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Dr Clifford Goodman Outlines Takeaways From a Health Economic Case Study on Repatha

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During an industry workshop at the Academy of Managed Care Pharmacy Annual Meeting in Denver, Colorado, Cliff Goodman, PhD, of the Lewin Group, moderated a session that provided a health economic case study on cardiovascular outcome data for Repatha (evolocumab), the PCSK9 inhibitor from Amgen.

Study results on Repatha's ability to cut cardiovascular death, heart attack, or stroke were recently presented at the 66th Scientific Session of the American College of Cardiology.

Goodman moderated a discussion between speakers Ransi Somaratne, MD, FACC, of Amgen, and Tanya GK Bentley, PhD, of the Partnership for Health Analytic Research, LLC, and recapped the takeaways of the discussion.

What was the key takeaway from the workshop?
The 3 main points of the workshop were basically that, whenever we seek to evaluate the value of a product the modeling inputs matter. The results of these value assessments depend and are driven by the assumptions we make in the inputs to the models. That's the first point. So when you evaluate the value of a product, you've got to pay close attention to the modeling inputs.

The second one, because this was a cardiovascular therapy, is that it was clear that the main determining factors of the modeling assessment were the efficacy of the therapy in the indicated population and the cardiovascular event rates that were entered into the model. And by cardiovascular event rates, I mean the rate of cardiovascular events that would be experienced in the target population.

And then another point is that, if you ascribe to general accepted thresholds—or I should say, ascribe to increasingly accepted thresholds—of cost-effectiveness based on cost per quality-adjusted life-year (QALY) gained, I was just the moderator but the analyses presented by our expert speakers suggest that this product, evolocumab, would be cost-effective. I would say it might be in the neighborhood of

approximately $100,000 to $150,000 per QALY gained. And importantly, that result depends on the use of available data, and the available real-world data, on cardiovascular event rates.

So those are the 3 main points: the first one was modeling inputs matter; the second one was, in cardiovascular therapies, efficacy and real-world cardiovascular event rates matter; and the third one is that if we kind of roll these assumptions and data sources and if we ascribe to increasingly accepted cost-effectiveness thresholds (eg, between $100,000 and $150,000 per QALY gained), it would appear that this therapy is cost-effective.

Stakeholders have different ideas of what value is, so what factors should drive value assessments?

We must recognize that different stakeholders necessarily have different economic perspectives; there is no one right perspective on value. Value looks different form the standpoint of a patient, a healthcare provider, a payer, and society.

Every stakeholder should consider their own perspectives regarding clinical impact, economic impact, and other implications. Every stakeholder should consider: Who are my target users? What information do they need to make a well-founded decision? And with regard to clinical impacts, maybe we care about individual and/or population clinical impact.

With regard to economic impacts, we care about anything ranging from patient out-of-pocket costs to national healthcare expenditures. So there's a range of clinical-economic impacts, as well as certain other implications about which we care.

By the way, other implications may include such matters as equity, impact on the broader strength of a regional or national economy, and potential impact on willingness to innovate. So those may be taken into account as well. And also, another implication to put in there is ability to meet unmet medical need.

What is industry's role in identifying value and cost-effectiveness?

As was made clear from this session, it is increasingly apparent that industry needs to be smart about anticipating the decision-making needs of its markets. And by doing that, industry can think early about what types of clinical and economic data need to be generated to influence, to inform and favorably influence, key decision makers.

Furthermore, in addition to this anticipation function, industry can, in some instances, help to educate and help inform decision makers about various biomedical, economic, and analytical matters that decision makers may not otherwise have known. So there's the anticipation function: who's going to

want what evidence, when?

And the other thing is, in some instances, industry can help educate informed decision makers so they will make better evidence-based decisions.

How do you expect the new administration in the White House will impact the move to value in healthcare?

I cannot speak to the specifics of the new administration on this issue; however, we see that leaders in the executive and legislative branches are calling attention to and scrutinizing some high-profile costs in healthcare and healthcare technology, including pharma and bio. And these leaders may benefit greatly from taking a broadly informed view about multi-stakeholder perspectives on value as opposed to only price tags on individual products and technologies. It's not just about the price tag; it's certainly relevant, but it's certainly one in multiple dimensions of healthcare.

Any last points from the workshop?

The session helped demonstrate that industry is listening and learning about what its markets value and is, by example, hearing in this session, is indeed generating primary and secondary data, including clinical economic, to help suppose those value assessments—industry is already responding.

Furthermore, we are seeing that the organizations in the United States that are taking different approaches to assessing value are increasingly aware of the need to modify, and continue to approve their methodologies for value assessment, including making certain improvements that had been suggested by industry.

The session helped illustrate that industry and value assessors are listening to each other and are trying to improve their approaches accordingly.