commonly used CD treatments.[2] When compared to at least one other medicine, the reduced hospitalization rate means payors could save nearly $230,000 annually in medical costs associated with CD-related hospitalizations for every 100 patients treated with SKYRIZI instead.[3] One reason for these savings is that in the first year of treatment, patients on SKYRIZI only experience CD-related hospitalizations at a rate of 4.5 per 100 patients.[4] Patients on another common CD medicine experience CD-related hospitalizations, at a rate of 12.9 per 100 patients.[5] That's a difference of 8.4 hospitalizations per 100 patients. For

[1] Manufacturers of drugs reviewed at the Board's earlier June 17 and July 15, 2026 meetings have had the benefit of the August 31, 2026 feedback deadline for months longer. The Board did not post the SKYRIZI dossier and clinical review until August 13, 2026—and the SKYRIZI clinical review was even posted after the review materials for the other drugs under review at the August 19, 2026 meeting. The practical result is that AbbVie has had markedly less time than manufacturers of other drugs under this year's review cycle to identify, analyze, and comment on the substance of the Board's materials. Accordingly, AbbVie has not had a full and fair opportunity to review the Board's SKYRIZI dossier and clinical review and expressly reserves all rights to identify and raise additional issues and deficiencies beyond those identified in this letter. Nothing in this letter should be construed as a waiver of AbbVie's right to raise such additional issues.

[2] Bayesian network meta-analysis (NMA) (Section 4.1.2.3: Efficacy) of phase 3 randomized controlled trials was conducted to assess the rates of clinical response (≥100-point change in the Crohn's disease activity index [CDAI] from baseline) at end of induction (4 to 12 weeks) and clinical remission (CDAI to obtain ITT effectiveness rates for biologic-naïve and biologic-failure populations. These effectiveness estimates were then weighted to estimate the effectiveness in a total population of moderate-to-severe CD patients. This was done using an analysis from the IBM® MarketScan® Commercial and Medicare Supplemental database that showed the proportion of biologic-naïve and biologic-experienced TIM initiations as being 50.1% and 49.9%, respectively (Data on File, AbbVie Inc. H22.DoF.015).

[3] Chapman CJ, Sharma D, Griffth J, Theigs C, Fang S. Evaluation of quality-of-care indicators among patients with Crohn's disease and ulcerative colitis in the United States: 2019- 2020. Poster presented at: American College of Gastroenterology (ACG 2022); October 21-26, 2022; Charlotte, NC.

[4] Peyrin-Biroulet L, Chapman JC, Colombel J-F, et al. Risankizumab versus ustekinumab for patients with moderate to severe Crohn's disease: Results from the phase 3b SEQUENCE study. Presented at the United European Gastroenterology Week (UEGW 2023), October 14-17, 2023. Copenhagen, Denmark, OP# LB01.

[5] Peyrin-Biroulet L, Chapman JC, Colombel J-F, et al. Risankizumab versus ustekinumab for patients with moderate to severe Crohn's disease: Results from the phase 3b SEQUENCE study. Presented at the United European Gastroenterology Week (UEGW 2023), October 14-17, 2023. Copenhagen, Denmark, OP# LB01

psoriasis patients, use of SKYRIZI drastically reduces the need for costly changes to dosage and the need to switch medicines. Compared to other medicines commonly used to treat psoriasis, SKYRIZI results in ~$600 to ~$6,000 less in spending for dose escalation.[6] Understanding these economic impacts is essential to the Board's processes, but members must also understand that SKYRIZI's cost-effectiveness is directly related to the improved outcomes experienced by patients, and patients must be at the center of any discussion that could decide their access to medicines. This Board's process attempts to supplant the expertise of physicians and other providers for their own, not least in its decision to create purported "therapeutic alternatives" that include medicines contraindicated for the conditions SKYRIZI treats. Payors often require multiple steps or medicine failures before a patient can get approval to use a medicine as effective as SKYRIZI. Those delays drive up costs throughout the health system, impede patient access, and worsen patient outcomes.

