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Amgen Cuts Repatha's Price By 60 Percent. Will Value-Based Pricing Support Value-based Patient Access?

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NOVEMBER 28, 2018 DOI: 10.1377/hblog20181127.943927



Recently, Amgen announced a 60 percent reduction in the [list price of its PCSK9 drug Repatha](#) for patients with statin-resistant elevated

cholesterol, following a commensurately substantial rebate offer from its principal competitors. The decision was good for patients, good for payers, and likely good for Amgen itself, to the extent it pulls the drug out of the sales doldrums where it has languished since its launch in 2015.

But the Repatha price reduction itself does not resolve the fundamental challenge in promoting innovation and access to treatments for cardiovascular disease, still the leading cause of mortality in the nation.

Value-Based Pricing?

The Repatha price cut can be considered a not-terrible outcome of a terrible process of price negotiations. Repatha and its competitor Praluent were launched with list prices north of \$14,000 per patient per year for the remainder of the patient's life, a budget-busting proposition if prescribed for the millions of patients with elevated cholesterol. The payers pushed back hard, with prior authorization requirements that [denied coverage for half of prescriptions](#) and with cost sharing requirements that contributed to adherence failure by half the patients whose prescriptions did receive authorization. Payers accused the manufacturers of pricing at levels that would bankrupt the health care system, while manufacturers accused payers of unethically blocking access for patients whose lives were at risk.

This war of all against all did achieve one intended goal, bringing prices down towards the 'value-based' benchmarks established by the nonprofit [Institute for Clinical and Economic Review](#) (ICER). Pharmaceutical firms traditionally have been critical of cost-effectiveness analysis generally and ICER specifically. When faced

with the brutally successful payer pushback against PCSK9 prescriptions, however, value-based pricing began to look reasonable. Regeneron and Sanofi, Amgen's competitors in the PCSK9 market, negotiated a deal with Express Scripts, the nation's largest pharmacy benefit manager (PBM), in which a price reduced to the ICER benchmark would be compensated by a reduction in prior authorization and out-of-pocket cost sharing. In an [article authored jointly with Steve Pearson of ICER and Scott Howell of Novartis](#), I refer to this as an exchange of value-based pricing for value-based access.

It is not obvious whether Amgen's new lower price, once it has been further reduced by payers seeking rebates, will approximate the ICER benchmark. It is also not obvious whether the manufacturer will be rewarded by payers with a lightening of access barriers. Express Scripts made favorable comments on the Amgen price cut but promised nothing. For its part, Amgen is highlighting the reduction in cost sharing to patients, which will result from a lower list price regardless of the payer response.

Value-Based Access?

As noted, cardiovascular disease remains the [leading source of mortality in the US](#), and its global prevalence is growing rapidly. The first priority, from a public health perspective, is to promote heart-healthy lifestyles and patient adherence to existing treatments. But there remains significant residual risk for patients who have tried and failed cheaper approaches or who are not appropriate candidates due to genetics or other personal characteristics. The PCSK9 pricing drama stemmed in part from the lack of a simple way to ensure that expensive new drugs targeting residual unmet needs would only be

used by patients non-responsive to existing therapies. This inability to differentiate, and the resulting payer concerns about over-prescription, explain the onerous prior authorization and cost sharing requirements.

The pace of cardiovascular drug innovation has [declined significantly in recent decades](#), due in part to inadequate 'push' incentives for research investments. These include the expense of mounting trials large enough to identify incremental improvements that affect substantial numbers of patients; the need for clinical rather than surrogate and biomarker study endpoints; and the shift in attention by governmental research and regulatory agencies towards treatments for oncology and orphan illnesses.

But the commercial problems experienced by the PCSK9 inhibitors and other recently launched cardiovascular drugs also raise concerns about inadequate 'pull' factors, the ability of product revenues to support research and, subsequently, the promotion and distribution activities necessary to reach a very specific group of patients and their prescribing physicians.

Research and development expenditures for cardiovascular drugs could benefit from further 'de-linkage' from industry profits. As I argue in a [white paper supported by the Laura and John Arnold Foundation](#), non-industry funding sources such as governmental and philanthropic grants, tax incentives, and innovation prizes should account for a greater share of overall research financing. But the challenge facing cardiovascular drug innovation is less one of expenditures on research than one of convincing physicians to prescribe and patients to adhere to effective novel medications.

Amgen and Regeneron/Sanofi now have reduced the net price of

PCSK9 inhibitors towards ICER's value-based benchmarks. If value-based prices of this sort are to be sustained, they need to be accompanied by value-based patient access. Access begins with the removal of onerous prior authorization and cost sharing obstacles but extends to active support for appropriate prescription and adherence. Such active support is necessary in many clinical areas, but is particularly challenging for cardiovascular disease therapies.

Targeting The Right Patients And Doctors

Whereas oncology and orphan drugs are prescribed by small numbers of specialists who are familiar with the latest drug launches and experienced in navigating payer controls, cardiovascular drugs are prescribed by large numbers of primary care physicians, cardiologists, and other medical specialists who manage a wide range of conditions and may lack familiarity with the drug innovation pipeline. Their practices often lack the staffing to navigate prior authorization and obtain copayment support on behalf of patients. In principle, physician education could be done by professional societies, medical centers, or other entities separate from the manufacturer. This 'academic detailing' has much to commend it but lacks the funding needed to reach the large number of physicians who manage cardiovascular disease.

Furthermore, patient adherence to effective cardiovascular drugs is low for reasons that go beyond payer-created barriers to access. Many patients are elderly, suffer from multiple co-morbid conditions, and already are taking several drugs. Convincing them to undergo the process needed to identify whether they are a candidate for an additional therapy can be difficult. Convincing them to continue taking

a novel drug that reduces the risk of adverse events but offers no symptom relief is equally difficult. Manufacturers' expenditures on advertising and patient support have been criticized as diverting patients from cheap generic to expensive novel medications, and criteria for appropriate promotion are needed. But there is a paucity of funding for non-manufacturer patient education and support, be they from physicians or community-based organizations, as evidenced in today's low adherence rates.

In the absence of adequate third-party alternatives, the identification and education of patients at serious residual risk for cardiovascular disease will need to be financed by industry itself. Value-based pricing and access extends beyond removal of administrative and financial barriers to include active support for appropriate patients and their prescribing physicians.

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"Amgen Cuts Repatha's Price By 60 Percent. Will Value-Based Pricing Support Value-based Patient Access?, " Health Affairs Blog, November 28, 2018.

DOI: 10.1377/hblog20181127.943927

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