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Specialty Medications: Traditional And Novel Tools Can Address Rising Spending On These Costly Drugs

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ABSTRACT Spending on specialty medications, which represented a small proportion of US pharmacy spending at the beginning of this decade, is growing by more than 15 percent annually. It is expected to account for approximately half ($235 billion) of total annual pharmacy spending by 2018. Among the numerous reasons for the high cost of this heterogeneous group of medications are the increasing size of target patient populations, the high cost of drug development, and a complex and uncoordinated delivery system. In this article we describe the evolution of the specialty market, characterize the current state of specialty medication use, and articulate key challenges and potential solutions. Fully realizing the potential value of the expanding universe of specialty medications will require collaborative efforts to reduce waste and promote value. Those who prescribe, dispense, deliver, and pay for specialty medications will need to employ a combination of traditional and novel management approaches, such as prior authorization, step therapy, tiered formularies, administration at lower-cost sites, and the unique tools being developed for cancer medications.

The prescription drug landscape is changing rapidly. Until recently, the pharmaceutical market was dominated by relatively simple chemical entities—referred to in the trade as "small molecules"—that enjoyed patent protection for a certain number of years. During that time they were known as "branded" products. Once the intellectual property protection lapsed, competitor "generic" varieties of the same chemical entities entered the market and rapidly replaced the branded products.

During the past decade there has been a tremendous increase in the launches of generic drugs, as patent protection lapsed for a variety of branded pharmaceuticals that were first marketed in the 1980s and 1990s.[1] Generic introductions moderated the upward cost trajectory of pharmaceutical treatment. In 2013, 84 percent of all prescriptions filled in the United States were for generic medications.[2]

Now the so-called generic wave is beginning to slow. Overall spending on pharmaceuticals is increasing again, in large part because of the growth in number and unit cost of products known as specialty medications. The class of specialty medications originally consisted of drugs that had to be infused or that required other specialized administration and handling. Many of them were "large" molecules that mimicked substances naturally occurring in humans. They were also generally more expensive than traditional medications.

Today the use of drugs considered to be specialty medications is exploding. Spending on medications that received a specialty designation from CVS Caremark increased by 15.6 percent between 2012 and 2013. In comparison, spending on traditional medications grew by only 0.8 percent in the same period.[3] Spending on

specialty medications nationally is expected to continue to increase, rising by over 16 percent annually in the period 2015–18 and accounting for over 50 percent ($235 billion) of total drug spending by 2018.[4]

The growth in specialty medication spending is generated by both the increased use of specialty medications and much higher prices over time for each unit of medication. The extent to which increased use is clinically rational can be unclear, and higher unit prices are often justified by the higher costs of development compared to older small-molecule drugs and the overall smaller patient populations being treated.[5]

However, we argue that this spending growth is not a given. We believe that significant opportunities exist to bend the cost curve of specialty medications by eliminating waste, inducing price competition, and reducing or preventing costly complications. To achieve these goals, payers must be willing to embrace a variety of traditional and novel management strategies.

In this article we describe the evolution of the specialty medication market and characterize the current state of specialty medication use. We then articulate the key challenges, ongoing debates, and potential solutions surrounding the costs of these medications. We also discuss the manner in which physicians, payers, pharmacy benefit managers, and pharmaceutical manufacturers are tightening their focus on trends in this critically important but undeniably expensive area of medicine.

Specialty Medication Definition And Market Overview

There is no uniform definition of *specialty medications*. However, there is a consensus that all of them are high cost (Medicare Part D uses a $600 per month threshold for the "specialty" designation), are relatively difficult to administer, require special handling, or require ongoing clinical assessment—or have some combination of these four characteristics. All of the characteristics are routinely used to define *specialty medications*. However, one recent survey indicated that cost is the dominant factor, with 85 percent of respondents at health plans rating cost as very or extremely important in their decision to assign the specialty designation to a medication.[6]

The medications that have received that designation are a heterogeneous group. They include small molecules that are produced on an industrial basis, such as dimethyl fumarate (Tecfidera), which is used in the treatment of multiple sclerosis; manufactured human proteins, such as growth hormone; and exquisitely designed monoclonal antibodies (such as trastuzumab) that target cancer cells or help control an inappropriately stimulated immune system (for example, infliximab).

