How to Respond with Feedback to ICER's Work

A Guide to ICER's Request for Input and Feedback from the Patient Community

Table of Contents

ICER
INSTITUTE FOR CLINICAL AND ECONOMIC REVIEW

How to Respond with Feedback to ICER's Work

Why Does ICER Request Your Input?

Health technology assessment (HTA) is a type of research process that involves all key participants in the health care system. **In order for ICER to understand how well a new drug works and how much it could cost, we want to involve the people that this new drug may impact.** That's why we invite patients, clinicians, health insurers, and drug makers to provide their perspectives on the new drug.

The patient community is an especially important partner for ICER because they can teach us about the patient lived experience and what matters most to patients when deciding on a new treatment option.

YOUR VOICE MATTERS

Patient community input helps ensure that the ICER report accurately reflects the impact of the condition on patients and caregivers, the benefits and risks of the new drug, as well as any costs related to the condition or treatment. Our hope in highlighting the patient perspective is that decision makers read the ICER report and determine **fair pricing and fair coverage for the new drug based on the needs and expectations of the patient community.**

ICER
INSTITUTE FOR CLINICAL AND ECONOMIC REVIEW

What Type of Input is Most Helpful?

ICER invites the patient community to let us know if our research plan includes what is most relevant, appropriate, and important for those living with the condition under review. When reviewing our work (Draft Scope, Modeling Analysis Plan, Draft Evidence Report), we'd love to receive feedback on the following:

When Reviewing the Draft Scope

Did ICER include the right patient POPULATION in our analysis? Are there certain groups of patients you think are important to include for this analysis?

Did ICER focus on the right INTERVENTION(S)?
Are there drugs in our review that should be added or removed based on what is most relevant for the patient community?

Did ICER compare the new drug(s) to the most appropriate COMPARATOR?
Based on what the patient community believes to be current standard of care, did ICER choose the right drug of comparison?

Did ICER include the most important OUTCOMES for patients? What does the patient community believe to be the most meaningful ways to measure how well a new treatment works?

When Reviewing the Modeling Analysis Plan & Draft Evidence Report

Did ICER include the most recent sources of DATA to support the analysis? If not, can you share any data (surveys, registries, abstracts, published articles) that would be important to include?

Did ICER accurately describe how this new drug may IMPACT the patient community? How might the new drug impact daily life, education, career, family, or any health disparities?

ICER
INSTITUTE FOR CLINICAL AND ECONOMIC REVIEW

How to Respond with Feedback to ICER's Work

When Can You Provide Input?

You are invited to provide input at **any time during the review** process by reaching out to the Program Manager or Director of Patient Engagement. However, ICER also has many **formal opportunities** during which you may provide written feedback or join a virtual meeting to give input.

1 Public Comment Period for Draft Scope

The Draft Scope is the proposed outline for ICER's research report. There is a 3-week public comment period to provide written comments on:

- the drug(s) and comparator under review
- the patient population of focus
- the health benefits and side effects that matter most to patients
- the outcomes most important to patients
- other considerations or context you would like to highlight

ICER is always happy to answer questions or provide assistance during any point of the process,

***Public comments are always posted publicly on the ICER website.**

2 Feedback on Modeling Analysis Plan

The Modeling Analysis Plan is the proposed methods for ICER's economic model to figure out a fair price range for the new drug under review. There is a 10-day period during which you may provide written comments on our modeling approach, assumptions, cost inputs, and the data sources used for this analysis.

***Feedback provided on the analysis plan is private.**

ICER
INSTITUTE FOR CLINICAL AND ECONOMIC REVIEW

How to Respond with Feedback to ICER's Work

3 Early Review of Draft Evidence Report

ICER invites one or two patient representatives to review the draft version of our report before publication. This gives the patient community an opportunity to see how ICER has summarized patient and caregiver input, and how this input helped informed our findings. Early reviewers can provide feedback and edits to the report that the ICER team will consider for revision before the draft report is published for public comment.

***Feedback provided during this report review is private.**

4 Public Comment on Draft Evidence Report

The Draft Evidence Report is the published draft version of ICER's results from the clinical and economic analysis. The report includes background information about the disease, insights from the patient community, and other pros and cons that we've identified through conversations with patients and clinicians. There is a 4-week public comment period during which you may provide written feedback on this version of the report.

***Public comments are always posted publicly on the ICER website.**

How to Respond with Feedback to ICER's Work

How Can You Provide Input?

- The Program Manager will always reach out via email with advanced notice about upcoming opportunities to review ICER's work and instructions for how to provide input.
- You can always reach out to the Program Manager at any point during the review to ask questions or request a phone/virtual meeting.
- The Director of Patient Engagement is also available to take any questions or discuss ICER's patient engagement program more broadly.

Public Comment Instructions

- Email comments to **publiccomments@icer.org**
- Submit as an attached **Word document** in **12-point Times New Roman font**
- **Draft Scope**: Three page maximum (not including references)
- **Draft Evidence Report**: Five page maximum (not including references)

The Institute for Clinical and Economic Review (ICER) is an independent nonprofit organization that does research on how well new treatments work and what a fair price should be. ICER's goal is for all patients to get safe and effective treatments at a fair price.

ICER
INSTITUTE FOR CLINICAL AND ECONOMIC REVIEW