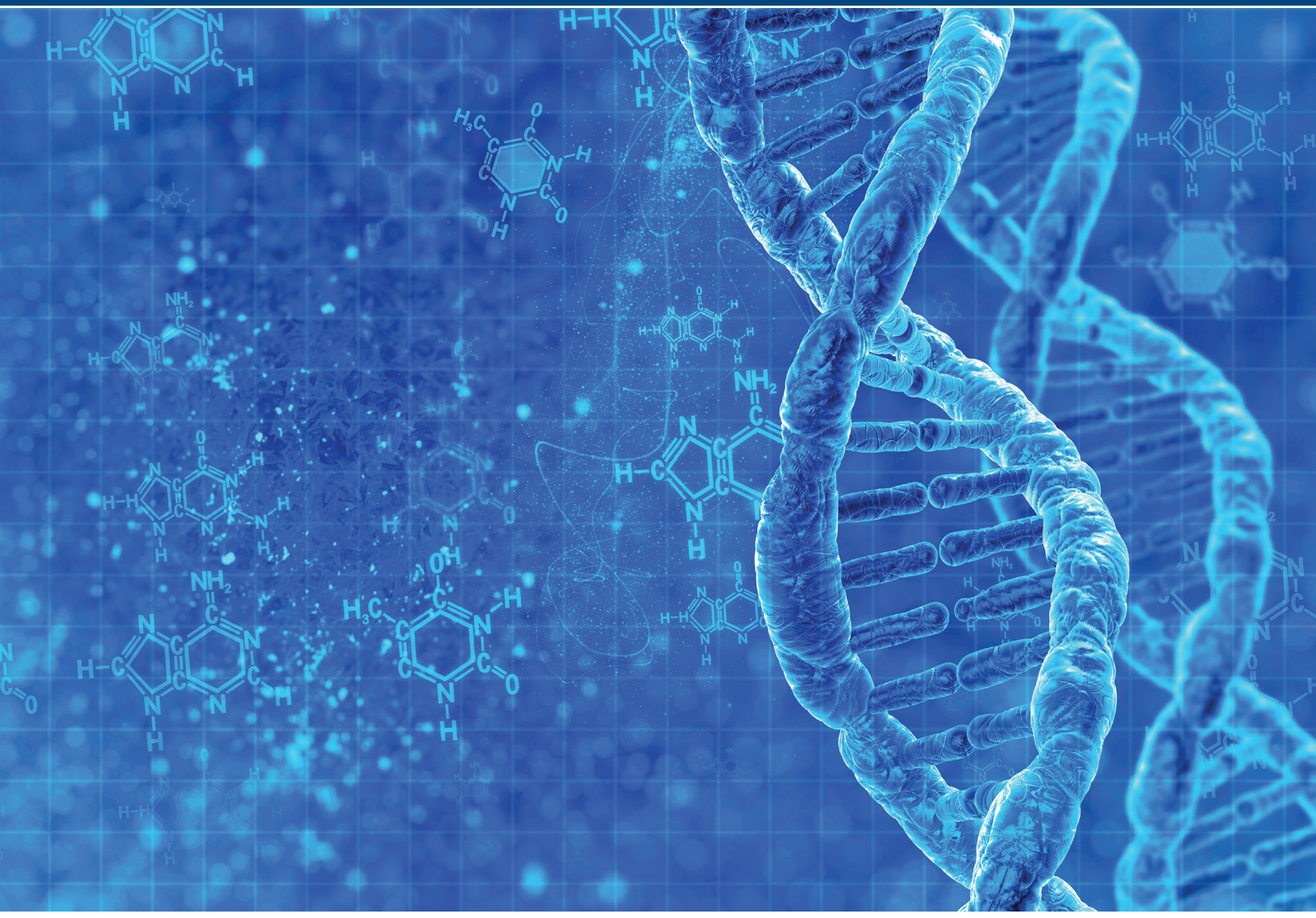
THE MANAGEMENT OF SPECIALTY DRUGS



SPCMA

A DIVISION OF THE
Pharmaceutical Care Management Association

CONTENTS

EXECUTIVE SUMMARY

Complex, innovative, and high-priced specialty drugs are entering the United States health care market at a rapid rate. 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. 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.

The total costs and utilization of specialty drugs will have a substantial impact on overall health care costs during the next decade. To address these challenges, payers rely on pharmacy benefit managers (PBMs) to manage the use of, and payment for, specialty drugs. PBMs offer a variety of tools to manage specialty drugs, including the use of specialty pharmacies. In doing so, the quality and continuity of care patients receive is improved, while ensuring that they derive the greatest value from their medications.

PBMs manage prescription drug plans that include specialty drugs for more than 266 million Americans who have health insurance through a variety of sponsors, including commercial health insurers, self-insured employers' plans, union plans, Medicaid, and Medicare plans. As such, PBMs are an essential partner to these payers in the health care system.

Over the next ten years, PBMs and specialty pharmacies will save payers and patients an estimated total of $250 billion on the cost of specialty medications and related non-drug medical costs when compared to what expenditures would be with limited use of PBMs and specialty pharmacies.[1] PBM tools that have been used for years in the small-molecule drug categories to control costs are continuing to be successfully leveraged in the specialty drug category. The continued use of these cost-saving tools will be essential as PBMs and payers work to manage expenses and enable access to these innovative drugs.

INTRODUCTION

The management of specialty drugs is receiving increased attention from patients, providers, payers, and policymakers due to the high prices of new specialty drugs and their aggregate impact on health care costs.[2] Specialty drugs increasingly account for a significant proportion of overall health care spending. This growth continues to be fueled by an expanding target population, increased medication complexity, and uncoordinated pricing and delivery systems. These factors act to generate both high launch prices and substantial escalation in the price of drugs already on the market.[3]

Payers share the burden of rising costs with individual patients and taxpayers. Due to growing patient utilization rates, a pipeline of expensive new specialty drugs, and ongoing drug manufacturer price increases specialty expenditures are expected to account for 50 percent of all drug spending by 2018.[4]

To reduce prescription drug costs and increase affordability, health plan sponsors and payers contract with PBMs to manage traditional and specialty drug benefits and utilization. PBMs use a number of tools to manage drug benefits effectively and increase the affordability, quality, and continuity of care that patients receive. In the case of specialty drugs, PBMs manage patient access to these medications, while working with specialty pharmacies to provide advanced clinical management programs that ensure the value of therapy is being optimized at the lowest possible cost.

