

SUPER SPENDING

U.S. TRENDS *in* HIGH-COST MEDICATION USE



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THE EXPRESS SCRIPTS LAB™



A NOTE FROM GLEN STETTIN, MD

Senior Vice President, Clinical, Research & New Solutions

IMPROVING CARE FOR THE COSTLIEST PATIENTS

Express Scripts conducted the following analysis to better understand patients with extremely high costs for prescription drugs under the pharmacy benefit. How large is the population of patients with extremely high drug costs? How has that population grown? What conditions and comorbidities contribute to their spending? Who makes up these populations? And most importantly, how can we help our clients identify new opportunities to improve care, quality of life and health outcomes for the patients who rely on these costly, complex therapies?

KEY FINDINGS:

- **More than half a million Americans filled at least \$50,000 worth of prescription drugs last year.** The estimated number of U.S. patients with annual medication costs greater than \$50,000 increased 63% in 2014, from 352,000 to 576,000 Americans. And the population of patients estimated to be taking at least \$100,000 worth of medication nearly tripled, increasing 193%, from 47,000 to 139,000 Americans.

- **Comorbidities and polypharmacy were prevalent among patients with extremely high drug costs.** Among patients whose drug costs reached at least \$100,000, more than one-third were treated for at least 10 conditions and more than 60% were taking at least 10 different prescription medications. Additionally, twice as many (2.3 times) patients taking a specialty medication also take an antidepressant, when compared to the total population.
- **Baby Boomers and men make up the majority of patients with high annual drug costs.** Baby Boomers (ages 51-70) surpassed all other age groups as the highest-cost medication users. Nationally, more men than women have costs equal to or greater than \$100,000.
- **Nine out of 10 patients with drug costs of \$50,000 or more used specialty medications.** Among Americans with annual medication costs at or exceeding \$100,000 under the pharmacy benefit, 32% used a cancer medication. Also, due to the latest generation of hepatitis C therapies that were introduced to the market last year, the number of patients in the highest-cost categories receiving medication treatment for hepatitis C jumped 733% in 2014.
- **Compounded medication use was the third-largest contributor to spend among patients with extremely high medications costs, after hepatitis C and cancer medication use.** Among Americans with annual drug costs at or above \$100,000, the proportion of patients using compounded medications grew 30% in 2014, and the costs for these compounded medications quadrupled. Use of compounded medications is slightly greater among women compared to men.
- **Plan sponsors cover the bulk of high-cost medication expenses.** For patients whose 2014 drug costs met or exceeded \$100,000 in 2014, plan sponsors paid an average of 98% of the total expense.

IMPLICATIONS:

1. **Clear opportunities exist to eliminate wasteful spending and improve medication adherence.**

Compounded therapies, in addition to therapies for hepatitis C and cancer medications, comprise nearly two-thirds of drug spending for patients whose costs were \$100,000 or more in 2014. Yet, unlike high-cost hepatitis C and cancer therapies, most compounded medications add little or no value to patient outcomes, and in a growing number of cases, may actually put a patient's health at risk.

Tightly managing the use of compounded medications offers a significant opportunity for payers to improve patient safety and reduce spending.

Express Scripts' solution for compounded medicine management, implemented in mid-2014, will reduce our clients' compounded medication spend by 95%, saving them more than \$1.9 billion in 2015 that would have otherwise been wasted.

Also reflected in this high-cost population are several conditions – particularly cancer and diabetes – that historically experience high levels of medication nonadherence, leading to even worse health outcomes. Use of home delivery pharmacy – where commercially insured patients are 11% to 19% more likely to be adherent than patients using a retail pharmacy, and Medicare beneficiaries are 29% more likely to be adherent – can significantly improve both costs and outcomes.

2. We can improve patient health by managing specialty and traditional medications together.

Patients at the top of the cost pyramid are afflicted with several comorbidities that increase the complexity and cost of their care. When we treat the whole patient – by providing a home pharmacy that offers integrated, coordinated care with specialist pharmacists, physicians, nurses, nutritionists and other specialists – we deliver more efficient, effective and personalized patient care.

