INSIGHTS 2013

ADVANCING THE SCIENCE OF PHARMACY CARE

SPECIALTY TREND MANAGEMENT

WHERE TO GO NEXT

CVS CAREMARK

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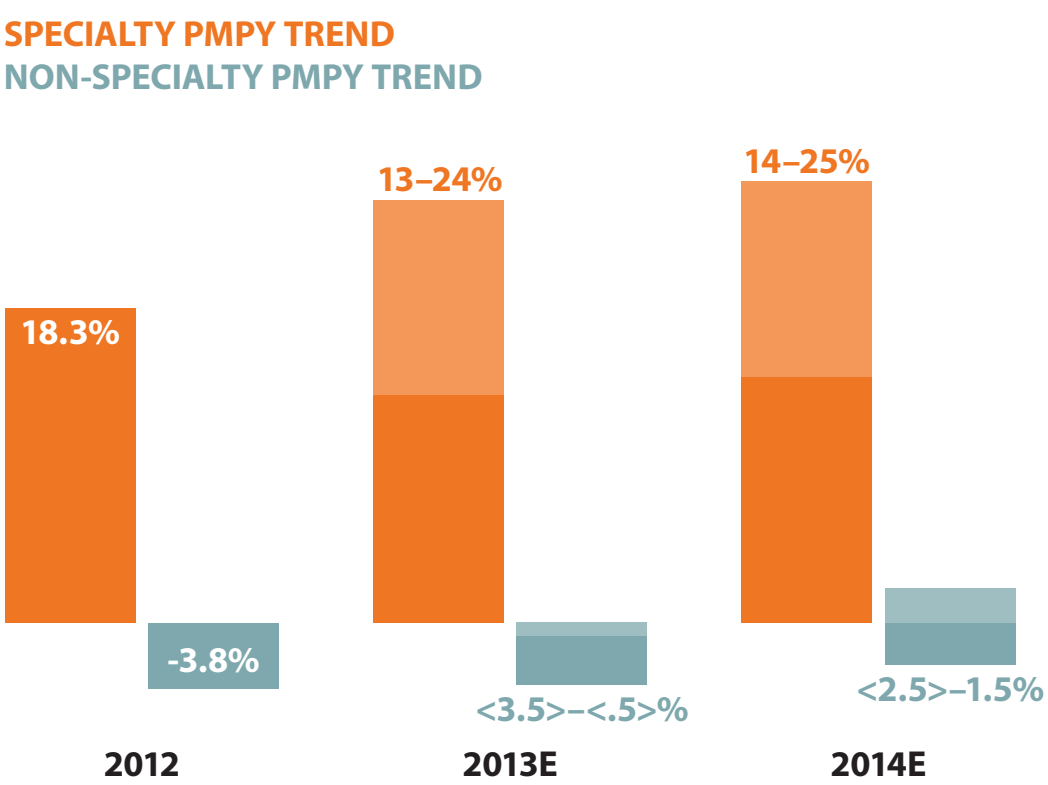
The Challenge: Double-digit specialty trend is driving pharmacy trend[1]



With a flood of new generics, spending on traditional drugs actually declined in 2012, and that decline is expected to continue for the next two years. On the other hand, specialty trend has tracked in the double digits for years and is expected to continue to rise.

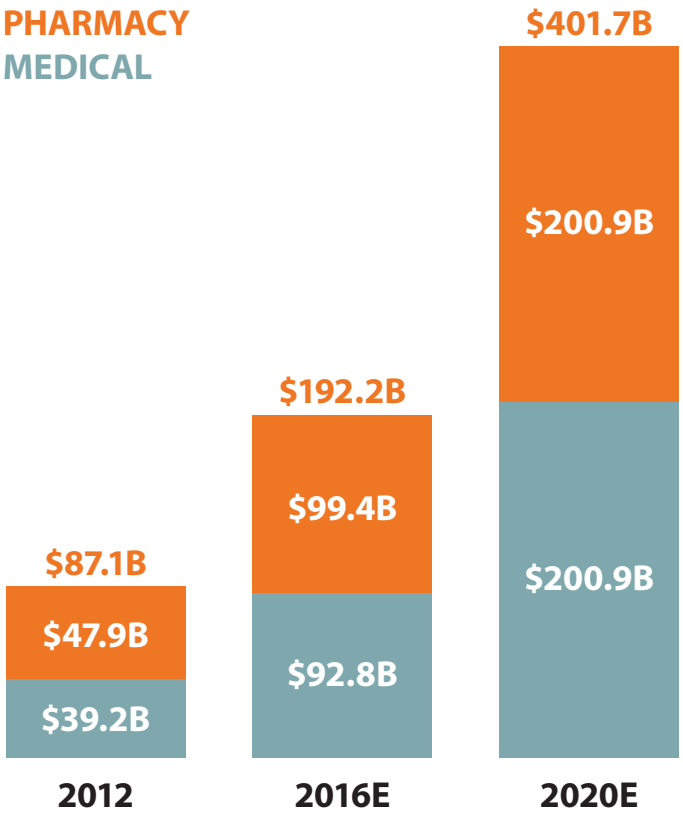
Consider:

- Last year, specialty accounted for **more than one quarter** of total prescription spend.
- With 16 new products, specialty drugs dominated 2012 launches and spending on new brands—**$3.9 billion of $7 billion total**.
- In 2013, the FDA began granting Breakthrough Therapy Designations, which could further fast-track new medicines, accelerating approval **from eight to 10 years down to just two**.
- New breakthrough products expected over the next few years include drugs for hepatitis C, multiple sclerosis, cystic fibrosis and a number of cancers—some of these medicines are likely to set **new standards for treatment.**[2]

1 CVS Caremark Analysis, CVS Caremark Specialty Analytics, 2013; CVS Caremark non-specialty drug trend, 2012, Caremark BOB trend cohort, Enterprise Analytics, 2013.
2 Source: Declining Medical Use and Costs: For Better or Worse? A Review of the Use of Medicines in the U.S., IMS Health Informatics, 2013.

The Challenge: Double-digit specialty trend is driving pharmacy trend

Anticipated Overall Specialty Spend



Specialty spend is expected to **more than quadruple** by 2020.

Nearly half of specialty spend occurs under the medical benefit, where it can be harder to see and manage.

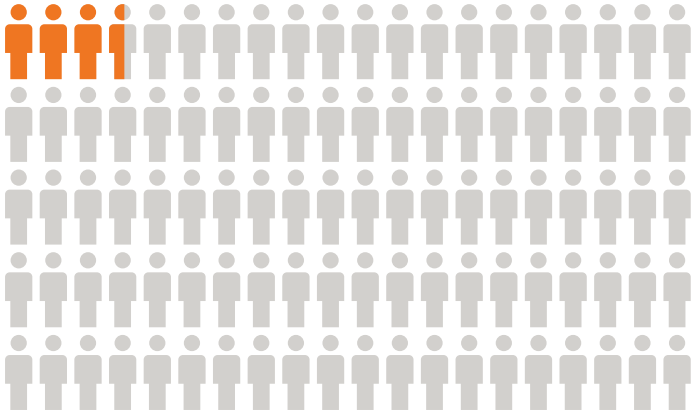
In 2012, specialty accounted for just under 20% of our clients' overall spend in the pharmacy benefit. Our research indicates that most plans spent nearly as much in the medical benefit.

