EXPRESS SCRIPTS®

# DRUG TREND REPORT

UPDATED OCTOBER 2013 BY THE RESEARCH AND NEW SOLUTIONS LAB

DrugTrendReport.com

Published annually since 1997, the Express Scripts *Drug Trend Report* provides the healthcare industry's most detailed analysis of prescription drug costs and utilization. In recent years, we created an online report for a more interactive experience. In 2013 and going forward, we're updating the site regularly for timely access to critical information. As the site continues to evolve, look for more enhancements and further integration with Healthcare Insights, the blog from The Express Scripts Research & New Solutions Lab. Sign up to receive updates at DrugTrendReport.com, or contact your Express Scripts representative for more information.

# COMMERCIAL

## COMMERCIAL FEATURE ARTICLES

Timely, topical and in-depth analysis of issues particularly relevant to the population covered by employers, health maintenance organizations, health insurers, union-sponsored benefit plans and third-party administrators.

# THE DUAL ROLE OF CAREGIVERS WITH CHRONIC CONDITIONS


Behind the scenes of the traditional healthcare system exists a role that is largely underappreciated: the role of caregiver. An estimated 42 million Americans spend an average of 20 hours a week caring for friends or loved ones.[1] They provide a spectrum of care that ranges from making phone calls to doctors and pharmacists to a daily routine that can include hands-on services such as cooking, cleaning, bathing and administering medications. But although many of these caregivers consider this noble act fulfilling and satisfying, a large segment of this dedicated population experiences reduced happiness, diminished engagement in daily activities, exacerbated health issues and a nonexistent work-life balance. In this article, we explore the cost of caregiving and the complications of the caregiver role.

CAREGIVERS ARE **29% MORE LIKELY** TO USE ANXIETY MEDICATIONS THAN NON-CAREGIVERS

### Caregiving: A Closer Look

In providing unpaid care for an acquaintance, friend or family member, caregivers often sacrifice considerable time and money. This personal sacrifice can create a great deal of stress[2] for many caregivers, sometimes leading them to neglect their own health and wellness. Yet caregivers are often at risk for both mental and physical health problems as they cope with the problems of others.[3]

As the population in need of health-related care grows, the demand for caregivers will increase as well. According to the U.S. Department of Health and Human Services' Administration on Aging, the number of Americans age 65 and older is expected to top 70 million in 2030.[4] Because older adults are the demographic group that is most likely to require caregiver services,[5] this growing population makes it

imperative to consider the dual role that caregivers play in the healthcare system. Caregivers don't just provide care and support for other patients; often, they are patients themselves, with their own healthcare needs.

To better understand the prevalence of caregiving among our members, and to recognize the special role-related challenges that they may face, Express Scripts conducted a telephone survey of members age 18 to 65 who were taking at least one prescription drug regularly for a long-term or chronic health condition. The 12,005 members who participated in the survey were questioned about their general health, well-being and medication-taking behavior. They were also asked: "In the past month, have you provided unpaid care to an adult relative or friend to help them take care of themselves?" The survey revealed that 34.6% of respondents had provided such care during the previous month. The amount of time spent providing care was not taken into consideration.

On average, caregivers were 52 years old, and almost two-thirds reported providing care for a parent, sibling, other relative or friend rather than to a spouse or an adult child in the month prior to the survey. Further, caregivers were more likely to be female than male (62.9% vs. 37.1%), and about one-third were providing care for more than one person. Providing care for more than one person at a time can intensify stress and increase the amount of resources devoted to caregiving.

The demands of caregiving appeared to change frequently, with caregivers reporting that they provided shifting levels of care at different times. When asked how their caregiving had changed in the past month, 35.6% of Express Scripts caregivers said they had increased the amount of care they were providing; by contrast, 14.9% had decreased the amount of care. Caregiving appeared, in general, to be an ongoing endeavor, with only 8.5% of caregivers saying they were new to the role and an even smaller 3.8% saying they had stopped providing care altogether in the past month.

Providing care over a distance was also something surveyed caregivers had to contend with, as only one in five Express Scripts caregivers resided in the same households as the patients in their care. Among the other 80% of caregivers, more than half (52.0%) lived within 15 miles of the primary recipient of their care, but 27.3% lived more than 15 miles away. Traveling to provide care affects the type of care and degree of supervision that can be provided. If the necessary care is time-sensitive (e.g., providing transportation to physician appointments) or if hands-on interaction is required (e.g., bathing or ensuring that medications are taken as prescribed), long distances involved in caregiving can become problematic. Moreover, already demanding requirements for time and energy are amplified when caregivers themselves have physicians to visit and medications to manage.

## Caregiver, Patient or Both?

We also reviewed pharmacy claims to determine which prescription medications caregivers were taking including those to treat chronic illnesses that are associated with stress, such as high blood pressure/heart disease, high cholesterol, depression and anxiety. Medications for high blood pressure/heart disease topped the list of prescription medications that caregivers were taking, followed by medications for high cholesterol and depression. (See table on the next page.) Although the prevalence of use of drugs to treat the top 10 conditions was somewhat similar among caregivers and noncaregivers (survey respondents who had not provided care in the previous month), utilization of medications in the therapy classes shown in the table below (with the exception of drugs to treat high cholesterol and to treat asthma) was consistently higher among caregivers than noncaregivers. This finding isn't surprising given the reduced amount of time available to manage one's own health as a result of this added role.

## Medication Use Among Caregivers and Noncaregivers

| THERAPY CLASS | CAREGIVERS | NONCAREGIVERS | RELATIVE DIFFERENCE |
|---|---|---|---|
| High Blood Pressure/Heart Disease | 44.5% | 42.2% | 5.5% |
| High Cholesterol | 31.9% | 33.2% | -3.9% |
| Depression | 19.9% | 18.2% | 9.1% |
| Ulcer Disease | 19.9% | 18.1% | 9.9% |
| Hypothyroidism | 15.5% | 12.9% | 20.6% |
| Anxiety | 12.5% | 9.7% | 28.5% |
| Allergies | 10.6% | 10.2% | 3.9% |
| Diabetes* | 9.2% | 8.6% | 6.5% |
| Asthma | 8.5% | 8.5% | 0.8% |
| Seizures | 6.0% | 5.6% | 7.7% |

*Oral anti-diabetes medications only

As further evidence of the stresses associated with the dual caregiver-patient role, the survey found that even after controlling for factors such as age, gender and income, Express Scripts caregivers were more likely to rate themselves as being in poorer health — fair, poor or very poor health as compared to good, very good, or excellent health — than were noncaregivers (14.6.% vs. 12.4%). Not surprisingly, a higher proportion of caregivers also reported being "not very happy" or "not at all happy" than did noncaregivers (5.3% vs. 3.5%).

Being a caregiver also was associated with at least one negative health behavior. The review of pharmacy claims showed that only 63.9% of caregivers were adherent to all of their medications compared to 67.8% of noncaregivers. Particularly important is the finding that 73.2% of noncaregivers took their antidepressant medications as prescribed at least 80% of the time, whereas only 66.6% of caregivers achieved this same rate of compliance. Through noncompliance with their own antidepressant medications, caregivers may affect their own health as well as their ability to provide quality, reliable care to those for whom they are caring.

## The Future: A Simpler Life for Caregivers

Those receiving the care think of caregivers as heroes. Others consider them to be the safety net of our healthcare system as estimates project the economic value of their unpaid contributions to be approximately $450 billion,[1] a figure that far exceeds national spending for home healthcare and nursing home care.[6] In either case, caregivers are vital to providing healthcare in the U.S., and their obligations will increase as the population in need of care grows. Because caregivers' actions enable individuals to live in community settings rather than institutions, they will become increasingly important as time goes on. After all, if we don't take care of our caregivers, they will soon be the ones needing care.

As the healthcare industry works toward solutions to simplify the lives of caregivers, we wonder what would happen if we began to look at this role differently. Perhaps technology, actionable data and advanced screening can help us better understand and meet the special needs of this group as they have in other areas of our industry. Express Scripts is committed to making this critical role easier.

## Footnotes


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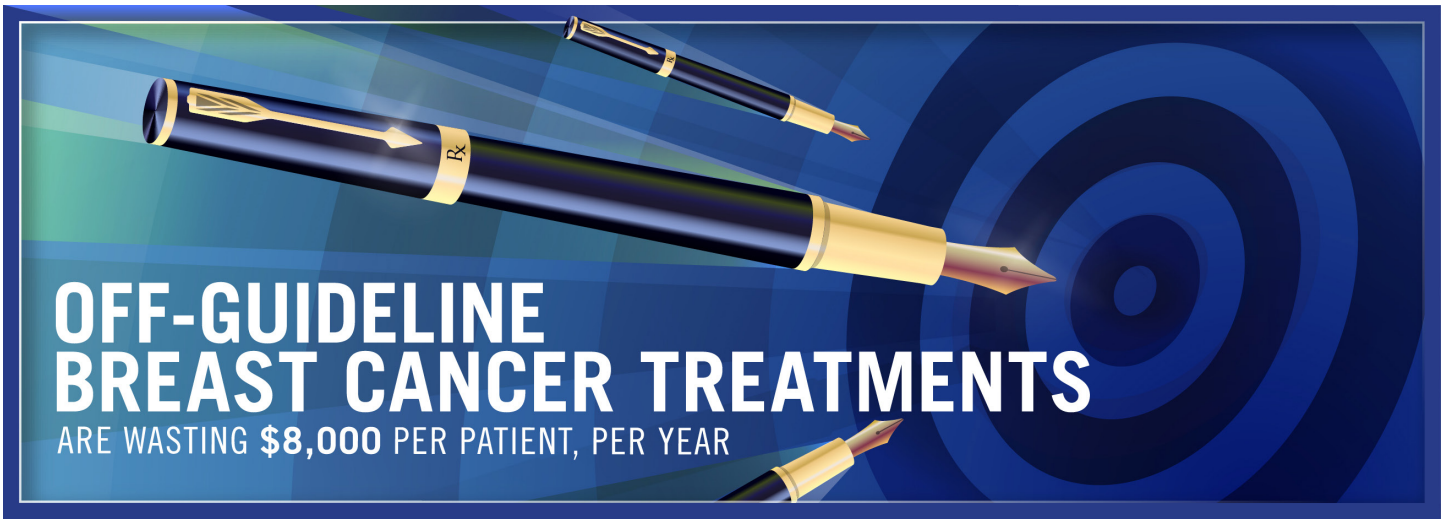
## SPECIALTY FEATURE ARTICLES

Timely, topical and in-depth analysis focusing on specialty issues particularly relevant to the population covered by employers, health maintenance organizations, health insurers, union-sponsored benefit plans and third-party administrators.

# THE COST-EFFECTIVENESS OF EVIDENCE-BASED BREAST CANCER TREATMENT GUIDELINES




Millions of Americas are fighting cancer every day, and clinicians are fighting right along with them. To help clinicians make the best treatment decisions, evidence-based guidelines have been developed and are continually refined as new solutions are discovered. Guidelines for many diseases, including cancer, direct treatment decisions and optimize outcomes based on impartial, systematic appraisal of research data about treatment success from both clinical trials and physician practices.[1] The costs of treatment are rarely considered in developing these guidelines.[2]

With the costs for cancer treatment continuing to rise, Express Scripts researchers examined the relationship between breast cancer drug therapy based on established guidelines and cancer treatment costs. The study revealed that more than 20% of certain breast cancer patients are not treated according to guidelines and that this off-guideline treatment is needlessly costing the healthcare system an average of almost $8,000 more per patient per year.

### Experts, Evidence and Effectiveness

Cancer-therapy guidelines help physicians manage complex treatments by suggesting appropriate clinical pathways that include combinations, sequences and doses of cancer medications. They also consider patient-related factors — including age and menopausal status — as well as disease-specific inputs such as cancer stage at diagnosis and the presence of biomarkers (biological indicators of specific conditions or processes). Although guidelines are intended to provide the highest-quality care, the most favorable outcomes and the least amount of waste, treatment costs have not historically been considered when guidelines are established.[2]

For cancer treatment, advocacy groups such as the National Comprehensive Cancer Network (NCCN) and the American Society of Clinical Oncology (ASCO) serve as important sources of unbiased, authoritative recommendations. Guidelines and clinical literature published by these organizations are updated continually with the goal of giving providers access to the best, most current scientific evidence on which to base their treatment decisions.[3]

## The Rising Cost of Cancer

Fighting cancer is a complex and expensive process. Research from the National Cancer Institute estimates the national direct cost of cancer at $124.6 billion annually. Breast cancer, colorectal cancer and lung cancer are among the most common cancer types in the U.S. and are also the most expensive to treat. In 2010, treatment costs reached $16.5 billion for breast cancer, $14.1 billion for colorectal cancer and $12.1 billion for lung cancer.[4]

Drug costs typically have been lower than the costs of other cancer treatment options (such as mastectomy for breast cancer), even in patients with more advanced stages of the disease.[5] However, many new drug therapies that target cancer tumors with specific genetic profiles are very expensive.[6] Internal analyses of Express Scripts data from 2012 found that two-thirds of the cancer-drug prescriptions that Express Scripts members filled in 2012 had an average cost of at least $1,000 per prescription. The average cost for some individual cancer drugs was as high as $33,000 per prescription.

As prescription drug costs for cancer treatment rise — the cost of some cancer medications can reach more than $200,000 per course of treatment[7] — affordability and cost-effectiveness of treatment become important issues for plan sponsors. Therefore, Express Scripts researchers sought to examine the relationship between on-guideline treatment for breast cancer — that is, whether breast cancer drug therapy was prescribed according to NCCN guidelines — and cancer treatment costs. We determined the proportion of patients who received on-guideline treatment and the proportion who received off-guideline treatment, and then compared the cost of cancer-related therapy for the two groups of patients.

## Breast Cancer Treatment Analysis

The study focused on chemotherapy for female breast cancer patients. One of the three most prevalent cancer types,[8] breast cancer has well-established therapies and treatment protocols. Recent estimates suggest that 90% of female breast cancer patients live at least five years after successful treatment.[9]

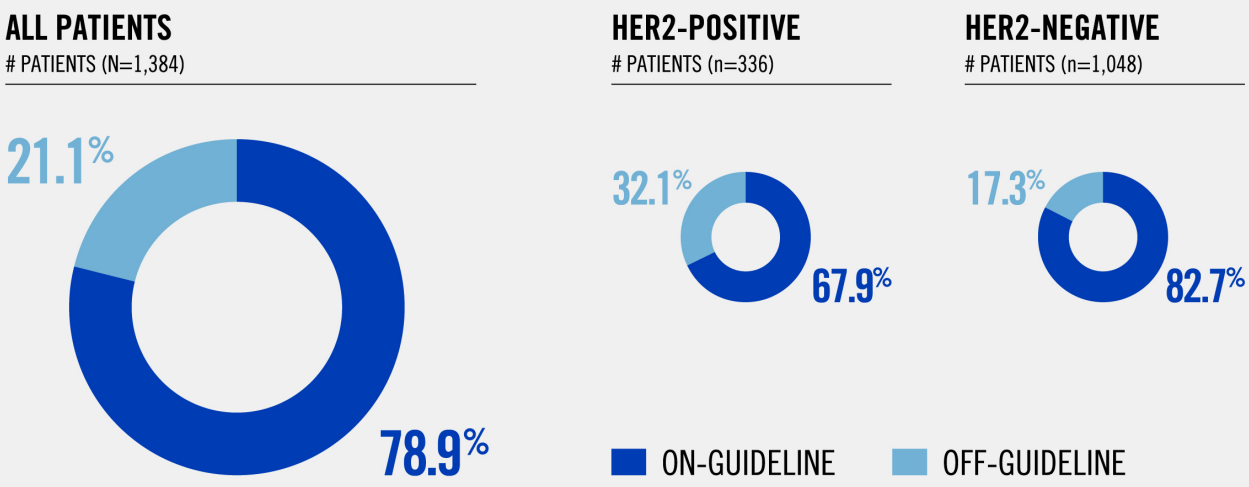
For breast cancer patients, the presence of biomarkers helps to guide treatment course. One such biomarker is human epidermal growth factor receptor 2 (HER2). HER2, when expressed in breast cancer, is associated with more aggressive disease.[10] Evidence suggests that targeted therapy with a medication called Herceptin® (trastuzumab), in combination with other similar cancer medications, decreases the risk of relapse for women with HER2-positive breast cancer.[11,12]

Using the Truven Health MarketScan® Commercial Claims Database,[13] the study evaluated integrated medical and pharmacy claims of 1,384 female breast cancer patients age 18 to 63. Newly diagnosed breast cancer patients who were being treated with injectable or oral solid prescription medications in 2009 and 2010 in any of several settings — hospitals, infusion centers, outpatient clinics, physicians' offices or their own homes — were identified and followed for one year. The observed cancer drug regimens were compared with 2012 NCCN recommendations to determine if patients were being treated according to evidence-based guidelines, and on this basis patients were assigned to either an on-guideline group or an off-guideline group. Guidelines from 2012 were used in order to account for treatment with newer therapies which may have been used in practice in 2009 or 2010, but had not yet made their way into evidence-based guidelines. The use of Herceptin or other HER2-targeted therapies was assumed to be an indication of a patient's HER2-positive status.

## Study Results: Potential Savings

The study revealed, first, that approximately one in five patients receiving chemotherapy for breast cancer was treated off-guideline and, second, that on-guideline treatment rates varied by HER2 biomarker status. Of the 1,384 patients in the study, 289 (21.1%) were treated off-guideline. Further, most patients receiving off-guideline therapy (62.6%) were HER2-negative, which means they did not test positive for the presence of the HER2 biomarker. (See figures below.)

### On-Guideline and Off-Guideline Care




Evaluating the relationship between guideline adherence and treatment costs showed that direct medical costs associated with treating breast cancer were 11.8% higher for patients who were being treated off-guideline. (See table below.) On average, each patient incurred an additional $7,959 in annual treatment costs when evidence-based guidelines were not followed. In addition, annual drug costs billed solely through the pharmacy benefit were slightly higher for patients whose treatment did not adhere to guidelines than for patients who were being treated according to guidelines ($4,203 vs. $4,145).

### Differences Between On-Guideline and Off-Guideline Treatment

| | MEDICAL COST | PHARMACY COST |
|---|---|---|
| Off-Guideline | $75,463 | $4,203 |
| On-Guideline | $67,504 | $4,145 |
| Difference Between On-Guideline and Off-Guideline Treatments | 11.8% | 1.4% |

## Summary

Although this research assumed that HER2 status was indicated accurately by the presence of prescriptions for HER2-targeted therapies, it is possible that HER2-negative patients were being treated with HER2-targeted therapies. This type of treatment would not have been appropriate for patients who were HER2-negative; therefore this assumption may have actually underestimated the rate of off-guideline treatment. In addition, because 2012 NCCN guidelines were used to compare treatments which occurred in 2009 or 2010, some misclassification of on- and off-guideline care may have occurred. Despite these limitations, however, the study still revealed that more than 20% of breast cancer patients were not treated according to evidence-based guidelines, with adherence to NCCN treatment recommendations being the determining factor. Further, patients who were treated according to the guidelines had lower breast cancer-related healthcare costs than did those treated off-guideline. Together, these results demonstrate that following evidence-based treatment guidelines can help lower healthcare costs among patients being treated with specialty cancer medications.

## Footnotes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## TOTAL TREND

The Commercial Total Trend measures the rate of change in total spend driven by utilization and unit cost for the population covered by employers, health maintenance organizations, health insurers, union-sponsored benefit plans and third-party administrators.

## COMPONENTS OF COMMERCIAL TREND, 2012

| | | TREND | | |
|---|---|---|---|---|
| | PMPY SPEND | UTILIZATION | UNIT COST | TOTAL |
| Traditional | $639.66 | 0.6% | -2.2% | -1.5% |
| Specialty | $207.19 | -0.4% | 18.7% | 18.4% |
| **TOTAL OVERALL** | **$846.85** | **0.6%** | **2.1%** | **2.7%** |

*January–December 2012 compared to same period in 2011*

### Key Insights

- Annual trend was 2.7%, driven by higher drug costs for specialty medications, which represent 24.5% of total PMPY spend. Compared to 2011, 2012 utilization was up 0.6% while unit costs increased 2.1%.
- The impact of specialty drugs on PMPY spend and overall trend is expected to continue. The Food and Drug Administration (FDA) approved 22 new specialty medications in 2012, some with price tags worth tens of thousands of dollars per month. For information on other newly approved drugs, see Brand Approvals.
- Traditional drugs had an annual decline in cost and total trend, due to the effect of the patent cliff — the wave of blockbuster patent expirations for drugs in many of the top therapy classes. Greater availability of generic alternatives and increased competition decreased costs to both payers and patients.

## TRADITIONAL THERAPY CLASS

The Commercial Traditional Therapy Class Trend section highlights key traditional therapy classes and explains factors driving trend for the population covered by employers, health maintenance organizations, health insurers, union-sponsored benefit plans and third-party administrators.

