US health payers and OINDPs

How the US health payment system may affect the success of new orally inhaled and nasal drug products

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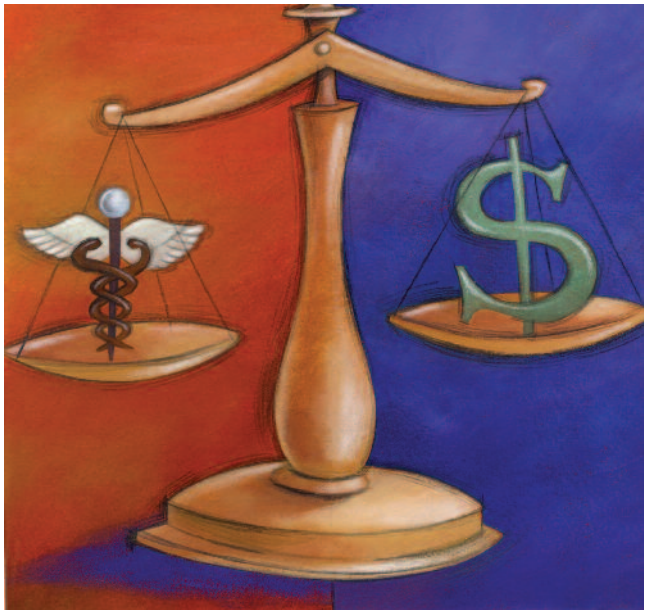


Two and a half years after David Balekdjian and Michael Russo, partners in consulting company The Bruckner Group, predicted in a *BusinessWeek* article that US healthcare payers' insistence on value would outweigh any physician, patient, or regulatory considerations for Exubera, Balekdjian presented a post-mortem to several hundred attendees at the 2008 AAPS Annual Meeting. Titled "The Exubera case: What lessons does it hold for new biopharmaceuticals developments?", the presentation emphasized the need for drug developers to consider payer requirements from the very beginning of a development project in order to ensure market success.

Exubera offered no hard evidence of any improvement in patient outcomes over injectable insulin, yet cost four times more, and the days when insurers would pay for any new therapeutic without evidence of a corresponding savings based on improved outcomes is long gone, Balekdjian says. He notes that since 2003, payers have been applying outcomes-based analysis (OBA) in which payers evaluate the value of pharmaceuticals on the basis of economic and patient considerations to small molecule drugs, and biologicals have come under the same type of scrutiny since 2005.

When presented with a newly approved drug, payers using OBA look for well-documented evidence of outcomes that generate significant improvements in treatment and, therefore, cost savings such as a reduction in hospitalizations or major improvements in symptoms. Each payer then decides how (or if) it will cover the product, in effect deciding how much access patients will have to the therapy and therefore the potential success or failure of the drug.

Focusing the early stages of development programs on obtaining regulatory approval and expecting that marketing efforts will convince physicians and patients to use the product, a paradigm that worked over the past several decades, now represents a strategic error, contends Balekdjian. US payers now play such an important role in the pharmaceutical marketplace that you can take the exact same compound and follow two different development paths, one that fails to take payers into account and one that focuses on outcomes, he suggests, and the first path will lead to a drug that fails to live up to expectations, like Exubera, and the second to market success.

Understanding how US healthcare payers operate, and how those operations affect pharmaceutical sales, presents a major challenge to Americans, much less to overseas drug developers. Patients may have drug coverage through any one of a number of private or government plans, or they may have no coverage at all [see sidebar], and they often switch from one coverage situation to another based on changes in income, employer, or marital status. At least 1,300 different companies offer health insurance coverage in the United States [1], and those companies typically offer multiple plans.

Steven Coulter, President of Government Business & Emerging Markets for BlueCross BlueShield of Tennessee (BCBST), a major insurer, notes that

there are "some irrational things about our business in terms of how we do benefits" and attributes much of the complexity to the relatively recent introduction of prescription drug coverage into the existing healthcare payment system. Thirty years ago, he points out, it was rare for employer plans to offer drug benefits, and until 2006, Medicare enrollees had no coverage at all for prescription drugs.

