MAGELLAN RX MANAGEMENT

MEDICAL PHARMACY TREND REPORT™

2016 SEVENTH EDITION

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Introduction

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

Approximately 50 percent of the annual specialty drug spend was billed under the medical benefit in 2015.[1] The FDA approved a record-setting 45 novel medications, including 6 biologics, besting its ten year average approval rate of 28 novel drugs per year.[2] In 2016, the FDA approved 13 new drugs that fell under the medical benefit. Approvals included four drugs for oncology or oncology support, three drugs for bleeding disorders, and two for rare pediatric neuromuscular disorders, the first in class to treat these conditions.

With the flood of specialty biologics to the market, drugs billed to the medical benefit (provider-administered infused or injected drugs paid under the medical benefit, also referred to as medical pharmacy), continue to be cost drivers for the overall drug trend. Over the last seven years, Magellan Rx Management's Medical Pharmacy Trend Reports have filled the gap for payers in staying informed on medical pharmacy current and evolving management strategies, market place conditions, and the medical benefit drug trend.

Aligned with previous editions, Magellan Rx Management's 2016 Medical Pharmacy Trend Report™ was derived from two complementary sources. First, we surveyed medical, pharmacy and network directors from 49 commercial and Medicare Advantage payers representing more than 109 million covered lives. Second, we completed an in-depth analysis of commercial and Medicare Advantage 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. Health plan claims data is reported from 2015 due to lag in medical claims data and to allow for adequate claims run out to more accurately reflect health plan spend.

We are excited to present a redesigned and more comprehensive report that we expect will provide a robust picture of medical pharmacy trend and management. Changes to the report include:

- Enhanced methodology for our medical pharmacy analytics. Based on our experience and knowledge of the data, calculations for our queries were updated to more accurately reflect expanded data run out time periods, data adjustments, and removal of the 'other' site of service classification.
- New, comprehensive survey responses specifically about the Medicare Advantage medical pharmacy benefit.
- Current payer implementations and successes of alternative payment models and future strategies of such models.
- Initial payer biosimilar strategies and what affect biosimilars had on their overall medical pharmacy management strategies.
- A more granular view of utilization management tools to understand payer strategies, and the most common processes and criteria payers used to approve and manage medical benefit drugs.
- A deeper dive into data reporting currently in use, outcomes payers have experienced, and how these systems affected management strategies.

Our most exciting change is the introduction of category specific profiles. We chose seven medical pharmacy categories having the largest impact in 2015-2016 and examined their market share, affect on PMPM spend, top drugs, overall patient costs, and current management strategies.

We know you will find our trend report useful and unique. The topics provide valuable insight on medical pharmacy, as well as key legislative outcomes and management trends affecting the medical pharmacy benefit. This trend report is another way Magellan Rx Management gives you the tools to make smarter decisions every day for managing medical pharmacy agents.

You can download the full report at www.MagellanRx.com

1. https://www.imshealth.com/en/about-us/news/ims-health-study-us-drug-spending-growth-reaches-8.5-percent-in-2015. Accessed March 2017.
2. https://www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugInnovation/default.htm. Accessed March 2017.

MagellanRx MANAGEMENT

MAGELLAN RX MANAGEMENT: MEDICAL PHARMACY TREND REPORT™
2016 Seventh Edition

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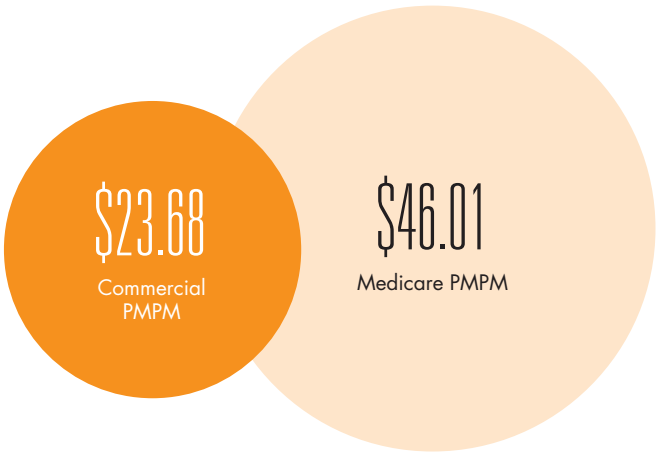
Executive

KEY FINDINGS ON THE CURRENT STATE OF MEDICAL BENEFIT DRUGS INCLUDED:

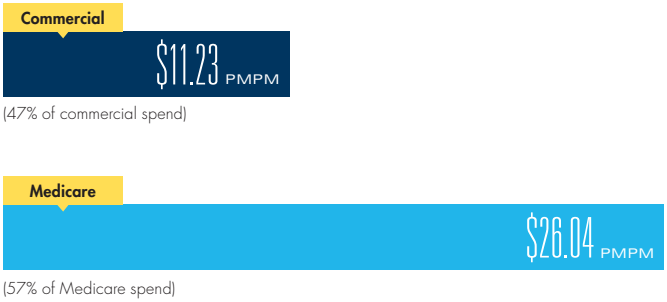
FIVE-YEAR TREND IN SPEND 2011-2015

Since 2011, spend for the commercial medical benefit increased **55 percent**. The Medicare medical benefit increased **5 percent**.

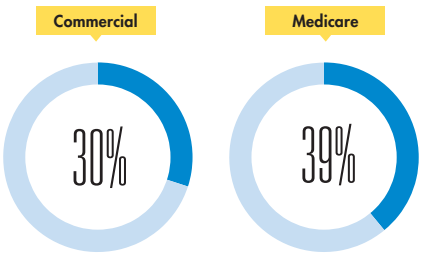
Commercial per-member-per-month (PMPM) year-over-year allowed amounts increased 13 percent to $23.68, while Medicare saw a 2 percent increase to $46.01.



ONCOLOGY AND ONCOLOGY SUPPORT ACCOUNT FOR

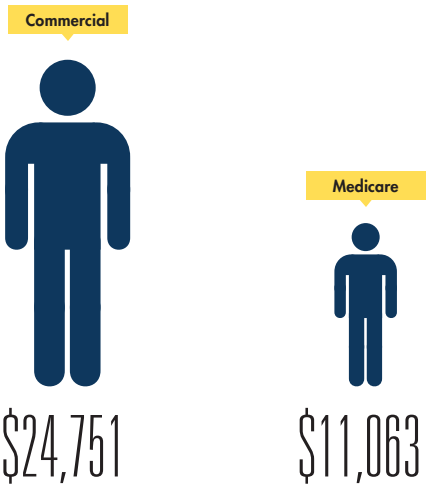


OF THE TOP 10 CATEGORIES, OPHTHALMIC INJECTIONS HAD THE HIGHEST YEAR-OVER-YEAR TREND



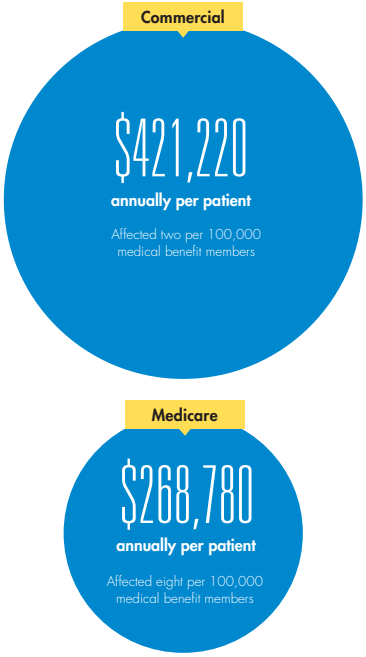
Summary

FOR THE TOP 25 DRUGS, THE AVERAGE ANNUAL COST PER PATIENT WAS:



The top 25 drugs represented 61 percent of commercial and 71 percent of Medicare medical pharmacy allowed amount PMPM.

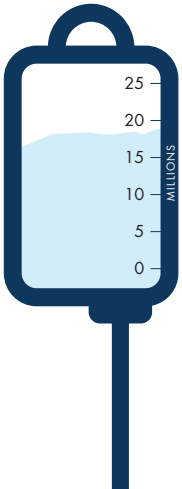
10 MOST EXPENSIVE MEDICAL BENEFIT DRUGS AVERAGED



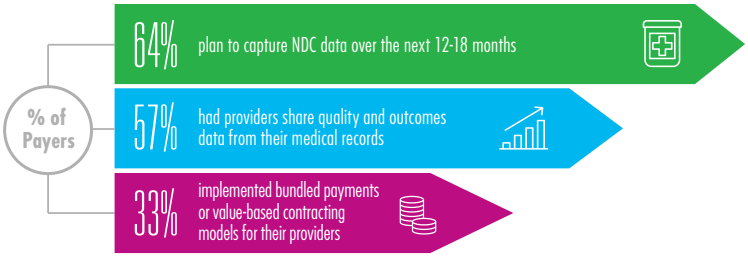
Spend for **unclassified codes** as a combined category accounted for **$0.45 PMPM and $0.70 PMPM** in commercial and Medicare, respectively, ranking among the top 10 categories for commercial and top 20 for Medicare.

