Curbing the Costly Trend: Exploring the Need for a Progressive Approach to the Management of Specialty Pharmaceuticals Under the Medical Benefit

Michael S. Jacobs, RPh; Kjel A. Johnson, PharmD, BCPS, FCCP, FAMCP

Background: Specialty injectables and protein-based biologic therapies represent the fastest growing segment of the drug trend for many plan sponsors. Coupled with the decline in spending on traditional pharmaceuticals and so-called blockbuster drugs coming off patent, the upward trend of specialty drug spending continues at an unprecedented rate, precipitating a shift in the focus of payers who manage prescription drugs.

Objectives: To characterize the current and future specialty drug spending and describe contemporary trends among payers for managing cost and quality in this segment, as well as to elucidate the shortcomings of the current efforts and to explore a comprehensive approach for addressing the cost and quality concerns directly associated with specialty injectables and protein-based biologics through interrelated management interventions.

Discussion: Although a notable decrease in spending on traditional pharmaceuticals was realized in 2010, disproportionate increases in specialty drug utilization and cost per unit fueled the continuing growth of the injectable and biologic markets. Each course of these therapies can cost in the tens of thousands of dollars, and this upward trend of specialty spending represents an escalation of an already significant spending for payers, employers, and members. Beyond the high cost and growing utilization of specialty pharmaceuticals, current management efforts have been met with variable degrees of success and have often proved challenging and, in some cases, even counterproductive. Common interventions used by payers nationwide for addressing specialty drug spending trend include specialty drug formularies, provider reimbursement strategies, distribution channel management, benefit design modifications, utilization management, and operational and administrative improvements such as postclaim edits. Although often overlooked, appropriate implementation of these tactics, and the extent to which they are integrated with overall drug benefit management, are key to the success of the pharmaceutical management program.

Conclusion: Conventional specialty pharmaceutical management initiatives offer promise in various areas, but incentives for the best protocols may be misaligned when they are applied individually. Conversely, a comprehensive approach that integrates effective components of the specialty pharmaceutical management interventions can improve the quality of care and control costs associated with these agents, with significant specialty drug management expertise and access to benchmarking data serving as the foundation for appropriate decision-making.
a majority of the drug trend by the end of 2013. With no end in sight, it is expected that 8 of the top 10 drugs—according to overall sales estimates—will be specialty products by 2016.

In addition to the high price and growing popularity of biologic agents and other targeted therapies, this trend has been simultaneously amplified by the declining impact of traditional pharmaceutical therapies, largely because of the increased prevalence of generic drugs and their use. Although these traditional pharmaceutical agents contributed only 1.1% to the overall prescription drug trend in 2010, an array of so-called blockbuster drugs—collectively worth more than $50 billion in 2010 US sales—are expected to lose patent protection after 2013. During this same timeframe, first-time generic drugs represent a significant 20% of current plan spending on prescription drugs and 8% of total prescription claims volume, likely resulting in notable cost-savings within the nonspecialty therapeutic classes as the generic pharmacy dispensing rate dramatically increases.

These interrelated factors have created a unique dichotomy for health plan sponsors: although the overall drug cost trend is essentially flat for nonspecialty therapeutics, specialty drug costs are escalating at an unprecedented rate.

This dynamic within the drug cost management domain has garnered increasing attention from health plan sponsors. Because recent efforts on the part of payers have yielded only moderate success in maintaining quality of care, while controlling specialty drug spending, consideration of more comprehensive management interventions for specialty agents is warranted. Although specialty drug initiatives based on formularies, provider reimbursement, benefit design, distribution channel management, fraud and error reduction, and utilization management have been incorporated alone or in various combinations by health plans across the country, success has been variable among the various plans. This may be attributed to the availability of only few payers’ strategies that comprehensively encompass all of these components, leaving certain issues in the complex specialty drug delivery system unaddressed. With the expectation that cost pressures related to the specialty drug sector will only increase in the future, the time to explore and implement effective pharmaceutical management strategies is clearly now.

The Specialty Drug Conundrum

**High Cost and Growing Utilization**

As the fastest growing segment of drug spending, specialty pharmaceuticals represent an area of urgent concern for plan sponsors and other stakeholders. Although traditional drug spending decreased noticeably in 2010 (to 1.4% from 4.8% in 2009), specialty drug spending increased by 19.6% during the same period (Figure 1). This trend was driven by a 7.0% increase in specialty drug prevalence versus a 0.7% decrease in traditional pharmaceuticals, and by a 9.2% increase in specialty drug cost per unit compared with only a 3.5% increase in the same category for traditional pharmaceuticals.

