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Managing The Costs Of Specialty Drugs

INTRODUCTION

While the term "specialty drugs" has no standard definition, these pharmaceuticals are universally associated with high costs and complex conditions. Unique and highly targeted, such drugs can provide significant improvement or even a cure for individuals with serious diseases. While their promise can be counted in years and quality of life, their usage is limited by price tags and/or other roadblocks. This is a critical issue for consumers, employers, providers, payers, pharmacies and pharmacy benefit managers (PBMs), all of whom have a stake in managing the costs of specialty drugs.

MASSIVE GROWTH OF SPECIALTY DRUGS

Specialty pharmaceuticals continue to grow both in number and percentage of drugs dispensed, a surge not expected to abate in the near future.

Advancements in biotechnology have led to the development of new specialty drugs, which act at the cellular level to change the course of disease rather than treating symptoms alone.[i] In many cases, these specialty drugs offer the most effective — and in some cases, the only — treatment for illnesses and conditions that historically had few treatment options, as explained by the Pharmaceutical Care Management Association.[ii] Given their complexity, these drugs often require active clinical management, considerable patient education and sophisticated logistical support for rigorous handling, administration and monitoring requirements. Patients taking a specialty drug often rely on enhanced clinical services to ensure safe use of the drug and optimize therapeutic outcomes.[iii]

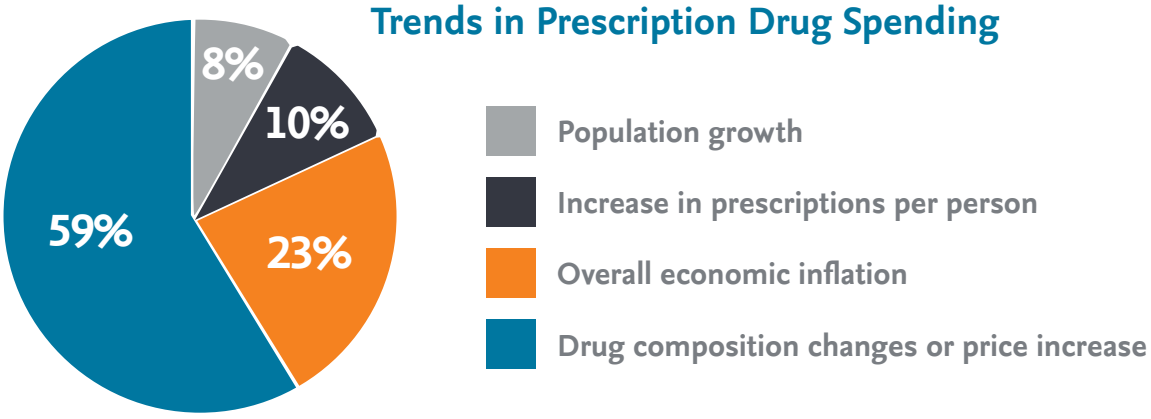
In 1990, only 10 specialty drugs were on the market, according to research done by The Pew Charitable Trust, but now there are more than 300,[iv] 33 of which became available in 2015 alone, making up half of all new drugs and biologics approved by the FDA that year.[v] At the end of 2016, nearly 700 specialty drugs reportedly were under development.[vi]

As plan sponsors grapple with soaring specialty pharmacy costs, health plans and PBMs are constantly on the lookout for ways to manage costs.

Because of higher prices and increased use, spending on specialty drugs also represents an increasing share of total health care costs, the Pew report notes, adding that in 2015, specialty drug spending reached $121 billion on a net price basis.[vii] By 2018, specialty drugs are expected to reach half of the total drug spend in the United States.[viii]

These numbers add up to a common tenet among experts such as Adam Fein, President of Pembroke Consulting, Inc, and CEO of the Drug Channels Institute, who says, "Specialty is the future of the pharmacy industry in terms of revenue."[ix]

This is evidenced by the growth of specialty pharmacies, which typically provide more extensive care management, counseling, case management and coordination of care with other stakeholders involved in a patient's treatment.[x]



Source: U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation. "Observations on Trends in Prescription Drug Spending," March 8, 2016.

INDUSTRY CHALLENGES

Even though specialty drugs are amazing in their capability, they are not without challenges for all involved. Many require significant patient education, disease-specific clinical monitoring and patient compliance and adherence programs. Side effects can be severe and more frequent than traditional drugs, requiring high levels of medicine adherence to improve outcomes. By nature, specialty drugs are limited in distribution, require special storage and administration (i.e. injection or infusion) and complicated dosing schedules.

