Dollars and Sense:
Putting Specialty Drug Costs in Perspective

Key Takeaways

- While specialty drugs constitute less than 1 percent of all U.S. prescriptions, they accounted for more than a quarter of the country's total pharmacy costs in 2013.
- Analysts caution the specialty drug marketplace is about to explode with much higher increases in coming years, as more high-cost specialty drugs enter the market.
- Health plans and policymakers must find ways to support development of and access to life-saving specialty drugs without jeopardizing the solvency of public insurance programs or driving private insurance premiums to unsustainable levels.

Specialty drugs — new, powerful and costly — are poised to drive up national drug spending at an alarming rate, even as spending on more conventional drugs decreases. Although this new category of drug lacks a formal definition, specialty drugs typically treat complex conditions, require special handling and administration and are extremely expensive to produce.

The combination of their clinical power and high cost has made the use of specialty drugs a critical challenge for health plans, including members of the Alliance of Community Health Plans (ACHP). ACHP and its 23 member plans are leaders at working together to address shared challenges and collaborate on solutions that enhance both quality of care and affordability.

While specialty drugs constitute less than 1 percent of all U.S. prescriptions, they accounted for more than a quarter of the country's total pharmacy costs in 2013.[1] The development and availability of these new medications presents a vexing dilemma for payers, providers and patients alike: how to reap the benefits of these potent drugs while managing their significant cost.

Case in point: Sovaldi, a Hepatitis C drug introduced in December 2013, dramatically improves treatment options for the estimated 3.2 million Americans affected.[2] Sovaldi appears to eliminate the virus in more than 90 percent of patients, with few side effects,[3] reducing the need for more costly interventions, such as a liver transplant.

But the drug has generated more attention for its cost than for its cure rates: It comes with a $1,000-per-pill price tag.[4] A 12-week course of treatment costs $84,000; patients who require longer treatment or a combination of drugs can rack up $150,000 in pharmacy bills alone.[5] And there is no skimping: To reap the drug's benefits, patients must strictly adhere to the full treatment regimen. Sales of Sovaldi reached $3.5 billion in the second quarter of 2014, and the drug is expected to exceed $10 billion in sales this year.[6]

Sovaldi is not an isolated outlier. Of the 12 anti-cancer drugs approved by the Food and Drug Administration (FDA) in 2012, nine were priced at more than $10,000 per month. And only three of the nine prolonged survival, two by under two months.[7] Yervoy, approved in 2011 to treat advanced-stage melanoma, costs $120,000 for the usual course of treatment. Treatment with newly approved cancer drugs Keytruda and Opdivo is estimated to cost $150,000 and $143,000 a year, respectively.[8,9]

Described by one expert as "a bonanza [year] of drug breakthroughs," 2013 saw the FDA approval of 36 new "molecular entities."[10] Specialty drugs comprised 60 percent of all new drug approvals in 2013, and dominate the current approval pipeline.[11]

With new and anticipated FDA approvals (and a new fast-track approval process for "breakthrough therapies" — defined as those drugs that are "intended alone or in combination with one or more other drugs to treat a serious or life-threatening disease or condition and [for which] preliminary clinical evidence

