White Paper

Payer Strategies to Manage Specialty Drugs Across Pharmacy and Medical Benefits

From the Editors at AIS Health

In 2015, spending on specialty drugs in the United States rose more than 21% from the previous year to $151 billion.[i] That's out of $425 billion total spent on medications in the U.S.[ii] And with the specialty pharma pipeline showing no sign of slowing, some estimates indicate that these costly medications will make up half of all drug costs by 2018.[iii] That means ensuring the right drug is given to the right patient at the right time is more important than ever for payers. There is a wide array of strategies that payers can utilize to do this, ranging from older tactics such as prior authorization and step therapy to newer ones such as clinical pathways, outcomes-based contracting and indication-specific pricing.

Payer Strategies to Manage Specialty Drugs Across the Pharmacy and Medical Benefits

Claims for specialty drugs can be adjudicated through the pharmacy benefit and the medical benefit. Often the distinction is made based on how the drug is administered: If patients can administer it themselves, such as a pill or a self-injected drug, then the therapy falls under the pharmacy benefit. But if the drug requires a health care professional to administer it, it usually falls under the medical benefit. Some classes of drugs including erythropoeitins and hereditary angioedema treatments may be covered under both benefits.[iv]

Although approximately half of the spending on specialty drugs falls under the medical benefit and the rest under the pharmacy benefit, some payers focus solely on managing specialty drugs adjudicated under the pharmacy benefit. While pharmacy benefit claims are much easier to manage due to more specific reimbursement codes and real-time adjudication of claims, that doesn't mean it's impossible to manage drugs that fall under the medical benefit. It just takes a little more work.

When there is a siloed approach to managing specialty drugs, this may lead to uneven costs for members, a situation that can incentivize them to choose treatments based solely on their out-of-pocket spending. For example, within the rheumatoid arthritis class, professionally administered Remicade (infliximab) is mainly covered under the medical benefit, while most

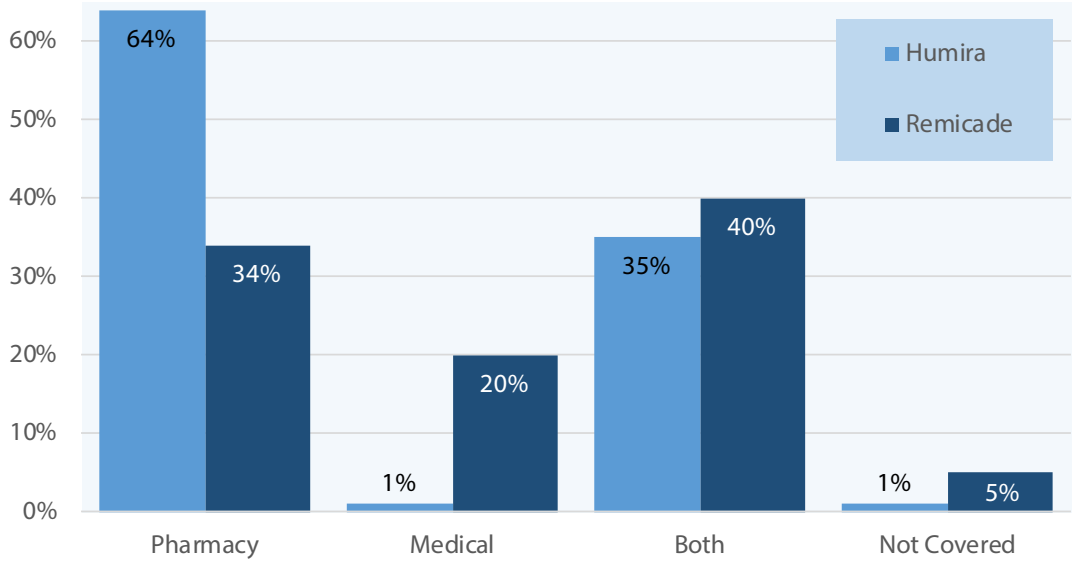

Figure 1: Coverage of Humira vs. Remicade among all payers.
Source: MMIT Analytics, accessed March 2017.