## TRADITIONAL TREND BY THERAPY CLASS

### Components of Trend for the Top 10 Commercial Traditional Therapy Classes, Ranked by PMPY Spend, 2012

| | | TREND | | |
|---|---|---|---|---|
| THERAPY CLASS | PMPY SPEND | UTILIZATION | UNIT COST | TOTAL |
| Diabetes | $79.24 | 1.5% | 9.5% | 11.0% |
| High Blood Cholesterol | $66.13 | -0.8% | -9.7% | -10.5% |
| High Blood Pressure/Heart Disease | $47.61 | 1.5% | -5.3% | -3.9% |
| Asthma | $43.42 | 1.5% | 0.4% | 2.0% |
| Ulcer Disease | $36.61 | 2.6% | -8.7% | -6.1% |
| Depression | $34.71 | 3.2% | -8.4% | -5.3% |
| Attention Disorders | $30.58 | 8.8% | 5.4% | 14.2% |
| Mental/Neurological Disorders | $27.12 | 0.1% | -12.1% | -12.1% |
| Pain | $23.71 | 0.7% | -5.7% | -5.0% |
| Infections | $17.46 | -2.9% | -13.8% | -16.7% |
| Other | $233.07 | -0.3% | 0.3% | 0.0% |
| **TOTAL TRADITIONAL** | **$639.66** | **0.6%** | **-2.2%** | **-1.5%** |

### Key Insights

- Utilization was up for 8 of the top 10 traditional therapy classes, while unit costs decreased in 7. This pattern generally reflects the impact of the patent cliff, in which many brand blockbuster medications lost patent protection, opening the market to generic competition and yielding lower drug costs.
- Diabetes medications had the highest traditional PMPY spend. Unit costs had the greatest impact on total trend, and were driven by cost increases among insulins including Humulin® R (Regular insulin human injection, USP (rDNA origin)) and Lantus® (insulin glargine).
- Utilization of medications used to treat depression increased 3.2%, but costs decreased 8.4%, leading to negative overall trend. Some of the increased use of antidepressants in recent years may

be due to the economic crisis and associated turmoil in the labor market.[1] The impact of the patent cliff on costs was seen as Lexapro® (escitalopram), the last remaining brand medication in the most commonly used class of antidepressants, lost patent protection and the original generic ended its exclusivity arrangement in 2012. Both increased competition and drove lower costs for the class.

- The largest increase in total spend was for medications used to treat attention disorders, impacted by both an 8.8% increase in utilization and a 5.4% increase in costs. There has been a notable increase in utilization of these drugs in adult patients[2] and treatment guidelines allow use in even younger patients than previously indicated.[3] Costs were affected by the shortage in 2012 of active ingredients contained in many of the medications in this class.[4]

## Footnotes


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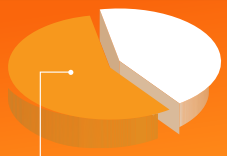
# DIABETES

## PHARMACY-RELATED WASTE

**37.9%** of patients are **NONADHERENT** to medication therapy[3]

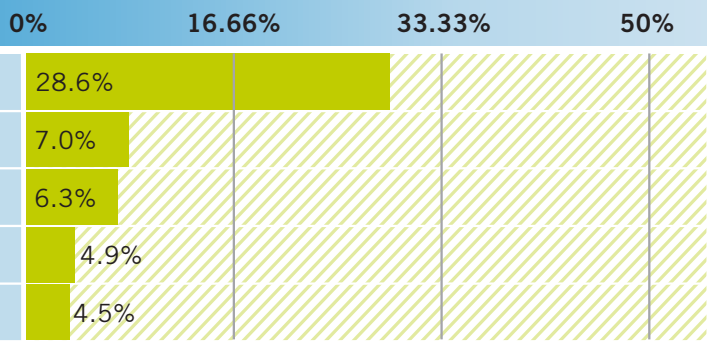
### SAVINGS OPPORTUNITY

| | |
|---|---|
| PHARMACY CHOICES | $22.28 |
| DRUG CHOICES | $22.84 |
| | $45.13 PMPY |



**57%** OF PMPY SPEND

## TOP DRUGS BY MARKET SHARE




## BY THE NUMBERS

| $79.24 | 0.961 | 5.9% | $82.48 |
|---|---|---|---|
| Cost PMPY | #Rx PMPY | Prevalence | Average Cost/Rx |

*Metrics are presented as an annualized estimate based on the previous calendar year.

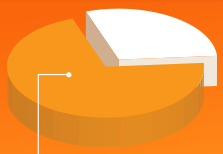
# HIGH BLOOD CHOLESTEROL

## PHARMACY-RELATED WASTE

**27.2%** of patients are **NONADHERENT** to medication therapy[3]

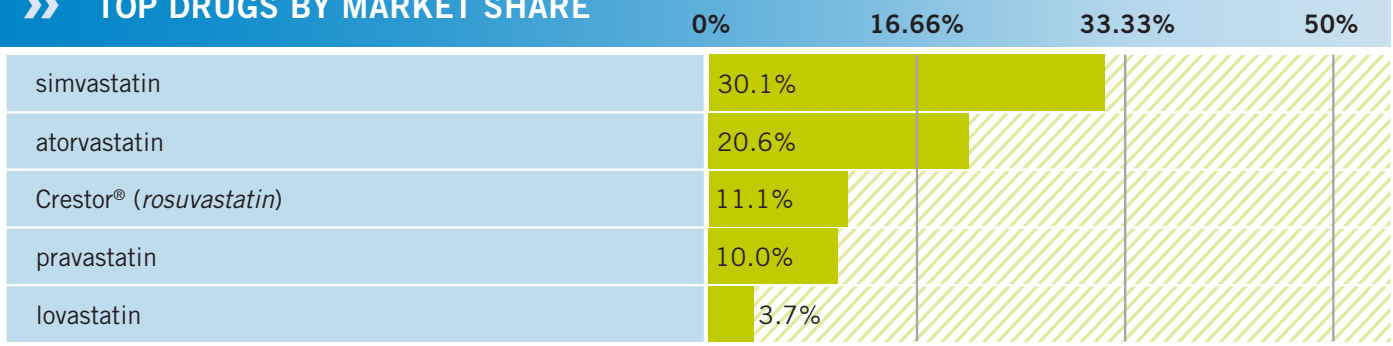
### SAVINGS OPPORTUNITY

| | |
|---|---|
| PHARMACY CHOICES | $16.02 |
| DRUG CHOICES | $30.79 |
| | $46.82 PMPY |



**70.8%** OF PMPY SPEND

## TOP DRUGS BY MARKET SHARE




## BY THE NUMBERS

| $66.13 | 1.382 | 13.4% | $47.87 |
|---|---|---|---|
| Cost PMPY | #Rx PMPY | Prevalence | Average Cost/Rx |

*Metrics are presented as an annualized estimate based on the previous calendar year.

# HIGH BLOOD PRESSURE/HEART DISEASE

## PHARMACY-RELATED WASTE

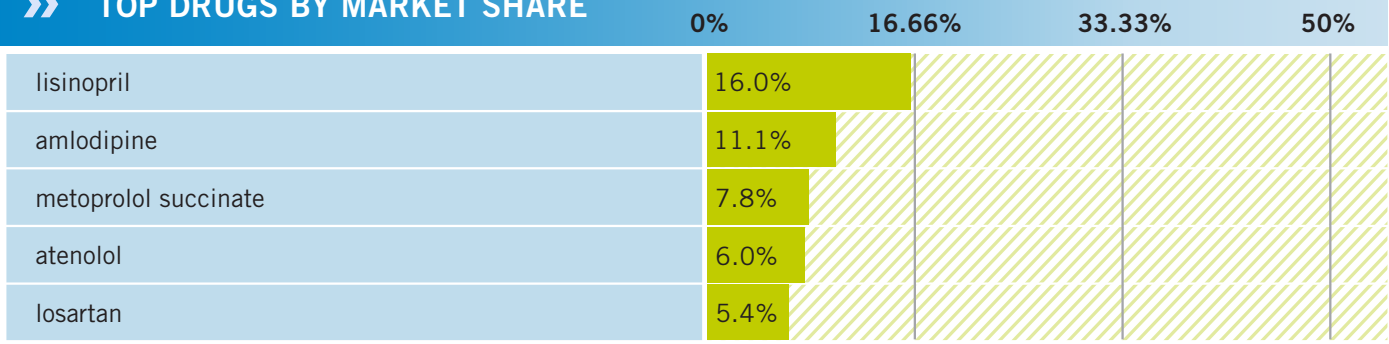
**28.1%** of patients are **NONADHERENT** to medication therapy[3]

### SAVINGS OPPORTUNITY

| | |
|---|---|
| PHARMACY CHOICES | $11.51 |
| DRUG CHOICES | $17.34 |
| | $28.85 PMPY |

**60.6%** OF PMPY SPEND

## TOP DRUGS BY MARKET SHARE




## BY THE NUMBERS

| $47.61 | 2.432 | 17.9% | $19.57 |
|---|---|---|---|
| Cost PMPY | #Rx PMPY | Prevalence | Average Cost/Rx |

*Metrics are presented as an annualized estimate based on the previous calendar year.

# ASTHMA

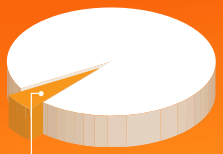
## PHARMACY-RELATED WASTE

80.2% pediatric
53.8% adult

of patients are **NONADHERENT** to medication therapy[3]

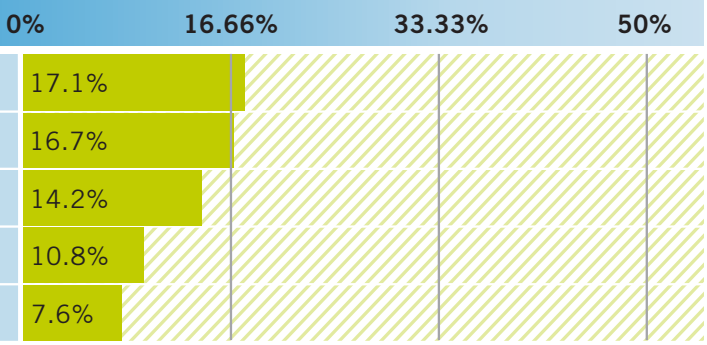
### SAVINGS OPPORTUNITY

| | |
|---|---|
| PHARMACY CHOICES | -$1.58 |
| DRUG CHOICES | $3.89 |
| | $2.32 PMPY |



5.3% OF PMPY SPEND

## TOP DRUGS BY MARKET SHARE




## BY THE NUMBERS

| $43.42 | 0.458 | 8.9% | $94.73 |
|---|---|---|---|
| Cost PMPY | #Rx PMPY | Prevalence | Average Cost/Rx |

*Metrics are presented as an annualized estimate based on the previous calendar year.

# ULCER DISEASE

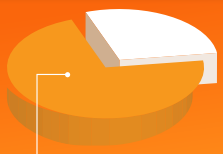
## PHARMACY-RELATED WASTE

A 10% decrease in proton pump inhibitor adherence among NSAID users is associated with a 6% increase in the risk of gastrointestinal complications.

Jonasson C, Hatlebakk JG, Lundell L, et al. Association between adherence to concomitant proton pump inhibitor therapy in current NSAID users and upper gastrointestinal complications. *Eur J Gastroenterol Hepatol*. 2013; 25(5): 531-538.

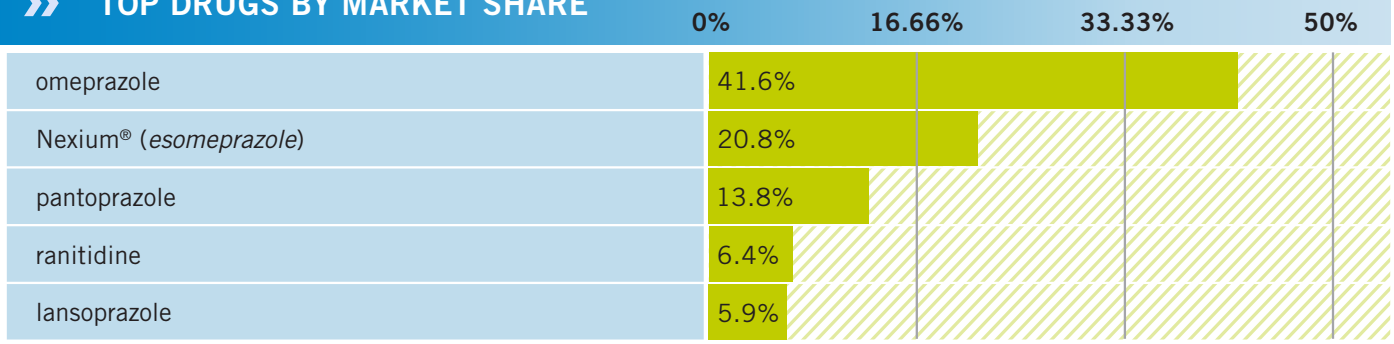
### SAVINGS OPPORTUNITY

| | |
|---|---|
| PHARMACY CHOICES | $10.21 |
| DRUG CHOICES | $15.92 |
| | $26.13 PMPY |



71.4% OF PMPY SPEND

## TOP DRUGS BY MARKET SHARE




## BY THE NUMBERS

| $36.61 | 0.633 | 8.8% | $57.85 |
|---|---|---|---|
| Cost PMPY | #Rx PMPY | Prevalence | Average Cost/Rx |

*Metrics are presented as an annualized estimate based on the previous calendar year.

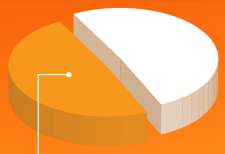
# DEPRESSION

## PHARMACY-RELATED WASTE

**39.9%** of patients are **NONADHERENT** to medication therapy[3]

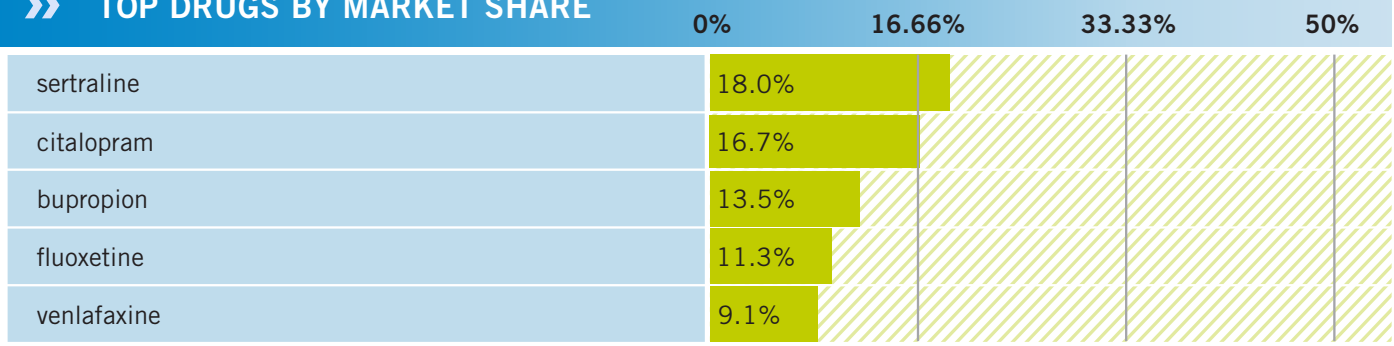
### SAVINGS OPPORTUNITY

| | |
|---|---|
| PHARMACY CHOICES | $9.07 |
| DRUG CHOICES | $7.93 |
| | $17.00 PMPY |



**49%** OF PMPY SPEND

## TOP DRUGS BY MARKET SHARE




## BY THE NUMBERS

| $34.71 | 0.903 | 10.5% | $38.44 |
|---|---|---|---|
| Cost PMPY | #Rx PMPY | Prevalence | Average Cost/Rx |

*Metrics are presented as an annualized estimate based on the previous calendar year.

# ATTENTION DISORDERS

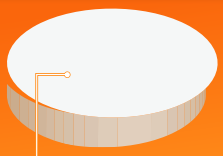
## PHARMACY-RELATED WASTE

Adherence, persistence and rates of switching are significantly lower in patients using long-acting stimulants to treat attention disorders compared to short-acting formulations.

Palli SR, Kamble PS, Chen H, Aparasu RR. Persistence of stimulants in children and adolescents with attention-deficit/hyperactivity disorder. *J Child Adolesc Psychopharmacol*. 2012; 22(2): 139-148.

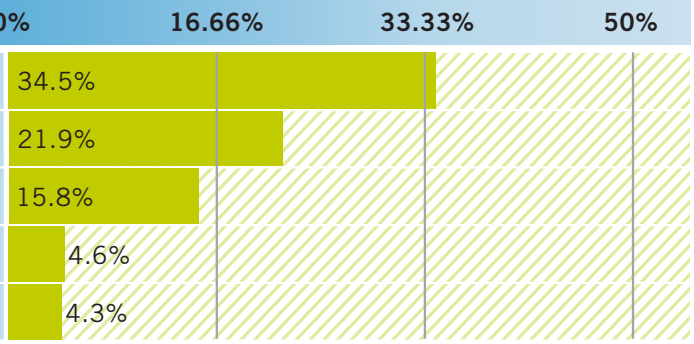
### SAVINGS OPPORTUNITY

| | |
|---|---|
| PHARMACY CHOICES | -$15.06 |
| DRUG CHOICES | $0.09 |
| | -$14.97 PMPY |



0% OF PMPY SPEND

## TOP DRUGS BY MARKET SHARE




## BY THE NUMBERS

| $30.58 | 0.205 | 2.6% | $148.84 |
|---|---|---|---|
| Cost PMPY | #Rx PMPY | Prevalence | Average Cost/Rx |

*Metrics are presented as an annualized estimate based on the previous calendar year.

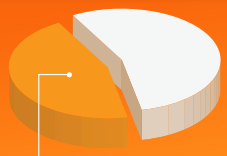
# MENTAL/NEUROLOGICAL DISORDERS

## PHARMACY-RELATED WASTE

**41.7%** of patients are **NONADHERENT** to medication therapy[3]

### SAVINGS OPPORTUNITY

| | |
|---|---|
| PHARMACY CHOICES | $7.34 |
| DRUG CHOICES | $4.86 |
| | $12.20 PMPY |



**45%** OF PMPY SPEND

## TOP DRUGS BY MARKET SHARE

| | 0% – 16.66% – 33.33% – 50% |
|---|---|
| donepezil | 15.0% |
| Abilify® (*aripiprazole*) | 12.3% |
| quetiapine | 11.0% |
| Namenda® (*memantine*) | 10.7% |
| risperidone | 10.7% |

## BY THE NUMBERS

| $27.12 | 0.159 | 1.9% | $170.20 |
|---|---|---|---|
| Cost PMPY | #Rx PMPY | Prevalence | Average Cost/Rx |

*Metrics are presented as an annualized estimate based on the previous calendar year.

# PAIN

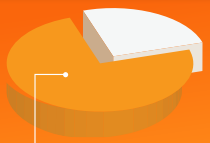
## PHARMACY-RELATED WASTE

Nonadherence in chronic pain patients is more closely related to concerns about medication and withdrawal than to level of pain or frequency of side-effects.

Broekmans S, Vanderschueren S. Concerns about medication and medication adherence in patients with chronic pain recruited from general practice. *Evid Based Nurs*. 2012; 15(2): 42-43.

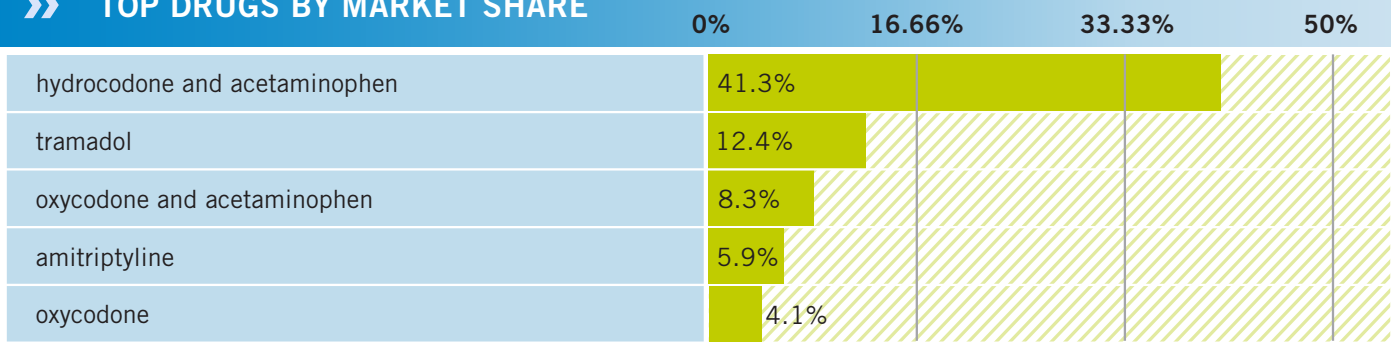
### SAVINGS OPPORTUNITY

| | |
|---|---|
| PHARMACY CHOICES | $4.11 |
| DRUG CHOICES | $13.54 |
| | $17.65 PMPY |



= 74.5% OF PMPY SPEND

## TOP DRUGS BY MARKET SHARE




## BY THE NUMBERS

| $23.71 | 0.745 | 18.2% | $31.83 |
|---|---|---|---|
| Cost PMPY | #Rx PMPY | Prevalence | Average Cost/Rx |

*Metrics are presented as an annualized estimate based on the previous calendar year.

