myMatrixx®
by Evernorth

Demystifying Drug Pricing in Workers' Compensation

2023 Report Series

Part Three: **The Impact of Specialty Drugs**

Rising drug costs continue to be a discussion point across the health care and workers' compensation fields, as well as the broader media landscape. In just one example, a recent USA Today story[1] covered drug price increases by major drug companies as a preemptive response to measures in the Inflation Reduction Act specifically intended to curb drug price inflation. Headlines such as these also generally align with public perception around high prices. In fact, a KFF poll published in August 2023[2] found that 82% of responders believe that the price of prescription drugs is unreasonable.

In light of this ongoing attention to drug prices, this series continues to closely examine the many factors contributing to pharmaceutical spend in workers' compensation. Employers, plan administrators and payers in the workers' compensation system regularly encounter increased prescription drug prices and a corresponding rise in spending. For many plan managers and payers, it can be particularly frustrating to see year-over-year improvements in areas such as generic substitution or opioid utilization but still have an increase in overall drug spending.

Identifying and addressing the real cost drivers in workers' compensation pharmacy programs requires deep analysis and an understanding of the current drug landscape—functions that should be central to the role of a pharmacy benefit manager (PBM). Segmenting and identifying specific cost drivers can help claims professionals, payers, plan managers and other stakeholders take appropriate action and build effective cost-management strategies.

In previous series, we discussed traditional drugs, followed by opioids as a special subcategory. Due to factors such as vigilant clinical management and an emphasis on generic substitution and efficiency, we concluded that aggregate spending is actually decreasing in the traditional drugs category. Proactive clinical management, cost-reduction strategies and opioid weaning continue to be effective in keeping prescription drug spending down.

In part three of this drug pricing series, we will focus on specialty drugs, a topic myMatrixx has covered in the past.[3] In health care, specialty drugs have become a primary driver in pharmaceutical spending[4] over the past five to 10 years. These are medications with a potential price tag in excess of $100,000 for a single claim. Even as spending and utilization of specialty drugs increased, many experts predicted that the impact on workers' compensation would be minimal. However, with more specialty drugs being developed for a wider range of conditions, this category will more than likely have a substantial impact on work-related cases over the next decade.

myMatrixx partnered with Accredo by Evernorth to co-author this white paper for workers' compensation professionals to educate them and provide expert insights to help lower their program costs.

Accredo
By EVERNORTH

Key takeaways from Part Three of our drug pricing series:

1. In workers' compensation, specialty drugs often impact claims involving orthopedic surgery, HIV, hepatitis C, arthritis, spasticity, rheumatoid arthritis and more recent conditions, such as long COVID.

2. The prevalence of these conditions in certain industries, the expansion of compensability for many conditions and the volume of specialty drugs in development will significantly impact the workers' compensation industry in the near future.

3. An understanding of the drugs currently under development and their potential prescription costs and length of time for therapy is required to develop a strategy for effective management of these novel therapies.

4. Due to the complexity of specialty medications, a limited number face competition from specialty generics and biosimilars, but more alternatives are in development.

1. Defining Specialty Drugs

Specialty drugs is not an official designation, and not every health plan or PBM has the same definition or list. Instead, specialty drugs is a general term to identify drugs specially developed for specific patient groups to treat chronic and complex conditions and that typically require specialized manufacturing and handling, such as temperature control.

Other common characteristics of specialty drugs include:

- Intense clinical-monitoring requirements to manage severe side effects
- Specialized patient training for handling and/or administration
- Clinical pharmacist oversight to ensure patient compliance
- The need for regular or frequent dosage adjustments
- Distribution through specific channels, including Accredo, an Evernorth specialty pharmacy

Although cost is no longer explicitly part of the definition for many organizations, these are very often high-cost drugs. Due to the complex administration, monitoring and handling requirements for specialty medications, dedicated specialty pharmacies play an essential role in fulfilling and administering prescriptions. A specialty pharmacy is equipped to meet the needs associated with this class of drugs.