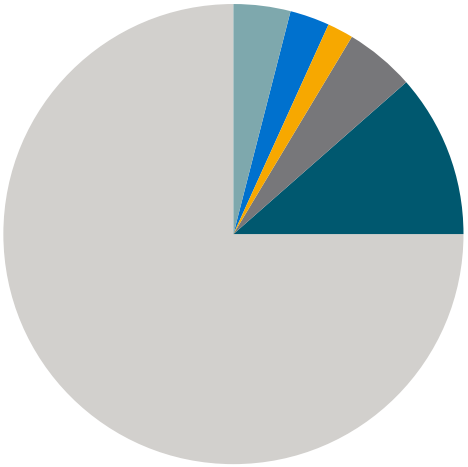
See following pages for new approaches to **increase visibility** and **improve management** of the medical part of your specialty spend.

CVS Caremark projection (2013) based on internal data and forecasts; McKinsey MPACT6 Model, Kaiser Family Foundation: Medicare at a glance, 2012; National Health Expenditure Projections 2011-2021 CMS; Avalere 2013 Medicaid Opt-Out Model, Milliman Specialty Medication Benchmark Study developed using the 2010 and 2011 Truven Health MarketScan Research Database for a commercial population (used for 2012 estimate).

The Challenge: Double-digit specialty trend is driving pharmacy trend

The **3.6% of members** who use specialty medications account for **25% of health care costs.**[3]





TOTAL HEALTH CARE COSTS

17%
Specialty drug costs under pharmacy benefit

13%
Specialty drug costs under medical benefit

7%
Non-specialty medication under the pharmacy benefit

20%
Medical costs related to specialty condition

43%
All other medical costs

A small proportion of patients account for this drug spend, but their contribution to overall health care spend is substantial. Managing specialty pharmacy is critical not only to control drug costs, but to provide the best clinical management for these patients, reducing adverse events, and helping to manage overall spending. Because the drugs and the conditions they treat are complex, management can be more complicated, but we believe that, with guidance, every plan can identify and implement measures that will significantly improve their results.

This issue of INSIGHTS is intended to help plans decide **where to go next** to manage their specialty spend.

3 Source: Milliman Specialty Medication Benchmark Study developed using the 2010 and 2011 Truven Health MarketScan© Research Database for a commercial population. Specialty drugs are identified by leveraging Milliman's Health Cost Guidelines definition and other CVS proprietary definitions. Specialty medication utilizers were defined as having at least two specialty medication claims across any place of service in the study period. Health care costs include total allowed costs incurred (prior to cost sharing) under the medical and pharmacy benefit. Medical costs associated with specialty conditions were identified using the primary ICD-9 diagnosis codes in the medical benefit data.

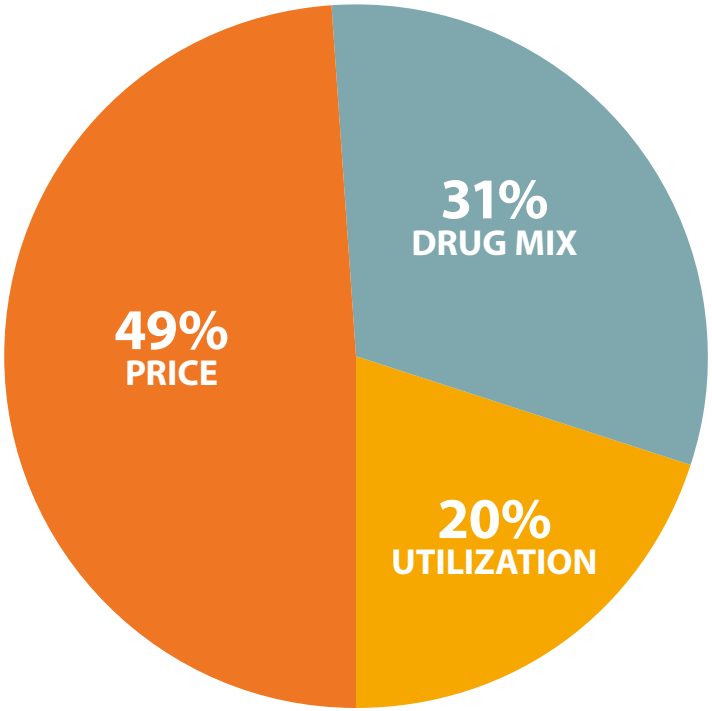
All trend management starts with price, mix and utilization

All trend management starts with price, mix and utilization

Specialty trend is driven by price, mix and utilization, just like traditional trend, but managing trend in the specialty realm is more complex. Compared to traditional drugs, fewer specialty products are substitutes for one another. There are few generics (or biosimilars) now and limited prospects for more generics in the near future. Dosage forms are more diverse, and many disease states are treated with complex regimens that comprise drugs with different routes of administration. For drugs that require administration in a medical facility, administration costs must also be factored in. Importantly, most plans spend about as much on specialty drugs in the medical benefit as in the pharmacy benefit, and medical drug spend can be less visible and harder to track and manage.

Many plans have foundational strategies in place to manage costs and ensure safe and effective use of specialty drugs under the pharmacy benefit, though few have truly exhausted all management opportunities.

In the following pages, we share insights and strategies to help expand management strategies—**where to go next**.



SPECIALTY TREND DRIVERS[1]

1 CVS Caremark book of business trend cohort; CVS Caremark Analysis, CVS Caremark Specialty Analytics, 2013.

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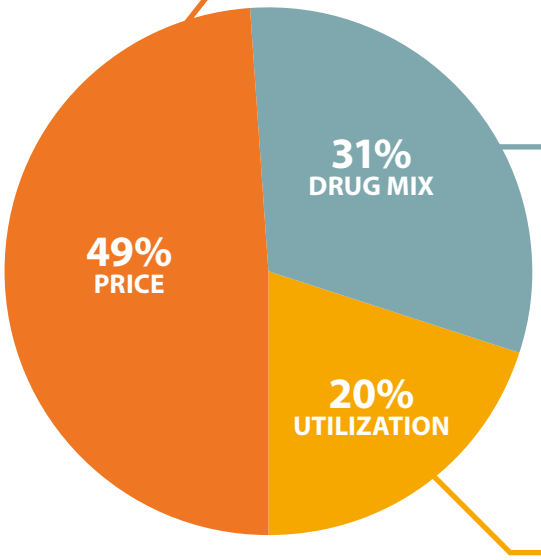

SPECIALTY TREND DRIVERS[1]

Price Influencers

Network Size

More restricted specialty networks provide better pricing, more consistent reporting and less variability in patient care and patient experience.

Site of Care

Because many of these drugs are infused or administered in medical facilities, site of care factors into the cost of drugs and their administration.

Inflation

Price inflation was the major trend driver in 2012. AWP trend for specialty drugs was 12.9 percent.[2]

Drug Mix Influencers

Generics

There are few generics in the specialty market or pipeline, particularly for biologic agents.

New Agents

New specialty launches have outnumbered those of traditional drugs for several years. New agents, which can be more effective, more convenient or have milder side effects, may displace the use of less expensive medications.

Lack of Product Competition

Although some categories have multiple options, many specialty products are breakthrough therapies with few close substitutes. The development of these medications is expensive and complex, patient populations are small, and the FDA approval pathway is still undefined, hampering the development of biosimilars.

Utilization Influencers

Approval of New Drugs/New Indications

New drugs are sometimes approved for use in conjunction with another drug, driving up the utilization of both.

Changes in Treatment Guidelines

These changes can drive or mitigate utilization of specialty agents.

