Roadmap for Collective Action

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PROJECT LEADS

Sarah Daugherty, Project Lead Principal Scientist Carelon Research	**Mark Cziraky, Project Co-lead** President Carelon Research

STEERING COMMITTEE MEMBERS

The Steering Committee consisted of researchers, payers, industry representatives, thought leaders in patient-centered research, and patient/member stakeholders

Rebekah Angove EVP Research and Evaluation and Director, Patient Insight Institute, Patient Advocacy Foundation	**Merrill Friedman** Public Policy Executive Director, Inclusive Policy & Advocacy, Elevance Health
Jennifer Bright President and CEO, ICHOM	**Cate Lockhart** Chief Science Officer, AMCP and Executive Director, BBCIC
Tich Changamire Vice President and Chief Medical Officer, Elevance Health Commercial Health Plans	**Cynthia Overton** Consumer Representative, National Advisory Board, Elevance Health
Melissa Clarke Chief Social and Community Officer, Elevance Health	**Kimberly Westrich** Chief Strategy Officer, National Pharmaceutical Council

WORKSHOP CO-FACILITATORS

Breakout sessions were co-facilitated by a payer and a patient representative

Rebekah Angove EVP Research and Evaluation and Director, Patient Insight Institute, Patient Advocacy Foundation	**Merrill Friedman** Public Policy Executive Director, Inclusive Policy & Advocacy, Elevance Health
Jennifer Bright President and CEO, ICHOM	**Cynthia Overton** Consumer Representative, National Advisory Board, Elevance Health
Vicki Fisher Director, Clinical Analytic Strategies, CarelonRx	**Mark Cziraky** President, Carelon Research
Geoffrey Crawford Staff Vice President, Medical Policy & Technology Assessment, Elevance Health	**Jennifer Marek** Medical Director, Guideline Research and Development, Carelon Medical Benefits Management

WORKSHOP PRESENTERS

Workshop 1: Building Capacity in Patient-Centered CER	Workshop 2: Aligning Patient-Centered CER with Payer Evidentiary Needs
Harv Feldman Deputy Executive Director for Patient-Centered Research Programs, Patient-Centered Outcomes Research Institute	**Beth Nauman** Senior Director of Health Services Research, Louisiana Public Health Institute
Erica Malik Chief Operating Officer, Center for Innovation & Value Research	**Brice Mohundro** Clinical Pharmacist, Louisiana Blue
Sarah Emond President and Chief Executive Officer Institute for Clinical and Economic Review	**Catherine Glover** Patient Partner
Marc Boutin Senior Advisor, Gilde Healthcare	**Emily Tsaio** Medical Policies Clinical Pharmacist, Premera Blue Cross
Mai Pham President, Institute for Exceptional Care	**Michael J. Constantino** Professor of Clinical Psychology and Director of the Psychotherapy Research Lab, University of Massachusetts Amherst
Eugean Jiwanmall Senior Research Analyst for Medical Policy & Technology Evaluation, Independence Blue Cross	**Maxwell Isaacoff** Director of External Affairs, Elevance Health
Cara Nikolajski Senior Director of Research, UPMC Center for High-Value Health Care	**Jason Harris** Vice President, Government Relations and Advocacy, National Psoriasis Foundation

EXECUTIVE SUMMARY

There is growing interest among industry sponsors to partner with patients throughout the drug development process, however, there remains a hesitancy among many sponsors to invest the resources needed to conduct patient-centered comparative clinical effectiveness research (CER) if payers are unlikely to meaningfully incorporate this type of evidence into their decision-making.

Recent advancements in payer activities signal a positive interest in how to be more aware of the patient experience, however, greater alignment between the evidence generated by industry sponsors, member preferences, and payer evidentiary needs is possible.

To this end, Carelon Research invited public and private payers to join other key stakeholders in conversation about how to advance the integration of patient-centered CER into payer decision-making. This interactive series of workshops brought together leaders across the healthcare ecosystem to explore the following key questions:

- How is patient-centered CER currently utilized in payer decision-making?
- What knowledge gaps in interpreting or applying results of patient-centered CER exist among payers? How do we address these gaps?
- What patient-centered CER evidentiary gaps exist?
- What process improvements could be added to support the uptake of patient-centered CER?
- What are the top priorities we should focus on to advance the integration of patient-centered CER into payer decision-making?

Workshop participants identified and prioritized 11 unmet needs, recommended action items, and explored existing resources and resource gaps. As part of the co-creation exercise, the project team organized the unmet needs, action items, and resource gaps into three overarching areas that warrant additional attention to successfully integrate patient-centered CER into payer-decision making. The areas are:

1) reinforcing the integrity of the patient-centered data pipeline;
2) building payer capacity in patient-centered data elements, resources, and engagement; and
3) facilitating transparent bi-directional communication between payers, researchers and patients.

While all unmet needs were identified as important, the highest priority needs ranked by workshop participants fell within the data and capacity-building areas.

