May 10, 2024

VIA ELECTRONIC MAIL TO COMMENTS.PDAB@MARYLAND.GOV

Maryland Prescription Drug Affordability Board
16900 Science Drive, Suite 112-114
Bowie, MD 20715

Re: Comments on SKYRIZI®'s Referral to the Stakeholder Council

Dear Members of the Maryland Prescription Drug Affordability Board:

AbbVie Inc. (AbbVie or the Company) is submitting comments in response to the Maryland Prescription Drug Affordability Board's (PDAB's or the Board's) referral of AbbVie's product SKYRIZI® (risankizumab-rzaa) (SKYRIZI) to the Maryland Prescription Drug Affordability Stakeholder Council (PDASC).

As detailed further herein, given the value of SKYRIZI and its affordability to Maryland patients, AbbVie respectfully requests that SKYRIZI be removed immediately from the Board's list of drugs under consideration for cost review. We also have concerns that the Board has not adequately responded to AbbVie's requests for information pertaining to its selection of SKYRIZI and referral of the product to the PDASC. The lack of transparency regarding the Board's decision-making is contrary to the public interest, raises questions under Maryland's Administrative Procedure Act (APA) and has critically deprived AbbVie of the ability to effectively participate in the Board's selection process.

I. Background

AbbVie's mission is to discover and deliver 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 – immunology, oncology, neuroscience, and eye care. For nearly 20 years, AbbVie has been a leader in the field of immunology through significant investment in research and the development of new, innovative medicines and programs that meet the needs of patients, physicians, and payers.

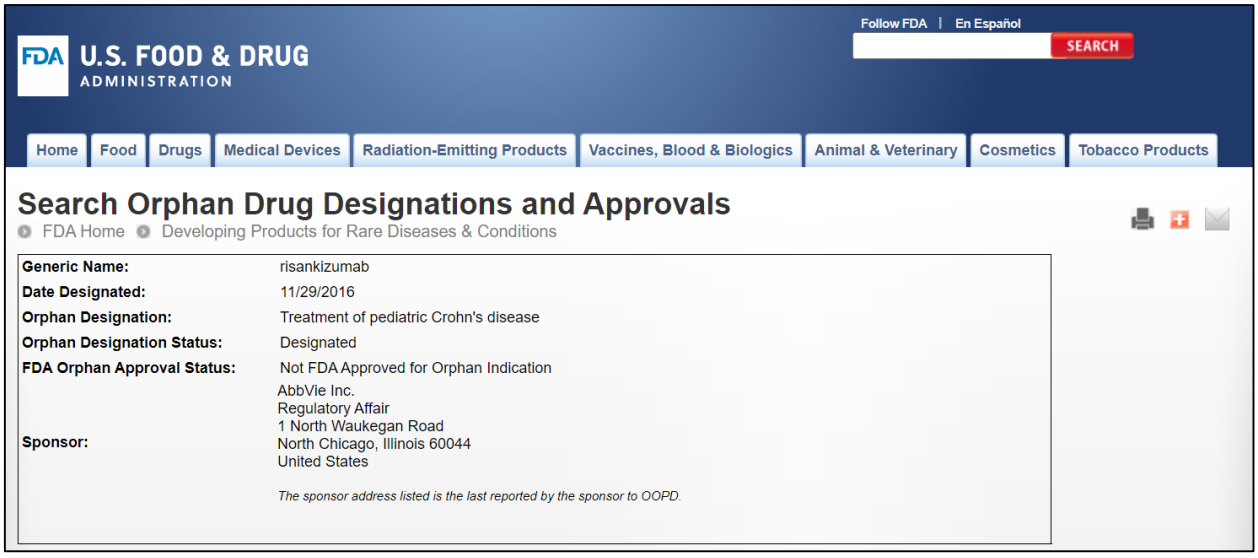
SKYRIZI is a prescription, biologic interleukin-23 antagonist that is indicated for the treatment of: (1) moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy (approved in April 2019); (2) active psoriatic arthritis in adults (approved in January 2022); and (3) moderately to severely active Crohn's disease in adults (approved in June 2022).[1] The successful discovery, development, manufacturing, and sale of biologics like SKYRIZI is a long, expensive and uncertain process. There are unique risks and uncertainties with biologics. For example, access to and supply of necessary biological materials, such as cell lines,

[1] SKYRIZI, Full Prescribing Information, https://www.rxabbvie.com/pdf/skyrizi_pi.pdf.

may be limited and current governmental regulations restrict access to and regulate the transport and use of such materials. In addition, the development, manufacturing and sale of biologics is subject to regulations that are often more complex and extensive than the regulations applicable to other pharmaceutical products. As a result, manufacturing biologics, especially in large quantities, is often complex and may require the use of innovative technologies. Such manufacturing also requires facilities specifically designed and validated for this purpose and sophisticated quality assurance and quality control procedures. Biologics are also frequently costly to manufacture because production inputs are derived from living animal or plant material.

