ICER Processes for Conducting Value Assessments

September 25, 2023

About ICER

The Institute for Clinical and Economic Review (ICER) is an independent non-profit research organization that evaluates medical evidence and convenes public deliberative bodies to help stakeholders interpret and apply evidence to improve patient outcomes and control costs. Through all our work, we seek to help create a future in which collaborative efforts to move evidence into action provide the foundation for a more effective, efficient, and just health care system. More information about ICER is available at http://www.icer.org.

Funding for our review activities comes from government grants and non-profit foundations, with the largest single funder being Arnold Ventures. No funding for these activities comes from health insurers, pharmacy benefit managers, or life science companies. We receive approximately 22% of our overall revenue from these health industry organizations to run a separate Policy Summit program, with funding approximately equally split between insurers/PBMs and life science companies. For a complete list of funders and for more information on ICER's support, please visit https://icer.org/who-we-are/independent-funding/.

About this Document

This document presents final updates to the ICER processes for conducting value assessments. For a full overview of ICER's methodologies, please refer to the ICER's 2023 Value Assessment Framework.

This update to the ICER processes for conducting value assessments builds upon our experience using the 2017-2019 and 2020-2023 Value Assessment Frameworks and processes in the evaluation of drugs, devices, tests, and delivery system innovations, as well as earlier iterations of the framework. During that time, we have actively sought the input of all stakeholders and made iterative changes to our procedures to enhance their transparency and to improve the ability of all parties to participate meaningfully in the process. We have also benefited from public comment opportunities during each framework revision cycle, including two comment periods for the 2020-2023 framework; the first being a call for open public input to propose changes to the framework, the second providing an opportunity for stakeholders to comment on proposed changes. During the 2023 public comment period, we received feedback from 32 organizations. Their comments can be found here along with our summary response to comments here. We wish to thank all of these commenters for the time and effort they put into these comments, and the many thoughtful contributions they have made.

This document reflects this combined experience, public input, and many additional discussions with stakeholders in various settings. This document will be updated on an ad hoc basis.

Table of Contents

1. Introduction

This document contains an overview and discussion of the processes that support ICER's value assessments. Detailed descriptions of the technical methods we use to conduct our assessments (e.g., the ICER Evidence-Based Medicine Rating Matrix, reference case for economic modeling) may be found in our Value Assessment Framework and on our website.

2. Topic Selection

ICER seeks to evaluate pharmaceutical treatments and other health care interventions that offer significant potential for improved patient outcomes, raise questions about comparative effectiveness in relation to other treatment options, involve underserved populations with the potential to reduce health disparities, and/or may have a significant financial impact on patients and the broader health system. Building on the work summarized in ICER's "Advancing Health Technology Assessment Methods that Support Health Equity" white paper,[1] we will continue to endeavor to elevate any health equity or health disparity issues connected with topic candidates during topic selection discussions. ICER's full list of topic selection criteria are described on ICER's website.

ICER's Pharmaceutical Intelligence team identifies potential topics through a process we call "horizon scanning." We also accept topic suggestions at any time from members of the public. To maintain the independence of our evaluations, we do not accept funding to review a specific intervention or intervention(s) and the final selection of which topics to pursue is ICER's alone. However, ICER's horizon scanning and topic selection efforts may leverage discussions with stakeholders, including members of ICER's advisory boards and independent voting committees as well as clinical societies and patient organizations, as needed to help us better evaluate available topic options. When evaluating emerging drug therapies, we strive to prioritize topics for which FDA approval is expected to align with the timeline for ICER's report and public meeting schedule, so as to provide stakeholders with an independent evaluation of the benefits, risks, and economic considerations surrounding a new treatment near the time of regulatory approval.

Newly selected topics are announced publicly five weeks after initiating the assessment to allow us to gather targeted input from stakeholders (patients, clinicians, manufacturers, and insurers) to inform the draft scope of its review.

