



**SPECIALTY DRUGS IN
WORKERS' COMPENSATION
A GUIDE FOR CLAIMS HANDLERS**

Specialty Drugs

Specialty drugs have been developed in response to demand for specialized medications for complex medical conditions.



Twenty years ago there were only 10 specialty drugs on the market and they were rarely seen in workers' compensation. Today there are over 300, and drugs such as anticoagulants and antivirals are making their way into claims. There is a great deal of confusion surrounding specialty drugs. What are they? How are they utilized in workers' comp? Why is this a hot topic?

What exactly are specialty drugs?

Although the FDA has not published a specific definition to classify specialty drugs, the generally accepted criteria include one or more of the following conditions:

- Medications with costs > \$600 per month
- Medications that treat rare or complex conditions
- Medications that require special handling
- Medications that use limited or restricted distribution networks
- Medications that require ongoing clinical assessment

There is a common misconception that specialty drugs are compounds; they are not. Specialty drugs are manufactured drugs that have been developed in response to demand for specialized medications for complex medical conditions.

Will specialty drugs impact workers' comp claims?

Yes! Although expenditures on specialty drugs currently represent a small fraction of total drug spend, the prescribing trend is climbing rapidly. How much impact specialty drugs will have on claims depends largely on the demographics of the insured population, but the cost associated with only one employee's claim could unexpectedly increase drug spend dramatically.

Injured workers who are most likely to receive specialty drugs include:

- Emergency first responders
- Healthcare workers
- Public safety personnel
- Law enforcement officers
- Correctional officers
- Firefighters in states with cancer presumption laws

Specialty Drugs *(continued)*

What else do I need to know?

Specialty drugs represent the fastest growing segment of the U.S. pharmaceutical market. In 2012, the FDA approved a record number of 39 new agents, 25 of which can be classified as specialty drugs. With increasing utilization and with over 180 new medications in the development pipeline, projections indicate that specialty drugs will account for half of all pharmacy costs in fewer than five years. These numbers should be concerning for payers, and efforts should be made to increase vigilance and management of this sector of pharmacy spending.

Although uncommon, the conditions and disease states associated with specialty drugs can arise from work-related injuries. Worker populations most at risk are:

- Workers with restricted mobility, such as post-orthopedic surgery patients
- Workers who have contact with blood or potentially infectious fluids
- Workers who are exposed to occupational needle sticks
- Workers who experience pain and are diagnosed later with rheumatoid arthritis or ankylosing spondylitis
- Workers whose pain is exacerbated by osteoarthritis
- Workers with traumatic brain or spinal cord injuries
- Firefighters and certain other workers in states with cancer presumption laws

Specialty drugs carry a hefty price tag. Cost drivers include expensive development costs, the relatively small number of patients who utilize the drugs, special handling requirements, restricted distribution networks, and the specialized knowledge and skills required to ensure safe and effective use of the medications.

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Are the high costs of specialty drugs justified?

Although specialty medications are very expensive, non-compliance with recommended drug therapies can be even more costly. The following is a real case example:

A small city employer currently has an employee who is infected with the hepatitis C virus. The employee did not receive timely drug therapy, and this patient has now developed cirrhosis and hepatocellular carcinoma. The current course of treatment includes Solvaldi + ribavirin while the patient awaits a liver transplant. The monthly medication costs of \$32,000 for this patient nearly equal the employer's entire \$34,000 drug spend for 2013 — and the average price tag of a liver transplant is \$280,000.

In contrast, the average annual cost for treating hepatitis C with the antiviral drug Solvadi is \$90,000. Moreover, if the Solvadi treatment is managed well, the cure rate is 89% and the improvement in the patient's quality of life is immeasurable.

Specialty Drugs *(continued)*

TOP 7 Specialty Drug Categories in Workers' Compensation

1. Anticoagulants
2. Antiretrovirals
3. Biologic DMARDs
(Disease Modifying Antirheumatic Drugs)
4. Hyaluronic Acid Derivatives
5. Hepatitis C Antivirals
6. Botulinium Toxins
7. Chemotherapeutic Agents

Anticoagulants

Anticoagulants are strongly recommended by the U.S. Agency for Healthcare Research and Quality (AHRQ) following orthopedic surgery to prevent deep vein thrombosis (DVT). Following surgery, restricted mobility increases a patient's risk. In rare cases, a blood clot can travel to the lungs and cause pulmonary embolism or even a heart attack or stroke.

