INTRODUCTION

Several years ago, health care industry analysts identified a development that employers and managed care organizations had already begun to notice: although used by only about 1% of plan members, specialty medications occupied a share of total drug expense that was both conspicuous and growing at an alarming rate.\(^1\)\(^-\)\(^4\) Since that time, specialty drug trend has outpaced even those forecasts,\(^5\)\(^-\)\(^8\) and additional cost growth is likely because of several key marketplace developments, including:

- The launch of several specialty medications for high-prevalence and/or chronic conditions, including multiple drugs costing between $85,000-$150,000 per treatment for hepatitis C viral infection, which affects about 3 million U.S. residents.\(^9\)\(^-\)\(^17\)

- Accelerations in the rate of drug price inflation, with some commonly used specialty medications more than doubling in price over the 5-year period ending in 2016.\(^18\)\(^-\)\(^21\)

- Diminished outlook for biosimilar cost savings due to price reductions and marketplace penetration that have underperformed relative to original projections.\(^22\)\(^-\)\(^26\)

Given these significant market developments, Archimedes developed a 5-year specialty drug forecast that spans the pharmacy and the medical benefit. The forecast represents commercial plan sponsors that cover specialty drugs as a part of their benefit offering.

RESULTS

Figure 1:
Specialty Drug Spend Forecast PMPY, Pharmacy and Medical Benefit

<table>
<thead>
<tr>
<th>Year</th>
<th>Pharmacy</th>
<th>Medical</th>
</tr>
</thead>
<tbody>
<tr>
<td>2016</td>
<td>$430</td>
<td>$292</td>
</tr>
<tr>
<td>2017</td>
<td>$503</td>
<td>$308</td>
</tr>
<tr>
<td>2018</td>
<td>$589</td>
<td>$326</td>
</tr>
<tr>
<td>2019</td>
<td>$683</td>
<td>$343</td>
</tr>
<tr>
<td>2020</td>
<td>$786</td>
<td>$361</td>
</tr>
</tbody>
</table>

PMPY=per member per year expenditures, measured as total allowed amount.
Findings of the Archimedes analysis indicate that specialty drug spend will increase by an average of more than $100 per member per year (PMPY) from 2016 to 2020, exceeding $1,000 PMPY beginning in approximately 2019. The forecasted 2020 spend represents a 220% rate of growth—more than a 3 fold increase—since 2010.\textsuperscript{27-29} We estimate that the percentage of specialty drug cost incurred under the pharmacy benefit will increase from 60% in 2016 to 69% in 2020, due to the growing number of oral oncology drugs and higher inflationary trends for specialty drugs under pharmacy.

**DISCUSSION**

The combination of therapeutic potential and rapidly rising costs has made specialty medication management one of the most critically important challenges facing plan sponsors today, leading some even to question whether the prescription drug benefit will remain financially viable in the coming years.\textsuperscript{14,30-31} Our findings certainly do nothing to allay those concerns, suggesting that for many plan sponsors, specialty medications have the potential to occupy such a large proportion of plan spending that it will be difficult—if not impossible—to cover other drugs and services. However, the factors underlying this rapid cost growth provide clues to effective management techniques. Three key actions, taken now, will help plan sponsors stem the tide:

- **Prior authorization.** Use prior authorization programs under both the pharmacy and medical benefits to target specialty medications to patients for whom they are clinically appropriate and promote cost-effective utilization. Managing inappropriate use is critical to counter the unintended effects of direct-to-consumer advertising and to combat high rates of specialty drug use inconsistent with approved labeling and/or treatment guidelines.\textsuperscript{27,32-36} It is important that plan sponsors not only implement prior authorization programs but also routinely monitor their performance to ensure the intended results are being achieved.

- **Site-of-care management.** Direct infusions to the least costly, clinically appropriate site of care to address the growing use of the outpatient hospital setting, a costly and frequently unnecessary site of care for specialty drug infusions.\textsuperscript{37,38}

- **Rebates from pharmaceutical manufacturers.** Ensure that the PBM contract passes through all revenues from manufacturers for both the pharmacy and medical benefits, including rebates, administrative fees, data fees, and price protection. In recent years, price protection provisions, which provide a cost threshold above which additional rebates are paid, have become more common in rebate contracts as a way to mitigate the impact of drug price inflation, which was 16% in 2015.\textsuperscript{11,39,40}
METHODOLOGY

Archimedes reviewed Medline-indexed and “gray” published literature, including PBM trend reports, published analyses of exchange enrollee characteristics and utilization, payer surveys, and policy assessments. We conducted quantitative analyses of these sources, as well as payer claims data. Assessments of the effects of biosimilar introductions were based on current pricing, as well as market uptake patterns for the 2 biosimilar and generic drugs introduced at the time of our analysis.

The study’s primary outcome was total specialty drug cost measured as allowed amount, i.e., total payments received by providers from all sources including payers and patients. Additionally, because the influx of new drugs could influence the mix of utilization in the pharmacy and medical benefits, we assessed trends in the proportion of expense incurred in each benefit. The forecast does not take into account rebates for specialty drugs as rebate dollars are not routinely disclosed by PBMs or health plans. The forecast does account for differences in the ways that specialty drugs are defined by various organizations, to the extent that these definitions were disclosed in the reports currently available.

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REFERENCES


REFERENCES (continued)