The U.S. Food and Drug Administration (FDA) first approved SKYRIZI (specifically, National Drug Code (NDC) 00074-2042-02) in 2019 pursuant to Biologics License Application (BLA) 761105. Since the product's initial approval, AbbVie has continued to invest substantially in research on the use of SKYRIZI to address unmet patient needs, including for rare diseases. For example, SKYRIZI has an FDA Orphan Drug Designation for the treatment of pediatric Crohn's disease (*see* Figure 1).[2] Crohn's disease is a type of inflammatory bowel disease which commonly involves the end of the small intestine and the large intestine. Children living with Crohn's disease may be affected by a delay in growth and sexual maturation, and may experience symptoms similar to those in adults including diarrhea, abdominal pain, rectal bleeding, and weight loss. AbbVie is currently sponsoring a Phase 3, multicenter study to assess the pharmacokinetics, efficacy, and safety of SKYRIZI in pediatric participants with moderately to severely active Crohn's disease.[3] The study began in December 2023, and is estimated to be completed in April 2029.

Figure 1*: *FDA Orphan Drug Designation for SKYRIZI



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

[3] Clinical Trials, *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*, https://clinicaltrials.gov/study/NCT05995353?term=m16-194&rank=1.

Significantly, the Board erroneously failed to include the "Orphan Drug Flag" for SKYRIZI® in the current version of its publicly available data Dashboard for the eight drugs referred to the PDASC (see Figure 2).[4]

Figure 2: FDA Excerpt of Maryland PDAB Dashboard Data for SKYRIZI

NDC11	Drug Name	Dose-Strength	Dose-Strength Unit of Measure	FDA Approval Date	Patent Expiration Date	Accelerated Approval Flag	Orphan Drug Flag	Only in Class Flag
00074-1050-01	Skyrizi	150	MG/ML	2019-04-23	.	0	0	1
00074-2042-02	Skyrizi	75	MG/0.83ML	2019-04-23	.	0	0	1
00074-2100-01	Skyrizi	150	MG/ML	2019-04-23	.	0	0	1

The Board defines the "Orphan Drug Flag" as identifying "prescription drug products listed on an FDA application that has at least one FDA Orphan Drug Designation." Per the Board's "Cost Review Eligibility and Selection Methodology" obtained by AbbVie in response to its public records request (*see* Section III, infra), this data element should "capture if a drug has any rare disease indications. Drugs can have multiple indications and only some of them may be for rare diseases. Some of these are designated but not approved indications."[5]

The Board's omission of such verifiable and publicly accessible information, coupled with other mistakes in the data set like incorrect FDA approval dates associated with two of the three SKYRIZI NDCs referred to the PDSAC[6] compounds our concerns regarding the veracity and relevance of the data and information relied upon by the Board in its selection process, which we address further in Section III.

As a threshold matter, and separate from the drug's persuasive value proposition discussed in Section II, SKYRIZI's orphan drug status provides additional support for our strong belief that SKYRIZI should be removed from the list of products the Board is considering for potential cost review.

The FDA Orphan Drug Designation is granted to drugs and biologics defined as those intended for the safe and effective treatment, diagnosis, or prevention of rare diseases or disorders that affect fewer than 200,000 people in the United States, or that affect more than 200,000 persons but are not expected to recover the costs of developing and marketing a treatment medicine.[7]

---

[4] Maryland PDAB, "Drugs Referred to the Stakeholder Council - Dashboard," at https://pdab.maryland.gov/documents/comments/drugs_referred_stakeholder_council_dashboard_2024.xlsx (last visited May 8, 2024). *See also* COMAR 14.01.04.03B(1)(d) (stating that "[t]o the extent practicable, Board staff may provide the following information for each prescription drug product in the dashboard: … (d) Whether the prescription drug product is designated by the Secretary of the FDA, under 21 U.S.C. §360bb, as a drug for a rare disease or condition").

