Magellan Rx Management

Medical Pharmacy Trend Report™

2015 SIXTH EDITION

Magellan Rx MANAGEMENT℠

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Introduction

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

Approximately 50 percent of the $124 billion[1] annual 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 stay current with the evolving management strategies and marketplace conditions impacting medical pharmacy utilization and spend. Over the last six years, Magellan Rx Management's Medical Pharmacy Trend Reports have served this purpose.

Magellan Rx Management's 2015 Medical Pharmacy Trend Report™ data was derived from two complementary sources. First, we surveyed medical, pharmacy, and network directors from 59 commercial payors representing approximately 130 million covered lives. Second, we completed an in-depth analysis of commercial and Medicare health plan medical paid claims data representing utilization across all outpatient sites of service, including physician offices, home infusion providers, specialty pharmacies, and hospital outpatient facilities.

We are excited to present our most comprehensive trend report to date. A number of new enhancements to the report include:

- Payors across the country indicated their process when forecasting medical benefit drugs to provide our readers with a better understanding of what payors are doing today to anticipate shifts in the market caused by the emergence of biosimilars and breakthrough therapies.
- Our first medical benefit drug forecast in the "Medical Benefit Drug Pipeline" section shows the impact of newly approved drugs through 2020 and select drugs yet to be approved.
- Payors provided information on how they are monitoring oncology treatment quality metrics, soon to be requirements of the Center for Medicare & Medicaid Innovation (the CMS Innovation Center) Oncology Care Model.
- We focused on reimbursements across outpatient sites of service, added specialty pharmacy, and identified key cost variances among different provider types for drugs and administration codes.
- Finally, in line with health plans becoming more sophisticated with medical benefit drug management, we enhanced the therapeutic category specific analysis in the medical paid claims data section to include details on spend, market share, and annual costs per patient.

We know you will find our trend report useful and unique. The topics provide valuable insight on current medical benefit drug trends and management issues facing commercial payors. It also includes a "Legislative Reimbursement Policy Updates" 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.MagellanRx.com.**

1. IMS Institute for Healthcare Informatics. Medicines Use and Spending Shifts: A Review of the Use of Medicines in the U.S. in 2014. April 2015. Accessed: http://www.imshealth.com/en/thought-leadership/ims-institute/reports/medicines-use-in-the-us-2014.

Executive Summary

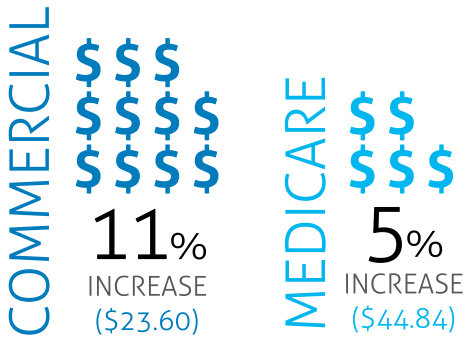
Several management trends and provider dynamics impacted the medical benefit drug landscape in 2015.

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 forward movement was seen with the approval of the first biosimilar in 2015 with many more in the pipeline. Concurrently, new medical benefit drugs continued to enter the market; as this report went to press, the U.S. Food and Drug Administration (FDA) had approved 16 medical benefit drugs in 2015.

KEY FINDINGS[2] IN THE REPORT INCLUDE:

- Commercial per-member-per-month (PMPM) allowed amounts of $23.60 and Medicare PMPM allowed amounts of $44.84 increased 11 and 5 percent, respectively, driven by inflation, utilization, drug mix, and shifts in site of service (***see "Utilization Trends" section***).

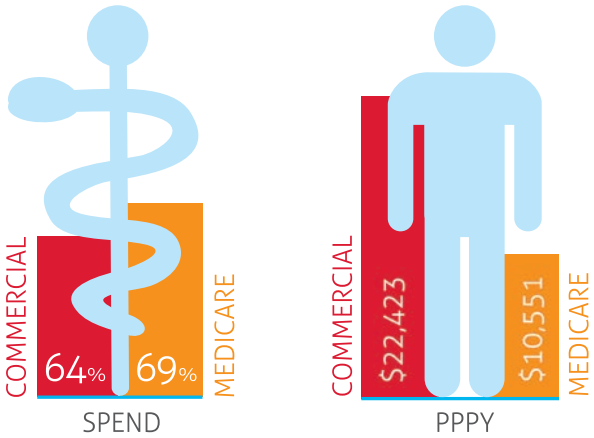
MEDICAL PHARMACY PMPM



- The highest spend categories for commercial in 2014 were oncology and oncology support medications representing 52.8 percent of medical pharmacy costs. Biologic drugs for autoimmune disorders (BDAIDs) represented the next highest spend category at 15.3 percent and included Crohn's disease/ulcerative colitis, rheumatoid arthritis, psoriasis/psoriatic arthritis, systemic lupus erythematosus, and ankylosing spondylitis (***see "Trend Drivers" section***).

- The highest spend categories for Medicare in 2014 included oncology and oncology support medications representing 63.1 percent of medical pharmacy costs. Ophthalmic injections or anti-vascular endothelial growth factor (anti-VEGF) intravitreal injections for the treatment of retina diseases was the second highest at 9 percent (***see "Trend Drivers" section***).

TOP 25 DRUGS



- For the top 25 drugs, the average annual cost for a commercial patient was $22,423, twice that of the Medicare population at $10,551. The top 25 drugs represented 64 percent of the total medical pharmacy spend in 2014 for the commercial population and 69 percent for Medicare (***see "Utilization Trends" section***).

2. The most recent year of medical benefit paid claims data analyzed in our 2015 trend report is from 2014 due to the lag associated with medical benefit claims processing and time needed for publishing.

- In 2014, the annual spend per patient per year (PPPY) for the top 10 highest-cost drugs averaged $353,000 for commercial and $271,000 for Medicare. These patients represented 0.02 percent of commercial and 0.04 percent of Medicare members. The top 10 highest-cost drugs tend to be used for conditions such as hereditary angioedema (HAE), rare hematologic disorders including hemophilia, diseases caused by inborn errors of metabolism, and cancer (***see "Trend Drivers" section***).

- In 2014, 53 percent of costs were billed from the hospital outpatient facility, up from 47 percent in 2010, for commercial and 40 percent, up from 24 percent in 2010, for Medicare (***see "Utilization Trends" section***).

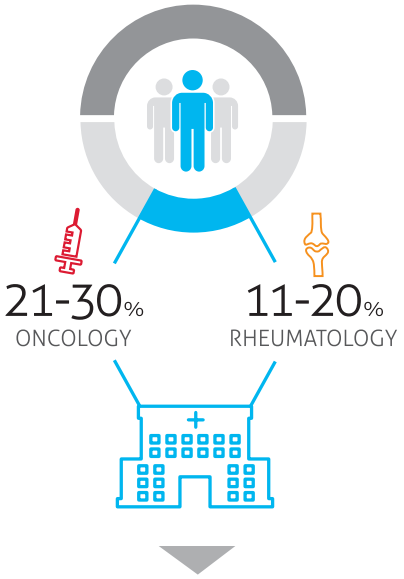
- More than half of payors (54 percent) proactively identified drug spend shifts as a result of major changes anticipated with the emergence of novel pipeline and breakthrough treatments. Although many payors undergo this forecasting, sudden shifts in the market may be an unanticipated challenge (***see "Management Trends" section***).

- Ninety-two percent of payors had product preferencing in place and the three leading therapeutic classes were BDAIDs (67 percent of payors), viscosupplementation, and multiple sclerosis (both 43 percent of payors). These three categories most frequently required step edits implemented as a requirement for rebates (***see "Medical Benefit Product Preferencing" section***).

- Thirteen percent of payors varied member cost-share requirements by drug and 23 percent varied cost-share requirements by site of service in 2015. Of those who did not vary cost share by drug or site of service, 35 and 49 percent said they had the system capability to vary cost-share requirements by drug and site of service, respectively (***see "Benefit Design" section***).

- Commercial medical benefit drug costs in the hospital outpatient setting were often double that of the physician office. 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 and BDAIDs. Often, administrative code reimbursement is four times more expensive in the hospital outpatient setting than the physician office for commercial members; for Medicare, it is frequently twice as costly in the hospital outpatient setting (***see "National Provider Trends" section***).

OFFICE-BASED PRACTICES PURCHASED BY HOSPITALS



- More than 50 percent of payors reported that office-based practices in their service areas were purchased by hospital systems. Of those payors, close to one-third reported that 21 to 30 percent of oncology practices and 11 to 20 percent of rheumatology practices had been acquired by hospitals. This phenomenon has yet to slow as a cost driver in this space and is increasingly affecting more practice types (***see "Provider Network Landscape" section***).

- More than 60 percent of payors provided 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, similar to last year, 95 percent of payors had no knowledge of their plan's percentage, indicating a need for better data capture around this measure (***see "Management Trends" section***).

2015 Report Methodology and Demographics

The methodology for the sixth 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 results of this study were a combination of findings from medical, pharmacy, and network directors at commercial payors as well as medical benefit paid claims data across key lines of business (i.e., commercial and Medicare) and outpatient sites of service (i.e., physician offices, homes via home infusion, specialty pharmacies, and hospital outpatient facilities).

The 2015 trend report contains four sections: 1) payor survey data, 2) health plan claims data, 3) medical benefit drug pipeline report, and 4) a legislative update section, which is included to provide insights into the effects of current government initiatives on the medical pharmacy benefit.

PAYOR SURVEY

Payor survey data was collected from a target list of payors consisting of top U.S. health plans based on number of lives. Data collection took place in June and July 2015 through a custom market research survey consisting of topics ranging from benefit design and distribution practices to utilization and management trends. Research topics were developed and aligned with six key management dynamics for medical benefit drugs. Validated results were analyzed based on percentage of payors or lives. Some weighting of results by number of lives was used to provide insights into marketplace impact of payor policies. Respondents of the survey included pharmacy and medical directors representing 129.7 million covered lives, an increase of 4.6 million lives compared to the 2014 report. Methodology for analyses of survey data included stratification of sample by covered lives, small versus large plans, and respondent type (e.g., medical, pharmacy, or network directors).

Last year's report identified seven key management dynamics, adding "management trends." In the 2015 report, "operational improvements" has been reallocated to "utilization management."

SURVEY RESPONDENT DEMOGRAPHICS

For the 2015 survey, a total of 59 respondents from unique plans representing 129.7 million covered lives participated. Close to half of respondents (46 percent) represented payors with less than 500,000 lives, while the next largest (27 percent) represented 1 to 5 million lives. Five payor respondents represented nearly two-thirds (63 percent) of covered lives in the survey (***see Table 1***).

TABLE 1: 2015 Respondent Sample

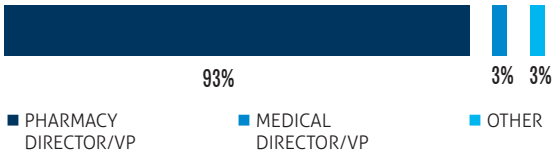
Covered Lives	Respondent Count	Total Respondent Lives	Total Lives (%)
Less Than 500,000	27	5,214,945	4%
500,000 to 999,999	11	7,560,000	6%
1,000,000 to 4,999,999	16	34,750,000	27%
5,000,000 or More	5	82,200,000	63%
TOTAL	**59**	**129,724,945**	**100%**

Year-over-year, 58 percent of payor organizations that responded in 2015 also responded to the 2014 survey. Experience level among respondents remained high, with an average of 23 years in the field and nine years in their current position. Unlike previous years, almost all respondents identified as pharmacy directors or vice presidents (93 percent); in addition, there was representation from medical directors. Medical directors responding identified as surgeons and physical medicine and rehabilitation (PM&R) practitioners. "Other" survey respondents represented operations and clinical services (***see Figure 1***).

FIGURE 1: 2015 Represented Specialties

% PAYORS

n=59 payors, 130 million covered lives



Survey respondents from national plans constituted 10 percent of payors, but represented 40 percent of total lives covered. Regional plans accounted for the other 60 percent of covered lives. These lives were split between fully insured lives (53 percent) and administrative services only lives (47 percent). Respondents indicated the majority of their members were covered under either a mixed HMO/PPO model (62 percent) or HMO model (30 percent). The balance of lives was covered under integrated delivery network (IDN), PPO, or staff/group models (*see Figure 2*).

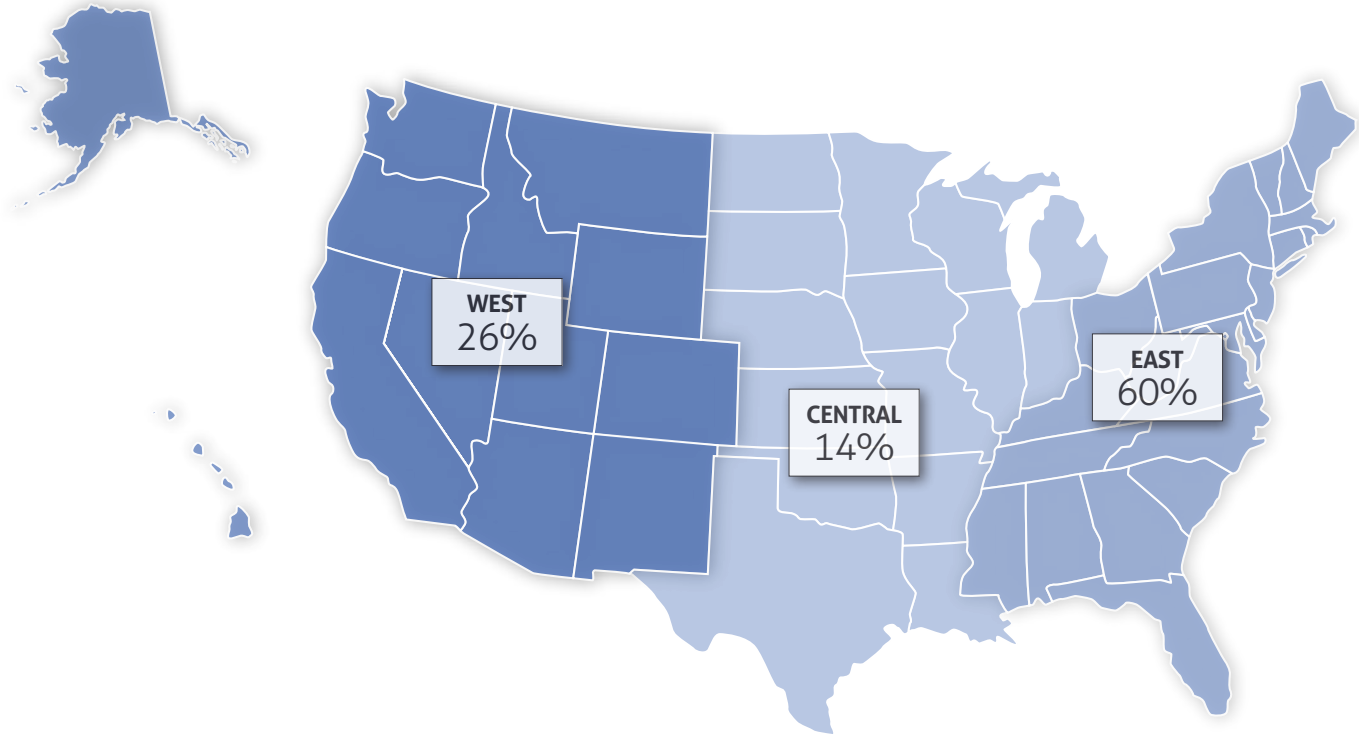
FIGURE 2: 2015 Organizational Model/Coverage Type

% PAYORS

n=59 payors, 130 million covered lives

The following map illustrates the geographic distribution of lives, showing more than half of the lives covered (60 percent) are located in the East (*see Figure 3*). This mirrors the 2014 report when 54 percent of lives were located in the East.

FIGURE 3: 2015 Regional Plans – Geographic Dispersion of Lives



DISEASE STATE OR DRUG CATEGORY REPRESENTED

Therapeutic classes represented in the survey were inclusive of current medical benefit drugs. To ensure accuracy of responses, payor respondents were given examples of drugs for each of the categories presented (*see Table 2*).

TABLE 2: Medical Benefit Drug Examples by Disease State or Drug Category in Payor Survey

Disease State or Drug Category	Example Drugs
Alpha-1-Antitrypsin Deficiency	Aralast, Glassia, Prolastin, Zemaira
Antiemetics: Chemotherapy-Induced Nausea and Vomiting (CINV)	Aloxi, Zofran IV, Kytril IV
Antihemophilic Factors	Advate, Xyntha, Recombinate
Anti-Vascular Endothelial Growth Factors (Anti-VEGFs)	Avastin, Zaltrap
Asthma	Xolair
Biologic Drugs for Autoimmune Disorders (BDAIDs)	Remicade, Orencia, Cimzia, Actemra, Simponi ARIA, Stelara
Bone Resorption Inhibitors: Oncology	Zometa, Aredia, Xgeva
Bone Resorption Inhibitors: Osteoporosis	Reclast, Boniva, Prolia
Botulinum Toxins	Botox, Xeomin, Dysport, Myobloc
Colony-Stimulating Factors (CSFs)	Neulasta, Neupogen, Leukine, Granix
Enzyme Replacement Therapy	Vpriv, Cerezyme, Elelyso
Erythropoiesis-Stimulating Agents (ESAs)	Aranesp, Procrit, Epogen
Folinic Acids	Leucovorin, Fusilev
Hereditary Angioedema	Cinryze, Berinert, Kalbitor
Intravenous Immune Globulin (IVIG)	Gamunex, Gammagard Liquid
Multiple Sclerosis	Tysabri
Oncology	Cytotoxic agents, Biologics, GnRH agents
Ophthalmic Injections	Lucentis, Eylea, Macugen, Avastin (bevacizumab)
Pulmonary Arterial Hypertension	Flolan, Remodulin, Revatio IV, Veletri, Tyvaso, Ventavis
Respiratory Syncytial Virus (RSV) Prevention	Synagis
Taxanes	Taxol, Abraxane
Viscosupplementation	Orthovisc, Synvisc, Supartz, Hyalgan, Euflexxa, Gel-One, Monovisc

HEALTH PLAN CLAIMS DATA

Health plan claims data were collected through secondary analyses of commercial and Medicare health plan medical paid claims data. Claims data were analyzed for medical pharmacy utilization across all outpatient sites of service, including the physician office, home infusion, specialty pharmacy, and hospital outpatient facility. Claims billed from participating and non-participating providers were included. Vaccines and radiopharmaceuticals were excluded from the analyses. Administration codes were analyzed separately in only one analysis (*see Tables 16 and 17*); their utilization was not included in any other analysis. Most analyses compared calendar years 2013 and 2014. In some cases, the past five years (2010 to 2014) were analyzed to show a longer period of year-over-year spend and trend.

Payor Trends Survey Data

Medical Benefit Product Preferencing

SUMMARY

> Ninety-two percent of payors have medical benefit product preferencing in place.

> Small plans tend to have product preferencing at higher rates than large plans.

PRODUCT PREFERENCING

Although rare for commercial payors to have a drug formulary for the medical benefit similar to formularies used for the pharmacy benefit, commercial payors do utilize tools to manage and preference products on the medical benefit. In line with this and to clarify the intent of this section, we termed this line of questions as medical benefit product preferencing versus medical benefit and drug formulary, as seen in previous trend reports.

Preferencing can mirror the pharmacy benefit with tools such as step edits and prior authorizations (PAs), but also includes provider reimbursement, policy/guideline criteria, and others. In 2015, almost all payors (92 percent) representing three-quarters of lives (76 percent) indicated they used one of these tools to manage their medical benefit products (*see Figure 4*).

In line with findings of the 2014 survey, small plans had more product preferencing in place over large plans. Of small plans, almost all (96 percent) had some medical benefit product preferencing; of large plans, the majority, although a smaller proportion (88 percent) have product preferencing (*see Figure 5*).

FIGURE 4: 2015 Payors with Medical Benefit Product Preferencing in Place

n=59 payors, 130 million covered lives

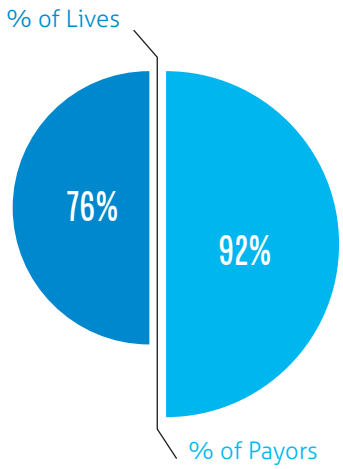
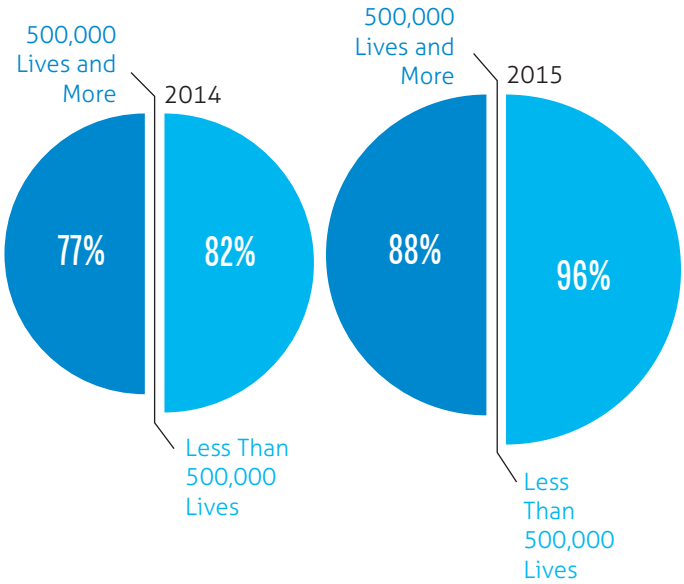


FIGURE 5: Medical Benefit Product Preferencing in Place by Plan Size 2014-2015

% PAYORS

n=38 payors, 113 million lives (2014); n=54 payors, 98 million lives (2015)

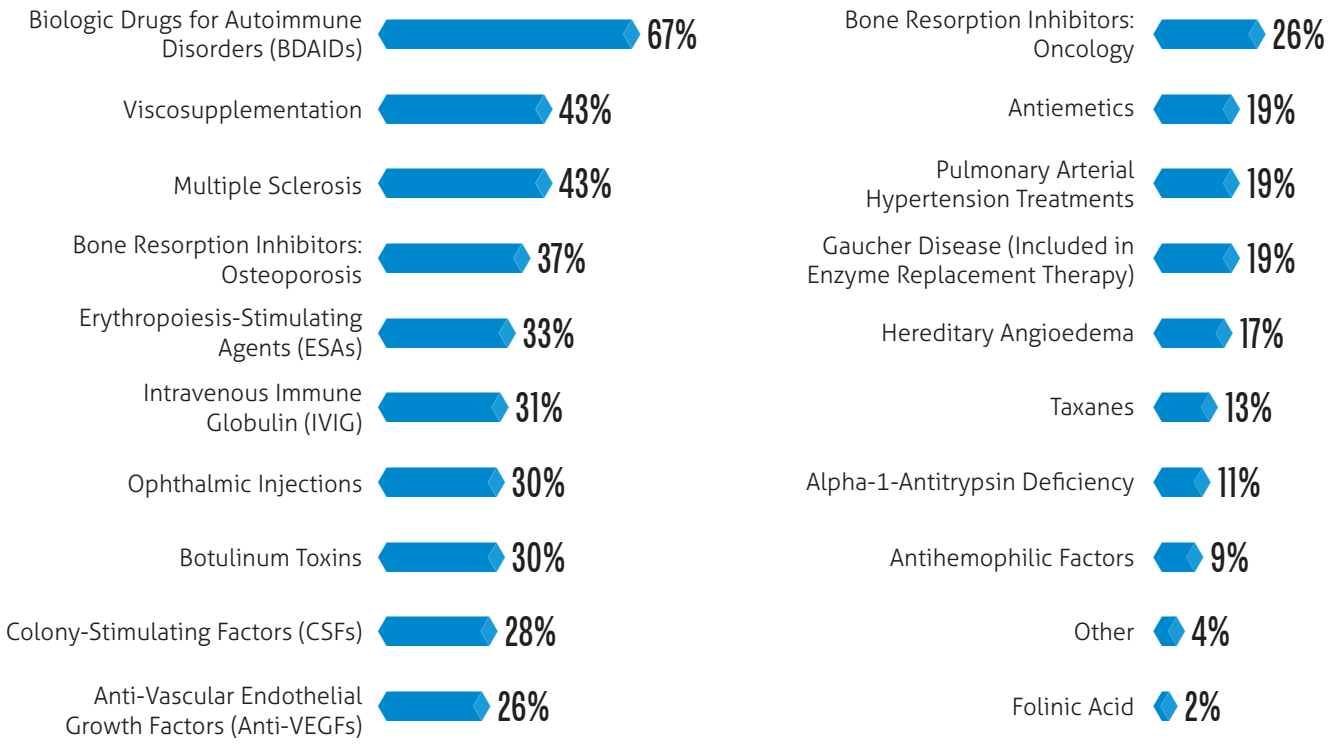


Specifically in 2015 at the individual payor level, biologic drugs for autoimmune disorders (BDAIDs), viscosupplementation (hyaluronic acids), and multiple sclerosis (MS) agents were subject to product preferencing. Although it is likely that payors have product preferencing on the pharmacy benefit for multiple sclerosis agents and requirements to utilize pharmacy benefit agents prior to medical benefit drugs, it is less likely that they have a preferred medical benefit drug to treat MS (***see Figure 6***).

FIGURE 6: 2015 Medical Benefit Disease State or Drug Category with Product Preferencing Currently in Place

% PAYORS

n=54 payors, 98 million covered lives



STEP EDITS

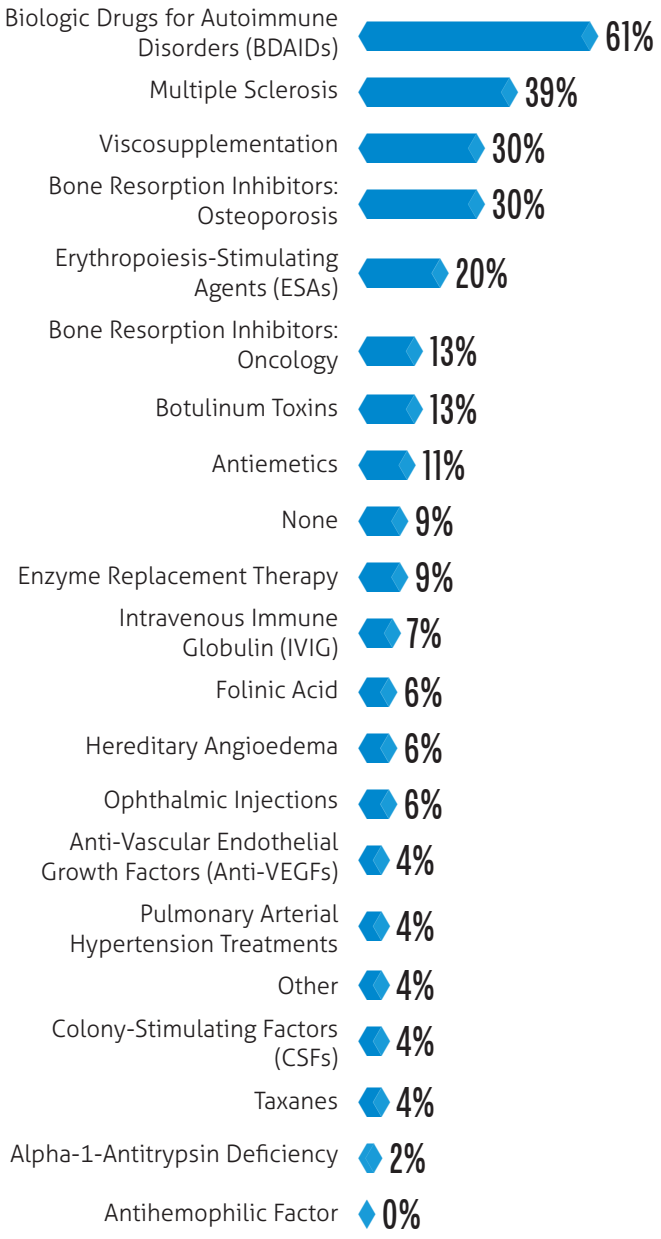
In a shift from the 2014 report, respondents were not asked to specify management tools used to preference drugs on the medical benefit. The payor survey instead focused on step edits and their implementation. It should be noted, step edits on the medical benefit differ from the pharmacy benefit as they are mainly driven by the medical policy and application of the policy by the health plan. Payors indicated the therapeutic classes most frequently requiring step edits were BDAIDs, multiple sclerosis, viscosupplementation, and bone resorption inhibitors for osteoporosis. For BDAIDs and MS agents, respondents indicated the reason for implementing a step edit was due to a requirement for receiving a drug rebate. The second most identified reason was recognition of an effective lower-cost drug in the therapeutic class. "Other" reasons payors indicated implementation of a step edit included clinical guidelines and adverse effect profiles (***see Figure 7***).

Specifically for viscosupplementation, respondents indicated step edits were driven by rebate requirements along with identification, by the payor, of an effective, lower-cost drug in the therapeutic class. This double-arm approach may be a result of the 2013 American Academy of Orthopaedic Surgeons (AAOS) osteoarthritis guideline revision stating "We cannot recommend using hyaluronic acid (HA) for patients with symptomatic osteoarthritis (OA) of the knee..."

FIGURE 7: 2015 Disease State or Drug Category with Step Edits

% PAYORS

n=54 payors, 98 million covered lives



REBATES

In 2015, more than half of payors (59 percent) equating to 57 percent of lives received rebates for provider-administered injectable or infused drugs billed under the medical benefit for commercial members (***see Figure 8***). Year over year, when assessing by plan size, larger payors saw a 9 percentage point increase in the number of rebates while smaller plans saw fewer rebates (***see Figure 9***).

FIGURE 8: 2015 Medical Benefit Drug Rebates Received

n=59 payors, 130 million covered lives

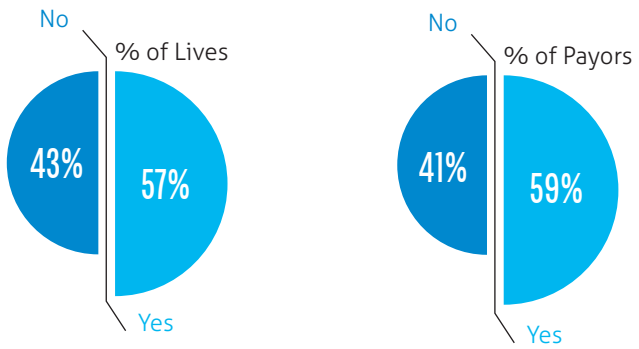
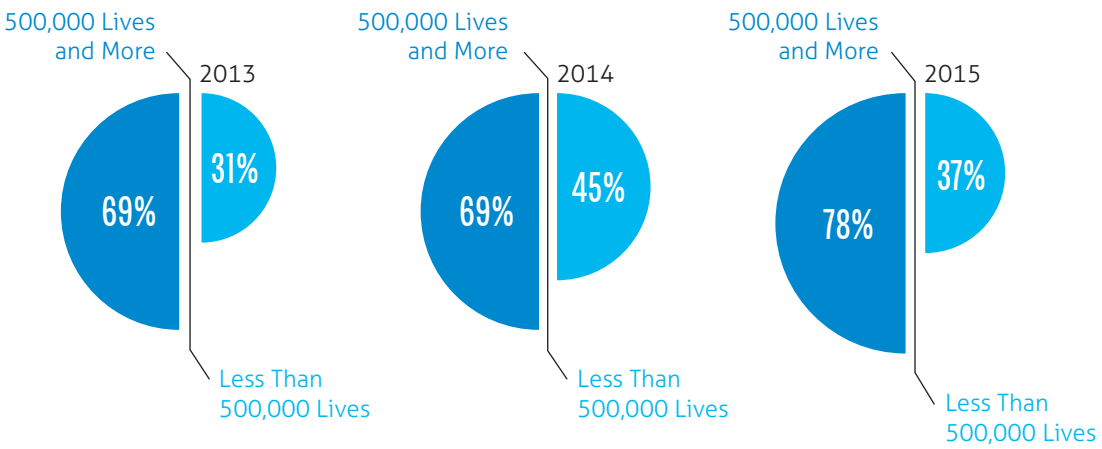


FIGURE 9: Medical Benefit Drug Rebates Received by Plan Size 2013-2015*

% PAYORS

n=27 payors, 82 million lives (2013); n=28 payors, 71 million lives (2014); n=35 payors, 74 million lives (2015)



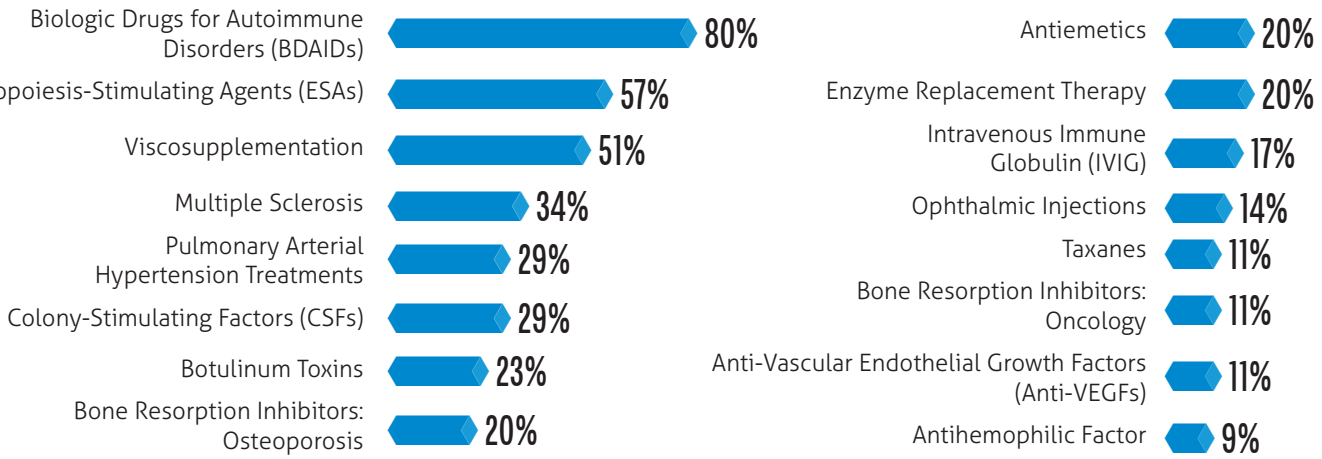
*Figures have been updated as of 5/23/2016.

By and large, BDAIDs received the most rebates with 80 percent of payors reporting a rebate for the class. Since 2013, that category consistently had the highest number of rebates over other therapeutic categories. As with product preferencing, 80 percent of payors with BDAIDs, 57 percent of payors with ESAs, and 51 percent of payors with viscosupplementation agents received rebates in 2015. Twenty-nine percent of payors received rebates for colony-stimulating factors (CSFs), the same percentage as last year, but there may be a significant shift in this category in future years based on the pending release of biosimilars for Neulasta and additional biosimilars for Neupogen in 2016 (***see Figure 10***). A third of payors reported rebates for multiple sclerosis agents, but it is unclear whether these rebates were for the medical benefit or if payors are referring to pharmacy benefit rebates for those agents used before medical benefit agents.

FIGURE 10: 2015 Disease State or Drug Category Where Payors Received Rebates for Medical Benefit Drugs

% PAYORS

n=35 payors, 74 million covered lives



PRODUCT CHOICE AND MONITORING

In 2015, we asked payors their research strategy when deciding how to preference products in a given therapeutic category. When choosing a preferred product, payors were split when it came to analyzing and comparing treatment outcomes (e.g., decreases in hospitalizations, disease exacerbations, emergency department [ED] visits, etc.) and total cost of care for the available agents in a drug therapy class and factoring this into their decision-making process (***see Figure 11***).

In addition, we set out to examine if payors monitored market share changes once they had established a preferencing strategy. Once a preferred product was selected and management tools were implemented, close to three-quarters of payors monitored changes in market share in the drug therapy class (***see Figure 12***).

FIGURE 11: 2015 Analyze and Compare Outcomes for Medical Benefit Drugs

% PAYORS

n=41 payors, 88 million covered lives

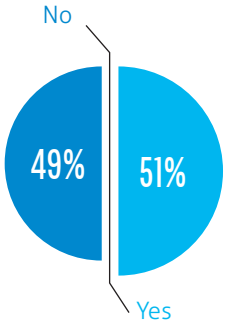
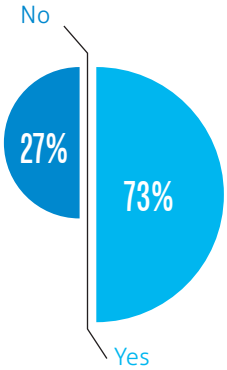


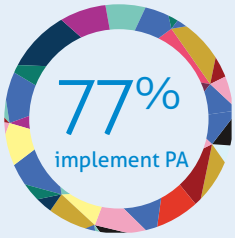
FIGURE 12: 2015 Monitor Market Share Changes for Medical Benefit Drugs

% PAYORS

n=41 payors, 88 million covered lives



Utilization Management



SUMMARY

> On average, 77 percent of payors implemented prior authorizations to manage use of medical benefit drugs for specific drug categories. Prior authorization represented the most utilized tool for the management of medical benefit drugs.

MANAGEMENT TOOLS

In 2015, payors indicated the top classes most managed were biologic drugs for autoimmune disorders (BDAIDs), oncology, erythropoiesis-stimulating agents (ESAs), multiple sclerosis, viscosupplementation (hyaluronic acid), and antihemophilic factors. The most commonly employed management tools were prior authorization (77 percent) and care/case management (26 percent). For multiple disease states, payors indicated physician education of the category as an "other" management technique. Management of oncology drugs through clinical pathways decreased from 27 percent in 2014 to 19 percent in 2015 (*see Table 3*).

TABLE 3: 2015 Utilization Management Tools for Medical Benefit Drugs by Disease State or Drug Category

% PAYORS

n=59 payors, 130 million covered lives

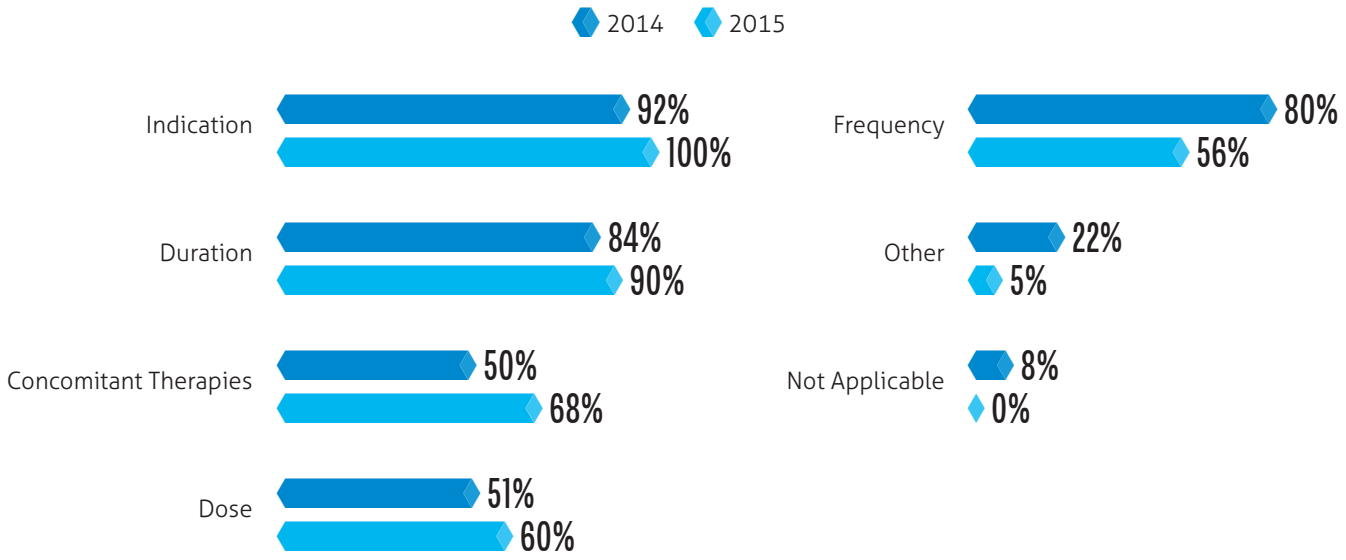
Disease State or Drug Category	Care Management (e.g., Disease Management or Case Management)	Prior Authorization	Step Edit Requirements	Clinical Pathways	Post-Service Claim Edits	None	Total Average Management
Biologic Drugs for Autoimmune Disorders (BDAIDs)	29%	88%	49%	0%	2%	3%	**29%**
Oncology	46%	78%	10%	19%	2%	2%	**26%**
Erythropoiesis-Stimulating Agents (ESAs)	31%	76%	20%	19%	2%	2%	**25%**
Multiple Sclerosis	19%	100%	25%	2%	2%	0%	**25%**
Viscosupplementation	17%	78%	32%	10%	3%	3%	**24%**
Antihemophilic Factors	42%	64%	0%	10%	8%	17%	**24%**
Intravenous Immune Globulin (IVIG)	39%	88%	0%	8%	3%	0%	**23%**
Hereditary Angioedema	32%	76%	12%	0%	0%	12%	**22%**
Asthma	32%	95%	3%	0%	2%	0%	**22%**
Bone Resorption Inhibitors: Osteoporosis	20%	76%	19%	12%	2%	2%	**22%**
Colony-Stimulating Factors (CSFs)	29%	66%	7%	19%	2%	3%	**21%**
Alpha-1-Antitrypsin Deficiency	27%	73%	15%	7%	2%	0%	**21%**
Pulmonary Arterial Hypertension	32%	78%	2%	7%	2%	2%	**20%**
Antiemetics	22%	49%	0%	15%	2%	32%	**20%**
Respiratory Syncytial Virus (RSV) Prevention	24%	88%	0%	0%	5%	0%	**19%**
Bone Resorption Inhibitors: Oncology	19%	76%	3%	2%	2%	10%	**19%**
Enzyme Replacement Therapy	34%	69%	0%	0%	0%	2%	**18%**
Ophthalmic Injections	0%	66%	5%	7%	2%	5%	**14%**
Botulinum Toxins	0%	85%	2%	5%	2%	29%	**16%**
TOTAL AVERAGE	**26%**	**77%**	**11%**	**7%**	**2%**	**5%**	**21%**

All payor respondents, regardless of their current management tools, provided additional insights into the prior authorization process. Based on percentage of lives, payors specified that the member's indication, duration of therapy, and any concomitant therapies prescribed to the member determined coverage of the drug. With the exception of frequency of dose, the top five prior authorization techniques were consistent with 2014. Review of frequency decreased from 80 percent in 2014 to 56 percent in 2015 (***see Figure 13***). Symbolizing a potential shift to precision medicine, payors indicated "other" tools included genetic markers, patient and drug outcomes data, and patient comorbidities.

FIGURE 13: Medical Benefit Drug Prior Authorization Review Criteria 2014-2015

% LIVES

n=41 payors, 120 million lives (2014); n=59 payors, 130 million lives (2015)



Benefit Design

cost-share requirements

13% varied by drug

23% varied by site of service

SUMMARY

- Coinsurance cost-share models made up close to half (49 percent) of the medical pharmacy benefit.
- Overall, 13 percent of payors varied their cost-share model by drug, while 23 percent of payors varied cost share by site of service.
- Covering drugs that may be billed under either the medical or pharmacy benefit had similar out-of-pocket costs for members.

MEMBER COST SHARE

In 2015, we asked commercial payors about member cost share as a percentage of the total annual medical pharmacy spend. Many payors (19 percent) were unaware of this cost share, and three-quarters of payors (75 percent) indicated 0 to 20 percent of the total medical pharmacy spend was shared with members. Few payors (7 percent) required their members to contribute more than 20 percent of the cost share for the medical benefit. This cost share takes into account all required contributions of members including copay or coinsurance, deductible, and max out-of-pocket (*see Figure 14*).