# INFECTIONS

## PHARMACY-RELATED WASTE

Adherence to twice-daily regimens of amoxicillin/clavulanic acid therapy is significantly higher than adherence to thrice-daily dosing regimens.

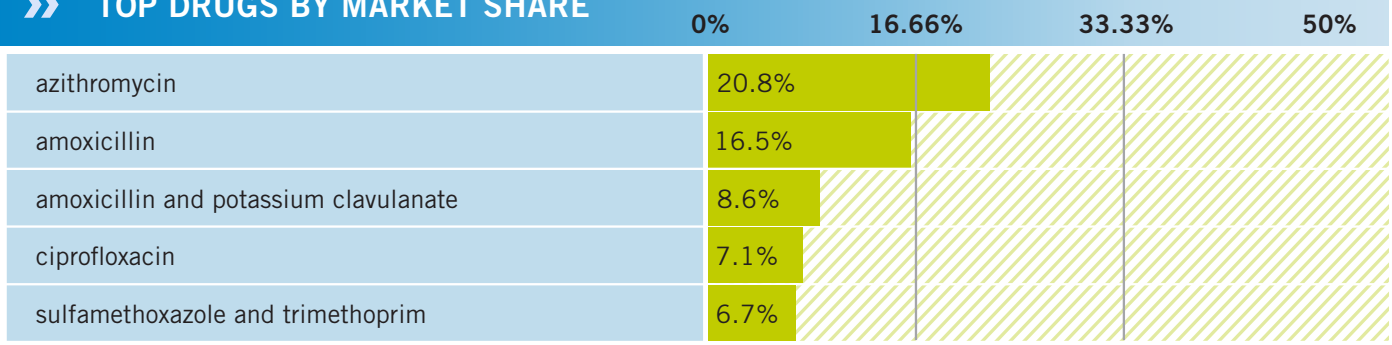
Llor C, Bayona C, Hernandez S, et al. Comparison of adherence between twice- and thrice-daily regimens of amoxicillin/clavulanic acid. *Respirology*. 2012; 17(4): 687-692.

### SAVINGS OPPORTUNITY

| | |
|---|---|
| PHARMACY CHOICES | $0.79 |
| DRUG CHOICES | $8.12 |
| | $8.92 PMPY |

= 51.1% OF PMPY SPEND

## TOP DRUGS BY MARKET SHARE




## BY THE NUMBERS

| $17.46 | 0.881 | 37.7% | $19.80 |
|---|---|---|---|
| Cost PMPY | #Rx PMPY | Prevalence | Average Cost/Rx |

*Metrics are presented as an annualized estimate based on the previous calendar year.

## SPECIALTY THERAPY CLASS

The Commercial Specialty Therapy Class Trend section highlights key specialty therapy classes and explains factors driving trend for the population covered by employers, health maintenance organizations, health insurers, union-sponsored benefit plans and third-party administrators.

## SPECIALTY TREND BY THERAPY CLASS

### Components of Trend for the Top 10 Commercial Specialty Therapy Classes, Ranked by PMPY Spend, 2012

| | | TREND | | |
|---|---|---|---|---|
| THERAPY CLASS | PMPY SPEND | UTILIZATION | UNIT COST | TOTAL |
| Inflammatory Conditions | $50.62 | 9.0% | 14.0% | 23.0% |
| Multiple Sclerosis | $37.98 | 0.5% | 17.3% | 17.8% |
| Cancer | $31.98 | 3.4% | 22.3% | 25.8% |
| HIV | $20.78 | -2.1% | 11.1% | 9.0% |
| Hepatitis C | $7.82 | 28.9% | 4.8% | 33.7% |
| Growth Deficiency | $7.41 | 1.7% | 7.7% | 9.5% |
| Anticoagulant | $6.74 | 1.7% | 0.3% | 2.1% |
| Pulmonary Hypertension | $5.71 | 5.1% | 6.2% | 11.3% |
| Respiratory Conditions | $5.56 | 1.5% | 25.7% | 27.2% |
| Transplant | $4.92 | 2.2% | -6.9% | -4.7% |
| Other | $27.68 | -24.9% | 43.7% | 18.8% |
| **TOTAL SPECIALTY** | **$207.19** | **-0.4%** | **18.7%** | **18.4%** |

### Key Insights

- Inflammatory conditions such as rheumatoid arthritis (RA) continued to have the highest PMPY spend, driven by a 9.0% increase in utilization and a 14.0% increase in costs, for a total trend of 23.0% in 2012. A new RA drug, Xeljanz® (tofacitinib), is the first oral disease modifying medication to be approved in this therapy class. Taking it is more convenient than using injectable medications, and the drug is associated with significant improvement in symptoms.[1] Xeljanz is likely to attract new and existing medication users away from other drugs. Some of the cost increases for older, injectable treatments in this class may be explained by concerns over future declining market share as oral medications, such as Xeljanz, become available.

- Utilization and costs for cancer medications increased 3.4% and 22.3%, respectively. Much of the increase in costs is driven by new drugs developed to treat unique genetic or proteomic profiles, a trend that has increased in recent years. Developing targeted medications requires additional research and incurs additional costs; but costs also increase as more patients initiate therapy on these newer, more-expensive therapies rather than trying older oncology medications as first-line therapies.
- Although utilization of HIV medications decreased 2.1%, 2012 costs increased by 11.1%, leading to an overall 9.0% increase in total spend. The patterns of change reflect switches from older, multi-pill regimens, some of which are available as generics, to more expensive combination therapies such as Atripla® (efavirenz, tenofovir, emtricitabine) and Truvada® (tenofovir, emtricitabine), which contain multiple active ingredients in a single pill.
- Hepatitis C continues to lead total trend for specialty drugs, driven almost entirely by increased utilization of the two new drugs introduced in May 2011, Incivek® (telaprevir) and Victrelis® (boceprevir).

## Footnotes

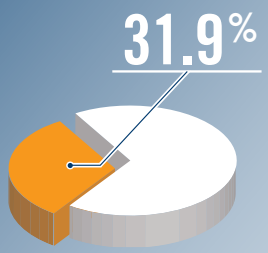
1. Van Vollenhoven RF, Fleischmann R, Cohen S, et al. Tofacitinib or adalimumab versus placebo in rheumatoid arthritis. *N Eng J Med*. 2012; 367(6): 508-519.

# INFLAMMATORY CONDITIONS

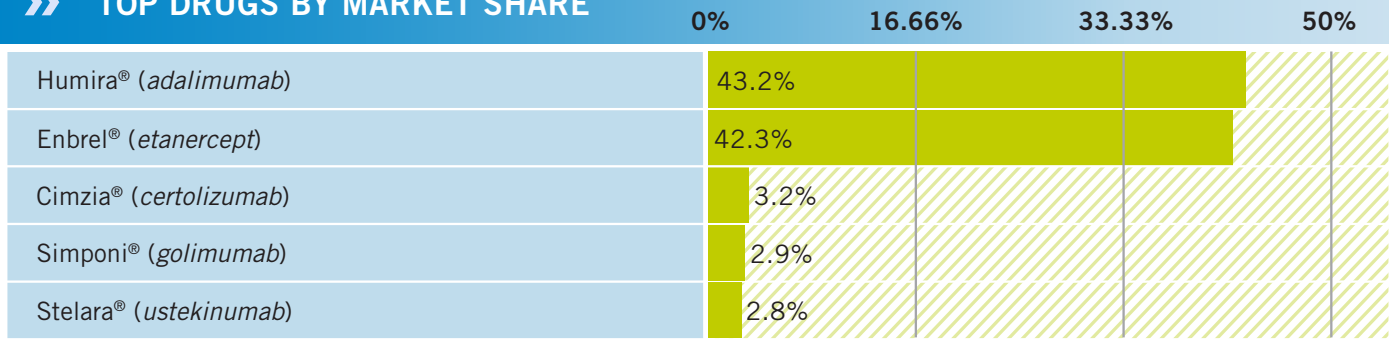
## PHARMACY-RELATED WASTE

**40.4%** of patients are **NONADHERENT** to medication therapy[3]

**Spend** in Medical Benefit




## TOP DRUGS BY MARKET SHARE




## BY THE NUMBERS

| $50.62 | 0.023 | 0.27% | $2,212.73 |
|---|---|---|---|
| PMPY Spend | #Rx PMPY | Prevalence | Average Cost/Rx |

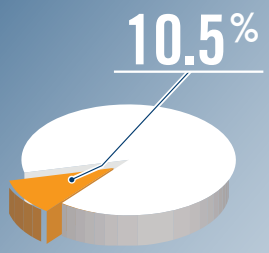
*Metrics are presented as an annualized estimate based on the previous calendar year.

# MUTIPLE SCLEROSIS

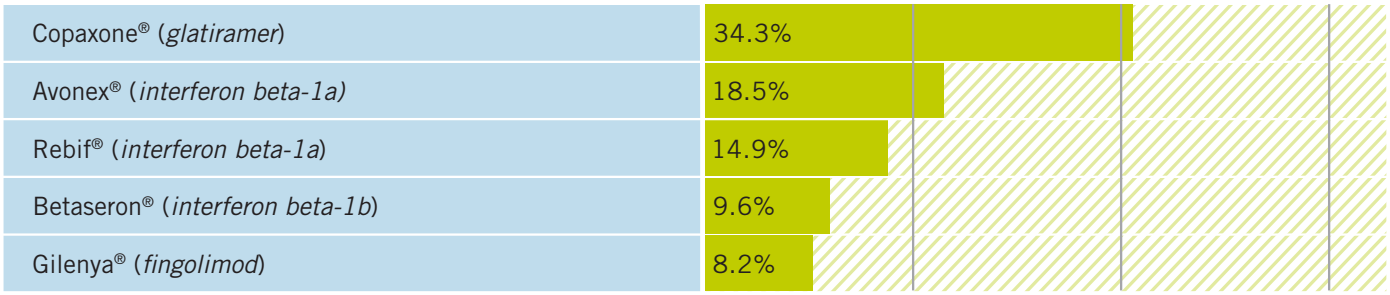
## PHARMACY-RELATED WASTE

**26.3%** of patients are **NONADHERENT** to medication therapy[3]

**Spend** in Medical Benefit




## TOP DRUGS BY MARKET SHARE




## BY THE NUMBERS

| $37.98 | 0.011 | 0.10% | $3,583.85 |
|---|---|---|---|
| PMPY Spend | #Rx PMPY | Prevalence | Average Cost/Rx |

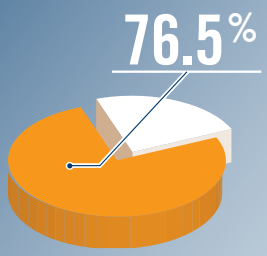
*Metrics are presented as an annualized estimate based on the previous calendar year.

## CANCER

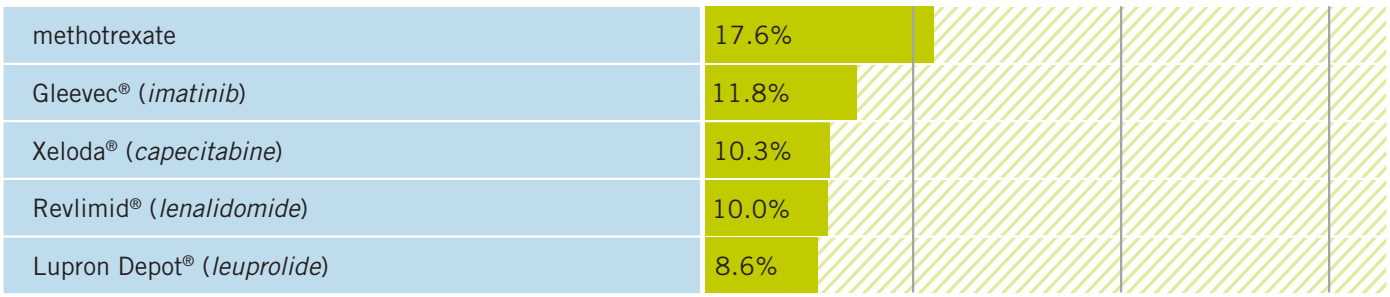
### PHARMACY-RELATED WASTE

**40.9%** of patients are **NONADHERENT** to medication therapy[3]

**Spend** in Medical Benefit




### TOP DRUGS BY MARKET SHARE




### BY THE NUMBERS

| $31.98 | 0.009 | 0.17% | $3,682.32 |
|---|---|---|---|
| PMPY Spend | #Rx PMPY | Prevalence | Average Cost/Rx |

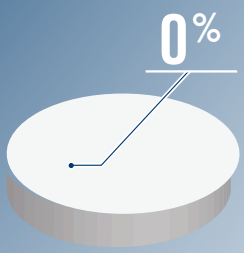
*Metrics are presented as an annualized estimate based on the previous calendar year.

## HIV

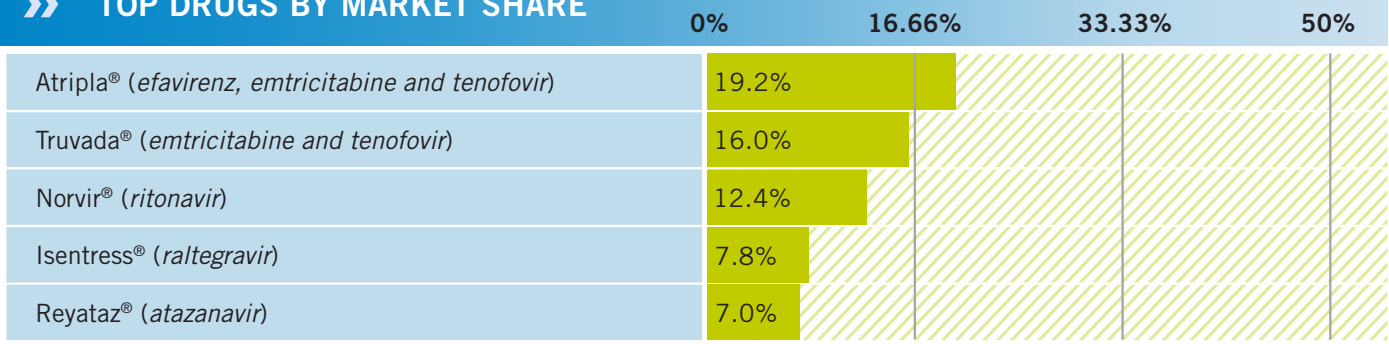
### PHARMACY-RELATED WASTE

**22.5%** of patients are **NONADHERENT** to medication therapy[3]

**Spend** in Medical Benefit




### TOP DRUGS BY MARKET SHARE




### BY THE NUMBERS

| $20.78 | 0.022 | 0.13% | $947.56 |
|---|---|---|---|
| PMPY Spend | #Rx PMPY | Prevalence | Average Cost/Rx |

*Metrics are presented as an annualized estimate based on the previous calendar year.

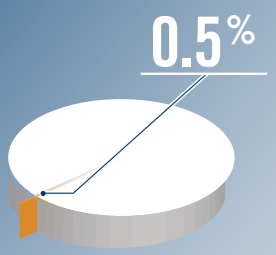
# HEPATITIS C

## PHARMACY-RELATED WASTE

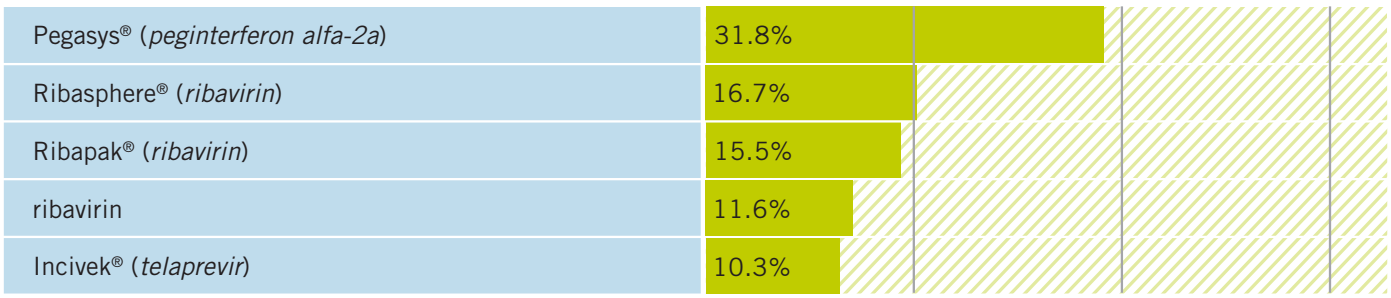
Sustained virologic response in hepatitis C patients decreases when patients are less than 60% adherent to dosing regimens of boceprevir.

Gordon SC, Lawitz EJ, Bacon BR, et al. Adherence to assigned dosing regimen and sustained virologic response among hepatitis c genotype 1 treatment-naive and peg/ribavirin treatment failures treated with boceprevir plus peginterferon alfa-2b/ribavirin. *J Hepatol* 2011;54 (Supplement 1):S173–S174.

**Spend** in Medical Benefit




## TOP DRUGS BY MARKET SHARE




## BY THE NUMBERS

| $7.82 | 0.002 | 0.02% | $3,284.27 |
|---|---|---|---|
| PMPY Spend | #Rx PMPY | Prevalence | Average Cost/Rx |

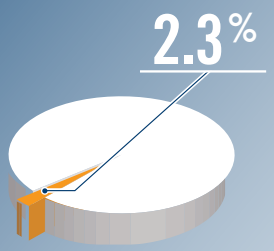
*Metrics are presented as an annualized estimate based on the previous calendar year.

## GROWTH DEFICIENCY

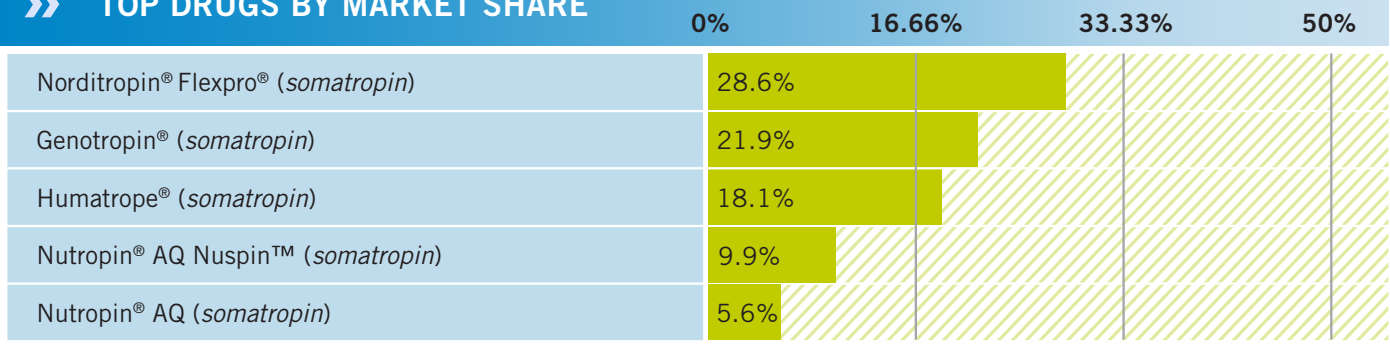
### PHARMACY-RELATED WASTE

**36.2%** of patients are **NONADHERENT** to medication therapy[3]

**Spend** in Medical Benefit




### TOP DRUGS BY MARKET SHARE




### BY THE NUMBERS

| $7.41 | 0.002 | 0.03% | $3,146.71 |
|---|---|---|---|
| PMPY Spend | #Rx PMPY | Prevalence | Average Cost/Rx |

*Metrics are presented as an annualized estimate based on the previous calendar year.

