Q&A

OPPORTUNITY OFFERED BY A GOOD CRISIS:

COVID-19 IMPACT ON INNOVATIVE PRICING MODELS

Interview With Roger Longman, Cofounder and Chairman of Real Endpoints LLC

"The takeaway from COVID-19 should be that it is easier to prevent a case than to treat one. The same logic can be applied to cancer detection and treatment."

Balancing the needs of patients, healthcare systems, drug manufacturers, and investors has never been trickier. The old model of banking on innovation to drive sky-high prices has long since expired. Payer pushback is leading to access restrictions that are not only affecting patients on the front lines but also negatively impacting companies' bottom line. Innovative drug pricing and value-based contracting models may be solutions for getting the price equation right from the outset.

This month's interview with Roger Longman of Real Endpoints LLC, a leading reimbursement-focused analytics and advisory firm, discusses innovative and value-based contracting models currently in use and reflects on the downstream effects of innovative pricing on patients and their out-of-pocket costs. As a recognized expert in biopharmaceutical strategy and reimbursement, Roger provides keen insight into the practical challenges payers face in implementing innovative contracting models in different healthcare systems.

VOS: We often hear about "innovative" contracting versus "value-based" contracting. How does this relate to innovative pricing; are they the same idea, as in 2 sides of the same coin?

Longman: I tend to view both as aspects of risk sharing that move us beyond volume-based reimbursement. We've now worked on many biotech/payer transactions in which a biotech agrees to more or less guarantee that a drug or diagnostic will perform based on certain benchmarks (eg, reduce specified costs, achieve particular clinical results—either measured directly or by proxy). And we've worked on agreements that cap a payer's or health system's cost for the drug or diagnostic.

In both cases, one could argue that the agreements are "value-based." In the former, the drug must deliver the promised value; in the latter, the parties together determine up front the value of the drug to the buyer's population. But they are also both risk-sharing deals. In the former, the payer pays a higher price if the drug works and the pharmaceutical company gets a lower price if it doesn't, and in the latter, the buyer agrees to buy a certain amount of drug, whether needed or not. The pharmaceutical company could end up getting a lower net average price if the buyers uses more drug than expected. And pricing is "innovative," that is, the real average net price isn't pre-determined—as with a traditional rebate-for-volume contract—but can change based on circumstances.

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VOS: The innovative contract often seems to come from the "buyer" side in reaction to a perceived high price. That being said, would you say that the biotech and medtech companies are now thinking about these ideas prior to setting a price?

Longman: I can't really speak to many medtech examples (apart from diagnostics). Most devices are sold to hospitals, where risk-sharing programs are less scalable and economically less meaningful to payers, and thus a lower priority. But for biotech, absolutely. In virtually every therapeutic category (with oncology a possible exception), only the most blinkered biopharmaceutical company wouldn't fully road test an innovative contract strategy. Payers are simply too powerful; they have the tools (and are creating more) to at least significantly slow down access, and more often shut it down.

But to quibble with how you phrase your question: Buyers may expect an innovative contract proposal from a biopharmaceutical company, but they don't want to develop the innovative contract and don't have the resources to do so. The structure must come from the biotech, and that structure has to allow for straightforward implementation and adjudication, create economically meaningful incentives, and define an independent, credible administrator to manage the analytics and financial reconciliation.

VOS: What are the biggest challenges to implementing an innovative contracting model, and do the challenges differ depending on the type of healthcare/payer system (eg, private payers versus single government payer)?

Longman: I'll need to divide the answer into the very big issues and the smaller, practical ones, as both are significant obstacles.

Starting with the very large: In my view, the most innovative recent arrangement was the one negotiated between Britain's National Health Service (NHS) and The Medicines Company (now part of Novartis). It did something the United States couldn't do: agree to buy a large volume of drug based on a preset price that ensured its cost-effectiveness, before the drug is approved. If the Centers for Medicare & Medicaid Services (CMS) or the Veterans Health Administration or any US or state government was allowed to do that, it could change things dramatically.

Another issue: Medicaid best price rules, and the opacity of how they might be applied, often limit the level of risk that biopharmaceutical companies are willing to take. CMS could change that rule with a stroke of the pen, and they should.

Perhaps most importantly, however, our private healthcare system by and large doesn't incentivize payers to make decisions based on the real value of the intervention. They're not paid to take the long view and thus don't value benefits that won't be realized for years (beneficiaries shift in and out of health plans too often). In addition, they by and large won't prioritize one kind of intervention over another based on a societal definition of value. When social benefits, even ones with long-term economic benefits, run up against short-term shareholder interests, the latter generally win.

This is not to say that the United States is immune to innovative pricing and contracting. There's plenty of activity, but it's often stymied by the practical challenges: is the contract easy to implement (eg, whether the endpoint around which the contract is constructed can be easily measured, generally through claims data)? The smaller the therapy's economic impact on the plan, the simpler the deal's management has to be. Is there an independent third party doing the analytics and financial reconciliation work that the payer doesn't have time to do and doesn't trust the pharmaceutical company with? For example, a payer has recently asked us to help with one agreement in particular in which, for an orphan drug, it has had to set up in effect a patient registry to track drug discontinuation by a fairly complicated set of timing metrics. That's a deal that other payers will learn to avoid, unless the pharmaceutical company sets up a third party to do the analytics.