With courses of therapy sometimes costing tens of thousands of dollars, this increased specialty drug cost per unit represents a significant escalation in costs for payers and plan members alike. Patent expirations contributed ~1.9% to the decline in traditional drug spending in 2010, and a surplus of high-volume traditional pharmacy-dispersed agents coming off patent through 2013 will undoubtedly continue this downward trend.

Meanwhile, the vast majority of medications in the specialty drug segment are well within their patent lifetime, and several new agents are being added on a regular basis from a drug pipeline overflowing with experimental biologies. As of 2010, cancer has led all therapeutic areas, with 907 drugs (38% of the entire pipeline) currently in development; more of these drugs advanced to phase 2
and 3 clinical trials in 2011 than in the previous year (Figure 2).\textsuperscript{1,3}

In addition, there is yet no US Food and Drug Administration (FDA)-approved mechanism to bring a generic specialty pharmaceutical drug (ie, biosimilar) to market in the United States, thereby mitigating potential future savings in the specialty drug segment related to patent expirations. (In February 2012, the FDA issued "guidance for industry" regarding biosimilars.\textsuperscript{4}) Furthermore, although biosimilars were originally expected to generate 30\% to 40\% savings, recent data suggest that most payers anticipate that biosimilars will be priced at a more modest 10\% to 20\% less than the cost of brand-name equivalent agents, because of the complexity of bringing these drugs to market.\textsuperscript{5}

**Payer Interventions**

Beyond the high cost and growing utilization of specialty pharmaceuticals, current management efforts have been met with variable success and have often proved challenging and even counterproductive. Common interventions used by payers nationwide for addressing specialty drug spending include medical benefit drug formularies, novel provider reimbursement strategies, distribution channel management, benefit design modifications, utilization management, and operational and administrative improvements such as postclaim edits. Among the most practical and effective of these specialty management interventions, medical benefit drug formularies are widely accepted by payers and by plan members.

Based on a recent survey of 60 commercial health insurance plans covering 153 million lives, approximately 66\% of plans operate with at least some established medical benefit injectable drug formulary.\textsuperscript{3} For almost all of these plan members, formularies are available for almost all erythropoietin-stimulating agents (ESAs) and for intravenous immunoglobulin (IVIG); by contrast, approximately only 66\% of biologic agents for the treatment of RA are subject to formularies.\textsuperscript{3} In addition, 57\% of the members covered by the surveyed plans have access to formularies for chemotherapy agents.\textsuperscript{3} The most frequently managed chemotherapy agents included in this survey were bevacizumab (Avastin), rituximab (Rituxan), and trastuzumab (Herceptin).

The benefit for health plans of using formularies in specialty drug management is 2-fold: (1) formularies allow plans to manage drug utilization in a simple, straightforward manner similar to that used under the pharmacy benefit for traditional medicines, and (2) by designating preferred agents in various drug classes, formularies can facilitate the negotiation of rebates by health plans with drug manufacturers.

Plans covering 76\% of the lives in the payer survey cited before reported that they receive rebates based on their implementation of a medical benefit drug formulary.\textsuperscript{3} From a plan member perspective, formulary status demonstrates a thorough clinical review, indicating that due diligence has been performed for therapies included in the formulary.\textsuperscript{3}

Considered by some stakeholders to be more challenging to implement than medical benefit drug formularies, changes to provider reimbursement programs
have, at times, yielded successful results, and at other times unfavorable results for payers and for providers alike. A deleterious outcome is often the result of reimbursement programs that produce perverse incentives. Plan stakeholders have long regarded the buy-and-bill system to be flawed, because healthcare providers prescribe therapies that allow them to generate the greatest possible income through drug margin. Today, approximately 6 of every 10 covered lives of surveyed plans reimburse providers for medical benefit injectables based on a percentage above the average sales price (ASP) methodology (known as “ASP plus”), which was made popular by the Medicare Modernization Act of 2005. Furthermore, based on the same payer survey, approximately only 1 in 4 covered lives are currently subject to the traditional average wholesale price provider reimbursement that once allowed administering physicians to generate significant practice revenue.

