Commentary

ISPOR’s Initiative on US Value Assessment Frameworks: The Use of Cost-Effectiveness Research in Decision Making among US Insurers

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Editor’s Note

In Spring 2016, the board of directors of the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) approved the Initiative on US Value Assessment Frameworks to inform the shift toward a value-driven health care system by promoting the development and dissemination of high-quality, unbiased value assessment frameworks, by considering key methodological issues in defining and applying value frameworks to health care resource allocation decisions. This initiative enlisted the expertise of leading health economists, including several who are not ISPOR members, to focus on what the field of health economics can provide to help inform the development and use of value assessment frameworks.

The preceding seven articles represent the culmination of ISPOR’s Special Task Force Report on US value assessment frameworks. The following four commentaries were invited to solicit reaction from key stakeholder groups, including perspectives from payers, patients, academia, and the pharmaceutical industry. Most of the commentaries were written and presented as typical commentaries. Nevertheless, for the payer perspective, Value in Health conducted a formal interview with Brian Solow, MD, Chief Medical Officer of Optum and Edmund J. Pezalla, MD, MPH, Chief Executive Officer of Enlightenment Bioconsult LLC to discuss the use of cost effectiveness decision making among US insurers.

Do US payers use cost-effectiveness criteria in their coverage decisions?

Edmund Pezalla: Maybe they do. The answer is, with the exception of a couple of really small plans such as the Empire Plan that has special formularies constructed on cost effectiveness for employer-based plans, nobody has a clinical policy that says we’re constructing this on cost-effectiveness grounds. A lot of plans look at cost effectiveness and they use it to project what they might want to do if they’re signing an outcomes-based contract or if they’re actively trying to promote one treatment over another. But most insurers don’t have formal policies allowing them to use cost-effectiveness research in decision making. There are a few insurers that have policies that explicitly say you shouldn’t use cost effectiveness, where decisions are based on clinical or other grounds.

Brian Solow: I think that’s an important point. I think that one has to understand that when they say “coverage decisions,” the answer is sort of two parts. In general, in the United States, it starts with a clinical determination at a pharmacy and therapeutic level, where cost does not come into play. It’s generally inferred that it should be a clinically based decision about how a drug is classified for possible coverage. Then when the cost question comes up, that can go to a business unit that will have the input from the clinical unit. So, if perhaps there are a few drugs in the same category that treat the same disease and they would define them both in the same class of drugs, then they might look at the cost information and make a contract on the basis of that information. But the pharmacy and therapeutics folks won’t have seen that. They’ll say, “You’ll want to use Allegra or you’ll want to use Claritin. It doesn’t matter which you put on the formulary to cover, they’re both equivalent to us.” So, you can do your own analysis, contract, cost effectiveness, etc.

So, exploring that a little deeper, how would plans define cost effectiveness?

Edmund Pezalla: If they’re looking at cost effectiveness, generally we don’t have plans with that as a threshold. There might be some plans (we mentioned the Empire Plan) where they rank or order things depending on their degree of cost effectiveness. Generally, cost effectiveness is used when you have two or more treatments where you can’t tell the difference clinically ... they’re
all very similar. This is what managed care or pharmacy benefit managers (PBMs) pray for every day—where everything will have the same clinical efficacy, so that you can choose just on the basis of price. That is essentially doing cost-effectiveness—an overly simplified version, where if you can’t tell the difference clinically, you can go for the cheaper thing, and that thing is therefore, by definition, more cost effective.

Brian Solow: If you just went by cost effectiveness for coverage decisions in the United States, you can’t do that. Even if something has been found not to be cost effective, that doesn’t mean the plan doesn’t cover it. There are a lot of drugs we use that probably aren’t very cost effective, but we basically don’t have a choice. And that’s the difference between our country and many other countries.

So, is it a simplistic cost-effectiveness analysis based on which drug is cheaper, if they are generally equivalent?

Brian Solow: Yes, and the other aspect you have to consider is that cost-effective models don’t account for the deals that the four big PBMs (which control most of the lives in the United States) are getting. Many plans are not paying $1000 for that drug, they’re paying $200. So, all the models of cost effectiveness, no matter who has done it (the Institute for Clinical and Economic Review [ICER], Boston, MA or whomever), may not really have any bearing because the models don’t know the true cost that the plans end up paying for the product.

Do you think expanding the list of considerations in cost-effectiveness analyses (i.e., severity of illness, value of hope, insurance value, real option value, or other elements suggested by the task force) would be useful to payers in their coverage decisions?

Brian Solow: I think not as much here in the United States as perhaps somewhere else. I think severity of illness is important, but when they talk about value of hope, insurance value, and option value, these are hard to quantify. Ed and I have been in this field for the past 15 to 20 years and we have not seen much of those types of issues come up. It becomes very clinical and then jumps very quickly to the finances. A drug has to clear that first clinical hurdle, because after that everything is ... I won’t say easy, but it’s doable. They still have to show clinical value.

It used to be that the drug companies would try and make up all these orphan drugs (i.e., the only drug to treat a certain disease). But I think even recently, we’ve seen new drugs for conditions such as muscular dystrophy, and some plans have decided that the value of these drugs is not worth it. And it’s the only drug for that disease, but they’re not covering it.

Edmund Pezalla: I agree with Brian. Payers are really focused on the clinical aspects first and then the cost. The other things mentioned, such as the insurance value and value of hope, are important, but they’re really more important from a societal point of view. And when you’re doing cost-effectiveness analysis, you have to clearly indicate whose point of view you’re using. There’s a societal point of view and a patient point of view. And most payers in the United States do not calculate reimbursements from the societal point of view. It’s a contract between them and the member to provide certain types of services, but there’s no additional payment for the societal value being added. So, if you’re a policymaker, you would take some of these things into account, especially if you’re a policymaker who has some responsibility for there being treatments available. The "option value," for example, is about keeping patients alive now because if they don’t die from cancer this year, they may be alive long enough to receive a new treatment in the next year. Although that’s a benefit to the patient, there’s really no way to take that into account in what you’re paying for insurance.

That’s part of the problem—we’re applying these ideas to decide what treatments we pay for, but we don’t apply these ideas when we come up with the premiums. There’s a disconnect.
How important is it for decision makers to allow for external considerations when they modify the choice of therapies?

Edmund Pezalla: It’s an important question if you’re using cost-effectiveness for decision making. At NICE, for example, they have to say to themselves, “Yes, we know it’s really cheap to treat this type of patient because we have a lot of generic medicines to treat blood pressure problems. But it’s really expensive to treat other conditions such as rheumatoid arthritis.” So, the question is if you’ve got a QALY threshold, you’re discriminating against patients whose treatments are expensive. We avoid that by not actually using thresholds, to be perfectly honest. And that’s one of the reasons why cost effectiveness hasn’t picked up and caught on in the US health care system, because there’s a lot of suspicion about cost-effectiveness analysis.

There was a “Letter to the editor” in JAMA Internal Medicine a few years ago mentioning how citizens in the United States were interviewed about using cost-effectiveness analysis in health care, and they were given an explanation of what it was and asked some questions. People were soundly against it because it brought too much cost into the equation, which they felt should be answered clinically.

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