One analysis of health plan claims data for commercial plan members showed that the administration of medical benefit drugs is most expensive in the hospital outpatient department. In fact, this location is often four times more expensive than the physician office.

coverage for self-administered Humira (adalimumab) is under the pharmacy benefit (see Figure 1, p. 1). If a payer has, for example, a $100 copayment for a $4,000 per month drug through the pharmacy benefit but 15% coinsurance on a similarly priced drug in the medical benefit, this would incentivize members to choose the drug in the pharmacy benefit because it will cost them less.

Some PBMs have maintained that moving specialty drugs from the medical benefit to the pharmacy benefit will make them easier to manage. While this approach has been discussed for many years, there hasn't been much action, for various reasons. For one thing, payers risk angering physicians who acquire drugs through the traditional buy-and-bill system, which provides them with some income. With that source of revenue gone, providers could simply send patients to the hospital outpatient department for drug administration, which most likely will cost payers much more money. Also, physicians and hospitals may be able to purchase drugs for less than specialty pharmacies can because of class-of-trade pricing, so it may not make financial sense for the health plan to move the drugs.

In addition, waste could be an issue: Patients may need only part of the medication in a vial, so physicians can bill for a partial vial, something that specialty pharmacies cannot do. Many provider-administered therapies are oncology drugs, and their dosing — not simply the amount of a drug, but even which drug should be administered — may be dependent upon results of tests undergone when patients arrive for their appointments. When physicians have a supply of medications to choose from rather than one shipped by a specialty pharmacy, this cuts down on waste. It also ensures that patients are treated in a timely fashion, as providers don't have to order new drugs, forcing patients to reschedule. According to an EMD Serono report, medications for hemophilia, respiratory syncytial virus and inflammatory conditions showed some movement from coverage under the medical benefit to the pharmacy benefit from 2011 to 2013.[v]

When a specialty pharmacy delivers a drug to a physician for administration, this is known as white bagging. Brown bagging is when a specialty pharmacy delivers a drug to a patient, who then must transport the medication to a health care professional for administration. A survey by Magellan Rx Management of 2015 medical pharmacy trends found that 26% of physician offices received medical benefit drugs through white bagging and 2% through brown bagging.[vi]

Prior Authorization, Step Therapy and Tiering

Probably the most common management tactic is prior authorization (PA), which requires physicians to get approval for a treatment before they can administer it (see Figure 2, p. 3). This usually consists of filling out a form to submit to the insurer, which then has to review and approve — or deny — the requested regimen. Some payers have made the process faster though. For example, Anthem Inc. in 2014 implemented a program for certain cancers under which physicians enter a requested regimen into a web portal, and if it is on an accepted clinical pathway, prior authorization is granted automatically. Some PAs also come with the requirement for physicians to provide various pieces of information before that approval is granted. These requirements are usually in line with a drug's FDA approved indication, as spelled out on the drug's label. For example, Priority Health requires that providers submit information verifying patients meet all the following requirements before the insurer will cover prostate cancer drug Provenge (sipuleucel-T):[vii]

"1. Diagnosis of asymptomatic, minimally symptomatic, or symptomatic metastatic castrate-resistant (hormone refractory) prostate cancer

2. Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1

3. Life expectancy greater than 6 months

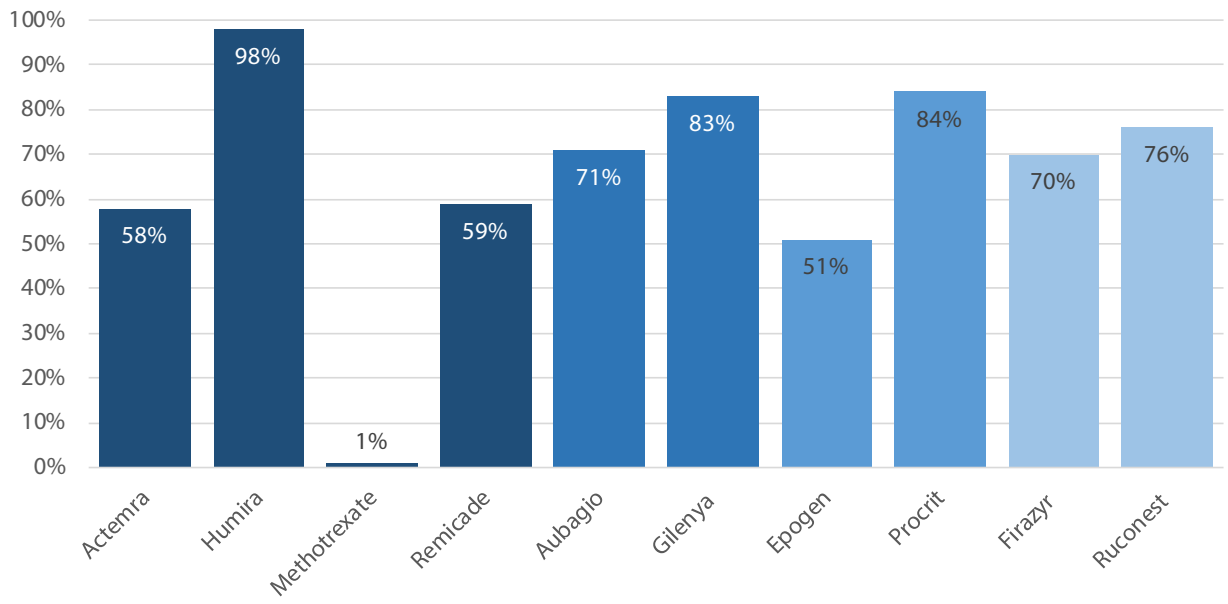

Figure 2: Percentage of covered lives with prior authorization and/or step therapy requirements for eight specialty drugs.
Source: MMIT Analytics, accessed March 2017.

4. Serum prostate-specific antigen (PSA) of 5 ng/mL or higher
5. Two sequential rising PSA levels obtained 2 – 3 weeks apart or other evidence of disease progression
6. Serum testosterone less than 50 ng/dL
7. Provenge will not be authorized for patients with any of the following:
   - Requirement for systemic corticosteroid use
   - Use of opioid analgesics for cancer-related pain
   - Visceral metastases
   - ECOG performance status of ≥ 2
   - Pathologic long-bone fractures
   - Spinal cord compression"

An additional long-time tactic is step therapy, by which physicians must start a patient on a certain treatment before moving to another, usually more expensive, regimen. For example, with many specialty drugs, a patient may need to start first on a nonbiologic treatment before a biologic, such as starting with methotrexate for rheumatoid arthritis before a biologic such as Humira can be dosed (see Figure 3, p. 4).

Another fairly common approach for the pharmacy benefit is placing specialty drugs into a separate cost-sharing tier from traditional nonspecialty medications; the specialty tier requires members to pay higher out-of-pocket costs. Growing in use, although still not commonly used, is splitting the specialty tier into two or more tiers.[viii] The higher the tier, the more that the patient cost share is.

Site-of-Care Optimization

Site-of-care optimization is a strategy used for drugs that are professionally administered, so it's primarily used for medications that fall under the medical benefit. These therapies may be administered in a variety of settings, including physician offices, hospital outpatient departments, patient homes and infusion suites. One analysis of health plan claims data for commercial plan

Payer/PBM	Rx Formulary Status	
	Humira	Methotrexate
Express Scripts PBM	Preferred (PA/ST) 69%	Generic Preferred 98%
CVS Caremark Rx	Preferred (PA/ST) 71%	Generic Preferred 100%
UnitedHealth Group, Inc.	Preferred (PA/ST) 66%	Generic Preferred 95%
Anthem, Inc.	Covered (PA/ST) 75%	Generic Preferred 96%
Aetna, Inc.	Specialty (PA/ST) 57%	Generic Preferred 100%
Humana, Inc.	Specialty (PA/ST) 82%	Generic 54%
OptumRx	Preferred (PA/ST) 56%	Generic Preferred 100%
Kaiser Foundation Health Plans	Preferred 70%	Generic Preferred 81%
CIGNA Health Plans, Inc.	Preferred (PA/ST) 82%	Generic Preferred 97%
Health Care Service Corporation	Preferred (PA/ST) 69%	Generic Preferred 78%
PA = prior authorization, ST = step therapy SOURCE: MMIT Analytics, accessed March 2017.		

