taking aim at trend
Gross Trend

2013
3.8%

2014
12.7%

Gross Trend
As predicted, prescription spending accelerated rapidly in 2014, driving our book-of-business gross trend to double digits—to 12.7 percent from 3.8 percent in 2013.*

Growth was largely driven by brand price increases and the ongoing increase in utilization of specialty pharmacy—the same forces that have driven trend for the last several years. In addition, plans faced substantial increases related to the new hepatitis C therapies and compounded pharmaceuticals. By our analysis, these two forces alone contributed 5.4 percent to book-of-business trend in 2014.

In this dynamic environment, we believe reviewing and understanding the forces that drive trend is instructive. Such understanding grounds the proactive strategies that can be used to target emerging trend drivers. That’s why we’re taking a closer look at the choices made by high-performing clients. Our “trendsetter” clients are early adopters of advanced management strategies. As you’ll see in this issue of Insights, that approach paid off in 2014.

*Unless otherwise noted, data citations refer to internal analysis of CVS Health book-of-business data. See page 14 for methodology.
As shown in Figure 1, price increases for brand drugs contributed more substantially to gross trend than any other factor. Price increases for non-specialty and specialty brands contributed a combined 10.7 percent—more than 80 percent of our total trend, even though brands comprised less than 20 percent of drugs dispensed to plan members in 2014. Non-specialty brand inflation reached 14.4 percent; specialty brands, 9.8 percent. It has been observed that drug manufacturers often respond to market challenges such as pending patent expirations and the increased availability of generics with price increases and strategies to retain market share. These price increases contributed to the rapid rise in drug trend.

In calculating trend, we review publicly available average wholesale prices (AWPs) and evaluate price increases on a consistent market basket of drugs. Because the metric reflects year-over-year change, newly launched drugs such as hepatitis C therapies Sovaldi and Harvoni are excluded.

Generic price increases received a great deal of media attention, but their effect on prescription drug trend was minimal compared to brand increases—just 1 percent, as shown in Figure 1. This is because prices for the generics members use most were relatively stable. In our analysis, the top 20 generics by utilization had...
0.0 percent increase in 2014, and these drugs were used at nearly 50 times the rate of the 20 generics with the highest AWP increases.

The effect of generic price increases was more than offset by the trend-moderating effect of mix—essentially the proportion of brand and generic drugs being dispensed—which decreased trend by 5.9 percent. With fewer new generics in 2014, the increase in generic dispensing rate (GDR) was modest compared to the recent past, finishing the year at 81.9 percent. The key point? Generics overall continue to be a moderating influence on trend.

Specialty pharmaceuticals accounted for nearly half of our gross trend. Non-specialty trend was 6.8 percent in 2014. Reflecting spend under the pharmacy benefit, our book-of-business specialty trend was 32.4 percent, nearly half of which—14.5 percent—can be attributed to the surge in prescribing for the new hepatitis C therapies. As shown in Figure 1, these therapies contributed 3.4 percent to our book-of-business trend. Without hepatitis C therapies, specialty trend was 17.9 percent.

In addition to the price increases cited above, specialty trend reflects increasing utilization. Specialty utilization growth is nearly four times that of non-specialty utilization growth—5.7 percent compared to 1.5 percent. In our book of business, the number of specialty prescriptions per million members per month has increased 22 percent over the last four years. Over the same time period, 88 new specialty drugs entered the market, and the U.S. Food and Drug Administration (FDA) approved 110 new indications for existing products. Both factors drive greater utilization, as does the aging of the population.

Compounds are medications that are customized for specific individuals and dispensed by a physician or a compounding pharmacist. Many compound claims are for topical medications; they are often used for hormone replacement or to treat pain and cosmetic scars. Their use has expanded rapidly over the past few years; compound spending doubled for some plans between 2013 and 2014.

CVS/caremark™ claims data shows that a compounded topical pain medication made with bulk powders (e.g., morphine, gabapentin and ketamine) can cost thousands of dollars per prescription. In our book of business, compounds contributed 2 percent to gross trend.

Reflecting spend under the pharmacy benefit, our book-of-business specialty trend was 32.4 percent, nearly half of which—14.5 percent—can be attributed to the surge in prescribing for the new hepatitis C therapies.
Trend management in this dynamic environment requires a proactive strategy that takes into account the various factors that affect drug spend: current top drug drivers but also pipeline agents and the opportunities and challenges they represent; emerging patterns of prescribing and utilization; manufacturer price increases and promotional efforts; and regulatory actions and FDA activity.