For commercial, medical-benefit drug cost is often **more than double in the hospital outpatient setting** versus the physician office for top categories such as autoimmune disorders and oncology support medications.

For a rare disorder drug such as Soliris, over a patient's treatment lifetime (averaged at 40 years), payers may incur more than **$18 million** in costs.



OVERALL PROVIDER LANDSCAPE



Medical Benefit Drug Trend

Medical pharmacy continues to be a costly expenditure in healthcare. In 2015, 4 percent of commercial members (44 per thousand unique members) and 12 percent of Medicare Advantage members (117 per thousand unique members) had a drug claim billed to the medical benefit (**see figure 1**).

Since 2011, medical pharmacy PMPM costs increased 55 percent in commercial and 5 percent in Medicare, with hospital outpatient spend driving the largest increases in trend across both lines of business. Commercial medical pharmacy spend in the hospital outpatient setting has grown by 72 percent and medical pharmacy spend in the home infusion/specialty pharmacy setting has grown by nearly 50 percent (**see figure 2 and appendix A2 for full chart**).

Over the most recent year analyzed, total medical pharmacy PMPM has increased 13 percent to $23.68 for commercial and two percent to $46.01 for Medicare. The majority of commercial spend (52 percent) occurred in the hospital outpatient setting and in the physician office (55 percent) for Medicare (**see figure 3**).

Medical drug spend in Medicare is growing in the physician-office setting and decreasing in other sites of care. In 2015, claims in the physician office setting accounted for 55 percent of the spend, up from 49 percent in 2014. The spend in the hospital outpatient setting trended down 10 percent in that same time period (**see figure 3**). Over the last five years, physician office spend has been variable accounting for a negative trend of 2 percent (**see figure 2**).

Reflective of the trend in spend, 52 percent of commercial members received their provider-administered injectable or infused drug in the hospital outpatient setting in 2015, and 74 percent of Medicare Advantage members most often received medical benefit drugs in the physician office. Commercial utilization of the hospital outpatient setting in 2015 reflects a reversal from 2014 when commercial members most often used the physician office. In spite of a six-point shift to the hospital outpatient setting in Medicare, as described earlier, the 2015 spend in this setting decreased 10 percent, suggesting a change in utilization, drug mix, and unit costs as responsible for the representative decrease in costs (**see figure 4**).

