Understanding the Top Challenges of Prescribing Specialty Medications

The growth of specialty medications has reached exponential proportions in the United States, estimated to make up half of the nation's spend on prescription drugs by 2021. There is no standard definition for specialty drugs, but these medications are typically highly complex and costly, requiring special handling and/or administration. Similarly, the factors driving the changing landscape of specialty drugs involve several components and challenges.

The landscape reflects the current health concerns of the patient population. As more and more Americans face serious chronic health concerns, manufacturers have developed new drugs to help treat these conditions. Manufacturers are also incentivized by the high profitability of these medications and low competition in the market — new legislation has made it easier to develop, market, and release specialty drugs in record time. The push isn't just from manufacturers; patients are also showing greater interest in personalized medicine and tailored treatment plans.

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However, the high cost of specialty drugs and the multi-step process to begin treatment plans remain a significant concern for healthcare providers and oftentimes are an obstacle for seriously ill patients. As more specialty drugs enter the market, prescribers can set their patients up for success by ensuring access to critical information at the time of prescription. Key to this success is an understanding of the driving forces behind the market's growth, common barriers and obstacles for prescribers, and ways to overcome those hurdles for better patient results.

The Fast Rise of the Specialty Drug Market

The quickly-increasing specialty medication market in the United States can be partly attributed to the parallel growth of chronic diseases. The CDC defines chronic diseases as “conditions that last a year or more and require ongoing medical attention and/or limit activities of daily living.” The most common conditions include heart disease, cancer, diabetes, stroke, and lung disease, etc. It’s estimated that 60% of the population has a single chronic disease, while 40% have two or more.

From 1990 to 2015, the number of FDA-approved specialty drugs available on the market rose from 10 to 300, representing a 2,900% increase. However, the growth of the market isn’t just a matter of meeting patient needs. Legislation and technology advancements have made it easier for these drugs to be developed and released.

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60%

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40%

of the population have two or more chronic diseases.

The Orphan Drug Act of 1983 was put in place to address the lack of medical advancement for smaller patient populations suffering from uncommon diseases. The Orphan Drug Act offered tax benefits, research subsidies, and financial incentives to pharmaceutical manufacturers who research and develop treatment for diseases that affect a smaller percentage of the population. It also made it easier to maintain market exclusivity and perform trials on smaller groups of patients.

The Orphan Drug Act was followed by the Rare Disease Act of 2002, which provides additional funding and the establishment of the Office of Rare Diseases under the National Institutes of Health. Both the Orphan Drug Act and the Rare Disease Act have led to greater research into chronic or uncommon diseases and the ongoing development of treatments.

In 2016, the 21st Century Cures Act was signed into law, with the purpose of accelerating the discovery, development, and delivery of innovative cures. This act authorized $6.3 billion in funding to drug research and development, biomedical research, greater mental health parity regulation, and modifications of the FDA's drug approval process. As a result, the FDA's drug approval process has been expedited. In some cases, the FDA now allows real-world evidence and data summaries rather than full clinical trials for new products or new applications of existing drugs — the FDA approved 32 specialty drugs in 2019 alone.

The percentage spent on specialty drugs rose significantly as well, jumping from 44.7% of the market in 2018 to 47.7% in 2019. It should come as no surprise then that specialty drugs are projected to account for half of the nation's drug spending by 2021.

Patients have also shown a greater interest in personalized medicine. The concept of personalized or precision medicine has been around for decades, particularly in the field of pharmacogenomics (how genes affect medication effectiveness). Today's patients are more apt to take charge of their care and explore treatment options in greater depth. For example, medicine tailored to genomic makeup brings a greater appeal to today's patient population and reflects similar trends in the consumer market. Combined with financial incentives, this interest has led to greater investment and development in specialty drugs that fall in line with the concept of personalized medicine.

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The number of specialty pharmacies has grown in tandem with these medications, projected to reach $500 billion in volume by the beginning of 2021. According to the Pharmacy Times, this increase "is directly related to the growth of specialty and limited distribution medications. More health systems will begin to adopt integrated specialty pharmacies to better manage their patient care and increase adherence rates."

Why Are Specialty Drugs So Expensive?

The high cost of specialty medications is one of the primary concerns for both healthcare providers and patients. According to an AARP report, in 2017 the average annual cost for one of the most widely used specialty medications was almost $79,000. Zolgensma, a type of gene therapy, became the most expensive single dose drug in 2019 with a list price of $2.1 million!