In 2014, prescription drug spending growth was higher than that of total U.S. health care spending. In part through the use of PBM specialty drug management tools, over the next ten years however, drug spending is projected to closely track overall healthcare spending.[5]

SPECIALTY DRUGS

Pharmaceutical research and discovery have undergone a dramatic shift in the last decade. Historically, manufacturers focused research efforts on small-molecule drugs that treat common conditions like high blood pressure, acid reflux, and pain. However, market forces and developments in science, manufacturing processes, and biotechnology have led drug companies to focus on creating more complex specialty drugs, many of which are biologics, that treat diseases such as multiple sclerosis, rheumatoid arthritis, hepatitis C, and certain forms of cancer. Recently, companies have begun developing specialty drugs for more common conditions, such as high cholesterol.

TARGET CONDITIONS FOR SPECIALTY DRUG TREATMENT[6]

Condition	Patient population	Estimated treatment costs
Hepatitis C	3.2 million patients	$100,000 per course of therapy
Alzheimer's disease	5.4 million patients	$35,000 annually
Oncology	14 million patients	>$100,000 annually
Inflammatory disorders	24–50 million patients	>$50,000 annually
High cholesterol	71 million patients	$10,000 annually

What is a Specialty Drug?

The definition of a specialty drug continues to evolve as the specialty drug pipeline advances and expands. These drugs are best defined by the full range of each product's attributes, rather than solely by cost and route of administration. A specialty drug possesses any number of these common attributes:

- Prescribed for a person with a complex or chronic medical condition, defined as a physical, behavioral, or developmental condition that may have no known cure, is progressive, and/or is debilitating or fatal if left untreated or under-treated;
- Treats rare or orphan disease indications;
- Requires additional patient education, adherence, and support beyond traditional dispensing activities;
- Is an oral, injectable, inhalable, or infusible drug product;
- Has a high monthly cost;
- Has unique storage or shipment requirements, such as refrigeration; and
- Is not stocked at a majority of retail pharmacies.

Specialty drugs are often more targeted and effective than the broad-spectrum drugs they are replacing as first- or second-line treatments.[7] When introduced to the market, these drugs typically have little or no competition, therefore allowing manufacturers to set high prices.

More than 500,000 Americans filled prescriptions with a value of at least $50,000 in 2014 — a 63 percent increase from the prior year — and the number of patients estimated to be taking at least $100,000 worth of medications nearly tripled from 47,000 to 139,000.[8] Historically, specialty drugs treated a small subset of diseases, but with recent advances, these drugs are now used for a wide range of conditions. In 2020, nine of the ten best-selling drugs by revenue will be specialty drugs, compared with three drugs in 2010, and seven in 2014.[9]

TOP SPECIALTY DRUG THERAPIES RANKED BY PERCENT OF SPECIALTY SPENDING[10]

Drug name	Therapy class	Percent of specialty spending	Method of administration
Humira® (adalimumab)	Inflammatory conditions	11.9%	Injection
Enbrel® (etanercept)	Inflammatory conditions	8.2%	Injection
Sovaldi® (sofosbuvir)	Hepatitis C	7.8%	Oral
Copaxone® (glatiramer)	Multiple sclerosis	5.0%	Injection
Tecfidera® (dimethyl fumarate)	Multiple sclerosis	3.4%	Oral
Avonex® (interferon beta-1a)	Multiple sclerosis	2.6%	Injection
Atripla® (efavirenz/ emtricitabine/ tenofovir)	HIV	2.4%	Oral
Gleevec® (imatinib)	Oncology	2.2%	Oral
Revlimid® (lenalidomide)	Oncology	2.2%	Oral
Olysio® (simeprevir)	Hepatitis C	2.1%	Oral

Specialty Drug Pipeline

By 2016, three out of every five new drugs approved by the Food and Drug Administration (FDA) will be specialty drugs.[11] Future growth trajectories in specialty spending were estimated to quadruple by 2020, reaching $400 billion, or 9.1 percent of national health spending.[12] However, the increasing prevalence of biosimilars in the market is anticipated to curtail the overall biologic market value growth, instead reaching $262 billion by 2019.[13]

PBMs play an important role in monitoring the pipeline and planning ahead for the therapeutic benefits and costs of these drugs. In assessing the specialty drug pipeline, PBMs and specialty pharmacies consider each drug's therapeutic use, anticipated launch date, expected cost per patient per year, clinical benefits, and the landscape of other related treatments already on the market. This process begins 18 to 24 months in advance of a drug's anticipated launch date and often involves direct input from pharmaceutical companies. PBMs and specialty pharmacies rely on the use of analytics, population variables, clinical study information, expert opinions, and medical societies to create a comprehensive launch plan for drug coverage.

PBMs and specialty pharmacies analyze pharmacy and medical benefit data to conduct pipeline reviews. From this, they translate findings into a forecast that includes expected costs for plan sponsors, the impact the drug will have on patient care, and expected future trends. Clinical trial data and national treatment guidelines inform the projected authorization algorithms and recommended approaches for contracting. Following a drug's launch, patient medication adherence is monitored with the goal of maximizing the drug's therapeutic value, and preventing adverse events, unnecessary hospitalizations, and need for retreatment.

CASE STUDY: High blood cholesterol

High blood cholesterol is often treated with low-cost generic drugs. An estimated 25 million people in the U.S. take statin drugs to treat high blood cholesterol. On average, these drugs reduce "bad" (LDL) cholesterol by 20 to 45 percent[14] and can cost $4 for a 30-day supply.[15] With the introduction of biologics in this therapeutic category, costs are expected to rise dramatically.

