Magellan Rx Management

Medical Pharmacy Trend Report™

2014 FIFTH EDITION

Magellan Rx MANAGEMENT℠

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Introduction

Magellan Rx Management is pleased to present the fifth edition of our Medical Pharmacy Trend Report,™ the only detailed source for reviewing current medical benefit drug management approaches and data benchmarking.

Now in its fifth edition, the annual trend report is the industry's key source for valuable data and detailed information on the state of the nation's medical benefit drug landscape. It was derived from two complementary sections. First, we surveyed medical, pharmacy and network directors from 48 commercial health plans representing more than 125 million covered lives. Second, we completed an in-depth analysis of commercial and Medicare health plan medical paid claims data representing utilization across all sites of service, including physician offices, home infusion providers and hospital outpatient facilities.

Approximately 50 percent of all specialty drug spend is billed on the medical benefit, yet visibility into this spend generally has been limited and benchmarks have not been broadly reported or discussed. As specialty drug costs continue to be a leading driver of overall drug trends, it is critical for payors to keep a pulse on the evolving management strategies and marketplace conditions impacting medical pharmacy utilization and spend. Over the last five years, our trend reports have served this purpose.

We are excited to present a number of new enhancements to the 2014 trend report, resulting in our most comprehensive trend report to date. We asked health plans across the country very specific questions about the management of medical benefit drugs to provide our readers with a better understanding of what health plans are doing today to manage spend and what they plan to do in the future. We focused on reimbursements across outpatient sites of service and identified key cost variances that exist among the different provider types. We included a new section in our health plan survey that focused on key management trends, such as oncology-specific pilot programs, palliative care and site of service management. We detailed our paid claims data analysis by line of business (LOB), allowing our readers to observe different trends in commercial and Medicare populations. We also added several new analyses to provide therapeutic category-specific views of medical benefit drug utilization.

Many dynamics impacted the medical benefit drug landscape in 2014. The shift in site of service or movement of provider-administered drugs from the physician office to the hospital outpatient facility remained a key cost driver of medical pharmacy spend across all commercial payors. Biosimilars continued to generate interest as potential cost-saving opportunities, and the first biosimilar product might be approved in early 2015. Lastly, when this report went to press, the FDA had approved 14 medical benefit drugs in 2014. Oncology drugs such as Cyramza, Beleodaq and Keytruda were priced near $75,000 or more for six months of treatment.

We believe you will find that our trend report is useful and unique. The topics provide valuable insight on current medical benefit drug trends and management issues facing commercial payors. It also includes a medical benefit drug pipeline and a "Key Legislative Outcomes and Management Trends" section. This trend report is another way Magellan Rx Management gives you the tools to make smarter decisions every day for managing specialty pharmacy benefits.

You can download the full report at **www.magellanhealth.com.**

2014 Survey Methodology and Demographics

The methodology for the fifth edition of the Magellan Rx Management Medical Pharmacy Trend Report™ was developed with original guidance from our payor advisory board as well as reader feedback on our previous trend reports.

This report includes a combination of primary and secondary research methodologies to deliver a comprehensive view of payor perceptions and health plan actions related to medical pharmacy (provider-administered infused or injected drugs paid under the medical benefit, also referred to as medical benefit drugs). These medical benefit drugs are commonly used to treat cancer, autoimmune disorders and immunodeficiencies.

The first section of this report was derived from a custom market research survey conducted among commercial health plan medical, pharmacy and network directors. The Web-based survey was designed to gather feedback about how managed care organizations operated around seven key management drivers for medical benefit drugs identified by Magellan Rx Management. The first six key management drivers have been reviewed in past reports; the seventh, "Management Trends," was a new survey category and is a new section in the 2014 trend report.

The second section of the report was derived from secondary analyses of commercial and Medicare health plan medical paid claims data that represented utilization across all sites of service, including the physician office, home and hospital outpatient facility. In addition, this report separated analyses by LOB and included multiple new analyses that showcased the current landscape of medical benefit drugs.

HEALTH PLAN SURVEY METHODOLOGY

Similar to our previous editions, the target list of payors consisted of top U.S. health plans based on number of covered lives. The sample was stratified by covered lives, national versus regional plans, geographic dispersion and respondent type (i.e., medical, pharmacy or network directors). Research topics were developed and aligned with the seven key management drivers for medical benefit drugs. The survey questions were defined, some questions were revised and many others were added to provide incremental value and greater specificity over the 2013 survey. The potential effect of the changes has been noted where appropriate in the results. The questions were pretested and the survey was deployed to a sample audience via a secure browser-based software program.

The data collection took place over a five-week period during August and September 2014. Following data collection, the results were validated, aggregated and analyzed for reporting herein. For the purposes of this report, survey results were primarily reported on a "percentage of lives" basis. Weighting individual responses in this manner provided an indication of the potential marketplace impact of payor policies on the number of covered lives, in addition to the percentage of payors incorporating any one policy. Historically, survey results also were reported at times with the health plans stratified into large- and small-sized plans, defined as 500,000 or more covered lives and less than 500,000 covered lives, respectively. For year-over-year comparison reporting, we continued to use the separation of plan size based on 500,000 covered lives. For new 2014 survey questions, we updated the definitions to 1,000,000 or more covered lives for large plans and less than 1,000,000 covered lives for small plans based on the average survey respondent number of covered lives with outliers removed. In certain responses, base sizes were small and care should be used when interpreting the data. Rarely, some percentages might add up to slightly more or less than 100 percent due to rounding effects.

REPRESENTATION OF SURVEY RESPONDENTS

For our 2014 survey, a total of 48 individual survey responses were received, representing 125.1 million covered lives. *See Figure 1: Survey Respondent Composition.*

FIGURE 1: Survey Respondent Composition

	COUNT	LIVES	% OF LIVES	% OF PAYORS
Less Than 500,000	22	4,826,500	4%	46%
500,000–999,999	8	5,377,000	4%	17%
1,000,000–4,999,999	14	33,550,000	27%	29%
5,000,000 or More	4	81,400,000	65%	8%
Total	**48**	**125,153,500**	**100%**	**100%**

Fifty-eight percent of the health plan organizations that responded in 2014 also provided responses to the 2013 survey. Similar to last year, current survey respondents tended to be very experienced, with an average of 23 years (versus 22 years in 2013) in the field and nine years in their current position. Survey responses from network, medical and pharmacy directors represented 32, 31 and 30 percent of covered lives, respectively. Internal medicine and family medicine were the leading specialties reported by these health plan medical directors. "Other" survey respondents included clinical program managers, clinical pharmacists and care management managers. *See Figure 2: Survey Respondent Composition.*

Of the total lives covered by the payors completing the survey, 58 percent (versus 59 percent in 2013) were fully insured lives, while the balance were only provided administrative services by the health plans. Survey respondents noted that the majority of their members (72 percent of lives in 2014 versus 67 percent in 2013) who received coverage were covered under mixed health maintenance organization (HMO)/preferred provider organization (PPO) products. Same as last year, two-thirds (65 percent) of total covered lives reflected commercial product coverage. Further examination of the fully insured population revealed that 32 percent of lives were covered through commercial HMO products and 30 percent of lives were covered through PPO products. The exchange product represented 6 percent of fully insured lives. The rest of the fully insured lives were split between Medicare (13 percent) and Medicaid (19 percent) HMO lives.

Survey respondents from national plans constituted 17 percent (versus 21 percent in 2013) of the respondents, yet they covered two-thirds (66 percent) of the total lives represented in this survey (down from 72 percent in 2013). Conversely, regional plans made up a larger percentage of payor respondents (83 percent), but reflected only 34 percent of the total covered lives. The map on page 6 illustrates that geographically more than half of the covered lives from these regional payor respondents are located in the East versus last year when nearly half of the covered lives were located in the West. *See Figure 3: Regional Plans – Geographic Dispersion of Lives.*

FIGURE 2: Survey Respondent Composition

% OF LIVES

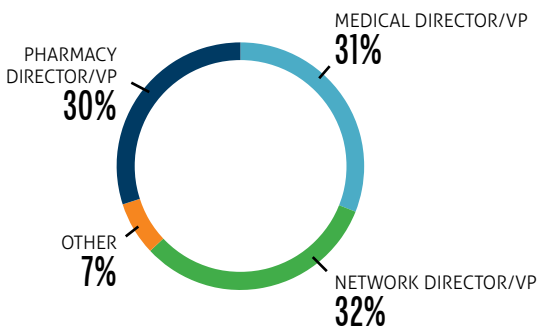
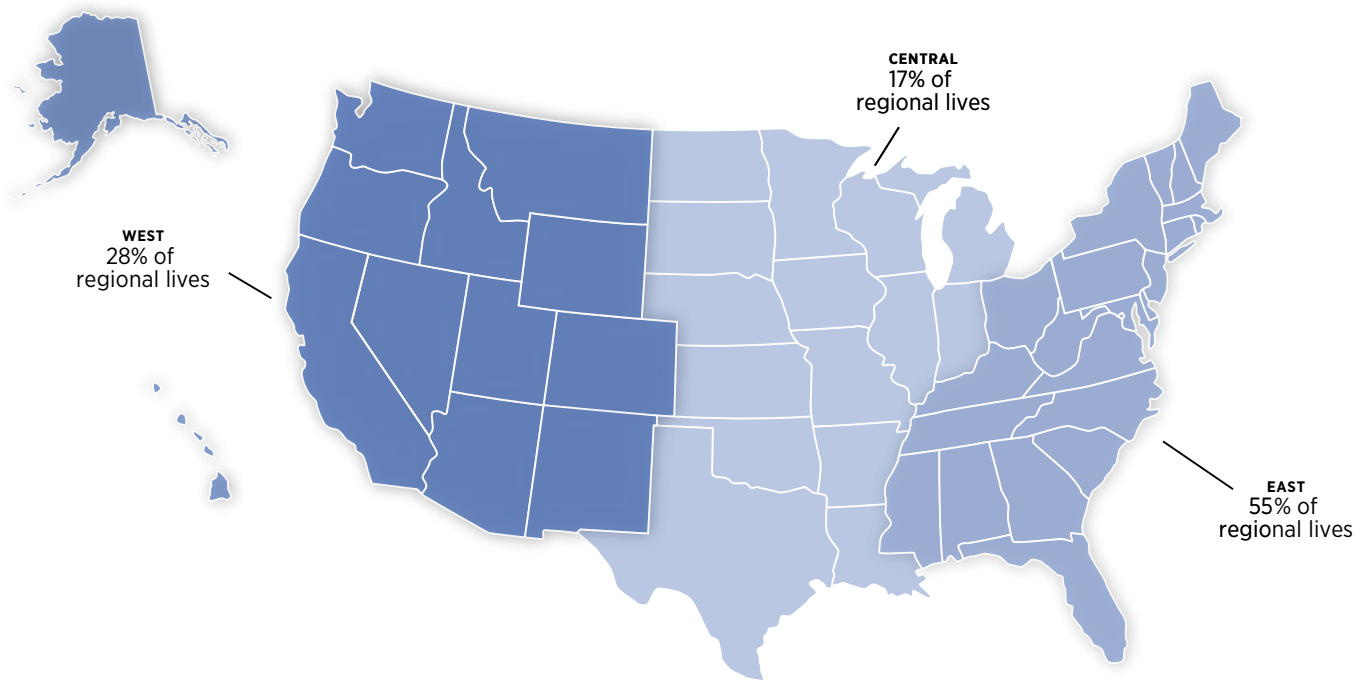


FIGURE 3: Regional Plans – Geographic Dispersion of Lives



HEALTH PLAN CLAIMS DATA METHODOLOGY

For these analyses, commercial and Medicare health plan medical paid claims data were analyzed for medical pharmacy utilization across all sites of service, including the physician office, home and hospital outpatient facility. Claims billed from participating and non-participating providers were included. Vaccines and A code radiopharmaceuticals were excluded from the analyses. Administration codes were analyzed separately in only one analysis (Figures 123 and 124); their utilization was not included in any other analysis. Most analyses compared calendar years 2012 and 2013. In some cases, the past four years (2010–2013) were analyzed to show a longer period of year-over-year spend and trend.

Report Summary and Conclusions

The Magellan Rx Management 2014 Medical Pharmacy Trend Report™ evaluated the management and trends of provider-administered infused or injected drugs paid under the medical benefit, also referred to as medical benefit drugs. The results of this study were a combination of findings from medical, pharmacy and network directors at commercial health plans as well as medical benefit paid claims data across key lines of business (i.e., commercial and Medicare) and sites of service (i.e., physician offices, homes via home infusion and hospital outpatient facilities).

Key findings from the Payor Survey Data section include:

- Health plans representing nine in 10 covered lives have product preferencing in place, preferring specific products in certain therapeutic classes on the medical benefit. The two leading therapeutic classes with a product-preferencing strategy in place for 2014 were erythropoiesis-stimulating agents (ESAs) (86 percent of covered lives) and oncology (84 percent). Tactics payors used to preference specific drugs paid through the medical benefit included prior authorization to drive step edit requirements (84 percent of covered lives) and differential physician reimbursement (47 percent).

- Health plans representing 44 percent of covered lives utilized a percent of charges model to reimburse hospital outpatient facilities for medical benefit drugs. Based on the weighted average of responses, these health plans paid approximately two-thirds of hospital outpatient facility billed charges. Payors reported that one-third of the hospitals in their networks were reimbursed for medical benefit drugs based on a fixed fee schedule versus a percent of charges arrangement.

- Eighty-one percent of payors did not vary member cost-share requirements by site of service in 2014. Of those who did not vary cost-share requirements by site of service, 13 percent said they were planning to vary cost-share requirements by site of service in the next plan year, signaling a desire to align incentives with members.

- For payors who did not have member contribution parity requirements in 2014, more than half reported that it would be more advantageous for members to have the drugs billed through their medical benefit, while one-third of health plans reported that members would have lower out-of-pocket costs if the drugs were billed through their pharmacy benefit. This highlights the continued need for more unified and consistent specialty drug management across the pharmacy and medical benefits.

- Nearly 60 percent of payors representing nine in 10 covered lives reported that oncology practices in their service areas were being purchased by hospital systems. Of those payors, nearly half reported that 10–20 percent of oncology practices had been purchased, with larger payors reporting that 31–40 percent of oncology practices had been acquired by hospital systems. This phenomenon continues to be a trending cost driver in this space.

- More than 80 percent of payors representing seven in 10 covered lives provided end-of-life/palliative care programs for their members who had cancer. When asked to report the percentage of members with cancer who received chemotherapy within the last two weeks of their lives, 79 percent of health plans representing 77 percent of covered lives had no knowledge of their plan's percentage, indicating a real need for better data capture around this measure. Nearly 80 percent of payors representing nine in 10 covered lives were looking to increase the use of palliative care programs at their organizations.

Key findings from the Health Plan Claims Data section include:

- Over the last four years, medical pharmacy allowed amounts have consistently experienced 9–13 percent year-over-year increases in the commercial population, while trends in the Medicare space have been less volatile, with an average of 2.8 percent annual trend. In 2013, payors experienced a per-member-per-month (PMPM) allowed amount of $21.07 for commercial medical pharmacy expenditures and $44.99 PMPM for Medicare members. Compared to the prior year, 2013 commercial and Medicare PMPM allowed amounts increased 13 and 5 percent, respectively, driven by inflation, utilization and drug mix.

- In 2013, 49 percent of commercial costs were billed from the hospital outpatient facility, up from 42 percent in 2010. For Medicare, we have observed similar trends, with the hospital outpatient spend accounting for 35 percent market share in 2013, up from 24 percent in 2010.

- In 2013, the average annual allowed cost per patient for the commercial population utilizing top 25 drugs was $20,915, significantly higher than the Medicare population at $4,943. The top 25 drugs represented 65 percent of the total medical pharmacy allowed amount in 2013 for the commercial population and 70 percent for the Medicare population.

- The top 10 drugs by annual allowed amount per patient tended to be used for conditions such as hereditary angioedema, rare hematologic disorders including hemophilia, diseases caused by inborn errors of metabolism, pulmonary arterial hypertension and cancer. In 2013, the average cost per patient per year across these 10 drugs exceeded $100,000, and most of these agents are lifelong therapies. Patients utilizing these top 10 drugs in 2013 represented 0.15 percent and 0.02 percent of the commercial and Medicare populations, respectively, but 6 percent of the total commercial and 4 percent of Medicare medical pharmacy expenses.

- For commercial members, oncology and oncology support medications represented 52 percent of medical pharmacy spend in 2013. Biologic drugs for autoimmune disorders represented the next highest spend category at 13.16 percent and included Crohn's disease/ulcerative colitis, rheumatoid arthritis, psoriasis/psoriatic arthritis, systemic lupus erythematosus and ankylosing spondylitis. For Medicare members, oncology and oncology support medications represented nearly 60 percent of medical pharmacy spend in 2013. Ophthalmic injections (8.76 percent) was the second highest spend category, followed by biologic drugs for autoimmune disorders at 7.44 percent.

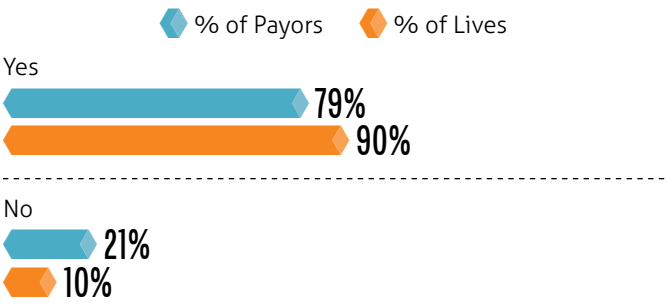
- For commercial members, drugs administered in the hospital outpatient facility, when indexed to average sales price (ASP), typically were reimbursed two to three times ASP versus a physician office setting which averaged ASP + 11–18 percent. Based on our data, the cost per drug per claim for Medicare still was higher in the hospital outpatient facility versus the physician office or home setting for most drugs; however, the dynamic was not as pronounced as it was in the commercial population. The index to ASP for drugs administered in the hospital outpatient facility ranged from ASP + 14–32 percent versus ASP + 7–13 percent in the physician office setting.

Payor Survey Data

Medical Benefit Product Preferencing

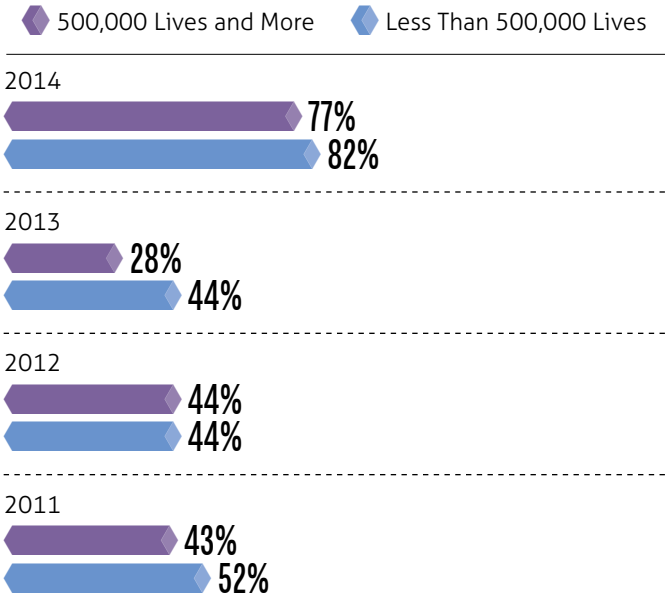
To clarify and refine the intent of this section of the trend report, we labeled it "Medical Benefit Product Preferencing" versus "Medical Benefit and Drug Formulary." Commercial payors utilize various tools to preference use of particular drugs paid through the medical benefit, such as prior authorization, step edits, provider reimbursement, policy criteria and others, although it's rare for a plan to have an actual medical benefit drug formulary as it would for drugs paid through the pharmacy benefit. In our 2013 trend report, health plans representing only 22 percent of covered lives reported that they had a medical benefit drug formulary for at least some therapeutic classes. In 2014, health plans representing nine in 10 covered lives stated that they preferred specific products in certain therapeutic classes on the medical benefit. Larger payors (defined as 500,000 or more lives in this analysis) were slightly less likely to have medical benefit product preferencing in place than smaller payors, with survey results yielding a much narrower variance than was observed in the 2013 trend report. *See Figure 4: 2014 Payors with Medical Benefit Product Preferencing in Place and Figure 5: Medical Benefit Product Preferencing in Place by Plan Size 2011–2014.*

FIGURE 4: 2014 Payors with Medical Benefit Product Preferencing in Place



n = 48 payors, 125 million covered lives (2014)

FIGURE 5: Medical Benefit Product Preferencing in Place by Plan Size 2011–2014[1]

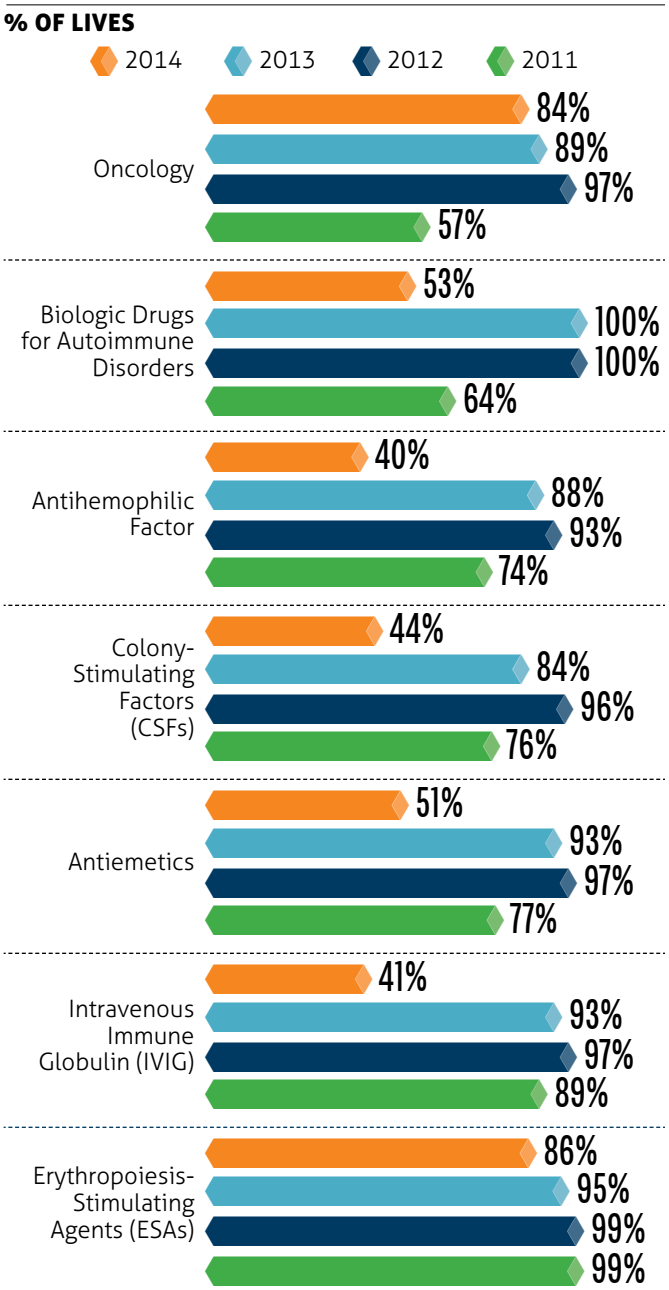


n = 28 payors, 100 million covered lives (2011)
n = 21 payors, 95 million covered lives (2012)
n = 16 payors, 36 million covered lives (2013)
n = 38 payors, 113 million covered lives (2014)

1. The 2011–2013 surveys utilized different terminology: "Medical Benefit and Drug Formulary" versus "Medical Benefit Product Preferencing."

For the 113.2 million members enrolled in plans with medical benefit product preferencing requirements in 2014, the two leading therapeutic classes were erythropoiesis-stimulating agents (ESAs) (86 percent) and oncology (84 percent). Compared to 2013, product preferencing was less prevalent across the full spectrum of therapeutic classes. This large discrepancy might be due to the substantial difference in covered lives enrolled in plans with product preferencing in 2014 versus those in 2013 (36 million lives). *See Figure 6: Medical Benefit Drug Therapeutic Classes with Product Preferencing Currently in Place 2011–2014.*

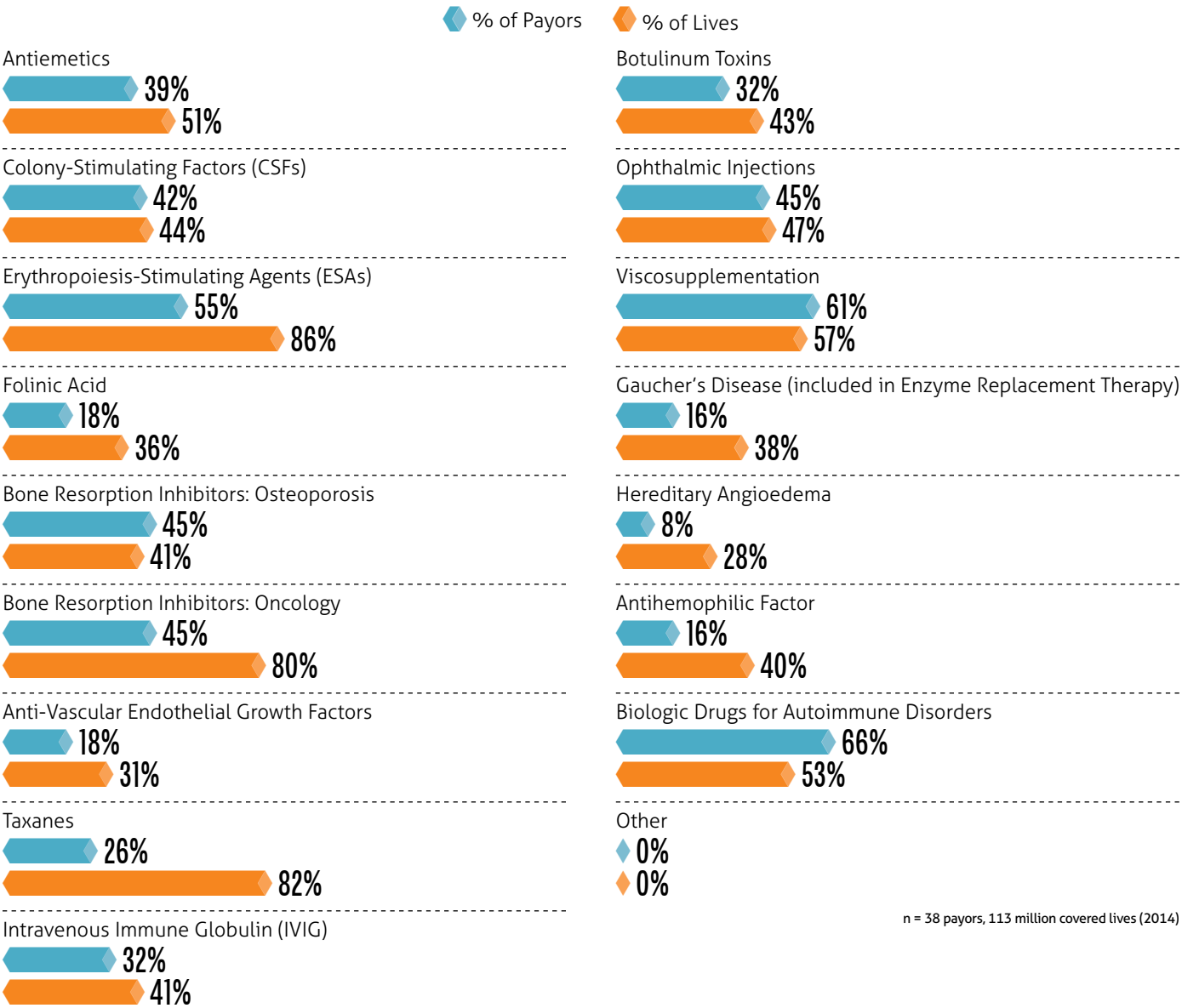
FIGURE 6: Medical Benefit Drug Therapeutic Classes with Product Preferencing Currently in Place 2011–2014



n = 28 payors, 100 million covered lives (2011)
n = 21 payors, 95 million covered lives (2012)
n = 16 payors, 36 million covered lives (2013)
n = 38 payors, 113 million covered lives (2014)

New in 2014, we provided more granular medical benefit drug therapeutic classes for survey respondents to select for the product preferencing questions. The oncology category in the previous figure was determined based on responses to the following therapeutic classes payors could select: Taxanes, Anti-Vascular Endothelial Growth Factors, Bone Resorption Inhibitors: Oncology and Folinic Acid. Of note in 2014, in addition to oncology and ESAs referenced earlier, more than half of the covered lives enrolled in plans with medical benefit product preferencing were for the following categories: Viscosupplementation (i.e., hyaluronic acid), Biologic Drugs for Autoimmune Disorders and Antiemetics. *See Figure 7: 2014 Medical Benefit Drug Therapeutic Classes with Product Preferencing Currently in Place.*

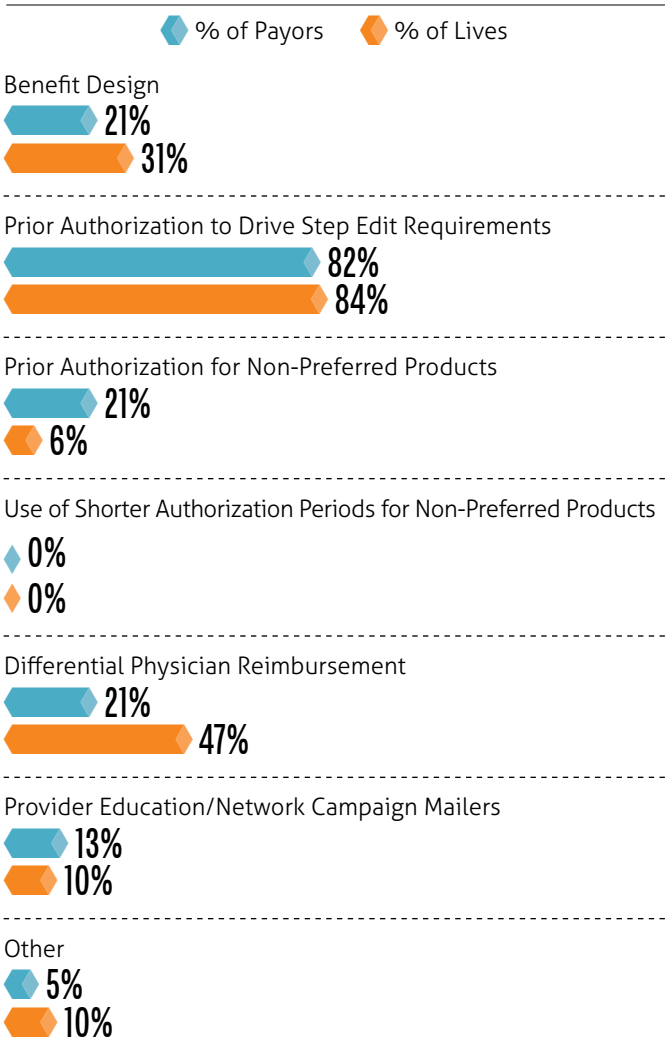
FIGURE 7: 2014 Medical Benefit Drug Therapeutic Classes with Product Preferencing Currently in Place



n = 38 payors, 113 million covered lives (2014)

Similar to our 2013 report, we asked what tactics payors used to preference specific drugs paid through the medical benefit. Payors were asked to select the most prevalent tools, up to a maximum of two choices. Health plans representing 84 percent of covered lives answered that they used prior authorization to drive step edit requirements, up from 76 percent in 2013. The next most frequently reported tactic was differential physician reimbursement, present in 47 percent of covered lives, down from 54 percent in 2013. *See Figure 8: 2014 Tools Used to Preference Products on the Medical Benefit.*

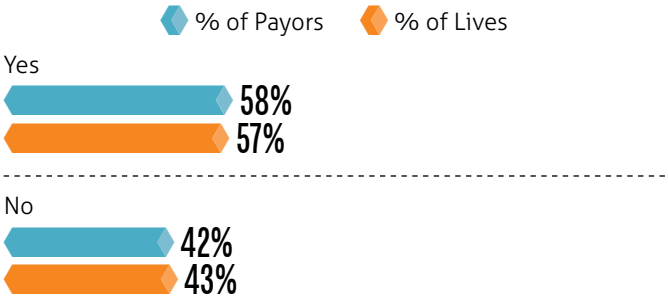
FIGURE 8: 2014 Tools Used to Preference Products on the Medical Benefit



n = 38 payors, 113 million covered lives (2014)

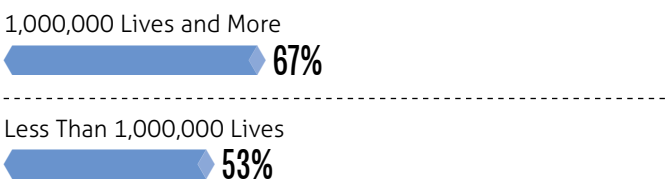
In 2014, plans representing 57 percent of covered lives responded that they received rebates on medical benefit drugs. Larger plans represented by 1,000,000 or more lives were more likely to receive rebates for medical benefit drugs (67 percent) versus smaller plans with less than 1,000,000 lives (53 percent). *See Figure 9: 2014 Medical Benefit Drug Rebates Received and Figure 10: 2014 Medical Benefit Drug Rebates Received by Plan Size.*

FIGURE 9: 2014 Medical Benefit Drug Rebates Received



n = 48 payors, 125 million covered lives (2014)

FIGURE 10: 2014 Medical Benefit Drug Rebates Received by Plan Size



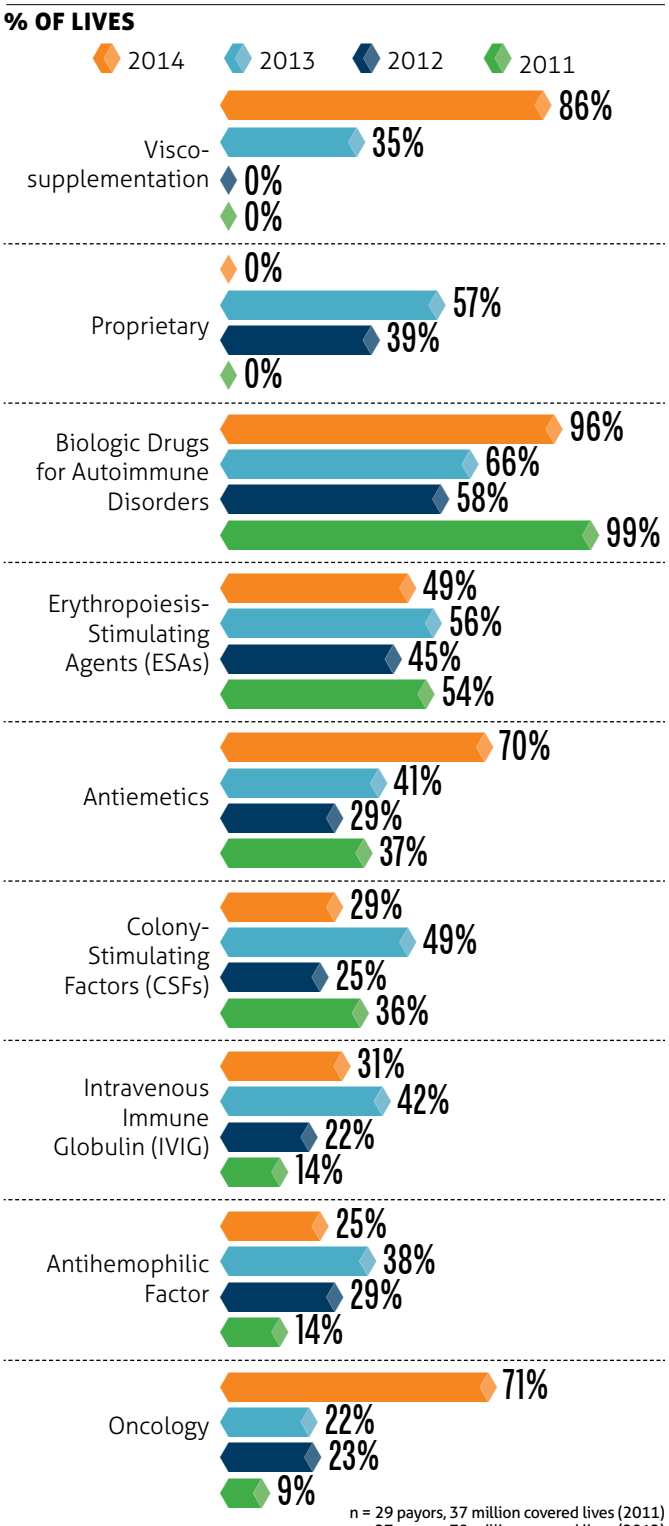
n = 28 payors, 71 million covered lives (2014)

There were substantial increases in the percentages of covered lives that received rebates for specific therapeutic classes in 2014 versus previous years.

- In 2014, 86 percent of health plan lives received rebates for viscosupplementation, up from 35 percent in 2013.
- Ninety-six percent of covered lives in 2014 received rebates for biologic drugs used to treat autoimmune disorders. The drug most typically rebated in this class is Remicade.
- Seventy percent of covered lives in 2014 received rebates for the antiemetics category, up from 41 percent in 2013.
- In 2014, 71 percent of covered lives received rebates for oncology, up from 22 percent in 2013. The oncology category was comprised of survey responses to receiving rebates for the following therapeutic categories: Taxanes, Anti-Vascular Endothelial Growth Factors, Bone Resorption Inhibitors: Oncology and Folinic Acid.

See Figure 11: Therapeutic Classes Where Payors Received Rebates for Medical Benefit Drugs 2011–2014.

