Pay-for-Performance and Drug Pricing: Impact and Response of Pharma
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Published March 2016
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# Pay-for-Performance and Drug Pricing: Impact and Response of Pharma

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Research objectives and methodology

Objectives
This FirstView Dossier Advisory report provides a detailed review, including multiple perspectives, of the core issues facing the American specialty drug market. Innovation is on the rise, as the FDA has approved over 40 new drugs in each of the past two years. About 60 percent of these approvals are specialty drugs, such as biologics and other injected agents. Pricing at launch for specialty drugs is high, and price increases in the following years tends to far outpace inflation. In response, payers, both public and commercial, have championed the shift from pay-for-service to pay-for-performance, placing the onus on manufacturers to demonstrate the value of their high-priced drugs in terms of improved care and outcomes. Even Medicare, which is excluded specifically from using its vast size to negotiate pricing with the industry, is developing experimental programmes that will rapidly invest in value over volume.

Significant challenges remain on key market-shaping issues, as many payers, physicians and patients see US Pharma pricing as “unsustainable.” In response, much progress has been made by Pharma in the past two years to improve the quality of Phase III and IV research programmes to include more appropriate active control groups and clinical outcomes, rather than surrogate measures.

Along with these programmes, commercial ventures that drive pharmaceutical sales, including insurance companies and pharmacy benefit managers (PBMs), will be analysed for the purpose of this report. The focus is on competing pricing pressures in the US, which include forces that are seeking to lower costs at a time when pricing for innovative drugs has been moving inexorably higher.

The objective is to provide the reader with a clear understanding of the battle-lines being drawn, and the intricate ways this “chess match” is being played by the relevant parties. Case studies are interwoven, which focus, for example, on the price war in the curative oral treatments for hepatitis C, and the lack of price competition among immunotherapeutic checkpoint inhibitors to treat non-small cell lung cancer.

Key questions that were asked of experts during the course of the research included:

- How is Novartis’ offer of pay-for-performance for a novel drug to keep heart failure patients out of the hospital being received by payers, given limits of
technology to unify specific patients, drug utilisation patterns, and clinical outcomes, relative to standard-of-care with a generic agent?

- The uptake of the newly launched expensive PCSK9 drugs has been slow, with the cooperation of manufacturers, Amgen and Sanofi/Regeneron. The latter are focused currently on small genotypic subgroups, waiting for the emergent clinical cardiac trial outcome data with dyslipidaemic patients, expected in 2016. If successful, potentially millions of patients will be eligible for the $14,000+ biologic treatments.

- Are creative pay-for-performance reimbursement strategies viable, such as paying by the indication for drugs that have multiple approvals across disease states? For example, Tarceva has a 5-month survival advantage in NSCLC but only a two-week survival advantage in pancreatic cancer, but the drug is currently reimbursed at the same price.

- With new cancer drugs priced at approximately three times the median income in the US, and the focus of drug development on combinations of branded therapies, how is access to optimal clinical care to be sustained?

**Methodology**

The analysis contained in this report is based on the insights and opinions of eight experts on the pricing pressures in the US markets, and the current attempts to deliver pay-for-performance improvements in care and outcomes, at lower cost. To qualify, respondents had to meet the following screening criteria:

- Between 10-30 years’ experience within Pharma and/or biotech
- A pricing and reimbursement (P&R) or health economics expert;
- Experience with a wide-range of disease indications

Details on each expert interviewed can be found in the appendix.

Interview questions were designed to evaluate how pricing in the specialty Pharma market has changed during the past few years, as well as the future marketplace for combinations of branded drugs reimbursement and market access. Primary market research was complemented with in-depth secondary research across multiple, publicly available sources of information. Data from other FirstWord reports were also used.
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Shift to pay-for-performance reimbursement

Key Insights

- Medicare experimental programmes via accountable care organisations (ACOs) have yielded modest results, but the shift is accelerating quickly. The impact, however, will be limited until rapidly increasing pharmaceutical cost calculations are utilised in determining profits and losses.

- The US Department of Health & Human Services (HHS) has reportedly achieved a shift of 30 percent of traditional, PFS Medicare payments to alternative payment models by the end of 2016. The goal remains 50 percent of payments by the end of 2018.

- Medications cannot be viewed as a siloed expense item in a value-based environment. Indeed, prescription drugs play a critical role in determining overall healthcare spending. Medicare needs to integrate pharmaceuticals into experimental programs and then general practice, so that the cost offsets and quality benefits resulting from optimised drug use can be recognised and calculated.

- The shift from volume to value may dissuade providers from the use of expensive, newly developed treatment options that may be less effective or have only a marginally higher success rate versus time-honoured therapies.

Medicare approach

In the first quarter of 2015, the US government laid out an ambitious goal to overhaul physician reimbursements. The plan is to tie physician fees more closely to the quality of care, rather than the quantity of care. Accordingly, Medicare will no longer reimburse doctors simply for every procedure performed regardless of patient outcome, as was the case under the PFS model. Instead, the government will evaluate whether patients are healthier, among other outcome measures, and will increasingly decline to pay for avoidable hospital visits under a model known as pay-for-performance (P4P). The US Department of Health & Human Services (HHS)
The challenges of tying drug performance to patient outcomes

One difficulty in implementing such risk-sharing schemes is that there is no comprehensive central infrastructure for data collection in the US, as there is in select European countries, so it would be difficult to track patient outcomes. A key hurdle, according to Jimenez and Roche CEO Severin Schwan, is that electronic health record (EHR) systems in the US aren't capable of accurately tracking drug adherence and tying that compliance rate to a drug’s role in reducing hospital stays or preventing emergency room admissions.123

Obstacles in the US to these novel reimbursement arrangements include the fragmented US healthcare system, with its plethora of EHR providers that are incapable of sharing data, and the fact that many healthcare providers are still resistant to EHR systems in general. ‘The basic infrastructure of electronic medical records, let’s call it ‘real-world data,’ is going to have to increase so that we can easily track and monitor outcomes,” Jimenez said, adding that “if you move to that kind of pricing system over a period of years, you will be able to take out a lot of waste.”

However, some patient outcomes can’t necessarily be attributed to the drug’s themselves and rather the result of patient choice and lifestyle. Leela Barham noted: “I think holding drug manufacturers responsible for outcome measures is ‘really tricky’ because the real value of a drug is when a patient takes it at the right time. Understandably, companies are always nervous being held to account for factors that they actually can’t control.”

With so many variables in play, in the absence of a clear etiologic pathway, Pharmacy Benefit Manager (PBM), Express Scripts, remains skeptical of Novartis “beyond the pill” offering and other similar risk sharing programmes. Indeed, insurers have provided Novartis feedback that the plan is too complicated, leaving the company to compete with a traditional pricing model.124

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