In 2015, and in line with 2014, close to half of payors indicated this cost share was through a coinsurance agreement when members participated with in-network providers. One-third of payors (34 percent) indicated their members were under a copayment model. For the last two years, we eliminated the option "require both" from the survey to streamline the results, creating a significant and continued increase in the rates of coinsurance (*see Figure 15*).

Not surprisingly, members who participated out-of-network were more likely to be required to pay under a coinsurance model. While nearly half (49 percent) of payors indicated members must pay coinsurance in-network, close to two-thirds (61 percent) of payors indicated members must participate in a coinsurance cost-share model when receiving care at an out-of-network provider (*see Figure 16*).

FIGURE 14: 2015 Commercial Members' Cost Share

% PAYORS

n=59 payors, 130 million covered lives

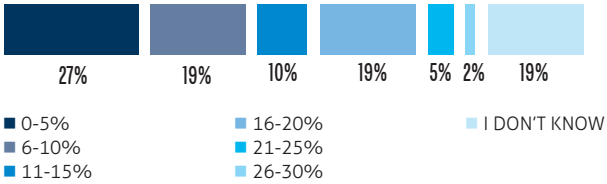


FIGURE 15: Payors' Required Member Contributions for Medical Benefit Drugs 2013-2015

% PAYORS

n=27 payors, 82 million lives (2013); n=48 payors, 125 million lives (2014); n=59 payors, 130 million lives (2015)

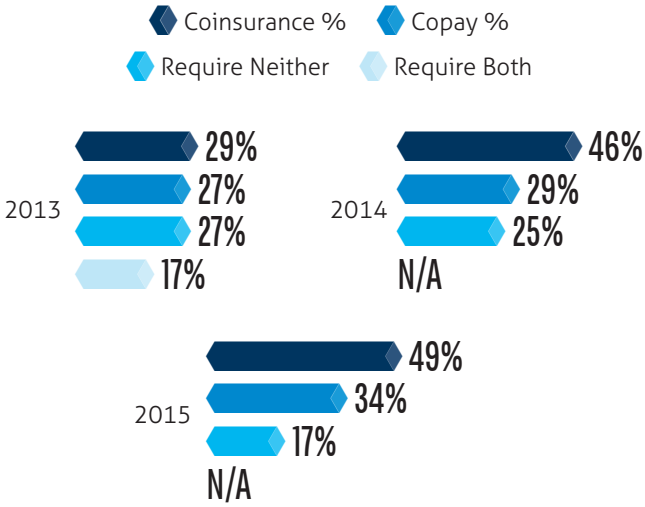
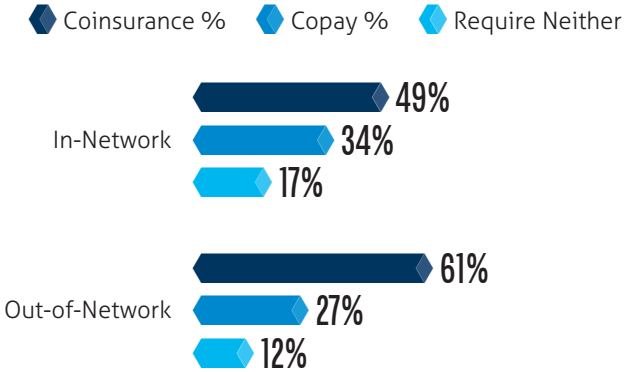


FIGURE 16: 2015 Payors' Required Member Contributions In-Network vs. Out-of-Network

% PAYORS

n=59 payors, 130 million covered lives



The shift to a coinsurance model had little effect on the coinsurance amount for the medical pharmacy benefit. Coinsurance continued to hover close to 20 percent across payors with the average being 19 percent in 2015 (*see Figure 17*). Copay amounts decreased to $44 from $51 in 2014, although not as low as copay levels in 2013 (*see Figure 18*).

FIGURE 17: Average In-Network Coinsurance Percentage for Medical Benefit Drugs 2011-2015

% LIVES

n=22 payors, 76 million lives (2011); n=24 payors, 97 million lives (2012); n=14 payors, 23 million lives (2013); n=22 payors, 51 million lives (2014); n=29 payors, 97 million lives (2015)

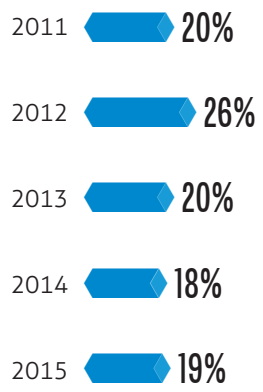
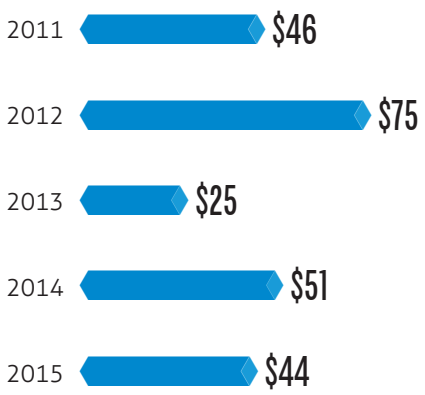


FIGURE 18: Average In-Network Copay Dollar Amount for Medical Benefit Drugs 2011-2015

% LIVES

n=8 payors, 77 million lives (2011); n=8 payors, 105 million lives (2012); n=3 payors, 35 million lives (2013); n=14 payors, 56 million lives (2014); n=20 payors, 21 million lives (2015)

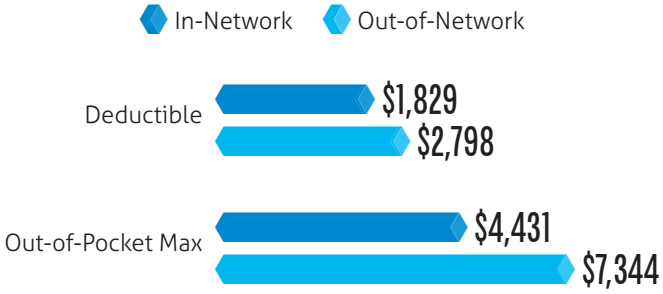


In 2014, we asked payors to estimate the anticipated annual deductible and out-of-pocket maximum cost per member in the next plan year. Last year, payors indicated that the majority of covered lives would have a deductible close to $2,400 in 2015. The actual weighted average deductible in 2015 was below this amount, at $1,829. Out-of-pocket maximums were closer to numbers estimated by payors in 2014. Last year, payors estimated out-of-pocket maximums to be around $4,300, while in 2015 these costs were slightly higher at $4,431. In 2015, out-of-network deductible costs were 53 percent higher than in-network costs, and out-of-network out-of-pocket max was 66 percent higher than in-network (*see Figure 19*).

FIGURE 19: 2015 Member Annual Deductible/ Out-of-Pocket Maximum

% LIVES

n=59 payors, 130 million covered lives

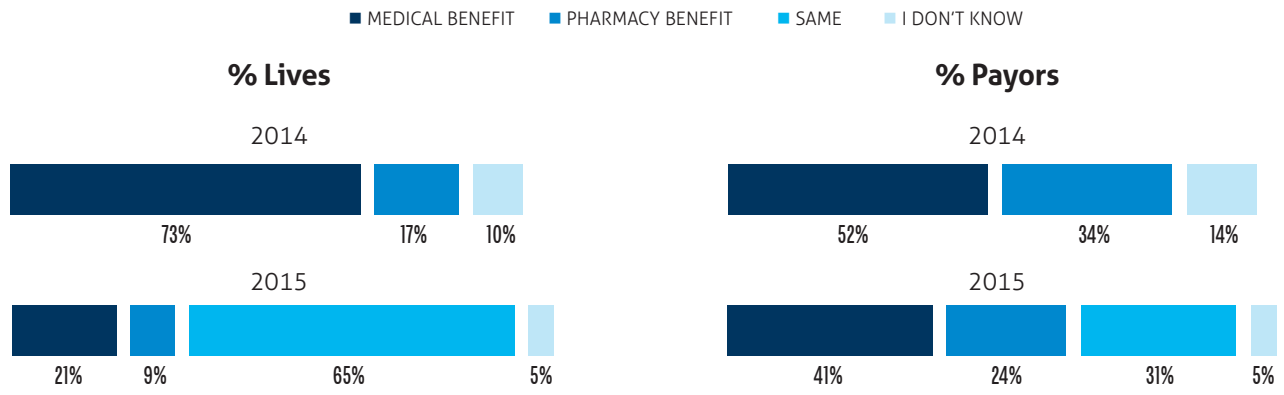


MEDICAL BENEFIT ADVANTAGE

In 2014, for 73 percent of lives, the cost share for drugs that could be billed under both medical and pharmacy benefits (e.g., Neulasta, Neupogen, Procrit, Aranesp, etc.) was more advantageous for a member when submitted under the medical benefit (*see Figure 20*). In 2015, less than one-quarter (21 percent) of lives saw a benefit from those same drugs being billed under the medical benefit. Overall, in 2015, 65 percent of lives were under benefit designs where there was little advantage to cost share under the medical benefit; as such, drugs billed under either benefit would incur the same out-of-pocket costs for members. Based on the percentage of payors surveyed, the benefit remained somewhat stable from 2014 to 2015, although there was a significant shift in payors who thought the benefits were similar in cost-share requirement, from 0 percent in 2014 to 31 percent in 2015.

FIGURE 20: Lower Member Drug Cost-Share Requirements Based on Medical vs. Pharmacy Benefits Coverage 2014-2015

n=29 payors, 70 million lives (2014); n=59 payors, 130 million lives (2015)

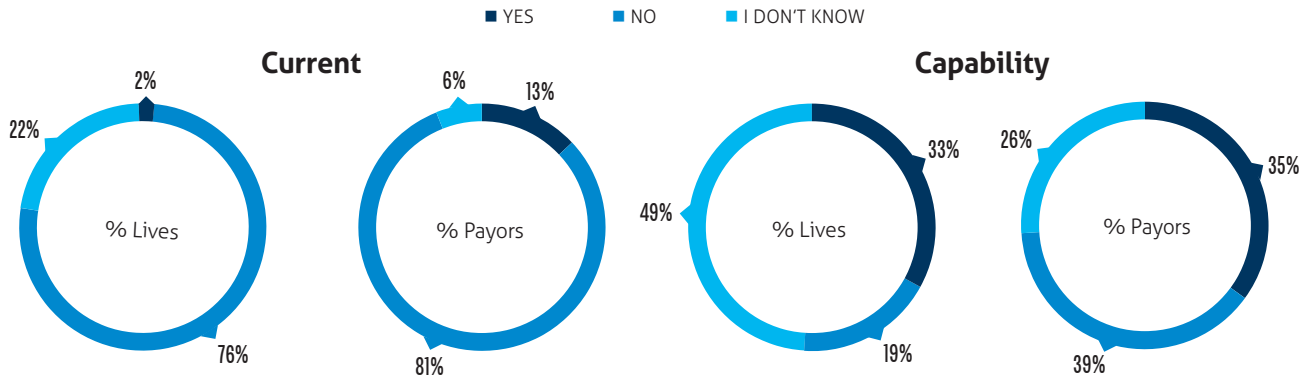


VARIABLE COST SHARE

In 2015, we asked if payors varied member cost-share requirements by medical benefit drug. Only 13 percent of payors varied member cost-share requirements by drug to drive to a preferred product on the medical benefit, although this is standard on the pharmacy benefit. When asked if payors had the ability to implement such a model if not already in place, responses were divided, with one-third of payors (35 percent) able to implement variable cost-share requirements (*see Figure 21*).

FIGURE 21: 2015 Payors' Practice with Varying Member Cost Share by Medical Benefit Drug

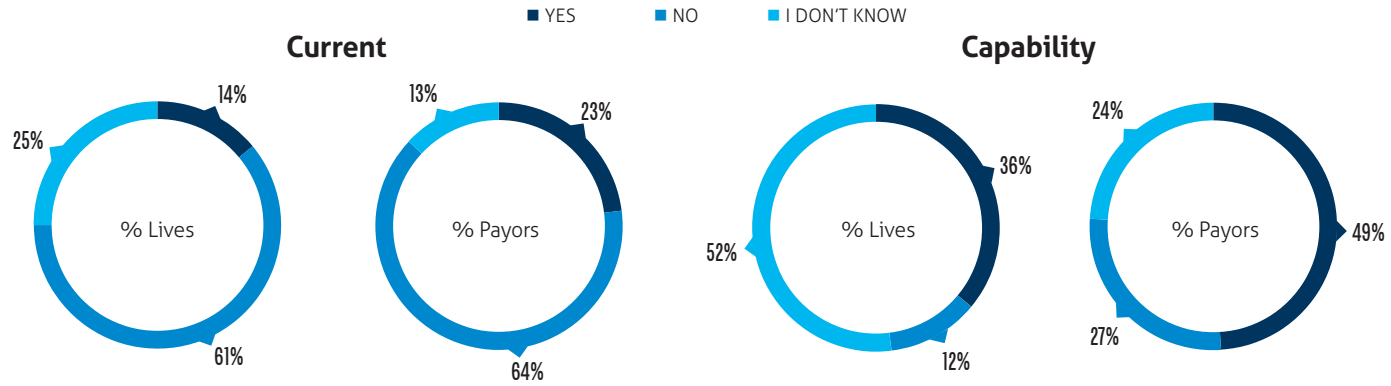
n=53 payors, 124 million lives (current); n=46 payors, 121 million lives (capability)



There was a shift when examining this variable cost share by outpatient site of service (e.g., physician office, home via home infusion, and hospital outpatient facility). In 2015, one-quarter (23 percent) of payors equating to 14 percent of lives varied member cost share based on the site of service of delivery. For those payors who did not vary cost share by provider type or were unaware of their organization's capability of varying cost share, close to half (49 percent) felt it was possible for their organization to undergo such a model (*see Figure 22*).

FIGURE 22: 2015 Payors' Practice with Varying Member Cost Share by Provider Type

n=53 payors, 124 million lives (current); n=41 payors, 106 million lives (capability)



Provider Reimbursement

SUMMARY

- Consistent over the last three years, payors reimbursed physician offices, home infusion providers, and specialty pharmacies using an ASP plus markup methodology.
- Hospital outpatient facilities overwhelmingly reimbursed based on percent of charges.
- Specialty pharmacies and home infusion companies used HCPCS codes; hospital outpatient facilities reimbursed through revenue codes.
- Newly released, unclassified HCPCS codes were most often reimbursed at an AWP discount methodology with an average discount of 16 percent across physician offices, home infusion providers, and specialty pharmacies. Hospital outpatient facilities continued to receive a percentage of billed charges for these agents.

REIMBURSEMENT APPROACH

Historically, our trend report has focused on physician office reimbursement methodologies. In 2014, we asked payors the same reimbursement methodology questions for home infusion providers and for hospital outpatient facilities. New in 2015, we expanded to round out provider types and included specialty pharmacies on the list of service providers.

In 2015, for the physician office setting, 72 percent of covered lives were under an average sales price (ASP) plus markup reimbursement model. In 2015, there was an increase in those payors using average wholesale price (AWP) minus a discount from 5 percent in 2014 to 26 percent in 2015 (***see Figure 23***). Respondents indicated "other" reimbursement approaches were capitated models and discounts based off of billed charges for the medical benefit drug.

In 2015, the weighted ASP plus average markup for physician offices was 9 percent, a drop from 2014, but a slight increase from 2013. While the ASP numbers excluded one outlier, one payor indicated a markup as high as 200 percent (***see Figure 24***). For the AWP model, the discount was on average 19 percent. For the second year in a row, some office-based providers saw no discount under the AWP model (***see Figure 25***).

FIGURE 23: Physician Office Reimbursement Approach Used by Payors for Drugs Paid Under Medical Benefit 2013-2015

% LIVES

n=27 payors, 82 million lives (2013); n=48 payors, 125 million lives (2014); n=59 payors, 130 million lives (2015)

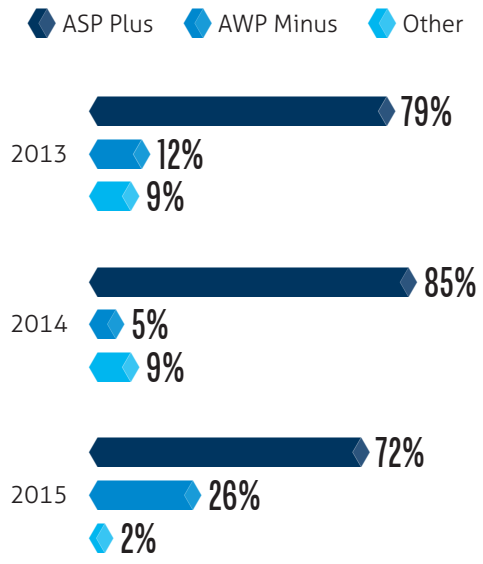


FIGURE 24: ASP Percent Markup for Physician Office Reimbursements 2013-2015

% LIVES

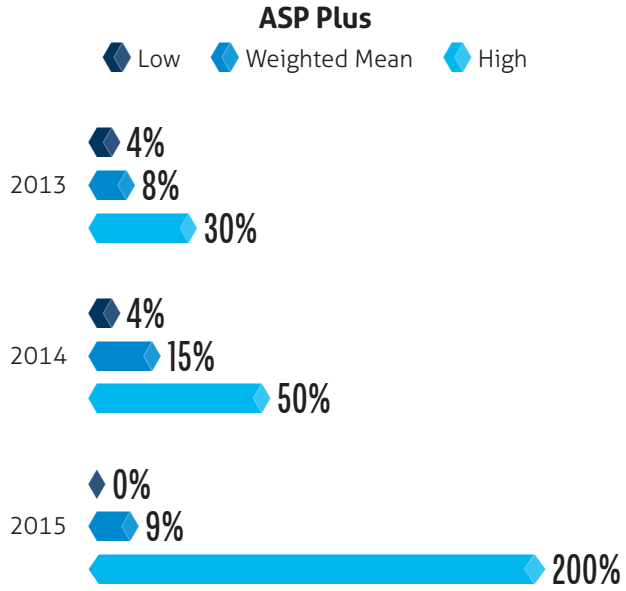
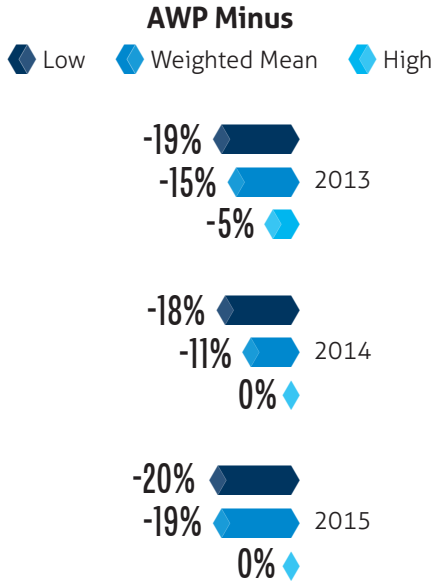


FIGURE 25: AWP Percent Discount for Physician Office Reimbursements 2013-2015

% LIVES

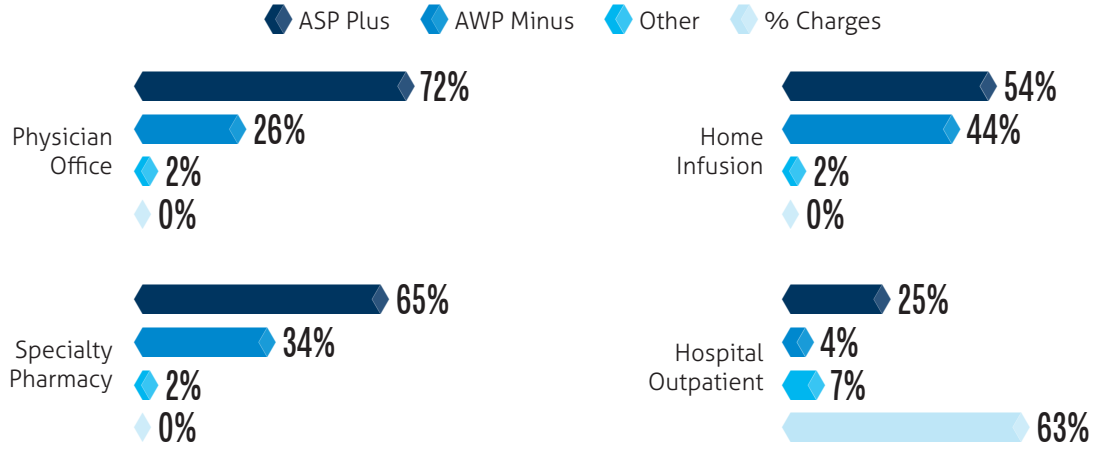


Reimbursement by provider type paints a more complete picture. In addition to examining home infusion and hospital outpatient facilities, in 2015 we asked payors about specialty pharmacies. Payors indicated 63 percent of lives in hospital outpatient settings were reimbursed based on the discount of submitted charges. Physician offices, specialty pharmacies, and home infusion providers were more likely reimbursed based on an ASP plus model. Very few payors reimbursed outside of either the ASP plus or AWP minus models for physician offices, specialty pharmacies, or home infusion providers. When they opted for "other" reimbursement methodology, it varied from a capitated model to cost minus or discount off submitted charges (*see Figure 26*).

FIGURE 26: 2015 Reimbursement Methodology by Provider Type

% LIVES

n=59 payors, 130 million covered lives



When examining the rates for ASP plus, on average hospitals saw the largest markup rates, although some payors experienced higher markups in physician office and home infusion settings (*see Figure 27*). Payors were more aggressive with physician offices with an AWP minus model, averaging a minus 19 percent versus other sites of service, reimbursing at an average of minus 16 percent (*see Figure 28*). Hospitals were reimbursed at an average of 50 percent of charges, although the spread of rates was large (18 to 100 percent) (*see Figure 29*).

FIGURE 27: 2015 ASP Percent Markup by Provider Type

% LIVES

n=38 payors, 94 million lives; (physician office); n=15 payors, 84 million lives (specialty pharmacy); n=19 payors, 70 million lives (home infusion); n=14 payors, 33 million lives (hospital outpatient)

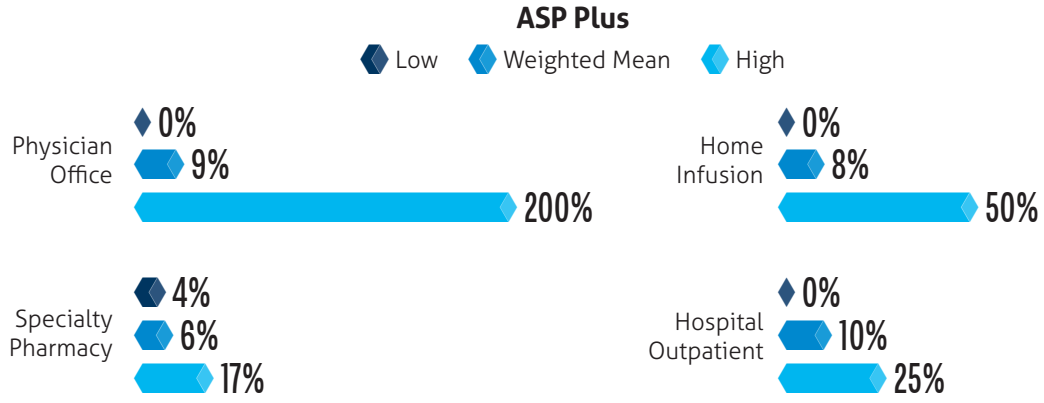


FIGURE 28: 2015 AWP Percent Discount by Provider Type

% LIVES

n=16 payors, 34 million lives (physician office); n=39 payors, 44 million lives (specialty pharmacy); n=34 payors, 57 million lives (home infusion); n=11 payors, 5 million lives (hospital outpatient)

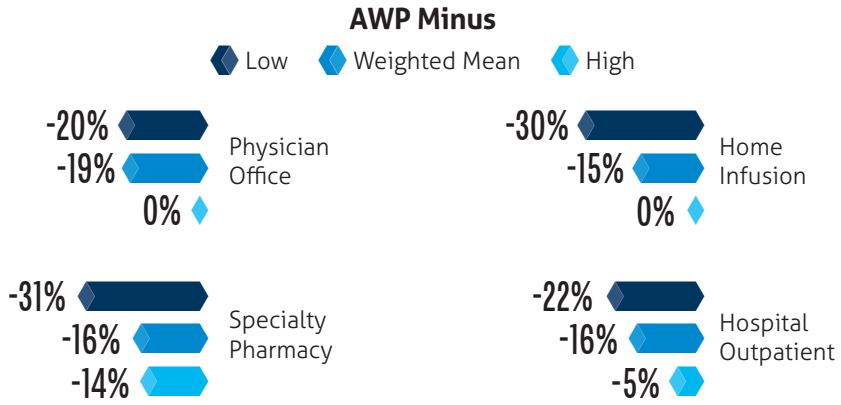
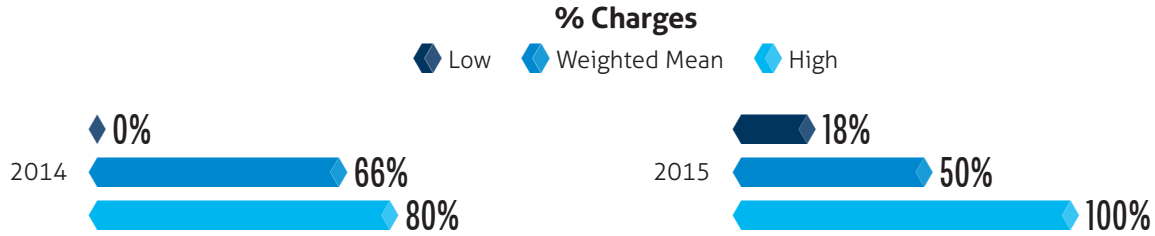


FIGURE 29: Percent of Billed Charges for Hospital Outpatient Facilities 2014-2015

% LIVES

n=18 payors, 55 million lives (2014); n=22 payors, 82 million lives (2015)

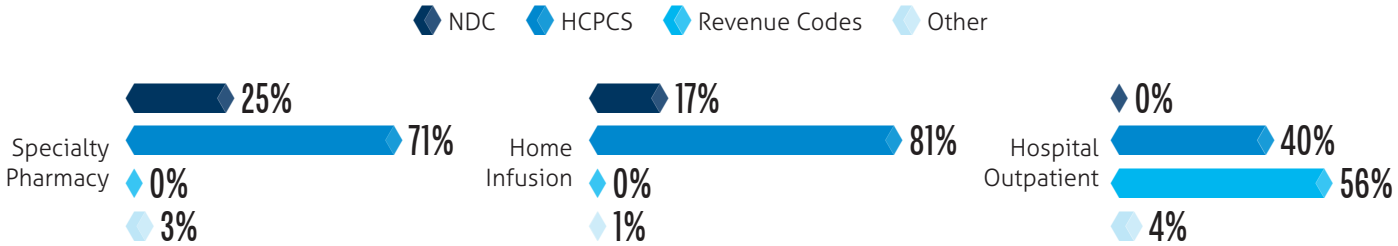


In 2015, payors indicated that 71 percent of covered lives under specialty pharmacy and 81 percent of covered lives under the home infusion setting were reimbursed based on the Healthcare Common Procedure Coding System (HCPCS) versus National Drug Codes (NDC). In the hospital setting, 40 percent of covered lives were under HCPCS, but the majority of covered lives (56 percent) were reimbursed based on revenue codes. Across all sites of service, internal charges and fee schedules were cited as "other" reimbursement models. It should be noted that in the home infusion and hospital outpatient settings, some payors (included in the "other" category) were unaware of the reimbursement coding system used in their organization (*see Figure 30*).

FIGURE 30: 2015 Reimbursement Coding Methodology by Provider Type

% LIVES

n=59 payors, 130 million covered lives



REIMBURSEMENT APPROACH FOR NEWLY RELEASED, UNCLASSIFIED MEDICAL BENEFIT DRUGS

In 2014 and 2015, we asked payors to indicate their reimbursement model specifically for newly released, unclassified (those that do not have an assigned, classified J-code) provider-administered injectable or infused drugs. In 2015, more than half of covered lives were under an AWP minus model, a balance-tipping shift from 2014. "Other" models outside of AWP minus reimbursement included AWP plus, discounted billing, and invoice plus reimbursement where a physician submits the invoice and receives cost plus a specified percentage (*see Figure 31*). In 2015, physician offices saw a discount of AWP minus 16 for newly released, unclassified medical benefit drugs (*see Figure 32*).

FIGURE 31: Physician Office Reimbursement Methodology for Newly Released, Unclassified Medical Benefit Drugs 2014-2015

% LIVES

n=48 payors, 125 million lives (2014); n=59 payors, 130 million lives (2015)

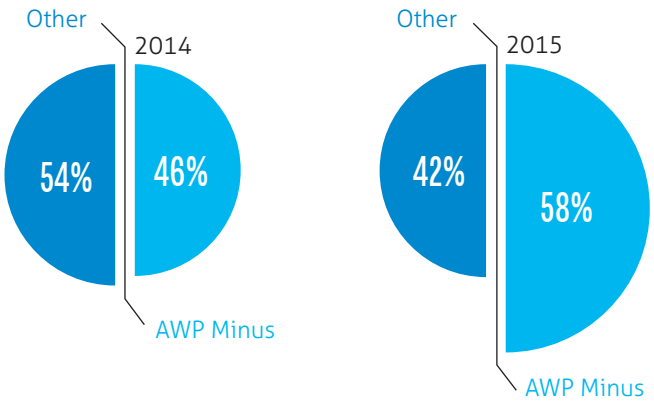
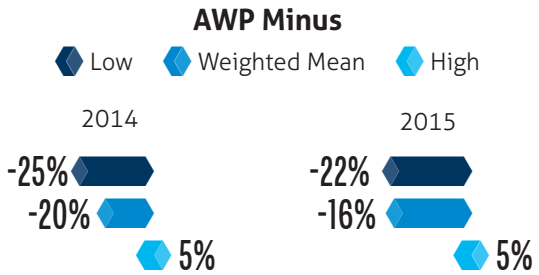


FIGURE 32: AWP Discount for Physician Office Reimbursements for Newly Released, Unclassified Medical Benefit Drugs 2014-2015

% LIVES

n=30 payors, 57 million lives (2014); n=46 payors, 78 million lives (2015)



Reimbursement for newly released, unclassified medical benefit drugs by provider type was much more streamlined for specialty pharmacies with almost all reimbursement based on an AWP minus model. "Other" reimbursement methodologies for specialty pharmacies included capitated models, discount off billed charges, and wholesale acquisition cost (WAC) plus or minus. Home infusion providers had more AWP minus reimbursement arrangements over "other" reimbursement methodologies, which included capitated rates, discount off billed charges, and AWP plus. Hospitals remained steady with the majority falling under a percent of charges model that saw similar charge rates to classified medical benefit drugs. Unlike with classified medical benefit drugs, hospitals' "other" arrangements included case rates. All sites of service averaged a minus 15 or 16 percent discount and hospitals saw an average reimbursement of 53 percent of billed charges (*see Figures 33, 34, and 35*).

FIGURE 33: 2015 Site of Service Reimbursement for Newly Released, Unclassified Medical Benefit Drugs

% LIVES

n=59 payors, 130 million covered lives

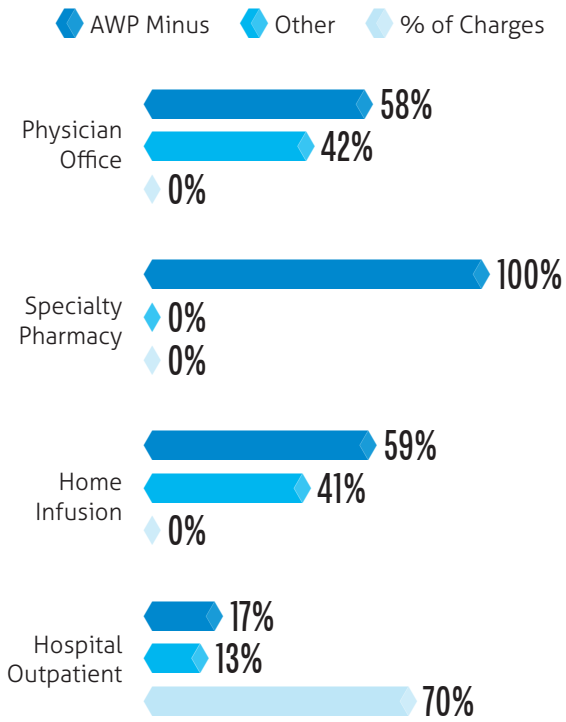


FIGURE 34: 2015 AWP Discount for Newly Released, Unclassified Medical Benefit Drugs

% LIVES

n=46 payors, 78 million lives (physician office); n=58 payors, 129 million lives (specialty pharmacy); n=43 payors, 76 million lives (home infusion); n=21 payors, 22 million lives (hospital outpatient)

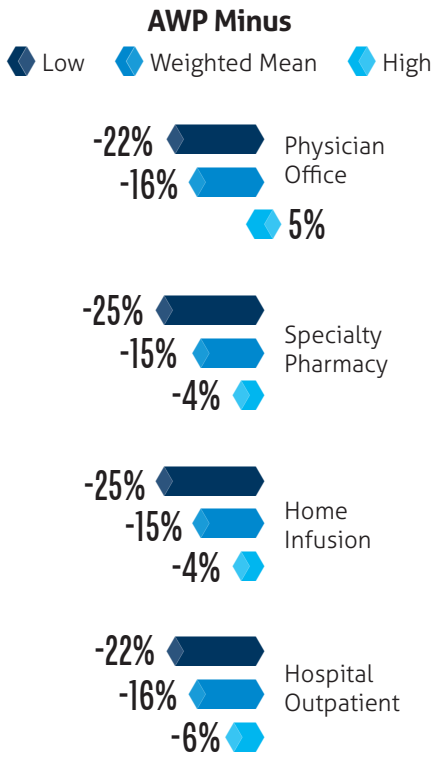
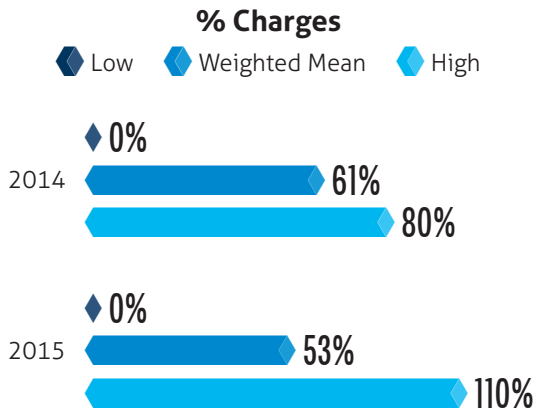


FIGURE 35: Percent of Billed Charges for Newly Released, Unclassified Medical Benefit Drugs in Hospital Outpatient Facilities 2014-2015

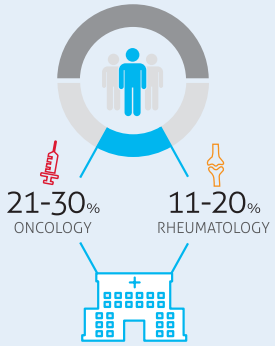
% LIVES

n=15 payors, 40 million lives (2014); n=25 payors, 91 million lives (2015)



Not shown here, but new in our 2015 survey, we asked payors how they reimbursed administration codes billed with medical benefit drugs. More than half (59 percent) of payors and half (50 percent) of covered lives were based under the current year (2015) Resource-Based Relative Value Scale (RBRVS) codes. The remaining half of covered lives were based on several methods included in the "other" option. Some of these methods reimbursed based on a percentage of the RBRVS value, while others reported using a Medicare or Medicaid fee schedule. Several payors also indicated payment based on a discount off of the physician's submitted charges.

Provider Network Landscape



SUMMARY

> Provider buy and bill (provider uses stock and bills plan) is the dominant form of medical pharmacy drug distribution.

> Acquisition of office-based practices continued at a rapid rate (51 percent of payors). Close to one-third of those payors indicated 21 to 30 percent of the oncology practices and 11 to 20 percent of rheumatology practices in their network were acquired by hospitals or health systems since 2005.

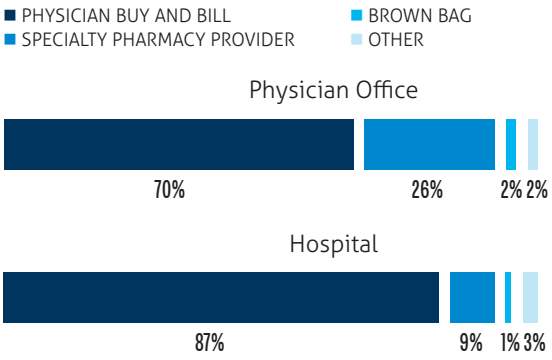
MEDICAL BENEFIT DRUG DISTRIBUTION

More than two-thirds of physician office drug volume (weighted average based on covered lives) was supplied through physician buy-and-bill methodology, while one-quarter was supplied by specialty pharmacy providers. Physician buy and bill saw an increase from 64 percent in 2014, while physician supply through specialty pharmacies remained steady. Buy and bill replaced brown bag supply as well as free-standing infusion centers and in-house pharmacies. New this year in the hospital setting, the majority of medical benefit drugs were obtained through buy and bill, and "other" methods included infusion suites and internal distribution networks (*see Figure 36*).

FIGURE 36: 2015 Physician Office and Hospital Percentage of Medical Benefit Drug Volume by Distribution Channel

% LIVES

n=59 payors, 130 million covered lives

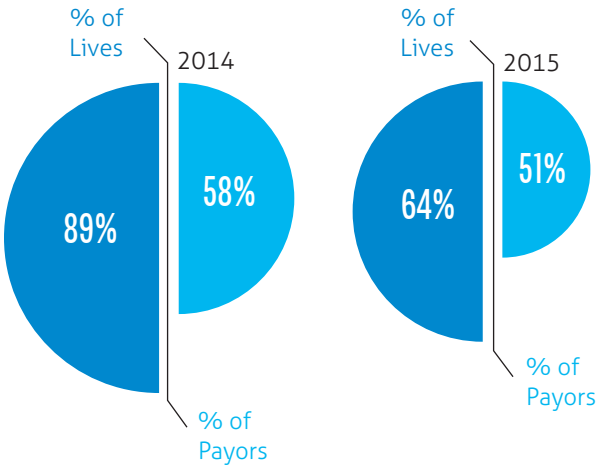


SPECIALTY OFFICE ACQUISITIONS

Down from 2014, payors continued to see the purchasing of practices by hospital systems. In 2015, more than half (51 percent in 2015 compared to 58 percent in 2014) saw the purchase of a specialty practice by a hospital system over the last 10 years. This affected nearly two-thirds of covered lives in the survey (*see Figure 37*). Almost all payors (97 percent) with office-based acquisitions in their areas indicated the types of office-based specialty practices acquired were oncology with similarly focused hematology practices close behind (*see Figure 38*).

FIGURE 37: Office-Based Practices Purchased by Hospital Systems over the Last 10 Years 2014-2015

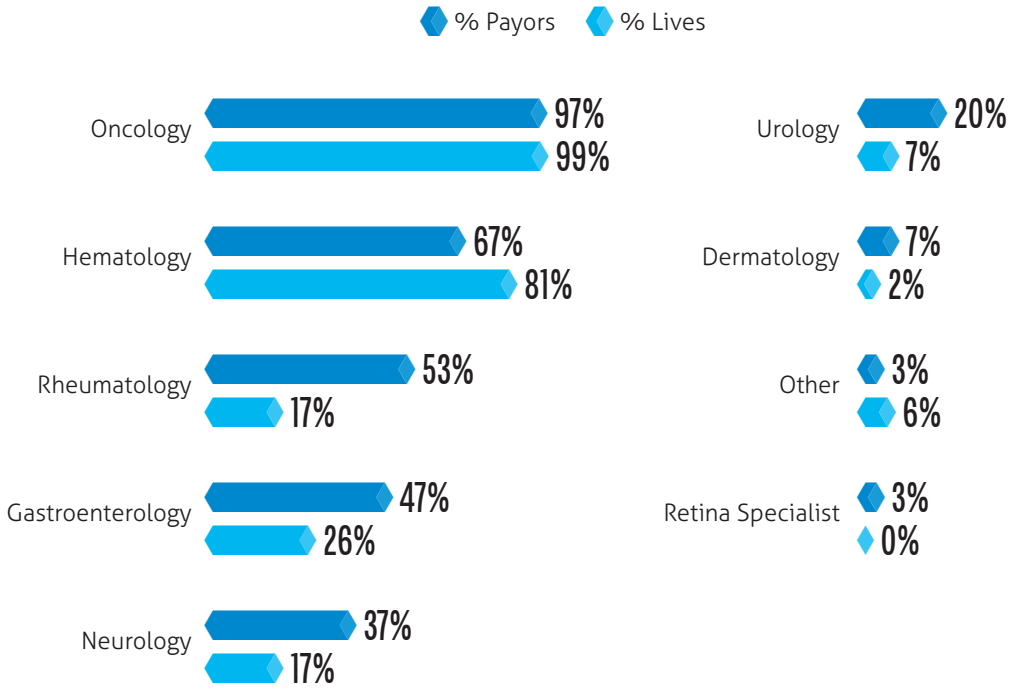
n=48 payors, 125 million covered lives (2014); n=59 payors, 130 million covered lives (2015)



In 2015, in addition to asking about oncology practices, we asked payors the type of specialties in their organization's network that had been purchased by hospital systems over the last 10 years. As with the survey in 2014, oncology/hematology practices saw the highest levels of consolidation (97 percent/67 percent of payors) along with rheumatology practices (53 percent of payors). Gastroenterology practices also saw high levels of consolidation, where 47 percent of payors experienced these purchases, although the purchases affected only about one-quarter of lives (***see Figure 38***).

FIGURE 38: 2015 Type of Office-Based Specialty Practice Purchased by Hospital Systems over the Last 10 Years

n=30 payors, 106 million covered lives



Of those payors who experienced a practice being purchased by a hospital or health system, close to one-third (30 percent for oncology and 31 percent for rheumatology) indicated that 21 to 30 percent of their independent, office-based oncology practices and 11 to 20 percent of rheumatology practices in their network were purchased by hospitals/health systems over the last 10 years (***see Figure 39***). Alarmingly, 20 percent of payors reported more than 50 percent of their office-based network oncology practices were purchased through hospital acquisitions since the implementation of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (***see Figures 39 and 40***). The MMA introduced the implementation of ASP plus 6 percent reimbursement by CMS, which negatively impacted the financial stability of office-based practices for oncology.

Other practices have been purchased over the last 10 years, though not at the same level as oncology and rheumatology practices (***see Figure 40***).