Demographic and/or Economic Changes

Changes in the economy and shifts in demographics, such as the aging of the baby boomer population, affect utilization.

1 CVS Caremark book of business trend cohort; CVS Caremark Analysis, CVS Caremark Specialty Analytics, 2013.
2 CVS Caremark 2012 BOB trend cohort. Enterprise Analytics, 2013.

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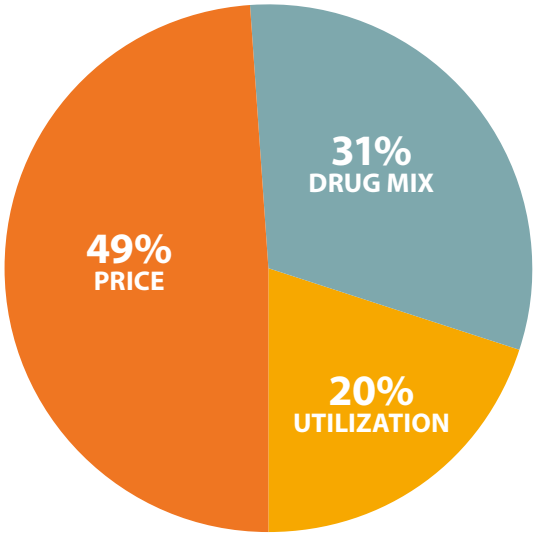

SPECIALTY TREND DRIVERS[1]

FOUNDATIONAL STRATEGIES

Managing price in specialty pharmaceuticals requires looking for the lowest cost source of drug and, in some cases, for the most cost-effective site of care. Using an exclusive specialty pharmacy can reduce a plan's cost for specialty medications. Plan sponsors should also consider narrowing infusion networks as part of a wider examination of their site of care strategy.

1 CVS Caremark book of business trend cohort; CVS Caremark Analysis, CVS Caremark Specialty Analytics, 2013.

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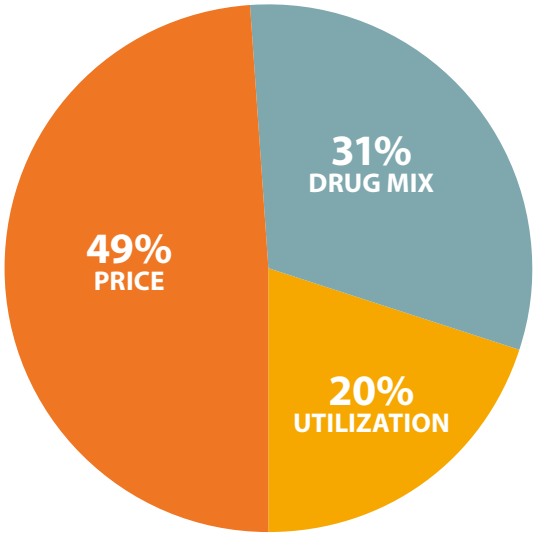

SPECIALTY TREND DRIVERS[1]

FOUNDATIONAL STRATEGIES

In categories with multiple specialty options, formulary exclusions and step therapy programs can help establish the most cost-effective frontline treatment and negate the impact of manufacturer copay assistance. By looking across the pharmacy and medical benefits in high-use categories, plans can increase the competitive pressures felt by the pharmaceutical manufacturers.

1 CVS Caremark book of business trend cohort; CVS Caremark Analysis, CVS Caremark Specialty Analytics, 2013.

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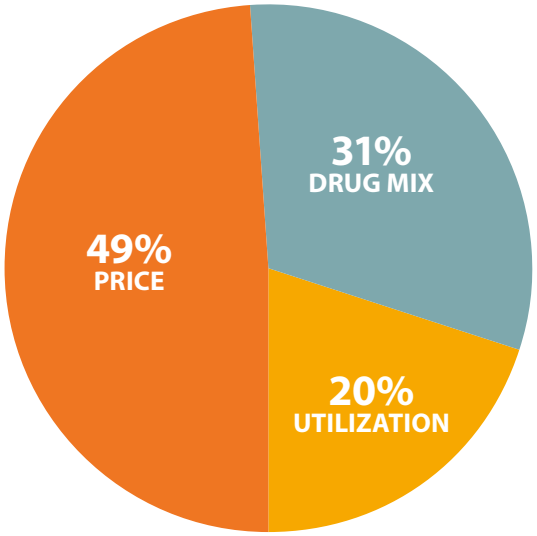


SPECIALTY TREND DRIVERS[1]

FOUNDATIONAL STRATEGIES

Utilization management programs ensure safe and effective use and reduce waste. Importantly, when new science suggests that older, often generic drugs are equal in efficacy to newer biologics, specialty pharmacies and PBMs are critical to driving adoption of these new guidelines.

On the following pages, find out how to **expand your specialty management strategies**.

1 CVS Caremark book of business trend cohort; CVS Caremark Analysis, CVS Caremark Specialty Analytics, 2013.

Drugs for a single condition can span the pharmacy and the medical benefit

In the specialty realm, drugs used to treat a single condition can have different routes of administration and mechanisms of action, and may be covered under either the medical or pharmacy benefit. Looking at the full range of options in a therapeutic category increases manufacturer competition and can broaden management opportunities for the payor.

ORAL

Covered under both pharmacy and medical benefit

Newer orals under medical can be more expensive than older infused agents

SC/IM

Subcutaneous (SC) or intramuscular (IM) injection

Often appropriate for self-administration

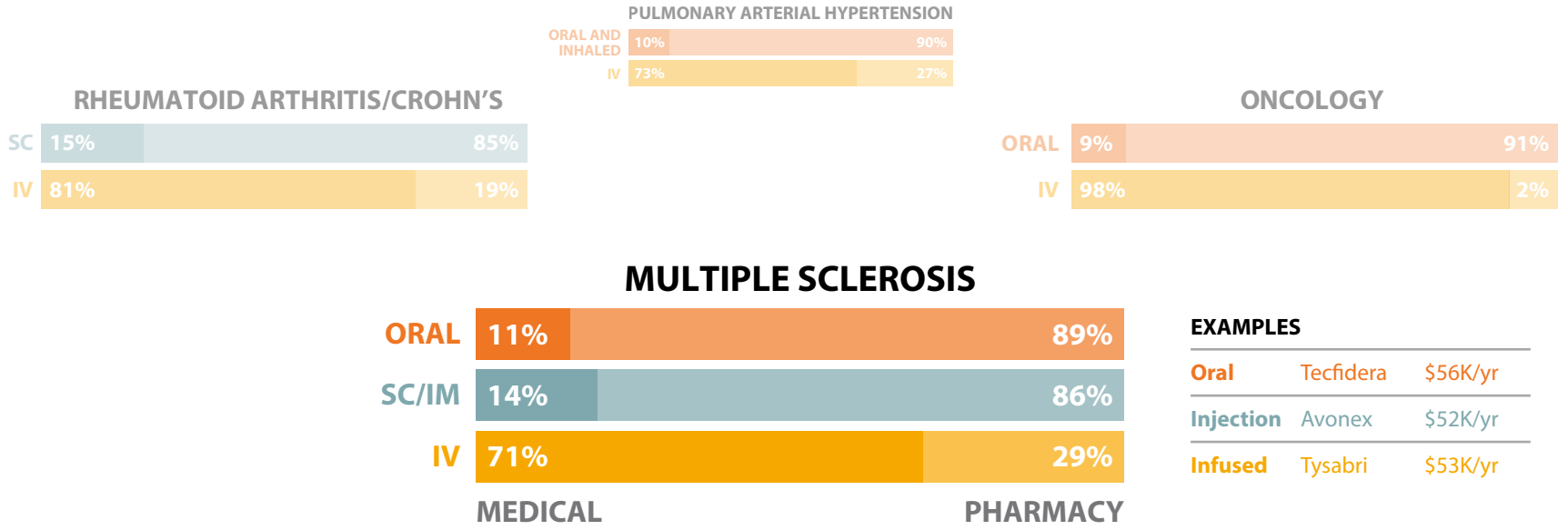
Covered under medical as well as pharmacy benefit