3. Timelines

Standard and Class Reports

ICER assessments typically span eight to ten months, depending on the number of interventions included in a given review. Throughout this process, we engage with relevant stakeholders (i.e., patients and patient advocacy organizations, clinicians and specialty societies, drug makers, and payers) to ensure that ICER's report addresses questions relevant to decision-makers and reflects the best available evidence at the time the report is released (stakeholder input opportunities are described in Section 4). ICER's process can be broadly divided into several phases, described in the list below, each of which builds on the work of previous phases. Appendix Figures A1-A2 provide a week-by-week overview of milestones and stakeholder input opportunities within the phases described below.

1. ***Scoping***: We notify selected stakeholders of our review and accept early input from stakeholders to inform our initial approach to the review (Draft Scope), to inform our understanding of the disease area and available treatments, as well as what evidence we should seek. We post the Draft Scope for public comment, after which we release a Revised Scope describing the updated research plan.
2. ***Draft Evidence Report***: We conduct the formal literature search and analysis of the clinical and economic evidence and issue a Draft Evidence Report for public comment.
3. ***Revised Evidence Report***: We review public comments from stakeholders and revise the draft report as needed before issuing a revised Evidence Report, which serves as the foundation for the subsequent public meeting.
4. ***Public Meeting***: We host a public meeting to present the findings of our Revised Evidence Report. One of ICER's independent appraisal committees deliberates and votes on key questions raised by the Report. A policy roundtable of experts from the stakeholder community discusses how best to apply the evidence and votes to real-world practice and policy.
5. ***Final Report***: We summarize the public meeting proceedings (i.e., the votes and policy roundtable discussion) and issue our Final Report, which includes recommendations to inform policymaking and practice considerations.

Report Updates

We recognize that new clinical or economic evidence may emerge following the posting of a Final Report that could change its conclusions. For example, new evidence could emerge demonstrating additional clinical benefits of therapy not captured in the studies available at the time of the original review, or the introduction of a novel therapy may raise new questions about the relative benefits and risks of the therapeutic options for a condition.

We have developed two approaches to consider new evidence that may emerge shortly after the approval of a new therapy, described below. In addition to these two approaches, we may determine that an ad hoc New Evidence Update may be needed at any time after the release.

12-Month Report Check-Up

Because our reports are designed to coincide with the FDA approval timeline, we recognize that available information is always changing, we offer stakeholders this opportunity to comment 12 months after public meetings so that any new information that stakeholders feel is relevant may be available for readers to reference.

One year after a public meeting, we will reach out to key stakeholders (manufacturers and clinical and patient experts who participated in the policy roundtable) to offer them the opportunity to submit comments on any evidence or coverage information that has become available since the public meeting. Their written comment will be included in an addendum to the existing report.

ICER Analytics

Our ICER Analytics platform provides stakeholders an opportunity to work directly with ICER models and examine how changes in parameter inputs would affect results. Specifically, manufacturers have the ability to enter new clinical evidence about their drugs into the Interactive Modeler and publish updated price benchmarks into the Evidence Compendium alongside ICER's findings. More information about ICER Analytics is available here.

New Evidence Update

A New Evidence Update would typically be required when there is new data on a small number of key outcomes for a limited subset of the interventions included in the original review, and is a standalone document that evaluates the impact of this evidence on the prior report conclusions. This form of update will not typically be presented at a public meeting, but will instead be posted to ICER's website and disseminated to stakeholders. A full update, in contrast, would be recommended when new evidence is available for many or most of the originally-assessed interventions such that revising the entirety of the original report is necessary. Full updates will follow the standard or class review timelines described above, including presentation at a public meeting.

4. Stakeholder Engagement

ICER's belief is that collaborative efforts among stakeholders, grounded in a civil and honest discussion of evidence on effectiveness and value, is essential to drive lasting improvements to the health care system on behalf of current and future patients. From the outset of each review, we actively engage and seek input from patients, caregivers, and patient advocacy organizations; clinical experts; drug manufacturers; and payers (i.e., public/private insurers, pharmacy benefit managers, and purchasers). Each of these stakeholders brings important expertise to ICER's process and is, ultimately, affected by any policy action catalyzed by ICER reviews.