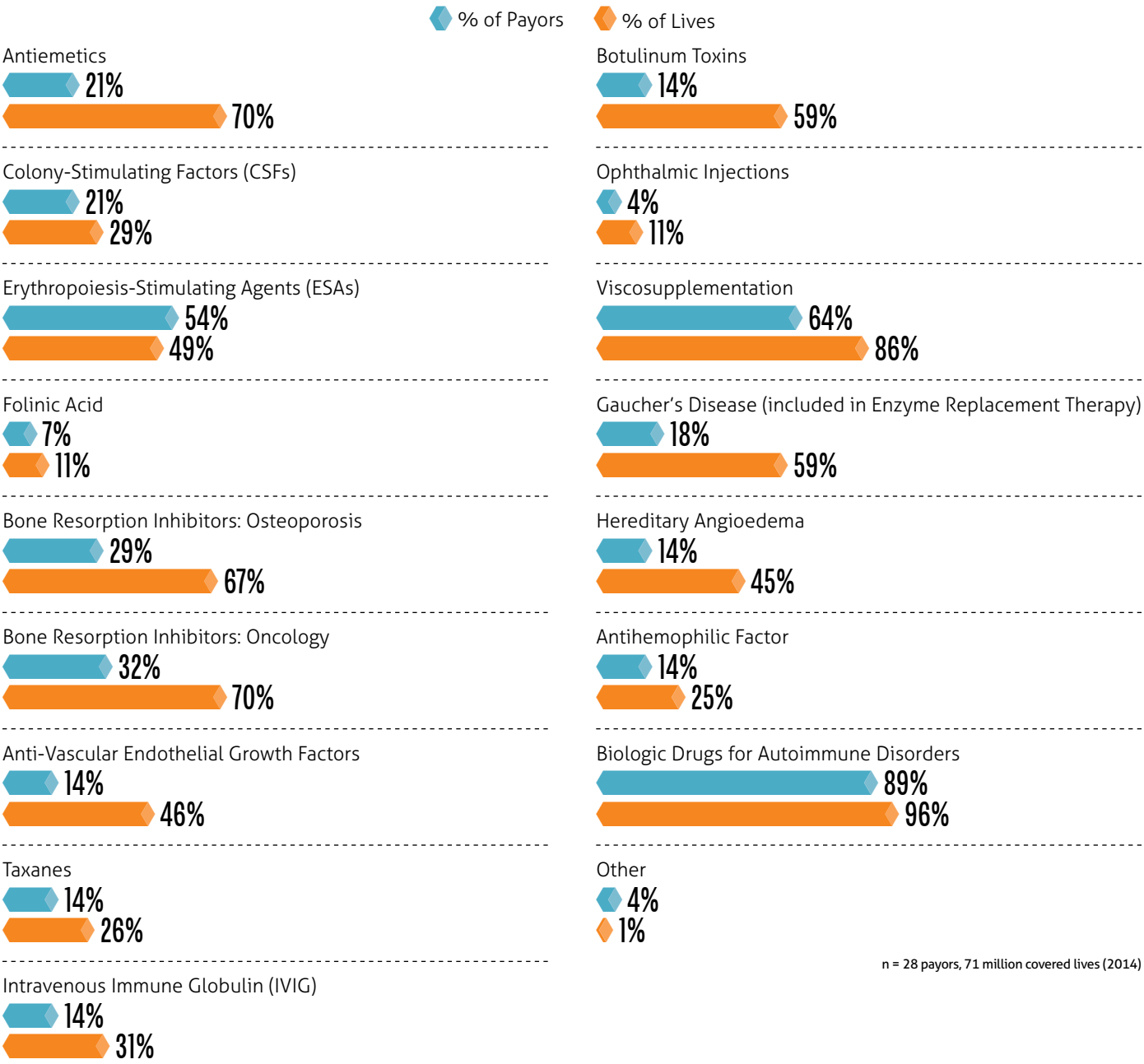
FIGURE 11: Therapeutic Classes Where Payors Received Rebates for Medical Benefit Drugs 2011–2014



n = 29 payors, 37 million covered lives (2011)
n = 27 payors, 78 million covered lives (2012)
n = 27 payors, 82 million covered lives (2013)
n = 28 payors, 71 million covered lives (2014)

Similar to Figure 7, new in 2014, we provided more granular medical benefit drug therapeutic classes for survey respondents to select for the medical benefit drug rebate questions. Of note in 2014, in addition to Viscosupplementation, Biologic Drugs for Autoimmune Disorders, Antiemetics and Oncology referenced earlier, more than half of the covered lives that received medical benefit drug rebates were for the following categories: Botulinum Toxins, Gaucher's Disease (included in Enzyme Replacement Therapy) and Bone Resorption Inhibitors: Osteoporosis and Oncology. *See Figure 12: 2014 Therapeutic Classes Where Payors Received Rebates for Medical Benefit Drugs.*

FIGURE 12: 2014 Therapeutic Classes Where Payors Received Rebates for Medical Benefit Drugs



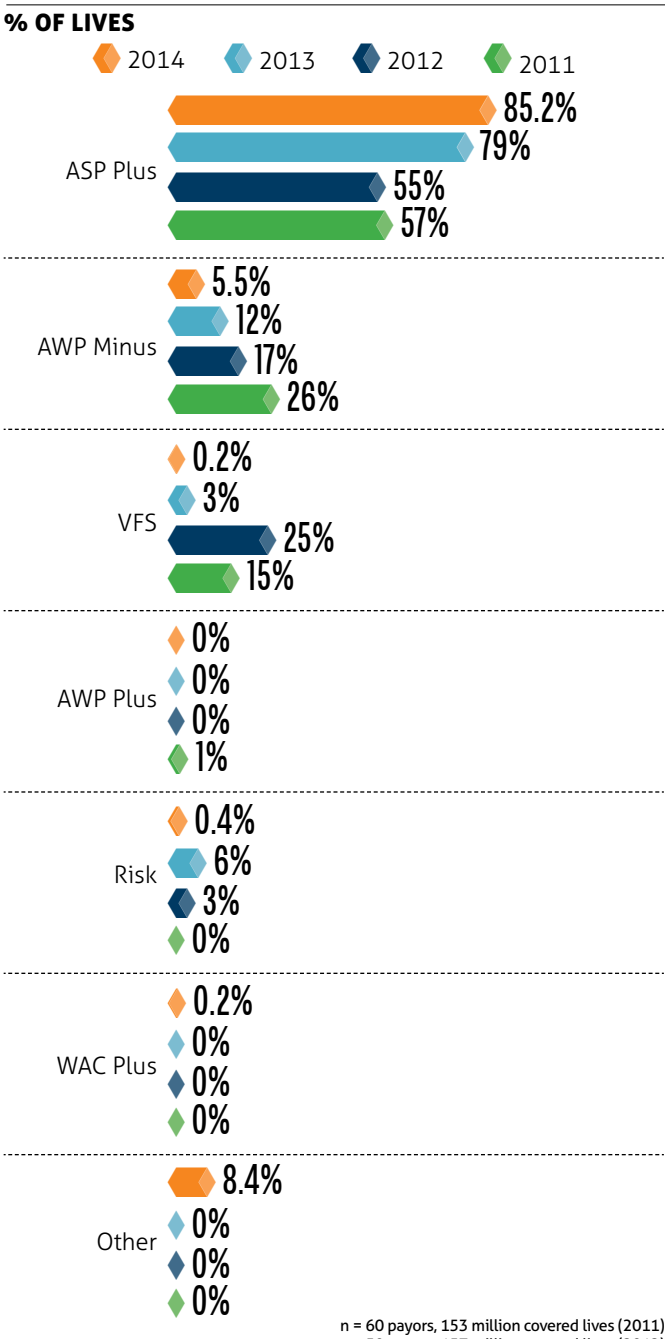
n = 28 payors, 71 million covered lives (2014)

Provider Reimbursement

Historically, our trend report has focused on physician office reimbursement methodologies. New in 2014, we asked payors the same reimbursement methodology questions for home infusion providers and for hospital outpatient facilities.

For the physician office setting in 2014, more than 85 percent of covered lives reimbursed physicians based on an average sales price (ASP) plus a mark-up methodology. Respondents who selected "other" predominantly reimbursed physician offices based on a percent of charges model. ASP-based reimbursement, created via the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 and implemented in 2005, has remained the predominant reimbursement methodology to physician offices, with more commercial plans year over year shifting away from average wholesale price (AWP) minus a discount methodology since our 2011 trend report. Variable fee schedule (VFS) and wholesale acquisition cost (WAC) plus strategies were utilized for less than 1 percent of covered lives in 2014. *See Figure 13: Physician Office Reimbursement Approach Used by Payors for Drugs Paid Under the Medical Benefit 2011–2014.*

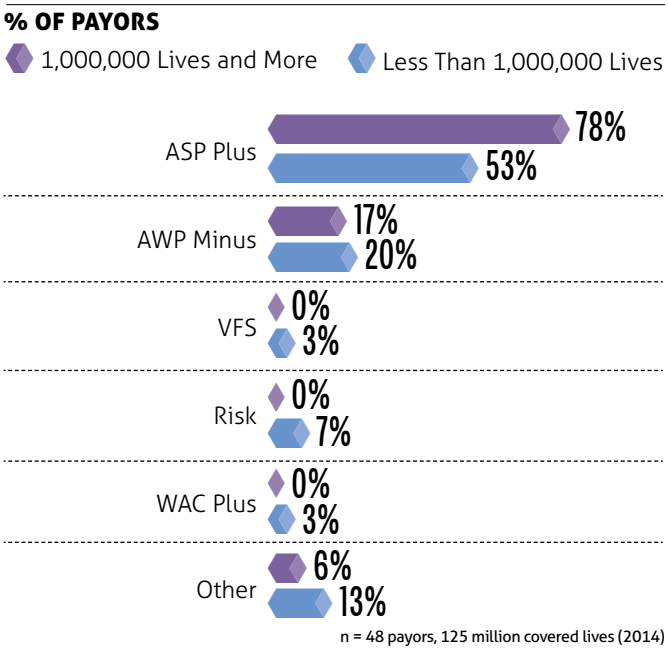
FIGURE 13: Physician Office Reimbursement Approach Used by Payors for Drugs Paid Under the Medical Benefit 2011–2014



n = 60 payors, 153 million covered lives (2011)
n = 50 payors, 157 million covered lives (2012)
n = 48 payors, 166 million covered lives (2013)
n = 48 payors, 125 million covered lives (2014)

Interestingly, we reviewed 2014 responses by plan size and observed that larger plans with 1,000,000 or more covered lives predominantly employed ASP- and AWP-based reimbursement methodologies, while plans with less than 1,000,000 lives utilized other reimbursement methodologies, such as WAC plus a markup, VFSs, risk arrangements and other methodologies referenced previously. *See Figure 14: 2014 Physician Office Reimbursement Approach Used by Payors for Drugs Paid Under the Medical Benefit.*

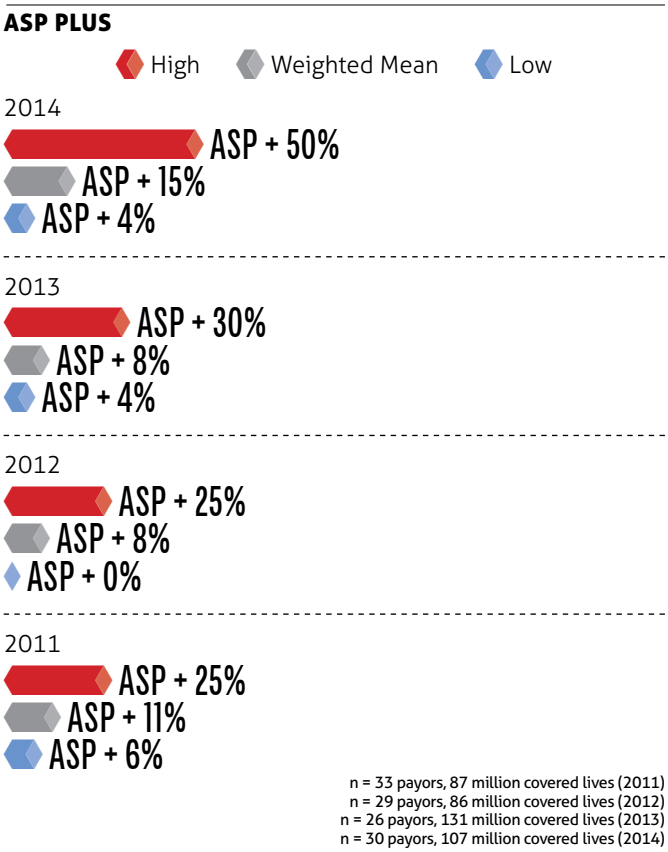
FIGURE 14: 2014 Physician Office Reimbursement Approach Used by Payors for Drugs Paid Under the Medical Benefit



n = 48 payors, 125 million covered lives (2014)

The weighted mean ASP markup in 2014 was 15 percent, an average reimbursement increase of 6.5 percent over 2013 survey responses. ASP markups in 2012 and 2013 remained consistent, but due to numerous influencing factors in the marketplace, it was not surprising to see the 2014 ASP markup increase. Such factors include independent, office-based physician practices exiting the space due to lower reimbursement since the MMA,[2] reducing Medicare reimbursement rates to ASP + 6 percent for medical benefit drugs (versus AWP minus 5 percent for medical benefit drugs prior to the MMA)[3] and more recent negative impacts due to sequestration. As a result, practices are merging and forming larger groups with greater bargaining power to negotiate increased reimbursement rates with commercial health plans. At the same time, health plans are interested in increasing medical benefit drug reimbursement to physician offices to preserve the lower-cost, community-based practice setting versus the alternative, where members receive infusion therapy at higher-cost, hospital outpatient facilities. *See Figure 15: ASP Percentage Markup for Physician Office Reimbursements 2011–2014.*

FIGURE 15: ASP Percentage Markup for Physician Office Reimbursements 2011–2014



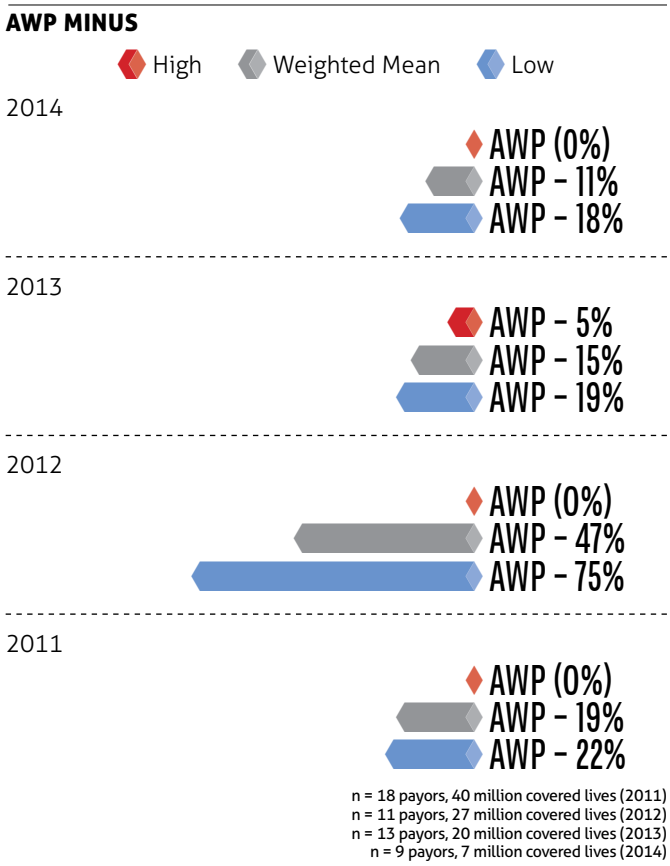
n = 33 payors, 87 million covered lives (2011)
n = 29 payors, 86 million covered lives (2012)
n = 26 payors, 131 million covered lives (2013)
n = 30 payors, 107 million covered lives (2014)

2. Community Oncology Alliance. Community oncology practice impact report: The changing landscape of cancer care, 2014. Accessed: http://www.communityoncology.org/pdfs/Community_Oncology_Practice_Impact_Report_10-21-14F.pdf.

3. Glied, S and Haninger, K. ASPE Issue Brief. Medicare Part B reimbursement of prescription drugs. June 2014. Accessed: http://aspe.hhs.gov/sp/reports/2014/medicarepart/ib_mprpd.cfm#_ftn1.

For the health plans representing 5.5 percent of covered lives that still reimburse physician offices on an AWP discount methodology, the weighted mean discount decreased in 2014 to AWP minus 11 percent versus AWP minus 15 percent in 2013. *See Figure 16: AWP Percentage Discount for Physician Office Reimbursements 2011–2014.*

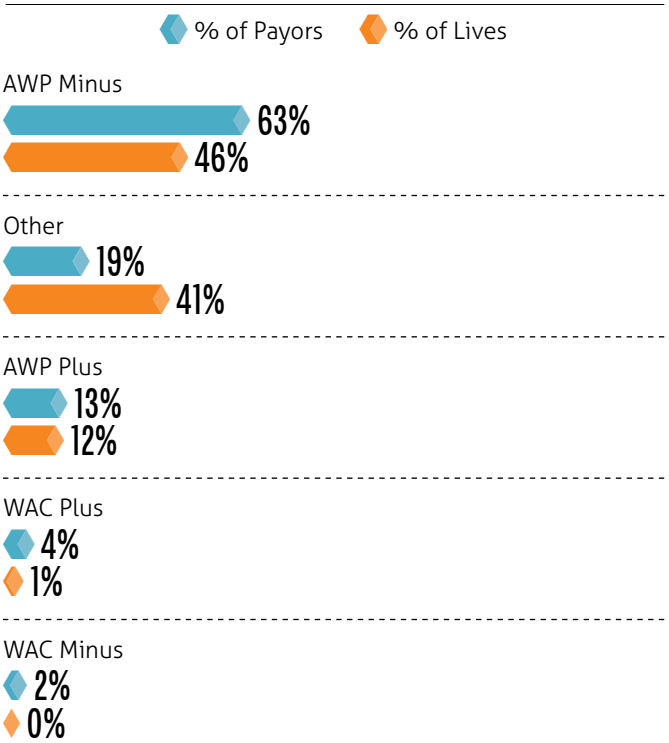
FIGURE 16: AWP Percentage Discount for Physician Office Reimbursements 2011–2014



n = 18 payors, 40 million covered lives (2011)
n = 11 payors, 27 million covered lives (2012)
n = 13 payors, 20 million covered lives (2013)
n = 9 payors, 7 million covered lives (2014)

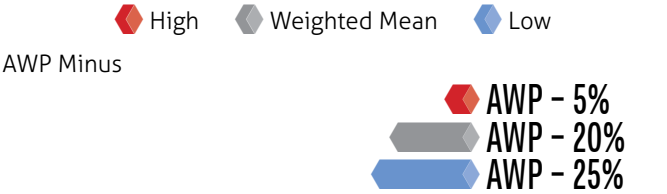
In our 2014 survey, we asked payors to describe their physician office reimbursement methodology for newly released medical benefit drugs (those that do not have assigned, classified J codes). Payors representing 46 percent of covered lives responded that they reimbursed these new drugs based on an AWP discount, with a weighted mean by percent of covered lives at AWP minus 20 percent. Payors representing 41 percent of covered lives chose "other" reimbursement methodologies that included percent of billed charges or cost plus models. *See Figure 17: 2014 Physician Office Reimbursement Methodology for Newly Released, Unclassified Medical Benefit Drugs and Figure 18: 2014 AWP Discount for Physician Office Reimbursements for Newly Released, Unclassified Medical Benefit Drugs.*

FIGURE 17: 2014 Physician Office Reimbursement Methodology for Newly Released, Unclassified Medical Benefit Drugs



n = 48 payors, 125 million covered lives (2014)

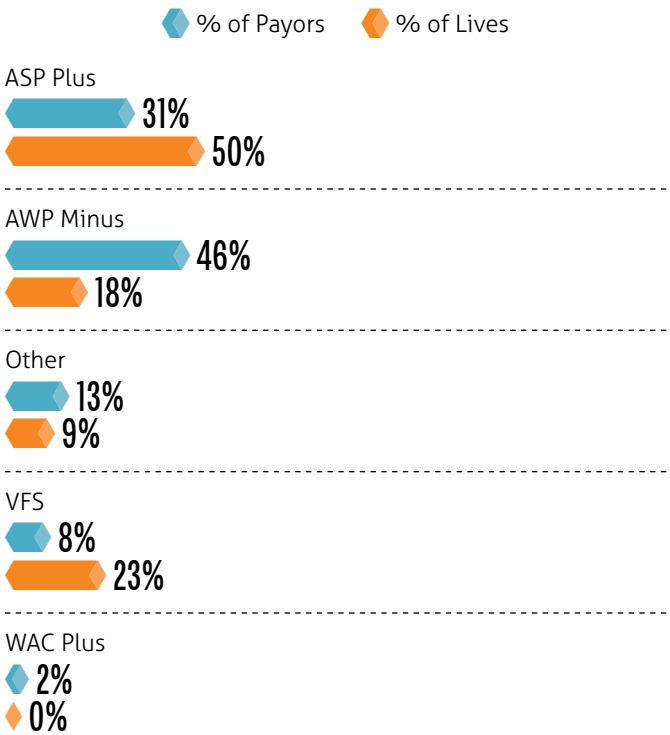
FIGURE 18: 2014 AWP Discount for Physician Office Reimbursements for Newly Released, Unclassified Medical Benefit Drugs



n = 30 payors, 57 million covered lives (2014)

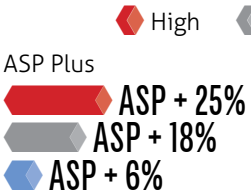
When asked how payors reimbursed home infusion providers, nearly one-third of health plans representing 50 percent of covered lives responded with an ASP plus markup methodology, followed by 8 percent of payors representing 23 percent of covered lives using VFSs (different tiers with markups and discounts to incentivize the use of lowest-cost alternative agents in applicable drug therapy classes). Nearly half of the health plan respondents representing 18 percent of covered lives used an AWP discount methodology. Thirteen percent of health plans representing 9 percent of covered lives chose "other" reimbursement methodologies, with responses including variable contracts and percent of billed charges. The weighted mean markup and discount in 2014 based on percent of covered lives was ASP + 18 percent and AWP minus 14 percent. *See Figure 19: 2014 Home Infusion Reimbursement Approach Used by Payors for Drugs Paid Under the Medical Benefit, Figure 20: 2014 ASP Percentage Markup for Home Infusion Reimbursement and Figure 21: 2014 AWP Percentage Discount for Home Infusion Reimbursement.*

FIGURE 19: 2014 Home Infusion Reimbursement Approach Used by Payors for Drugs Paid Under the Medical Benefit



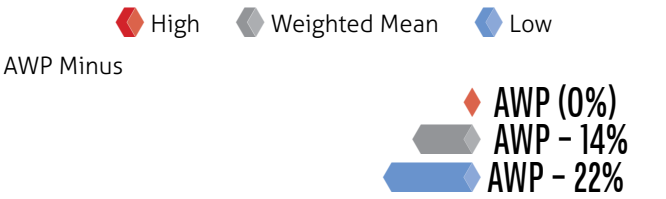
n = 48 payors, 125 million covered lives (2014)

FIGURE 20: 2014 ASP Percentage Markup for Home Infusion Reimbursement



n = 15 payors, 63 million covered lives (2014)

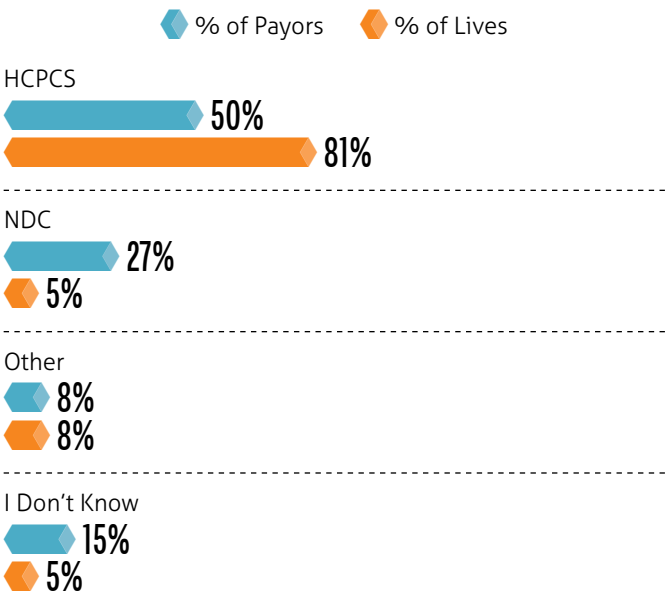
FIGURE 21: 2014 AWP Percentage Discount for Home Infusion Reimbursement



n = 22 payors, 23 million covered lives (2014)

Payors also were asked if they reimbursed home infusion providers for medical benefit drugs based on National Drug Code (NDC) or Healthcare Common Procedure Coding System (HCPCS). Half of the health plans representing approximately eight out of 10 covered lives responded that they reimbursed home infusion providers based on HCPCS, while approximately one-quarter (27 percent) of health plans representing only 5 percent of covered lives responded that they reimbursed home infusion providers based on NDC. Respondents who selected "other" explained that they used a combination of both HCPCS and NDC. *See Figure 22: 2014 Home Infusion Medical Benefit Drug Reimbursement by HCPCS or NDC.*

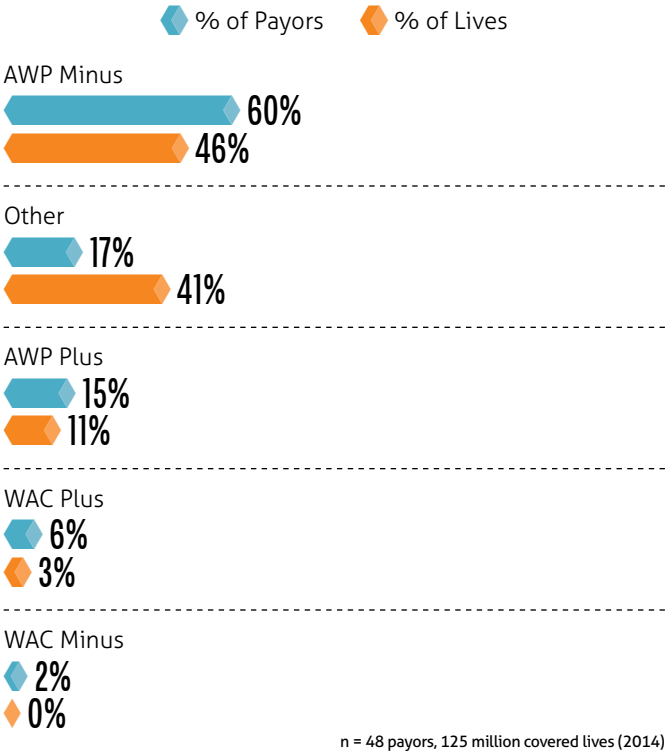
FIGURE 22: 2014 Home Infusion Medical Benefit Drug Reimbursement by HCPCS or NDC



n = 48 payors, 125 million covered lives (2014)

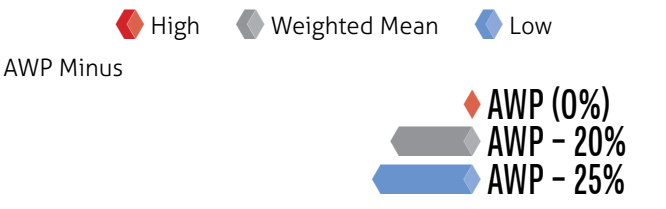
When payors were asked how they reimbursed newly released medical benefit drugs billed by home infusion providers without a classified HCPCS code, health plans representing nearly half (46 percent) of covered lives responded that they used an AWP discount methodology, followed by 41 percent of covered lives represented by "other" reimbursement methodologies, which predominantly were percent of billed charges. The weighted AWP discount used to reimburse home infusion providers for newly released, unclassified medical benefit drugs was AWP minus 20 percent, the same weighted mean discount reported for physician offices. *See Figure 23: 2014 Home Infusion Reimbursement Methodology for Newly Released, Unclassified Medical Benefit Drugs and Figure 24: 2014 AWP Discount for Home Infusion Reimbursement for Newly Released, Unclassified Medical Benefit Drugs.*

FIGURE 23: 2014 Home Infusion Reimbursement Methodology for Newly Released, Unclassified Medical Benefit Drugs



n = 48 payors, 125 million covered lives (2014)

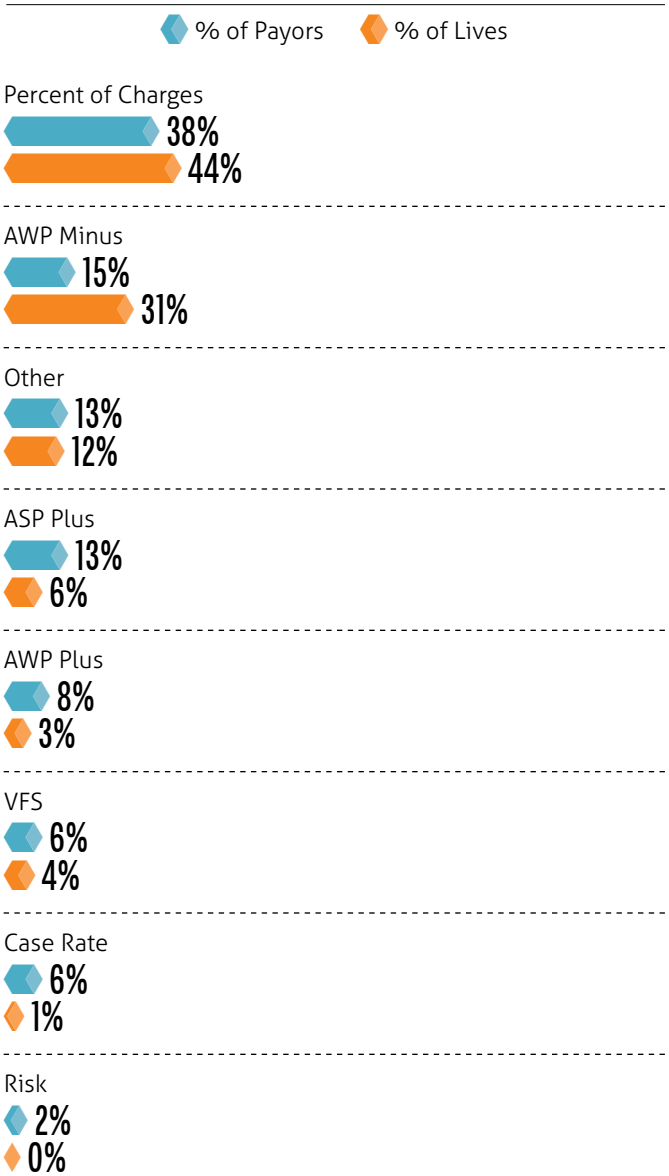
FIGURE 24: 2014 AWP Discount for Home Infusion Reimbursement for Newly Released, Unclassified Medical Benefit Drugs



n = 29 payors, 57 million covered lives (2014)

Payors were asked about their predominant hospital outpatient facility reimbursement methodology for medical benefit drugs, and health plans representing 44 percent of covered lives responded with a percent of charges model, followed by 31 percent of covered lives with an AWP minus approach. A small percent of covered lives were represented by alternate methodologies, such as risk arrangements, VFSs, ASP or AWP plus markup and case rates. Those who selected "other" responded that their contract methodologies across the networks were variable. *See Figure 25: 2014 Hospital Outpatient Facility Reimbursement Approach Used by Payors for Drugs Paid Under the Medical Benefit.*

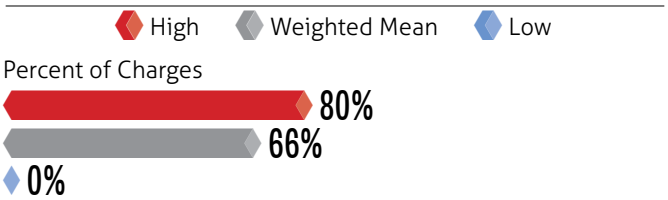
FIGURE 25: 2014 Hospital Outpatient Facility Reimbursement Approach Used by Payors for Drugs Paid Under the Medical Benefit



n = 48 payors, 125 million covered lives (2014)

A percent of billed charges arrangement occurs when a health plan agrees to pay a certain percentage of the hospital's charge master, an arbitrary way of establishing fees for services versus more transparent methods based on drug rate benchmarks such as ASP, WAC or AWP. A percent of billed charges reimbursement rate is typically much higher than an ASP-based or AWP-based reimbursement rate. The weighted mean based on percent of covered lives showed that health plans paid two-thirds of hospital outpatient facility billed charges. *See Figure 26: 2014 Percent of Billed Charges for Hospital Outpatient Facility Reimbursement.*

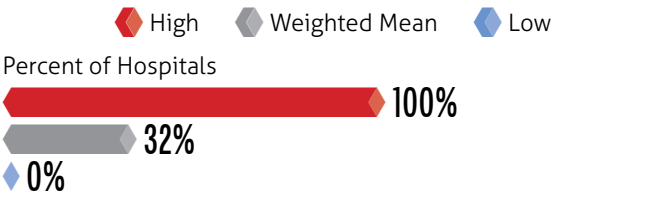
FIGURE 26: 2014 Percent of Billed Charges for Hospital Outpatient Facility Reimbursement



n = 18 payors, 55 million covered lives (2014)

Payors were asked what percentage of in-network hospitals were on fixed fee schedules versus percent of charges arrangements. The weighted mean was 32 percent or on average payors reported that one-third of the hospitals in their networks were reimbursed for medical benefit drugs off of fixed fee schedules versus percent of charges arrangements. *See Figure 27: 2014 Percentage of In-Network Hospitals on Fixed Fee Schedules.*

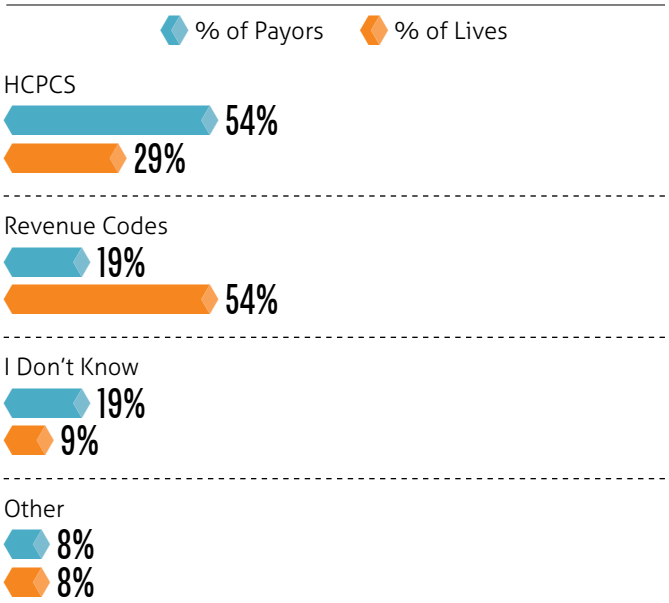
FIGURE 27: 2014 Percentage of In-Network Hospitals on Fixed Fee Schedules



n = 48 payors, 125 million covered lives (2014)

Hospital outpatient facilities bill health plans for drug services through two predominant methodologies, HCPCS or revenue codes based on the health plan requirements. HCPCS codes identify the chemical entity that is administered, while revenue codes more generically identify pharmacy claims and require the HCPCS to be submitted to provide additional details. With HCPCS-based reimbursements, you can easily derive the drug costs compared to revenue codes where medical benefit drug reimbursements might be included in bundled rates, the HCPCS is not submitted on the claim line or the HCPCS is not stored in the health plans' claims systems for subsequent analyses. More than half of payors representing less than 30 percent of covered lives reimbursed drugs administered in hospital outpatient facilities based on HCPCS codes, while 19 percent of payors representing more than half of covered lives reimbursed hospitals based on revenue codes. Those who selected "other" responded that they reimbursed through a combination of HCPCS and revenue codes or a combination of HCPCS and NDCs. *See Figure 28: 2014 Hospital Outpatient Facility Medical Benefit Drug Reimbursement by HCPCS or Revenue Codes.*

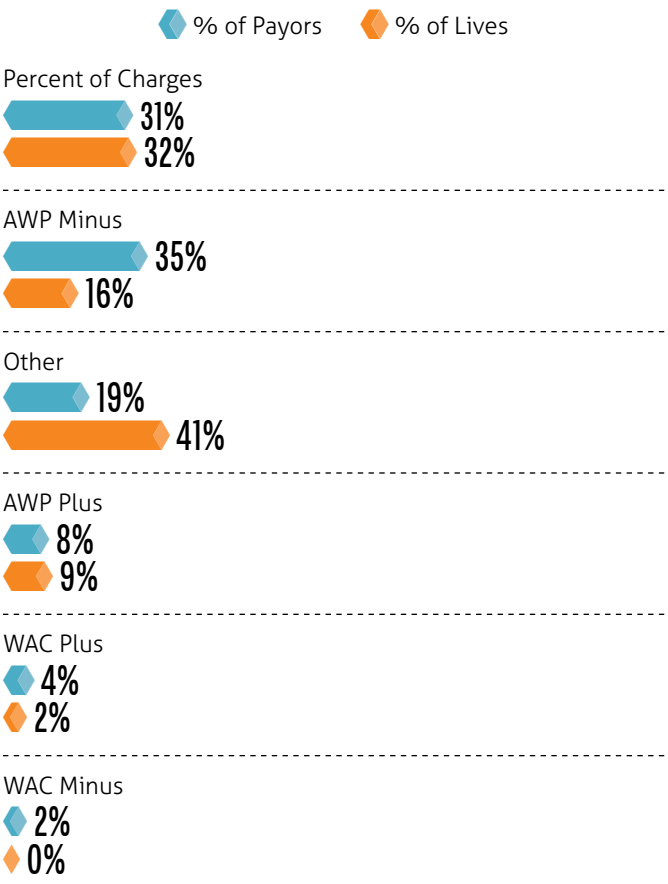
FIGURE 28: 2014 Hospital Outpatient Facility Medical Benefit Drug Reimbursement by HCPCS or Revenue Codes



n = 48 payors, 125 million covered lives (2014)

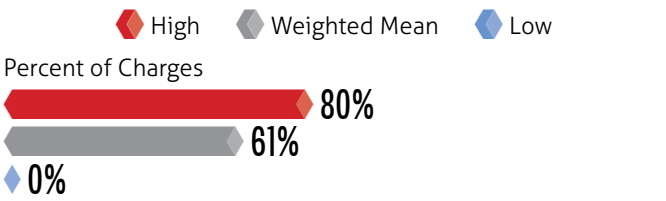
When health plans received claims billed for newly released medical benefit drugs without classified HCPCS codes from hospital outpatient facilities, payors representing almost one-third of covered lives reimbursed the claims at percent of billed charges and 35 percent of health plans representing 16 percent of covered lives used an AWP minus methodology. When reimbursing based on percent of charges, the weighted mean reimbursement was 61 percent of billed charges. When reimbursing based on an AWP discount, the weighted mean reimbursement was AWP minus 17 percent. Payors representing 41 percent of covered lives responded that they utilized "other" reimbursement methodologies that included predominantly percent of charges followed by cost plus models. *See Figure 29: 2014 Hospital Outpatient Facility Reimbursement Methodology for Newly Released, Unclassified Medical Benefit Drugs, Figure 30: 2014 Percent of Billed Charges Reimbursements to Hospital Outpatient Facilities for Newly Released, Unclassified Medical Benefit Drugs and Figure 31: 2014 AWP Discounts for Hospital Outpatient Facilities for Newly Released, Unclassified Medical Benefit Drugs.*

FIGURE 29: 2014 Hospital Outpatient Facility Reimbursement Methodology for Newly Released, Unclassified Medical Benefit Drugs



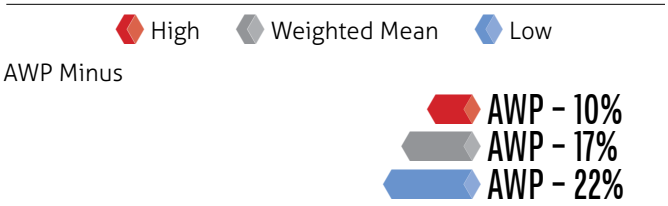
n = 48 payors, 125 million covered lives (2014)

FIGURE 30: 2014 Percent of Billed Charges Reimbursements to Hospital Outpatient Facilities for Newly Released, Unclassified Medical Benefit Drugs



n = 15 payors, 40 million covered lives (2014)

FIGURE 31: 2014 AWP Discounts for Hospital Outpatient Facilities for Newly Released, Unclassified Medical Benefit Drugs

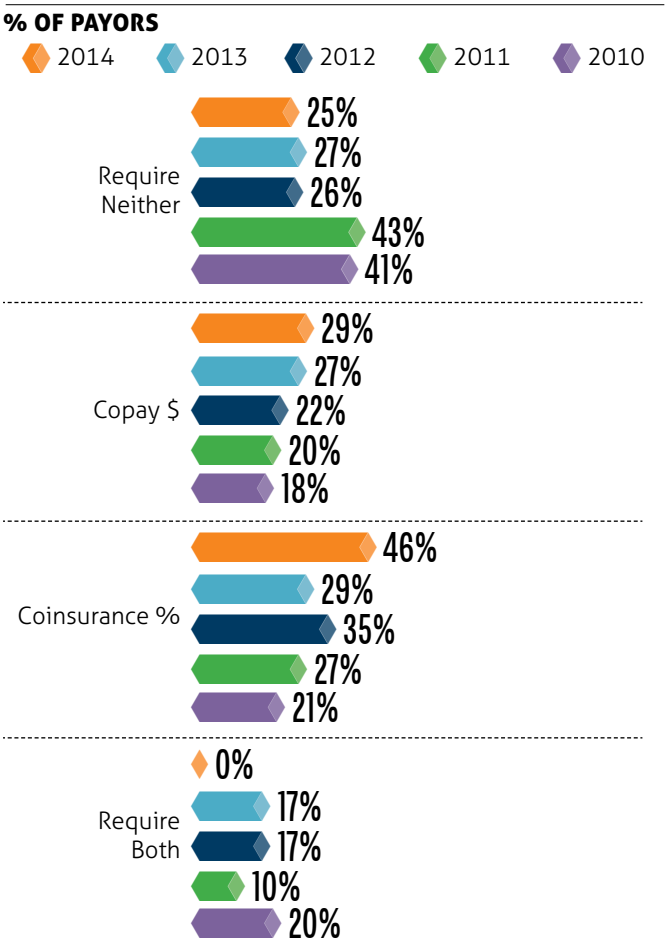


n = 17 payors, 20 million covered lives (2014)