A new class of biologic specialty drugs, PCSK9 inhibitors, aims to treat patients with a hereditary form of high cholesterol and those at high risk of heart problems who have not responded to aggressive statin therapy.[16] In initial trials, PCSK9 inhibitors reduced cholesterol levels up to 60 percent from baseline levels.[17] However, cardiovascular outcome trials are still underway, with results expected by late 2017/early 2018.[18]

With an annual cost of almost $15,000 per patient,[19] PCSK9 inhibitors were predicted to generate about $2.5 billion in annual sales by 2020.[20] However, PBMs harnessed the competition in the marketplace to extract significant savings from drug manufacturers through formulary placement negotiations and drug rebating. In the coming years, PBMs expect to spend far less on PCSK9 inhibitors than initial industry forecasts.[21]

Expensive specialty drugs like these will continue to enter therapeutic categories previously dominated by less costly small-molecule drugs. This dynamic is causing payers to heavily rely on PBM drug management tools to control costs and ensure patient care is not compromised.

By monitoring the pipeline and working with all necessary stakeholders, both in advance and following the launch of specialty drugs, PBMs and specialty pharmacies help patients achieve better clinical outcomes while improving total health care value.

Biosimilars

With numerous specialty drug patents expiring in the next five years,[22] manufacturers are readying new biosimilars for introduction into the market. By 2020, 12 biologic products with global sales of more than $67 billion could face biosimilar competition.[23] A biosimilar is a biologic product that is approved and judged by the FDA to be highly similar to another FDA-approved biologic product (known as a reference product) and has no clinically meaningful differences in terms of safety and effectiveness from the reference product. Only minor differences in clinically inactive components are allowable in biosimilars.[24]

Patient advocates and payers anticipate biosimilars will foster competition and deliver increased savings from negotiated discounts. Competition between a biologic drug and a biosimilar is much more likely to resemble brand-to-brand competition than it is to resemble the dynamics of brand-to-generic competition.[25]

Savings estimates range from $44 billion to as high as $250 billion over the first ten years that biosimilars are available to patients.[26] The Congressional Budget Office estimated that biosimilars would initially be priced about 25 percent below their brand-name counterparts and after several years of competition would be priced as much as 40 percent below the reference product, saving the federal government nearly $6 billion over ten years.[27] More recent analyses estimate the cost of biosimilars to be around 20 percent lower than that of branded biologic therapies.[28] Nevertheless, this remains a significant reduction since many biologics command hundreds of thousands of dollars for annual treatments.

Limited Distribution Drugs

Some specialty drugs are only available through select specialty pharmacies. The decision to limit the distribution of these drugs is made by the drug's manufacturer. Such restrictions are often associated with the small population

of patients who use the drug, and the unique monitoring parameters, high cost, and complex handling and distribution requirements for each specialty drug.

These limited distribution specialty drugs often treat small and geographically diverse populations and cannot be properly stocked, supported, and supplied through retail pharmacies, so they are made available through qualified preferred specialty pharmacies.[29] Limited distribution models enable manufacturers to:[30]

- Meet additional FDA requirements imposed during the drug approval process;
- Track drug inventory to prevent diversion and counterfeiting;
- Maintain the integrity and quality of drugs as they move through the supply channel; and
- Ensure that special dosing and lab monitoring requirements are followed.

While retail pharmacies might hope to dispense limited distribution specialty drugs, few are equipped to deliver the clinical management and logistical services such products require. Manufacturers point to the obstacles and impracticality of producing enough drug product to stock the nation's 64,000 retail pharmacies, while also efficiently managing the large scale of expired products.

Some manufacturers maintain their own pharmacies, either wholly owned by themselves or through a third party. These pharmacies are sometimes referred to as specialty pharmacies, but are actually standard dispensing pharmacies as they typically dispense only one manufacturer's drug(s), lack recognized specialty pharmacy accreditation, do not offer the full suite of services typically found in a specialty pharmacy, and are not aligned to payer plan design.

SPECIALTY BENEFIT DESIGN AND MANAGEMENT

PBMs employ a number of strategies and tools to support the needs of patients who are prescribed specialty drugs (as well as their health care providers) while controlling costs for health plans. PBMs have developed key strategies to maintain access to high-quality care while ensuring that money spent on specialty drugs is not wasted. These strategies include:

- **Negotiating rebates from drug manufacturers:** Rebates are a form of discount that are contractually negotiated between the manufacturer, who is primarily motivated by the opportunity to gain market share, and the PBM, who requires the manufacturer to return some of the money paid for the product. These rebates allow the PBM to provide savings to its payer clients and patients.
- **Negotiating discounts from drugstores:** Pharmacies agree to discounts in order to participate in a plan's specialty pharmacy network. The more selective the network, the greater the discount since each pharmacy will benefit from increased business.
- **Offering more affordable pharmacy channels:** PBM-managed mail service and specialty pharmacy channels typically give plan sponsors deeper discounts than retail pharmacies. These channels also help encourage the use of preferred, lowest-cost drug products for additional savings.
- **Optimizing site of care:** PBMs manage where certain specialty products can be administered, such as in a patient's home instead of more expensive sites like outpatient facilities or physician offices.
- **Encouraging use of lowest-cost drug option:** PBMs use several tools to encourage the use of the lowest-cost drug option. These include formularies, tiered cost sharing, prior authorization, step therapy protocols, generic incentives, consumer education, and physician outreach.
- **Reducing waste and improving adherence:** PBMs use drug utilization review (DUR) to reduce waste such as poly-pharmacy and implement patient adherence programs to help patients adhere to their prescription regimens. Both programs improve clinical outcomes, as well as control prescription expenditures.