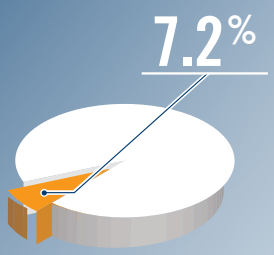
# ANTICOAGULANTS

## PHARMACY-RELATED WASTE

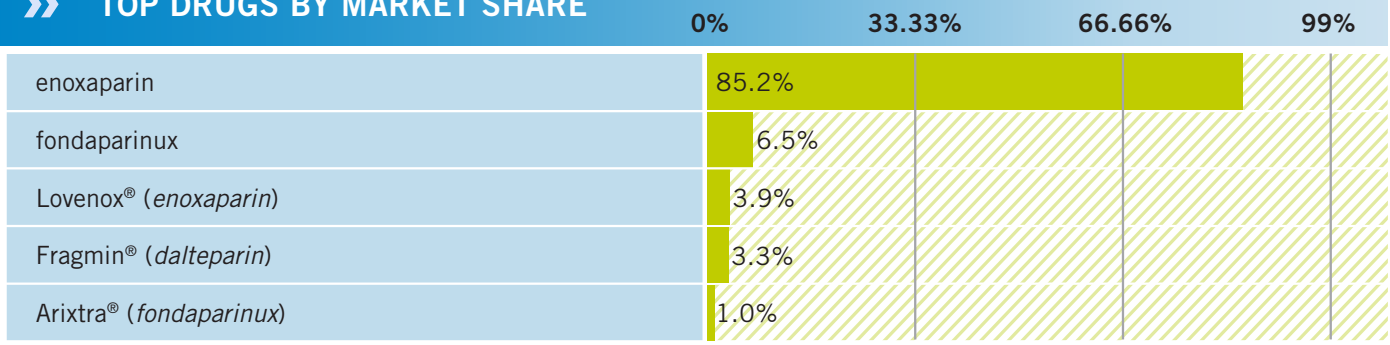
Noncompliant high-risk warfarin patients have a 3 times greater risk of recurrence of venous thromboembolism than patients who are compliant.

Chen SY, Wu N, Gulseth M, et al. One-year adherence to warfarin treatment for venous thromboembolism in high-risk patients and its association with long-term risk of recurrent events. *J Manag Care Pharm*. 2013; 19(4): 291-301.

**Spend** in Medical Benefit




## TOP DRUGS BY MARKET SHARE




## BY THE NUMBERS

| $6.74 | 0.007 | 0.33% | $985.18 |
|---|---|---|---|
| PMPY Spend | #Rx PMPY | Prevalence | Average Cost/Rx |

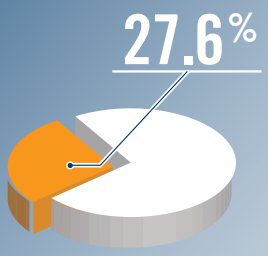
*Metrics are presented as an annualized estimate based on the previous calendar year.

# PULMONARY HYPERTENSION

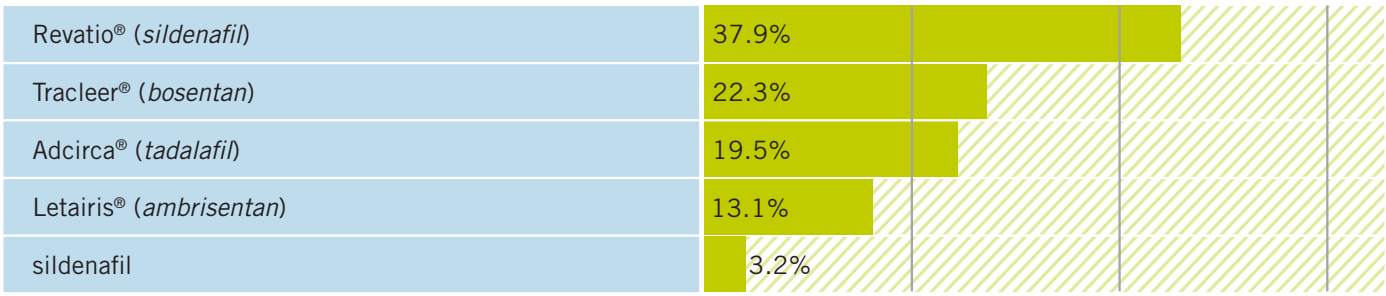
## PHARMACY-RELATED WASTE

**24.7%** of patients are **NONADHERENT** to medication therapy[3]

**Spend** in Medical Benefit




## TOP DRUGS BY MARKET SHARE




## BY THE NUMBERS

| $5.71 | 0.002 | 0.01% | $3,748.39 |
|---|---|---|---|
| PMPY Spend | #Rx PMPY | Prevalence | Average Cost/Rx |

*Metrics are presented as an annualized estimate based on the previous calendar year.

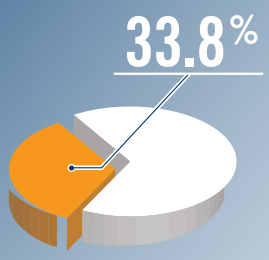
# RESPIRATORY CONDITIONS

## PHARMACY-RELATED WASTE

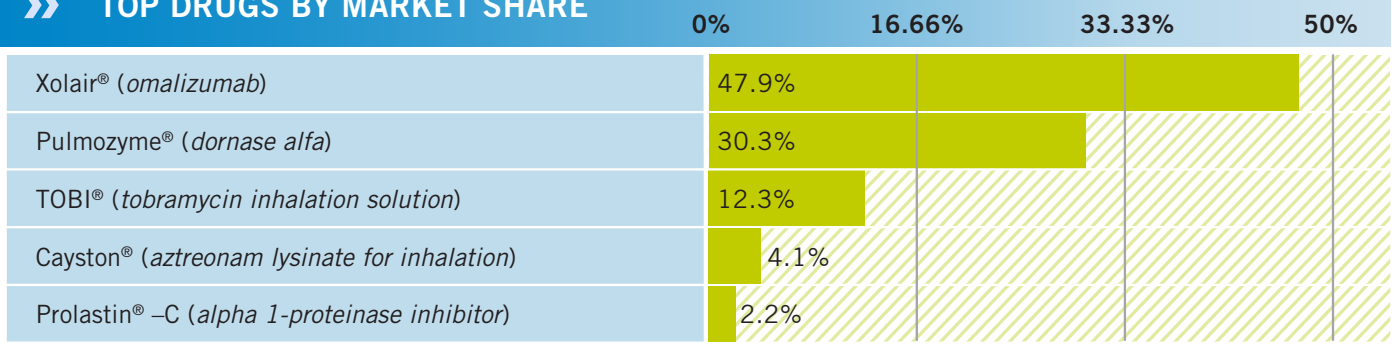
The incidence rate of pulmonary exacerbations in nonadherent patients taking medications such as dornase alfa and tobramycin was 2.43 times that of patients who were adherent to their medications.

Eakin MN, Bilderback A, Boyle MP, et al. Longitudinal association between medication adherence and lung health in people with cystic fibrosis. *J Cyst Fibros*. 2011; 10(4): 259-264.

**Spend** in Medical Benefit




## TOP DRUGS BY MARKET SHARE




## BY THE NUMBERS

| $5.56 | 0.002 | 0.02% | $3,344.83 |
|---|---|---|---|
| PMPY Spend | #Rx PMPY | Prevalence | Average Cost/Rx |

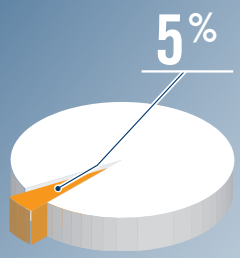
*Metrics are presented as an annualized estimate based on the previous calendar year.

# TRANSPLANT

## PHARMACY-RELATED WASTE

**32.7%** of patients are **NONADHERENT** to medication therapy[3]

**Spend** in Medical Benefit




## TOP DRUGS BY MARKET SHARE

| | 0% — 16.66% — 33.33% — 50% |
|---|---|
| mycophenolate | 33.3% |
| tacrolimus | 24.6% |
| Prograf® (*tacrolimus*) | 11.4% |
| Myfortic® (*mycophenolate*) | 6.7% |
| Rapamune® (*sirolimus*) | 5.2% |

## BY THE NUMBERS

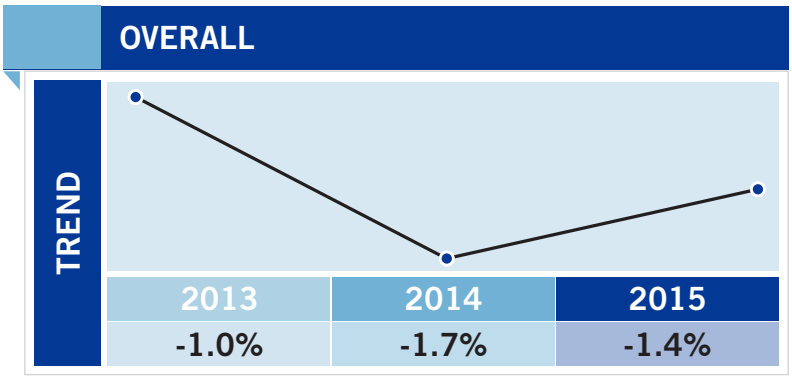
| $4.92 | 0.017 | 0.13% | $286.34 |
|---|---|---|---|
| PMPY Spend | #Rx PMPY | Prevalence | Average Cost/Rx |

*Metrics are presented as an annualized estimate based on the previous calendar year.

## TRADITIONAL THERAPY CLASS FORECAST

The Traditional Therapy Class Forecast predicts future trend based on research about current and past cost and utilization patterns for traditional therapy classes. Our methodology analyzes three years of prescription data, demographics, and changes in guidelines and medication availability.

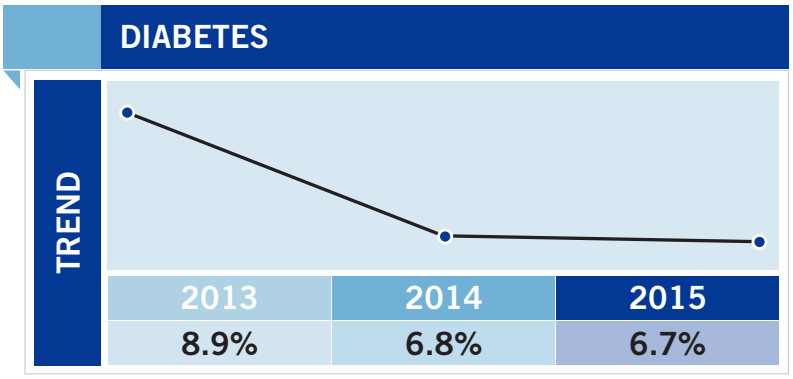
## OVERALL TRADITIONAL FORECAST




### Drivers

- Spend for traditional drugs will continue to decline year over year through at least 2015, primarily as a result of declines in drug costs. Utilization is expected to remain relatively stable.
- Additional savings opportunities still loom on the horizon. For example, in 2013, drugs whose annual sales total $14 billion will lose patent protection, including some frequently utilized medications such as Lidoderm® (lidocaine) and Cymbalta® (duloxetine).
- Other patent expirations in 2014 and 2015 will further drive down drug costs by increasing the availability of generic medications in the most highly utilized therapy classes.

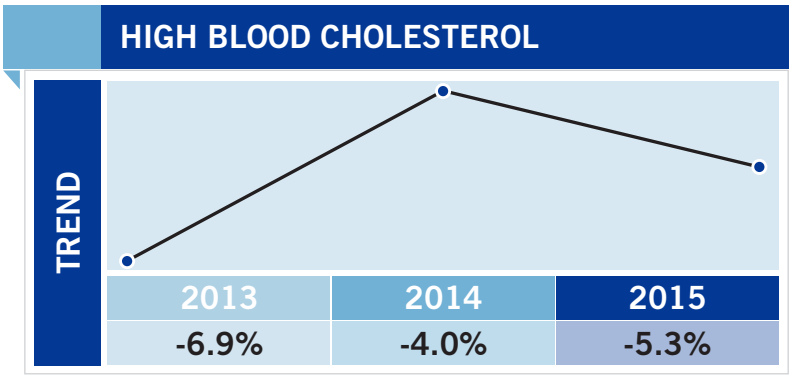
## DIABETES




### Drivers

- Diagnosis and treatment of type 2 diabetes continue to increase utilization in this class, driven by the large number of overweight and obese individuals in the U.S.
- Brand inflation of the long-acting insulins and newer drugs for treating type 2 diabetes will result in an increase in unit cost trend.
- A new class of medications, sodium-dependent glucose cotransporter 2 (SGLT-2) inhibitors, is expected to gain market share, as these medications are associated with weight reduction.
- Food and Drug Administration (FDA) approval of competitors to existing dipeptidyl peptidase-4 (DPP-4) inhibitors and glucagon-like peptide-1 (GLP-1) agonists and to the SGLT-2 inhibitors will contribute to brand inflation.

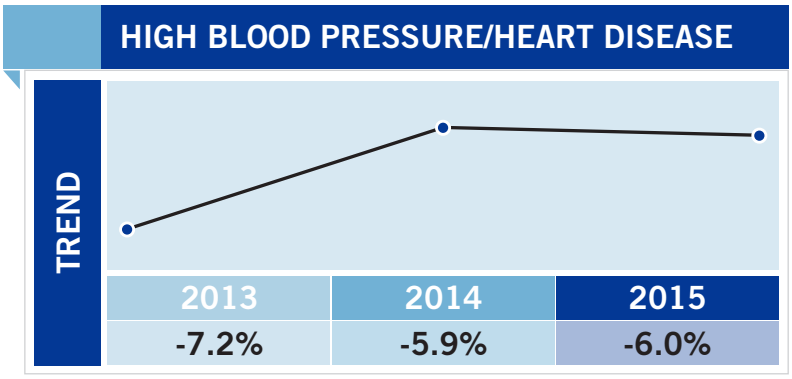
## HIGH BLOOD CHOLESTEROL




### Drivers

- Lipitor's® (atorvastatin) patent expiration (December 2011) and the expiration of Ranbaxy's generic exclusivity arrangement are primary drivers of a decrease in year-over-year cost in this therapy class.
- Tricor's® (fenofibrate) patent expiration (November 2012) will contribute to lower costs for the class in 2013.
- New cholesterol guidelines scheduled for release in late 2013 are expected to increase awareness and treatment. But the guidelines' release is not expected to affect overall trend, given major cost decreases in this therapy class.

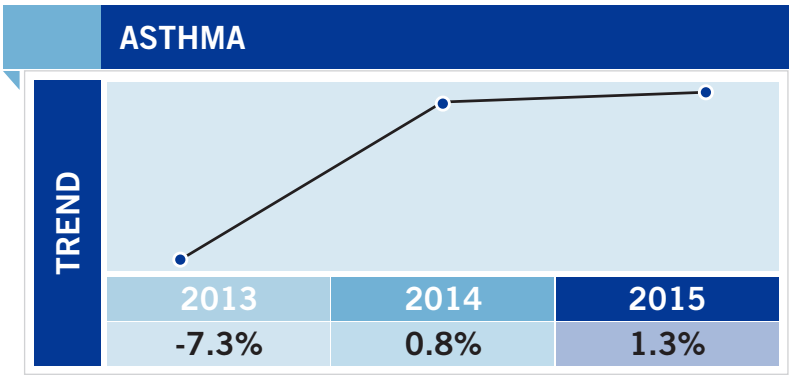
## HIGH BLOOD PRESSSURE/HEART DISEASE




### Drivers

- The availability of generic medications across subclasses and the limited pipeline of new brand drugs will contribute to decreases in unit costs.
- The angiotensin receptor blocker (ARB)-specific "patent cliff" will keep trend negative in 2013 and 2014.
- New guidelines to be released in the spring or summer of 2013 are expected to increase utilization, which will slow the deceleration of costs.

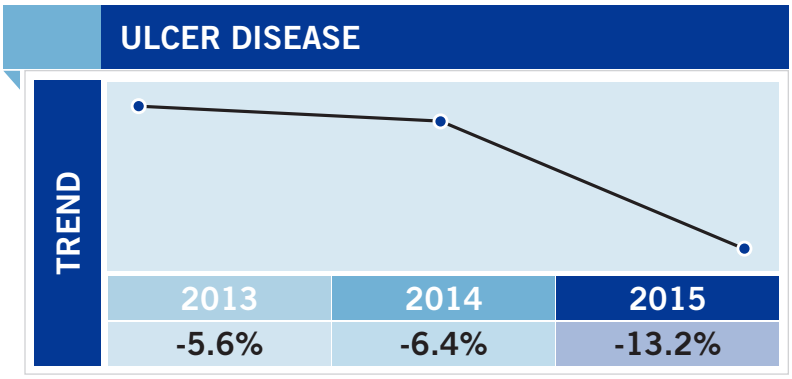
## ASTHMA




### Drivers

- Generic formulations of Singulair® (montelukast) will keep trend negative in 2013.
- With barriers to interchangeable generics and direct-to-consumer advertisements played on heavy rotation, Advair® Diskus (fluticasone propionate and salmeterol) will drive positive trend after 2013.
- Continuity of branded inhalers will contribute to positive trend, impacted by regulations banning chlorofluorocarbons (CFC), which were used in older inhalers. The regulations not only resulted in the market withdrawal of generic albuterol inhalers in late 2008, but also contributed to a delay in generics to other inhalers whose patents have expired.
- New long-acting inhaled drugs for treating chronic obstructive pulmonary disease (COPD) will compete on the market over the next few years. These once-to-twice-daily products will offer treatment options for patients with COPD, but at a cost.

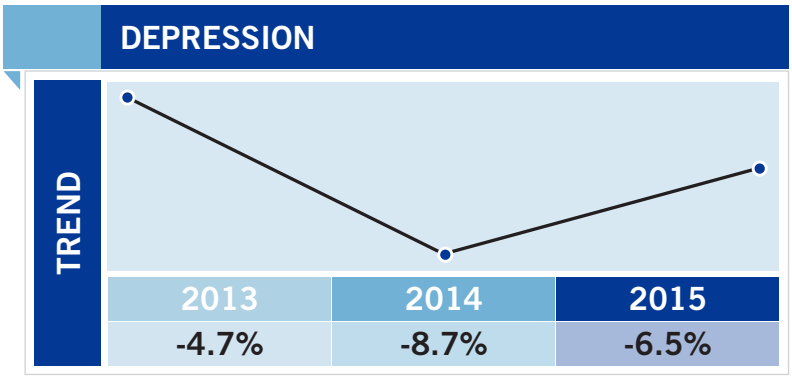
## ULCER DISEASE




### Drivers

- A lack of pipeline activity, heavy genericization and over-the-counter use in this class are contributing to the expected sharp decline in year-over-year costs.
- Patent expirations for two remaining high-market-share brands — Aciphex® (rabeprazole), whose patent will expire in November 2013, and Nexium® (esomeprazole), whose patent will expire in May 2014 — will further decrease costs.

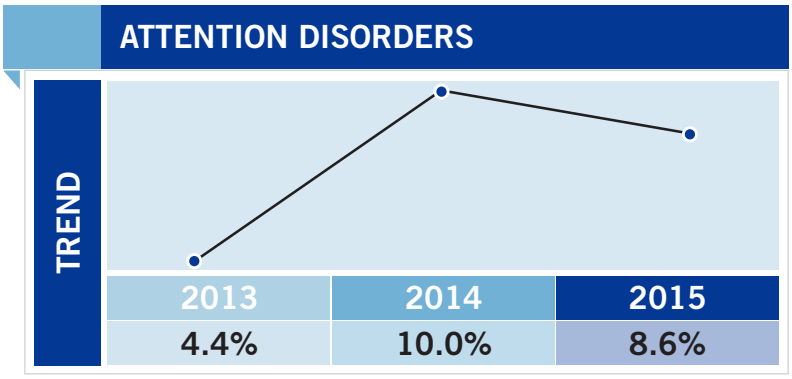
## DEPRESSION




### Drivers

- The antidepressant market is expected to stabilize somewhat after the patent expiration for Lexapro® (escitalopram), which will result in the deceleration of year-over-year cost decreases in 2013. However, the class has many generics already, with blockbuster Cymbalta® (duloxetine), a serotonin-noripenephrine reuptake inhibitor (SNRI), expected to lose patent protection in 2013.
- New SNRIs such as levomilnacipran and edivoxetine are promising, but their impact will be limited by existing competition in the class.

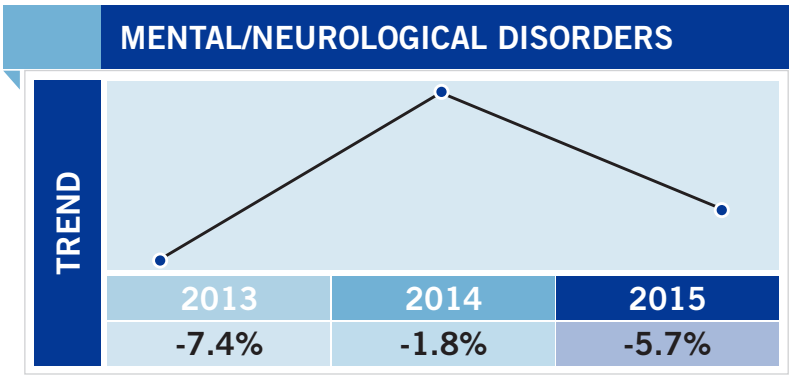
## ATTENTION DISORDERS




### Drivers

- Stabilization after the 2012 shortage of generic products is contributing to the deceleration of drug cost increases in 2013.
- Competition among generic formulations of many highly utilized medications is also expected to dampen cost increases.
- Trend is expected to accelerate in 2014 as utilization continues to increase among young and middle-age adults, and the Drug Enforcement Administration enforces supply limitations of key ingredients.