Dispensing specialty drugs is not simply a matter of stocking these drugs. Compared to traditional pharmacy, offering specialty drugs requires unique clinical and operational capabilities and significant investment.[xi]

GETTING IN

Despite challenges, competition is fierce as established specialty pharmacies are gaining momentum, payers are setting up adherence programs and controlling formularies, and regional and national drug chains are weighing in.

Since specialty drugs represent one of the fastest-growing segments of the pharmacy market, many retail pharmacies are developing strategies to take advantage of this revenue stream. These strategies include achieving accreditation to deliver specialty services and mergers and acquisitions.

Both H-E-B and Thrifty White earned full accreditation in 2016 to deliver specialty pharmacy services to patients with complex and chronic diseases. H-E-B has earned full accreditation from Utilization Review Accreditation Commission (URAC) and Accreditation Commission for Health Care (ACHC). Thrifty White has also earned URAC along with accreditation from Center for Pharmacy Practice Accreditation (CPPA).[xii]

In 2015, Meijer Inc. acquired Aureus Health Services, a national specialty pharmacy and health management provider. Hy-vee acquired specialty pharmacy Amber in 2014, following Giant Eagle's purchase of Rx21 Specialty the year prior.[xii]

So where does this leave the community pharmacy that has not entered the specialty market? According to experts, many are on the outside looking in, hampered by high prices, inadequate infrastructure and the fact that drug manufacturers, payers, PBMs and employer health plans are establishing increasingly narrower networks for limited distribution drugs. Add in the fact that some 70 percent of all pharmacy-dispensed specialty drugs were distributed via mail and central-fill pharmacies,[xiii] this further limits potential for other entities and formats.

Still, experts say community pharmacies can find the right niches and build on the relationships they've developed with patients as trusted medical providers. One pharmacist who successfully made the move into the specialty arena attributes his success to "the ability of community pharmacies to focus on the patient and establish programs to educate, manage and follow those with complex diseases."[xiii]

And it's well worth the effort, according to McKesson. While the margin on specialty drugs is often lower than traditional drugs, their higher cost can lead to significant profits in and of themselves and by the fact that patients who take specialty medications typically have three to 11 additional prescriptions, making them valuable patients.[xiv]

DIGGING OUT

Specialty drugs on this rising scale represent a new world in which cost-management strategies must take center stage. This effort is complicated by the fact that traditional methods, such as substituting a generic, just don't, and often can't, work. This leaves savings more challenging to find without massive cost shifting.[xv]

SPECIALTY DRUGS COST DRIVERS INCLUDE[xvi]:

- Complicated to manufacture, distribute, dispense and administer
- Require unusual resource-intensive handling or dispensing procedures
- Complicated dosing regimens
- Minimal generic substitutions available
- Smaller patient populations (greater cost among fewer persons)
- Require related diagnostics, monitoring and additional services and increased focused clinical management
- Require risk evaluation and mitigation strategies
- Adherence issues impact outcomes
- Entail complicated billing with increased prior authorizations
- Limited distribution networks

MANAGING COSTS

It is clear that the economics of specialty drugs constrains their distribution and use and has the industry in flux. To rectify this, various stakeholders are looking at ways to manage costs to effectively provide critical drugs to those who need them while maintaining financial viability.

ADJUDICATION

Adjudication for specialty drugs is processed by two separate means: through PBMs and through employee healthcare benefit programs. The PBM method offers more potential in managing costs due to the level of detail in the adjudication process.

PBMs use National Drug Codes (NDCs) to adjudicate. NDCs provide a level of precision that enables tracking – and potentially control – of each specialty drug's cost at each dosage level and quantity dispensed. In contrast, entities that dispense drugs as part of the benefit package typically adjudicate specialty drugs using Healthcare Common Procedure Coding System (HCPCS) J Codes, which are inclusive of many different drugs and provide little detail[xxiv] regarding specific manufacturer, strength, package size or quantity.

To take advantage of rebates, The Centers for Medicare & Medicaid Services (CMS) won't pay claims submitted with HCPCS codes, unless the claim is for a single source drug. Experts recommend that employee health plans adjudicate specialty drugs using NDCs as well. Until they do, one contends, it is "unlikely" that healthcare providers can control the costs of these pharmaceuticals.[xvii]

" . . . without the ability to track which drugs are being dispensed and at what dosage level and quantity, one cannot possibly control the drugs' costs."[xviii]

CONTRACT CLARITY

As noted, there is no one definitive description of "specialty drug," but most health plans – and CMS – consider cost a determining factor. This lack of a clear definition raises issues, especially when contracting.