FIGURE 39: 2015 Percentage of Office-Based Practices Purchased by Hospital Systems over the Last 10 Years

% PAYORS

n=30 payors, 106 million covered lives

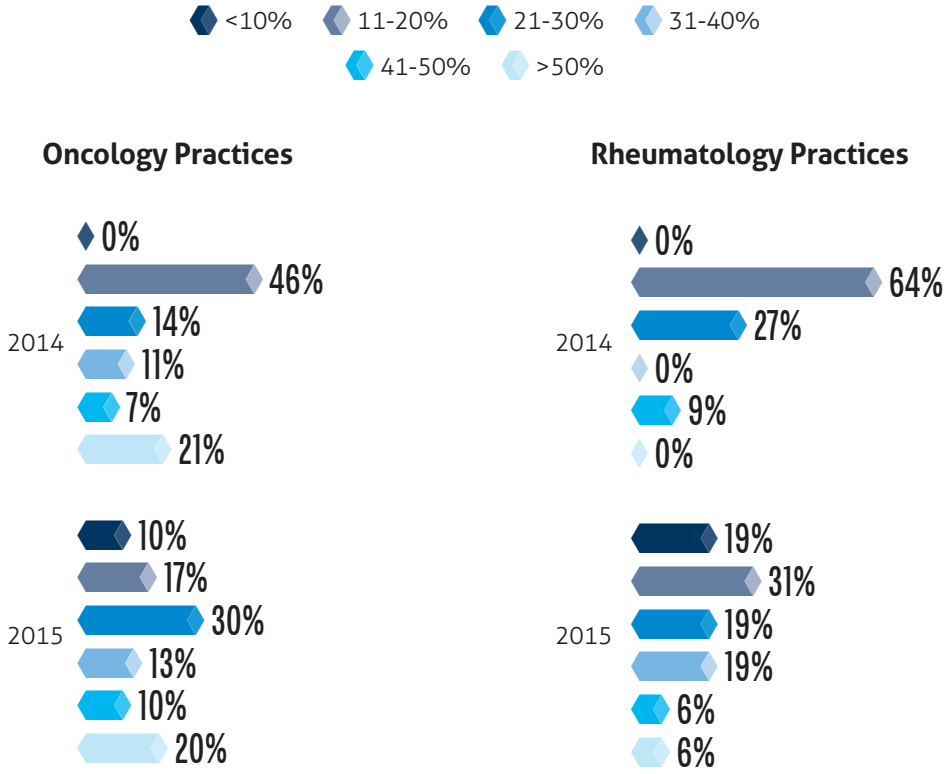
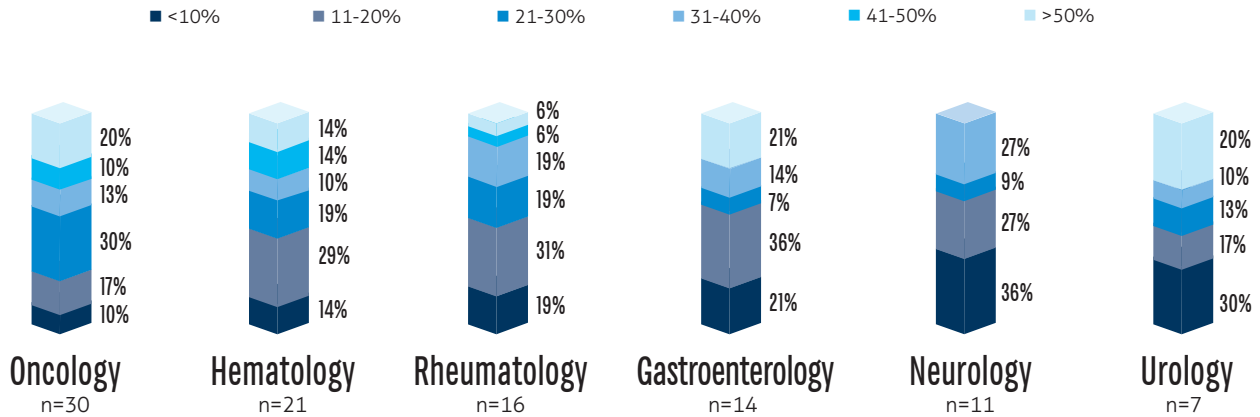


FIGURE 40: 2015 Percentage of Practices Purchased by Hospital Systems over the Last 10 Years

% PAYORS

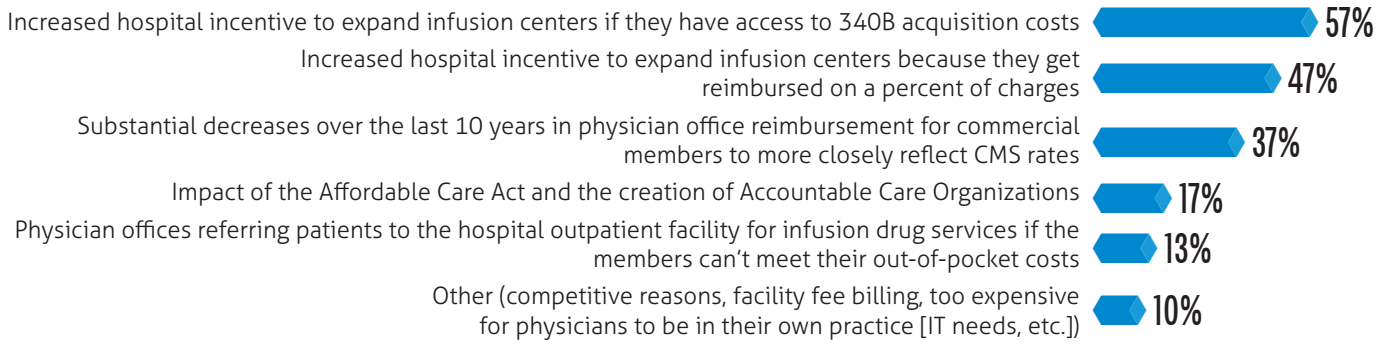


Payors were able to select several reasons they believed independent practices were being purchased. Payors indicated the top reason was the increased incentive for hospitals to expand infusion centers if they are able to access 340B acquisition costs. Close to half of payors also indicated that the increased hospital incentive to expand infusion centers is because they get reimbursed on a percent of charges. Over one-third of payors indicated physician office reimbursement for commercial members has substantially decreased over the last 10 years to more closely reflect CMS rates. In 2014, the decrease in physician office reimbursement was the top reason although it gained comparable support in 2015 (37 percent in 2015 versus 26 percent in 2014) (***see Figure 41***).

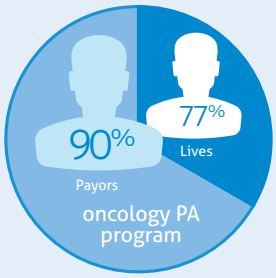
FIGURE 41: 2015 Reasons Why Independent Practices Were Being Purchased by Hospital Systems

% PAYORS

n=30 payors, 106 million covered lives



Management Trends



SUMMARY

> For payors who implemented oncology-specific pilot programs (34 percent), almost all (90 percent), equating to over three-quarters (77 percent) of lives, were under an oncology-specific prior authorization management program.

> Eighty percent of lives (69 percent of payors) do not currently track oncology quality measures, such as those proposed for inclusion in the Oncology Care Model.

> Palliative care programs were a major component of oncology care for members; most members are placed in programs once they do not have a curative diagnosis. Many patients still receive chemotherapy within the last two weeks of life, although only 5 percent of payors knew what percentages of patients were represented.

ONCOLOGY PROGRAMS

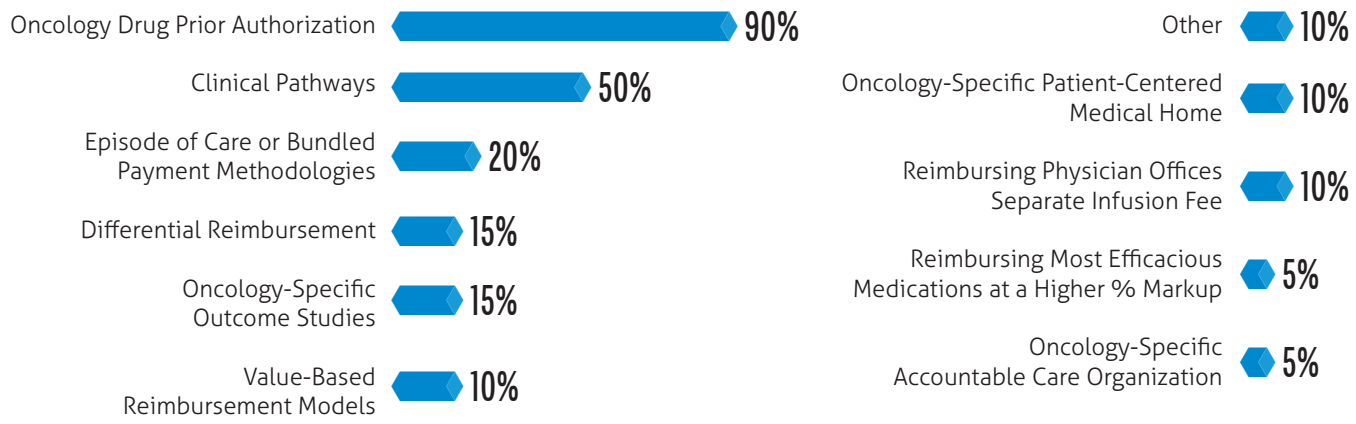
For the second year, we added a section of the survey that asked payors about health plan medical benefit drug management trends. The topics remained oncology-specific programs, palliative care programs, and site of service management.

Payors were asked what oncology-specific pilot programs their organization implemented for commercial members. Thirty-four percent of payors representing 77 percent of covered lives had oncology-specific pilot programs in place in 2015. By and large, the majority of payors (90 percent) offered their members an oncology drug prior authorization management program. Half of payors offered programs based on clinical pathways. Use of additional programs was low, which indicated payors may be willing to try new management approaches with a small number of providers in their network and not implement network wide (*see Figure 42*).

FIGURE 42: 2015 Oncology-Specific Pilot Programs Initiated by Payors

% PAYORS

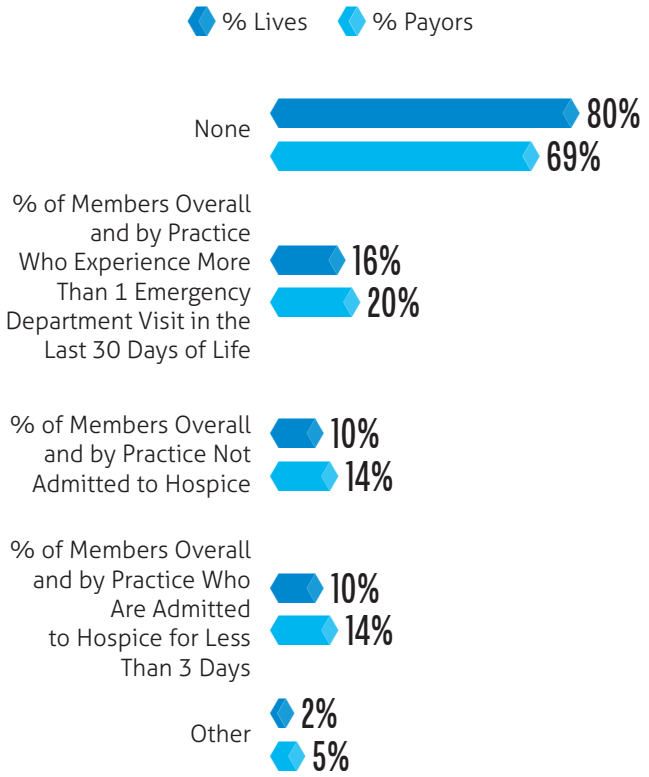
n=20 payors, 100 million covered lives



In 2015, the CMS Innovation Center introduced the Oncology Care Model to create patient-centered oncology medical homes (see ***"Legislative Updates"*** section). Along with this, the American Society of Clinical Oncology (ASCO) has previously introduced the Quality Oncology Practice Initiative (QOPI), set to routinely assess care and quality improvement efforts within oncology practices. In light of these initiatives, we asked payors what movement was made over the last year toward tracking and improving quality measures and preparing for the oncology Patient-Centered Medical Home (PCMH) model. Payors were asked if their organization tracked quality measures around emergency department and hospice admissions for their members with cancer. The majority of lives (80 percent) and payors (69 percent) were not in plans currently tracking these quality measures. A small portion of payors tracked emergency department visits as well as hospice admittance (***see Figure 43***).

FIGURE 43: 2015 Tracking of Oncology Quality Measures

n=59 payors, 130 million lives



PALLIATIVE CARE PROGRAMS

In an effort to understand supportive care for members with cancer, we asked payors what initiatives they currently had in place and at what point they are offered during a member's course of treatment. Close to two-thirds of payors and over half of covered lives were under palliative care programs (***see Figure 44***). Compared to previous years, the number of lives in palliative care programs declined to little over half (54 percent), although the number of payors has remained high (***see Figure 45***).

FIGURE 44: 2015 Payors Providing Palliative Care Programs to Members with Cancer

n=59 payors, 130 million lives

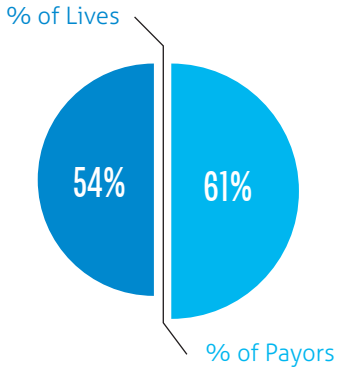
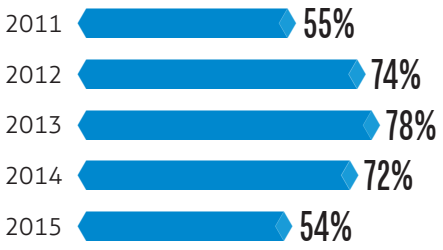


FIGURE 45: Payors Providing Palliative Care Programs to Members with Cancer 2011-2015

% LIVES

n=60 payors, 153 million lives (2011); n=50 payors, 157 million lives (2012); n=48 payors, 166 million lives (2013); n=48 payors, 125 million lives (2014); n=59 payors, 130 million lives (2015)



Payors indicated the majority of these members with cancer were placed under a palliative care program once they no longer had a curative diagnosis. A small segment of payors indicated "other" circumstances for placing a member under a palliative care program would be specific risk factors of the patient or if they offered a palliative care option at any point during treatment (***see Figure 46***). Payors indicated an average of 15 percent of their cancer patients were currently enrolled in the organization's palliative care program (***see Figure 47***).

When asked what percentage of members with cancer received chemotherapy within the last two weeks of their lives, only 5 percent of payors knew what percentages of patients were represented. Of that 5 percent, nearly one-third (30 percent) of their members with cancer received chemotherapy in the last two weeks of their lives (***see Figures 48 and 49***).

FIGURE 46: 2015 Time of Start of Palliative Care Program

% LIVES

n=36 payors, 71 million covered lives

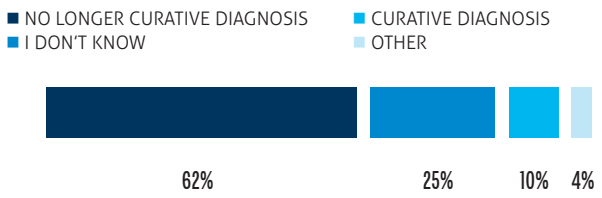


FIGURE 47: 2015 Percentage of Cancer Patients Enrolled in Palliative Care Program

% LIVES

n=36 payors, 71 million covered lives

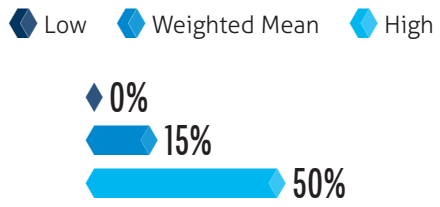


FIGURE 48: 2015 Payors Who Knew Percentage of Members with Cancer Who Received Chemotherapy Within the Last Two Weeks of Life

% PAYORS

n=59 payors, 130 million lives

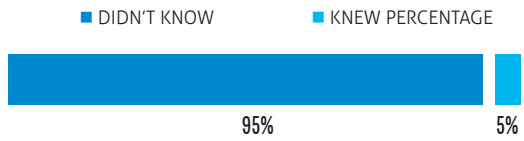
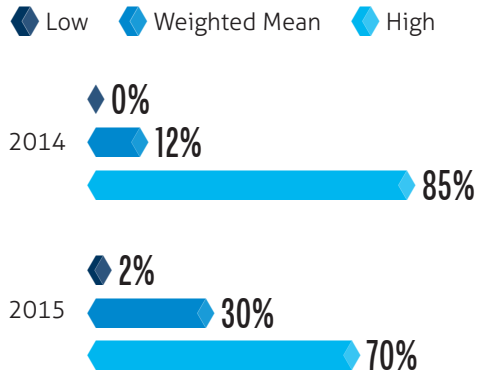


FIGURE 49: Percentage of Members with Cancer Who Received Chemotherapy Within the Last Two Weeks of Life 2014-2015

% LIVES

n=10 payors, 29 million lives (2014); n=6 payors, 6 million lives (2015)

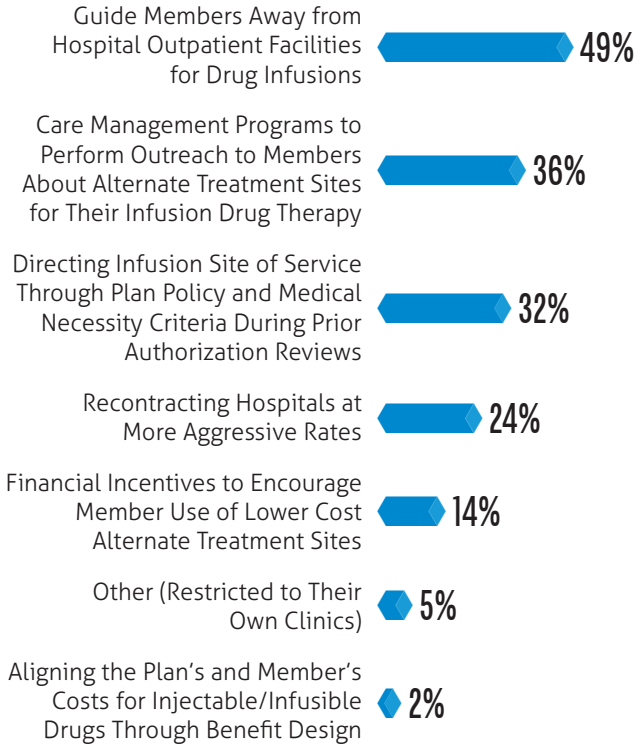


Outside of disease-specific management programs, payors were asked how they managed the shift in site of service for medical benefit drugs from lower-cost sites of service to higher-cost sites of service. Payors indicated that for the majority of covered lives, payors guided members away from hospital outpatient facilities for drug infusions. Recontracting hospitals at more aggressive rates was another management approach (***see Figure 50***).

FIGURE 50: 2015 Payors' Approaches to Managing Medical Benefit Drugs' Sites of Service

% PAYORS

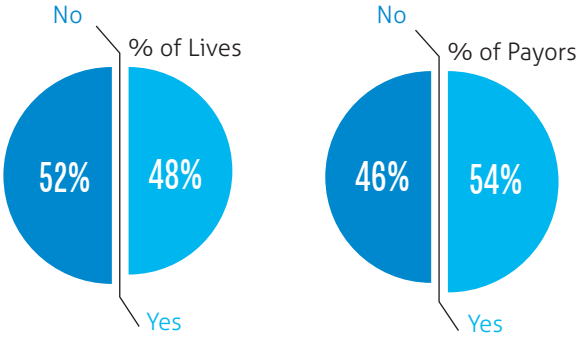
n=59 payors, 130 million lives (2015)



We sought to examine forecasting programs in place at health plans to proactively identify major changes to the pipeline of a drug category or the emergence of curative treatment (as is the case with hepatitis C on the pharmacy benefit). Little more than half of payors actively performed drug spend forecasting on the medical benefit (***see Figure 51***). For more information on medical benefit drug forecasting, see the "***Medical Benefit Drug Pipeline***" section.

FIGURE 51: 2015 Forecasting Performed for Medical Benefit Drug Spend

n=59 payors, 130 million lives (2015)

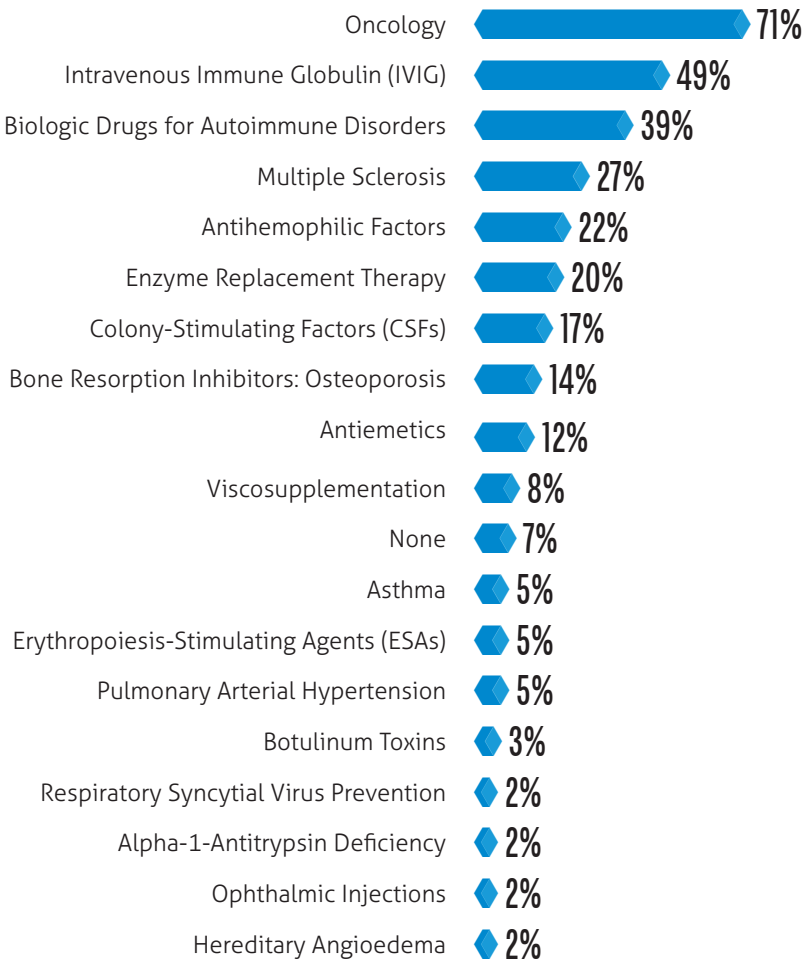


Despite the various management techniques and programs payors had in place, there were several drug categories that presented challenges. Consistent with 2014, oncology and IVIG were identified as difficult to manage (*see Figure 52*).

FIGURE 52: Medical Benefit Disease State or Drug Category Payors Had Challenges Managing

% PAYORS

n=59 payors, 130 million lives (2015)



Health Plan Claims Data

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.

Utilization Trends

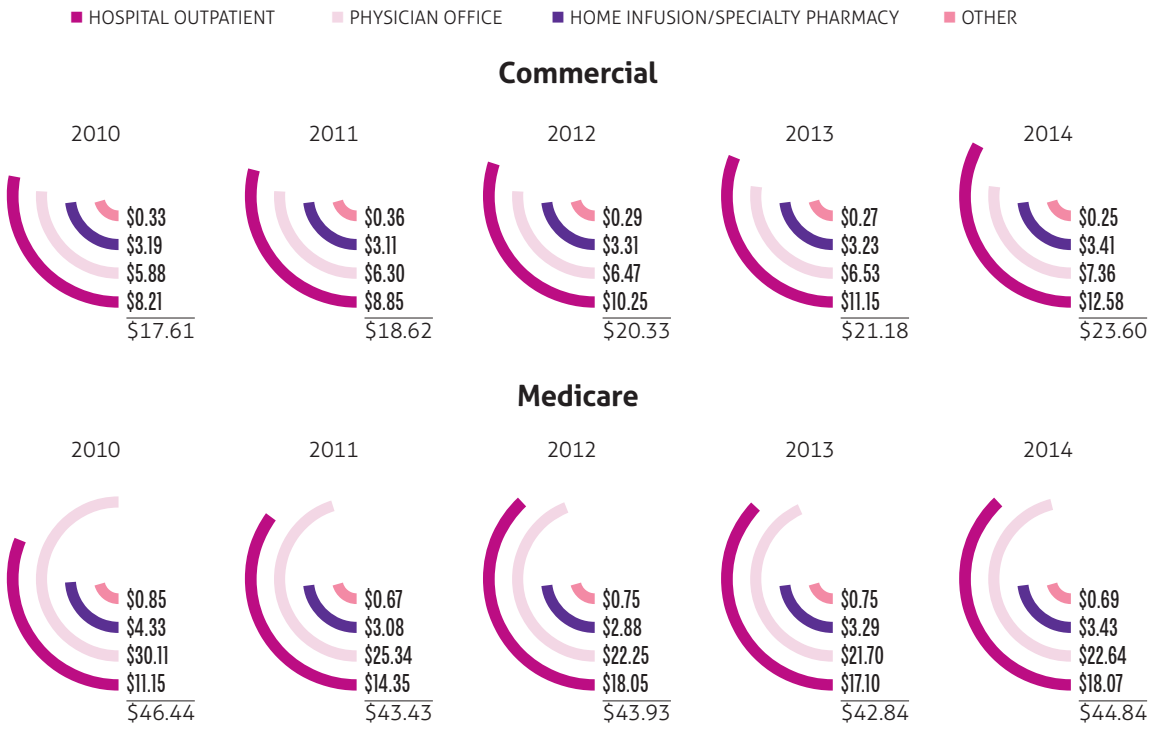
SUMMARY

- Although half of members[3] were treated in the physician office setting, commercial spend for the medical benefit was concentrated in the hospital outpatient setting (53 percent), while Medicare members and spend were concentrated in the physician office setting.
- Medical pharmacy allowed amount PMPM in 2014 for commercial was $23.60 while Medicare was close to double that at $44.84.
- Over the last year, commercial and Medicare allowed amount PMPMs have increased 11 and 5 percent, respectively.

Over the last five years, the medical pharmacy allowed amount[4] per member per month (PMPM) for commercial has increased on average 8 percent annually, while Medicare has seen variable changes with a net 1 percent decrease every year. The overall allowed amount PMPM in 2014 for commercial was $23.60 while Medicare was close to double that amount at $44.84 (*see Figure 53*).

This dynamic is typical as Medicare medical pharmacy spend is generally two to three times higher than commercial. From 2013 to 2014, commercial and Medicare allowed amount PMPMs increased 11 and 5 percent, respectively. From a cumulative perspective, 2010 to 2014 commercial medical pharmacy spend has increased 34 percent and has decreased 3 percent for Medicare (*see Table 5*).

FIGURE 53: Medical Pharmacy Allowed Amount PMPM by LOB by Site of Service 2010-2014

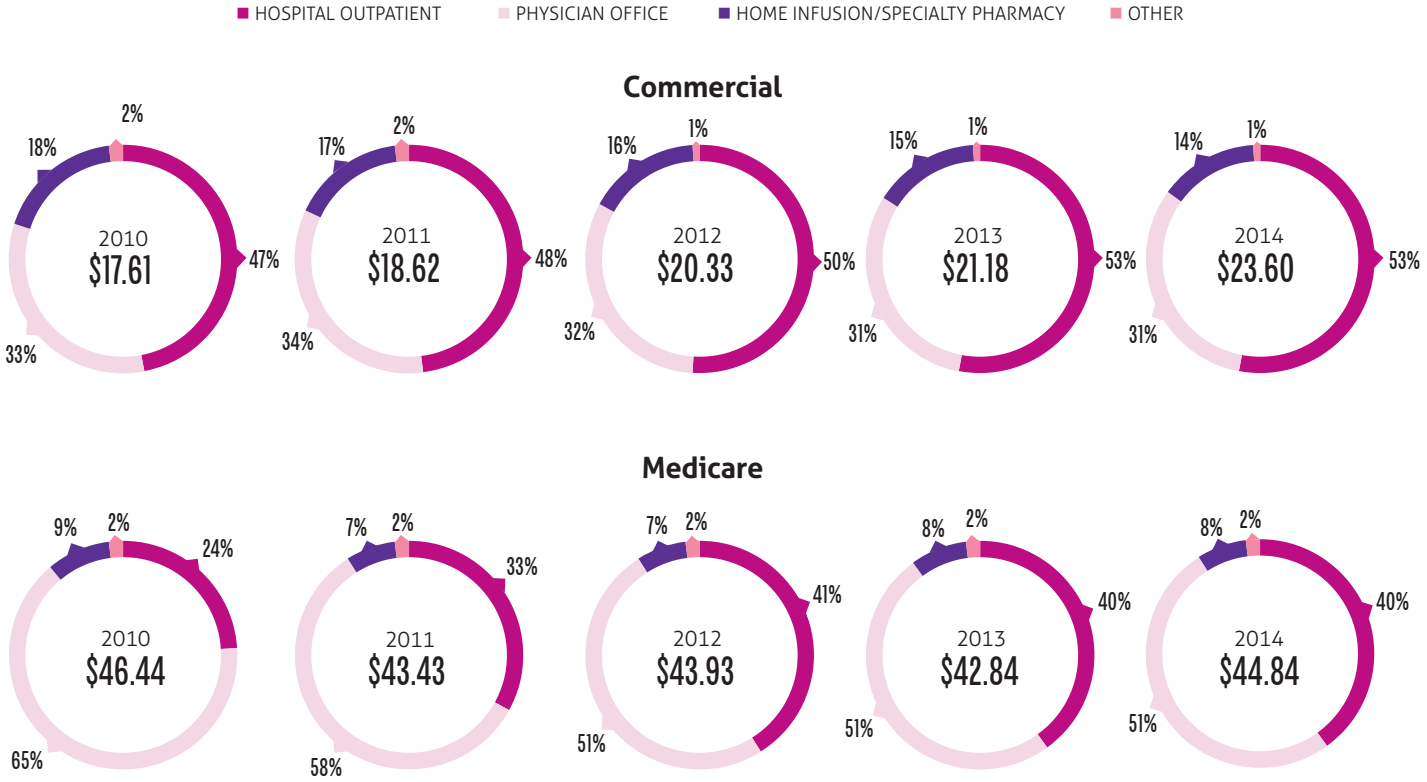


3. Members refers to the health plan members who received provider-administered injectable or infused drugs.

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.

Over the last five years, hospital outpatient spend has continued to increase and accounted for more than half (53 percent) of commercial medical pharmacy spend by 2014. Conversely, although hospital spend has increased for Medicare, the majority of spend was found in the physician office setting (51 percent in 2014). Medicare spend in the physician office was highest in 2010 when it represented 65 percent of health plan costs for Medicare members and has steadily decreased, leveling out to 51 percent over the last three years. Hospital outpatient represented 24 percent of Medicare spend in 2010 and has since increased to 40 percent of spend in 2014 (***see Figure 54***).

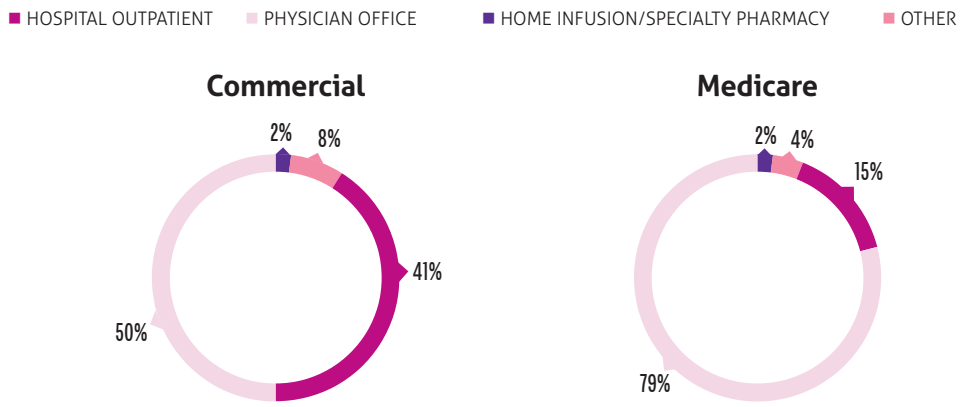
FIGURE 54: Medical Pharmacy Percentage Spend by LOB by Site of Service 2010–2014



Across all medical benefit drugs (represented by more than 800 HCPCS codes) and lines of business, the majority of members received their provider-administered injectable or infused drug in the physician office. For the commercial medical benefit, half of members were treated in the physician office. For the Medicare benefit, 79 percent of members received their medical benefit drugs in the physician office. The "other" sites of service were comprised of various locations, such as dialysis centers, emergency departments, and ambulatory surgical centers.

For the commercial population, spend for each site of service was inversely proportional to utilization distribution. Although 53 percent of spend took place in the hospital and one-third (31 percent) was in the physician office setting, half of commercial members were treated in the physician office while 41 percent were seen in the hospital setting. For the Medicare medical benefit, the difference was more dramatic with 40 percent of the spend occurring in the hospital outpatient setting, but only 15 percent of members received their provider-administered drugs in hospital outpatient facilities (***see Figure 55***).

FIGURE 55: 2014 Medical Pharmacy Market Share Percentages by Members by LOB and Site of Service



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

Trend Drivers

80%
spend in top 50 drugs

9%
increased cost per commercial patient

SUMMARY

> Over the last five years, there has been a 21 percent increase in the representative cost of the top 25 drugs on the commercial medical benefit. The total increase for the top 100 medical benefit drugs was 31 percent.

> In 2014, for both commercial and Medicare, close to or more than 80 percent of drug spend occurred in the top 50 medical benefit drugs.

> Across all medical pharmacy utilization, the annual cost per patient for commercial members increased by 9 percent, and the Medicare annual cost per patient decreased by 3 percent.

CATEGORY LANDSCAPE

Regardless of line of business (LOB), oncology drugs had the highest allowed amount PMPM. There were five drug categories or disease states with a commercial allowed amount PMPM over $1.00. Two of the five were oncology treatments, two others fell under biologic drugs for autoimmune disorders (BDAIDs), and the last category was immune globulin (IG). The results were similar in Medicare with two exceptions. Ophthalmic injections were $0.26 under the commercial medical benefit, but almost 15 times higher under Medicare at $3.86. The other was erythropoiesis-stimulating agents (ESAs) for oncology support with an allowed amount PMPM of $0.12 on the commercial benefit, but almost 12 times that on the Medicare medical benefit at $1.40. Commercial spend was $8.79 for oncology and $2.98 for oncology support agents, totaling $11.77 and representing half of medical pharmacy spend. Medicare cancer drug spend was more than double at $20.28 for oncology and $6.67 for oncology support, totaling $26.95 and representing 60 percent of medical pharmacy spend (***see Figures 56 and 57***).

FIGURE 56: 2014 Commercial PMPM by Disease State or Drug Category

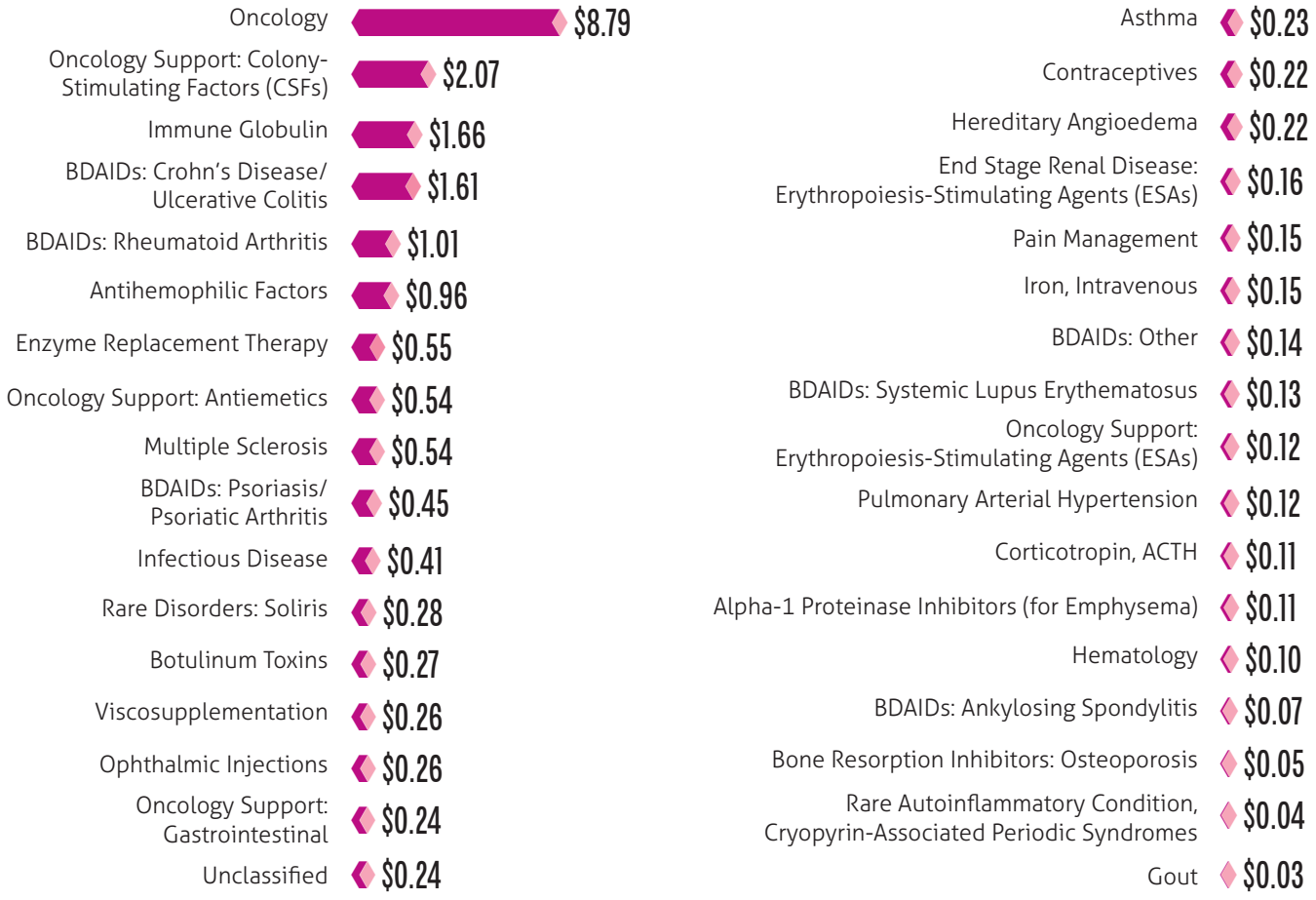
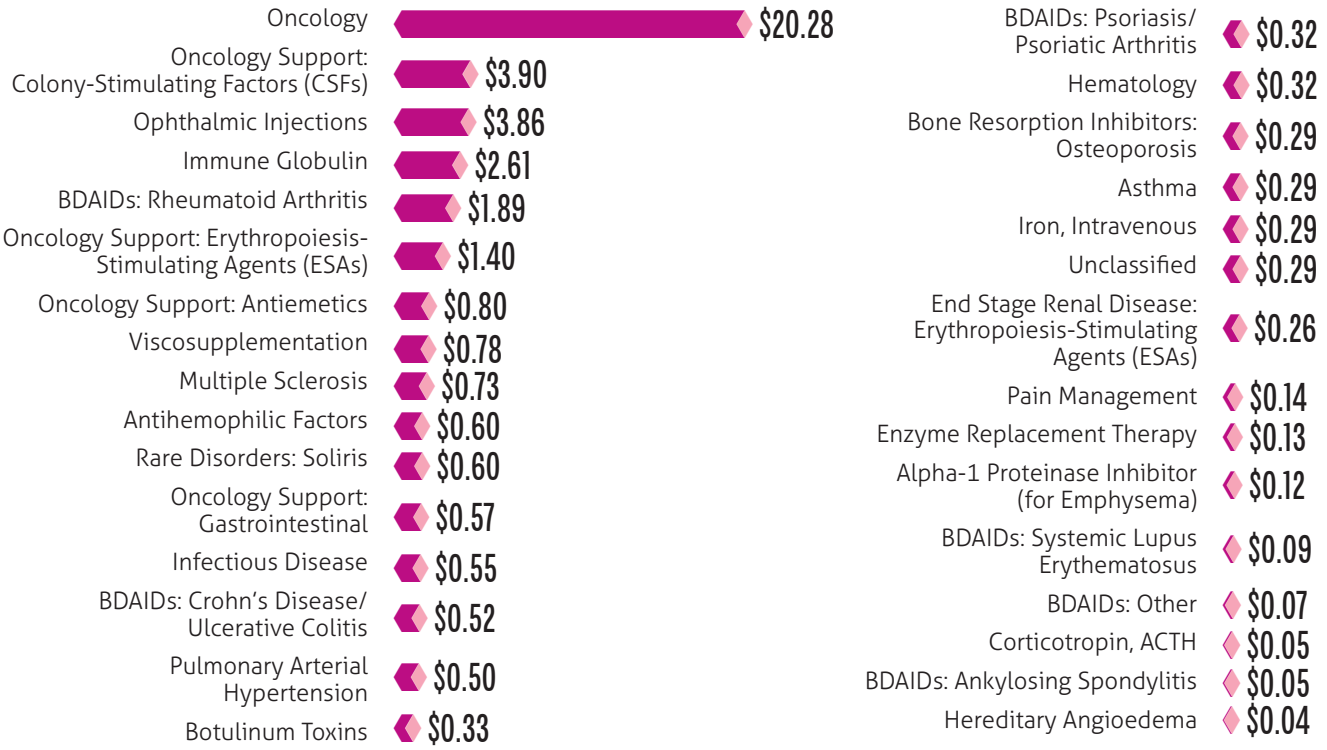


FIGURE 57: 2014 Medicare PMPM by Disease State or Drug Category



Similar to last year, we grouped the medical benefit drugs into disease state or drug therapy category based on labeled indications. For drugs with multiple indications, we separated the drugs' spend into two or more disease states based on the ICD-9 codes billed per claim line. Three views are provided by disease state or drug category: the percentage of allowed amount PMPM, the percentage of members who received a medical benefit drug, and the change in average sales price (ASP) and/or average wholesale price (AWP) from 2013 to 2014 (*see Table 4*).

For the commercial medical benefit in 2014, oncology represented more than 50 percent of drug spend: 39.5 percent for oncology and 13.3 percent for oncology support. BDAIDs represented another 15.3 percent of the allowed amount PMPM. When analyzing the impact on members, the highest classified number of claims was under the pain management category (30.6 percent) followed by infectious disease (19.9 percent) and oncology support (19.8 percent). The high percentage of members receiving an oncology support agent is likely due to utilization of antiemetics, namely ondansetron (Zofran), for non-oncology treatments.

For the Medicare medical benefit, oncology, at more than 60 percent when combined with oncology support, also represented the highest spend, but ophthalmic injections was the second highest category for spend, representing 9 percent of medical benefit spend over 6.9 percent for BDAIDs agents. With the exception of oncology (16.9 percent), Medicare paralleled commercial from a member perspective, although ranked slightly differently, with oncology supportive agents (16.4 percent) followed by pain management (15.1 percent) and infectious disease agents (14.1 percent).

Overall, price increases may be attributed to the number of reported drug shortages, which have nearly tripled between 2005 and 2010 and have risen almost 75 percent over the last five years.[5] In addition, pharmaceutical companies maintain the authority to increase prices at anytime during the drug's lifecycle, barring repercussions, as in the case of Turing Pharmaceuticals 2015 decision to increase the price of Daraprim by 5,000 percent. The company has since been called to testify to the U.S. House Committee on Oversight and Government Reform and has since introduced programs allowing hospitals, which see 80 percent of affected patients, to acquire Daraprim at a 50 percent reduced cost.[6]

5. Based on information provided by manufacturers to the University of Utah Drug Information Service. Reproduced with permission from Erin R. Fox, Pharm.D., Director, Drug Information Service, University of Utah Health Care. Source: http://www.ashp.org/DocLibrary/Policy/DrugShortages/OPA-National-Drug-Shortages.pdf.

6. Business Wire. Turing Pharmaceuticals AG to Testify at Congressional Hearing on Drug Pricing. Accessed: http://www.businesswire.com/news/home/20160122005852/en/Turing-Pharmaceuticals-AG-Testify-Congressional-Hearing-Drug.