Benefit Design

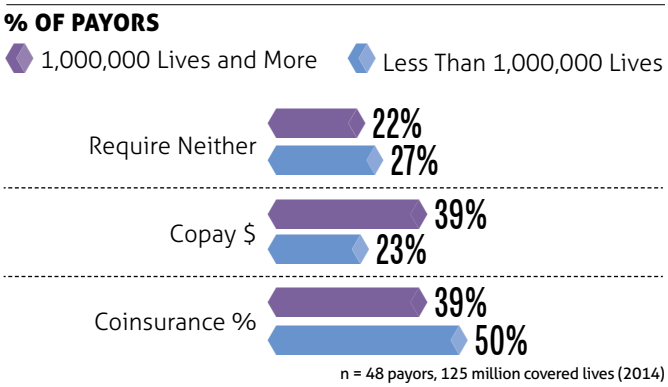
When examining members' out-of-pocket contribution requirements for medical benefit drugs, plans that required neither copays nor coinsurance remained steady over the last three years. Plans that required copays steadily increased from 2010 to 2014. The largest change observed in 2014 was the percentage of payors who required co-insurance at 46 percent, up from 29 percent in 2013. In previous years, payors also had the option to select "require both copay and coinsurance"; this answer was eliminated in our 2014 survey to refine the results. Of plans that required member copays for medical benefit drugs, larger plans with more than 1,000,000 covered lives were more likely to require copays (39 percent) than smaller plans with less than 1,000,000 covered lives (23 percent). Of plans that required coinsurance, smaller plans were more likely to require coinsurance (50 percent) versus larger plans (39 percent). *See Figure 32: Payors' Predominant Required Member Contribution for Medical Benefit Drugs 2010–2014 and Figure 33: 2014 Payors' Predominant Required Member Contribution for Medical Benefit Drugs by Plan Size.*

FIGURE 32: Payors' Predominant Required Member Contribution for Medical Benefit Drugs 2010–2014



n = 60 payors, 146 million covered lives (2010)
n = 60 payors, 153 million covered lives (2011)
n = 50 payors, 157 million covered lives (2012)
n = 48 payors, 166 million covered lives (2013)
n = 48 payors, 125 million covered lives (2014)

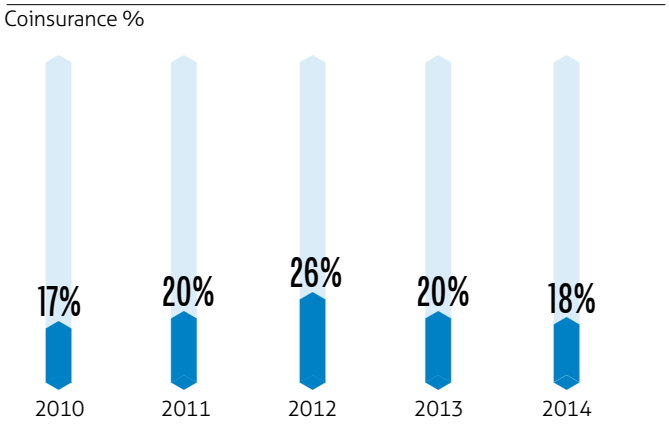
FIGURE 33: 2014 Payors' Predominant Required Member Contribution for Medical Benefit Drugs by Plan Size



n = 48 payors, 125 million covered lives (2014)

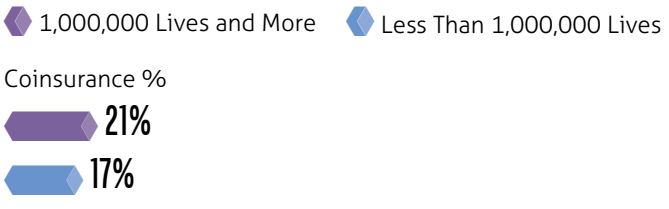
In 2014, members enrolled in plans with coinsurance requirements on average were responsible for 18 percent of medical benefit drug costs, down from 20 percent and 26 percent in 2013 and 2012, respectively. The 2013 trend report asked survey respondents to project coinsurance percentages for 2014, which on a weighted basis was expected to be higher at 21 percent. In 2014, larger plans with 1,000,000 or more members required higher member cost-share contributions at 21 percent, while plans with less than 1,000,000 members required lower coinsurance at 17 percent. *See Figure 34: Average Coinsurance Percentage for Medical Benefit Drugs 2010–2014 and Figure 35: 2014 Average Coinsurance Percentage for Medical Benefit Drugs by Plan Size.*

FIGURE 34: Average Coinsurance Percentage for Medical Benefit Drugs 2010–2014



n = 25 payors, 91 million covered lives (2010)
n = 22 payors, 76 million covered lives (2011)
n = 24 payors, 97 million covered lives (2012)
n = 14 payors, 23 million covered lives (2013)
n = 22 payors, 51 million covered lives (2014)

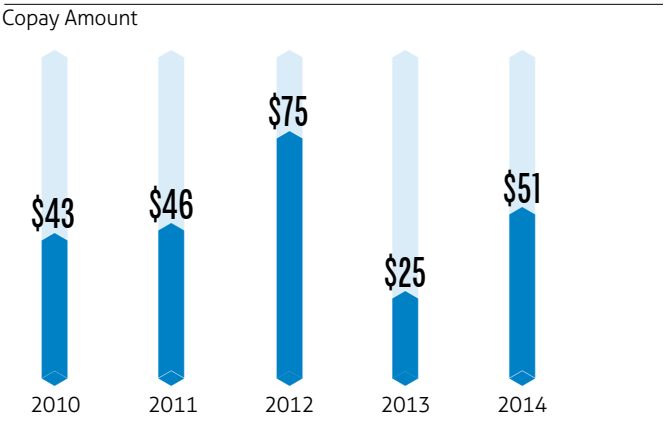
FIGURE 35: 2014 Average Coinsurance Percentage for Medical Benefit Drugs by Plan Size



n = 22 payors, 51 million covered lives (2014)

In 2014, members enrolled in plans with copay requirements for medical benefit drugs on average paid $51 per infusion, more than double the reported copay amount in 2013 at $25, but still less than the $75 copay reported in 2012. The 2013 trend report asked survey respondents to project copays for 2014, which on a weighted basis by covered lives, was expected to be only slightly lower at $48. Contrary to the dynamic observed with coinsurance, smaller plans required higher copays at $58, while larger plans required smaller copays at $44. *See Figure 36: Average Copay Dollar Amount for Medical Benefit Drugs 2010–2014 and Figure 37: 2014 Average Copay Dollar Amount for Medical Benefit Drugs by Plan Size.*

FIGURE 36: Average Copay Dollar Amount for Medical Benefit Drugs 2010–2014



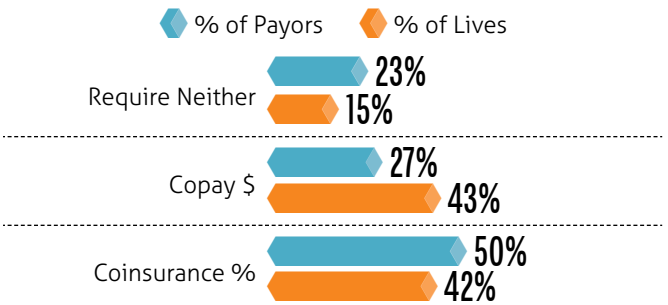
n = 23 payors, 64 million covered lives (2010)
n = 18 payors, 77 million covered lives (2011)
n = 18 payors, 105 million covered lives (2012)
n = 13 payors, 35 million covered lives (2013)
n = 14 payors, 56 million covered lives (2014)

FIGURE 37: 2014 Average Copay Dollar Amount for Medical Benefit Drugs by Plan Size

n = 14 payors, 56 million covered lives (2014)

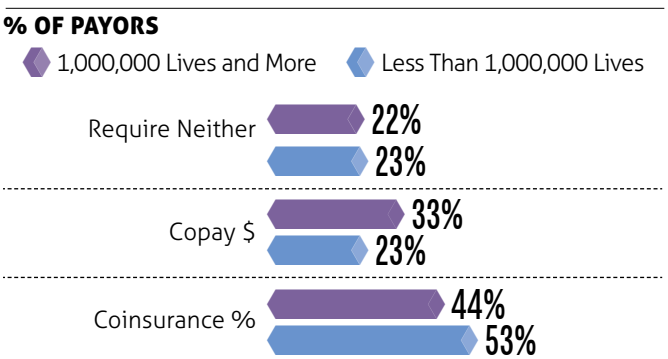
Payors were asked what their predominant required member contribution for medical benefit drugs would be for the next plan year. Compared to their responses for this plan year, co-insurance was expected to increase from 46 percent of payors to 50 percent, while payors who did not require copays and coinsurance or only copays were expected to decrease slightly. Both small and large plans likely would utilize member co-insurance requirements for medical benefit drugs next year (53 percent and 44 percent, respectively). *See Figure 38: Payors' Predominant Required Member Contribution for Medical Benefit Drugs for the Next Plan Year and Figure 39: Payors' Predominant Required Member Contribution for Medical Benefit Drugs for the Next Plan Year by Plan Size.*

FIGURE 38: Payors' Predominant Required Member Contribution for Medical Benefit Drugs for the Next Plan Year



n = 48 payors, 125 million covered lives (2014)

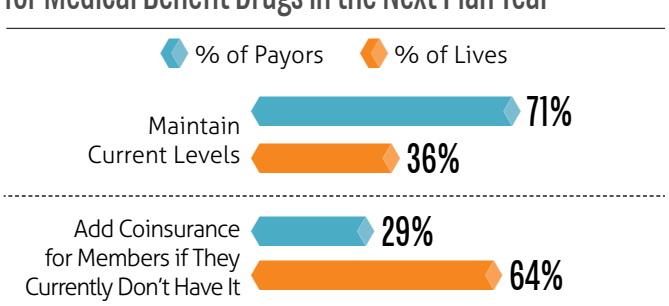
FIGURE 39: Payors' Predominant Required Member Contribution for Medical Benefit Drugs for the Next Plan Year by Plan Size



n = 48 payors, 125 million covered lives (2014)

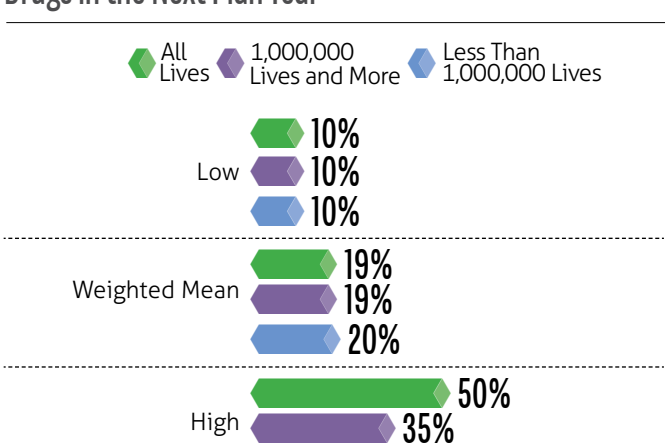
Of the plans that responded that their predominant member contribution requirement in the next plan year for medical benefit drugs would be coinsurance, more than 70 percent of payors (36 percent of covered lives) planned to maintain their current coinsurance percentage requirements, while just less than 30 percent (64 percent of covered lives) intended to add coinsurance requirements for members who currently didn't have coinsurance for medical benefit drugs in 2014. Weighted across all covered lives, the anticipated average coinsurance percentages in the next plan year would be 19 percent, which was very similar to the currently reported 2014 coinsurance requirement of 18 percent. *See Figure 40: Benefit Design Changes Regarding Coinsurance for Medical Benefit Drugs in the Next Plan Year and Figure 41: Coinsurance Percentage for Medical Benefit Drugs in the Next Plan Year.*

FIGURE 40: Benefit Design Changes Regarding Coinsurance for Medical Benefit Drugs in the Next Plan Year



n = 24 payors, 52 million covered lives (2014)

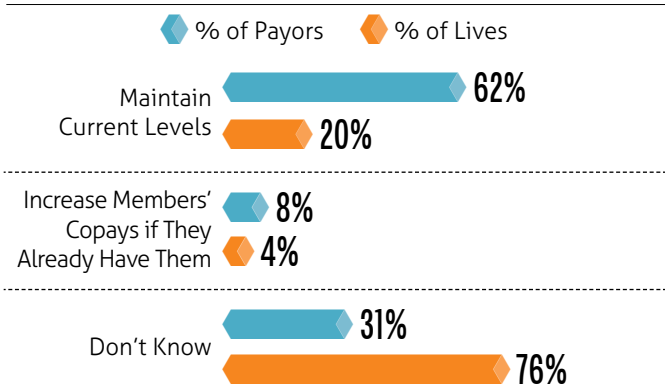
FIGURE 41: Coinsurance Percentage for Medical Benefit Drugs in the Next Plan Year



n = 24 payors, 52 million covered lives (2014)

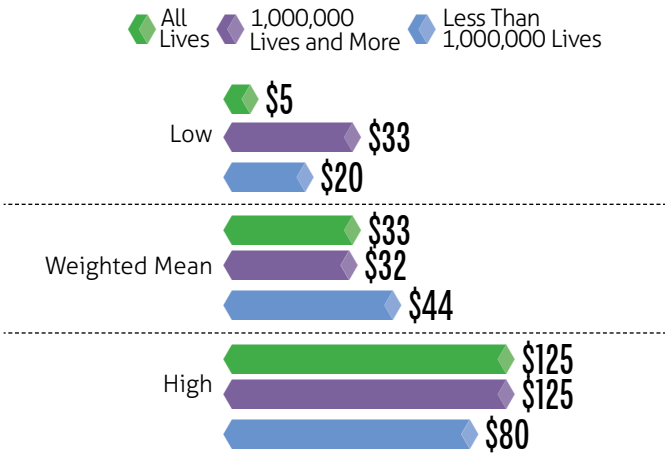
Of the plans that reported that their predominant member contribution requirement for medical benefit drugs in the next plan year would be a copay, more than 60 percent of payors responded that they would maintain their current copay dollar amount requirement, while only 8 percent would increase the member copay dollar amount. Nearly one-third of payors representing three-quarters of covered lives responded that they didn't know at the time of the survey if they would maintain current copays or increase them. The anticipated copay amount for medical benefit drugs in the next plan year, based on a weighted mean, was $33 for all covered lives, while smaller plans would see a higher copay of $44 and larger plans would see a lower copay of $32. The projected copays would be decreases from copays reported for 2014 ($51 in 2014 versus $33 in the next plan year). *See Figure 42: Benefit Design Changes Regarding Copays for Medical Benefit Drugs in the Next Plan Year and Figure 43: Copay Dollar Amounts for Medical Benefit Drugs in the Next Plan Year.*

FIGURE 42: Benefit Design Changes Regarding Copays for Medical Benefit Drugs in the Next Plan Year



n = 13 payors, 54 million covered lives (2014)

FIGURE 43: Copay Dollar Amounts for Medical Benefit Drugs in the Next Plan Year



n = 13 payors, 54 million covered lives (2014)

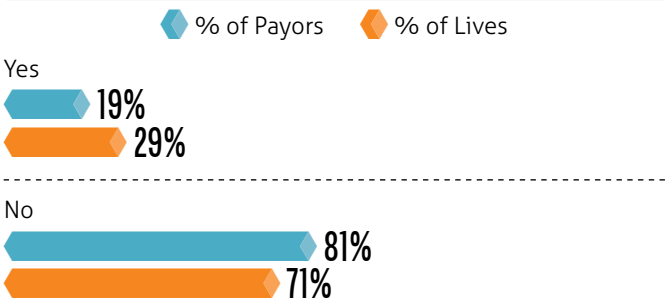
Payors who had cost-share requirements were asked if they varied the members' coinsurance percentages or copay dollar amounts for medical benefit drugs by site of service (i.e., physician offices, homes via home infusion providers and/or hospital outpatient facilities) to align the members' out-of-pocket expenses with their costs (i.e., lower coinsurance or copay amounts for lower-cost sites of service). Eighty-one percent of payors responded that they did not vary members' cost-share requirements by site of service. Of those, 13 percent said they were planning to vary cost-share requirements by site of service in the next plan year. Payors who responded that they varied cost-share requirements this year or planned to in the next year used the following tactics:

- Cover 100 percent of costs (no member cost-share requirement) when member used preferred vendors, home infusion providers and/or office-based settings and

- Based on the place-of-service (POS) code submitted on the claim, cost-share requirement would be reduced for physician office or home-infusion settings versus hospital outpatient facilities.

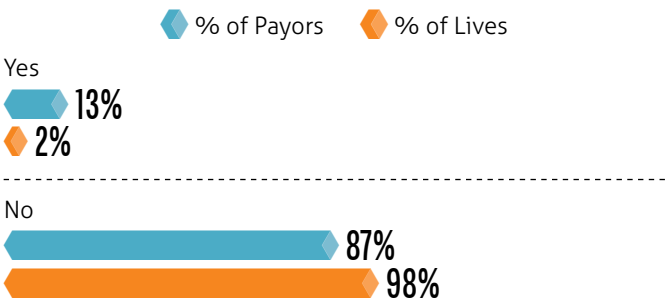
See Figure 44: 2014 Payors Who Varied Members' Cost Share by Site of Service for Medical Benefit Drugs and Figure 45: Payors Who Currently Don't but Planned to Vary Members' Cost-Share Requirements by Site of Service for Medical Benefit Drugs in the Next Plan Year.

FIGURE 44: 2014 Payors Who Varied Members' Cost Share by Site of Service for Medical Benefit Drugs



n = 37 payors, 107 million covered lives (2014)

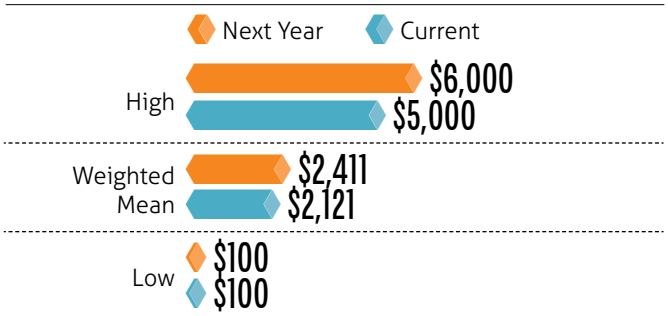
FIGURE 45: Payors Who Currently Don't but Planned to Vary Members' Cost-Share Requirements by Site of Service for Medical Benefit Drugs in the Next Plan Year



n = 30 payors, 76 million covered lives (2014)

The weighted average annual member deductible in 2014 based on number of covered lives was approximately $2,121. When asked about annual deductibles in the next plan year, payors reported that they expected to see higher annual member deductible requirements of $2,411. *See Figure 46: Payors' Predominant Member Annual Deductible Amount in 2014 and in the Next Plan Year.*

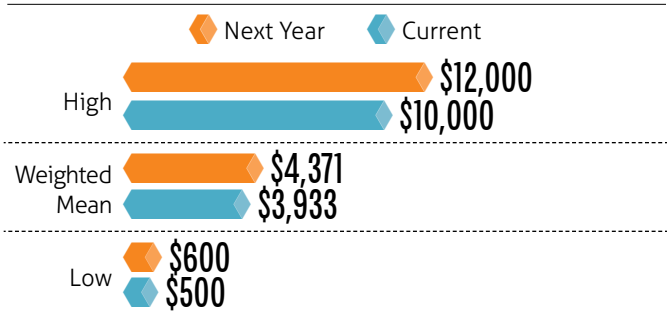
FIGURE 46: Payors' Predominant Member Annual Deductible Amount in 2014 and in the Next Plan Year



n = 48 payors, 125 million covered lives (2014)

When examining maximum out-of-pocket (MOOP) costs, on average members were subjected to nearly a $4,000 cost share annually. This cost requirement was expected to grow to $4,371 annually in the next plan year. *See Figure 47: Payors' Predominant Member MOOP Cost in 2014 and in the Next Plan Year.*

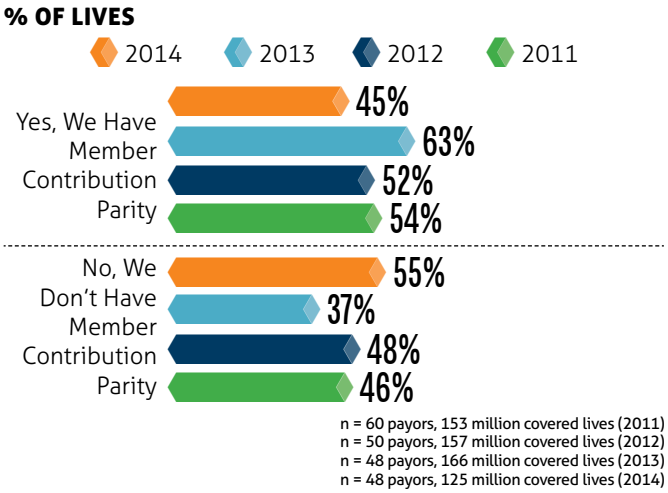
FIGURE 47: Payors' Predominant Member MOOP Cost in 2014 and in the Next Plan Year



n = 48 payors, 125 million covered lives (2014)

As more oral medications had become available, where traditionally only injectable/infusible therapies had been the primary options, we asked payors if they had member contribution parity (equal copays/coinsurance amounts) between intravenous (IV) and oral products. Health plans representing 45 percent of covered lives responded that they did have member contribution parity — the lowest reported percentage over the last four years — down from 63 percent in 2013. *See Figure 48: Payors with Member Contribution Parity Between IV and Oral Products 2011–2014.*

FIGURE 48: Payors with Member Contribution Parity Between IV and Oral Products 2011–2014

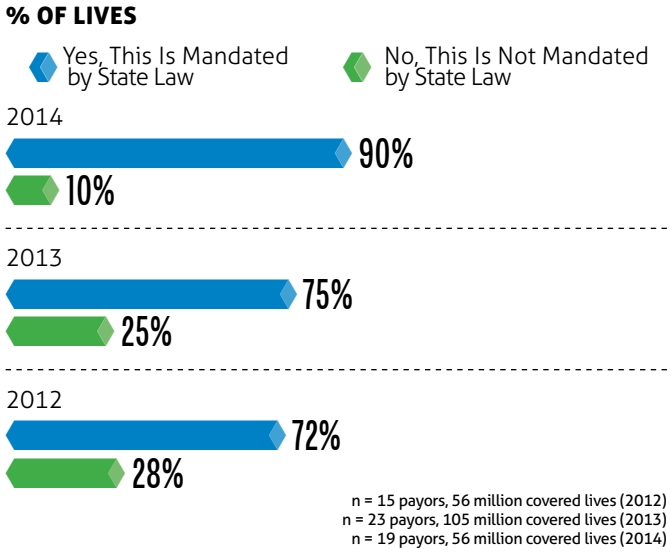


For payors with member contribution parity between IV and oral products, plans representing nine out of 10 covered lives responded that the parity requirement was mandated by state law, an increase from 2012 and 2013 responses when health plans representing three-quarters of covered lives said it was a state requirement. We asked these payors if they had removed copays and coinsurances for all impacted drugs with IV and oral options covered under medical and pharmacy benefits to meet the member contribution parity requirements. Nearly one-third of plans representing more than eight out of 10 covered lives responded that they did remove any member cost share on both the medical and pharmacy benefit for drugs with both IV and oral options to meet the member contribution parity requirements. Payors who did not remove all member cost-share requirements for drugs with both IV and oral options clarified the methods used to meet member contribution parity requirements:

- Members paid their pharmacy benefit copays up front and could submit claims to the medical plans for evaluation and comparison to the medical benefit cost-sharing requirement. Members were refunded the difference if applicable.
- Oral and IV drugs were available under both benefits with the same cost share.
- Cost share on the pharmacy benefit was lowered and cost share on the medical benefit was raised.
- Mandate allowed for a $50 or less difference; established cost shares on both benefits were not to exceed this difference.

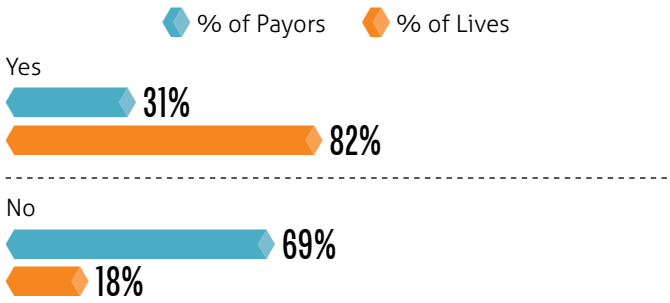
See Figure 49: Member Contribution Parity Requirement Mandated by State Law 2012–2014 and Figure 50: 2014 Payors Who Removed Member Cost Share to Meet Parity Contribution Requirements.

FIGURE 49: Member Contribution Parity Requirement Mandated by State Law 2012–2014



n = 15 payors, 56 million covered lives (2012)
n = 23 payors, 105 million covered lives (2013)
n = 19 payors, 56 million covered lives (2014)

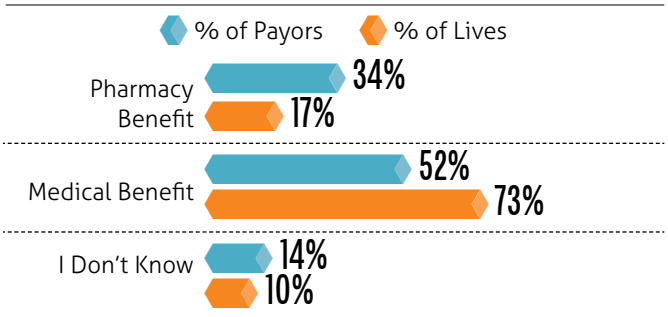
FIGURE 50: 2014 Payors Who Removed Member Cost Share to Meet Parity Contribution Requirements



n = 13 payors, 51 million covered lives (2014)

For payors who did not have member contribution parity requirements in 2014, more than half of health plans reported that it would be more advantageous (lower out-of-pocket cost-share requirements) for members to have the drugs billed through their medical benefits, while one-third of health plans reported that members would have lower out-of-pocket costs if the drugs were billed through their pharmacy benefits. *See Figure 51: 2014 Lower Member Drug Cost-Share Requirements Based on Medical Versus Pharmacy Benefits Coverage.*

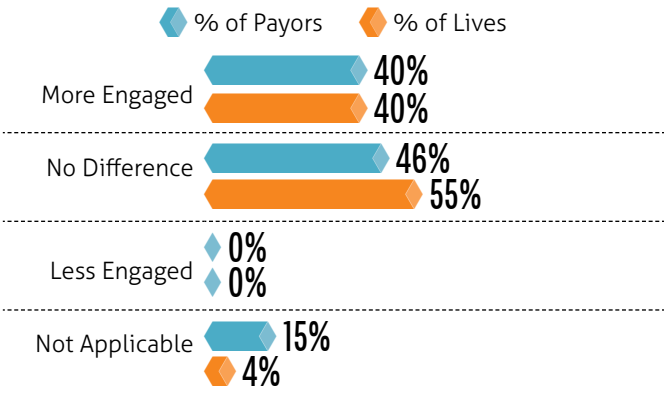
FIGURE 51: 2014 Lower Member Drug Cost-Share Requirements Based on Medical Versus Pharmacy Benefits Coverage



n = 29 payors, 69 million covered lives (2014)

With managing specialty drug costs on both the pharmacy and medical benefits at the forefront of most drug-management industry presentations, employers were turning to their medical carriers for medical benefit drug management solutions. Payors were asked if employers were more or less engaged in developing benefit designs for medical benefit drugs in 2014 compared to 2013. Payors representing more than half of covered lives reported that there was no difference compared to 2013, while plans representing four out of 10 covered lives reported that employers were more engaged in developing benefit designs for medical benefit drugs in 2014 versus 2013. No payors responded that employers were less engaged. *See Figure 52: 2014 Employer Engagement with Health Plans in Developing Benefit Designs for Medical Benefit Drugs.*

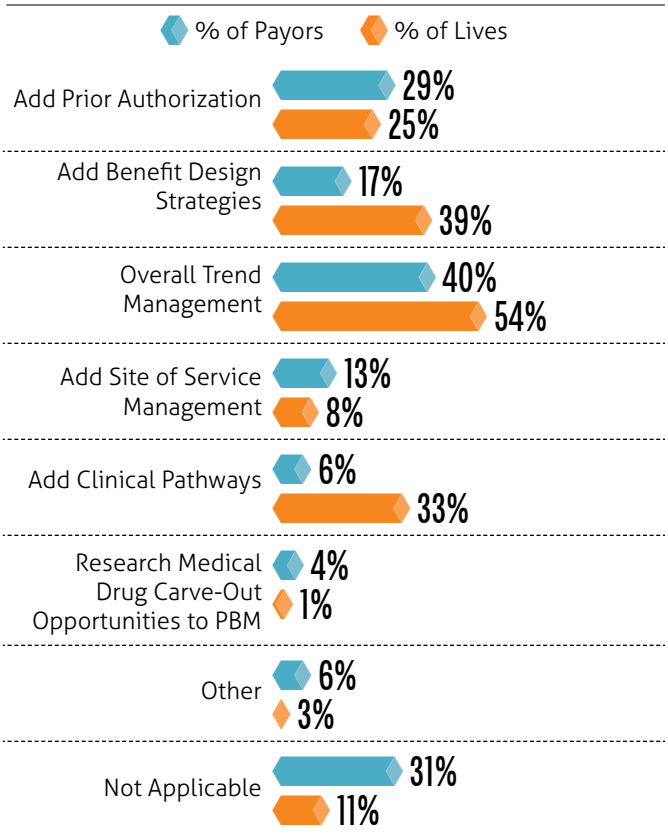
FIGURE 52: 2014 Employer Engagement with Health Plans in Developing Benefit Designs for Medical Benefit Drugs



n = 48 payors, 125 million covered lives (2014)

When employers engaged with their medical carriers on medical benefit drug management, they predominantly were looking for overall trend management (top response from health plans representing 54 percent of covered lives). Payors could select up to the two most predominant options that applied to their experience. Other management solutions employers requested included benefit design strategies (response from health plans representing 39 percent of covered lives), adding clinical pathways (one-third of covered lives) and adding prior authorization requirements for medical benefit drugs (one-quarter of covered lives). Nearly one-third of plans reported that this question was not applicable to their business model. *See Figure 53: 2014 Employer Requests for Medical Benefit Drug Management.*

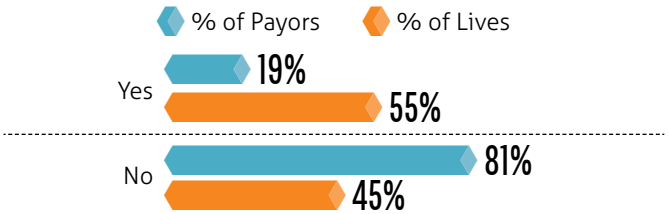
FIGURE 53: 2014 Employer Requests for Medical Benefit Drug Management



n = 48 payors, 125 million covered lives (2014)

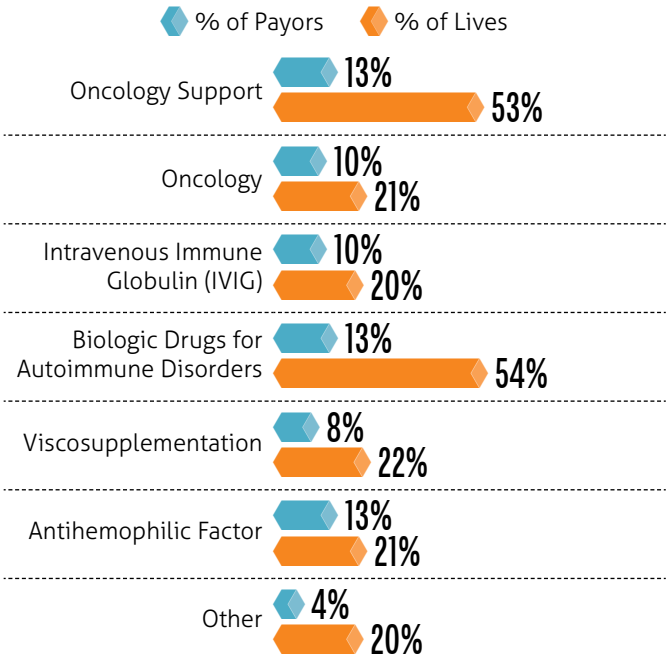
Nineteen percent of payors, representing more than half of covered lives, noted that their self-insured clients were carving out medical benefit drugs to the pharmacy benefit manager (PBM) for management under the pharmacy benefit. The top therapeutic classes of medical benefit drugs self-insured clients were carving out to the PBM for management under the pharmacy benefit included oncology support (e.g., Aranesp, Procrit, Neulasta, Neupogen), biologic drugs for autoimmune disorders (e.g., Remicade, Orencia, Cimzia) and antihemophilic factor (e.g., Advate, Xyntha, Recombinate). Payors who selected "other" therapeutic classes of medical benefit drugs included enzyme replacement therapy, hereditary angioedema and pulmonary arterial hypertension. *See Figure 54: 2014 Self-Insured Clients Carving Out Medical Benefit Drugs to the PBM for Management Under the Pharmacy Benefit and Figure 55: 2014 Therapeutic Classes of Medical Benefit Drugs Self-Insured Clients Were Carving Out to the PBM for Management Under the Pharmacy Benefit.*

FIGURE 54: 2014 Self-Insured Clients Carving Out Medical Benefit Drugs to the PBM for Management Under the Pharmacy Benefit



n = 48 payors, 125 million covered lives (2014)

FIGURE 55: 2014 Therapeutic Classes of Medical Benefit Drugs Self-Insured Clients Were Carving Out to the PBM for Management Under the Pharmacy Benefit

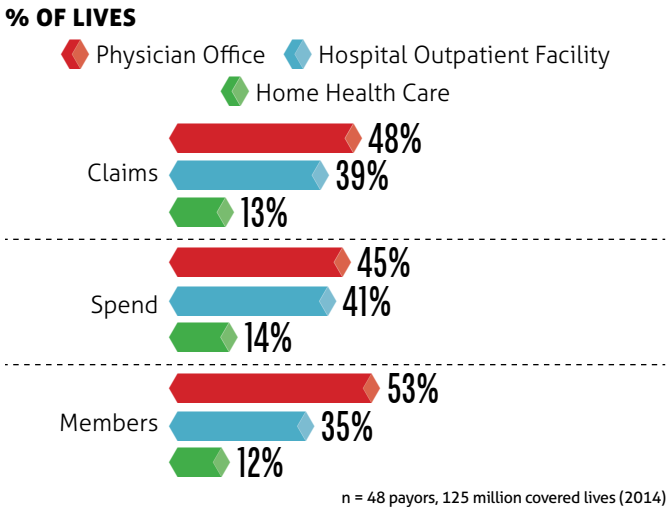


n = 9 payors, 68 million covered lives (2014)

Distribution Channel Management

Medical benefit drugs were predominantly administered in the following three outpatient settings: physician offices, homes via home infusion providers and hospital outpatient facilities. In past surveys, we asked payors what percentage of claims were billed from each of these settings as well as from hospital inpatient facilities. In 2014, we tailored the question to outpatient service settings only and inquired about the percentage of claims, spend and members represented by each site of service. Average results were weighted based on number of covered lives. Across medical benefit utilization, payors reported that physician offices represented 48 percent of claims, 45 percent of spend and 53 percent of members, while hospital outpatient facilities represented 39 percent of claims, 41 percent of spend and 35 percent of members. Due to the higher costs of services administered in hospital outpatient facilities, it had been anticipated that these sites would have larger market shares by spend versus claims or members. *See Figure 56: 2014 Percentage of Medical Benefit Drug Claims, Spend and Members Represented by Each Outpatient Site of Service.*

FIGURE 56: 2014 Percentage of Medical Benefit Drug Claims, Spend and Members Represented by Each Outpatient Site of Service



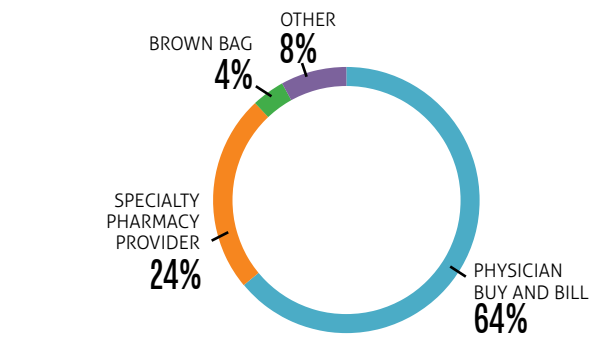
n = 48 payors, 125 million covered lives (2014)

Specifically for the physician office site of service, payors provided insights on the percentage of medical benefit drugs distributed to members through each of the following channels:

- Physician buy and bill (provider uses stock and bills plan),
- Specialty pharmacy provider (pharmacy or distributor ships to provider's office and provider doesn't bill for drug),
- Brown bag (member takes drug to provider's office for administration) and
- Other.