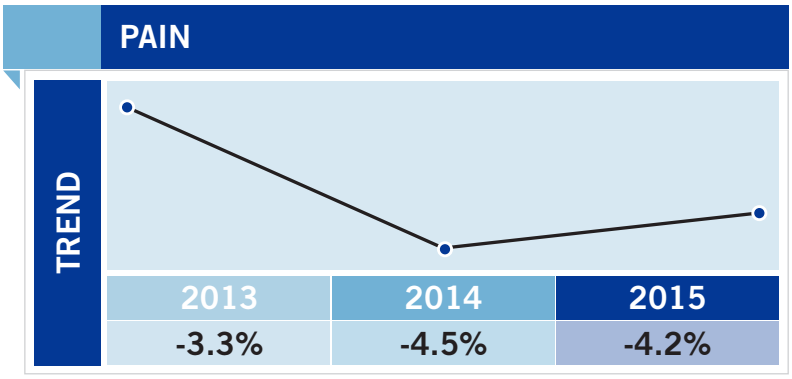
## MENTAL/NEUROLOGICAL DISORDERS




### Drivers

- Negative trend is expected to continue in 2013, driven by a continuing wave of patent expirations for highly utilized medications such as Zyprexa® (olanzapine) in 2011 and Geodon® (ziprasidone) and Seroquel® (quetiapine) in 2012.
- The rate of decrease in year-over-year drug costs is expected to slow in 2014 prior to the April 2015 patent expiration for Abilify® (aripiprazole), the best-selling atypical antipsychotic.

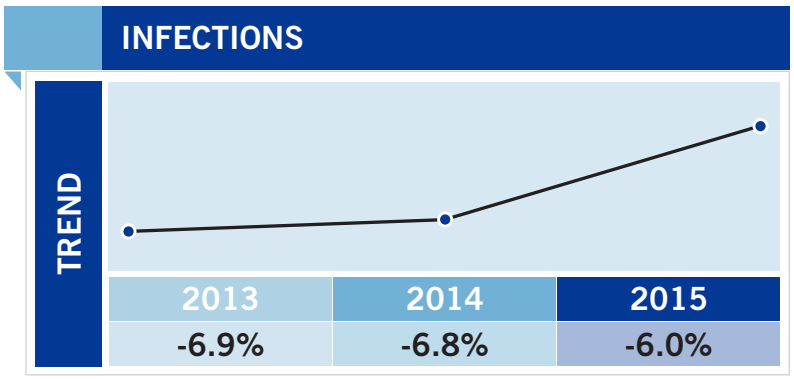
## PAIN




### Drivers

- Increasing availability of generic formulations of some pain medications, including narcotics, is driving the expected negative trend in the next few years, along with decreased utilization of narcotics, which may be influenced by public and legal scrutiny of use.
- The Food and Drug Administration's (FDA) ruling to deny generics to OxyContin® (oxycodone) is expected to somewhat mitigate the decrease in year-over-year drug spend.

## INFECTIONS



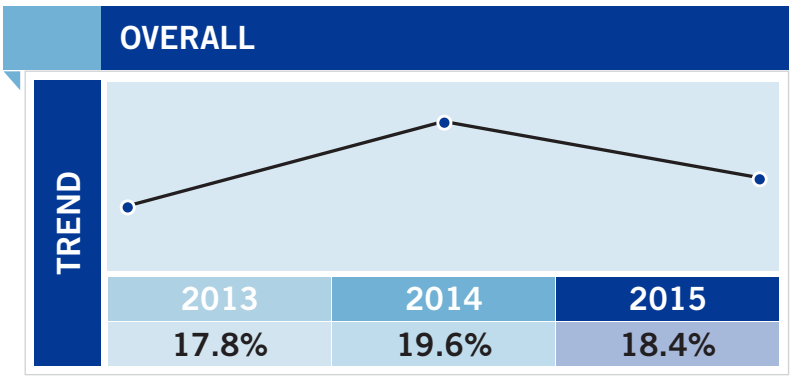

### Drivers

- The forecasted year-over-year decrease in costs is being driven by the availability of generic anti-infective medications in this therapy class.
- Generics to the broad-spectrum quinolone, Avelox® (moxifloxacin), expected in March 2014, are also likely to contribute to negative trend.
- Trend in this therapy class is also heavily influenced by the intensity of the influenza season, which is likely to be milder in 2013-2014 than it was in 2012-2013, partly due to an expected increase in the availability of new influenza vaccines FluMist® Quadrivalent (influenza vaccine) and Flucelvax® (influenza virus vaccine).

## SPECIALTY THERAPY CLASS FORECAST

The Specialty Therapy Class Forecast predicts future trend based on research about current and past cost and utilization patterns for specialty therapy classes. Our methodology analyzes three years of prescription data, demographics, and changes in guidelines and medication availability.

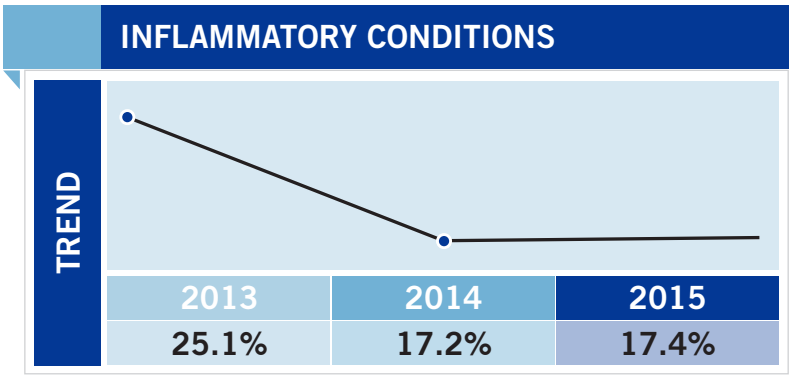
## OVERALL SPECIALTY FORECAST




### Drivers

- Less than 1% of prescriptions filled in 2012 were for specialty medications, yet they accounted for 25% of total prescription drug expenditures. By 2019 or 2020, specialty drugs are expected to represent 50% of plan sponsors' overall drug spend. The top three therapy classes inflammatory conditions, multiple sclerosis and cancer are expected to account for more than 50% of that overall spend.
- At least 60% of the new drugs expected to gain approval from the Food and Drug Administration (FDA) in 2013 alone will be specialty drugs.
- The primary driver of specialty drug spend will be a continuing increase in drug costs. Costs will rise as newer, more-sophisticated therapies with price tags worth tens and hundreds of thousands of dollars are brought to market.
- The introduction of biosimilars in key therapy classes with high-cost, highly utilized drugs has the potential to alter the trajectory of specialty drug spend.

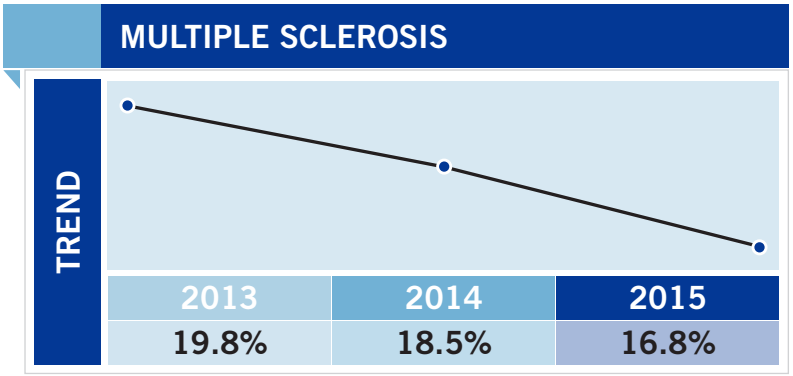
## INFLAMMATORY CONDITIONS




### Drivers

- Double-digit trend in this therapy class is expected to continue due to general brand inflation and competition for profits among older disease-modifying drugs because of Xeljanz® (tofacitinib), the new oral medication indicated to treat rheumatoid arthritis.
- The absence of biosimilars on the horizon is also expected to keep costs in this therapy class high.
- Utilization is expected to increase slightly as patients begin therapy with these drugs after expansion of indications and as physicians become increasingly comfortable prescribing specialty medications to treat conditions such as rheumatoid arthritis, Crohn's disease and psoriasis.

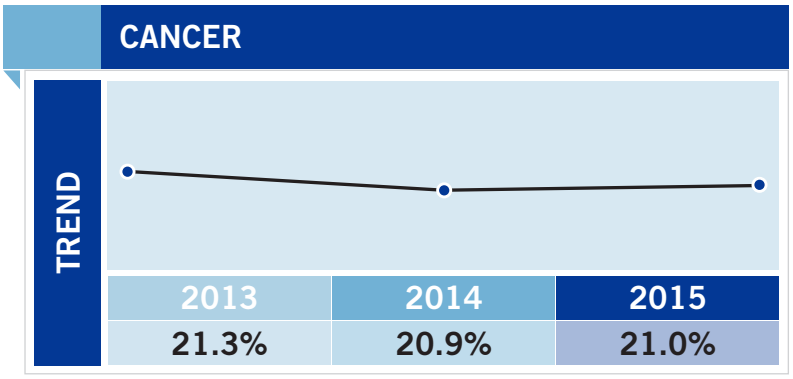
## MULTIPLE SCLEROSIS




### Drivers

- Continued manufacturer increases in drug prices and the approval of additional therapies, including the new oral agent, Tecfidera® (dimethyl fumarate), are expected to drive double-digit growth in drug spend for multiple sclerosis (MS) medications in the next few years.
- Because the average onset of disease tends to be in younger patients, new utilization is expected to slow as the population ages. However, the lack of new utilizers is not expected to drastically alter the trajectory of year-over-year cost increases.

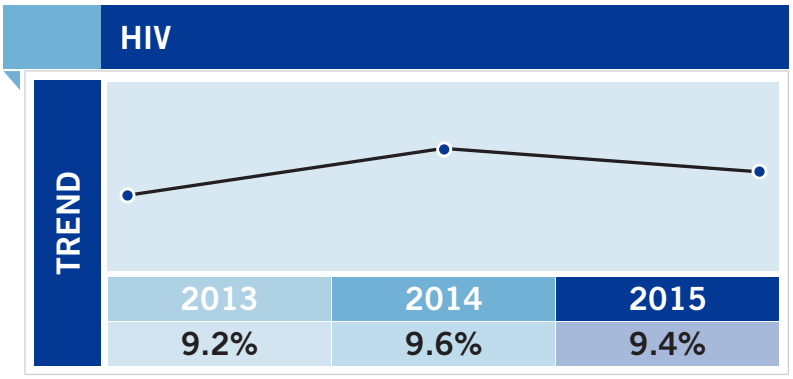
## CANCER




### Drivers

- The Food and Drug Administration (FDA) is increasingly approving new, highly targeted therapies that treat cancer based on a patient's specific genetic or proteomic profiles. These drugs are often associated with a more expensive research and development process, which may lead to higher price tags in this therapy class.
- High inflation rates for older medications whose manufacturers may be trying to protect profit margins may also contribute to double-digit increases in year-over-year drug costs.
- The stacking of therapies is more common as cancer survivorship increases and patients add additional therapies over time.

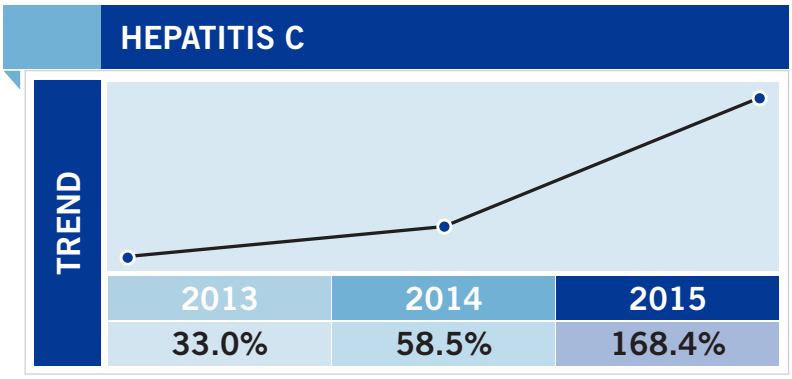
## HIV




### Drivers

- Cost increases are expected to mount due to the shift from multiple, older generic regimens to single-pill branded combination therapies with steep price tags.

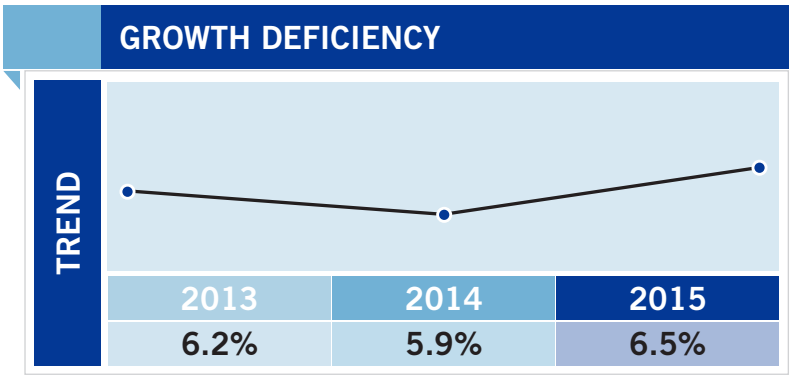
## HEPATITIS C




### Drivers

- Although the increase in new hepatitis C patients will continue to decelerate in 2013, new patients are still using protease inhibitors Incivek® (telaprevir) and Victrelis® (boceprevir), which are more expensive than other medications in the class.
- New interferon-free regimens are expected to gain Food and Drug Administration (FDA) approval beginning in late 2013, which will drive dramatic cost increases. Costs are expected to be especially high beginning in late 2014, when an all-oral regimen is expected to be approved for patients with genotype 1 hepatitis C, the most common type.
- An increase in the number of newly diagnosed patients resulting from the issuance of new screening guidelines, along with a secondary warehousing of patients waiting to initiate therapy with new medications, is expected to result in a steadily rising rate of new users.

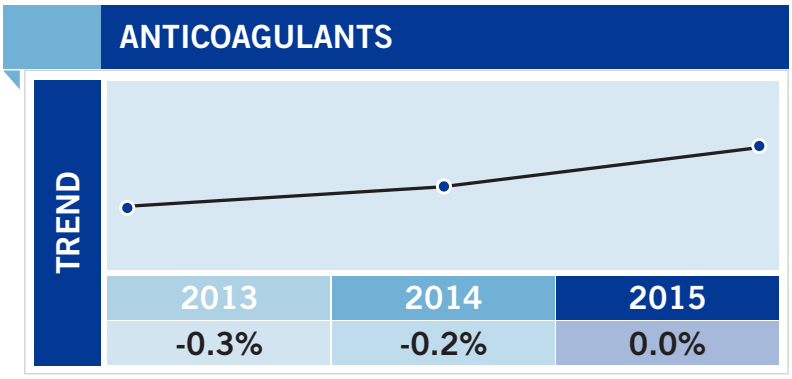
## GROWTH DEFICIENCY




### Drivers

- With limited novel or biosimilar growth hormone therapies in the pipeline, the increase in year-over-year drug costs is expected to contribute to stable increases in PMPY spend in the next few years.

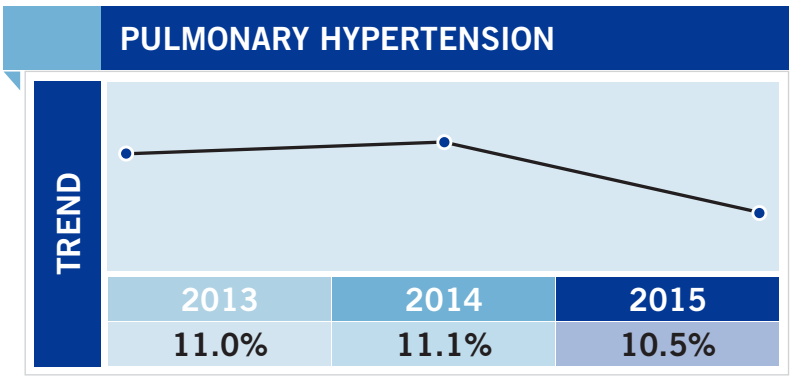
## ANTICOAGULANTS




### Drivers

- Utilization and costs in the class are expected to decline due to the future introduction of oral anticoagulants that will be considered traditional medications rather than specialty medications.
- The decline in costs is expected to be tempered in 2014 and 2015 by flat, rather than decreasing, costs for generic Lovenox® (enoxaparin). Because there are few competitors, slight brand inflation may occur.

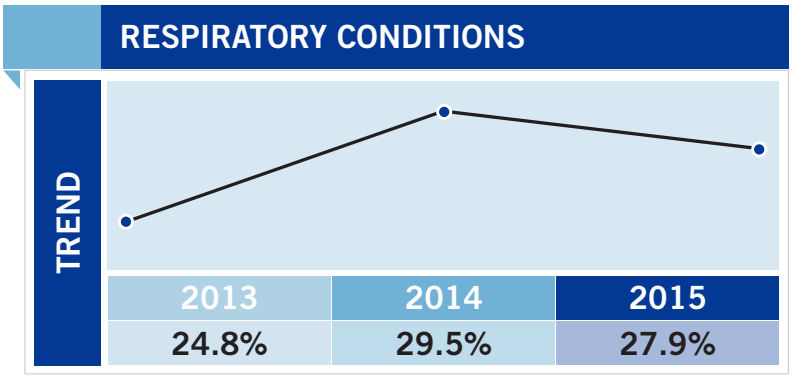
## PULMONARY HYPERTENSION




### Drivers

- Two new oral therapies — riociguat and Opsumit™ (macitentan) — that are expected to be approved in the near future will contribute to increased costs and utilization in this class.
- The launch of generics to Revatio® (sildenafil) in late 2012 is expected to mitigate trend.
- Generics to Tracleer® (bosentan) are expected to be approved in late 2015; their effect on trend won't be clear until 2016 and beyond.

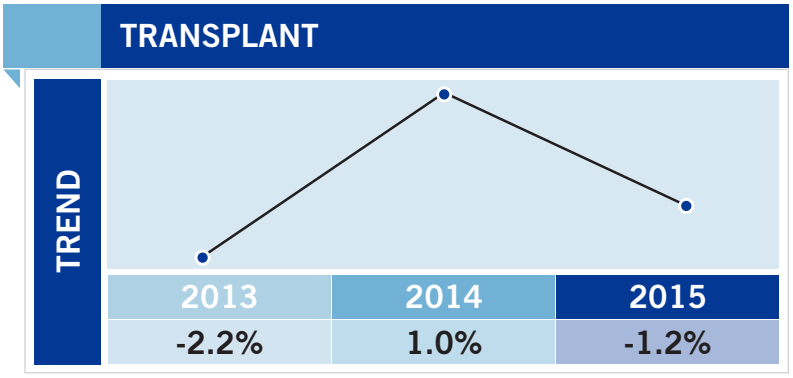
## RESPIRATORY CONDITIONS




### Drivers

- High-cost brands including Kalydeco® (ivacaftor), a treatment for some patients with cystic fibrosis (CF), will continue to drive increased spend in this class.
- Other new drugs to treat CF, including the recently approved TOBI® Podhaler (tobramycin inhalation powder), also will impact this class. Lumacaftor, an oral, pipeline drug to treat the underlying disease in as many as half of CF patients, is expected to significantly increase utilization and drug costs in this class.
- Esbriet® (pirfenidone), which may be the first drug approved to treat idiopathic pulmonary fibrosis, may impact trend in 2014.

## TRANSPLANT




### Drivers

- Drug costs are expected to be relatively stable, driven by the availability of generics in this class.
- No new brand or generic drugs that would impact this class are on the horizon.

# MEDICARE

## MEDICARE FEATURE ARTICLES

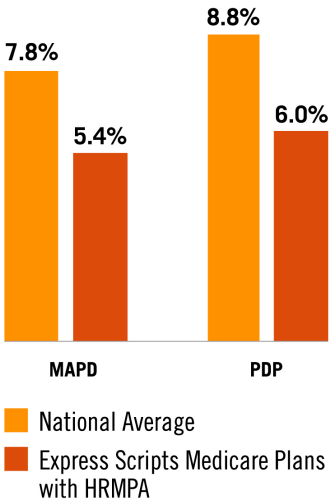
Timely, topical and in-depth analysis of issues particularly relevant to Medicare Advantage Part D (MAPD) Plans, Employer Group Waiver Plans (EGWPs) and standalone Prescription Drug Plans (PDPs).

# HOW PRIOR AUTHORIZATION CAN HELP MEMBERS AND BOOST STAR RATINGS


High-risk medications (HRM), also known as high-alert or high-hazard medications, are drugs that have an increased risk of harmful side effects even when used as indicated and for which a safer alternative is available. Controlling their usage will both increase patient safety and boost star ratings. The five-star rating system from the Centers for Medicare & Medicaid Services (CMS) includes a category for Patient Safety and Accuracy of Drug Pricing. A specific measure, known as D14, rates Medicare Part D Prescription Drug Plans (PDPs) and Medicare Advantage Plans (MAPDs) based on the percentage of plan members age 65 and older who fill prescriptions for certain high-risk medications even though safer drug options are available.[1]

The HRM rate measures the percentage of plan members, as a subset of all plan members, who receive at least two fills for a high-risk prescription medication. It is incorporated as part of a plan's overall star rating, which can range from 1 to 5 (with 5 being the highest).