TABLE 4: Percentage of Allowed Amount PMPM and Members by Disease State or Drug Category by LOB and ASP/AWP Trends 2013-2014

	Commercial		Medicare		ASP/AWP Trends	
Disease State or Drug Category	**% of Allowed Amount PMPM**	**% of Members**	**% of Allowed Amount PMPM**	**% of Members**	**ASP 2013-2014**	**AWP 2013-2014**
Oncology	39.5%	5.5%	47.5%	16.9%	12.0%	11.0%
Oncology Support	**13.3%**	**19.8%**	**15.6%**	**16.4%**		
Colony-Stimulating Factors (CSFs)	9.3%	1.4%	9.1%	3.4%	5.0%	10.0%
Antiemetics	2.4%	18.0%	1.9%	9.5%	0.0%	0.0%
Gastrointestinal	1.1%	0.1%	1.3%	0.2%	6.0%	6.0%
Erythropoiesis-Stimulating Agents (ESAs)	**0.6%**	**0.4%**	**3.3%**	**3.4%**	**9.0%**	**4.0%**
Biologic Drugs for Autoimmune Disorders (BDAIDs)	**15.3%**	**1.6%**	**6.9%**	**1.7%**		
Crohn's Disease/Ulcerative Colitis	7.2%	0.6%	1.2%	0.2%	n/a	n/a
Rheumatoid Arthritis	4.5%	0.6%	4.4%	1.1%	4.0%	4.0%
Psoriasis/Psoriatic Arthritis	2.0%	0.2%	0.8%	0.1%	5.0%	7.0%
Systemic Lupus Erythematosus	0.6%	0.0%	0.2%	0.0%	1.0%	1.0%
Ankylosing Spondylitis	0.3%	0.0%	0.1%	0.0%	n/a	n/a
Immune Globulin	7.4%	0.4%	6.1%	0.7%	3.0%	4.0%
Antihemophilic Factors	4.3%	0.1%	1.4%	0.0%	2.0%	3.0%
Enzyme Replacement Therapy	2.4%	0.0%	0.3%	0.0%	2.0%	2.0%
Multiple Sclerosis	2.4%	0.1%	1.7%	0.2%	n/a	15.0%
Infectious Disease	1.9%	19.9%	1.3%	14.1%	3.0%	6.0%
Rare Disorders: Soliris	1.3%	0.0%	1.4%	0.0%	3.0%	2.0%
Botulinum Toxins	1.2%	1.7%	0.8%	1.9%	3.0%	1.0%
Viscosupplementation	1.2%	4.2%	1.8%	10.2%	1.0%	13.0%
Ophthalmic Injections	1.2%	1.0%	9.0%	11.0%	0.0%	1.0%
Unclassified	1.1%	6.7%	0.7%	4.3%		
Asthma	1.0%	0.2%	0.7%	0.2%	9.0%	8.0%
Contraceptives	1.0%	5.5%	0.0%	0.1%	20.0%	6.0%
Hereditary Angioedema	1.0%	0.0%	0.1%	0.0%	7.0%	13.0%
End Stage Renal Disease: Erythropoiesis-Stimulating Agents (ESAs)	0.7%	0.2%	0.6%	0.6%	10.0%	3.0%
Pain Management	0.7%	30.6%	0.3%	15.1%	18.0%	9.0%
Iron, Intravenous	0.7%	1.7%	0.7%	3.4%	-1.0%	6.0%
Pulmonary Arterial Hypertension	0.6%	0.0%	1.2%	0.1%	6.0%	4.0%
Corticotropin, ACTH	0.5%	0.0%	0.1%	0.0%	5.0%	1.0%
Alpha-1 Proteinase Inhibitor (for Emphysema)	0.5%	0.0%	0.3%	0.0%	2.0%	9.0%
Hematology	0.4%	0.0%	0.8%	0.1%	5.0%	7.0%
Bone Resorption Inhibitors: Osteoporosis	0.2%	0.6%	0.7%	3.1%	4.0%	0.0%

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

TOP DRUG SPEND LANDSCAPE

New this year, we analyzed the overall distribution of the medical benefit drug spend by quadrants, the top 10, 25, 50, and 100. This was a representation of the top 100 drugs in each year, whereas the top 25 drugs in Tables 6 and 7 reflect only the year 2014. In 2014, the top 25 drugs represented almost two-thirds (64 percent) of the total spend for commercial medical benefit drugs. The top 100 represented 92 percent of the total PMPM for commercial. This was consistent with 2013 when the top 25 represented 63 percent and the top 100 represented 91 percent. Since 2010, there has been a 21 percent increase in the representative cost of the top 25 drugs on the commercial medical benefit. The total increase across all medical benefit drugs was 34 percent.

Spend for Medicare medical benefit drugs shifted in the opposite direction of commercial, with a net decrease in spend over five years, although the proportion of spend among the four segments was comparable to the commercial medical benefit. For the Medicare medical benefit, the top 25 drugs represented 69 percent of allowed amount PMPM while the top 100 represented 94 percent. This is also consistent from 2013 to 2014, with the top 25 and top 100 representing 66 and 94 percent, respectively (***see Table 5***).

TABLE 5: Top 100 Medical Benefit Drugs by Allowed Amount PMPM and Percentage Change 2010-2014

	2010	2011	2012	2013	2014	2014 % of Total	% Change 2010-2011	% Change 2011-2012	% Change 2012-2013	% Change 2013-2014	% Change 2010-2014
COMMERCIAL											
Top 10	$8.73	$9.21	$9.75	$9.72	$10.83	46%	6%	6%	0%	11%	24%
Top 25	$12.45	$12.61	$13.38	$13.35	$15.05	64%	1%	6%	0%	13%	21%
Top 50	$14.94	$15.47	$16.52	$16.52	$18.64	79%	4%	7%	0%	13%	25%
Top 100	$16.53	$17.33	$18.82	$19.24	$21.62	92%	5%	9%	2%	12%	31%
TOTAL PMPM	**$17.60**	**$18.60**	**$20.31**	**$21.18**	**$23.60**		**6%**	**9%**	**4%**	**11%**	**34%**
MEDICARE											
Top 10	$23.55	$21.42	$21.89	$19.41	$20.60	46%	-9%	2%	-11%	6%	-13%
Top 25	$35.08	$31.85	$31.45	$28.36	$30.82	69%	-9%	-1%	-10%	9%	-12%
Top 50	$41.65	$38.33	$38.36	$35.10	$37.66	84%	-8%	0%	-8%	7%	-10%
Top 100	$45.16	$42.05	$42.15	$40.15	$42.30	94%	-7%	0%	-5%	5%	-6%
TOTAL PMPM	**$46.25**	**$43.41**	**$43.92**	**$42.84**	**$44.84**		**-6%**	**1%**	**-2%**	**5%**	**-3%**

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

As with past trend reports, we isolated the top 25 medical benefit drugs by PMPM spend. Starting last year, we separated the top 25 drugs by LOB and calculated the average medical pharmacy annual cost (allowed amount) per patient and compared the change year-over-year. New this year, we calculated the change in ASP and AWP for these top 25 drugs. Commercial drugs new to the top 25 list include Perjeta, Cerezyme, and Orencia, while the top five drugs remained the same since our first edition. Medicare drugs new to the top 25 list include Yervoy, Soliris, Aloxi, and Orencia, while Medicare also kept the top five drugs intact. Across all medical pharmacy utilization, the annual cost per patient for commercial members increased 9 percent and the Medicare annual cost per patient decreased 3 percent (***see Tables 6 and 7***).

OTHER HIGHLIGHTS INCLUDE:

- Almost all drugs have increased their year-over-year allowed amount PMPM, while 11 of 25 commercial drugs and 10 of 25 Medicare drugs have decreased their annual cost per patient from 2013 to 2014 (***see Tables 6 and 7***).
- Although newer cancer treatments typically have less toxic side effects on blood cells, Neulasta has seen increased utilization as it has become a standard supportive care agent for patients treated with chemotherapy. It faces competition over the next few months with the pending approval of its biosimilar sometime in 2016 (***see Tables 6 and 7***).
- Oxaliplatin (Eloxatin) saw an almost complete decrease (-93 percent) in ASP and a 24 percent decrease in AWP due to introduction of generic oxaliplatin in 2012. MS/Crohn's drug Tysabri saw the largest increase in ASP (14 percent) as well as a 16 percent increase in AWP (***see Table 6***).

- For commercial, Erbitux, Cerezyme, Soliris, Abraxane, and Sandostatin LAR all saw increases in allowed amount PMPM of over 20 percent. The top two drugs by commercial spend — Remicade and Neulasta — saw a 17 and 20 percent increase, respectively, in allowed amount PMPM (*see Table 6*).
- Yervoy, new to the Medicare list in 2014, saw a year-over-year increase of 28 percent with potential increased usage in the Medicare population due to reinduction treatment, increased physician comfort with administration, as well as increased risk/incidence of melanoma in the aging population (*see Table 7*).
- For Medicare, Soliris and Abraxane both saw increases in PMPM greater than 60 percent, and Eylea saw an increase of 30 percent. Conversely, Soliris saw the greatest decrease in annual cost per patient at -20 percent. Abraxane saw the highest increase in annual cost per patient at 20 percent (*see Table 7*).
- On the top Medicare medical benefit drug listing, Eligard/Lupron Depot saw the largest drop in ASP (-3 percent) while Vidaza saw the largest drop in AWP (-8 percent) (*see Table 7*).
- Across all medical benefit drugs, ASP rates trended 11 percent from 2013 to 2014, while AWP increased 18 percent (*see Tables 6 and 7*).

TABLE 6: Commercial Top 25 Medical Benefit Drugs by Allowed Amount PMPM, Annual Cost per Patient, and ASP/AWP Trends 2013-2014

			Allowed Amount PMPM			Annual Cost per Patient			ASP/AWP Trends	
RANK	HCPCS	BRAND	2013	2014	% Change	2013	2014	% Change	ASP Trend	AWP Trend
1	J1745	Remicade	$2.16	$2.52	17%	$26,073	$27,512	6%	6%	9%
2	J2505	Neulasta	$1.58	$1.89	20%	$17,846	$19,261	8%	10%	9%
3	J9035	Avastin	$1.36	$1.40	3%	$21,665	$18,810	-13%	3%	4%
4	J9310	Rituxan	$1.12	$1.24	11%	$28,998	$29,992	3%	5%	3%
5	J9355	Herceptin	$1.02	$1.16	14%	$41,276	$41,778	1%	5%	3%
6	J7192	Advate/Helixate/ Kogenate/Recombinate	$0.66	$0.59	-10%	$183,488	$173,751	-5%	1%	0%
7	J1569	Gammagard Liquid	$0.46	$0.55	20%	$40,953	$44,503	9%	5%	7%
8	J2323	Tysabri	$0.47	$0.54	14%	$36,882	$42,829	16%	14%	16%
9	J1561	Gamunex-C/Gammaked	$0.49	$0.52	6%	$54,587	$52,003	-5%	4%	1%
10	J9305	Alimta	$0.37	$0.41	11%	$34,120	$32,782	-4%	3%	4%
11	J0897	Xgeva/Prolia	$0.34	$0.38	13%	$5,257	$4,657	-11%	0%	2%
12	J9263	Eloxatin	$0.41	$0.33	-20%	$12,877	$9,190	-29%	-93%	-24%
13	J9306	Perjeta		$0.31			$36,755			0%
14	J9228	Yervoy	$0.29	$0.31	7%	$159,514	$142,278	-11%	3%	3%
15	J9264	Abraxane	$0.22	$0.29	33%	$23,220	$25,016	8%	0%	0%
16	J9171	Taxotere	$0.32	$0.29	-11%	$9,172	$7,681	-16%	-38%	-18%
17	J1300	Soliris	$0.21	$0.28	36%	$389,657	$342,054	-12%	3%	2%
18	J9055	Erbitux	$0.19	$0.28	48%	$36,755	$43,334	18%	1%	2%
19	J1786	Cerezyme	$0.19	$0.27	47%	$235,440	$317,386	35%	0%	0%
20	J2469	Aloxi	$0.26	$0.27	2%	$2,284	$2,182	-4%	2%	2%
21	J9041	Velcade	$0.23	$0.26	14%	$28,251	$29,599	5%	3%	3%
22	J0585	Botox	$0.22	$0.26	20%	$1,989	$2,130	7%	-1%	0%
23	J2353	Sandostatin LAR	$0.20	$0.24	22%	$36,628	$40,735	11%	6%	6%
24	J2357	Xolair	$0.19	$0.23	20%	$15,390	$15,094	-2%	9%	8%
25	J0129	Orencia	$0.19	$0.22	16%	$16,679	$19,402	16%	5%	8%
TOP 25 TOTALS			**$13.13**	**$15.05**	**15%**	**$22,079**	**$22,423**	**2%**		
TOTAL MEDICAL PHARMACY			**$21.18**	**$23.60**	**11%**	**$1,577**	**$1,713**	**9%**	**11%**	**18%**

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

TABLE 7: Medicare Top 25 Medical Benefit Drugs by Allowed Amount PMPM, Annual Cost per Patient, and ASP/AWP Trends 2013-2014

			Allowed Amount PMPM			Annual Cost per Patient			ASP/AWP Trends	
RANK	HCPCS	BRAND	2013	2014	% Change	2013	2014	% Change	ASP Trend	AWP Trend
1	J9310	Rituxan	$3.34	$3.49	4%	$22,088	$23,522	6%	5%	3%
2	J2505	Neulasta	$3.25	$3.48	7%	$12,149	$12,873	6%	10%	9%
3	J2778	Lucentis	$2.66	$2.76	4%	$9,246	$9,164	-1%	0%	0%
4	J9035	Avastin	$2.19	$2.43	11%	$3,599	$3,967	10%	3%	4%
5	J1745	Remicade	$2.04	$1.69	-17%	$18,477	$17,887	-3%	6%	9%
6	J9305	Alimta	$1.50	$1.54	3%	$26,080	$24,695	-5%	3%	4%
7	J9355	Herceptin	$1.19	$1.47	24%	$31,248	$30,686	-2%	5%	3%
8	J0897	Xgeva/Prolia	$1.10	$1.39	26%	$3,102	$2,755	-11%	0%	2%
9	J9041	Velcade	$1.15	$1.25	9%	$23,617	$22,977	-3%	3%	3%
10	J1569	Gammagard Liquid	$1.00	$1.10	10%	$43,338	$37,787	-13%	5%	7%
11	J9033	Treanda	$0.91	$1.00	9%	$23,692	$26,026	10%	4%	4%
12	J9264	Abraxane	$0.60	$0.97	61%	$14,882	$17,842	20%	0%	0%
13	J0178	Eylea	$0.69	$0.89	30%	$9,065	$8,307	-8%		0%
14	J9055	Erbitux	$0.62	$0.77	23%	$26,849	$29,177	9%	1%	2%
15	J2323	Tysabri	$0.62	$0.73	18%	$33,336	$39,149	17%	14%	16%
16	J0885	Procrit	$0.69	$0.72	4%	$3,267	$3,370	3%	11%	5%
17	J0881	Aranesp	$0.63	$0.68	9%	$5,172	$5,192	0%	7%	3%
18	J9228	Yervoy	$0.50	$0.63	28%	$98,080	$109,789	12%	3%	3%
19	J9217	Eligard/Lupron Depot	$0.60	$0.63	4%	$1,882	$1,887	0%	-3%	0%
20	J1300	Soliris	$0.37	$0.60	64%	$325,714	$261,405	-20%	3%	2%
21	J2353	Sandostatin LAR	$0.52	$0.57	10%	$27,468	$30,177	10%	6%	6%
22	J1561	Gamunex-C/Gammaked	$0.55	$0.55	0%	$35,897	$29,154	-19%	4%	1%
23	J9025	Vidaza	$0.49	$0.51	4%	$23,320	$23,579	1%	-2%	-8%
24	J2469	Aloxi	$0.41	$0.49	20%	$1,197	$1,263	5%	2%	2%
25	J0129	Orencia	$0.49	$0.47	-3%	$13,884	$15,892	14%	5%	8%
TOP 25 TOTALS			**$28.10**	**$30.82**	**10%**	**$10,590**	**$10,551**	**0%**		
TOTAL MEDICAL PHARMACY			**$42.84**	**$44.84**	**5%**	**$2,050**	**$1,994**	**-3%**	**11%**	**18%**

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

Although unclassified Healthcare Common Procedure Coding System (HCPCS) codes were not listed in the top 25 drugs this year, in total they still represented $0.24 for commercial spend and $0.37 for Medicare spend. Unclassified codes with at least $0.01 allowed amount PMPM are included in the following table (***see Table 8***). Code J3490 represents many unclassified injectable drugs, such as powders, solutions, anesthesia, antihistamines, cardiovascular agents, and antibiotics. J9999 is specific to oncology drugs and represented the following products in 2014: Cyramza, Keytruda, Marqibo, Gazyva, and Beleodaq. J3590, an unclassified code specific to biologics, was billed with Entyvio, Sylvant, HyQvia, Vimizim, and Ruconest. C9399 is an unclassified code specific for hospital outpatient facility use. Code J8499 is an unclassified code representing oral prescription drugs not used for chemotherapy (not otherwise specified). Please note: Medicare unclassified spend is represented as $0.29 PMPM in Figure 57 which redistributes intravitreal use of bevacizumab to the Ophthalmic Injections drug category.

TABLE 8: 2014 Unclassified Code Utilization by Allowed Amount PMPM for Commercial and Medicare

HCPCS	Commercial	Medicare
J3490	$0.15	$0.14
C9399	$0.04	$0.11
J3590	$0.03	$0.05
J9999	$0.02	$0.06
J8499	$0.01	$0.01
TOTAL	**$0.24**	**$0.37**

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 may not qualify for the top 25 drug listings. On the commercial medical benefit, 10 drugs cost more than $190,000 annually for treatment. On the Medicare medical benefit, 10 drugs cost patients more than $100,000 each year. Antihemophilic factors have the highest annual allowed cost per patient for both commercial and Medicare. On the commercial medical benefit, Novoseven costs payors over $750,000 per patient annually. On the Medicare benefit, Xyntha cost more than $800,000 per patient annually.

Cerezyme (used for the treatment of Gaucher disease), Soliris (used in the treatment of paroxysmal nocturnal hemoglobinuria and atypical hemolytic-uremic syndrome), and Cinryze (used to treat hereditary angioedema) are the only high-cost drugs to sit in both the commercial and Medicare top medical benefit drugs by annual allowed cost per patient in 2014. Cerezyme costs were comparable across the commercial and Medicare medical benefit (roughly $317,000 and $366,000, respectively). Soliris was more costly on the commercial medical benefit costing about $342,000 versus $261,000 on Medicare. Cinryze boasted another story and was priced 2.6 times higher on the commercial medical benefit than on Medicare (***see Figures 58 and 59***).

Other items to note include:

- Acthar — used mainly for infantile spasm; multiple sclerosis exacerbations; inflammatory disorders; and proteinuria in nephrotic syndrome, a rare kidney disease — is the eighth highest PPPY cost drug in Medicare (***see Figure 58***). Although CMS has spoken on the controversial use of the drug, Medicare is unable to limit its use as long as it continues to keep FDA approval.[7]
- Yervoy, currently ranking 14 and 18 on the top 25 commercial and Medicare medical benefits, respectively, impacts the Medicare medical benefit annual cost per patient coming in at nearly $110,000. In October 2015, Yervoy was approved for combination therapy with Opdivo for the treatment of patients with BRAF V600 wild-type unresectable or metastatic melanoma, foreshadowing a potentially large shift in cost as well as utilization for the treatment in coming years[8] (***see Figure 59***).

7. A Little Drug from Questcor Pharmaceuticals, Inc. (QCOR) Generates Controversy and a $220 Million Medicare Bill. August 2014. Accessed: http://www.biospace.com/News/a-little-drug-from-questcor-pharmaceuticals-inc/342417.

8. Nivolumab in Combination with Ipilimumab. October 2015. Accessed: http://www.fda.gov/Drugs/InformationOnDrugs/ApprovedDrugs/ucm465274.htm.

FIGURE 58: 2014 Highest-Cost Commercial Medical Benefit Drugs by Annual Cost per Patient and Allowed Amount PMPM

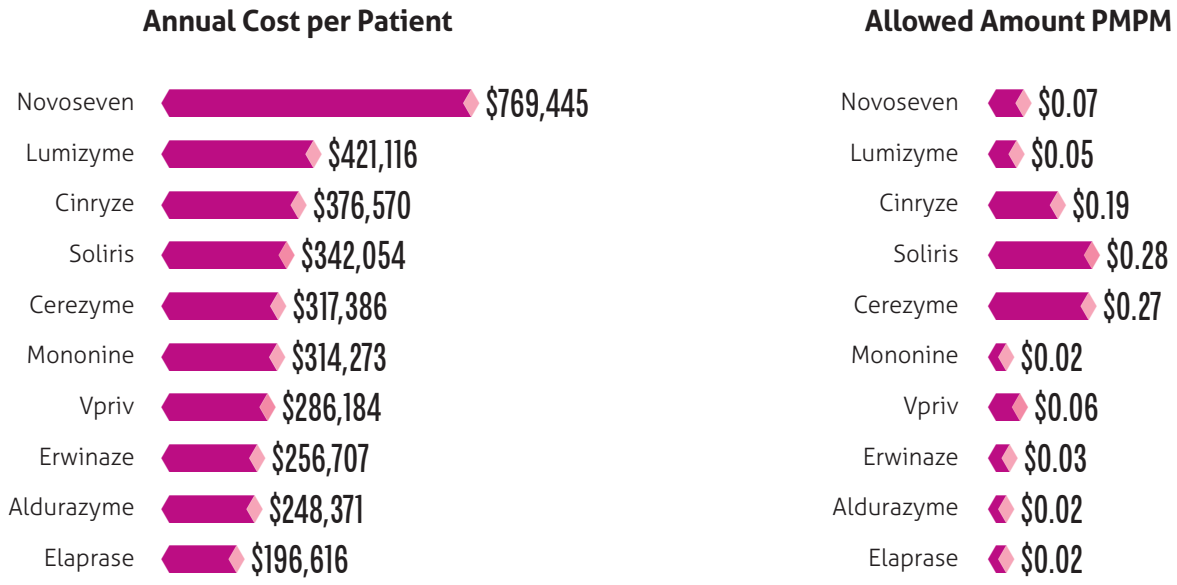
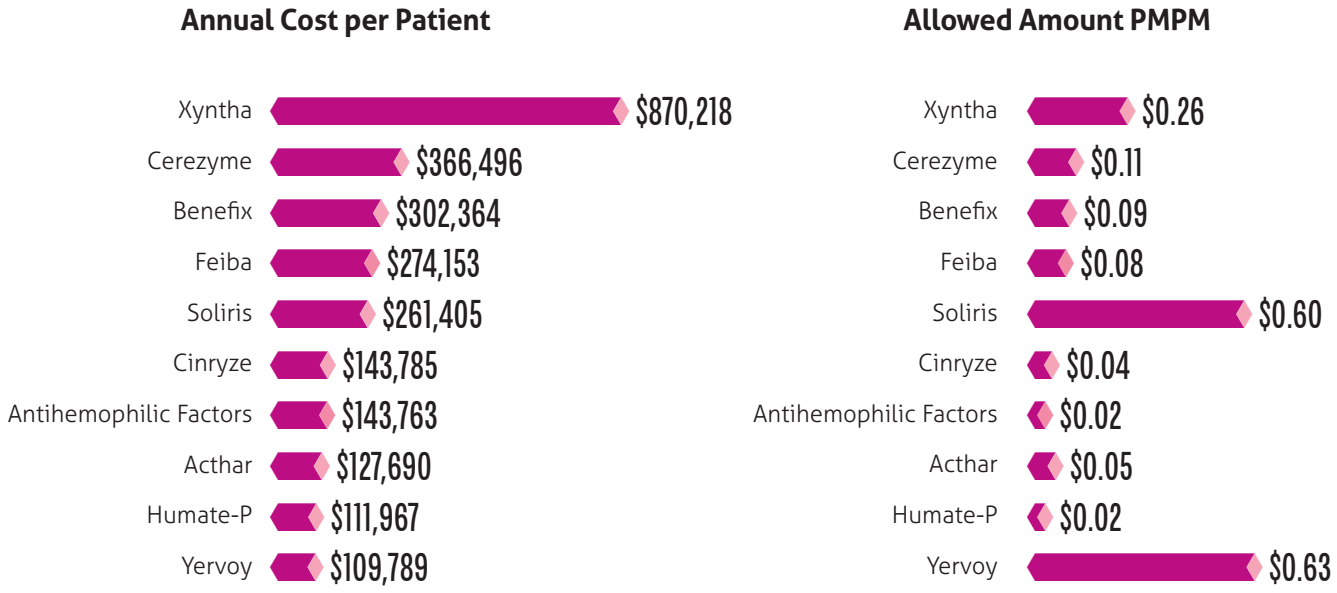


FIGURE 59: 2014 Highest-Cost Medicare Medical Benefit Drugs by Annual Cost per Patient and Allowed Amount PMPM*



*J7199 (Hemophilia-clotting factor, not otherwise classified) represented Obizur, Alprolix, and Eloctate in 2014.

Although these are the highest-cost drugs across the commercial and Medicare populations, they are rarely utilized. These top 10 highest-cost drugs tend to be used for conditions such as hereditary angioedema (HAE), rare hematologic disorders including hemophilia, diseases caused by inborn errors of metabolism, and cancer. On the commercial medical benefit, Soliris and Cerezyme saw the most use, while Soliris and Yervoy were the most utilized under Medicare (*see Table 9*).

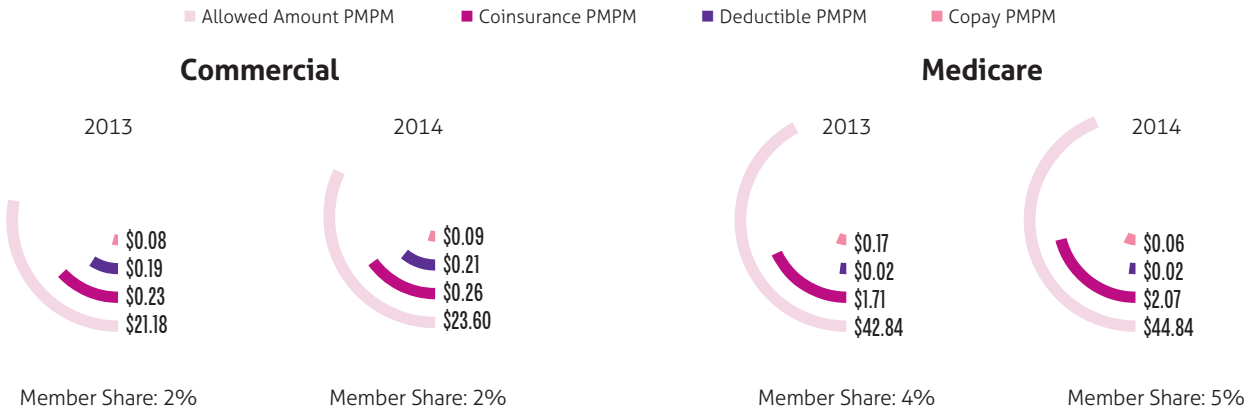
TABLE 9: 2014 Percentage of Member Utilization of Highest-Cost Medical Benefit Drugs

Commercial Drug	% Members
Novoseven	0.001%
Lumizyme	0.001%
Cinryze	0.004%
Soliris	0.007%
Cerezyme	0.007%
Mononine	0.001%
Vpriv	0.001%
Erwinaze	0.001%
Aldurazyme	0.001%
Elaprase	0.001%

Medicare Drug	% Members
Xyntha	0.001%
Cerezyme	0.001%
Benefix	0.001%
Feiba	0.001%
Soliris	0.009%
Cinryze	0.001%
Antihemophilic Factors	0.001%
Acthar	0.002%
Humate-P	0.001%
Yervoy	0.024%

Total cost of care for a member typically includes a deductible, coinsurance or copay, and maximum out-of-pocket (MOOP) contribution for drug services billed to the medical benefit. Through our analyses, we found that the actual medical benefit cost share for commercial and Medicare members was 2 and 5 percent, respectively, in 2014. As with last year's report, the claim lines analyzed were drug-specific and members may have paid their deductibles or reached their out-of-pocket maximums based on other non-drug medical services. Discrepancies may also have existed in the payor benefit, which may have included coinsurance or copay requirements for the office visit and not necessarily the drug service (*see Figure 60*).

FIGURE 60: Member Cost Share for Medical Benefit Drugs by LOB 2013-2014



DIAGNOSIS CODE TRENDS

As with controversial drugs such as Acthar and drugs with new indications like Abraxane, medical benefit drugs may be used to treat multiple indications. Again this year, we reviewed this dynamic for five prominent medical benefit drugs by allowed amount PMPM on the commercial and Medicare medical benefits. Only the primary ICD-9 code submitted on the claim was included in this analysis.

Of note on the commercial benefit was Avastin, originally approved in 2004 for colorectal cancer treatment, where its highest use was for other retinal disorders (ICD-9 362) often including diagnoses such as "wet" age-related macular degeneration. Use for retinal disorders was close to double that of its next highest diagnosis for colon cancer. Acthar's high number of claims for nephrotic syndrome and multiple sclerosis demonstrates its use by prescribers as a substitution for steroids (*see Table 10*).

Most medical benefit drug claims are submitted with more than one ICD-9 code. However, it is interesting to observe that for cancer drugs, frequently V58, an undefined/non-specific ICD-9 is billed as the primary diagnosis code, likely followed by more specific ICD-9's in the secondary and beyond diagnosis code fields. Diagnosis codes with $0.02 spend or greater, or more than 0 percent claims were included in this list.

TABLE 10: 2014 Commercial Top Diagnosis Codes for Key Medical Benefit Drugs

ICD-9 Code	Primary Diagnosis	PMPM	% Claim	% PMPM
	Avastin			
V58	Encounter for other and unspecified procedures and aftercare (radiotherapy)	$0.41	12%	30%
153	Malignant neoplasm of hepatic flexure	$0.25	18%	18%
191	Malignant neoplasm of cerebrum, except lobes, and ventricles	$0.21	7%	15%
183	Malignant neoplasm of ovary	$0.14	5%	10%
162	Malignant neoplasm of trachea	$0.14	6%	10%
154	Malignant neoplasm of rectosigmoid junction	$0.06	5%	4%
174	Malignant neoplasm of nipple and areola of female breast	$0.03	1%	2%
180	Malignant neoplasm of endocervix	$0.02	1%	1%
182	Malignant neoplasm of corpus uteri, except isthmus	$0.02	0%	1%
362	Other retinal disorders	$0.01	34%	0%
250	Diabetes mellitus without mention of complication, type II, or unspecified type, not stated as uncontrolled	$0.00	5%	0%
	Abraxane			
V58	Encounter for other and unspecified procedures and aftercare (radiotherapy)	$0.10	16%	33%
174	Malignant neoplasm of nipple and areola of female breast	$0.08	31%	26%
157	Malignant neoplasm of head of pancreas	$0.06	27%	20%
162	Malignant neoplasm of trachea	$0.03	15%	11%
	Acthar			
581	Nephrotic syndrome with lesion of proliferative glomerulonephritis	$0.04	39%	37%
340	Multiple sclerosis	$0.02	19%	20%
345	Generalized nonconvulsive epilepsy, without mention of intractable epilepsy	$0.02	13%	16%
	Sandostatin LAR			
209	Malignant carcinoid tumor of the small intestine, unspecified portion	$0.12	46%	51%
259	Delay in sexual development and puberty, not elsewhere classified	$0.03	17%	14%
	Yervoy			
172	Malignant melanoma of skin of lip	$0.17	64%	55%
V58	Encounter for other and unspecified procedures and aftercare (radiotherapy)	$0.11	29%	37%

On the Medicare medical benefit, primary diagnosis codes for most of these five drugs were more expansive than the commercial medical benefit, indicative of less stringent drug policies and the absence of step edits. An example is Yervoy which was utilized in both kidney and lung cancers in the Medicare population, but limited to melanoma only in commercial. Abraxane is more often used to treat Medicare patients with pancreatic cancer over breast cancer, the opposite utilization seen with commercial (*see Table 11*).

TABLE 11: 2014 Medicare Top Diagnosis Codes for Key Medical Benefit Drugs

ICD-9 Code	Primary Diagnosis	PMPM	% Claim	% PMPM
	Avastin			
153	Malignant neoplasm of hepatic flexure	$0.63	7%	26%
162	Malignant neoplasm of trachea	$0.49	3%	20%
V58	Encounter for other and unspecified procedures and aftercare (radiotherapy)	$0.40	3%	16%
183	Malignant neoplasm of ovary	$0.29	2%	12%
154	Malignant neoplasm of rectosigmoid junction	$0.16	2%	7%
191	Malignant neoplasm of cerebrum, except lobes, and ventricles	$0.13	1%	5%
362	Other retinal disorders	$0.10	74%	4%
189	Malignant neoplasm of kidney, except pelvis	$0.04	0%	2%
174	Malignant neoplasm of nipple and areola of female breast	$0.02	0%	1%
182	Malignant neoplasm of corpus uteri, except isthmus	$0.02	0%	1%
171	Malignant neoplasm of connective and other soft tissue of head, face, and neck	$0.02	0%	1%
250	Diabetes mellitus without mention of complication, type II, or unspecified type, not stated as uncontrolled	$0.01	5%	0%
	Abraxane			
157	Malignant neoplasm of head of pancreas	$0.27	28%	28%
174	Malignant neoplasm of nipple and areola of female breast	$0.21	22%	22%
V58	Encounter for other and unspecified procedures and aftercare (radiotherapy)	$0.20	18%	20%
162	Malignant neoplasm of trachea	$0.19	22%	19%

ICD-9 Code	Primary Diagnosis	PMPM	% Claim	% PMPM
	Acthar			
340	Multiple sclerosis	$0.05	93%	99%
	Sandostatin LAR			
209	Malignant carcinoid tumor of the small intestine, unspecified portion	$0.27	50%	47%
259	Delay in sexual development and puberty, not elsewhere classified	$0.18	29%	31%
V58	Encounter for other and unspecified procedures and aftercare (radiotherapy)	$0.02	3%	3%
239	Neoplasm of unspecified nature of digestive system	$0.02	1%	3%
	Yervoy			
172	Malignant melanoma of skin of lip	$0.35	48%	55%
V58	Encounter for other and unspecified procedures and aftercare (radiotherapy)	$0.20	38%	32%
189	Malignant neoplasm of kidney, except pelvis	$0.03	8%	5%
162	Malignant neoplasm of trachea	$0.02	4%	3%
190	Malignant neoplasm of eyeball, except conjunctiva, cornea, retina, and choroid	$0.02	2%	4%

Market Share Trends

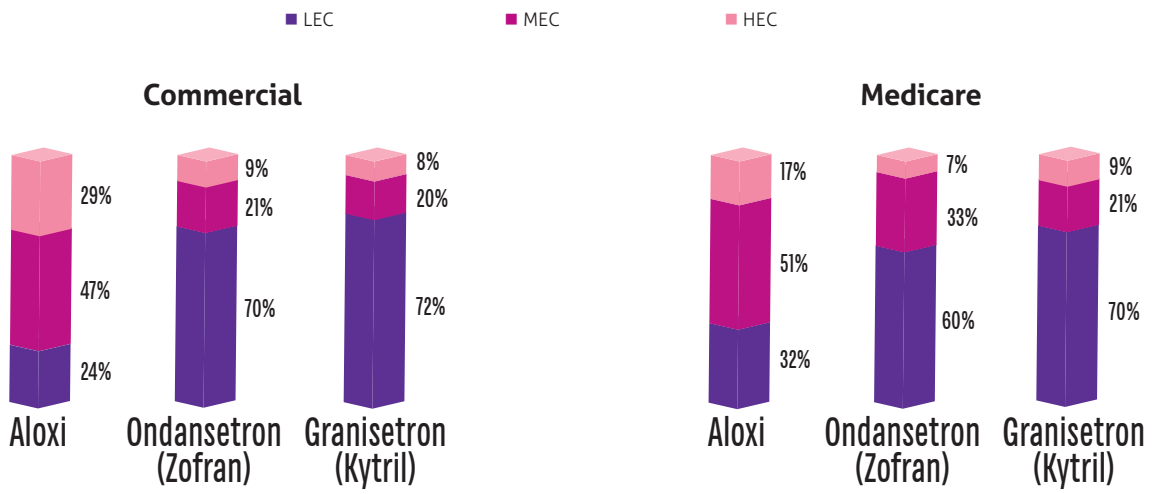
New this year, we enhanced the analysis of the impact on prescribing patterns by consolidating all drug categories into one section. This section presents category-by-category analysis of the utilization of the following medical benefit drug categories:

ANTIEMETICS

As in previous trend reports, we analyzed the three intravenous serotonin (5-HT3) receptor antagonists 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.

Aloxi's use in oncology 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). Even so, under the commercial medical benefit, Aloxi was used 24 percent of the time in low emetogenic chemotherapy (LEC) regimens and 32 percent of the time under the Medicare medical benefit. For both commercial and Medicare, there was higher utilization of granisetron and ondansetron for patients receiving LEC. For Medicare, the use of Aloxi occurs for LEC patients at higher rates than commercial, illustrating more open management of the drug on the Medicare medical benefit (*see Figure 61*).

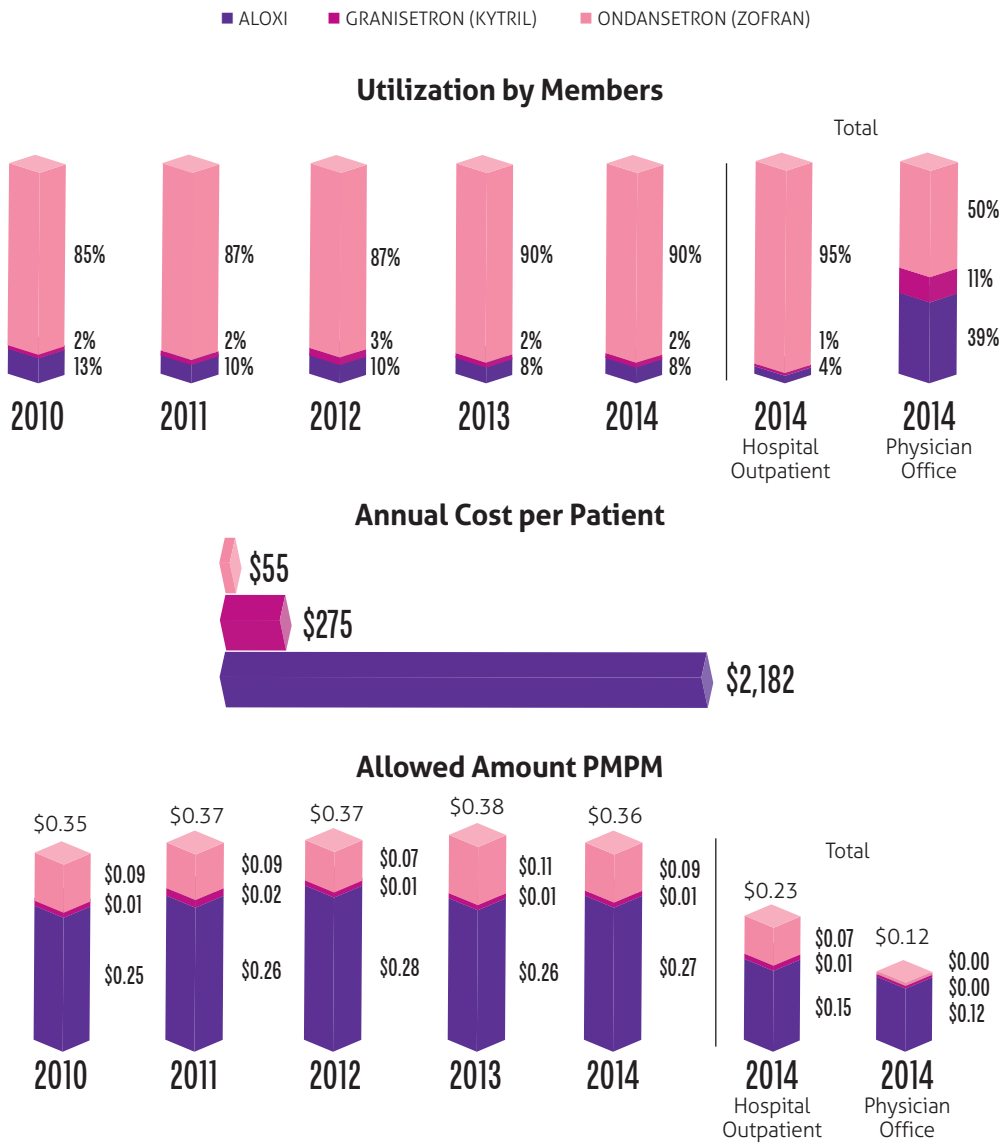
FIGURE 61: 2014 Percentage of Antiemetic Allowed Amount PMPM by Chemotherapy Regimen Potential Level of Emetogenicity



For commercial and Medicare medical benefits, hospitals overwhelmingly opted to use ondansetron (Zofran), the lowest-cost antiemetic for the treatment and/or prevention of nausea and vomiting. In 2014, physician offices utilized Aloxi for 39 percent of their commercial patients and 49 percent of Medicare. As mentioned earlier, physician offices, namely oncologists, utilize antiemetics for CINV, while hospitals utilize antiemetics for reasons beyond just chemotherapy, which contributes to the higher use of ondansetron (Zofran). The annual cost per commercial patient per year for ondansetron (Zofran) in the physician office setting is $55 versus $2,182 for Aloxi (*see Figures 62 and 63*).

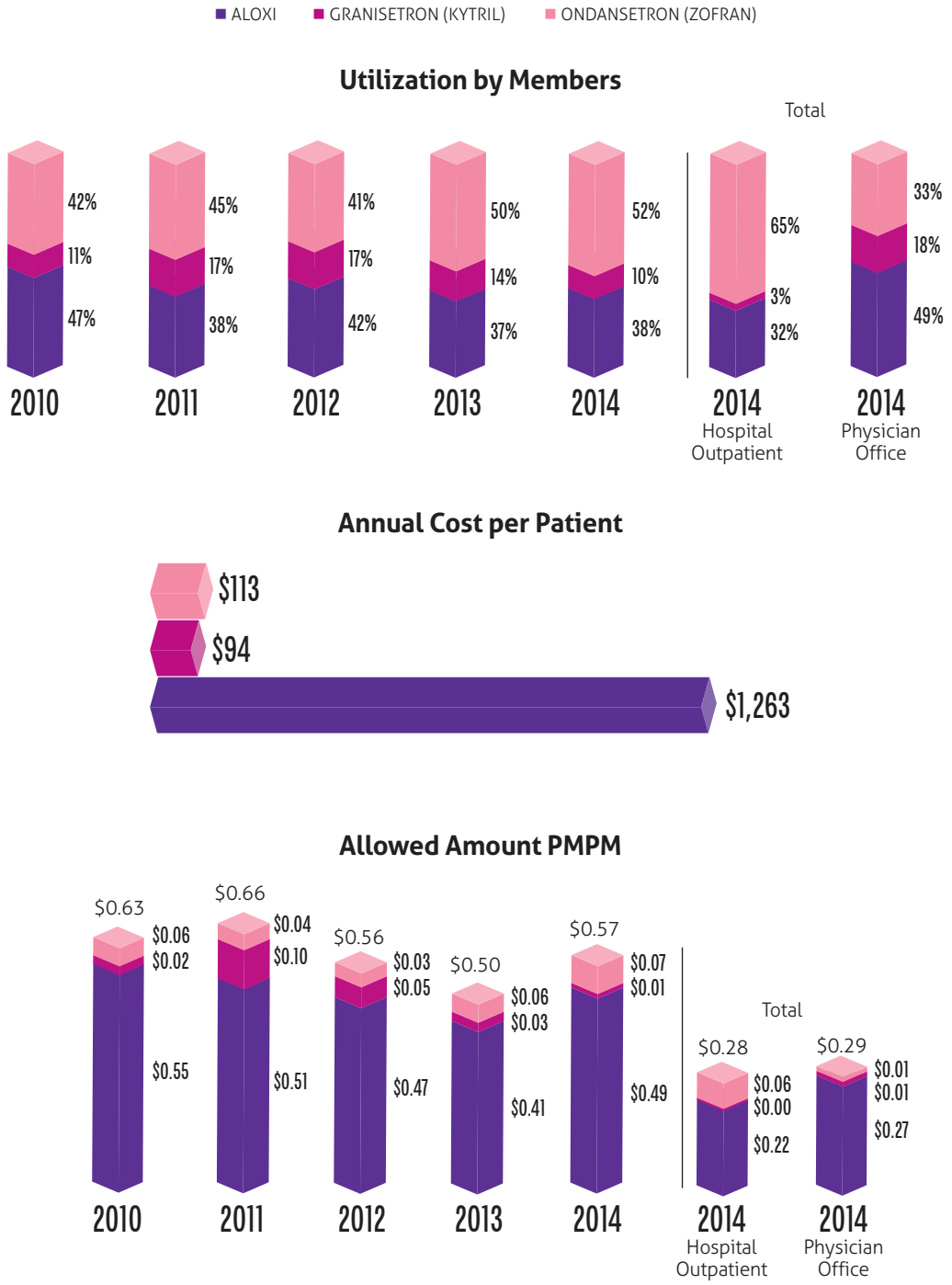
With oncology being the significant spend in both commercial and Medicare, it is important to analyze the allowed amount PMPM for therapies under the oncology support category, specifically the antiemetics used to treat nausea as a result of chemotherapy. In 2014, even with higher utilization of ondansetron, Aloxi, the highest-cost therapy for antiemetics, commanded the bulk of spend in both commercial and Medicare. Almost all spend in commercial and Medicare physician offices was accounted to Aloxi.

