

## Value-based Pricing: When Meds Underperform, Manufacturers Are Underpaid



Medicine isn't a field where guarantees are routinely offered or

reasonably expected...and that includes anything resembling a money-back guarantee. However, health insurers and pharmacy benefit managers are increasingly seeking quantifiable reassurance that certain drugs will be worth their high price tags—reassurance in the form of deals that promise reduced costs when new medications fall short of expectations.

Some of the newest “blockbuster” pharmaceuticals on the market have, in certain cases, shown lackluster results regarding long-term efficacy. This has encouraged pharmacy benefit managers (like Express Scripts), and insurers (like Cigna and Aetna) to ask drug manufacturers (like Astra Zeneca, Merck, and Novartis) to accept less for relatively poor performers.

Because objective data is crucial in determining which medications should be subject to this type of arrangement, measurables are key. Unsurprisingly, therefore, meds used to treat heart disease and diabetes are ideal for the pricing microscope since those conditions can at least in part be monitored via lab test results (i.e., cholesterol levels, glucose readings in the blood).

### A straightforward idea, but not as easy to put into practice

The pay-for-performance pricing typically entails insurers offering a set-price reimbursement for a medication, providing the pharmaceutical company has agreed to pay a penalty if the drug fails to perform as promised.

Considering the use of hard-and-fast data, the agreement appears to be simple to implement.

Not exactly.

Having measurables in place doesn't guarantee parties with competing interests will agree on how that data is obtained. Further, access to the required data isn't always straightforward or cost-effective.

Patrick Davish is associate vice president for global market access at Merck & Co. [“The data underneath the metrics are a real issue for both sides,” he says.](#) “Even the most sophisticated payers don't have all the data you'd imagine them to have. ... It's also administratively burdensome.”

Merck reports approximately twelve pay-for-performance agreements in place involving around eight medications. Those include the 2009 arrangement put in place with Cigna (and more recently, this past October with Aetna) for the diabetes meds Janumet and Januvia.

Since February of 2016, Aetna and Cigna also have “value-based” compromises set up with Novartis (based in

Switzerland) for the heart medication Entresto. The arrangement allows for Entresto to be designated with “preferred status” in the insurers’ formularies and offers the payers the safety net of a lower cost if the drug fails to positively impact the frequency of hospitalization events for patients suffering from congestive heart failure.

Dr. Ed Pezalla is the national medical director for pharmacy policy and strategy for the Connecticut-based Aetna.

“The contract allows us to cover [Entresto] more broadly,” he says, “and there’s an incentive for us to put specific programs in place for patients taking the drug. We would have covered it otherwise, but probably with more restrictions; and we probably wouldn’t have had incentive to do adherence programs.”

## Patient non-adherence: the wildcard in the scenario

Adherence, of course, is where the patient fits in this equation. The bio-benchmarks can only truly reflect drug efficacy when the patient takes it as prescribed. Otherwise, the labs might be measuring the individual’s degree of compliance to medication protocol.

“If [the patients are] not adherent,” Pezalla says, “they’re removed from the denominator: They’re not in the program and not getting the benefit of being on the medication. If they’re adherent, we reap the benefits with the patients.”

Increasingly, insurers are instituting a variety of measures to remind patients to follow through with prescription instructions; to determine whether patients are complying; and, if patients should cease taking the drug, to exercise the option of removing coverage for that pharmaceutical from the individual’s healthcare benefits.

## Is patient non-adherence sinking many value-based pricing deals?

Dr. Steve Miller is chief medical officer of St. Louis-based Express Scripts, the country’s largest pharmacy benefit manager. He theorizes that many pay-for-performance arrangements fail because of patient non-compliance and says that the administrative financial burden associated with uncovering and resolving these problems preclude true savings.

Miller has noted how complex an outcome-based deal can be and how intense the conflict between drug manufacturers and insurers in some cases—the former potentially arguing that the patient’s non-adherence is wholly to blame for the drug’s poor performance, the latter that the patient was prevented from adhering to the prescription regimen because of an unanticipated side effect of the drug, and therefore the blame rests with the drugmaker.

This is one reason Express Scripts does not agree to arrangements that depend on outcomes; rather, it takes on the responsibility for its patients’ adherence. In some deals, it provides health plan reimbursements (partial or full) when a patient fails to comply with medication protocol, at the same time granting the pharma companies preferred formulary status and receiving the meds at reduced prices for that consideration.

For more information/questions regarding any legal matters, please email [info@nelsonhardiman.com](mailto:info@nelsonhardiman.com) or call 310.203.2800.