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Review

An overview of specialty drugs

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Abstract

Specialty pharmaceuticals are high-priced drugs used to treat ailments that are uncommon, complex, chronic, and challenging to treat. Specialized drug handling, proper monitoring of clinical results, and efficient cost controls are necessary for these medications. This article's main focus is on the various approaches being used in the USA to manage the utilization of specialty pharmaceuticals, their costs, and the correlated outcomes. These outcomes include higher patient cost burdens and improved health insurance plan benefit designs with formulary modifications. The utilization of specialty pharmacies for drug delivery, a greater focus on care coordination and evidence-based medicine, healthcare reform, and laws are other strategies for managing specialized drugs. Spending on healthcare is on the rise both domestically and internationally, with a growing share of that spending going toward specialized medications.

Keywords: pharmaceutical innovation, high priced specialty, clinical outcome monitoring.

INTRODUCTION

Few individuals knew about specialized pharmaceuticals at the start of the twenty-first century. Specialty pharmaceuticals were used to treat extremely rare or possibly lethal conditions like HIV/AIDS and Multiple Sclerosis, but the term "specialty drugs" was not widely used. In less than 20 years, the market for specialized drugs has expanded significantly. Ten specialty medications were available in 1990, but by 2012, there were about 300 agents that fit the bill for a specialty drug. The fact that 40% of the agents currently in the pharmaceutical pipeline will probably be regarded as specialty agents when they are introduced to the market is even more astonishing.

Drug Bank.com states that there are 2,166 biotech medications available compared

Fig 1: Specialty Drugs

History

In 2017, the price of specialty drugs rose at a rate that was more than three times higher than the overall inflation rate (2.1 percent vs. 7.0 percent). Retail costs for 97 commonly used specialty prescription medications grew by 7.0 percent in 2017. Compared to specialty medicine price increases seen over the previous ten years (2008–2017), which ranged from 7.1 percent to 9.7 percent, this average yearly rise was less by two [1]. The majority of specialty medications are self-administered, reimbursed by pharmacy benefit plans, and overseen by Pharmacy Benefit Managers (PBMs). The remaining 50% are office-administered medications, which are infused or provided in doctor's offices, infusion clinics, at home, or as an inpatient in a hospital.

What is a speciality drug

As the pipeline for specialty drugs develops and widens, the definition of a specialty drug is also changing. The best way to characterize these medications is to consider all of their features, not just the price and mode of administration [2]. A specialty drug may have one or more of the following characteristics in common: prescribed for an individual with a complicated or chronic medical illness, which is characterized as a physical, behavioral, or developmental disorder that is progressing, may not have a recognized treatment, and may be deadly or severely crippling if untreated; addresses indications for orphan or uncommon diseases; demands more patient care, adherence, and education than is typical for dispensing; is a medication that can be ingested orally, injected, inhaled, or infused; has a large monthly expense; possesses special needs for shipping or storage [3].

Specailty drug pipeline

Specialty pharmaceuticals will account for three of every five newly authorized drugs by the Food and Drug Administration (FDA) by 2016. Specialty spending growth trends were projected to treble by 2020, reaching $400 billion, or 9.1% of the total amount spent health care in the country [4]. The overall biologic market value growth is expected to be restrained by the growing prevalence of biosimilars in the market, reaching $262 billion by 2019. PBMs are crucial for keeping an eye on the pipeline and forecasting the costs and therapeutic advantages of these medications. PBMs and specialty pharmacies evaluate the specialty medication pipeline by taking into account each drug's intended purpose, projected launch date, projected annual cost per patient, clinical advantages, and the availability of alternative treatments in the market**.**

Fig 2: Specialty drug pipeline

Scope and cost of specialty drugs

Because of the complexity and diversity of the US health system, the review article's case studies and results from specialty pharmaceutical use strategies targeted at cost reduction are mostly centred on the US. Since the escalating costs of specialty pharmaceuticals are a global issue, a follow-up review concentrating on non-US options where there is more governmental engagement as a payer rather than a variety of private and public insurance plans would be necessary [5]. A few instances are provided using data from the EU, namely pertaining to the use of cost-effectiveness analysis and the prescription of biosimilars, as there is more data available from the EU in these areas. The total amount spent on healthcare in the United States, including hospital stays, doctor visits, and prescription fills, is still rising. Roughly 11% of medical expensed.

