

The Evolution of Value Assessment in the US: Considerations and Controversies

October 4, 2022

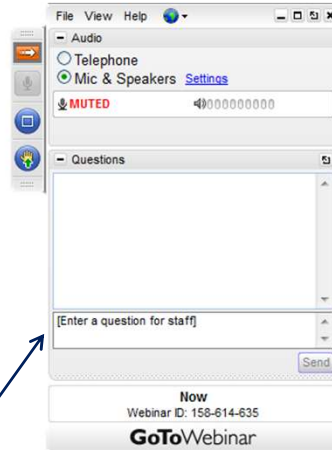


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How to ask a question



Type your question in the “Questions” area, then click “Send”

Webinar overview

Within the value assessment context, our expert panel will:

- Discuss the evolution of these frameworks in the US
- Explore payer perspectives and factors for decision making
- Elucidate considerations and controversies in applying value assessments to inform coverage and reimbursement
- Identify emerging trends that will affect the landscape

HTO

Which organization type do you most closely identify with?



- Payer or hospital/health system
- Life sciences manufacturer
- Consultancy
- Academia
- Other

HTO

What is your level of familiarity with value assessment tools?



- Extremely familiar
- Very familiar
- Somewhat familiar
- Not very familiar
- Not familiar at all

Slide 5

HT0 Polling question for AMCP to program
Hydery, Tasmina, 2022-09-29T17:47:21.376

Slide 6

HT0 Polling question for AMCP to program
Hydery, Tasmina, 2022-09-29T17:47:29.858

HTO



How do you primarily use value frameworks within your organization?

- I review and evaluate value frameworks
- I use value frameworks in my decision-making process
- I develop or generate evidence for value frameworks
- I currently do not use value frameworks

Panelists

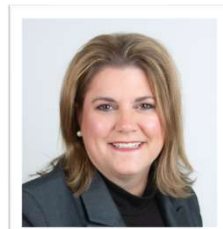
Moderator



Joseph Washington, PharmD, MPH
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Senior Director;
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Assistant Director;
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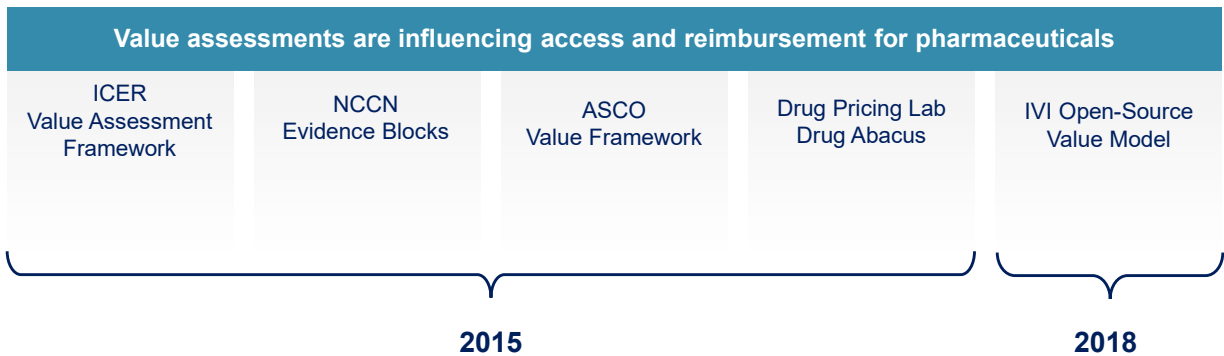
Slide 7

HT0 Polling question for AMCP to program
Hydery, Tasmina, 2022-09-29T17:47:33.235

What is value assessment?

WHAT?	WHY?	WHO?
		
<p>An approach to measure the “value” (often in terms of clinical benefit and cost) of healthcare interventions and provide those results to stakeholders in a clear, actionable, and user-friendly format</p>	<p>To aid stakeholder decision making and optimize treatment outcomes and value for money in policy and practice</p>	<p>In the US, there are several private-sector initiatives undertaken by nonprofit organizations, including leading medical organizations and professional societies</p>

The use of value assessments in the US is maturing



Value assessment tools have different purposes and structures

	ICER Value Assessment Framework	NCCN Evidence Blocks	ASCO Value Framework	Drug Pricing Lab Drug Abacus	IVI Open-Source Value Model
Primary audience	Payers and policymakers	Physicians and patients	Physicians and patients	Payers and policymakers	Payers, policymakers, academics, providers, patients
Services assessed	Primarily pharmaceutical, some healthcare services	Pharmaceutical	Pharmaceutical	Pharmaceutical	Pharmaceutical (aspirational: some healthcare services)
Conditions assessed	Any condition	Oncologic	Oncologic	Oncologic	Any condition



Key: ASCO – American Society of Clinical Oncology; ICER – Institute for Clinical and Economic Review; IVI – Innovation and Value Initiative; NCCN – National Comprehensive Cancer Network.