The essential building blocks of a trend management strategy—formulary, clinical programs, and network and utilization management—are constants, but a wide range in how they’re applied exists. We’ve identified high-performing clients—our trendsetters—and the CVS/caremark solutions they used to get ahead of trend in 2014. We share the results they achieved in the following pages.

As part of CVS Health, CVS/caremark offers clients an unmatched range of management solutions, most of which can be implemented throughout the plan year so that clients can respond effectively to emerging trends. Moreover, with our multiple touchpoints and consumer expertise, we’ve developed and incorporated engagement strategies to facilitate transitions for members. Such strategies include personalized, proactive communication to affected members and prescribers. We make a point of providing sufficient lead time for members and prescribers to change or transfer a prescription and help avoid gaps in therapy.

3 keys to trendsetter management

1. Leverage competition and network strategies to manage price increases. Trendsetters take maximum advantage of our formulary strategies, generic opportunities and rebates.

2. Manage utilization rigorously to drive use of generics and preferred products.

3. Support members to make easier transitions to more cost-effective drugs and networks. Also, help them stay adherent so they achieve the desired health outcomes.
Managing price increases with formulary

We’ve led the industry with our formulary strategies that incorporate selective drug coverage, tiering and utilization management to drive cost-effective solutions while providing clinically appropriate alternatives for members. Most drug classes have multiple generic and low-cost brand options that cover the same indications and are as safe and effective as more costly brand options in the same class.

Many brand drugs, including new launches, do not provide material clinical and/or financial advantages when compared to available drug options within the same therapeutic class. We have specified that new-to-market products would not automatically be added to the formulary. Similarly, line extensions are not automatically added. This approach allows us the time for a thorough review to determine formulary status of a new drug. If a new product offers a clear clinical or financial advantage, review will be expedited.

**Trend result based on reductions in unit cost holding utilization constant. For most plans, moving to a 90-day design improves medication adherence which helps reduce total health care trend.**

Managing price increases with network strategies

Managed network options can help plans reduce prescription trend while still offering members excellent access. In today’s marketplace, cost-conscious members are receptive to narrower network options that offer fewer choices of where to fill their prescriptions but deliver lower costs for every fill.

Approximately one-third of our new clients adopt some version of a narrow network. We build our networks with a focus on providing access, choice and convenience—to maintain member satisfaction—along with competitive pricing to help reduce total costs.

**Trend result based on reductions in unit cost holding utilization constant. For most plans, moving to a 90-day design improves medication adherence which helps reduce total health care trend.**

*Mail pricing at CVS retail for ERISA governed plans. The Maintenance Choice program is available to self-funded employer clients that are subject to ERISA. Non-ERISA plans such as insured health plans, plans for city, state or government employees, and church plans need CVS/caremark Legal’s approval prior to offering the Maintenance Choice program. Prices may vary between mail service and CVS/pharmacy due to dispensing factors, such as applicable local or use taxes.

**Trend result based on reductions in unit cost holding utilization constant. For most plans, moving to a 90-day design improves medication adherence which helps reduce total health care trend.**
Managing specialty pharmacy

With rapidly increasing utilization, an ever-expanding list of high-priced therapies, and limited generic competition, specialty pharmacy presents the full range of prescription spend management challenges. Adding to these challenges is the complexity of the specialty patient. Only a small percentage of members use specialty medications, but they account for approximately one-fourth of total health care spend. Only about one-third of that spend is for the specialty drugs themselves. In fact, the average specialty patient often has several comorbid conditions being treated simultaneously with the specialty condition.

The three trendsetter solutions presented here, encompassing formulary, network and utilization management, address all these challenges. Underlying principles for these solutions include:

**Condition-level management:** Specialty conditions generally follow a predictable progression over time. We evaluate prescribed medications in the context of the patient’s disease state rather than as an individual event. This approach enables a broader drug selection and creates more opportunities to manage trend. Our goal is a cost-effective, clinically appropriate sequence through therapy for every patient.

**Broader approach to clinical care:** Members using our specialty pharmacy have the support of our CareTeams that include specialty pharmacists who have expertise and experience with the specific condition being addressed. In addition, we have specially trained nurses who are equipped to address a patient’s concerns beyond the specialty medication, including common comorbidities. Their availability can significantly increase member engagement and help reduce the number of hospitalizations and emergency room visits, reducing total health care costs.

**Breakthrough specialty patient experience:** Through Specialty Connect™, specialty pharmacy patients have seamless access to their specialty prescription(s) at most of our 7,800 CVS/pharmacy locations or e-prescribing to any CVS Health pharmacy.* Once the prescription comes in, the patient is advised that our CareTeam will be calling them, generally within hours.

