

Managing Office-Administered Drugs: An Economist's Perspective

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Summary

As the use of biologic medications grows and continues to expand, managed care must begin managing the costs of these medications. The impact of biologic medications on managed care costs is hidden within medical benefits and has not been managed. There are also some barriers and opportunities when it comes to managing these drugs from a managed care perspective. Payers are going to have to determine which management strategy or combination of strategies will work to begin managing their costs.

Key Points

- Biologic products are significant portion of drug spend but the costs may be hidden within medical benefits.
- The buy & bill reimbursement system for biologics misaligns financial incentives.
- Managed care payers have to do something to begin managing the costs of biologic products.

MOST MANAGED CARE PAYERS HAVE A plan for managing costs of their high cost medications such as statins or proton pump inhibitors. The plans can identify their per member per month costs in each category of medication paid for through pharmacy benefits. When it comes to pharmaceuticals, many payers have not begun to target managing costs covered through medical benefits. As an example, a number of payers do not fully appreciate that oncology supportive care products, such as red blood cell growth factors, are the third largest category of drug spend for managed care.

In 2005 three specialty biologic groups (red blood cell growth factors, white blood cell growth factors and monoclonal antibodies) accounted for \$17.8 billion in U.S. sales (Exhibit 1).¹ Specialty biologics, which are typically paid for through medical benefits and not pharmacy benefits, account for 18 percent of total drug spend. By 2008, they are expected to account for 26 percent of total spend. There are more than 370 experimental biologic drugs in the drug development pipeline, which are only going to increase the percentage of total spend. The specialty market is projected to grow at twice the rate of the traditional market. Yet, little managed care attention

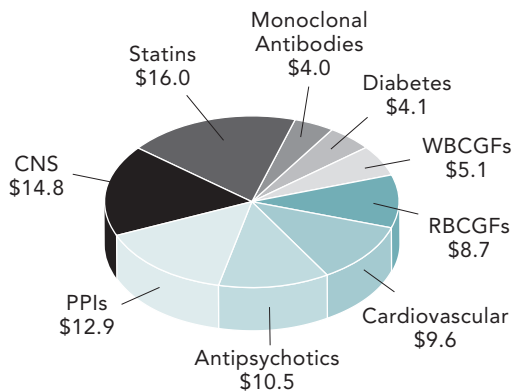
has focused on this area. The growth of specialty agents is already a major problem for managed care, employers, and consumers in terms of healthcare premium increases.

Payers are motivated to address managing costs in this area because of the definite savings opportunities and the very real threat of what is going to happen to the budgets as the number of new biologics increases. Although there is motivation to address this issue, there are significant barriers to action. The main barrier is network management.

In order to manage the network, the plans are going to have to manage the oncologists, who are the primary prescribers of these products. Most biologics, which are given in physician's offices, are purchased by the office, and then billed to the plan using J codes at the time of administration to an individual patient. This has been known as "buy & bill". The returns on drug margins are a significant part of oncologists' income (Exhibit 2). Administration fees are insufficiently low because it is expected that the drug margin is going to compensate.

The second barrier to managing biologic costs is whether the savings from management are visible. In payments for retail pharmacy services, plans have

**Exhibit 1: Leading US Therapeutic Categories
2005 U.S. Sales (\$Billions)¹**

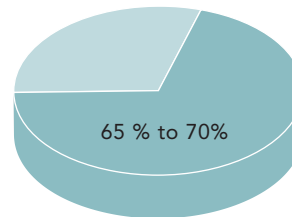


WBCGF, white blood cell growth factors;
RBCGF, red blood cell growth factors;
PPIs, proton pump inhibitors

¹Source IMS Health, IMS National Sales Perspectives, 1/2006

**Exhibit 2: Buy and Bill does provide incentives
for in-office administration**

Physician Percentage
of Total Profits
by Drug and Other



■ Profits from Drugs
■ Other Profits

Physicians' and Payers'
incentive structure
can be misaligned

- Site of care migrates to the more cost-effective and patient-friendly office

And

- Buy & Bill is a very effective means of managing distribution

But,

- But & Bill may also generate incentives for higher-cost therapies

dedicated people or outside providers who are charged with monitoring the costs and the savings from managing the distribution network. The real magnitude of pharmacy costs in medical benefit costs has been less visible to health plans and payers cannot manage what they do not measure. The way biologics are billed through J-codes does not capture differences in dosing with an individual product.

Tracking costs and savings is further complicated when these drugs are reimbursed by a mix of pharmacy and medical benefits. The mix of benefits hides the costs and utilization of the category. Additionally, payers do not tend to manage across pharmacy and medical claims. Without an owner for the category and any line item budget or targets, no action occurs.