Although switching to tighter ASP reimbursement methodology would seemingly reduce providers’ drug margins and lead to lower overall drug costs, several undesirable consequences may arise from such an approach. First, under an ASP-plus methodology, providers may be incentivized to choose higher-cost therapies to compensate for the lower reimbursement rate. In addition, the unfavorable reimbursement associated with ASP plus may result in fewer providers continuing to administer injectable drugs in their practices, which will invariably lead to increased referrals to the higher-cost hospital outpatient setting for drug administration.

Looking at the top 10 drugs by annual spending per 1 million lives in 2010, administration in the hospital setting generally resulted in at least twice the cost of provider-administered injectables delivered in the physician’s office (Table 1). The high cost associated with specialty drug acquisition and/or administration via alternative means to physician buy-and-bill is likewise one reason why distribution channel management may be a challenge for payers. Some plans have taken provider reimbursement-based initiatives a step further, by removing specialty injectables from the practices’ domain or encouraging their administration in other settings.

Furthermore, outside of payers’ control, the Community Oncology Alliance reported last year that more than 300 oncology practices had been purchased by hospitals in the previous 4 years. Although nearly 50% of all specialty injectables are still administered in the physicians’ offices via the traditional buy-and-bill method, 25% are now administered in the outpatient setting and 15% in the home health setting.

The trend of delivering provider-administered drugs outside of the office is increasing, as facilities develop accountable care organizations. Some payers, working in conjunction with pharmacy benefit managers, may maintain provider office administration but eliminate

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**Figure 2** Drugs in the Pipeline in Phase 2 or 3 Clinical Trials for Key Cancer Types

<table>
<thead>
<tr>
<th>Drug Type</th>
<th>Phase 2 trials</th>
<th>Phase 3 trials</th>
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<tbody>
<tr>
<td>Breast</td>
<td>73</td>
<td>30</td>
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<tr>
<td>Non-small-cell lung cancer</td>
<td>56</td>
<td>30</td>
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<tr>
<td>Non-Hodgkin lymphoma</td>
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<td>18</td>
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<tr>
<td>Colorectal</td>
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<td>16</td>
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<tr>
<td>Ovarian</td>
<td>31</td>
<td>13</td>
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<tr>
<td>Melanoma</td>
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<td>15</td>
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<tr>
<td>Prostate</td>
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<td>13</td>
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<tr>
<td>Renal</td>
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<td>10</td>
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<tr>
<td>Head and neck</td>
<td>15</td>
<td>10</td>
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<tr>
<td>Acute myelogenous leukemia</td>
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the physicians’ ability to buy and bill, by mandating that drug acquisition be routed through the specialty pharmacy. However, with acquisition costs through the specialty pharmacy being 17% higher, on a weighted average basis, than those in the provider’s office, this strategy is now viewed as leading to increased costs.3 Furthermore, when drugs are shipped to the provider’s office rather than taken from the provider’s buy-and-bill stock, waste can occur (eg, because patients are subsequently being switched to alternate therapies, are incapable of tolerating the product, or are enrolled in hospice programs).

Beyond higher costs at the plan level for drug acquisition outside of the buy-and-bill strategy, facility administration of specialty drugs may also come at a higher cost to patients, accompanied by a potential decline in quality of care. In addition to the inconvenience of having to visit another site outside of their providers’ offices, patients receiving their specialty therapeutics in the outpatient setting often have to deal with scheduling difficulties, wait times, and cumbersome hospital and standardized protocols.

These complications may ultimately affect patient quality-of-care issues, such as nonadherence, as members face barriers to hassle-free pharmaceutical delivery. Furthermore, when providers who would otherwise be administering specialty drugs in their own offices are denied payment as a result of a change in distribution channel, that opportunity for direct patient contact and the continuity—and therefore quality—of care for members may potentially be disrupted.

**Benefit Design**

Similar to efforts targeting the drug distribution channel, the use of benefit design as a means of managing specialty injectables has the potential to generate both harm and good within the system. Although removing cost-related barriers from the patient results in expanded access and/or adherence to evidence-based therapy, plan members who are not influenced by cost-sharing considerations have no incentive to be “smart shoppers” when it comes to their healthcare. Conversely, when cost-sharing parameters are so prohibitive that patients are financially unable to procure necessary treatment, payers have ultimately failed in their mission to provide quality healthcare.