A review of drugs recently approved by the Food and Drug Administration (FDA) demonstrates the appeal of specialty medications to pharmaceutical manufacturers. New drugs can receive FDA approval under two different regulatory approaches: the new drug application that has been used for small molecules and the biologic license application for "biologics"—medications that are based on copies of existing large molecules in the human body.[7]

In 2013 the FDA approved twenty-seven new molecular entities (including both those that filed for approval with new drug applications and those that used biologic license applications). Fifteen of these entities were specialty medications, including breakthrough therapies for chronic lymphocytic leukemia, mantle cell lymphoma, and hepatitis C.[8,9] The current pipeline of products is similarly skewed toward specialty medications, with novel drugs being developed to treat rheumatoid arthritis, inflammatory bowel disease, hepatitis C, growth hormone deficiency, and multiple sclerosis.[10]

The high cost of these medications is a vexing issue for patients, prescribers, and payers. The average monthly cost to payers and patients for a specialty medication is $3,000—more than ten times greater than that for nonspecialty medications.[11] Exhibit 1 shows the monthly costs of common specialty medications.

Specialty medications are used by a small percentage of the population. However, their high prices and the frequent need for their long-term chronic administration mean that they account for a significant proportion of overall health care spending. In one population with commercial insurance, specialty medications accounted for almost 10 percent of overall health care expenditures.[12] These findings highlight the growing concentration of prescription drug costs in a small, chronically ill population.

Drivers Of Rising Specialty Medication Costs

Spending on specialty medications is increasing for a variety of reasons. Some of them are related to the medications' target populations, some to the increasing complexity and effectiveness of new medications, and some to the financial organization of their delivery (Exhibit 2). These factors act to generate both high launch prices and substantial escalation in the price of drugs already on the market: In 2013 the average wholesale price of existing specialty pharmaceuticals increased by over 10 percent.[3]

EXHIBIT 1

Approximate Monthly Cost Of Commonly Used Specialty Medications, 2014

Medication	Sample indication for medication use[a]	Monthly cost for sample indication[b]
Provenge (sipuleucel-T)	Metastatic prostate cancer	$105,800[c]
Solvaldi (sofosbuvir)	Hepatitis C	29,900
Olysio (simeprevir)	Hepatitis C	23,600
Rituxan (rituximab)	Non-Hodgkin's lymphoma	21,900[d]
Gleevec (imatinib)	Chronic myeloid leukemia	11,900
Avastin (bevacizumab)	Metastatic colorectal cancer	11,600[d]
Revlimid (lenalidomide)	Multiple myeloma	9,300
Neulasta (pegfilgrastim)	Neutropenia	5,700
Copaxone (glatiramer)	Multiple sclerosis	5,000
Tecfidera (dimethyl fumarate)	Multiple sclerosis	4,900
Humira (adalimumab)	Rheumatoid arthritis	4,000
Remicade (infliximab)	Rheumatoid arthritis	4,000[d]

SOURCE Authors' analysis of data from the following sources: (1) Fryar CD, Gu Q, Ogden CL. Anthropometric reference data for children and adults: United States, 2007–2010 [Internet]. Hyattsville (MD): National Center for Health Statistics; [cited 2014 Aug 19]. Vital Health Stat 11(252). 2012. Available from: http://www.cdc.gov/nchs/data/series/sr_11/sr11_252.pdf (for fiftieth percentile height and weight). (2) EMD Serono. EMD Serono specialty digest, 9th edition (Note 19 in text) (for average price paid by Medicare Part D and commercial plans as a function of average wholesale price). [a]The sample indications were selected from the manufacturers' indications for use when multiple on-label indications existed. When only one indication was present, that indication was listed. [b]The calculation of monthly treatment cost is based on the average wholesale price (from the MediSpan database as of April 2014) less 17 percent, which represents the approximate cost to commercial payers and Medicare Part D plans. For medications that require dosing based on weight or body surface area, the calculation is based on the fiftieth percentile for men ages twenty and older. All dosing information is taken from the product label—that is, the manufacturer-issued prescribing information for each medication. If a product label listed a range of acceptable doses, then the highest or most frequent dosing schedule was used for the calculation. The maintenance dose was used wherever there was a difference between the loading and maintenance doses. Clinical Drug Information LLC. MediSpan Master Drug Data Base v2.5. Indianapolis (IN): Clinical Drug Information LLC; 20 Sep 2008. (Note that this database is no longer available online in this form; the author accessed it 2014 Apr 30. Wolters Kluwer now owns the MediSpan databases.) [c]Cost for the entire treatment course. Provenge is delivered in three separate administrations over one month. [d]Infused medication. The cost shown is for the product alone and does not include the cost of drug administration.