[5] Maryland PDAB, "Cost Review Eligibility and Selection Methodology" (version provided to AbbVie on April 29, 2024).

[6] NDC 00074-2042-02 was approved pursuant to BLA761105 on April 23, 2019. NDCs 00074-1050-01 and 00074-2100-01, however, were not approved until more than two years later, on April 26, 2021, pursuant to BLA761105 S009 and S010, respectively. *See* U.S. Food and Drug Administration, Drugs@FDA: FDA-Approved Drugs Database, Biologics License Application 761105, at https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=761105.

[7] 21 C.F.R. § 316.

Maryland should follow the lead of other jurisdictions that have implemented prescription drug affordability boards that generally do not select rare disease therapies for cost assessment. As such states recognize, and in addition to the variables that can complicate bringing a biologic product to market, as discussed above, the small number of patients in rare disease populations can create unique challenges for drug development and present different market considerations compared to other therapies, among other pertinent considerations. Relatedly, the currently marketed presentations of SKYRIZI are "Only in Class" and have no therapeutic equivalents identified in FDA's Orange Book. SKYRIZI has both unique clinical and economic value. It is not a suitable candidate for cost review by the Board.

II. SKYRIZI is a Valuable and Affordable Treatment Option for Maryland Patients

At AbbVie, we are driven by the potential for innovative medicines to have a remarkable impact on patients. We also recognize that innovative treatments can only make a difference if patients can get the medicines that they and their providers choose. Innovation, pricing, and access must work in harmony, which is why we are committed to ensuring that patients who need our medicines can access them. Our approach to pricing aims to drive broad and rapid access to our medicines, while addressing the world's toughest health challenges, and we price our medicines to reflect the value they bring to patients and their families, the health system and to society.[8] We also consider the affordability and accessibility of our medicines for a diverse set of stakeholders, including patients, providers, governments and other payers, as well as the long-term sustainability of our innovation and societal impact.

To these ends, we urge the Board to view the value of SKYRIZI with a patient-centric lens. As detailed herein, SKYRIZI is an effective treatment option that fulfills an unmet need for patients with autoimmune conditions. Notably, utilization of SKYRIZI relevant to the Board's selection process – *i.e.*, by "a unit of State or local government, health benefit plan, or Maryland Medical Assistance Program"[9] – is quite low relative to commercial utilization of the product. Conflating the metrics for these different payor and reimbursement environments is not appropriate for a variety of reasons addressed herein.

Additionally, because SKYRIZI is affordable to patients, as well as the broader healthcare system generally and in Maryland specifically, selection of the drug for a cost review would not further the statutory purpose of the PDAB "to protect State residents, State and local governments, commercial health plans, health care providers, pharmacies licensed in the State, and other stakeholders within the health care system from the high costs of prescription drug products."[10] Again, SKYRIZI should not be among the products considered for cost review.

A. SKYRIZI is an Important Treatment Option that Fulfills Unmet Patient Needs

[8] AbbVie, "Pricing and Access of Our Innovative Medicines (2003)," at https://www.abbvie.com/content/dam/abbvie-com2/pdfs/about/pricing-and-access-of-our-innovative-medicines.pdf.
[9] Md. Code Ann., Health-Gen. § 21-2C-14.
[10] Md. Code Ann., Health-Gen. § 21-2C-02(b).

SKYRIZI is a vital treatment option for patients with autoimmune conditions. For example, psoriasis is the most prevalent autoimmune disease in the United States, affecting 3% of the U.S. adult population, or approximately eight million Americans.[11] In addition to the visible signs of psoriasis (*e.g.*, raised plaques, scales on skin), the associated physical, emotional, mental, and social burden can negatively impact patients' quality of life.[12] Moreover, an estimated 30% of people with psoriasis will go on to develop psoriatic arthritis, which is characterized by painful swelling in the joints and reduced range of motion.[13]

Though advancements have been made in recent years for the treatment of these conditions, there remains significant need for the patients suffering from the diseases, the prescribers treating them, and entities budgeting for and covering the costs of therapies.