Table 4.1 provides a broad overview of the formal stakeholder input opportunities by report phase. Additional details about these opportunities can be found on ICER's website, which includes links to dedicated engagement guides for drug manufacturers and an information portal for patients/patient advocacy organizations, as well as information on logistical considerations such as formatting requirements and page limits for individual comment opportunities. Subsequent sections of this chapter provide broad information on engagement opportunities by stakeholder type.

Table 4.1. Overview of Formal Stakeholder Input Opportunities

Review Phase	ICER Public Documents and Events	Stakeholder Input Opportunities	Potential Impact of Stakeholder Input
Scoping	• Topic Announcement • Draft Scoping Document • Revised Scoping Document • Public comments received on Draft Scoping Document	• Early engagement with targeted stakeholders (key informant interviews and written feedback) • Public comment on Draft Scoping Document (written)* • Key informant interviews (discussion) • Share Your Story Form	• Informs research plan, background knowledge of condition, understanding of patient experience
Draft Evidence Report	• Research Protocol • Model Analysis Plan • Draft Evidence Report • Draft Voting Questions	• Feedback on preliminary model (written and discussions; invited stakeholders)† • Public comment on Draft Evidence Report (written)*	• Continuation of above impact • Informs interpretation of evidence • Provides insights into considerations not represented in evidence base • Refinement of analyses
Evidence Report	• Evidence Report • Revised Voting Questions • Public comments received on Draft Evidence Report • ICER response to public comments	• See above public comment opportunity on Draft Evidence Report	• Continuation of above impact • Revisions to quantitative and qualitative aspects of ICER report
Public Meeting	• Public Meeting (via webcast) • Public Meeting Agenda • Evidence Presentation Slides	• Oral Public Comments* • Oral Public Comment Summary (written)* • Participation on Policy Roundtable (invited stakeholders only)*	• Informs discussion and independent appraisal committee votes • Informs policy recommendations discussed during Policy Roundtable
Final Evidence Report	• Final Evidence Report and Meeting Summary • Final Policy Recommendations • "Report-at-a-Glance" Summary • ICER Snapshot: Patient-Friendly Summary	• Post-meeting debriefs with key patient organizations	• Final report reflects the stakeholder input gathered throughout review, including policy guidance

*Denotes stakeholder input that is publicly released in original form (the commenter is publicly identifiable)

†Manufacturers and other stakeholders who are able to provide detailed feedback on the technical aspects of the preliminary model structure, assumptions, and inputs.

Patient Engagement Program

Conducting meaningful health technology assessment requires involving the patient community in the entire review process. The goal of ICER's Patient Engagement Program is to identify, invite, and involve the patient community in our assessments to ground our work in their lived experience and thereby improve the quality and relevance of our findings for all stakeholders. From the outset of each review, we seek input from patients, caregivers, and patient advocacy groups to understand the depth and diversity of lived experience with a disease and available treatments. ICER's patient engagement strategy involves outreach to national and regional disease-specific groups, relevant umbrella organizations or social impact groups dedicated to a certain community or cause, and to individual patients and caregivers.

Opportunities for contributing to ICER's review process include the touchpoints outlined in the table below and span from topic launch through the publication of the Final Evidence Report. ICER's approach to patient engagement is intended to provide a flexible system under which individual patients, caregivers, and patient advocacy groups can engage in different capacities depending on their organizational focus and resources. Examples include a submission to ICER's Share Your Story Form, virtual meetings with the ICER research team, written comments on ICER's draft methods and findings, expert review of our draft report, and participation during a public meeting as an oral commenter or policy roundtable participant. Detailed information and guidance for the patient community can be found on ICER's Patient Portal.

Table 4.2. Opportunities for the Patient Community to Participate in ICER's Review

Patient Engagement Phase of ICER Review	Opportunity to Participate
Share Your Lived Experience	• Share Your Story Form • Scoping call with ICER review team • Patient & caregiver small group discussion
Respond to Our Work	• Early written input • Public comment on Draft Scope • Feedback on Research Protocol • Feedback on Model Analysis Plan • Expert review of Draft Report*
Participate at the Public Meeting	• Attend the Public Meeting • Deliver an oral comment at the Public Meeting • Serve as patient representative for the Public Meeting* • Serve on Policy Roundtable* • Provide feedback on Draft Policy Recommendations*

Empower Your Community with Evidence	• Provide feedback on the ICER Snapshot: Patient-Friendly Summary of the report • Post-meeting debrief to provide feedback on ICER review participation • Share the ICER report with your community and decision makers to continue advocating for fair pricing and access for the treatment(s) under review

*As described below, some of the above-listed activities are by invitation only.