UNMET NEED	NEED TYPE
*** Validated patient-centered outcome assessments preferred by patients may not be well established.**	**Data**
Many clinical trials and observational studies used to inform payer decision-making do not incorporate patient-centered data. Patient perspectives are brought to payers as an afterthought with minimal perceived evidentiary value.	
*** Many payers are unfamiliar with how to incorporate patient-centered CER into their review processes.**	
Implementation of policies may not work as intended and could be improved with patient input. A formal process to track outcomes and incorporate patient experience feedback into policy review may not be well established.	
*** Payers may not know which data patients value.**	**Capacity**
*** Some payers lack experience integrating patient-centered CER into decision-making and navigating related resources.**	
*** Many payers are unfamiliar with how to identify, select and engage patient representatives as well as evaluate quality of engagement to ensure meaningful patient input.**	

Publications and evidence synthesis reports often do not communicate how patient input informed the evidence generated, making it difficult for payers to recognize evidence that is patient-centered during their review process.	**Communication**
A lack of bidirectional and transparent communication between stakeholders about patient-centered CER evidentiary gaps and resources remain.	
While payer policies are public, they may not be accessible, understandable and/or useful to members.	
A payer-agnostic industry standard is lacking for how to inform the patient about the temporary coverage due to limited evidence under the accelerated approval pathway and update patients about policy changes when new evidence emerges.	

**identified as high priority (defined as most important or most feasible) by workshop participants*

All stakeholders within the healthcare ecosystem have an important role and responsibility to support the development of patient-centered payer policies and programs. Several action items identified in the workshop series are listed below by stakeholder type:

- **researchers**: to identify and incorporate patient-centered outcomes that matter to patients early into their study design and communicate transparently in their publications about how patient and public input shaped the evidence generated.
- **patients and community-based organizations**: to identify core data elements that reflect patient experience and partner with researchers and payers to generate and apply research and data that are meaningful and relevant to the communities represented
- **non-profits, foundations, sponsors/funders**: to centralize patient-centered research, resources and training relevant to payers, and provide a trusted space where multi-stakeholder communication about future evidentiary needs can occur.
- **payers**: to request research that reflects the most important needs and preferences of patients in their membership, expect transparency from manufacturers about how patient and public involvement shaped the evidence reviewed, and proactively communicate where policy implementation has suggested evidentiary gaps exist.

The ideas discussed during the workshop series, along with milestones, potential metrics, and stakeholder designations were assembled by the project team into this Roadmap for Collective Action.

BACKGROUND

There is growing interest among industry sponsors to partner with patients throughout the drug development process, however, there remains a hesitancy among many sponsors to invest the resources needed to conduct patient-centered comparative clinical effectiveness research (CER) if payers are unlikely to meaningfully incorporate this type of evidence into their decision-making. Patient-centered CER is a type of comparative effectiveness research guided by questions and concerns that are meaningful to patients.[1] According to a recent global survey of corresponding authors, 46.9% of pragmatic clinical trials did not incorporate any public or patient engagement with the top two reasons being 'no requirement to do so' and 'did not seem relevant'.[2] While the FDA has provided a clear set of recommendations for industry sponsors on how to integrate stakeholder perspectives into drug development research[3], payers have been less clear about the role and value patient-centered CER provides in their coverage and formulary decision-making. This lack of transparency among payers leads to a narrower set of evidentiary claims presented by sponsors and reviewed by payers to support coverage and formulary decisions. Greater alignment between the evidence generated by industry sponsors, member preferences, and payer evidentiary needs is possible.

Recent advancements in payer activities signal a positive interest in how to be more aware of the patient experience, with payers recognizing that patient preferences and patient-reported outcomes can serve as key drivers and indicators, respectively, in value-based resource utilization. As more patient-centered CER is generated, revisiting several topics with payers and other key stakeholders is necessary including:

- patient-centered CER knowledge gaps among payers
- resource and information channel limitations
- promising practices for patient-centered CER integration into payer decision-making
- potential evidentiary standards for patient-centered CER from the payer perspective

To this end, Carelon Research invited public and private payers to join other key stakeholders in conversation about how to advance the integration of patient-centered CER into payer decision-making. This interactive series of workshops brought together leaders from across the healthcare ecosystem to explore the utility of patient-centered CER in payer decision-making. A roadmap for collective action was co-created by workshop participants to identify opportunities to support the alignment of payer evidentiary standards, member needs and industry-sponsored evidence.