IV

More likely to be covered under the medical benefit

Administered in a physician's office, in an outpatient center, at the hospital, or in-home

Total cost includes the cost of the drug itself and its administration



EXAMPLES

Oral	Tecfidera	$56K/yr
Injection	Avonex	$52K/yr
Infused	Tysabri	$53K/yr

Source: CVSCaremark Specialty Analytics. Annual drug costs based on average wholesale price (AWP) accessed summer 2013. Remicade dosing and cost based on weight of average U.S. male. Costs do not include fees for administration.

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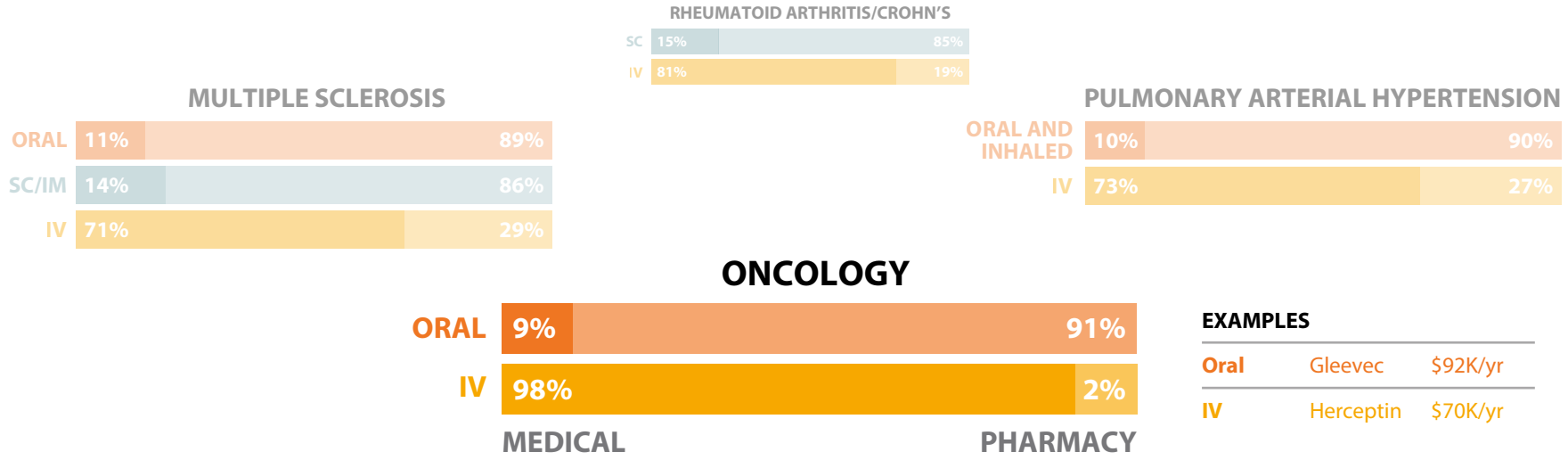

EXAMPLES

Oral	Gleevec	$92K/yr
IV	Herceptin	$70K/yr

Source: CVSCaremark Specialty Analytics. Annual drug costs based on average wholesale price (AWP) accessed summer 2013. Remicade dosing and cost based on weight of average U.S. male. Costs do not include fees for administration.

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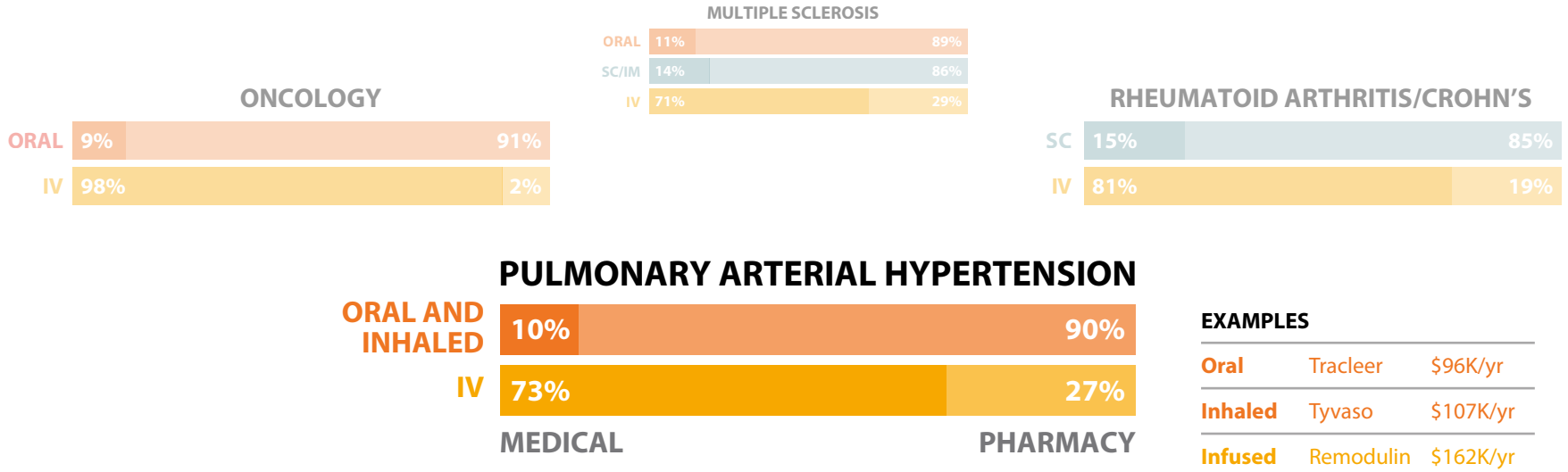

EXAMPLES

Oral	Tracleer	$96K/yr
Inhaled	Tyvaso	$107K/yr
Infused	Remodulin	$162K/yr

Source: CVSCaremark Specialty Analytics. Annual drug costs based on average wholesale price (AWP) accessed summer 2013. Remicade dosing and cost based on weight of average U.S. male. Costs do not include fees for administration.