FIGURE 1

Percentage of Members With a Medical Pharmacy Claim 2011-2015

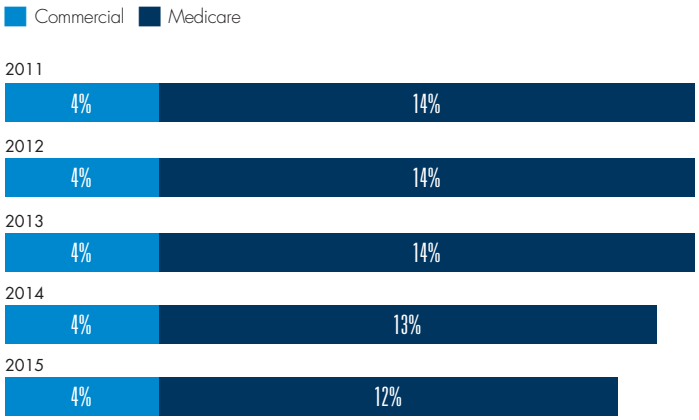


FIGURE 2

Medical Pharmacy PMPM Trend by Site of Service by LOB 2011-2015

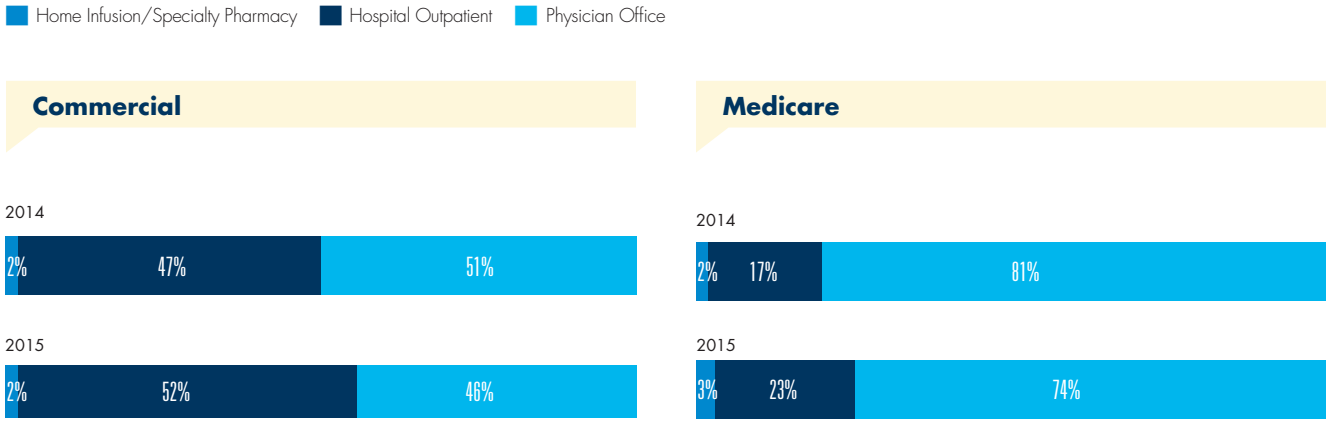
	2011-2015 % PMPM CHANGE
Commercial	
Home Infusion/Specialty Pharmacy	48%
Hospital Outpatient	72%
Physician Office	37%
Total	55%
Medicare	
Home Infusion/Specialty Pharmacy	11%
Hospital Outpatient	18%
Physician Office	-2%
Total	5%

FIGURE 3

Medical Pharmacy Allowed Amount PMPM by LOB by Site of Service 2014-2015

FIGURE 4

Medical Pharmacy Site of Service Mix by Members by LOB 2014-2015



Trend Drivers

Category Landscape

Drug spend on the medical benefit was driven by two high-cost specialty drug categories: oncology and biologic drugs for autoimmune disorders (BDAIDs). Six of the top 10 disease states or drug categories in commercial and five of the top 10 in Medicare came from oncology, oncology support, or BDAIDs. In total, these top 10 disease categories touch 25 per thousand commercial members and 75 per thousand Medicare Advantage members (**see figures 5 and 6**). A full report of all medical benefit drugs is located in the appendix (**A5 and A6**).

In 2015, the top 10 medical benefit categories accounted for 76 percent of commercial spend and 83 percent of Medicare Advantage spend. In 2015, for both commercial and Medicare, oncology injectable and infusible drugs led the pack in the medical benefit trend constituting $8.45 or 36 percent of spend for commercial and $19.07 or 41 percent of spend for Medicare (**see figures 5 and 6**).

For commercial, oncology support, comprised of four categories (antiemetics, colony-stimulating factors (CSFs), erythropoiesis-stimulating agents (ESAs) and gastrointestinal (e.g. Sandostatin LAR)), accounted for a total of $2.78 or 12 percent of PMPM spend, the majority being spent on CSF agents. In total, commercial oncology and oncology support agents accounted for $11.23 PMPM or 47 percent of medical pharmacy spend. BDAIDs, of which there are six categories (Crohn's Disease (CD)/ulcerative colitis (UC), psoriasis/psoriatic arthritis, rheumatoid arthritis (RA), systemic lupus erythematosus, ankylosing spondylitis, and other), accounted for $3.55 or 15 percent of PMPM spend, the majority of which was in CD/UC.

In Medicare, oncology support totaled $8.45, or 36 percent of PMPM spend, again mainly in the CSF category. In total, oncology and oncology support accounted for $26.04 PMPM or 57 percent of medical pharmacy spend in Medicare. In total, BDAIDs accounted for $3.80 or 8 percent of the PMPM spend but only the RA category was represented in the top 10 at $2.49 PMPM (**see figure 6 and appendix A6**). More detailed analysis of the oncology, oncology support, and BDAID categories can be found in the category analysis sections.