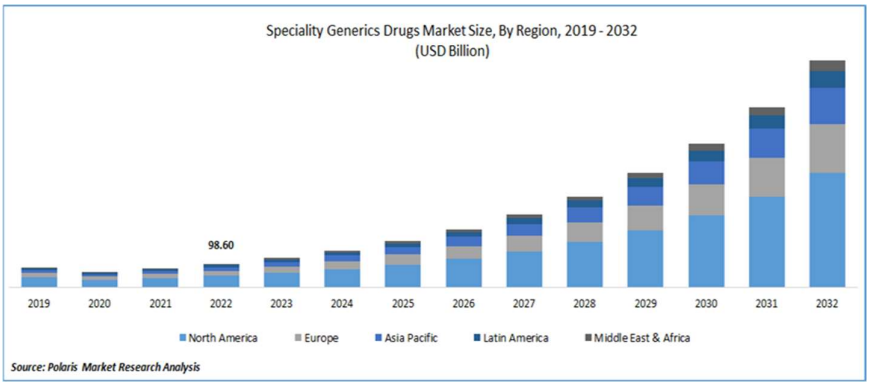

Fig 3: Speciality generics drugs market size, By Region, 2019-2032

How specality drug priced

What a Price Tag! The cost of "specialty drugs" is undoubtedly the main concern. Undoubtedly, a plan would want a member with a rare disease to get treatment and return to the workforce. However, plans are reluctant to handle this ethical policy-setting process since it requires weighing the cost of these pharmaceuticals against the benefit for a single member against the profitability of the plan for many members [6]. Why do these medications cost so much? The short answer is that their high price is permitted by the market. Unlike many other nations, the government does not determine product prices in the U.S. health care market; rather, manufacturers do. Price tags are the outcome of such public health and economic policies**.**

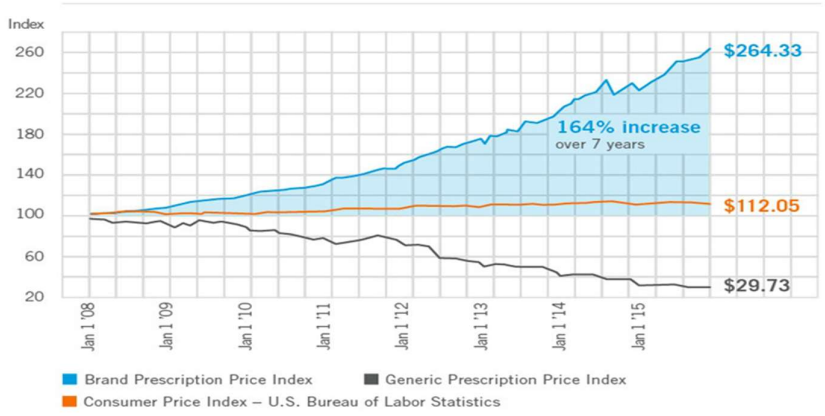

Fig 4: Drug pricing levels

Out data list

Specialty medications are priced by PBMs as a reduction from the Average Wholesale Price. Dispensing fees are usually non-existent since the "professional fee" is covered by the difference in price between purchasing the medication and selling it to payers. Over the past ten or so years, PBM/Plan contracts have made reference to a list of medications that are considered "specialty drugs," each of which is included with an associated AWP discount [7]. This practice raises three problems. First, as mentioned, the "discount off" has no influence on the cost to the manufacturer, the efficacy of the medication, or the price to buy the medication, which

keeps rising at the manufacturer's whim. This is because the manufacturer sets AWP. Secondly, on the day the list is updated**.**