The effectiveness of psoriasis medicines – measured by levels of skin clearance – matters to patients. A lack of initial response to treatment or lack of sustained response to treatment results in 62% of treatment discontinuations within the first year.[14] In clinical trials, SKYRIZI has demonstrated not only high levels skin clearance for patients with psoriasis, but lasting clearance over time with the convenience of every twelve-week dosing. These results include patients who are historically more difficult to treat, such as patients who weigh more, patients with severe disease and/or patients who have been treated with prior psoriasis medications.[15,16] Importantly, SKYRIZI also has demonstrated significant improvements in patients' psoriasis symptoms, and quality of life and depression/anxiety.[17]

SKYRIZI also offers meaningful benefits over alternative treatment options; for example, SKYRIZI has a comparable safety profile to STELARA® (ustekinumab), another commonly used biologic plaque psoriasis therapy, and provides predictability and durability between doses, over time, and across patient types with standard dosing regimen.[18] SKYRIZI also provides durable

[11] National Psoriasis Foundation. Statistics. https://www.psoriasis.org/content/statistics.
[12] Boehncke WH, Schon MP. Psoriasis. Lancet. 2015;386(9997):983–994.
[13] Mease PJ, Gladman DD, Papp KA, et al. Prevalence of rheumatologist-diagnosed psoriatic arthritis in patients with psoriasis in European/North American dermatology clinics. Journal of the American Academy of Dermatology. 2013;69(5):729-735.
[14] Strober B, Zema CL, Holmes C, et al. Reasons for drug discontinuation among psoriasis patients in the Corrona Psoriasis Registry. Submitted to the 28th European Academy of Dermatology and Venerology. Oct 9-13, 2019; Madrid, Spain.
[15] SKYRIZI (risankizumab-rzaa) [package insert]. North Chicago, IL: AbbVie Inc.
[16] Gordon KB, Strober B, Lebwohl M, et al. Efficacy and safety of risankizumab in moderate-to-severe plaque psoriasis (UltIMMa-1 and UltIMMa-2): results from two double-blind, randomized, placebo-controlled and ustekinumab-controlled phase 3 trials. Lancet. 2018;392(10148):650-661.
[17] Augustin M, Lambert J, Zema C, Thompson EHZ, Yang M, Wu EQ, Garcia-Horton V, Geng Z, Valdes JM, Joshi A, Gordon KB. Effect of Risankizumab on Patient-Reported Outcomes in Moderate to Severe Psoriasis: The UltIMMa-1 and UltIMMa-2 Randomized Clinical Trials. JAMA Dermatol. 2020 Dec 1;156(12):1344-1353. doi: 10.1001/jamadermatol.2020.3617. PMID: 33052382; PMCID: PMC7557488.
[18] Strober B, Eyerich K, Hong HC, et al. Long-term efficacy and safety of switching from ustekinumab to risankizumab: results from the open-label extension LIMMitless. Presented at: 28th European Academy of Dermatology and Venereology (EADV) Congress; October 9-13, 2019; Madrid, Spain.

skin clearance through six years,[19] as demonstrated in our clinical trials/long-term extensions as well as a favorable benefit-risk profile and predictable real-world treatment patterns with the lowest rates of dose escalation and switching rates.

In network meta-analyses, SKYRIZI had one of the most favorable long-term benefit-risk profiles, with the highest Psoriasis Area and Severity Index (PASI) response rate and lowest safety event rates compared with other treatments.[20] In the real-world, up to ~32% of patients with psoriasis taking any class of biologic dose escalated in the first 12 months after initiating treatment and 26% of patients treated with biologics switched to another treatment within 2 years of initiation. Both dose escalation and switching are treatment patterns that can lead to additional healthcare costs for payers.[21]

Psoriasis patients that dose escalated their biologic treatment had substantial annual mean per person psoriasis-related outpatient prescription pharmacy costs across treatments from $5,202 to $16,475. In addition, switching treatments within the first year of start was associated with a 28.2% higher mean total cost of care compared to patients who did not switch.[22] In the real-world, at the 30% threshold, the percentage of patients with dose escalation in the maintenance period was significantly lower with SKYRIZI (2.0%) compared with other biologics (adalimumab, ustekinumab, secukinumab, ixekizumab, and guselkumab; 17.9%, 10.0%, 15.7%, 18.0%, and 7.2%, respectively; $p < 0.0001$).[23] In addition, switch rates varied between specific biologics, with the lowest switch rates observed for patients treated with SKYRIZI at 8.5% followed by guselkumab at 15.7%, ustekinumab at 24.5%, ixekizumab at 25.1%, secukinumab at 30.4%, and adalimumab at 38.9%, over 24 months.[24]