ICER's early outreach focuses on identifying the outcomes of greatest importance to the patient community, including related evidence, which informs ICER's selection of outcomes measures to include and prioritize in its clinical assessment, as well as the selection of cost-consequence measures used in ICER economic models. Learnings from these and subsequent conversations also inform a dedicated chapter in each ICER report on the patient experience that precedes sections describing the clinical and economic evidence. This sequence ensures that readers and appraisal committees are presented with information on patient perspectives in the early pages of each assessment, allowing them to interpret the subsequent evidence and analyses through the lens of the patient experience.

Engagement opportunities during the report development phases include providing written feedback or feedback during a virtual meeting on our proposed methods, sources of data, and draft findings. We invite a representative from a patient organization to serve as an expert reviewer on a pre-publication version of the draft report to ensure the accuracy and comprehensiveness of sections describing the patient experience.

ICER public meetings include patients and advocacy organization representatives on Policy Roundtables and also provide an opportunity for oral public comments prior to the appraisal committee vote. There are typically eight overall participants on the roundtable, of which two seats are reserved for patients and representatives from advocacy organizations. Patient and advocacy representatives participate throughout the day, providing insight and commentary to the appraisal committee members as they review the evidence presentation and while the committee deliberates and votes. They then participate during the formal roundtable discussion, contributing to conversations pertaining to insurance coverage policy and future research needs. Patient representatives who participated on the policy roundtable then have the opportunity to review and provide feedback on the draft policy recommendations before they are published within the Final Evidence Report.

In ICER's 2023 Value Assessment Framework update, ICER's Patient Engagement Program will strengthen these existing processes while also introducing the following important new elements:

1. **Amplify the new "Share Your Story" online form to increase accessibility and ease of individual patient and caregiver testimonials during the initial scoping phase of ICER's process.**
   In response to patient community input, we have simplified the previous Patient and Care Partner Input Questionnaire into the Share Your Story Form. This form is not intended to be a validated survey tool but rather to help ground the ICER team in a stronger qualitative understanding of patients' lived experience. The five-question form asks about the impact of the disease on daily life, experience with past or current treatments, hopes for a new treatment, access and affordability challenges, and impact on caregivers. This form is publicly available on ICER's Patient Portal and shared directly with the patient community during onboarding for a new drug review.

2. **Formalize small-group patient and caregiver discussions after the scoping phase, ensuring inclusion of diverse patient community voices, to enhance understanding of the lived experience.**
   To help address gaps in the published data and literature, we now convene small group patient and caregiver discussions in order to probe deeper into patient insights. These discussions last for one hour and typically include four to five individual patients or caregivers and a smaller subset of the ICER review team. Our goal is to have between one to three of these group discussions per drug review, allowing us to speak with a greater diversity of patients. These group discussions will typically take place during the draft report phase and result in a narrative summary of the key patient insights in the Patient Perspectives chapter of our report.

3. **Compensate patient representatives fairly for their time, expertise, and contributions to the small-group patient discussions and public meetings.**
   With a commitment to help address potential financial barriers that may hinder the inclusion of diverse patient participation in our process, we have formalized honoraria payments for select activities requiring more extensive contributions. Individual patients and caregivers who participate in a small-group discussion will be compensated $100 for one hour of their time. Patient experts who review and provide feedback on our draft evidence reports will be compensated $500. Patient experts who serve as panelists at our full-day public meeting and participate in our policy roundtable will be compensated $500. These honoraria amounts are comparable to the honoraria provided to other experts or stakeholders who participate in our reviews in the same capacity.