Having a choice of pharmacies is important. Selecting the right pharmacy matters most. Express Scripts' integrated approach delivers optimal care through our specialty pharmacy, Accredo®, and our Therapeutic Resource Centers®, while effectively managing cost trends.

3. Pioneering new approaches in cancer care can lead to improved patient access to breakthrough therapies and a more sustainable benefit for payers.

Each new discovery in the field of oncology offers tremendous progress in the successful treatment of cancer. Yet, the definition of success varies for each individual patient. For one patient, a therapy may lead to remission; for another, that same therapy may add a few more weeks of life.

What payers and patients **pay** for a therapy should align with the value that therapy will deliver to each individual patient. This value-based approach makes therapy more affordable and accessible for all patients. We have the scientific research to help guide the discussion, and coupled with the increasing number of available cancer therapies – including the potential of biosimilars – we now have the opportunity to advance this important value/care discussion for cancer and other complex conditions.

The rapid growth in the population of patients with extremely high medication costs threatens the affordability of medical coverage for all beneficiaries and their plan sponsors. A comprehensive management approach that effectively balances patient care, outcomes and cost will help ensure new, innovative medications are readily available and affordable to the patients who need them most.

Sincerely,

A handwritten signature in black ink that reads "Glen D. Stettin". The signature is fluid and cursive, with the first name "Glen" and last name "Stettin" clearly legible.

Glen Stettin, M.D.

MAJOR COST DRIVERS

MULTIPLE CONDITIONS,
PRESCRIPTIONS AND
PRESCRIBERS

AGE & GENDER TRENDS

METHODOLOGY

MAJOR COST DRIVERS

The estimated number of Americans with drug costs exceeding \$50,000 increased 63% in 2014, from 352,000 to 576,000. The estimated size of the population at the highest end of this spectrum – **where annual medication costs exceed \$100,000 per patient** – jumped 193%, from an estimated 47,388 to 138,722 Americans. This population now represents 6.5% of total U.S. drug spend (up from 2.5% in 2013).

As noted in Table 1 below, the 0.2% of patients with annual spending at or above \$50,000 accounted for 16% of total spend, while the costliest 5% of patients accounted for 61% of the country's total medication spend.

TABLE 1: DISTRIBUTION OF PATIENTS

BY COST CATEGORY

COST CATEGORY	% TOTAL PATIENTS		% TOTAL COST	
	% TOTAL	CUMUL. %	% TOTAL	CUMUL. %
≥\$100,000	0.05%	0.05%	6.5%	6.5%
\$50,000 - \$99,999	0.17%	0.22%	9.2%	15.7%
\$10,000 - \$49,999	1.8%	2.0%	27.6%	43.2%
\$5,000 - \$9,999	3.1%	5.1%	17.8%	61.0%
\$1,000 - \$4,999	15.6%	20.7%	29.6%	90.7%
<\$1,000	48.2%	68.9%	9.3%	100.0%
NON-UTILIZERS	31.1%	100.0%		
TOTAL	100.0%		100.0%	

Use of specialty medications was high among patients with drug costs at or above \$50,000; 92.4% used high-priced drugs commonly used to treat rare and complex diseases. While these medications historically have been used with very small patient populations, they increasingly are being approved for the treatment of conditions with larger patient populations. New medications approved by the FDA hit a near record high of 51 in 2014, and 27 of them were specialty treatments.

The increase in the population of patients with extremely high drug costs was significant for Medicare and Medicaid, too. While only one in 200 Medicare beneficiaries and one in 1,000 Medicaid beneficiaries had prescription drug costs greater than \$50,000 in 2014, these rates are 63% and 100% higher, respectively, than the previous year.