CASE STUDY: Hepatitis C

The initial pricing controversy around hepatitis C drugs provides an example of the benefits of competition in the drug marketplace. An estimated 3.2 million people in the U.S. have chronic hepatitis C, with an additional 30,000 new cases annually.[31] When Gilead's hepatitis C treatment Sovaldi® was introduced to the market, the cost of treatment renewed a national debate on the high price of drugs.

Offering a projected cure rate of 95 percent, Sovaldi® entered the market at $1,000 per pill — over $84,000 for a typical 12-week course of treatment. Once associated medical costs were factored in, the total cost of treatment neared $100,000.[32]

When a competing drug entered the market several months later, PBMs were able to gain leverage on the pricing of the two hepatitis C drugs. After a year-long campaign advocating for more reasonable drug pricing, the PBM Express Scripts announced an agreement with AbbVie, makers of the new hepatitis C medication Viekira Pak™. The unprecedented arrangement addressed affordability for payers and access for patients.[33] In turn, this new marketplace competition prompted Gilead to begin offering an average discount of 46% on their drug.[34]

Due to this competition, the cost to cure hepatitis C is now at a level that allows health plan sponsors to expand treatment options to a broader range of patients, not just those with the most severe cases.[35] These unexpectedly large price cuts provide more evidence that competition gives payers and PBMs enormous power, even when purchasing differentiated, highly valuable therapies.[36]

Specialty Pharmacies

Specialty pharmacies were established in direct response to the industry's need to better procure, store, and dispense specialty drugs, as well as better manage therapy for patients on specialty drugs. Among other things, these pharmacies specialize in the unique storage and shipping requirements that oral, injectable, inhalable, and infusible products require. Pharmacists and personnel working for these specialty pharmacies provide patient education and clinical support beyond the capabilities of a traditional retail pharmacy.

Since retail and manufacturer-affiliated pharmacies are not typically equipped to manage the full range of products and services that PBMs and payers require for the distribution and management of specialty drugs, they rely on the technology and expertise of specialty pharmacies to properly dispense these drugs.

Specialty Pharmacy Functions

Specialty pharmacies must offer a full range of clinical and operational services to enhance the safety, quality, and affordability of care for patients receiving specialty medications. This includes:

Clinical Services

- **Health care provider access:** Specially trained pharmacists, nurses, and clinicians are accessible to patients around the clock to provide guidance and insight on disease states, as well as the use and management of specialty drugs.
- **Physician consultations:** Consults directly with physicians to address patient side effects, adverse drug reactions, non-compliance, and other patient concerns.
- **Care management:** Performs disease and drug-specific patient care management services that meet the unique needs of each patient and incorporate multiple safeguards when dispensing and delivering the drug to ensure patient safety.
- **Clinical outcome measures:** Collects data and tracks outcomes for specific patients.

- **Patient adherence programs:** Manages patient adherence and persistency of drug regimens.
- **REMS programs:** Manages care for manufacturer Risk Evaluation and Mitigation Strategies (REMS) program requirements, including REMS reporting, Phase IV trials, the dispensing of FDA trial drugs under strict protocols, and related clinical and cognitive counseling.

Operational Services

- **Supply chain management:** Adheres to rigorous storage, shipping, and handling standards to meet product label shipping requirements, such as temperature control and the timely delivery of products in optimal conditions.
- **Care coordination:** Offers coordinating services with other health care providers, including those providing skilled nursing services, custodial care, infusion administration, and direct-to-physician distribution.
- **Insurance navigation:** Expedites access to therapy by working directly with insurers and navigating their benefits, utilization management, and prior authorization processes.
- **Patient assistance:** Facilitates eligible patients' enrollment in patient assistance programs and access to charitable resources.
- **Plan optimization:** Aligns economic incentives across medical and pharmacy benefits while helping patients navigate the complexity of sometimes-siloed benefit structures.

As the specialty drug pipeline continues to grow, so do the services required of specialty pharmacies. These pharmacies are regularly innovating to develop new capabilities that serve the evolving needs of patients, providers, payers, and drug manufacturers.

Accreditation

Specialty pharmacies undergo formal accreditation reviews to demonstrate their ability to meet predetermined criteria and standards established by independent, professional accrediting agencies. Although specialty pharmacy accreditation is a baseline requirement for inclusion in PBM preferred specialty pharmacy networks, it is not necessarily a requirement to dispense specialty drugs to patients.

Multiple organizations, including URAC and the Accreditation Commission for Health Care (ACHC),[37] accredit specialty pharmacies and provide an external validation of the services offered to patients, providers, and payers. Accreditation organizations collaborate with industry experts to create standards that ensure quality is maintained throughout all aspects of pharmacy operations, patient care management, and quality improvement processes. Of the 64,000 pharmacies in the U.S., 378 have achieved specialty pharmacy accreditation from either URAC or ACHC. One-quarter of these pharmacy locations are accredited by both organizations.[38]

Accreditation criteria do not include requirements for how economics are managed, how to carry out payer plan design, or how to encourage the lowest-cost drug option. Because of this, PBMs maintain their own criteria for specialty pharmacies to be included in their preferred networks. These criteria pick up where accreditation organizations leave off in terms of fulfilling payer and plan sponsor specialty benefit plan design.

Formulary Management

Among the most important tools used by PBMs to manage specialty drug costs are drug formularies. A formulary is a continually updated list of prescription drugs approved for reimbursement by the PBM's payer client. PBMs typically develop a basic formulary and offer it to payers, who may customize it. It is ultimately up to the payer client to decide on the exact formulary that will be used in conjunction with its benefits plan, as well as the techniques that will be applied to encourage formulary compliance.

The primary consideration in the development of a formulary is clinical appropriateness: what is the most appropriate therapy for a given disease or condition? PBMs use panels of experts called Pharmacy and Therapeutics (P&T) Committees to determine the most clinically appropriate drugs for a given drug class and indication. These committees are made up of physicians, pharmacists, and individuals with other appropriate clinical expertise. PBMs design their formularies based on P&T Committee recommendations and factor in a number of cost-saving elements, such as biosimilar availability and negotiated rebates.

