Pink Sheet
Pharma intelligence | informa

As Drug Value Frameworks Gain Traction, Patients Seek More Input

By Cathy Kelly

'PATIENTS ARE READY AND WILLING TO have conversations' about trade-offs, National Health Council's Perfetto says.

• • •

Patient groups could have a key role in shaping drug value assessment frameworks as the tools evolve and move toward solidifying a role in prescribing and coverage decisions, according to comments at an International Society for Pharmacoeconomics and Outcomes Research meeting on value frameworks Sept. 23.

Two key takeaways from the meeting were:

1. The frameworks are here to stay, despite continued opposition from drug firms to many of them, and
2. There is an opportunity for patients to influence how the frameworks are structured and used.

The meeting was held as part of a new ISPOR initiative to develop best practice recommendations on the appropriate definition and use of value frameworks for drugs.

Drug manufacturers are also expected to take advantage of the opportunity to participate in the ISPOR effort, which includes employees of the Pharmaceutical Research and Manufacturers of America on its steering committee. Manufacturers have opposed the new frameworks based on concerns they will influence prescribing or coverage decisions based on a narrow set of cost and effectiveness metrics that may not allow for different patient preferences, among other issues.

Health policy expert Mark McClellan welcomed the ISPOR initiative in the keynote address at the meeting. "This is the year of value frameworks isn't it? There are a lot of them out there and it's time to undertake an effort like this one to make sure we're getting it right," he said.

McClellan is director of the Robert J. Margolis Center for Health Policy at Duke University and was formerly FDA commissioner and administrator of the Centers for Medicare and Medicaid Services.

He noted the drug value frameworks so far offer only "incremental" resources to prescribers and payers. However, he added, "one of the emerging uses [for the frameworks] and reason I think this is really the year of value frameworks, is that we are moving into payment reforms that are explicitly, at least in name, about value."

> **The "reason I think this is really the year of value frameworks, is that we are moving into payment reforms that are explicitly, at least in name, about value" – Mark McClellan**

Nevertheless, he emphasized, "you can't have value-based payment without a value framework underlying it ... that a lot of different stakeholders, particularly patients, actually have confidence in."

McClellan added "to the extent that these value frameworks are moving along and becoming more widely used, the ones that are gaining the most traction are the ones that don't just talk about focusing on patients but actually have credibility for capturing what really matters to patients."

As ISPOR and framework developers fine tune the tools, McClellan suggested "a good focus should begin with

getting a model that stakeholders can broadly accept. Thinking carefully about matching a value framework with its intended purpose and audience is important for that."

He advised "thinking carefully about what constitutes the elements of value. Is it just outcomes? Is it reduced anxiety? Is it other impacts of treatment such as productivity, maybe reduced infection rates? All of those could potentially go in."

The value frameworks have grown out of the private sector in the US, which differs from Europe, where many such evaluation tools have come from the government. Most of the US developers are health care providers and a number of the frameworks so far focus on oncology drugs (*see box below*).

In general, the value frameworks use comparative effectiveness analyses in a systematic way to assess the value of a drug relative to its cost. But the existing frameworks vary in their approach to evaluation and in their targeted end user *(Also see "Scoring Value: New Tools Challenge Pharma's US Pricing Bonanza" - In Vivo, 21 Oct, 2015.)*.

Frameworks developed by the American Society for Clinical Oncology, the National Comprehensive Cancer Network and the American College of Cardiology with the American Heart Association are geared mainly toward assisting physicians and patients with prescribing decisions. *(Also see "Oncology Drug Value Tools From NCCN, ASCO To Get Real-World Testing" - Pink Sheet, 3 Dec, 2015.)*

DRUG VALUE FRAMEWORK SPONSORS IN THE US

- American Society for Clinical Oncology
- National Comprehensive Cancer Network
- American College of Cardiology/American Heart Association
- Institute for Clinical and Economic Review
- Memorial Sloan Kettering Cancer Center/ RealEndpoints
- FasterCures/Avalere

Quantification Is The Challenge

A framework developed by the non-profit Institute for Clinical and Economic Review (ICER) is aimed at guiding reimbursement policies. *(Also see "ICER Eyes QALY Ratios, Budget Impacts In Methods Review" - Pink Sheet, 28 Jul, 2016.)* The ICER evaluations encompass comparative effectiveness, cost-effectiveness and budget impact elements.

The framework sponsored by Memorial Sloan Kettering Cancer Center in collaboration with research and consulting firm RealEndpoints, is meant to inform patients and policymakers about the value of cancer drugs relative to their price. *(Also see "'DrugAbacus' Pricing Tool Helps Payers Calculate Fair Value Of Cancer Drugs" - , 19 Jun, 2015.)* RealEndpoints' RxScorecard also produces value scores for multiple drugs, both marketed and in development, across categories.

The framework developers offered ISPOR suggestions at the meeting regarding key issues that should be considered for frameworks. For example, ICER Chief Science Officer Dan Ollendorf pointed out "if there is an attempt ... to come up with a quantified value framework that has multiple attributes but is still quantified only, you're going to hear from the patient community and I don't think it's going to be pretty.

"There are certain constructs that just can't be quantified because they're so disease-population specific that it would be difficult, if not impossible" to do so, Ollendorf said.

RealEndpoints CEO Roger Longman said that "any value framework that is going to be accepted and used has to reflect multiple points of view around value definition. If it can't do that, it will not be used." He explained that different points of view can be accommodated by "customizing the weights of each of the elements to reflect the relative importance within your decision-making. There is no one-size-fits-all analysis."

Patient-Focused Framework Planned By FasterCures, Avalere

A new value framework for drugs, designed to primarily represent the patient perspective, is being planned by research advocacy organization FasterCures in partnership with Avalere Health.

The framework will address the value and cost of treatment to the individual patient, as well as the strength of evidence underlying an assessment of value. It will seek to support shared decision-making between prescribers and patients and to include a patient-friendly tool that is easily understandable.

The groups plan to present a draft version of the framework at the Faster Cures "Partnering for Cures" conference in mid-November.

The frameworks are all continuing to evolve and ISPOR will work to help direct their progress with development of a policy white paper. A draft version is scheduled to be released in early 2017.

Expanding The Breadth Of Cost-Effectiveness Analysis

The initiative was prompted by the determination that "each of the recent value frameworks has strengths and weaknesses but those vary and each has important limitations," according to a tentative work plan for the project.

In addition, the group determined that "expanding the breadth of cost-effectiveness analysis has the potential to capture and reflect some ... other elements of value that can be important for health sector decision-making." ISPOR President Lou Garrison, professor emeritus of the University of Washington School of Pharmacy, told the meeting that the patient perspective will be an important contributor to those additional elements of value.

Garrison also noted that ISPOR will have to consider "trade-offs" between the various attributes of value that go into the framework.

National Health Council Senior VP Eleanor Perfetto agreed, pointing out that "patients are ready and willing to have conversations about those trade-offs. They're just usually not included in the conversation. And if they're included [in deliberations] early enough, you'll find out there are some attributes you can take off the list and not even ask them to trade off because they don't care about them."

Published online April 7, 2017