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AMCP PARTNERSHIP FORUM:

HEALTH TECHNOLOGY ASSESSMENT AND VALUE ASSESSMENT FRAMEWORKS TO INFORM COVERAGE REIMBURSEMENT

Abstract

Health technology assessment (HTA) and value assessment frameworks can serve as resources for determining the value of pharmaceuticals and other health interventions. To improve value assessments and their application to formulary decision making, AMCP held a multistakeholder Partnership Forum in Arlington, Va., on Aug. 30 and 31, 2022. Forum participants were asked to 1) outline considerations for how value should be recognized in a system of constrained resources, 2) explore the evolution of value frameworks to guide coverage and reimbursement decisions, and 3) identify education and managed care tools to aid the application of value assessment findings. A key theme from the forum was that increasing value through iinnovative novel pharmaceutical product coupled with more complete data results should be recognized. However, defining value may vary based on perspective. While utilizing value assessments is one part of determining coverage and reimbursement, coverage decision makers advocated that more value assessments are needed from trusted resources. Participants also identified best practices to continue improvement of current value assessment tools and processes. Several areas noted for improvement include more robust data collection, analytical systems, and increased education on value assessment tools and frameworks across the health care industry.

Introduction

In the ongoing transition in health care coverage from paying for volume to paying for value, health technology assessment (HTA) and assessment frameworks can serve as important resources for determining the value of pharmaceuticals and other health innovations. Available frameworks provide insights for health plans and pharmacy benefit managers (PBMs) as they assess appropriate use and standards in clinical practice and to determine coverage and reimbursement for novel treatments. These tools must be based on sound methods, must use solid scientific evidence and widely accepted economic models, and must consider the totality of the evidence by incorporating the views of patients, thus resulting in aligned value across stakeholders.[1]

Though the United States does not have a national program to broadly evaluate the value of health technologies and guide coverage and pricing decisions, organizations exist that provide services for broader use. The Agency for Healthcare Research and Quality (AHRQ) is once such public entity which conducts HTA through various programs, including its Evidence-based Practice Center program.[2] Another example is the Institute for Clinical and Economic Review (ICER), a private, independent organization that evaluates the clinical and economic value of various health innovations.[2]

Forum participants were presented a 2022 online survey that sought to characterize managed care decision makers' opinions on the various available value assessment frameworks in making coverage decisions.[3] Survey respondents (n=51) included national and regional health plans, integrated delivery networks, and PBMs across commercial and government books of business. Results indicated that value assessments tend to be more useful for formulary decisions than pricing negotiations, but they are used for both. For ICER value assessments, specifically, use is most prevalent for high-cost drug or disease states, like rare or orphan diseases, and for oncology/hematology conditions. The survey also found that ICER value assessments were used to expand and narrow existing coverage. Additional results revealed that comparative clinical effectiveness is the most influential component of the ICER reports in decision making although long-term cost effectiveness, potential budget impact, health-benefit price benchmarks, and key policy implications were also influencers.[3]

Even with this demonstrated use of available value assessment resources, managed care decision makers primarily continue to use internal processes for assessing their coverage decisions, which poses challenges.[4] For instance, internal processes often lack transparency and involve duplicated efforts across organizations. Additionally, several uncertainties exist, such as what evidence should be considered in deliberations, how to value treatments for rare and orphan conditions, the best way to incorporate patient perspectives, and health equity considerations. Lastly, constraints may exist on which elements can be included when assessing Medicare and Medicaid coverage decisions.[4]

To improve value assessment frameworks and their application to formulary decision making, AMCP held a multistakeholder Partnership Forum in Arlington, Va., on Aug. 30 and 31, 2022. This group of nearly fifty stakeholders included representatives from managed care decision makers, PBMs, integrated delivery system leaders, employer benefit consultants, value assessors, researchers, pharmaceutical manufacturers, patient groups, and other key stakeholders. Forum participants were asked to 1) outline considerations for how value should be recognized in a system of constrained resources, 2) explore the evolution of value frameworks to guide coverage and reimbursement decisions, and 3) identify education and managed care tools to aid the application of value assessment findings. To accomplish this, they reviewed the results of an industry survey, engaged in panel sessions, and participated in breakout groups.

These proceedings were synthesized from the two-day forum; however, they should not be construed as a consensus nor the perspective of individual participants' organizations.

