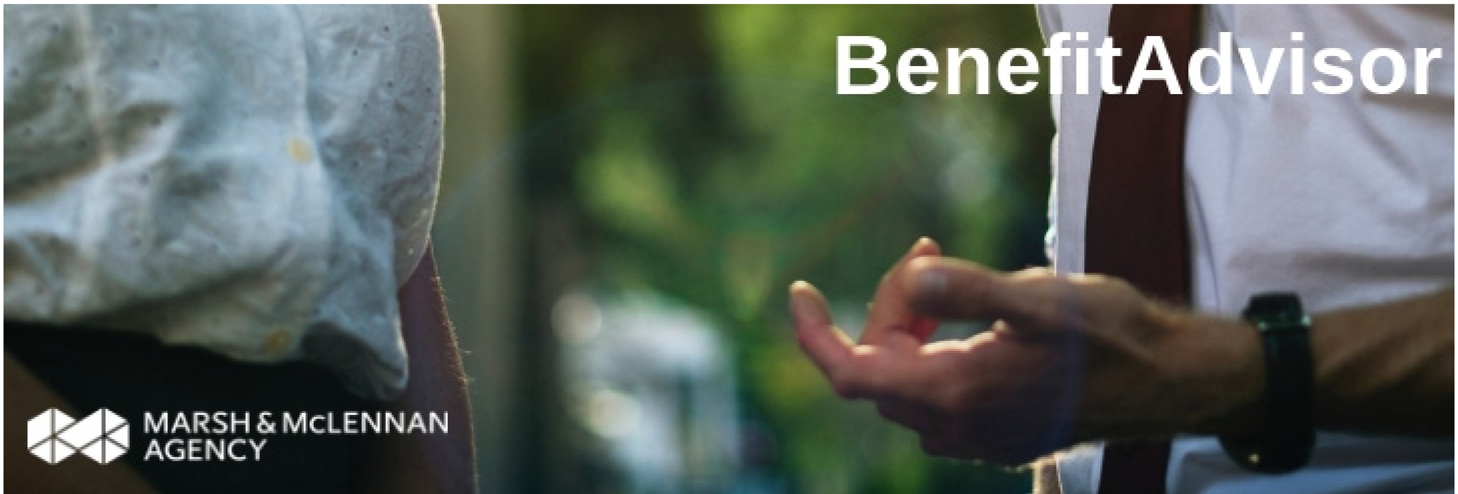

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SPECIALTY MEDICATIONS – THE CHALLENGE FACING EMPLOYERS

Health plan costs challenge most employers. A significant factor in annual medical plan cost increase is the cost and use of specialty medications. According to Intercontinental Medical Statistics (IMS), expenditures for specialty drugs are growing faster than any other health care component. Employers, insurers, the government, and patients are all concerned about these increasing costs.

This *Benefit Advisor*:

- Defines specialty medications
- Explains the current state of the specialty medication marketplace
- Offers options employers can consider to manage pharmacy expenditures

The cost of specialty medications will continue to rise for the next decade and beyond. It is critical to manage this market segment tightly to ensure these drugs are used appropriately and priced reasonably.

SPECIALTY MEDICATIONS DEFINED

Although there is no official definition, specialty medications do share some or all the following specific characteristics:

- They are expensive compared to other medications and could cost anywhere from a thousand dollars to hundreds of thousands of dollars a month.
- When they are manufactured using living organisms, they are called biologics.
- They require special administration either by injection or infusion.
- They need to be prescribed by specialist.
- They may require complex follow up or ongoing monitoring.
- They are used to treat serious medical conditions for which few or no other therapies are available.

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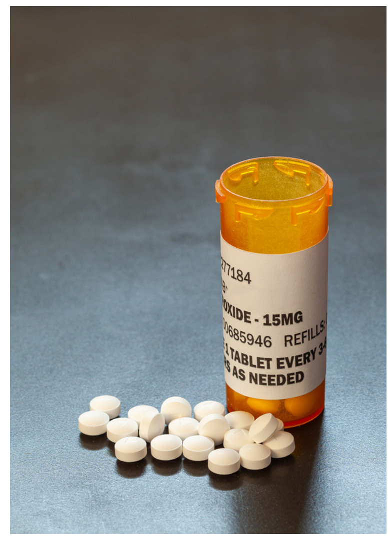
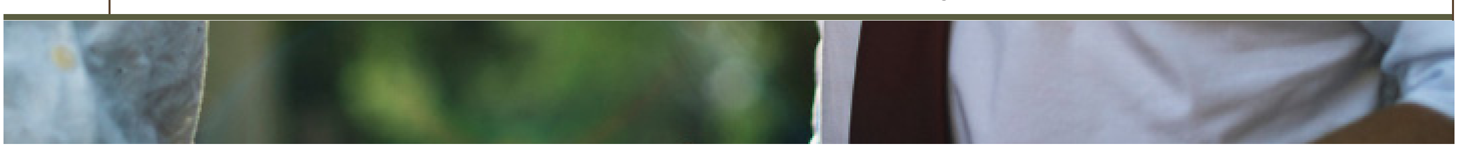


We welcome your comments and suggestions regarding this issue of our Benefit Advisor. For more information, please contact your Account Manager or visit our website at www.mma-mi.com.