And one category has been particularly resistant to innovative pricing and contracting: oncology. In the first place, CMS significantly curtails any incentives biopharmaceutical

companies have to negotiate on price by including the category as a "protected class" and covering drugs not by labeled indication but by the indication's inclusion in one of the approved compendia, like National Comprehensive Cancer Network. Private payers generally follow the government's lead. Meanwhile, oncologists and the provider systems who increasingly employ them generate significant income through the buy-and-bill system. And they get paid more, thanks to the buy-and-bill system, for using more expensive drugs. Payers are beginning to exert more influence on pharmacy benefit oncologics, and as they do, pharmaceutical companies will likely start to explore innovative contracting in cancer as well as other categories.

VOS: What type of innovative contracting model has gotten the most traction (ie, subscription, dynamic- or indication-based, pay-as-you-go) or does it depend on the underlying patient population, meaning orphan disease versus hepatitis C?

Longman: Innovative contracting is most active today in rare disease drugs. Certain companies, like Alnylam and bluebird bio, are philosophically committed to them. That's not to say that innovative contracting is absent from chronic disease drugs. We've just finished a project with discussions between one large pharmaceutical company and several health plans on a major primary care therapeutic. But it is true that payers have the most interest in innovative deals for drugs that will constitute new spend, that is, spending they can't predict—like orphans, where the small numbers of patients make individual-plan prevalence predictions challenging—or that is likely to be significant. In terms of structure, most plans are looking at outcomes-based agreements, with clinical or economic endpoints. Subscription (or cost-capped plans) are still relatively rare, although increasingly of interest.

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VOS: What does the future of innovative pricing look like, especially with the pandemic now top of mind? In other words, does a public health emergency overshadow the need for innovative pricing with vaccines becoming a public good?

Longman: If you're asking, will the pandemic force companies to price COVID-19 vaccines and therapeutics innovatively? The answer is, probably. What I wonder, however, is whether the enormous costs we've incurred as a result of the pandemic won't at least encourage government to think differently about other major diseases (eg, cardiovascular, diabetes, respiratory) that kill more people each year than COVID-19 will. In virtually all these cases, we wait until the situation is acute, when our treatments will be least successful and most costly.

The takeaway from COVID-19 should be that it is easier to prevent a case than to treat one. The same logic can be applied to cancer detection and treatment. We focus our resources by and large on treating cancer, often in later stages at very high cost. There are burgeoning technologies from venture-backed companies that can detect dozens of cancers far earlier than is possible with current technologies and thus enable treatment far less expensively and with far greater efficacy. But in each case, payers will be required to make an upfront commitment, with payback over the long-term. I discussed in an answer to one of your previous questions the innovation represented by The Medicines Company/Novartis/NHS deal: it is certainly possible for a government to have learned a lesson from COVID-19—either buy early and cheap, or buy late and expensive—and apply it to our country's biggest medical problems.

VOS: Is there anything else you'd like to add or that we haven't asked you that you feel is important for our audience to know about innovative pricing models?

Longman: One thing we haven't discussed related to innovative pricing is patients and their costs. The actual net price of drugs paid by payers is often utterly unrelated to the price the patient pays. And those costs are often unaffordable. Once a patient's cost is over $50, they abandon prescriptions at rates starting at 30%. Payers, driven by their employer customers, charge these copays to help mitigate their own rising drug costs. And there's some rationale for it: copays steer patients to the drugs that plans and pharmacy benefit managers prefer, drugs that work pretty well for most and are usually cheaper for the plan. And if patients share in the costs, they should make cost-effective decisions about their treatment. But payers' response to COVID-19 weakens this argument. All of the top insurers have expanded access to (and cut patient costs of) telehealth services; eliminated patient cost-sharing for COVID-19–related diagnosis and treatment; and waived or at least increased refill limits on prescriptions. They've done this because they know that patients will avoid testing and treatment if their costs are too high.

Meanwhile, the pharmaceutical industry has developed a complex set of patient support programs, mostly focused on copay assistance, to do what payers have largely just done in response to the COVID-19 emergency. Payer copays and the pharmaceutical industry's copay assistance are managerially completely disconnected. Payers want to use copays to steer patients away from one brand to another or away from branded therapy entirely; the pharmaceutical industry wants to make sure patients can get the drugs they're prescribed.

I don't pretend this challenge is easy to solve. I suspect that government incentives should be part of the answer. Government is certainly a major player here, with CMS's rules forbidding copay assistance for Medicare patients who also, unlike beneficiaries with employer coverage, often face uncapped out-of-pocket costs. But there are certainly innovative solutions out there, including capped out-of-pocket copays.

And now that payers, thanks to COVID-19, are experimenting with new copay programs, we shouldn't waste, as I believe Machiavelli suggested, "the opportunity offered by a good crisis," and instead directly address the medical problem of increasing patient out-of-pocket costs."