In 2011, 43% of plans required neither a copay nor coinsurance from members for medical injectables, and 27% of plans required coinsurance only.4 Copay is a less common strategy for specialty therapies, being the sole requirement for medical injectables by 20% of plans.

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**Table 1: Spending and Utilization per 1 Million Lives, by Site of Service for the Top 10 Medical Injectables**

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<tbody>
<tr>
<td>Remicade</td>
<td>1</td>
<td>32</td>
<td>34</td>
<td>6</td>
<td>32</td>
<td>26</td>
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<tr>
<td>Avastin</td>
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<td>40</td>
<td>6</td>
<td>40</td>
<td>40</td>
<td>1</td>
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<td>8</td>
<td>-16</td>
<td>13</td>
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<tr>
<td>Neulasta</td>
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<td>26</td>
<td>5</td>
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<td>Rituxan</td>
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<td>36</td>
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<td>-10</td>
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<td>24</td>
<td>6</td>
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<td>Herceptin</td>
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<td>4</td>
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<td>Lucentis</td>
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<td>12</td>
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<td>Taxotere</td>
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<td>2</td>
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<td>29</td>
<td>-28</td>
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<td>38</td>
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<td>13</td>
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<td>10</td>
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<td>145</td>
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<tr>
<td>Gammagard</td>
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<td>-4</td>
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<td>Eloxatin</td>
<td>10</td>
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ESRD indicates end-stage renal disease; SPP, specialty pharmacy provider.

Only 10% of plans required coinsurance and a copay from their members for specialty therapeutics. Smaller managed care organizations tend to use less cost-sharing, with 64% of plans with <500,000 members requiring neither a copay nor coinsurance from the patient, and with no plans of this size requiring both. Still, more aggressive cost-sharing on specialty drugs for members appears to be on the rise overall. Regardless of a plan size, the weighted mean coinsurance for medical injectables among payers increased from 20% in 2011 to an estimated 22% in 2012, whereas the average copay amount increased from between $45 and $46 in 2011 to an estimated $64 in 2012.

Aside from the cost-sharing component of benefit design, genomic testing and preventive and palliative care programs offer other opportunities for managing specialty drug utilization, specifically for oncology therapies. As a means of eliminating unnecessary prescribing of costly agents to patients who will receive no therapeutic benefit from these medications, genomic tests for so-called personalized medicines are available for a select number of targeted biologics.

Among the available tests, HER2 and KRAS analyses have experienced the greatest uptake, by 84% and 82% of plans in 2011, respectively. Likewise, the vast majority of plans in 2011 (83%) had HEDIS (Healthcare Effectiveness Data and Information Set) cancer screening/prevention programs in place. Recognizing the potential for inappropriate utilization of oncology therapies near the end of life, the majority of payers (55%) have also incorporated palliative care programs, and approximately half (53%) of them are covered under the general medical benefit.

**Utilization Management Initiatives**

Furthering efforts to promote the use of “the right therapy for the right patient at the right time,” utilization management initiatives are also used to encourage evidence-based prescribing. Although prior authorization (PA) immediately comes to mind when considering these measures, a simple “yes” or “no” based on clinical criteria is just the tip of the iceberg. Evolving from conventional PA interventions, modern utilization management measures can take myriad forms, ranging from straightforward step edits to intensive case management. Regardless of the model, 74% of plans use some form of utilization management for provider-administered injectables. The prevalence of utilization management varies according to therapeutic class, with PA being the most common for biologic RA therapies (63%), IVIG (60%), ESAs (58%), and chemotherapy (58%). Case management is most frequently used for IVIG (46%) and hemophilia therapies (49%), and step edits are the most common for biologic therapies for RA (21%). The prevalence of utilization management tools by class is outlined in Table 2.

These utilization management techniques vary in terms of scope and have, therefore, also yielded varying results for payers. Looking specifically at PA—one of the simplest forms of utilization management—some criteria are universal (eg, FDA indication applies to 100% of covered lives) or nearly universal (eg, compendia listing applies to 85% of covered lives). Other criteria are less common but remain prevalent, such as prior therapy failure (78%) and the dose-to-weight approach in therapeutic range for indication (61%).

The consistency across plans in terms of implementing PA criteria is likely a result of the proven and well-established use of this form of utilization management among a high proportion of health plans.