POPULATION Perhaps the most fundamental driver of rising specialty medication spending is population based. The US population is in the midst of a well-chronicled demographic shift, with 10,000 Americans expected to turn sixty-five every day until 2030.[13]

The aging of the population underlies health care cost trends generally. However, it plays an especially important role in the costs of specialty medications, as more people age into diseases such as rheumatoid arthritis and various types of cancer. On average, older people use more specialty medications than younger people do. Thus, the aging of the population contributes significantly to the forecasted increase in specialty medication spending.[14]

SCIENTIFIC ADVANCES Advances in understanding the basic mechanisms of disease, combined with the ability to synthesize large proteins that interact with receptors on target cell membranes with exquisite specificity, have led to increases in the cost of development and production of specialty medications. In addition, previously untreatable conditions can be treated with new products such as genetically engineered human proteins (for example, growth hormone) or specific blood factors.

The biologic medications that have recently been brought to market and those that are still in the pipeline take a variety of forms. These include genetically engineered antibodies, such as rituximab; recombinant fusion proteins (protein-based medications created through the union of two separate genes), such as etanercept; and antibody-drug conjugates (medications that combine the targeting capability of monoclonal antibodies with the cytotoxic capability of antineoplastics), such as brentuximab vedotin.

There are also novel therapies that use patients' own immune cells. Sipuleucel-T, for example, is an FDA-approved treatment for metastatic prostate cancer that involves removing the patient's immune cells, exposing those cells (in vitro) to a protein that is commonly present on the exterior of prostate cancer cells, and linking the exposed cells to an immune stimulating substance before they are delivered back to the patient. After this modification, the cells are targeted (through exposure to the prostate cancer antigen) and stimulated so that they specifically and more selectively kill prostate cancer cells upon reintroduction. This process is both complex and costly, and it illustrates the increasing level of technology that drives a portion of the pricing for specialty medications.

TARGET POPULATIONS Another driver of increased spending on specialty medications is a change in their target populations. Until recently, specialty medications were generally for rare conditions, and thus they were used to treat relatively small patient populations. The cost of development for breakthroughs, therefore, had to be recouped through the treatment of a smaller pool of patients compared to that for traditional agents. This enabled manufacturers to charge high unit prices without significant pushback from payers.[15] This is no longer the case.

The recent introduction of sofosbuvir (Sovaldi), a hepatitis C medication, is illustrative. In contrast to the case with most specialty medications, the pool of patients for whom sofosbuvir may be appropriate is considerable: Over three million patients in the United States are estimated to be carriers of hepatitis C. The potential financial impact of the treatment—which costs $84,000 for sofosbuvir alone in the United States and which also involves the use of other medications and associated medical care—is extraordinary.