ENGAGEMENT APPROACH

A wide range of stakeholders were invited to participate in this three-part workshop series consisting of panel discussions and breakout sessions. Participants were identified through a snowball sampling method starting with the Steering Committee members, workshop presenters and their professional networks. A contract was also established with AMCP to recruit through their Market Insight Panel. The

[1] https://www.pcori.org/research-related-projects/about-our-research/research-we-fund

[2] Vanderhout S, Nevins P, Nicholls SG, et al. Patient and public involvement in pragmatic trials: online survey of corresponding authors of published trials. *CMAJ Open*. 2023;11(5):E826-E837. Published 2023 Sep 19. doi:10.9778/cmajo.20220198

[3] U.S. Food & Drug Administration. FDA Patient-Focused Drug Development Guidance Series for Enhancing the Incorporation of the Patient's Voice in Medical Product Development and Regulatory Decision Making. Published February 2024. Accessed July 2024. Retrieved from: https://www.fda.gov/drugs/development-approval-process-drugs/fda-patient-focused-drug-development-guidance-series-enhancing-incorporation-patients-voice-medical

largest stakeholder group who participated were payers, followed by researchers, patients, and other stakeholders (see Table 1). Payer participants represented a range of national and regional organizations (see Table 2).

Table 1: Distribution of Workshop Registrants by Stakeholder Type and Attendance

Type	Registered	Attended at least 2 workshops
Payer	33	13
Researcher	15	6
Patient Advocate	7	4
Other Stakeholder	12	5
Clinician	2	0
Funder	3	1
Policy Maker	2	1
Total	**74**	**30**

Table 2: Payer Workshop Registrants Affiliations

Company	
Aetna/CVS	HCSC acquired Cigna Medicare*
Anthem National	Highmark Inc*
BCBS of Massachusetts	Independence Blue Cross*
BCBS of Michigan*	Louisiana Blue*
CareSource	OncoHealth*
Centene*	Premera Blue Cross*
Clinical Solutions	Prime Therapeutics*
Devoted Health*	Sharp Health Plan*
Elevance*	Ohio State University*

**attended at least one workshop*

Workshop 1 was focused on building payer capacity through panel discussions. Participants gained a foundational understanding of patient-centered CER; its key components and quality indicators, while exploring the potential impact of patient-centered CER on value assessment, medical and pharmacy coverage decisions, and care management.

Workshop 2 presented a series of case studies demonstrating successful examples of patient-centered CER and promising practices integrating patient-centered CER or patient perspective into payer clinical policy committees. In addition, three breakout sessions were held in Workshop 2 to discuss five core questions:

1. How is patient-centered CER currently utilized in payer decision-making?
2. What knowledge gaps in interpreting or applying results of patient-centered CER do you think exist among payers? How can we address these gaps?
3. What patient-centered CER evidentiary gaps exist?
4. What process improvements could be added to support the uptake of patient-centered CER?
5. What are the top priorities we should focus on to advance the integration of patient-centered CER into payer decision-making?

The ideas shared during Workshop 2 breakout sessions were sorted into a list of unmet needs and supporting action items.

Workshop 3, the capstone workshop, held several multi-stakeholder breakout sessions to reassess and prioritize the unmet needs identified in Workshop 2. The following questions were discussed:

1. Are the needs presented representative of your experience?
2. What would you add or change?
3. How would you prioritize these unmet needs in terms of importance and feasibility?
4. What would you add or revise from the initial list of actions related to these needs?
5. Who are the key stakeholders responsible for these action items?
6. What resources are you aware of that might support progress in this area?
7. What resource gaps remain?

Collectively, the multi-stakeholder workshop participant comments and ideas shaped the roadmap presented here.

