Arthritis Foundation®

Yes

October 23, 2023

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

Dear Members of the MD Prescription Drug Affordability Board:

On behalf of the Arthritis Foundation, representing the nearly 60 million Americans and more than 1.4 million Maryland residents living with doctor-diagnosed arthritis, we appreciate the opportunity to comment on the ongoing work of the Maryland Prescription Drug Affordability Board (PDAB).

We thank the PDAB for holding opportunities for patients to provide input on their experiences during meetings, through submitted written comments and also appreciate ongoing opportunities for stakeholders to ask questions and provide feedback. We would like to provide feedback on the following:

1. The process of soliciting patient feedback
2. Our data and insights on the patient experience taking biologic medicines
3. Examples of our work with value assessment to inform your methodological considerations for determining affordability

Patient Engagement Process

We encourage PDAB staff to prioritize the following for future efforts:

- Coordinating with the patient advocacy community well in advance of any specific drug affordability consideration so we can collectively determine effective outreach practices.
- Working closely with the health care provider community to recruit patient experiences when considering specific drug affordability; providers have the most consistent and wide-reaching touchpoints with patients and are in a unique position to communicate with patients on those specific drugs. Providers have limited time, so having pamphlets or even a QR code they can give patients could make a substantial difference in recruitment efforts.

In our experience surveys can provide critical insights but often lead to more questions as to why a patient may have answered a question a certain way or about the outcome of their experience. We hope the PDAB would offer focus groups to gather insights to help fill in those gaps and if there are remaining gaps in understanding what leads to affordability and accessibility challenges for patients, we urge the PDAB to collaborate with patient advocacy organizations to conduct follow-up patient stakeholder opportunities.

Arthritis Foundation Data and Insights

We regularly collect survey and focus group data from patients on their experiences with prescription drugs, including impacts of out-of-pocket costs, impacts of step therapy and prior authorization, and general experiences finding the right treatment.

Out-of-Pocket Costs

The list price of Rheumatoid Arthritis (RA) biologics ranges from $5,000 to $8,000+ per dose, and patient cost-sharing varies depending on their plan type. These drugs are typically placed on specialty tiers with either co-insurance or higher co-pays. For those paying co-insurance, costs can reach into the thousands for one fill. Many patients with commercial insurance rely on some sort of copay assistance to help afford their cost-sharing, which can cause significant problems when they enroll in Medicare or experience restrictions in the use of copay assistance.

In a survey conducted by the Arthritis Foundation in 2021, patients cited out-of-pocket costs as one of the top three barriers to accessing care. Of all surveyed, 37% have had trouble affording their out-of-pocket costs this past year. Of those, 54% say they have incurred debt or suffered financial hardship because of it. Out-of-reach costs can lead to non-adherence which results in myriad negative impacts to health. In our survey, trouble affording out-of-pocket medical expenses had negative impacts on care: 45% delayed refilling a prescription, 41% say their health care worsened, and 41% switched medications as a result.

Utilization Management

Arthritis Foundation data demonstrates that inappropriate use of utilization management (UM) such as step therapy and prior authorization can lead to delays in care, resulting in negative financial, emotional, and physical consequences. Patients living with arthritis are particularly susceptible to these kinds of insurance practices, and many utilization management protocols tend to apply policies that do not adequately align with clinical guidelines or what the provider deems is in the patient's best interest. Inappropriate use of UM practices can lead to treatment delays and disease worsening. When inappropriately used, step therapy can undermine the clinical judgment of health care providers and put patients' health at unnecessary risk. Many patients must try multiple drugs before finding one that works for them, so the ability to remain on a drug that works is critical.

A 2023 Arthritis Foundation survey on utilization management issues found the following:

- Nearly 60% of patients reported having difficulty getting their doctor-prescribed medication.
- Over 70% of patients surveyed have experienced step therapy multiple times, with 12% having experienced it 5 or more times.
- Nearly half of patients indicated they experienced joint damage due to the step therapy protocols,

  - 25% developed non-joint related health complications, and
  - 70% of patients reported suffering from stress, depression, and anxiety as a result.
- More than half of patients indicated their arthritis was at least somewhat well-managed prior to step therapy.
- While more than half of patients requested an exception to the step therapy requirement, it was only granted about 1/3rd of the time with the most likely reason cited for the exemption request was due to having already tried and failed the drug the health plan was requiring.
- Over 70% of patients had to go through prior authorization process because their health plan required it.