2. Specialty Drugs Cost Drivers

To develop an effective specialty drug strategy, workers' compensation claims managers and professionals can benefit from understanding exactly why this class of drugs can be so costly. The very nature of specialty drugs means that research, development, manufacturing and administration are all typically far more complex than even high-cost traditional drugs.

Specific cost drivers of specialty drugs across the category include:

High research costs: Specialty drugs are often derived from living cells, which are far more chemically complex than simple pharmaceutical molecules, such as aspirin. Breakthroughs for these drugs require substantial research and development (R&D) even beyond other pharmaceuticals.

Unique manufacturing processes: Many of these drugs typically cannot be mass-produced in the same manner as traditional drugs. They must be created in highly controlled lab settings often using advanced techniques to grow complex biological molecules.

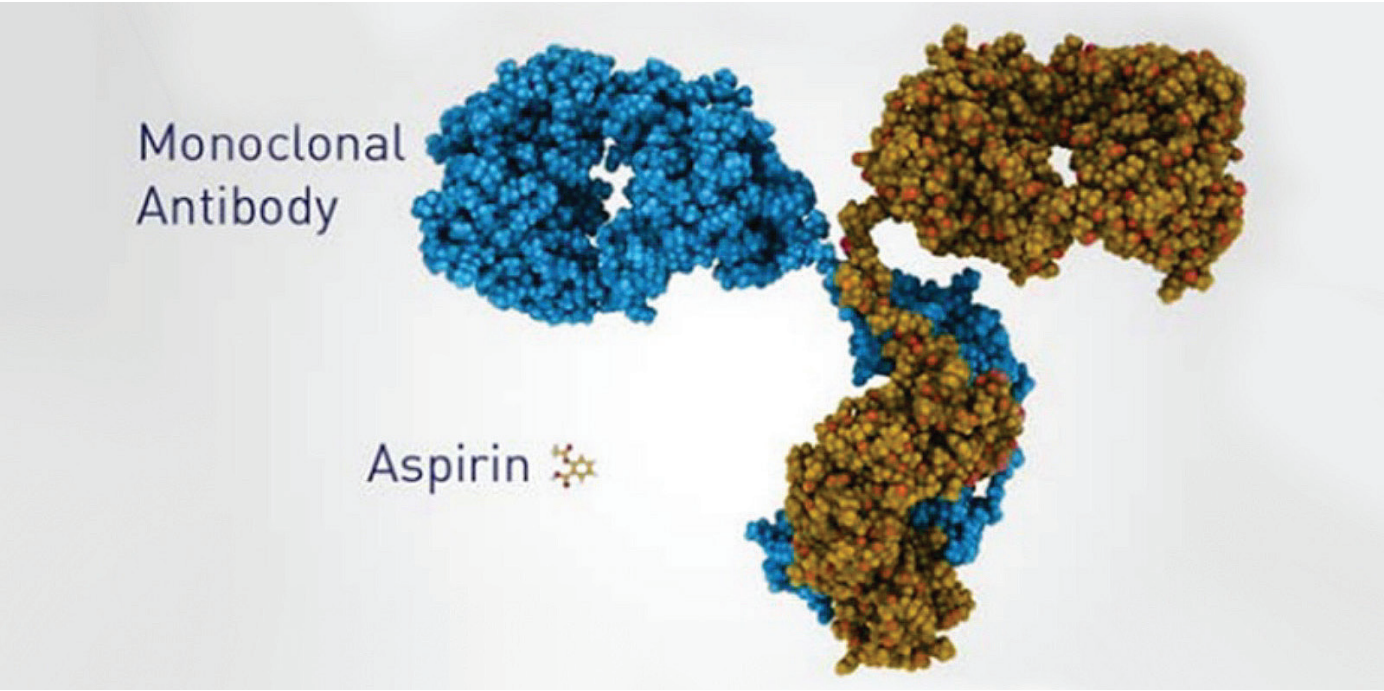
Requirement of special handling and storage: Once manufacturing is complete, specialty drugs generally must be shipped and stored in carefully controlled conditions, such as refrigerated or freezing temperatures.

Specialized administration: Often, specialty drugs are not pills; they are commonly delivered as injections or infusions. Many specialty drugs must be administered in a clinical or hospital setting by specially trained providers.