Conversely, fledgling utilization management initiatives, such as clinical pathways, are less common and have more variable results. Based on consensus therapeutic guidelines established by the National Comprehensive Cancer Network, clinical pathways are more narrow and prescriptive and allow for active, clinician-driven management of treatment recommendations. The theoretical end result of these initiatives is improved quality of care, with a noticeable reduction in therapeutic variation in clinical practice.

Still, despite several implementations among health plans nationwide, clinical pathways programs have so far only yielded subjective data to support their effectiveness and utility in clinical practice, and only 15% of payers with such a program report being satisfied with the results. For example, a recent study from 8 practices in the US Oncology network reported that annual outpatient costs for patients with non–small-cell lung cancer who were treated according to pathways protocols were 35% lower than those of patients treated off pathway, with no difference in 12-month overall survival. However, although retrospective costs were less for patients treated according to a pathway versus those who were off pathway, this was driven by the fact that many off-pathway patients were given ineffective and costly third- through sixth-line therapies, and this type of inappropriate prescribing can be easily managed through PA. Moreover, the study was not designed to demonstrate if pathways are capable of reducing or eliminating third-line (17% of off-pathway patients vs 1% of pathway patients) and fourth- through sixth-line treatment (15% of off-pathway patients vs 0% of pathway patients), which—as stated earlier—is likely the key driver of the higher costs.

This latter component of the data suggests that the value of pathways lies in reducing unnecessary care in...
### Table 2: Prevalence of Utilization Management Tools, by Therapeutic Class

<table>
<thead>
<tr>
<th>Therapeutic class</th>
<th>PA, %</th>
<th>Case management, %</th>
<th>Disease management, %</th>
<th>Clinical pathway guidelines, %</th>
<th>Differential reimbursement, %</th>
<th>Step edit requirements, %</th>
<th>Failure of generic first, %</th>
<th>NCCN guidelines, %</th>
<th>Formulary presence, %</th>
<th>None, %</th>
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</thead>
<tbody>
<tr>
<td>Intravenous immunoglobulin</td>
<td>60</td>
<td>46</td>
<td>28</td>
<td>30</td>
<td>34</td>
<td>4</td>
<td>0</td>
<td>29</td>
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<td>1</td>
<td>61</td>
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<td>Colony-stimulating agents</td>
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<td>36</td>
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<td>3</td>
<td>0</td>
<td>8</td>
<td>36</td>
<td>13</td>
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<tr>
<td>Biologic response modifiers (eg, Orenica, Remicade)</td>
<td>63</td>
<td>28</td>
<td>31</td>
<td>30</td>
<td>27</td>
<td>21</td>
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<td>Hemophilia</td>
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<td>Chemotherapy-induced nausea and vomiting</td>
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<td>43</td>
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end-of-life situations, which has been achieved through simpler authorization and palliative care interventions. Further evaluation is necessary to determine the precise role that clinical pathways play in utilization management programs.

Operational Improvements

Operational improvements, such as postclaim edits, represent the final means by which payers have managed specialty drug utilization and unit cost. Although medical claims data are not as “clean” (ie, error-free) as pharmacy claims data, these interventions have demonstrated promise as plan stakeholders become increasingly savvy about identifying and sorting the necessary information. In 2011, claims reviews conducted to monitor appropriate dosing regimens overall (54%), as well as appropriate dosing with weight-based medications (50%), were employed by plans representing at least half of the covered lives, with FDA label indications (46%) and adherence to treatment guidelines (44%) also being frequently targeted.1

Furthermore, plans representing only 30% of covered lives were not conducting edits. Nevertheless, although existing edit tools may capture severe outliers, for most plans there remains a paucity of detailed content necessary for optimizing the opportunities for improvement with this form of specialty drug management. Outside vendors with the ability to integrate medical and pharmacy claims data, as well as the technology to sort and analyze the data in a manner that produces useful results, provide an immediate solution to this problem.

A Medical Pharmacy Management Approach

As a function of high cost and administrative complexity, specialty drug management represents a pressing concern and top priority for health plan sponsors and stakeholders. Although few will deny the scope of the problem, the variable success of management interventions to date indicates that some solutions have limited effect. Limits in data capture can certainly account for some of the challenge; for example, cancer stage is not included in payer claims data or provider claims submission, often necessitating precertification to capture such data elements.