Development and maintenance of formularies is an ongoing activity, as they must be constantly updated to keep pace with new therapies, recent evidence from

clinical research, changes in medical practice, and FDA guidance. Most PBMs update their formularies quarterly. In cases where a specific non-formulary or non-preferred drug is the clinically appropriate medication for an individual, drug benefit plans have an appeals mechanism in place. Patients whose appeals are successful can obtain benefits for the non-preferred product as if it had preferred status on the formulary.

Effective use of formularies can minimize overall medical costs, improve patient access to more affordable care, and provide patients an improved quality of life. With less effective, higher-cost drugs routinely being replaced on formularies by more effective and affordable drugs, patients may experience improved outcomes, have fewer office visits, and lower out-of-pocket costs.[39]

Access and Utilization Management

Utilization management tools are especially important in specialty drug classes. They can limit a patient's exposure to inappropriate drugs and lower the high cost of treatment by favoring clinically effective, lower price products. PBMs and plan sponsors manage specialty drug costs by employing a number of tools, including drug utilization review, prior authorization, step therapy, quantity or dose limits, and comparative effectiveness reviews.

Drug Utilization Review (DUR)

Because they administer drug claims for insurers, PBMs are often the only source of information for a patient's history of prescribed medications filled and paid for using insurance. This is especially important when patients are prescribed medications by multiple physicians or when patients use more than one retail or specialty pharmacy to purchase their prescriptions.

To assure appropriate utilization of prescriptions and consistency with specialty benefit design, PBMs perform DUR for all prescription drug claims. *Point-of-sale* DUR immediately detects potentially inappropriate drug utilization for individual prescription drug claims, such as drug interactions or multiple fills of the same drug. Conversely, *retrospective* DUR is conducted to detect broad patterns of inappropriate prescribing and utilization over time. DUR criteria and decision algorithms are generally developed in consultation with PBM P&T Committees.

Clinical Prior Authorization

Clinical prior authorization (PA) is the requirement for the pre-approval of a drug before a pharmacy dispenses it to a patient as a covered benefit. The major goals of PA requirements are to assure appropriateness and suitability of the prescribed medication for the specific patient, as well as reduce waste due to inappropriate utilization. PA is generally used for drugs that have significant off-label use, are very expensive, have less expensive alternatives available, or require medical justification to assure safety or cost-effectiveness.

As with other management techniques, it is up to a PBM's health plan or employer client to decide whether and how prior authorization will be applied to its health benefit plan.

Comparative Effectiveness

In recent years, increased use of comparative effectiveness reviews has created another tool to better manage rising specialty drug costs. By using literature reviews to compare the effectiveness of two different treatments, information can be gathered that allows payers to encourage clinicians to prescribe (and patients to use) more effective and higher value alternative treatments.[40]

Adherence and Compliance

PBMs and specialty pharmacies offer patients a comprehensive suite of clinical programs that promote safe and effective medication therapy to improve health. Through these programs, specialty pharmacies give patients the information and clinical support they need to make decisions about their health care and derive the most value from their treatment.

Using a holistic approach, specialty pharmacies provide high-touch comprehensive support for patients with complex or chronic conditions to improve medication adherence and compliance, including:[41]

- **Medication adherence programs:** Offers services to encourage patients not to abandon medication therapy by engaging, educating, and communicating with patients and prescribers. By utilizing a variety of tools, including interactive voice response calls, emails, texts, letters, mobile app medication reminders, and one-on-one pharmacist outreach and consultation, specialty pharmacies help patients manage side effects

CASE STUDY: Organ transplant medications[42]

Medication adherence rates are often very low for organ transplant recipients. Reasons for non-adherence include patient-related components, such as misunderstanding the importance of immunosuppressive therapy, confusion on how to take the medication regimen, forgetfulness, and lack of follow-up with the medical team. Medication-related reasons for non-adherence include high pill burdens, high frequency and severity of drug interactions, and adverse effects.

Specialty pharmacies aim to reduce variability in the delivery of clinical services while improving appropriate medication use and managing adverse effects that are inherent with transplant drug regimens. In addition to providing basic dispensing and counseling services, specialty pharmacies use trained nurses and pharmacists to engage and educate transplant recipients on strategies to improve the success of their organ transplants.

Specialty pharmacies with set requirements for clinical programs and services can play an important role in improving adherence and quality of care, as well as reducing the overall costs for patients with complex and costly conditions.

and other issues that could otherwise result in their premature discontinuation of treatment and sub-optimal outcomes.

- **Medication Therapy Management:** Provides high-risk patients with a range of services, including comprehensive medication reviews and one-on-one consultations with a pharmacist to ensure that the safest and most cost-effective medications are used.
- **Drug utilization reviews:** Delivers prescription savings and ensures patient safety by targeting unsafe and clinically inappropriate medications due to drug interactions, incorrect prescribing, duplicate therapy, and wrong doses or duration of therapy.

These programs are designed to improve patient outcomes and reduce the overall cost of care. By leveraging new technologies, these payer and PBM-affiliated specialty pharmacies improve patients' experience and provide multiple avenues to increase patient engagement. Through these specialty pharmacy programs, patients receive tailored care for high-risk and high-cost conditions.

Site of Care Optimization

Previously, virtually all specialty drugs were administered via injection or infusion in a physician's office, clinic, or infusion center. Today, however, many specialty drugs are able to be self-administered. Others, including new drugs for cancer, multiple sclerosis, and hepatitis C, are taken orally. PBMs work in close collaboration with specialty pharmacies to manage the site of care where drugs are delivered since more specialty products can be administered by the patient at home instead of at costly sites, such as outpatient facilities or physician offices.[43] Guided by PBM and payer benefit design, specialty pharmacy nurses and pharmacists conduct clinical patient needs assessments and are critical to ensuring that patients receive care in the safest and most cost-effective settings.