Figure 3: The 10 largest payers' most prevalent formulary status for Humira and Methotrexate.

members showed that the administration of medical benefit drugs is most expensive in the hospital outpatient department.[ix] In fact, this location is often four times more expensive than the physician office.[x]
An analysis of health plan claims data by Magellan Rx Management found, for example, that Remicade's cost per claim was $4,132 in a physician's office, $5,002 through home infusion or specialty pharmacy and $8,930 in the hospital outpatient department. And the cost per claim for Neulasta (pegfilgrastim) was $3,741 in the physician's office, $3,731 through home infusion or specialty pharmacy and $7,207 in the hospital outpatient setting.[xi]

Payers have implemented different approaches in order to direct members to the most appropriate setting for drug administration, including offering financial incentives for members to go to certain locations and requiring them to use certain sites of service through plan policy. Beyond this, some payers have begun setting up infusion networks to which they can direct members. According to Magellan Rx Management, in 2015, 59 payers representing 130 million lives were using the following approaches to managing site of care:[xii]

Split Fills

Many specialty drugs may have side effects that patients cannot tolerate or fail to be therapeutically beneficial, so rather than filling a prescription for the first month of treatment, some payers use split fills. This approach to quality limits reduces the potential waste by splitting the first month of treatment in two. Instead of patients

Guide members away from hospital outpatient facilities for drug infusions	49%
Care management programs to perform outreach to members about alternate treatment sites for their infusion drug therapy	36%
Directing infusion site of service through plan policy and medical necessity criteria during prior authorization reviews	32%
Recontracting hospitals at more aggressive rates	24%
Financial incentives to encourage member use of lower cost alternate treatment sites	14%
Other (restricted to their own clinics)	5%
Aligning the plan's and member's costs for injectable/infusible drugs through benefit design	2%

receiving 28 or 30 days' worth of drug, they'll first receive enough for 14 or 15 days. A specialty pharmacy will confirm with a patient or provider before the second fill of the prescription is dispensed. Some programs do this for the first month of the medication, while others may extend into the second month or more. Therapeutic categories that use split fills include oral oncology, hepatitis C, anti-inflammatories and multiple sclerosis.[xiii]

Clinical Outcomes

As payers and PBMs have gathered much of the low-hanging fruit offered by these traditional management tactics, they are trying to find new ways to drill down in terms of which drugs are most appropriate for which members. One way to do this is by making decisions based on clinical outcomes data. Armed with this information, payers may use the data in a number of arrangements.

For example, some payers have created preferred products within therapeutic categories that have multiple medication options. This means that they may set up their drug benefit designs to encourage the use of certain treatments over others by creating two tiers of drugs: preferred and not preferred. They can incentivize the use of preferred drugs by having patients pay lower out-of-pocket costs for them.

For instance, there are more than 10 specialty drugs to treat multiple sclerosis, and those options allow payers to prefer some treatments over others (see Figure 4, below). And the erythropoiesis-stimulating agents Epogen and Procrit are the same drug — epoetin alfa — sold by different companies, which allows payers to take varying coverage stances (see Figure 5, page 6).

As biosimilars come onto the U.S. market, placing these products on a preferred tier may be an approach payers take to encourage their use.

Various resources can help payers determine when this approach is appropriate, and perhaps the most widely used are guidelines and recommendations from professional associations, as well as peer-reviewed articles in journals. The most valuable evidence is head-to-head studies comparing one drug to another. Clinical trial data may be useful, and once a product is on the market, real-world evidence is even more helpful. In addition, if all clinical and safety aspects of the medications are the same, payers may place a drug on a preferred tier if they

Payer/PBM	Rx Formulary Status	
	Aubagio	Gilenya
Express Scripts	Covered (PA/ST) 69%	Preferred (PA/ST) 68%
CVS Caremark Rx	Preferred (PA/ST) 71%	Preferred (PA/ST) 71%
UnitedHealth Group, Inc.	Covered (PA/ST) 59%	Covered (PA/ST) 60%
Anthem, Inc.	Covered (PA/ST) 84%	Covered (PA/ST) 77%
Aetna, Inc.	Specialty (PA/ST) 37%	Specialty (PA/ST) 57%
Humana, Inc.	Not Covered 75%	Specialty (PA/ST) 82%
OptumRx	Covered (PA/ST) 53%	Covered (PA/ST) 53%
Kaiser Foundation Health Plans	Not Covered 43%	Covered (PA/ST) 68%
CIGNA Health Plans, Inc.	Preferred (PA/ST) 81%	Preferred (PA/ST) 70%
Health Care Service Corporation	Specialty 41%	Specialty 33%

PA = prior authorization, ST = step therapy
SOURCE: MMIT Analytics, accessed March 2017.