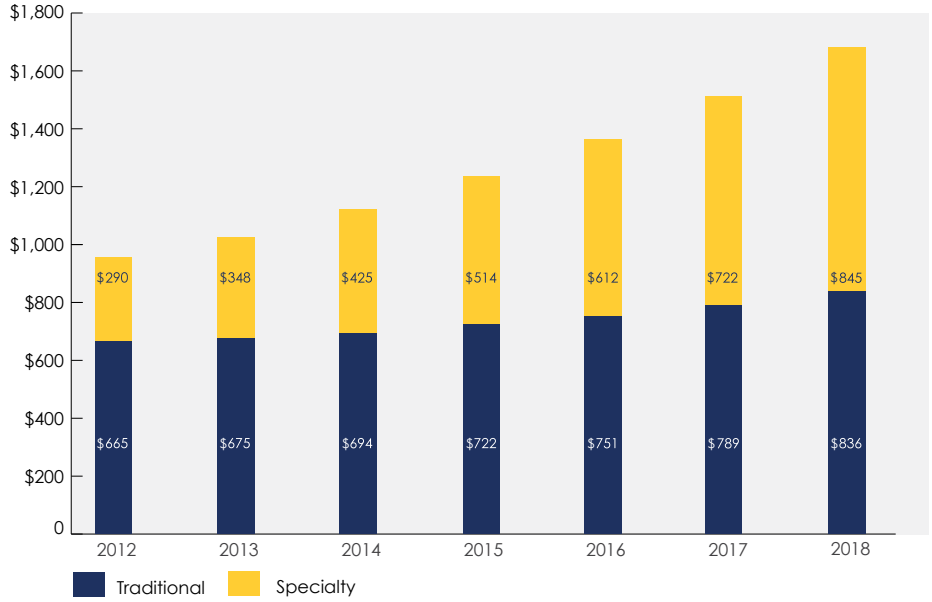
ACHP
ALLIANCE OF COMMUNITY HEALTH PLANS

The Alliance of Community Health Plans (ACHP) *is a national leadership organization bringing together innovative health plans and provider groups that are among America's best at delivering affordable, high-quality coverage and care. ACHP's member health plans provide coverage and care for more than 18 million Americans. These 23 organizations focus on improving the health of the communities they serve and are on the leading edge of innovations in affordability and quality of care, including primary care redesign, payment reforms, accountable health care delivery and use of information technology.*

Specialty Drugs…

- ***Treat complex patient conditions*** and ongoing chronic conditions like multiple sclerosis, diabetes, cancer and rheumatoid arthritis, and often require careful monitoring and oversight.
- ***Require special storage and handling and/or administration,*** and often can be administered only by a clinician.
- ***Are expensive to develop and manufacture.*** Many are biologics, drugs made from live organisms, rather than from the chemical compounds that comprise most conventional drugs. This makes specialty drugs expensive to manufacture and difficult to replicate.

Figure 1. Projected Drug Spending for Commercial Plan Sponsors



Source: Specialty Drug Trend Across Pharmacy and Medical Benefit
http://www.artemetrx.com/wp-content/uploads/2014/08/artemetrx-specialty-drug-trends.pdf

indicates [they] may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development"[12]); more screening of patients and better diagnostic tools; increased access to care through the Affordable Care Act; improved outcomes that significantly prolong the lives of patients with chronic conditions; and an aging population,[13] spending on specialty drugs is expected to increase 67 percent between 2013 and the end of 2015.[14] (Figure 1)

Until recently, specialty drugs were used by a relatively small portion of the population, and their cost was generally not included in total prescription drug spending. Rather, the costs associated with specialty drugs were reflected in other categories of spending (such as physician and hospital care) because they often required physician administration[15] and were covered as a medical benefit.

Medicare, for example, has typically covered most specialty drugs under Part B (medical coverage). Generally speaking, Part B drugs must be administered under a physician's supervision and Part D drugs are self-administered. But with the development of more specialty drugs that can be taken orally, the costs are shifting to the Part D prescription drug benefit. Self-administered drugs are more likely to be covered under a health plan's pharmacy benefit.[16] Oral drugs are not the only type that patients can take without a doctor's help; a few drugs can also be self-administered using specially-prepared injections.

WHY ARE SPECIALTY DRUGS SO EXPENSIVE?

The high and growing rate of spending on specialty drugs is due to a combination of factors.

First, specialty drugs are usually complex in structure, making them expensive to develop and manufacture, and brand-name biologics enjoy a 12-year period of exclusivity,[17] longer than the patents that protect most conventional drugs once they come to market. As a result, many specialty drugs are unique in their therapeutic class, with little or no competition to constrain price increases. Only a few generic versions of the very simplest biologics exist. Called "biosimilars," these drugs are not identical in composition to their brand name match, as generics are for conventional drugs; the complex nature of biologics makes this nearly impossible.[18] The FDA is still defining an approval process for biosimilars, which makes their development in the near future even less likely.

Second, when use of a specialty drug expands beyond its initial target population, total utilization increases, and often so does the

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unit cost. Here is just one example of the expanding use of a specialty drug: Remicade first won FDA approval in August 1998 to treat Crohn's disease. Today it is also used to treat rheumatoid arthritis, psoriasis, ankylosing spondylitis, psoriatic arthritis and ulcerative colitis.[19] Remicade was in the top 5 highest-expenditure Medicare Part D drugs in 2010, with $900 million in expenditures.[20] Specialty drugs such as Remicade that treat inflammatory conditions are the costliest specialty therapy class, and experienced brand price inflation of 15 percent in 2013.[21] Use of this class of specialty drugs is predicted to increase more than 20 percent annually in 2014, 2015 and 2016.[22]

DRUG SPENDING TRENDS: THE CALM BEFORE THE STORM

It is tempting not to worry too much about the cost of prescription drugs, since in recent years this category has accounted for a declining portion of national health spending. In 2012 (the last year for which data are available), prescription drugs accounted for about 9.4 percent ($263 billion) of total national health spending (about $2.8 trillion), down from 9.7 percent in 2011,[23] marking the third year of decline.