Over the last two years, more health plans in conjunction with PBMs have begun implementing these site-of-care strategies.[44] The hospital outpatient setting is widely recognized as one of the most costly settings for the infusion of specialty injectable products. As a result, plan sponsors are increasingly developing strategies to direct patients to more convenient and less costly sites of service. Research finds that implementing site-of-care management can save between 12 and 34 percent — up to $1.7 billion nationally per year.[45] To realize these savings, plan designs may:

- Redirect specialty medication and administration from hospital outpatient settings to doctor offices, ambulatory clinics, or patient homes where clinically appropriate;
- Re-contract with outpatient networks to establish drug-pricing benchmarks; and
- Recommend that clients move specialty medications from the medical benefit to the pharmacy benefit when clinically appropriate.

Clinical considerations are of utmost importance when determining which products can be safely transitioned to a specific site of care. To be deemed eligible for a site of care transition, patients receiving these medications need to be evaluated for their condition severity, comorbidity burden, complete medical treatment regimen, and treatment pathway, in addition to their medication's route of administration.[46]

Improved Clinical Outcomes

With an increasing number of oral and injectable specialty drugs being administered at home instead of a clinical setting, patient adherence is an increasingly important determinant of treatment success. Greater use of coordination and adherence programs provided by specialty pharmacies shows particular promise in improving outcomes and reducing costs.[47] Studies have found that patients using specialty pharmacies with integrated refill reminders and comprehensive care management programs are more likely to achieve optimum adherence compared with patients who do not use specialty pharmacies.[48]

Before beginning treatment with specialty drugs, patients need to understand their condition, potential treatment side effects, expected long-term outcomes, and the costs they will face. Through specialty pharmacies, patients are provided with access to clinical management services that offer this necessary information. Specialty pharmacies have demonstrated increased drug compliance rates nearly 10 percent higher than those seen in the retail pharmacy sector.[49]

Preferred Specialty Pharmacy Networks

To maximize the patient benefit of drug treatments, preferred specialty pharmacy networks are used to deliver high-quality, accessible pharmacy services.[50] By contracting with select pharmacies, PBMs can ensure consistent care management and access to specialty medications while promoting affordability in the specialty channel.

It is important to note the distinction between these PBM-managed preferred pharmacy networks and the drug manufacturer-operated limited distribution networks [see page 5]. Both may similarly limit the number of pharmacies that may dispense and manage patients on a certain specialty drug. However, each has different motivations for doing so. To be included in a preferred specialty pharmacy network, the pharmacy must agree to meet criteria that ensure patients safely and appropriately use their medications, that payer benefit designs are supported, and desired clinical outcomes are achieved.

Payers rely on PBMs to identify the highest-quality and most cost-efficient specialty pharmacies. Due to the proliferation of specialty pharmacies now involved in the acquisition and distribution of specialty products, PBMs create quality standards and metrics to ensure that the specialty pharmacies they contract with offer the highest quality of care in the industry.

Through these processes, PBMs ensure that patients receive comprehensive patient care services that meet the highest industry standards.[51] To maintain in-network status, specialty pharmacies are required to consistently demonstrate their ongoing ability to meet or exceed each standard while offering competitive rates. PBMs optimize drug distribution via specialty pharmacy networks to reduce inappropriate utilization, improve patient adherence, improve clinical outcomes, and reduce non-drug medical costs.

Cost Savings from Preferred Specialty Pharmacy Networks

The process of creating preferred networks often involves intense negotiation and competitive bidding. The degree to which preferred networks are managed efficiently has a significant effect on consumers' cost sharing and premiums. The Federal Trade Commission has argued in numerous reports and opinions that laws preventing preferred pharmacy networks lead to higher drug prices and higher premiums, hence removing an effective means of cost control from the system.[52]

CREDENTIALING CRITERIA FOR PREFERRED SPECIALTY PHARMACY NETWORKS MAY INCLUDE, BUT ARE NOT LIMITED TO:[53]

Standards	Description
Accreditation	Specialty pharmacy is accredited by one or more independent specialty pharmacy accreditation organizations.
Organizational structure	Specialty pharmacy has a detailed organizational structure in place to support all necessary operations.
Pharmacy accessibility	Clinical staff members are available to speak with patients at all times of the day to answer any questions or concerns they have regarding their treatment.
Appropriate therapy	Specialized pharmacists verify the correct medication is being prescribed at the correct dose and frequency.
Care coordination	Specialty pharmacy staff provide patients with all necessary supplies, specialty drug administration training, and support.
Adherence management	Specialty pharmacy staff contact patients before each scheduled fill to arrange the dispensing of their next dose, identify potential adherence barriers, and manage treatment effects.
Ancillary supplies	Patients are provided with all necessary supplies needed to administer their medications.
Counseling	Pharmacists provide patients with relevant information regarding their specialty drug and disease state.
Specialty medication fulfillment	Specialty pharmacies ensure that specialty medications are stocked and readily accessible for patient dispensing as soon as requested.
Cold chain management	Specialty pharmacies have detailed cold chain management procedures that include thorough tracking requirements.
Specialty clinical protocols	Pharmacists closely follow all disease state and drug-specific clinical protocols for dispensing, monitoring, and patient follow-up processes.
Patient assistance programs	Patients have access to financial assistance programs provided through drug manufacturers, foundations, and other organizations.
Patient education	Specialty pharmacies ensure multiple languages and methods of education are available to patients.

FUTURE CONSIDERATIONS

Scientific advances and innovation in specialty pharmacy will accelerate in the coming years, adding to the arsenal of cures and beneficial treatments for a wide range of conditions.[54] To ensure patients can fully benefit from these new treatments while limiting unnecessary costs to the system, PBMs in conjunction with specialty pharmacies will continue to develop and employ tools to navigate this evolving field.

