May 13, 2024

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

VIA EMAIL ONLY TO:
comments.pdab@maryland.gov

Re: PDAB Public Comments – Maryland Prescription Drug Affordability Board List of "Therapeutic Alternatives"

Dear Members of the Maryland Prescription Drug Affordability Board:

AbbVie Inc. is submitting comments in connection with the Maryland Prescription Drug Affordability Board's ("PDAB's") published list of "therapeutic alternatives" to AbbVie's product SKYRIZI®, and the PDAB's May 20th, 2024 meeting at which it plans to discuss whether to approve the list of therapeutic alternatives. **AbbVie has serious concerns with the PDAB's approach to defining "therapeutic alternatives" and the drugs that the PDAB has considered as alternatives to SKYRIZI. Accordingly, AbbVie objects to the list of therapeutic alternatives and urges the PDAB to vote to not approve the list.**

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.

I. Background

SKYRIZI (Risankizumab-rzaa) is a prescription, biologic interleukin-23 antagonist that is indicated for the treatment of: (a) moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy; (b) active psoriatic arthritis in adults; and (c) moderately to severely active Crohn's disease in adults.[1] Since the U.S. Food and Drug Administration (FDA) first approved SKYRIZI in 2019, AbbVie has continued to sponsor research on the use of SKYRIZI to address unmet patient needs, including for rare diseases. For example, pursuant to an FDA orphan designation for the "[t]reatment of pediatric Crohn's disease,"[2] AbbVie currently is sponsoring a Phase 3, multicenter study to assess the pharmacokinetics, efficacy, and safety of SKYRIZI in pediatric participants with moderately to

[1] Skyrizi®, Full Prescribing Information, https://www.rxabbvie.com/pdf/skyrizi_pi.pdf.
[2] FDA, Search Orphan Drug Designations and Approvals: Risankizumab, https://www.accessdata.fda.gov/scripts/opdlisting/oopd/detailedIndex.cfm?cfgridkey=544716.

severely active Crohn's disease. The study began in December 2023, and is estimated to be completed in April 2029.[3]

Maryland released a list of "therapeutic alternatives" for SKYRIZI on April 11, 2024.[4] Maryland's PDAB regulations define "therapeutic alternative" as a "drug product that has the same or similar indications for use as a particular drug but is not a therapeutic equivalent to that drug." For the reasons stated below, we request that the Board vote to not approve the list of therapeutic alternatives as published.

II. The Maryland Definition of "Therapeutic Alternatives" Does Not Adequately Consider Key Product Differences and Does Not Serve Patient Needs

We have concerns that the "therapeutics alternatives" definition created by the PDAB to identify and compare drug products approved for treatment of the same condition does not account for significant variance in factors such as safety, efficacy, clinical outcomes, and manufacturing costs, nor does the definition account for alignment with clinical guidelines. The current definition also does not account for patient specific factors that may need to be considered during treatment selection such as comorbidities and/or contraindications.

A. The Maryland Therapeutic Alternative List Ignores Important Differences in Labeled Indications & Clinical Guidelines That Guide Patient Care & Treatment Decisions

In particular, various treatment guidelines for immune-mediated inflammatory diseases (IMIDs) such as rheumatoid arthritis, psoriatic arthritis, and inflammatory bowel diseases have recommended a "treat-to-target" (T2T) approach, which involves starting effective treatment early for better long-term outcomes, given the availability of multiple treatment options.[5,6,7] Recent advancements in drug discovery have led to the development of Jak inhibitors and IL-23 and IL-17 agents, which have shown to be more effective than anti-TNFs in clinical trials. These developments in IMID therapies have made it possible to achieve clinical remission, whereas in the past, when conventional therapies and anti-TNFs dominated the treatment landscape, only

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[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.

[4] https://dsd.maryland.gov/regulations/Pages/14.01.01.01.aspx

[5] Smolen JS, Breedveld FC, Burmester GR, et al. Treating rheumatoid arthritis to target: 2014 update of the recommendations of an international task force. Annals of the rheumatic diseases. 2016;75(1):3-15.