We surveyed payers to evaluate the uptake and impact of value assessment in their decision making



Online survey

Quantitative survey, including open-ended questions, was fielded from June 30, 2022, to July 19, 2022



Format

- Double blinded, 30-minute survey
- Topics covered included value assessment frameworks and tools



Participants

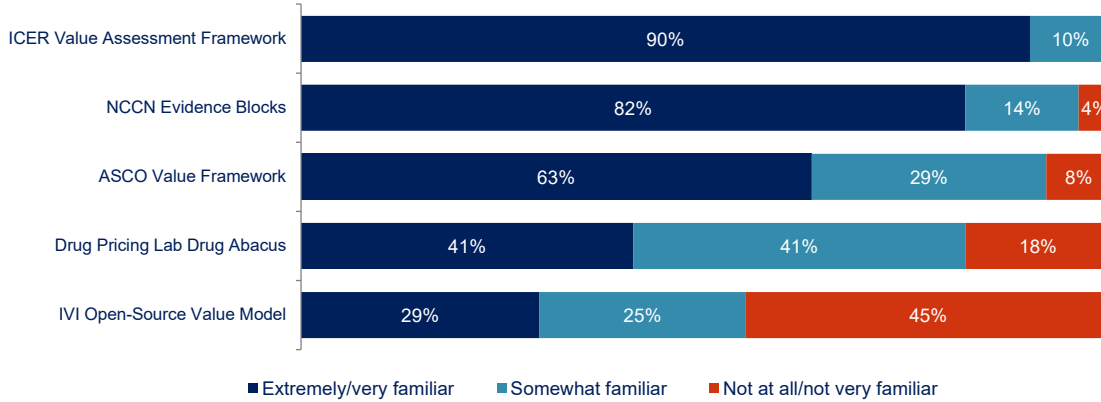
A total of 51 advisors from health plans, IDNs, and PBMs



Key: IDN – integrated delivery network; PBM – pharmacy benefit manager.

Respondents have varying levels of familiarity with value assessment tools

Familiarity with value assessment frameworks/tools



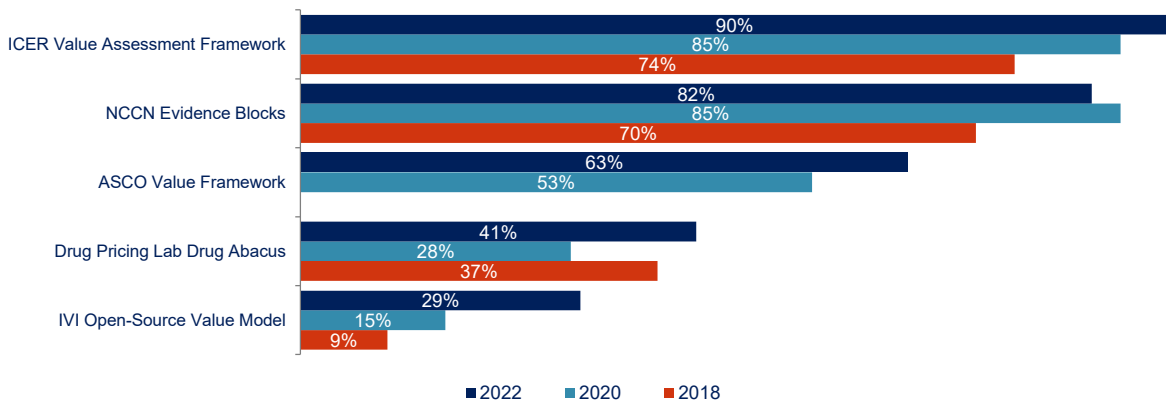
N=51.

Q: Please describe your current level of familiarity with the following value assessment frameworks/tools:

Key: ASCO – American Society of Clinical Oncology; ICER – Institute for Clinical and Economic Review; IVI – Innovation and Value Initiative; NCCN – National Comprehensive Cancer Network.