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**Trendsetter solution**

**Advanced specialty formulary**
Includes specialty generics and clinically effective brands. New-to-market exclusions.

**Exclusive specialty pharmacy with retail pick-up option**
Requires the use of CVS/specialty™ pharmacy for specialty medications. Provides access to CareTeam, including a pharmacist 24/7, embedded care management nurse and online support. Convenient delivery or pick-up at most CVS/pharmacy locations.

**Specialty guideline management**
Reviews specialty prescription use for safety, cost effectiveness and appropriate utilization. Available for more than 50 therapy classes. Includes evaluations of outcomes and progress of therapy.

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**Trendsetter result**

**23.9%**
Gross specialty trend

**13.2%**
Without hepatitis C therapies

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*In-store pick up currently is not available in Arkansas, Oklahoma and West Virginia. Some states require first fill prescriptions to be transmitted directly to the dispensing specialty pharmacy. Other restrictions may apply.
Targeting spend on hepatitis C therapies

The hepatitis C therapies introduced since late 2013 had an unprecedented market impact. They changed the standards of treatment, transformed prescribing patterns and made existing therapies obsolete.

The 2014 trend impact of these therapies was primarily related to a surge of prescribing for Sovaldi, the first new drug to be launched. Prior to Sovaldi’s launch, hepatologists had begun “warehousing” patients, delaying treatment in anticipation of the launch of more effective and tolerable agents. With Sovaldi’s launch, many of these patients entered treatment.

Harvoni and Viekira Pak, both launched in late 2014, broadened management opportunities for payors. Additional agents are expected to launch in 2015 and 2016. Despite increased competition, budgeting will continue to present challenges, not only due to the cost of the therapies but also to anticipated increased rates of utilization.

More than 3 million Americans are estimated to be infected with the hepatitis C virus (HCV); more than half don’t know they are infected. The U.S. Centers for Disease Control and Prevention has recommended testing for all baby boomers, and testing is being promoted in the media. In the short term, analysts project ongoing high utilization and cost as previously warehoused and newly diagnosed patients begin treatment.

While the hepatitis C therapies are undoubtedly expensive, their effect on quality of life and their economic impact on health care costs should also be taken into consideration. The CVS Health Research Institute evaluated them against the cost effectiveness of other common treatments such as drug treatment for hypertension or diabetes and medical procedures such as angioplasty and implantable defibrillators. In this evaluation the new therapies were found to have similar cost-effectiveness to angioplasty for a person with stable coronary artery disease, but were less cost effective than many other drug interventions.

Over time, as additional hepatitis C therapies enter the market and competitive forces take hold, it is expected that the cost of these therapies will drop, and the cost effectiveness will improve.

Trendsetter solution

Manage drug cost: In selecting Harvoni as our preferred formulary agent for our standard formulary clients, CVS/caremark negotiated to obtain the best value for our clients while providing members with clinically appropriate treatment options. When permitted, use of Exclusive Specialty provides additional value.

Ensure appropriate medication use: Our specialty guideline management (SGM) programs help ensure appropriate use with a review for clinical appropriateness of therapy.

Support patient compliance: These therapies are highly effective as long as patients comply and complete therapy. Therefore, we support the best possible scenario for patient adherence.

• Product selection facilitates adherence. Our preferred product, Harvoni, is a well-tolerated drug taken once daily for eight to 24 weeks, depending on patient history and diagnosis. Most patients will not need add-on therapies, reducing the risk of problematic side effects and improving compliance.

• Every member initiating and continuing to fill an oral therapy through one of our channels receives the full support of our dedicated CareTeam.

• The team provides condition- and therapy-specific education and proactive, personalized support by phone. Three months after therapy is concluded, the prescriber is contacted to obtain the patient’s sustained virologic response (SVR) to determine if the patient has cleared the hepatitis C virus.

• Prescribers are engaged with VitalReach™, a web-based tool providing 24/7 access to critical data, updated daily on their patients who started oral HCV therapy with CVS/specialty.

Trendsetter result

Projected 2015 client savings due to hepatitis C strategy: more than $1 billion
Managing compounds

The rise in spend for compounds over the last two years was an atypical market event, unrelated to a new drug introduction, a clinical breakthrough or change in treatment guidelines. In our current dynamic market environment, such events demonstrate the need for both proactive monitoring of emerging trends and the ability to respond quickly and decisively.