FIGURE 62: Commercial Utilization of Antiemetics by Members, Annual Cost per Patient, and Allowed Amount PMPM 2010-2014



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

FIGURE 63: Medicare Utilization of Antiemetics by Members, Annual Cost per Patient, and Allowed Amount PMPM 2010-2014

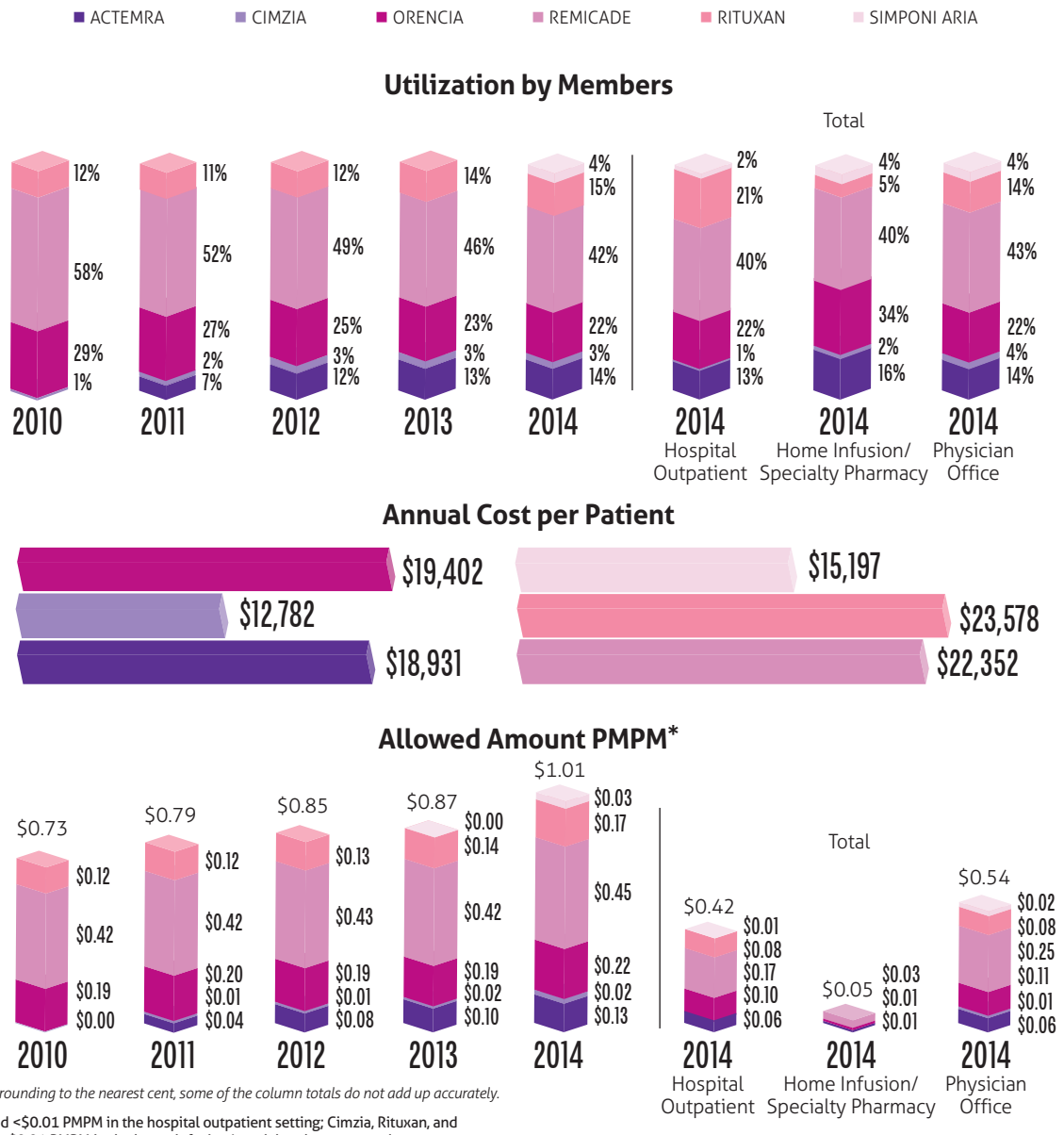


Please note: Due to rounding to the nearest cent, some of the column totals do not add up accurately.

BIOLOGIC DRUGS FOR AUTOIMMUNE DISORDERS (BDAIDs): RHEUMATOID ARTHRITIS

For biologic drugs for autoimmune disorders (BDAIDs) used specifically for the treatment of rheumatoid arthritis (RA), we examined three anti-TNF-alpha agents, Cimzia, Remicade, and Simponi ARIA, and three additional biologics often prescribed under the medical benefit, Rituxan, Orencia, and Actemra. Under the commercial medical benefit for BDAIDs used to treat RA, Rituxan had the highest cost per patient ($23,578) in 2014 and Remicade (the second highest cost agent at $22,352 per year) saw the largest use across all sites of service. Hospital outpatient (40 percent) and physician office settings (43 percent) utilized Remicade most frequently over other RA treatments. Orencia was the next highest utilized agent in RA treatments and had its greatest market share by members in the home infusion/specialty pharmacy setting. Rituxan market share has been consistent since 2010 and was more frequently used in the hospital outpatient setting (*see Figure 64*).

FIGURE 64: Commercial Utilization of BDAIDs: Rheumatoid Arthritis by Members, Annual Cost per Patient, and Allowed Amount PMPM 2010-2014

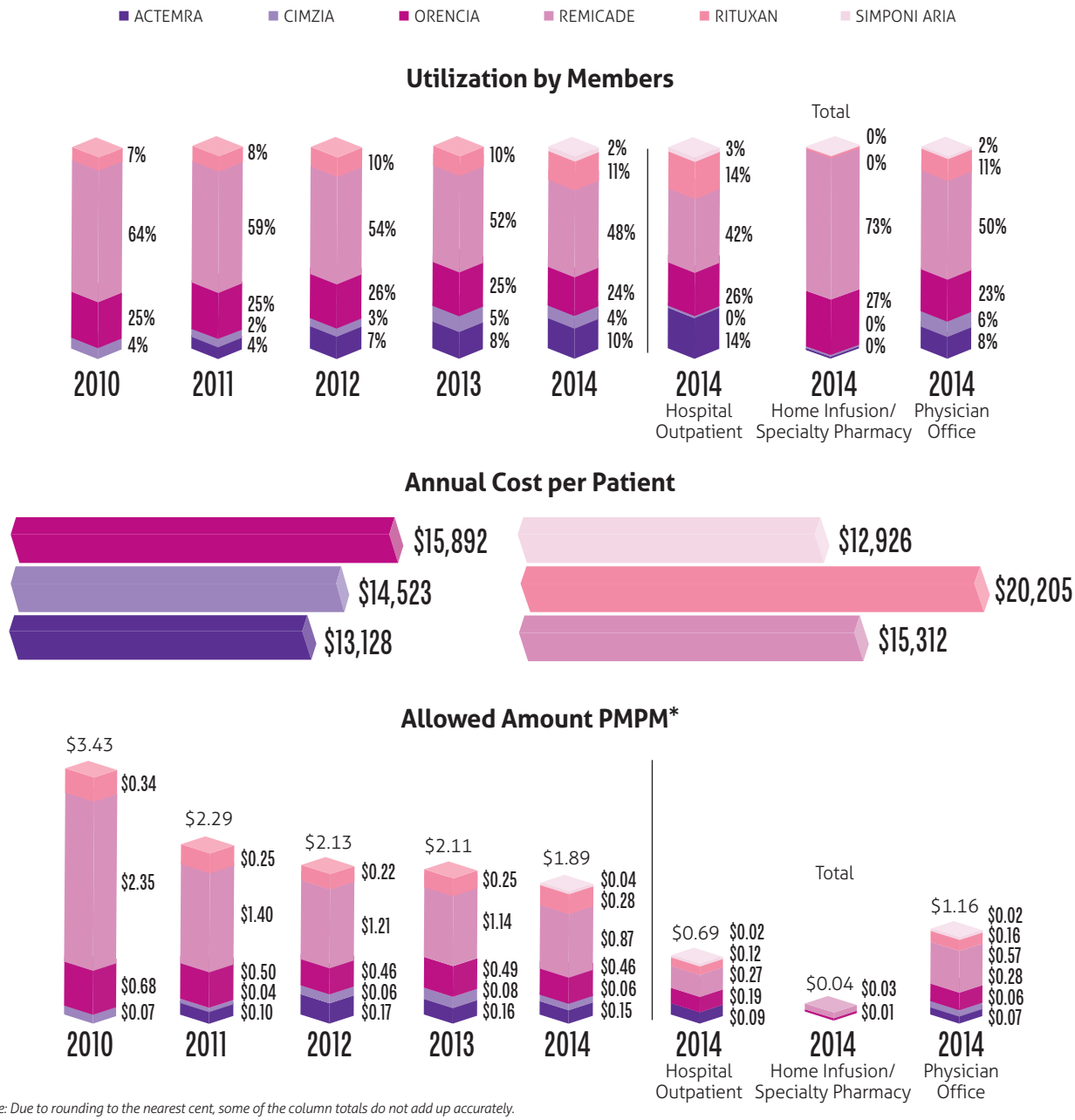


Please note: Due to rounding to the nearest cent, some of the column totals do not add up accurately.

*In 2014, Cimzia had <$0.01 PMPM in the hospital outpatient setting; Cimzia, Rituxan, and Simponi ARIA had <$0.01 PMPM in the home infusion/specialty pharmacy setting.

Medicare operates in parallel with the commercial medical benefit, with Remicade maintaining the highest market share. Annual cost per patient for BDAIDs: RA drugs differs not only in price, but in rank. On the Medicare benefit, Rituxan ($20,205) and Orencia ($15,892) costs were higher than Remicade ($15,312) and Cimzia costs ($14,523) were comparable, whereas on the commercial benefit, Cimzia was the lowest-cost agent. The overall allowed amount PMPM for BDAIDs: RA has decreased substantially year-over-year from its highest in 2010 at $3.43 to its lowest at $1.89 in 2014 (*see Figure 65*).

FIGURE 65: Medicare Utilization of BDAIDs: Rheumatoid Arthritis by Members, Annual Cost per Patient, and Allowed Amount PMPM 2010-2014



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

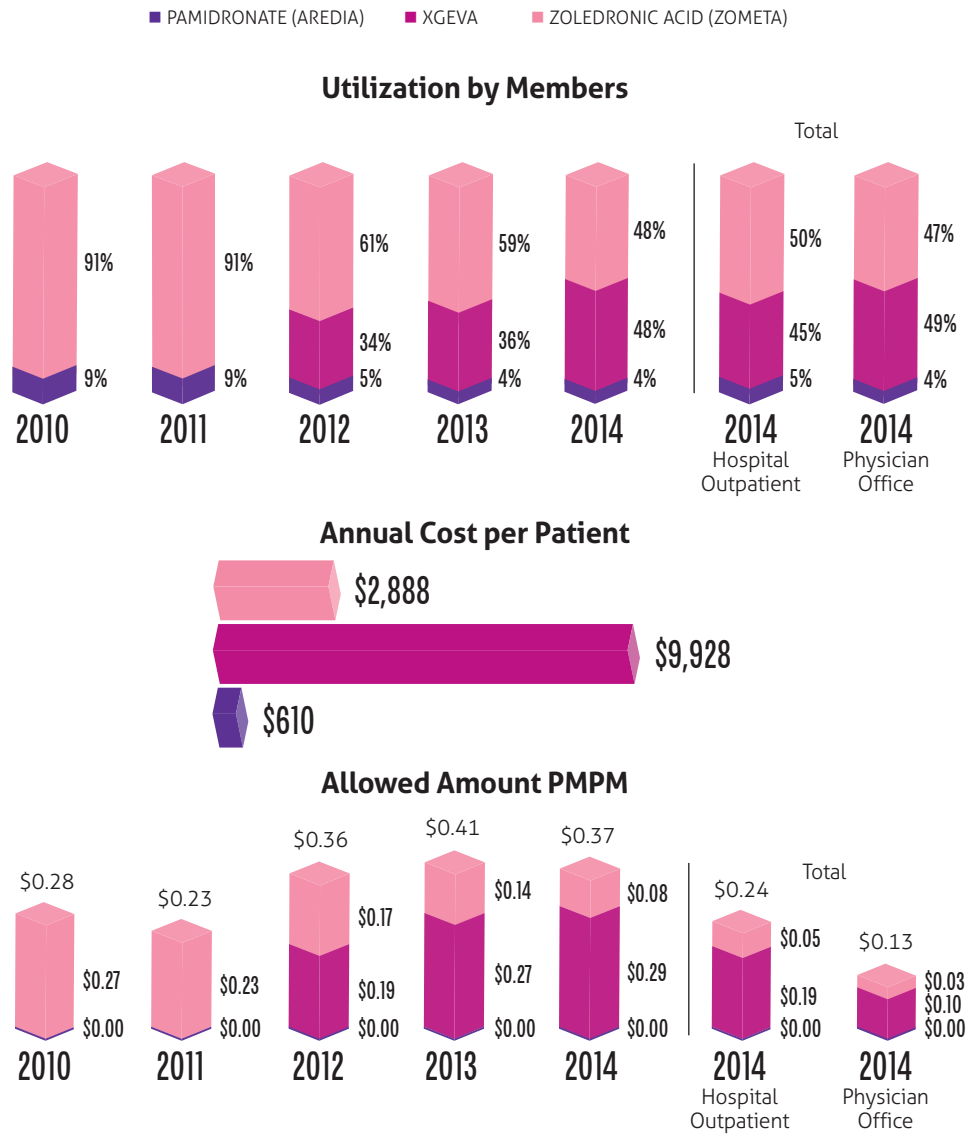
*In 2014, Cimzia had <$0.01 PMPM in the hospital outpatient setting; Actemra, Cimzia, Rituxan, and Simponi ARIA had no use in the home infusion/specialty pharmacy setting.

BONE RESORPTION INHIBITORS: ONCOLOGY

Three infusion agents are used to treat cancer metastases to the bone: generic pamidronate (Aredia), generic zoledronic acid (Zometa), and, most recently, Xgeva. Xgeva and Zometa both have drug counterparts that treat osteoporosis: Prolia and Reclast, respectively. Bisphosphonate generic zoledronic acid (Zometa) remains the market leader carrying close to two-thirds of market share in both commercial and Medicare.

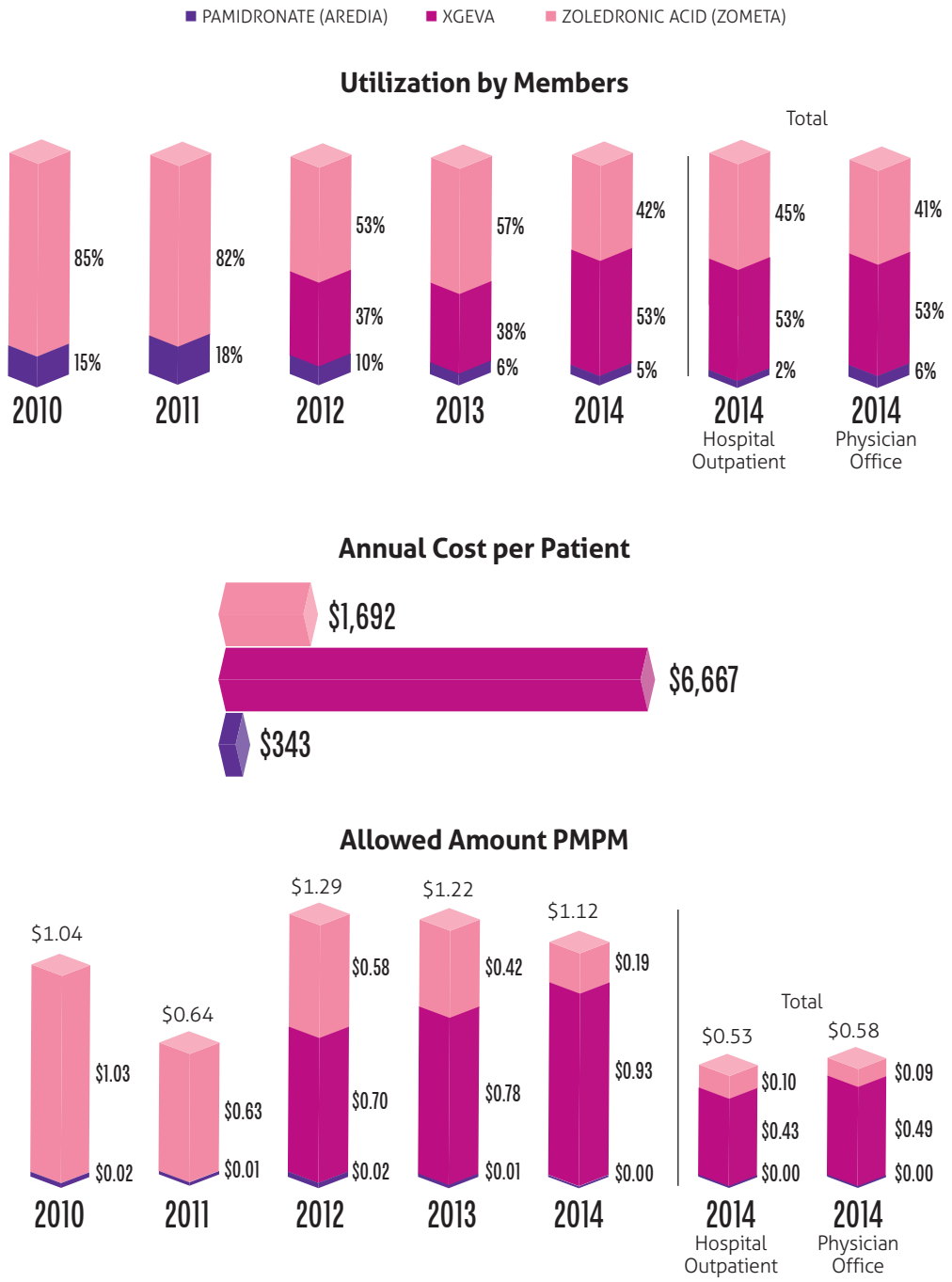
In 2014, for commercial and Medicare, zoledronic acid market share was 50 and 45 percent for hospital outpatient, and 47 and 41 percent for physician office settings. As a lowest-cost agent, $610 in commercial and $343 in Medicare, pamidronate maintains the smallest market share (4 percent). Regardless of the four times higher cost than zoledronic acid, newer agent Xgeva has made an impact on the category with its efficacy. It accounts for 48 percent of commercial market share and 53 percent of Medicare market share across all sites of service (*see Figures 66 and 67*).

FIGURE 66: Commercial Utilization of Bone Resorption Inhibitors for Oncology by Members, Annual Cost per Patient, and Allowed Amount PMPM 2010-2014



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

FIGURE 67: Medicare Utilization of Bone Resorption Inhibitors for Oncology by Members, Annual Cost per Patient, and Allowed Amount PMPM 2010-2014



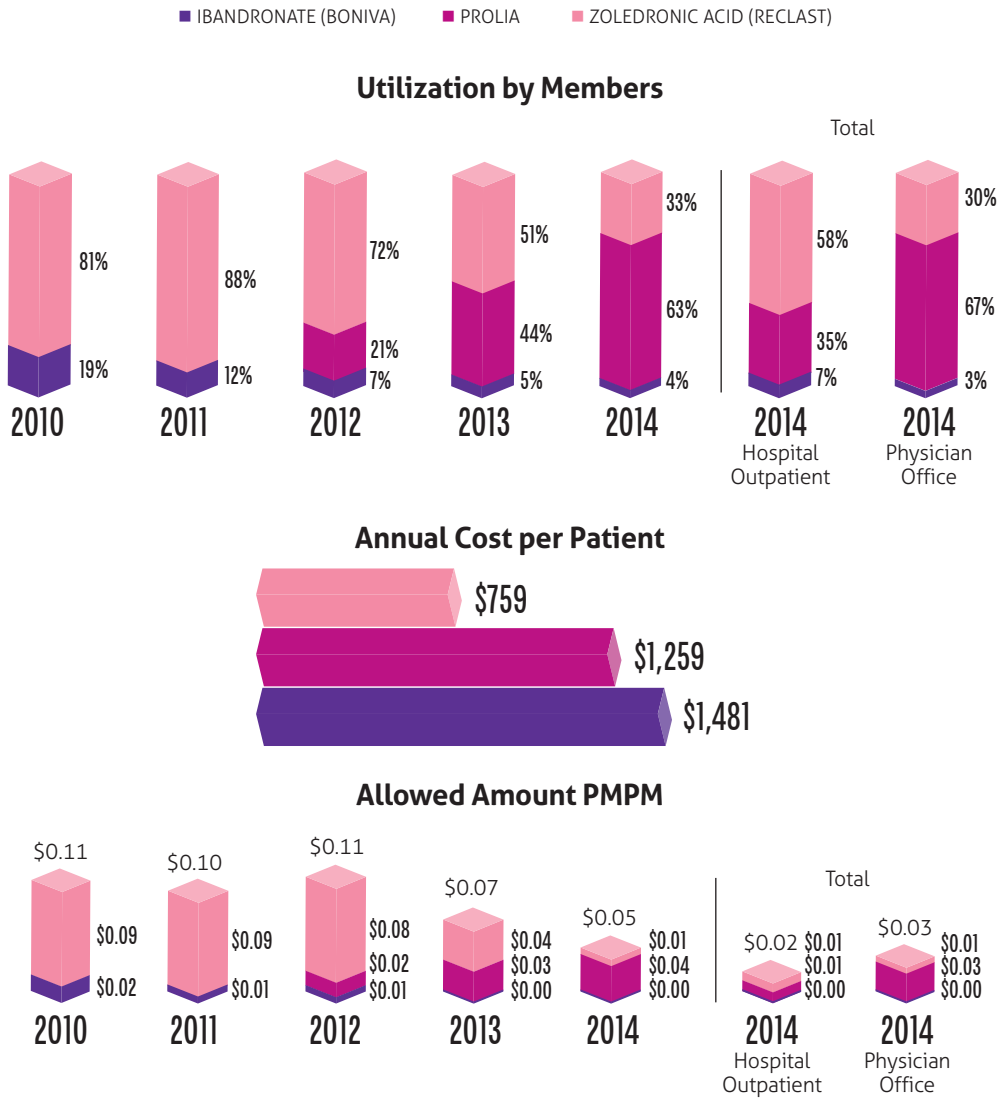
Please note: Due to rounding to the nearest cent, some of the column totals do not add up accurately.

BONE RESORPTION INHIBITORS: OSTEOPOROSIS

Three provider-administered agents are used to treat osteoporosis: zoledronic acid (Reclast), ibandronate (Boniva IV), and, most recently, Prolia. As noted previously, Prolia and Reclast both have drug counterparts that treat bone metastases: Xgeva and Zometa, respectively.

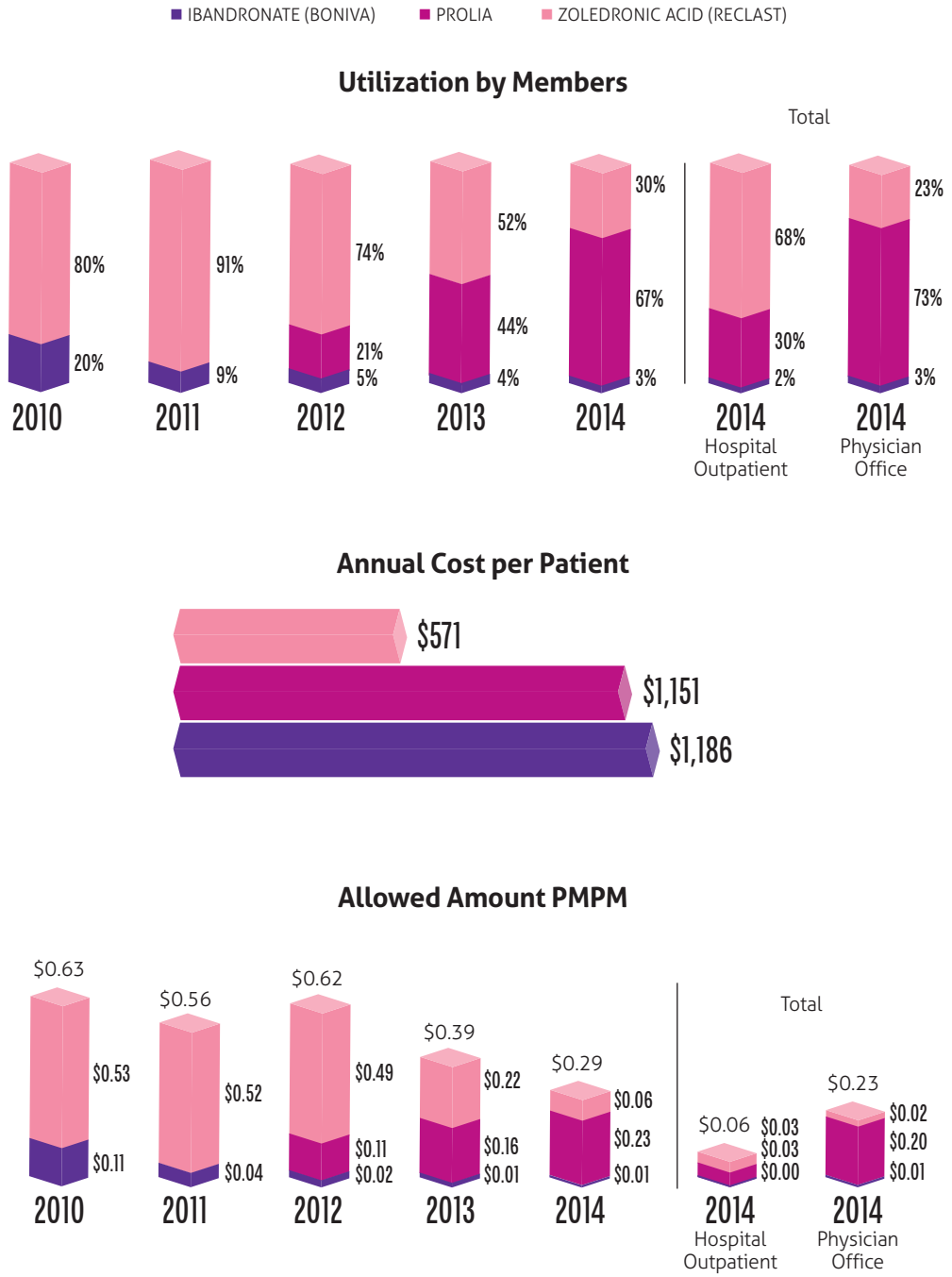
Across both commercial and Medicare, the utilization of zoledronic acid, although a lower-cost generic, has been replaced by Prolia. For the commercial medical benefit in 2014, zoledronic acid accounted for 33 percent of market share and the majority of the remainder went to Prolia with 63 percent. For the Medicare medical benefit, zoledronic acid made up 68 percent of hospital outpatient utilization and 23 percent of physician office utilization, suggesting that hospitals with infusion capabilities are more likely to prescribe zoledronic acid versus physician offices, which are more inclined to provide a subcutaneous injection that does not require an in-office infusion suite (*see Figures 68 and 69*).

FIGURE 68: Commercial Utilization of Bone Resorption Inhibitors for Osteoporosis by Members, Annual Cost per Patient, and Allowed Amount PMPM 2010-2014



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

FIGURE 69: Medicare Utilization of Bone Resorption Inhibitors for Osteoporosis by Members, Annual Cost per Patient, and Allowed Amount PMPM 2010-2014



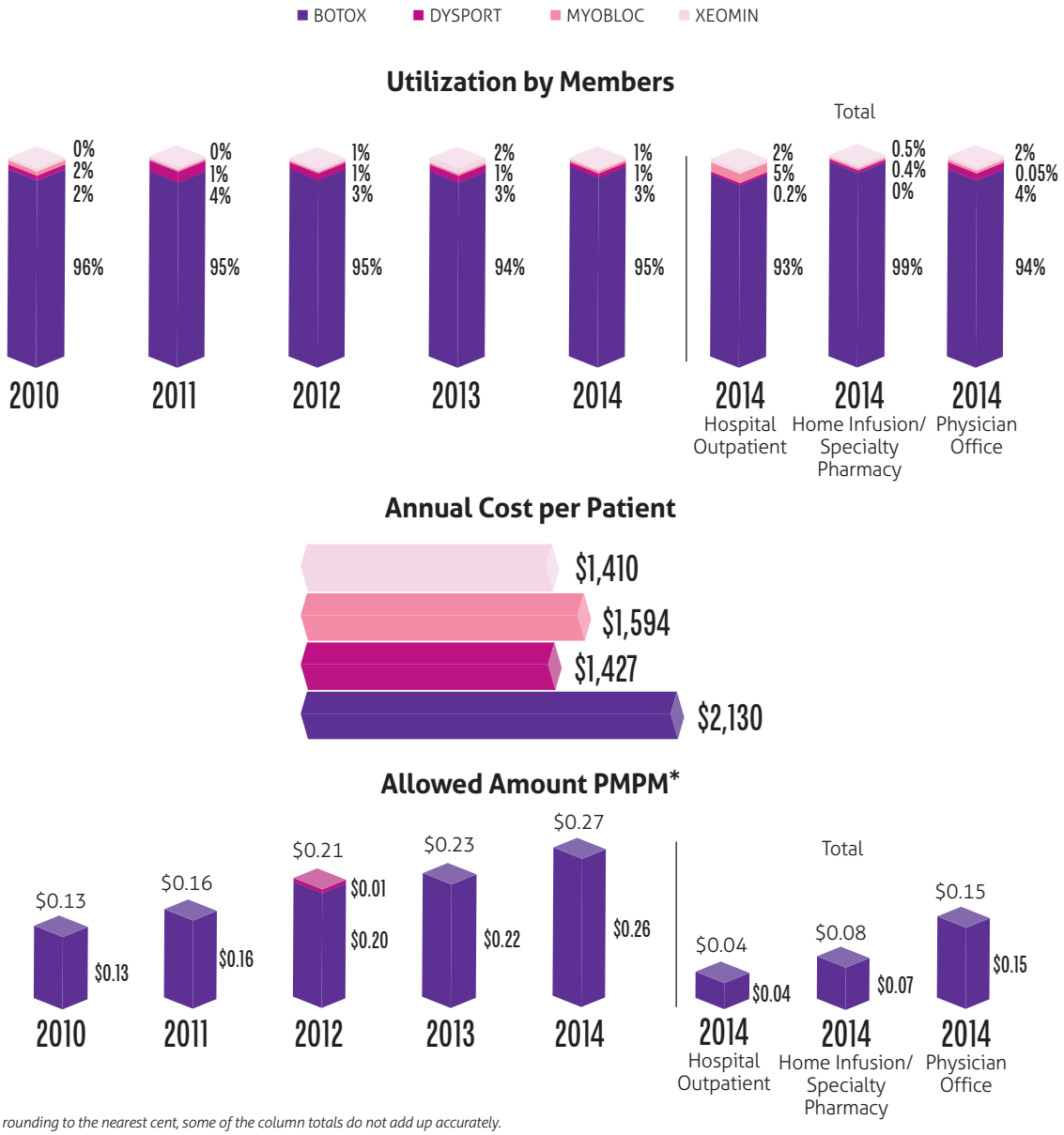
Please note: Due to rounding to the nearest cent, some of the column totals do not add up accurately.

BOTULINUM TOXINS

Four medical benefit drugs are available in the botulinum toxins drug class to treat musculoskeletal conditions: Botox, Dysport, Myobloc, and Xeomin. Botox has the most FDA-labeled indications, including its most frequent use in migraine headaches, and is the most commonly prescribed for off-label uses based on available supporting literature.

Botox continues to dominate commercial and Medicare market share for botulinum toxins. Although it is nearly twice the cost of other agents in the category for the commercial benefit, it also maintains 95 percent utilization. In Medicare, the cost is lower than that of Dysport and Myobloc and also maintains a 95 percent utilization rate (*see Figures 70 and 71*).

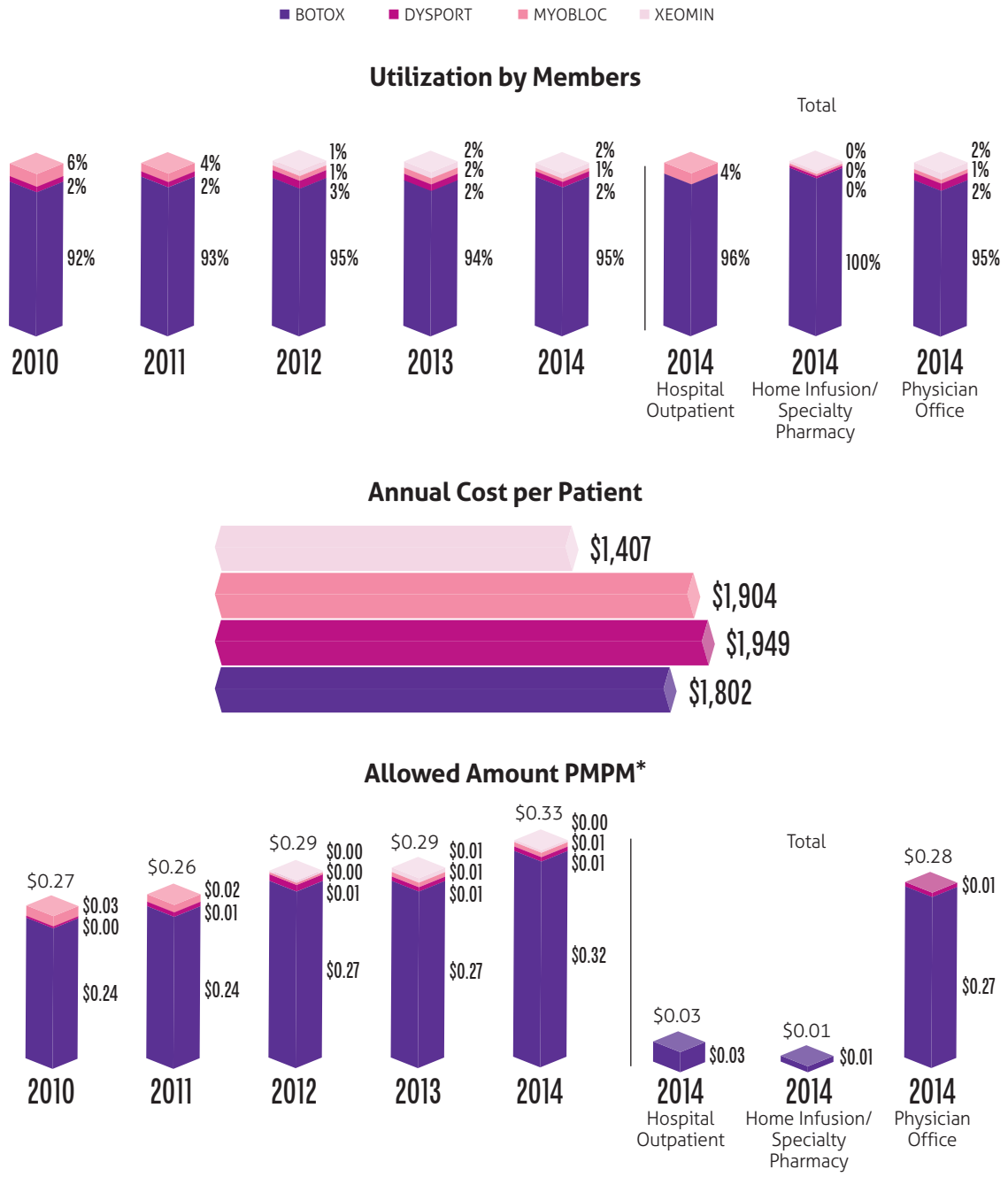
FIGURE 70: Commercial Utilization of Botulinum Toxins by Members, Annual Cost per Patient, and Allowed Amount PMPM 2010-2014



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

*From 2010-2014, Myobloc saw <$0.01 PMPM. In 2014, Dysport, Myobloc, and Xeomin had <$0.01 PMPM in the hospital outpatient and physician office settings; Dysport had no use; and Myobloc and Xeomin had <$0.01 PMPM in the home infusion/specialty pharmacy setting.

FIGURE 71: Medicare Utilization of Botulinum Toxins by Members, Annual Cost per Patient, and Allowed Amount PMPM 2010-2014



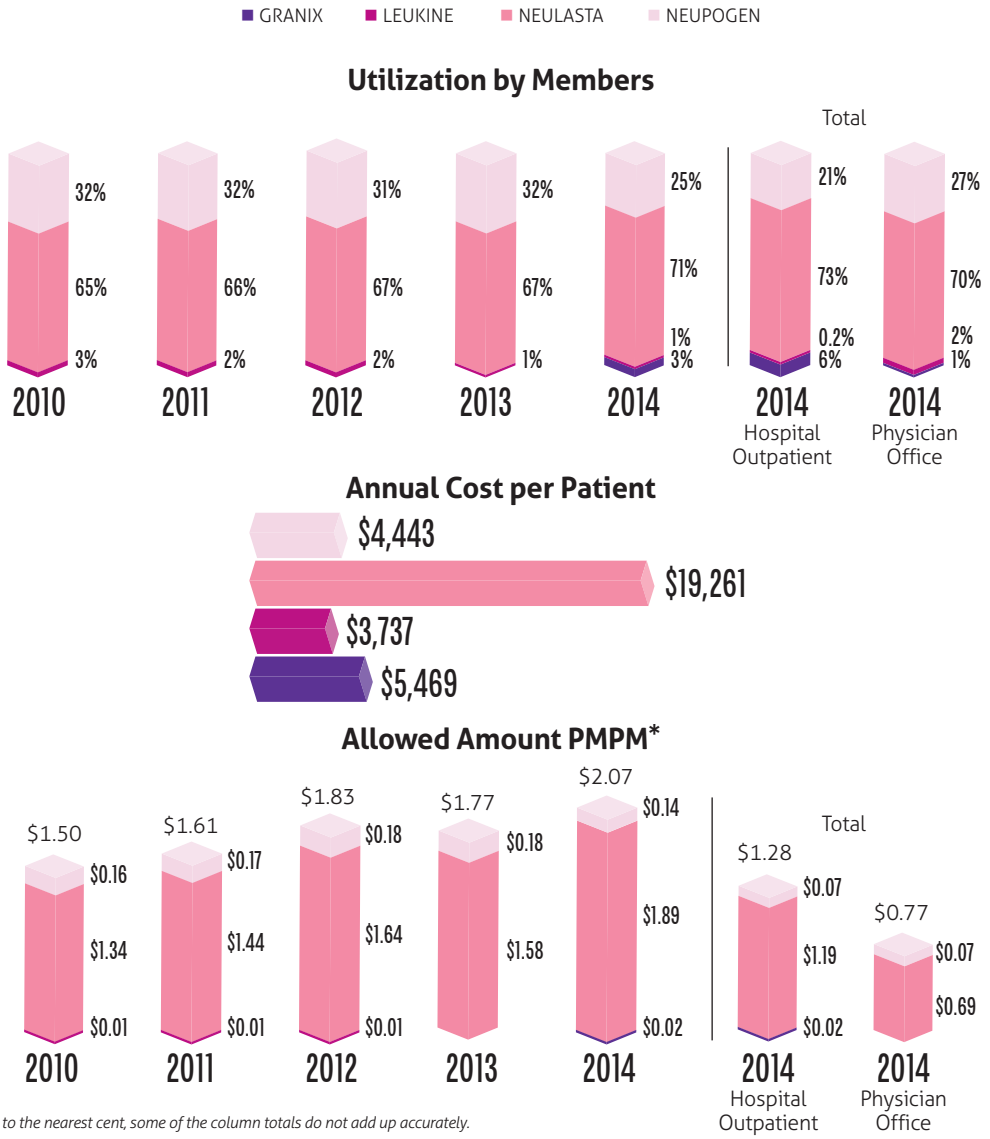
Please note: Due to rounding to the nearest cent, some of the column totals do not add up accurately.

*In 2014, Dysport and Xeomin had no use and Myobloc had <$0.01 PMPM in the hospital outpatient setting; Dysport, Myobloc, and Xeomin had no use in the home infusion/specialty pharmacy setting; Myobloc and Xeomin had <$0.01 PMPM in the physician office setting.

COLONY-STIMULATING FACTORS (CSFs)

In 2014, four medical benefit drugs were available under the CSFs class: Granix, Leukine, Neulasta, and Neupogen. In 2014, across both commercial and Medicare, Neulasta, with the highest annual cost per patient at $19,261 in commercial and $12,873 in Medicare, was the market share leader in hospital outpatient and physician office settings. As previously mentioned, Neulasta has seen increased utilization as it has become a standard regimen for patients treated with chemotherapy. Over the next couple of years, market share of the treatment may change with the release of biosimilars in 2016 (*see "Medical Benefit Drug Pipeline" section*), potentially eroding share from the brand. Neupogen maintained one-quarter of the market share in the CSFs category with 25 percent in commercial and 26 percent in Medicare. Neupogen has experienced coding changes over the last several years, and in 2016, its description was updated to note that it excludes biosimilars. Other agents in the category, Leukine and Granix, had comparable costs to Neupogen, but 5 percent or less market share across all sites of service and LOBs (*see Figures 72 and 73*).

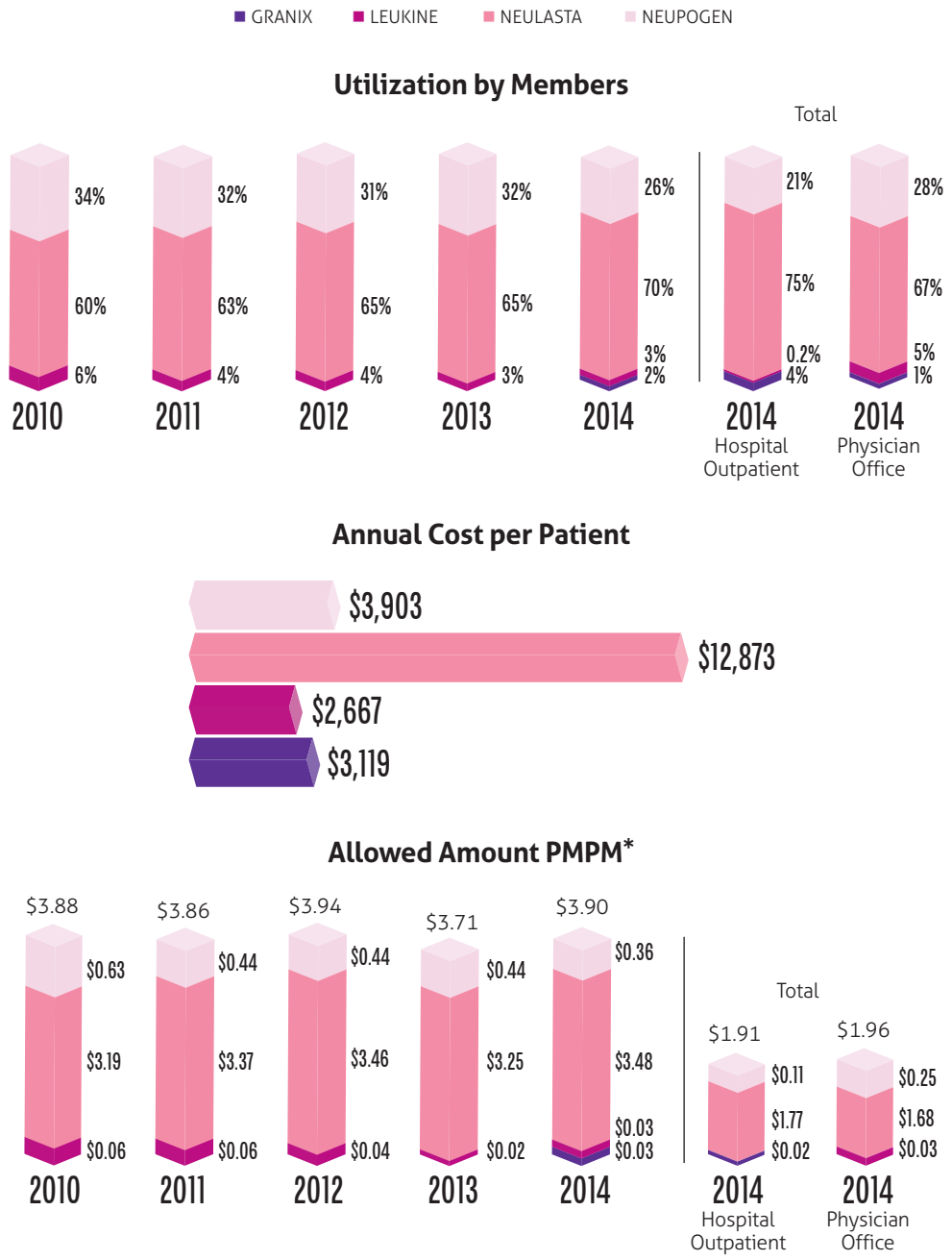
FIGURE 72: Commercial Utilization of Colony-Stimulating Factors (CSFs) by Members, Annual Cost per Patient, and Allowed Amount PMPM 2010-2014



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

*In 2014, Leukine had <$0.01 PMPM in the hospital outpatient setting; Granix and Leukine had <$0.01 PMPM in the physician office setting.