Nearly two-thirds of physician office drug volume (weighted average based on number of covered lives) was supplied via a buy-and-bill methodology, while one-quarter was supplied by specialty pharmacy drug replacement or fulfillment services. "Other" responses included infusion center and in-house pharmacy. *See Figure 57: 2014 Physician Office Percentage of Medical Benefit Drug Volume by Distribution Channel.*

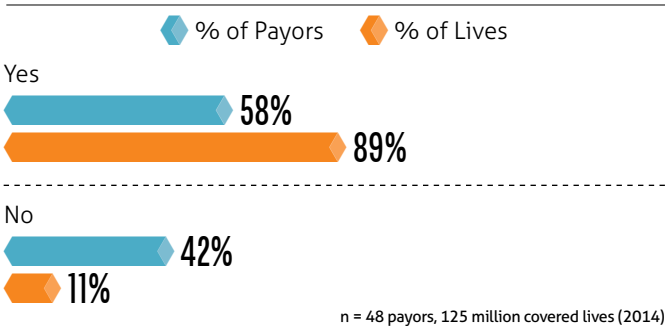
FIGURE 57: 2014 Physician Office Percentage of Medical Benefit Drug Volume by Distribution Channel



n = 48 payors, 125 million covered lives (2014)

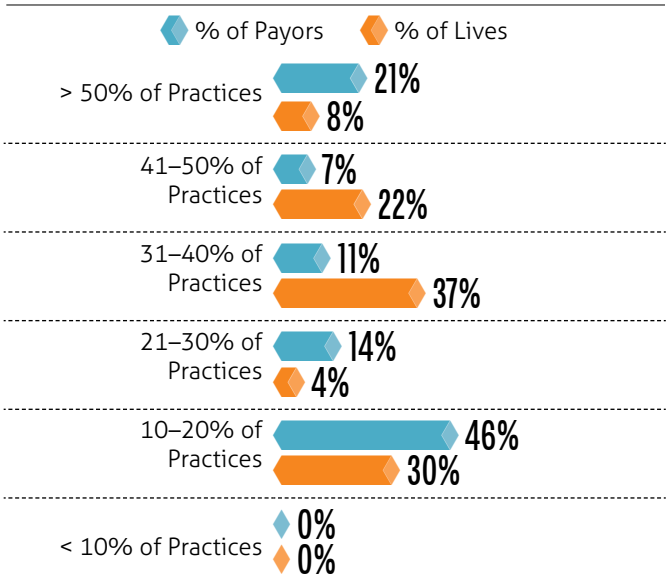
Nearly 60 percent of payors representing nine in 10 covered lives reported that oncology practices in their service areas were being purchased by hospital systems, up from 48 percent in our 2013 survey. Of those payors who reported that hospital systems were purchasing oncology practices, nearly half reported that 10–20 percent of oncology practices had been purchased, although payors representing the largest percentage of covered lives reported that 31–40 percent of oncology practices had been acquired by hospital systems. Alarmingly, 21 percent of payors reported that more than half of oncology practices in their service areas had been acquired by hospital systems. *See Figure 58: 2014 Oncology Practices Purchased by Hospital Systems and Figure 59: 2014 Percentage of Oncology Practices Purchased by Hospital Systems.*

FIGURE 58: 2014 Oncology Practices Purchased by Hospital Systems



n = 48 payors, 125 million covered lives (2014)

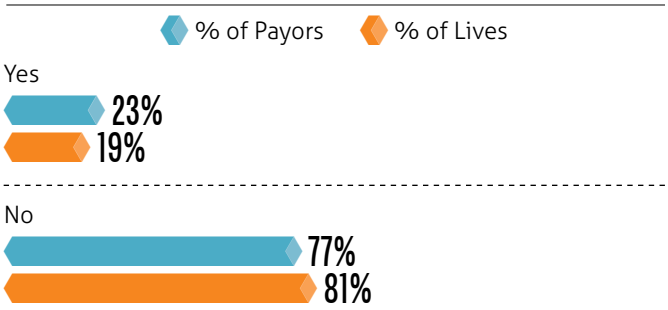
FIGURE 59: 2014 Percentage of Oncology Practices Purchased by Hospital Systems



n = 28 payors, 111 million covered lives (2014)

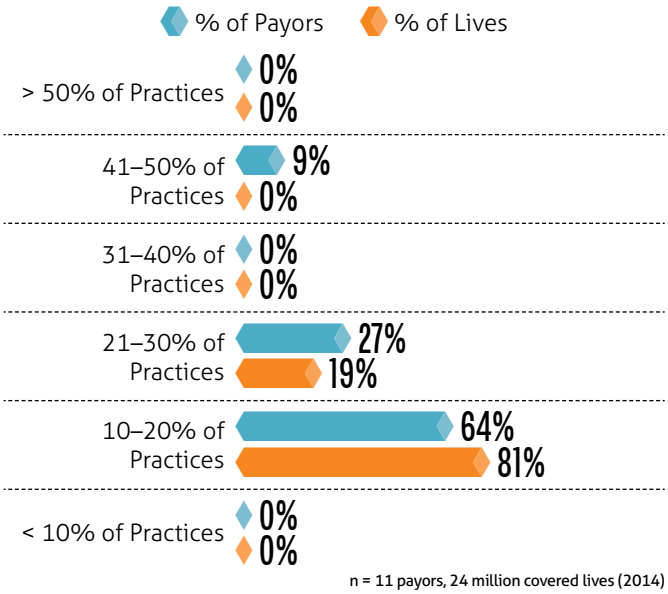
When payors were asked specifically about rheumatology practices, only one-quarter of payors representing two in 10 covered lives reported that rheumatology practices were being purchased by hospital systems, a much lower percentage versus oncology practices. Of those payors who reported that rheumatology practices were being purchased by hospital systems in their service areas, nearly two-thirds of the health plans representing eight in 10 covered lives reported that 10–20 percent of rheumatology practices in their service areas had been acquired by hospital systems. *See Figure 60: 2014 Rheumatology Practices Purchased by Hospital Systems and Figure 61: 2014 Percentage of Rheumatology Practices Purchased by Hospital Systems.*

FIGURE 60: 2014 Rheumatology Practices Purchased by Hospital Systems



n = 48 payors, 125 million covered lives (2014)

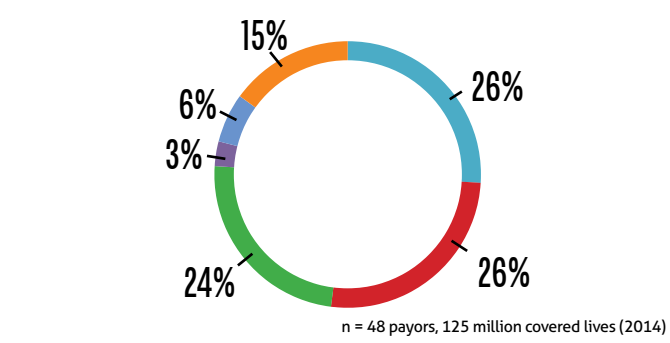
FIGURE 61: 2014 Percentage of Rheumatology Practices Purchased by Hospital Systems



n = 11 payors, 24 million covered lives (2014)

Payors provided reasons why they believed independent practices in their service areas were being purchased. Payors were allowed to select the predominant options that applied to their networks, with a maximum of two selections. The three most commonly selected reasons included 1) physician office reimbursements for commercial members had substantially decreased over the last 10 years to more closely reflect CMS rates, 2) increased hospital incentives to expand infusion centers if they had access to 340B acquisition costs and 3) increased hospital incentives to expand infusion centers because they got reimbursed on a percent of charges. Payors who selected "other" noted current administrative challenges offices were facing. Payors who had not seen independent, office-based practices purchased by hospital systems in their networks responded with "not applicable." *See Figure 62: 2014 Reasons Why Independent Practices Were Being Purchased by Hospital Systems.*

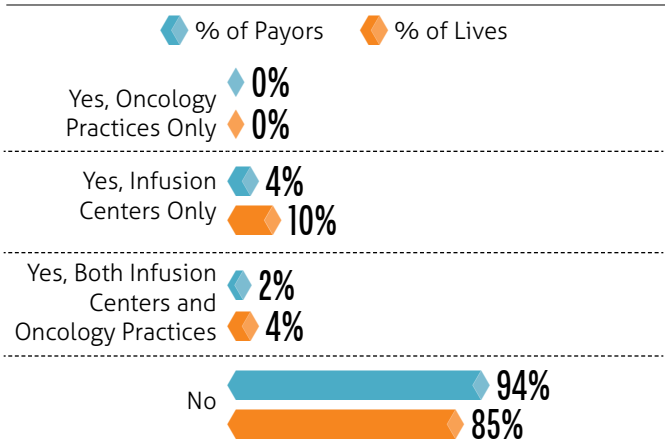
FIGURE 62: 2014 Reasons Why Independent Practices Were Being Purchased by Hospital Systems



n = 48 payors, 125 million covered lives (2014)

One cost-management solution to impact and reverse the shift of medical benefit drug administrations to higher-cost sites of service is for health plans to open and manage their own infusion centers. When payor survey respondents were asked if they were considering opening infusion centers or oncology practices in their networks, 94 percent of payors responded that they were not. Four percent of payors responded that they were considering opening infusion centers, while 2 percent responded that they were considering opening both infusion centers and oncology practices. *See Figure 63: 2014 Payors Considering Opening Infusion Centers or Oncology Practices.*

FIGURE 63: 2014 Payors Considering Opening Infusion Centers or Oncology Practices

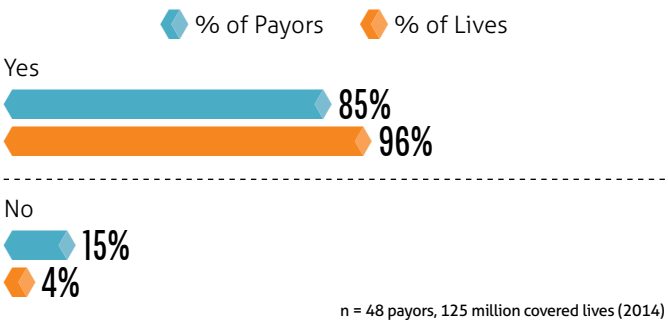


n = 48 payors, 125 million covered lives (2014)

Utilization Management

In 2014, 85 percent of payors representing 96 percent of covered lives managed utilization of medical benefit drugs compared to our 2013 survey in which health plans representing only 38 percent of covered lives reported that they managed utilization of medical benefit drugs. *See Figure 64: 2014 Payors Managing Utilization of Medical Benefit Drugs.*

FIGURE 64: 2014 Payors Managing Utilization of Medical Benefit Drugs



n = 48 payors, 125 million covered lives (2014)

Out of the payor respondents who managed utilization of medical benefit drugs, autoimmune disorders, cancer, immunodeficiencies, multiple sclerosis, inborn errors of metabolism and rare diseases, pulmonary arterial hypertension, hemophilia, alpha-1-antitrypsin deficiency, hereditary angioedema and respiratory syncytial virus prevention were the categories most often managed by payors (at least 20 percent of payor respondents). The most commonly employed utilization management tools were prior authorization, followed by post-service claim edits, step edit requirements and clinical pathways. Prior authorization was the predominant utilization management tool, consistent with our 2013 survey responses. Payor respondents could select all disease state categories and utilization management tools that applied to their business models. *See Figure 65: 2014 Utilization Management Tools for Medical Benefit Drugs by Disease State Categories.*

FIGURE 65: 2014 Utilization Management Tools for Medical Benefit Drugs by Disease State Categories

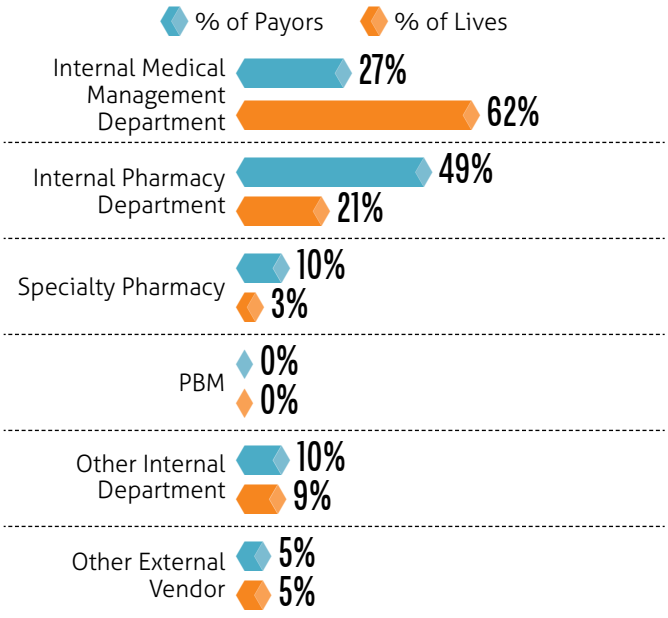
% OF PAYORS

	CARE MANAGEMENT (E.G., DISEASE MANAGEMENT OR CASE MANAGEMENT)	PRIOR AUTHORIZATION	STEP EDIT REQUIREMENTS	CLINICAL PATHWAYS	POST-SERVICE CLAIM EDITS	OTHER	NONE
Autoimmune Disorders	24%	98%	39%	10%	22%	5%	0%
Cancer	32%	85%	20%	27%	22%	5%	5%
Immunodeficiencies	24%	80%	15%	2%	22%	2%	5%
Multiple Sclerosis	20%	88%	34%	7%	20%	5%	2%
Osteoporosis	7%	80%	32%	2%	20%	5%	5%
Osteoarthritis	5%	59%	22%	2%	22%	7%	17%
Age-Related (Wet) Macular Degeneration	2%	68%	15%	2%	20%	5%	20%
Inborn Errors of Metabolism and Rare Diseases	20%	85%	10%	2%	15%	2%	7%
Pulmonary Arterial Hypertension	22%	83%	12%	2%	17%	2%	10%
Hemophilia	27%	68%	7%	2%	15%	5%	15%
Alpha-1-Antitrypsin Deficiency	27%	83%	7%	2%	15%	2%	10%
Hereditary Angioedema	22%	80%	7%	2%	17%	2%	10%
Musculoskeletal Conditions	10%	85%	15%	2%	22%	5%	2%
Asthma	17%	93%	24%	2%	15%	5%	5%
Respiratory Syncytial Virus Prevention	24%	93%	10%	2%	15%	2%	0%
Other	0%	12%	2%	0%	5%	7%	80%

n = 41 payors, 120 million covered lives (2014)

Of the payors who responded that they managed utilization of medical benefit drugs, more than one-quarter of payors representing 62 percent of covered lives responded that their internal health plan medical management departments administered their utilization management programs versus nearly half of payors representing 21 percent of covered lives who responded that their internal health plan pharmacy departments administered their utilization management programs. *See Figure 66: 2014 Medical Benefit Drug Utilization Management Program Administrator.*

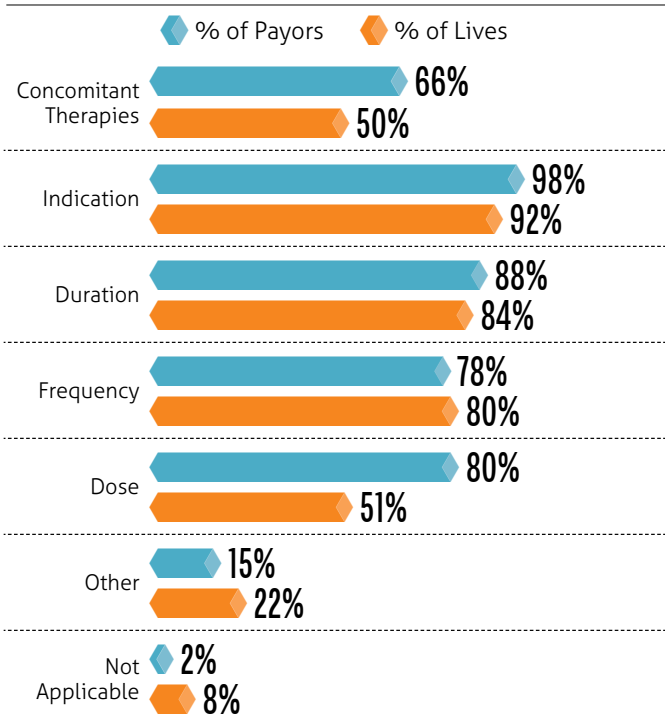
FIGURE 66: 2014 Medical Benefit Drug Utilization Management Program Administrator



n = 41 payors, 120 million covered lives (2014)

Payors who managed the utilization of medical benefit drugs provided additional insights into their prior authorization programs review criteria. Payors predominantly reviewed the member's indication, drug dose, frequency of drug administration and duration of drug use. Although still significant, fewer payors reviewed concomitant therapies prescribed to the member during the prior authorization review versus the four elements mentioned above. Of the payors who selected "other," their responses included previous products utilized for the same indication, prescriber specialty and genetic mutations or biomarker status. *See Figure 67: 2014 Medical Benefit Drug Prior Authorization Review Criteria.*

FIGURE 67: 2014 Medical Benefit Drug Prior Authorization Review Criteria

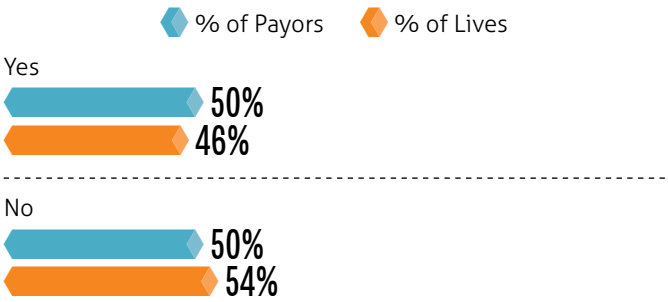


n = 41 payors, 120 million covered lives (2014)

Operational Improvements

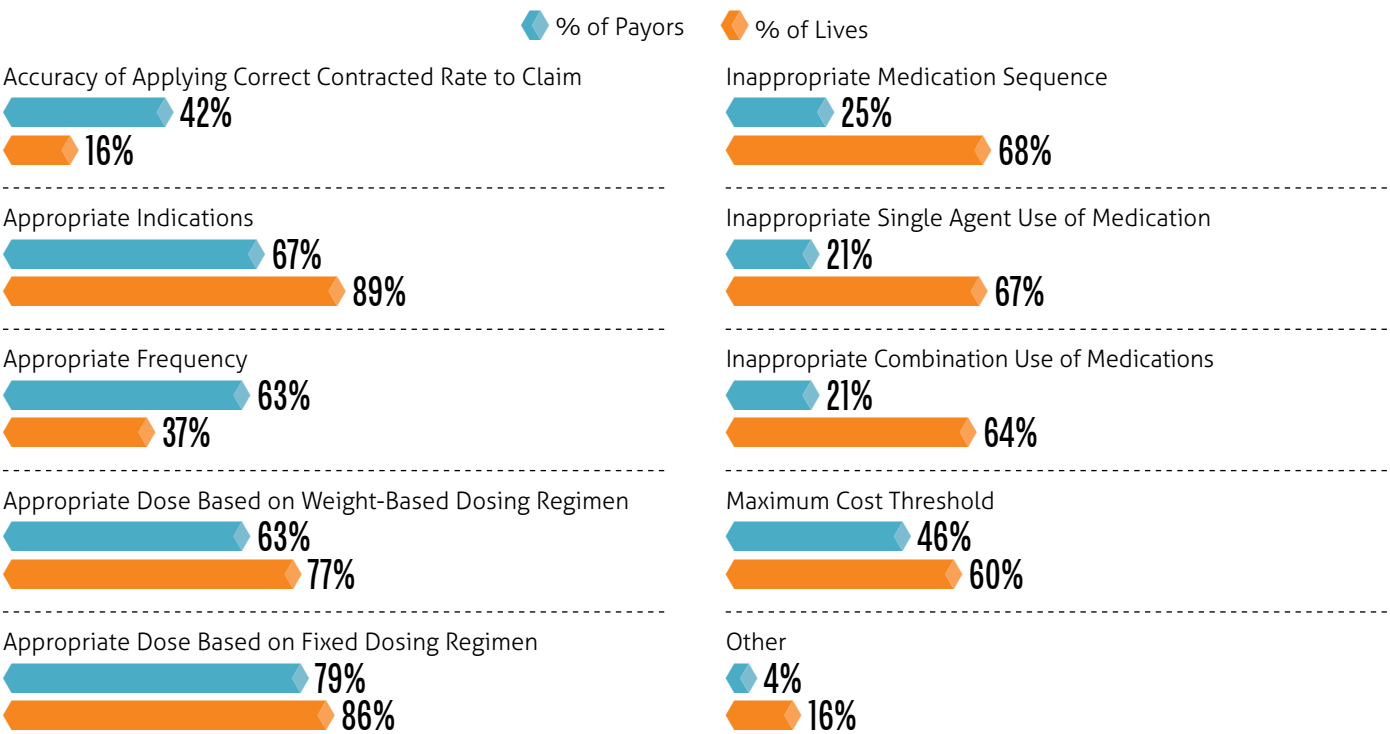
Half of the payor survey respondents representing nearly half of covered lives reported that they administered post-service, pre-payment edits on medical benefit drug claims. Through use of post-service, pre-payment claim edits, based on percentage of payors, health plans most frequently reviewed medical benefit drug claims for 1) appropriate doses based on fixed dosing regimens, 2) appropriate indications, 3) appropriate doses based on weight-based dosing regimens, 4) appropriate frequency, 5) maximum cost thresholds and 6) accuracy of applying correct contracted rates to the claims. *See Figure 68: 2014 Payors Conducting Post-Service, Pre-Payment Edits on Medical Benefit Drug Claims and Figure 69: 2014 Medical Benefit Drugs Post-Service, Pre-Payment Review Criteria.*

FIGURE 68: 2014 Payors Conducting Post-Service, Pre-Payment Edits on Medical Benefit Drug Claims



n = 48 payors, 125 million covered lives (2014)

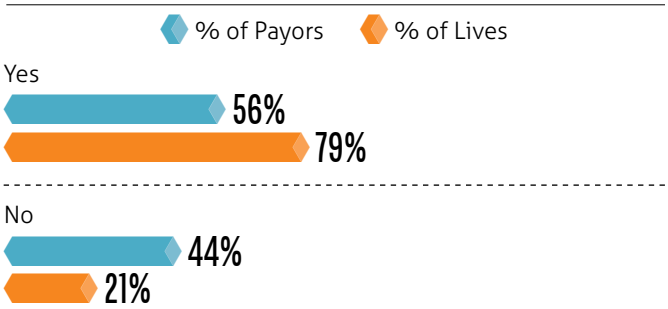
FIGURE 69: 2014 Medical Benefit Drugs Post-Service, Pre-Payment Review Criteria



n = 24 payors, 58 million covered lives (2014)

Fifty-six percent of payors representing nearly eight out of 10 covered lives reported that medical benefit drugs were included in their health plans' post-service, post-payment audit/recovery efforts. Although not surveyed, typically payors who managed medical benefit drugs with post-service, pre-payment claim edits versus post-service, post-payment claim edits realized more cost savings due to initial correct payments versus commencing collection efforts after claims had been incorrectly paid. *See Figure 70: 2014 Medical Benefit Drugs Included in Post-Service, Post-Payment Audit/Recovery Efforts.*

FIGURE 70: 2014 Medical Benefit Drugs Included in Post-Service, Post-Payment Audit/Recovery Efforts



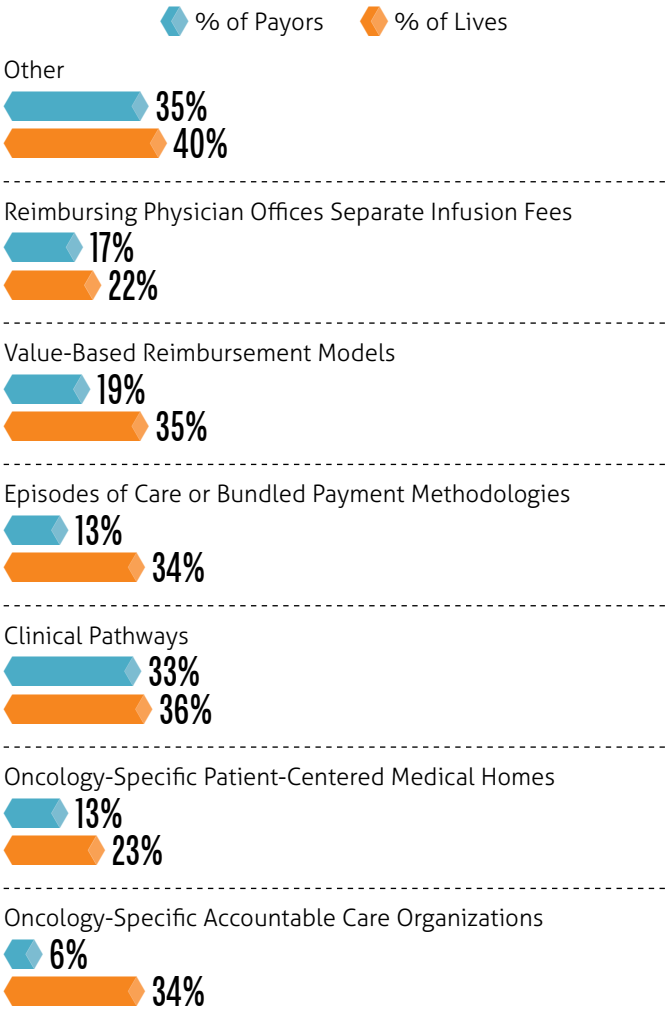
n = 48 payors, 125 million covered lives (2014)

Management Trends

New in 2014, we created a survey section dedicated to health plan medical benefit drug management trends and included key topics such as oncology-specific pilot management programs, palliative care programs and site of service management.

Payors were asked if they had initiated any oncology-specific pilot programs in their networks. Thirty-five percent of payors representing 40 percent of covered lives responded that they had initiated "other" oncology-specific pilot programs. Most of the "other" responses were from payors who did not have any oncology-specific pilot programs in their networks. Additional responses from payors for the "other" category included outcomes studies, increased provider reimbursements for effective medications and enhancing generic drugs reimbursement rates. One-third of payors representing 36 percent of covered lives responded that they had initiated oncology-specific clinical pathways in their networks. *See Figure 71: 2014 Oncology-Specific Pilot Programs Initiated by Payors.*

FIGURE 71: 2014 Oncology-Specific Pilot Programs Initiated by Payors



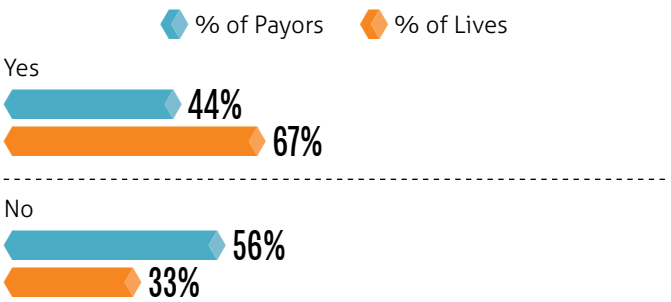
n = 48 payors, 125 million covered lives (2014)

Payors who implemented clinical pathways programs for oncology management versus prior authorization programs did so for the following reasons:

- Fixed program costs relative to clinical episodes placed the physicians at financial risk versus the payors,
- To provide standardization and appropriate utilization,
- To utilize both prior authorization and clinical pathways programs, as clinical pathways are specific only to certain cancers,
- Program provided aligned incentives and reduced member and provider disruption,
- To elicit better outcomes and patient safety,
- To reward providers for narrowing their chemotherapy regimen choices and
- State legislature requirements.

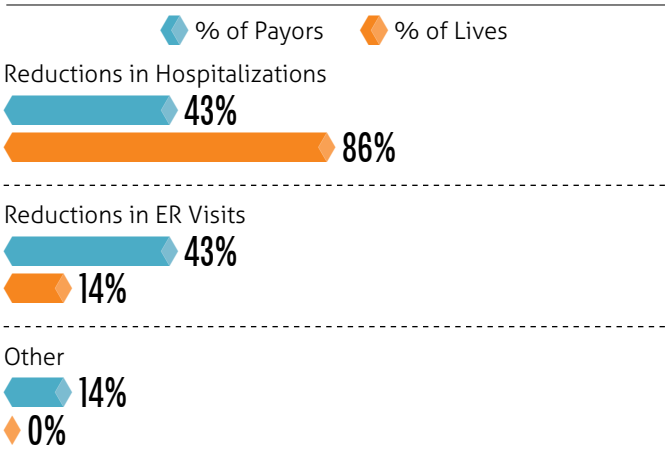
For health plans that had initiated oncology clinical pathways programs in their networks, 44 percent of payors representing two-thirds of covered lives saw medical cost reductions with their pilots, beyond just use of lower-cost drugs when clinically appropriate. Medical cost reductions were predominantly due to reductions in hospitalizations and emergency room (ER) visits. *See Figure 72: 2014 Medical Cost Reductions Beyond Use of Lower-Cost Drugs with Oncology Clinical Pathways and Figure 73: 2014 Drivers of Medical Cost Reductions Beyond Use of Lower-Cost Drugs with Oncology Clinical Pathways.*

FIGURE 72: 2014 Medical Cost Reductions Beyond Use of Lower-Cost Drugs with Oncology Clinical Pathways



n = 16 payors, 45 million covered lives (2014)

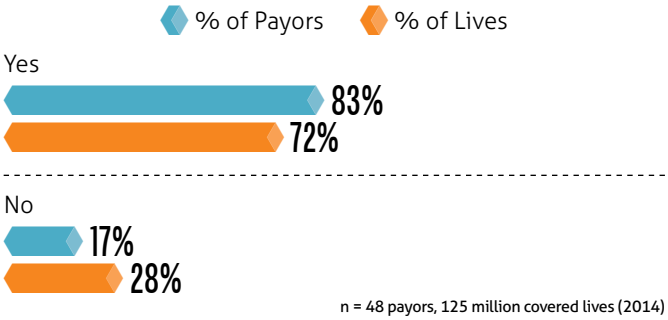
FIGURE 73: 2014 Drivers of Medical Cost Reductions Beyond Use of Lower-Cost Drugs with Oncology Clinical Pathways



n = 7 payors, 30 million covered lives (2014)

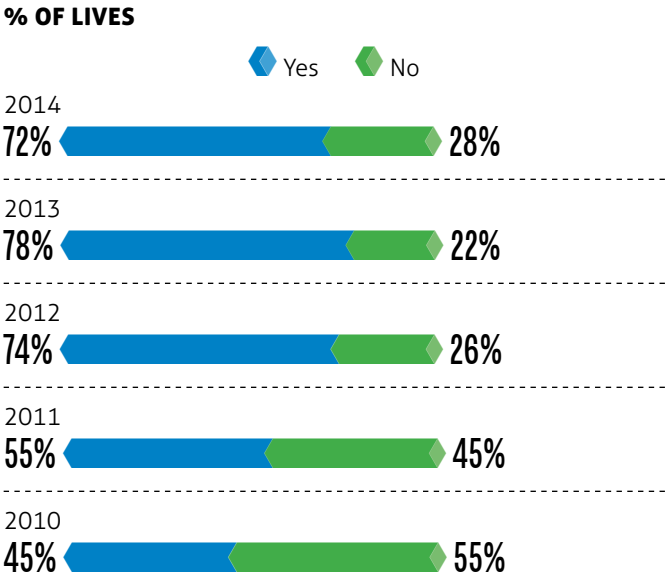
More than 80 percent of payors representing seven in 10 covered lives provided end-of-life/palliative care programs for their members who had cancer. The percentages of covered lives provided with an option for a palliative care program decreased from 78 percent in 2013. *See Figure 74: 2014 Payors Providing Palliative Care Programs to Members with Cancer and Figure 75: Payors Providing Palliative Care Programs to Members with Cancer 2010–2014.*

FIGURE 74: 2014 Payors Providing Palliative Care Programs to Members with Cancer



n = 48 payors, 125 million covered lives (2014)

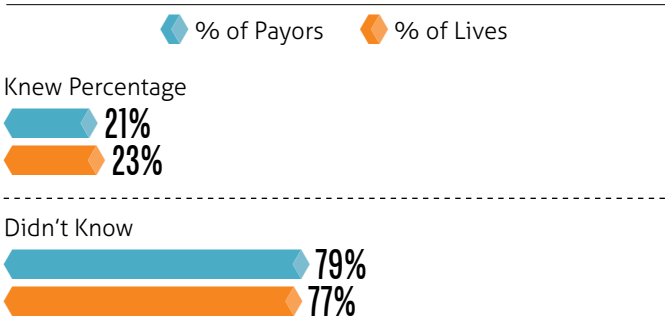
FIGURE 75: Payors Providing Palliative Care Programs to Members with Cancer 2010–2014



n = 60 payors, 146 million covered lives (2010)
n = 60 payors, 153 million covered lives (2011)
n = 50 payors, 157 million covered lives (2012)
n = 48 payors, 166 million covered lives (2013)
n = 48 payors, 125 million covered lives (2014)

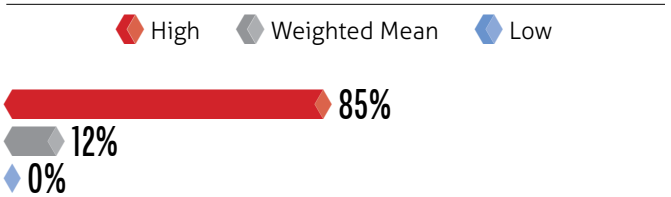
When asked what percentage of members with cancer had received chemotherapy within the last two weeks of their lives, only 21 percent of health plans representing 23 percent of covered lives knew their plans' percentages. Of those payors who reported that they knew the percentage, using a weighted average based on number of covered lives, 12 percent of members received chemotherapy within the last two weeks of life; however, responses covered a range from 0 to 85 percent, indicating a need for improved data collection and management in this area. *See Figure 76: 2014 Payors Who Knew Percentage of Members with Cancer Who Received Chemotherapy Within Last Two Weeks of Life and Figure 77: 2014 Percentage of Members with Cancer Who Received Chemotherapy Within Last Two Weeks of Life.*

FIGURE 76: 2014 Payors Who Knew Percentage of Members with Cancer Who Received Chemotherapy Within Last Two Weeks of Life



n = 48 payors, 125 million covered lives (2014)

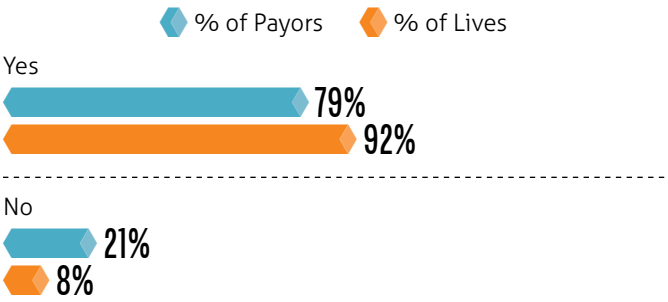
FIGURE 77: 2014 Percentage of Members with Cancer Who Received Chemotherapy Within Last Two Weeks of Life



n = 10 payors, 29 million covered lives (2014)

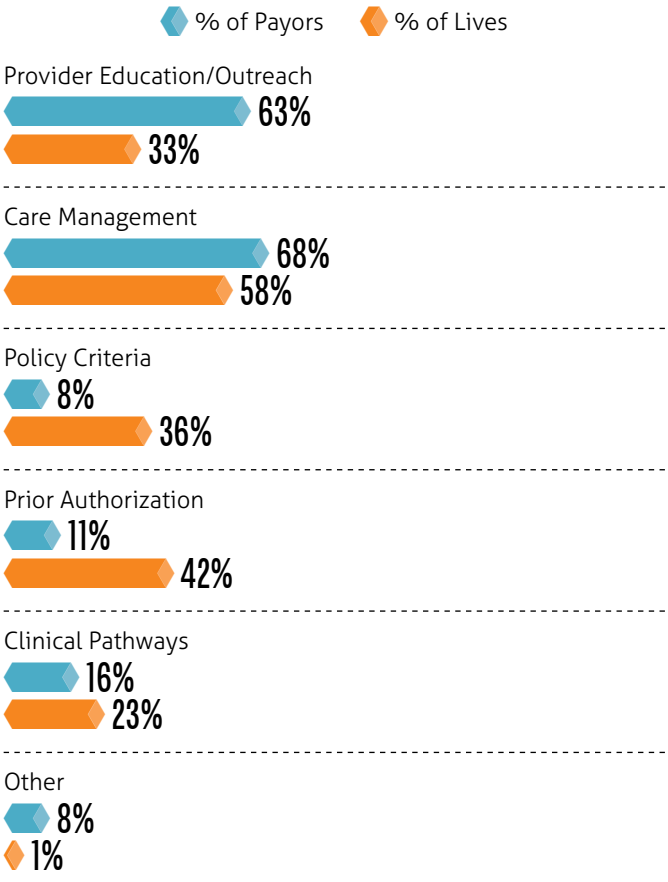
Nearly 80 percent of payors representing nine in 10 covered lives stated that they were looking to increase the use of palliative care programs at their organizations. The tools these payors intended to use to drive this change were predominantly care management and provider outreach and education. *See Figure 78: 2014 Payors Looking to Increase Use of Palliative Care Programs and Figure 79: 2014 Tools Payors Intend to Implement to Increase Use of Palliative Care Programs.*

FIGURE 78: 2014 Payors Looking to Increase Use of Palliative Care Programs



n = 48 payors, 125 million covered lives (2014)

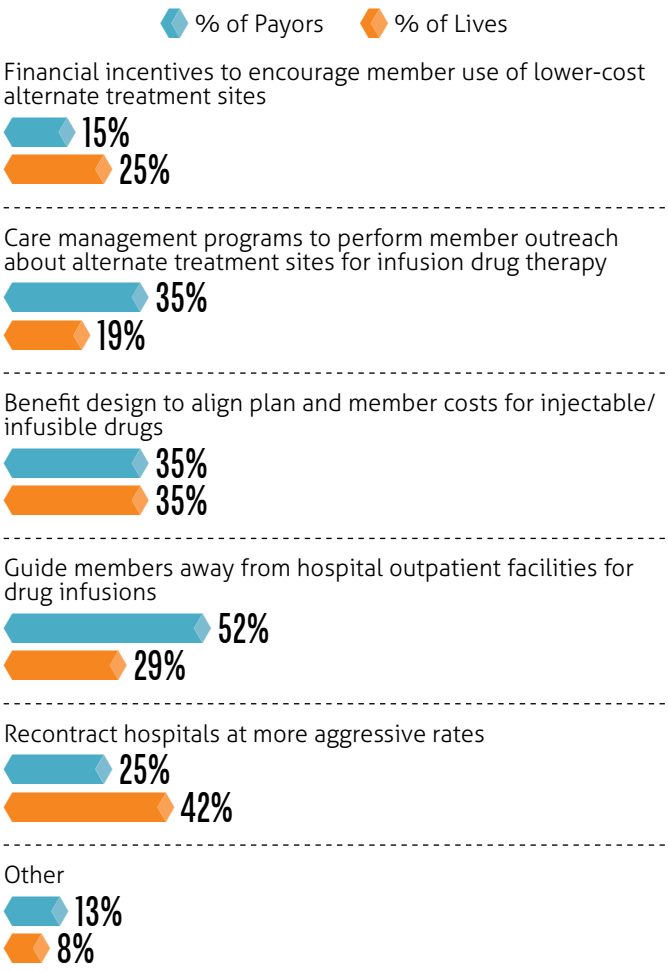
FIGURE 79: 2014 Tools Payors Intend to Implement to Increase Use of Palliative Care Programs



n = 38 payors, 115 million covered lives (2014)

Payors were asked which approaches they used to manage the shift in site of service for medical benefit drugs from lower-cost sites of service (e.g., physician offices, homes) to higher-cost sites of service (e.g., hospital outpatient facilities). Payors could select the predominant approaches that applied, up to two choices. More than half of payors representing 29 percent of covered lives responded that their approach was to guide members away from hospital outpatient facilities for drug infusions. About one-third of payors responded that their approach included aligning the plan's and member's costs for medical benefit drugs through benefit design and utilizing care management programs to perform outreach to members about alternate treatment sites for their infusion drug therapy. *See Figure 80: 2014 Payors' Approaches to Managing Medical Benefit Drugs Sites of Service.*

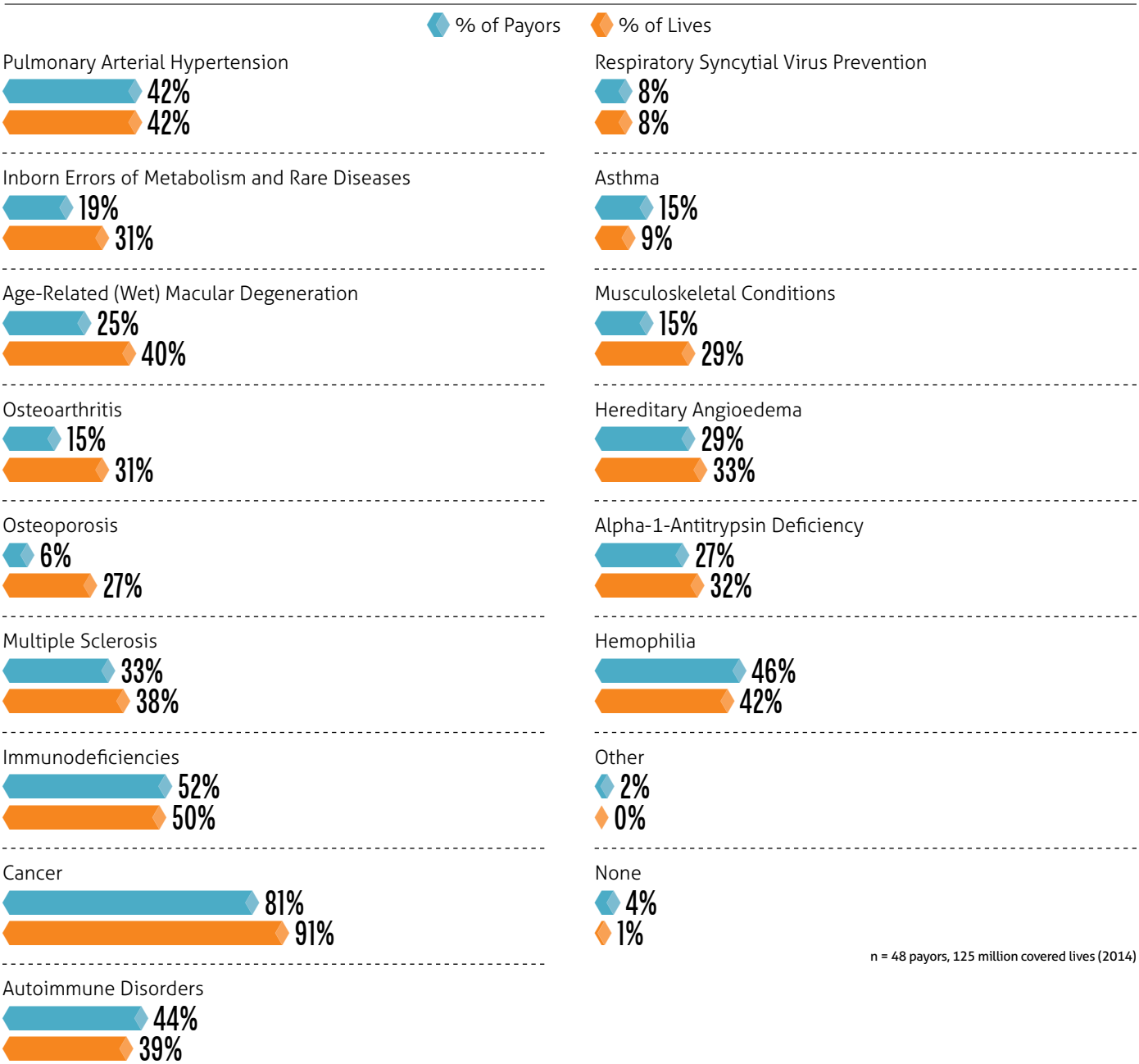
FIGURE 80: 2014 Payors' Approaches to Managing Medical Benefit Drugs Sites of Service



n = 48 payors, 125 million covered lives (2014)

Even with the variety of medical benefit drug management approaches health plans were using or planned to put in place, payors still responded that there were specific medical benefit disease states their organizations had challenges managing. Cancer was by far the predominant reported disease state, followed by immunodeficiencies, hemophilia, autoimmune disorders and pulmonary arterial hypertension. *See Figure 81: 2014 Medical Benefit Disease States Payors Had Challenges Managing.*

FIGURE 81: 2014 Medical Benefit Disease States Payors Had Challenges Managing



n = 48 payors, 125 million covered lives (2014)

Health Plan Claims Data

Utilization Trends

Over the last four years, medical pharmacy allowed[4] amounts had 9–13 percent year-over-year increases in the commercial population versus fluctuating changes in the Medicare population with an average of 2.8 percent annual trend. In 2013, commercial payors experienced $21.07 allowed amount per member per month (PMPM) for medical pharmacy, while payors saw $44.99 PMPM for Medicare members. This dynamic is not unusual as Medicare medical pharmacy allowed amount PMPMs are typically two to three times higher than commercial. Compared to 2012, 2013 commercial and Medicare PMPM allowed amounts increased 13 percent and 5 percent, respectively. *See Figure 82: Medical Pharmacy Allowed Amount PMPM by Line of Business (LOB) 2010–2013.*

FIGURE 82: Medical Pharmacy Allowed Amount PMPM by LOB 2010–2013

	YEAR			
LOB	2010	2011	2012	2013
Commercial	$15.57	$16.91	$18.67	$21.07
Medicare	$41.56	$44.16	$42.65	$44.99

The allowed amount PMPM is separated by site of service for commercial versus Medicare in Figure 83. In 2013, 49 percent of commercial costs were billed from the hospital outpatient facility, up from 42 percent in 2010. From 2010–2013, the commercial population saw a 4–6 percent annual trend in allowed amount PMPM market share in the hospital outpatient facility. The commercial physician office market share by allowed amount PMPM remained at 37 percent in 2010–2012, but in 2013 decreased to 34.6 percent. The "other" sites of service are comprised of various locations, such as dialysis centers, emergency departments and ambulatory surgical centers. The site of service associated with the largest annual commercial allowed amount PMPM increase from 2012–2013 was the hospital outpatient facility, followed by the physician office setting, home infusion/specialty pharmacy and, lastly, "other."

