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. According to the 2016 Health Care Financial Benchmarks Survey by Willis Towers Watson, pharmacy cost increases accounted for half of the projected 5.2% annual medical cost growth trend. Even more interesting, Willis Towers Watson estimates that when projecting cost increases through 2020, the *specialty* drug spend will exceed what employers will pay for inpatient hospitalizations. For example, the per employee per year (PEPY) cost for pharmacy coverage is expected to be $3,472 by 2020 compared to the expected $3,235 specific to inpatient costs. Many employers and plan sponsors today recognize that pharmacy costs comprise 20% to 25% of the total health care spend.

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

Increases in the cost of specialty medication are driving the majority of overall pharmacy benefit trend. While slowing down slightly, pharmacy trend is estimated to be in the double digits in 2019 and 2020. This is due to the impact of new specialty medications, expanded indications for use, inflation and aging demographics. Various trend reports suggest that specialty drugs will account for 40% to 50% of the total pharmacy benefit cost for years to come.

There are several conditions that drive the vast majority of specialty spend. These include Autoimmune disorders (namely Rheumatoid Arthritis), Multiple Sclerosis, Cancer, Hepatitis C and Growth Deficiency. The cost dynamic is not one of volume or prevalence, however; it's one of high pharmaceutical prices. While most plan sponsors will attribute less than 1% to 2% of all prescription claims to specialty medication, those costs are the primary component of an unsustainable trend.

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 2015-2016 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

19 plan sponsors representing more than 95 health plans completed the two formal survey questionnaires in 2015 and 2018. In aggregate, these organizations provide benefit coverage to 5,000,000 lives with a total drug spend of $6.7 billion per year, including $2 billion dollars on specialty drugs. The most recent survey in 2018 included 11 plan Sponsors representing 50 health plans. Other important 2015-2016 trend results are summarized below:

- Total drug trend averaged 7.9%
- Traditional drug trend averaged 2.4%
- Less than 2.0% of claims were for specialty drugs
- Specialty drug trend averaged 17.1%, but a quarter of plans exceeded 24%
- Three year average for Specialty Drug trend exceeded 26% 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
- 100% of respondents use prior authorization across some or all specialty categories
- 82% of respondents use a carve-out specialty distribution capability
- 63% 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, 91% of them are concerned about increased financial hardship on members due to higher cost sharing. Over 80% 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. Finally, over 80% of respondents are concerned about corresponding medical complications due to decreases in medication adherence.

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 help address these concerns, the Public Sector Healthcare Roundtable suggest the following possible legislative actions:

- 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 to promote further competition at a lower cost.

- Reduce the market exclusivity period for brand biologic products to allow for increased competition (*Improving Access to Affordable Prescription Drugs Act,* S. 771).

- Increase funding for private and public research efforts on comparative effectiveness, such as Institute for Clinical and Economic Review (ICER) 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.

- 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.

- To avoid patient or provider confusion, reverse recent FDA decision allow brand biologics and their biosimilar alternatives to be assigned the same International Nonproprietary Name.

- Address excessive spending on direct-to-consumer advertising by pharmaceutical companies to eliminate unnecessary and inappropriate utilization.

- Encourage contingent pricing for drugs, tying cost to effectiveness and focusing on reimbursing based on efficacy where it truly exists.

Conclusion

2017 was a very active year for the FDA. First-time drug approvals in the U.S. reached an all-time high, with 46 new therapies cleared for use - up from 22 the previous year. Specialty drugs accounted for 28 out of 46 (60.8%) newly approved drugs. The focus on new drug approvals continues to be broad in spectrum but with a focus in the oncology and rare disease space. Plan sponsors are reacting with a renewed focus on how to best optimize utilization of these specialty medications and minimize waste.

Current management approaches include enrolling in clinical management programs (e.g. step therapy, prior authorization and quantity limits) and considering alternate benefit designs. However, while employers can 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.

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