FIGURE 73: Medicare Utilization of Colony-Stimulating Factors (CSFs) by Members, Annual Cost per Patient, and Allowed Amount PMPM 2010-2014



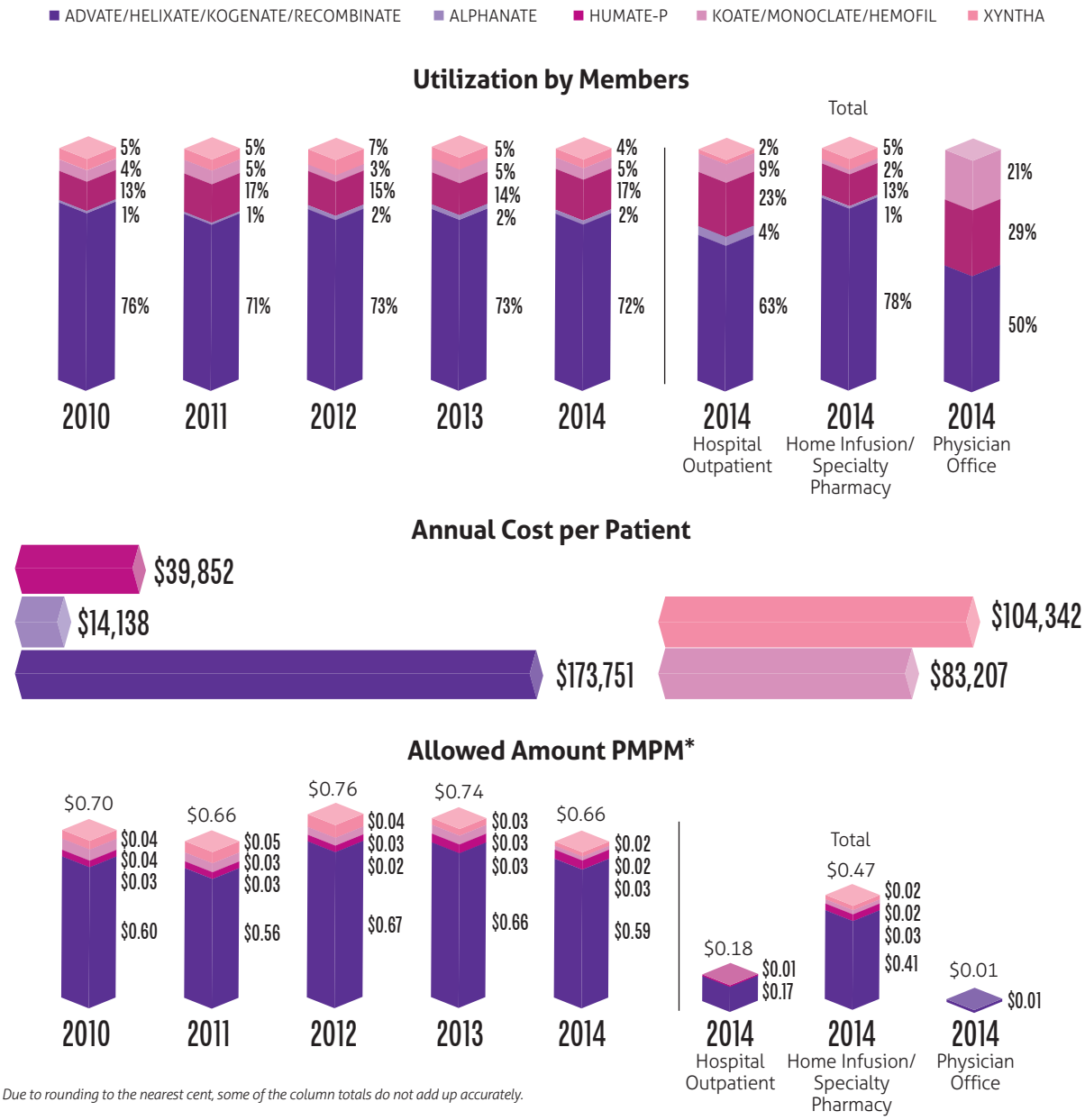
Please note: Due to rounding to the nearest cent, some of the column totals do not add up accurately.

*In 2014, Leukine had <$0.01 PMPM in the hospital outpatient setting; Granix had <$0.01 PMPM in the physician office setting.

FACTOR VIII

Classified in 2014, 10 medical benefit drugs were available under the Factor VIII class: Advate, Alphanate, Hemofil M, Helixate, Humate-P, Koate-DVI, Kogenate FS, Monoclate-P, Recombinate, and Xyntha. For the commercial medical benefit, J7192 (representing Advate, Helixate FS, Kogenate FS, and Recombinate) and Humate-P had the highest market share across all sites of service; more than three-quarters (78 percent) of home infusion/specialty pharmacy settings used J7192 and 13 percent used Humate-P (*see Figure 74*).

FIGURE 74: Commercial Utilization of Factor VIII Agents by Members, Annual Cost per Patient, and Allowed Amount PMPM 2010-2014

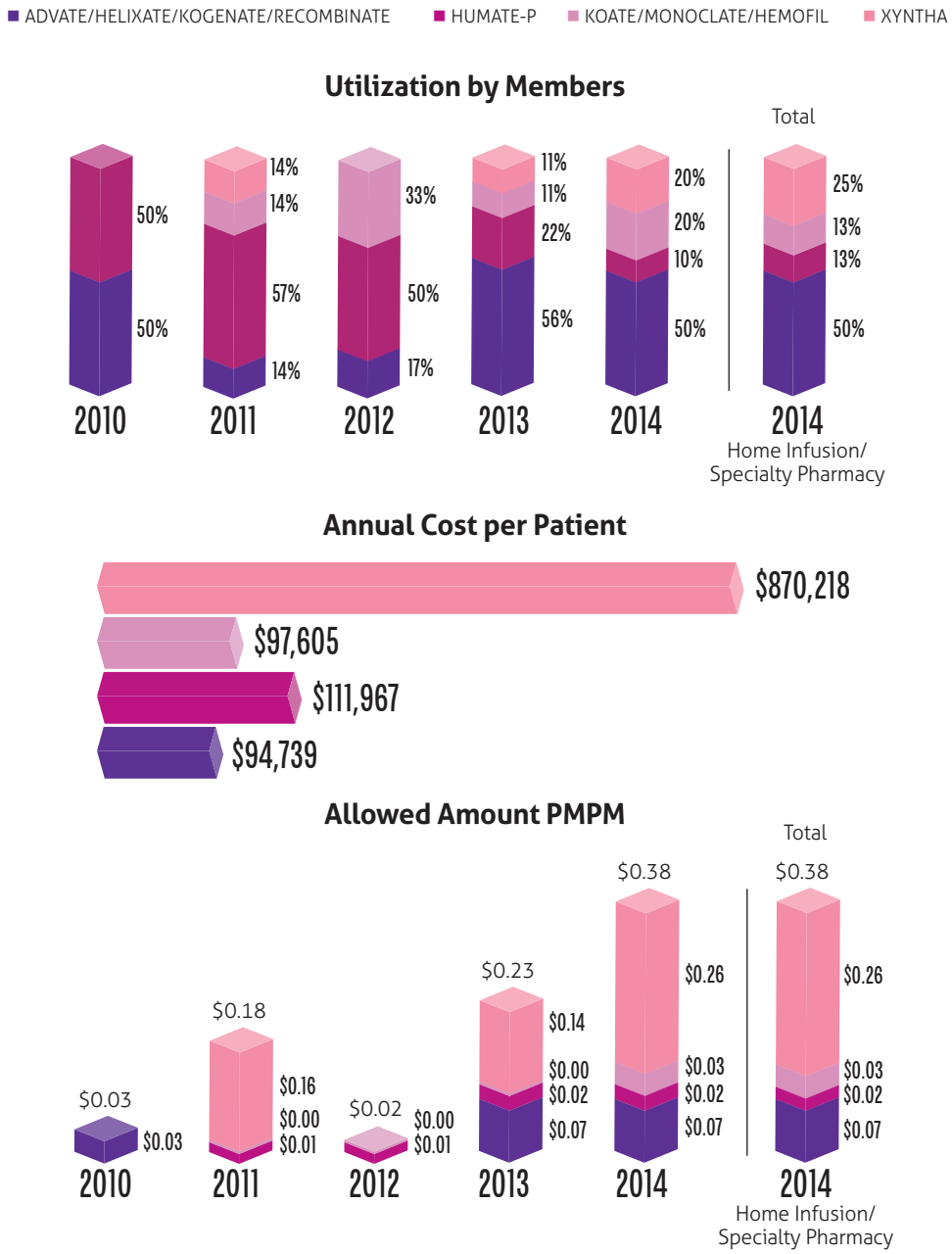


Please note: Due to rounding to the nearest cent, some of the column totals do not add up accurately.

*In 2014, Alphanate, Koate/Monoclate/Hemofil, and Xyntha had <$0.01 PMPM in the hospital outpatient setting; Alphanate had <$0.01 PMPM in the home infusion/specialty pharmacy setting; Alphanate and Xyntha had no use; and Humate-P and Koate/Monoclate/Hemofil had <$0.01 PMPM in the physician office setting.

The Medicare medical benefit was similar although slightly lower with 50 percent of J7192 use and 13 percent of Humate-P use in the home infusion/specialty pharmacy setting. Xyntha makes a stronger impression on the Medicare benefit accounting for 25 percent of Medicare home infusion/specialty pharmacy use. Humate-P, which was frequently prescribed for Medicare members from 2010 to 2011, has decreased to only 10 percent utilization in 2014 (*see Figure 75*).

FIGURE 75: Medicare Utilization of Factor VIII Agents by Members, Annual Cost per Patient, and Allowed Amount PMPM 2010-2014

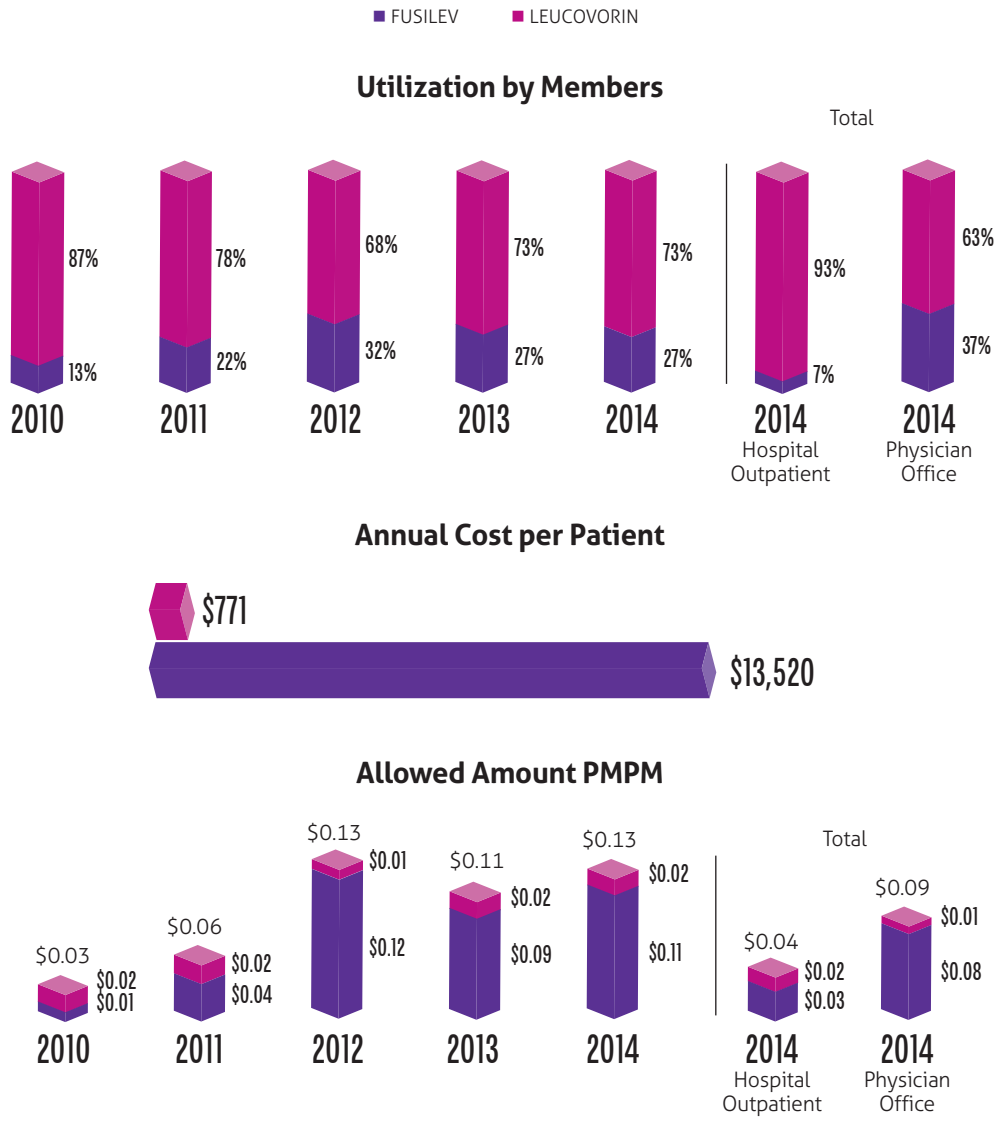


Please note: Due to rounding to the nearest cent, some of the column totals do not add up accurately.

FOLINIC ACID

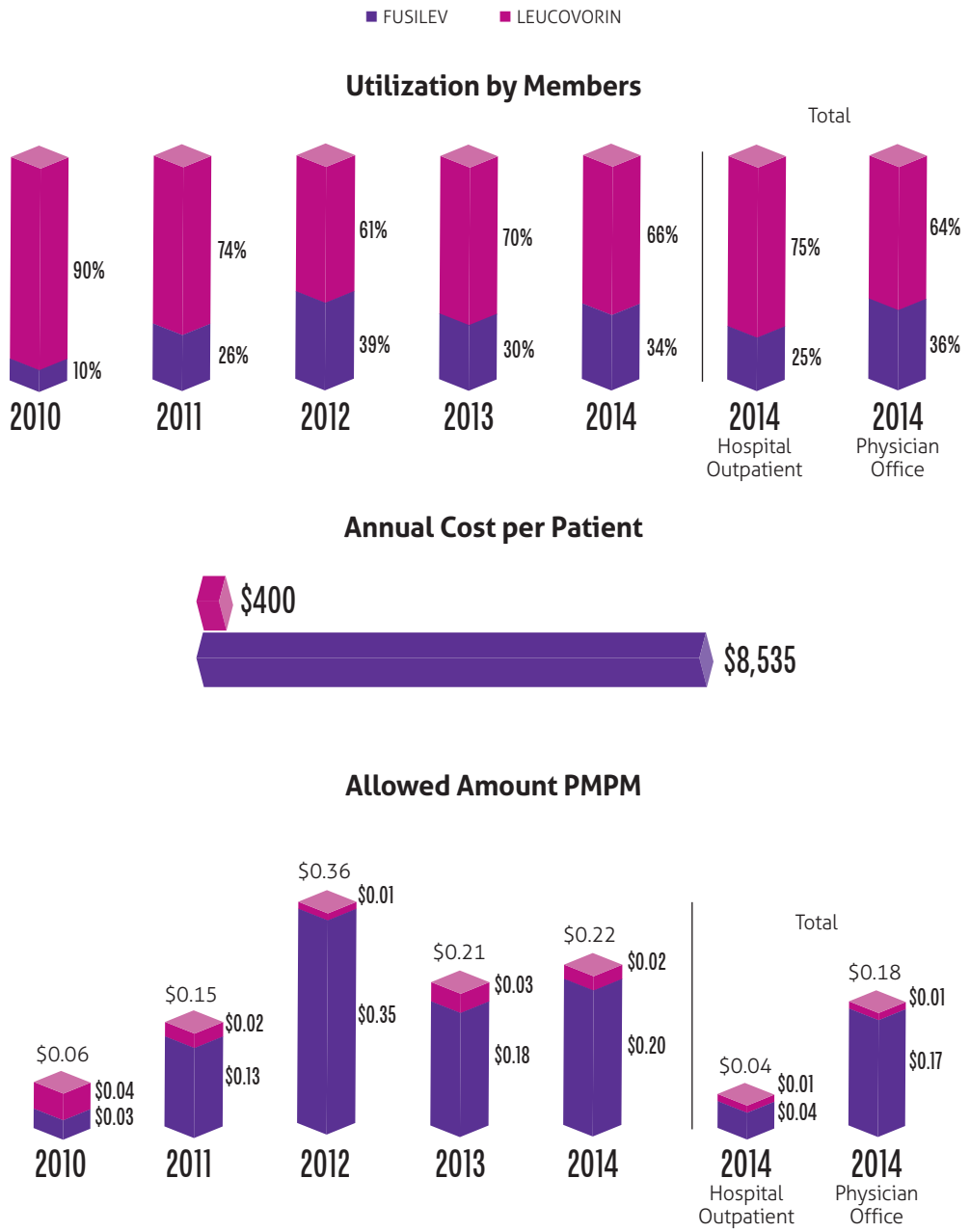
Folinic acid products levoleucovorin (Fusilev) and leucovorin are predominantly used in combination chemotherapy with 5-fluorouracil to increase the efficacy of fluorouracil therapy to treat patients with colorectal cancer. Leucovorin was used most commonly for this indication until drug shortages impacted its availability and alternatives were needed. In 2014, commercial and Medicare costs for Fusilev were more than 17 times that of leucovorin, but shortages of leucovorin were a catalyst for physician office settings utilizing Fusilev with an approximate 60/40 percent split favoring leucovorin for commercial and Medicare, while hospital outpatient settings were utilizing these agents with an approximate 90/10 percent split for leucovorin for commercial and 70/30 split for Medicare (***see Figures 76 and 77***).

FIGURE 76: Commercial Utilization of Folinic Acid Agents by Members, Annual Cost per Patient, and Allowed Amount PMPM 2010-2014



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

FIGURE 77: Medicare Utilization of Folinic Acid Agents by Members, Annual Cost per Patient, and Allowed Amount PMPM 2010-2014



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

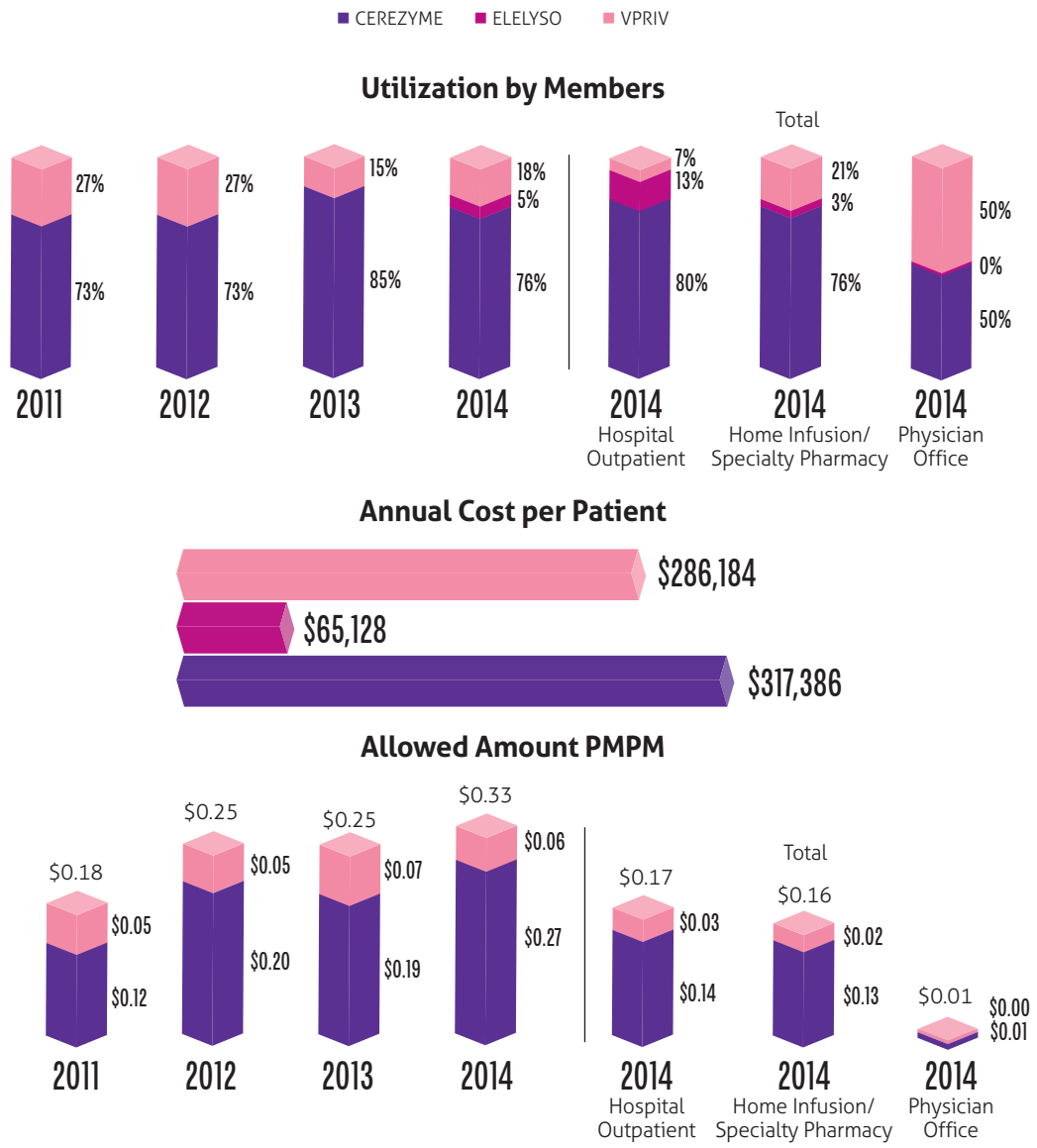
GAUCHER DISEASE

Three infusion enzyme replacement therapies, Cerezyme, Elelyso, and Vpriv, are available on the medical benefit to treat patients with Gaucher disease. On the commercial medical benefit in 2014, the majority of market share for Gaucher disease (76 percent) went to Cerezyme, while Medicare was exclusively Cerezyme. Under the commercial medical benefit in 2014, home infusion/specialty pharmacy and hospital outpatient settings made room for Elelyso with 3 and 13 percent shares, respectively.

The first oral glucosylceramide synthase inhibitor, Cerdelga, was approved in 2014 and may begin to influence the utilization of Cerezyme, Elelyso, and Vpriv on the medical benefit (*see Figure 78*).

The Medicare medical benefit was even more restricted with all sites of service over the last five years only prescribing Cerezyme (*see Figure 79*).

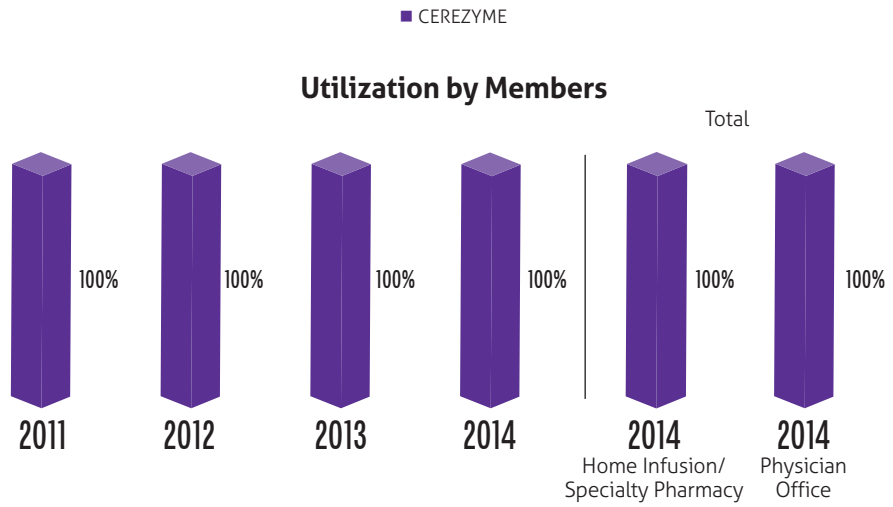
FIGURE 78: Commercial Utilization of Gaucher Agents* by Members, Annual Cost per Patient, and Allowed Amount PMPM 2010-2014

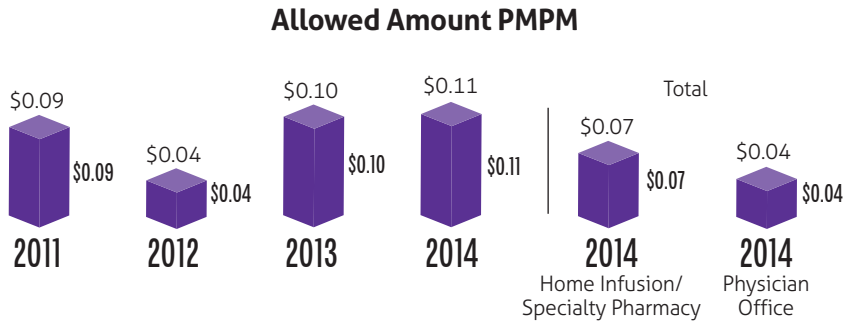


Please note: Due to rounding to the nearest cent, some of the column totals do not add up accurately.

*There was no utilization of Gaucher agents in 2010.

FIGURE 79: Medicare Utilization of Gaucher Agents* by Members, Annual Cost per Patient, and Allowed Amount PMPM 2010-2014





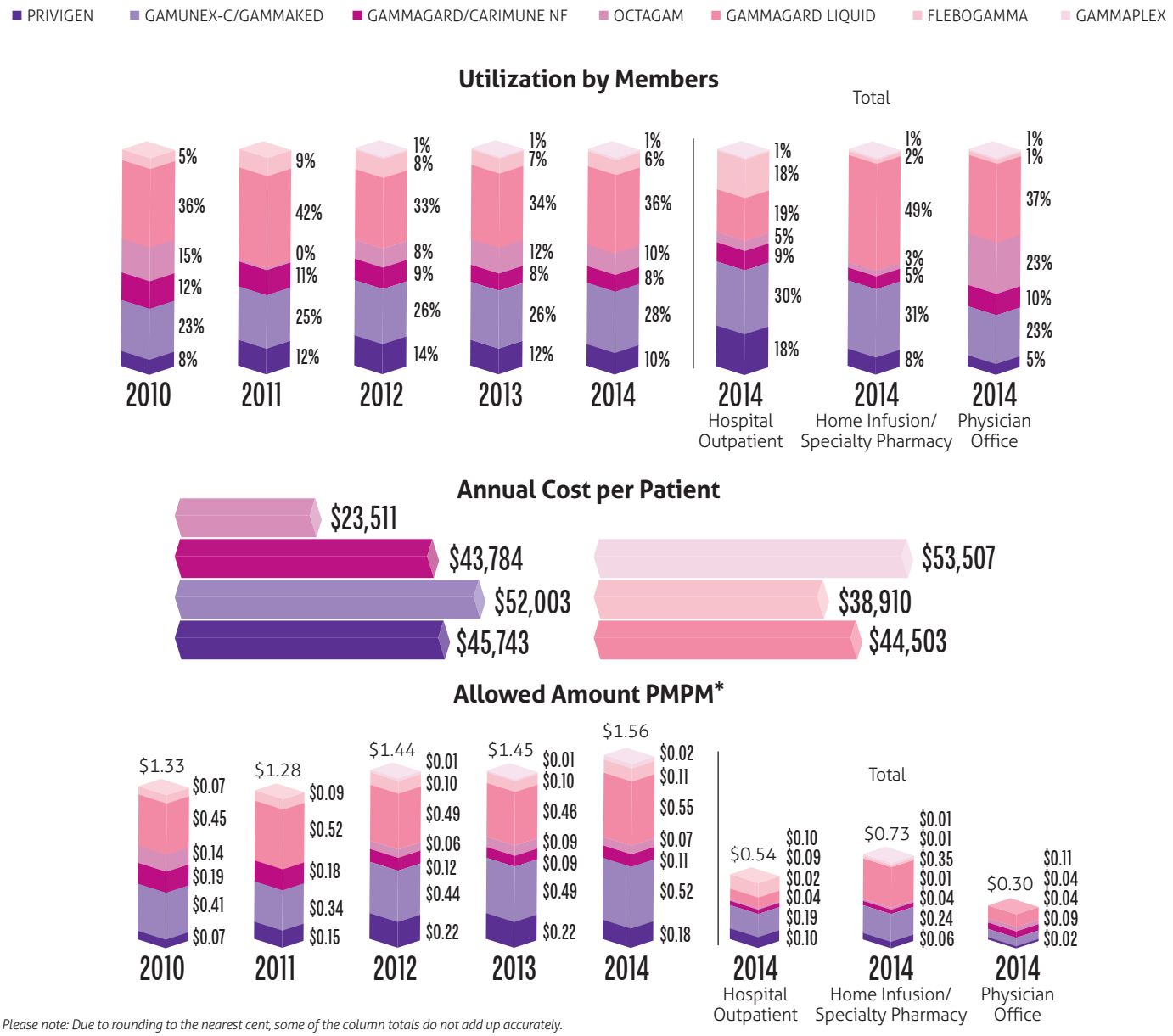
Please note: Due to rounding to the nearest cent, some of the column totals do not add up accurately.

*There was no utilization of Gaucher agents in 2010.

INTRAVENOUS IMMUNE GLOBULIN (IVIG)

Intravenous immune globulin (IVIG) had one of the larger lists of agents available in the class on the medical benefit with seven HCPCS/nine agents. With comparable costs and allowed amount PMPM, market share for the broader IVIG category was spread out between six of the seven codes. On the commercial and Medicare medical benefits in 2014, Gammagard Liquid available as a subcutaneous (SQ) injection as well as intravenous (IV), was able to capture the most market share at nearly 40 percent. More specifically, for the commercial medical benefit in 2014, home infusion/specialty pharmacy providers utilized Gammagard Liquid for nearly 50 percent of members, followed by Gamunex-C/Gammaked at 31 percent share (*see Figure 80*).

FIGURE 80: Commercial Utilization of IVIG Agents by Members, Annual Cost per Patient, and Allowed Amount PMPM 2010-2014

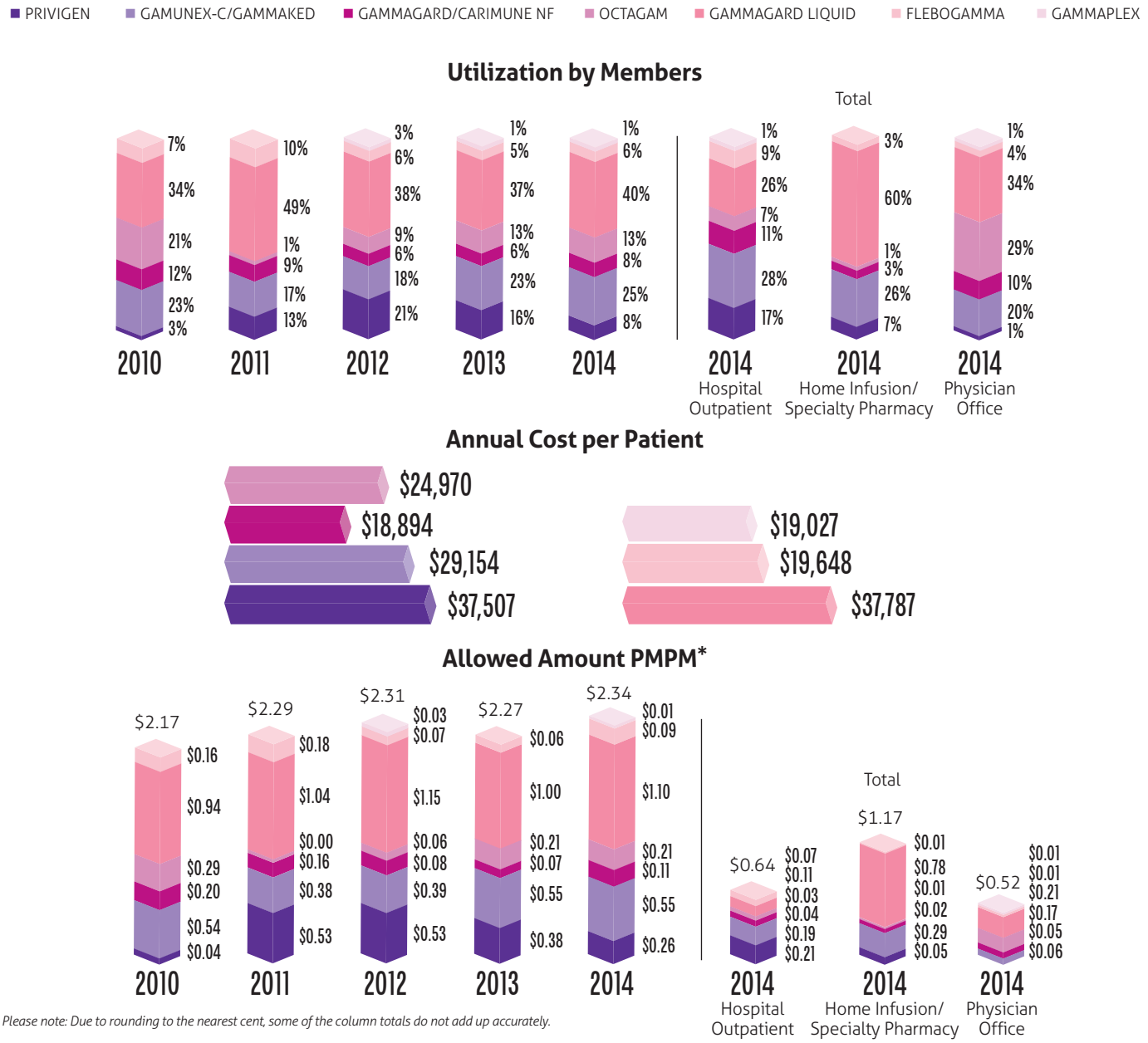


Please note: Due to rounding to the nearest cent, some of the column totals do not add up accurately.

*In 2014, Gammaplex had <$0.01 PMPM in the hospital outpatient setting; Flebogamma and Gammaplex had <$0.01 PMPM in the physician office setting.

Under Medicare, home infusion/specialty pharmacy providers had a similar market share ratio as commercial with Gammagard Liquid (60 percent) and Gamunex-C/Gammaked (26 percent). Physician office settings followed the commercial medical benefit with Gamunex-C/Gammaked (20 percent), Octagam (29 percent), and Gammagard Liquid (34 percent). Hospital outpatient settings were similar to commercial in their use of Gamunex-C/Gammaked (28 percent) and Privigen (17 percent) (*see Figure 81*).

FIGURE 81: Medicare Utilization of IVIG Agents by Members, Annual Cost per Patient, and Allowed Amount PMPM 2010-2014



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

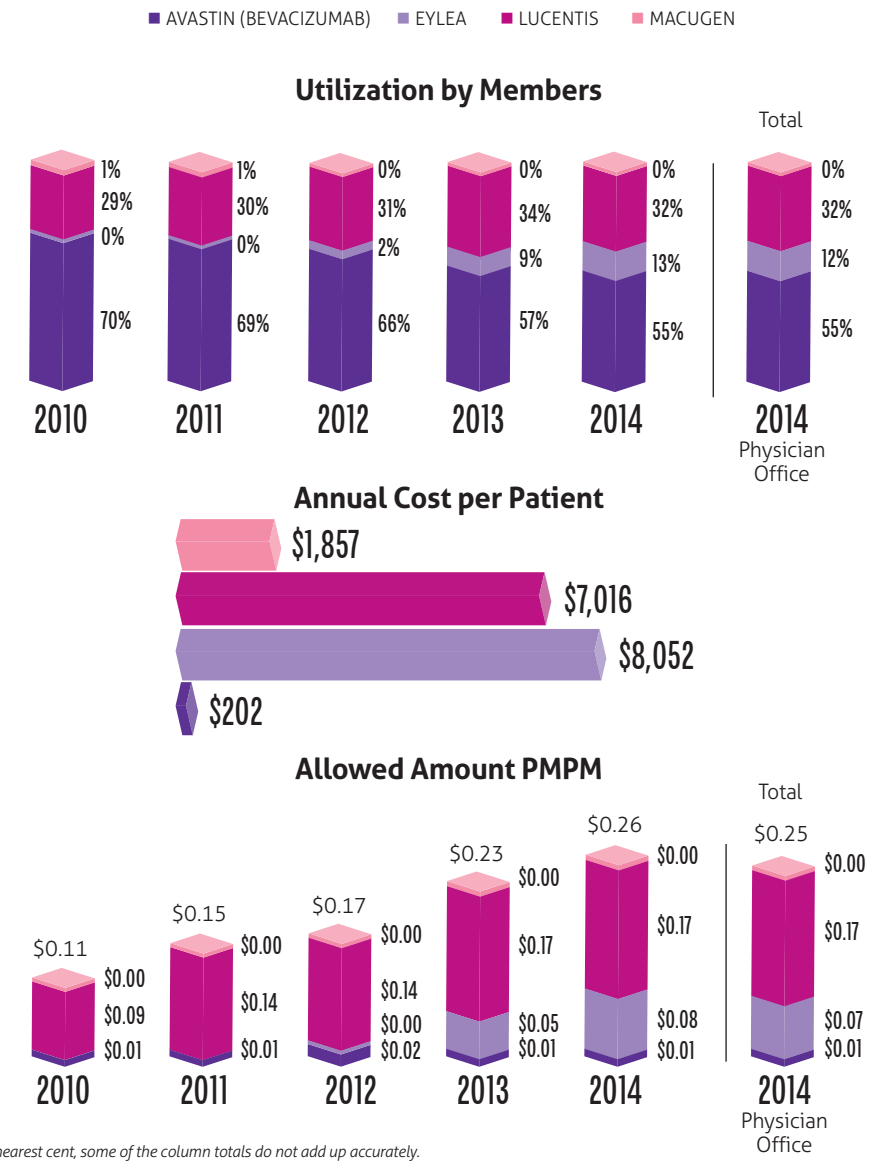
*In 2014, Gammaplex had <$0.01 PMPM in the hospital outpatient setting; Gammaplex was not used in the home infusion/specialty pharmacy setting; Privigen had <$0.01 PMPM in the physician office setting.

OPHTHALMIC INJECTIONS

Knowing that ophthalmic injections were a top spend driver, especially for payors with Medicare populations, we evaluated the drugs used to treat age-related macular degeneration (AMD) and other retina diseases. We analyzed the HCPCS codes billed with the following ocular diagnosis codes in the primary, secondary, or tertiary fields: ICD-9s 362.01, 362.02, 362.03, 362.04, 362.05, 362.06, 362.07, 362.35, 362.36, 362.53, and 362.83. Bevacizumab (Avastin) utilization was analyzed across classified and unclassified codes. It is important to note that while Macugen, Lucentis, and Eylea are FDA-labeled to treat specific retina diseases, Avastin is not. Bevacizumab is commonly used off-label for the treatment of retina diseases due to available evidence-based supporting literature.

For the commercial population, Lucentis represented the largest spend, although bevacizumab represented a larger portion of members. 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 82*).

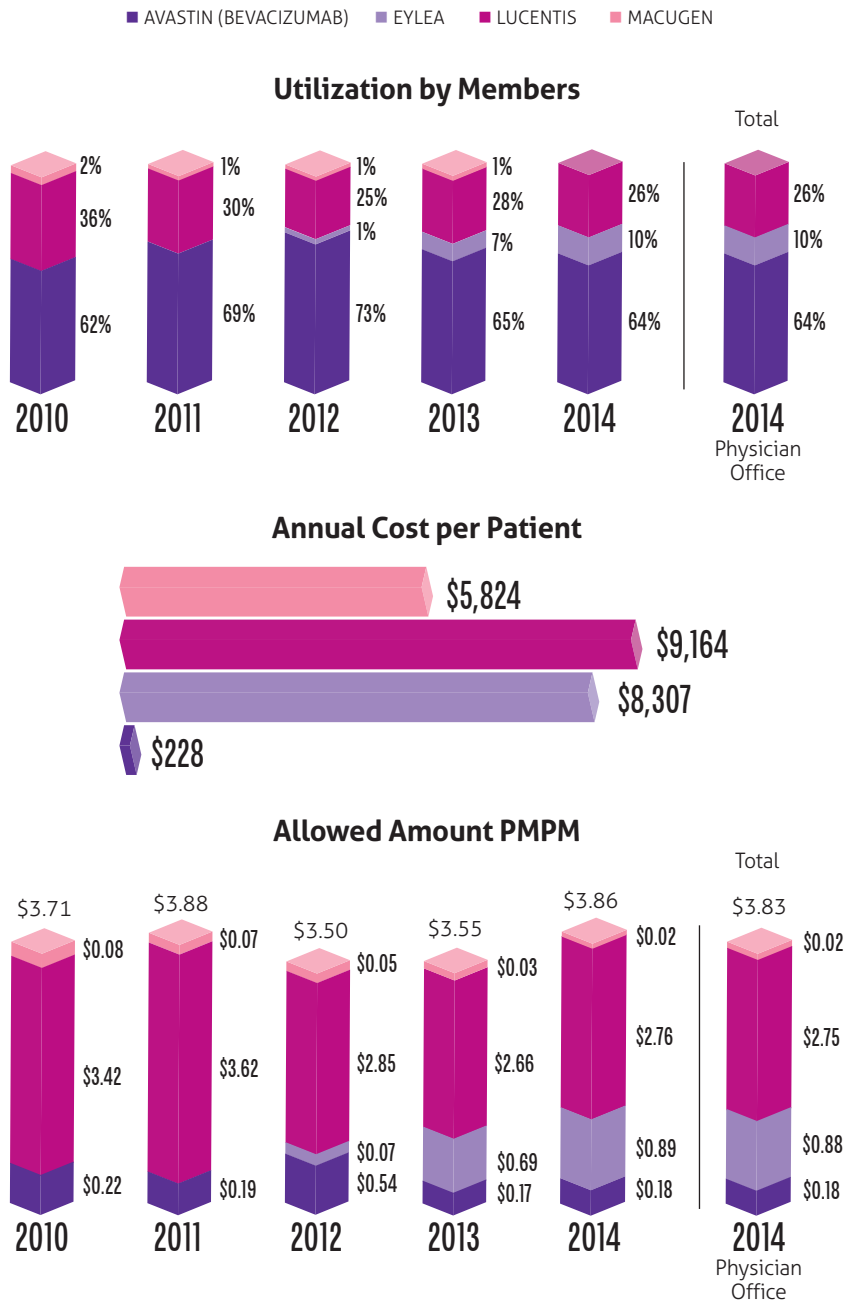
FIGURE 82: Commercial Utilization of Ophthalmic Injections by Members, Annual Cost per Patient, and Allowed Amount PMPM 2010-2014



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

Bevacizumab represented the majority of members 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 have a 20 percent coinsurance for medical benefit drugs. When Eylea entered the market in 2012, the market shares for both Lucentis and Avastin decreased in both LOBs (*see Figure 83*).

