

April 3, 2017

Steven Pearson, MD, MSc
President, Institute for Clinical and Economic Review
Boston, MA 02109 USA

RE: ICER Public Engagement Process

Dear Dr. Pearson,

On behalf of the 54 million adults and nearly 300,000 children in the United States with doctor-diagnosed arthritis, the Arthritis Foundation appreciates the opportunity to provide comments to the Institute for Clinical and Economic Review (ICER) on the *ICER Patient Participation Guide and ICER Guide to Open Input for Patients*. The Arthritis Foundation believes robust stakeholder engagement is a critical component of any value framework or economic review that will have a direct impact on people with arthritis and the providers who treat them. Information from clinicians who have daily contact with this patient population is also an important component of developing a robust stakeholder engagement process.

First, we applaud ICER for developing a public engagement process and welcoming public input. In addition to the Arthritis Foundation's review of the patient participation materials, we also asked five patients with rheumatoid arthritis, consisting of a broad range of ages and demographics, to review the proposed materials. We hope together our comments will inform ICER's patient engagement processes and help to ensure the voices of the people who suffer from arthritis are heard. Please find our specific comments on the patient participation process below.

Give Open Input on a New Topic

The Arthritis Foundation asks that ICER expand on their outreach mechanisms to patients. Patients who might be interested in being involved may be unaware that a review is happening. Expanding beyond posting on the ICER website and exploring additional avenues will be necessary for ICER to gain comprehensive patient input. We also suggest developing metrics to see how many patients are responding and work to grow that number over time. This is a great way to show the patient community that ICER is committed to engaging patients.

We also continue to have concerns around the review timeline and the timelines for feedback. Three weeks is a very short time, particularly given that a patient may not learn of the opportunity right away. We recommend ICER explore ways that patients, providers, and caregivers be alerted in advance that the document is due to be posted for comment to allow ample time for feedback. We are also concerned that the posted deadlines are deceiving: if a patient submits input towards the end of a posted comment period, how will ICER ensure their feedback is incorporated with such a short time before the next document is posted? If ICER does not expand their timeline, we suggest setting the input deadline at the point at which

feedback will stop being reviewed or incorporated.

Comment on Draft Scoping Document and Draft Evidence Report

We are concerned the requirements around font and font size may be difficult for patients who are older or have difficulty using technology. We suggest loosening and potentially even applying a separate standard in regards to formatting for patient contributors. We also note the same concerns regarding timeline in this section.

A brief summary of the information learned through open input and public comment is posted with the revised scoping document, but again we ask that ICER also highlight the actual changes that are made. Highlighting and explaining what changes were made as a result of the input received will provide a higher level of transparency and show ICER's commitment to the patient voice.

Registering for Oral Comment at Public Meeting

It appears that the priority for public comment slots is split between two categories—patients in one category, and patient advocacy groups, clinical and research stakeholders in the second category. This grouping does not appear to ensure that patients or patient advocacy groups have priority, given that they are combined with clinical and research stakeholders. We suggest subdividing the priority categorization to ensure priority for patients and patient advocacy organizations.

Attending a Public Meeting

In an effort for ICER to show full transparency, it should be made clear if ICER offers stipends or other reimbursement for patient travel to a public meeting. We fear only patients with financial resources or who are local to the meeting location will be able to participate in a public meeting. We suggest travel stipends to foster greater diversity of patient involvement in the public meetings. Alternatively, ICER should allow for webinar participants to provide real-time comments. Further, the policy roundtable appears to be comprised of “1-2 patients;” we suggest ensuring that patients comprise an equal number of the roundtable participants relative to other experts in attendance. We also encourage ICER to explore ways to reach underserved populations, which will help broaden the patient voice.

Overall Feedback

The overwhelming conclusion of our review is that it is critically important that patients are involved in all ICER reviews because they are the ones facing daily challenges with step therapy, other insurance-related denials and delays, and significant out-of-pocket costs. ICER should continue to explore vehicles for incorporating patient input and how that input will help ICER understand the patient perspective. We believe this includes better outreach at the beginning of any review process to ensure patients are truly aware of the opportunity.

Further than simply including the patient voice is doing so in a meaningful way. In ICER's Draft Evidence Report, the changes that have been made based on patient and other input are highlighted; we suggest highlighting changes made based on patient and other input throughout all phases of review. Additionally, it would be valuable to highlight areas where patient input was collected but did not change the end result, and offer an explanation of why that was the case. We also suggest establishing a more robust dialogue with patients at the beginning of the process rather than waiting until the public meeting, to ensure that comments from patients are fully understood and able to be incorporated throughout the process.

However, the ability for patients to provide input at public meetings is also vitally important. ; Facilitating travel for patients to attend in-person meetings cannot be overlooked. Without assistance, only patients with financial resources will be able to attend and we believe the discussion will lack a critical voice—particularly within the realm of a cost conversation.

In conclusion, the Arthritis Foundation fights to ensure people with arthritis have timely access to the medications they need to function in daily life. We continue to reiterate that attempting to make decisions about the value of a drug without broad-based robust supporting data from patients and providers who are in daily contact with patients is a questionable practice. We applaud ICER for taking the time to create a public engagement process and we ask that ICER continue their work in developing patient friendly tools for input, summaries, and reports throughout the duration of the review process. All report summaries should be concise and easily understood by a patient. We welcome the opportunity to work with ICER on improving their patient engagement process.

Again, thank you for the opportunity to comment on the *ICER Patient Participation Guide and ICER Guide to Open Input for Patients*. Please contact Cindy McDaniel, Arthritis Foundation Senior Vice President of Consumer Health & Impact, at 404-965-7613 or cmcdaniel@arthritis.org with questions or for more information.



Cindy McDaniel
Senior Vice President of Consumer Health & Impact
Arthritis Foundation