

August 7, 2020

Comments Re: “Fair” Drug Coverage: Criteria for Appropriate Cost-Sharing and Prior Authorization Protocols for Pharmaceutical Coverage

Institute for Clinical and Economic Review (ICER) and the Office of Health Economics (OHE)

To Whom it May Concern:

On behalf of the 54 million American adults and 300,000 children with doctor-diagnosed arthritis, the Arthritis Foundation appreciates the opportunity to comment on the ICER/OHE White Paper “‘Fair’ Drug Coverage: Criteria for Appropriate Cost-Sharing and Prior Authorization Protocols for Pharmaceutical Coverage.” As you know, autoimmune forms of arthritis can be complex and difficult to treat, and often require the use of specialty drugs like biologics to manage. We appreciate the effort to establish ethical goals and implementation criteria around drug coverage, as the challenges in the current health care system can present significant barriers to patients seeking to find a drug that works for them and to remain on it.

The Arthritis Foundation routinely collects quantitative and qualitative data to better understand the experiences and challenges of people with arthritis, and we believe our data can be informative to ICER as it continues its work. In particular, our INSIGHTS program is an online assessment that collects data on physical health, mental health, and experience of care based on the PROMIS 29 measure set. This ongoing assessment has revealed critical insights thus far on the impact of pain, co-morbidities like depression and anxiety, and inequities in the healthcare system. This data is being used to inform our access to care agenda, and our work with the clinical and scientific communities.

Below please find our comments on the White Paper.

Introduction and Background

Many of the topics covered in this white paper such as prior authorization and step therapy are pervasive in arthritis drug coverage and therefore important in our patient population. While we understand that ICER wanted to keep the scope limited and that topics such as rebates fall outside that scope, we believe that any examination of coverage issues must include discussion of rebates and other market issues. It is difficult – if not impossible – to disentangle formulary design and utilization management from the rebate system. Although determining ethical criteria for the use of step therapy, prior authorization, and cost-sharing is laudable, without addressing the larger market forces it does not get to the root of the problem. From our experience meeting with payers, manufacturers, and others throughout the healthcare ecosystem, the broken rebate system

underpins the subsequent benefit design, much of which disadvantages patients. This is evident in the body of the white paper itself, which mentions challenges around rebates, for example highlighting how they can impede fair coverage in the ethical considerations for step therapy.

The background section discusses overall benefit design highlighting the structure of formularies and their two fundamental types: open and narrow. Payers typically use narrow formularies to control costs, and many of the drugs that get onto formulary are ones for which the companies can offer the highest rebates. Despite the fact that clinical staff within payer companies may employ a scientific approach to coverage criteria and recommendations, those considerations are not always reflected in practice. While we don't have full insight into the process, as patients and patient groups are typically not invited to participate in P&T Committees, the Arthritis Foundation has participated in many forums with payers and our take-away is that the clinical/scientific side of the house is quite separated from the business side. It is hard to reconcile what we hear presented from the clinical/scientific side about their process and the benefits of prior authorization with what we see in practice. This leads us to believe that distorted market incentives ultimately drive coverage decisions. There are far too many cases in which drugs that show better clinical efficacy and/or have lower list prices cannot get onto formulary. An acute example of this was presented by ICER itself during the RA drug review update in winter of 2019, which noted that despite similar clinical efficacy and lower list prices, none of the major commercial payers cover the biosimilars of Remicade as first-line therapy. Patients must try and fail on the reference drug before getting access to the biosimilar, effectively shutting the biosimilar out of the market. This is clearly not related to clinical efficacy, but solely to rebate leverage.

When it comes to utilization management protocols, our quantitative and qualitative research with arthritis patients shows a consistent theme: these challenges are daunting and incredibly time consuming for patients, and they are often steered in their decisions by how many “hoops they have to jump through” rather than by what the provider determines is the most effective treatment for their unique needs. To the Arthritis Foundation, this is the hallmark of a broken system. In our annual advocacy priorities survey, prior authorization has come up as the top healthcare-related challenge every single year. Step therapy is also very common for rheumatoid arthritis drugs and when inappropriately administered has led to devastating health outcomes for many of our patients. A survey of more than 1,400 patients conducted in 2016 by the Arthritis Foundation revealed that over half of all patients reported having to try two or more different drugs prior to getting the one their doctor had originally ordered. Step therapy was stopped in 39 percent of cases because the drugs were ineffective, and 20 percent of the time due to worsening conditions. Incredibly, nearly a quarter of patients who switched insurance providers were required to repeat step therapy with their new carrier.

[Principles of Appropriate Access to Drugs Described in Prior Literature](#)

We agree that long-term costs and benefits should be a critical component in coverage decisions. The arthritis community is heterogeneous and each unique patient deserves care tailored to their needs, rather than retrofit from a one-size-fits-all paradigm. Those with chronic diseases may have different needs than other consumers of health care and should be appropriately considered by payers. Even within a chronic disease like rheumatoid arthritis, heterogeneity of the disease can make the right treatment protocol very different in otherwise seemingly similar patients, so there must be flexibility in the system to allow for that variability. We also agree there is a need for appropriate appeals processes that are more transparent and easier to navigate. There cannot be trust in a system that is opaque. A clear example of this came from an arthritis patient who participated in a CMS listening session in December 2019; she has been on the same drug for over a decade but has had to go through prior authorization every year. It does not make sense to her why she should have to go through prior authorization every single year, and she notes that if there is a reason for it, she could accept that, but she has never been given a reason.