There are also several innovative drugs in de-

EXHIBIT 2

Reasons For The High Cost Of Specialty Medications

Reason	Challenge
Aging of the population	As the population ages, there are more patients eligible for specialty medications.
Complexity of development and production	Specialty medications are often derived from living cells that are cultured in a laboratory and can be more difficult to develop and produce than older small molecules.
Targeted population shifting	Specialty medications were used to treat rare diseases, but they are increasingly targeting more common conditions, which greatly expands the cost implications.
High launch prices	Launch prices often exceed internationally accepted cost-effectiveness ratios.
Price escalation once on the market	After launch, there tends to be significant and continuous price inflation.
Complex and uncoordinated insurance payments	Specialty medications can be covered by either the payer's medical benefit or pharmacy benefit, depending on patterns of administration. This creates challenges for payers in the development of coordinated approaches to managing costs across the population.
Legal considerations	Despite the the Affordable Care Act's establishment of a legal pathway for generic biologics (biosimilars), the Food and Drug Administration has yet to promulgate final regulations, and the pathway remains relatively unattractive to manufacturers.
Provider incentives	Many infused and injected drugs are bought and billed by providers under the medical benefit. In such cases, the reimbursement system typically rewards physicians for prescribing costly specialty medications.
Shifts in site of service	Hospitals' acquisition of specialty practices allows for the administration of drugs at higher-cost centers than freestanding physician offices.

SOURCE Authors' analysis.

velopment for the treatment of subpopulations of patients with common chronic diseases. The prices of these drugs may approximate those for existing specialty medications. One example is inhibitors of the enzyme proprotein convertase subtilisin/kexin type 9 (PCSK-9). These inhibitors are infused agents that are currently in Phase III clinical trials for the treatment of hypercholesterolemia.[16]

Concerns about the trajectory of specialty medication spending are amplified by the escalating product of high unit prices and the rising number of people who could be treated by new medications.

PAYMENTS AND CLAIMS Growth in spending on specialty medications is also driven by complicated payment and claims processing pathways that often involve multiple carriers. Unlike traditional small molecules, which are predominantly paid for through a health plan's pharmacy benefit (Part D in Medicare), many specialty medications are paid for through the medical benefit (Part B in Medicare).

Pharmacy benefit managers have developed a number of mechanisms for addressing the cost of medications that they reimburse, including prior authorization, formulary control, and step therapy. These have worked well for traditional medications, bringing the yearly growth in prescription drug spending below 2 percent for most of the past ten years. This is in comparison to an inflation-adjusted average annual growth in spending of over 10 percent between 1997 and 2003.[1] However, payers have been comparatively slow to adopt such approaches for specialty medications, especially those reimbursed through the medical benefit.[6]

BIOLOGICS Yet another reason for high spending on specialty medications is the strong intellectual property protection enjoyed by most biologics. The entry of generics into the market has been a significant factor in controlling prices of traditional drugs.[2] However, the legislation allowing for abbreviated approval of generics—the Drug Price Competition and Patent Term Restoration Act of 1984, generally known as the Hatch-Waxman Act—does not apply to biologics, which are the most costly subset of specialty pharmaceuticals.

The Biologics Price Competition and Innovation Act of 2009, enacted as part of the Affordable Care Act, directed the FDA to define the studies required for abbreviated approval of follow-on versions of biologic drugs, known as biosimilars. However, the FDA has not yet released final guidance documents, which has reduced manufacturers' desire to pursue the abbreviated pathways.[17] The FDA has received only one application for approval of a biosimilar (Sandoz's filgastrim) under the terms of the 2009 act. This has effectively created longer periods of exclusivity for innovators that generate higher cumulative earnings and further drive pharmaceutical development toward costly biologics.

PHYSICIAN REIMBURSEMENT The structure of reimbursement, particularly physician reimbursement, drives the use—and thus the overall cost—of specialty treatments. Many infused

and injected specialty medications are commonly administered in the office setting and are procured by physician practices according to the so-called buy-and-bill business model. In this model, physicians purchase the specialty medications from wholesalers, manage and maintain an inventory of the medications in their practice settings, administer them to patients, and bill insurance companies according to a fee schedule that builds in a margin for the providers beyond the separate fees billed for their professional services.