FIGURE 5

2015 Commercial PMPM of Top 10 Disease States or Drug Categories by Spend

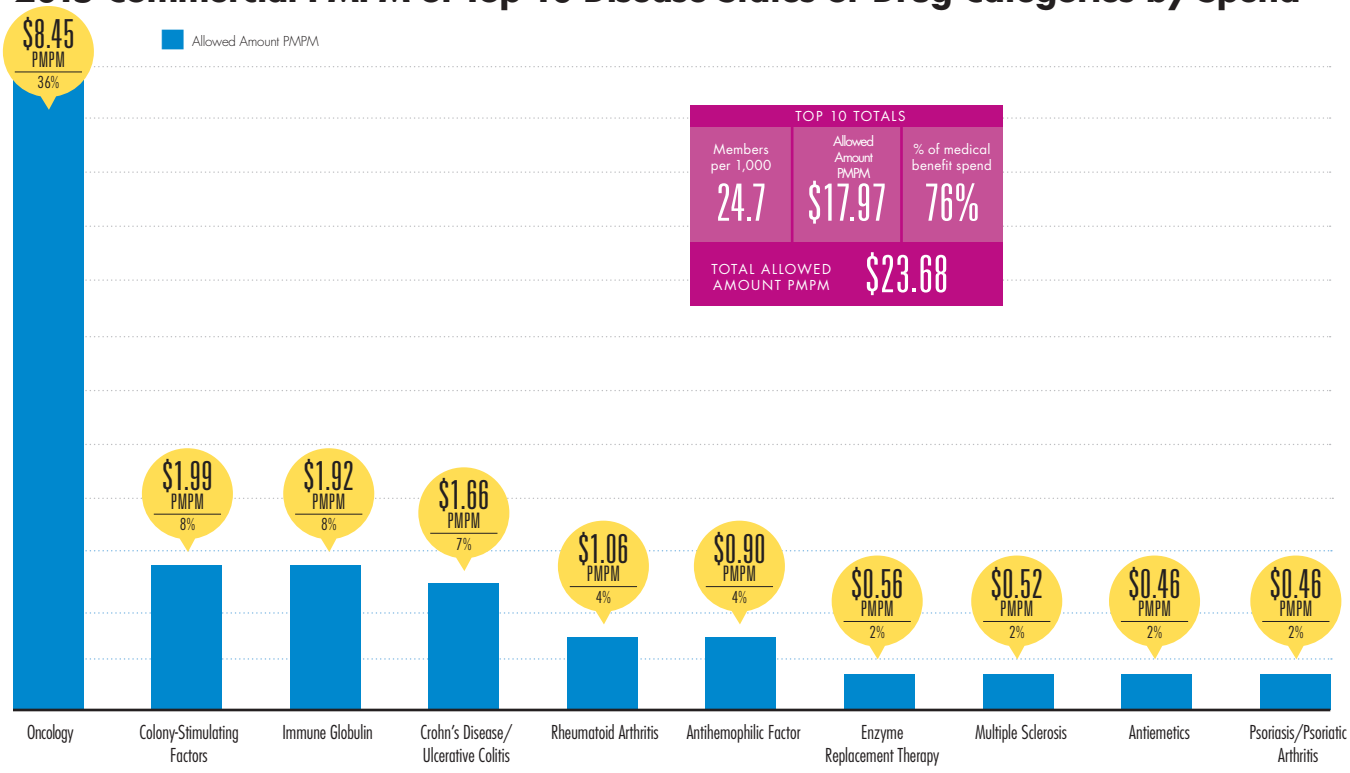
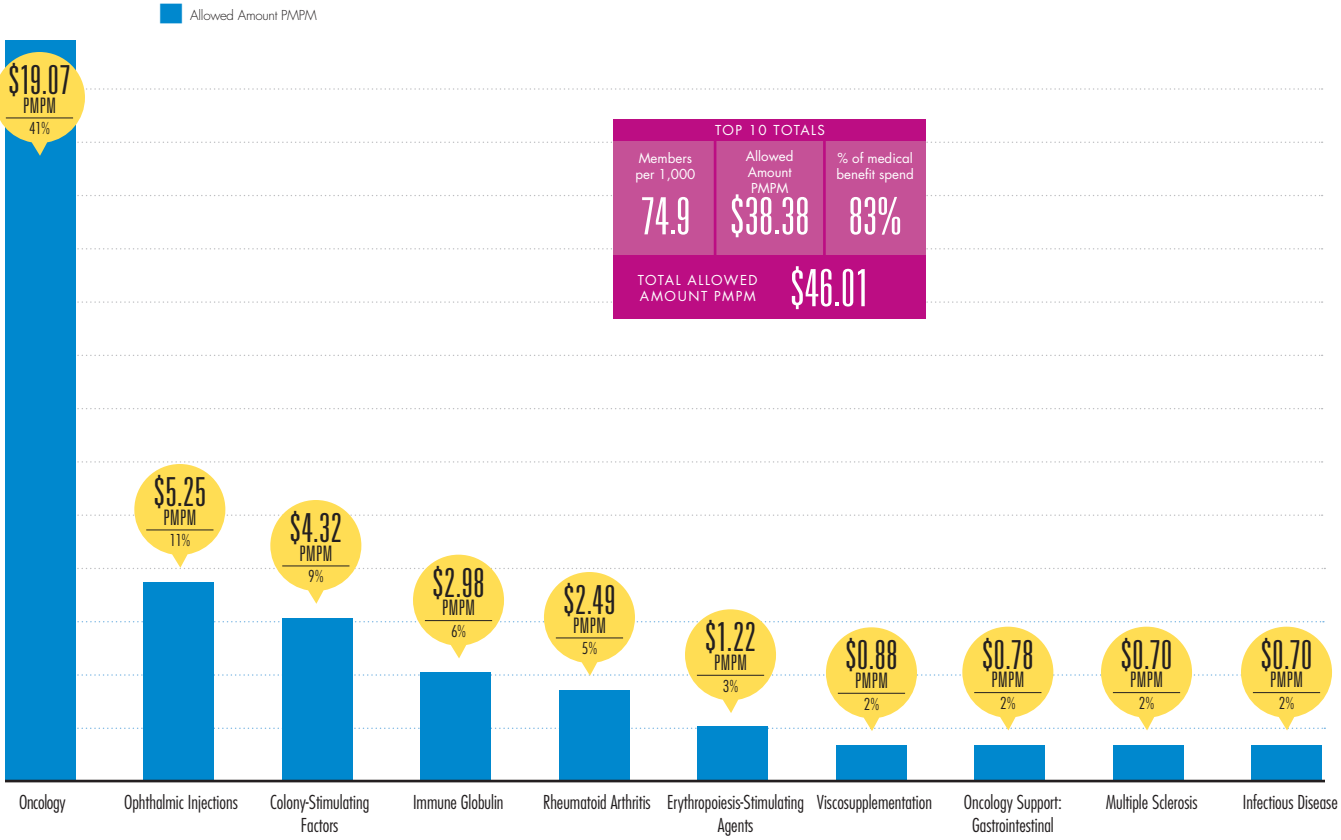