There are positive and negative aspects of buy & bill when it comes to the way specialty drugs are distributed and dispensed. Administration in the physician office is more cost-effective and patient-friendly than hospital based administration. Without question, patients prefer administration in the physician's office. Most oncologists' offices have a set up to handle these products. The big problem with buy and bill is it generates inappropriate financial incentives. Any kind of a reimbursement system where the physician is going to be paid based on some percentage of an average wholesale price (AWP) or some

percentage of an average sales price (ASP), there is going to be some incentive to use higher cost products. The average oncology practice obtains about two thirds of its profits from the drug margin.² The disadvantages of the buy & bill system are going to get magnified with the increasing numbers of progressively higher cost biologics.

Fundamentally, the issue is the plans and the doctors each have financial incentives, which are clearly not alike. Assuming all else is equal, the plans want the least expensive product dispensed yet the physician's income is based on the more expensive products being dispensed. As more biologic equivalents are approved, more situations around incentives are going to arise.

Altering the profit from the drug margin that the oncologists make will be an issue. Plans have to address how they introduce a program and what competing plans are doing in the same area. The response of physicians has to be considered. A large percent of the oncologists would either threaten to leave or would consider no longer offering on-site administration. This would drive patients to other, possibly more costly sites to get their biologic products. Patient advocates and employers would also be concerned about changes. Many physicians realize that the whole buy and bill system is fundamentally flawed. There is an appreci-

No Owner
No Budget
No Action

Exhibit 3: Exposing Costs Will Reveal Actual Cost Savings Opportunity



- Even if the less expensive product dominates the Pharmacy benefit, the more expensive product could dominate the Medical benefit
- Different product utilization in Medical results from misaligned incentives

ation that the system has to change, but no one is interested in being the first group of physicians subject to such change.

Most plans have good insight into the pharmacy costs as a lot of effort has been expended over the years with formulary management, prior authorization procedures, stepped therapy, and guidelines. The tools and systems to implement these programs come through the pharmacy benefit managers. On the other hand, the medical benefits have not seen the same amount of focus on managing costs. There is a mixture of how biologics are dispensed and billed. Some are dispensed in the physician's office and paid through medical benefits. Others are dispensed in the retail pharmacy and paid from pharmacy benefits. Plans should be concerned if there is a big difference in the relative share of product being dispensed in the two systems.

There is visibility on pharmacy-based costs versus the less visible pharmaceutical costs on the medical benefit side (i.e., an iceberg effect, [Exhibit 3]). Assuming two products have the same clinical efficacy, the less expensive biologic is going to tend to have a greater share of what is being dispensed at the pharmacy than the more expensive product. More of the expensive product will be used on the

medical side because of the financial incentive. The successful payer would put into place the same kinds of techniques to manage costs on the medical benefit side as have been used on the pharmacy side. A successful payer approach will align product utilization in medical and pharmacy. Then similar shares of the two products would be seen on both sides of the equation. Impacting even just one of the categories of biologics will result in significant savings.

There are four major alternative strategies for plans to reap potential savings on biologic products. These include utilization guidelines, product preference, rational reimbursement, and a managed injectable program. Utilization guidelines are where the plan suggests appropriate utilization through guidelines, but may or may not enforce utilization management. Utilization is an issue with biologic products but utilization guidelines and management do not target the inappropriate incentives. Product preference works through a prior authorization or step-therapy program where the plan controls biologic choice at the physician's office. If a non-preferred product is used, there is a higher cost to the patient through a higher co-pay or coinsurance. Rational reimbursement occurs where

the plan alters reimbursement so that physicians are reimbursed a higher amount for a preferred product. Rational reimbursement usually will mean a lower reimbursement rate for a high cost product and higher reimbursement rate for a lower-cost product. The last option is a managed injectable program. With such a program, the physician acquires the product through specialty pharmacies thereby eliminating buy and bill.

Each alternative for managing costs will have to be compared along four dimensions – physician office impact, cost savings, ease of implementation, and opportunity for future utilization management. The impact on the office should be considered in a couple of different ways. The first is how operations will be affected. A high volume oncology office treating patients from several different plans that might have preferred deals with several different managed injectable or specialty pharmacies to deliver product would be difficult to administer and may be more costly for the physician's office. The other impact on the office is changes to physician compensation.

The second dimension for comparing alternative cost management strategies is the potential cost savings. Plans obviously should be looking at the different amounts of cost savings that are potentially available under these different alternatives. The third consideration is how easy the option to implement will be. Existence or need for billing procedures, infrastructure, or product management systems has to be considered. Lastly, how each alternative program might facilitate broader management over product utilization has to be considered.