TABLE 2: PERCENT OF PATIENTS WITH ANNUAL DRUG COSTS ABOVE \$50,000

BY PLAN TYPE

PLAN TYPE	2013		2014	
	% PATIENTS	% TOTAL COST	% PATIENTS	% TOTAL COST
MEDICAID	0.05%	7.3%	0.10%	14.0%
MEDICARE	0.30%	9.1%	0.50%	14.9%
COMMERCIAL	0.11%	9.7%	0.18%	16.1%
OVERALL	0.14%	9.5%	0.22%	15.7%

The population of Medicare beneficiaries with annual drug costs at or exceeding \$50,000 increased **63%** in 2014.

COST SHIFTS FROM PATIENT TO PAYER

While the population of high-cost medication users grew, so did the population of patients reaching their plan's out-of-pocket maximums. Insured patients who used more than \$100,000 worth of medications in 2014 paid, on average, only 1.7% of the total cost out of pocket. The remaining amount, covered by their plan sponsors, averaged \$156,911 per patient. In contrast, insured patients with less than \$1,000 of annual drug costs were responsible, on average, for 35% of the total amount of their spend.

Across the cost spectrum, patients in 2014 paid an average of 13.5% of their total medication costs, down from 14.9% in 2013.

TABLE 3: 2014 AVERAGE ANNUAL COST PER PATIENT

BY COST CATEGORY

COST CATEGORY	TOTAL	PLAN	OUT-OF-POCKET	% OOP
≥ \$100,000	\$159,693	\$156,911	\$2,782	1.7%
\$50,000 - \$99,999	\$69,018	\$67,245	\$1,773	2.6%
\$10,000 - \$49,999	\$19,351	\$18,186	\$1,165	6.0%
\$5,000 - \$9,999	\$7,051	\$6,107	\$944	13.4%
\$1,000 - \$4,999	\$2,400	\$1,926	\$474	19.8%
<\$1,000	\$256	\$166	\$89	34.9%
OVERALL	\$1,370	\$1,185	\$185	13.5%

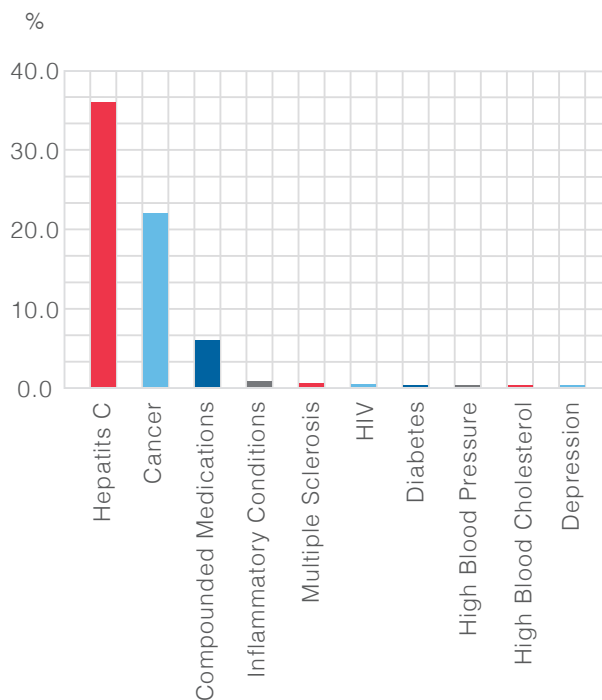
Nearly 2/3 of the total spend for patients with annual drug costs exceeding \$100,000 in 2014 was for hepatitis C, cancer, and compounded treatments.

THREE DRUG CATEGORIES DROVE SPEND FOR HIGH-COST USERS

Hepatitis C and cancer treatments, along with compounded products, were responsible for nearly two-thirds of the medication costs for patients whose 2014 prescription drug bills equaled or exceeded \$100,000.