FIGURE 6

2015 Medicare PMPM of Top 10 Disease States or Drug Categories by Spend



In looking at categories most utilized by percentage of members, all of the highest utilized categories for commercial were outside of the top 25 spend categories demonstrating high volume but low cost. Corticosteroids accounted for 29 percent of commercial members utilizing a medical pharmacy agent, yet ranked 31 among medical benefit categories. Pain management composed 12 percent of members who utilized a medical pharmacy agent, but ranked 22 of 49 categories by spend (**see figure 7**).

Similarly, in Medicare, corticosteroids represented 38 percent of members utilizing a medical pharmacy agent but ranks 27 out of 42 categories. Pain management was also a highly utilized category in Medicare representing 6 percent of Medicare members who utilized a medical pharmacy agent, but ranked 29 of 42 categories. Other high-volume categories were on par with their ranking by spend.

FIGURE 7

2015 PMPM of Most Utilized Disease States or Drug Categories by Percentage of Members

	Commercial				
RANK	THERAPY	% OF MEMBERS	MEMBERS PER 1,000*	CATEGORY RANK BY SPEND	PMPM
1	Corticosteroids	29%	58.6	31	$0.11
2	Pain Management	12%	29.5	22	$0.19
3	Infectious Disease	7%	16.3	12	$0.42
4	Sedatives/Anesthesia	7%	18.6	32	$0.10

	Medicare				
RANK	THERAPY	% OF MEMBERS	MEMBERS PER 1,000*	CATEGORY RANK BY SPEND	PMPM
1	Corticosteroids	38%	126.9	27	$0.18
2	Oncology	6%	22.1	1	$19.07
3	Pain Management	6%	20.7	29	$0.09
4	Ophthalmic Injections	4%	14.6	2	$5.25

*Members per thousand includes overlap with other therapies and not unique members.

