



Injectable Drugs: The New Frontier in Pharmacy Management



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Most health plans have long ago established mechanisms

to manage their outpatient drug benefit. Some elect to handle this effort internally, while others find it more practical to contract the work to a pharmacy benefit management (PBM) organization. Either way, the approach to managing this complex and financially burdensome benefit now integrates many well-proven techniques, including formularies, mandatory generics, drug utilization review, physician reporting or academic detailing, and sophisticated “online adjudication” algorithms. Some plans have gone further by establishing incentives and capitation arrangements with physicians as a way of honing their senses to prescribing effectiveness. Without such tools, it is likely that the trend of rising pharmacy costs we have seen in the past 5 years¹ would have been considerably higher.

It is therefore remarkable that despite the success of such benefit programs, most health plans have yet to apply this approach to all drugs currently used in healthcare. Limiting management to outpatient products only is particularly costly when considering biotechnology injectable drugs.

INJECTABLE DRUGS

Many new drugs launched today are composed of proteins that cannot tolerate the hostile environment of the stomach. These drugs are cre-

FIGURE

New Biotechnology Drug and Vaccine Approvals/Indications, by Year



Source: Biotechnology Industry Organization. Available at www.bio.org.

ated by the use of recombinant DNA technology and are referred to as “biotechnology drugs”; many of them are injectable agents (or “injectables”) and are often administered by a physician.

Data compiled by the Biotechnology Industry Organization have shown an explosion in biotechnology drug approval in recent years (Figure).² Because many of these medications require administration by a physician, they are often excluded from outpatient drug benefit plans, which has ramifications to plans as well as to patients.

With the biotechnology industry poised to introduce hundreds of new, often expensive, products to the market in the next several years,² the time is ripe to introduce a change in our approach to pharmacy benefit programs.

A \$750–\$45 GAP

Covering approximately 400,000 members, Independent Health plan

is a nonprofit, independent practice association model of health maintenance organization located in the Buffalo-Niagara Falls region of western New York. Like most plans, we have classified the drugs that fall into the outpatient drug benefit program based on whether or not they are designed to be “capable of self-administration.” This classification covers a wide range of dosing forms, including oral, rectal, ocular, topical, and injectable. By definition, then, physician-administered drugs are not covered under drug benefit programs.

The significant financial impact injectable and physician-administered biotechnology drugs have on health plans is illustrated in the Table (page 6). In 2002, the average cost per injectable drug prescription administered through Independent Health pharmacy claims system was \$750, compared with the \$45 average for all others.³ These numbers speak for themselves.



THE COMPLEXITY OF PHARMACY MANAGEMENT

Selective billing codes. One must wonder why physician-administered drugs have fallen below the radar screen of PBMs. The reasons may vary. It may be the result of the pricing-and-payment model established by the Centers for Medicare and Medicaid Services (CMS) used as a guide for coverage by many plans. Drugs are given a CMS Common Procedural Coding System billing code (eg, J code), or they can be billed under a “wild card” code (eg, J99999, J3490) and reimbursed at an average wholesale price (AWP) minus 5%. Consequently, health plans generally cover under their medical benefits all drugs that are administered and billed properly in this manner.

Who is in charge? The types of controls for outpatient pharmacy benefits are seldom in place for other drugs, which raises another

issue. Within a health plan, who is in charge of managing these drugs? Is it the reimbursement department, which often has little or no drug expertise? Or is it the pharmacy director, who generally only has sufficient energy to focus on the outpatient drug benefits?

Physician drug income. Possibly the main reason plans have shied away from tackling this area aggressively is the intermingling of reimbursement fees and physician drug income. Physicians accept a plan’s reimbursement fees for administrative activity, albeit low, because they can make profits by purchasing the drugs well below the AWP-minus-5% reimbursement. Thus, to effectively facilitate change under this model, the pharmacy and reimbursement functions within the healthcare system must work together to reach decisions and make simultaneous adjustments acceptable to physicians.

Until only a few years ago physicians tended to argue that the existing model of drug reimbursement

worked, and they were making decisions based on clinical appropriateness rather than on drug profits. However, recent pressure from the publication of articles such as “Drug Sales Bring Huge Profits, and Scrutiny, to Cancer Doctors,”⁴ has led to physicians’ greater willingness to support other approaches to drug management.