Lack of generic equivalents: Because of the complexity of many of these drugs, it is often not possible to develop and approve a generic equivalent.

Prescribing practices: In a large number of cases, specialty drugs are medically necessary for serious conditions, such as HIV or hepatitis C. In other situations, higher-cost specialty drugs are prescribed for conditions or injuries before other therapies have been attempted.

Higher price tag: Since specialty drugs are developed for smaller populations of patients than traditional drugs, prices are often higher.



The monoclonal antibody (blue) is a large molecule. A single monoclonal antibody weighs more than 800 times what an aspirin molecule (gold) weighs.

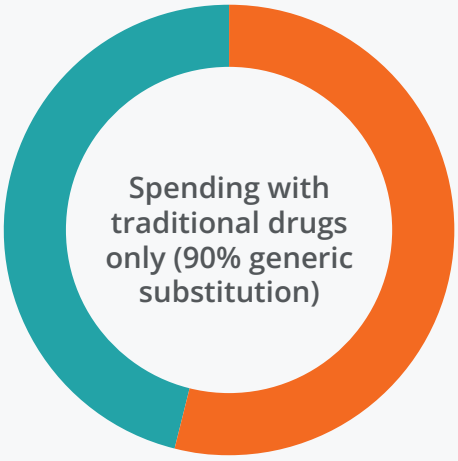
3. Specialty Drugs and Workers' Compensation

A high proportion of new drugs under review by the Food and Drug Administration (FDA) includes specialty drugs, and 54% of novel drug approvals by the FDA Center for Drug Evaluation and Research (CDER) in 2022 were for rare diseases.[5] For years, workers' compensation claims have primarily involved traditional drug therapy, such as pain medication for an orthopedic injury. With so many new drugs in development, the result is a growing list of work-related cases with a high potential for specialty drug utilization, including:

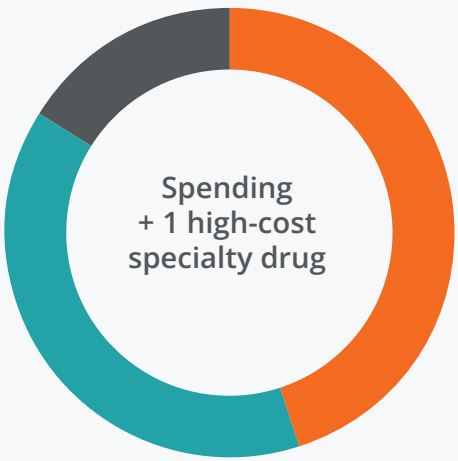
+ Patients with restricted mobility, such as those recovering from orthopedic surgery
+ Workers exposed to HIV or hepatitis C through blood, needlestick injuries, or other potentially infectious fluids
+ Injured workers who experience pain and later diagnosed with rheumatoid arthritis or ankylosing spondylitis
+ Injured workers with pain exacerbated by osteoarthritis
+ Patients with chronic migraines or cervical dystonia
+ Certain workers who develop cancer in states with cancer presumption
+ Workers with certain COVID compensable claims

Specific specialty drugs that could be encountered in workers' compensation cases include anticoagulants, antiretrovirals, disease-modifying antirheumatic drugs (DMARDs), viscosupplements, antivirals, Botox® and chemotherapy agents. Although the likelihood of a case requiring high-dollar specialty drugs is still relatively low for many payers, the proportionally high cost of these drugs means that even one specialty drug prescription in a workers' compensation portfolio can drastically increase overall pharmacy spending. This is especially true for self-insured employers managing their own claims portfolios, although this category can be a significant source of increased spending for any size employer, plan or payer. Understanding and properly managing a case requiring specialty medications is critical from both a treatment and cost management standpoint.

How One Specialty Drug Can Impact Pharmacy Strategy



NAME-BRAND TRADITIONAL DRUGS	$188,545
GENERIC TRADITIONAL DRUGS	$216,990
TOTAL	$405,535



HIGH-COST SPECIALTY DRUG	$74,462
NAME-BRAND TRADITIONAL DRUGS	$188,545
GENERIC TRADITIONAL DRUGS	$216,990
TOTAL	$479,997

4. Biologicals and Biosimilars Explained

Biologicals are an important subset of specialty drugs. They can be defined as a varying category of drugs consisting of large and complex molecules. Biological drugs may be produced using biotechnology by modifying a living system including microorganisms, plant cells or animal cells.