Fair Design and Implementation Criteria

Cost-Sharing. We agree with the ethical goals for cost-sharing outlined in this paper. It is not uncommon for all drugs for autoimmune forms of arthritis to be placed in a specialty tier, which is financially untenable for many patients given the rising use and rate of co-insurance. High Deductible Health Plans (HDHPs) may be intended in many cases to reduce health care utilization, but when trying to keep a chronic disease patient stable, we should incentivize utilization rather than discourage it. Accessible utilization of care helps patients manage their disease and in so doing reduces long-term health care costs.

We agree out-of-pocket costs must be based on net drug price, not list price, and that high value drugs for chronic disease should be included in pre-deductible coverage, per the above points. However we oppose the recommendation that patients should shoulder the higher cost of drugs that are not considered “fairly priced” when there are no other options for them on the basis that it is more equitable for the entire health care system. Rather we would suggest that this is indicative of a broken system, emphasizing our earlier point that while that it may be equitable within this broken construct, it is not equitable in the aggregate.

We agree with the implementation criteria around transparency, and we have supported recent proposals from the administration around real-time benefit tools and helping patients and providers to know the cost-sharing requirements at the point of care.

Timing of Coverage Following FDA Approval: We agree with the ethical goals outlined in this section, and that there should be expeditious review by payers and that prior authorization considerations should not be tools for reducing utilization or incentivizing patient steering. In terms of coverage, patients who have exhausted the available treatments on the market should be included in the population of candidates for early access along with the patients that have rapidly progressive disease/fatal conditions. We hosted an externally-led Patient-Focused Drug Development meeting on juvenile

idiopathic arthritis in 2018, and many of the attendees told stories of having tried every therapy indicated for their disease, and being at the end of the line, not knowing what to do next, and feeling desperate for a new therapy to try.¹ Their risk tolerance for new therapies may be very different than for those with multiple treatment options for their disease, and this differential must be taken into account by healthcare stakeholders.

Clinical Eligibility Criteria. We agree with many of the ethical goals outlined in this section. With regard to prior authorization, we have been a strong supporter of the AMA consensus statement published in January 2018. This publication can serve as a set of specific, practical tools that can accomplish some of the goals ICER highlights, especially those related to mitigating against misuse and overutilization of medications. We believe that all parties interested in the issue of prior authorization, especially the by six major trade associations across the health care system that signed onto the consensus statement, should put their full weight behind implementing the recommendations.

We appreciate the discussion on systemic racism playing a role in determining eligibility criteria and the need for input from and consideration for underrepresented communities. Our INSIGHTS data, in addition to published studies across rheumatology, show specific ways in which health disparities and inequality present in arthritis. This is evident in how specific symptoms for conditions like osteoarthritis present, how seriously their symptoms are taken, especially around pain, and what access and experience of care is like. There is also a ripple effect, as these inequities lead to more severe work limitations, impacting productivity and day-to-day life, thereby exacerbating the disparities.

On implementation criteria, we agree that there should be transparency about coverage requirements to consumers before plan selection and during care, in addition to the need for robust appeals and time limits. In a November 2019 Arthritis Foundation survey, 95% of respondents wanted to know which drugs required prior authorization before making treatment decisions; 75% wanted to know the status every step of the way, not just when the prior authorization is approved; 90% wanted clear, transparent instructions on the process itself; and the overwhelming majority wanted a streamlined way to manage prior authorization, such as an online portal.

Economic Step Therapy and Switching. Discussions about treatment decisions based on economic considerations can present a slippery slope. We agree that step therapy and switching should not be applied if there is evidence that switching could cause harm, but our question is: who determines risk and harm? Patients and patient groups must be part of this process from the very beginning, and every effort must be made to ensure they are not adversely impacted by economic considerations in drug coverage.

On implementation criteria, we feel similarly as the previous section: that transparency, flexibility, and robust appeals are critical.

¹ <https://www.arthritis.org/getmedia/25118249-ea68-45b5-bfe4-c20904ddc32c/FINAL-JIA-PFDD.pdf>

Conclusion

Again, thank you for the opportunity to comment. There are multiple organizations and government agencies undergoing similar work, ultimately trying to identify common-sense, common-ground solutions to ensure affordable, equitable prescription drug coverage for patients. We urge ICER to work with these stakeholders so we can collectively implement health care policies that will improve care for patients while lowering health system costs. We look forward to working with you as you finalize this white paper, and in the meantime please contact us with any questions or for further information.

Sincerely,



Anna Hyde
Vice President of Advocacy and Access
Arthritis Foundation