The Medicare population saw a large increase (45 percent) in allowed amount PMPM in the hospital outpatient facility from 2010–2011. From 2011–2013, the annual allowed amount PMPM trend was approximately 4 percent. The physician office represented the majority of allowed amount PMPM, accounting for 64 percent market share in 2010, reduced to 55 percent market share in 2013. On average, there has been a 5 percent annual decrease in physician office allowed amount PMPM market share since 2010. *See Figure 83: Medical Pharmacy Allowed Amount PMPM by LOB by Site of Service 2010–2013.*

FIGURE 83: Medical Pharmacy Allowed Amount PMPM by LOB by Site of Service 2010–2013

ALLOWED PMPM	YEAR			
LOB	2010	2011	2012	2013
Commercial	**$15.57**	**$16.91**	**$18.67**	**$21.07**
Home Infusion/Specialty Pharmacy	$2.71	$2.65	$2.65	$2.99
Hospital Outpatient Facility	$6.58	$7.56	$8.69	$10.30
Other	$0.53	$0.36	$0.42	$0.49
Physician Office	$5.75	$6.35	$6.91	$7.29
Medicare	**$41.56**	**$44.16**	**$42.65**	**$44.99**
Home Infusion/Specialty Pharmacy	$3.38	$3.08	$2.95	$3.52
Hospital Outpatient Facility	$10.10	$14.65	$15.65	$15.95
Other	$1.45	$0.77	$0.83	$0.86
Physician Office	$26.63	$25.65	$23.23	$24.65

Please note: Due to rounding to the nearest cent, some of the column totals do not add up accurately.

Although the hospital outpatient facility represented nearly half of the spend for the commercial population, it had represented less than 40 percent of market share by claims and less than 30 percent of members[5] over the last four years. This dynamic will be discussed further during the site of service analyses in the "National Provider Trends" section, which will outline drug cost variances by site of service. For the commercial population in the physician office setting, the market shares by claims and members remained relatively consistent over the last four years, around 50 percent and 60 percent, respectively.

4. Allowed amount or dollars is a field provided in claims data sets and typically represents the combination of plan paid and member liability or cost share.

5. Members refers to the health plan members who received provider-administered injectable or infused drugs.

PLEASE NOTE: Throughout the entire Health Plan Claims Data section, costs were rounded to the nearest cent. Detailed percentages in the tables and text were calculated utilizing raw data.

For the Medicare population, the majority of claims and members had been in the physician office setting over the last four years. The proportion of claims billed from the physician office setting increased from 2010 at an average annual trend of 3 percent. As with the allowed amount PMPM trend seen earlier, the hospital outpatient facility saw an increase in market shares for both claims and members in 2011, but the proportion of claims and members decreased gradually in 2012 and 2013. *See Figure 84: Medical Pharmacy Market Share Percentages by Claims and Members by LOB and Site of Service 2010–2013.*

FIGURE 84: Medical Pharmacy Market Share Percentages by Claims and Members by LOB and Site of Service 2010–2013

CLAIMS	MARKET SHARE BY CLAIMS BY YEAR				MARKET SHARE BY MEMBERS BY YEAR			
LOB	2010	2011	2012	2013	2010	2011	2012	2013
Commercial								
Home Infusion/ Specialty Pharmacy	4.0%	3.8%	3.5%	3.5%	3.2%	2.7%	2.4%	2.4%
Hospital Outpatient Facility	36.3%	37.0%	37.2%	38.5%	29.4%	29.7%	29.1%	28.8%
Other	9.7%	7.7%	8.3%	8.1%	8.6%	6.9%	7.9%	8.1%
Physician Office	50.0%	51.6%	51.0%	49.9%	58.9%	60.7%	60.6%	60.7%
Medicare								
Home Infusion/ Specialty Pharmacy	3.3%	3.4%	4.1%	4.3%	3.5%	2.8%	2.4%	2.5%
Hospital Outpatient Facility	15.2%	18.3%	16.6%	16.5%	14.4%	16.5%	15.7%	15.4%
Other	16.4%	8.9%	7.4%	7.3%	5.9%	4.6%	4.9%	5.6%
Physician Office	65.2%	69.4%	71.9%	71.9%	76.2%	76.2%	77.2%	76.6%

Trend Drivers

As with past trend reports, we have analyzed the top 25 medical benefit drugs by spend. New in 2014, we separated the top 25 drugs by LOB and calculated the average medical pharmacy annual cost (allowed amount) per patient and compared it to the previous year. Across all medical pharmacy utilization, the cost per patient for commercial members increased 8 percent and for Medicare members 6 percent in 2013 versus 2012. Cost per patient increases might be due to several factors, including manufacturer price increases as well as changes in unit costs based on the rendering provider (e.g., physician office, home infusion, specialty pharmacy or hospital outpatient facility). Cost per patient decreases were most commonly seen in Healthcare Common Procedure Coding System (HCPCS) codes with generic availability, such as Eloxatin and Taxotere. *See Figure 85: Commercial Top 25 Medical Benefit Drugs by Allowed Amount PMPM and Cost per Patient and Figure 86: Medicare Top 25 Medical Benefit Drugs by Allowed Amount PMPM and Cost per Patient.*

FIGURE 85: Commercial Top 25 Medical Benefit Drugs by Allowed Amount PMPM and Cost per Patient

COMMERCIAL			ALLOWED PMPM		COST/PATIENT		PMPM	COST/PATIENT
RANK	HCPCS CODE	BRAND NAME	2012	2013	2012	2013	% CHANGE	% CHANGE
1	J1745	Remicade	$1.79	$2.16	$21,696	$24,647	21%	14%
2	J2505	Neulasta	$1.50	$1.60	$15,735	$16,856	7%	7%
3	J9035	Avastin	$1.17	$1.44	$19,452	$21,918	22%	13%
4	J9310	Rituxan	$1.02	$1.15	$27,044	$28,630	13%	6%
5	J9355	Herceptin	$0.87	$0.98	$36,341	$38,143	12%	5%
6	J7192	Advate/Helixate/ Kogenate/Recombinate	$0.57	$0.60	$173,272	$180,938	6%	4%
7	J1569	Gammagard Liquid	$0.45	$0.47	$37,554	$41,605	4%	11%
8	J1561	Gamunex-C/Gammaked	$0.39	$0.45	$41,180	$53,117	15%	29%
9	J2323	Tysabri	$0.39	$0.43	$31,213	$33,887	12%	9%
10	J9263	Eloxatin	$0.65	$0.41	$23,919	$12,009	-37%	-50%
11	J9305	Alimta	$0.38	$0.40	$29,782	$32,973	7%	11%
12	J0897	Xgeva/Prolia	$0.23	$0.38	$5,046	$4,814	66%	-5%
13	J9228	Yervoy	$0.14	$0.35	$109,391	$168,471	151%	54%
14	J9171	Taxotere	$0.40	$0.35	$10,285	$9,197	-13%	-11%
15	J1459	Privigen	$0.19	$0.28	$34,787	$50,499	51%	45%
16	J2469	Aloxi	$0.26	$0.28	$2,106	$2,247	8%	7%
17	J2778	Lucentis	$0.20	$0.26	$9,604	$9,483	30%	-1%
18	J9041	Velcade	$0.23	$0.25	$26,671	$28,658	10%	7%
19	J1300	Soliris	$0.24	$0.23	$439,344	$416,593	-1%	-5%
20	J9264	Abraxane	$0.17	$0.22	$24,430	$22,217	27%	-9%
21	J9055	Erbitux	$0.22	$0.22	$36,746	$35,359	-2%	-4%
22	J0585	Botox	$0.18	$0.22	$1,917	$2,051	21%	7%
23	J2353	Sandostatin LAR Depot	$0.16	$0.19	$32,252	$32,190	22%	0%
24	J9033	Treanda	$0.13	$0.19	$27,497	$34,312	47%	25%
25	J2357	Xolair	$0.16	$0.18	$14,378	$15,190	17%	6%
TOP 25 TOTALS			**$12.08**	**$13.70**	**$20,974**	**$20,915**	**13%**	**0%**
TOTAL MEDICAL PHARMACY			**$18.67**	**$21.07**	**$1,371**	**$1,486**	**13%**	**8%**

Please note: Due to rounding to the nearest cent, some of the column totals do not add up accurately.

FIGURE 86: Medicare Top 25 Medical Benefit Drugs by Allowed Amount PMPM and Cost per Patient

MEDICARE			ALLOWED PMPM		COST/PATIENT		PMPM	COST/PATIENT
RANK	HCPCS CODE	BRAND NAME	2012	2013	2012	2013	% CHANGE	% CHANGE
1	J9310	Rituxan	$3.68	$3.80	$21,481	$22,087	3%	3%
2	J2505	Neulasta	$3.40	$3.55	$11,241	$11,648	5%	4%
3	J2778	Lucentis	$2.78	$3.10	$9,291	$9,517	12%	2%
4	J9035	Avastin	$2.34	$2.46	$3,308	$3,689	5%	12%
5	J1745	Remicade	$1.88	$2.24	$16,415	$17,969	19%	9%
6	J9305	Alimta	$1.48	$1.64	$21,524	$26,653	10%	24%
7	J1569	Gammagard Liquid	$1.16	$1.23	$43,466	$45,404	6%	4%
8	J9355	Herceptin	$1.08	$1.22	$29,530	$30,656	12%	4%
9	J0897	Xgeva/Prolia	$0.89	$1.19	$3,281	$2,885	34%	-12%
10	J9041	Velcade	$1.16	$1.15	$23,673	$23,406	-1%	-1%
11	J9033	Treanda	$0.65	$1.14	$19,644	$24,944	76%	27%
12	J0178	Eylea	–	$0.79	–	$9,676	–	–
13	J2785	Lexiscan	$0.68	$0.75	$233	$232	10%	0%
14	J0885	Procrit/Epogen	$0.76	$0.73	$3,044	$3,171	-4%	4%
15	J9055	Erbitux	$0.73	$0.70	$28,211	$29,101	-4%	3%
16	J9217	Eligard/Lupron Depot	$0.77	$0.67	$2,021	$1,918	-12%	-5%
17	J9264	Abraxane	$0.38	$0.65	$14,813	$15,709	71%	6%
18	J9025	Vidaza	$0.48	$0.62	$21,437	$25,742	28%	20%
19	J9263	Eloxatin	$1.85	$0.62	$18,429	$6,403	-67%	-65%
20	J0881	Aranesp	$0.65	$0.59	$4,242	$4,748	-9%	12%
21	J2353	Sandostatin LAR Depot	$0.53	$0.55	$23,087	$28,539	3%	24%
22	J2323	Tysabri	$0.34	$0.49	$24,394	$29,595	45%	21%
23	J1459	Privigen	$0.45	$0.47	$26,590	$33,010	4%	24%
24	J7325	Synvisc/Synvisc-One	$0.50	$0.47	$957	$955	-6%	0%
25	J1561	Gamunex-C/Gammaked	$0.32	$0.47	$27,362	$32,230	44%	18%
TOP 25 TOTALS			**$28.94**	**$31.27**	**$4,773**	**$4,943**	**8%**	**4%**
TOTAL MEDICAL PHARMACY			**$42.65**	**$44.99**	**$1,642**	**$1,743**	**5%**	**6%**

Please note: Due to rounding to the nearest cent, some of the column totals do not add up accurately.

Several important trends were identified from the top 25 medical benefit drugs listing by LOB. A few of them are highlighted below:

- Two ophthalmic injections used to treat neovascular (wet) age-related macular degeneration (AMD) and other ocular indications were present on the Medicare top 25 drug listing (Lucentis and Eylea) with a combined allowed amount PMPM of $3.89 in 2013 versus the commercial population, which only had Lucentis in the top 25 with $0.26 PMPM. This was due to the different demographics represented by these two groups, as AMD mainly affects older populations. Also of note, the allowed amount cost per patient per year for Avastin was dramatically lower in the Medicare population versus the commercial population. Part of this might be due to a larger utilization of Avastin for ocular indications (administered as a small dose) in Medicare versus the commercial population.

- Remicade was the top drug by allowed amount PMPM for commercial payors versus the fifth highest cost driver for Medicare. The annual cost per patient was lower for Medicare members, which might be due to variances in payor drug reimbursement rates to providers for commercial versus Medicare members as well as differences in the percentages of utilization by indication.

- Neulasta had the second highest allowed amount PMPM for both populations; however, the Medicare PMPM was higher than the commercial due to the larger utilization of oncology and oncology supportive medications in the Medicare population, although the cost per patient was lower than commercial.

- The utilization of J0897, which represented both Xgeva and Prolia, continued to grow with 66 percent and 34 percent annual allowed amount PMPM increases for commercial and Medicare, respectively. The annual allowed cost per patient decreased in both populations, suggesting that in 2013 there might have been more utilization of the osteoporosis agent Prolia, which was administered as a smaller dose and less frequently than its oncology counterpart, Xgeva.

- Yervoy had the largest annual trend from 2012–2013, 151 percent for the commercial population. Increased utilization was the major driver for this trend. Due to the high annual allowed amount cost per patient for this drug ($168,471 in 2013 versus $109,391 in 2012) coupled with its limited utilization compared to other biologic chemotherapy agents, the allowed amount PMPM could be variable from year to year.

- In 2013, the average annual allowed cost per patient for the commercial population utilizing top 25 drugs was $20,915, significantly higher than the Medicare population at $4,943.

The top 25 drugs represented 65 percent of the total medical pharmacy allowed amount in 2013 for the commercial population and 70 percent for the Medicare population. The top 25 drugs represented less of the overall medical pharmacy spend since our first trend report in 2010, when the top 25 medical benefit drugs based on 2009 data comprised more than 80 percent of the total medical pharmacy spend.[6] For this reason, we also included listings of the top 26–50 drugs per LOB. The top 50 drugs represented 80 percent of commercial and 86 percent of Medicare total medical pharmacy spend in 2013. *See Figure 87: Commercial Top 26–50 Medical Benefit Drugs by Allowed Amount PMPM and Cost per Patient and Figure 88: Medicare Top 26–50 Medical Benefit Drugs by Allowed Amount PMPM and Cost per Patient.*

FIGURE 87: Commercial Top 26–50 Medical Benefit Drugs by Allowed Amount PMPM and Cost per Patient

COMMERCIAL			ALLOWED PMPM		COST/PATIENT		PMPM	COST/PATIENT
RANK	**HCPCS CODE**	**BRAND NAME**	**2012**	**2013**	**2012**	**2013**	**% CHANGE**	**% CHANGE**
26	J3357	Stelara	$0.13	$0.18	$22,142	$25,903	41%	17%
27	J9201	Gemzar	$0.20	$0.17	$7,479	$5,831	-14%	-22%
28	J1786	Cerezyme	$0.16	$0.17	$293,875	$295,344	7%	0%
29	J0878	Cubicin	$0.13	$0.17	$5,992	$7,174	31%	20%
30	J0129	Orencia	$0.17	$0.17	$14,076	$15,218	3%	8%
31	J3490	Unclassified	$0.15	$0.15	$259	$256	6%	-1%
32	J0641	Fusilev	$0.12	$0.14	$10,807	$13,425	17%	24%
33	J1441	Neupogen	$0.12	$0.14	$4,433	$4,719	9%	6%
34	J1453	Emend	$0.10	$0.13	$1,828	$1,938	32%	6%
35	J9045	Carboplatin	$0.13	$0.13	$2,466	$2,394	-2%	-3%
36	J0885	Procrit/Epogen	$0.11	$0.12	$4,056	$4,379	10%	8%
37	Q9967	Low Osmolar Contrast Material	$0.12	$0.12	$111	$113	0%	2%
38	J9395	Faslodex	$0.09	$0.12	$12,837	$15,098	39%	18%
39	J9265	Taxol	$0.13	$0.12	$2,469	$2,171	-12%	-12%
40	J7325	Synvisc/Synvisc-One	$0.12	$0.12	$1,019	$1,039	0%	2%
41	J2785	Lexiscan	$0.09	$0.11	$311	$333	29%	7%
42	J7195	Benefix/Rixubis	$0.12	$0.11	$112,688	$127,166	-4%	13%
43	J0598	Cinryze	$0.09	$0.11	$217,630	$422,146	31%	94%
44	J9070	Cytoxan	$0.06	$0.11	$1,153	$2,350	85%	104%
45	J3262	Actemra	$0.08	$0.11	$12,911	$15,810	36%	22%
46	J0178	Eylea	–	$0.11	–	$10,524	–	–
47	J3487	Zometa	$0.16	$0.11	$4,730	$3,852	-35%	-19%
48	J9999	Unclassified	$0.05	$0.10	$19,678	$25,617	89%	30%
49	J9217	Eligard/Lupron Depot	$0.08	$0.10	$2,630	$2,872	20%	9%
50	J7302	Mirena	$0.10	$0.10	$787	$771	-2%	-2%
TOP 26–50 TOTALS			**$2.82**	**$3.24**	**$1,241**	**$1,404**	**15%**	**13%**
TOTAL MEDICAL PHARMACY			**$18.67**	**$21.07**	**$1,371**	**$1,486**	**13%**	**8%**

Please note: Due to rounding to the nearest cent, some of the column totals do not add up accurately.

6. ICORE Healthcare. 2010 Medical injectable & oncology trend report.™

FIGURE 88: Medicare Top 26–50 Medical Benefit Drugs by Allowed Amount PMPM and Cost per Patient

MEDICARE			ALLOWED PMPM		COST/PATIENT		PMPM	COST/PATIENT
RANK	HCPCS CODE	BRAND NAME	2012	2013	2012	2013	% CHANGE	% CHANGE
26	J9395	Faslodex	$0.51	$0.46	$12,843	$11,993	-9%	-7%
27	J0129	Orencia	$0.41	$0.46	$11,782	$12,948	13%	10%
28	J2469	Aloxi	$0.47	$0.46	$1,189	$1,159	-4%	-3%
29	J9171	Taxotere	$0.69	$0.45	$6,523	$4,168	-35%	-36%
30	Q2043	Provenge	$0.23	$0.42	$92,444	$95,959	82%	4%
31	J9228	Yervoy	$0.32	$0.38	$86,816	$105,572	18%	22%
32	J3487	Zometa	$0.54	$0.32	$4,062	$3,000	-40%	-26%
33	J1300	Soliris	$0.11	$0.32	$356,630	$326,233	175%	-9%
34	J0585	Botox	$0.28	$0.30	$1,758	$1,808	8%	3%
35	J1441	Neupogen	$0.30	$0.29	$3,480	$3,430	-3%	-1%
36	J0878	Cubicin	$0.22	$0.28	$4,887	$5,479	29%	12%
37	J0894	Dacogen	$0.34	$0.27	$27,816	$29,357	-19%	6%
38	J2796	Nplate	$0.21	$0.27	$36,965	$46,734	31%	26%
39	J9999	Unclassified	$0.08	$0.26	$16,894	$29,052	235%	72%
40	J7195	Benefix/Rixubis	$0.08	$0.26	$175,685	$635,241	224%	262%
41	J3488	Reclast	$0.45	$0.25	$1,227	$1,176	-44%	-4%
42	J2357	Xolair	$0.25	$0.24	$18,433	$16,656	-5%	-10%
43	J7323	Euflexxa	$0.23	$0.23	$773	$780	1%	1%
44	J9043	Jevtana	$0.13	$0.23	$33,482	$39,639	70%	18%
45	J0641	Fusilev	$0.33	$0.22	$8,456	$9,128	-31%	8%
46	J1568	Octagam	$0.06	$0.22	$10,884	$29,030	287%	167%
47	J1453	Emend	$0.20	$0.22	$1,196	$1,162	5%	-3%
48	J7185	Xyntha	–	$0.20	–	$996,031	–	–
49	J3285	Remodulin	$0.25	$0.20	$123,735	$121,437	-22%	-2%
50	Q2051	Zometa/Reclast	–	$0.19	–	$1,380	–	–
TOP 26–50 TOTALS			**$6.71**	**$7.42**	**$4,011**	**$4,674**	**11%**	**17%**
TOTAL MEDICAL PHARMACY			**$42.65**	**$44.99**	**$1,642**	**$1,743**	**5%**	**6%**

Please note: Due to rounding to the nearest cent, some of the column totals do not add up accurately.

Some of the trends identified from the top 26–50 medical benefit drugs listing by LOB are presented below:

- Unclassified codes were present in the top 26–50 medical benefit drugs listing in both LOBs. J3490 represented a large number of unclassified injectable drugs, such as antihistamines, antibiotics, solutions, anesthesia and cardiovascular agents. Of special note, Elelyso was associated with J3490 in 2012. J9999 is an unclassified code specifically for drugs used to treat cancer. In 2012, it represented the following agents: Erwinaze, Adcetris, Perjeta, Zaltrap, Kyprolis and Synribo. In 2013, it represented Marqibo, Kadcyla, Perjeta, Zaltrap, Kyprolis, Synribo and Gazyva. Unclassified codes will be discussed further in the "Insights for 2014" section, Figure 125.

- Individual Zometa and Reclast HCPCS codes decreased in allowed amount PMPM from 2012–2013 due to generic drug availability; a change in HCPCS code to a combined Q code (Q2051), effective from July 1 to December 31, 2013; and a utilization shift to other products that treated the same conditions, which will be discussed further in the "Management of Spend Drivers" section, Figures 108–111.

- Similar to the dynamic we observed with Yervoy in the commercial population, Soliris experienced a large allowed amount PMPM annual trend from 2012–2013, with 175 percent in the Medicare population. The drug is used to treat a small population and is administered every two weeks for lifelong treatment. The annual allowed amount cost per patient decreased from $356,630 in 2012 to $326,233 in 2013; however, the factor influencing the increase in allowed amount PMPM was the number of utilizing members per year. More information about this drug will be included in the "Management of Spend Drivers" section, Figure 99.

The top 10 drugs from the 2013 top 25 listing represented 46 percent and 48 percent of overall medical pharmacy allowed amount PMPM for commercial and Medicare, respectively. Most of the top 10 drugs' allowed amounts PMPM for both LOBs increased year over year, except Avastin, due to the removal of its labeled metastatic breast cancer indication in late 2011. The allowed amount PMPM of Eloxatin in 2013 decreased in the commercial population due to generic availability. Medicare saw a decrease in Lucentis spend from 2011–2012, which might have been driven by the entrance of Eylea into the market (the FDA approved it to treat AMD in November 2011 and macular edema following central retinal vein occlusion in September 2012) or the dynamic could be specific to our data set. Medicare also saw fluctuating trends related to Remicade from 2010–2013. Overall, the top 10 drugs had an average annual trend from 2010–2013 of 9.6 percent for commercial and 5.3 percent for Medicare. *See Figure 89: Commercial Top 10 Drugs by Allowed Amount PMPM 2010–2013 and Figure 90: Medicare Top 10 Drugs by Allowed Amount PMPM 2010–2013.*

FIGURE 89: Commercial Top 10 Drugs by Allowed Amount PMPM 2010–2013

RANK	HCPCS CODE	BRAND NAME	2010	2011	2012	2013
1	J1745	Remicade	$1.47	$1.56	$1.79	$2.16
2	J2505	Neulasta	$1.16	$1.28	$1.50	$1.60
3	J9035	Avastin	$1.34	$1.29	$1.17	$1.44
4	J9310	Rituxan	$0.77	$0.89	$1.02	$1.15
5	J9355	Herceptin	$0.67	$0.79	$0.87	$0.98
6	J7192	Advate/Helixate/ Kogenate/Recombinate	$0.50	$0.49	$0.57	$0.60
7	J1569	Gammagard Liquid	$0.38	$0.45	$0.45	$0.47
8	J1561	Gamunex-C/ Gammaked	$0.34	$0.31	$0.39	$0.45
9	J2323	Tysabri	$0.24	$0.31	$0.39	$0.43
10	J9263	Eloxatin	$0.49	$0.63	$0.65	$0.41
TOTAL			**$7.37**	**$8.02**	**$8.80**	**$9.69**

Please note: Due to rounding to the nearest cent, some of the column totals do not add up accurately.

FIGURE 90: Medicare Top 10 Drugs by Allowed Amount PMPM 2010–2013

RANK	HCPCS CODE	BRAND NAME	2010	2011	2012	2013
1	J9310	Rituxan	$3.26	$3.48	$3.68	$3.80
2	J2505	Neulasta	$3.03	$3.37	$3.40	$3.55
3	J2778	Lucentis	$3.13	$3.63	$2.78	$3.10
4	J9035	Avastin	$2.52	$2.37	$2.34	$2.46
5	J1745	Remicade	$2.72	$2.21	$1.88	$2.24
6	J9305	Alimta	$1.24	$1.39	$1.48	$1.64
7	J1569	Gammagard Liquid	$0.93	$1.04	$1.16	$1.23
8	J9355	Herceptin	$0.94	$0.94	$1.08	$1.22
9	J0897	Xgeva/Prolia	–	–	$0.89	$1.19
10	J9041	Velcade	$0.72	$1.06	$1.16	$1.15
TOTAL			**$18.48**	**$19.50**	**$19.84**	**$21.57**

Please note: Due to rounding to the nearest cent, some of the column totals do not add up accurately.

Gammagard liquid, J1569, was represented in the top 10 drug listing for both LOBs and showed year-over-year increases in allowed amount PMPM. To determine whether this specific immune globulin agent was trending or if the entire immune globulin class was trending, we analyzed intravenous and subcutaneous immune globulin products over the last four years. Overall, most immune globulin products experienced increases in allowed amount PMPM from 2010–2013 for both LOBs. Vivaglobin was discontinued in 2011. J1566, Gammagard S/D and Carimune NF (powders), saw allowed amount PMPM decreases due to provider preference for liquid agents. The average annual trend in allowed amount PMPM for the immune globulin category from 2010–2013 was 9.5 percent and 9.4 percent for the commercial and Medicare populations, respectively. *See Figure 91: Immune Globulins by Allowed Amount PMPM by LOB 2010–2013.*

FIGURE 91: Immune Globulins by Allowed Amount PMPM by LOB 2010–2013

ALLOWED PMPM			YEAR			
LOB	HCPCS CODE	BRAND NAME	2010	2011	2012	2013
Commercial	J1459	Privigen	$0.07	$0.13	$0.19	$0.28
	J1557	Gammaplex	–	–	$0.01	$0.01
	J1559	Hizentra	–	$0.05	$0.06	$0.06
	J1561	Gamunex-C/Gammaked	$0.34	$0.31	$0.39	$0.45
	J1562	Vivaglobin	$0.04	$0.00	$0.00	–
	J1566	Gammagard S/D/Carimune NF	$0.13	$0.15	$0.10	$0.06
	J1568	Octagam	$0.10	$0.00	$0.05	$0.10
	J1569	Gammagard Liquid	$0.38	$0.45	$0.45	$0.47
	J1572	Flebogamma	$0.07	$0.07	$0.06	$0.04
	J1599	Immune Globulin NOS	–	$0.00	$0.00	$0.00
COMMERCIAL TOTAL			**$1.13**	**$1.17**	**$1.31**	**$1.48**
Medicare	J1459	Privigen	$0.16	$0.53	$0.45	$0.47
	J1557	Gammaplex	–	–	$0.03	$0.01
	J1559	Hizentra	–	$0.01	$0.07	$0.15
	J1561	Gamunex-C/Gammaked	$0.42	$0.38	$0.32	$0.47
	J1562	Vivaglobin	$0.03	$0.01	$0.00	$0.00
	J1566	Gammagard S/D/Carimune NF	$0.20	$0.16	$0.11	$0.08
	J1568	Octagam	$0.18	$0.00	$0.06	$0.22
	J1569	Gammagard Liquid	$0.93	$1.04	$1.16	$1.23
	J1572	Flebogamma	$0.15	$0.19	$0.06	$0.05
	J1599	Immune Globulin NOS	–	$0.14	$0.00	–
MEDICARE TOTAL			**$2.08**	**$2.45**	**$2.26**	**$2.67**

Please note: Due to rounding to the nearest cent, some of the column totals do not add up accurately.

Certain medical benefit drugs had very high annual costs per patient associated with their use; however, due to the limited population they impacted, their overall allowed amount PMPM might not put them into the top 25 or 50 drug listings. The top 10 drugs by annual allowed amount per patient by LOB were analyzed based on 2012 and 2013 data. These agents tended to be used for conditions such as hereditary angioedema, rare hematologic disorders including hemophilia, diseases caused by inborn errors of metabolism, pulmonary arterial hypertension and cancer. In 2013, the average cost per patient per year for all 10 drugs listed by LOB exceeded $100,000, and most of these agents are lifelong therapies. The percentage of total members showed that these drugs individually represented 0.10 percent or less of all members who received a medical benefit drug in 2013. Since these drugs only impacted one to a few members per plan, the drug mix, cost per patient and allowed amount PMPM could vary considerably from year to year. *See Figure 92: Top Medical Benefit Drugs by Annual Allowed Cost per Patient in 2012 and Figure 93: Top Medical Benefit Drugs by Annual Allowed Cost per Patient in 2013.*

FIGURE 92: Top Medical Benefit Drugs by Annual Allowed Cost per Patient in 2012

LOB	HCPCS CODE	BRAND NAME	COST/PATIENT	ALLOWED PMPM	% OF TOTAL MEMBERS
Commercial	J1300	Soliris	$439,344	$0.24	0.02%
	J7193	Mononine	$338,177	$0.04	0.00%
	J1743	Elaprase	$312,656	$0.01	0.00%
	J7198	Feiba	$305,189	$0.04	0.00%
	J1786	Cerezyme	$293,875	$0.16	0.02%
	J0221	Lumizyme	$260,640	$0.01	0.00%
	C9289	Erwinaze	$223,813	$0.03	0.00%
	J0598	Cinryze	$217,630	$0.09	0.02%
	J3385	Vpriv	$214,468	$0.03	0.01%
	J7192	Advate/Helixate/ Kogenate/ Recombinate	$173,272	$0.57	0.12%
Medicare	J1300	Soliris	$356,630	$0.11	0.00%
	J0180	Fabrazyme	$223,372	$0.07	0.00%
	J7195	Benefix/Rixubis	$175,685	$0.08	0.00%
	J1786	Cerezyme	$165,770	$0.04	0.00%
	J7686	Tyvaso	$139,953	$0.13	0.00%
	J3285	Remodulin	$123,735	$0.25	0.01%
	J0257	Glassia	$119,403	$0.03	0.00%
	Q2043	Provenge	$92,444	$0.23	0.01%
	J9302	Arzerra	$92,357	$0.11	0.00%
	J9228	Yervoy	$86,816	$0.32	0.01%

FIGURE 93: Top Medical Benefit Drugs by Annual Allowed Cost per Patient in 2013

LOB	HCPCS CODE	BRAND NAME	COST/PATIENT	ALLOWED PMPM	% OF TOTAL MEMBERS
Commercial	J0221	Lumizyme	$861,438	$0.04	0.00%
	J7193	Mononine	$566,703	$0.04	0.00%
	J0598	Cinryze	$422,146	$0.11	0.01%
	J1300	Soliris	$416,593	$0.23	0.02%
	J1743	Elaprase	$332,477	$0.02	0.00%
	J7198	Feiba	$323,194	$0.04	0.00%
	J1786	Cerezyme	$295,344	$0.17	0.02%
	J3385	Vpriv	$251,084	$0.03	0.00%
	J1931	Aldurazyme	$193,384	$0.00	0.00%
	J7192	Advate/Helixate/ Kogenate/ Recombinate	$180,938	$0.60	0.10%
Medicare	J7185	Xyntha	$996,031	$0.20	0.00%
	J7195	Benefix/Rixubis	$635,241	$0.26	0.00%
	J7198	Feiba	$491,260	$0.10	0.00%
	J1300	Soliris	$326,233	$0.32	0.00%
	J7192	Advate/Helixate/ Kogenate/ Recombinate	$179,627	$0.07	0.00%
	J9315	Istodax	$169,900	$0.09	0.00%
	J0180	Fabrazyme	$133,940	$0.04	0.00%
	J3285	Remodulin	$121,437	$0.20	0.01%
	J1786	Cerezyme	$116,880	$0.04	0.00%
	J9228	Yervoy	$105,572	$0.38	0.01%

Many medical benefit drugs can be used to treat a variety of indications. We reviewed this dynamic for five drugs by the percentage of claims and allowed amount PMPM per primary diagnosis in 2013. Only diagnoses representing at least 1 percent of claims or PMPM were listed. Except for Lucentis, ICD9s were categorized by the first three digits only.

Of note for the commercial population, Botox was approved for use in migraines in October 2010, which represented the drug's largest use by allowed amount and claims, even though Botox had been on the market since 1989. The largest use of Remicade was for gastrointestinal diseases, mainly Crohn's disease and ulcerative colitis. Although Tysabri was labeled to treat Crohn's disease, overwhelmingly it was prescribed for its other labeled indication, multiple sclerosis. Rituxan was predominantly used for lymphoma and only 11 percent of its use by claims was attributable to rheumatoid arthritis. *See Figure 94: Commercial Top Diagnosis Codes for Key Medical Benefit Drugs in 2013.*

FIGURE 94: Commercial Top Diagnosis Codes for Key Medical Benefit Drugs in 2013

ICD9 CODE	PRIMARY DIAGNOSIS	% of TOTAL HCPCS CLAIM COUNT	% of TOTAL HCPCS ALLOWED PMPM
	J0585: BOTOX		
346	Migraine with aura, without mention of intractable migraine without mention of status migrainosus	40%	43%
333	Other degenerative diseases of the basal ganglia	20%	20%
705	Anhidrosis	9%	6%
342	Flaccid hemiplegia and hemiparesis affecting unspecified side	2%	5%
343	Congenital diplegia	2%	4%
721	Cervical spondylosis without myelopathy	2%	4%
780	General symptoms	3%	2%
351	Bell's palsy	4%	2%
728	Infective myositis	1%	2%
340	Multiple sclerosis	1%	2%
723	Spinal stenosis in cervical region	1%	1%
701	Circumscribed scleroderma	3%	1%
596	Bladder neck obstruction	1%	1%
344	Quadriplegia, unspecified	0%	1%
565	Anal fissure	1%	1%
50	Smallpox	2%	0%
784	Headache	1%	0%
	J1745: REMICADE		
555	Regional enteritis of small intestine	36%	39%
714	Rheumatoid arthritis	28%	24%
556	Ulcerative (chronic) enterocolitis	15%	16%
696	Psoriatic arthropathy	13%	13%
720	Ankylosing spondylitis	4%	3%
558	Other and unspecified non-infectious gastroenteritis and colitis	0%	1%
058	Other human herpesvirus	0%	1%
135	Sarcoidosis	0%	1%
	J2323: TYSABRI		
340	Multiple sclerosis	96%	97%
555	Regional enteritis of small intestine	2%	1%
058	Other human herpesvirus	1%	1%

ICD9 CODE	PRIMARY DIAGNOSIS	% of TOTAL HCPCS CLAIM COUNT	% of TOTAL HCPCS ALLOWED PMPM
	J2778: LUCENTIS		
362.52	Exudative senile macular degeneration	46%	56%
362.07	Diabetic macular edema	23%	14%
362.36	Venous tributary (branch) occlusion	5%	6%
362.83	Retinal edema	5%	5%
362.35	Central retinal vein occlusion	4%	4%
250.5	Diabetes with ophthalmic manifestations, type II or unspecified type, not stated as uncontrolled	6%	4%
362.51	Non-exudative senile macular degeneration	1%	2%
362.53	Cystoid macular degeneration	2%	2%
362.02	Proliferative diabetic retinopathy	2%	1%
362.01	Background diabetic retinopathy	1%	1%
362.43	Hemorrhagic detachment of retinal pigment epithelium	0%	1%
362.16	Retinal neovascularization NOS	1%	1%
362.05	Moderate non-proliferative diabetic retinopathy	1%	0%
	J9310: RITUXAN		
202	Nodular lymphoma, unspecified site, extranodal and solid organ sites	41%	36%
058	Other human herpesvirus	11%	14%
714	Rheumatoid arthritis	11%	13%
200	Reticulosarcoma, unspecified site, extranodal and solid organ sites	10%	9%
204	Acute lymphoid leukemia, without mention of having achieved remission	9%	9%
287	Allergic purpura	4%	4%
446	Polyarteritis nodosa	2%	2%
710	Systemic lupus erythematosus	1%	2%
201	Hodgkin's paragranuloma, unspecified site, extranodal and solid organ sites	1%	1%
273	Polyclonal hypergammaglobulinemia	1%	1%
340	Multiple sclerosis	1%	1%
288	Neutropenia, unspecified	1%	1%
694	Dermatitis herpetiformis	1%	1%
283	Autoimmune hemolytic anemias	1%	1%
285	Sideroblastic anemia	1%	1%
341	Neuromyelitis optica	0%	1%

The Medicare population had a few differences in utilization from the commercial population.

- For Botox, migraine represented the second most common use.
- Remicade was used most frequently for rheumatoid arthritis versus gastrointestinal diseases.
- Lucentis had less utilization for diabetic macular edema and more use for AMD than the commercial population.
- Rheumatoid arthritis represented a smaller portion of claims and allowed amount for Rituxan in the Medicare versus commercial population.

See Figure 95: Medicare Top Diagnosis Codes for Key Medical Benefit Drugs in 2013.