Unlike traditional small-molecule medications, such as aspirin, that have standard production methods and well-defined structures, biological products have a sophisticated manufacturing process involving cell cultures. Although certain non-biological specialty drugs may have a generic version when the patent expires just like traditional drugs, this is not possible with biologicals. Instead, biosimilar products are biological products manufactured to resemble reference biological products. However, there are several key differences between generics and biosimilars.

The Biologics Price Competition and Innovation Act (BPCIA),[6] which was signed into law as part of the Patient Protection and Affordable Care Act (PPACA) of 2010, has created a pathway for the approval of biosimilars that has helped make biological products more affordable. Due to the complexity of the R&D and manufacturing processes and other factors, biologicals cannot effectively have generic versions created, even after the patent expires. With biosimilars, the new product can obtain interchangeability status with the reference drug. Without interchangeability status, the prescriber must write the prescription for the biosimilar instead of the reference product. Even with interchangeability status, certain states such as Texas, require the dispensing pharmacist to notify the prescriber of the change.

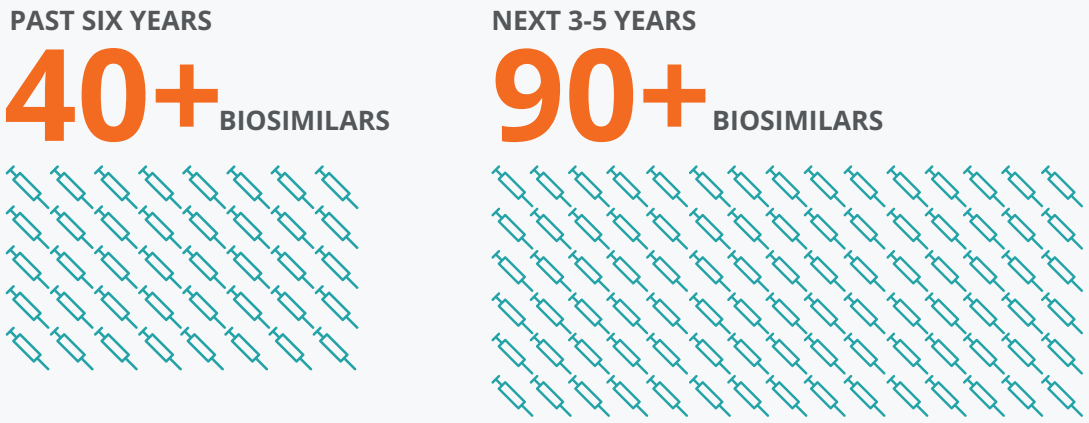
Despite attempts to facilitate the availability of biosimilars and interchangeability status, manufacturers can still exploit certain loopholes, such as the use of "patent thickets." According to a recent Evernorth report,[7] this describes a practice where manufacturers of branded biologics engulf the U.S. Patent and Trademark Office with overlapping, follow-on patents with different expiration dates for a single drug to prevent or delay competition from coming to market. Combined with other practices and legal maneuvers, this can enable manufacturers to extend monopolies on branded drugs beyond the end of the original patent and increase prices over an extended period.

Together, these tactics can make the lag time for biosimilars to displace the reference product much longer than that of traditional generic drugs. A proactive clinical intervention is needed to narrow this gap. According to information from Evernorth, more than 90 biosimilars are in development. The FDA has approved 38, and 22 are available for use as of 2022.[8] Furthermore, like generics, there are multiple biosimilars for many of the brand-name reference products.

