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

October 4, 2022

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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
Which organization type do you most closely identify with?

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

What is your level of familiarity with value assessment tools?

- Extremely familiar
- Very familiar
- Somewhat familiar
- Not very familiar
- Not familiar at all
Polling question for AMCP to program
Hydery, Tasmina, 2022-09-29T17:47:21.376

Polling question for AMCP to program
Hydery, Tasmina, 2022-09-29T17:47:29.858
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
Polling question for AMCP to program
Hydery, Tasmina, 2022-09-29T17:47:33.235
What is value assessment?

**WHAT?**
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.

**WHY?**
To aid stakeholder decision making and optimize treatment outcomes and value for money in policy and practice.

**WHO?**
In the US, there are several private-sector initiatives undertaken by nonprofit organizations, including leading medical organizations and professional societies.

The use of value assessments in the US is maturing

Value assessments are influencing access and reimbursement for pharmaceuticals

- **ICER Value Assessment Framework**
- **NCCN Evidence Blocks**
- **ASCO Value Framework**
- **Drug Pricing Lab Drug Abacus**
- **IVI Open-Source Value Model**

Value assessment tools have different purposes and structures

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


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

Since 2018, familiarity with all value assessment tools has increased
ICER and NCCN value assessments are the most useful for formulary decisions

ICER Value Assessment Framework: 57% extremely/very, 33% somewhat, 10% not very/at all
NCCN Evidence Blocks: 49% extremely/very, 37% somewhat, 14% not very/at all
ASCO Value Framework: 29% extremely/very, 35% somewhat, 35% not very/at all
Drug Pricing Lab Drug Abacus: 14% extremely/very, 33% somewhat, 53% not very/at all
IVI Open-Source Value Model: 6% extremely/very, 39% somewhat, 55% not very/at all

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

ICER Value Assessment Framework: 53% extremely/very, 29% somewhat, 10% not very/at all
NCCN Evidence Blocks: 29% extremely/very, 22% somewhat, 49% not very/at all
ASCO Value Framework: 22% extremely/very, 24% somewhat, 55% not very/at all
Drug Pricing Lab Drug Abacus: 18% extremely/very, 24% somewhat, 59% not very/at all
IVI Open-Source Value Models: 6% extremely/very, 27% somewhat, 67% not very/at all

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.
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

<table>
<thead>
<tr>
<th>Most important factors</th>
<th>Appropriate metrics and outcomes are included</th>
<th>Comparative clinical effectiveness information</th>
<th>Methodologically rigorous and unbiased methods</th>
<th>Part of a transparent and open process</th>
</tr>
</thead>
<tbody>
<tr>
<td>Least important factors</td>
<td>Identification of health disparities</td>
<td>Inclusion of provider perspective</td>
<td>Inclusion of patient perspective</td>
<td>Inclusion of societal perspective</td>
</tr>
</tbody>
</table>

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

| Improve awareness of value assessments and provide education to their users | Make changes to current value assessment methods and processes | Seek validation and broader acceptance of value assessment tools and methods |
| Conduct more assessments | Models should be more user friendly and generalizable |
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

Report usage

- 75% Reviewed
- 45% Applied findings
- 45% Integrated findings into therapeutic class reviews
- 33% Integrated findings into product monographs

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

- High-cost drug or disease states: 78%
- Rare/orphan disease states: 71%
- Oncology/hematology disease states: 67%
- Crowded therapeutic areas/disease states: 47%
- Primary care disease states: 29%
- COVID-19: 8%
- Digital therapeutics: 4%
- Other: 6%

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

- High cholesterol (N=15)
- Alzheimer’s disease (N=14)
- Atopic dermatitis (N=13)
- Multiple myeloma (N=12)
- Chemotherapy-induced neutropenia (N=11)
- Myasthenia gravis (N=10)
- Ulcerative colitis (N=9)
- Hemophilia (N=8)
- Asthma (N=8)

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

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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

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https://www.amcp.org/Resource-Center/meeting-proceedings-findings/partnership-forum-health-technology-assessment-and-value-frameworks-inform-coverage-reimbursement
Generalizability to plan membership is needed; off-the-shelf reports offer insights but are insufficient

- Patient demographics
- Anticipated epidemiology
- Treatment patterns
- Costs of care
- Line of business implications

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

- FDA novel drug approvals
- Private value assessments (IVI and ICER)


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.”

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.

Real-world evidence can inform clinical and economic inputs

Average number of RWE studies per report

<table>
<thead>
<tr>
<th>Category</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population</td>
<td>1.0</td>
</tr>
<tr>
<td>Interventions</td>
<td>0.1</td>
</tr>
<tr>
<td>Comparators</td>
<td>0.5</td>
</tr>
<tr>
<td>Outcome</td>
<td>2.1</td>
</tr>
<tr>
<td>Effectiveness</td>
<td>0.6</td>
</tr>
<tr>
<td>Safety</td>
<td>0.5</td>
</tr>
<tr>
<td>Treatment</td>
<td>0.5</td>
</tr>
</tbody>
</table>

Key: RWE – real-world evidence.


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 quantitative
- Tested methods to develop trusted inputs
- Culture
- Technical capacity
- Understanding of tradeoffs with additional core elements
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

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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 ;]
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

- Credible scientific expertise and experience, grounded in rigorous methods and practical application
- Strong clinical expertise across numerous therapeutic areas and disease states
- Extensive first-hand experience and depth of market access knowledge
- Scientific modeling and evidence synthesis expertise
- Market access specialists
- Strategic marketing intelligence
- Value assessment
- Leading policy experts
- Established networks of key stakeholders provide ongoing insights on ICER/VAFs


FormularyDecisions

Life sciences manufacturers

- Includes pharmaceutical, biotech, and medical devices
- Evidence and landscape review

HCDM community

- Insights, preferences, and attitudes
- Closed platform of verified HCDMs

FormularyDecisions provides qualified payer access to product information

Key: HCDM – healthcare decision maker.
[@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?

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