Figure 4: The 10 largest payers' most prevalent formulary status for Aubagio and Gilenya.

Payer/PBM	Rx Formulary Status	
	Epogen	Procrit
Express Scripts	Not Covered 74%	Preferred (PA/ST) 77%
CVS Caremark Rx	Not Covered 61%	Preferred (PA/ST) 46%
UnitedHealth Group, Inc.	Covered 60%	Preferred 55%
Anthem, Inc.	Covered (PA/ST) 84%	Covered (PA/ST) 71%
Aetna, Inc.	Specialty (PA/ST) 35%	Specialty (PA/ST) 58%
Humana, Inc.	Specialty (PA/ST) 80%	Specialty (PA/ST) 62%
OptumRx	Covered 65%	Preferred 83%
Kaiser Foundation Health Plans	Covered (PA/ST) 42%	Preferred 78%
CIGNA Health Plans, Inc.	Preferred (PA/ST) 79%	Preferred (PA/ST) 81%
Health Care Service Corporation	Preferred (PA/ST) 46%	Preferred (PA/ST) 46%
PA = prior authorization, ST = step therapy *SOURCE: MMIT Analytics, accessed March 2017.*		

Figure 5: The 10 largest payers' most prevalent formulary status for Epogen and Procrit.

are able to get rebates from the therapy's manufacturer. Rebates are becoming more common particularly within specialty drug classes.

These same evidence-based resources also can be used to implement a clinical pathways arrangement. Such tactics are most common within different cancers, and they help guide regimen choices best suited to each patient. Payers tend to let providers have a hand in establishing these, and they are enforced mostly by incentives for providers to use them rather than penalties if they do not. One of the first payers to implement a pathways program was CareFirst BlueCross BlueShield, and it began with breast, lung and colon cancers, conditions chosen because they made up the bulk of CareFirst's oncology costs. Many payers that have implemented similar pathways programs have launched with these same three cancers as well.

A relatively newer strategy is outcomes-based contracting, which consists of deals with pharma manufacturers that are based on clinical outcomes of plan members taking a particular drug. A recent study showed that only a small portion of plans have such arrangements in place, but the number is growing.xiv Harvard Pilgrim Health Care, Inc. is one insurer that has multiple deals in place. In early 2017, the insurer said it had signed outcomes-based contracts with Amgen Inc. for its anti-inflammatory treatment Enbrel (etanercept) and Eli Lilly and Co. for its osteoporosis medication Forteo (teriparatide).

The arrangements may take different forms in the sense of what aspects will be measured. Some might focus on patient adherence to make sure people taking the drug are getting the greatest possible benefit from it and that the product isn't wasted. Others may look at a series of patient health outcomes measures in order to compare those with agreed-upon benchmarks to help determine how effective a drug is. With these programs, payers will receive a discount on their costs for a drug if these outcomes aren't met.

Indication-based formularies may prefer a particular product for one use but not for another that it's approved for. Rebates are in play with many of these decisions as well.

Indication-specific pricing also is a tactic that a few PBMs have been exploring. This takes place with products that are approved for multiple indications. If a drug has shown better clinical outcomes in one condition versus another, the PBM will pay different prices for the drug depending on its use. Similarly, indication-based formularies may prefer a particular product for one use but not for another that it's approved for. Rebates are in play with many of these decisions as well. At the beginning of 2016, Express Scripts Holding Co. launched its Oncology Care Value program that features an indication-specific pricing model for drugs to treat certain cancers. For example, Tarceva (erlotinib) is indicated for both lung cancer and pancreatic cancer, but the average survival rate in people with lung cancer was 5.2 months versus chemotherapy, compared with two weeks for pancreatic cancer. Based on those outcomes, Express Scripts believes the cost of the medication for people with pancreatic cancer should be lower than when it's used to treat lung cancer.

Citations

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About AIS Health

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