SKYRIZI also is an important treatment option for patients with Crohn's disease (CD), a chronic, inflammatory bowel disease that affects nearly one in 100 Americans.[25] Specifically, SKYRIZI is the first advanced treatment to evaluate the impact of treatment on both clinical and endoscopic outcomes.[26] Head-to-head data compared to ustekinumab in patients with prior anti-TNF failure has shown superiority in terms of endoscopic remission at Week 48 (SEQUENCE trial) (31.8% for SKYRIZI and 16.2% for STELARA®). Secondary endpoints tested for

[19] Papp KA, et al. Long-term Safety and Efficacy of Risankizumab for the Treatment of Moderate-to-Severe Plaque Psoriasis: Final Analysis of Results From the LIMMitless Open-label Extension Trial For up to 6 Years of Follow-up. Poster 53833. Presented at the 2024 American Academy of Dermatology (AAD) Annual Meeting, March 8–12, 2024, San Diego, CA, USA

[20] Accessed at https://pubmed.ncbi.nlm.nih.gov/34862951/

[21] Bagel J, Glick B, Wu JJ, et al. Dose escalation and associated costs in biologic treatment of psoriasis based on real world data. J Med Econ. 2021;24(1):792-791 https://pubmed.ncbi.nlm.nih.gov/37154473/

[22] Wu JJ, Patel M, Li C, et al. Real world switch rates of biologics and associated costs in patients with psoriasis. Presented at the 2023 American Academy of Dermatology Annual Meeting; March 17-21, 2023; New Orleans, LA.

[23] Accessed at https://pubmed.ncbi.nlm.nih.gov/37025014/

[24] Accessed at https://pubmed.ncbi.nlm.nih.gov/37154473/

[25] Crohn's and Colitis Foundation, Overview of Crohn's Disease, https://www.crohnscolitisfoundation.org/patientsandcaregivers/what-is-crohns-disease/overview.

[26] SKYRIZI, Full Prescribing Information, *supra*.

superiority at Week 48 and included higher rates of clinical remission, steroid-free endoscopic remission, and steroid-free clinical remission at Week 48 for SKYRIZI.[27]

B. SKYRIZI is Affordable and Accessible to Patients and the Broader Healthcare System

AbbVie has comprehensive programs that enable patients, including those in Maryland, to access our medicines at prices they can afford. AbbVie offers patient support programs (PSPs) that set a new industry standard for patient service by focusing on a high-touch, highly personal, human health care experience delivered through a combination of personal interactions, digital solutions, and sophisticated data management. For example, eligible commercially insured patients may qualify for SKYRIZI Complete, which offers a Savings Card that reduces patient cost-sharing to as little as $5 per dose.[28] Additionally, under myAbbVie Assist, low-income patients who are uninsured, unemployed, or have recently lost insurance coverage may be eligible to receive SKYRIZI at no cost.[29]

AbbVie's understanding is that the PDAB is particularly interested in the cost of SKYRIZI for its state employee insurance plan members, who to our knowledge have coverage under a commercial plan/plans. If not otherwise restricted from doing so under your plans, your employees with commercial insurance coverage are eligible to apply for cost-sharing assistance from AbbVie according to program's terms and conditions. Specifically, each employee that received such assistance could pay as little as $5 per dose out of pocket.[30]

Further, we believe that the state of Maryland, for its employee insurance plan(s), may or has contracted with CVS Caremark under one of its PBM options; we are unaware due to the lack of records production to date whether the PDAB and Council has examined out of pocket cost for SKYRIZI per employee under said plan(s) and if not, we encourage you to do so.

Understanding our access programs and the individualized needs of patients, physicians, and payers is only one part of a large solution to the issue of access, and AbbVie is committed to working with all stakeholders to ensure patients receive the treatments they need to live their best life.

