AiARTHRITIS
INTERNATIONAL FOUNDATION FOR AUTOIMMUNE & AUTOINFLAMMATORY ARTHRITIS

May 13, 2024

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

RE: Public Comments on Therapeutic Alternatives for Skyrizi

Dear Members and Staff of the Maryland PDAB and Stakeholder Council:

The International Foundation for Autoimmune & Autoinflammatory Arthritis (AiArthritis), a patient organization led by people affected by AiArthritis diseases, shares the committee's goal of lowering patient out-of-pocket costs so that they can more easily maintain their health. We appreciate the opportunity to provide comments on behalf of the thousands of people in Maryland who rely on Skyrizi to manage their active Psoriatic Arthritis and Crohn's Disease.

While we understand the board was asked to discuss therapeutic alternatives as part of the review, we appreciate the opportunity to explain why considering costs of "other options" has a limited place in drug affordability reviews.

People with Heterogeneous Diseases Cannot Be Treated with a One-Size-Fits-All Approach

We know many patients will not respond to existing therapies, so when they find the right one there should be no alternative. Of the thousands of people living with Psoriatic Arthritis and Crohn's Disease in Maryland, generally only between 40-60% respond well to any given treatment and of those up to 80% fail to achieve remission.[1] [2] This is, in part, due to the heterogeneity of these conditions combined with the current trial-by-error process of finding the drug that works best for the individual. Ask any patient who has found the right biologic and they will all tell you the same thing: "Do not disrupt my continuity of care!" Yet, unfortunately, year after year - and in some cases month after month - patients battle this very fight due to insurance formulary design and efforts by payers to move patients to less costly options (i.e., step therapy and non-medical switching).

Uncontrolled inflammation leads to comorbidities. Excess comorbidity is associated with poorer outcomes, including worse physical disability, functional decline, lower remission rates, poorer quality of life, and increased mortality. Up to 70% of AiArthritis disease patients, including

[1] https://www.gastroenterologyandhepatology.net/archives/june-2022/approach-to-treatment-failure-in-inflammatory-bowel-disease/
[2] https://pubmed.ncbi.nlm.nih.gov/35245701/

those with Psoriatic Arthritis and Crohn's Disease, will develop at least one comorbidity in their lifetime. Multiple diagnosis adds to the complexity of treatment matching.[3]

Continuity of Care Equates Better Outcomes and Lower Healthcare Costs

The right treatment matters. It often takes months, even years, for a person with AiArthritis diseases to be diagnosed. As a result, uncontrolled inflammation can lead to more aggressive disease and often to comorbidities (which makes the treatment of already heterogeneous diseases more complex). Even if diagnosis is not delayed, finding the right treatment still involves a trial-and-error process, taking months each time to determine level of efficacy.

The reality for patients and for their doctors is the right treatment matters. Failure to maintain access to a therapy that is working increases the chance for increased disease activity and decreases their chance to ever achieve remission (which equates to more long term health costs to state consumers and the state healthcare system).

Therapeutic alternative options are similar to non-medical switching (NMS) insurance protocols. NMS is the process of suggesting or requiring a stable patient to switch to a different drug for cost reasons, rather than for what is best for their disease stability and outcomes. Studies that include both Crohn's Disease and Psoriatic Arthritis have shown that NMS was associated with significantly worse clinical outcomes, including increased flares, poor control, and increased health care resource utilization.[4] In a recent study, switching or discontinuation from a therapy for nonmedical or economic reasons following stable response was associated with significantly worse clinical outcomes (disease flares and severity) and increased health care resource utilization among patients with Crohn's Disease (CD), Psoriasis (Ps), and Psoriatic Arthritis (PsA) - all diseases treated by Skyrizi. Recommendations from this study include, "Third-party payers might also want to consider the risk associated with policies that may result in nonmedical switching when making formulary decisions.

Alternative therapies should only be considered options when the patient and their doctor are determining an initial or new drug course. The drugs used to treat AiArthritis diseases are large molecule treatments that take time for adjustment and efficacy. Once a patient has achieved their disease targets (i.e., low disease activity or remission), requiring them to try another drug could cause decreased effectiveness if they must switch back to the original medication. These unintended health consequences translate to increased ER visits, hospitalizations, physician visits and lab tests – which also drive up health care costs.[5]

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[3] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6907158/
[4] https://www.sciencedirect.com/science/article/pii/S0149291817301790
[5] https://www.arthritis.org/health-wellness/treatment/treatment-plan/you-your-doctor/treatment-guidelines-for-psoriatic-arthritis-arth

Recommended Treat-to-Target Approach Improves Outcomes

Best treatment decisions for heterogeneous diseases should implement a Treat-to-Target (T2T) method, personalizing therapy options to the individual's disease severity and accompanying comorbidities.[6] Clinical practice guidelines include recommendations meant to optimize patient care that are informed by the benefits and harms of alternative care options, rather than prescribing a one-size-fits-all approach to patient care.[7] There is mounting evidence that targeted strategies are cost effective, reduce morbidity, and improve patient outcomes.[8]

Adding Payer-Initiated Cost Savings Strategies to the PDAB Process Is Not Putting Patient Needs First

For years patient organizations and persons affected by these diseases have been fighting insurance company protocols that limit access to the treatments that are working well. Every year, sometimes more than once a year, patients fear their insurance company will remove the drug that has enabled them to work, to go to school, to attend family events, to hold their child - to live relatively normal lives. The justification for requesting a patient switch to a different medication is based on "therapeutic alternative options."

We know under 60% of any given biologic will work for persons diagnosed with the same AiArthritis disease. We know it can take years to find 'the one' that works best for us. We know "options" are great for those who need them. We know the more our continuity of care is disrupted the less chance we have to ever achieve remission. We know this, we live it, and, therefore, we fight to be heard - *There are no alternatives to the treatment that works. Period.*

Thank you for considering our input and do not hesitate to reach out to me at tiffany@aiarthritis.org with any questions.

Sincerely,

Tiffany Westrich-Robertson

Tiffany Westrich-Robertson
Chief Executive Officer
Person living with non-radiographic axial spondyloarthritis
International Foundation for Autoimmune & Autoinflammatory Arthritis

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[6] https://erar.springeropen.com/articles/10.1186/s43166-022-00128-y
[7] https://erar.springeropen.com/articles/10.1186/s43166-022-00128-y
[8] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10022708/