Since 2018, familiarity with all value assessment tools has increased

Familiarity with value assessment frameworks/tools (extremely/high)

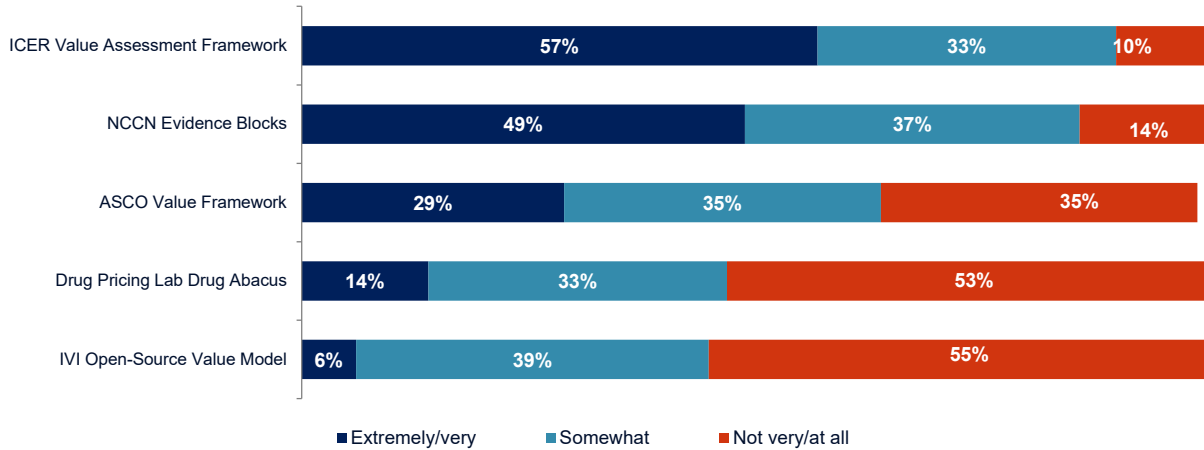


2022: N=51; 2020: N=47; 2018: N=54. (Note: Respondents were not surveyed on their familiarity with the ASCO framework in 2018.)

Q: Please describe your current level of familiarity with the following value assessment frameworks/tools:

Key: ASCO – American Society of Clinical Oncology; ICER – Institute for Clinical and Economic Review; IVI – Innovation and Value Initiative; NCCN – National Comprehensive Cancer Network.

ICER and NCCN value assessments are the most useful for formulary decisions

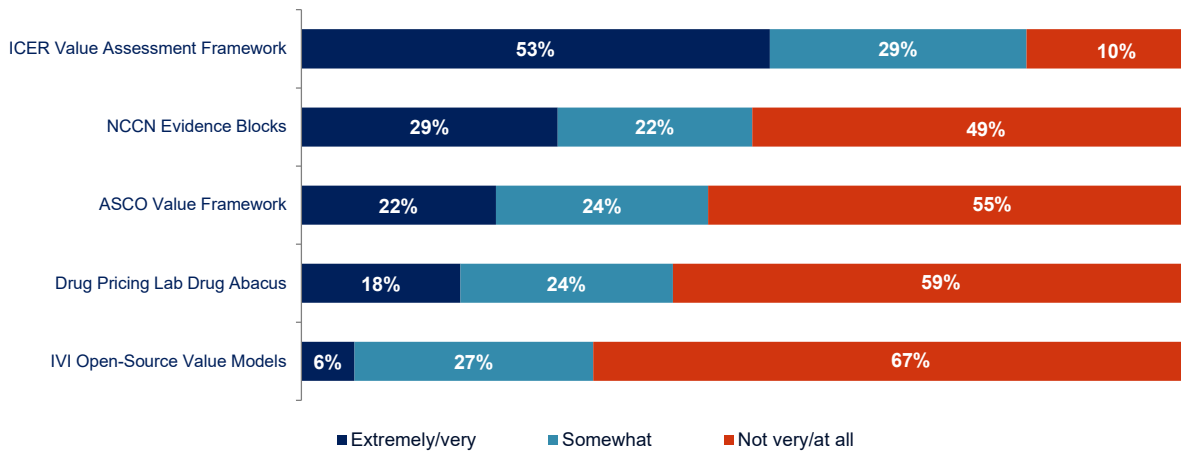


N=51.