Although all of these specialty pharmaceutical management interventions offer promise in different capacities, various initiatives should be applied in concert to maximize savings and improvements in quality of care. Modifications to provider reimbursement, for example, have led some dispensing physicians to choose higher-cost therapies to generate greater practice revenue. In extreme cases where reimbursement has become so unfavorable that providers can no longer afford to administer drugs in their offices, members are referred to the hospital or to outpatient facilities, where drug and drug administration costs are generally higher and patient care is fragmented; for example, the prescribing provider and the administering provider can be at different sites of service. Benefit designs with increased cost-sharing, often used as a method for managing the cost of care by the plan sponsor, can manifest out-of-pocket costs prohibitive to necessary treatment.

Tried and true utilization management techniques, such as PA, remain a key piece of the puzzle, but these measures must be applied in a clinically sound manner, lest they become an obstacle to effective, evidence-based prescribing. Furthermore, newer utilization management initiatives, such as clinical pathways, may be conceptually intriguing but require buy-in from providers with diverse practice patterns for the treatment of specific diseases.

Taking all of these factors into consideration, an appropriate approach should integrate effective components from the specialty pharmaceutical management interventions discussed above to improve the quality of care and to control costs associated with specialty drugs on behalf of payers. Significant specialty drug management expertise and access to benchmarking data serve as the foundation of such an approach.

A successful medical pharmacy management strategy should include a combination of interventions, such as formulary management and rebate contracting, clinical audits on targeted products through National Drug Codes and J-codes, and guiding more intensive professional intervention with severely ill patients via case managers within the plan.

Regardless of the specific approach, a medical pharmacy management strategy begins with integrated claims data, which are then leveraged to make precise and informed decisions regarding reimbursement, site of service, benefit design, and/or utilization management that can be executed internally or even carved out when necessary. As plans become increasingly sophisticated, they will strive to integrate traditional pharmacy with self-administered and provider-administered specialty therapies. This integration allows for a comprehensive approach that is tailored to the unique and specific needs of the evolving specialty market, which affords payers the ability to manage complex drug management scenarios, such as oral versus infused chemotherapy, and stepped-care programs for diseases such as RA across all benefits.

When developing a medical pharmacy management strategy, it is critical to note that the physician buy-and-bill strategy continues to be the most efficient method of minimizing waste and taking advantage of the lowest acquisition costs for drugs. As such, a well-thought-out
approach promotes the use of physician office administration as the most cost-effective site of care for oncology, rheumatology, and other patients receiving infused drugs.

Another component of a comprehensive and customizable approach includes the establishment of therapeutic interchange protocols when several drugs are available to treat a particular condition. Through these interventions, providers are informed and encouraged to initiate therapy with the least costly and highest-quality alternative therapy before moving on to other more costly treatments.

Results from such a specialty drug management program demonstrate that this comprehensive approach can reduce the total therapy cost for the patient, while maintaining or improving the overall quality of care. Specifically, payers integrating the program have saved an average of $17 million per 1 million covered lives. Approximately 33% of this savings stemmed from fraud and error prevention, another 33% resulted from utilization management, and the final 33% was realized through formulary and drug mix management.

This particular strategy promotes physician choice, while also ensuring that all individual care is within nationally accepted clinical guidelines as published by a variety of independent organizations. Web-based systems are often used for a majority of the drug authorizations and have been rated favorably for provider satisfaction and ease of use by physician offices, which benefit from minimized disruptions in workflow. Furthermore, this type of claims management and editing technology brings the same proven techniques utilized in pharmacy benefit management to the management of drugs billed under the medical benefit, which reduces overuse, overbilling, errors, and outright fraud.

Conclusions

Considering the complex and interrelated processes faced by plan sponsors in the specialty pharmaceutical domain, it has become apparent that simple, one-dimensional solutions will not adequately address the alarming rate at which costs are rising, while at the same time maintaining or improving quality of care. In fact, among the diverse array of management techniques used by plan sponsors for medical injectables, many have even been counterproductive in that they ultimately lead to further increase in overall costs and/or declining quality of care. At least part of the reason behind this suboptimal management to date is the fact that plan sponsors do not recognize all of the factors influencing the specialty drug trend, including unintended consequences, and/or they are ill-equipped for monitoring and characterizing the use of these products within their own member populations and provider networks.