Today, many facets of healthcare payment remain in flux, particularly due to the economic situation and because President Obama has declared his intention to overhaul the entire system. Coverage rules and costs vary widely and change frequently. However, it is probably still useful for product developers of OINDPs to be aware of some of the factors that currently affect coverage.

Payer strategies to influence prescribing behavior

Although 90% of prescriptions in the US are filled at retail pharmacies [2], in most cases, the cost to the patient is determined by a third-party payer instead of by the pharmacy. "Coverage," emphasizes Balekdjian, "does not equal access"; inclusion on a formulary no longer means that the payer will automatically pay for the drug. Payers influence physician prescribing habits by providing education programs, by tracking prescriptions and issuing "report cards" to doctors, by requiring prior authorization (PA) or the failure of other therapies prior to access to certain drugs, and through structuring their formularies to require higher co-pays for drugs perceived to have a lower value.

Treatment restrictions. OINDPs are frequently subject to such restrictions by payers; about half of plans enforce step-care protocols or treatment guidelines for allergic rhinitis and for asthma [2] that require failed attempts by doctors and patients to use lower cost therapies prior to coverage of more expensive treatments.

According to the *Novartis Pharmacy Benefit Report*, in 2007, approximately half of commercial/group plans enforced some treatment limits for allergic rhinitis; of those, more than 70% required step care, 50% required PA for some drugs, and 41% had dispensing limits. For asthma, more than 45% of commercial plans enforced limits, with 51% of those requiring step care, 52% requiring PA, and 57% having dispensing limits. Fewer plans, only 13%, placed limits on COPD medications. Medicaid and Medicare Part D plans had similar limits. The number of plans requiring adherence to these types of guidelines is expected to rise in 2009 [2].

Formulary structure. Third-party payers, who reimburse approximately 83% of prescriptions filled by retailers [2], maintain a formulary for each prescrip-

What kinds of coverage do US patients have?

Private insurance

In 2007, more than half of adults under age 65, about 92 million people, had private insurance coverage, mostly through their employers.[1] Not all employers offer health insurance to employees, and only about 80% of commercial plans offer prescription drug benefits. About 6% of Americans purchased individual health insurance in 2007.[2] Non-elderly adults are not guaranteed access to private health insurance.

Government health coverage

Medicare

US citizens over age 65, and some disabled citizens, qualify for Medicare, a government health insurance system that enrolled 44 million people in 2007.[3] Medicare did not offer any drug benefit prior to 2006; enrollees now have the option of selecting a privately administered "Medicare Advantage" plan with drug coverage (MA-PD) or a stand-alone prescription drug plan (PDP). The drug plans operate similarly to other commercial insurance programs.

Medicaid

No one under the age of 65 qualifies automatically for government health coverage, including children and those living in poverty; however, some categories, including low-income families with children and disabled individuals may qualify for Medicaid. Each of the 50 states administers its own version of Medicaid.

Other government programs

The State Children's Health Insurance Plan (SCHIP) may cover families whose income makes them ineligible for Medicaid but who still cannot afford private health insurance. Native Americans, military personnel, civilian military employees, and dependents are covered through various government programs.

Uninsured

In 2007, about 45 million Americans, or 15% of the population, lacked insurance at a given point in time, with about twice that many uninsured at some time over the past year.[4] With increasing unemployment, the numbers of uninsured in 2009 are likely much higher. Without any health insurance, patients must pay the full retail cost of prescription drugs.

