AiARTHRITIS
INTERNATIONAL FOUNDATION FOR AUTOIMMUNE & AUTOINFLAMMATORY ARTHRITIS

"We don't represent the patient voice, we *are* the patient voice."

October 17, 2023

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

RE: Public Comments - Maryland Prescription Drug Affordability Stakeholder Council Meeting, October 23rd, 2023/Upper Payment Limits Action Plan

Dear Members of the Maryland Prescription Drug Affordability Board and Stakeholder Council:

The International Foundation for Autoimmune & Autoinflammatory Arthritis (AiArthritis), a patient organization led by people affected by AiArthritis diseases, is grateful for the opportunity to submit public comments throughout this drug affordability process. We hope the Board and Stakeholder Council will consider these statements as you continue forward with your drug affordability program.

About AiArthritis. AiArthritis is a leader in advancing education, advocacy, and research for those impacted by autoimmune and autoinflammatory arthritis (AiArthritis) diseases through peer-led guidance, collaboration, and resources that are driven by patient-identified issues and patient-infused solutions. As we are led by patients we understand how important it is to be able to access safe, efficacious, and affordable treatments. As patients living with heterogeneous conditions, we also understand there is no one-size-fits-all drug - even for those diagnosed with the same disease. Through lived experience, we also know that disrupting continuity of care often leads to uncontrolled disease, comorbidities, and significantly decreased rates of remission.

On behalf of patients and care partners residing in Maryland, we thank the state for recognizing a need to address the high costs of prescription drugs. ***However, we have some concerns regarding the proposed UPL framework, including the use of value assessments, uncertainty how much patients will be involved in the development and execution, and the potential negative implications around accessing innovative, new therapies.***

We understand the Maryland PDAB was established in response to this issue, and with the "ultimate goal of patient protection" and ensuring drug affordability for State and local governments, and employers.[1] We also understand the Stakeholder Council was established to provide stakeholder input to assist the Board in making decisions to protect the State, its residents, and other stakeholders in the Maryland health care system. It is for these reasons we feel it is important to address both groups with these comments.

We appreciate every opportunity given to patients that enables us to have a voice in matters involving our healthcare. While there are many things we would like to address, and hopefully will be able to in the future, these comments focus on the October 23rd agenda item Upper Payment Limits (UPLs).

[1] https://pdab.maryland.gov/news_archive.html

UPL Framework and Innovation

In the most recent meetings of the Board (July 24th, September 13th, and September 18th 2023), the regulatory structure and associated UPL framework development and implementation were discussed. Given the presentation planned for the October 23rd meeting of the Stakeholder Council will revisit this subject, we would like to take this opportunity to highlight areas for consideration.

Upper Payment Limits July 24th, 2023 presentation[2] (Board Staff)- concerns and considerations

- "The upper payment limits set under subsection (a) of this section shall: (1) Be **for prescription drug products that have led or will lead to an affordability challenge."** For those living with AiArthritis diseases and who utilize drug manufacturer copay assistance programs, affordability is not an issue - as demonstrated in the Colorado PDAB online discussion group sessions. With exception of one person who felt challenged to meet a $35 copay during a difficult time, everyone reported any adherence issues (including skipping doses or stretching out doses) were due to payer utilization management procedures and not due to affordability. *(See AiArthritis Public Comments to CO PDAB)*[3] For this reason, we recommend the Board clarify to whom the affordability issue is targeting per the Maryland PDABs statement of protection (*i.e. with the "**ultimate goal of patient protection**" and ensuring **drug affordability for State and local governments, and employers**, Reference 1*). **If the drug end user (patients and care partners) are deemed to not be the focus of affordability challenges, for clarity and transparency purposes, it is imperative to outline how their testimony will be considered and weighted in the 60 day public comments phase.**
- Regarding "Key Decisions for UPL Action Plan, How do you determine an UPL: Frameworks and Setting UPLs," the first methodology explored are Value Assessments, which assign value to drugs based largely on general patient populations for a specific diagnosis. ***Missing from the Cons list is a very important piece - current Value Assessment Frameworks lack inclusion of consideration for diseases that are heterogenous and where patients are also diagnosed with comorbidities (i.e., dual diagnosis, heart disease, lung disease, and other conditions that add complexity to their situation). In AiArthritis diseases, comorbidities are extremely common, with an estimated 70% who will develop these if they are not matched to a treatment they will respond to or if they experience disruption in continuity of care (most often due to payer practices of prior authorization, step therapy, non-medical switching, or accumulator programs)***.