High-Risk Medication Rates



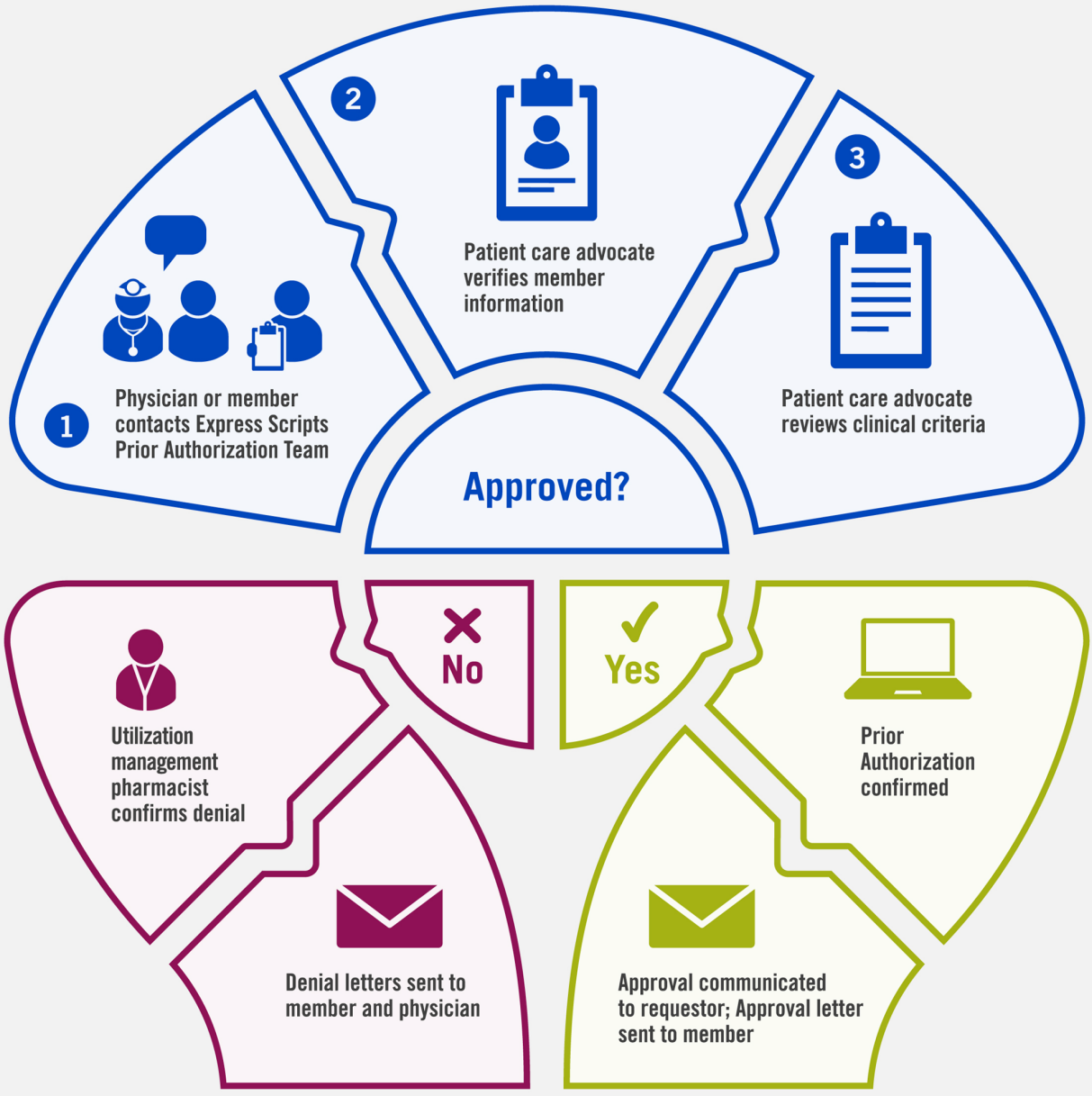

CMS treats the high-risk medication measure as an intermediate outcome measure, weighting it three times more than some other measures, including process measures such as enrollment timeliness. Thus, the HRM measure is a high-impact performance area for Medicare Part D plan sponsors. In practice, the HRM star rating is aggregated, along with the star ratings for other outcome and process measures, into a total star rating for a given MAPD or PDP. According to the 2013 CMS technical notes, the national numeric average HRM rates in 2011 were 7.8% for MAPDs and 8.8% for PDPs, which translate to an average star rating of 3.1 out of 5 for both plan types.[1]

## Patient Safety through Prior Authorization

Express Scripts designed its High-Risk Medication Prior Authorization (HRMPA) program in 2011 to drive patient safety by monitoring the real-time dispensing of CMS-classified high-risk medications. The HRMPA program supports plan sponsors' prior authorization (PA) and medical exception initiatives, offers review services 24 hours a day throughout the year, and gives physicians and pharmacists easy access to PA information.

In 2011, the original HRMPA program monitored high-risk medications in two therapeutic classes: skeletal muscle relaxants and first-generation (sedating) antihistamines. Since then, the Express Scripts program has expanded to align with CMS's updated HRM list, including PA and step therapy implementations for barbiturates and benzodiazepines. Additional HRMs are being evaluated for inclusion in the future. The figure below shows how our HRMPA program promotes the use of safer alternative prescription drugs at the point of service.

### High-Risk Medication Prior Authorization Program Methodology



Express Scripts researched the effect of our HRMPA program on the use of high-risk medications among our Medicare plan members. The study involved more than 65 health plan contracts representing more than 2.2 million Medicare lives. Clients with CMS contracts were grouped into two categories based on whether they used the Express Scripts HRMPA program. Similar to the methodology used by CMS in measuring the HRM rate, researchers calculated the percentage of Medicare Part D beneficiaries who received two or more prescription fills for a drug with a high risk of serious side effects in the elderly in 2011. Using an unadjusted test of association (two-sample t-test), the study analyzed whether the numerical averages between the two groups differed on the percentage of high-risk medications that the plan members received.

Results showed that across MAPD and PDP plans, HRM prescriptions were received by 7.4% of members in contracts that did not have the HRMPA program in place, compared to an HRM rate of only 5.5% in contracts that did have the Express Scripts HRMPA program. (See table below.) Notably, Express Scripts MAPD and PDP plans overall — including those without the HRMPA program — dispensed lower percentages of high-risk medications to Medicare beneficiaries than the national averages for their counterpart plans.

### High-Risk Medication Rate Comparison

| | NATIONAL AVERAGE | EXPRESS SCRIPTS MEDICARE PLANS | | |
|---|---|---|---|---|
| | | OVERALL AVERAGE | WITHOUT HRMPA | WITH HRMPA |
| MAPD | 7.8% | 6.8% | 7.1% | 5.4% |
| PDP | 8.8% | 8.4% | 9.1% | 6.0% |
| | | | 7.4% Overall | 5.5% Overall |

On average, beneficiaries whose plan sponsors implemented the HRMPA program had an HRM rate which was 1.9 percentage points less than that of beneficiaries whose plan sponsors did not implement HRMPA ($P<0.05$). For MAPDs, 5.4% of plan members with HRMPA received high-risk medications compared to 7.1% of those without the program — a significant difference of 1.7 percentage points ($P<0.05$). For PDPs, the difference was 3.1 percentage points, with only 6.0% of plan members with HRMPA receiving high-risk medications compared to 9.1% of those without an HRMPA program.

## Healthier Outcomes and Higher Star Ratings

The evidence clearly shows that plan sponsors can achieve healthier outcomes — and a higher CMS star rating — by strategically using advanced clinical pharmacy benefit management solutions to more effectively monitor and control the high-risk medications that members receive.

## Footnotes

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## TOTAL TREND

The Medicare Total Trend measures the rate of change in total spend driven by utilization and unit cost for the population covered by Medicare Advantage Part D (MAPD) Plans, Employer Group Waiver Plans (EGWPs) and standalone Prescription Drug Plans (PDPs).

## COMPONENTS OF MEDICARE TREND, 2012

| | | TREND | | |
|---|---|---|---|---|
| | PMPY SPEND | UTILIZATION | UNIT COST | TOTAL |
| Traditional | $1,908.70 | 1.8% | -2.6% | -0.7% |
| Specialty | $353.62 | -2.7% | 26.8% | 24.1% |
| TOTAL OVERALL | $2,262.32 | 1.8% | 0.7% | 2.5% |

**January–December 2012 compared to same period in 2011*

### Key Insights

- PMPY spend for Medicare was more than double that of the Commercial book of business, as Medicare beneficiaries use more medications overall. However, total trend was slightly lower, driven by lower costs for traditional drugs, which represent a larger proportion of total spend for Medicare compared to the Commercial book of business.
- For traditional medications, annual utilization increased 1.8%, offset by an annual cost decrease of 2.6%, resulting in negative total traditional trend. However, a 26.8% increase in costs for specialty medications led to positive annual specialty trend.

## COMPONENTS OF MEDICARE TREND, MAPD

| | | TREND | | |
|---|---|---|---|---|
| | PMPY SPEND | UTILIZATION | UNIT COST | TOTAL |
| Traditional | $2,018.80 | 2.8% | -1.0% | 1.9% |
| Specialty | $357.44 | -2.1% | 27.9% | 25.8% |
| **TOTAL OVERALL** | **$2,376.25** | **2.8%** | **2.1%** | **4.9%** |

*January – December 2012 compared to same period in 2011*

### Key Insights

- PMPY spend and total trend were higher for MAPD plans than for EGWPs or PDPs.

## COMPONENTS OF MEDICARE TREND, EGWP

| | | TREND | | |
|---|---|---|---|---|
| | PMPY SPEND | UTILIZATION | UNIT COST | TOTAL |
| Traditional | $1,826.41 | 0.7% | -3.3% | -2.6% |
| Specialty | $358.07 | -5.9% | 25.8% | 20.0% |
| **TOTAL OVERALL** | **$2,184.48** | **0.7%** | **-0.2%** | **0.5%** |

*January – December 2012 compared to same period in 2011*

### Key Insights

- PMPY spend and total trend were lower for EGWPs than for MAPDs, but higher than PMPY spend and total trend for PDPs.

## COMPONENTS OF MEDICARE TREND, PDP

| | | TREND | | |
|---|---|---|---|---|
| | PMPY SPEND | UTILIZATION | UNIT COST | TOTAL |
| Traditional | $1,706.76 | 0.2% | -6.7% | -6.5% |
| Specialty | $340.65 | -3.3% | 26.6% | 23.3% |
| **TOTAL OVERALL** | **$2,047.40** | **0.1%** | **-2.8%** | **-2.6%** |

*January – December 2012 compared to same period in 2011*

### Key Insights

- PDPs had a negative overall trend, driven by a decrease in cost for traditional medications, many of which are newly available as generics. Total trend for PDPs was lower than that of other Medicare plans.

## TRADITIONAL TREND BY THERAPY CLASS

The Medicare Traditional Therapy Class Trend section highlights key traditional therapy classes and explains factors driving trend for the population covered by Medicare Advantage Part D (MAPD) Plans, Employer Group Waiver Plans (EGWPs) and standalone Prescription Drug Plans (PDPs).

## TRADITIONAL TREND BY THERAPY CLASS

### Components of Trend for the Top 10 Medicare Traditional Therapy Classes, Ranked by PMPY Spend, 2012

| | | TREND | | |
|---|---|---|---|---|
| THERAPY CLASS | PMPY SPEND | UTILIZATION | UNIT COST | TOTAL |
| Diabetes | $278.72 | 4.5% | 10.6% | 15.2% |
| High Blood Cholesterol | $209.58 | 1.5% | -8.2% | -6.7% |
| High Blood Pressure/Heart Disease | $194.28 | 1.7% | -2.9% | -1.2% |
| Mental/Neurological Disorders | $144.58 | 2.4% | -19.3% | -16.9% |
| Asthma | $122.56 | 3.8% | 5.5% | 9.3% |
| Ulcer Disease | $95.19 | 7.7% | -12.1% | -4.4% |
| Blood Modifying | $78.67 | -2.8% | -33.8% | -36.6% |
| Pain | $77.35 | 4.1% | -2.8% | 1.3% |
| Depression | $70.66 | 4.7% | 0.2% | 4.9% |
| Urinary Disorders | $64.29 | 1.3% | -7.4% | -6.1% |
| Other | $572.81 | 0.2% | 6.3% | 6.5% |
| **TOTAL TRADITIONAL** | **$1,908.70** | **1.8%** | **-2.6%** | **-0.7%** |

### Key Insights

- Diabetes medications had the highest overall trend, driven primarily by increased costs. Although changes in costs reflect the impact of new drugs such as Tradjenta® (linagliptin), increased prices for insulin drugs drove much of the change.
- Costs for medications used to treat mental/neurological disorders have declined 19.3%, driven by patent expirations for Seroquel® (quetiapine) and Geodon® (ziprasidone) in 2012, and continued utilization of generic olanzapine and donepezil in place of brands Zyprexa® and Aricept®.
- Utilization of pain medications increased 4.1% in 2012 compared to 2011, but unit costs dropped by 2.8%, leading to a relatively flat overall trend. Recent data suggest that growth in pain medication prescriptions for elderly patients has outpaced that of other age groups, in part due to pharmaceutical

manufacturer influence on doctors and pain advocacy groups.[1] Although narcotic pain medications have been the subject of scrutiny because of prescription drug abuse, their use in elderly patients may be more accepted because of the perception of clinical need.

- A 33.8% drop in unit costs led to a significant negative total trend for the blood modifying class. This was almost exclusively driven by the May 2012 expiration of the blockbuster brand drug Plavix® (clopidogrel), which had captured 85% of market share in the class before the patent expired. The average cost per prescription for generic clopidogrel was 29.9% of the average cost for brand Plavix.

## Footnotes

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## SPECIALTY TREND BY THERAPY CLASS

The Medicare Specialty Therapy Class Trend section highlights key specialty therapy classes and explains factors driving trend for the population covered by Medicare Advantage Part D Plans (MAPD), Employer Group Waiver Plans (EGWPs) and standalone Prescription Drug Plans (PDPs).

## SPECIALTY TREND BY THERAPY CLASS

### Components of Trend for the Top 10 Medicare Specialty Therapy Classes, Ranked by PMPY Spend, 2012

| | | TREND | | |
|---|---|---|---|---|
| THERAPY CLASS | PMPY SPEND | UTILIZATION | UNIT COST | TOTAL |
| Cancer | $108.39 | 11.8% | 21.1% | 32.8% |
| Multiple Sclerosis | $51.68 | 8.5% | 18.2% | 26.7% |
| Inflammatory Conditions | $47.69 | 7.4% | 13.0% | 20.4% |
| HIV | $30.31 | 1.6% | 9.1% | 10.7% |
| Pulmonary Hypertension | $25.58 | 9.8% | 4.0% | 13.8% |
| Anticoagulants | $16.57 | 1.0% | 3.7% | 4.7% |
| Hepatitis C | $10.83 | 63.5% | 46.9% | 110.4% |
| Immune Deficiency | $10.63 | 34.6% | -0.8% | 33.8% |
| Blood Cell Deficiency | $10.43 | -8.2% | 8.0% | -0.2% |
| Osteoporosis | $9.52 | 9.1% | 2.9% | 12.0% |
| Other | $32.00 | -28.1% | 55.2% | 27.1% |
| **TOTAL SPECIALTY** | **$353.62** | **-2.7%** | **26.8%** | **24.1%** |

### Key Insights

- Utilization of cancer medications increased 11.8% in comparison to 2011, contributing to the overall 32.8% increase in PMPY spend. Much of the increase was driven by new medications such as Afinitor® (everolimus) and Zelboraf® (vemurafenib), which provide second- and third-line treatment options for patients with certain treatment-refractory cancers. However, increased utilization was also seen for Avastin® (bevacizumab) and fluorouracil, both of which might be prescribed off-label to treat non-cancer conditions, such as macular degeneration and actinic keratoses ("sun spots"), which mainly afflict elderly patients.[1,2]
- A 63.5% increase in utilization of medications used to treat hepatitis C was coupled with a 46.9% increase in unit costs, resulting in a triple-digit total trend for the class. The increases primarily

resulted from two fairly new hepatitis C drugs, Incivek® (telaprevir) and Victrelis® (boceprevir), approved in mid-2011. The drugs are the first new hepatitis C treatments in more than a decade and the first oral antivirals to treat hepatitis C; however, both must be used in combination with older drugs. Utilization is likely to be especially high among patients born between 1945 and 1965; not only are hepatitis C virus infection rates more prevalent in this age group,[3] but physicians may have been reluctant to prescribe previous therapies for older patients because of increased comorbidities or the fear of adverse treatment events.[4]

- An 8.2% decrease in utilization of medications used to treat blood cell deficiencies in Medicare beneficiaries led to a negative total trend for the therapy class. The decrease was driven by changes in utilization of erythropoiesis-stimulating agents (ESAs) such as Procrit® (epoetin alfa) and Aranesp® (darbepoetin alfa), likely in response to recent FDA recommendations for more conservative dosing of these drugs in some patients. Several post-marketing studies found that ESAs are associated with an increased risk of cardiovascular events such as stroke, thrombosis and even death.[5] In response, the Centers for Medicare and Medicaid Services altered coverage rules.[6]
- Utilization of medications used to treat immune deficiencies increased 34.6% in 2012, leading to a 33.8% total trend. Utilization increases are likely related to expanded FDA-approved indications for Gammagard® Liquid (immune globulin),[7] the most commonly used immune deficiency medication among Medicare beneficiaries, and to an increase in off-label use of immunoglobulin products by the aging population.[8,9]

## Footnotes


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# MEDICAID

## MEDICAID FEATURE ARTICLES

Timely, topical and in-depth analysis of issues particularly relevant to the population covered by Medicaid.

# THE OVERRELIANCE ON RESCUE MEDICATIONS FOR MEDICAID ASTHMA PATIENTS


Two general types of medications are used to treat asthma. Some are classified as controller medications, which aid in preventing asthma exacerbations (worsening of symptoms). Controller medications should be taken daily on a long-term basis to reduce airway inflammation, decrease mucus production and desensitize the lungs to environmental triggers.[1,2] The second main type of asthma medications is rescue medications, which are used on an as-needed basis for acute symptom relief. Rescue medications work by helping to relax airways.[3] In general, rescue medications should be used judiciously, and using rescue medications to treat acute asthma symptoms more than two days per week likely indicates the need for controller medications.[2]

## Asthma and Medicaid

Among Medicaid beneficiaries for whom Express Scripts manages pharmacy benefits, asthma is the most prevalent and costly condition at the per-member-per-year (PMPY) level. In 2012, 15.1% of Medicaid beneficiaries used asthma medications at a PMPY cost of $59.47, which represented a 6.2% increase in PMPY spend between 2011 and 2012. Spend in the class increased despite the patent expiration of the blockbuster drug Singulair® (montelukast), which prior to losing patent protection on August 3, 2012, held more than 10% of the Medicaid asthma therapy class market share.[4]

In addition to being expensive, asthma and its treatments are especially important for Medicaid because of the complex relationship between asthma and income — further confounded by a possible contribution of urban environments to asthma exacerbations. Asthma disproportionately impacts populations with low annual household incomes,[5] and may be more prevalent in urban environments. Both groups include many receiving healthcare benefits through Medicaid. Some studies suggest that Medicaid patients

with asthma have more attacks and use more healthcare resources than similar patients with private insurance or even no insurance.[6,7]

A recent Express Scripts examination of asthma medication utilization among Medicaid beneficiaries sheds light on some of the utilization drivers in the class. Specifically, Express Scripts researchers compared utilization of rescue and controller medications over time and across different subpopulations of gender, urbanicity and age. Our goals were to determine what kinds of medications were used by Medicaid beneficiaries and whether utilization patterns changed between 2011 and 2012.

## Utilization of Controller and Rescue Medications

Among 315,600 Medicaid beneficiaries age 0 to 64 who were using any type of asthma medication in 2012, a greater proportion of beneficiaries were using rescue medications than controller medications. In our study, 90% of beneficiaries filled at least one prescription for a rescue medication, only 42.4% filled a prescription for a controller medication and about one-third used both rescue medications and controller medications. Notably, 55.7% were using only rescue medications, implying inadequate asthma control, which often leads to increased medical resource utilization[8] (data not shown).