FIGURE 1: TOP 10 CONDITIONS AMONG PATIENTS WITH MORE THAN \$100,000 RX SPEND IN 2014

BY % CONTRIBUTION TO COST



Hepatitis C

The number of patients with hepatitis C who had annual medication costs at or above \$50,000 leapt 733% in 2014. These patients also constituted 39% of the total number patients with drug costs reaching \$100,000 or higher. Medicare patients, who represent 13.2% of patients in the analysis, accounted for 29.9% of all hepatitis C medication users.

Cancer

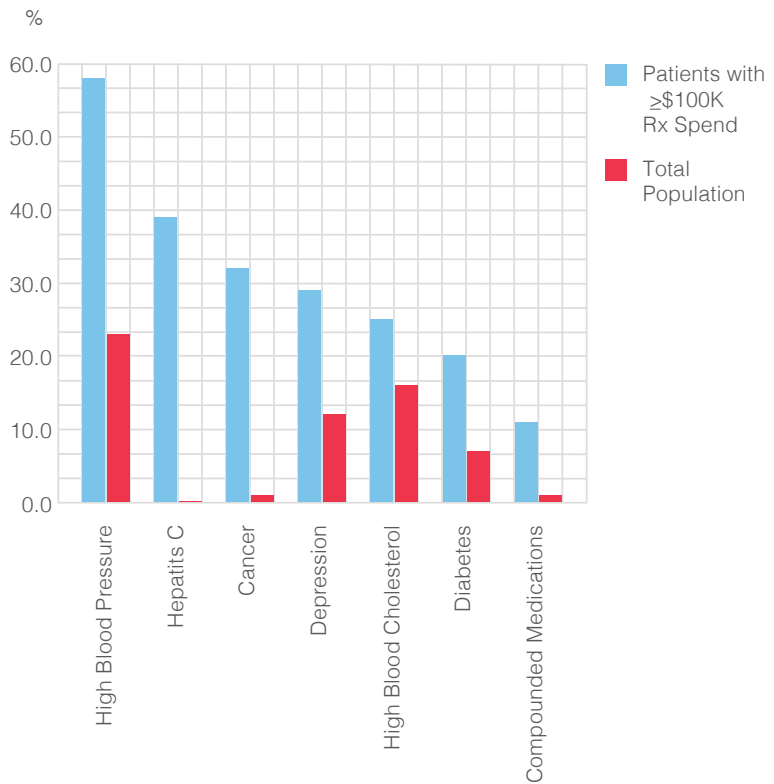
Of patients with medication costs at or exceeding \$100,000, 32% were treated for cancer in 2014.

Compounded Medications

Among Americans with annual drug costs at or above \$100,000, the number of patients using compounded medications grew 30% in 2014, and the costs for these compounded medications increased 1,032%, from \$12.6 million in 2013 to \$142.1 million 2014.

FIGURE 2: TOP THERAPY CLASSES

BY PREVALENCE OF RX USE



**GLEN STETTIN, MD**

Senior Vice President
Clinical, Research & New
Solutions at Express Scripts

The latest generation of hepatitis C therapies first entered the U.S. market at the very end of 2013. They are well tolerated and highly effective, but they were also priced unsustainably high for payers and therefore inaccessible to patients who could benefit from them. On Dec. 22, 2014, we announced our Hepatitis Cure Value Program – an agreement with the drugmaker AbbVie that would significantly lower the cost to cure hepatitis C in the United States, saving our clients more than \$1 billion and expanding access to this curative therapy to **all** of our patients, not just the sickest. The program also financially guarantees that patients receiving therapy through our Accredo specialty pharmacy will adhere to their full regimens. Even for regulated markets that cannot adopt all elements of this program, many of these same best practices in utilization management and formulary structure can be applied to support therapy completion while managing costs.

Treatment for cancer will continue to see increases in cost and utilization due to expanded indications for several cancer drugs, the development of new, more targeted therapies, and increasing survival rates of patients living with cancer who continue medication therapy. Express Scripts has accumulated the unique set of tools and partnerships needed to begin bringing down the cost of cancer medications while improving health outcomes.