Comprehensive management approaches that effectively balance patient care, outcomes, and cost are helping ensure that new, innovative medications are readily available and affordable to the patients who need them most. Through the use of specialty pharmacies, utilization management tools, adherence and compliance programs, and preferred specialty pharmacy networks, PBMs are providing a superior level of service to patients, providers, and payers. These services better align what payers and patients pay for a therapy with the value it is intended to deliver. This in turn makes therapies more affordable and accessible for all patients and preserves plans' ability to cover new, more costly medications.

PBMs are on the forefront of these strategies. Over the next ten years, PBMs and specialty pharmacies will save Medicare, Medicaid, commercial payers, and consumers an estimated total of $250 billion on the cost of specialty medications and related non-drug medical costs when compared to what expenditures would be with limited use of PBMs and specialty pharmacies.[55] State or federal laws and regulations that place restrictions on PBMs' ability to manage specialty drugs and specialty pharmacy networks could substantially increase prescription drug costs, thus affecting patients, employers, and health plan sponsors in every state.

ENDNOTES

[1] Visante. (2016, Jan). *Pharmacy Benefit Managers (PBMs): Generating Savings for Plan Sponsors and Consumers.*

[2] Hirsch, B. R., Balu, S., Schulman, K. A. (2014). *The impact of specialty pharmaceuticals as drivers of health care costs.* Health Affairs, 33 (10):1714-1720.

[3] Lotvin, A. M., Shrank, W. H., Singh, S. C., Falit, B. P, Brennan, T. A. (2014). *Specialty medications: Traditional and novel tools can address rising spending on these costly drugs.* Health Affairs, 33 (10):1736-1744.

[4] Johnson, S. G. (2013). *Specialty Drugs are Forecasted to be 50 Percent of All Drug Expenditures in 2018.* Prime Therapeutics LLC.

[5] Drug Channels. (2015, Aug 11). *New CMS Forecast: Drug Spending Grows Along with Impossible Hospital and Doctor Spending.* Retrieved: http://www.drugchannels.net/2015/08/new-cms-forecast-drug-spending-grows.html

[6] OptumRx. (2014, Dec 10). *Pipeline Trends and Opportunities.*

[7] Express Scripts. (2015). *The Express Scripts 2014 Drug Trend Report.*

[8] Express Scripts. (2015). *Super spending: U.S. trends in high-cost medication use.*

[9] Drug Channels. (2015, Jul 28). *Pharma's Bright Future: Meet the Top 10 Drugs of 2020.* Retrieved: http://www.drugchannels.net/2015/07/pharmas-bright-future-meet-top-10-drugs.html

[10] Express Scripts. (2015). *The Express Scripts 2014 Drug Trend Report.*

[11] Prime Therapeutics. (2014). *2014 Report on Prescription Drug Costs.*

[12] UnitedHealth Group. (2014). *The growth of specialty pharmacy: Current trends and future opportunities.*

[13] GlobalData. (2014, Jun 10). *Lucrative Biosimilars Space to Erode Biologics Market from 2019.* Retrieved: http://healthcare.globaldata.com/media-center/press-releases/pharmaceuticals/lucrative-biosimilars-space-to-erode-biologics-market-from-2019-says-globaldata

[14] Optum. (2015, Jan 20). *New cholesterol drugs pack huge price tag.* Retrieved: https://www.optum.com/thought-leadership/new-cholesterol-drugs.html

[15] Consumer Reports. (2014). *Evaluating statin drugs to treat high cholesterol and heart disease: Comparing effectiveness, safety, and price.* Retrieved: https://www.consumerreports.org/health/resources/pdf/best-buy-drugs/StatinsUpdate-FINAL.pdf

[16] Staton, T. (2015, Oct 7). *Two's company for PCSK9 meds as Praluent, Repatha both nab coverage from top PBM.* FiercePharma. Retrieved: http://www.fiercepharma.com/story/twos-company-pcsk9-meds-praluent-repatha-both-nab-coverage-top-pbm/2015-10-07

[17] Optum. (2015, Jan 20). *New cholesterol drugs pack huge price tag.* Retrieved: https://www.optum.com/thought-leadership/new-cholesterol-drugs.html

[18] Mathon, J. (2015, Aug 31). *PCSK9 Race: Amgen, Sanofi, and Regeneron First Out of Gate, But Pfizer Poised To Make Up Lost Ground.* Citeline.

[19] Casey, T. (2015). *PCSK9 inhibitors lower cholesterol, but is cost a concern?* Cardiovascular Business. Retrieved: http://www.cardiovascularbusiness.com/topics/healthcare-economics/pcsk9-inhibitors-lower-cholesterol-costs-are-high

[20] Beasley, D. (2015, May 26). *Fight over hot new cholesterol drugs may be won in milligrams.* The New York Times.

[21] Staton, T. (2015, Oct 7). *Two's company for PCSK9 meds as Praluent, Repatha both nab coverage from top PBM.* FiercePharma. Retrieved: http://www.fiercepharma.com/story/twos-company-pcsk9-meds-praluent-repatha-both-nab-coverage-top-pbm/2015-10-07

[22] Generic Pharmaceutical Association. (2014). *The Next Frontier for Improved Access to Medicines: Biosimilars and Interchangeable Biologic Products.*

[23] Generics and Biosimilars Initiative. (2014, Jan 20). *US$67 billion worth of biosimilar patents expiring before 2020.* Retrieved: http://www.gabionline.net/Biosimilars/General/US-67-billion-worth-of-biosimilar-patents-expiring-before-2020/

[24] Food and Drug Administration. (2015). *Biosimilars.* Retrieved: http://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/therapeuticbiologicapplications/biosimilars/default.htm

[25] Drug Channels. (2015, Feb 5). *What Gilead's Big Hepatitis C Discounts Mean for Biosimilar Pricing.* Retrieved: http://www.drugchannels.net/2015/02/what-gileads-big-hepatitis-c-discounts.html

[26] Generic Pharmaceutical Association. (2014). *The Next Frontier for Improved Access to Medicines: Biosimilars and Interchangeable Biologic Products.*

[27] Congressional Budget Office. (2008, Jun 25). *S. 1695 Biologics Price Competition and Innovation Act of 2007.*

[28] GlobalData. (2014, Jun 10). *Lucrative Biosimilars Space to Erode Biologics Market from 2019.* Retrieved: http://healthcare.globaldata.com/media-center/press-releases/pharmaceuticals/lucrative-biosimilars-space-to-erode-biologics-market-from-2019-says-globaldata

[29] CVS/caremark. (2015). *CVS/caremark 2015 Service Benefit Plan Specialty Drug List.* Retrieved: https://www.caremark.com/portal/asset/FEPSpecialtyDrugList.pdf

[30] Atlantic Information Services, Inc. (2015). *Specialty pharmacy trends and strategies: 2015.* Washington, DC.