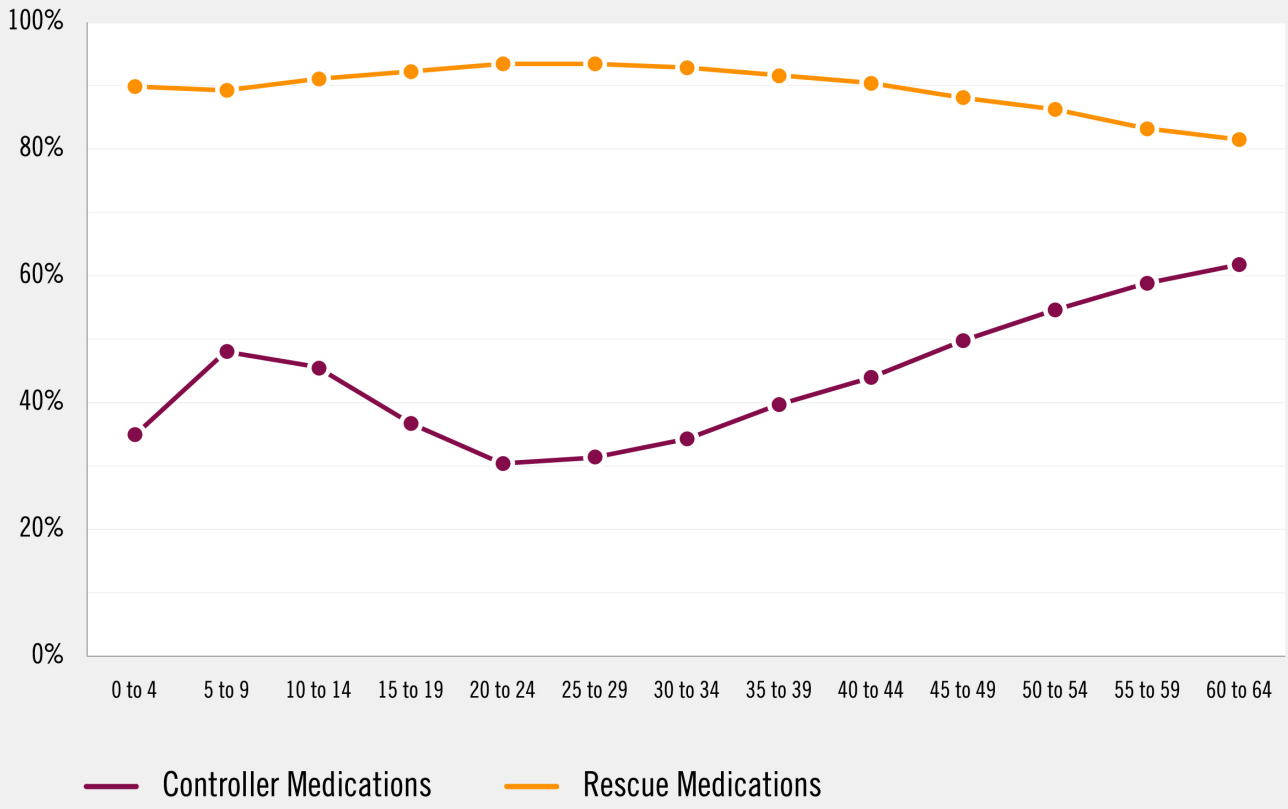
Patterns of controller and rescue medication use by gender and urbanicity are shown in the table below. Little difference was seen between males and females using rescue medications (89.8% vs. 90.2%, respectively), but a slightly higher percentage of males used controller medications (43.9% vs. 41.2%). A higher percentage of nonurban than urban patients had claims for controller medications (45.8% vs. 42.3%), but a greater percentage of urban patients than nonurban patients filled prescriptions for rescue medications (90.2% vs. 84.7%).

**Utilization of Controller and Rescue Medications by Gender and Urbanicity, 2012**

| | ALL | MALE | FEMALE | URBAN | NON-URBAN |
|---|---|---|---|---|---|
| Controller Medications | 42.4% | 43.9% | 41.2% | 42.3% | 45.8% |
| Rescue Medications | 90.0% | 89.8% | 90.2% | 90.2% | 84.7% |

Utilization of controller and rescue medications by age is shown in the figure below. With regard to age, controller medication use was higher for children age 5 to 9, and for 10 to 14 year olds, and then declined in young adults before increasing again among older beneficiaries. At the same time, rescue medication use experienced only a slight increase among older teenagers and young adults before declining for beneficiaries older than age 30. The increase among older beneficiaries partially reflects the increased prevalence of chronic obstructive pulmonary disease (COPD), as many asthma controller medications are also used to treat COPD, a progressive condition that generally does not produce symptoms in patients younger than age 40.

## Utilization of Controller and Rescue Medications by Age, 2012



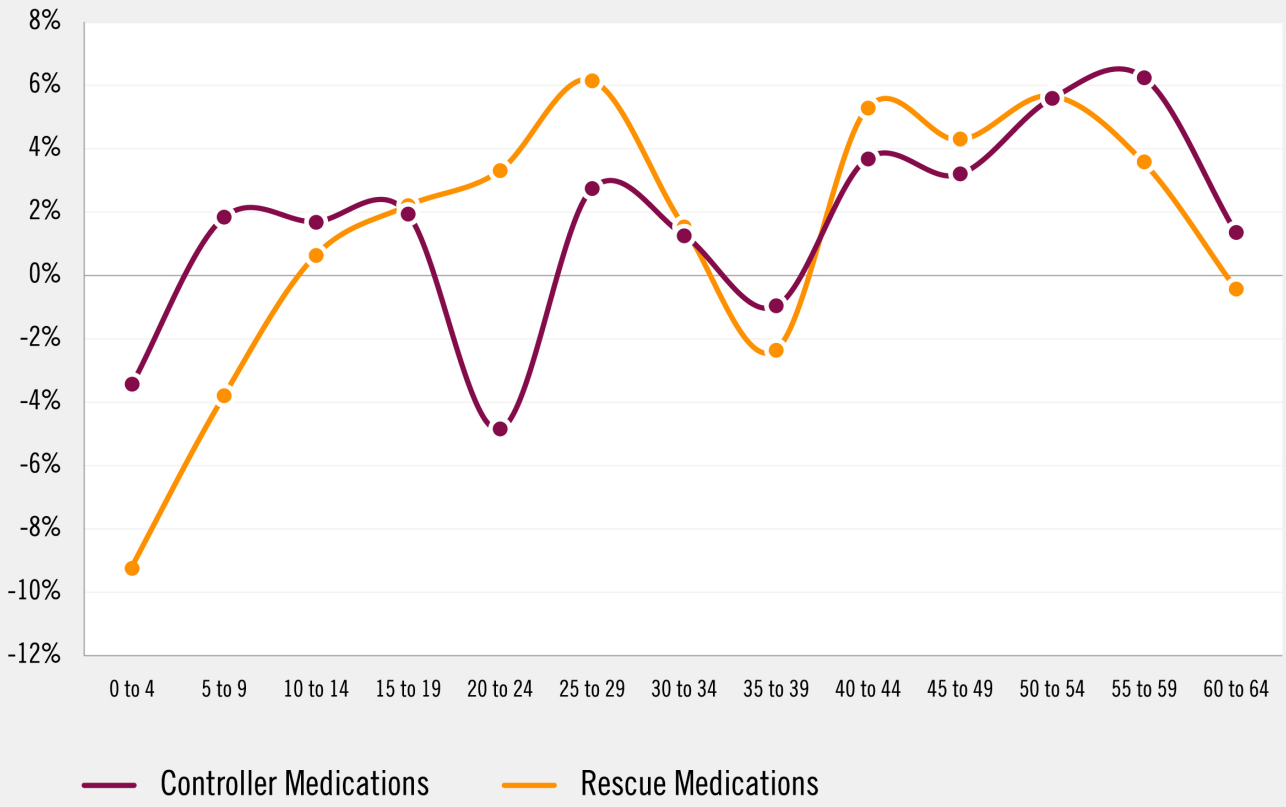
The study also examined utilization trend — the year-to-year change in the total days' supply of medication. (See table below.) Between 2011 and 2012, the amount of rescue medications being used increased at a faster rate (2.0%) than did the amount of controller medications (0.8%). Male beneficiaries had larger increases in utilization than females. There was also a slight gap in rescue utilization trend between urban and nonurban populations.

**Utilization Trend for Controller and Rescue Medications by Gender and Urbanicity, 2011 to 2012**

| | ALL | MALE | FEMALE | URBAN | NON-URBAN |
|---|---|---|---|---|---|
| Controller Medications | 0.8% | 1.1% | 0.6% | 0.9% | 0.8% |
| Rescue Medications | 2.0% | 2.2% | 1.7% | 2.0% | 2.8% |

Breaking down utilization by age, rescue medication utilization increased the most (6.2%) among beneficiaries age 25 to 29. (See figure below.) Utilization of rescue medications increased 5.7% in patients age 50 to 54. The change in controller medication utilization was also high in beneficiaries age 50 to 54 (5.6%), topped only by a 6.3% increase for those age 55 to 59. Increases in asthma drug utilization among older Medicaid beneficiaries may reflect increased COPD diagnoses in older patients.[8] Utilization of controller medications decreased the most (-4.9%) among beneficiaries age 20 to 24, whereas rescue medication utilization decreased the most (-9.3%) among the youngest Medicaid beneficiaries, those age 0 to 4.

**Utilization Trend for Controller and Rescue Medications by Age, 2011 to 2012**




## Summary

Across all Medicaid subpopulations in our study, the most commonly used asthma medications were rescue medications, as opposed to controller medications. Additionally, utilization trend increased at a faster rate for rescue medications than for controller medications. Both findings are counter to asthma treatment guidelines, which recommend daily, long-term use of controller medications to prevent asthma exacerbations. Frequent use of rescue medications suggests poor asthma management, resulting in avoidable asthma exacerbations and potentially increasing overall healthcare expense.

Understanding basic utilization patterns among Medicaid beneficiaries with asthma is an important step in identifying additional opportunities for further education and intervention. More comprehensive explorations of utilization patterns are needed to reveal more detailed information about the true extent of controller medication underutilization and rescue medication overutilization. Just as important, determining and addressing the reasons for poor utilization help Express Scripts and Medicaid plan sponsors enable patients to make better decisions that ultimately lead to healthier outcomes.

## Footnotes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## TOTAL TREND

The Medicaid Total Trend measures the rate of change in total spend driven by utilization and unit cost for the population covered by Medicaid.

## COMPONENTS OF MEDICAID TREND, 2012

| | | TREND | | |
|---|---|---|---|---|
| | PMPY SPEND | UTILIZATION | UNIT COST | TOTAL |
| Traditional | $337.26 | 3.8% | 1.5% | 5.3% |
| Specialty | $113.32 | -0.8% | 16.7% | 15.9% |
| **TOTAL OVERALL** | **$450.58** | **3.8%** | **4.0%** | **7.8%** |

*January–December 2012 compared to same period in 2011*

### Key Insights

- Total overall Medicaid PMPY spend increased 7.8% in 2012, driven nearly equally by increases in utilization and drug costs. Although utilization increased significantly for traditional medications, it decreased for specialty medications. Cost increases for specialty medications far outpaced those for traditional drugs (16.7% vs. 1.5%).
- Many of the top specialty therapy classes in 2012, such as those used to treat HIV, inflammatory conditions and multiple sclerosis, had double-digit cost increases, leading to an overall annual trend of 15.9%. However, overall annual specialty trend for Medicaid was lower than that for both the Commercial and Medicare populations. This may be related to the kinds of specialty medications used by Medicaid beneficiaries, who tend to be younger than beneficiaries in other populations.

## COMPONENTS OF TREND, MEDICAID AGES 0-19, 2012

| | | TREND | | |
|---|---|---|---|---|
| | PMPY SPEND | UTILIZATION | UNIT COST | TOTAL |
| Traditional | $162.35 | 3.5% | -0.5% | 3.0% |
| Specialty | $39.04 | 1.0% | 6.4% | 7.4% |
| **TOTAL OVERALL** | **$201.39** | **3.4%** | **0.3%** | **3.8%** |

*January – December 2012 compared to same period in 2011*

### Key Insights

- Total overall trend in the youngest Medicaid beneficiaries was lower than the total overall trend across all Medicaid beneficiaries (3.8% vs. 7.8%). This was driven by relatively flat utilization of specialty medications and slightly lower unit costs in 2012 compared to 2011.

## COMPONENTS OF TREND, MEDICAID AGES 20-34, 2012

| | | TREND | | |
|---|---|---|---|---|
| | PMPY SPEND | UTILIZATION | UNIT COST | TOTAL |
| Traditional | $336.90 | 10.4% | 2.5% | 13.0% |
| Specialty | $123.33 | 9.4% | 13.5% | 23.0% |
| **TOTAL OVERALL** | **$460.23** | **10.4%** | **5.1%** | **15.5%** |

*January – December 2012 compared to same period in 2011*

### Key Insights

- Total trend for beneficiaries ages 20 to 34 was 15.5%, driven by increased utilization of traditional medications and increases in both utilization and costs for specialty medications.

## COMPONENTS OF TREND, MEDICAID AGES 35-64, 2012

| | | TREND | | |
|---|---|---|---|---|
| | PMPY SPEND | UTILIZATION | UNIT COST | TOTAL |
| Traditional | $930.56 | 12.8% | 2.2% | 15.0% |
| Specialty | $364.36 | 7.7% | 22.5% | 30.2% |
| **TOTAL OVERALL** | **$1,294.93** | **12.8%** | **6.1%** | **18.9%** |

*January – December 2012 compared to same period in 2011*

### Key Insights

- PMPY spend and total trend were higher in Medicaid beneficiaries ages 35 to 64 than in other age groups. Spend increased 18.9%, driven by growth in utilization for both traditional and specialty medications, and a 22.5% increase in costs for specialty medications. Specialty medications accounted for a larger proportion of total PMPY spend than in other age groups.

## COMPONENTS OF TREND, MEDICAID AGES 65+, 2012

| | | TREND | | |
|---|---|---|---|---|
| | PMPY SPEND | UTILIZATION | UNIT COST | TOTAL |
| Traditional | $378.42 | 2.4% | -5.4% | -3.0% |
| Specialty | $60.54 | -14.7% | 36.3% | 21.6% |
| **TOTAL OVERALL** | **$438.96** | **2.3%** | **-2.5%** | **-0.2%** |

*January – December 2012 compared to same period in 2011*

### Key Insights

- Among beneficiaries ages 65 and older, total trend decreased by 0.2%, driven by decreased utilization of specialty medications and lower costs for traditional medications.

## TRADITIONAL TREND BY THERAPY CLASS

The Medicaid Traditional Therapy Class Trend section highlights key traditional therapy classes and explains factors driving trend for the population covered by Medicaid.

## TRADITIONAL TREND BY THERAPY CLASS

### Components of Trend for the Top 10 Medicaid Traditional Therapy Classes, Ranked by PMPY Spend, 2012

| | | TREND | | |
|---|---|---|---|---|
| THERAPY CLASS | PMPY SPEND | UTILIZATION | UNIT COST | TOTAL |
| Asthma | $59.47 | 6.2% | 0.0% | 6.2% |
| Diabetes | $42.53 | 0.9% | 10.5% | 11.4% |
| Pain | $26.75 | 2.3% | -5.6% | -3.2% |
| Mental/Neurological Disorders | $21.12 | 10.6% | -13.8% | -3.2% |
| Infections | $20.27 | -1.5% | -4.2% | -5.7% |
| Attention Disorders | $17.41 | 12.3% | 4.1% | 16.4% |
| Seizures | $14.18 | 6.7% | -3.1% | 3.6% |
| High Blood Pressure/Heart Disease | $10.00 | 0.3% | 0.9% | 1.2% |
| Allergies | $8.96 | 12.8% | -7.5% | 5.4% |
| Chemical Dependence | $8.38 | 15.4% | 8.9% | 24.3% |
| Other | $108.19 | 3.6% | 3.1% | 6.8% |
| **TOTAL TRADITIONAL** | **$337.26** | **3.8%** | **1.5%** | **5.3%** |

### Key Insights

- Asthma medications had the highest PMPY spend in the Medicaid population. Total spend increased 6.2% compared to 2011, driven by increased utilization. The patent for one of the most utilized drugs in this class, Singulair® (montelukast sodium), expired in August 2012. Generic montelukast, which was not protected under a generic exclusivity arrangement, immediately gained market share, which helped keep unit costs flat in the class.
- Declines in both utilization and unit costs for medications used to treat infections, primarily among generic antibiotics such as amoxicillin, azithromycin and levofloxacin, led to a 5.7% decline in total spend. Utilization changes likely reflect the mild 2011-2012 flu season; because the influenza virus and bacterial respiratory infections have similar symptoms, flu often is treated mistakenly with

antibiotics. Decreased antibiotic use may have been even more pronounced if the 2012-2013 flu season had not been so early, severe and widespread.

- Total spend for medications used to treat attention disorders increased 16.4%, impacted primarily by a 12.3% increase in utilization. While some evidence suggests that utilization of attention disorders medications may be increasing among adults,[1] some of the increase in utilization among Medicaid beneficiaries specifically may come from increased prescribing to low-income children in an effort to improve school performance and grades.[2]
- The rise in the number of Americans seeking treatment for drug and alcohol abuse3 resulted in increased use of medications used to manage chemical dependence, such as Campral® (acamprosate), Suboxone® (buprenorphine, naloxone) and disulfiram. Utilization of these medications in 2012 increased 15.4% over 2011 utilization, and unit costs rose 8.9%, leading to the highest total trend among traditional medications.

## Footnotes


1. Moyer CS. Challenges of adult ADHD. Amednews.com August 27, 2012. Available at: http://www.ama-assn.org/amednews/2012/08/27/hlsa0827.htm. Accessed February 3, 2013. .
2. Schwartz A. Attention disorder or not, pills to help in school. The New York Times. October 9, 2012. Available at: http://www.nytimes.com/2012/10/09/health/attention-disorder-or-not-children-prescribed-pills-to-help-in-school.html?hp&_r=1&. Accessed February 6, 2013.
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## SPECIALTY TREND BY THERAPY CLASS

The Medicaid Specialty Therapy Class Trend section highlights key specialty therapy classes and explains factors driving trend for the population covered by Medicaid.

## TRADITIONAL TREND BY THERAPY CLASS

### Components of Trend for the Top 10 Medicaid Specialty Therapy Classes, Ranked by PMPY Spend, 2012

| | | TREND | | |
|---|---|---|---|---|
| THERAPY CLASS | PMPY SPEND | UTILIZATION | UNIT COST | TOTAL |
| HIV | $23.40 | -7.3% | 5.2% | -2.1% |
| Hepatitis C | $12.49 | -1.6% | 33.5% | 31.9% |
| Inflammatory Conditions | $10.98 | 12.8% | 14.4% | 27.2% |
| Cancer | $10.42 | 5.3% | 16.9% | 22.2% |
| Hemophilia | $8.69 | 0.0% | 2.2% | 2.2% |
| Multiple Sclerosis | $8.09 | 1.8% | 16.1% | 17.9% |
| Pulmonary Hypertension | $6.64 | 17.6% | 17.8% | 35.4% |
| Growth Deficiency | $6.38 | 13.3% | 10.4% | 23.7% |
| Respiratory Syncytial Virus Prevention | $4.52 | 2.3% | 12.6% | 14.9% |
| Respiratory Conditions | $3.93 | 12.5% | 18.3% | 30.8% |
| Other | $17.77 | 2.5% | 17.3% | 19.8% |
| **TOTAL SPECIALTY** | **$113.32** | **-0.8%** | **16.7%** | **15.9%** |

### Key Insights

- Utilization of HIV medications declined 7.3%, while unit costs increased 5.2%. However, declines in utilization actually reflect the changes in the number of individual prescriptions as patients move from daily regimens of multiple individual medications such as Sustiva® (efavirenz) and Emtriva® (emtricitabine) to combination drugs such as Atripla® (efavirenz, tenofovir, emtricitabine) and Truvada® (tenofovir, emtricitabine). Although the multi-drug combination products are more expensive than single-pill versions, some of which are available generically, taking fewer pills per day is associated with increased adherence in this therapy class.[1]
- Unit costs for medications indicated to treat hepatitis C virus increased 33.5% in 2012, driven by two novel oral drugs, Incivek® (telaprevir) and Victrelis® (boceprevir), approved in mid-2011. However,

utilization was negative in the Medicaid population, as fewer new patients initiated therapy on the new medications.

- Total trend for pulmonary hypertension (PAH) medications was 35.4% in 2012, driven by increases in both utilization and cost. The utilization of PAH drugs in the pediatric population may be related to increased awareness of the condition in recent years. However, a recent Food and Drug Administration (FDA) warning against the use of Revatio® (sildenafil) for pediatric PAH patients[2] may have shifted utilization to more-expensive drugs such as Remodulin® (treprostinil) and Letairis® (ambrisentan).
- Although utilization of medications that treat respiratory conditions increased 12.5%, the 30.8% total trend was also driven by an 18.3% increase in unit costs. New medications in this class such as Kalydeco® (ivacaftor), which costs almost $300,000 per patient per year,[3] offer new promise to some patients with rare conditions like cystic fibrosis by treating the underlying cause of disease rather than the symptoms.