Q: How useful are the following value assessment frameworks/tools for informing formulary decisions within your organization?

Key: ASCO – American Society of Clinical Oncology; ICER – Institute for Clinical and Economic Review; IVI – Innovation and Value Initiative; NCCN – National Comprehensive Cancer Network.

ICER's value assessments are the most useful for pricing negotiations



N=51.

Q: How useful are the following value assessment frameworks/tools for informing pricing negotiations within your organization?

Key: ASCO – American Society of Clinical Oncology; ICER – Institute for Clinical and Economic Review; IVI – Innovation and Value Initiative; NCCN – National Comprehensive Cancer Network.

Methodology and transparency are among the most important factors when selecting a value assessment framework/tool

Alternate perspectives and identification of health disparities are among the lowest

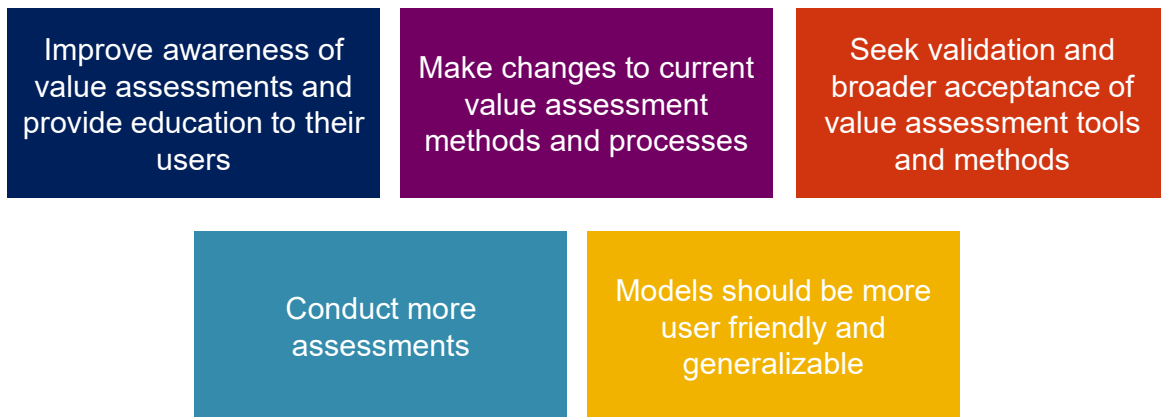
Most important factors	Appropriate metrics and outcomes are included	Comparative clinical effectiveness information	Methodologically rigorous and unbiased methods	Part of a transparent and open process
Least important factors	Identification of health disparities	Inclusion of provider perspective	Inclusion of patient perspective	Inclusion of societal perspective



N=51.

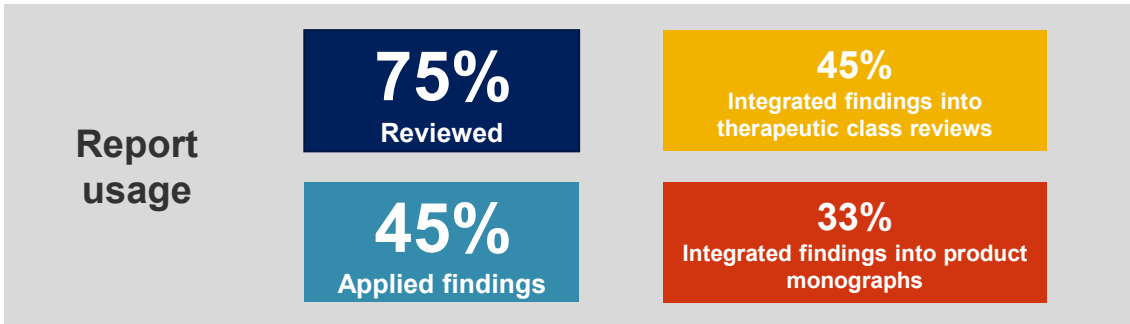
Q: How important are each of the following when selecting a value assessment framework/tool to utilize within your organization?
 "Specialty society opinion of framework" was provided in the free text when "Other" was selected.