Biosimilars to Remicade® (infliximab), which treats rheumatoid arthritis among other conditions, were among the first biosimilars. Remicade® spending declined from $8.3 billion in 2021 to $6 billion in 2022, while spending on Remicade biosimilars increased, including Inflectra, a biosimilar produced by Celltrion/Pfizer, which grew from $1.5 to $3 billion.[9]

By the end of 2023, 11 biosimilars to Humira® (adalimumab), another widely used biologic for patients living with rheumatoid arthritis and other inflammatory conditions, will be available in the United States.[7] In workers' compensation cases where a workplace injury or condition exacerbates preexisting rheumatoid arthritis, interchangeability status for Humira biosimilars could have a tremendous cost-savings impact.

Biosimilars entering the market



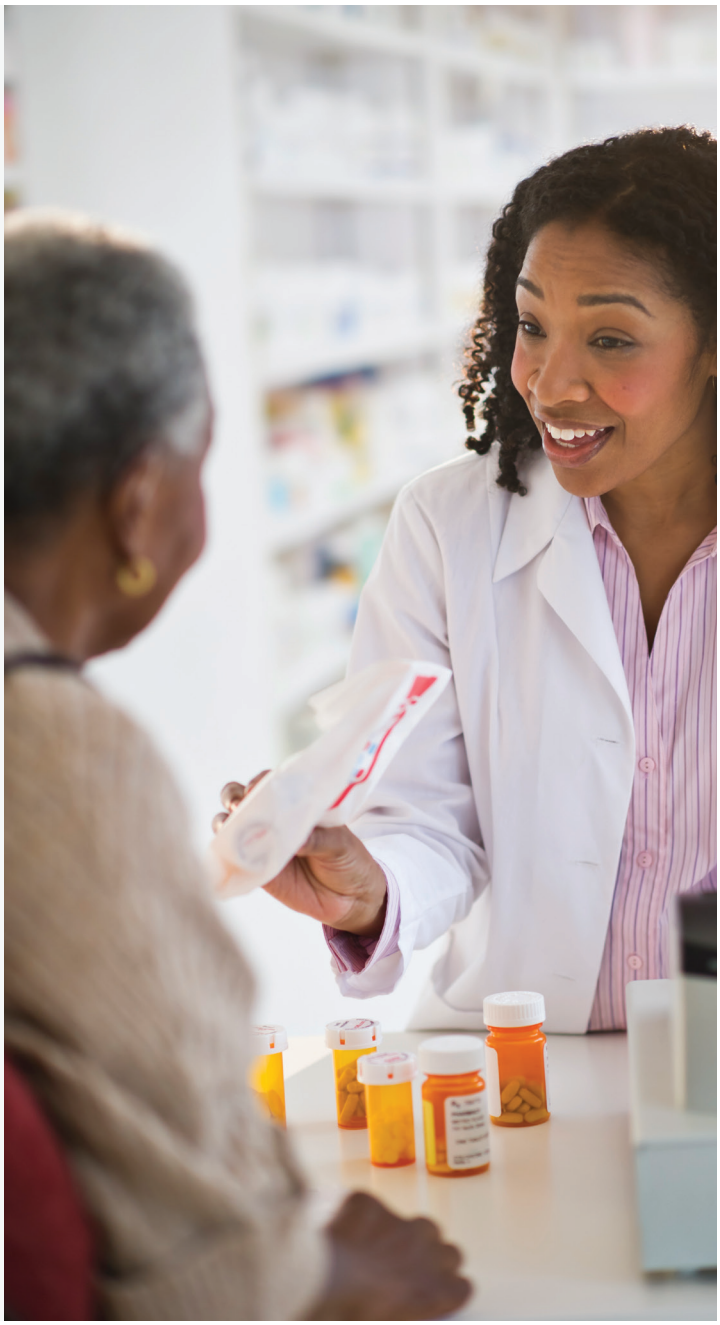
The FDA Purple Book[10] is a key resource for prescribers, pharmacists, claims professionals and other parties to help navigate the shifting specialty drugs landscape as more biosimilar drugs are approved. Similar to the Orange Book for traditional drugs, the Purple Book has information on biological products, including both biosimilar and interchangeable biologicals, that have been approved. According to the FDA, this searchable database contains all essential information on drugs regulated by the Center for Biologics Evaluation and Research (CBER) including biosimilar, interchangeable and reference products as well as allergenic, cellular therapy, gene therapy, hematologic drugs and vaccines.