What makes the costs so disproportionate to the size of the patient populations? First, these drugs often take longer and cost more to develop than non-specialty medications. The manufacturers also face less competition in the market due to patents and a lack of generic alternatives.

Because these drugs make up only 2% of all prescriptions, manufacturers do not have volume on their side to increase profit margins. However, the high price points are no doubt attractive to manufacturers in general. These prices are often increased annually as well.

These drugs now make up 17% of the average employer's pharmacy costs. As a result, the high prices have led to higher insurance premiums, as well as specialty ties in insurance plans. In many cases, patients must pay a greater percentage of the overall cost for the medication than they would with non-specialty drugs.

50%

of all prescription costs can be expected to come from specialty medications by 2021.

17%

of the average employer's pharmacy costs are made up of specialty drugs.

2%

of all prescription drugs are made up by specialty drugs.

$79,000

the average annual price of specialty drugs.

Still, there may be price-pressure on the horizon for at least some specialty drugs, especially those with patents set to expire in the next few years. The growth of the biosimilar market may lead to lower prices for patients prescribed biologics (biosimilars are highly similar to another already approved biological medicine). According to the Pharmaceutical Care Management Association (PCA), prices for biosimilars are typically 20% less than their brand name counterparts and may fall by as much as 40% after several years on the market.

Because biosimilars have no meaningful clinical difference in terms of safety and effectiveness, experts predict that their price wars with biologics will resemble that of a brand-to-brand rather than brand-to-generic competition. Total estimated savings range from $44 billion to $250 billion over the first decade biosimilars are made available to patients.

The PCA also indicates that the clock is ticking for at least 12 biologic products with patents expiring between 2020 and 2022. These 12 products have global sales of over $67 billion, making them very attractive targets for biosimilar manufacturers.

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Complexities of Prescribing, Dispensing, and Managing Specialty Drugs

In recent years, the top-selling specialty medications have been prescribed to treat rheumatoid arthritis, Crohn's disease, uveitis, multiple myeloma and lymphoma, and lung, breast, ovarian, renal, and colon cancers. Most commonly prescribed by by specialists rather than primary care physicians, these drugs come with high price tags. The heightened cost is a particular concern for healthcare providers when evaluating medication access and adherence for their patients.

Patients with chronic or complex health concerns may delay or avoid treatment due to fears surrounding cost. Others may fail to take the medication as prescribed to prolong paying for the next refill or treatment. Patients may also be unaware of the high price tag of these medications and face “sticker shock” at the pharmacy, choosing not to fill the prescription after all.

The process leading up to the prescription is often long and stressful for the patient, involving referrals, follow-ups, testing, and diagnosis. The amount of time it takes for a patient to start specialty medication can take from one to two weeks — sometimes even a month. Patients on more than one specialty medication have multiple timelines and price points to juggle, all while dealing with chronic, often debilitating conditions.

Plus, if providers struggle to find critical information at the time of prescription, it could further hinder some of these administrative tasks. At the same time, providers must navigate requests for prior authorizations, denials, and requests for more alternative medications. These tasks only increase the time-to-fill the prescription. On average, tasks can add up to 15 hours per week, which takes time away from patient care.

The National Council for Prescription Drug Programs (NCPDP) found that 75% of specialty prescribers find it difficult to access some or all of the following information:

- **Availability of lower-cost alternatives**
- **Prior authorization requirements**
- **Patient prescription benefit data**
- **The patient’s predicted out-of-pocket costs**

This lack of accessibility can lead to patients beginning medication later than desired or never filling the prescription at all if the cost is too high. Other key issues at the time of dispensing include which pharmacy to use—if the patient’s local retail pharmacy is unable to fill the prescription, providers may try a specialty pharmacy. This step increases the timeline and may not be successful if the pharmacy has insurance or distribution constraints.

It is not uncommon for providers to send specialty medications to multiple pharmacies until they find an option that works with the patient's insurance and location. At the end of the day, time-to-fill can be high for specialty medications due to more complex insurance and pharmacy workflows, in addition to the financial obstacles for the patient.

Long approval or dispensing timelines are frustrating for just about all patients and their providers. Prior authorizations are a regular request for specialty drugs prescriptions and they often result in delayed treatments. Ninety-one percent of healthcare providers say prior authorizations delay care and 75% say the process has caused patients to abandon treatment. This statistic is particularly concerning when considering patients with chronic and/or complex illnesses.