There are many ways to make value assessments more useful and relevant



Influence of ICER's value assessments on payer coverage decisions

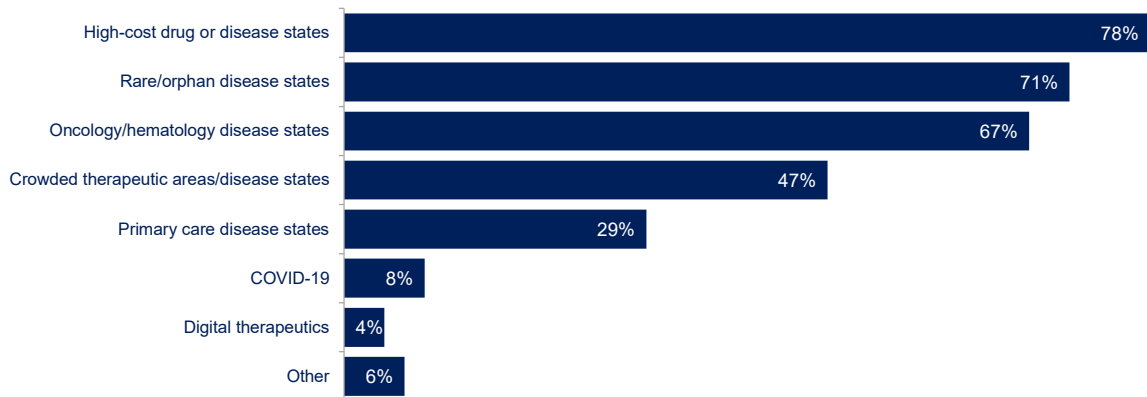
Nearly half of payers have applied the findings of >1 ICER report in the past 2 years



N=51.
 Q: Which statement(s) best describe your organization's experience with the ICER Value Assessment Framework in the last 24 months?
 Key: ICER – Institute for Clinical and Economic Review.

Use of ICER value assessments is most prevalent for high-cost drugs or disease states

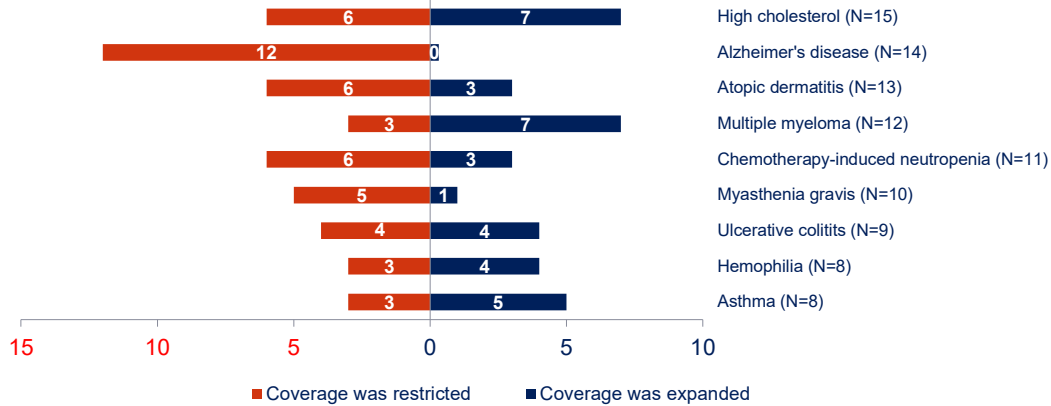
Current use of ICER value assessments



N=51.
 Q: In which of the following areas are you currently utilizing the ICER Value Assessment Framework?
 Key: ICER – Institute for Clinical and Economic Review.

ICER value assessments inform both coverage expansions and restrictions

Coverage decision revisions based on ICER assessment



Note: Numbers may not add up to total due to "other" response (not shown on chart)
 Q: How have you revised a prior coverage decision based on the [assessment topic] ICER report or update in the last 24 months?
 Key: ICER – Institute for Clinical and Economic Review.

Considerations and challenges: Lessons from AMCP Partnership Forum, August 30-31

- Develop shared understanding across stakeholders
- Solve important issues through collaborative approach
- Align on actionable results

Goals

- Outline considerations for how value should be rewarded
- Identify education and tools to apply value assessment findings
- Explore the evolution of value frameworks



<https://www.amcp.org/Resource-Center/meeting-proceedings-findings/partnership-forum-health-technology-assessment-and-value-frameworks-inform-coverage-reimbursement>

Value assessment results are used in multiple ways

Confirm clinical evidence



Provides additional checks and balances for identifying and evaluating clinical net benefits and harms