The profitability of the buy-and-bill model for providers has declined significantly during the past 10–15 years, driven in large part by reductions in reimbursement associated with the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. However, the economic incentive for physicians to administer more medications and select the highest cost option remains intact.[18] Profit margins associated with treating Medicare patients are typically quite limited. Nonetheless, the practice remains very profitable for the treatment of commercially insured patients.[19]

Controlling The Costs Of Specialty Medications

We find that payers have hesitated to aggressively manage spending on specialty medications because of the impression that the products are vital to patients' health. The experience with lysosomal storage disorders, such as Gaucher's disease or Fabry disease, serves as a paradigmatic example. Patients who have one of this group of rare diseases lack a functioning enzyme without which life is significantly impaired or impossible. The biologic medications used to treat such disorders replace the enzyme that the patient's body cannot produce, permitting a near-normal quality of life.

In these situations, as well as in others that might not be quite as high stakes, well-organized patient advocacy groups appropriately ensure that others hear their message that receiving the medications is a matter of life or death. And payers have chosen to accept the usually high spending required for them.

That approach to determining payer coverage for specialty medications is changing. As mentioned above, these medications now include agents for more common and less life-threatening conditions, and the growth in costs in this segment of health care can no longer be ignored. However, it is challenging to simply apply traditional utilization management techniques to specialty medications. In this context, payers and pharmacy benefit managers have started to experiment with both adjustments to existing programs and novel strategies.[20]

In 2013 the average wholesale price of existing specialty pharmaceuticals increased by over 10 percent.

TRADITIONAL SOLUTIONS

▶PRIOR AUTHORIZATION AND STEP THERAPY: The most straightforward traditional utilization management approach is to employ prior authorization to ensure that medications are being prescribed according to accepted practice guidelines and FDA drug labeling. Under this approach, physicians must obtain prior approval for use of the medication from the insurer or pharmacy benefit manager in order for payment to occur.

In many clinical settings, guidelines do not favor the use of specialty medications, particularly as first-line therapies. In these circumstances, policies requiring an adequate trial of a cheaper therapy (known as "step therapy") before initiating use of the specialty medication are clinically advisable and typically generate significant savings.[21,22]

For example, in the treatment of rheumatoid arthritis, a trial whose results were published in the *New England Journal of Medicine* in 2013 compared the efficacy of a combination of three generically available, oral disease-modifying antirheumatic drugs with that of a combination of an injected biologic drug (etanercept) and oral methotrexate in patients who had previously failed with methotrexate alone.[23] The authors found the regimen of three generic drugs to be no less effective than the combination of the biologic and oral methotrexate and suggested that the generic regimen be tried before use of a specialty medication was initiated. These findings endorse the use of step therapy to promote the prescribing of generics as first-line treatment for rheumatoid arthritis before resorting to much higher-price injectable specialty medications such as etanercept (Enbrel) and adalimumab (Humira) or infusions such as infliximab (Remicade).

Ensuring appropriate use based on guidelines

Cost control in oncology presents many unique challenges beyond the nature of the diagnoses.

and drug labeling through prior authorization is the first traditional approach that should be tried to reduce spending on specialty medications.

▶**TIERED FORMULARIES:** Another traditional approach that could be applied to specialty medications is the use of tiered formularies that require higher patient cost sharing for more expensive therapies. Multiple diseases (including rheumatoid arthritis, multiple sclerosis, pulmonary arterial hypertension, and certain cancers) can be treated with a variety of medications, some of them inexpensive generic medications and some expensive specialty medications. In these diseases, tiering drugs can both shift the mix of products toward cheaper generic options and reduce the unit price of branded drugs by encouraging manufacturers to offer discounts or rebates in exchange for a preferred formulary position that would impose a lower copayment.

However, traditional tiered formularies are becoming less effective in the face of manufacturers' copayment or coupon programs, which continue to proliferate.[24] Such programs essentially pay the share of the medication's cost for which the patient is responsible, at least for some period of time, which overcomes the copay's incentive to preferentially use cheaper products. One analysis showed that 62 percent of the coupons associated with these programs were introduced by manufacturers when a lower-cost therapeutic alternative was available, which is precisely the situation in which a tiered formulary is customarily employed.[25]

The financial return from prescriptions that are subsequently filled more than equals the manufacturer's cost in subsidizing copays at least long enough to get a patient started on therapy. Thus, for specialty formulary approaches to be successful, coverage of nonpreferred products must be denied altogether.