FIGURE 95: Medicare Top Diagnosis Codes for Key Medical Benefit Drugs in 2013

ICD9 CODE	PRIMARY DIAGNOSIS	% of TOTAL HCPCS CLAIM COUNT	% of TOTAL HCPCS ALLOWED PMPM
	J0585: BOTOX		
333	Other degenerative diseases of the basal ganglia	42%	36%
346	Migraine with aura, without mention of intractable migraine without mention of status migrainosus	16%	18%
342	Flaccid hemiplegia and hemiparesis affecting unspecified side	5%	10%
351	Bell's palsy	11%	5%
596	Bladder neck obstruction	4%	4%
340	Multiple sclerosis	2%	4%
721	Cervical spondylosis without myelopathy	2%	4%
728	Infective myositis	2%	4%
788	Renal colic	3%	2%
781	Abnormal involuntary movements	1%	1%
530	Achalasia and cardiospasm	1%	1%
438	Late effects of cerebrovascular disease, cognitive deficits	0%	1%
723	Spinal stenosis in cervical region	1%	1%
344	Quadriplegia, unspecified	0%	1%
722	Displacement of cervical intervertebral disc without myelopathy	0%	1%
780	General symptoms	1%	1%
334	Friedreich's ataxia	0%	1%
	J1745: REMICADE		
714	Rheumatoid arthritis	66%	59%
555	Regional enteritis of small intestine	13%	17%
696	Psoriatic arthropathy	10%	12%
556	Ulcerative (chronic) enterocolitis	5%	6%
720	Ankylosing spondylitis	2%	2%
058	Other human herpesvirus	1%	1%
136	Other and unspecified infectious and parasitic diseases	0%	1%

ICD9 CODE	PRIMARY DIAGNOSIS	% of TOTAL HCPCS CLAIM COUNT	% of TOTAL HCPCS ALLOWED PMPM
	J2323: TYSABRI		
340	Multiple sclerosis	96%	96%
058	Other human herpesvirus	2%	2%
	J2778: LUCENTIS		
362.52	Exudative senile macular degeneration	70%	74%
362.07	Diabetic macular edema	9%	6%
362.36	Venous tributary (branch) occlusion	4%	4%
362.83	Retinal edema	4%	4%
362.35	Central retinal vein occlusion	3%	3%
250.5	Diabetes with ophthalmic manifestations, type II or unspecified type, not stated as uncontrolled	3%	2%
362.16	Retinal neovascularization NOS	2%	2%
362.53	Cystoid macular degeneration	1%	1%
362.51	Non-exudative senile macular degeneration	1%	1%
	J9310: RITUXAN		
202	Nodular lymphoma, unspecified site, extranodal and solid organ sites	41%	40%
058	Other human herpesvirus	13%	13%
204	Acute lymphoid leukemia, without mention of having achieved remission	13%	13%
200	Reticulosarcoma, unspecified site, extranodal and solid organ sites	13%	13%
714	Rheumatoid arthritis	5%	7%
273	Polyclonal hypergammaglobulinemia	3%	3%
287	Allergic purpura	2%	2%
288	Neutropenia, unspecified	2%	1%
446	Polyarteritis nodosa	1%	1%
283	Autoimmune hemolytic anemias	1%	1%
710	Systemic lupus erythematosus	0%	1%
340	Multiple sclerosis	0%	1%

In a similar approach, we evaluated the most predominant uses of immune globulins by distribution of claims, members and allowed amount PMPM across the top nine indications and all "other" indications, trended from 2010–2013. The immune globulin drug class represented 11 HCPCS codes and included both intravenous and subcutaneous formulations. Although there were several FDA-labeled indications, immune globulins were commonly used for off-label conditions such as multiple sclerosis.

Utilization by indication remained relatively stable for the commercial population over the last four years. There had been more variability in the Medicare population for the top two indications, immunodeficiencies and inflammatory and toxic neuropathy; use in immunodeficiencies increased over the last four years with its allowed amount PMPM more than doubling, while use for inflammatory and toxic neuropathy decreased. *See Figure 96: Commercial Top Diagnoses by Claims, Members and Allowed Amount PMPM for Immune Globulin 2010–2013 and Figure 97: Medicare Top Diagnoses by Claims, Members and Allowed Amount PMPM for Immune Globulin 2010–2013.*

FIGURE 96: Commercial Top Diagnoses by Claims, Members and Allowed Amount PMPM for Immune Globulin 2010–2013

COMMERCIAL — **CLAIM DISTRIBUTION**

ICD9 CODE	PRIMARY DIAGNOSIS	2010	2011	2012	2013
279	Disorders involving the immune mechanism	47.32%	48.75%	52.62%	50.32%
357	Inflammatory and toxic neuropathy	21.12%	23.04%	20.67%	22.12%
340	Multiple sclerosis	6.33%	6.18%	5.30%	4.39%
710	Diffuse diseases of connective tissue	3.51%	2.97%	3.17%	4.02%
358	Myoneural disorders	3.61%	3.78%	3.59%	3.34%
204	Lymphoid leukemia	1.67%	2.09%	1.89%	2.15%
287	Purpura and other hemorrhagic conditions	2.77%	2.23%	2.63%	1.66%
356	Hereditary and idiopathic peripheral neuropathy	2.09%	1.76%	0.92%	1.37%
202	Other malignant neoplasms of lymphoid and histiocytic tissue	1.01%	1.09%	0.83%	1.25%
All other		10.56%	8.11%	8.36%	9.37%

COMMERCIAL — **MEMBER DISTRIBUTION**

ICD9 CODE	PRIMARY DIAGNOSIS	2010	2011	2012	2013
279	Disorders involving the immune mechanism	40.78%	38.47%	41.55%	42.88%
357	Inflammatory and toxic neuropathy	14.12%	15.49%	14.19%	14.57%
204	Lymphoid leukemia	3.08%	4.07%	4.45%	4.75%
287	Purpura and other hemorrhagic conditions	6.99%	6.76%	6.00%	4.62%
340	Multiple sclerosis	4.93%	4.95%	4.32%	4.24%
358	Myoneural disorders	3.43%	4.00%	4.00%	3.66%
710	Diffuse diseases of connective tissue	2.95%	2.62%	2.90%	3.59%
202	Other malignant neoplasms of lymphoid and histiocytic tissue	2.33%	2.40%	2.52%	2.76%
V58	Encounter for other and unspecified procedures and aftercare	1.10%	2.25%	1.87%	1.73%
All other		20.29%	18.98%	18.19%	17.20%

COMMERCIAL — **ALLOWED AMOUNT PMPM**

ICD9 CODE	PRIMARY DIAGNOSIS	2010	2011	2012	2013
279	Disorders involving the immune mechanism	$0.35	$0.36	$0.42	$0.47
357	Inflammatory and toxic neuropathy	$0.31	$0.34	$0.35	$0.40
710	Diffuse diseases of connective tissue	$0.09	$0.08	$0.09	$0.11
358	Myoneural disorders	$0.06	$0.07	$0.08	$0.07
202	Other malignant neoplasms of lymphoid and histiocytic tissue	$0.01	$0.01	$0.01	$0.06
340	Multiple sclerosis	$0.06	$0.07	$0.08	$0.06
287	Purpura and other hemorrhagic conditions	$0.05	$0.05	$0.06	$0.04
356	Hereditary and idiopathic peripheral neuropathy	$0.03	$0.02	$0.02	$0.03
204	Lymphoid leukemia	$0.01	$0.02	$0.02	$0.03
All other		$0.16	$0.14	$0.17	$0.21

FIGURE 97: Medicare Top Diagnoses by Claims, Members and Allowed Amount PMPM for Immune Globulin 2010–2013

MEDICARE — **CLAIM DISTRIBUTION**

ICD9 CODE	PRIMARY DIAGNOSIS	2010	2011	2012	2013
279	Disorders involving the immune mechanism	25.83%	19.31%	32.76%	38.59%
357	Inflammatory and toxic neuropathy	36.10%	29.86%	23.62%	20.62%
358	Myoneural disorders	9.31%	9.34%	4.90%	8.32%
340	Multiple sclerosis	4.34%	7.11%	7.26%	6.86%
287	Purpura and other hemorrhagic conditions	1.28%	6.48%	8.53%	5.88%
359	Muscular dystrophies and other myopathies	0.00%	0.52%	2.32%	3.65%
204	Lymphoid leukemia	4.15%	4.58%	4.55%	2.84%
710	Diffuse diseases of connective tissue	1.02%	1.20%	1.62%	1.52%
203	Multiple myeloma and immunoproliferative neoplasms	0.96%	0.34%	2.54%	1.52%
All other		17.03%	21.26%	11.90%	10.20%

MEDICARE — **MEMBER DISTRIBUTION**

ICD9 CODE	PRIMARY DIAGNOSIS	2010	2011	2012	2013
279	Disorders involving the immune mechanism	27.86%	26.85%	32.33%	36.81%
357	Inflammatory and toxic neuropathy	24.38%	17.59%	16.67%	14.88%
287	Purpura and other hemorrhagic conditions	4.98%	8.80%	10.67%	7.57%
204	Lymphoid leukemia	7.46%	7.41%	8.33%	5.74%
340	Multiple sclerosis	3.48%	3.70%	4.00%	5.48%
358	Myoneural disorders	6.97%	5.56%	4.33%	5.22%
202	Other malignant neoplasms of lymphoid and histiocytic tissue	4.48%	4.63%	3.33%	3.13%
710	Diffuse diseases of connective tissue	1.00%	1.39%	1.33%	2.09%
203	Multiple myeloma and immunoproliferative neoplasms	1.00%	0.93%	1.67%	1.83%
All other		18.41%	23.15%	17.33%	17.23%

MEDICARE — **ALLOWED AMOUNT PMPM**

ICD9 CODE	PRIMARY DIAGNOSIS	2010	2011	2012	2013
279	Disorders involving the immune mechanism	$0.33	$0.31	$0.50	$0.71
357	Inflammatory and toxic neuropathy	$0.85	$0.86	$0.62	$0.67
358	Myoneural disorders	$0.20	$0.27	$0.14	$0.29
340	Multiple sclerosis	$0.16	$0.26	$0.20	$0.22
287	Purpura and other hemorrhagic conditions	$0.04	$0.13	$0.24	$0.20
359	Muscular dystrophies and other myopathies	$0.00	$0.01	$0.11	$0.10
204	Lymphoid leukemia	$0.04	$0.11	$0.10	$0.07
710	Diffuse diseases of connective tissue	$0.10	$0.06	$0.06	$0.07
333	Other extrapyramidal disease and abnormal movement disorders	$0.06	$0.08	$0.05	$0.04
All other		$0.31	$0.35	$0.24	$0.29

Management of Spend Drivers

Across the top 50 drugs by allowed amount, the top 10 by LOB with the greatest PMPM percentage change from 2012–2013 are detailed in Figures 98 and 99. The drugs' ranks were based on their allowed amount PMPM from the earlier top 50 drug listings. Newer drugs to market were frequently included on these listings, such as Eylea, Xgeva/Prolia, Yervoy, Provenge and Jevtana. J9999 was included due to the significant change in oncology drugs associated with its spend from 2012–2013 based on FDA approval dates. For the commercial population specifically, two drugs used to treat autoimmune disorders were on this top 10 trending list: Actemra and Stelara. For the Medicare population, Soliris had a large increase in allowed amount PMPM from 2012–2013 due to its high year-over-year variability based on the limited number of patients with these rare hematologic diseases (paroxysmal nocturnal hemoglobinuria [PNH] and atypical hemolytic uremic syndrome [aHUS]). The trend also might be specific to our data set. *See Figure 98: Commercial Top 10 Drugs by Allowed Amount PMPM Percentage Change 2012–2013 and Figure 99: Medicare Top 10 Drugs by Allowed Amount PMPM Percentage Change 2012–2013.*

FIGURE 98: Commercial Top 10 Drugs by Allowed Amount PMPM Percentage Change 2012–2013

HCPCS CODE	BRAND NAME	RANK	2010	2011	2012	2013
J0178	Eylea	46	–	–	$0.00	$0.11
J0897	Xgeva/Prolia	12	–	$0.00	$0.23	$0.38
J1459	Privigen	15	$0.07	$0.13	$0.19	$0.28
J3262	Actemra	45	–	$0.04	$0.08	$0.11
J3357	Stelara	26	$0.00	$0.09	$0.13	$0.18
J9033	Treanda	24	$0.07	$0.14	$0.13	$0.19
J9070	Cytoxan	44	$0.01	$0.03	$0.06	$0.11
J9228	Yervoy	13	–	–	$0.14	$0.35
J9395	Faslodex	38	$0.04	$0.06	$0.09	$0.12
J9999	Unclassified	48	$0.03	$0.08	$0.05	$0.10
TOTAL			**$0.22**	**$0.57**	**$1.10**	**$1.94**

Please note: Due to rounding to the nearest cent, some of the column totals do not add up accurately.

FIGURE 99: Medicare Top 10 Drugs by Allowed Amount PMPM Percentage Change 2012–2013

HCPCS CODE	BRAND NAME	RANK	2010	2011	2012	2013
J0178	Eylea	12	–	–	–	$0.79
J1300	Soliris	33	–	–	$0.11	$0.32
J1561	Gamunex	25	$0.42	$0.38	$0.32	$0.47
J1568	Octagam	46	$0.18	$0.00	$0.06	$0.22
J2323	Tysabri	22	$0.37	$0.35	$0.34	$0.49
J9033	Treanda	11	$0.45	$0.65	$0.65	$1.14
J9043	Jevtana	44	–	–	$0.13	$0.23
J9264	Abraxane	17	$0.29	$0.26	$0.38	$0.65
J9999	Unclassified	39	$0.12	$0.28	$0.08	$0.26
Q2043	Provenge	30	–	$0.09	$0.23	$0.42
TOTAL			**$1.83**	**$2.01**	**$2.31**	**$4.99**

Please note: Due to rounding to the nearest cent, some of the column totals do not add up accurately.

We grouped the medical benefit drugs into disease state or drug therapy categories based on labeled indications. For drugs with multiple labeled indications, we separated the drugs' spend into two or more disease states based on the ICD9s billed per claim line. Two different views are provided: the percentage of allowed amount PMPM by disease state or drug category and the percentage of members who received a medical benefit drug by disease state or drug category. The "other" therapy class was driven by frequently utilized low-cost agents, such as hydration or compounding solutions, diagnostic agents, analgesics, anesthesia and cardiovascular agents. Please note: Only categories with more than 0.01 percent were listed in the following four figures.

For commercial members, oncology and oncology support medications represented close to 52 percent of medical pharmacy spend in 2013: oncology 39.12 percent and oncology support 12.79 percent. Biologic drugs for autoimmune disorders was the next highest spend category, which includes Crohn's disease/ulcerative colitis, rheumatoid arthritis, psoriasis/psoriatic arthritis, systemic lupus erythematosus and ankylosing spondylitis, at 13.16 percent. *See Figure 100: Commercial Percentage of Allowed Amount PMPM by Disease State or Drug Category.*

FIGURE 100: Commercial Percentage of Allowed Amount PMPM by Disease State or Drug Category

THERAPY CLASS	2012	2013
Oncology	39.53%	39.12%
Biologic Drugs for Autoimmune Disorders	12.22%	13.16%
Crohn's Disease/Ulcerative Colitis	5.65%	6.21%
Rheumatoid Arthritis	4.41%	4.29%
Psoriasis/Psoriatic Arthritis	1.71%	2.02%
Systemic Lupus Erythematosus	0.21%	0.38%
Ankylosing Spondylitis	0.24%	0.26%
Oncology Support	13.39%	12.79%
Colony-Stimulating Factors (CSFs)	8.97%	8.57%
Antiemetics	2.45%	2.38%
Gastrointestinal	0.85%	0.92%
Erythropoiesis-Stimulating Agents (ESAs)	1.07%	0.86%
Oncology Support: Other	0.05%	0.05%
Immune Globulin	7.02%	7.02%
Other	6.23%	6.37%
Antihemophilic Factor	4.56%	4.11%
Multiple Sclerosis	2.21%	2.16%
Infectious Disease	1.77%	1.89%
Ophthalmic Injections	1.20%	1.75%
Enzyme Replacement Therapy	1.54%	1.68%
Unclassified	1.35%	1.43%
Viscosupplementation	1.33%	1.27%
Rare Disorders: Soliris	1.27%	1.11%
Botulinum Toxins	1.01%	1.08%
Asthma	0.84%	0.87%
Contraceptives	0.73%	0.64%
End-Stage Renal Disease: Erythropoiesis-Stimulating Agents (ESAs)	0.76%	0.62%
Hereditary Angioedema	0.50%	0.57%
Pulmonary Arterial Hypertension	0.74%	0.56%
Iron, Intravenous	0.52%	0.53%
Alpha-1 Proteinase Inhibitors (for Emphysema)	0.37%	0.43%
Bone Resorption Inhibitors: Osteoporosis	0.56%	0.43%
Hematology	0.24%	0.26%
Rare Autoinflammatory Conditions, Cryopyrin-Associated Periodic Syndromes	0.04%	0.06%
Gout	0.03%	0.05%
Infertility	0.04%	0.04%
Growth Hormone	0.01%	0.01%

For Medicare members, oncology and oncology support medications represented nearly 60 percent of medical pharmacy spend in 2013: oncology 44.85 percent and oncology support 14.75 percent. Ophthalmic injections was the second-highest spend category at 8.76 percent, followed by biologic drugs for autoimmune disorders at 7.44 percent. *See Figure 101: Medicare Percentage of Allowed Amount PMPM by Disease State or Drug Category.*

FIGURE 101: Medicare Percentage of Allowed Amount PMPM by Disease State or Drug Category

THERAPY CLASS	2012	2013
Oncology	47.49%	44.85%
Oncology Support	15.50%	14.75%
Colony-Stimulating Factors (CSFs)	9.12%	8.95%
Erythropoiesis-Stimulating Agents (ESAs)	3.31%	2.94%
Antiemetics	1.79%	1.61%
Gastrointestinal	1.25%	1.21%
Other	0.03%	0.04%
Ophthalmic Injections	6.98%	8.76%
Biologic Drugs for Autoimmune Disorders	6.49%	7.44%
Rheumatoid Arthritis	4.65%	5.16%
Crohn's Disease/Ulcerative Colitis	1.16%	1.29%
Psoriasis/Psoriatic Arthritis	0.48%	0.73%
Systemic Lupus Erythematosus	0.08%	0.16%
Ankylosing Spondylitis	0.12%	0.10%
Immune Globulin	5.29%	5.94%
Other	5.18%	5.24%
Viscosupplementation	2.20%	2.12%
Antihemophilic Factor	0.35%	1.49%
Infectious Disease	1.27%	1.17%
Unclassified	1.45%	1.12%
Multiple Sclerosis	0.87%	1.10%
Bone Resorption Inhibitors: Osteoporosis	1.44%	1.05%
Pulmonary Arterial Hypertension	1.31%	0.90%
End-Stage Renal Disease: Erythropoiesis-Stimulating Agents (ESAs)	1.10%	0.73%
Botulinum Toxins	0.69%	0.72%
Rare Disorders: Soliris	0.27%	0.70%
Hematology	0.48%	0.60%
Asthma	0.59%	0.53%
Iron, Intravenous	0.45%	0.40%
Alpha-1 Proteinase Inhibitors (for Emphysema)	0.34%	0.19%
Enzyme Replacement Therapy	0.26%	0.17%
Cystic Fibrosis	0.00%	0.03%
Hereditary Angioedema	0.01%	0.01%
Contraceptives	0.01%	0.00%

When analyzing the same categories by percentage of members who received medical benefit drugs, the categories with the highest percentages tended to be those with lower claims and annual costs per patient, including infectious disease and antiemetics (which are used frequently outside of oncology). Although oncology represented 39.12 percent of the allowed amount PMPM for commercial members, only 9.27 percent of members who received medical benefit drugs in 2013 were prescribed a drug to treat cancer. *See Figure 102: Commercial Percentage of Members by Disease State or Drug Category.*

FIGURE 102: Commercial Percentage of Members by Disease State or Drug Category

THERAPY CLASS	2012	2013
Infectious Disease	31.58%	31.27%
Oncology Support	26.65%	27.21%
Antiemetics	23.29%	23.97%
Colony-Stimulating Factors (CSFs)	2.34%	2.27%
Erythropoiesis-Stimulating Agents (ESAs)	0.88%	0.81%
Gastrointestinal	0.09%	0.11%
Other	0.05%	0.05%
Unclassified	11.66%	12.26%
Oncology	9.11%	9.27%
Viscosupplementation	6.66%	6.95%
Contraceptives	6.26%	4.57%
Botulinum Toxins	2.12%	2.38%
Biologic Drugs for Autoimmune Disorders	2.17%	2.20%
Rheumatoid Arthritis	1.01%	0.97%
Crohn's Disease/Ulcerative Colitis	0.84%	0.89%
Psoriasis/Psoriatic Arthritis	0.32%	0.34%
Bone Resorption Inhibitors: Osteoporosis	1.56%	1.39%
Ophthalmic Injections	0.59%	0.92%
Immune Globulin	0.55%	0.55%
End-Stage Renal Disease: Erythropoiesis-Stimulating Agents (ESAs)	0.35%	0.28%
Asthma	0.23%	0.23%
Multiple Sclerosis	0.23%	0.23%
Infertility	0.08%	0.10%
Antihemophilic Factor	0.10%	0.09%
Enzyme Replacement Therapy	0.02%	0.02%
Pulmonary Arterial Hypertension	0.03%	0.02%
Alpha-1 Proteinase Inhibitors (for Emphysema)	0.02%	0.02%
Rare Disorders: Soliris	0.01%	0.01%
Gout	0.00%	0.01%
Hereditary Angioedema	0.01%	0.01%

For the Medicare population, oncology was at the top of the list for both the highest spend disease state as well as the most frequently utilized therapy class by members who received medical benefit drugs. The fourth most frequently utilized category was the viscosupplementation class or hyaluronic acids used for osteoarthritis of the knee. Its allowed amount PMPM in 2013 represented 2.12 percent of overall medical pharmacy spend, but its member share represented 14.17 percent. *See Figure 103: Medicare Percentage of Members by Disease State or Drug Category.*

FIGURE 103: Medicare Percentage of Members by Disease State or Drug Category

THERAPY CLASS	2012	2013
Oncology	27.24%	26.40%
Oncology Support	18.25%	18.02%
Antiemetics	9.13%	9.50%
Colony-Stimulating Factors (CSFs)	4.43%	4.33%
Erythropoiesis-Stimulating Agents (ESAs)	4.40%	3.92%
Gastrointestinal	0.24%	0.20%
Other	0.05%	0.07%
Infectious Disease	15.10%	16.10%
Viscosupplementation	14.00%	14.17%
Unclassified	8.91%	8.79%
Ophthalmic Injections	4.26%	5.23%
Bone Resorption Inhibitors: Osteoporosis	5.73%	4.79%
Biologic Drugs for Autoimmune Disorders	1.99%	2.22%
Rheumatoid Arthritis	1.56%	1.71%
Crohn's Disease/Ulcerative Colitis	0.27%	0.32%
Psoriasis/Psoriatic Arthritis	0.16%	0.19%
Botulinum Toxins	2.06%	2.19%
End-Stage Renal Disease: Erythropoiesis-Stimulating Agents (ESAs)	1.21%	0.86%
Immune Globulin	0.69%	0.75%
Multiple Sclerosis	0.17%	0.18%
Asthma	0.14%	0.15%
Pulmonary Arterial Hypertension	0.06%	0.05%
Antihemophilic Factor	0.03%	0.02%
Contraceptives	0.10%	0.02%
Alpha-1 Proteinase Inhibitors (for Emphysema)	0.02%	0.02%
Infertility	0.02%	0.01%
Rare Disorders: Soliris	0.00%	0.01%
Enzyme Replacement Therapy	0.01%	0.01%

Oncology support therapy continued to be an area of significant spend for payors. For the antiemetics class, three intravenous serotonin (5-HT_3) receptor antagonists are approved to treat or prevent chemotherapy-induced nausea and vomiting (CINV): Zofran (generic available: ondansetron), Kytril (generic available: granisetron) and Aloxi. All three are administered at different frequencies and have varying costs per treatment cycle. The FDA-labeled indication for Aloxi is more specific than that of Zofran or Kytril and is limited to prevention of acute CINV associated with initial and repeat courses of moderately or highly emetogenic chemotherapy (HEC) and for the prevention of delayed emesis following moderately emetogenic chemotherapy (MEC). With this dynamic in mind, our analysis showed that Aloxi still was used 32 percent of the time in low emetogenic chemotherapy (LEC) regimens, which was a slight decrease from 2012 at nearly 36 percent. *See Figure 104: Percentage of Antiemetic Allowed Amount PMPM by Chemotherapy Regimen Potential Level of Emetogenicity.*

FIGURE 104: Percentage of Antiemetic Allowed Amount PMPM by Chemotherapy Regimen Potential Level of Emetogenicity

		ALOXI		ZOFRAN		KYTRIL	
	REGIMEN	2012	2013	2012	2013	2012	2013
Commercial	LEC	35.60%	32.11%	61.06%	64.82%	61.84%	69.84%
	MEC	35.58%	42.37%	30.52%	23.26%	28.80%	22.74%
	HEC	28.82%	25.52%	8.42%	11.92%	9.35%	7.43%
Medicare	LEC	35.90%	32.38%	56.58%	56.36%	61.38%	64.17%
	MEC	45.17%	49.67%	35.02%	33.74%	34.83%	29.67%
	HEC	18.93%	17.95%	8.40%	9.90%	3.79%	6.16%

New in 2014, we analyzed the impact on prescribing patterns due to drug shortages. Folinic acid products Fusilev (brand name) and leucovorin (generic name) were predominantly used in combination chemotherapy with 5-fluorouracil to increase the efficacy of fluorouracil therapy to treat patients with colorectal cancer. Leucovorin was used most commonly for this indication until drug shortages impacted its availability and alternatives were needed. Based on the analysis below, Fusilev went from approximately 12 percent and 11 percent market share by members in 2010 up to approximately 34 percent and 32 percent in 2013 for commercial and Medicare, respectively. The Fusilev market share was highest in 2012 and started to decrease in 2013, most likely due to the increased availability of leucovorin. *See Figure 105: Percentage of Folinic Acid Utilization by Members 2010–2013.*

FIGURE 105: Percentage of Folinic Acid Utilization by Members 2010–2013

LOB	HCPCS CODE	BRAND NAME	2010	2011	2012	2013
Commercial	J0640	Leucovorin	87.97%	76.98%	64.43%	66.03%
	J0641	Fusilev	12.03%	23.02%	35.57%	33.97%
Medicare	J0640	Leucovorin	88.78%	73.94%	61.25%	67.76%
	J0641	Fusilev	11.22%	26.06%	38.75%	32.24%

Several additional drug therapy classes have multiple agents available to treat the same indication(s), although the drugs in the class might have varying mechanisms of action, doses, administration frequencies and costs. Knowing that ophthalmic injections were a top spend driver, especially for payors with Medicare populations, we evaluated the drugs that were used to treat AMD and other ocular diseases. We analyzed the HCPCS codes represented in Figures 106 and 107 billed with the following ocular diagnosis codes in the primary, secondary or tertiary claim line: ICD9 fields 362.01, 362.02, 362.03, 362.04, 362.05, 362.06, 362.07, 362.30, 362.35, 362.36, 362.52, 362.53 and 362.83. J3490 might represent Avastin spend for payors who managed this indication through unclassified code billing based on National Drug Code (NDC) or it might represent Eylea utilization prior to receiving a Q code in July 2012 and a J code in January 2013. It is important to note that while Macugen, Lucentis and Eylea are FDA-labeled to treat specific ocular indications, Avastin is not. Avastin is commonly used off-label for intraocular injections due to evidence-based supporting literature.

For the commercial population, Lucentis represented the largest spend, although Avastin might represent a larger portion of members when combining its oncology J code (analyzed for ocular utilization only), its ocular-specific C code and utilization from unclassified code J3490. Eylea represented the second largest drug by spend, while Macugen was rarely utilized due to its limited isoform binding to vascular endothelial growth factor (VEGF) versus all active isoforms as seen with other VEGF inhibitors. *See Figure 106: Commercial Utilization of Ophthalmic Injections 2010–2013.*

FIGURE 106: Commercial Utilization of Ophthalmic Injections 2010–2013

HCPCS CODE	BRAND NAME	2010	2011	2012	2013
CLAIM COUNT					
J2778	Lucentis	37.57%	38.86%	37.26%	40.58%
J9035	Avastin	38.42%	35.75%	30.12%	23.80%
J3490	Unclassified	22.82%	24.13%	28.26%	20.12%
J0178	Eylea	0.00%	0.00%	0.01%	14.82%
C9257	Avastin	0.61%	0.54%	0.41%	0.53%
J2503	Macugen	0.58%	0.71%	0.55%	0.15%
Q2046	Eylea	0.00%	0.00%	3.39%	0.00%
MEMBER COUNT					
J2778	Lucentis	27.63%	30.32%	30.70%	33.83%
J9035	Avastin	41.56%	40.40%	32.51%	27.98%
J3490	Unclassified	28.72%	27.65%	31.14%	24.78%
J0178	Eylea	0.00%	0.00%	0.02%	12.54%
C9257	Avastin	1.04%	0.78%	0.58%	0.73%
J2503	Macugen	1.04%	0.85%	0.46%	0.14%
Q2046	Eylea	0.00%	0.00%	4.57%	0.00%
ALLOWED PMPM					
J2778	Lucentis	$0.09	$0.15	$0.20	$0.26
J0178	Eylea	–	–	$0.00	$0.11
J3490	Unclassified	$0.00	$0.00	$0.02	$0.01
J9035	Avastin	$0.00	$0.00	$0.00	$0.01
C9257	Avastin	$0.00	$0.00	$0.00	$0.00
J2503	Macugen	$0.00	$0.00	$0.00	$0.00
Q2046	Eylea	–	–	$0.02	–
TOTAL		**$0.10**	**$0.16**	**$0.25**	**$0.38**

Please note: Due to rounding to the nearest cent, some of the column totals do not add up accurately.

Avastin represented the majority of members and claims in the Medicare population, although its allowed amount PMPM was significantly less than Lucentis and Eylea. This dynamic might be driven by benefit design as Medicare beneficiaries typically had a 20 percent coinsurance for medical benefit drugs. When Eylea entered the market, the market shares for both Lucentis and Avastin decreased in both LOBs. Please note: The decrease in overall ocular indication allowed amount PMPM for the Medicare population in 2012 was not expected and might be specific to our data set. *See Figure 107: Medicare Utilization of Ophthalmic Injections 2010–2013.*

FIGURE 107: Medicare Utilization of Ophthalmic Injections 2010–2013

HCPCS CODE	BRAND NAME	2010	2011	2012	2013
CLAIM COUNT					
J9035	Avastin	48.26%	49.92%	48.07%	41.09%
J2778	Lucentis	44.32%	43.54%	33.87%	36.04%
J3490	Unclassified	5.03%	4.80%	14.87%	12.62%
J0178	Eylea	0.00%	0.00%	0.00%	8.91%
J2503	Macugen	2.36%	1.69%	0.98%	0.86%
C9257	Avastin	0.03%	0.04%	0.27%	0.47%
Q2046	Eylea	0.00%	0.00%	1.94%	0.00%
MEMBER COUNT					
J9035	Avastin	52.65%	57.61%	50.84%	46.33%
J2778	Lucentis	37.00%	34.61%	28.62%	30.55%
J3490	Unclassified	8.20%	6.20%	16.23%	13.82%
J0178	Eylea	0.00%	0.00%	0.00%	7.66%
C9257	Avastin	0.10%	0.09%	0.70%	0.97%
J2503	Macugen	2.05%	1.48%	0.72%	0.65%
Q2046	Eylea	0.00%	0.00%	2.89%	0.02%
ALLOWED PMPM					
J2778	Lucentis	$3.11	$3.60	$2.76	$3.08
J0178	Eylea	–	–	–	$0.78
J9035	Avastin	$0.15	$0.15	$0.14	$0.13
J3490	Unclassified	$0.04	$0.02	$0.16	$0.07
J2503	Macugen	$0.08	$0.07	$0.04	$0.04
C9257	Avastin	$0.00	$0.00	$0.00	$0.00
Q2046	Eylea	–	–	$0.15	$0.00
TOTAL		**$3.38**	**$3.84**	**$3.25**	**$4.10**

Three infusion agents are used to treat cancer metastases to the bone: Aredia, Zometa and, most recently, Xgeva. Xgeva and Zometa both have drug counterparts that treat osteoporosis: Prolia and Reclast, respectively. In the analysis below, use of Xgeva and Zometa was only for oncology indications. Q2051 was included since J3487 was no longer payable by Medicare after July 1, 2013. The Q code represented both Zometa and Reclast from July 1 through December 31, 2013. The change in HCPCS code occurred due to generic availability of both Zometa and Reclast as zoledronic acid in March and April 2013, respectively. Aredia also is available as generic pamidronate disodium.

For the commercial population, Zometa still remained the most utilized drug in 2013 by claims and members; however, Xgeva represented the largest spend in the category, nearly double the allowed amount PMPM of Zometa. Aredia was rarely utilized and lost additional market share after Xgeva entered the market. *See Figure 108: Commercial Utilization of Bone Resorption Inhibitors to Treat Bone Metastases in Cancer 2010–2013.*

FIGURE 108: Commercial Utilization of Bone Resorption Inhibitors to Treat Bone Metastases in Cancer 2010–2013

HCPCS CODE	BRAND NAME	2010	2011	2012	2013
CLAIM COUNT					
J0897	Xgeva	0.00%	0.00%	35.39%	44.20%
J3487	Zometa	90.44%	91.70%	59.89%	35.48%
Q2051	Zometa	0.00%	0.00%	0.00%	16.69%
J2430	Aredia	9.56%	8.30%	4.72%	3.62%
MEMBER COUNT					
J3487	Zometa	90.47%	90.96%	63.99%	42.38%
J0897	Xgeva	0.00%	0.00%	30.64%	31.48%
Q2051	Zometa	0.00%	0.00%	0.00%	22.20%
J2430	Aredia	9.53%	9.04%	5.37%	3.94%
ALLOWED PMPM					
J0897	Xgeva	–	–	$0.18	$0.29
J3487	Zometa	$0.22	$0.20	$0.16	$0.11
Q2051	Zometa	–	–	–	$0.04
J2430	Aredia	$0.00	$0.00	$0.00	$0.00

The same dynamic was seen in the Medicare population: Zometa still remained the most utilized drug in 2013 by claims and members; however, Xgeva represented the largest spend in the category. The major difference between the two populations was the higher allowed amount PMPM for these agents in the Medicare population versus the commercial population due to a higher proportion of members with cancer. *See Figure 109: Medicare Utilization of Bone Resorption Inhibitors to Treat Bone Metastases in Cancer 2010–2013.*

FIGURE 109: Medicare Utilization of Bone Resorption Inhibitors to Treat Bone Metastases in Cancer 2010–2013

HCPCS CODE	BRAND NAME	2010	2011	2012	2013
CLAIM COUNT					
J0897	Xgeva	0.00%	0.00%	31.74%	41.45%
J3487	Zometa	80.08%	81.78%	54.93%	35.71%
Q2051	Zometa	0.00%	0.00%	0.00%	15.22%
J2430	Aredia	19.92%	18.22%	13.33%	7.63%
MEMBER COUNT					
J3487	Zometa	81.38%	82.14%	56.33%	40.81%
J0897	Xgeva	0.00%	0.00%	31.98%	32.00%
Q2051	Zometa	0.00%	0.00%	0.00%	20.44%
J2430	Aredia	18.63%	17.86%	11.69%	6.74%
ALLOWED PMPM					
J0897	Xgeva	–	–	$0.62	$0.78
J3487	Zometa	$0.79	$0.63	$0.54	$0.32
Q2051	Zometa	–	–	–	$0.11
J2430	Aredia	$0.02	$0.01	$0.01	$0.01

Similar to the trends observed with bone resorption inhibitors used to treat bone metastases, a comparable dynamic was seen with their use in osteoporosis. Reclast was the predominant bone resorption inhibitor utilized over Boniva (generic made available March 2014) until the FDA approved Prolia for its first osteoporosis indication in June 2010. In 2013, Prolia represented the majority of utilization by claims, members and allowed amount PMPM for both LOBs. *See Figure 110: Commercial Utilization of Bone Resorption Inhibitors to Treat Osteoporosis 2010–2013 and Figure 111: Medicare Utilization of Bone Resorption Inhibitors to Treat Osteoporosis 2010–2013.*

FIGURE 110: Commercial Utilization of Bone Resorption Inhibitors to Treat Osteoporosis 2010–2013

HCPCS CODE	BRAND NAME	2010	2011	2012	2013
CLAIM COUNT					
J0897	Prolia	0.00%	0.00%	36.20%	58.63%
J3488	Reclast	66.41%	76.22%	53.26%	25.08%
Q2051	Reclast	0.00%	0.00%	0.00%	11.75%
J1740	Boniva	33.59%	23.78%	10.54%	4.54%
MEMBER COUNT					
J0897	Prolia	0.00%	0.00%	32.39%	54.80%
J3488	Reclast	81.24%	87.72%	61.94%	32.02%
Q2051	Reclast	0.00%	0.00%	0.00%	10.32%
J1740	Boniva	18.76%	12.28%	5.67%	2.85%
ALLOWED PMPM					
J0897	Prolia	–	–	$0.03	$0.07
J3488	Reclast	$0.08	$0.08	$0.08	$0.04
Q2051	Reclast	–	–	–	$0.01
J1740	Boniva	$0.01	$0.01	$0.01	$0.00

FIGURE 111: Medicare Utilization of Bone Resorption Inhibitors to Treat Osteoporosis 2010–2013

HCPCS CODE	BRAND NAME	2010	2011	2012	2013
CLAIM COUNT					
J0897	Prolia	0.00%	0.00%	37.28%	57.42%
J3488	Reclast	68.94%	81.83%	55.16%	27.49%
Q2051	Reclast	0.00%	0.00%	0.00%	11.29%
J1740	Boniva	31.06%	18.17%	7.56%	3.80%
MEMBER COUNT					
J0897	Prolia	0.00%	0.00%	32.27%	52.38%
J3488	Reclast	83.07%	91.07%	63.59%	34.91%
Q2051	Reclast	0.00%	0.00%	0.00%	10.53%
J1740	Boniva	16.93%	8.93%	4.13%	2.17%
ALLOWED PMPM					
J0897	Prolia	–	–	$0.20	$0.36
J3488	Reclast	$0.51	$0.52	$0.45	$0.25
Q2051	Reclast	–	–	–	$0.08
J1740	Boniva	$0.08	$0.04	$0.02	$0.01

Since Prolia and Xgeva are billed under the medical benefit with the same HCPCS code, J0897, we analyzed the utilization of each drug separately based on variances in indication, dosing and frequency. In the 2013 commercial population, Prolia represented 19 percent (up from 14 percent in 2012) of allowed amount PMPM, while Xgeva represented 81 percent (down from 86 percent in 2012). In the 2013 Medicare population, Prolia represented 32 percent (up from 24 percent in 2012) of allowed amount PMPM, while Xgeva represented 68 percent (down from 76 percent in 2012). Please note: Based on indication and dosing assumptions utilized in the analysis, total allowed amounts PMPM will be slightly lower than other figures in this report. *See Figure 112: J0897 Utilization of Xgeva Versus Prolia in Commercial and Medicare Populations.*

FIGURE 112: J0897 Utilization of Xgeva Versus Prolia in Commercial and Medicare Populations

		ALLOWED PMPM		COST/PATIENT	
LOB	BRAND NAME	2012	2013	2012	2013
Commercial	Xgeva	$0.18	$0.29	$25,930	$30,909
	Prolia	$0.03	$0.07	$5,383	$5,714
Medicare	Xgeva	$0.62	$0.78	$19,076	$19,705
	Prolia	$0.20	$0.36	$4,513	$4,482

Four medical benefit drugs are available in the botulinum toxin drug class to treat musculoskeletal conditions: Botox, Dysport, Myobloc and Xeomin. Botox has the most FDA-labeled indications and is the most commonly prescribed for off-label uses based on available supporting literature. Each botulinum toxin agent has varying biologic activities, sizes, storage considerations, serotypes and costs.