Recognizing Value Amidst Constrained Resources

Definitions of Value May Vary

An important aspect of recognizing value identified by participants was that defining value, fair price, and reimbursement may vary based on the perspective. Participants determining value should be flexible for each population but informed by a core set of inputs regardless of perspective, such as transparency and a focus on the patient. Other variable inputs may increase or decrease value and potentially the subsequent reimbursement. Examples, such as improving health equity or addressing a serious chronic condition, were seen by participants as opportunities for an increased value while developing a product based on others' funding or research or using common resources were deemed less valuable.

Participants maintained that value assessments and their results should have certain consistent characteristics. To optimize access, coverage decisions should be based on results from clinical trials and high-quality, real-world data, thus supporting the most informed decisions regarding value across the patient population. Assessments should also be dynamic and updated as the latest information becomes available, which requires timely data and enough resources to maintain ongoing evaluation. Value assessment results need to be transparent and reproducible, which can moderate the challenge of multiple perspectives on value.

Considerations for Recognizing Value

Several considerations were presented for review related to paying for value and can be found in Table 1. Participant feedback on the importance of these considerations is noted and provided within the table.

Table 1. Considerations for Recognizing Value

The considerations listed below were presented to the Forum Participants for discussion. Commentary from the forum participants was captured and noted.

Consideration	Additional commentary
Value assessments and evaluation of fair value provide important managed care pharmacy tools to help patients access the medications they need.	· Perspective matters as the definition of value may vary by stakeholder. · Medication type, intended treatment population, and disease severity are among the items that should be considered in the evaluation of value.
Products with fair value should be available to patients with serious, chronic conditions with appropriate access and consideration of $0 no cost or low-cost sharing. Conversely, products without fair value may have access requirements and higher cost-sharing.	· Patients should share in the benefits of fair pricing. · Uncertainty about who should define what is considered a serious chronic condition. · Has the potential to align incentivize pricing with value, thus demonstrating fair value.
Value assessment should help identify settings of care and patient populations for whom treatments are high or low value.	Calibrate value based on circumstances and/or the population coverage (e.g., centers of excellence).
Paying for value offers greater transparency compared to other tools to manage costs, such as rebates.	The definitions of value and process transparency must be clearly defined.
Paying for value can recognize innovation differently than other policies, such as reference-based pricing or capitated prices do not.	The effects on innovation may vary based on the number of existing competitors.
Paying for value is dynamic as treatments used over time will need to monitor a product's efficacy for improvement (or decline), thereby increasing (or decreasing) value.	Gene therapy may be less dynamic because it targets a small treatment population.

Primarily, participants felt that an innovation that increases clinical value in the form of better outcomes should be recognized. One way to recognize an innovation is through improved access with appropriate coverage criteria and lower patient out-of-pocket costs. Furthermore, increased access can enhance the quality of care when the clinical value is properly aligned to specific patient populations. Improving patient affordability, thereby supporting patient adherence, may lead to better quality outcomes that are more cost-effective for the health care system overall. Additionally, improved cost predictability that aligns with treatment selection could lead to decreased provider burden, mitigate administration costs, and reduce utilization of low-value products that produce sub-par outcomes.

Participants believed recognizing value could drive further innovation and drive clinical trial diversity, thus improving health equity.

Participants observed unintended consequences could be associated with recognizing increasing value. It may inadvertently reduce the breadth of innovations if development becomes focused on high-cost disease and product categories or on decreased innovation in undervalued products. If product selection is too rigid, it could result in less access overall. Additionally, high-priced product categories could exacerbate budget constraints. Lastly, bias could be introduced depending on who conducts the assessment and how clinical value, and fair price are defined.

Participants noted that though recognizing value is the goal, it would require balancing different compromises in a system of constrained resources. When increased value results in a higher fair price, it may lead to fewer available resources to distribute among other priorities. Finding a fair price that allows more room in a budget to pay for other treatments or services would be ideal.

The Evolving Role of Value

Value Assessments Are One Part of Payer Coverage and Reimbursement Decision

Table 2 outlines the description of the most commonly used value assessments with participant commentary added.

Table 2. Payer Uses for Value Assessments
The uses for value assessments listed below were presented to the Forum Participants for discussion.

Use	Description
Confirm clinical evidence	Provides additional checks and balances for identifying and evaluating clinical net benefits and harms.
Develop utilization management	· Assists in recognizing subpopulations of patients or care settings where high-value care can be optimized. · Informs utilization management strategies such as step therapy and prior authorization.
Appreciate patient perspectives	· Allows better understanding of patient and caregiver experiences and determination of endpoints that matter to patients. · Incorporate the needs from a patient perspective in shared decision-making tools.
Guide care management	Ensures high-value interventions are optimized in care management scenarios.
Support financial arrangements	· Differentiates relative value of products to aid rebate negotiations. · Signals potential for and informs development of value-based agreements.
Assess budget impact	Aids forecasting and budget impact, crucial for state and federal programs, and is important for all coverage decision makers and all lines of business.