Identify potential utilization management criteria



Guides subpopulations of patients or care settings where high-value care can be optimized; used to inform step therapy, prior authorization, or prescriber guidance; address health equity lens

Inform rebate negotiations and risk-sharing arrangement



Informs rebate team and signals need for value-based agreement



Value assessment results are used in multiple ways

Enable understanding of patient perspectives



Understand patient experiences; guide decision makers on endpoints that matter to patients; inform the need for shared decision-making tools

Assess budget impact; plan care scenarios



Aid forecasting and budget impact, especially for state Medicaid and employee and federal programs

Guide care management



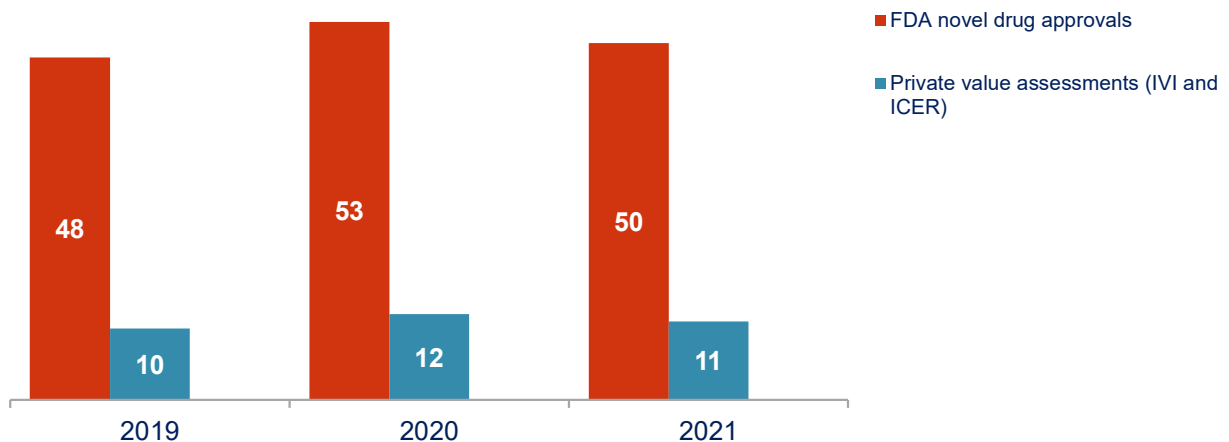
Facilitate clinical treatment and care management programs to optimize high-value products



Generalizability to plan membership is needed; off-the-shelf reports offer insights but are insufficient



Private value assessments are conducted only for a small proportion of all novel drug approvals



Challenges exist on evidence inputs and how reports are put into policy

Hereditary transthyretin amyloidosis: “The economic modeling and resulting QALY cost assignments were undermined by an inability to translate improvements ... to understandable effect on patient lives.”

Lupus nephritis: “Report highlighted substantial uncertainty over the results for Black patients... present affordability and access issues concerning their use.”

Spinal muscular atrophy: “Establishes a fair price for the value that a drug provides. Challenge is continued healthcare affordability.”

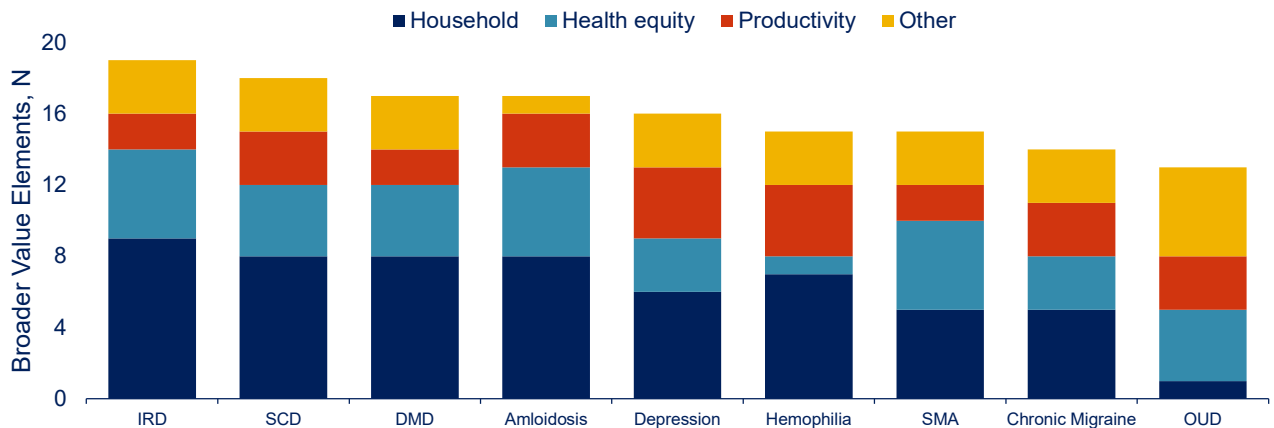
Atopic dermatitis: “Wait with hope that plan sponsors do not create requirements for OOP spending that cause major barriers to appropriate access for vulnerable patients.”