Compounding medications is as old as the pharmacy profession. Customizing medication by combining and altering ingredients provides alternatives to patients unable to use more standard therapy. However, compounded medications do not undergo the same rigorous review process as FDA-approved medications and therefore are not intended for widespread use. Most compounded medications do not provide any additional clinical value over FDA-approved alternatives that are readily available to patients at far lower costs.

MULTIPLE CONDITIONS, PRESCRIPTIONS AND PRESCRIBERS

Patients at the upper spectrum of prescription spending often are afflicted with numerous comorbidities that contribute to the complexity and cost of their care.

Among patients whose costs reached \$100,000 or higher, more than one-third were being treated for 10 or more different medical conditions, with more than 60% taking 10 or more different medications.

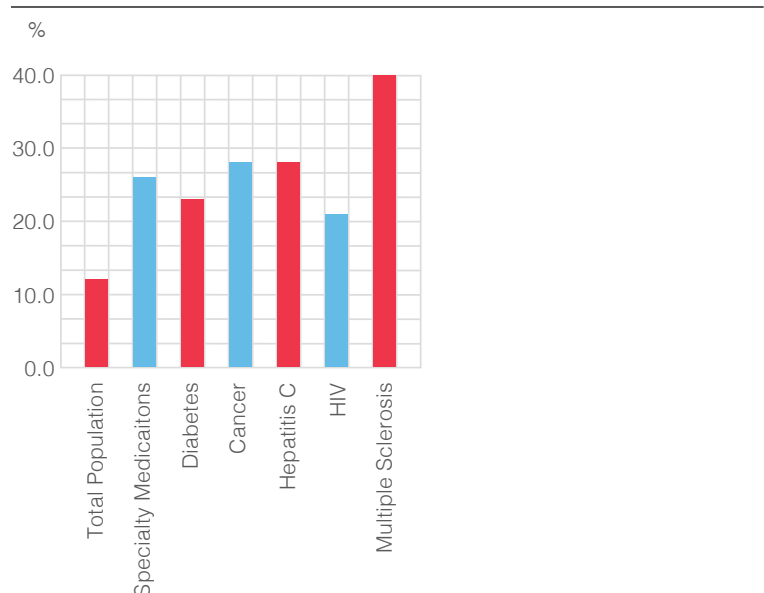
For Medicare patients with \$100K or more of spend in prescription drug costs in 2014, 38% had 10 or more different conditions and 67% were taking 10 or more drugs.

Multiple comorbidities were prevalent among patients with cancer and other complex conditions, such as multiple sclerosis, HIV and hepatitis C. The most common comorbidities included diabetes, high blood pressure, high blood cholesterol and depression.

Depression was particularly common among patients with annual drug spend of greater than \$50,000 or more in 2014, with nearly one in three patients having at least one prescription for an antidepressant. Additionally, twice as many patients taking a specialty medication also had one or more prescriptions for an antidepressant, when compared to the total population of patients.

Patients who use specialty medications take an antidepressant at more than **2.3 times** the rate of the general population.

FIGURE 3: PREVALENCE OF CONCOMITTANT ANTIDEPRESSANT USE



1 in 4 patients
had Rx's from
4 different
prescribers.

MULTIPLE MEDICATIONS, MULTIPLE PRESCRIBERS

Contributing to the complexity and cost of managing several concurrent conditions are the number of prescribers caring for patients.

- One of every four patients had prescriptions from at least four different prescribers.
- For patients who spent \$100,000 or more in 2014, only 4% had all of their medications prescribed by one physician. The majority of patients – 72% – received prescriptions from at least four prescribers.
- More than half of the patients with annual drug costs at or above \$10,000 were prescribed their medications by physicians from at least four different specialty areas.

The average annual drug costs for patients with one prescriber was \$529 in 2014. Conversely, the 1% of patients who received prescriptions from at least 10 prescribers experienced, on average, annual medication costs above \$9,000.

