Assessing the Unsustainable Cost of Specialty Medications: A Survey of Public Sector Health Plans

PUBLIC SECTOR HEALTHCARE ROUNDTABLE

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Background

Pharmacy costs continue to be a primary contributor to the overall increasing health care cost trend. Willis Towers Watson estimates that pharmacy costs represent about 20% of overall health care spend in 2019 and will reach 25% by 2020. According to the latest report from IQVIA on U.S. pharmaceutical use and spending, Americans filled 5.8 billion prescriptions of 30-day equivalents in 2018 which is up 2.7% from the prior year. About two-thirds of prescriptions were for chronic disease and specialty medication accounted for 2.2% of overall prescription volume. The use of specialty drugs is growing by more than twice the rate of non-specialty "traditional" drugs. The trend is impacted by new drug approvals (more than two-thirds of approvals in 2018 were specialty), and also the emerging use of specialty drugs for potentially chronic diseases such as atopic dermatitis, asthma, and migraine, which have historically been treated with traditional drugs. While only accounting for about 2% of all drug volume, many industry trend reports anticipate specialty accounting for half of all drug spend in the upcoming year or two.

It is very difficult to truly define specialty medication. Administrators such as pharmacy benefit managers and insurance carriers have different definitions, which can make negotiations on price and adjudication challenging. Instead, many organizations look to describe the various characteristics of a specialty medication in order to help further define these drugs. The following are typical characteristics of a specialty medication:

- Are often biologicals (drugs created through biologic processes to mirror bodily proteins and antibodies)
- Considered "large molecules" as compared to small molecules used in traditional medication
- Treatments derived from a source that is manufactured from a living cell or plant to create a complex mixture of molecules
- Are very expensive – the average specialty medication may cost over $2,500 per prescription
- May or may not be infusible or injectable
- May require frequent dosing adjustments or are subject to wastage
- May have limited or exclusive distribution channels as established by a pharmaceutical company
- Require special handling or temperature control requirements

- Require a greater amount of pharmaceutical oversight and clinical monitoring
- Require significant side effect management
- Require training and support for administration of the medicine

As the definition of a specialty drug is varied, so too are the types of drugs considered to be specialty; they can treat a disease as common as atopic dermatitis affecting nearly 3 million people in the U.S. or a disease that affects less than 150 people worldwide. The latter scenario would be considered an orphan disease—typically those that affect less than 200,000 people per year—and have been gaining a great deal of attention recently due to the cost of therapies, and in some cases, promises of cure. In 2018, 34 of the 59 new drug approvals were for orphan disease, with the majority being for various types of cancer or inherited genetic disorders.

In 2019, the trend is well underway with a number of high-profile orphan drug approvals. The world's most expensive drug was approved in the mid-year at over $2 million for the one-time, curative, gene therapy treatment. There are nearly 300 gene and cellular therapy drugs in development currently. While the population that would be treated with some of these potentially curative drugs is relatively very small, the associated price tags are putting pressure on the health care system and employers are tasked with identifying novel mechanisms for payment.

The budget impact from rare disease and gene therapy drugs will be relatively minimal due to the small populations being treated. The primary drivers of spend continue to be the injectable immunotherapy drugs that treat conditions such as arthritis, psoriasis, and ulcerative colitis. Cancer treatment, Multiple Sclerosis, and HIV all remain at the top of the list for driving spend as well. Many of the treatments for these conditions are specialty drugs that have little or no competition from generics or biosimilars. Conversely, new drugs to treat many of these conditions are being approved and often times they have better safety and efficacy than the existing products on the market. This results in loyalty to brand name products over time as they continue to be first-class treatment options in many cases. It will be increasingly important for plan sponsors to manage existing specialty drug spend to the full extent possible so that resources are available for the highly innovative products in the pipeline.

Overview and Methodology

Plan sponsors, including those in the Public Sector HealthCare Roundtable, are key stakeholders for providing health care benefits at an affordable cost. Over 15% of the American workforce, or some 22.3 million Americans, are employed at the federal, state, and local governments. The magnitude of spend is also much higher when compared to other domestic industries for both employees and retirees.

To learn how public sector health plan are approaching specialty drug costs, the Public Sector HealthCare Roundtable and Willis Towers Watson partnered to develop a comprehensive survey questionnaire. The survey consisted of questions surrounding specialty drugs and the costs associated with administering health care plans for the 2017-2018 plan year. Its goal was

to shed light on how public entities are addressing the issue and identify available solutions that ensure continued access to these critical medications with fair, affordable and sustainable pricing.