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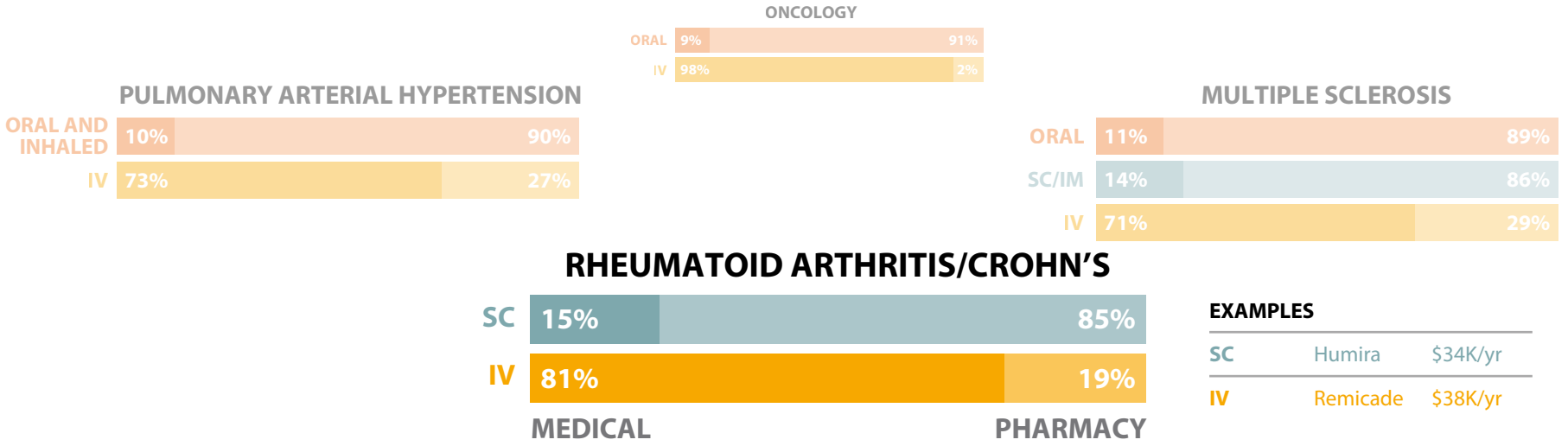

EXAMPLES

SC	Humira	$34K/yr
IV	Remicade	$38K/yr

Source: CVSCaremark Specialty Analytics. Annual drug costs based on average wholesale price (AWP) accessed summer 2013. Remicade dosing and cost based on weight of average U.S. male. Costs do not include fees for administration.

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WHERE TO GO
NEXT

Clinical appropriateness is of primary importance to prescribers, but therapy choices are influenced by other factors as well. Prescribers may favor an infused drug that can be administered in the office. Many prescribers have become accustomed to a "buy and bill" approach for certain products; the mark-up they charge on the drug and the fee charged for administration can account for significant practice revenue. The patient's out-of-pocket cost—whether a copay or coinsurance—can be a consideration for both patient and prescriber.

This range of issues further complicates specialty management for payors, but incremental and strategic changes can improve cost management and maintain clinical options. **The stepped approach described here expands on formulary and preferred drug strategies to gradually introduce more intensive management.** Each step can be adapted to fit the priorities and utilization patterns of an individual plan.

Hear **Dr. Alan Lotvin, EVP Specialty Pharmacy** describe how to start expanding your specialty management strategy

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Expand preferred drug strategies in high-use categories. In competitive, high-use categories with multiple medications—such as rheumatoid arthritis—look at available options across the medical and pharmacy benefit to take advantage of market competition. Consider making a self-injectable preferred over an infused drug. If there are multiple infused drugs, consider determining a preferred infused agent.

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Make your goal the administration of the most appropriate drug irrespective of benefit coverage. Consider moving drugs that are typically self-administered and those that are commonly infused in the home—such as IVIG—to the pharmacy benefit for better visibility and management. Non-oncologic infused drugs—such as Xolair and Tysabri for multiple sclerosis, or Remicade for rheumatoid arthritis—can be made available under both the medical and pharmacy benefit.

Drugs for a single condition can span the pharmacy and the medical benefit

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Use UM techniques, such as prior authorization, to support use of the most appropriate, cost-effective therapies for an entire category, whether a particular drug is covered under the medical or pharmacy benefit.

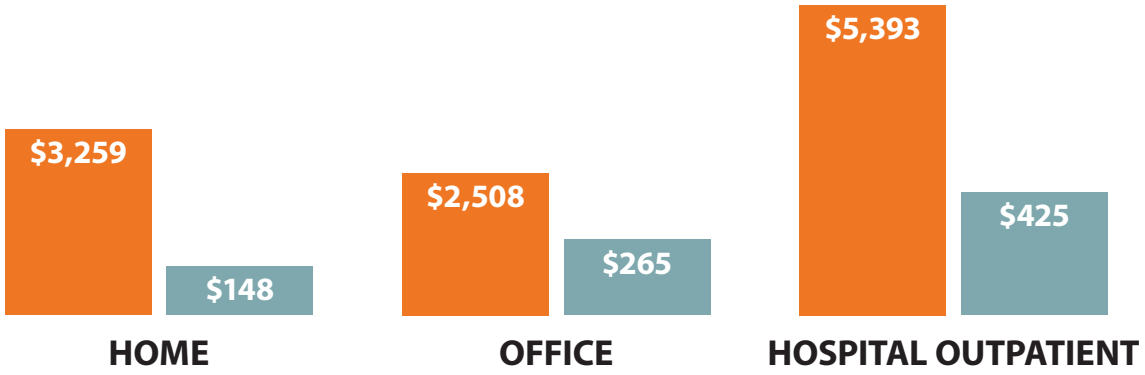
Costs for an infused drug can vary wildly based on where it's administered

Infused drugs

- Common in the treatment of cancer, immune deficiencies, Crohn's disease, multiple sclerosis, rheumatoid arthritis and other conditions
- Estimated to account for **$35 billion** of the specialty market[1]
- Make up as much as **33% of specialty drugs** in the pipeline[2]
- Most often covered under the medical benefit

Infused therapies can be administered in a physician office, infusion center, or as an outpatient procedure in a hospital; many can be administered in the home. Cost of administering the drug is incremental to the cost of the drug itself. When the drug is ordered by the provider, plans are typically charged the cost of the drug plus a percentage; these are "buy and bill" drugs.

DRUG COST BY SITE OF SERVICE[3]
AVERAGE COST OF ADMINISTRATION



Remicade, Standard dosing of 70 kg patient

Infusions are increasingly being done in the hospital setting, **where costs for both the drug and its administration can be the highest**.

1 EvaluatePharma
2 EMD Serono Specialty Digest
3 CVS Caremark Internal Data, 2013

Costs for an infused drug can vary wildly based on where it's administered

Costs for an infused drug can vary wildly based on where it's administered

WHERE TO GO
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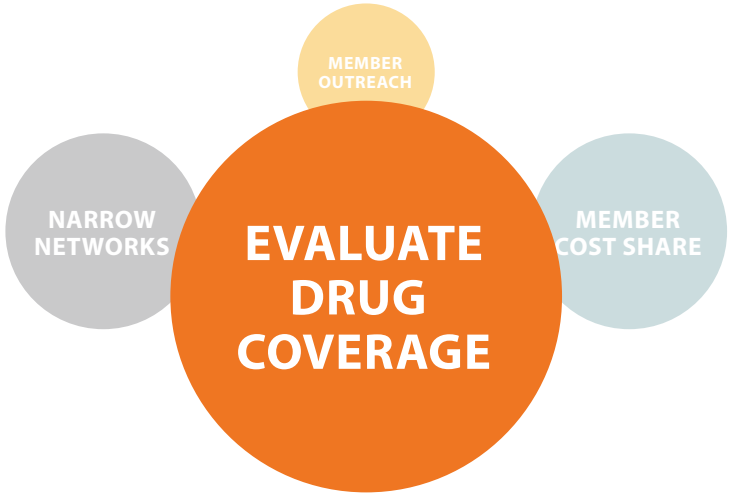
The hospital is typically the least cost-effective site of care for infusions. Plans can take a stepped approach to move infusions out of the hospital setting and increase utilization of cost-effective sites of care. Begin with a comprehensive look at overall strategy.



