U.S. Presidential Mandate on Value-Based Drug Pricing – Moonshot or Wormhole?

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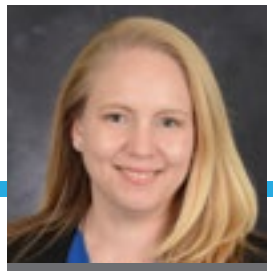
What's old is new again, and value-based drug pricing is anticipated to be the cornerstone of a soon-to-be-released U.S. presidential executive order on drug pricing. Building on consultation with industry and government experts, the executive order is the policy follow-up to statements from President Trump's January 11TH press conference promising to "create new bidding procedures for the drug industry because they're getting away with murder" that will "save billions of dollars over a period of time." Simply by placing the terms value and pricing in proximity, the initiative generates hope that drugs will become a better value for patients and that recent examples of exploitive pricing (e.g., Daraprim, EpiPen) don't become a regular occurrence. But is value-based pricing really a prescription for large-scale savings?

The concept of value-based pricing of pharmaceuticals is not a new one – it has appeared in many forms in different countries, including the U.K. and Italy, for more than a decade with many reported agreements in the U.S. over the last few years. Value-based pricing can also be referred to as outcomes-based pricing, performance-based risk sharing, or financial risk sharing. The approach is attractive for linking the price paid to achievement of specific outcomes or metrics, implying payment only for the value achieved or the risk avoided. It sounds empowering – a bit like the classic consumer money-back guarantee – but the reality is, of course, more complex. Imagine this model applied to the EpiPen. Would you be happy if Mylan, the maker of the EpiPen, simply paid you (or your heirs) and your health plan back for the cost of your EpiPen if the pen failed to work and you were rushed to the hospital? Would you be happy continuing to pay about $600 for it every time your allergic reaction resolved as expected when it used to only cost $100? Maybe not.

Value-based pricing models could allow payers to share the financial risk of a drug not working at all, not working as well as planned, or not working well for every patient within their plan. Drug makers would pay a full or partial rebate of the list price of the drug based on the drug's real-world performance.

However, certain negotiating dynamics must prevail between payers and manufacturers to make value-based pricing agreements, well, valuable. Today, U.S. payers offering commercial and Medicare Part D plans generally negotiate rebate agreements, often volume-based, with drug manufacturers based on their internal Pharmacy and Therapeutics (P&T) Committee's assessment of a drug. These assessments are largely focused on evaluation of clinical trial data on efficacy and safety balanced against cost. The core of manufacturer-payer negotiation today focuses on balancing access restrictions against price concessions – essentially, what cost (in discounts or rebates) is the manufacturer willing to pay to make the therapy available to more patients, and how far is the payer willing, and able, to go to block patient access to the drug?



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For payers and manufacturers both to have interest in pursuing a more complex, value-based pricing arrangement rather than agreeing only on a simple discount or rebate for a specific drug, they must have both the means and the motivation to put an arrangement like this in place. That depends primarily on four factors, which are outlined below.

Since these conditions will differ across payers based on their experience, plan structures, and patient populations, as well as across manufacturers and individual drugs, a broad mandate on value-based pricing will be difficult to construct, and likely even more difficult to put into action.

To date, use of these agreements in the U.S. has not been widespread, although a recent growth in use suggests increasing interest and importance on all sides. Assessing the number and content of value-based pharmaceutical pricing arrangements in the U.S. is challenging – the specifics of the contracts are highly confidential and both parties must be in agreement to make the deals public. As of June 2016, the University of Washington's Department of Pharmacy reported a cumulative 46 U.S. performance-based risk-sharing agreements were tracked in their database since 1997, but with no indication of the number of those agreements still active.[1] Harvard Pilgrim,[2,3] Aetna,[4] Cigna,[4,5] Humana,[6] Anthem[7-9] and others have all

Uncertainty	**Clinical evidence presents uncertainty** Clinical trials with single arms, surrogate endpoints with weak validation, or data confounding create greater uncertainty regarding the benefits of a novel drug. If the U.S. Food and Drug Administration (FDA) becomes less stringent on clinical trial design, as proposed by the current administration, frequency of uncertain outcomes may increase. Managing the uncertainty associated with a drug's potential benefit is the most powerful argument for value-based agreements, as there are likely to be dichotomous views on the probability of benefit, with greater optimism on the part of manufacturers and greater skepticism from payers.
Control	**Therapeutic alternatives available** Payers have limited ability to restrict when there are few or no alternatives available, and manufacturers have limited motivation to offer price concessions when they are the only game in town. **Lack of mandates and protections** Part D plans are subject to Centers for Medicare and Medicaid Services (CMS) rules on protected classes of drugs, such as those for transplant rejection. The coverage mandate may limit negotiating power.
Incentives	**Unsuccessful existing rebates** Payers will not be motivated to replace existing and proven volume-based rebates with less-certain performance-based agreements. **Potential benefit exceeds operational costs** Tracking patient use and outcomes is inherently more time consuming and costly than tracking prescription volume, and assessing the potential value and performance of treatments to inform contract design requires time and significant actuarial skill. Payers will need to expect worse outcomes than the manufacturer expects in order for both parties to agree to terms they each find acceptable.
Implementation	**Outcomes must be** • **Meaningful:** Both parties must agree on a measure of interest, relevant to the drug and patient population, and relevant to cost or quality measures that impact a payer. • **Measurable:** Measuring the outcome of interest must be feasible within the payer's covered lives and within the process of patient care, without adding significantly to provider or patient cost or time. • **Proximal:** With member turnover frequency generally assumed at two years and contract duration often shorter, outcomes that take a long time to mature may generate limited interest. **Appropriate use is manageable** Both payers and manufacturers may be concerned about ensuring appropriate use, or at least accounting for it in an agreement. Use of the drug in the "wrong" population or in an unexpected way (e.g., intermittent vs. continuous) can impact performance and therefore financial outcomes.

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publicly announced that they've made such agreements for products such as Entresto, Praluent, Repatha, Trulicity and others. The frequency of announcements of contracts certainly seems to be increasing, but the number and scope (number of patients affected), as well as the impact on price, are not transparent in public disclosures. Regardless, the frequency is likely to continue to increase if only because there is public relations value in announcing agreements – pharmaceutical manufacturers get credit for being flexible on pricing, and insurers get credit for being innovative and tough negotiators for their customers and members. The impact of a broad government mandate will be interesting to observe, given the diversity of private entities and public players, at the national and state level, involved.

Value-based pricing is potentially a valuable solution to the financial risk associated with the uncertainty of a drug's performance in the real world, or over the longer term.

But how do we ensure that the starting point for the risk sharing is meaningful? Going back to the EpiPen example, where do we start the value-based negotiation, $600 or $100? Clinical groups like the American Society of Clinical Oncology, non-profits like the Institute for Clinical and Economic Review, and numerous other stakeholders are generating public debate on how we assess baseline drug value, but an outcomes-based contract that uses current prices as its starting point is not likely to yield much in terms of savings.

Gaining experience with value-based contracts is likely to increase in importance for both manufacturers and payers. If guidelines for regulatory approval are relaxed and the overall level of uncertainty on value increases, developing value-based agreements may become a more critical tool to enable payers and manufacturers to mitigate against the financial risk associated with data uncertainty. However, it is likely to take a long, long time – if that point can ever be reached or measured – before a presidential mandate on value-based pricing yields dramatic savings for payers or patients. Nonetheless, performance-based agreements are increasing in prominence and may become an increasingly important tool for bridging the value divide for manufacturers introducing highly innovative therapies with great clinical promise, but limited immediate proof. ■

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