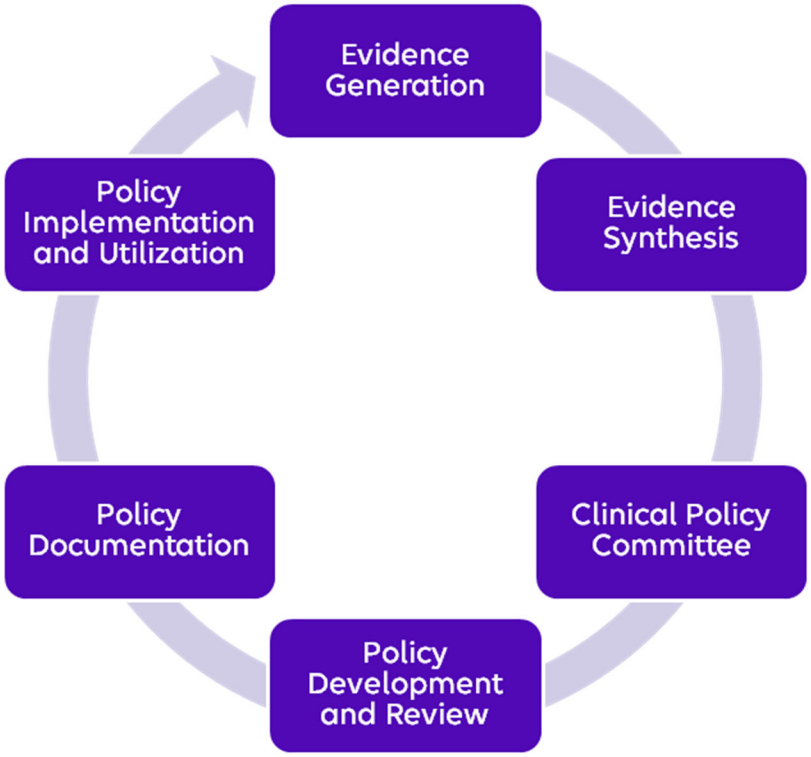
INTRODUCTION TO THE ROADMAP FOR COLLECTIVE ACTION

Six key touchpoints in the payer review process were identified where patient insights have the potential to impact payer decision-making (Figure 1). This framework acknowledges that successful integration of patient-centered evidence is contingent on the ability to access a variety of resources, tools, and stakeholder engagements that contextualize and elevate the uptake of evidence in payer policy decision-making. This framework also acknowledges the cyclical nature of evidence generation and the importance of utilizing feedback from policy implementation and utilization to identify future evidence gaps.

The roadmap describes the unmet needs identified during the workshop and considers them along these six touchpoints. We consolidated the needs across the framework into two sections: 1) evidence generation and synthesis 2) process integration within clinical policy committees, policy development, documentation and implementation.

Workshop participants prioritized the needs as most important to address or most feasible to achieve in the immediate future. These needs are labeled HIGH PRIORITY. Specific action items, existing resources, and resource gaps were also identified by workshop participants. Stakeholder designations, (R) for responsible and (I) for involved, provide suggestions for what is needed to initiate and fill the gaps identified. The existing resource list provided at the end of the document reflects the most common resources used by participating workshop attendees. Milestones and potential metrics for the two sections, along with the stakeholder designations, were assembled and organized by the project team and members of the Steering Committee.

Figure 1: High-Impact Touchpoints for Patient Input in Payer Decision-Making



HIGH-IMPACT TOUCHPOINT 1 & 2: EVIDENCE GENERATION AND SYNTHESIS

This first section of the roadmap describes unmet needs, action items and resource gaps related to evidence generation and synthesis. To advance the ability of the payer to identify and interpret patient-centered CER at these critical touchpoints, three overarching areas warrant continued attention: the integrity of the patient-centered data pipeline, bolstering payer capacity in patient-centered CER, and encouraging bi-directional communication.

1) **Patient-centered policies rely on the integrity of the patient-centered data pipeline.**
The type, quality, and comprehensiveness of evidence produced and shared with payers directly impacts how and what evidence-based policies are patient-centered. If the evidence is incomplete because it does not capture research questions or outcomes that patients care about, then it is difficult for the policies payers develop to reflect what patients need. The integrity of the patient-centered data pipeline needs to be reinforced by each stakeholder in the healthcare ecosystem beginning with identifying the needs of patients and the people who care for them, ensuring the uptake of patient-centered research questions and outcomes by researchers, and communicating the value of the patient-centered evidence generated so it can be applied by payers to support evidence-based policies that are patient-centered.

2) **Bolstering payer capacity in patient-centered CER will enhance payers' ability to identify, interpret, and apply this evidence**. Building payer capacity is one of the first steps to advancing the integration of patient-centered CER in payer decision-making. Continued efforts by funders, non-profits, and researchers need to be made to increase payer knowledge about what type of data elements patients value and how those elements should be measured, highlight the impact patient engagement in research has on shaping the evidence generated, and reinforce access to curated patient-centered research resources tailored for payer needs.

3) **Proactive and transparent bi-directional communication is needed to identify patient-centered evidentiary gaps.** Payer guidance for evidence generators and synthesizers should encourage evidence that contains standard data elements that reflect the most important needs and preferences of patients in their membership. Payers should also require dossier reports to include transparent descriptions of patient and public involvement and the impact the involvement had on the research. New processes and channels are needed to support proactive bi-directional communication and engagement among payers, researchers and patients to identify where policy implementation falls short and additional evidence is needed.

[HIGH PRIORITY NEED] Validated patient-centered outcome assessments preferred by patients may not be well established					Need Type: Data
Actions Identified	**Stakeholder Responsible (R) & Involved (I)**				
	Payer	**Patient**	**Researcher**	**Industry**	**Other**
Condition-specific and condition-agnostic validated measures important to patients need to be identified and publicly documented.		I	R		Sponsors Non-profits
Objective and validated scales preferred by patients are used to measure patient experience including symptoms, health outcomes, quality of life and preference sensitive treatment decisions.		I	R	R	
Condition-specific quality of life measures are used in research because they add more value to payers than generic quality of life measures during medical and formulary policy development.	I	I	R	R	
Standards for a common set of patient-centered outcomes are developed by condition and across conditions.		I	R		Sponsors Non-profits
Resource Needs Identified					
Standard measures for economic impact		I	R		Sponsors Non-profits
Policies that emphasize use of standardized patient-centered measures vs. bespoke measures	I	I	R	R	Sponsors Non-profits
Centralized repository of validated PRO measures by condition of interest		I	R		Sponsors Non-profits
Need: Many clinical trials and observational studies used to inform payer decision-making do not incorporate patient-centered data. Patient perspectives are brought to payers as an afterthought with minimal perceived evidentiary value.					**Need Type:** Data
Actions Identified	**Payer**	**Patient**	**Researcher**	**Industry**	**Other**
Early engagement of patients and stakeholder communities is planned in research development and conduct	I	R	R	R	Sponsors
Produce data that is representative of patient population including demographics, geography, economics			R	R	Sponsors
Select patient-centered outcomes early in study design as primary or secondary endpoints		I	R	R	Sponsors
Expand the type of patient-centered data generated in observational study designs and broaden the type of evidence payers consider when making policy decisions.	I		R	R	Sponsors
Use policy reports from ICER and NICE to identify evidentiary gaps in research.			R	R	Non-profits