4. **Enhance accessibility and inclusivity of public meetings that allow for remote attendance and closed captions on virtual meetings.**
   We recognize that logistical barriers also exist in the patient community's ability to participate in our process. We offer virtual attendance at our public meetings and options for remote public testimony for those who may not be able to join in real time due to other constraints. If we return to in-person meetings, we are committed to offering a hybrid meeting structure that continues to support virtual attendance, while also offering travel grants to accommodate any financial barriers for patients who may be interested in providing their testimony in-person. In addition, closed captioning is now available for all public meetings, public webinar livestreams, and recordings to enhance the inclusivity of our meetings.

5. **Convene a Patient Council to advise and strengthen ICER's current Patient Engagement Program.**
   In July 2023, ICER formally announced the creation of a Patient Council that will advise on ICER's patient engagement strategy, outreach, and processes for input into our evidence reviews and broader initiatives. The Council is comprised of six patient advocates who represent a diverse range of communities. Council members will meet quarterly to evaluate ICER's current patient engagement program, identify opportunities to strengthen the process and diversity of participation, and advise on ensuring accessibility and inclusivity of ICER's public-facing materials. The Council can also advise ICER on how best to capture the impact of patient engagement on specific drug reviews and across ICER's broader health policy initiatives.

6. **Produce patient-friendly resources to guide the community through ICER's process and summarize ICER's report findings.**
   Building on our Patient Portal and existing summaries, we are creating educational resources for the patient community to better explain our review process, how to participate, and how the patient perspective was incorporated into our report findings. These resources will be co-created with our patient community partners when appropriate and reviewed by our Patient Council.

The updates to our patient engagement program reflect our ongoing commitment to learn from the experiences of the patient community, identify gaps in outreach and effective communication, and update our approach to facilitate more impactful patient engagement. The launch of our Patient Council also signals our long-term commitment to partner with the patient community and iterate on our patient engagement strategy more broadly and consistently.

Clinical Experts

We seek input from clinical experts throughout its review process. Initial outreach begins shortly after a topic is selected and informs ICER's understanding of how clinicians weigh available treatment options and how emerging therapies may fit into current practice patterns. Clinicians help surface nuances contained in the clinical evidence base for approved and investigational agents, and help identify key sources of evidence (i.e., published research, grey literature, conference proceedings) that we may consider during its review. During later stages of the review process, we seek input from clinical experts to validate our interpretation of the clinical evidence; these opportunities include ad hoc outreach for advice during ICER's systematic review and analysis of evidence, and through participation as a formal expert reviewer of a pre-publication version of ICER's draft report.

Clinical experts serve in a role analogous to that of patients and patient advocacy organization representatives during public meetings, providing input and guidance to the appraisal committee throughout the presentation of the evidence and deliberation on voting questions, as well as playing an active role during the subsequent roundtable discussion. In addition to participating in discussions about what may represent clinically-reasonable insurance coverage policy and future research needs, clinical experts may also be asked to comment on how an emerging therapy may change clinical practice and key questions that should be resolved by clinical specialty societies to promote evidence-based medicine. Clinicians who participate on the policy roundtable then have the opportunity to review and provide feedback on the draft policy recommendations before they are published within the Final Evidence Report.

Manufacturers

ICER's outreach to manufacturers begins shortly after a topic is selected and is focused on companies that produce the interventions of interest, but also includes manufacturers of branded comparator products. We schedule scoping discussions with manufacturers soon after the topic is selected and before it is publicly announced to inform ICER's research and modeling approach. At the end of the scoping phase, we also issue a request for data to manufacturers, responses to which inform ICER's clinical and economic evaluations. ICER has developed a policy under which it can accept "data in confidence" from drug developers, details of which can be found on ICER's website.

During the draft report phase, we offer several additional opportunities for manufacturers to comment on its draft approach, including through ad hoc discussions surrounding release of a research protocol and participation in the "Preliminary Methods, Assumptions, and Inputs" presentation, which is followed by subsequent discussion and an additional opportunity to provide data to inform ICER's modeling effort. Upon publication of the Draft Evidence Report, manufacturers are invited to participate in a formal model sharing program, which is described later in this section, and provides an opportunity for evaluation of executable models.