Between 2009 and 2012, the (weighted) average annual price increase of prescription medications was just 2.7 percent. This small average increase was due in part to the expiration of patents for a number of commonly used brand name drugs, including Lipitor and Plavix, which opened the door to less-costly generic alternatives. In addition, fewer new branded drugs came to market in recent years, and the weak economy kept some patients from seeing doctors and filling prescriptions.

As a result, overall drug spending increased a modest 5.4 percent in 2013; specialty drug spending increased 14 percent.[24] And while this was the lowest increase in specialty drug spending since 2007, analysts caution the specialty drug marketplace is about to explode with much higher increases in the coming years, as more high-cost specialty drugs enter the market. In addition, with fewer branded drugs slated to come off patent, the favorable trend in total drug spending is not expected to last.[25]

MEDICARE: PREPARING FOR THE BABY BOOMERS

Medicare drug spending follows national patterns: Expenditures fall significantly as popular drugs lose patent protection and rise as new high-cost specialty drugs, especially biologics, enter the market at a rapid pace. Between 2009 and 2012, overall Medicare spending grew about 3.4 percent annually, while its annual drug expenditures rose 6.1 percent. Since 2009, Part B drug spending has grown 7.4 percent annually, and Part D has grown 5.8 percent. In 2012, combined Medicare spending for all drugs in Parts B and D totaled $103 billion ($13.2 for Part B and $89.8 for Part D).[26]

Medicare beneficiaries are more likely to use specialty drugs than younger populations. Recent data show that spending on specialty drugs for Medicare beneficiaries is twice that in the commercial population; other analysis found similar patterns.[27] Specialty drugs accounted for 11 percent of Part D drug spending in 2013, up from 8.5 percent in 2011.[28] In fact, spending on specialty drugs used to treat three conditions — cancer, multiple sclerosis and rheumatoid arthritis — contributed $6.9 billion, or 68 percent, of the total growth in drug spending in 2013.[29]

Sovaldi is expected to have a significant effect on Part D costs. Although it is unknown how many infected Medicare beneficiaries will receive the new treatment for Hepatitis C, we do know that approximately 270,000 people with the Hepatitis C virus were enrolled in Medicare Part D in 2013.[30] A recent report by actuarial firm Milliman for the Pharmaceutical Care Management Association postulated that if 50 percent of Hepatitis C virus-infected Medicare Part D beneficiaries were eventually treated with the $84,000 course of treatment for Sovaldi, this would add approximately $11 billion to Part D; CMS projects that total costs for Part D will be $75 billion in 2015.[31]

In addition, the baby boomer generation is just beginning to place increasing pressure on the program. The epidemic of Hepatitis C is concentrated in this generation, with the peak infection rate occurring in those born in the 1950s. The bulk of this infected population will age into Medicare eligibility during the next 10 years.[32]

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CHALLENGES TO HEALTH PLANS AND POLICYMAKERS

Sovaldi and other specialty drugs already available or coming to market soon represent an extraordinary lifeline for patients in need, especially those who will get a second chance at life thanks to these breakthrough pharmaceuticals. It is hard to put a price on that.

But of course there is a price, and often a high one.

Typically, health plans and other payers employ a variety of tools to manage prescription drug spending, including evidence-based coverage and formulary design, member cost-sharing and utilization controls. Some payers are able to negotiate with drug manufacturers to obtain rebates or other discounts. But the power of these tools is considerably weakened when important specialty medications have few or no therapeutic competitors.

As state Medicaid directors consider ways to manage pricey Hepatitis C drugs like Sovaldi, some have limited coverage exclusively to those with advanced liver disease. A Department of Veterans Affairs panel has also recommended this policy.[33] Treating even two-thirds of the estimated 3.2 million Americans with the virus could reach $200 billion.[34]

Some of these high costs may be offset by corresponding savings as individuals return to better health and require fewer health care services. In the case of Hepatitis C, the rate of new infections is declining (most people were infected before 1992, when a test to screen donated blood was widely implemented).

But there is no doubt that the introduction of powerful, game-changing new medications and their unprecedented high costs will continue to pose challenges to health plans and policymakers: How can they support development of and access to life-saving specialty drugs without jeopardizing the solvency of public insurance programs or driving private insurance premiums to unsustainable levels? ACHP member health plans look forward to collaborating with policymakers to address this challenge.

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