Forum discussion determined that value assessment results are often used as a supplement to the initial clinical evaluation during the coverage and reimbursement decision making process. Additionally, value assessment can be used to improve patient care through better understanding of patient and caregiver experiences. This includes determining which endpoints are most meaningful to patients. Whenever possible, value assessments should support decision makers as they manage care with the goal of ensuring the optimization of high-value interventions.

Furthermore, value assessment findings can aid contract negotiations by differentiating the relative value of products and support the development of value-based agreements. They can also help establish cost-effectiveness and aid in budget impact and forecasting.

Participants cautioned that though the uses for assessing value can serve as tools to address health care costs, value is not synonymous with affordability. To illustrate this, consider that gene therapy might provide value in treating a specific condition but may still be unaffordable given a particular budget.

Participants Advocate for More Value Assessments by Trusted Sources

Decisionmakers in attendance expressed the need for additional value assessments, especially those evaluating cost effectiveness. Participants noted a willingness to consider additional value assessments produced by trusted sources as a supplement to their internal research. Additional debate was had on the potential role of a central advisory body, which might set HTA standards, provide guidance to independent HTA organizations, or augment the currently available pool of HTA results. For these results to be most useful, participants would want them to be reproducible, flexible enough to meet the patient population, timely, and grounded in science. For fair pricing guidance, specifically, there would be a need for transparency around the assessment inputs and the results, for instance, whether the proposed price considers best price protections, rebates, and other pricing tools and programs.

New Inputs to Value Assessment Frameworks Need Time for Uptake

Discussions indicated a desire to better incorporate emerging endpoints, such as social determinants of health and the patient perspective, into value assessment frameworks. Much of these data are not currently available or still emerging. Also, it takes time to build a data collection infrastructure, develop evidence, establish standardization, and expand staff capabilities and capacity to support these expanded data inputs.

Improving Value Assessment

Participants identified best practices and actions to achieve continued improvement of value assessment frameworks and the application of their findings (See Table 3).

Table 3. Improving Value Assessment

The areas for improving value assessments are listed below and were presented to the Forum Participants for discussion. Commentary from the discussion was captured and noted.

Topic	Need	Participant Suggested Best Practice or Action
Data and Systems	Collection	· Build infrastructure to collect additional data not consistently being captured today (e.g., ethnicity, socioeconomic factors). · Broaden data collected from research by increasing diversity in clinical trial participation and conduct real-world studies.
	Quality/Integrity	· Utilize and enforce current data standards such as ICD-10 codes; expand standards (e.g., National Council for Prescription Drug Programs (NCPDP) to require Z codes for Social Determinates of Health (SDOH)
	Interoperability	Integrate systems to leverage all available data; link together for ease of analysis.
	Accessibility	Establish greater accessibility through more timely and transparent shared evidence generation; allowing data to follow patients.
Education	Tools and frameworks	Provide opportunities for user training on existing tools and frameworks.
	Pharmacoeconomics	Increase expertise in Pharmacoeconomics (PE) analysis with additional formal education opportunities (e.g., fellowships, graduate programs) and increased awareness of current PE applications.
	Value	Raise awareness of current applications of the value assessment process.
	Trust	Drive trust to across stakeholders through validated value assessment formats and transparent rationale for value assessment.
Payers and Coverage Decision Makers	Committees	Prioritize clinical factors in coverage decisions; consider utilization management and economic factors separately.
	Benefit design	Allow true value-based benefit design by removing limitations (e.g., redesign qualified high-deductible plans to cover non preventive but high value at no cost).
	Cost	Transparent cost analysis to allow the most efficient decision making and clear communication of cost to all stakeholders.
	Access	Ensure fair access by utilizing innovative tools (e.g., value-based agreements).
Tools and Frameworks	Patient perspective	Consider meaningful clinical outcomes in trials; incorporate ICD-10 Z codes to describe social risks or needs.
	Subpopulations	Leverage innovation (e.g., digital biomarkers, sensors) for data collection and inputs to potentially increase identification of subpopulation specificity and integrate health equity.
	Generalizability	Incorporate patient-level data to understand how the results may impact a specific plan population.
	Flexibility	Create flexibility in tools and frameworks to allow modeling of various scenarios, populations, and plan designs.