TOWARD A NEW MANAGEMENT MODEL

Injectable drugs that fall within the outpatient drug benefit category are typically those administered subcutaneously (eg, etanercept [Enbrel[®]], interferon beta-1a [Avonex[®]], or epinephrine [EpiPen[®]]) or intramuscular products that patients can be trained to inject themselves (eg, menotropin [Repronex[®]] or follitropin-beta [Follistim[®]] for infertility). At Independent Health, occasionally we struggle with the definition (or classification) of specific drugs or drug classes, when use of such drugs

TABLE

Pharmacy Trends: Burden and Benefits of Biotechnology Drugs in 2002 (Independent Health)

Clinical category	Biotechnology treatment	Cost per prescription	Annual cost
Multiple sclerosis	<i>Interferons</i>		
	Interferon beta-1a (Avonex [®])	\$872.25	\$10,467.00
	Interferon beta-1b (Betaseron [®])	\$1020.48	\$12,245.76
	Interferon beta-1a (Rebif [®])	\$1120.18	\$13,442.16
	Glatiramer acetate (Copaxone [®])	\$941.54	\$11,298.48
Chronic myeloid leukemia	Imatinib mesylate (Gleevec [®])	\$2,438.19	\$29,258.28
Growth problems	<i>Growth hormones</i>		
	Somatropin (Nutropin [®])	\$1,481.13	\$17,773.61
	Somatrem (Protropin [®])	\$1,481.13	\$17,773.61
Oncology	Ibritumomab tiuxetan (Zevalin [®])	\$28,154.25 AWP	1 time only
	Rituximab (Rituxan [®])	\$3,250.00 AWP	\$13,000.00 (4 doses) \$26,000.00 (8 doses)
Hepatitis C	<i>Interferons and ribavirin</i>		
	Peginterferon alpha-2b (PEG-Intron [®])	\$2,913.89	\$32,052.79 (48 wk)
	Ribavirin (Rebetol [®])	\$2,913.89	\$32,052.79 (48 wk)
Pulmonary hypertension	Treprostinil sodium (Remodulin [®])	\$2,580.00	\$50,760.00
	Pump	\$1,650.00/mo	\$18,800.00

AWP = average wholesale price.

Source: Independent Health plan, 2002. Data on file.



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can offset high-cost medical expenditures and should, therefore, be made available to all members, even those without pharmacy benefits.

Such was the case with the subcutaneously administered low-molecular-weight heparin (LMWH) products (eg, enoxaparin sodium [Lovenox[®]], dalteparin sodium [Fragmin[®]], and tinzaparin sodium [Innohep[®]]). Because some patients lack pharmacy benefits, and because LMWHs can offset the high cost of hospital stays, Independent Health, and likely other plans, has let these agents be included in the pharmacy benefit plan, but has created home-care options for deep vein thrombosis avoidance of hospital admissions for patients without pharmacy benefits. This type of a solution constitutes a “win-win” compromise, allowing care for patients even without drug benefits, while retaining current drug classifications and controlling costs.

PRACTICAL TIPS

Independent Health has recently initiated efforts to apply our pharmacy management skills to all physician-administered drugs. Although still in its early stages, some lessons from this new approach can already be shared for the benefit of other plans.

Initiate an injectable drug subcommittee in your pharmacy and therapeutics (P&T) committee:

- Review newly launched physician-administered drugs using the same discipline used by your P&T for self-administered drugs.
- Assess clinical, safety, and economic information compared with available options. Do not be limited by the boundaries of your benefit (eg, for rheumatoid arthritis, self-administered tumor necrosis factor [TNF]- α agents are available (etanercept [Enbrel[®]], adalimumab [Humira[®]]) and physician-infused agents (infliximab [Remicade[®]]).
- The subcommittee should be free to establish use-criteria that may prefer one drug to another regardless of benefit considerations.

Build a physician-administered drug formulary:

- The traditional outpatient drug formulary is essentially just a communication tool to providers and patients. It indicates what the plan covers, which restrictions may apply, and what copayments may be required. A physician-administered drug formulary would have the same function.
- In the outpatient setting, the patient carries a prescription to the pharmacy and the pharmacist performs an adjudication step before relinquishing his inventory to the patient. If there are restrictions or issues on coverage, the pharmacist can attempt to correct them with the provider and readjudicate to ensure payment. This is a strong system, which fosters compliance with the formulary.

Physician-administered drugs should be handled in a

similar manner. Physicians should have access to a current, preferably Web-based, formulary informing them, before they administer the drug, whether it requires preapproval, or even if they must obtain the drug from another source.

Assess the distribution channel and administrative fees simultaneously:

- Several well-groomed specialty pharmacies around the country can provide aggressive pricing, medical review services, and reliable delivery to physicians' offices for scheduled drug administration.⁵ The formulary tool for physicians should indicate the requirement to use such a service and provide the ordering instructions to do so.
- For drugs obtained from the specialty pharmacy, no “profit” opportunity exists for the physician, so the plan will have to engineer an administration fee that will compensate providers for their professional services. This will require much discussion with the affected providers.

CONCLUSION

With many new biotechnology drugs in the pipeline and with their rapid approval, a change in benefit management is sorely needed, in light of the staggering difference in expenditures between injectables and all other drugs. It makes perfect sense to apply our pharmacy management skills to all drugs used within a health plan. Indeed, managing escalating costs of physician-administered drugs will likely become the new frontier for pharmacy managers. The necessary tools are already in their tool kit. ■

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