Which infused drugs are covered under the pharmacy and which under the medical benefit? Those that are typically administered in the home should be covered under the pharmacy benefit, where they're easier to track and manage.

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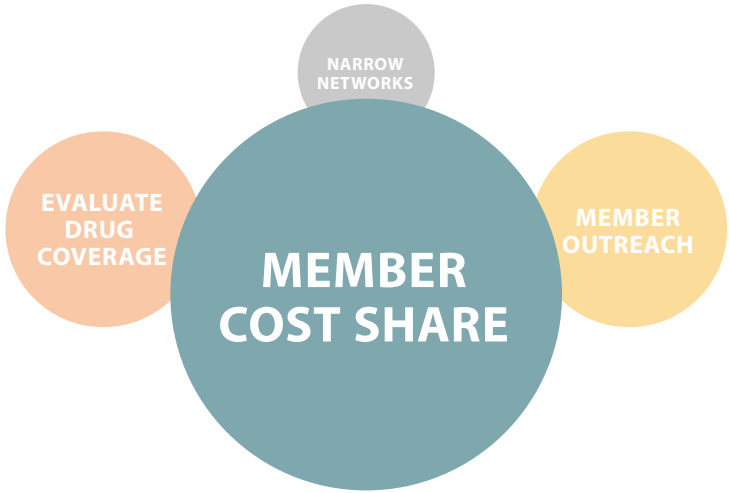

Do member cost share strategies align with appropriate site-of-care choices? Is member cost for the drug higher for home infusion than it would be for an office- or hospital-administered product?

Costs for an infused drug can vary wildly based on where it's administered

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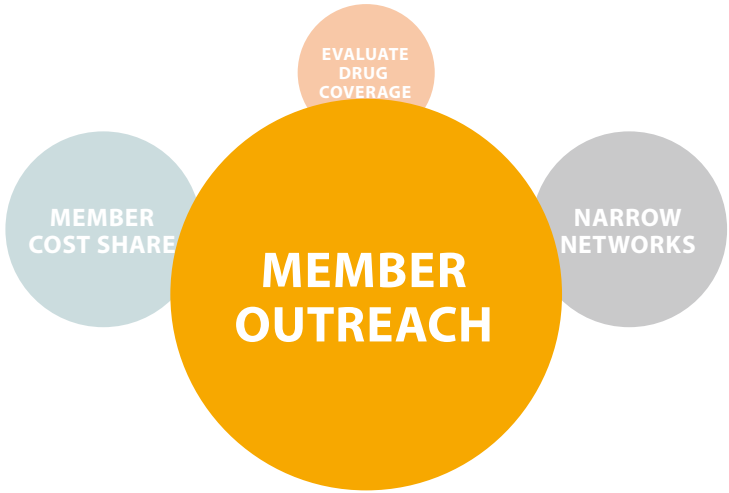

Would members move voluntarily to a lower cost site of care? For many members home infusion or use of an ambulatory infusion suite can offer greater convenience than the hospital setting, and they may make the change if the plan makes the appropriate outreach or incentivizes the use of a lower cost site of care.

Costs for an infused drug can vary wildly based on where it's administered

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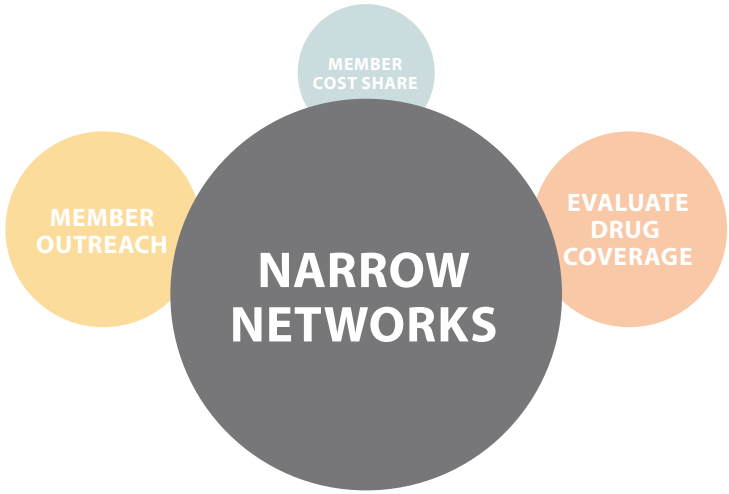
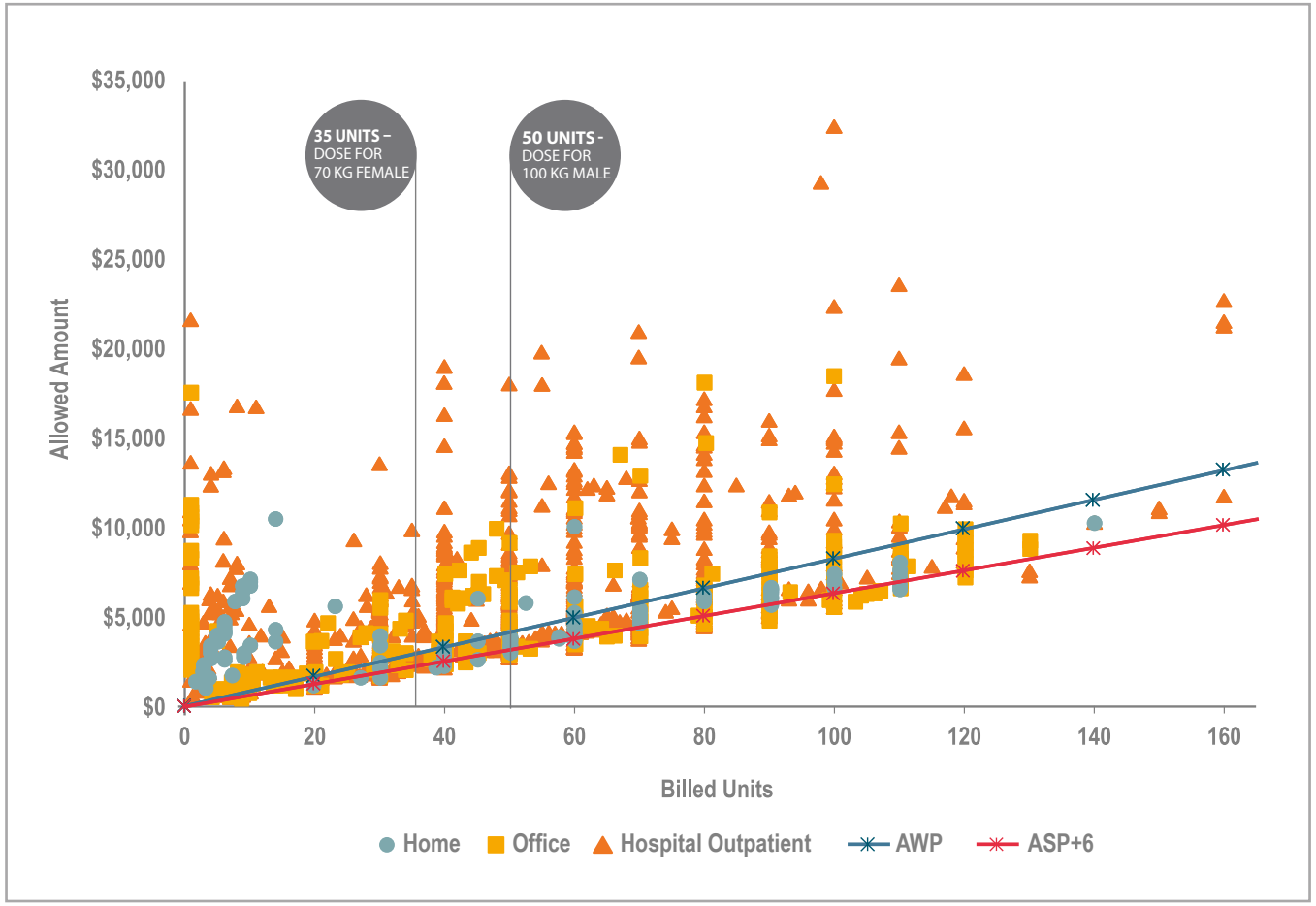