Delays in receiving medication and treatment put the patient's well-being, comfort, and even life at risk. Delayed access to care results in significantly higher risks of complications, negative impacts on clinical outcomes, and even mortality.

Furthermore, these medications typically require on-going care and monitoring, which can only be achieved through significant patient involvement. Hurdles when starting new treatment plans for critical health conditions can also lead to reduced adherence on the part of the patient. To mitigate these risks, physicians must be able to readily access information about coverage, benefits, and potential medication costs when prescribing specialty drugs to patients.

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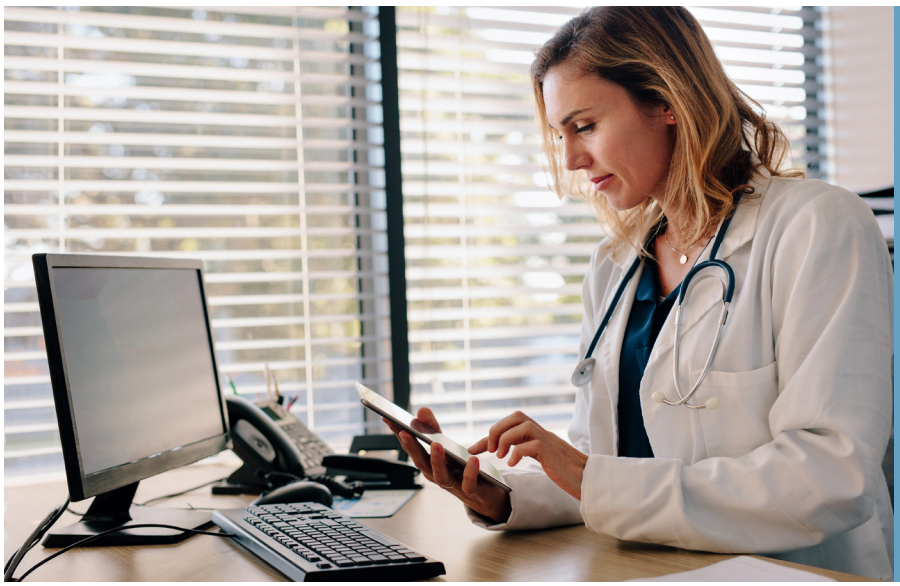
What is the Impact on Elderly and Low Income Patients?

Underserved and uninsured patients are at higher risk to face barriers when attempting to access specialty drugs. According to the Congressional Budget Office, net spending on specialty drugs under Medicare Part D rose from $8.7 billion in 2010 to $32.8 billion in 2015. For Medicaid, spending on these medications nearly doubled from $4.8 billion in 2010 to $9.9 billion in 2015.

While many specialty drugs are covered under Medicare Part D, patients may be required to shoulder more of the financial responsibility, similar to privately-insured patients. Additionally, arrival of the Medicare prescription "donut hole" signals a gap in financial support and may be the end of the prescription access for cash-strapped seniors. Medicare provides resources to pharmaceutical assistance programs and Extra Help subsidies to assist enrollees with affording these medications. The Center for Medicare Advocacy has also compiled a list of helpful resources for assistance. The Patient Advocate Foundation offers recommendations for helping the uninsured access critical medication and has a National Financial Resource Directory.



> *"RXNT's Specialty Patient Enrollment functionality integrates with Electronic Health Records (EHR) to auto-populate enrollment forms and send them directly to the pharmacy at time of prescription. "*

How RXNT Helps Patients Get Specialty Medicines

Workflow inefficiencies and inaccessible information have delayed vital patient specialty medicines long enough. No patient should have to deal with serious health complications and concerns due to delayed access to the medications they need. Likewise, no healthcare provider should have to navigate barrier after barrier when helping patients start critical treatment plans.

That's why we've partnered with Surescripts to reduce delays and speed up time to therapy. Specialty Patient Enrollment functionality is integrated with our Electronic Health Records (EHR) to auto-populate enrollment forms and send them directly to the pharmacy at time of prescription. No more fumbling with faxes and filling out paper forms.

The pharmacist can request any additional information needed through this electronic process and receive thorough details via the EHR. The result? Fewer administrative tasks and a quicker time to therapy for patients. Plus, communicate with specialty hubs and receive consent to transfer patient enrollment forms. To find out more about RXNT's Specialty Patient Enrollment functionality, take a look at its key features and benefits in more detail.