Patients with medication costs below \$1,000 in 2014 filled an average of 12 prescriptions – spanning four unique medications – at an average cost of \$20 per fill. In contrast, patients with medication costs at or above \$100,000 in 2014 filled an average of 68 monthly prescriptions – spanning 13 unique medications – at an average cost of \$2,300 per fill.

TABLE 4: PERCENT OF PATIENTS WITH MULTIPLE PRESCRIBERS AND PRESCRIBER SPECIALTIES

BY COST CATEGORY

COST CATEGORY	NUMBER OF UNIQUE PRESCRIBERS			
	1	2	3	4 OR MORE
≥\$100,000	3.8%	10.2%	13.7%	72.3%
\$50,000 - \$99,999	5.6%	12.4%	15.7%	66.2%
\$10,000 - \$49,999	6.4%	11.7%	14.1%	67.8%
\$5,000 - \$9,999	8.2%	14.0%	16.2%	61.6%
\$1,000 - \$4,999	13.0%	19.9%	19.8%	47.4%
<\$1,000	41.4%	27.3%	15.5%	15.8%
TOTAL	32.4%	24.6%	16.5%	26.5%

COST CATEGORY	NUMBER OF UNIQUE PRESCRIBER SPECIALTIES			
	1	2	3	4 OR MORE
≥\$100,000	5.2%	15.9%	22.0%	56.9%
\$50,000 - \$99,999	7.0%	18.6%	23.6%	50.8%
\$10,000 - \$49,999	8.5%	18.0%	21.6%	52.0%
\$5,000 - \$9,999	10.9%	21.3%	23.3%	44.6%
\$1,000 - \$4,999	17.3%	28.2%	24.6%	30.0%
<\$1,000	49.3%	30.6%	13.3%	6.9%
TOTAL	39.1%	29.2%	16.5%	15.1%



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Coordinating care for patients is essential for ensuring the best outcomes, yet achieving optimal alignment across all parties on a patient's care team is particularly challenging. This is especially concerning for Medicare plans, as polypharmacy exposes particularly vulnerable seniors to drug interactions from high-risk medications.

The complexity and number of conditions patients in this highest-cost bracket are living with requires a “whole patient,” integrated approach to care. For example, patients treated for cancer through Express Scripts' Oncology Therapeutic Resource Center have a primary pharmacist specialized in cancer care who coordinates with the registered dietitian on staff at Accredo and the patient's physicians, nurses, other specialist pharmacists and nutritionists involved in the patient's case. Specialist pharmacists in our Oncology TRC are experts in treatment, risk, possible side effects and drug interactions. They know the best way to communicate with patients, spending an average of 24 minutes talking with each cancer patient.

This holistic model provides better patient care and can more effectively manage costs.

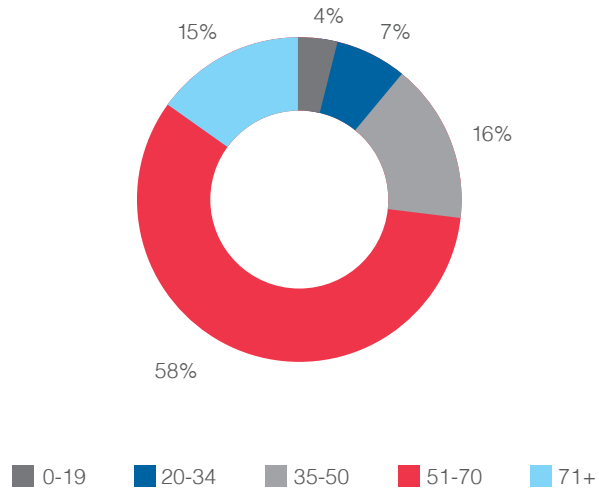
In 2014,
3 out of 5
patients with
annual medication
costs exceeding
\$100,000 were
Baby Boomers.

AGE & GENDER TRENDS

Baby Boomers stand out as the age group primarily responsible for high-cost medication trends. Americans 51-70 years old made up 58% of the population with annual drug costs at or exceeding \$100,000, and the number of Boomers in this category grew by 243% from 2013 to 2014. Approximately 18% of the Baby Boomers in this analysis are Medicare beneficiaries.