Evaluate alternatives, including narrow infusion networks. Many plans have found that limiting specialty pharmacy networks has led to improved cost and care outcomes. Narrow infusion networks are likely to produce similar improvements, and as infused drugs account for a larger portion of spend, more plans are likely to explore this approach.

Variation in dosing and pricing can escalate drug costs under the medical benefit

Medical claims systems were built to adjudicate a broad range of services, and prior to the rapid rise in spend on specialty pharmaceuticals, drug utilization was not a primary focus. As medical drug use has become more prevalent, many adjudication systems have not comparably evolved, complicating the process of monitoring claims for accuracy. This, along with industry-wide variation in reimbursement strategies, has led to wide variation in medical claims' dosing and pricing—as shown in the exhibit here—an analysis of claims for Remicade used in the treatment of Inflammatory Bowel Disease.



Source: Milliman Remicade Benchmark Study developed using the 2010 and 2011 Milliman *Health Cost Guidelines* database for a commercial population. Remicade claims were identified by Healthcare Common Procedure Coding System (HCPCS) J1745. Remicade claims were limited to those with an ICD-9 diagnosis code associated with Inflammatory Bowel Disease. Remicade costs include total allowed costs incurred (prior to cost sharing) under the medical benefit within the physician office, outpatient hospital and home health settings.

Variation in dosing and pricing can escalate drug costs under the medical benefit

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WHERE TO GO
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Our analysis of claims data shows that variation in billing like that shown here is not specific to a single drug or disease. Strategies discussed on previous pages—expanding preferred drug strategies, promoting use of cost-effective sites of care—address some of the issues. Additionally, CVS Caremark now has sophisticated systems that can crosswalk through medical claims to help identify editing and repricing opportunities before the claim is paid.

Through post-service review we can help assure that the drug is being administered:

- At clinically appropriate dosages
- For the correct indication
- At recommended frequency

We can also help assure that the claim is being paid:

- Accurately
- According to fee schedule

Putting it all together: Holistic management of RA improves cost and clinical outcomes

Here is an example of how our strategies work together holistically as a patient proceeds through therapy for rheumatoid arthritis. The goal of CVS Caremark management is to help guide patient and provider to cost-effective, clinically appropriate decisions whether the therapy falls under the medical or pharmacy benefit.

Hear **Dr. Surya Singh, Corporate VP, Specialty Client Solutions**, explain how cross-benefit management can help reduce costs over both the long and short-term.

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Has the patient tried and failed an oral agent—methotrexate?

- Consider implementing a **prior authorization requiring that the patient try a generic, non-specialty drug as front-line treatment**. The prescriber can consider use of a specialty medication if the patient fails with the generic.

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If the patient has failed with the generic, what is the most cost-effective course of action with a biologic?

- With multiple specialty options for rheumatoid arthritis, **designate a self-injectable agent as preferred**.
- To help ensure consistent pricing, designate a narrow network—a preferred source for the selected agents.
- Provide support to **help the patient transition to self-injecting the medication**.
- For more comprehensive management, **carve out self-injectables** from the medical benefit.

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If an infused agent is chosen, what strategies would be employed?

- When multiple infused drugs exist within the same category, as is true for rheumatoid arthritis, implement a **preferred infused agent**.
- For most infused agents, the physician's office, an outpatient center, or the home are more cost-effective sites of care than the hospital. **Support appropriate site of care choices** with plan design and cost share strategies as well as patient outreach.
- Work to ensure **accurate and appropriate pricing, dosing and frequency** as early in the process as possible to help accustom providers to working within plan benchmarks and guidelines.

Every plan can improve their specialty trend management

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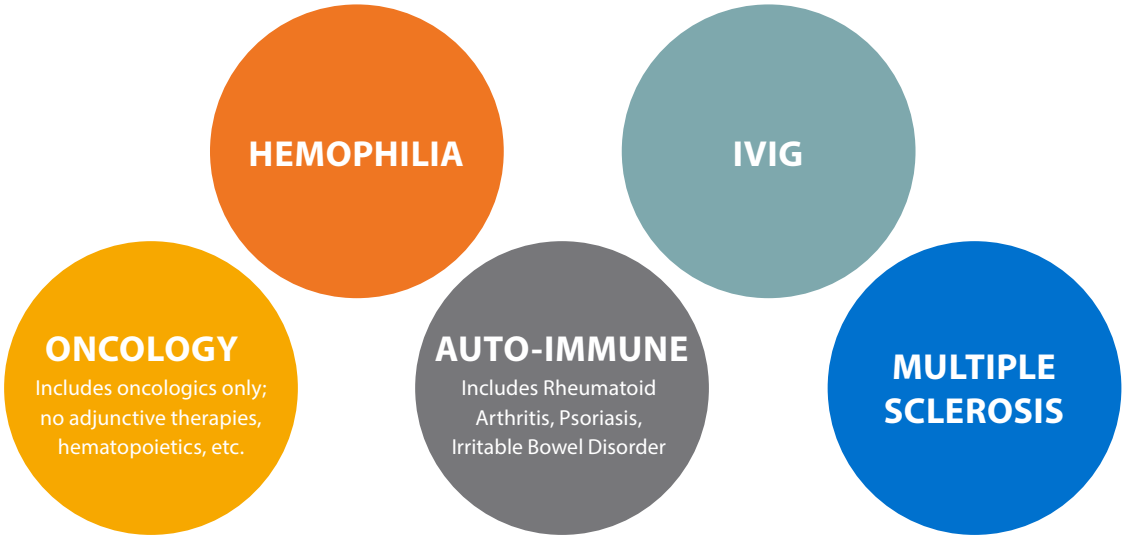
WHAT YOU COULD
SAVE

In our experience, every plan can improve their management of specialty pharmaceuticals, regardless of strategies in place now. The potential rewards are substantial. **Our analytics team evaluated the impact of our programs on spend and trend for five top therapeutic categories in a population of one million.**

Over 50% of specialty spend is in these **five therapeutic categories:**



2013 Total Estimated Specialty Spend for these Categories: **$214M***

2014 Total Estimated Specialty Spend for these Categories: **$253M***

*Spend and savings figures are projected on a commercial population of one million and a year-over-year spend increase of 18 percent. Projected savings under the medical benefit apply only to drugs eligible for program management. Not all programs may be appropriate for a specific plan. This analysis is for illustrative purposes and does not represent an existing or future contractual guarantee of CVS Caremark.
Data Source: CVS Caremark Enterprise Analytics 2013.