In this case, our strategy is based on the premise that compounds have a limited place in therapy, especially when non-compounded FDA-approved products are unavailable or cannot be used. However, there is limited evidence documenting clinical efficacy of some compounded medications, so safety and efficacy are primary concerns. High costs are also of concern.

**Trendsetter solutions**

- Prior authorization for compounds costing more than $300
- Exclusions for bulk chemical and high-cost bases
- Member and prescriber education about compounded medications in advance of implementation of strategy

**Trendsetter result**

94% decrease in compound spend in one month, from $1 million per month to $52,000*

*2014 case study, CVS/caremark Analytic Consulting Services. Savings results will vary based on a variety of factors including things like demographics, plan design and other programs implemented by the client.
Looking ahead

In this volatile market, forecasting and vigilant oversight of emerging events become more critical. This year we are launching a suite of interactive tools to help enable plans to identify emerging drivers and trends in their own population. Currently available to clients with our Rx Insights™ reporting, these tools are being enhanced on an ongoing basis. They provide insights clients can use to support strategic responses on:

- Trend performance
- Primary contributing factors to changes in spend
- Key drugs and classes driving utilization patterns
- Drugs and classes with price increases
- Impact of generic launches on drug mix
- Effect of new drugs and outliers
- Opportunities for utilization management and review
- Peer benchmarking

Our new tools also incorporate targeted pipeline surveillance to help clients know what to expect from new drugs before they’re launched, including whether prospective launches are expected to offer clinical advantage over existing products. These pipeline insights and our consultative teams will support clients in having a clear idea of potential budget impact and management strategy.

Key launch anticipated in 2015: PCSK9 inhibitors

One potential market-changing event is the anticipated launch of two drugs representing a new class of specialty medications targeting a highly prevalent condition—high cholesterol. The proprotein convertase subtilisin/kexin 9 enzyme inhibitors (known as PCSK9 inhibitors) have shown efficacy in combating high cholesterol, a very common condition in the United States and around the world.7

Depending on the indications for which these drugs are approved and how they are prescribed, the effect on the U.S. health care system could be substantial, even larger than some of the recent drug launches (e.g., hepatitis C).
Several pharmaceutical companies are developing PCSK9 inhibitors. The first two drugs in the class could receive FDA approval by mid-2015. The drugs are injectables and are initially projected to treat people with familial hypercholesterolemia, a relatively rare genetic form of high cholesterol.8

Evidence from clinical trials suggests that these drugs are well-tolerated and highly effective—one agent demonstrated low-density lipoprotein (LDL) reductions of 46 percent to 64 percent after 12 weeks.9 While labeling and recommendations are unknown prior to approval, use of these agents with patients who are intolerant of or resistant to statins is a distinct possibility. In addition, physicians may prescribe specialty medications for off-label use. If treatment guidelines extend to all patients with a history of cardiovascular disease, as many as 15 million Americans may eventually be eligible for PCSK9 inhibitor therapy to treat high cholesterol. Depending on the price and eventual set of indications, this category of drugs could grow to become the most costly part of pharmaceutical treatment.

Management strategy: CVS/caremark has been closely monitoring the progress of the application process for these new agents. As with the new hepatitis C medications, we are ready to assist our clients with strategic management from day one and will provide updates as the FDA decisions evolve. Aggressive formulary and utilization management are expected to be key in managing utilization.

Biosimilars getting closer?
The FDA’s first approval of a biosimilar in March 2015 is an encouraging sign for payors who have been waiting years for follow-on products and some relief from specialty pharmaceutical pricing through increased competition. However, analysts do not expect that this approval will open a floodgate of biosimilars like what the market experienced with generics for non-specialty medications.

With the adoption of the Hatch-Waxman Act in 1984, Congress facilitated widespread adoption of generic medications and transformed the pharmaceutical industry. Generic drugs now account for more than 80 percent of prescriptions, up from less than 20 percent at the time of the law’s passage. In the decade that began in 2002, American payors and patients saved more than $1 trillion.10

While Congress sought similar reforms for biologic drugs with the 2010 Biologics Price Competition and Innovation Act, which was part of the Affordable Care Act, the FDA has yet to issue final guidance. Manufacturers are developing and have applied for approval of biosimilars, but progress has been slow. Issues11 include:

Two pathways to approval. There are two ways for biologics to come to market: the standard Biologic License Application process for brands and the Abbreviated Biologic License Application, established in 2010, that defines true biosimilars. Regardless of which path leads to approval, the FDA will only approve a biosimilar product if it has the same mechanism of action, route of administration, dosage form and strength as the reference product, and can only be approved for

Prospective biosimilar launches
Reference drugs and current annual U.S. spend ($M)

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Source: UBS Securities, LLC. March 15, 2015. Spend includes retail, mail and medical.
the same indications and conditions of use. Biosimilars have no clinically meaningful differences but are not considered a generic version of the reference product.