To overcome these challenges, a comprehensive approach to specialty injectable management is warranted. Furthermore, before implementing initiatives that address preferred agents, reimbursement, distribution channel, benefit design, utilization, and claims data, a thorough assessment of unique plan characteristics in each of these categories is necessary. In the management of specialty pharmaceuticals, knowledge is truly power, and the level of data collection and assessment in this capacity will invariably determine the success of these interventions. After plan-specific needs have been defined, a unique management approach can be carefully constructed to combat inappropriate utilization and unmitigated spending on several fronts. Ultimately, the future of specialty management lies in the ability to integrate all drugs, paid under any benefit, and administered at any site of service.

Author Disclosure Statement

Mr Jacobs and Dr Johnson have reported no conflicts of interest.

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Managing Medical Benefit Drugs Under Specialty Pharmacy: The Next Critical Challenge for Managed Care

The tremendous increase in the cost of specialty pharmaceuticals is a significant concern for health plan pharmacy managers. As discussed in the article by Jacobs and Johnson, the reasons for this growth include new product approvals, price increases, increased utilization, and the overall share of the market that these products represent. Historically, health plans have been very effective at using utilization management tools for traditional, small-molecule pharmaceuticals, and pharmacy benefit managers have successfully assisted plans in this process. The use of prior authorizations, step edits, quantity limits, treatment guidelines, and benefit designs with increasing patient out-of-pocket (OOP) costs have effectively helped to manage drug spending and drug trends in many therapeutic categories. Traditionally, drugs covered under the medical benefit were not managed by pharmacy.

PHARMACY/MEDICAL DIRECTORS: The growth in specialty pharmacy drug spending over the past few years has been unprecedented; however, this growth has been masked by the significant launches of a number of blockbuster generic agents, including atorvastatin, clopidogrel, and losartan. An evaluation of the specialty drug distribution costs compared with the medical benefit drug buy-and-bill rates based on average sales price (ASP) usually favors the ASP pricing over the specialty pharmacy pricing. This supports maintaining the buy-and-bill methodology as the primary reimbursement approach for medical benefit drugs.

A new challenge is to effectively apply utilization management methods to the large-molecule specialty drugs that are managed under the medical benefit. The significant number of drugs in the pipeline, including more than 90 agents for orphan diseases, as reported by the Pharmaceutical Research and Manufacturers of America, as well as 900 drugs for cancer, will present unique challenges as plans try to manage this tidal wave of potential new agents. The promise of biosimilars is encouraging as a means for price relief for select drugs in the future. The recent US Food and Drug Administration guidance on the potential approval process for biosimilars provides manufacturers some idea on the requirements for submission and approval. The anticipated price discounts will not mirror the small molecules, where a decrease of 80% to 90% off the price of the reference drug is very common. I disagree with the current consensus that the discounts on biosimilars will be in the 10% to 20% range, because this will allow the innovator companies to simply contract to retain the existing business, and health plans could block the offering of biosimilars and avoid the challenge of driving utilization of biosimilars. Rather, I expect the discounts to be in the 30% to 50% range, to encourage plans to adopt and aggressively promote biosimilar agents.

Additional challenges faced by health plan pharmacy managers include the ability to effectively track utilization of medical and pharmacy claims and target appropriate interventions to control costs. Plans need to develop robust reporting capability to effectively monitor the impact of interventions and detect unintended consequences, including site of care shifts or product selection changes that promote increased profits or decreased costs to the physician practices, while increasing overall health plan drug costs.

Patient cost-sharing is another trend that will benefit the plan management strategies, by engaging the patient in the product selection discussion, when appropriate, with OOP costs that will vary by product, based on formulary tiers or on different coinsurance rates on a branded agent compared with a preferred agent, generic product, or an approved biosimilar.

The role of diagnostic tests, biomarkers, and personalized medicine holds promise for improved patient outcomes based on targeted treatment approaches. In addition, the opportunity for outcomes-based contracting increases with the ability to target patients and predict outcomes more accurately for specific therapies.

The successful plan managers must use a comprehensive approach to the management of medical injectables that will rely heavily on a strong information technology infrastructure for reporting and claims management, incorporation of diagnostics into treatment programs, maximizing existing and new utilization management tools, and encouraging manufacturers to engage in outcomes-based contracting on their products.

James T. Kenney, Jr, RPh, MBA
Pharmacy Operations Manager
Harvard Pilgrim Health Care