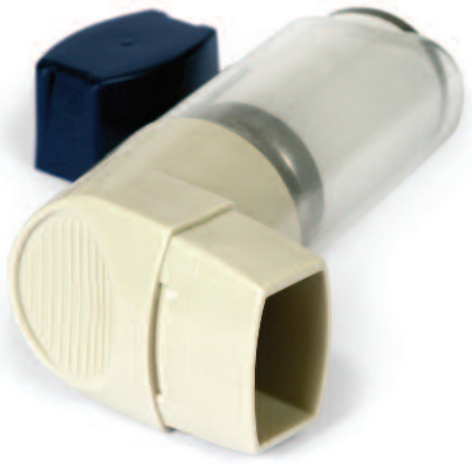
1. *Novartis Pharmacy Benefit Report*

2. Robert Wood Johnson Foundation, www.rwjf.org/reports/grr/043650.htm

3. Centers for Medicare and Medicaid Services, cms.hhs.gov/reportstrustfunds

4. National Coalition on Healthcare, www.nchc.org/facts/coverage.shtml

tion drug plan. Each payer offers multiple prescription drug options, and every hospital has its own formulary, meaning that thousands of different formularies are in effect throughout the US. Most of the formularies involve a tiered structure plan with higher co-pays for more expensive drugs. More than 80% of third-payer formularies had 3-, 4-, or 5-tier structures in 2008, with 13% of group plans anticipating a move from 3 to 4 tiers in 2009 [2].



Generics are usually on the first tier, with the lowest co-pay, in the range of $5-25, often $10. The greater the number of tiers, the higher the top co-pay amount, so that 3-tier formularies typically have a maximum co-pay of $50 or $60, and 4-tier formularies might have a maximum co-pay of $120 or $150. A patient using a maintenance inhaler, a rescue inhaler, and a branded nasal spray could easily be required to pay hundreds of dollars per month for their prescriptions [2].

Most payers try to include at least one drug in each category in their formulary, and most try to keep at least one in Tier 2. Each payer makes its own decisions about inclusion, placement, and co-pay level, so a patient with one plan may pay $30 for Rhinocort and $60 for Nasonex, while a patient with a different plan may pay $50 for Rhinocort and $25 for Nasonex.

Although a Pharmacy and Therapy (P&T) committee made up of practicing clinicians, pharmacists, and payer personnel evaluates drugs for inclusion on the formulary based on considerations like efficacy and patient need, the location on a particular tier is usually a cost issue, according to Terry Shea, Director, Pharmacy Management at BCBST: "Since most drugs in a therapeutic category are all equally safe, approved by the FDA, and, give or take, equally effective, it becomes a cost decision; we consider cost to the payer, cost to the customer, and cost to the employer group. Those drugs placed in the middle tier are the ones that have the more attractive cost."

If a formulary already has several drugs in a category on Tier 2, the payer has little incentive to add new ones unless the new product has demonstrated a proven, substantial increase in value, not a feature that adds convenience or a theoretical, but unproven, improvement in dosing. An inhaler with a built-in spacer is nice, say Coulter and Shea, but not if it adds $15 to the cost of the product: "Our customers [employers who purchase health plans] are concerned about affordability, and that's what they keep telling us. In that case, companies need to make sure that they are bringing value with a device, not just expense, because if the employer can't afford the benefit, then the patient is going to have to pay full price."

Patient cost and prescriptions

Let's say that a US physician treating a patient with asthma has a choice of four brands of dry powder inhalers; all four provide effective long-term maintenance therapy, and the patient has health coverage. All four probably have similar ex-manufacturer costs. So, the doctor will choose to write a prescription for one of them based on a differentiated benefit of some sort: an improvement in symptom relief, a more convenient dosing schedule, or a better dose counter, right?

Probably not, according to Shea: "If everybody has a DPI, and it's all the same drug, the cost of the inhaler is really going to determine which will be used. One might be more convenient, one might fit in your pocketbook better, one might have a nicer dose counter, but it's all going to come down to price." If Inhaler A costs the patient $30; Inhaler B, $50; Inhaler C, $100; and Inhaler D, $120, the annual difference between the lowest and highest costs might be more than $1,000, enough to discourage patients from using the most expensive product.

Even the difference in cost between the lower co-pays can affect sales, says Cindy Mundy, an analyst with Decision Resources: "I've had trouble getting across to overseas colleagues and clients that when a co-pay goes from $25 to $50 or from $30 to $60, that leap may seem inconsequential to a drug developer, but to struggling families, that's not an inconsequential expense. And it will matter more and more because more people in the current economic climate are having more budget issues."

If an emergency room doctor writes a prescription for a Xopenex HFA inhaler, for example, Shea suggests, "Momma may take Johnny to the corner drug store to have the prescription filled, and the pharmacist comes back and says, 'That will be $50,' Momma will say, 'I can't afford that. Is there something on my health plan's formulary?' and the pharmacist will call back to the hospital. A versus B will save Momma $15-20—maybe they will wind up with albuterol instead of Xopenex."