[31] Centers for Disease Control and Prevention. (2015). *Hepatitis C statistics and surveillance*. Retrieved: http://www.cdc.gov/hepatitis/hcv/statisticshcv.htm

[32] Lotvin, A. M., Shrank, W., Chang, A., Armstrong, L., Brennan, T. (2014). *Harvoni utilization in the weeks after launch: Patterns and implications.* CVS Health. Retrieved: https://www.cvshealth.com/sites/default/files/styles/CVS_Health_Harvoni_Utilization_Post_Launch.pdf

[33] Express Scripts. (2015). *The Express Scripts 2014 Drug Trend Report.*

[34] Wehrwein, P. (2015, Apr). *A conversation with Steve Miller, MD: Come in and talk with us, Pharma*. Managed Care. Retrieved: http://www.managedcaremag.com/archives/2015/4/conversation-steve-miller-md-come-and-talk-us-pharma

[35] Express Scripts. (2015). *The Express Scripts 2014 Drug Trend Report.*

[36] Drug Channels. (2015, Feb 5). *What Gilead's Big Hepatitis C Discounts Mean for Biosimilar Pricing*. Retrieved: http://www.drugchannels.net/2015/02/what-gileads-big-hepatitis-c-discounts.html

[37] Drug Channels. (2015, Feb 3). *The Specialty Pharmacy Boom Continues*. Retrieved: http://www.drugchannels.net/2015/02/the-specialty-pharmacy-boom-continues.html

[38] Fein, Adam J. (2016, Jan). *The 2016 Economic Report on Retail, Mail, and Specialty Pharmacies*. Drug Channels Institute. Retrieved: http://drugchannelsinstitute.com/products/industry_report/pharmacy/

[39] Health Policy Alternatives. (2003). *Pharmacy Benefit Managers: Tools for Managing Drug Benefit Costs, Quality, and Safety.*

[40] Health Affairs. (2013, Nov 25). *Health Policy Brief: Specialty Pharmaceuticals.*

[41] Catamaran. (2015). *2015 Informed Trends.*

[42] Tschida, S., Aslam, S., Khan, T. T., Sahli, B., Shrank, W. H., Lal, L. S. (2013). *Managing Specialty Medication Services Through a Specialty Pharmacy Program: The Case of Oral Renal Transplant Immunosuppressant Medications*. Journal of Managed Care Pharmacy. 19(1): 26-41.

[43] Health Affairs. (2013, Nov 25). *Health Policy Brief: Specialty Pharmaceuticals.*

[44] EMD Serono. (2015). *EMD Serono Specialty Digest™, 11th Edition.*

[45] Dorholt, M. (2014, Jun). *Advancing drug trend management in the medical benefit. Managed Care.*

[46] Vora, J. B. (2014). *Evaluation of medical specialty medications: Utilization and management opportunities.* Milliman.

[47] UnitedHealth Group. (2014). *The growth of specialty pharmacy: Current trends and future opportunities.*

[48] Visaria, J., Henderson, R., Glave Frazee, S. (2013, Dec 5). *Specialty Pharmacy Improves Adherence to Imatinib.* American Journal of Pharmacy Benefits.

[49] UnitedHealth Group. (2014). *The growth of specialty pharmacy: Current trends and future opportunities*.

[50] Duffant, B., Garg, A., Shah, K. (2014). *Overview of the specialty drug trend: Succeeding in the rapidly changing U.S. specialty market.* IMS Health.

[51] Atlantic Information Services, Inc. (2015). *Specialty pharmacy trends and strategies: 2015*. Washington, DC.

[52] Herrick, D. (2015, Apr). *New Drug Plan Regulations Protect Pharmacies, Harm Consumers*. National Center for Policy Analysis.

[53] Atlantic Information Services, Inc. (2015). *Specialty pharmacy trends and strategies: 2015*. Washington, DC.

[54] Reinke, T. (2014, Dec). *Specialty agents with expedited approval may fuel 2015 pharmacy costs*. Managed Care.

[55] Visante. (2016, Jan). *Pharmacy Benefit Managers (PBMs): Generating Savings for Plan Sponsors and Consumers.*

About sPCMA

PBMs administer prescription drug plans for more than 266 million Americans. With the costs and complexity of specialty drug treatments rising, PBMs offer a number of services designed to improve the quality of care for patients across the nation while managing overall costs to the health care system. To encourage complete coordination across the continuum of patient care, payers depend on PBMs' utilization management tools, including the use of specialty pharmacies, to ensure that the value of therapy is optimized, at the most reasonable costs possible.

sPCMA Mission

The rapid and ever-changing growth of the specialty pharmacy industry presents a multitude of challenges and opportunities for the overall health care industry. sPCMA was established as a division of PCMA to provide thought leadership and advocacy to the industry on matters of public policy, industry relations, and the value of specialty pharmacies. sPCMA:

- Defines and promotes the value of specialty pharmacy;
- Illuminates emerging policy issues affecting the industry;
- Serves as a public voice on matters related to specialty pharmacy; and
- Provides a forum for members to engage opinion leaders, policymakers, and other authorities.

A DIVISION OF THE
Pharmaceutical Care Management Association

325 7th Street, NW, 9th Floor | Washington, DC 20004 | spcma.org