Resource Needs Identified					
Alignment of outcomes for trials and post market clinical practice (they should be harmonized if not standardized).	I		R	R	Clinicians
[HIGH PRIORITY NEED] Payers may not know which data patients value.					**Need Type:** Capacity
Actions Identified	**Payer**	**Patient**	**Researcher**	**Industry**	**Other**
Interactive webinars are hosted to continue dialogue with payers and other stakeholders on what patient-centered CER is, how it can inform payer decision-making, and what needs remain unmet	R	R	R	R	Sponsors Non-profits Clinicians
Guidelines for evaluating a full range of patient experience data and its relevance in the payer review process	I	R	R		Sponsors Non-profits
Regular assessments of payer knowledge, attitudes, and expectations regarding patient-centered CER to gauge progress and identify gaps where additional support is needed	I		R		Sponsors Non-profits
Resource Needs Identified					
Incentives to include patients in the evidentiary gap discussion are needed.	R	R	R	R	Sponsors Non-profits
[HIGH PRIORITY NEED] Some payers lack experience integrating patient-centered CER into decision-making and navigating related resources.					**Need Type:** Capacity
Actions Identified	**Payer**	**Patient**	**Researcher**	**Industry**	**Other**
Develop a centralized repository of curated resources tailored to payers and vetted by payers and patients as trusted sources	I	I	R		Non-profits
Invest in a network that supports identifying patient-centered CER gaps important to patients and payers.	R	R	R	R	Sponsors
Need: Publications and evidence synthesis reports often do not communicate how patient input informed the evidence generated, making it difficult for payers to recognize evidence that is patient-centered during their review process.					**Need Type:** Communication
Actions Identified	**Payer**	**Patient**	**Researcher**	**Industry**	**Other**
Researchers identify in publications the patient-centered activities, methods and data.		I	R	R	Sponsors
Journals require researchers document how patient and public involvement influenced the research conducted.		I	I	I	Journals
Payers encourage manufacturers and researchers to demonstrate how they have incorporated patient insights into their research.	R		I	I	

Manufacturer dossiers and evidence synthesis reports are created with explicit summaries documenting how patient and public involvement informed research.	I		R	R	
A patient-centered badge or seal is created to identify research and evidence that meets a basic standard for high quality		I	R		Sponsors Non-profits
Resource Needs Identified					
Adapt the AMCP dossier to include patient and public involvement in section 5.0B Additional Supporting Evidence AMCP-Format-5.0-JMCP-web_0.pdf	I		R	R	Non-profits

Need: A lack of bidirectional and transparent communication between stakeholders about patient-centered CER evidentiary gaps and resources remain.	**Need Type:** Communication

Actions Identified	Payer	Patient	Researcher	Industry	Other
Create a 'coalition of the willing' that continues to build momentum to advance integration and adapt resources available	R	R	R	R	Non-profits
Payers proactively communicate about top evidentiary priorities and collaborate with patients to identify shared goals	R	I	I	I	
Host town halls to invite a multi-stakeholder discussion around a particular topic (health condition, benefit, or service) identified as important to members	R	I	I	I	Sponsors Non-profits
Payers establish a standing patient committee with rotating members from a variety of PAOs, CBOs and non-profits to discuss evidentiary gaps	R	I			Non-profits
Incentives need to be aligned so that patients are willing to work with payers and researchers	R	I	R	R	Sponsors Non-profits

Milestones			
Milestone Type	**Milestone**	**Timeframe***	**Examples of Metrics**
Data	Standardized sets of patient-centered outcome measures (condition-specific and cross-condition) are adopted as standard patient-centered data and reviewed by at least 3 payer organizations.	Short-term	Cited in ≥2 payer policy recommendations
	Payer guidance requesting transparent reporting on standard patient-centered data elements, stakeholder engagement, and quality indicators of patient-centered CER is published.	Short-term	Document dissemination; adoption by ≥2 payer organizations