As costs to patients rise, they may fill prescriptions and then use the medication less often than necessary in order to stretch out their supplies, or they

may simply not fill prescriptions at all. In 2007, approximately 14% of Americans under age 65, about 36 million, reported that they could not afford to fill at least one prescription over the previous 12 months [3]. For low-income people with chronic conditions, a category that likely includes many children with asthma and elderly with COPD, the percentage unable to fill prescriptions rose to 41% [3].

How are OINDPs ranked on formularies?

As Mundy points out, inhaled asthma drugs are a special case due to the lack of generics and because even relatively expensive drugs save payers significant money in emergency department and hospitalization costs. And Coulter notes that COPD patients, who are more likely to be over the age of 65 and therefore covered by Medicare, have the ability to shop around for a drug benefits plan that has the lowest co-pay for drugs they want. As a result, payers have incentives to place inhaled asthma and COPD products on lower tiers than other comparably priced drugs.

Of 5 major insurers surveyed by Decision Resources, 60% had placed 5 different maintenance therapies on Tier 2 of their formularies, and Advair was included on Tier 2 by 4 of the 5 payers. "Tier 2 for drugs priced like asthma drugs is really anomalous," says Mundy; "Compared to branded drugs for other indications, the out-of-pocket costs are dramatically lower."

Still, there may be limits to payers' willingness to keep such expensive therapies on lower tiers. Mundy notes that Symbicort was not universally covered in 2008, and Asmanex is being added slowly to formularies, with at least one payer surveyed placing it in Tier 3 instead of Tier 2. Pharmaceutical companies need to understand, she emphasizes, that the situation can change at any time; with out-of-pocket costs skyrocketing, next generation drugs may get unfavorable tier placement if they set their prices too high.

The transition from CFCs to HFAs has left American patients without generic alternatives for albuterol MDIs, meaning that most payers now have no rescue inhalers on Tier 1 of their plans. Since the beginning of 2009, most patients now must pay between $30 and $60 per inhaler instead of $5-25. The uninsured population, especially common in inner cities where childhood asthma rates may approach 20%, says Mundy, is often at the mercy of whatever free clinic or hospital will give them drugs, and therefore prescriptions for rescue medications may be more affected by hospital formularies than are other drugs.

Payers may be more likely to place a greater number of new nasal sprays for allergic rhinitis in higher tiers given the number of available alternatives and relatively low cost benefits. A sampling of 5 3-tier formularies showed Flonase on Tier 3 of all 5 and Rhinocort Aqua on Tier 3 for 4 out of the 5. Veramyst is on Tier 2 of 2 plans, Tier 3 of 2 plans, and not included in the formulary of the 5th.

For drugs available in other dosage forms, payers will undoubtedly take a hard look at any perceived benefit of inhaled or nasal delivery. In their 2006 *BusinessWeek* article, Balekdjian and Russo pointed out that patient non-compliance regarding inhaler use "is rampant" and that significant compliance data would be necessary to convince payers of the superiority of inhalation [4]. They also suggested that experience with FluMist called into question "whether needle-phobia is even that significant an issue" [4].

Where pharmaceutical companies can demonstrate a real benefit of inhaled or nasal delivery at a similar or slightly higher cost than other dosage forms, the OINDP version will likely land on the same tier as other forms, says Shea, who cites nasal spray versions of migraine medications Zomig and Immitrex as good examples. A survey of 5 plans showed Zomig nasal spray on the same tier as oral Zomig, generally Tier 2, on 3 of the 5; however, 2 of the plans had the oral form on Tier 1 with the nasal spray on Tier 2.

Changes on the horizon?

Healthcare coverage in the United States could undergo radical reform in the next few years, or attempts to fix the system could fail yet again. A recent poll found the US public split on whether President Obama should go ahead with health care reform or wait until the economy improves [5]. Almost 80% of voters polled, however, agreed that reducing health care spending is important. One way or the other, cost will undoubtedly remain a major factor in the potential success of new OINDPs.

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