III. The Maryland PDAB Has Not Adequately Responded to AbbVie's Public Information Act Request, Adversely Impacting AbbVie's Ability to Effectively Participate in the Cost Review Process

By letter dated March 29, 2024, AbbVie submitted a public records request of the Maryland PDAB pursuant to the Maryland Public Information Act (PIA),[31] seeking all documents and information related to the PDAB's selection of SKYRIZI for potential cost review and its referral

[27] 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.
[28] SKYRIZI Complete, https://www.skyrizi.com/skyrizi-complete/save-on-skyrizi-costs./.
[29] myAbbVie Assist, https://www.abbvie.com/patients/patient-support/patient-assistance.html.
[30] SKYRIZI Complete, *supra*.
[31] Md. Code Ann., General Provisions §§ 4-101–4-601,

to the PDASC. The PDAB responded to AbbVie's PIA request on April 29, 2024 (the Board's Response), the same date as the PDASC's meeting to discuss SKYRIZI and the other seven drugs referred by the PDAB.

A. The Board's Response Does Not Provide Sufficient Information to Determine Why SKYRIZI Was Selected

As AbbVie will further discuss in a separate correspondence, our view is that the Board's Response to AbbVie's PIA request was inadequate for several reasons, including but not limited to the following:

- Many of the documents in the Board's Response are publicly available materials that do not directly relate to the Board's selection of SKYRIZI generally or for referral to the PDASC specifically. For example, the Board's Response includes copies of statutes, regulations, and materials posted on the PDAB's website (*e.g.*, public meeting agendas, comment letters).
- Although the Board's Response includes limited Board correspondence and documentation relating to its drug selection process, the materials are heavily redacted and do not provide insight on the Board's discussions involving SKYRIZI or other prescription drug products with similar spending and costs.
- The spreadsheets in the Board's Response are limited to information on SKYRIZI, and thus generally are not helpful in assessing why SKYRIZI was selected in comparison to other pharmaceutical products.

Critically, the documents in the Board's Response collectively — and in combination with publicly available information — fail to answer a key and valid question under Maryland's PDAB process —why SKYRIZI?

The product has clear and well-defined clinical and economic value to patients and payors alike supported by an extensive body of data, information, health care provider and patient accounts, and other highly relevant information, only a sample of which is referenced in this comment letter. SKYRIZI has an FDA Orphan Drug Designation. Two of the three SKYRZI NDCs identified by the Board have been on the market for less than five years. The drug is categorized as "Only in Class." The information included in the Board's Response does not provide a clear explanation regarding its selection criteria and how application of such criteria resulted in the Board's inclusion of SKYRIZI on the list of eight products for referral to the PDASC. In fact, we were actually provided with information that cuts the opposite way. For example, SKYRIZI's rank relative to other potentially eligible drugs more strongly supports *not* selecting SKYRIZI than it does to further justify or validate the Board's decision.

The intent of Maryland's PDAB law is "to protect State residents, State and local governments, commercial health plans, health care providers, pharmacies licensed in the State, and other stakeholders within the health care system from the high costs of prescription drug products."[32] If the Board does not provide meaningful information regarding how it determines

[32] Md. Code Ann., Health-Gen. § 21-2C-02(b).

whether a drug will lead to an affordability challenge, AbbVie and the broader public have no way to determine whether the Board is acting consistently with its charge. Conversely, if the requested information is not being shared because it simply does not exist, that fact in and of itself is significant and should be disclosed for the public to consider. Without more, the Board's selection of SKYRIZI and referral of the product to the PDASC seems arbitrary and sets a concerning precedent with respect to how patient access to effective and affordable therapies could be impacted by an ill-defined process.

B. Without Adequate Information to Understand the Board's Selection Criteria and Decision-Making Process, AbbVie is Deprived of an Ability to Meaningfully Engage in the Board's Selection Process

The requested records are critical to affording AbbVie a fair opportunity to engage with the PSADC and the PDAB about SKYRIZI. Indeed, the very purpose of the PDASC is to provide stakeholder input to assist the PDAB in its decision-making.[33] There is a member of the PDASC who specifically represents brand name drug corporations. As the manufacturer of a drug under consideration for potential cost review, AbbVie is a relevant stakeholder that must be afforded a meaningful opportunity to have its views heard.