- **The dossier's metrics utilized for measuring affordability are fundamentally unreliable metrics for measuring affordability are unreliable.** Gross APAC spend, WAC trend, and broad therapeutic-alternative groupings do not reliably measure patient affordability or clinical substitutability. These metrics ignore net cost, omit direct comparative evidence, and rely on comparators that are not meaningfully interchangeable or otherwise appropriate. WAC in particular is not what patients, payers, PBMs, or government programs actually pay. For SKYRIZI in 2024, the dossier itself reports an average gross spend of $17,962 per claim against a net spend of $12,427 per claim after price concessions—a difference of $5,535 per claim, or 30.8 percent—yet the dossier's own rubric still scores "price evaluation" using the 7.1 percent WAC trend rather than any net-cost metric. Relatedly, the dossier's scoring rubric marks "less expensive therapeutic alternative available" as "Yes" based solely on WAC comparisons, without any net-cost or clinical-substitutability analysis to support that conclusion. Indeed, the purported therapeutic alternatives underlying this and other scoring determinations are themselves fundamentally flawed comparators, many of which appear to have been so designated by the Board based solely on the fact that they share one or more indications with SKYRIZI, without regard to, among other things, clinical effectiveness differences in mechanism of action, dosing, safety profile, or line of therapy that bear directly on whether a product is a clinically appropriate substitute.

- **Independent of whether these are the right metrics, the underlying data itself is incomplete.** By the dossier's own admission, APAC excludes self-insured plans regulated under ERISA, which account for 46% of Oregon lives, potentially skewing the patient out-of-pocket analysis. The dossier's own commercial carrier data call is likewise limited to fully-insured plans covering only approximately 800,000 Oregonians and, like APAC, excludes ERISA-regulated coverage entirely. Compounding this gap, the dossier suppresses enrollee counts in numerous cells throughout its own tables whenever a cell contains 30 or fewer individuals and applies additional "secondary suppression" to prevent back-calculation of other suppressed values—meaning the dossier's own quantitative tables are, by design, incomplete in ways the Board cannot fully access. A data set with these structural gaps, calculation errors, and missing populations cannot support a reliable affordability conclusion for SKYRIZI.

[6] DoF H21.DoF.98 v2, HEOR Feb 2022

- **Notwithstanding the above, the dossier's own data does not provide a sufficient basis for concluding that SKYRIZI is unaffordable.** Even taking the dossier's flawed and incomplete data at face value, its own data supports the opposite conclusion. The dossier reports a median enrollee out-of-pocket cost of $0 per claim for SKYRIZI, $0 median out-of-pocket cost for Medicaid enrollees, no step-therapy requirements, universal plan coverage, and price concessions that reduce the gross-to-net cost. Accordingly, the Board should not draw an affordability conclusion from this record; if anything, the available evidence instead indicates that SKYRIZI is an affordable, broadly covered treatment option, particularly when assessed using actual patient out-of-pocket costs, net-cost considerations, coverage requirements, and broader value to patients and the healthcare system.

- **The review materials exclude head-to-head trials, 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, 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 purported comparators.

- **The clinical review's own comparator table is stale by its own terms.** The clinical review states that its therapeutic alternative comparisons are "based upon the label in effect at the time of the drug's selection by the board for review in 2024" and expressly acknowledges "significant developments" that have occurred since—including that SKYRIZI itself was approved for pediatric plaque psoriasis and psoriatic arthritis in 2026. A drug comparison that omits its own subject's most recent pediatric approvals cannot support a reliable, up-to-date affordability or comparability assessment.

* * *

In conclusion, the Board's assessment of SKYRIZI more strongly supports a gross-spend and budget-impact narrative than a broad conclusion of patient-level affordability. Its central limitations are the use of incomplete gross claims data, inadequate integration of net-cost and patient-support context, an overbroad therapeutic-alternative framework, omission of broader value and cost-offset evidence, and several internal data-quality issues. These are not isolated technical disagreements. They are cumulative defects in the Board's data, methodology, comparator selection, clinical evidence base, patient-affordability analysis, and quality-control process. Taken together, they preclude a reliable conclusion that SKYRIZI presents an affordability challenge for Oregonians. For these reasons, AbbVie respectfully requests that the Board:

1. Remove SKYRIZI from the 2026 affordability review and determination 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 flaws identified herein.

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.