Upper Payment Limits: Example Framework September 18th, 2023 presentation[4] (Board Staff)- concerns and considerations

- "What drugs are most appropriate for UPLs - Dealing with manufacturer market power - Curbing monopoly pricing, Discouraging collusion and promoting competition, and Discouraging anticompetitive behavior." As mentioned previously, AiArthritis agrees there is a need to lower the costs of prescription drugs and understands the Board's move to establish UPLs as part of this process.

[2] https://atapadvocates.com/the-pbm-problem
[3] https://drive.google.com/file/d/1LfyObDnncBB45aGQ_mA4qfS5p4-YvnKg/view?usp=share_link
[4] https://pdab.maryland.gov/documents/meetings/2023/pdab_UPL_example_framework_20230918.pdf

- We would like to take this opportunity to remind the Board and the Advisory Council that a large percentage of high costs are due to Pharmacy Benefit Managers (PBMs) negotiation processes. Legislation like the Pharmacy Benefit Manager Transparency Act and other efforts to put cost savings back into the pockets of patients may play into solving this issue.[5]
  - In conjunction with our above comment and speaking specifically in regards to biologic medicines used to treat AiArthritis diseases, we strongly disagree with this statement, "Because of PBM-Insurer market power, **they can make money while passing the costs on to patients.**" *We have seen no evidence as of yet that demonstrates PBMs pass savings on to our patient community.*

- "It is possible to use different methods and frameworks in different circumstances." We applaud this suggestion and recommend the Board and Advisory Council dive deeper into this statement by inviting Patient Organizations and other stakeholders to weigh in on the possibilities.
- "Other countries have made decisions on how to set payment amounts in different situations." While this is true, in countries where governments set drug control prices, this has impeded medical research funding and, in turn, patients have access to fewer treatment options. Of all the new drugs released worldwide between 2011 and 2017, only two-thirds were available in the United Kingdom, and fewer than half were available in Canada, France, and Japan. By contrast, nearly 90 percent were available in the United States.[6] In diseases like AiArthritis, when there are no one-size-fits-all treatments for any singular disease diagnosis, access to new therapies is vital to remain productive members of society.

Regarding innovation. Price control policies are not guaranteed to directly impact the price that most patients pay for highly innovative therapies – as stated above, the savings will generally be accrued by the commercial or public payer/PBM. Instead, patients will suffer from unnecessary delays in connecting patients with highly innovative therapies, fewer treatment options, and more barriers to accessing the life-changing care they need. For people living with AiArthritis diseases, waiting for an effective treatment to become available could prove permanently harmful. While the expenses associated with revolutionary research may carry high risks, the investment can bear greater health improvements for all.

Patient Involvement in the Process

Cost Review Study Process and Public Comment Procedures Regulation at 14.01.01.05. In reviewing past minutes, we are glad to see in the Summary of Key Themes in Comments on the Second Draft of Cost Review Study Process that multiple people requested opportunities for public feedback throughout the selection (including the Arthritis Foundation and in conjunction with the Value in the States Coalition, of which AiArthritis is a proud member).[7] We are equally pleased that a Public Comment Procedures Regulation at 14.01.01.05 General Provisions was created and that patients and care partners will have the opportunity to provide perspectives within 60 days of the date the drug selected for cost review is posted.

[5] https://www.commerce.senate.gov/2023/1/7
[6] https://insidesources.com/medical-science-gives-aiarthritis-patients-plenty-to-look-forward-to/
[7] https://pdab.maryland.gov/documents/regulations/Arthritis_foundation_comments.pdf

We are including these comments here simply to remind the Advisory Council and the Board the importance of including the patient voice in all aspects of this process. If at any time you are unsure how this can be achieved, please do not hesitate to contact us.

In closing, we would like to extend gratitude again on behalf of AiArthritis, and all persons living with our diseases, for this opportunity to participate in this process and to provide comments that we hope can help as you evolve it. To the Stakeholder Council specifically, we encourage those who directly or indirectly represent patient and care partner voices (i.e., Public Member, Employers, Physicians, Dentists, Nurses, and advocacy groups for seniors and diverse communities) to take this information provided and consider incorporating it into your recommendations to the Board. As an organization that operates through peer-to-peer collaboration, we look at this as an opportunity to be an extension of this Council and invite you to lean on us for additional information or guidance as needed.

Thank you for considering our suggestions 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

Anika Rahman

Anika Rahman

International Advocacy and Policy Manager
Care Partner/Undiagnosed "Mystery Patient"