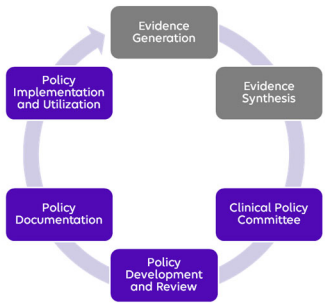
Capacity	A webinar series for payers on interpreting and applying patient-centered CER is hosted and co-led by patient and payer representatives.	Short-term	Attendance (≥50 participants/session)
	A curated central repository of patient-centered CER resources by therapeutic area is tailored to a payer audience.	Short-term	Repository launch; user analytics showing ≥30 stakeholder visits during the year after posting
Communication	Criteria for patient-centered evidence badge/seal for research publications is developed and implemented by journals.	Long-term	Badge design approved; first 10 publications adopting it
	Dossiers include a section on patient and public involvement (e.g. AMCP Dossier Section 5.0B templates).	Short-term	Template revision published; ≥3 manufacturers adopt format
	Annual multi-stakeholder town halls are hosted by payers to share evidentiary gaps and progress.	Short-term	≥2 town halls completed; summary reports disseminated

**short-term (0-2 years) and long-term (2+years)*

HIGH-IMPACT TOUCHPOINT 3-6: PROCESS INTEGRATION OF EVIDENCE TO POLICY IMPLEMENTATION

This second section of the roadmap describes unmet needs, action items and resource gaps related to the implementation process by which evidence is contextualized, policies are developed and documented for members, and clinical policies applied in practice are evaluated to inform future evidentiary gaps. This section acknowledges the cyclical nature of evidence generation and policy implementation. Generating high quality patient-centered evidence is not enough to ensure integration if payers are unfamiliar with how to identify, interpret, and apply patient-centered CER throughout their processes.

Integrating patient-centered CER into policy development requires additional attention to: expanding payer networks to include trusted patient partners, layering patient experience data and applying it in policy development, and developing bi-directional communication channels that support strong implementation and build trust.



1) **Payer networks need to be expanded to include trusted patient partners.**
Given the CMS requirements for certain health plans to include at least one patient representative on the P&T Committee starting January 2026, many payers will need to begin to identify, select and engage patients in a way they haven't before, as partners and advisors. Although this type of engagement is new for payers, existing resources, if curated and centralized, can support payers in developing their own practices and processes. The engagement of trusted patient partners will elevate the discussion of patient-centered CER and patient experience during policy development.

4) **Processes that layer patient experience data may help contextualize evidence reviewed during policy development.**
Patient advisors will bring patient perspective to policy development AND no one advisor is expected to represent the needs of all patients with a particular condition. New processes are needed to support the review and integration of additional resources that capture the complexity of the patient journey and broaden understanding of patient preferences and experience. Promising practices include: leveraging existing patient advocacy organization resources to capture patient journey information, developing a standing patient advisory committee to inform policy development discussions, and creating a summary document of patient insights from a variety of secondary sources that helps contextualize the evidence reviewed during committee discussions.

2) **Developing bi-directional communication channels that support strong policy implementation and build trust among payers, patients and other stakeholders.**
New channels of communication are needed to promote trust between payers, patients, and other key stakeholders. Transparent bi-directional communication about payer policies and implementation improvements need to be bolstered. Promising practices include working with patients to improve the public presentation of payer policies, with special attention to temporary policies related to the accelerated approval pathway and using member feedback to refine policy implementation and identify future evidentiary gaps. More public forums are needed where payers and patients proactively communicate top evidentiary priorities and collaborate to identify shared goals.

[HIGH PRIORITY NEED] Many payers are unfamiliar with how to identify, select and engage patient representatives as well as evaluate quality of engagement to ensure meaningful patient input.					**Need Type:** Capacity
Actions Identified	**Stakeholders Responsible (R) & Involved (I)**				
	Payer	**Patient**	**Researcher**	**Industry**	**Other**
Identifying patient representatives and partners as consultants or advisors for medical policy or P&T Committee and other payer review committees.					
• Establish a network of collaborators consisting of patients, patient advocacy organizations, community-based organizations, HBCUs and Hispanic academic institutions who are willing to participate in a payer consultation or payer review committee.	**R**	**R**			**Non-profits**
• Identify patient consultant responsibilities, qualifications, time commitment, compensation and conflicts of interest	**R**	**I**			
• Partner with research organizations that conduct patient engagement to prepare committees and facilitate bi-directional multi-stakeholder engagement	**R**	**I**	**R**		**Non-profits**
Selecting patient representatives as consultants or advisors for medical policy or P&T Committee and other payer review committees.					
• Identify selection criteria and a process by which patient representatives are chosen	**R**	**I**			
• Set up paid contracts with patient partners who serve as consultants	**R**	**I**			
Engaging patient representatives for medical policy or P&T Committee and other payer review committees.					
• Develop layered processes to ensure that multiple patient perspectives are represented in policy committee discussions	**R**	**I**	**R**		**Non-profits**
• Create and provide formal training to patient advisors on payer terminology, clinical criteria, and review process	**R**	**I**	**R**		**Non-profits**
• Create and provide formal training to committee members on effective multi-stakeholder engagements	**R**	**I**	**R**		**Non-profits**