WORLD CLASS. LOCAL TOUCH.

		Trend Increases		
	Therapy Class	**Utilization**	**Unit Cost**	**Total**
1.	Inflammatory Conditions	3.6%	10.5%	14.1%
2.	Diabetes	2.3%	1.8%	4.1%
3.	Oncology	4.4%	13.7%	18.1%
4.	Multiple Sclerosis	-7.8%	3.0%	-4.8%
5.	HIV	5.4%	6.3%	11.7%
6.	Pain and Inflammation	-4.2%	-6.9%	11.1%
7.	Attention Disorders	2.0%	-10.2%	-8.2%
8.	Asthma	2.1%	-8.5%	-7.3%
9.	High Blood Pressure/Heart Disease	1.9%	-15.3%	-13.4%
10.	Depression	4.5%	-8.3%	-3.8%
11.	Skin Conditions	1.7%	3.1%	4.8%
12.	Contraceptives	0.9%	-10.5%	-9.6%
13.	High Cholesterol	2.0%	-29.0%	-27.0%
14.	Anticoagulants	3.9%	7.8%	11.7%
15.	Seizures	0.1%	5.9%	6.0%

- They are administered through specialty pharmacies.
- They may require special handling such as temperature control.

Members may obtain specialty medications through their pharmacies or specialty pharmacies. Medications administered in a hospital setting are often purchased by the hospital.

While these medications can be very expensive, they can be life changing. In some cases, they can prevent potentially more expensive treatment. For example, the Hepatitis C drugs approved about five years ago can cure Hepatitis C which can cause liver failure. Harvoni, one of the first medications approved, initially sold for approximately $75,000. This expensive medication affected many employers' health plans, especially if they had several members with Hepatitis C. Competition over time, however, lowered the price. In fact, many people treated when these medications first came out were cured, so usage has not remained significant over time.

Many look solely at the cost of specialty medications without considering the life-saving or life-improving effect they have on their health plan members. Managing these medications is critical to controlling cost and making sure the medications are used only when other lower cost treatment options are not available.

CURRENT STATE OF THE SPECIALTY MEDICATION MARKETPLACE

The news media often focus on newly approved drugs that are typically high in cost and in many cases limited in applicability. For example, the latest $2 million drug received significant media attention. It was used to treat a rare genetic disorder in children, so potential use was very limited. A recent Mayo Clinic Proceedings study showed the average annual cost of cancer drugs increased from roughly $10,000 before the year 2000 to over $100,000 by 2012.

For the most part, employers should be concerned with increased usage and rising cost. The *2018 Express Scripts Drug Trend Report* showed the trend for pharmacy cost was relatively flat in 2018. The picture was mixed depending on usage and unit cost.

The Express Scripts top 15 Therapy Classes ranked per member per year spend for commercial plans is shown in the table at the top of page 2.

Interestingly, only two categories showed lower utilization. The decreased usage in the pain category was likely due to significant attempts to reduce opioid

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use throughout the country. Also, Hepatitis C medications dropped out of the top 15 for the first time in many years because of significantly reduced use and unit cost.

Many of the medications in the list are considered specialty medications. The growing use of these medications is concerning. According to a *2017 National Business Group Health Policy Brief*:

- In 2014, 51 new drug therapies were approved. Twenty-seven of these new approvals were considered specialty medications.
- In 2015, 45 new drug therapies were approved and approximately half were specialty medications.
- In 2016, 26 new drug therapies were approved, nine were for rare diseases, six were for various types of cancer, two were for Hepatitis C, one was for Parkinson's disease, and one was for a rare liver disease. Nineteen of these were considered specialty medications.

According to that policy brief, the growing number of specialty medications is taking a toll on employer's health plan cost. At this point, more than half of the drugs in development are considered specialty medications. These medications were expected to make up half of overall drug spend by 2018. In 2020, nine of the ten best selling drugs by revenue are expected to be specialty medications.

With the growing number of specialty medications on the market and their use in more widespread clinical therapy classes, employers need to manage specialty medications efficiently to help keep cost in check.

OPTIONS FOR MANAGING PHARMACY SPEND

Pharmacy benefit managers (PBMs) offer a host of options to help manage specialty medication usage and cost. Employers may want to meet with their PBM to discuss controlling the cost of these medications.

Some options include:

- **Limiting first fills to less than a month (typically 14 days)** – Many specialty medications have harsh side effects that patients can't tolerate. A 30- or 90-day supply of the medication would be expensive especially If the patient can only tolerate it for a week or 10 days. Thus a shorter time on these medications can limit waste. It is not uncommon for patients to struggle with side effects from these medications.