We should note that previous research has suggested that higher cost sharing for specialty medications will result not in decreased use but in higher costs for consumers.[26] This is true in isolation. However, most economic drivers in formulary management move patients from one agent to a therapeutically equivalent alternative.[27]

▶**LOWEST-COST SITE OF CARE:** Another approach to cost control for specialty medications is to encourage the administration of the medications at the lowest-cost site of care. As discussed above, injected and infused medications used by commercially insured patients can be dispensed by specialty pharmacies (through the pharmacy benefit) or can be acquired by providers and administered by clinical staff (through the medical benefit under a buy-and-bill system).

The fees paid to providers using the buy-and-bill method vary significantly by the site of care. In most instances, the highest-cost site of drug administration is the hospital outpatient center.[28] In one study, drugs administered at this site were found to cost over 50 percent more than the same products administered in physicians' offices or patients' homes, when costs associated with the administration and the evaluation of the patient were considered.[12]

This discrepancy has led many payers and pharmacy benefit managers to develop programs that limit the use of hospital outpatient centers for infusions. However, hospitals' acquisition of specialist physician practices[29] has made it difficult for payers to transition patients to community providers. This has forced insurers and pharmacy benefit managers to focus on patient self-injection and nurse-assisted home infusion for a limited spectrum of clinically appropriate agents.

ONCOLOGY TREATMENT, A SPECIAL CASE A final set of tools for reducing specialty medication costs focuses on the subset of medications that are used to treat cancer. Spending on cancer medications in the United States is second only to spending on products that are designed to prevent or treat cardiovascular disease.[30] The robust pipeline of cancer agents, rapid increase in the use of expensive chemotherapy, and high launch prices make it critical to manage the use of oncology drugs.[31]

The fact that restricting care for cancer patients is politically sensitive has historically caused payers to tread lightly in this area. However, in the face of extreme spending growth, payers and pharmacy benefit managers have become increasingly willing to implement aggressive management tools. Yet cost control in oncology presents many unique challenges beyond the nature of the diagnoses.

Almost 80 percent of all cancer therapies, and an even greater percentage of the most costly

drugs, are bought and billed by physicians.[12] Drug margin accounts for over 60 percent of oncologists' revenue,[32] and a wide range of prices creates particularly perverse incentives in a "cost plus" reimbursement system.[33] Consider the example of metastatic non-small-cell lung cancer, the cost of clinically equivalent therapy for which—and, hence, providers' profit—differs by a factor of thirty ($200 per month for Paclitaxel and carboplatin or another platinum-based drug versus $6,000 per month for Pemetrexed and a platinum-based drug).[34]

This dynamic has led many payers to experiment with adjustments to provider incentives. Such changes have taken many forms, including alternative fee schedules that increase payments for generics,[35] oncology medical homes with augmented care management fees,[36] shared savings based on fee-for-service benchmarks,[37] and bundled payments tied to the profit margin of a predetermined regimen.[38,39] In some cases, the results have been quite promising. However, savings from reduced use of chemotherapy have proved elusive.

For example, the Michigan Oncology Medical Home Demonstration Project replaced a payment methodology based on average sales price (ASP) with reimbursement based on medication acquisition cost plus a global care management fee.[36] The project demonstrated savings from reduced hospitalizations and emergency department visits. Thus far, it has not reported on changes in drug spending.

Similarly, UnitedHealthcare implemented a pilot program that eliminated providers' ability to profit on each drug, providing instead an upfront lump-sum payment for each episode of care plus drug reimbursement that approximated providers' acquisition costs. The program generated significant overall savings through reductions in chemotherapy-related complications. Remarkably, however, drug spending increased under the new payment system.[39]

One additional cost control mechanism that has received attention—though there has been limited uptake of it—is the use of oncology pathways programs. The precise model differs according to the vendor that designed and sells the program. However, most models combine a physician decision support tool that outlines acceptable drug regimens for each disease state with some financial incentive to prescribe cheaper agents. Preliminary evidence suggests that use of the pathways minimizes treatment variation and may even reduce costly complications.[40]

Nonetheless, payers approach cancer cost containment gingerly. One reason is the complexity of the disease. Poor performance status, past history of chemotherapy, or a specific genetic marker may render a patient eligible for a more expensive therapy. Moreover, in oncology, treatment selection depends heavily on patients' preferences and requires trade-offs between efficacy and various toxicities. Policies that mandate or merely encourage the use of a particular drug when there is an alternative with a different toxicity profile can be criticized for reducing patients' autonomy.