5. Effective Cost-Reduction Strategies for Specialty Drugs

Due to the high associated costs, the medically necessary nature of many of the medications in this category and the lack of lower-priced competition, there are limited ways to reduce spending on specialty drugs if there is a claim. First, clinical review of a specialty prescription to ensure it is necessary and appropriate should be part of any pharmacy management program. For clinically appropriate specialty medications, effective approaches include intervention strategies to confirm generic or biosimilar use when available and ensuring compliance to reduce waste and promote positive treatment outcomes.

Plan sponsors can work to mitigate dramatic cost increases by implementing an aggressive range of spend controls and evaluating the programs that are right for their patient population, including:

- Trend management programs, such as utilization management
- Patient education to avoid costly and dangerous gaps in care and adverse events
- Days' supply programs
- Therapy management to avoid waste
- Dosing and regimen optimization
- Value-based solutions
- Physician engagement to ensure optimal generic, biosimilar adoption and utilization management program compliance



6. Staying Informed of Biosimilar Costs

When available, biosimilars have the potential to keep costs down, but there are fundamental differences between biosimilar substitution strategies and generic substitution for traditional drugs, although there are specialty generics on the market that do benefit from generic conversion. It is critical to understand that biosimilars are brand-name drugs themselves that compete with the original brand-name drug which may help to reduce overall costs.

Because generic substitution laws do not apply to biosimilars, realizing savings from this category requires an advanced, aggressive intervention strategy from the PBM combined with education for both providers and patients on their safety, effectiveness and availability. This typically means staying informed of any new and pending lower-cost biosimilar or interchangeable specialty drugs as they come to market and proactively adjusting utilization managements programs.

7. How Compliance Plays a Role in Workers' Compensation

Drug compliance is extremely important for any plan managers and payers seeking to minimize spending and ensure effective outcomes for specialty drugs. For injured patients who have been prescribed one or more specialty drugs, complications can arise. In turn, these complications could lead to higher costs—beyond the costs of paying for repeat drug therapy. Together, this can create a risk to outpace the original treatment therapy.

It is vital that workers' compensation programs follow specific compliance requirements for specialty drugs and have a strategy in place to ensure injured patients stay on their treatment plans. Unlike pain medication, where the presence of symptoms can encourage patients to stay on a drug plan, benefits may not be easily seen with specialty drugs. Whether due to resistance to the treatment plan or forgetfulness, missing specialty drug treatment comes with higher risks compared to traditional drugs.