- **Step therapy** – This option requires patients to try less costly medications first to see whether they work. If so, the plan continues to pay for the lower cost medication. If not, the plan will cover the specialty medication. This system helps control cost and the process ensures the patient really does need the specialty medication since other, more established treatments were not effective.
- **Prior Authorization** – This requires a medical provider to review the patient's situation and confirm that the specialty medication is necessary and effective for the patient's condition. In some cases, these specialty medications have not been proven effective for treating certain conditions. Prior authorization ensures the specialty medication is being used for the condition it has been approved to treat.
- **Exclusive Specialty Medication Pharmacy** – Some PBMs own their specialty medication pharmacies and others contract with independent ones. These pharmacies specialize in these medications. They have negotiated aggressive pricing but they also offer expert clinical support in using the medication and managing the logistics involved with receiving and administering the medications.
- **Formulary terms** – The terms of the formulary are important, especially when more than one specialty medication is used for a specific medical condition. If PBMs can negotiate favorable pricing and/or rebates on specific medications, they place them on the formulary. Some plans even have five- or six-tier

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plan designs with lower cost sharing for medications on the preferred specialty pharmacy formulary.

- **Capturing manufacturer assistance or coupons** – Some specialty medication manufacturers offer coupons or help with the substantial costs. If a PBM cannot identify whether the member used a coupon, the plan processes the claim as if the member had paid the full negotiated cost. Some PBMs can identify when members use these coupons and reprocess the claims to reflect the actual amount paid, rather than just the negotiated fee. These coupons and the financial assistance pharmaceutical manufacturers offer ultimately lower plan costs.

While pharmacy benefit managers use these measures to help manage costs, employers can also consider other cost control options. They should check their medical and pharmacy plans to see whether they cover specialty medications. In some cases, the hospital must provide these medications. In other cases, patients may choose where to obtain a specialty medication. In general, hospitals are the most expensive place to obtain the medication since they mark up the price of the drug when they bill the plan. The medical plan has a negotiated rate, but many times the PBM has a better discount.

It is best to exclude as many medications as you can from the medical plan and cover them instead under the pharmacy plan. Along the same lines, employers should understand how their plans cover infusion therapies. These therapies are considered specialty medications. They can be delivered in various settings, such as in a hospital, an infusion center, a physician's office or even at a member's home. Most health plans steer infusion patients to the least expensive setting. However, it is worth checking with your health plan to make sure it is using the most cost-efficient method to cover these infusion therapies.

In addition, employers should ask about case management or care management programs that medical plan vendors or PBMs offer. These programs will often help members manage serious conditions effectively. The case manager will also make sure the member is following the treatment plan and taking medications as recommended. Patients must take these specialty medications as prescribed and must complete the treatment regimens in order for the treatment to be successful.

A handful of employers are getting employees involved in controlling specialty medication costs. Some employers are using medical tourism which encourages employees to travel to a location where the medical prescription or service is less expensive. The cost savings are significant enough to offset travel and lodging cost. PEHP Health and Benefits, for example, provides health insurance to Utah's public employees. The health plan will pay patients to fly to San Diego and then drive them to Tijuana to obtain specific medications at a highly discounted rate. The health plan will share some of the savings with patients who are willing to travel to save the plan money. Under Utah state law, plans must offer cash back to those who travel for less expensive treatment.

The plan estimates it saves 40 to 60 percent on the cost of specific medications after netting out travel cost and incentives paid to members. The health plan screens those patients who take part in this voluntary program to make sure travel is appropriate. The plan identifies certain medications for the medical tourism program. It offers incentives for members to shop for better prices in the states as well. While this aggressive plan may keep costs down, employers need to consider whether medications purchased over the border are safe.

Some employers have chosen to work with mail order pharmacies that obtain medications from Canada and then import them for health plan members. This approach is illegal. The FDA does not allow health plans or PBMs to import medications. The Trump Administration has outlined a proposal to allow the United States to import cheaper prescriptions from Canada. Rules were proposed at the end of 2019 on when re-importation from Canada would be permitted. These rules

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and processes have not been finalized. However, Canada is now considering legislation to block the ability for Canadian firms to send medications to the United States.

Employers should also keep an eye on *biosimilar* medications. In 2009, Congress passed an act that allows a quicker pathway to licensing biological products that are shown to be biosimilar or interchangeable with an FDA approved biological product. Generics are not an option for biologics because it is difficult to duplicate the environment and organisms used in manufacturing them. Biosimilar medications will help stem the cost of some of these specialty medications over time, but the expense will still be a challenge for employer-sponsored health plans.

CONCLUDING THOUGHTS

Specialty medications have had an impact on health plan cost. They will continue to be an issue since many medications in the development pipeline will be considered specialty medications.

To control these costs, you will need to work with your vendors. In fact, it may make sense to talk to your PBM at least once a year to become familiar with usage patterns under your plan and the options available to help control cost. You may also want to meet with your health plan vendor to discuss infusion therapies and other covered specialty medications to see whether there are less expensive ways to purchase them. MMA

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