• Provide a dossier of materials to patient representatives, where appropriate, in advance of policy committee meetings to ensure accessibility and full understanding	R	I			
• Develop a list of specific questions to ask the patient partner and provide ahead of conversation	R				
• Conduct a prep meeting ahead of consultation and/or policy committee meeting	R				
• Inform patients how their input is or is not being used to inform policy decisions and the rationale behind the final decision	R				
Evaluating quality of engagement with patient representatives and other committee members to determine value-add and areas for improvement.					
• Determine short, medium, and long term engagement goals for the committee where engagement is taking place.	R	I			
• Measure output relative to goals	R	I			
• Use a validated instrument to evaluate engagement quality such as the Public and Patient Engagement Evaluation Tool (PPEET) or Patient Engagement In Research Scale (PEIRS).	R	I			
[HIGH PRIORITY NEED] Many payers are unfamiliar with how to incorporate patient-centered CER into their review processes.					**Need Type:** Data
Actions Identified	**Payer**	**Patient**	**Researcher**	**Industry**	**Other**
Consider layering in different patient experience data sources to supplement patient engagement and broaden the perspectives that contextualize and integrate patient-centered CER into the evidence review.	R	I			
• Consider creating a standing patient advisory committee	R	I			
• Leverage existing patient advocacy organization resources, such as patient-centered dossiers, to capture the patient journey and understand totality of burden of illness or treatment experience.	R	I			
• Develop a concise patient insights brief that summarizes relevant patient-centered findings from secondary sources and incorporate them into committee materials.	R	I	I		
Resource Needs Identified					
Bi-directional training for payers and patients	R	R	I		Non-profits
Knowledge generation and layering of materials to bring broad patient experience data into committee discussions	R	I	R		Non-profits

Define the role and responsibilities of the patient representative or advisor in the evidence review process	R	I			
Use of AI to simplify clinical evidence reviewed in committees	R				
Need: While payer policies are public, they may not be accessible, understandable and/or useful to members					**Need Type:** Communication
Actions Identified	**Payer**	**Patient**	**Researcher**	**Industry**	**Other**
Conduct a needs assessment among members to identify what needs patients have when trying to understand coverage and benefits using publicly posted policies.	R	I	I		
Develop a search engine that will help members find the policies relevant to their needs	R	I	I		
Broaden and test accessibility and readability of policy documents	R	I	I		
Develop plain language, non-technical summaries to post alongside policies	R	I	I		
Conduct an evaluation to gauge improvements once policy documentation adjustments have been made	R	I	I		
Resource Needs Identified					
Utilize member advisory committees to provide insights on implementation of policies and member feedback	R	I			
Use of AI to produce plain language summaries of clinical policies	R				
Need: A payer-agnostic industry standard is lacking for how to inform the patient about the temporary coverage due to limited evidence under the accelerated approval pathway and update patients about policy changes when new evidence emerges.					**Need Type:** Communication
Actions Identified	**Payer**	**Patient**	**Researcher**	**Industry**	**Other**
Proactively curate existing resources at ICHOM, COMET, FDA, and PFDD to understand relevance of surrogate outcomes used in accelerated approval pathway and identify desired outcomes for future clinical trials	R	I	I		
Implement a standard Risk Evaluation and Mitigation Strategies (REMS)-type program for the accelerated approval pathway to inform the patient about the temporary coverage due to limited evidence and update patients about policy changes when new evidence emerges.	R	I	I		**Policy-makers** **Non-profits**
Establish a payer-agnostic communication strategy that informs all patients about the limited evidence the product has as part of the accelerated approval pathway.	R	I			**Policy-makers** **Clinicians**

Identify a transparent and coordinated approach to who and how patients are informed of a change in coverage status due to new evidence.	R	I			Policy-makers Clinicians
Identify patient perspectives on benefit/risk considerations (e.g., patient safety/adverse event potential) for technologies with limited evidentiary support	I	I	R		

Need: Implementation of policies may not work as intended and could be improved with patient input. A formal process to track outcomes and incorporate patient experience feedback into policy review may not be well established.	**Need Type:** Capacity

Actions Identified	Payer	Patient	Researcher	Industry	Other
Summarize existing sources of patient input from formulary addition requests or other patient feedback mechanisms to highlight areas where policy implementation may not be working well.	R	I	I		Clinicians
Formalize report back process to policy committees and encourage further evaluation by policy and operational teams to determine necessary revisions	R				
Use patient-centered outcomes identified as important to the patient community in outcomes-based contracts.	R	I	R	R	Clinicians
Utilize outcomes-based contract and patient feedback to direct future evidence generation.	R	I	I		Clinicians
Consider soliciting feedback from personnel (member outreach, case managers) who work directly with patients and members and may inform payers about quality of implementation and unmet member needs.	R		I		
Resource Needs Identified					
Guidance for payers on how to encourage research and outcome-based contract data collection in areas identified as evidentiary gaps by ICER, NICE and others.	I	I	R		Non-profits