**Ability to substitute.** The important point is not which pathway a competitive drug takes to market because neither approach currently allows the sort of pharmacist-driven interchangeability that we see with oral solids. A biosimilar can be filled when prescribed by a physician, but a pharmacist cannot substitute the brand version of a drug with a biosimilar without notification to the prescriber. Several states already have enacted laws that prevent pharmacists from substituting biosimilars for their reference products.12

**Absence of exclusivity.** Adding to the uncertainty around potential revenue, manufacturers do not have the prospect of a period of exclusivity for the first biosimilar approved for a reference product. Such exclusivity has been an important incentive for generic manufacturers of small-molecule pharmaceuticals.

**Management strategy:** For the foreseeable future we expect biosimilars to behave more like brands than traditional generics, and we anticipate that payors and their pharmacy benefits managers will play an important role in encouraging the adoption of biosimilars and encouraging price competition.

The tools CVS/caremark uses to provide access to these drugs and managing costs for members and clients, include:

- Member cost-sharing aligned with plan objectives
- Formulary exclusion and step therapy*
- Prior authorization and other utilization management strategies

**The evolving landscape**

The prescription drug landscape has changed profoundly over the last several years, and it’s changing still. Generics now dominate dispensing. The majority of new drug launches are specialty pharmaceuticals that increasingly target more common conditions and account for an ever-larger portion of the prescription spend. Payors are looking for tighter control. Members face higher copays.

They both, as well as prescribers and even manufacturers, are adjusting to a more outcomes-based world.

In this environment, a drug’s cost is perceived more and more as a key component of product selection. Fifty-four percent of physicians say they already consider cost to a significant degree when prescribing.13

As costs continue to rise, purchasers will look for demonstrated value, especially compared to existing therapies. Evaluation will include not just the drug’s direct effects—it cures hepatitis C—but also its downstream value. How much will long-term savings—reducing the costs of chronic treatment, organ damage and other adverse effects—offset the costs of the drugs themselves?

In a recent survey by PricewaterhouseCoopers Health Research Institute, 60 percent of insurers agreed that drug makers must demonstrate a comparative clinical benefit to be considered for formulary placement; 45 percent felt that a clear cost savings argument was necessary.14

To some degree, this shift reflects the global market for pharmaceuticals. Economic issues are commonly addressed in pharmaceutical regulatory reviews in Europe, and they can be a deciding factor.

As we look ahead to future breakthroughs and blockbusters in this landscape, **CVS Health** has the teams, resources and strategy to support our clients and their members in achieving optimal clinical outcomes with cost-effective prescription choices.

*Subject to state law restrictions.
Trend methodology

This Insights report addresses prescription drug use for members with prescription benefits administered by CVS/caremark during the 2014 calendar year. All trend calculations are based on a trend cohort group. The trend cohort includes only plan sponsors that paid at least some portion of the cost for prescriptions dispensed to their members.

The cohort includes clients in the commercial segments (i.e., health plan and employer) as well as Medicare Part D and Medicaid plans. All clients in the trend cohort have at least 24 months of continuous claim and eligibility data. Clients with excessive changes to their gross cost PMPM were excluded, as were clients with contractual prohibitions from inclusion. Among commercial clients, average eligibility must be within +/- 20 percent period over period. For Medicare Part D and Medicaid, average eligibility must be within +/- 25 percent period over period.

The 2014 CVS/caremark trend cohort consists of more than 23 million members.

Specialty trend includes all claims for drugs from the universal specialty drug list, regardless of dispensing pharmacy, dispensed in the 24-month period. Non-specialty trend is based on claims for all drugs excluding the universal specialty drug list.

Utilization trend is calculated as the change in days supply per member per month (PMPM) from 2013 to 2014.

Price increase trend, including for generics, is the year-over-year change in published AWP per unit for a consistent market basket of drugs (GPI14 level). Because it is a measure of year-over-year change, new drugs or drugs that are no longer dispensed are excluded. The price increase metric does not reflect the impact of discounts, rebates, or any form of negotiated pricing.

Trendsetter metrics are calculated for clients in our cohort for whom we have 12 months of data after they have implemented specific management solutions.

Data used for this report is used in accordance with applicable law and our client agreements.
Source notes


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