A consulting firm reported having reviewed hundreds of PBM/insurer contracts, all of which, a representative said, "contained either no definition for specialty drugs or a definition that is so elastic that it is essentially entirely useless."[xix]

Among the firm's suggestions for payers establishing clarity when entering into a contract with a PBM are to:

- Define "specialty drug" as all drugs on an exhibit list, including every specialty drug available, as well as drug-by-drug minimum discount guarantees
- Include an amendment clause for the exhibit list as new drugs enter the market
- Solidify pricing terms to prevent manipulation
- Require PBMs to provide pass-through pricing for every drug dispensed, with invoicing reflective of the PBM's actual drug cost and other potentially cost-saving initiatives.[xx]

UTILIZATION MANAGEMENT

At a recent conference, payers reportedly were getting more aggressive about managing specialty drugs under both the pharmacy and medical benefits, with many reiterating their reliance on the utilization management tools that are already well established in pharmacy benefit management of specialty drugs. They also said that tighter formulary management is becoming routine for specialty pharmaceuticals.[xxi]

Additional reports note that, in an attempt to increase the efficiency of their drug benefit policies, payers are increasingly excluding drugs from their formularies to create cost savings, negotiate higher rebates from drug manufacturers and limit cost increases.

Step therapy and prior authorization are among other tactics payers are employing to ensure the appropriate use of medications and manage total drug spending.

The use of these tactics and others, such as quantity limits and partial fills, can assure health plan beneficiaries are getting the most clinically appropriate and cost-effective medicines at the right time.[xxii] These efforts plus drug utilization and comparative effectiveness reviews also can limit a patient's exposure to inappropriate drugs and lower the high cost of treatment by favoring clinically effective, lower-price products.[xxiii]

ADHERENCE PROGRAMS

According to the Pharmaceutical Care Management Association (PCMA), PBMs increasingly are working with specialty pharmacies to provide advanced clinical management programs that ensure the value of therapy is being optimized at the lowest possible cost.[xxiv]

These efforts include medication adherence programs that offer services to "encourage patients not to abandon medication therapy by engaging, educating and communicating with patients and prescribers." By utilizing tools such as interactive voice response calls, emails, texts, letters, mobile app medication reminders, patient education and one-on-one pharmacist outreach and consultation, the PCMA says, specialty pharmacies help patients manage side effects and other issues that could otherwise result in their premature discontinuation of treatment and suboptimal outcomes.

PATIENT COUNSELING

Specialty pharmacies also are ramping up their role as trusted advisers, providing more comprehensive, high-touch and frequent counseling sessions supported by adherence and disease-specific surveys; proactive counseling on mitigation strategies for adverse events and initiating other interactions to foster adherence and help patients avoid the sometimes immediate consequences of poor adherence.

RISK EVALUATION AND MITIGATION STRATEGIES

Many specialty drugs fall under Risk Evaluation and Mitigation Strategies (REMS), an FDA-required distribution and care management restriction program that manufacturers must implement to help ensure the benefits of taking a drug will outweigh the risks. REMS requirements can impact the clinician as well as the pharmacy or pharmacist; via limited distribution, they reduce the availability of certain specialty drugs to an even smaller number of pharmacies or physician offices, limiting access.[xxv]

BIOSIMILARS: HOPE ON THE HORIZON?

The entry of biosimilars in the United States is projected to do for specialty drug pricing what generic drugs did for brands, that is, significantly lower costs.[xxvi]

Simply put, biosimilar drugs are less costly versions of biologics that are built from living and chemical compounds. They are different from generics because the active ingredients in brand and generic drugs must match, whereas, in biosimilars, there may be other ingredients included, thus they are not exact copies. The two drug types are alike, however, in that much like a generic is similar to the brand drug, each biosimilar drug is similar to an already approved biologic drug. Thus, biosimilars have the advantage of being able to extrapolate and "piggyback" on the branded drug to get approval for all the original drug's indications.[xxvii]

According to the Federal Trade Commission (FTC), biosimilars have the potential to save the U.S. healthcare system $250 billion through 2022. Furthermore, the global biosimilars market, according to an analysis by Frost & Sullivan, "will see exponential growth" over the next decade. This growth will not only save the healthcare system money; it also can improve patient outcomes and be a significant economic driver.[xxviii]

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CONCLUSION

Comprehensive management approaches that effectively balance patient care, outcomes and costs can help ensure that new, innovative medications are readily available and affordable to the patients who need them most.[xxix]

While there is no immediate or simple solution, many stakeholders can take steps toward resolution by arming themselves with the best drug information and tools that help them deliver needed drugs while protecting their bottom line.

Leading drug compendia companies are seeking to play a role in addressing this issue with drug database information that flags limited-distribution drugs and identifies where they are available, providing retail pharmacies faster access to specialty drugs suppliers and more control over the dispensing process.

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