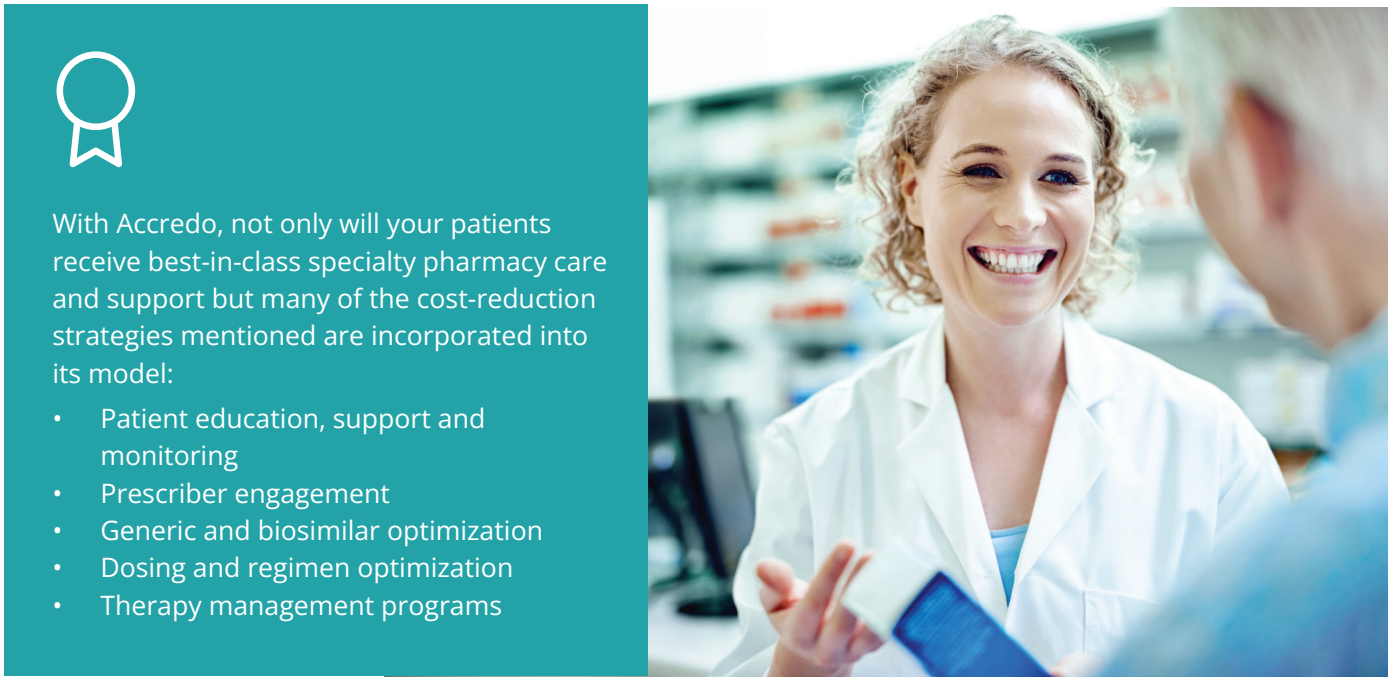
For example, when using DMARDs for inflammatory conditions, a risk of complications exists from missing scheduled doses, including further joint damage, osteoporosis, carpal tunnel syndrome, and even heart and lung problems. This could ultimately result in cardiovascular events, such as a stroke or heart attack. The current average cost of treatment after a severe heart attack, including direct and indirect costs, can be as high as one million dollars, according to a study from the National Business Group on Health.[11]

To prevent complications or the need for repeat drug therapy, compliance programs can help ensure the drug is being properly and consistently administered.

8. How Evernorth, myMatrixx and Accredo Can Help

Evernorth is a leading voice in the industry for drug affordability, biosimilar advocacy and availability. As part of the larger Evernorth Health Services–administered pharmacy benefits network, workers' compensation cases managed by myMatrixx have access to Accredo, one of the nation's leading specialty pharmacies. Accredo provides individualized care for patients requiring specialty medications through Therapeutic Resource Centers. Accredo Therapeutic Resource Centers provide expert patient care through deep disease state specialization: specialized pharmacists, nurses, patient care advocates and other experts with extensive training and experience in specific conditions and specialty medications.

Accredo employs more than 600 in-sourced field nurses to assist patients with medications in their homes. In addition, Accredo goes beyond the prescription by helping patients understand their condition and therapy while providing additional care services, such as dietician and social worker support.



With Accredo, not only will your patients receive best-in-class specialty pharmacy care and support but many of the cost-reduction strategies mentioned are incorporated into its model:

- Patient education, support and monitoring
- Prescriber engagement
- Generic and biosimilar optimization
- Dosing and regimen optimization
- Therapy management programs

myMatrixx is well-positioned to take advantage of the savings generated from biosimilars through this partnership. As a full-service PBM, myMatrixx is committed to using proactive clinical intervention, data analysis and reporting to provide solutions that improve the health of injured workers requiring specialty medications while promoting financial value and accountability for stakeholders in the workers' compensation system.

Conclusion

With indications pointing to increased utilization of and spending on specialty medications in workers' compensation in the coming years, it is incumbent on PBMs to provide solutions that improve injured workers' health while promoting financial accountability for the prescribing of specialty medications.

In the next part, we will conclude this drug pricing series with a discussion of physician dispensing and compounding in the current workers' compensation landscape. Despite recent progress, this is another area requiring segmentation and careful examination to provide full clarity on pharmaceutical spending in our industry.

Working together, working for better

Learn more about our Workers' Compensation products and solutions at: **myMatrixx.com.**

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