Value Assessment Examples

The Arthritis Foundation has engaged in two RA-specific value assessment-related efforts since 2016:

Institute of Clinical and Economic Review (ICER) RA Review 2017

The Arthritis Foundation participated in an Institute of Clinical and Economic Review (ICER) review of RA drugs in 2016-2017 and as part of this effort we conducted a survey of RA patients' experience with taking biologics. Among the findings: a majority had taken multiple biologics over the course of their RA and many switched early in treatment, including 56% of respondents who had been on or taken Enbrel for less than two years. The most cited reason across all biologics was the drug did not work. Specific to Enbrel, 48% cited it did not work, 19% had bad side effects, and 9% had insurance changes. 35% of respondents indicated challenges accessing their medications and when asked the impact of insufficient treatment, 57% cited they had to take additional medications for things like pain, depression, and anxiety; 42% missed work or school; 40% experienced joint damage or worsening of disease; 22% developed non joint-related symptoms related to their disease; 19% had to leave their job or school; and 11% had to be hospitalized.

As a result of this survey, ICER took into consideration the high level of variability in treatment efficacy and the consequences of disruptions of treatment and indicated in the final report that step therapy is not appropriate in all cases.

Innovation and Value Initiative (IVI) RA Model and White Paper 2021

In its update to its RA model in 2019, IVI worked with the Arthritis Foundation to identify RA patients with whom to conduct a focus group in order to better incorporate patient experience data into their modeling. The focus group yielded important and invaluable insights and as a result we co-authored a white paper highlighting the key themes and best practices for this patient-centered approach. From the paper:

- Traditional clinical trials and research do not always capture the full complexity of living with RA, including comorbid conditions, fatigue, mental health, and the impact of hormonal changes.
- Access to effective treatment may be driven by insurance coverage or haphazard testing of treatments rather than by clinical guidelines.
- Costs related to RA include far more than direct medication costs and need to be captured.
- While RA is a progressive disease, people living with it are seeking independence and normalcy versus just symptom management.

The focus groups revealed a diverse range of experiences. From the paper:

- While severity of RA and response to treatment vary among individuals, commonly experienced symptoms include significant joint pain and weakness, stiffness, and fatigue.
- Most participants described fatigue as a largely unaddressed impact of RA, and a factor further exacerbated by many of the RA treatments as a side effect.
- Multiple individuals pointed to hormonal changes (puberty, pregnancy, menopause, etc.) as “triggers” to the onset of symptoms or treatment failures.
- Nearly every participant described significant psychological impacts of the disease, including depression, anxiety, and social isolation.
- Co-occurring conditions are common, and when present, complicate outcomes. Multiple participants reported co-occurring health conditions, including type 1 diabetes, fibromyalgia, spondyloarthropathy, lupus, anxiety, and depression.

The paper noted that even with only 14 participants, there was wide diversity in time to diagnosis (between 6 months and 5 years) and time to finding an effective treatment (between 1 year and never); treatment experiences from the paper:

- Participants reported that treatment choices appeared to be based on trial and error or insurance coverage, rather than clinical guidelines or assessment by their clinician.
- Many had difficulty finding effective treatment over time. Most were concerned about the durability of treatment and the lack of clarity about what might trigger sudden change or failure of a treatment. Several reported never finding a fully effective treatment option despite extensive regimen testing.
- Multiple individuals were concerned about running out of treatment options; there was a sense that each treatment had a “shelf life” or limited time horizon.
- Participants reflected a common experience or understanding that insurance coverage, socioeconomic status, and race impact the quality of and access to treatment.
- Participants described the impact of treatment on choices to have children, how having children impacts treatment options, and the ability to have children.

Also from the paper:

Other areas of less frequently measured costs that have high impact on patients' experiences and outcomes include:

- Time spent in seeking, receiving, and recovering from treatment, with some calculating this cost to be upwards of a month a year.
- Diminished ability to work and lost wages due to early retirement or career impact, including choosing lower paying jobs to ensure health insurance access.
- Heavy burden of RA on caregivers (spouses, parents, and siblings), such as anxiety, missed work time, childcare, and job choice based on health insurance.
- Ancillary costs of seeking and receiving treatment, including transportation costs, non-medical supportive expenses (e.g., assistive devices), and non-covered benefits.

Lastly, navigating health plan prescription coverage, particularly for higher cost medications in high deductible plans, can be of particular concern for those living with arthritis and the chronic disease patient community. One area is the recent inclusion of copay accumulator programs that are often hidden in health plans. These programs prevent patients from counting copayment assistance from a third party (be it from a manufacturer or foundation or other source) from counting toward their deductible and out of pocket maximums. Not only are these programs often difficult to find within plan coverage materials, but the application makes it very difficult for patients to budget for their health costs and be able to fill their medications and maintain treatment. 19 states, DC and Puerto Rico have all passed laws to prohibit copay accumulator programs and we hope Maryland will join in this effort to ensure ***all copays count*** so patients facing high costs can apply assistance as a payment should they need it.

We hope these insights and examples will be valuable to the PDAB as it embarks upon the next phase of affordability considerations. We welcome the opportunity to provide further insights and to serve as a resource to the PDAB in the coming weeks and months ahead. Thank you for your consideration, and we look forward to engaging with you in the future.

Sincerely,

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