FIGURE 4: BREAKDOWN OF PATIENTS WITH MORE THAN \$100,000 RX COSTS IN 2014

BY AGE



Among Boomers in this high-cost category, in 2014, 50% were being treated for cancer, 77% were being treated for hepatitis C and 46% were using compounded drugs.

Among the Gen Xers (ages 35-50) with annual drug costs at or above \$100,000, 31% were using compounded medications.

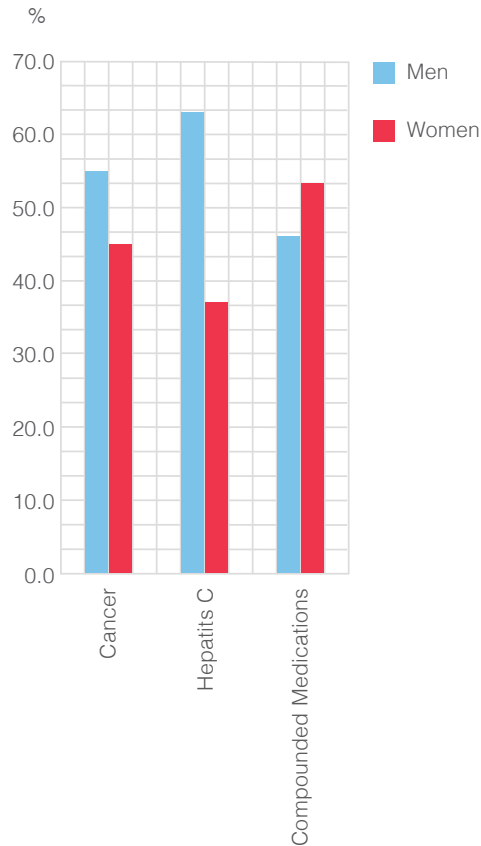
MEN LEAD HIGH-COST UTILIZATION UNDER THE PHARMACY BENEFIT

Men represent 55.8% of patients with annual prescription costs exceeding \$100,000, an increase of 6% from 2013 to 2014.

As shown in the chart below, among patients with prescription costs greater than or equal to \$100,000, men had higher prevalence of cancer and hepatitis C medication use, while prevalence of compounded medication use was higher among women.

FIGURE 5: PREVALENCE OF LEADING CONDITIONS AMONG PATIENTS WITH MORE THAN \$100,000 RX SPEND IN 2014

BY GENDER





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Baby Boomers accounting for nearly 60% of the highest-cost patient population is a significant finding in this analysis, as it highlights serious implications and opportunities for payers.

An estimated 78 million Americans were born during the Baby Boom. The Department of Health and Human Services estimates a staggering 11,000 Boomers become eligible for Medicare every day. Coupled with their high prevalence of complex and costly conditions, Medicare plans will need to consider every possible option for improving medication adherence, patient health outcomes and cost as Boomers age into Medicare eligibility.

Closely managed plans have an advantage in caring for this population. Use of copayment tiers, utilization management protocols, the Express Scripts National Preferred Formulary and exclusive or select use of home delivery from the Express Scripts PharmacySM for maintenance medications drives better health outcomes while reducing wasteful spending.

METHODOLOGY

This analysis examined the prescription drug claims of 31.5 million insured Americans from 2013 through 2014. The research included 26 million commercially insured members, 4.2 million Medicare beneficiaries and 1.3 million with Medicaid coverage.

U.S. population estimates are based on 2013 figures from Kaiser Family Foundation's Health Insurance Coverage of the Total Population.¹

This analysis does not reflect additional medications that may have been administered within a medical setting, as these would not be billed through the pharmacy benefit.

¹Henry J. Kaiser family Foundation. Health insurance coverage of the total population. <http://kff.org/other/state-indicator/total-population>. March 2014. Accessed May 7, 2015.