In both the commercial and Medicare populations, Botox held the vast majority of market share for claims, members and allowed amount PMPM. *See Figure 113: Commercial Utilization of Botulinum Toxins 2010–2013 and Figure 114: Medicare Utilization of Botulinum Toxins 2010–2013.*

FIGURE 113: Commercial Utilization of Botulinum Toxins 2010–2013

HCPCS CODE	BRAND NAME	2010	2011	2012	2013
CLAIM COUNT					
J0585	Botox	96.87%	95.41%	94.55%	94.37%
J0586	Dysport	1.48%	3.38%	3.44%	3.64%
J0588	Xeomin	0.00%	0.00%	1.07%	1.21%
J0587	Myobloc	1.64%	1.21%	0.94%	0.78%
MEMBER COUNT					
J0585	Botox	96.37%	94.81%	94.49%	93.66%
J0586	Dysport	1.84%	4.03%	3.52%	4.02%
J0588	Xeomin	0.00%	0.00%	1.05%	1.38%
J0587	Myobloc	1.79%	1.16%	0.94%	0.94%
ALLOWED PMPM					
J0585	Botox	$0.11	$0.14	$0.18	$0.22
J0586	Dysport	$0.00	$0.00	$0.01	$0.01
J0587	Myobloc	$0.00	$0.00	$0.00	$0.00
J0588	Xeomin	–	–	$0.00	$0.00

FIGURE 114: Medicare Utilization of Botulinum Toxins 2010–2013

HCPCS CODE	BRAND NAME	2010	2011	2012	2013
CLAIM COUNT					
J0585	Botox	94.28%	93.87%	94.11%	94.12%
J0586	Dysport	1.68%	2.16%	2.92%	2.58%
J0587	Myobloc	4.04%	3.96%	1.12%	1.72%
J0588	Xeomin	0.00%	0.00%	1.85%	1.58%
MEMBER COUNT					
J0585	Botox	93.13%	93.26%	95.09%	93.82%
J0586	Dysport	2.44%	2.17%	2.33%	2.39%
J0587	Myobloc	4.43%	4.57%	1.10%	2.09%
J0588	Xeomin	0.00%	0.00%	1.47%	1.69%
ALLOWED PMPM					
J0585	Botox	$0.21	$0.24	$0.28	$0.30
J0586	Dysport	$0.00	$0.01	$0.01	$0.01
J0587	Myobloc	$0.02	$0.02	$0.00	$0.01
J0588	Xeomin	–	–	$0.00	$0.00

Viscosupplementation therapy or treatment with hyaluronic acids (HAs) for osteoarthritis of the knee includes multiple options: Hyalgan/Supartz, Euflexxa, Orthovisc, Synvisc/Synvisc-One, Gel-One and, most recently, Monovisc. The HA products have varying doses and number of administrations per course of therapy. In May 2013, the American Academy of Orthopaedic Surgeons (AAOS) revised its guidelines regarding the treatment of osteoarthritis of the knee and recommended against the use of intra-articular HA injections in symptomatic disease.[7] Instead of only reviewing annual utilization trends from 2010–2013, we also analyzed 2013 more closely based on the first half of the year (prior to the AAOS recommendation) versus the second half of the year (after the AAOS recommendation was released).

For both the commercial and Medicare populations, the AAOS guidelines had no significant impact on overall allowed amount PMPM in the second half of 2013 versus the first half of 2013. Both Medicare and commercial populations had similar HA utilization trends in 2013, with Synvisc and Euflexxa having the largest percentages of members. In 2010, Hyalgan/Supartz (both products share HCPCS code J7321) had the second highest percentage of members, but by 2013, they were reduced to third and fourth for the Medicare and commercial populations, respectively. Due to the varying number of administrations per HA agent per course of treatment, some products have higher market shares by members but lower market shares by claims due to fewer injections per course of therapy. *See Figure 115: Commercial Utilization of Viscosupplementation 2010–2013 and Figure 116: Medicare Utilization of Viscosupplementation 2010–2013.*

FIGURE 115: Commercial Utilization of Viscosupplementation 2010–2013

HCPCS CODE	BRAND NAME	2010	2011	2012	1H2013	2H2013
CLAIM COUNT						
J7321	Hyalgan/Supartz	41.89%	33.67%	30.48%	29.45%	28.41%
J7323	Euflexxa	16.15%	21.26%	24.60%	26.44%	28.00%
J7325	Synvisc/Synvisc-One	27.44%	28.30%	25.78%	23.78%	21.57%
J7324	Orthovisc	14.53%	16.77%	19.12%	20.00%	21.24%
J7326	Gel-One	0.00%	0.00%	0.02%	0.32%	0.77%
MEMBER COUNT						
J7325	Synvisc/Synvisc-One	40.46%	42.97%	40.32%	37.67%	35.00%
J7323	Euflexxa	16.53%	20.33%	23.50%	24.89%	25.69%
J7324	Orthovisc	14.28%	14.70%	16.89%	17.94%	18.81%
J7321	Hyalgan/Supartz	28.73%	22.01%	19.22%	18.78%	18.76%
J7326	Gel-One	0.00%	0.00%	0.06%	0.71%	1.73%
ALLOWED PMPM						
J7325	Synvisc/Synvisc-One	$0.09	$0.11	$0.12	$0.12	$0.11
J7323	Euflexxa	$0.03	$0.04	$0.05	$0.06	$0.06
J7324	Orthovisc	$0.03	$0.03	$0.04	$0.05	$0.05
J7321	Hyalgan/Supartz	$0.04	$0.03	$0.04	$0.04	$0.04
J7326	Gel-One	–	–	$0.00	$0.00	$0.01
TOTAL		**$0.19**	**$0.22**	**$0.25**	**$0.27**	**$0.26**

Please note: Due to rounding to the nearest cent, some of the column totals do not add up accurately.

7. American Academy of Orthopaedic Surgeons. Summary of treatment recommendations. Treatment of osteoarthritis (OA) of the knee (non-arthroplasty) evidence-based guideline, 2nd edition. Accessed: http://www.aaos.org/research/guidelines/OAKSummaryofRecommendations.pdf.

FIGURE 116: Medicare Utilization of Viscosupplementation 2010–2013

HCPCS CODE	BRAND NAME	2010	2011	2012	1H2013	2H2013
CLAIM COUNT						
J7321	Hyalgan/Supartz	36.01%	24.30%	26.24%	24.20%	29.59%
J7323	Euflexxa	17.29%	28.57%	29.29%	30.89%	27.23%
J7325	Synvisc/Synvisc-One	33.24%	35.95%	31.34%	28.58%	26.89%
J7324	Orthovisc	13.46%	11.18%	13.12%	16.05%	15.50%
J7326	Gel-One	0.00%	0.00%	0.02%	0.28%	0.79%
MEMBER COUNT						
J7325	Synvisc/Synvisc-One	46.01%	48.13%	46.58%	43.57%	41.79%
J7323	Euflexxa	16.09%	24.93%	26.77%	27.03%	25.46%
J7321	Hyalgan/Supartz	24.83%	16.42%	15.49%	15.92%	17.22%
J7324	Orthovisc	13.08%	10.52%	11.11%	12.92%	13.79%
J7326	Gel-One	0.00%	0.00%	0.05%	0.57%	1.74%
ALLOWED PMPM						
J7325	Synvisc/Synvisc-One	$0.43	$0.53	$0.50	$0.47	$0.46
J7323	Euflexxa	$0.10	$0.20	$0.23	$0.25	$0.21
J7324	Orthovisc	$0.11	$0.09	$0.11	$0.13	$0.14
J7321	Hyalgan/Supartz	$0.15	$0.10	$0.10	$0.10	$0.12
J7326	Gel-One	–	–	$0.00	$0.01	$0.02
TOTAL		**$0.79**	**$0.92**	**$0.94**	**$0.95**	**$0.95**

Please note: Due to rounding to the nearest cent, some of the column totals do not add up accurately.

National Provider Trends

Provider-administered drugs paid through the medical benefit to treat outpatient conditions typically were rendered in physician offices (obtained via buy and bill or from specialty pharmacies through drug fulfillment or replacement), homes via home infusion or specialty pharmacy providers, or hospital outpatient facilities. A collection of drugs from our top 25 listing that represent agents used to treat cancer or its supportive care, immunodeficiencies or autoimmune disorders is identified below. The trend of services shifting from a physician office setting to a hospital outpatient facility had been established in previous trend reports and continued to be the marketplace dynamic in 2013.

For commercial members, the allowed amount per drug per claim was significantly higher in the hospital outpatient facility than in the physician office or home setting. Drugs administered in the hospital outpatient facility, when indexed to the average sales price (ASP), typically were reimbursed two to three times ASP versus a physician office setting which averaged ASP + 11–18 percent (excluding Gammagard liquid, which is typically administered in the home setting). Please note: Drugs like Xgeva/Prolia, Avastin, Tysabri and Rituxan typically only were rendered in physician offices or hospital outpatient facilities versus home settings. Use of these agents in home infusion/specialty pharmacy settings was more likely related to a specialty pharmacy dispensing the product for use in a physician office or hospital outpatient facility, but the place-of-service (POS) field on the claim was submitted inaccurately. *See Figure 117: Commercial Cost per Claim for Top Drugs by Provider Type and Indexed to ASP in 2013.*

FIGURE 117: Commercial Cost per Claim for Top Drugs by Provider Type and Indexed to ASP in 2013

		COST/CLAIM			ASP INDEX (4Q13)		
PROVIDER TYPE		HOSPITAL OUTPATIENT FACILITY	HOME INFUSION/ SPECIALTY PHARMACY	PHYSICIAN OFFICE	HOSPITAL OUTPATIENT FACILITY	HOME INFUSION/ SPECIALTY PHARMACY	PHYSICIAN OFFICE
HCPCS CODE	BRAND NAME						
J0897	Xgeva/Prolia	$3,504	$849	$1,437	2.48	1.07	1.13
J1569	Gammagard Liquid	$6,590	$3,813	$5,368	2.41	1.29	2.10
J1745	Remicade	$8,182	$4,393	$3,772	3.00	1.26	1.13
J2323	Tysabri	$6,156	$4,050	$4,167	1.72	1.12	1.18
J2505	Neulasta	$6,894	$4,160	$3,402	2.05	1.41	1.16
J9035	Avastin	$8,745	$5,853	$4,120	2.31	1.20	1.11
J9041	Velcade	$2,282	–	$1,619	2.02	–	1.15
J9305	Alimta	$9,109	–	$5,815	2.10	–	1.12
J9310	Rituxan	$9,434	$11,608	$5,647	2.10	0.71	1.12
J9355	Herceptin	$5,406	–	$2,867	1.75	–	1.11

Based on our data, the cost per drug per claim for Medicare still was higher in the hospital outpatient facility versus the physician office or home setting for most drugs; however, the dynamic was not as pronounced as it was in the commercial population. The index to ASP for drugs administered in the hospital outpatient facility ranged from ASP + 14–32 percent versus ASP + 7–13 percent in the physician office setting (excluding Gammagard liquid, which is typically administered in the home setting). Of note, the cost per claim in the Medicare population was significantly less than the commercial population, which might be due to variances in unit costs, dose per claim and claims per year or frequency of administrations. Lastly, ocular diagnoses were excluded from Avastin utilization in both the commercial and Medicare data sets for this analysis since nearly all ophthalmic injections are performed in the physician office setting. *See Figure 118: Medicare Cost per Claim for Top Drugs by Provider Type and Indexed to ASP in 2013.*

FIGURE 118: Medicare Cost per Claim for Top Drugs by Provider Type and Indexed to ASP in 2013

		COST/CLAIM			ASP INDEX (4Q13)		
PROVIDER TYPE		HOSPITAL OUTPATIENT FACILITY	HOME INFUSION/ SPECIALTY PHARMACY	PHYSICIAN OFFICE	HOSPITAL OUTPATIENT FACILITY	HOME INFUSION/ SPECIALTY PHARMACY	PHYSICIAN OFFICE
HCPCS CODE	BRAND NAME						
J0897	Xgeva/Prolia	$1,734	$915	$1,221	1.22	1.22	1.09
J1569	Gammagard Liquid	$3,405	$4,599	$6,110	1.41	1.29	1.52
J1745	Remicade	$3,731	$4,061	$3,306	1.25	1.30	1.07
J2323	Tysabri	$4,177	$3,951	$2,838	1.14	1.08	1.12
J2505	Neulasta	$3,541	$3,061	$3,343	1.20	1.04	1.13
J9035	Avastin	$4,603	$1,900	$3,777	1.28	1.04	1.07
J9041	Velcade	$1,753	–	$1,561	1.32	–	1.11
J9305	Alimta	$5,958	–	$5,462	1.28	–	1.09
J9310	Rituxan	$5,779	$2,993	$4,841	1.20	1.04	1.08
J9355	Herceptin	$3,560	–	$2,744	1.22	–	1.08

For the commercial population, most of the drugs analyzed saw utilization shifts since 2010 from the physician office setting to the hospital outpatient facility. Gammagard liquid, an intravenous immune globulin agent, did not experience the same site of service trends as other drugs. Its utilization saw more growth in the physician office setting coupled with a decrease in percentage of claims and spend in the home setting and a decrease in percentage of members in the hospital outpatient facility. Utilization of Tysabri remained consistent in the physician office setting, but its market share moved from the home infusion/specialty pharmacy setting to the hospital outpatient facility. Since drugs administered in the hospital outpatient facility for commercial members typically cost at least double the amount than when administered in a physician office setting or the home, the percentage of allowed amount PMPM in the hospital outpatient facility was much higher than the hospital's percentage of members or claims by drug. For example, 29 percent of commercial members received Xgeva or Prolia in the hospital outpatient facility in 2013, which represented 63 percent of total allowed amount PMPM for Xgeva and Prolia in 2013. *See Figure 119: Commercial Utilization of Top Medical Benefit Drugs by Site of Service Based on Claims, Members and Allowed Amount PMPM 2010–2013.*

FIGURE 119: Commercial Utilization of Top Medical Benefit Drugs by Site of Service Based on Claims, Members and Allowed Amount PMPM 2010–2013

HCPCS CODE	BRAND NAME	2010	2011	2012	2013	2010	2011	2012	2013	2010	2011	2012	2013
CLAIM COUNT		**HOSPITAL OUTPATIENT FACILITY**				**HOME INF./SPECIALTY PHARMACY**				**PHYSICIAN OFFICE**			
J0897	Xgeva/Prolia	0%	0%	38%	40%	0%	0%	1%	5%	0%	100%	61%	55%
J1569	Gammagard Liquid	18%	16%	16%	17%	71%	75%	66%	66%	10%	9%	17%	17%
J1745	Remicade	28%	31%	34%	36%	9%	8%	7%	8%	63%	61%	59%	56%
J2323	Tysabri	34%	38%	41%	44%	20%	15%	15%	12%	46%	47%	45%	44%
J2505	Neulasta	30%	35%	42%	45%	0%	0%	0%	0%	70%	65%	58%	54%
J9035	Avastin	38%	48%	52%	53%	0%	0%	0%	0%	62%	52%	48%	47%
J9041	Velcade	25%	35%	43%	50%	0%	0%	0%	0%	75%	65%	57%	50%
J9305	Alimta	39%	44%	49%	53%	0%	1%	1%	0%	61%	55%	51%	47%
J9310	Rituxan	33%	42%	46%	52%	1%	1%	1%	1%	66%	57%	54%	47%
J9355	Herceptin	35%	43%	50%	57%	0%	0%	0%	0%	65%	56%	50%	43%
MEMBER COUNT		**HOSPITAL OUTPATIENT FACILITY**				**HOME INF./SPECIALTY PHARMACY**				**PHYSICIAN OFFICE**			
J0897	Xgeva/Prolia	0%	0%	30%	29%	0%	0%	1%	11%	0%	100%	69%	60%
J1569	Gammagard Liquid	34%	31%	24%	25%	52%	54%	51%	51%	14%	15%	26%	24%
J1745	Remicade	31%	33%	36%	38%	10%	9%	8%	9%	59%	58%	57%	54%
J2323	Tysabri	35%	38%	38%	45%	19%	19%	16%	12%	46%	43%	46%	43%
J2505	Neulasta	35%	41%	46%	49%	0%	0%	0%	0%	65%	59%	53%	51%
J9035	Avastin	40%	47%	46%	47%	0%	1%	0%	0%	60%	52%	54%	52%
J9041	Velcade	38%	47%	50%	53%	0%	0%	0%	0%	62%	53%	50%	47%
J9305	Alimta	42%	46%	50%	51%	0%	0%	1%	0%	58%	53%	50%	49%
J9310	Rituxan	39%	46%	49%	51%	2%	1%	2%	2%	59%	53%	49%	47%
J9355	Herceptin	40%	47%	54%	58%	0%	1%	1%	0%	60%	52%	45%	42%
ALLOWED PMPM		**HOSPITAL OUTPATIENT FACILITY**				**HOME INF./SPECIALTY PHARMACY**				**PHYSICIAN OFFICE**			
J0897	Xgeva/Prolia	0%	0%	56%	63%	0%	0%	0%	2%	0%	100%	44%	35%
J1569	Gammagard Liquid	25%	23%	23%	25%	64%	69%	61%	55%	11%	8%	17%	20%
J1745	Remicade	43%	47%	51%	55%	7%	6%	6%	6%	49%	47%	44%	39%
J2323	Tysabri	43%	48%	51%	54%	18%	13%	12%	10%	39%	39%	37%	37%
J2505	Neulasta	46%	51%	59%	63%	0%	0%	0%	0%	54%	49%	41%	37%
J9035	Avastin	56%	65%	68%	71%	0%	0%	0%	0%	43%	34%	32%	29%
J9041	Velcade	35%	44%	52%	58%	0%	0%	1%	0%	65%	56%	48%	42%
J9305	Alimta	49%	53%	59%	64%	0%	1%	0%	0%	51%	46%	40%	36%
J9310	Rituxan	46%	56%	58%	64%	1%	1%	1%	1%	53%	43%	41%	35%
J9355	Herceptin	51%	61%	64%	71%	0%	1%	0%	0%	49%	39%	36%	29%

Compared to the commercial population, Medicare saw much larger shifts in site of service from the physician office setting to the hospital outpatient facility since 2010, especially for oncology drugs. The percentage of Gammagard liquid utilization decreased in both physician offices and hospital outpatient facilities and moved to the home setting. The hospital outpatient facility percentage of claims and members by drug closely correlated to the percentage of allowed amount PMPM for Medicare members since drugs in this setting did not have the same high cost differential versus the physician office or home settings as seen with the commercial population. *See Figure 120: Medicare Utilization of Top Medical Benefit Drugs by Site of Service Based on Claims, Members and Allowed Amount PMPM 2010–2013.*

FIGURE 120: Medicare Utilization of Top Medical Benefit Drugs by Site of Service Based on Claims, Members and Allowed Amount PMPM 2010–2013

HCPCS CODE	BRAND NAME	2010	2011	2012	2013	2010	2011	2012	2013	2010	2011	2012	2013
CLAIM COUNT		**HOSPITAL OUTPATIENT FACILITY**				**HOME INF./SPECIALTY PHARMACY**				**PHYSICIAN OFFICE**			
J0897	Xgeva/Prolia	0%	0%	32%	32%	0%	0%	0%	1%	0%	0%	68%	67%
J1569	Gammagard Liquid	19%	24%	25%	9%	29%	47%	59%	73%	52%	28%	15%	18%
J1745	Remicade	25%	29%	40%	44%	8%	8%	8%	7%	67%	64%	53%	49%
J2323	Tysabri	38%	38%	31%	48%	5%	5%	5%	1%	57%	58%	64%	51%
J2505	Neulasta	27%	36%	49%	53%	0%	0%	0%	0%	73%	64%	51%	47%
J9035	Avastin	29%	34%	39%	57%	0%	0%	0%	0%	71%	66%	61%	43%
J9041	Velcade	24%	41%	58%	60%	0%	0%	0%	0%	76%	59%	42%	40%
J9305	Alimta	22%	37%	55%	61%	0%	0%	0%	0%	78%	63%	45%	39%
J9310	Rituxan	24%	38%	58%	63%	0%	0%	0%	0%	76%	62%	42%	37%
J9355	Herceptin	36%	43%	63%	57%	0%	0%	0%	0%	64%	57%	37%	43%
MEMBER COUNT		**HOSPITAL OUTPATIENT FACILITY**				**HOME INF./SPECIALTY PHARMACY**				**PHYSICIAN OFFICE**			
J0897	Xgeva/Prolia	0%	0%	24%	22%	0%	0%	0%	1%	0%	0%	76%	77%
J1569	Gammagard Liquid	33%	38%	44%	22%	26%	26%	36%	55%	41%	36%	20%	22%
J1745	Remicade	27%	32%	39%	46%	8%	7%	7%	6%	65%	61%	54%	49%
J2323	Tysabri	39%	44%	38%	57%	4%	9%	7%	2%	57%	47%	55%	42%
J2505	Neulasta	30%	38%	49%	57%	0%	0%	0%	0%	70%	62%	51%	43%
J9035	Avastin	28%	32%	31%	45%	1%	0%	0%	0%	71%	68%	69%	54%
J9041	Velcade	32%	53%	57%	61%	0%	0%	0%	0%	68%	47%	43%	39%
J9305	Alimta	22%	39%	57%	63%	0%	0%	0%	0%	78%	61%	43%	37%
J9310	Rituxan	30%	42%	59%	65%	0%	0%	0%	0%	70%	57%	41%	34%
J9355	Herceptin	42%	51%	60%	63%	0%	0%	0%	0%	58%	49%	40%	37%
ALLOWED PMPM		**HOSPITAL OUTPATIENT FACILITY**				**HOME INF./SPECIALTY PHARMACY**				**PHYSICIAN OFFICE**			
J0897	Xgeva/Prolia	0%	0%	42%	40%	0%	0%	0%	0%	0%	0%	58%	59%
J1569	Gammagard Liquid	15%	20%	19%	6%	24%	50%	67%	70%	61%	30%	15%	23%
J1745	Remicade	28%	30%	45%	46%	8%	8%	9%	8%	63%	62%	46%	46%
J2323	Tysabri	35%	38%	35%	58%	6%	5%	7%	1%	59%	57%	58%	41%
J2505	Neulasta	27%	39%	51%	55%	0%	0%	0%	0%	73%	61%	49%	45%
J9035	Avastin	36%	45%	50%	62%	0%	0%	0%	0%	64%	55%	50%	38%
J9041	Velcade	27%	45%	61%	62%	0%	0%	0%	0%	73%	55%	39%	38%
J9305	Alimta	27%	43%	59%	63%	0%	0%	0%	0%	73%	57%	41%	37%
J9310	Rituxan	29%	45%	66%	67%	0%	0%	0%	0%	71%	55%	34%	33%
J9355	Herceptin	44%	50%	70%	63%	0%	0%	0%	0%	56%	50%	30%	37%

Specific to the physician office site of service, we analyzed the physician specialties with the highest medical pharmacy spend. Similar to past trend reports, oncologists, hematologists or both specialties combined represented the highest proportion of medical benefit drug spend by specialty. In both LOBs, ophthalmology was a trending specialty from 2012–2013, with a 51 percent allowed amount PMPM increase for commercial and 23 percent for Medicare. "Other" represented the fourth highest spend specialty in both LOBs and included cardiology, podiatry, anesthesiology, pain management, nephrology and generically labeled drug, infusion or clinic services. Please note: Less than 1 percent of claims were submitted with a blank specialty field. Based on the analysis requirements, a subset of health plan claims data was utilized and the total allowed amounts PMPM will not exactly match other reports. *See Figure 121: Medical Pharmacy Allowed Amount PMPM by Physician Office Specialty by LOB 2012–2013.*

FIGURE 121: Medical Pharmacy Allowed Amount PMPM by Physician Office Specialty by LOB 2012–2013

		ALLOWED PMPM		% OF TOTAL ALLOWED PMPM	
LOB	SPECIALTY	2012	2013	2012	2013
Commercial	Hematology/Oncology	$2.05	$2.15	30.66%	29.78%
	Oncology	$1.18	$1.07	17.65%	14.86%
	Hematology	$0.88	$1.00	13.15%	13.87%
	Other	$0.53	$0.70	7.93%	9.72%
	Rheumatology	$0.54	$0.59	8.11%	8.21%
	Ophthalmology	$0.27	$0.40	3.99%	5.57%
	Gastroenterology	$0.22	$0.27	3.24%	3.76%
	Internal Medicine	$0.29	$0.18	4.35%	2.49%
	Orthopedic Surgery	$0.14	$0.15	2.08%	2.02%
	Obstetrics/Gynecology	$0.11	$0.13	1.58%	1.84%
	Neurology	$0.12	$0.12	1.80%	1.71%
	Urology	$0.09	$0.11	1.34%	1.51%
	Infectious Disease	$0.09	$0.10	1.32%	1.41%
	Family Practice	$0.08	$0.10	1.16%	1.37%
	Radiation Oncology	$0.03	$0.06	0.42%	0.89%
	Allergy/Immunology	$0.04	$0.04	0.60%	0.60%
	Dermatology	$0.02	$0.02	0.31%	0.33%
	(Blank)	$0.02	$0.00	0.30%	0.05%
Medicare	Oncology	$6.32	$4.71	29.47%	22.86%
	Hematology/Oncology	$3.52	$4.25	16.42%	20.64%
	Ophthalmology	$3.24	$3.97	15.10%	19.28%
	Other	$2.39	$2.18	11.14%	10.60%
	Hematology	$0.98	$2.12	4.58%	10.27%
	Rheumatology	$1.04	$0.97	4.86%	4.71%
	Urology	$0.88	$0.80	4.12%	3.88%
	Orthopedic Surgery	$0.46	$0.47	2.15%	2.26%
	Internal Medicine	$1.58	$0.24	7.34%	1.18%
	Neurology	$0.24	$0.20	1.12%	0.99%
	Family Practice	$0.39	$0.17	1.82%	0.81%
	Gastroenterology	$0.15	$0.16	0.71%	0.77%
	Radiation Oncology	$0.01	$0.12	0.05%	0.58%
	Infectious Disease	$0.07	$0.10	0.32%	0.47%
	Allergy/Immunology	$0.05	$0.07	0.22%	0.36%
	Obstetrics/Gynecology	$0.05	$0.04	0.22%	0.18%
	Dermatology	$0.03	$0.04	0.16%	0.17%
	(Blank)	$0.04	$0.00	0.19%	0.00%

Please note: Costs were rounded to the nearest cent. Detailed percentages in the table and text were calculated utilizing raw data.

Insights for 2014

Although a member typically has a deductible, coinsurance or copay and a maximum out-of-pocket contribution for drug services billed through the medical benefit, the member cost share, when analyzed in comparison to overall medical pharmacy costs, was small, at 3 percent and 6 percent in 2013 for commercial and Medicare, respectively. However, the claim lines included in this analysis were drug-specific, and we recognize that members might have already paid their deductibles or reached their out-of-pocket maximums due to other non-drug medical services. In addition, some payors have coinsurance and copay requirements for the office visit, but not necessarily for the drug service. The majority of commercial member cost share was captured in the deductible and coinsurance fields, while the majority of Medicare cost share was seen in coinsurances, followed by copays. Due to utilizing a subset of the data with member cost shares for this analysis, the allowed amounts PMPM varied slightly and will not match the other reports. *See Figure 122: 2013 Member Cost Share for Medical Benefit Drugs by LOB.*

FIGURE 122: 2013 Member Cost Share for Medical Benefit Drugs by LOB

2013

LOB	COPAY PMPM	DEDUCTIBLE PMPM	COINSURANCE PMPM	ALLOWED PMPM	MEMBER SHARE % OF TOTAL MEDICAL RX SPEND
Commercial	$0.02	$0.25	$0.27	$20.27	3%
Medicare	$0.20	$0.03	$2.41	$45.35	6%

2012

LOB	COPAY PMPM	DEDUCTIBLE PMPM	COINSURANCE PMPM	ALLOWED PMPM	MEMBER SHARE % OF TOTAL MEDICAL RX SPEND
Commercial	$0.03	$0.21	$0.23	$18.19	3%
Medicare	$0.21	$0.03	$2.07	$42.86	5%

Administration code spend should be considered when discussing medical pharmacy to understand the total costs of drug infusion services. Drug administration codes with at least $0.01 PMPM spend or greater were included in Figures 123 and 124 along with the total spend across all drug administration codes per LOB. For both commercial and Medicare, the PMPM spend for top administration codes and overall administration codes remained stable from 2012–2013. Drug administration codes were inclusive of all sites of service (i.e., physician office, home via home infusion and hospital outpatient facility). *See Figure 123: Commercial Top Administration Codes by Allowed Amount PMPM and Figure 124: Medicare Top Administration Codes by Allowed Amount PMPM.*

FIGURE 123: Commercial Top Administration Codes by Allowed Amount PMPM

CPT	CPT DESCRIPTION	2012	2013
96413	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug	$0.91	$0.96
96365	Intravenous infusion, for therapy, prophylaxis or diagnosis (specify substance or drug); initial, up to 1 hour	$0.36	$0.39
96375	Therapeutic, prophylactic or diagnostic injection (specify substance or drug); each additional sequential intravenous push of a new substance/drug	$0.33	$0.39
96372	Therapeutic, prophylactic or diagnostic injection (specify substance or drug); subcutaneous or intramuscular	$0.31	$0.30
96361	Intravenous infusion, hydration; each additional hour	$0.30	$0.28
96374	Therapeutic, prophylactic or diagnostic injection (specify substance or drug); intravenous push, single or initial substance/drug	$0.26	$0.21
96367	Intravenous infusion, for therapy, prophylaxis or diagnosis (specify substance or drug); additional sequential infusion of a new drug/substance, up to 1 hour	$0.16	$0.17
96415	Chemotherapy administration, intravenous infusion technique; each additional hour	$0.14	$0.15
96417	Chemotherapy administration, intravenous infusion technique; each additional sequential infusion (different substance/drug), up to 1 hour	$0.13	$0.14
96360	Intravenous infusion, hydration; initial, 31 minutes to 1 hour	$0.12	$0.10
96366	Intravenous infusion, for therapy, prophylaxis or diagnosis (specify substance or drug); each additional hour	$0.09	$0.10
96411	Chemotherapy administration; intravenous, push technique, each additional substance/drug	$0.08	$0.09
96416	Chemotherapy administration, intravenous infusion technique; initiation of prolonged chemotherapy infusion (more than 8 hours), requiring use of a portable or implantable pump	$0.06	$0.07
99601	Home infusion/specialty drug administration, per visit (up to 2 hours)	$0.07	$0.07
96401	Chemotherapy administration, subcutaneous or intramuscular; non-hormonal anti-neoplastic	$0.05	$0.06
96409	Chemotherapy administration; intravenous, push technique, single or initial substance/drug	$0.06	$0.06
96376	Intravenous push, single or initial substance/drug; each additional sequential intravenous push of the same substance/drug provided in a facility	$0.04	$0.04
96402	Chemotherapy administration, subcutaneous or intramuscular; hormonal anti-neoplastic	$0.02	$0.02
96523	Irrigation of implanted venous access device for drug delivery systems	$0.02	$0.02
99602	Home infusion/specialty drug administration, per visit (up to 2 hours); each additional hour	$0.01	$0.02
96368	Intravenous infusion, for therapy, prophylaxis or diagnosis (specify substance or drug); concurrent infusion	$0.02	$0.02
96521	Refilling and maintenance of portable pump	$0.01	$0.01
96450	Chemotherapy administration, into CNS (e.g., intrathecal), requiring and including spinal puncture	$0.02	$0.01
96420	Chemotherapy administration, intra-arterial; push technique	$0.01	$0.01
GRAND TOTAL		**$3.59**	**$3.73**

Please note: Due to rounding to the nearest cent, some of the column totals do not add up accurately.

FIGURE 124: Medicare Top Administration Codes by Allowed Amount PMPM

CPT	CPT DESCRIPTION	2012	2013
96413	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug	$3.11	$3.11
96365	Intravenous infusion, for therapy, prophylaxis or diagnosis (specify substance or drug); initial, up to 1 hour	$0.78	$0.80
96372	Therapeutic, prophylactic or diagnostic injection (specify substance or drug); subcutaneous or intramuscular	$0.78	$0.72
96411	Chemotherapy administration; intravenous, push technique, each additional substance/drug	$0.47	$0.49
96375	Therapeutic, prophylactic or diagnostic injection (specify substance or drug); each additional sequential intravenous push of a new substance/drug	$0.43	$0.47
96401	Chemotherapy administration, subcutaneous or intramuscular; non-hormonal anti-neoplastic	$0.34	$0.43
96361	Intravenous infusion, hydration; each additional hour	$0.40	$0.42
96367	Intravenous infusion, for therapy, prophylaxis or diagnosis (specify substance or drug); additional sequential infusion of a new drug/substance, up to 1 hour	$0.34	$0.33
96374	Therapeutic, prophylactic or diagnostic injection (specify substance or drug); intravenous push, single or initial substance/drug	$0.42	$0.30
96409	Chemotherapy administration; intravenous, push technique, single or initial substance/drug	$0.35	$0.26
96415	Chemotherapy administration, intravenous infusion technique; each additional hour	$0.21	$0.21
96417	Chemotherapy administration, intravenous infusion technique; each additional sequential infusion (different substance/drug), up to 1 hour	$0.19	$0.20
96366	Intravenous infusion, for therapy, prophylaxis or diagnosis (specify substance or drug); each additional hour	$0.16	$0.16
96360	Intravenous infusion, hydration; initial, 31 minutes to 1 hour	$0.18	$0.14
96402	Chemotherapy administration, subcutaneous or intramuscular; hormonal anti-neoplastic	$0.10	$0.13
99601	Home infusion/specialty drug administration, per visit (up to 2 hours)	$0.12	$0.12
96416	Chemotherapy administration, intravenous infusion technique; initiation of prolonged chemotherapy infusion (more than 8 hours), requiring use of a portable or implantable pump	$0.09	$0.09
96420	Chemotherapy administration, intra-arterial; push technique	$0.05	$0.06
96523	Irrigation of implanted venous access device for drug delivery systems	$0.05	$0.05
96521	Refilling and maintenance of portable pump	$0.05	$0.03
99602	Home infusion/specialty drug administration, per visit (up to 2 hours); each additional hour	$0.02	$0.02
96450	Chemotherapy administration, into CNS (e.g., intrathecal), requiring and including spinal puncture	$0.00	$0.01
96368	Intravenous infusion, for therapy, prophylaxis or diagnosis (specify substance or drug); concurrent infusion	$0.02	$0.01
96376	Intravenous push, single or initial substance/drug; each additional sequential intravenous push of the same substance/drug provided in a facility	$0.01	$0.00
GRAND TOTAL		**$8.65**	**$8.58**

Please note: Due to rounding to the nearest cent, some of the column totals do not add up accurately.

Unclassified HCPCS codes J9999 and J3490 were present in the 2013 top 50 drug listing for the commercial population and J9999 was present in the Medicare population. In 2013, unclassified codes represented 2.9 percent of all commercial claims and 2.2 percent of Medicare claims. In terms of spend, unclassified codes represented 1.4 percent of commercial and 1.1 percent of Medicare allowed amount PMPM. As mentioned earlier, J3490 represents many unclassified injectable drugs, such as antihistamines, antibiotics, solutions, anesthesia and cardiovascular agents. J9999 is specific to oncology drugs and represented the following products in 2013: Marqibo, Kadcyla, Perjeta, Zaltrap, Kyprolis, Synribo and Gazyva. J3590, an unclassified code specific to biologics, was billed with Jetrea utilization in 2013, an ophthalmic intravitreal injection for treatment of symptomatic vitreomacular adhesion. C9399 is an unclassified code limited to hospital outpatient facility use only. Please note: Only unclassified codes with at least $0.01 allowed amount PMPM are included below. *See Figure 125: 2013 Unclassified Code Utilization by Allowed Amount PMPM for Commercial and Medicare.*

FIGURE 125: 2013 Unclassified Code Utilization by Allowed Amount PMPM for Commercial and Medicare

LOB	HCPCS CODE	2013 ALLOWED PMPM
Commercial	J3490	$0.15
	J9999	$0.10
	C9399	$0.02
	J3590	$0.01
	J8499	$0.01
COMMERCIAL TOTAL		**$0.30**
Medicare	J9999	$0.26
	J3490	$0.14
	J3590	$0.08
	C9399	$0.02
MEDICARE TOTAL		**$0.50**

Please note: Due to rounding to the nearest cent, some of the column totals do not add up accurately.

We analyzed evidence-based versus non-evidence-based utilization of high-spend drugs by indication for the commercial population based on FDA label, compendia and evidence-based literature. The drugs included in the analysis represented 54 percent of overall commercial allowed amount PMPM and included high-cost medical benefit drugs used to treat cancer, autoimmune disorders, immunodeficiencies, age-related (wet) macular degeneration, osteoporosis and osteoarthritis. We reviewed four diagnoses, or ICD9s, per claim line to locate an appropriate diagnosis.