Patients across the spectrum of disease severity are receiving specialty medications.

Payers and pharmacy benefit managers have limited ability to affect the use and price of infused drugs for fee-for-service Medicare beneficiaries. However, they are well equipped to affect spending for the commercially insured and Medicare Advantage populations. Fundamentally, all of the cost management techniques discussed above—many of which were first used by pharmacy benefit managers in claims adjudicated through the pharmacy benefit—are equally applicable to claims adjudicated through the medical benefit. This is especially important in cancer, since infused chemotherapies make up the bulk of spending on cancer drugs.[12]

Some policy makers might contend that Medicare regulations make cost management more difficult, especially in oncology.[41] Under Medicare Part D regulations, there are six "protected classes" of drugs: anticonvulsants, antidepressants, antipsychotics, antiretrovirals, antineoplastics (cancer drugs), and immunosuppressants used to treat organ rejection.[42] All drugs in a protected class must be covered by the Medicare Part D plan, and many states have similar requirements for commercially insured patients.[41]

However, other forms of utilization management noted above can apply, as long as they are reviewed by a pharmacy and therapeutics committee that remains insulated from cost considerations. Nearly all pharmacy benefit managers rely on such committees for approval of all utilization management. Thus, short of excluding a drug, there are a wide range of management techniques available. Medicare policies often influence the commercial sector, but private payers are not bound to accept the Medicare framework

and will continue to seek innovative ways to contain costs.

Conclusion

Specialty medications address the needs of an increasingly broad range of patients across several therapeutic areas, including infectious diseases, inflammatory diseases, and cancer. There is no single consensus definition for *specialty medications*. Nonetheless, it is clear that the paradigm has shifted: These medications are no longer only for patients with life-threatening conditions. Patients across the spectrum of disease severity are receiving specialty medications.

As medicine continues its inexorable march toward greater complexity and specificity, the introduction of novel therapies for previously untreatable conditions becomes more commonplace. This offers new hope to patients, but it simultaneously drives costs to higher, and perhaps less sustainable, levels.

Ultimately, there is no one "magic bullet" that can slow the rising costs of specialty medications. But progress is possible, and in fact it is already under way. The introduction of meaningful specialty generics and the subsequent introduction of the first biosimilars during the remainder of the 2010s should provide new opportunities for the application of traditional pharmacy tools such as tiered formularies and step therapy. Patient advocacy groups, ethicists,[21] manufacturers, and providers may question some of these efforts. Nonetheless, their inevitability is increasingly recognized by many of these same stakeholders.

Several forces are converging to reshape the payment landscape, and they will also influence the future of specialty medications. With the passage of the Affordable Care Act, momentum is growing for widespread payment reform that rewards providers for improved outcomes and greater efficiency, instead of for the volume of services delivered. In this setting, profit centers in fee-for-service arrangements become cost centers for risk-bearing entities, which forces providers to think beyond effectiveness and to consider value when selecting therapies.

As payment reform takes hold, providers should play a more central role in the management of specialty medication cost growth, and they will need to partner with payers to develop sophisticated systems to promote value. Providers' responses may vary according to the impact of cost management tools on their reimbursement, but payers will march forward because the costs are too prominent to be ignored.

Successful management efforts will use a variety of tools and require the collaboration of those who prescribe, dispense, deliver, pay for, and receive specialty medications. Only with such a multifaceted and holistic approach can the potential value available from the expanding universe of specialty medications be fully realized. ■

The authors are employees of CVS Caremark, a company that sells specialty medications.

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