Topic	Need	Participant Suggested Best Practice or Action
Health care Industry	Shared vision of value	Articulate a national, shared vision of the meaning of value with flexibility for the intended population and plan.
	HTA expansion	Expand the availability and use of HTA via public and private collaborations; developing better methods for non-drug evaluations.
	Funding for HTA analysis	Employ a PDUFA-like mechanism that includes a feedback process from all relevant stakeholders.
	Legislative initiatives and national standards	Formulate national industry standards related to HTA; improve transparency of current pricing structures and input.
	Incentives	Recognize value for the patient population with appropriate coverage; consider other direct and indirect incentives that might be useful to capture additional value.

HTA = health technology assessment; PDUFA = Prescription Drug User Fee Act; SDOH = Social Determinants of Health; Z codes = ICD-10 codes used for social, economic, and environmental determinants

Data and Systems

Needs highlighted by participants focused on collection, quality, integrity, interoperability, and accessibility of data. Suggested actions offered by participants included building infrastructure to collect additional data elements, such as demographic and drug side effects, which are less likely to be captured today. To broaden data collected from research, participants suggested increasing diversity in clinical trial participation and conducting real-world studies. Another action recommended by participants was to use and enforce current data standards, such as ICD-10 codes to ensure data quality and integrity. Additional actions included the following: integrate systems to leverage all available data (e.g., data available through electronic medical records), link data components together for ease of analysis, establish greater accessibility of data through more transparent shared evidence generation, and allow data to follow patients.

Education

Educational needs emphasized by participants included user training on existing tools and frameworks as well as additional formal pharmacoeconomic education opportunities, such as fellowships and graduate programs. Raising awareness and education of their current applications and ongoing efforts to advance and improve frameworks will increase trust and confidence in value assessment results. Increasing education and awareness should be across all areas of health care and all stakeholders, including coverage decision makers, employers, providers, and patients.

Coverage Decision Makers

A best practice identified was to prioritize clinical factors in the process of making coverage decisions and to consider utilization management and economic factors in separate expert committees. Additional best

practices include ensuring fair access by applying a broad definition that encompasses factors, such as cost, transportation needs, and geographic considerations and that include utilizing innovative tools, such as value-based agreements.

Participants proposed allowing true value-based benefit design by removing current limitations. For example, in a value-based benefit, payers might remove deductibles from high-value products to encourage their use. However, in high-deductible health plans today, this is prohibited for non-preventive products.

HTA Tools and Frameworks

Key needs for HTA tools and value assessment frameworks identified by participants included incorporation of the patient perspective, the ability to identify subpopulation results, and the flexibility to model the effect of potential impacts in various scenarios and populations. To meet these needs, participants recommended actions, such as utilizing ICD-10 Z codes to describe social risks or needs and leverage innovation for increased data collection from sensors, digital therapeutics, and electronic medical records (EMRs) at the patient level.

Health Care Industry

Participants supported the expanded availability and use of HTA by encouraging public and private collaborations and improving methods for non-drug evaluations, such as surgical procedures and medical devices. Participants encouraged the articulation of a national, shared vision on the meaning of value. They acknowledged that factors highly valued in the United States, like choice, may differ compared to other countries with more established national HTA programs. Participants also recognized the need for funding and proposed a PDUFA-like funding mechanism developed to include a data feedback process from all relevant stakeholders. Lastly, participants called for AMCP to support these educational goals with activities, including interactive workshops on value assessment tools or through various other paths, such as webinars, learning sessions, handouts, and collaboration.

Additionally, participants promoted the need for industry best practices, such as standards related to HTA and increased transparency of current pricing structures that utilize 340B Drug Pricing Program and rebates.

Limitations

This Partnership Forum has limitations, which can include a different mix of stakeholders or individuals resulting in alternative discussion outcomes. During breakout groups, participants were provided prepared topics and considerations to focus their discussions; without these, the groups' discussions may have encompassed different topics or addressed different considerations.

Conclusion

Over two days, experts from across the health care industry came together to outline considerations for how value in health care should be recognized in a system of constrained resources. The forum explored the evolution of value frameworks to guide coverage and reimbursement decisions and identified educational needs and managed care tools to aid the application of value assessment findings. A key theme from the forum was

the challenge of defining value, how the definition may vary based on perspective, and that increasing value through innovation and validated through robust data analysis should be recognized. Additionally, while utilizing value assessments is one part of determining coverage and reimbursement, all stakeholders advocated for the need for additional value assessments to be conducted by trusted sources. Participants identified best practices and actions to improve value assessment through more robust data collection, sound analytical systems, and increased education on value assessment tools and frameworks across the health care industry.

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