Antiretrovirals

Antiretrovirals are used to prevent transmission of the HIV virus. If workers have a risk of HIV exposure, it is imperative that the organization's Pharmacy Benefit Manager (PBM) establishes a formulary that does not delay benefits. The injured worker must be able to pick up medication from the pharmacy immediately to begin therapy within hours of exposure. myMatrixx has developed a specialized PEP (post-exposure prophylaxis protocol) formulary that is designed to ensure that PEP initiation is not delayed for an exposed worker, while also ensuring that the client does not pay for HIV medication not related to a workplace injury.

Biologic DMARDs (Disease Modifying Antirheumatic Drugs)

Workers' compensation claims for biologic DMARDs may be most commonly related to diagnoses of rheumatoid arthritis (RA) or ankylosing spondylitis (AS), which are inflammatory conditions that result in pain. It should be noted that a person is genetically predetermined to have RA or AS, but because workers who report an onset of pain on



the job can be diagnosed later with RA or AS, experience dictates that these conditions are sometimes accepted as compensable.

Hepatitis C Antivirals

Hepatitis C antivirals are used to treat people infected with the hepatitis C virus (HCV). The occupational risk of HCV exposure is likely most prevalent for healthcare workers; however, exposure to blood and other potentially infectious fluids can occur across a wide variety of occupations, including emergency responders, public safety personnel, law enforcement officers, and correctional officers.

As noted previously, the latest specialty drugs developed to treat HCV are expensive; however, they can be cost effective in comparison to the average cost of a liver transplant (\$280,000), and patients typically experience good outcomes with these drugs, with a cure rate of 89%.

Botulinium Toxins (Botox®)

In addition to the cosmetic indication most frequently associated with Botox® (onabotulinumtoxinA), Botox has been approved to treat several other conditions, but only a few are potentially related to workers' compensation injuries:

- Chronic migraine headaches
- Upper limb spasticity associated with traumatic brain injury or spinal cord injury
- Cervical dystonia associated with trauma
- Overactive bladder associated with spinal cord injury

Specialty Drugs *(continued)*

Chemotherapeutic Agents

Cancer medications meet all five criteria identified by the American Journal of Managed Care for specialty drug classification: cost is typically more than \$600 per month, prescriptions are for rare conditions, most require special handling, have restricted distribution, and require ongoing clinical monitoring.

Thirty-three states have adopted cancer presumption laws for firefighters and certain other emergency medical service providers. Cancer presumption laws essentially remove the traditionally required burden of proof prescribed upon the employee that an injury, illness, or disease is caused by occupational exposure. Work-relatedness of the affliction is automatically presumed.

What is the best approach to balancing quality care with cost containment?

Because the medical conditions where specialty drugs are indicated are complex, it is extremely important to ensure that the most appropriate treatment is utilized and that the patient strictly adheres to the drug therapy regimen. Adverse side effects and drug interactions are common, and clinical monitoring from the pharmacy benefit manager (PBM) and treating providers is essential.

myMatrixx has created complex care management programs designed to monitor the therapy and care of critically-injured or ill patients, as well as others who require specialty medications. By combining pharmacy and nursing services under one program, myMatrixx has created a system that monitors FDA approval of new specialty drugs and expansion indications of existing drugs and informs our clients of new specialty medications and the potential impact on their injured worker population.



myMatrixx also provides medication therapy management programs that encourage patients to be part of their recovery by:

- Monitoring and facilitating adherence to complex drug regimens
- Reporting all adverse drug events or side effects
- Informing treating physicians of non-adherence or other medication-related concerns
- Ensuring client dollars are not wasted as a result of therapy failure

Claims adjusters and nurse case managers play a vital role by:

- Identifying patients with chronic conditions that may be treated with a specialty drug
- Verifying the appropriateness of the specialty drug therapy with the pharmacists within the organization or with their PBM
- Recognizing that denial of the specialty medication might not be an option
- Coordinating with the PBM to manage the patient's care through specialty programs offered by the PBM
- Ensuring adherence to the prescribed drug therapy regimen, especially when outcomes are improved with timely administration

Specialty Drugs *(continued)*



About myMatrixx

myMatrixx is a full-service pharmacy and ancillary benefit management company focused on the workers' compensation market. By combining advanced technology, clinical expertise, and comprehensive reporting, myMatrixx simplifies the management of claims. Our results-driven solutions deliver reduced costs for our clients and improve outcomes for their injured workers. For more information, visit www.mymatrixx.com.



For an in-depth look at the impact of specialty drugs in workers' compensation, download myMatrixx's comprehensive white paper [here](#).