FIGURE 83: Medicare Utilization of Ophthalmic Injections by Members, Annual Cost per Patient, and Allowed Amount PMPM 2010-2014

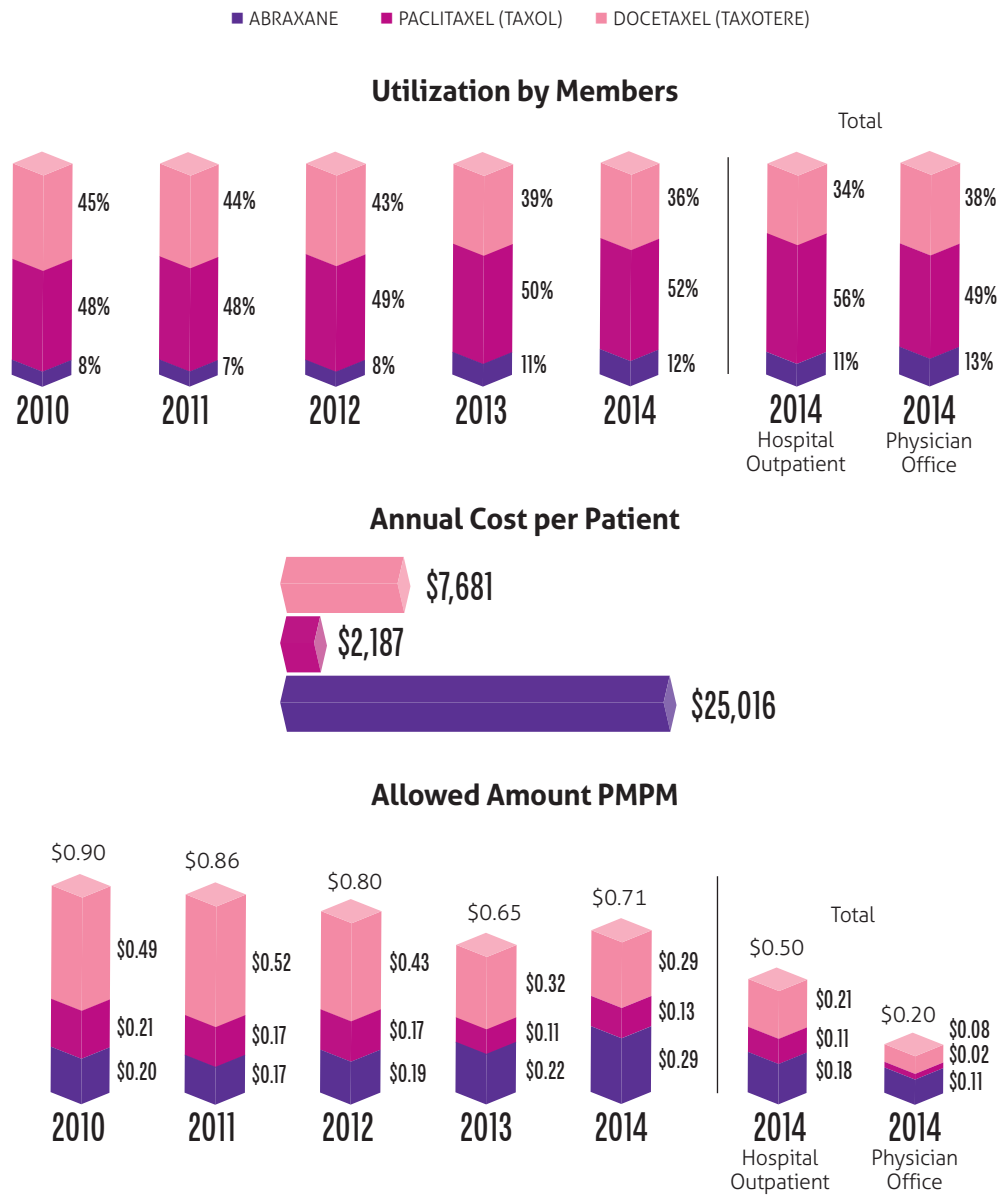


Please note: Due to rounding to the nearest cent, some of the column totals do not add up accurately.

TAXANES

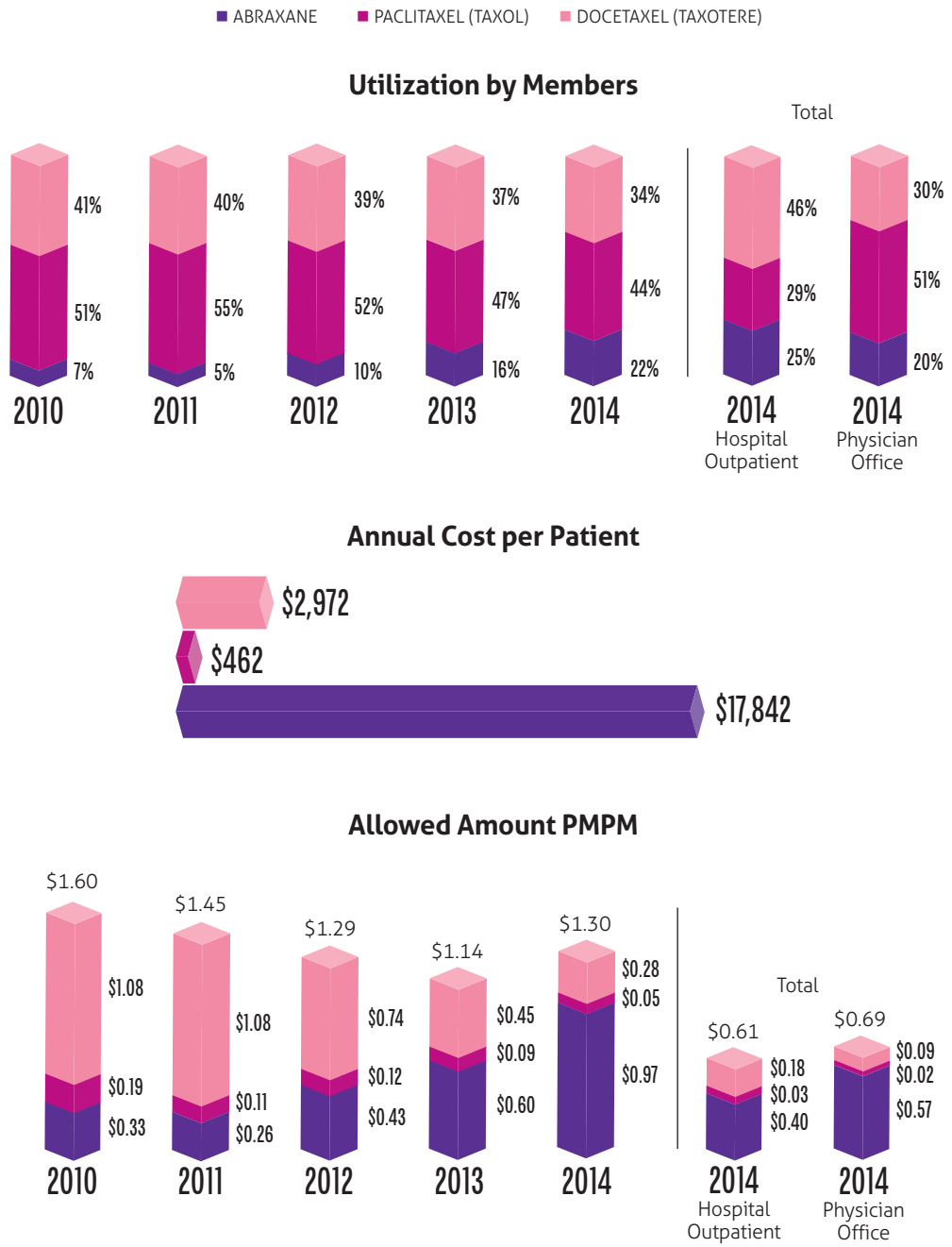
For this analysis, we evaluated three taxane agents — Abraxane, paclitaxel (Taxol), and docetaxel (Taxotere) — two generic and one branded. Across all sites of service and all LOBs, the lowest-cost agent, paclitaxel, was the most utilized. Paclitaxel had nearly half or more of the market share for commercial hospital outpatient and physician office settings as well as Medicare physician office settings. Abraxane, sometimes used for patients hypersensitive to generic taxanes, took 12 percent of the commercial medical benefit across all sites of service in 2014. In Medicare, it was used more frequently in the hospital outpatient setting (25 percent) than the physician office (20 percent). Abraxane was more than 12 times the cost of paclitaxel (Taxol) in commercial and more than 35 times the cost in Medicare (*see Figures 84 and 85*).

FIGURE 84: Commercial Utilization of Taxanes by Members, Annual Cost per Patient, and Allowed Amount PMPM 2010-2014



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

FIGURE 85: Medicare Utilization of Taxanes by Members, Annual Cost per Patient, and Allowed Amount PMPM 2010-2014

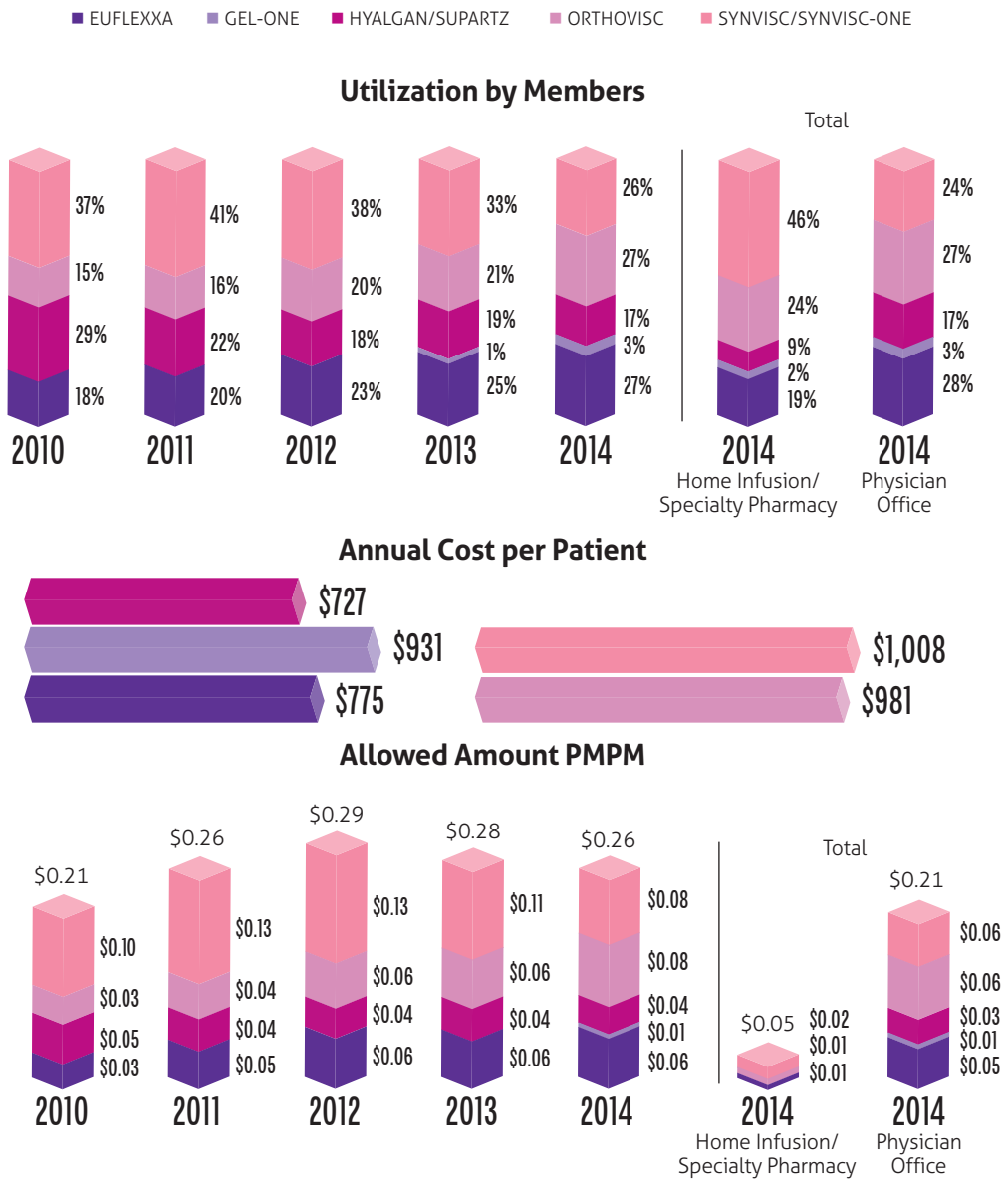


Please note: Due to rounding to the nearest cent, some of the column totals do not add up accurately.

VISCOSUPPLEMENTATION

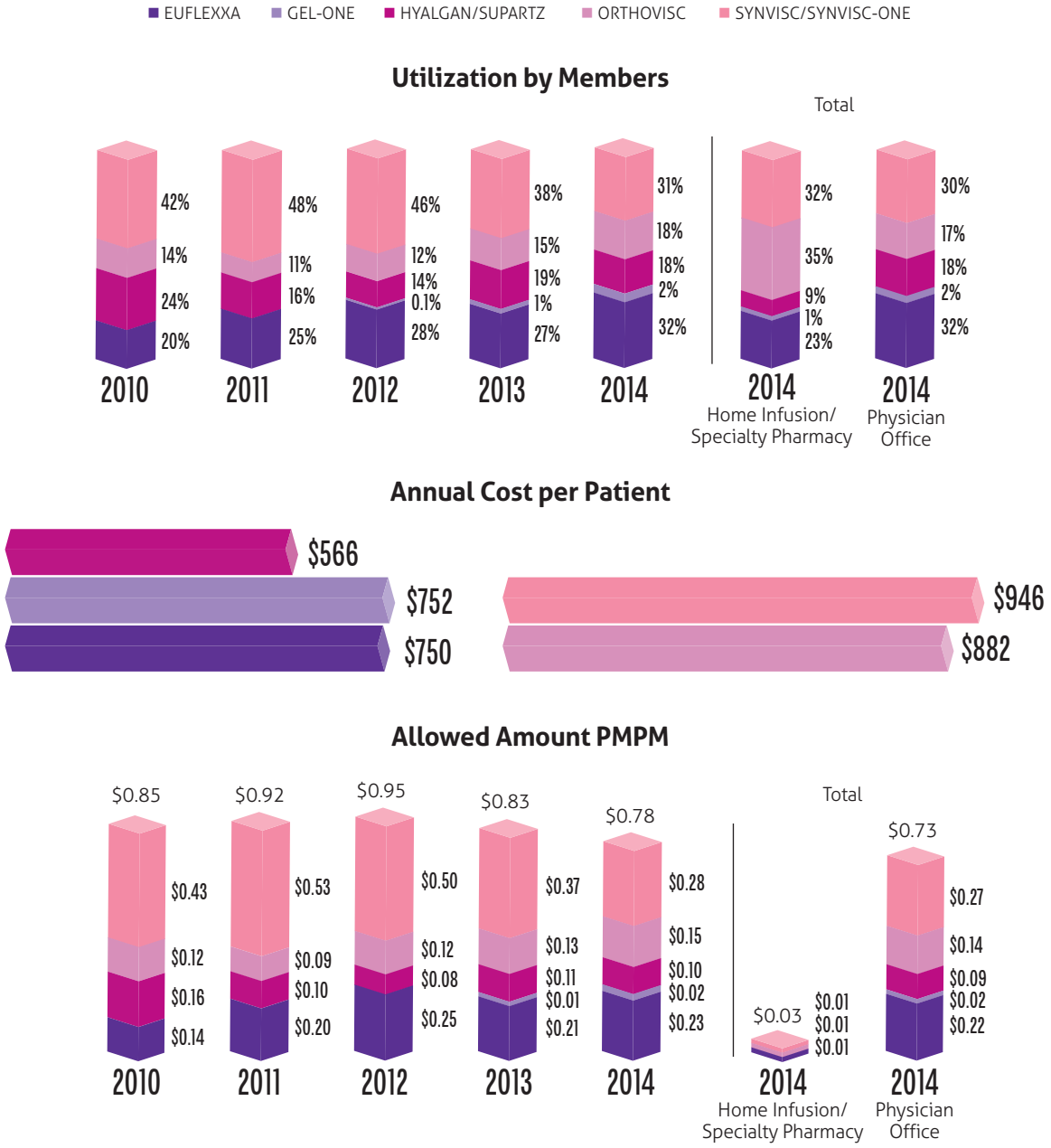
Viscosupplementation therapy or treatment with hyaluronic acids (HAs) for osteoarthritis of the knee in 2014 included multiple options: Hyalgan, Supartz, Euflexxa, Orthovisc, Synvisc/Synvisc-One, and Gel-One. The HA products have varying doses and number of administrations per course of therapy. Commercial utilization trends in 2014 favored Orthovisc and Euflexxa, while Medicare saw more utilization of Euflexxa and Synvisc/Synvisc-One. By site of service, the major agents varied where close to half (46 percent) of commercial home infusion/specialty pharmacy providers utilized Synvisc/Synvisc-One. The physician office was on par with the higher utilization of Synvisc/Synvisc-One, Orthovisc, and Euflexxa. The dominant provider type administering HA injections was office-based practices (*see Figures 86 and 87*).

Figure 86: Commercial Utilization of Viscosupplementation by Members, Annual Cost per Patient, and Allowed Amount PMPM 2010-2014



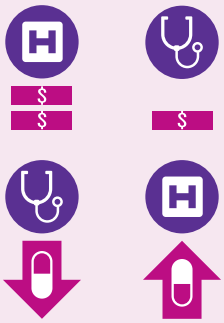
Please note: Due to rounding to the nearest cent, some of the column totals do not add up accurately.

FIGURE 87: Medicare Utilization of Viscosupplementation by Members, Annual Cost per Patient, and Allowed Amount PMPM 2010-2014



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

National Provider Trends



SUMMARY

> Commercial medical benefit drug costs in the hospital outpatient setting are generally double that of the physician office.

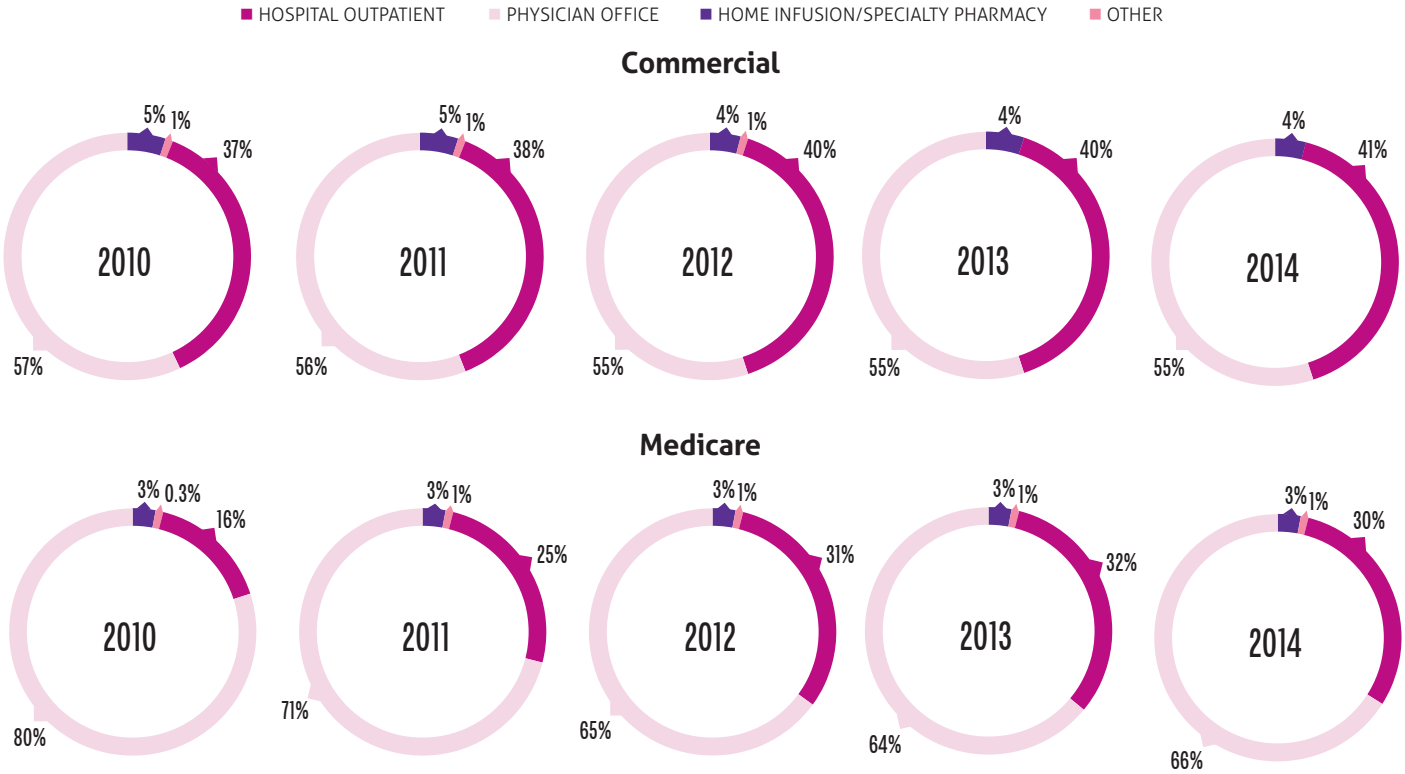
> On a disease category level, Medicare claims for oncology and biologic drugs for autoimmune disorders saw a decrease in the physician office since 2010, while hospital outpatient use increased and leveled off over the last two years.

HIGH-COST CATEGORY TRENDS

This year, we added a customized look at the disease states with the highest spend, oncology and BDAIDs, evaluating their market share by site of service. Over the last five years, oncology has maintained a 60/40 physician office/hospital split indicating a higher incidence of members receiving treatment in the physician office on the commercial medical benefit. Medicare maintains closer to 70/30 physician office/hospital outpatient split.

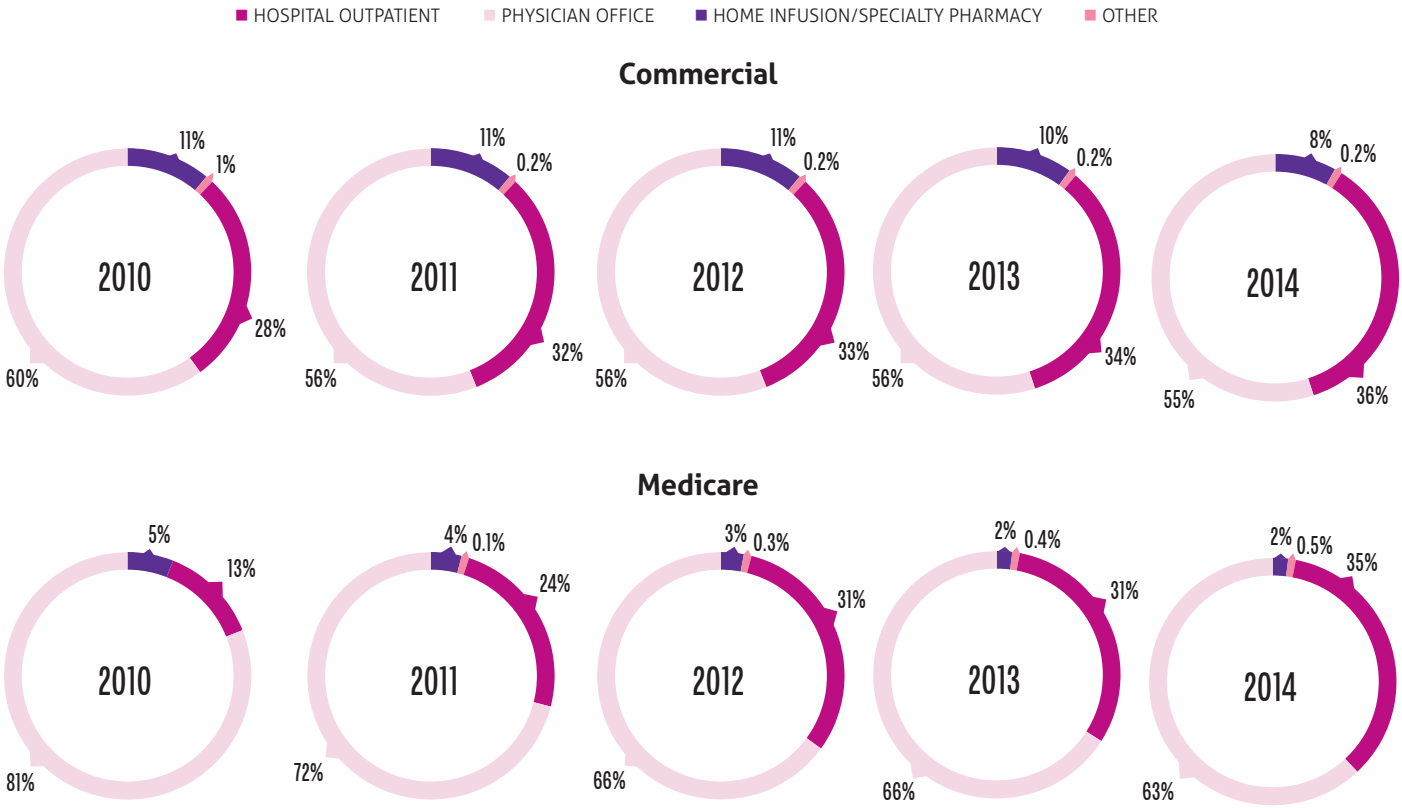
BDAIDs tell a similar story as oncology in terms of physician office/hospital market share percentages. As expected, the home infusion setting is used more frequently for the administration of BDAIDs to commercial members due to safety and monitoring requirements versus oncology agents. Across both disease categories, physician office use by Medicare members has decreased since 2010, while hospital outpatient use increased and leveled off over the last two years (***see Figures 88 and 89***).

FIGURE 88: Oncology Medical Pharmacy Market Share Percentages by Members by LOB and Site of Service 2010-2014



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

FIGURE 89: BDAIDs Medical Pharmacy Market Share Percentages by Members by LOB and Site of Service 2010-2014



HIGH-COST DRUG 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 are identified below. In 2014, commercial medical benefit drug costs in the hospital outpatient setting were often double that of the physician office. The trend of services shifting from a physician office setting to a hospital outpatient facility had been established in previous reports and continued to be the marketplace dynamic in 2014 (*see Table 12*).

TABLE 12: 2014 Commercial Cost per Unit and Claim for Top Drugs by Provider Type

Brand Name	Cost per Unit			Cost per Claim		
	Hospital Outpatient	Home Infusion/ Specialty Pharmacy	Physician Office	Hospital Outpatient	Home Infusion/ Specialty Pharmacy	Physician Office
Botox	$11.79	$5.60	$6.11	$2,079	$1,055	$918
Gammagard Liquid	$92.73	$56.74	$72.22	$7,099	$4,022	$5,369
Gamunex-C/Gammaked	$142.18	$56.98	$66.21	$7,322	$3,684	$4,448
Herceptin	$131.78	$82.98	$91.55	$6,430	$5,200	$3,495
Neulasta	$7,207	$3,731	$3,741	$7,207	$3,731	$3,741
Orencia	$83.24	$29.04	$28.47	$5,668	$2,230	$2,292
Remicade	$214.21	$92.81	$80.67	$8,930	$5,002	$4,132
Soliris	$356.28	$253.70	$217.29	$34,265	$20,841	$21,436
Xgeva/Prolia	$34.60	$15.78	$15.54	$3,549	$959	$1,415
Yervoy	$274.82		$151.60	$60,306		$36,331

For Medicare members, although claim costs were more similar across sites of service than commercial, the cost trend follows suit with drugs administered in the hospital outpatient facility generally having higher allowed amount per drug per claim. Gammagard Liquid served as an outlier where cost per claim was higher in the physician office and highest in home infusion/specialty pharmacy settings (*see Table 13*).

TABLE 13: 2014 Medicare Cost per Unit and Claim for Top Drugs by Provider Type

Brand Name	Cost per Unit			Cost per Claim		
	Hospital Outpatient	Home Infusion/ Specialty Pharmacy	Physician Office	Hospital Outpatient	Home Infusion/ Specialty Pharmacy	Physician Office
Botox	$5.89	$5.57	$5.54	$910	$1,101	$776
Gammagard Liquid	$42.83	$50.31	$46.81	$2,833	$4,569	$3,909
Gamunex-C/Gammaked	$47.29	$42.80	$41.42	$3,859	$3,836	$2,441
Herceptin	$93.87		$80.61	$3,754		$2,800
Neulasta	$2,392	$4,691	$3,501	$2,392	$4,691	$3,501
Orencia	$28.97	$28.89	$27.32	$2,147	$2,889	$2,109
Remicade	$82.40	$84.51	$74.66	$3,948	$4,486	$3,438
Soliris	$209.85		$189.44	$19,387		$16,671
Xgeva/Prolia	$17.69	$18.71	$14.57	$1,817	$1,283	$1,139
Yervoy	$181.62		$127.62	$39,377		$32,183

For the commercial population, most of the drugs analyzed saw utilization shifts since 2010 from the physician office setting to the hospital outpatient facility. In the hospital outpatient setting, Botox and Gamunex-C/Gammaked maintained their utilization while Gammagard Liquid, Herceptin, and Yervoy decreased utilization in 2014. In the home infusion/specialty pharmacy setting, most agents maintained the same level of utilization or saw a decrease in utilization. Only Gammagard Liquid saw an increase in utilization in the home infusion/specialty pharmacy setting. Botox, Gamunex-C/Gammaked, Herceptin, and Yervoy all saw increases in utilization in the physician office. Botox shifted from specialty pharmacy to physician office, while Herceptin shifted from the hospital to the physician office. Yervoy, which may have gained comfort with physicians administering the treatment in office, saw a dramatic decrease in hospital use and corresponding increase in the physician office setting (*see Table 14*).

TABLE 14: Commercial Utilization of Top Medical Benefit Drugs by Site of Service Based on Members 2010-2014

		Hospital Outpatient					Home Infusion/Specialty Pharmacy					Physician Office				
HCPCS	Brand Name	2010	2011	2012	2013	2014	2010	2011	2012	2013	2014	2010	2011	2012	2013	2014
J0585	Botox	13%	9%	10%	9%	↔ 9%	51%	47%	48%	35%	↓ 34%	37%	44%	43%	56%	↑ 57%
J1569	Gammagard Liquid	34%	32%	24%	26%	↓ 23%	54%	54%	52%	54%	↑ 59%	12%	14%	24%	21%	↓ 18%
J1561	Gamunex-C/ Gammaked	33%	29%	36%	37%	↔ 37%	46%	47%	41%	44%	↔ 44%	21%	24%	23%	18%	↑ 20%
J9355	Herceptin	39%	49%	54%	56%	↓ 55%	1%	0%	1%	0%	↔ 0%	61%	51%	46%	44%	↑ 45%
J2505	Neulasta	37%	42%	46%	49%	↑ 53%	0%	0%	0%	0%	↔ 0%	62%	58%	53%	50%	↓ 47%
J0129	Orencia	16%	21%	19%	23%	↑ 24%	17%	12%	12%	9%	↔ 9%	67%	67%	68%	68%	↓ 67%
J1745	Remicade	29%	33%	35%	38%	↑ 41%	13%	9%	7%	7%	↔ 7%	59%	58%	58%	55%	↓ 52%
J1300	Soliris	33%	38%	42%	32%	↑ 44%	50%	31%	26%	36%	↓ 31%	17%	31%	32%	32%	↓ 25%
J0897	Xgeva/Prolia	0%	0%	33%	29%	↑ 32%	0%	0%	1%	9%	↓ 7%	0%	100%	66%	63%	↓ 62%
J9228	Yervoy	0%	0%	79%	84%	↓ 62%	0%	0%	0%	0%	↔ 0%	0%	0%	21%	16%	↑ 38%

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

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 and BDAIDs. In 2014, Herceptin, Neulasta, Orencia, and Remicade saw physician office utilization shift to hospital outpatient facilities. Botox utilization shifted from the home infusion/specialty pharmacy setting to both the physician office and the hospital outpatient facility. Overall, utilization in the home infusion/specialty pharmacy setting stayed the same although there was a 5-point increase in utilization of Gamunex-C/Gammaked and a 2-point increase in Gammagard Liquid (*see Table 15*).

TABLE 15: Medicare Utilization of Top Medical Benefit Drugs by Site of Service Based on Members 2010–2014

		Hospital Outpatient					Home Infusion/Specialty Pharmacy					Physician Office				
HCPCS	Brand Name	2010	2011	2012	2013	2014	2010	2011	2012	2013	2014	2010	2011	2012	2013	2014
J0585	Botox	19%	8%	13%	10%	↑ 12%	27%	14%	12%	5%	↓ 3%	54%	78%	75%	84%	↑ 85%
J1569	Gammagard Liquid	15%	38%	43%	28%	↑ 30%	62%	26%	37%	53%	↑ 55%	23%	36%	20%	20%	↓ 15%
J1561	Gamunex-C/ Gammaked	31%	31%	41%	46%	↓ 40%	38%	25%	33%	31%	↑ 36%	31%	44%	26%	23%	↑ 24%
J9355	Herceptin	35%	51%	60%	56%	↑ 65%	0%	0%	0%	0%	↔ 0%	65%	49%	40%	44%	↓ 35%
J2505	Neulasta	24%	38%	49%	54%	↑ 56%	0%	0%	0%	0%	↔ 0%	76%	62%	51%	46%	↓ 44%
J0129	Orencia	23%	25%	35%	41%	↑ 46%	14%	12%	7%	1%	↔ 1%	64%	63%	58%	58%	↓ 53%
J1745	Remicade	15%	32%	39%	43%	↑ 44%	17%	7%	7%	4%	↓ 3%	68%	61%	54%	53%	↓ 52%
J1300	Soliris	0%	0%	100%	100%	↓ 82%	0%	0%	0%	0%	↔ 0%	0%	0%	0%	0%	↑ 18%
J0897	Xgeva/Prolia	0%	0%	24%	24%	↔ 24%	0%	0%	0%	1%	↓ 0%	0%	0%	76%	75%	↑ 76%
J9228	Yervoy	0%	0%	45%	65%	↑ 74%	0%	0%	0%	0%	↔ 0%	0%	0%	55%	35%	↓ 26%

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

ADMINISTRATIVE CODE TRENDS

Analysis of administrative spend is in line with examining total cost of drug treatment on the medical benefit. Drug administration codes with at least $0.01 spend were included in the following figure by LOB. Aligned with the dominant oncology drug spend, for both commercial and Medicare administration codes, the most spend occurs with administration of IV chemotherapy. Analysis of drug administration code spend is inclusive of all sites of service (home infusion/specialty pharmacy, hospital outpatient, and physician office) and as expected, administration of medical benefit drugs is more costly in the hospital outpatient facility than other outpatient sites of care. Frequently, it is four times more expensive in the hospital than physician office setting for commercial members; for Medicare, it is frequently twice as costly in the hospital (*see Tables 16 and 17*).

TABLE 16: 2014 Commercial Top Administration Codes by Allowed Amount PMPM, Unit Cost, and Site of Service*

COMMERCIAL

CPT Code	CPT Description	Allowed Amount PMPM			Unit Cost			Total PMPM
		Hospital Outpatient	Home Infusion/ Specialty Pharmacy	Physician Office	Hospital Outpatient	Home Infusion/ Specialty Pharmacy	Physician Office	
96413	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug	$0.75	$0.00	$0.28	$574.07	$330.69	$206.79	$1.03
96375	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); each additional sequential intravenous push of a new substance/drug	$0.47	$0.00	$0.04	$96.53	$38.97	$34.79	$0.54
95165	Supervision of preparation and provision of antigens for allergen immunotherapy; single or multiple antigens (specify number of doses)	$0.00	$0.00	$0.50	$26.95	$12.04	$13.47	$0.50
96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour	$0.38	$0.00	$0.09	$340.56	$72.60	$79.75	$0.49
96372	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular	$0.17	$0.00	$0.19	$74.73	$27.40	$28.64	$0.40
96374	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); intravenous push, single or initial substance/drug	$0.27	$0.00	$0.02	$166.67	$70.85	$72.92	$0.35
90460	Immunization administration through 18 years of age via any route of administration, with counseling by physician or other qualified healthcare professional; first vaccine/toxoid component	$0.00	$0.00	$0.34	$25.92	$39.84	$22.16	$0.34
90471	Immunization administration (includes percutaneous, intradermal, subcutaneous, or intramuscular injections); 1 vaccine (single or combination vaccine/toxoid)	$0.04	$0.01	$0.27	$65.99	$11.77	$23.54	$0.34
96361	Intravenous infusion, hydration; each additional hour	$0.27	$0.00	$0.01	$113.72	$20.47	$21.60	$0.33
96367	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); additional sequential infusion of a new drug/substance, up to 1 hour	$0.13	$0.00	$0.06	$180.72	$42.54	$43.52	$0.20
96415	Chemotherapy administration, intravenous infusion technique; each additional hour	$0.13	$0.00	$0.04	$210.06	$55.91	$45.78	$0.17
96417	Chemotherapy administration, intravenous infusion technique; each additional sequential infusion (different substance/drug), up to 1 hour	$0.12	$0.00	$0.04	$298.79	$169.62	$103.92	$0.16
96360	Intravenous infusion, hydration; initial, 31 minutes to 1 hour	$0.11	$0.00	$0.01	$283.56	$97.76	$79.61	$0.14
96366	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); each additional hour	$0.09	$0.00	$0.01	$117.09	$26.00	$31.34	$0.11
90461	Immunization administration each additional component	$0.00	$0.00	$0.11	$13.78	$17.60	$11.22	$0.11
96411	Chemotherapy administration; intravenous, push technique, each additional substance/drug	$0.09	$0.00	$0.02	$350.57	$157.03	$92.31	$0.11
95117	Immunotherapy injections	$0.00	$0.00	$0.10	$76.40	$21.47	$14.81	$0.10
99601	Home infusion/specialty drug administration, per visit (up to 2 hours)	$0.00	$0.09	$0.00	$87.77	$112.20	$113.80	$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	$0.07	$0.00	$0.02	$676.22	$245.03	$218.38	$0.09
96401	Chemotherapy administration, subcutaneous, or intramuscular; non-hormonal anti-neoplastic	$0.03	$0.00	$0.04	$225.04	$41.10	$83.33	$0.07
96409	Chemotherapy administration; intravenous, push technique, single or initial substance/drug	$0.05	$0.00	$0.01	$427.86	$383.29	$156.40	$0.06

Table 16 continues on page 83

TABLE 16: 2014 Commercial Top Administration Codes by Allowed Amount PMPM, Unit Cost, and Site of Service*

continued from page 82

COMMERCIAL

CPT Code	CPT Description	Allowed Amount PMPM			Unit Cost			Total PMPM
		Hospital Outpatient	Home Infusion/ Specialty Pharmacy	Physician Office	Hospital Outpatient	Home Infusion/ Specialty Pharmacy	Physician Office	
96376	Intravenous push, single or initial substance/drug; each additional sequential intravenous push of the same substance/ drug provided in a facility	$0.05		$0.00	$91.75		$64.47	$0.06
90472	Immunization administration each additional vaccine	$0.00	$0.00	$0.03	$25.67	$11.17	$14.32	$0.03
99602	Home infusion/specialty drug administration, per visit (up to 2 hours); each additional hour	$0.00	$0.03	$0.00	$40.00	$57.23	$55.68	$0.03
96402	Chemotherapy administration, subcutaneous or intramuscular; hormonal anti-neoplastic	$0.02		$0.01	$225.88		$50.30	$0.02
96368	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); concurrent infusion	$0.02	$0.00	$0.00	$160.94	$43.52	$14.67	$0.02
96523	Irrigation of implanted venous access device for drug delivery systems	$0.02	$0.00	$0.00	$123.98	$37.96	$36.41	$0.02
96450	Chemotherapy administration, into central nervous system (CNS) (e.g., intrathecal), requiring and including spinal puncture	$0.02		$0.00	$323.85		$219.08	$0.02
90473	Immune administration oral/nasal	$0.00	$0.00	$0.02	$34.95	$18.14	$23.08	$0.02
G0008	Administration of influenza virus vaccine	$0.00	$0.00	$0.01	$36.13	$18.38	$21.83	$0.02
96521	Refilling and maintenance of portable pump	$0.01	$0.00	$0.01	$101.18	$151.10	$181.42	$0.02
95115	Immunotherapy 1 injection	$0.00	$0.00	$0.02	$36.87	$15.84	$13.27	$0.02
96420	Chemotherapy administration, intra-arterial; push technique	$0.00		$0.01	$554.48		$348.58	$0.01
G0009	Administration of pneumococcal vaccine	$0.00	$0.00	$0.00	$75.50	$20.25	$22.68	$0.01
Grand Total		**$3.31**	**$0.13**	**$2.33**				**$6.05**

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

*"Other" site of service not included.

TABLE 17: 2014 Medicare Top Administration Codes by Allowed Amount PMPM, Unit Cost, and Site of Service*

Medicare

CPT Code	CPT Description	Allowed Amount PMPM			Unit Cost			Total PMPM
		Hospital Outpatient	Home Infusion/ Specialty Pharmacy	Physician Office	Hospital Outpatient	Home Infusion/ Specialty Pharmacy	Physician Office	
96413	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug	$1.28	$0.00	$0.61	$325.02	$137.52	$146.80	$1.90
96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour	$0.46	$0.00	$0.21	$185.86	$92.08	$70.01	$0.84
96372	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular	$0.26	$0.00	$0.38	$40.11	$23.49	$23.82	$0.77
96375	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); each additional sequential intravenous push of a new substance/drug	$0.45	$0.00	$0.07	$35.59	$22.89	$22.85	$0.66
96374	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); intravenous push, single or initial substance/drug	$0.23	$0.00	$0.04	$105.98	$53.01	$57.61	$0.63
96361	Intravenous infusion, hydration; each additional hour	$0.18		$0.02	$37.59		$16.22	$0.40
96367	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); additional sequential infusion of a new drug/substance, up to 1 hour	$0.14	$0.00	$0.14	$60.46	$27.73	$30.75	$0.29

Table 17 continues on page 84

TABLE 17: 2014 Medicare Top Administration Codes by Allowed Amount PMPM and Site of Service*

continued from page 83

Medicare

CPT Code	CPT Description	Allowed Amount PMPM			Unit Cost			Total PMPM
		Hospital Outpatient	Home Infusion/ Specialty Pharmacy	Physician Office	Hospital Outpatient	Home Infusion/ Specialty Pharmacy	Physician Office	
90471	Immunization administration (includes percutaneous, intradermal, subcutaneous, or intramuscular injections); 1 vaccine (single or combination vaccine/toxoid)	$0.04	$0.00	$0.21	$55.86	$12.58	$21.07	$0.27
96401	Chemotherapy administration, subcutaneous or intramuscular; non-hormonal anti-neoplastic	$0.12	$0.00	$0.12	$133.48	$74.42	$72.08	$0.25
G0008	Administration of influenza virus vaccine	$0.02	$0.00	$0.15	$18.38	$22.11	$21.74	$0.18
96360	Intravenous infusion, hydration; initial, 31 minutes to 1 hour	$0.07		$0.03	$118.50		$61.92	$0.18
96415	Chemotherapy administration, intravenous infusion technique; each additional hour	$0.09		$0.07	$53.08		$32.19	$0.16
95165	Supervision of preparation and provision of antigens for allergen immunotherapy; single or multiple antigens (specify number of doses)	$0.00		$0.15	$29.37		$12.02	$0.16
96417	Chemotherapy administration, intravenous infusion technique; each additional sequential infusion (different substance/drug), up to 1 hour	$0.07	$0.00	$0.08	$62.12	$64.03	$68.66	$0.15
96366	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); each additional hour	$0.08	$0.00	$0.03	$39.90	$27.25	$19.24	$0.14
96409	Chemotherapy administration; intravenous, push technique, single or initial substance/drug	$0.09		$0.04	$248.99		$117.01	$0.14
99601	Home infusion/specialty drug administration, per visit (up to 2 hours)	$0.02	$0.09	$0.00	$83.33	$106.60	$88.64	$0.11
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	$0.00	$0.04	$332.41	$151.21	$153.11	$0.10
96411	Chemotherapy administration; intravenous, push technique, each additional substance/drug	$0.04	$0.00	$0.03	$66.62	$63.31	$65.86	$0.07
96402	Chemotherapy administration, subcutaneous or intramuscular; hormonal anti-neoplastic	$0.03		$0.03	$91.69		$34.65	$0.06
96523	Irrigation of implanted venous access device for drug delivery systems	$0.04		$0.01	$55.13		$24.93	$0.06
96420	Chemotherapy administration, intra-arterial; push technique	$0.00		$0.04	$92.67		$127.82	$0.05
G0009	Administration of pneumococcal vaccine	$0.01	$0.00	$0.03	$38.62	$22.21	$22.48	$0.04
95117	Immunotherapy injections	$0.00		$0.04	$28.40		$11.21	$0.04
99602	Home infusion/specialty drug administration, per visit (up to 2 hours); each additional hour	$0.00	$0.02	$0.00	$40.00	$49.81	$45.00	$0.02
96521	Refilling and maintenance of portable pump	$0.00		$0.02	$110.01		$124.93	$0.02
G0010	Administration of hepatitis B vaccine	$0.00		$0.00	$55.44		$26.32	$0.02
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	$34.55		$22.19	$0.02
90472	Immunization administration each additional vaccine	$0.00	$0.00	$0.01	$49.13	$12.16	$12.56	$0.01
96368	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); concurrent infusion	$0.00	$0.00	$0.01	$37.04	$20.96	$20.08	$0.01
95115	Immunotherapy 1 injection	$0.00		$0.01	$31.23		$9.50	$0.01
90474	Immunization administration for vaccines/toxoids	$0.00		$0.01	$4.32		$14.26	$0.01
Grand Total		**$3.81**	**$0.12**	**$2.66**				**$7.77**

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

*"Other" site of service not included.