Manufacturers are also invited to participate in ICER's public meeting through participation in an oral public comment session and as formal participants on the policy roundtable, where they provide insights into topics such as pricing, perspectives on insurance coverage policy, and clinical trial design and outcomes selection.

Payers

The timing of ICER outreach to payers depends on the topic under review and whether the payer perspective may be especially important in shaping ICER's research plan. In these cases, we will reach out and invite a payer to a scoping call before the release of the revised scoping document. These conversations inform selection of treatments of interest, comparators, and key outcomes to help ensure that ICER's research answers questions central to the development of evidence-based coverage policy; as well as ICER's initial understanding of payer approaches. At public meetings, payers participate on the Policy Roundtable to discuss considerations around coverage policy development and the intersection of pricing, access, and affordability.

Additional Opportunities for Stakeholder Input

Identification of Low-Value Care

In its reports, we seek to include information on wasteful or lower-value services in the same clinical area that could be reduced or eliminated to create "headroom" in health care budgets for higher-value innovative services. These services, including treatments and mechanisms of care, are ones that would *not* be directly affected by the intervention under review, as these would be captured in the economic model (e.g., an effective intervention for acute pain management that would reduce emergency department visits). Rather, these services are those used in the current management of the condition that represent ineffective or overused approaches to care (e.g., use of imaging for uncomplicated headache).[2] The goal of this section is to highlight for policymakers the opportunities for reallocating resources from lower value services in order to help make headroom for the added cost of high-value drugs and other high-value services.

We request input on these categories from patients, clinicians, manufacturers, and payers through requests in draft and revised scoping documents, draft reports, and during discussion calls. Services that meet the criteria described above may be included in ICER reports with attribution to the organization that identified the service, as well as citations provided by the commenting organization.

Economic Model Transparency

ICER's approach to economic model transparency is based on the Modeling Good Research Practices Task Force report on "Model Transparency and Validation" jointly produced by the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) and the Society for Medical Decision-Making (SMDM).[3] We aim to include information in each report that describes model structure and processes, all major inputs and sources for data, and key assumptions used in our economic analyses, so that readers can judge their confidence in the results while preserving the intellectual property rights of those with whom we collaborate.

ICER's commitment to open and transparent engagement extends to the sharing of economic models with drug manufacturers to provide an opportunity to comment on executable versions of the model. This is supplemented by an earlier touchpoint during week 15 of an assessment called a "Preliminary Methods, Assumptions, and Inputs Presentation," during which manufacturers, patient groups, and other invited stakeholders with expertise in economic modeling may provide feedback on an early version of the model before ICER posts a draft report. At the same time, we publicly release a Model Analysis Plan to the Open Science Framework website describing the modeling approach. Further, all economic models used in ICER assessments are added to the Interactive Modeler section of ICER Analytics at the conclusion of each review. ICER Analytics may contain disease models from prior reports that are relevant to the current review.

Detailed information about ICER's Economic Model Transparency Program can be found on ICER's website, with additional information included in the manufacturer engagement guide described earlier in this section.

Public Meetings

Structure and Purpose

We host a public meeting for each assessment that can be broken down into four broad stages: 1) presentation of the Evidence Report findings; 2) testimony and discussion with manufacturer representatives and patient/public commenters; 3) deliberation and vote by the independent appraisal committee on key questions surrounding the clinical and economic evidence; and 4) a policy roundtable discussion with patients, clinical experts, manufacturers, and payers to explore how to apply the evidence and votes to real-world practice and policy. This stepwise process represents ICER's goal to facilitate decision-making that is grounded in a thorough and public exploration of the evidence. Importantly, we do not issue formal policy recommendations prior to a public meeting to reflect the reality that analysis of the evidence does not, in isolation, provide "the" answer to the complex circumstances surrounding pricing, coverage policy, and clinical practice; rather, our analysis serve as the foundation for discussions surrounding these topics.

Stakeholders are involved during each broad meeting phase, details of which can be found in Table 4.3 below. Each meeting is open to the public, with a recording available for those who cannot attend the webinar live.