Deciding which alternative will work for which individual plan will depend on the competitive circumstances where the plan does business. The impact of each alternative strategy on the four dimensions varies. As for the impact on the office, rational reimbursement will have the least impact on office operations. Rational reimbursement also respects physician choice regarding therapy but insulates the plan from excess costs. Although they have little impact on office operations, utilization guidelines could lead to physician opposition depending upon the steps taken to enforce. Suggested guidelines would minimize opposition by respecting physician choice. Product preference may pose a threat of backlash driven by perceived interference in the delivery of care and possible lack of additional compensation to physicians. A managed injectable program may pose the greatest threat for physicians because it eliminates the buy and bill opportunity without additional physician compensation.

As for cost savings, product preference is likely to

yield the greatest cost savings and utilization guidelines present the greatest uncertainty regarding cost savings. It is unclear how successful utilization guidelines have been in driving cost savings. Product preference offers a greater opportunity for cost savings than rational reimbursement because it does not require higher reimbursement for the preferred product. Rational reimbursement offers savings that can be locked-in and made independent of utilization, but also shares some of the savings with the physicians. Additionally, rational reimbursement could be driven by plan-neutral differentials that eliminate plan risk in realizing savings. Managed injectable program cost savings opportunities can be limited if reimbursement through specialty pharmacies is tied to AWP.

Ease of implementation is going to be dependent upon plan infrastructure. Infrastructure generally exists for the dissemination of utilization guidelines, but enforcement may require a prior authorization mechanism or refusal to reimburse. Product preference likely requires a prior authorization mechanism to be in place. The timing of rational reimbursement implementation may be problematic if providers and plans need to renegotiate. Additionally, systems may need to be configured to support reimbursement at different levels. Managed injectable program implementation requires an infrastructure for specialty pharmacies to bill the plan. There may be concern over an injectable program implementation and smooth operation in a large oncology office, serving patients from different plans. Specialty pharmacy distribution of biologics works relatively well for drive up infusion centers and low-volume specialty practices that do not utilize many specialty products.

Because all it changes is reimbursement for the different products, rational reimbursement offers the least opportunity for future utilization management initiatives. Utilization management requires some enforcement of utilization guidelines. Product preference may require a prior authorization procedure that could form the baseline for more significant utilization management initiatives. With a managed injectable program, the plan can use the specialty pharmacy to begin utilization management.

Product preference is the best alternative in terms of fewest potential problems and the advantage of significant cost savings. The one problem is that it has a significant impact on physician product choice and how the physician practices. A compromise is to use some combination of utilization guidelines, utilization management, and a rational reimbursement program to yield the quickest return and mitigate some deleterious impacts on the physician offices.

Rational reimbursement is an ideal complement to utilization guidelines/utilization management (UG/UM) initiatives. On its own, rational reimbursement will not generate any UG/UM savings, whereas UG/UM will have little impact on product choice. A full-fledged strategy should combine the two. Rational reimbursements can lock-in product choice savings; UG/UM may be implemented while network management addresses physician contracting for rational reimbursement. Rational reimbursement could help plans sell new fee schedules by softening potential opposition. Plans are likely to face opposition if they attempt to move from AWP to ASP reimbursement. UG/UM alone would not mitigate impact to offices, and could engender more backlash if guidelines are enforced through prior authorization. Rational reimbursement would address practice economics by providing physician compensation. Combining the two aligns the incentives and also brings in some of the management techniques.

From an implementation perspective, plans should be taking three steps. The first step is to expose the potential for the savings by prioritizing categories in terms of value, growth, and clinical differentiation, examining medical claims data regarding pharmacy utilization, and comparing biologic utilization under medical benefit to pharmacy benefit. The next step is to customize a solution by assigning ownership within the organization and evaluating potential approaches according to specific priorities so that there is a balance between savings and physician backlash. The last step is to enlist allies. This is going to require working with the physicians, understanding the network economics, understanding the economics of the physician's

office, and working with specialty pharmacies.

To be successful at managing biologic products, payers need to have alignment between the physicians and the plans, momentum, and commitment. Now is clearly a time to be moving in this direction. It is going to require some real commitment from the plans to push programs forward. A failure to act is going to jeopardize the plan's future going forward. There are too many biologics queued up at the FDA. The growth rates are too high and the biologics are too expensive. In order to continue to provide the kind of care the plans presumably want to provide, something must be done to address the specialty products.

Conclusion

Over the next decade, there are significant opportunities for managed care to address some of the problems being faced with the high-cost specialty products and utilization management. In the long run, the buy and bill system for biologic reimbursement will probably go away and be replaced by a much better designed program built along the lines of managed injectables. This is going to take several years to happen. If plans do not do anything, they are going to be facing some very substantial and significant cost increases that could jeopardize their ability to provide quality care for their patient populations. **JMCM**

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