Milestones			
Milestone Type	**Milestone**	**Timeframe***	**Examples of Metrics**
Data	A standardized evidence summary template that highlights patient-centered CER and patient experience data is used by payers to inform policy committee discussions.	Short-term	Template finalized; piloted by ≥2 payer orgs
	Pilot a process by which patient-centered outcomes-based contracts or member feedback and formulary requests inform payer policy revisions and future evidentiary gaps.	Long-term	Process documented; number of pilots launched; evidence summaries published

Capacity	Bi-directional training modules for patient representatives and payers are produced and utilized to support policy committee engagement during policy development and review.	Short-term	Modules completed; ≥10 participants trained
	A payer-patient engagement coalition is formed with participation of at least 5 national organizations	Short-term	Coalition MOU signed; shared engagement charter
	Validated engagement evaluation tools (e.g., PPEET or PIERS) are implemented by ≥3 payer committees to ensure high quality engagement is occurring on policy committees.	Long-term	Evaluation data reviewed and reported within the relevant committee
Communication	Plain-language policy summaries are piloted in at least 3 high-impact therapeutic areas.	Short-term	Member comprehension test conducted
	A policy search tool is created to support members when locating coverage policies and piloted among at least 2 payer organizations.	Long-term	Search tool launched and evaluated for usability
	A set of patient-facing communication guidelines are established for products under the accelerated approval pathway, co-created by at least 3 payers and 2 patient advocacy groups.	Long-term	Guideline publication

**short-term (0-2 years) and long-term (2+years)*

Existing Resources Identified in Workshops		
Resource Type	**Resource List**	**Resource Description**
Data	ICHOM: Patient-centered outcomes through value-based healthcare	ICHOM Standard Sets are derived from co creation with patients and represent validated in-use metrics. See ICHOM webinars and case studies for examples of using outcomes measurement in payment contracting.
	PCORI research repository PCORI in the Literature | PCORI	A comprehensive repository of peer-reviewed articles that report findings from PCORI-funded patient-centered comparative clinical effectiveness research (CER) studies.
	National Core Indicators https://www.nationalcoreindicators.org	NCI IDD is a national effort to measure and improve the performance of state developmental disabilities service systems. NCI reports, which are freely and publicly available, allow for comparisons among states, and available in formats that are accessible to all stakeholders, including people who receive services and their families.

	FDA Patient Focused Drug Development guidance CDER Patient-Focused Drug Development | FDA	Patient-focused drug development (PFDD) is a systematic approach to help ensure that patients' experiences, perspectives, needs, and priorities are captured and meaningfully incorporated into drug development and evaluation.
	PFMD patient experience data navigator PED Navigator - PEM Suite	The aim the Global PED Navigator provide an all-encompassing guide for PED collection and understanding.
	ICER reports ICER | Working Towards Fair Pricing, Fair Access, & Future Innovation	ICER reports are created to advance the use of evidence to improve health care affordability and access for all patients and their families.
	The Center for Innovation in Value Research 05-2023-Economic-Impacts-Framework-Report_FINAL.pdf	A Research Framework to Understand the Full Range of Economic Impacts on Patients and Caregiver.
Capacity	National Health Council Fair-Market Value Calculator Access the NHC Patient Compensation Tools - National Health Council	Guidance on how companies can provide fair compensation and reimbursements to patients, caregivers, and patient representatives who are involved in patient-engagement activities.
	Homepage - Patient Engagement for Medicines Development	PFMD provides a trusted, global space where patients, industry, regulators, and health systems collaborate. Agile, holistic, and non-competitive, PFMD enables the adoption of shared frameworks and solutions that drive innovation, better health outcomes, and stronger systems worldwide.
	PCORI guidance on patient engagement Engagement Resources | PCORI	PCORI-funded studies and projects have collectively gathered a large body of practice-based learnings and evidence that can support researchers and their partners in engagement.
	National Health Council Value Classroom - National Health Council	Plain language terms and definitions in value assessment, how-to-guides for patients to engage in value assessment discussions.
	Engagement scorecard on patient-centered research **11231_CMSS_Plybk_Scorecards_V3**	This model, co-developed by Council of Medical Specialty Societies (CMSS) and Patient-Led Research Collaborative (PLRC), takes the form of scorecards which serve to evaluate how effective a patient group and research partner collaboration will be at conducting truly patient-led research.
	FDA Patient Representative Program About the FDA Patient	An example of how to select and engage patient advisors to inform scientific, technical, and policy decisions. The FDA Patient Representative Program offers patients and caregivers the opportunity

	Representative Program | FDA	to provide critical advice to the agency as it regulates medical products—drugs, biologics, and devices.
Communication	FDA guidance on AAP Accelerated Approval – Expedited Program for Serious Conditions | FDA	This draft guidance for industry sponsors represents the current thinking of the Food and Drug Administration on the accelerated approval pathway. Document dated December 2024.
	Patient and public partnership | The BMJ	Example of a journal (BMJ) implementing transparent co-production of content in partnership with patients.