Emphasis added in red for specific challenges.

Begolka WS, et al. The ICER review is in: hope amidst uncertainty. *J Manag Care Spec Pharm.* 2022;28(1):115-118. Stamer C, Gleason P. Spinal muscular atrophy therapies: ICER grounds the price to value conversation in facts. *J Manag Care Spec Pharm.* 2019;25(12):1306-1308. Newman TV et al. Emerging treatments for lupus nephritis: health equity considerations in clinical research and coverage. *J Manag Care Spec Pharm.* 2021;27(10):1500-1502. Berk, JL. TTR gene silencers for hereditary ATTR amyloidosis: more than ICER recognized. *J Manag Care Spec Pharm.* 2019;25(1):15-16.

Adequately assessing fair value may require additional elements of value

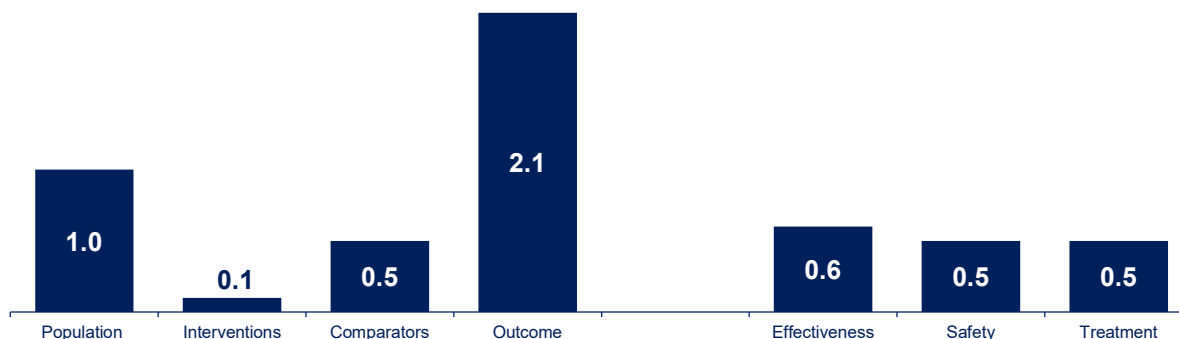


DMD – Duchenne muscular dystrophy; IRD – inherited retinal disease; OUD – opioid use disorder; SCD – sickle cell disease; SMA – spinal muscular atrophy.

Shafrin J, et al. For which diseases do broader value elements matter most? An evaluation across 20 ICER evidence reports. *J Manag Care Spec Pharm.* 2021;27(5):650-659.

Real-world evidence can inform clinical and economic inputs

Average number of RWE studies per report



Key: RWE – real-world evidence.

Jiao B, et al. The use of real-world evidence in ICER's scoping process and clinical evidence assessment. *J Manage Care Spec Pharm.* 2020;26(12):590-595.

29

Value assessment is maturing; time, evidence, culture, infrastructure needed

Emerging trends and broader value elements

- Patient preferences
- Equity
- Productivity
- Severity of condition
- Process improvements
- Criminal justice system
- Education
- Social services
- Scientific spillover

Needs

- Better data and data collection
- Quantitative vs qualitative
- Tested methods to develop trusted inputs
- Culture
- Technical capacity
- Understanding of tradeoffs with additional core elements



30

Xcenda provides education and strategic insights on value assessment frameworks

- Value frameworks overview and methodologies
- Understanding and navigating assessment processes
- Market research on payer perspectives and use of VAFs
- Analysis of implications of VAFs on patient access to medications



KWO

Subscribe to VAF Publications: *Health Policy Weekly* and *HTA Quarterly* at xcenda.com/subscribe-to-newsletters



The value corner

IQWiG: Smarter than a QALY?