Table 4.3. Public Meeting Agenda Overview

Agenda Item	Primary Participants
1. Presentation of the Evidence and Economic Modeling, Q&A/Discussion	ICER staff and consultants, appraisal committee, patient and clinician members of the policy roundtable
2. Manufacturer Public Comments and Discussion	Manufacturer(s), ICER staff and consultants, and appraisal committee
3. Public Comments from Patients, Clinicians, and Public	Patients, clinicians, payers, researchers, other stakeholders, and appraisal committee
4. Voting on Clinical Effectiveness and Value Questions; Additional Discussion	Moderator; appraisal committee; clinical, patient, and subject-matter experts from the policy roundtable
5. Policy Roundtable Discussion	Moderator, policy roundtable participants including clinical experts, patient representatives, payers and manufacturer(s)
6. Reflections from Voting Panel	Moderator, appraisal committee
7. Summary and Closing Remarks	Moderator

Independent Appraisal Committees

Each public meeting involves deliberation and voting on key questions related to the Evidence Report by an independent appraisal committee. We currently convene three such committees: the New England and the Midwest Comparative Effectiveness Public Advisory Councils (CEPACs), and the California Technology Assessment Forum (CTAF). These committees are standing bodies (i.e., they do not change from one meeting to the next), and members are recruited for their clinical and policy expertise in technology assessment, including research methods, economic analysis, evidence-based practice, and patient advocacy, among other disciplines. All members meet strict conflict of interest requirements to limit any bias that may be introduced by the presence of certain personal or financial relationships. One implication of this approach is that, by design, ICER appraisal committees do not necessarily include those affected by the condition under review, whether they are individual patients or practicing clinicians, though this may occur from time to time (i.e., a neurologist may serve on an appraisal committee for a neurology topic, provided he or she does not have any disqualifying conflicts). This approach aligns with that of many other organizations, including the United States Preventive Services Task Force (USPSTF) and all international HTA organizations.

We recognize how vital the patient and clinical expert perspective is to our review process and public meeting, which is why we seek input from patient and clinical experts throughout the report development process, and by including several such experts as active participants as throughout our public meetings, including in the development of any policy recommendations that emerge

from the voting results. This approach provides members of ICER appraisal committees with sufficient insight into the patient experience and clinical practice to inform voting.

Additional information about these independent appraisal committees, including current membership and conflict of interest criteria, can be found on ICER's website.

Voting Questions

For a full overview of voting questions, please refer to ICER's Value Assessment Framework.

Policy Roundtable Discussion

Each public meeting culminates in a discussion of how to apply the evidence and appraisal committee votes to real-world practice and policy. All stakeholders participate in this discussion, and the typical composition of a policy roundtable includes two patients and/or representatives from patient advocacy organizations; two clinical experts in the topic under review; representative from the manufacturer(s) of the therapies under review; and two payer/purchaser representatives (i.e., public and/or private insurers, pharmacy benefit managers, or employers). While the specific topics of discussion may vary from one meeting to the next, the broad themes of these discussions are generally consistent and include discussion of:

- The specific actions that each participant in the health care system can take to assure that the introduction of new treatment options address concerns about health disparities and health equity
- Evidence-based insurance coverage policy (i.e., patient eligibility criteria, special considerations for patient subpopulations, step therapy, provider criteria, etc.)
- Pricing and payment mechanisms (i.e., outcomes-based contracting and other innovative approaches to payment)
- Future research needs (i.e., study of additional outcomes measures, long-term data needs, key questions that can be addressed by real-world evidence, etc.)
- The guidance that clinical specialty societies and patient organizations should provide to their communities.

These conversations serve as the foundation for policy recommendations for stakeholders that are included in each final report.

References

1. Agboola F, Whittington MD, Pearson SD. Advancing Health Technology Assessment Methods that Support Health Equity. 2023.
2. Eddy DM, Hollingworth W, Caro JJ, Tsevat J, McDonald KM, Wong JB. Model transparency and validation: a report of the ISPOR-SMDM Modeling Good Research Practices Task Force-7. *Medical decision making : an international journal of the Society for Medical Decision Making.* 2012;32(5):733-743.
3. Linley WG, Hughes DA. Societal views on NICE, cancer drugs fund and value-based pricing criteria for prioritising medicines: a cross-sectional survey of 4118 adults in Great Britain. *Health economics.* 2013;22(8):948-964.