Every plan can improve their specialty trend management

Our **comprehensive management strategy** includes:

Exclusive Specialty Pharmacy

Site of Care Alignment

Claims Edits/Repricing

Dose/Waste Management

Specialty Guideline Management

Medical PA

Cross-Benefit Preferred Drug Plan Designs

Medical Carve Out

Every plan can improve their specialty trend management

WHAT YOU COULD
SAVE

With these trend management strategies in place, **your potential range of savings in 2014 for these five therapeutic categories for a 1M population:**

$28M–$38M

11%–15%
of your specialty spend
for these categories

Projected Trend Reduction
13%–18%

*Spend and savings figures are projected on a commercial population of one million and a year-over-year spend increase of 18 percent. Projected savings under the medical benefit apply only to drugs eligible for program management. Not all programs may be appropriate for a specific plan. This analysis is for illustrative purposes and does not represent an existing or future contractual guarantee of CVS Caremark.
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Patients using specialty medications face many challenges

Compared to the average patient, they're more likely to:

- Have multiple diagnoses
- See more specialists
- Fill more prescriptions
- Have more lab tests, ER visits and hospitalizations

Not surprisingly, they also have higher overall costs—**as much as 8.5 times higher** according to one study.[1]

CVS Caremark offers a range of services to make managing care for these patients easier for both the patients and their prescribing physicians:

- Easier intake of specialty prescriptions through CVS/pharmacy
- Expert clinical support through our Specialty Pharmacy CareTeam
- Whole-patient support through our care management services
- Even injection training through MinuteClinic

These services can **improve outcomes** and **help avoid unnecessary costs** for patients and plans.

1 Milliman Specialty Medical Drug 2010 Commercial Benchmark Study, November 2012.

Patients using specialty medications face many challenges

One in four patients who try to fill a specialty prescription at a retail pharmacy is turned away without adequate guidance.[2] Soon patients will be able to access our specialty pharmacy services easily through their local CVS/pharmacy. With Specialty Connect, the local pharmacist will help them get started and put them in touch with the specialty pharmacy. Patients will have ongoing clinical support from our specialty pharmacy CareTeam. They can talk about their condition, drug therapy, and any concerns from the privacy of their own home with our expert CareTeam clinicians.

Compared to patients using standard retail pharmacies to fill their specialty prescriptions, **patients in our Specialty Connect pilot started therapy more quickly, remained on therapy more consistently, and had fewer days without therapy**. Both patients and prescribers appreciate the greater ease and convenience. The service will be launched nationwide at all CVS/pharmacies starting in 2014.

2 New England Opinion focus group of specialty patients, calls to 150 retail pharmacies (CVS and competitors) on January 13-15, 2012.

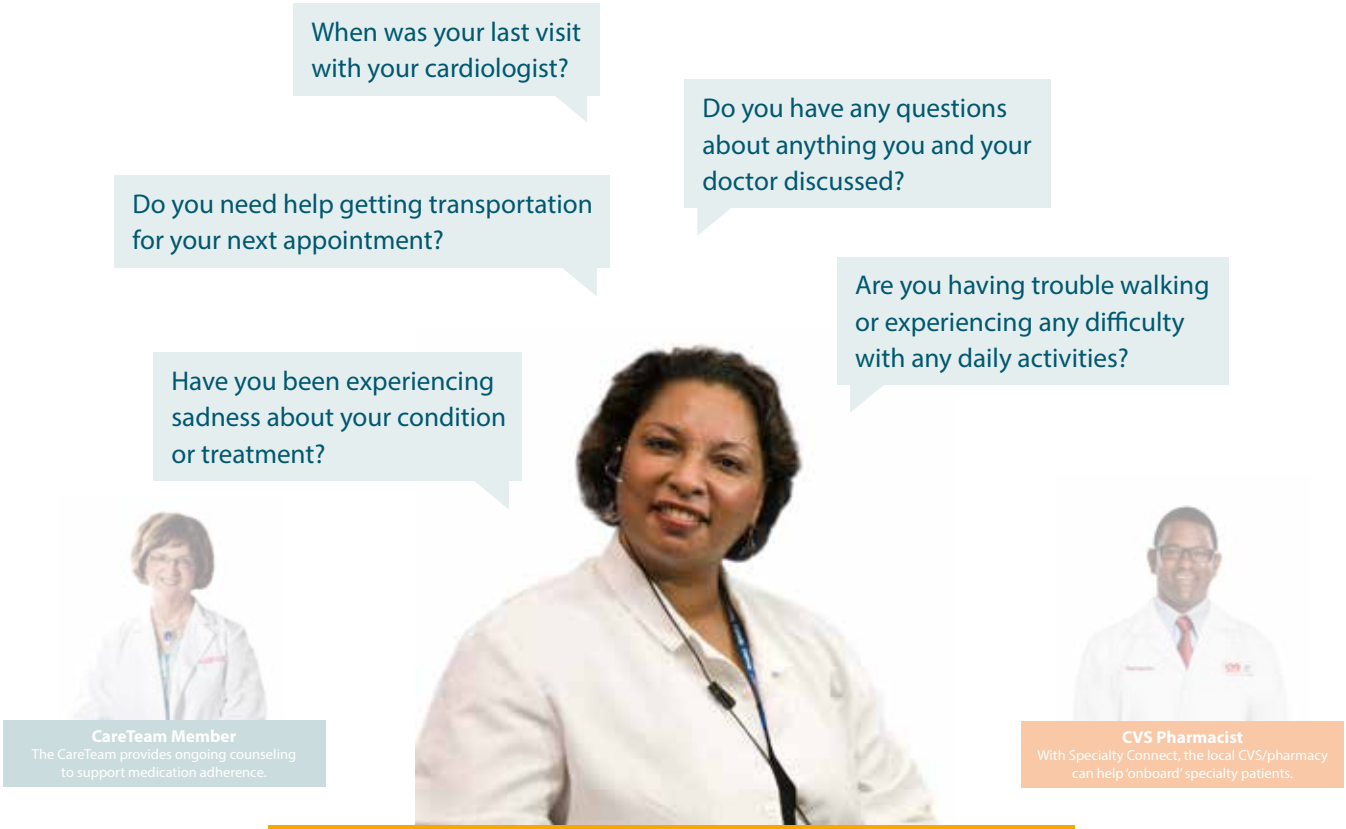
Patients using specialty medications face many challenges

Once enrolled, our specialty pharmacy patients work with therapy-specific CareTeams. They speak with their therapy-specific CareTeam as needed from the privacy of their own homes. In addition to helping patients with clinical questions, CareTeam specialists monitor outcomes and side effects and assist with refills, prior authorizations, and benefit verification—helping to execute plan strategy for improved clinical and cost outcomes. These services can reduce drug and total health care costs. Oral oncology patients using a specialty pharmacy had **13% lower costs.**[3]

3 The American Journal of Pharmacy Benefits, 2012; 4(4): 165-174.

Patients using specialty medications face many challenges

Specialty patients typically incur not just higher pharmacy costs, but higher overall costs due to comorbidities, hospitalizations and outpatient costs. Our care management nurses help patients with issues related to their rare condition, even if they are not currently taking a specialty medication. They also help a member transition to a less expensive site of care for infused drugs when appropriate. Combining care management with our CareTeam services ensures that all members with specialty conditions are given the appropriate, whole-patient care, reducing overall costs by up to 11.1%.[4]



Complete Patient Management
Care management nurses focus on helping patients manage needs related to their condition.

4 Accordant Book of Business 2012.

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