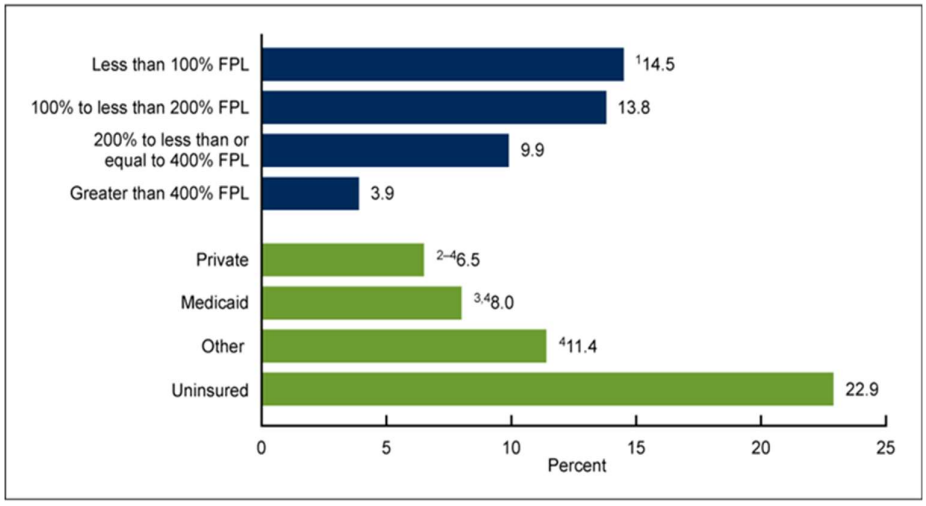

Fig 5: Data List Percentage

Cost and utilization starategies for speciality pharmaceuticals in USA benefit and management

Specialty pharmaceutical management should balance the need for innovative therapies while employing enhanced benefit design strategies to control unsustainable rising costs of specialty drugs [8]. This paper will review some strategies that have been employed control these healthcare costs. With new health insurance plan benefit structures, there has been a shift to an increased cost burden for patient

Biosimilars

A biosimilar is an FDA approved medicine that has been developed to be highly similar to the original biologic reference product and has no clinically meaningful differences compared to it. Biosimilars work the same way as the original biologic reference product by creating a similar response in your body [9].

Biologies

Many speciality drugs are biologics. Biologics are product derived from a living organism that can be many times the size of a conventional (small molecule) drug and having a more complex structure Biologics may be sensitive to heat and contamination, making then more difficult to ship and store [10].

Afforadability of specialty drugs and patient compilance with care plan

According to a 2007 study by employees of express script or its wholly owned subsidiary cura script on specialty pharmacy costs, if payers manage cost control through copayments with patients, there is an increased risk that patients will forego essential but expensive specialty drugs. In 2007 these researchers suggested in the adoption of formularies and other traditional drug-management tools. They also recommended specialty drug utilization management programs that guide treatment plans and improve outpatient compliance.

The impact of speciality drug trend and spend

Even though less than 2% of the population uses specialty drugs, those prescriptions account for a staggering 51% of total pharmacy spending[1]. Since specialty medications typically impact drug trend the most addressing the high cost of specialty medication is crucial. At a member level, plan sponsors see an average annual cost of $38,000 to cover a specialty patient's drugs compared to just $492 for the coverage of a non-specialty patient's costs.

That is 75x more to cover a specialty patient over the course of a year.[1] For most patients, these are life-sustaining, and even life-saving therapies, which presents the challenge of balancing affordability with the access to care. Additionally, plans will continue to be impacted from the COVID-19 pandemic and delayed care resulting in delayed diagnoses of specialty conditions., while cancer screenings also significantly declined (mammograms by 87%, colonoscopies by 90% and pap smears by 83%). This indicates that the market is expecting a rebound of visits and specialty patients to come, which could continue to drive up specialty drug trend.

Fig 6: Speciality drugs spending and tending.

CONCLUSION

Managing specialized medications is not insurmountable. However, plans must acknowledge that additional resources might be required when costs rise. These resources include unbiased advisors as well as medical and pharmacy staff who are not involved in medicine distribution, formulary management, or rebate administration. Innovative PBMs will save expenses to the greatest extent possible by utilizing alternate pricing sources like NADAC. The actual specialty pharmaceuticals are biologics and orphan drugs; employers may finally have the relief they need to cover them thanks to national law, which was not the subject of this study. The role of Foundation programs may also be determined by the involvement of the court system. Employers can best control the cost and usage of these medications in the interim by creating a well-thought-out plan.

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