A. Review Timelines

A1. Standard Review Timeline

	Week	Milestones	Comments
Topic Selected and Project Kickoff	0	Project Kickoff Stakeholder Outreach Begins	ICER notifies relevant stakeholders and begins scoping calls with patient groups, clinical experts, manufacturers, payers to inform the draft scope for the assessment.
Draft Scope	1		
	2		
	3		
	4		
	5	Topic Announced Publicly Draft Scoping Document Posted	ICER puts out a press release stating the topic under review and posts the draft scoping document for public comment. Stakeholders have 15 business days to comment on the draft scope.
Final Scope	6	Public Comment Period	ICER continues to hold scoping calls with stakeholders to inform the revised scope for the assessment.
	7		
	8		
	9	Revised Scoping Document Posted ICER Sends Request for Data	ICER sends formal requests for data to each manufacturer. Supplemental data requests may be sent on an ad hoc basis.
Draft Evidence Report	10	Research Protocol Posting	Posting of clinical evidence review protocol
	11		
	12		
	13	Mfr. Evidence Submissions Due	
	14		
	15		
	16		
	17	Preliminary Model Presentation Posting of Model Analysis Plan	Individual discussion calls with invited stakeholders 2-3 days after the preliminary model presentation. After reviewing ICER's preliminary model presentation, stakeholders may send written feedback and supplemental data.
	18		
	19	Supplemental Data Submission Due	Written feedback and supplemental data sent in response to ICER's preliminary model presentation are due 11 business days after call.
	20		
	21		
	22		
	23		
	24	Draft Evidence Report Posted	
Evidence Report	25	Public Comment Period	Stakeholders have 20 business days to comment on the Draft Evidence Report. When possible, economic models are available for review by manufacturers.
	26		
	27		
	28		
	29		

	Week	Milestones	Comments
	30		
Public Meeting	31	Evidence Report Posted	
	32		
	33	Public Meeting	Stakeholders can pre-register to give an oral comment; invited stakeholders can participate in policy roundtable discussion and manufacturer feedback on economic modeling opportunity.
Final Report	34		
	35		
	36	Final Evidence Report Posted	Send written summary of oral comments, if applicable. Participate in optional post-review debrief call.

Legend: Document Release | Data Request | Input Opportunity

A2. Modified Timeline for Large Class Reviews

ICER Process	Week	Milestones	Class Review Adaptation
Topic Selected	0	Topic Selected Stakeholder Outreach Begins	
Draft Scope	1		
	2		
	3		
	4		
	5		
	6	Topic Announced Publicly Draft Scoping Document Posted	
Final Scope	7	Public Comment Period	
	8		
	9		
	10	Revised Scoping Document Posted ICER Sends Request for Data	
Draft Evidence Report	11	Research Protocol Posting	
	12		+3 weeks for systematic literature review and model development timelines
	13		
	14	Mfr. Evidence Submissions Due	
	15		
	16		
	17		
	18		
	19		
	20		
	21	Preliminary Model Presentation Posting of Model Analysis Plan	
	22		
	23	Supplemental Data Submission Due	
	24		
	25		+1 week to address feedback on preliminary model
	26		
	27		
	28		+1 week to facilitate revision of longer and more complex report
	29	Draft Evidence Report Posted	
Evidence Report	30	Public Comment Period	+1 week to public comment period to facilitate review of longer report
	31		
	32		
	33		

ICER Process	Week	Milestones	Class Review Adaptation
	34		
	35		
	36		
	37		+1 week to review a higher volume of stakeholder comments
	38	**Evidence Report Posted**	
Public Meeting	39		
	40		+1 week to allow voting committees sufficient time to review complex report
	41	**Public Meeting**	
Final Report	42		
	43		
	44	**Final Evidence Report Posted**	

Legend: Document Release | Data Request | Input Opportunity