Evidence-based versus non-evidence-based utilization remained relatively consistent from 2012–2013. Evidence-based utilization accounted for 95 percent of claims and 92 percent of spend in 2013. *See Figure 126: Commercial Evidence-Based Versus Non-Evidence-Based Utilization of High-Cost Medical Benefit Drugs 2012–2013.*

FIGURE 126: Commercial Evidence-Based Versus Non-Evidence-Based Utilization of High-Cost Medical Benefit Drugs 2012–2013

CLAIM COUNT	2012	2013
Evidence-Based	95.37%	94.78%
Non-Evidence-Based	4.63%	5.22%
ALLOWED PMPM	**2012**	**2013**
Evidence-Based	92.60%	91.52%
Non-Evidence-Based	7.40%	8.48%

The entrance of generics for medical benefit drugs that previously were available as brand name only led to significant decreases in drug costs. Both the branded and generic agents were billed with the same HCPCS code. We reviewed two oncology drugs: Taxotere (generics available March 23, 2011) and Hycamtin (generics available December 15, 2010). The impact to ASP for Taxotere was 46 percent year-over-year decreases from 2011–2013. Hycamtin saw a larger impact in 2012 versus 2011 with a 67 percent decrease, followed by a 55 percent decrease from 2012–2013. *See Figure 127: Average ASP Rates for Taxotere and Hycamtin 2011–2013 and Annual Percent Changes.*

FIGURE 127: Average ASP Rates for Taxotere and Hycamtin 2011–2013 and Annual Percent Changes

		AVERAGE ASP RATES			AVERAGE ASP RATE CHANGES	
HCPCS CODE	BRAND NAME	2011	2012	2013	2011 VS 2012	2012 VS 2013
J9171	Taxotere	$17.77	$9.62	$5.17	-46%	-46%
J9351	Hycamtin	$15.67	$5.13	$2.32	-67%	-55%

For the commercial population, overall spend for Taxotere decreased 15 percent in the first year the generic formulations were available and 13 percent in the second year. Hycamtin was associated with lower commercial spend, but saw more dramatic changes in allowed amount PMPM in the first year of generic product availability with a 20 percent decrease in spend followed by an additional 39 percent in the second year. Even though the overall allowed amount PMPM and annual costs per patient saw significant reductions in the two years following generic availability, the cost per unit substantially changed only in year one, followed by a smaller change in year two. The cost per unit for all three years was much higher than ASP per unit. This might be due to 1) the percentage of each drug's total utilization by site of service where reimbursement in the hospital outpatient facility typically was based on a percent of charges model that rarely reflected unit cost changes with generic entrants and 2) commercial payors placing higher reimbursement markups on these products in the physician office setting to maintain fair provider margins as their acquisition costs and revenue dramatically decreased. *See Figure 128: Commercial Spend Impact Due to Generic Drug Introductions for Taxotere and Hycamtin 2011–2013.*

FIGURE 128: Commercial Spend Impact Due to Generic Drug Introductions for Taxotere and Hycamtin 2011–2013

ALLOWED PMPM		YEAR			% CHANGE	
HCPCS CODE	BRAND NAME	2011	2012	2013	2011 VS 2012	2012 VS 2013
J9171	Taxotere	$0.48	$0.40	$0.35	-15%	-13%
J9351	Hycamtin	$0.03	$0.03	$0.02	-20%	-39%
COST/PATIENT		YEAR			% CHANGE	
HCPCS CODE	BRAND NAME	2011	2012	2013	2011 VS 2012	2012 VS 2013
J9171	Taxotere	$12,217	$10,285	$9,197	-16%	-11%
J9351	Hycamtin	$10,873	$7,958	$5,893	-27%	-26%
COST/UNIT		YEAR			% CHANGE	
HCPCS CODE	BRAND NAME	2011	2012	2013	2011 VS 2012	2012 VS 2013
J9171	Taxotere	$26.22	$21.32	$19.35	-19%	-9%
J9351	Hycamtin	$29.68	$17.26	$16.53	-42%	-4%

Medicare experienced more pronounced impacts than the commercial population due to generic product availability. Also, Medicare did not see the same cost-per-unit dynamic as commercial during the second year of generic drug availability and continued to see similar year-over-year cost-per-unit decreases. This might be due to the fact that Medicare typically reimbursed physician offices at ASP + 6 percent, whereas commercial plans paid a higher markup in general to physician offices and in some cases very generous markups for generic non-trending drugs. In addition, as we've seen in previous analyses, reimbursement in the hospital outpatient facility for these drugs was only marginally more expensive than the physician office setting. *See Figure 129: Medicare Spend Impact Due to Generic Drug Introductions for Taxotere and Hycamtin 2011–2013.*

FIGURE 129: Medicare Spend Impact Due to Generic Drug Introductions for Taxotere and Hycamtin 2011–2013

ALLOWED PMPM		YEAR			% CHANGE	
HCPCS CODE	BRAND NAME	2011	2012	2013	11 VS 12	12 VS 13
J9171	Taxotere	$1.09	$0.69	$0.45	-36%	-35%
J9351	Hycamtin	$0.08	$0.03	$0.02	-61%	-32%
COST/PATIENT		YEAR			% CHANGE	
HCPCS CODE	BRAND NAME	2011	2012	2013	11 VS 12	12 VS 13
J9171	Taxotere	$8,761	$6,523	$4,168	-26%	-36%
J9351	Hycamtin	$10,094	$3,899	$2,502	-61%	-36%
COST/UNIT		YEAR			% CHANGE	
HCPCS CODE	BRAND NAME	2011	2012	2013	11 VS 12	12 VS 13
J9171	Taxotere	$21.43	$13.86	$9.53	-35%	-31%
J9351	Hycamtin	$18.22	$9.00	$4.63	-51%	-49%

In February 2008, the FDA granted accelerated approval of Avastin for use in combination with paclitaxel to treat patients who had not received chemotherapy for metastatic HER2-negative breast cancer. By November 2011, FDA Commissioner Margaret Hamburg revoked the agency's accelerated approval of the breast cancer indication for Avastin. During this time and after, the National Comprehensive Cancer Network (NCCN) breast cancer guideline committee continued to support the use of Avastin in combination with paclitaxel to treat recurrent or metastatic HER2-negative breast cancer that hadn't been treated with chemotherapy. In 2014, the NCCN expanded its support and included use in progressive breast cancer with no clinical benefit after three consecutive endocrine therapies. Although this indication was compendia-supported, Avastin spend for members with metastatic breast cancer drastically decreased since 2009. In 2013, commercial and Medicare plans paid 4 percent and 2 percent, respectively, of their overall Avastin spend for metastatic breast cancer. *See Figure 130: Avastin Allowed Amount PMPM for Metastatic Breast Cancer 2009–2013 by LOB.*

FIGURE 130: Avastin Allowed Amount PMPM for Metastatic Breast Cancer 2009–2013 by LOB

ALLOWED PMPM	YEAR				
LOB	2009	2010	2011	2012	2013
Commercial	$0.37	$0.34	$0.20	$0.08	$0.06
Medicare	$0.37	$0.30	$0.14	$0.10	$0.05

Medical Benefit Drug Pipeline and Legislative Trends

Drug Pipeline

FIGURE 131: Medical Benefit Drugs Approved in 2014[8]

BRAND NAME	GENERIC NAME	APPROVAL DATE	ROUTE OF ADMINISTRATION	INDICATION	DISEASE STATE PREVALENCE (IN THE U.S.)	ESTIMATED COST (AWP)[9]	ADDITIONAL COMMENTS
Vimizim	elosulfase alfa	2/14/2014	Intravenous (IV) infusion	Mucopolysaccharidosis type IVA-Morquio A syndrome	800 patients	$380,000 per year	Rare disease
Alprolix	coagulation factor IX (recombinant), Fc fusion protein	3/28/2014	IV infusion	Hemophilia B	3,300 patients	Dose dependent; $2.85 per unit; approx. $300,000 per year	First long-acting recombinant product for factor IX deficiency; allows dosing every 7–10 days
Cyramza	ramucirumab	4/21/2014	IV infusion	Advanced gastric cancer	Approx. 22,220 patients diagnosed with stomach cancer in 2014	Approx. $75,000–$100,000 for 6 months of therapy, based on body weight	Vascular endothelial growth factor-2 (VEGF2) inhibitor; first FDA-approved therapy for this indication
Sylvant	siltuximab	4/23/2014	IV infusion	Multicentric Castleman's disease (MCD)	Approx. 1,100–1,300 patients	Approx. $153,000 per year, based on body weight	First drug to be approved for MCD
Entyvio	vedolizumab	5/20/2014	IV infusion	Moderate to severe ulcerative colitis and Crohn's disease in adults	Approx 1.4 million patients with inflammatory bowel disease	Approx. $35,000 for 6 doses (1 year of maintenance therapy)	Integrin receptor antagonist thought to be gut-selective
Eloctate	antihemophilic factor (recombinant), Fc fusion protein	6/6/2014	IV infusion	Hemophilia A	16,000 patients	Dose dependent; $1.98 per unit; approx. $550,000 per year	First long-acting recombinant factor VIII product; allows dosing every 3–5 days
Beleodaq	belinostat	7/3/2014	IV infusion	Peripheral T-cell lymphoma (PTCL)	Approx. 8,000–10,000 patients	Approx. $277,700 for 6 months of therapy, based on BSA	Histone deacetylase inhibitor; approval based on tumor response rate and duration of response
Ruconest	conestat alfa	7/17/2014	Slow IV infusion	Acute attacks of hereditary angioedema (HAE)	6,000–10,000 HAE patients	Approx. $11,400 per dose	Orphan drug status; first recombinant C1 esterase inhibitor therapy
Keytruda	pembrolizumab	9/4/2014	IV infusion	Advanced or unresectable melanoma	76,100 patients	Approx. $75,000 per 6 months of therapy	First programmed cell death 1 (PD1) inhibitor to market in U.S.
HyQvia	immune globulin (IG) with recombinant human hyaluronidase	9/12/2014	SQ infusion	Primary immunodeficiency (PI)	500,000 patients	Not yet available	First SQ IG for PI; every 3–4 weeks SQ infusion to 1 site
Obizur	antihemophilic factor (recombinant) porcine sequence	10/24/2014	IV infusion	Acquired hemophilia type A	Approx. 300 patients diagnosed per year	Not yet available	Orphan drug status due to rarity of acquired hemophilia type A
Lemtrada	alemtuzumab	11/14/2014	IV infusion	Relapsing forms of multiple sclerosis	More than 400,000 patients	$158,000 per 2-course treatment	Initial dosage of 5 consecutive days, then 3 days 1 year later
Blincyto	blinatumomab	12/3/2014	IV infusion	Philadelphia chromosome negative (Ph-) relapsed/refractory B-cell precursor acute lymphoblastic leukemia (ALL)	More than 66,000 patients with 6,000 new cases diagnosed in 2014	$178,000 per year	First bispecific T-cell engager (BiTE) antibody specific to CD19 and CD3; approved under accelerated approval 6 months early
Opdivo	nivolumab	12/22/2014	IV infusion	Metastatic melanoma	Approx. 76,100 Americans diagnosed in 2014	$12,500 per month or $150,000 per year	PD1 inhibitor immunotherapy

8. New drug approvals and pricing information accurate as of February 2015 print date.

9. Drug cost information was obtained from publicly available sources.

FIGURE 132: Medical Benefit Drug Pipeline

THERAPEUTIC CATEGORY	DRUG	MECHANISM OF ACTION	INDICATION	ROUTE OF ADMINISTRATION	EXPECTED APPROVAL DATE	ADDITIONAL COMMENTS
Autoimmune disorders	brodalumab	IL-17a inhibitor	Moderate to severe plaque psoriasis	SQ injection	2015	AMAGINE-3 is a head-to-head trial with Stelara
Bleeding disorders	BAX 855	Recombinant factor VIII	Hemophilia A	IV infusion	2015	Extended half-life; recombinant factor VIII (pegylated form of Advate)
Muscular dystrophy	eteplirsen	Morpholino antisense oligomer (triggers excision of exon 51)	Duchenne muscular dystrophy (DMD)	IV infusion	2015	Orphan drug status, fast track designation
Oncology	necitumumab	Epidermal growth factor receptor (EGFR) inhibitor	Metastatic squamous non-small cell lung cancer (NSCLC)	IV infusion	Early 2015	Squamous cell represents 30% of all NSCLC
Oncology	talimogene laherparepvec	Oncolytic virus immunotherapy	Malignant melanoma	Intra-tumoral injection	2015–2016	First oncolytic virus
Oncology	bavituximab	Phosphatidylserine (PS) targeting monoclonal antibody	Late stage non-squamous NSCLC	IV infusion	2015	Fast track designation
Oncology	elotuzumab	Cell surface (CS) 1 glycoprotein binder	Multiple myeloma	IV infusion	2015	Breakthrough therapy designation
Oncology	daratumumab	IgG1x antibody that targets CD38	Multiple myeloma	IV infusion	2015	Breakthrough therapy designation
Oncology	volasertib	Polo-like kinase (PLK) 1 inhibitor	Acute myeloid leukemia (AML)	IV infusion or oral	2015	Breakthrough therapy designation
Rare diseases	sebelipase alfa	Recombinant lysosomal acid lipase (LAL) enzyme replacement therapy	LAL deficiency	IV infusion	2015	Fast track and breakthrough therapy designations

MEDICAL BENEFIT DRUG PIPELINE FORECAST

The pipeline for specialty medical benefit drugs is robust, with many novel, breakthrough therapies. Specifically in the area of oncology, the programmed cell death 1 (PD1) and programmed death-ligand 1 (PD-L1) inhibitors offer unique, new mechanisms of action to treat cancer with immunotherapies. Numerous agents in this class in the pipeline treat a variety of cancers, including malignant melanoma, NSCLC, RCC, Hodgkin's lymphoma, bladder cancer and head and neck cancer. Many additional agents in this class currently are in clinical trials and will move into the pipeline for 2016. Several other advanced, targeted mechanisms of action are being studied in the area of oncology therapies, with many new drugs on the horizon, making this the largest therapeutic area of growth in the pipeline currently and in the near future.

Several agents are in development for hemophilia bleeding disorders. Recombinant therapies to extend half-life and prolong time between infusions are emerging. Additional therapies to treat many different forms of hemophilia also are being studied.

Muscular dystrophy is an unexpected area of development, with several agents being studied specifically for Duchenne muscular dystrophy (DMD).

The category of rare diseases continues to be an area of growth with many agents in development. These drugs have unique, new pathways to treat small incidence diseases and they can significantly improve quality of life for these patients.

In summary, the pipeline continues to grow with a variety of medications that offer significant clinical improvements over existing therapies. Preparing for the impact of these new agents in the market remains an important consideration in medical benefit drug management.

Key Legislative Outcomes and Management Trends

REIMBURSEMENT POLICY UPDATES

Over the next 10 years, the Affordable Care Act (ACA) is expected to expand health care coverage to approximately 30 million individuals who most likely would have had limited access to insurance prior to the law's implementation. While 2013 largely was spent anticipating open enrollment in the exchanges and for state decisions on Medicaid expansion, the focus in 2014 shifted to payment reform and cost containment issues with expectations for policies on biosimilars, payment reform and the 340B program.

BIOSIMILARS

Biosimilar biologics (known commonly as biosimilars) have come to the forefront of health policy discussions as the potential for biosimilar competition becomes a reality. The ACA included the Biological Price Competition and Innovation (BPCI) Act,[10] which created an abbreviated approval pathway for biosimilars, analogous to the generic drug pathway passed under the Hatch-Waxman Act of 1984.[11] The BPCI grants reference products 12 years of exclusivity, after which the U.S. Food and Drug Administration (FDA) may approve a biosimilar under this pathway. The FDA is expected to approve the first biosimilar product in early 2015, a supportive cancer therapy: filgrastim.[12] However, it is important to note that as of January 2015, the FDA had not finalized guidance for the biosimilar pathway nor issued any guidance on interchangeability.

The European Union (EU) was the first region to create a biosimilar regulatory pathway and has authorized the sale of biosimilars since 2006. Specifically, EU regulations grant reference products 10 years of exclusivity, after which a biosimilar can be licensed and sold. To date, the EU has authorized 17 biosimilars.[13] Several other countries followed the EU's lead and have established regulatory pathways for the approval and sale of biosimilars: Australia, Canada, Japan, Turkey, Singapore, South Africa and Taiwan.[14] In the EU, biosimilars are on average 30 percent lower in price than branded biologics and are estimated to save between $11.8 billion and $33.4 billion euros in eight EU countries from 2007–2020.[15]

Some stakeholders believe biosimilars will have similar success to that seen in the EU and to the generic drug market. The Generic Pharmaceutical Association (GPhA) estimates that over the past decade (2002–2011) generic drugs have saved the American health care system about $1 trillion.[16] However, while stakeholders may compare biosimilars to generic drugs or label biosimilars as generic biologics, there are significant scientific and manufacturing challenges to ensuring that a biosimilar is equivalent to the innovator product. Due to inherent differences between biosimilar and innovator products, there are concerns that clinical efficacy and side effects might be different with biosimilars compared to the reference products. Pharmacy substitution policies regarding biosimilars have received significant attention, and states have been active with legislation on the topic. For example, eight states have passed legislation and 14 states have pending legislation defining when a biosimilar may be substituted for a reference biologic.[17] The main issues defined in such legislation include whether 1) the FDA has determined the biosimilar is interchangeable, 2) the pharmacy needs to notify the prescribing physician or patient of substitution and 3) the prescriber indicating "brand medically necessary" blocks the pharmacist's ability to substitute.

Incentives or disincentives to use biosimilars in the U.S. based on reimbursement and cost sharing still are largely speculative, except under the Medicare Part B program. The statute specifically sets reimbursement for Medicare Part B physician-administered biosimilars at ASP + 6 percent of the reference product's ASP, a dynamic significantly different from the brand/generic multi-source ASP and AWP dynamics. It is unclear if there is potential for CMS to address interchangeable biosimilars differently from biosimilars; the statute does not differentiate and only addresses biosimilar reimbursement under Medicare Part B.

10. Biologics Price Competition and Innovation Act of 2009, Pub. L. 111–148, 124 Stat. 119.

11. Drug Price Competition and Patent Restoration Act of 1984, Pub. L. 98-417, 98 Stat. 1585.

12. Novartis. FDA accepts Sandoz application for biosimilar filgrastim. July 24, 2014. Accessed: http://www.novartis.com/newsroom/media-releases/en/2014/1835571.shtml.

13. European Medicines Agency. European public assessment reports. Accessed: http://www.ema.europa.eu/ema/index.jsp?curl=pages%2Fmedicines%2Flanding%2Fepar_search.jsp&murl=menus%2Fmedicines%2Fmedicines.jsp&mid=WC0b01ac058001d124&searchTab=searchByAuthType&alreadyLoaded=true&isNewQuery=true&status=Authorised&status=Withdrawn&status=Suspended&status=Refused&keyword=Enter+keywords&searchType=name&taxonomyPath=&treeNumber=&searchGenericType=biosimilars&genericsKeywordSearch=Submit.

14. European Commission. What you need to know about biosimilar medicinal products. Accessed: http://ec.europa.eu/enterprise/sectors/healthcare/files/docs/biosimilars_report_en.pdf.

15. Haustein R, de Millas C, Höer A, Häussler B. Saving money in the European healthcare systems with biosimilars. *Generics and Biosimilars Initiative Journal.* 2012;1(3-4);120-6. Accessed: http://gabi-journal.net/saving-money-in-the-european-healthcare-systems-with-biosimilars.html.

16. Generic Pharmaceutical Association. New study finds generic prescription drugs saved consumers and the U.S. health care system $1 trillion over past decade. Accessed: http://www.gphaonline.org/gpha-media/press/new-study-finds-generic-prescription-drugs-saved-consumers-and-the-u-s-health-care-system-1-trillion-over-past-decade.

17. National Conference of State Legislatures. State laws and legislation related to biologic medications and substitution of biosimilars. August 2014. Accessed: http://www.ncsl.org/research/health/state-laws-and-legislation-related-to-biologic-medications-and-substitution-of-biosimilars.aspx#2013-14.

MARKETPLACE: EXPERIMENTING WITH PAYMENT SYSTEMS

The delivery of health care's triple aim — improving the experience of care, improving the health of populations and reducing per capita costs of health care — has been a goal of public and private entities for more than a decade. The ACA focused mainly on increasing insurance coverage as a way to improve the health of populations and improve the care experience; however, only a few provisions under the ACA worked to reduce per capita costs of care. Two of the most significant cost-focused provisions of the ACA were 1) the creation of the Medicare Shared Savings Program (MSSP) Accountable Care Organizations (ACOs) and 2) the creation of the Center for Medicare & Medicaid Innovation (CMMI), a sub-agency under CMS tasked with authorizing, evaluating and scaling payment reform demonstrations in both Medicare and Medicaid programs. CMMI has undertaken many significant payment reform initiatives: CMMI implemented the MSSP ACOs, created an additional category of ACOs (the Pioneer ACOs), provided grant monies for two rounds of health care innovation awards and now is developing shared savings arrangements in various specialties, starting with oncology.

Medicare ACOs

Both of the Medicare ACO programs are currently in their third years and early results indicate mild successes. *(For information on the design of each program, see Figure 133: Medicare ACOs.)* In September 2014, CMS released results from year 1 of the MSSP program and year 2 of the Pioneer program.[18] MSSP ACOs found modest savings for the Medicare program, with 53 of the original 220 MSSP ACOs holding spending below the targets by $652 million and earning shared savings performance payments of more than $300 million. Overall, the Medicare program will save about $345 million. An additional 53 ACOs reduced health costs compared to their benchmarks, but did not qualify for shared savings, as they did not meet the minimum savings threshold of 2 percent. The MSSP ACOs improved on 30 of 33 quality measures. Pioneer ACOs generated estimated total model savings of more than $96 million and qualified for shared savings payments of $68 million. Pioneer ACOs saved the Medicare Trust Fund approximately $41 million. Pioneer ACOs achieved lower per capita growth in spending for the Medicare program at 1.4 percent, which is about 0.45 percent lower than Medicare fee-for-service (FFS). Eleven Pioneer ACOs earned shared savings, three generated shared losses and three elected to defer reconciliation until after the completion of performance year 3.

While these savings are small in comparison to total Medicare payments of $583 billion in 2013, cost containment in the Medicare program is a needed accomplishment.

FIGURE 133: Medicare ACOs

	PIONEER ACOs	MSSP ACOs
Minimum Population per ACO	15,000 (5,000 if rural)	5,000
Risk	Shared risk by 2nd year; population-based payment in 3rd year	Bonus only or shared risk
Total Population (Medicare and non-Medicare)	50% of all revenues must be in ACO-like arrangements by end of 2nd year	No requirements
Selection of ACOs	Competitive: chosen by CMMI on experience and readiness	Any that meets program requirements
Share of Savings	Higher	Lower

Patient-Centered Medical Homes

In general, all oncology patient-centered medical homes (PCMHs) use evidence-based guidelines, care plans and processes; invest in infrastructure changes to provide better care coordination (e.g., EMRs, round-the-clock nursing availability) and document performance to facilitate measurement and accountability. While no specific payment methodology accompanies oncology PCMHs, some payors, including CMMI, are looking to experiment with monthly per-beneficiary payments to support the cost of needed infrastructure changes to ensure that meaningful care coordination is implemented.

In 2012, CMMI awarded $1 billion to applicants across the country to test new payment and service delivery models designed to deliver better care and lower costs for Medicare, Medicaid or CHIP enrollees over three years. Five of the initial 106 awards were oncology-focused initiatives to develop oncology medical homes or create more robust care models outside of the existing categories of benefits covered by traditional Medicare, Medicaid or CHIP. While highly anticipated, the second set of awards, also totaling $1 billion, did not include any oncology-focused initiatives. Since these programs have not reached maturity — most demonstrations are in the second year — results for the five awards are sparse.

The most closely followed oncology demonstration is the COME HOME demonstration, under which CMMI awarded $19.8 million to Innovative Oncology Business Solutions Inc. (IOBS) to establish PCMHs at seven sites around the country. To date, IOBS has implemented triage pathways at all seven sites and has developed and implemented novel diagnostic

18. Centers for Medicare & Medicaid Services. Medicare ACOs continue to succeed in improving care, lowering cost growth. September 16, 2014. Accessed: http://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2014-Fact-sheets-items/2014-09-16.html.

and therapeutic pathways. Early results show hospitalization rates from a couple of practices dropped by as much as 30 percent.[19] Overall, CMS is expecting IOBS to save CMS $33.4 million; no results have been released marking the progress toward this goal.

Specialty Care Payment Models

CMMI contracted with MITRE, Brookings and RAND to develop frameworks for specialty care payment models. CMMI first focused on oncology and now is exploring options for cardiology and gastroenterology. CMMI's first preliminary model design for oncology care (described below) signals that the agency could pursue retrospective shared-savings like arrangements, similar to some of the MSSP ACO concepts, to redefine how specialty care is reimbursed and encourage infrastructure investment.

In August 2014, CMMI released its draft plan for an Oncology Care Model (OCM)[20] and in February 2015 released a request for applications outlining the final specifications of the program.[21] Through OCM, CMMI aims "to test the effect of better care coordination, improved access to practitioners and appropriate clinical care on improving health outcomes at a lower cost." At its core, OCM is a multi-payor shared savings model encompassing all cancer types based on the total cost of care for a six-month chemotherapy episode.

Payors and Providers

CMMI intends for OCM to be a multi-payor model that includes Medicare FFS (OCM-FFS) and other payors (OCM-OP). Other payors beyond Medicare FFS will be able to participate in OCM by entering into a Memorandum of Understanding (MOU) with CMMI, which acknowledges that there might be differences between OCM-FFS and OCM-OP in certain areas, such as selection of performance-based payment measures.

Providers would be expected to engage in practice transformations, including:

- Employ one or more designated patient navigator/care coordinators,
- Document a care plan that contains the 13 components in the Institute of Medicine Care Management Plan outlined in the Institute of Medicine report "Delivering High-Quality Cancer Care: Charting a New Course for a System in Crisis,"
- Provide and attest to 24-hours-a-day, seven-days-a-week patient access to an appropriate clinician who has real-time access to the practice's medical records,
- Utilize data for continuous quality improvement and
- Use an ONC-certified EHR and attest to Stage 2 of meaningful use by the end of the fourth model performance year.

Payors and providers will apply separately to participate in OCM. CMMI would prioritize practices that would be participating in OCM with Medicare FFS and other payors.

Payment

For participating practices, Medicare FFS would include three different payment types:

- Normal FFS payments (including drug reimbursement at ASP + 6 percent),
- A $160 per-beneficiary-per-month (PBPM) payment to fund the enhanced services required under the model and
- A performance-based payment determined by the practice's achievement of Medicare savings (based on 4 percent savings) and achievement of the performance-based quality measures. Please note: This payment might vary among other — non-Medicare FFS — payors.

For the OCM-FFS, CMMI will calculate risk-adjusted benchmark expenditures based on historical data, trend the benchmark expenditures to the performance period and incorporate a discount that Medicare would retain to set the target price for performance period episodes. Then, CMMI will retrospectively reconcile actual performance period expenditures against the target prices, and participants could be paid up to the full difference through the performance-based payment. (Payment would depend upon attainment of quality measure performance.)

Definition of Episode

OCM will include approximately 90 percent of all cancer cases by targeting high-volume cancer types (at a minimum breast, prostate, lung, colorectal, lymphoma, leukemia, ovarian and pancreatic). OCM-FFS episodes would initiate on the date of an initial chemotherapy administration claim and would include the costs of all Medicare A, B and D services received during the episode period. The episode would terminate six months after a beneficiary's chemotherapy initiation; however, subsequent episodes are possible if chemotherapy continues.

19. Burns J. COME HOME program set to save $33.5M over 3 years. August 25, 2014. OncLive. Accessed: http://www.onclive.com/publications/oncology-business-news/2014/August-2014/COME-HOME-Program-Set-to-Save-335M-Over-3-Years#sthash.PdVAUoqv.dpuf.

20. Center for Medicare & Medicaid Innovation. Preliminary design for an oncology-focused model. Accessed: http://www.advisory.com/~/media/Advisory-com/Research/OR/Blog/2014/CMS%20Innovation%20Center%20oncology%20model%20preliminary%20design%20paper.pdf.

21. Center for Medicare & Medicaid Innovation. Oncology care model (OCM) request for applications (RFA) February 2015. Accessed: http://innovation.cms.gov/Files/x/ocmrfa.pdf.

FIGURE 134: ASCO's Proposed Payments Under CPOC

PAYMENT TYPE	DESCRIPTION
New Patient Payment	Practice receives a single new patient payment to compensate the practice for all of the physician and staff time the practice devotes to initial patient evaluation, treatment planning and patient education, replacing current payments to the practice for CPT-based evaluation and management (E&M). The costs of any diagnostic testing ordered by the practice still would be billed and paid separately.
Treatment Month Payment	Practice receives a single treatment month payment during each month the patient is receiving treatment. This payment would replace all current CPT-based payments for chemotherapy administration, therapeutic injections/infusions, hydration services and established patient E&M visits. The payments would be made if the patients were using oral medications or infused/injected drugs.
Active Monitoring Month Payment	Practice receives an active monitoring month payment each month if the patient still is under the active care of the oncology practice, but does not receive any treatment for cancer during the month.
Transition of Treatment Payment	Practice receives a transition of treatment payment each month in addition to either a treatment month payment or an active monitoring month payment to reflect the additional time involved in treatment planning and patient education when significant changes occur in the patient's disease or treatment plan.

ASCO — Consolidated Payments for Oncology Care

The American Society for Clinical Oncology (ASCO) released its payment reform proposal, Consolidated Payments for Oncology Care (CPOC), in May 2014. Under CPOC, CMS and private health plans would pay an oncology practice a monthly fee for each patient currently under the care of the practice based on the patient's phase of treatment instead of continuing to bill CPT codes separately in an FFS manner. The fees would vary depending on what phase of treatment the patient is in. *See Figure 134: ASCO's Proposed Payments Under CPOC.*

ASCO also proposes to decouple drug price and reimbursement from practice revenue. Reimbursing drugs based on a percentage of ASP incentivizes use of more expensive drugs. ASCO does not provide a specific payment methodology but states payment should 1) reimburse the practice for the cost of purchasing the drugs and 2) provide adequate compensation for the practice's expenses and risk associated with purchasing and maintaining a comprehensive inventory of high-complexity, potentially dangerous, expensive drugs.

In addition to this proposal to create monthly payment bundles based on treatment phase, ASCO is developing a tool for physicians to use to measure the value of treatments based on clinical efficacy, toxicity and cost. ASCO has not publicly released specifics of the rating system and it is unclear how such a tool for physicians would be used.

Commercial Payor Experimentation

While Medicare has not allowed oncology providers to establish ACOs through the MSSP or Pioneer programs, commercial payors have entered into specific ACO-like arrangements with oncology providers to try to improve care coordination and patient satisfaction while controlling costs.

United Healthcare's oncology episode-based payment demonstration, conducted between October 2009 and December 2012, has garnered the most attention.[22] Under this pilot, participating medical oncologists were reimbursed up front for an entire cancer treatment program, marking a shift away from the current FFS approach, which rewards volume or high-cost drug selection. The oncologists were paid the same fee regardless of the drugs administered to the patients, separating the oncologists' income from drug selection. Patient visits were reimbursed as usual, using the FFS contract rates, and chemotherapy medications were reimbursed based on the ASP.

United Healthcare's preliminary results showed that in the episode group, better care coordination led to reduced use of emergency rooms and lower hospitalization rates, which in turn reduced health care spending by 34 percent compared to the control group. Overall, the total cost of care for the 810 patients treated was $64.76 million, $33.36 million lower than the control group. However, the tools used to manage medication costs — pathway adherence and invoice-based reimbursement — did not lead to savings; the demonstration group saw anti-cancer medication expenditures increase by $13.46 million compared to the control group.

Additionally, two oncology ACOs run by Florida Blue, partnering with Baptist Health South Florida/Advanced Medical Specialties in Miami and the Moffitt Cancer Center in Tampa,

22. United Healthcare. New cancer care payment model reduced heath care costs, maintained outcomes. July 8, 2014. Accessed: http://www.uhc.com/news-room/2014-news-release-archive/cancer-care-payment-model.

Florida, have found modest shared savings between payors and providers, but found that drug spending did not change significantly under shared savings arrangements.

As of July 2014, WellPoint began a pilot in six states (Indiana, Kentucky, Michigan, Ohio, Wisconsin and Georgia) that provided incentive payments of $350 per month per patient to oncologists who treated patients with breast, colorectal or lung cancers using treatment regimens that were "on pathway."[23] WellPoint estimated that pathways would be applicable to 80–90 percent of the patients treated.

340B Program

The 340B Drug Pricing Program requires drug manufacturers to provide outpatient drugs to eligible health care organizations/covered entities at significantly reduced prices. The GAO estimates that the 340B program, which started as a small discount drug program to improve access to expensive drugs for indigent patients, accounts for $6 billion in outpatient drug spending, or about 2 percent of U.S. health spending in 2011, which translates into savings of $1.6 billion (assuming Medicaid pricing).[24]

Orphan Drug Exclusion

The ACA expanded eligibility of the 340B program to critical access hospitals, freestanding cancer hospitals, rural referral centers and sole community hospitals.[25] With the expansion, the ACA exempted orphan drugs from 340B program discounts for newly eligible entities. The statute was ambiguous regarding which indications of an orphan product should be exempt from 340B program discounts, which led to Health Resources and Services Administration (HRSA) interpreting the statute to mean only orphan indications of orphan products should be exempt. PhRMA challenged this ruling in the D.C. District Court. In May 2014, the district court ruled in favor of PhRMA, vacating HRSA's substantive rule on the grounds that HRSA did not have the authority to issue the rule, finding that HRSA only had rulemaking authority over administrative dispute resolution processes, methodology for calculating ceiling prices and imposing civil monetary penalties.

Before the D.C. District Court ruled that HRSA did not have broad rulemaking authority in the 340B program, the agency was poised to release what has become known as the "340B megarule." The megarule was supposed to codify much of the subregulatory guidance issued by the agency and address definitions of an eligible patient, compliance requirements for contract pharmacy arrangements, hospital eligibility criteria and eligibility of off-site facilities. HRSA stated it is exploring options for releasing the megarule, as it believes this rule is necessary for the continued success of the 340B program.

340B Oversight

Controversy continues about oversight of the 340B program. In 2011, a GAO report described federal oversight of the program as insufficient to ensure that hospitals and drug companies were adhering to the rules.[26] In response, HRSA undertook hospital audits for the first time in the program's history, auditing 51 hospitals in 2012, and made all hospitals recertify themselves as eligible for the program. Pharmaceutical companies continue to ask for more oversight and clarification regarding appropriate use of 340B drug discounts. Additionally, HRSA continues to encourage states to clarify Medicaid billing procedures to prevent duplicate billing. A number of states revised these provisions in 2014.

Site of Service Shifts — 340B Pricing and Hospital Incentives

The 340B program rules allow a covered entity hospital to expand its purchasing and dispensing of 340B drugs to patients treated at new locations, as long as the new locations are integral parts of the hospital and included on the most recent cost reports. In addition, the individuals receiving care at the new locations need to meet each of the components in the definition of a patient. The growing trend of 340B-eligible hospitals acquiring community oncology practices has led to a significant growth in the number of cancer patients treated per 340B hospital. Covered entities have been successful in increasing access to 340B drugs, which has increased 340B prescribing and the number of patients receiving cancer/chemotherapy care in hospital outpatient departments.

Payor Policies Site of Service

Government and commercial payors, including CMS, are concerned about the increase in hospital outpatient services, including oncology services. As of April 1, 2014, Highmark, the largest private insurer in Pennsylvania, implemented a policy to stop reimbursing health systems at higher hospital outpatient rates for cancer treatment performed in physician offices.[27] During the CY 2014 rulemaking process, CMS highlighted press about physician-based practices acquired by hospitals.

23. Nelson R. WellPoint offers oncologists incentives to follow pathways. June 12, 2014. Medscape. Accessed: http://www.medscape.com/viewarticle/826681.

24. U.S. Government Accountability Office. Manufacturer discounts in the 340B program offer benefits, but federal oversight needs improvement. September 23, 2011. Accessed: http://www.gao.gov/products/GAO-11-836.

25. Sections 7101-7103, Patient Protection and Affordable Care Act of 2010, Pub. 111-148.

26. U.S. Government Accountability Office. Manufacturer discounts in the 340B program offer benefits, but federal oversight needs improvement. September 23, 2011. Accessed: http://www.gao.gov/products/GAO-11-836.

27. Nixon A. Highmark won't pay hospital rates for care in physician offices. February 26, 2014. Accessed: http://triblive.com/business/headlines/5666639-74/highmark-health-hospital#axzz2wFpD9liz.

CMS expressed concern that beneficiaries were liable for additional facility fees when these physician practices were located within a hospital department. CMS continues to seek a better understanding of how the growing trend of hospital acquisitions of physician offices and subsequent treatment of these locations as off-campus, provider-based outpatient departments affect payments under the Medicare Physician Fee Schedule (MPFS) and the Hospital Outpatient Prospective Payment System, as well as beneficiary cost sharing.

The Protecting Access to Medicare Act of 2014 (Pub. L. 113-93) (PAMA) granted CMS the authority to engage in data collection to support valuation of services paid under MPFS. To understand how this trend is affecting Medicare, including the accuracy of payments made through the MPFS, CMS needs to analyze data to assess the extent to which this shift toward hospital-based physician practices is occurring. Beginning in 2015, CMS will collect information on the type and frequency of physician services and outpatient hospital services at off-campus, provider-based departments. CMS also will require the use of place-of-service (POS) and HCPCS modifiers to identify services provided at on-campus hospital outpatient departments versus off-campus, provider-based departments. The modifiers would be reported on both CMS-1500 claim forms for physician services and UB-04 forms (CMS Form 1450) for hospital outpatient services.

MOLECULAR DIAGNOSTICS

Molecular diagnostics are becoming a bigger focus of personalized medicine and personalized cancer care, and payor policies surrounding coding, coverage and reimbursement continue to evolve. In 2014, PAMA's one-year sustainable growth rate (SGR) fix created a pathway for more centralized Medicare coverage and pricing for advanced diagnostics, which are defined as sole source multi-analyte tests with unique algorithms that yield a single result or tests that are cleared or approved by the FDA.[28] Under PAMA, CMS will set payment rates for advanced diagnostics based on the median payment rates from private payors. Applicable laboratories will be required to report payment rates beginning in 2016, for use in setting payment rates beginning in 2017.

Palmetto's MolDX program continues to take the lead in setting coverage and reimbursement policies for molecular diagnostics and uniquely allows for differential payments for FDA-approved test kits. Palmetto, a Medicare Administrative Contractor, began the MolDX program in 2011 to identify specific diagnostics, gather data on clinical validity and utility via technology assessments and provide higher reimbursements for tests demonstrating clinical utility and undergoing FDA approval. Currently, the MolDX program only applies to those Medicare jurisdictions in which Palmetto processes claims (J-11: North Carolina, South Carolina, Virginia and West Virginia) or recently processed claims (J-E: California, Nevada and Hawaii).*

In the molecular diagnostics arena, an issue to watch is the FDA's role in regulating laboratory-developed tests (LDTs). While these tests will not be priced based on the policies created under PAMA, the FDA released draft guidance stating its intent to regulate certain LDTs.[29] Such regulation has the potential to significantly change the landscape of molecular diagnostics. To date, the coding nomenclature does not differentiate LDTs versus FDA-approved test kits, with the exception of the unique Palmetto MolDX program and unique related nomenclature. As molecular diagnostics are used more and more to drive treatment decisions, payors and regulators are becoming increasingly interested in understanding exactly what information is being provided and how it should be reimbursed.

**When Noridian took over as the Medicare Administrative Contractor for J-E, it contracted with Palmetto to keep the MolDX program in place.*

28. Section 216, Protecting Access to Medicare Act of 2014, Pub. L. 113-93.

29. U.S. Dept. of Health & Human Services. Framework for regulatory oversight of laboratory-developed tests (LDTs). July 31, 2014. Accessed: http://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/UCM407409.pdf.

Glossary

AAOS . . . . . American Academy of Orthopaedic Surgeons
ACA . . . . . Affordable Care Act
ACO . . . . . accountable care organization
aHUS . . . . . atypical hemolytic uremic syndrome
ALL . . . . . acute lymphoblastic leukemia
AMD . . . . . age-related (wet) macular degeneration
AML . . . . . acute myeloid leukemia
ASCO . . . . . American Society for Clinical Oncology
ASP . . . . . average sales price
AWP . . . . . average wholesale price
BiTE . . . . . bispecific T-cell engager
BPCI . . . . . Biological Price Competition and Innovation
BSA . . . . . body surface area
CD . . . . . cluster of differentiation
CHIP . . . . . Children's Health Insurance Program
CINV . . . . . chemotherapy-induced nausea and vomiting
CMMI . . . . . Center for Medicare & Medicaid Innovation
CMS . . . . . Centers for Medicare & Medicaid Services
CNS . . . . . central nervous system
CPOC . . . . . Consolidated Payments for Oncology Care
CPT . . . . . Current Procedural Terminology
CS . . . . . cell surface
CSF . . . . . colony-stimulating factor
CY . . . . . calendar year
DMD . . . . . Duchenne muscular dystrophy
EGFR . . . . . epidermal growth factor receptor
EHR . . . . . electronic health record
E&M . . . . . evaluation and management
EMR . . . . . electronic medical record
ER . . . . . emergency room
ESA . . . . . erythropoiesis-stimulating agent
ESRD . . . . . end-stage renal disease
EU . . . . . European Union
FDA . . . . . U.S. Food and Drug Administration
FFS . . . . . fee for service
GAO . . . . . U.S. Government Accountability Office
GPhA . . . . . Generic Pharmaceutical Association
HA . . . . . hyaluronic acid
HAE . . . . . hereditary angioedema
HCPCS . . . . . Healthcare Common Procedure Coding System
HDAC . . . . . histone deacetylase
HEC . . . . . highly emetogenic chemotherapy
HER2 . . . . . human EGFR 2
HMO . . . . . health maintenance organization
Home Inf. . . . . home infusion
HRSA . . . . . Health Resources and Services Administration
ICD . . . . . International Classification of Diseases
IG . . . . . immune globulin
IL . . . . . interleukin
IOBS . . . . . Innovative Oncology Business Solutions Inc.
IV . . . . . intravenous
IVIG . . . . . intravenous immune globulin
LAL . . . . . lysosomal acid lipase
LDT . . . . . laboratory-developed test
LEC . . . . . low emetogenic chemotherapy
LOB . . . . . line of business
MAC . . . . . Medicare Administrative Contractor
MCD . . . . . multicentric Castleman's disease
MEC . . . . . moderately emetogenic chemotherapy
MMA . . . . . Medicare Prescription Drug, Improvement, and Modernization Act or Medicare Modernization Act
MolDX . . . . . Molecular Diagnostic Services
MOOP . . . . . maximum out-of-pocket
MOU . . . . . Memorandum of Understanding
MPFS . . . . . Medicare Physician Fee Schedule
MSSP . . . . . Medicare Shared Savings Program
NCCN . . . . . National Comprehensive Cancer Network
NDC . . . . . National Drug Code
NOS . . . . . not otherwise specified
NSCLC . . . . . non-small cell lung cancer
OCM . . . . . Oncology Care Model
ONC . . . . . The Office of the National Coordinator for Health Information Technology
OP . . . . . other payor
PA . . . . . prior authorization
PAMA . . . . . Protecting Access to Medicare Act
PBM . . . . . pharmacy benefit manager
PBPM . . . . . per beneficiary per month
PCMH . . . . . Patient-Centered Medical Home
PD1 . . . . . programmed cell death 1
PD-L1 . . . . . programmed death-ligand 1
PhRMA . . . . . Pharmaceutical Research and Manufacturers of America®
PI . . . . . primary immunodeficiency
PLK . . . . . polo-like kinase
PMPM . . . . . per member per month
PNH . . . . . paroxysmal nocturnal hemoglobinuria
POS . . . . . place of service
PPO . . . . . preferred provider organization
PS . . . . . phosphatidylserine
PTCL . . . . . peripheral T-cell lymphoma
RCC . . . . . renal cell carcinoma
SGR . . . . . sustainable growth rate
SQ . . . . . subcutaneous
UM . . . . . utilization management
VEGF . . . . . vascular endothelial growth factor
VFS . . . . . variable fee schedule
WAC . . . . . wholesale acquisition cost

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