Survey Results

22 plan sponsors representing 138 health plans completed the survey in 2019. In aggregate, these organizations provide benefit coverage to 6,400,000 lives with a total drug spend of approximately $7.8 billion per year, including $3.7 billion dollars on specialty drugs. Other important 2017-2018 trend results are summarized below:

- Total drug trend averaged 3.0%
- Traditional drug trend averaged -.5%
- Only 1% of claims were for specialty drugs
- Specialty drug trend averaged 8.7%
- Four-year average for Specialty Drug trend was almost 16% annually

Plan sponsors responding to the survey stated they are attempting to control these daunting cost trends with the following strategies:

- 100% of respondents use targeted strategies to control specialty drug costs
- 91% of respondents use prior authorization across some or all specialty categories
- 77% of respondents use a carve-out specialty distribution capability
- 55% use a separate copay or coinsurance tier for specialty medications

In addition to basic plan and cost control information, the survey collected data on future expectations. In the most recent survey, 68% of respondents are concerned about increased financial hardship on members due to higher cost sharing. 68% of respondents are concerned about corresponding medical complications due to decreases in medication adherence. Finally, 55% of respondents are worried about the uncertainty of their organization’s ability to continue providing a high-quality health and benefits plan to their members.

Considerations

The creation of innovative specialty medications by the pharmaceutical industry has been beneficial. However, the high cost of these medications are creating significant barriers to access for American citizens and risking the financial stability of public and private sector health plans.

To address these concerns, the Public Sector Healthcare Roundtable offers the following policy recommendations:

- Provide the resources and regulatory flexibility to the U.S. Food and Drug Administration (FDA) to allow the fast-tracking of biosimilar or generic alternative drugs to market in order to promote further competition and lower costs.
- Reduce the market exclusivity period for brand biologic products to allow for increased competition (*Affordable Medicines Act*) and oppose the ratification of the 2018 USMCA exclusivity floor.
- Curb brand manufacturer's misuse of REMS strategies to block generic manufacturers from obtaining samples of brand drugs needed for bioequivalence testing and FDA approval by passing the Creating and Restoring Equal Access to Equivalent Samples (*CREATES Act*)
- Increase funding for private and public research efforts on comparative effectiveness, such as Institute for Clinical and Economic Review (ICER), a non-profit organization that evaluates evidence on the value of medical tests and treatments, and the Patient Centered Outcomes Research Institute (PCORI).
- Bring greater transparency to prescription drug pricing to encourage pharmaceutical manufacturers to publicly disclose production costs, including research and development investments, and discounts to various payers for specific high-cost drugs. Support state-based efforts to force manufacturers to disclose research and develop costs.
- Ensure public programs can take advantage of recent developments in value-based purchasing to ensure all parts of the U.S. health care system can benefit from market-based negotiating efforts to lower drug prices (*PAVE Act*).
- Address excessive spending on direct-to-consumer advertising by pharmaceutical companies to eliminate unnecessary and inappropriate utilization (*Drug-price Transparency in Communications (DTC) Act*).
- Finalize the Trump Administration proposal to tie the cost of certain Part B drugs to international pricing standards and request the program be expanded to all Part B covered medications.

Conclusion

Two-thirds of all the newly approved drugs in 2018 were considered specialty drugs. This was similar to the trend seen in 2017. For the first time ever, the majority of new drug approvals (34) were for orphan drugs to treat rare diseases. Nearly three-fourths (43 of the 59) of novel drug approvals in 2018 were designated in one or more of FDA's expedited approval categories of Fast Track, Breakthrough, Priority Review and/or Accelerated Approval. About one-third (32%) of drugs approved in 2018 were the first in their drug class.

However, while employers have taken extensive actions to try and mitigate the impact of specialty drug cost increases, they cannot solve the problem by themselves. The importance of measuring and addressing the cost of specialty medication is critical and, if not addressed by public policy actions, will place a significant burden on the affordability of these drugs for individuals, plan sponsors, and government agencies.

2019 Specialty Medications Survey Responding Organizations

Alabama – Alabama Public Education Employees' Health Insurance Plan (PEEHIP)
Alaska – State of Alaska – Alaska Care
Alaska – University of Alaska
California – California Public Employees Retirement System (CalPERS)
Colorado – Colorado Public Employees Retirement Association
Kansas – State of Kansas
Kentucky – Teachers' Retirement System of Kentucky
Kentucky – University of Kentucky/Know Your Rx Coalition
Montana – State of Montana
New Jersey – New Jersey Division of Pensions & Benefits, Department of Treasury
North Carolina – North Carolina State Health Plan
Ohio – Ohio Public Employees Retirement System
Ohio – School Employees Retirement System of Ohio
Ohio – State Teachers Retirement System of Ohio
South Carolina – South Carolina Public Employee Benefit Authority
Texas – Employees Retirement System of Texas
Texas – Teachers Retirement System of Texas
Utah – Public Employee Health & Benefits/Utah State Retirement System
Washington State – Washington State Health Care Authority
West Virginia – West Virginia Public Employee Insurance Agency
Wisconsin – Wisconsin Department of Employee Trust Funds

Post Office Box 26368
Alexandria, VA 22313
703.684.5236
www.healthcareroundtable.org