Medical Benefit Drug Pipeline

PIPELINE REPORT FINDINGS

The pipeline for specialty provider-administered injectable or infused medications is robust, with many novel, breakthrough therapies scheduled to be released over the next few years. Specifically, in 2016, oncology is the therapeutic class with the largest pipeline. In the emerging area of immunotherapy for the treatment of cancer, several new products using programmed cell death 1 (PD1) and programmed death-ligand 1 (PD-L1) inhibitors as the mechanism of action are included in the pipeline. These agents are being studied individually and with other chemotherapies to treat malignant melanoma, non-small cell lung cancer (NSCLC), renal cell carcinoma (RCC), Hodgkin lymphoma, bladder cancer, and head and neck cancer. In addition, adoptive cell transfer (ACT) therapies are on the horizon and thought to be a significant advancement in the oncology space. The majority of ACT agents are currently in Phase I trials, but accelerated research is promising. Lastly, utilizing chimeric antigen receptor (CAR) T-cell therapies that target the CD19 antigen could become the standard of care for various lymphomas and leukemias, including acute lymphoblastic leukemia (ALL) and chronic lymphocytic leukemia (CLL).

Growth in other therapeutic classes illustrated in the 2015 pipeline report indicates:

- Hemophilia, although a rare disorder, has several agents of recombinant antihemophilic factor VIII, IX, and von Willebrand factor in the pipeline. These agents provide for a decreased number of infusions and allow increased time between doses.
- New humanized interleukin-5 inhibitors for eosinophilic asthma offer an option for patients unable to maintain control of their asthma. The approval of Nucala in November 2015 is further indication of growth in the asthma category.
- Pediatric and rare diseases have several orphan agents in the pipeline that have been identified as breakthrough therapies. These therapies are in high demand and they have been fast tracked by the FDA for expedited development and review.
- The next step in the autoimmune class is the release of a biosimilar for one of its branded agents.

2015 DRUG APPROVALS

In 2015, 16 specialty provider-administered injectable or infused medications were approved. Of these 16 medications, 14 were approved for intravenous (IV) infusions, two for subcutaneous (SQ) injections, and one for intratumoral injection. (Zarxio was approved for both SQ injection and IV infusion.) Indications accounted for a wide range of drug classes including oncology, blood disorders, and asthma (***see Table 18***).

TABLE 18: Medical Benefit Drugs Approved in 2015[9]

Brand Name	Generic Name	Approval Date	Route of Administration	Indication	Disease State Prevalence	Estimated Cost (AWP)[10]	Comment
Zarxio	filgrastim-sndz	3/6/15	SQ injection or IV infusion	Neutropenia	Varies	Approximately $4,600 per cycle	First biosimilar application approved in the U.S. Biosimilar to Neupogen, which is approved for all the same indications.
Unituxin	dinutuximab	3/10/15	IV infusion	First-line therapy for pediatric patients with high-risk neuroblastoma	Approximately 650 new cases of neuroblastoma/year. Estimated 425 high risk in the U.S.	$150,000 per year	Approved as part of first-line regimen in combination with isotretinoin, sargramostim, and aldesleukin.
Ixinity	recombinant coagulation factor IX (trenonacog alfa)	4/29/15	IV infusion	Hemophilia B in adults and children ≥ 12 years	Approximately 4,000 people in the U.S.	$750,000 per year	No human or animal proteins are added during any stage of manufacturing or formulation of Ixinity.
Nuwiq	recombinant factor VIII-simoctocog alfa	9/15/15	IV infusion	Hemophilia A in adults and children	Approximately 16,000 people in the U.S.	Approximately $44,000 per month or $530,000 per year	First recombinant factor derived from human cell line not chemically modified or fused with another protein.
Coagadex	coagulation factor X human	10/20/15	IV infusion	Hereditary factor X (10) deficiency in adults and children ≥ 12 years	Approximately 300-600 people in the U.S.	Dependent on number and severity of bleeds	Orphan drug status. Priority review and fast track status led to approval.
Onivyde	irinotecan liposome injection	10/22/15	IV infusion	Metastatic pancreatic cancer	Approximately 49,000 new cases of pancreatic cancer diagnosed each year in the U.S.	Approximately $70,000 per 6 months	Priority review and orphan drug designation. Approved for use in combination with 5-FU/leucovorin after trial of gemcitabine. Not approved for single agent use.
Yondelis	trabectedin	10/23/15	IV infusion	Metastatic liposarcoma (LPS) and leio-myosarcoma (LMS)	Approximately 12,000 new cases of soft tissue sarcoma in the U.S. annually.	Approximately $78,000 per 6 months	First treatment to be approved for LPS in the U.S. Approved for use in patients who have been previously treated with anthracycline and ifosfamide. Also being studied in breast and prostate tumors and pediatric sarcomas.
Imlygic	talimogene laherparepvec (T-VEC)	10/27/15	Intratumoral injection	Malignant melanoma	Approximately 74,000 people diagnosed with melanoma in the U.S.	Amgen working to limit average cost of therapy to $65,000 per treatment course for eligible participating institutions	First oncolytic virus immunotherapy. Expected to only be administered in institutions.

9. New drug approvals and pricing accurate as of February 2016 print date.

10. Drug cost information obtained from publicly available sources.

Table 18 continues on page 87

TABLE 18: Medical Benefit Drugs Approved in 2015

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Brand Name	Generic Name	Approval Date	Route of Administration	Indication	Disease State Prevalence	Estimated Cost (AWP)	Comment
Nucala	meprolizumab	11/4/15	SQ injection (health professional administered)	Severe asthma in adults and children ≥ 12 years	Asthma affects more than 22 million people in the U.S., and severe asthma accounts for 5 to 10% of that population.	Approximately $36,000 per year	Approved for people ≥ 12 years for eosinophilic asthma. Humanized IL-5 antagonist.
Adynovate	recombinant, pegylated factor VIII	11/13/15	IV infusion	Hemophilia A in adults and children ≥ 12 years	Estimated 16,000 people in the U.S.	Approximately $590,000 annually	Long-acting pegylated factor VIII. It is the 10th recombinant factor VIII to be approved by the FDA.
Darzalex	daratumumab	11/16/15	IV infusion	Multiple myeloma	Approximately 26,850 diagnosed in 2015	Approximately $135,000 annually	First-in-class monoclonal antibody that binds to CD38-expressing cancer cells.
Portrazza	necitumumab	11/24/15	IV infusion	Metastatic squamous NSCLC	Approximately 221,000 new cases of all lung cancers in the U.S. in 2015. Squamous cell represents about a third of all NSCLC.	Approximately $11,430 per month or $137,160 per year	Epidermal growth factor receptor (EGFR) inhibitor.
Empliciti	elotuzumab	11/30/15	IV infusion	Multiple myeloma	Approximately 26,850 diagnosed in 2015	Approximately $120,000 annually	Monoclonal antibody that targets the cell-surface protein signaling lymphocytic activation molecule family member 7 (SLAMF7), which is found on both myeloma cells and natural killer (NK) cells.
Kanuma	sebelipase alfa	12/8/15	IV infusion	Liposomal acid lipase deficiency (LAL-D)	Approximately 3,000 patients in the U.S.	Approximately $48,000 per month for infants, up to 6 months based on weight	First approved therapy for LAL-D, an ultra-rare metabolic disease associated with significant morbidity and premature mortality.
Vonvendi	vonicog alfa	12/8/15	IV infusion	von Willebrand disease	Approximately 3 million in the U.S.	TBD	First recombinant von Willebrand factor.
Bendeka	bendamustine	12/8/15	IV infusion	Chronic lymphocytic leukemia (CLL) and indolent B-cell non-Hodgkin lymphoma (NHL)	Varies	Approximately $65,000 to $100,000 for 6-8 cycles	Low volume (50 ml), 10-minute infusion version of bendamustine vs. Treanda at 500 ml and 30-60-minute infusion.

PIPELINE AGENTS

There are 18 noteworthy specialty provider-administered injectable or infused medications awaiting approval in the autoimmune disorders, bleeding disorders, hematological, oncology, pediatric diseases, rare diseases, and respiratory diseases categories. The majority of agents are in the oncology category with four specialty oncology drugs awaiting approval for use in non-small cell lung cancer. Biosimilars is an area of expected growth over the next year, with four expected agents to be the first biosimilars to Neulasta, Neupogen, Procrit, and Remicade. Six of the 15 other agents up for near-term approval are seeking orphan designation (***See Table 19***).

TABLE 19: Medical Benefit Drug Pipeline

Therapeutic Category	Drug	Mechanism of Action	Indication	Route of Administration	Expected Approval	Comments
Autoimmune disorders	CT-P13 infliximab (Inflectra)	TNF inhibitor	RA, Crohn's, UC, ankylosing, PsA, psoriasis	IV infusion	TBD	Biosimilar to Remicade. Pending litigation will delay market availability several months after approval.
Bleeding disorders	albutrepenonacog alfa	Recombinant coagulation factor IX with recombinant albumin, rIX-FP	Hemophilia B	IV infusion	2016	Orphan designation. Long-acting recombinant factor IX.
Bleeding disorders	BAY 81-8973 (Kovaltry)	Recombinant factor VIII	Hemophilia A	IV infusion	2016	Orphan designation.
Hematological	pegfilgrastim	Granulocyte colony-stimulating factor (CSF)	Treatment of neutropenia	SQ injection	TBD	Biosimilar to Neulasta.
Hematological	filgrastim (Grastofil)	Granulocyte colony-stimulating factor (CSF)	Treatment of neutropenia	SQ injection	TBD	Biosimilar to Neupogen.
Hematological	epoetin alfa (Retacrit)	Erythropoiesis-stimulating agent (ESA)	Treatment of anemia	IV infusion/ SQ injection	TBD	Biosimilar to Epogen/Procrit.
Oncology	bavituximab	Phosphatidylserine (PS)-targeting monoclonal antibody	Late stage non-squamous NSCLC	IV infusion	2016	Fast track designation. SUNRISE Trial (Phase III) — treatment of second-line NSCLC.
Oncology	paclitaxel poliglumex	Microtubule inhibitor	Ovarian cancer	IV infusion	2016	Biologically enhanced chemotherapeutic agent that links paclitaxel to a biodegradable polyglutamate polymer.
Oncology	volasertib	Polo-like kinase-1 (PLK1) inhibitor	Acute myeloid leukemia (AML)	IV infusion or oral	2016	Orphan/breakthrough therapy designation. Currently in Phase III clinical trials for previously untreated AML ineligible for intensive remission induction therapy.
Oncology	atezolizumab	Programmed death-ligand 1 (PD-L1) inhibitor	NSCLC	IV infusion	TBD	Breakthrough therapy designation. In trials for melanoma, breast, bladder, and renal cancers. Biomarker testing for PD-L1 also in development.

Table 19 continues on page 89

TABLE 19: Medical Benefit Drug Pipeline

continued from page 88

Therapeutic Category	Drug	Mechanism of Action	Indication	Route of Administration	Expected Approval	Comments
Oncology	durvalumab	Programmed death-ligand 1 (PD-L1) inhibitor	NSCLC/head and neck cancer	IV infusion	TBD	Fast track designation for NSCLC. In trials for gastric, pancreatic, and bladder cancers and in multiple combinations.
Oncology	avelumab	Programmed death-ligand 1 (PD-L1) inhibitor	NSCLC	IV infusion	TBD	In trials for bladder, gastric, head and neck, renal, and ovarian cancer; mesothelioma; and Merkel cell carcinoma.
Oncology	pidilzumab	Programmed death-ligand 1 (PD-L1) inhibitor	Melanoma	IV infusion	TBD	In trials for solid and hematologic malignancies such as non-Hodgkin lymphoma (NHL) and diffuse large B-cell lymphoma (DLBCL).
Oncology	rindopepimut	EGFRvIII peptide vaccine	Glioblastoma multiforme	Intradermal	2017	Orphan designation. Glioblastoma multiforme is most common and most aggressive malignant primary brain tumor in humans.
Pediatric diseases	drisapersen	Antisense oligonucleotide	Duchenne muscular dystrophy (DMD)	SQ injection	Early 2016	Orphan drug, fast track, and breakthrough therapy designation. DMD affects approximately 1 in every 3,500 live male births.
Pediatric diseases	eteplirsen	Morpholino antisense oligomer (triggers excision of exon 51)	Duchenne muscular dystrophy (DMD)	IV infusion	2/26/16	Orphan drug and fast track designation.
Rare diseases	defibrotide	Polydisperse oligonucleotide antithrombotic	Hepatic veno-occlusive disease	IV infusion	3/31/16	Life-threatening complication that can develop after SCT. Approximately 1,500 people in the U.S.
Respiratory diseases	reslizumab	IL-5 inhibitor	Moderate to severe eosinophilic asthma	IV infusion	3/30/16	Combination of exacerbation reduction and lung function improvement.

Forecasting growth of new drugs can be extremely helpful in understanding possible impact. Table 20 provides examples of potential five-year forecasts of sales growth for a sample of drugs from Tables 18 and 19. The figures below do not reflect actual sales, but instead represent predictive values and have been provided for information and educational purposes only. The numbers in this table represent prediction of U.S. sales in millions of dollars (*see Table 20*).

TABLE 20: Medical Benefit Drug Forecasting (Predicted U.S. Sales in Millions of Dollars)[11]

Drug Name	2015	2016	2017	2018	2019	2020
Unituxin	$4	$10	$13	$15	$18	$22
Yondelis	$0.70	$7.04	$17.59	$24.63	$39.77	$54.47
Imlygic	$6.18	$30.71	$51.84	$61.91	$86.45	$97.05
Nucala	$18.86	$124.06	$257.87	$459.58	$555.23	$655.91
Adynovate	$26.15	$54.80	$98.31	$155.72	$217.73	$264.05
Yet to Be Approved						
eteplirsen	$0.00	$17.15	$101.50	$187.30	$316.96	$376.95
necitumumab	$0.00	$84.92	$183.98	$232.43	$278.93	$302.38
atezolizumab	$0.00	$142.14	$540.58	$1,184.76	$1,849.57	$2,437.49

11. EvaluateLTD. EvaluatePharma.® November 2015. Accessed: http://www.evaluategroup.com/public/EvaluatePharma-Overview.aspx.

Legislative Reimbursement Policy Updates

The Affordable Care Act (ACA) focused on three main areas of health care: insurance reforms/patient protections, coverage expansion, and cost containment. The early years of ACA implementation focused largely on the first two areas, and in 2015, the U.S. Department of Health and Human Services (HHS) and Congress continued to pursue cost containment and payment reform activities.

In January 2015, HHS announced payment reform goals for shifting reimbursement methodologies from paying for volume to paying for value by increasingly tying reimbursement to the value of healthcare provided to Medicare beneficiaries.[12] In March 2015, Congress repealed the flawed sustainable growth rate (SGR) methodology and replaced it with a system to incentivize high-quality, low-cost care, as well as shifts into alternative payment models.[13] In the context of these policy changes, debate continues about high prices charged for drugs and biologics and how the value of products should be determined.

12. HHS. Better, Smarter, Healthier: In Historic Announcement, HHS Sets Clear Goals and Timeline for Shifting Medicare Reimbursements from Volume to Value. Press release. January 26, 2015. Accessed: http://www.hhs.gov/news/press/2015pres/01/20150126a.html .

13. Medicare Access and CHIP Reauthorization Act of 2015. Pub. L. 114-10, 129 Stat. 87.

Physician Payment Changes — Medicare Access and CHIP Reauthorization Act of 2015 (MACRA)

SGR REPEAL

In April 2015, Congress passed the Medicare Access and Children's Health Insurance Program (CHIP) Reauthorization Act of 2015 (MACRA)[14] that repeals the sustainable growth rate (SGR) and provides five years of annual updates of 0.5 percent to transition to the new physician payment system (July 2015 through 2019). Payment rates would then remain frozen for six years (2020 to 2025). After that, physicians not participating in an eligible alternative payment model (APM) would receive annual payment increases of 0.25 percent. Beginning in 2019, physicians will have a choice of two different payment pathways: a Merit-Based Incentive Payment System (MIPS) or participation in an eligible APM.

CREATION OF MIPS, APM INCENTIVES, AND PHYSICIAN-FOCUSED PAYMENT MODELS (PFPMs)

Congress created MIPS to further invest in value-based purchasing concepts within the Medicare physician fee schedule (MPFS). Beginning in 2019, MIPS will adjust physician payment based on a physician's rating across four factors: quality, resource use, electronic health record (EHR) meaningful use, and clinical improvement activities. In 2019, payment can be adjusted up or down 4 percent and will increase each year until 2022, when the adjustment can be up to 9 percent and will remain at 9 percent in perpetuity. The four components of MIPS will build on the current quality measures and concepts in the Physician Quality Reporting System (PQRS), EHRs/Meaningful Use (MU), and the value-based payment modifier (VBM). PQRS, MU, and VBM are all slated to sunset under MACRA at the end of 2018; in 2019, MIPS will be the only Medicare quality reporting program.[15]

Between 2019 and 2024, physicians who successfully participate in alternative payment models (APMs) and receive a significant portion of revenue (25+ percent) from APMs that require the practice to bear more than nominal risk will be exempt from MIPS and receive a 5 percent bonus. CMS will issue rules implementing the MIPS and APM incentives in 2016, providing more clarity regarding how physicians and practices will be rated under MIPS, exempted from MIPS, and eligible for the APM bonus payments. CMS hopes that physicians will be enticed to participate in risk-bearing APMs to 1) avoid MIPS and 2) receive bonus payments. In 2026 and beyond, physicians in APMs qualify for a 0.75 percent update; all others will receive a 0.25 percent annual update. Sufficient participation (defined as greater than 25 percent of Medicare revenue) in eligible APMs[16] exempts physicians from participating in MIPS.[17]

Payment Reform Updates — Accountable Care Organizations

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 CMS Innovation Center, a sub-agency under CMS tasked with authorizing, evaluating, and scaling payment reform demonstrations in both Medicare and Medicaid programs. The Innovation Center has undertaken many significant payment reform initiatives, including implementing the MSSP ACOs, creating an additional category of ACOs (the Pioneer ACOs), providing grant monies for two rounds of healthcare innovation awards, and developing shared savings arrangements in various specialties, starting with oncology.

PIONEER ACO CMS ACTUARY DETERMINATION

In May 2015, the CMS Actuary completed an evaluation of the Pioneer ACO model, highlighting $384 million Medicare savings from the Pioneer ACOs in the first two years ($300 per participating beneficiary per year).[18] This payment model is the first to meet the criteria for expansion to a larger population, which include that the model must: 1) reduce spending under the applicable title without reducing the quality of care or improve the quality of patient care without increasing spending, 2) The Chief Actuary of CMS certifies that such expansion would reduce (or would not result in any increase in) net program spending under the applicable titles, and 3) The Secretary determines that such expansion would not

14. Medicare Access and CHIP Reauthorization Act of 2015. Pub. L. 114-10, 129 Stat. 87.

15. Ibid.

16. Note: Greater than nominal risk for the provider is required for an APM to qualify as an eligible APM.

17. Ibid.

18. HHS. Affordable Care Act Payment Model Saves More Than $384 Million in Two Years, Meets Criteria for First-Ever Expansion. Press release. May 4, 2015. Accessed: http://www.hhs.gov/about/news/2015/05/04/affordable-care-act-payment-model-saves-more-than-384-million-in-two-years-meets-criteria-for-first-ever-expansion.html.

deny or limit the coverage or provision of benefits under the applicable title for applicable individuals.[19] Overall, the Pioneer ACOs are one piece of a larger framework intended to move the U.S. healthcare system toward a system that reimburses stakeholders based on quality, not quantity. Expansion of the Pioneer ACOs aligns with HHS' goal announced in 2015 to tie 30 percent of Medicare payments to quality and value by 2016 and 50 percent of payments by 2018.[20]

NEXT GENERATION ACO

In line with continuing to create opportunities for providers to enter into risk-based contracts with CMS, the Innovation Center announced the Next Generation ACO in March 2015.[21] The purpose of the model is to test whether strong financial incentives for ACOs can improve health outcomes and reduce expenditures for Medicare fee-for-service (FFS) beneficiaries. The model offers financial arrangements with higher levels of risk and reward than current Medicare ACO initiatives, using refined benchmarking methods that 1) reward quality performance, 2) reward both attainment of and improvement in cost containment, and 3) ultimately transition away from reference to ACO historical expenditures. The model additionally offers a selection of alternative payment mechanisms to enable a graduation from FFS reimbursements to capitation. The "Next Generation" model will offer more predictable financial targets, give providers and beneficiaries more opportunities to coordinate care, and use quality standards consistent with other Medicare programs. ACOs will take on more risk than current models.

ACO INVESTMENT MODEL

The ACO Investment Model provides ACOs with prepaid shared savings to encourage the creation of new ACOs in rural and underserved areas and encourage existing Medicare Shared Savings Program (MSSP) ACOs to take on more financial risk.[22] The new model builds upon the Advance Payment Model and aims to foster new market growth and improve Medicare beneficiaries' care outcomes. CMS will recover the money from the prepaid payments given to ACOs through an offset of the ACOs' earned shared savings.

Payment Reform Updates — Specialty Payment Models

The initial Center for Medicare & Medicaid Innovation (the CMS Innovation Center), healthcare delivery, and payment reform initiatives focused on primary care and the accountable care organizations. As the Innovation Center continues to pursue HHS' goal of value-based purchasing and alternative payment models, it is developing more specialty-focused models.

ONCOLOGY CARE MODEL UPDATE

The Oncology Care Model (OCM) is a five-year model slated to begin in spring 2016. OCM looks to develop multi-payor patient-centered oncology medical homes with a shared savings payment component encompassing the total cost of patient care during a six-month cancer "chemotherapy" episode. Under the OCM, practices will enter into payment arrangements that include financial and performance accountability for episodes of care surrounding chemotherapy administration to cancer patients.

Forty-three payors and 443 practices submitted letters of intent (LOIs); and all payors and about a third of the practices submitting LOIs completed applications. CMS is expected to make an announcement in the first quarter of 2016.

COMPREHENSIVE CARE FOR JOINT REPLACEMENT

The Comprehensive Care for Joint Replacement (CCJR) Payment Model is the first mandatory demonstration proposed by the CMS Innovation Center. Under the proposed model, acute care hospitals in certain selected geographic areas will receive retrospective bundled payments for episodes of care for lower extremity joint replacement (LEJR) or reattachment of a lower extremity. The model would require providers to manage costs while meeting quality goals for patient care for LEJR. CMS believes this model will further the agency's goals in improving the efficiency and quality of care for Medicare beneficiaries for these common medical procedures.

19. CMS Actuary. Certification of Pioneer Model Savings. April 10, 2015. Accessed: http://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ActuarialStudies/Downloads/Pioneer-Certification-2015-04-10.pdf.

20. HHS. Better, Smarter, Healthier: In Historic Announcement, HHS Sets Clear Goals and Timeline for Shifting Medicare Reimbursements from Volume to Value. Press release. January 26, 2015. Accessed: http://www.hhs.gov/news/press/2015pres/01/20150126a.html.

21. Center for Medicare & Medicaid Innovation. Next Generation ACO Model: Request for Applications. March 2015. Accessed: https://innovation.cms.gov/Files/x/nextgenacorfa.pdf.

22. Centers for Medicare & Medicaid Services (CMS). New Affordable Care Act Initiative to Support Care Coordination Nationwide. Press release. October 15, 2014. Accessed: https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2014-Press-releases-items/2014-10-15-3.html.

CMS will test CCJR for a five-year performance period, beginning January 1, 2016, and ending December 31, 2020.

MILLION HEARTS DEMO

The Million Hearts Cardiovascular Risk Reduction Model (MH Model) is a five-year randomized-controlled trial that will test heart attack prevention care delivery models combined with value-based payments that reward population level improvements in predicted cardiac risk. The MH Model will begin in January 2016 and end by December 2020. It supports the Million Hearts goal to prevent 1 million heart attacks and strokes as well as CMS' objective to increase use of better models of care delivery and value-based payments. CMS will reward provider groups based solely on reduction in predicted cardiac risk for the overall patient population.

Value Frameworks and Tools for Physicians

Throughout 2015, the drug pricing and assessment of value have escalated, particularly spurred by the financial impact of the hepatitis C products and the concomitant implications on state budgets given the role of Medicaid in hepatitis C, Medicare expenditures under Medicare Part D, as well as the associated impact on premiums across payor systems. Debates about drug pricing are likely to continue throughout the 2016 election year. Alongside price discussions is the question of value: Is the price proportional to the outcomes delivered? As such, several stakeholders have published or released frameworks or tools that attempt to quantify value in a way that could be used by physicians — when discussing treatment options with patients — and payors when determining coverage policies.

ICER – ETAP

In July 2015, the Institute for Clinical and Economic Review (ICER) announced its plan to launch the Emerging Therapy Assessment and Pricing (ETAP) Program.[23] The ETAP Program seeks to address what it considers rapidly rising costs of drugs and other therapies through independent analysis of the drugs' comparative effectiveness, cost-effectiveness, and potential budget impact. ICER says it "will use transparent methods to calculate for each new drug a value-based price benchmark anchored to the real benefits the drug brings to patients."

In September 2015, ICER finalized its framework and later finalized two reports evaluating the cost-effectiveness and budget impact of two new cholesterol-lowering drugs in the PCSK9 class[24] and a new heart failure treatment.[25] For the PCSCK9s, ICER reported that the price should be approximately 33 percent of list price ($14,600 per year) to achieve a cost-effectiveness benchmark of $150,000 per quality adjusted life year. Further, to avoid a significant increase in drug spending, the value-based price benchmark should be approximately 15 percent of list price ($2,177/year compared to $14,600/year). The heart failure evaluation found that at list price ($4,560), the new drug, Entresto, has a cost-effectiveness ratio of $50,915; however, due to potential budget impact, ICER determined the value-based price benchmark to be approximately 91 percent of list price ($4,168/year compared to $4,560/year).

ICER is an independent third party and its analyses are not specifically tied to any reimbursement levels or metrics; however, these analyses may provide additional leverage when payors engage with manufacturers.

ASCO'S VALUE FRAMEWORK

In June 2015, ASCO released its value framework methodology, in which it states the intention to create an interactive tool to help physicians and patients assess the value of cancer treatment options and facilitate shared decision making.[26] The tool would allow the comparison of a new treatment regimen to the current standard of care for a particular cancer indication using data from a prospective, randomized trial. Given the specific clinical concerns associated with different treatment settings, ASCO's methodology outlines two different versions of the framework: one for advanced cancer and a second for potentially curative treatment (e.g., adjuvant or neoadjuvant therapy).

23. Institute for Clinical and Economic Review. "ICER Launches New Drug Assessment Program with $5.2 Million Award from the Laura and John Arnold Foundation." July 21, 2015.

24. ICER. PCSK9 Inhibitors for Treatment of High Cholesterol: Effectiveness, Value, and Value-Based Price Benchmarks. Final report. November 24, 2015. Accessed: http://cepac.icer-review.org/wp-content/uploads/2015/04/Final-Report-for-Posting-11-24-15.

25. ICER. CardioMEMS™ HF System (St. Jude Medical) and Sacubitril/Valsartan (Entresto,™ Novartis) for Management of Congestive Heart Failure: Effectiveness, Value, and Value-Based Price Benchmarks. Final report. December 1, 2015. Accessed: http://ctaf.icer-review.org/sites/default/files/u148/CHF_Final_Report_120115.pdf.

26. American Society of Clinical Oncology. "American Society of Clinical Oncology Statement: A Conceptual Framework to Assess the Value of Cancer Treatment Options." June 22, 2015.

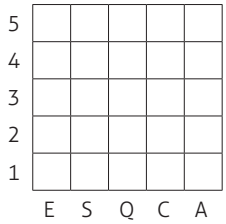
ASCO's tool combines points in the categories of clinical benefit (scored based on percent improvement in overall survival, progression-free survival, or response rate), toxicity (scored based on the relative toxicity of the new treatment regimen against the comparator regimen), and statistically significant improvement in palliation or in treatment-free interval (e.g., proxies for quality of life) to generate the Net Health Benefit (NHB) of a new treatment regimen and then compares this to the control treatment being investigated in the clinical trial.[27] The NHB is ultimately juxtaposed against the direct cost of the treatment to produce an overall summary assessment. ASCO's framework provides two types of cost estimates to consider the value of an intervention: 1) the societal cost (e.g., the drug acquisition cost [DAC][28]) and 2) the patient cost of each regimen. Cost information (in both DAC and patient cost) is provided as a monthly cost of the treatment regimen for the advanced treatment framework, and as a total cost of the regimen for the curative framework.

Due to significant critiques of its methodology,[29] it is unclear when ASCO will finalize the methodology and release the interactive tool.

NATIONAL COMPREHENSIVE CANCER NETWORK

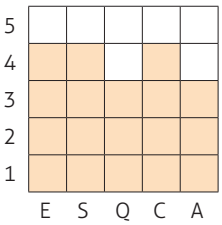
In March 2015, the National Comprehensive Cancer Network (NCCN) first released details of its NCCN Evidence Blocks, which display ratings based on expert consensus on five dimensions of value: efficacy, safety, quality of evidence, consistency of evidence, and affordability. The NCCN Evidence Blocks provide visual representations of value for each regimen in NCCN's clinical guidelines — the more shading of the 5x5 Evidence Block translates to a more favorable rating. In October and November 2015, NCCN released Evidence Blocks for multiple myeloma, chronic myeloid leukemia, and kidney cancer and announced its intention to release additional Evidence Blocks for breast, colon, non-small cell lung, and rectal cancers by the end of 2015.[30] However, NCCN has yet to release any more evidence blocks. Further, by the end of 2016, NCCN Evidence Blocks are expected to be contained within all the NCCN Clinical Practice Guidelines. Like NCCN's guidelines, the Evidence Blocks are based on consensus among experts. To date, there has been no evidence of payors creating or limiting coverage policies based on a regimen's performance on the Evidence Blocks. NCCN intends for the Evidence Blocks to be a tool for physicians when reviewing the guidelines and facilitating discussions about treatment options with patients (***see Figure 90***).

FIGURE 90: NCCN Evidence Blocks Categories and Definitions



E=EFFICACY OF REGIMEN/AGENT
S=SAFETY OF REGIMEN/AGENT
Q=QUALITY OF EVIDENCE
C=CONSISTENCY OF EVIDENCE
A=AFFORDABILITY OF REGIMEN/AGENT

EXAMPLE EVIDENCE BLOCK



E=4
S=4
Q=3
C=4
A=3

DRUGABACUS

Also in 2015, Peter Bach and Memorial Sloan Kettering developed an interactive tool to calculate the appropriate monthly drug cost that should be charged to obtain a specific cost per life year gained threshold.[31] The tool allows the user to modify inputs such as the incremental cost per life year gained, toxicity discount, novelty multiplier, cost of development multiplier, rarity of disease multiplier, and population burden of disease multiplier. The base case is set to calculate prices based on a threshold of $120,000 per life year gained, a 15 percent toxicity discount, and all multipliers set to 1.0.

27. American Society of Clinical Oncology. "American Society of Clinical Oncology Statement: A Conceptual Framework to Assess the Value of Cancer Treatment Options." June 22, 2015.

28. Note: ASCO used October 2014 average sales price (ASP) values for intravenous products as well as information from UnitedHealthcare on oral drugs.

29. Pitts PJ, Goldberg RM. Undermining Patient Values: The ASCO Value in Cancer Care Task Force Framework. J Comm Biotech 2015;21:10-14.

30. National Comprehensive Cancer Network. "NCCN Unveils Evidence Blocks for CML and Multiple Myeloma." October 16, 2015.

31. DrugAbacus. http://www.drugabacus.org.

The Web application currently evaluates 54 drugs of which only nine drugs have Abacus-suggested prices below actual prices: Gazyva, Gleevec, Halaven, Sprycel, Tarceva, Torisel, Velcade, and Zevalin.

Part B Biosimilars Payment Policy

In October 2015, CMS finalized its proposal to 1) place all biosimilar biological products of the same reference product in the same billing and payment code and 2) base the payment amount for a biosimilar biological product on the ASP of all NDCs assigned to the same billing and payment code.[32] This approach is similar to the ASP calculation for multiple source drugs except that the reference product is not included. CMS did not address whether a product's interchangeability status should be the basis for a different approach for Medicare Part B payment, but may do so in the future.

CMS anticipates that biosimilar biological products will have lower ASPs than the corresponding reference products, and expects the Medicare Program will realize savings from the utilization of biosimilar biological products. However, due to lack of data (number of biosimilars to be approved, market penetration, prices, etc.) and experience, CMS did not quantify the potential savings to Medicare Part B or the impact on physician offices (***see Table 21***).

Under CMS' policy, individual biosimilar manufacturers will not be able to control reimbursement for products directly — reimbursement could fluctuate quarterly based on price changes made by all manufacturers. In a competitive situation, there is a financial incentive for physicians to use the lowest-cost product.

TABLE 21: Proposed Reimbursement for Biosimilar Agents

Description	Price Set by Manu	Market Share	ASP	Medicare Reimbursement	Margin for Physician
Reference	$1,000	N/A	$1,000	ASP + 6% = $1,060	$60 (6%)
Biosimilar 1	$700	33%	$600	ASP + 6% of reference product ASP = $660	-$40 (-5.7%)
Biosimilar 2	$600	33%			$60 (10%)
Biosimilar 3	$500	33%			$160 (32%)
Description	**Price Set by Manu**	**Market Share**	**ASP**	**Medicare Reimbursement**	**Margin for Physician**
Reference	$1,000	N/A	$1,000	ASP + 6% = $1,060	$60 (6%)
Biosimilar 1	$700	10%	$530	ASP + 6% of reference product ASP = $590	-$40 (-5.7%)
Biosimilar 2	$600	10%			-$10 (-1.7%)
Biosimilar 3	$500	80%			$90 (18%)

32. Biosimilars CMS Final Rule.

Some stakeholders are concerned this could result in shortages, similar to those sometimes seen in the generic market, ultimately undermining the purpose of biosimilar availability. Additionally, this policy could create problems for payors when trying to identify which product has been administered and if it has been administered appropriately (e.g., on label or within compendia listings); FDA has stated that it will work with CMS to create a way to differentiate among products (e.g., establish modifiers).

This policy will carry over into pass-through payment under the outpatient prospective payment system (OPPS). By statute, pass-through payment must equal payment for a product under 1847A; biosimilars receiving pass-through payment will be paid based on the blended ASP.

340B

OVERVIEW OF 340B PROGRAM

Congress established the 340B Drug Pricing Program in 1992, which requires manufacturers to provide substantial discounts for sales of covered drugs to covered entities as a prerequisite to qualifying for Medicaid reimbursement.[33] 340B-covered entities must limit the use of discounted drugs to the outpatient care of individuals who meet the program's definition of a "patient," among other requirements.

The 340B program reduces the burden on covered entities that provide uncompensated or undercompensated care. In addition, drugs purchased by the covered entity at a discount can be sold to all individuals who meet the program's definition of a "patient" regardless of their insurance status. Therefore, for patients who are covered by private insurance or Medicare, a covered entity can benefit financially from the difference between the discounted cost of the drug and the amount reimbursed by the patient's insurance. This difference can be quite significant when aggregated over a large number of patients.

Since 1992, the program has largely been implemented through guidance instead of formal rulemaking and regulation like most federal statutory programs. In 2014, the D.C. Circuit Court held that the Health Resources & Services Administration (HRSA) does not have rulemaking authority for the 340B program outside of civil monetary penalties, dispute resolution, and ceiling prices.[34] Due to this ruling, HRSA was forced to convert its omnibus regulation — intended to create clear and enforceable policies to govern the program — into guidance, because it does not have explicit rulemaking authority. At this time, it is unclear how HRSA will be able to enforce the guidance, if finalized.

HIGHLIGHTS FROM THE MEGA-GUIDANCE[35] INCLUDE:

- **Patient Eligibility:** The proposed guidance includes a six-part patient definition that is more robust than previous definitions and creates more requirements when 340B-covered entities are claiming a patient is a patient of the organization.
- **Off-Site Facility:** The guidance reiterates use of Medicare cost reports for eligibility purposes; however, CMS sought comment on other ways to determine off-site facility eligibility. This issue is particularly important due to Congress' recent passage of the Bipartisan Budget Act of 2015,[36] which excludes off-campus provider sites purchased by hospitals after the date of enactment (November 2, 2015) from billing under the OPPS. This change, without another option for determining off-site facility, may exclude future off-campus provider sites from 340B eligibility.
- **Duplicate Discounts:** HHS sought comments regarding other ways to determine when covered entities are using 340B products for Medicaid patients for purposes of avoiding duplicate discounts. This is an effort to allow covered entities to make carve-in/carve-out determinations on an MCO contract-by-contract basis. If implemented, this could complicate oversight of duplicate discounts.
- **Limited Distribution Plan:** The guidance provided clarification about how the 340B program functions when manufacturers choose a limited distribution network; in a limited distribution network, a manufacturer has to provide products to 340B-covered entities at or below the ceiling price and cannot place undue burdens on 340B-covered entities. However, the guidance would require manufacturers to submit distribution plans to HHS to ensure the manufacturer is not implementing restrictive criteria on 340B-covered entities compared to non-340B entities. This could create significant issues if a company's competitive strategy for distribution is made public.

33. Public Health Service Act. Pub. L. 78-410, 58 Stat. 682. / 42 U.S.C. § 256b.

34. Pharmaceutical Research and Manufacturers of America (PhRMA) v. HHS, 43 F. Supp. 3d 28 (D.D.C. 2014).

35. 340B Drug Pricing Program Omnibus Guidance, 80 Fed. Reg. 52300 (August 28, 2015).

36. Bipartisan Budget Act of 2015. Pub. L. 114-74.

Glossary

AAOS ..... American Academy of Orthopaedic Surgeons
ACA ..... Affordable Care Act
ACO ..... accountable care organization
ACT ..... adoptive cell transfer
ALL ..... acute lymphoblastic leukemia
AMD ..... age-related (wet) macular degeneration
AML ..... acute myeloid leukemia
APM ..... alternative payment model
ASCO ..... American Society of Clinical Oncology
ASP ..... average sales price
AWP ..... average wholesale price
BDAIDs ..... biologic drugs for autoimmune disorders
CAR ..... chimeric antigen receptor
CCJR ..... Comprehensive Care for Joint Replacement
CHIP ..... Children's Health Insurance Program
CINV ..... chemotherapy-induced nausea and vomiting
CLL ..... chronic lymphocytic leukemia
CMS ..... Centers for Medicare & Medicaid Services
CMS Innovation Center ..... Center for Medicare & Medicaid Innovation
CNS ..... central nervous system
CPT ..... Current Procedural Terminology
CSF ..... colony-stimulating factor
DLBCL ..... diffuse large B-cell lymphoma
DMD ..... Duchenne muscular dystrophy
ED ..... emergency department
EGFR ..... epidermal growth factor receptor
EHR ..... electronic health record
ESA ..... erythropoiesis-stimulating agent
ETAP ..... Emerging Therapy Assessment and Pricing
FDA ..... U.S. Food and Drug Administration
FFS ..... fee for service
HA ..... hyaluronic acid
HAE ..... hereditary angioedema
HCPCS ..... Healthcare Common Procedure Coding System
HEC ..... highly emetogenic chemotherapy
HHS ..... U.S. Department of Health and Human Services
HMO ..... health maintenance organization
HRSA ..... Health Resources and Services Administration
ICD ..... International Classification of Diseases
ICER ..... Institute for Clinical and Economic Review
IDN ..... integrated delivery network
IG ..... immune globulin
IL ..... interleukin
IV ..... intravenous
IVIG ..... intravenous immune globulin
LAL-D ..... liposomal acid lipase deficiency
LEC ..... low emetogenic chemotherapy
LEJR ..... lower extremity joint replacement
LOB ..... line of business
LOIs ..... letters of intent
MACRA ..... Medicare Access and CHIP Reauthorization Act of 2015
MCO ..... managed care organization
MEC ..... moderately emetogenic chemotherapy
MH Model ..... Million Hearts Cardiovascular Risk Reduction Model
MIPS ..... Merit-Based Incentive Payment System
MMA ..... Medicare Prescription Drug, Improvement, and Modernization Act or Medicare Modernization Act
MOOP ..... maximum out-of-pocket
MPFS ..... Medicare Physician Fee Schedule
MS ..... multiple sclerosis
MSSP ..... Medicare Shared Savings Program
MU ..... meaningful use
NCCN ..... National Comprehensive Cancer Network
NDC ..... National Drug Code
NHB ..... Net Health Benefit
NHL ..... non-Hodgkin lymphoma
NK ..... natural killer
NSCLC ..... non-small cell lung cancer
OA ..... osteoarthritis
OCM ..... Oncology Care Model
OPPS ..... outpatient prospective payment system
PA ..... prior authorization
PCMH ..... patient-centered medical home
PD1 ..... programmed cell death 1
PD-L1 ..... programmed death-ligand 1
PFPM ..... Physician-Focused Payment Model
PhRMA ..... Pharmaceutical Research and Manufacturers of America®
PLK1 ..... polo-like kinase-1
PMPM ..... per member per month
PM&R ..... physical medicine and rehabilitation
PPO ..... preferred provider organization
PPPY ..... per patient per year
PQRS ..... Physician Quality Reporting System
PS ..... phosphatidylserine
QOPI ..... Quality Oncology Practice Initiative
RA ..... rheumatoid arthritis
RBRVS ..... Resource-Based Relative Value Scale
RCC ..... renal cell carcinoma
RSV ..... respiratory syncytial virus
SCT ..... stem cell transplantation
SGR ..... sustainable growth rate
SLAMF7 ..... signaling lymphocytic activation molecule family member 7
SQ ..... subcutaneous
VBM ..... value-based payment modifier
VEGF ..... vascular endothelial growth factor
WAC ..... wholesale acquisition cost

Notes

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