Thinking about HTAs and what could/should be

CAR-T hits the QAL(y)

Shepherding German HTA into the US; Adopt with caution

More patient-friendly idea: ICER could add an emoji rating; This one would be meh :|



HTA QUARTERLY | FALL 2020
Incorporating the Patient Voice in Value Assessments: The Evolution of ICER's Approach to Patient Engagement

HTA QUARTERLY | WINTER 2020
ICER's Growing Influence on Payer Decision Making: The Impact of ICER Assessments on Market Dynamics and Patient Access

HTA Quarterly | Spring 2021
A comparison of the Innovation and Value Initiative's Open-Source Value Project and the Institute for Clinical and Economic Review's value assessment framework

May 11, 2021
ICER seeks to improve healthcare decision making with new customizable analytic tools

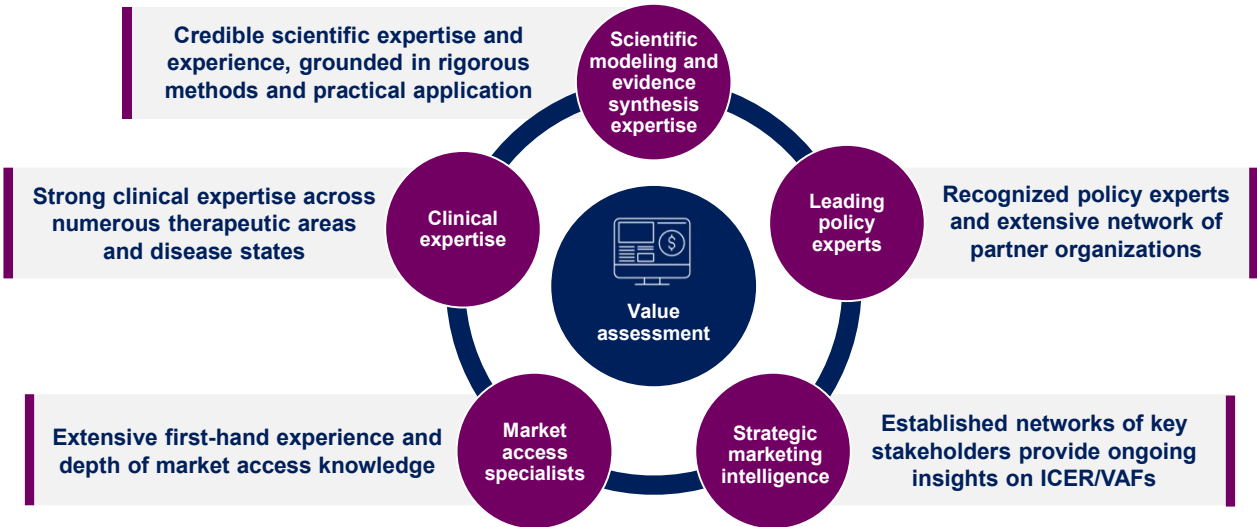


Slide 32

KW0 [@Hydery, Tasmina] can we include the link to subscribe on the slide? If so, it's:
xcenda.com/subscribe-to-newsletters
Kimberly Westrich, 2022-09-30T16:52:38.715

HT0 0 I like this idea! [@Washington, Joseph]- can you pass this edit along to Kristine? We can wait until tomorrow AM in case there are others as folks are reviewing their slides
Hydery, Tasmina, 2022-10-03T16:35:21.711

Xcenda takes a holistic approach to value assessments



Key: ICER – Institute for Clinical and Economic Review; VAF – value assessment framework.

HTO

FormularyDecisions®

Life sciences manufacturers



Includes pharmaceutical, biotech, and medical devices

Evidence and landscape review

Insights, preferences, and attitudes

HCDM community



Closed platform of verified HCDMs

FormularyDecisions provides qualified payer access to product information



Key: HCDM – healthcare decision maker.

Slide 34

HTO [@Hayes, Becky] - slides 35-39 were previously approved by OOC and are from the FormularyDecisions Demonstration Support Presentation
Hydery, Tasmina, 2022-09-23T16:37:29.851

For inquiries on the FormularyDecisions platform or questions related to information exchange between payers and life sciences manufacturers:

Email Xcenda at insights@xcenda.com

Contact us at <http://www.xcenda.com>



Thank You





Questions?

For a list of upcoming webinars, visit
www.amcp.org/calendar