## Footnotes


1. Airoldi M, Zaccarelli M, Bisi L, et al. One-pill once-a-day HAART: a simplification strategy that improves adherence and quality of life of HIV-infected subjects. *Patient Prefer Adherence*. 2010; 4: 115-125.
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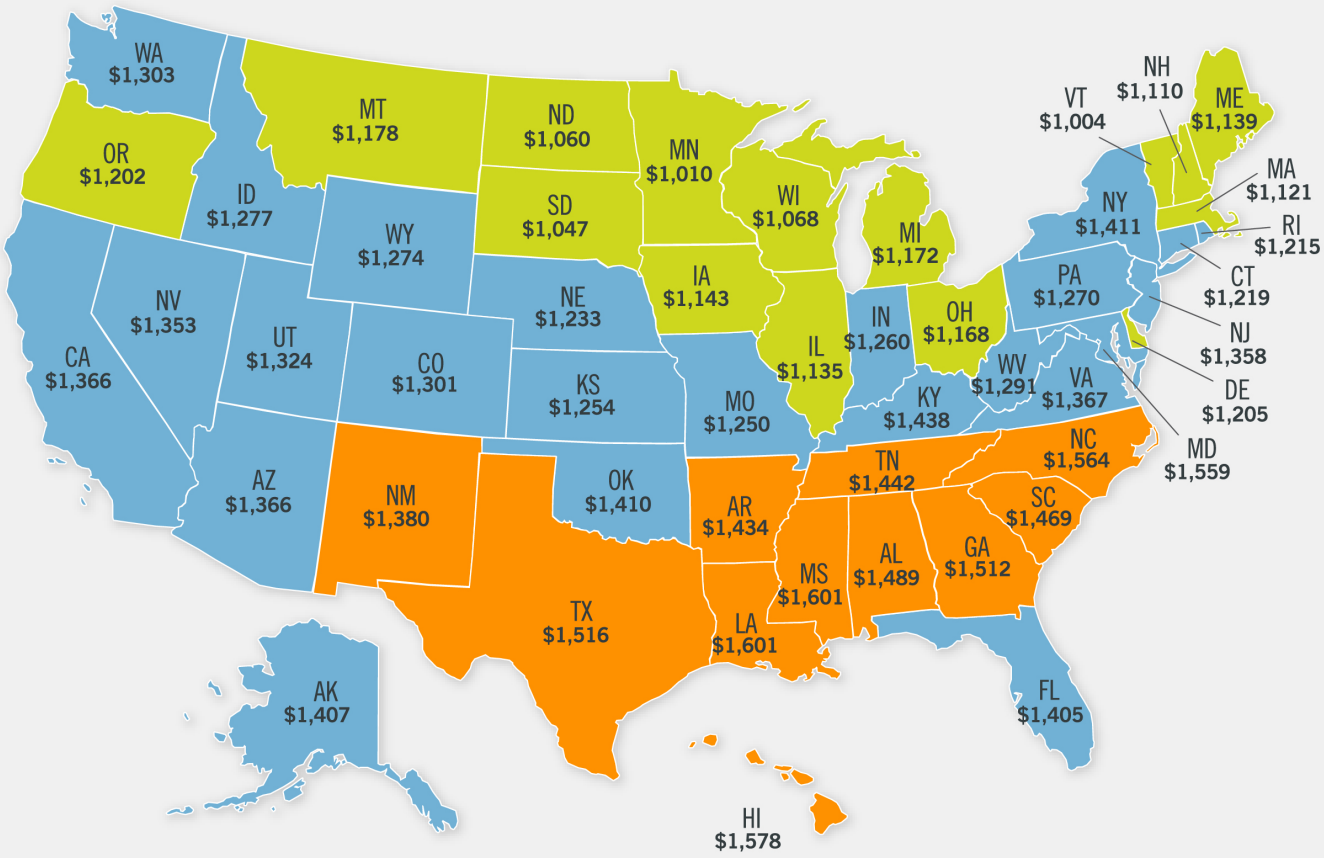
# TREND DRIVERS

## PHARMACY RELATED WASTE

Since 2010, Express Scripts has employed a rigorous, scientific approach to the study of pharmacy-related waste, which is defined as extra medication-related spending that provides no additional clinical benefits.

## PHARMACY-RELATED WASTE ACROSS AMERICA

### State-by-State Look at Per Capita Pharmacy-Related Waste




Dollars represent 2012 per capita medication-related waste

States ranking in the highest one-third of waste

States ranking in the middle one-third of waste

States ranking in the lowest one-third of waste

For more than 25 years, Express Scripts has worked to eliminate waste in the pharmacy benefit. Suboptimal pharmacy-related behavior by U.S. consumers wasted more than $418 billion in 2012 — more than what the country spends in total on prescription drugs.[1] The amount of waste varies greatly by state, but the highest one-third of waste occurs in the Southeast. The states with the highest waste (more than $1,600 per person) are Mississippi and Louisiana, with North Carolina and Hawaii not far behind. Vermont, Minnesota and the Dakotas have the lowest amount of waste per person, but it still adds up to more than $1,000 in costs that provide no additional health benefits.

To achieve healthier outcomes and save billions of dollars for patients, employers and the government, we need to drive behavioral changes by making better drug choices, better pharmacy choices and better health choices.

## Footnotes

1. IMS Institute for Healthcare Informatics. Declining medicine use and costs: for better or worse? A review of the use of medicines in the United States in 2012. May 2013. Available at: http://tinyurl.com/k2e3yf9. Accessed June 5, 2013.

## PATENT EXPIRATIONS

The Patent Expirations section shows newly introduced generics, listed by generic launch date.

## PATENT EXPIRATIONS 2013

| BRAND NAME (GENERIC NAME) | PRIMARY INDICATION | ESTIMATED ANNUAL SALES (MILLIONS) | GENERIC LAUNCH DATE | EXCLUSIVITY (YES OR NO) |
|---|---|---|---|---|
| Campral® (acamprosate) | Alcohol Dependence | $21 | Aug 12 | Y |
| Temodar® (temozolomide) | Glioblastoma Multiforme and Anaplastic Astrocytoma | $423 | Aug 12 | Y |
| Ranexa® (ranolazine) | Angina | $443 | Aug 1 | Y |
| Stalevo® (carbidopa/levodopa/ entacapone) | Parkinson's Disease | $139 | July 25 | Y |
| Glumetza® (metformin extended release) | Diabetes | $144 | July 23 | Y |
| Aricept® 23mg (donepezil) | Alzheimer's Disease | $93 | July 24 | Y |
| Lamictal® ODT™ (lamotrigine orally disentegrating tablets) | Epilepsy | $51 | July 16 | Y |
| Trilipix® (fenofibric acid delayed release 45mg, 135mg) | Hyperlipidemia | $554 | July 15 | N |
| Dacogen® (decitabine for injection) | Myelodysplastic Syndrome | $260 | July 11 | N |
| Prandin® (repaglinide) | Diabetes | $200 | July 11 | N |
| ProCentra® (dextroamphetamine oral solution) | Attention Deficit Hyperactivity Disorder and Narcolepsy | $10 | July 10 | N |
| Metrogel® (metronidazole topical gel 1%) | Rosacea | $110 | July 1 | N |
| Rilutek® (riluzole) | Amyotrophic Lateral Sclerosis | $64 | June 18 | N |

## Key Insights

- In June, the U.S Food and Drug Administration (FDA) approved several generic versions of Rilutek (riluzole), the only drug indicated to treat amyotrophic lateral sclerosis (ALS). ALS, also called Lou Gehrig's disease, has no cure. The disease gradually weakens muscles, eventually causing swallowing problems, breathing difficulty and paralysis. Although the exact way that riluzole works is not clear, it is known to protect nerve cells in the brain and spinal cord from damage by chemicals in the body. It has only moderate effects, however, in slowing the progression of disability and in lengthening life expectancy for ALS patients. Generic riluzole is expected to carry a much higher cost than most other generics.
- The first generic for the highest available strength of Aricept (donepezil 23mg) was released at the end of July. Used to delay the progression of Alzheimer's disease, donepezil is taken once daily. As symptoms worsen, the dose is typically increased. Generics for lower doses (5mg and 10mg tablets, and 5mg and 10mg orally disintegrating tablets) have been available since 2011 and 2010, respectively.
- Although the patent for Campral (acamprosate) expired in 2009, it was only in July that the FDA approved the first generic for the brand drug. Released in August, generic acamprosate is prescribed as a long-term maintenance treatment for patients who have overcome alcoholism. Although acamprosate's exact mechanism of action is not completely understood, it is believed to help normalize the brain's chemical balances, which are disturbed by excessive alcohol consumption. It is used in combination with psychological counseling and other support.
- On Aug. 12, 2013, a generic was launched for Temodar (temozolomide) capsules. The generic manufacturer, Teva, has 180 days of generic exclusivity for temozolomide. Along with radiotherapy, temozolomide is indicated for treating both glioblastoma multiforme, the most common type of cancerous brain tumor, and anaplastic astrocytoma, another brain cancer, that has worsened despite treatment with other anticancer drugs.

## BRAND APPROVALS

The Brand Approvals section is an overview of brand medications newly approved by the U.S. Food and Drug Administration (FDA) with specific details about some of these generally more expensive products.

## BRAND APPROVALS 2013

| BRAND NAME (GENERIC NAME) | PRIMARY INDICATION | APPROVAL DATE |
|---|---|---|
| Naftin® Gel (naftifine) | Athlete's Foot | June 27 |
| Rixubis [coagulation factor IX (recombinant)] | Hemophilia B | June 27 |
| Brisdelle™ (paroxetine mesylate) | Menopausal Hot Flashes | June 28 |
| Zubsolv® (buprenorphine/naloxone sublingual tablets) | Opioid Dependence | July 3 |
| Khedezla® (desvenlafaxine extended release) | Depression | July 10 |
| Gilotrif™ (afatinib) | Non-Small Cell Lung Cancer | July 12 |
| Simponi® Aria™ (golimumab) | Rheumatoid Arthritis | July 18 |
| Astagraf XL™ (tacrolimus extended release) | Kidney Transplant Rejection | July 19 |
| Lo Minastrin™ FE (norethindrone acetate/ ethinyl estradiol/ferrous fumarate) | Oral Contraception | July 24 |
| Fetzima™ (levomilnacipran extended release) | Depression | July 25 |
| Injectafer® (ferric carboxymaltose) | Anemia | July 25 |
| Tivicay® (dolutegravir) | Human Immunodeficiency Virus | Aug 12 |
| Epaned™ (enalapril for oral solution) | Hypertension | Aug 13 |
| Trokendi XR™ (topiramate extended release) | Epileptic Seizures | Aug 16 |
| Mirvaso® (brimonidine gel) | Rosacea | Aug 23 |
| Valchlor™ (mechlorethamine gel) | Cutaneous T-Cell Lymphoma | Aug 23 |

### Key Insights

- Recently approved Rixubis [coagulation factor IX (recombinant)] is the first hemophilia product to be indicated both to control acute bleeding and to prevent bleeding episodes for patients 16 years old and older with hemophilia B. A less common form of the condition than hemophilia A, hemophilia B accounts for about one-fifth of all hemophilia cases in the U.S.[1] Rixubis will compete with BeneFIX® [coagulation factor IX (recombinant)], which is approved for control, but not prevention, of bleeding for patients with hemophilia B.

- The U.S Food and Drug Administration (FDA) approved Brisdelle (paroxetine mesylate) for the management of menopausal symptoms such as night sweats and hot flashes. It contains an active ingredient that is similar to that in the selective serotonin reuptake inhibitor (SSRI) antidepressant, Paxil® (paroxetine hydrochloride), but Brisdelle is given in a lower dose. Although low doses of SSRIs may be prescribed for off-label use to treat menopausal symptoms, Brisdelle is the first SSRI to receive the specific indication.
- Gilotrif (afatinib) oral tablets are indicated for the first-line treatment of metastatic non-small cell lung cancer (NSCLC) with certain mutations that increase the production of epidermal growth factor receptor (EGFR). Overactivity of EGFR, which is associated with the growth, spread and aggressiveness of some cancers, affects approximately 10% of NSCLC patients.[2] When the FDA approved Gilotrif, the agency also approved a companion diagnostic test for EGFR-activating mutations in a patient's NSCLC cells. A diagnosis of EGFR mutations must be confirmed before Gilotrif can be prescribed.
- ViiV Healthcare received FDA approval for its once-daily add-on HIV therapy, Tivicay (dolutegravir). Tivicay is the second integrase inhibitor to be approved by the federal agency, after Merck's twice-daily Isentress® (raltegravir), which has been on the U.S. market since 2007. A third integrase inhibitor, once-daily elvitegravir, is expected to be approved in the next year. Integrase inhibitors block HIV replication by preventing viral DNA from infiltrating into human immune cells (T-cells).
- Galderma's Mirvaso (brimonidine topical gel 0.33%) was approved to treat rosacea-associated facial redness in adult patients by shrinking blood vessels that have become distended under the skin. In the U.S., some 16 million individuals have rosacea. Similar treatments on the market include Metrogel® (metronidazole gel 1%), also made by Galderma, which recently lost patent protection.

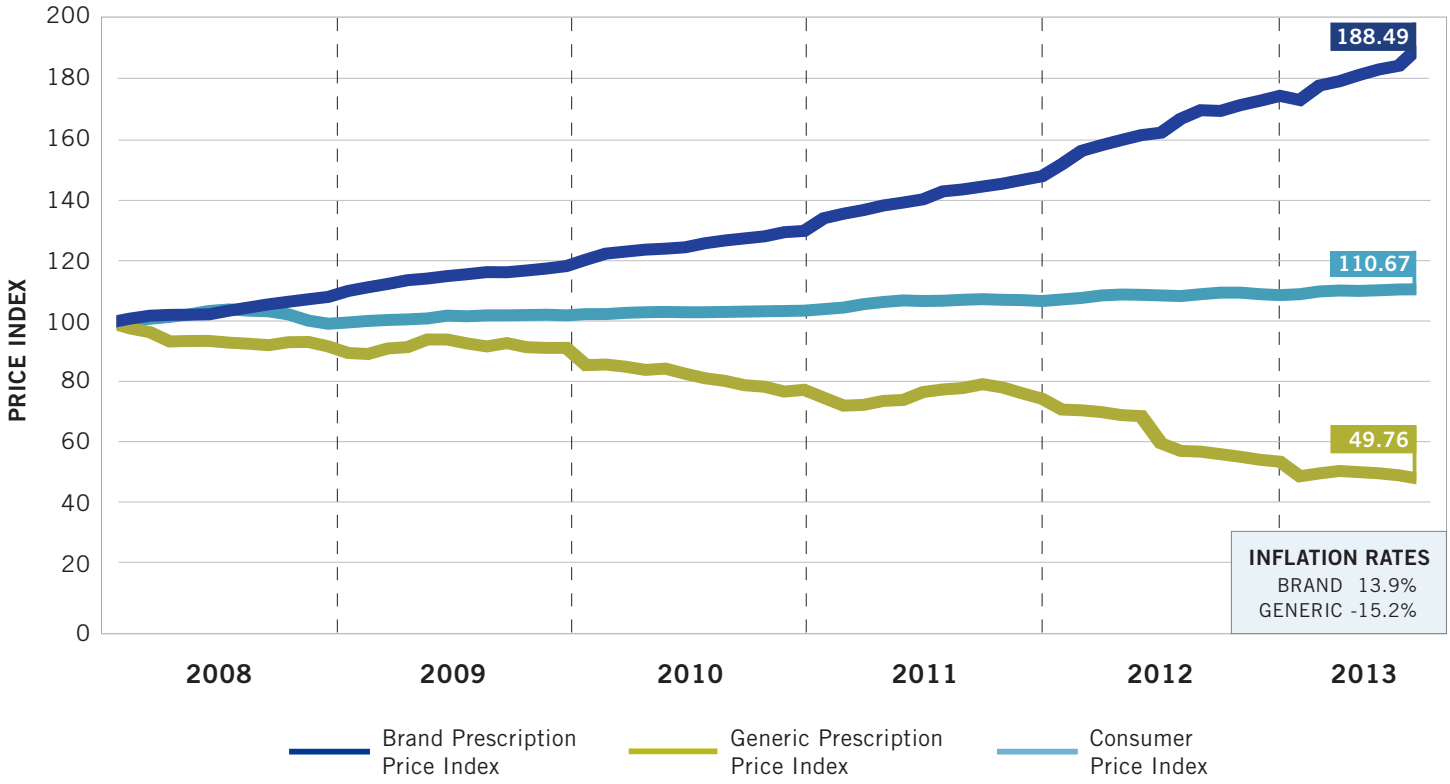
## Footnotes


1. Zaiden RA. Hemophilia B. Medscape website. http://emedicine.medscape.com/article/779434-overview. Updated July 15, 2013. Accessed Sept. 24, 2013.
2. Lovly C, Horn L, Pao W. EGFR mutation in non-small cell lung cancer. My Cancer Genome website. http://www.mycancergenome.org/content/disease/lung-cancer/egfr. Sept. 17, 2012. Accessed Aug. 7, 2013.

## PRESCRIPTION PRICE INDEX

The Express Scripts Prescription Price Index (PPI) is a measure of price inflation that tracks changes in price over time for a fixed market basket of the most commonly used brand and generic prescription medications.

## PRESCRIPTION PRICE INDEX




### Key Insights

- An unchanged market basket of brand drugs that cost $100 in 2008 would cost $188.49 today (in 2008 dollars). Conversely, a market basket of generic drugs that cost $100 in 2008 would cost only $49.76 today (in 2008 dollars).
- The steep discounts offered previously as a result of increased utilization of newly available generics have begun to slow as the rate of patent expirations decelerates from 2012, the year dubbed the Patent Cliff because of the wave of patent expirations for blockbuster brand drugs. Generic deflation was 15.2% in July, down from 29.8% at the beginning of 2013.
- In contrast to the dramatic price changes experienced for brand and generic drugs between July 2012 and July 2013, inflation across a broad market basket of goods and services as measured by the Consumer Price Index (CPI) was only 2.0% during the same period.

## PHARMACY LANDSCAPE NEWS

The Pharmacy Landscape News section features important drug study findings, pharmacy landscape patterns, and relevant policy decisions.

# PHARMACY LANDSCAPE NEWS

### FDA Changes OxyContin Labeling

In April 2013, the Food and Drug Administration (FDA) added abuse-deterrent language to the labeling for Purdue's abuse-resistant form of OxyContin® (oxycodone controlled release) tablets. At the same time, the FDA ruled that the benefits of the original OxyContin formulation which Purdue had phased out in 2010 for safety reasons did not outweigh its abuse potential. The ruling means that the FDA will not approve generics to the original OxyContin formulation. The abuse-deterrent formulation of OxyContin is more difficult to crush than the original OxyContin and is also difficult to inject or inhale.[1]

### Cancer Drug Shortages Affect Treatment

Drug shortages among chemotherapeutic agents have received wide media attention, raising concerns about treatment delays and suboptimal therapy. In a survey of oncologists, 83% reported being unable to prescribe a standard course of therapy because of a shortage.[2] The commonly used oncology agents that continue to be affected by ongoing shortages include liposomal doxorubicin, which is indicated to treat refractory multiple myeloma, refractory ovarian cancer and AIDS-related Kaposi's sarcoma; leucovorin, a chemotherapeutic-enhancing or protective agent; and thiotepa, approved for treating lymphoma, breast cancer and ovarian cancer.[3] The FDA has responded to the shortages of some drugs by allowing temporary importation of similar products from other countries and approving generic formulations of others.[4]

### Qsymia Distribution Expanded

The FDA has approved a modification to the Risk Evaluation and Mitigation Strategy (REMS) for Qsymia™ (phentermine and topiramate extended release), which is indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in some adult patients. Qsymia's REMS informs prescribers and women who are or who may become pregnant while taking it about an increased risk of birth defects. Under the REMS revision, Qsymia now can be dispensed through certified retail pharmacies[5] as well as through the Qsymia Home Delivery Network of certified home delivery pharmacies, including the Express Scripts Pharmacy℠.

### Compounding Pharmacies Issue Full Product Recalls

In the aftermath of the fungal meningitis outbreak that was linked to the New England Compound Center, a compounding pharmacy, priority FDA inspections of compounding firms that produce sterile products have resulted in penalties and numerous product recalls. As of June 1, 2013, multiple U.S. compounding pharmacies had issued total recalls of sterile products in 2013 because of concerns about possible product contamination.[6]

### Several States Vote to Defeat Anti-Biosimilars Legislation

On June 2, 2013, the Illinois legislature became the 13th state legislative body to defeat a proposed biosimilars substitution bill,[7] which would have required additional administrative tasks of pharmacists and physicians before a biosimilar drug could be substituted for a brand biologic drug. In March, Virginia had become the first state to pass similar legislation.[8] Although the FDA has not yet approved any biosimilars for use in the U.S., a pathway for approval is nearing realization.

## Footnotes


1. U.S. Food and Drug Administration. FDA approves abuse-deterrent labeling for reformulated OxyContin [press release]. April 16, 2013. Available at: http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm348252.htm. Accessed June 6, 2013.
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