[6] Coates LC, Soriano ER, Corp N, et al. Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA): updated treatment recommendations for psoriatic arthritis 2021. Nature Reviews Rheumatology. 2022;18(8):465-479.

[7] Turner D, Ricciuto A, Lewis A, et al. STRIDE-II: an update on the Selecting Therapeutic Targets in Inflammatory Bowel Disease (STRIDE) Initiative of the International Organization for the Study of IBD (IOIBD): determining therapeutic goals for treat-to-target strategies in IBD. Gastroenterology. 2021;160(5):1570-1583.

40-60% of patients were able to meet the guideline-defined endpoints.[8,9,10,11] Such advanced therapies like SKYRIZI have the potential to elevate the standard of care by enabling the attainment of more rigorous treatment targets as outlined in clinical guidelines. In IMIDs, there have been studies showing that patients who achieve a state of stringent disease control through these therapies are more cost-effective to manage compared to those with ongoing active disease.

SKYRIZI is categorized as "Only in Class" and has no therapeutic equivalents listed in FDA's Orange Book. And yet, the Maryland PDAB asserts methotrexate and cyclosporine are therapeutic alternatives for SKYRIZI. Moreover, and unlike SKYRIZI, neither drug has an FDA approved indication to treat psoriatic arthritis or Crohn's disease (FDA labels can be found here and here). The current (2019) American College of Rheumatology and National Psoriasis Foundation Guidelines on Psoriasis only cite use of cyclosporine as an option in combination therapy with a biologic, not as monotherapy. The guidelines also recognize that while efficacy may be augmented with combination treatment, there is an unknown level of safety risk due to significant adverse events. Therefore, if a patient is being treated for psoriasis by a provider who is following clinical guidelines, SKYRIZI is most likely being used in a population where treatment with methotrexate or cyclosporine has already failed to manage their condition. For this population, it would not be feasible to consider either drug as an effective therapeutic alternative.

For Crohn's disease, several drugs listed as therapeutic alternatives for SKYRIZI do not have FDA approved indications for Crohn's disease or are *contraindicated*. Sotyktu and Otezla do not have an FDA approved indication for Crohn's disease (FDA labels can be found here and here). Cosentyx, Taltz, Siliq and Bimzelx (i.e. IL-17) are contraindicated for Crohn's disease. Considering these drugs as a therapeutic alternative to SKYRIZI for the treatment of Crohn's would be irresponsible and dangerous.

B. Maryland Has Not Appropriately Considered Patient Choice and Access

Determinations related to cost-review may negatively impact patient access and ultimately patient outcomes. The PDAB must place utmost importance on patients and ensure their actions do not adversely impact patient health.

To our knowledge, in developing this list of therapeutic alternatives, the PDAB has not performed an assessment of what patients need and value from these medicines. Treatment decisions are best navigated between trained clinicians specializing in treatments and the patient, who presents with a unique set of clinical features often accompanied by impacts on their quality of life.

III. Conclusion

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[8]Curtis JR, Fox KM, Xie F, et al. The Economic Benefit of Remission for Patients with Rheumatoid Arthritis. Rheumatology and Therapy. 2022;9(5):1329-1345.

[9] Kremer JM, Pappas DA, Kane K, et al. The Clinical Disease Activity Index and the Routine Assessment of Patient Index Data 3 for achievement of treatment strategies. The Journal of Rheumatology. 2021;48(12):1776-1783.

[10] Zardin-Moraes M, da Silva ALFA, Saldanha C, et al. Prevalence of psoriatic arthritis patients achieving minimal disease activity in real-world studies and randomized clinical trials: systematic review with metaanalysis. The Journal of Rheumatology. 2020;47(6):839-846.

[11] Armuzzi A, Tarallo M, Lucas J, et al. The association between disease activity and patient-reported outcomes in patients with moderate-to-severe ulcerative colitis in the United States and Europe. BMC gastroenterology. 2020;20(1):1-11.

We appreciate the opportunity to provide our comments on the list of drugs that are being considered as therapeutic alternatives to SKYRIZI. However, as outlined in this letter, we have serious concerns with the list created by the PDAB. For those reasons, AbbVie objects to the list of therapeutic alternatives and urges the PDAB to vote to not approve the list.

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