AbbVie has serious concerns about its ability to develop and submit informed comments that effectively address the PDAB's rationale for referring SKYRIZI to the Stakeholder Council when we do not currently have meaningful insight into the methodology, standards, criteria, data, and other information underlying the PDAB's decision to select our product. Moreover, in the absence of same, we are unable to independently verify the PDAB's assessment or offer the PDASC our alternative view of the value, benefits and patient access and affordability of SKYRIZI. What the Board has made publicly available to date does not inspire confidence. For example, the PDAB's published data on patient out-of-pocket costs for the selected drugs including SKYRIZI does not seem to include manufacturer-provided copay assistance, which as highlighted above results in many patients paying as little as $5 per dose for SKYRIZI. Rather, the data appears to only represent the patient's annual prescription drug cost sharing, which includes a deductible, copay, or coinsurance defined by the patient's health insurance plan, providing an incomplete picture of a patient's actual cost.[34] Further, our understanding is that the underlying data files are limited to only privately fully-insured and self-insured non-ERISA health insurance plans for Maryland and Non-Maryland residents and do not include any ERISA plans.[35] The fact that the Board seems to rely heavily on commercial market metrics in selecting products for potential cost review when utilization in such contexts would not, pursuant to existing law, even be covered by a upper payment limit (UPL) established for a drug is also very concerning.

[33] Maryland Prescription Drug Affordability PDAB, "Prescription Drug Affordability Stakeholder Council, 2022 Stakeholder Council Meeting," at https://pdab.maryland.gov/pdab_stakeholder_2022.html ("The purpose of the Prescription Drug Affordability Stakeholder Council is to provide stakeholder input to assist the PDAB in making decisions to protect the State, its residents, and other stakeholders in the Maryland health care system").
[34] Accessed at https://pdab.maryland.gov/cost_review_process.html
[35] *Id*.

Without the benefit of the requested documents and related other information, AbbVie is unable to understand, analyze, and independently verify the methodology and underlying data that the PDAB used to identify which drugs to refer to the PDASC. At its April 29 meeting, the PDASC discussed *the drugs referred by the PDAB*; based on such discussion and its evaluation of the public comments received, the PDASC will provide input to the PDAB that will inform the PDAB's decision whether to select a drug for cost review, a process that may ultimately result in establishment of an UPL for a reviewed drug. Accordingly, we view the records request and cost review processes as necessarily linked.

At its March 25, 2024 meeting, several PDAB members expressed concerns about the quality of available data (*e.g.*, dated claims information), raising legitimate questions regarding the veracity of the data and information the PDAB relied upon to select the eight drugs referred to the PDASC. AbbVie shares these concerns, as the PDAB's product selections may not accurately reflect the eligible drugs that pose actual affordability challenges to Maryland patients. The PDAB has only provided a limited subset of data in a public dashboard which, among other issues, lacks context and complete source information.[36] The mistakes in the Board's publicly available data Dashboard substantially validates our concerns about the quality of the information upon which the Board's decision-making relies. Additionally, the PDAB's Response to AbbVie's PIA request does not provide sufficient information for AbbVie to verify the PDAB's analysis and to understand why SKYRIZI was selected over other products that the Board ranked at a higher position. Impacted stakeholders like AbbVie are, therefore, unable to engage in the cost review process fairly and fully.

AbbVie believes that it is critically important that the PDAB provide manufacturers and other key stakeholders including patients with an opportunity to provide meaningful and informed feedback during this process, and the PDASC's input for the Board consider *all* of the stakeholders it is charged with representing. Without the criteria and underlying data that the PDAB is relying on to determine which drugs are subject to a cost review, the PDASC and PDAB will not receive the information it needs for fulsome deliberations.

IV. Conclusion

We appreciate the opportunity to highlight the value and affordability of SKYRIZI to Maryland patients and payors alike. However, as noted, we are unable to comment completely nor with the benefit of full public transparency into the Board's process to date including the inability of the PDAB to produce records. **For these reasons and many others outlined in this letter, AbbVie objects to the selection of SKYRIZI and referral of the product to the PDASC, and respectfully requests that the PDAB immediately remove SKYRIZI from the list of products under consideration for potential cost review.**

[36] *See* Maryland PDAB, "Drugs Referred to the Stakeholder Council- Dashboard," at https://pdab.maryland.gov/documents/comments/drugs_referred_stakeholder_council_dashboard_2024.xlsx.

Please contact Emily Donaldson at emily.donaldson@abbvie.com with any questions.

Sincerely,

Hayden Kennedy
Vice President, Global Policy & U.S. Access Strategies
Government Affairs
On behalf of AbbVie Inc