Drug Landscape

Just as only a few medical benefit therapeutic categories drove spend in 2015, a limited number of medical benefit drugs represented the majority of payer costs. For both the commercial and Medicare medical pharmacy benefits, the top 50 drugs made up close to 80 percent of spend. Of the 925 Healthcare Common Procedure Coding System (HCPCS) codes examined for the medical benefit analyses, the top 100 represent 90 percent of the total PMPM costs for commercial and 96 percent for Medicare (**see figures 8 and 9**).

From 2014 to 2015, in commercial, the impact of the top 100 drugs increased in all segments with the PMPM of the top 10 drugs and the top 100 drugs increasing by 9 percent and 11 percent, respectively. The top 25 drugs in the commercial population make up 61 percent of spend. In Medicare, the trend from 2014 to 2015 increased across all segments, but at a lower rate. The top 10 drugs saw a 7 percent increase in impact and accounted for half (50 percent) of total Medicare spend. The top 25 drugs accounted for almost three-quarters of spend (71 percent).

The top 25 commercial drugs that made up 61 percent of spend were in line with top therapeutic classes. Of the top categories, twelve oncology, two immune globulin, and four autoimmune drugs were included in the top 25. In addition, colony-stimulating factors (CSFs), multiple sclerosis immunomodulating agents, antihemophilic factor agents and antiemetics had drugs in the top 25. Overall, the top 25 drugs were similar year over year. New to the list in 2015 was Cinryze with a 4 percent increase in PMPM, swapping out one of the highest cost medical pharmacy agents, Cerezyme, from the previous year (**see figure 9**).

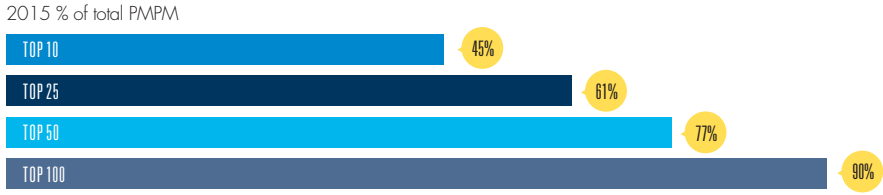
Specifically in commercial, Remicade continued to be the highest spend agent. Remicade saw an 11 percent change in PMPM from $2.31 in 2014 to $2.56 in 2015. Remicade, Neulasta (7 percent increase in PMPM), Avastin (1 percent increase in PMPM), Herceptin (15 percent increase in PMPM), and Rituxan (7 percent increase in PMPM), remained the top five drugs by spend and have

FIGURE 8

Medical Pharmacy Percentage Spend by LOB 2014-2015

Commercial

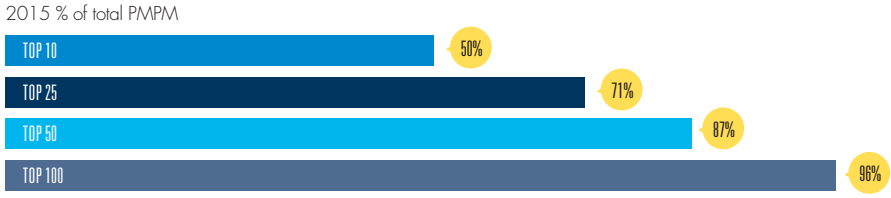
	2014 PMPM	2015 PMPM	2014-2015% PMPM change
Top 10	$9.74	$10.65	9%
Top 25	$13.51	$14.54	8%
Top 50	$16.71	$18.19	9%
Top 100	$19.27	$21.31	11%
All Medical Benefit Drugs	$20.95	$23.68	13%



Commercial top 25 medical benefit drugs equaled 61 percent of total PMPM

Medicare

	2014 PMPM	2015 PMPM	2014-2015% PMPM change
Top 10	$21.68	$23.11	7%
Top 25	$31.53	$32.79	4%
Top 50	$39.19	$39.83	2%
Top 100	$43.40	$44.21	2%
All Medical Benefit Drugs	$45.23	$46.01	2%



Medicare top 25 medical benefit drugs equaled 71 percent of total PMPM

been since the first edition of this report.

Also in commercial, oncology drug Perjeta saw the largest increase in PMPM with a 47 percent jump from $0.28 in 2014 to $0.42 in 2015. Another oncology agent, Eloxatin, saw the largest decrease in PMPM of 18 percent, primarily due to generic availability of oxaliplatin, decreasing from $0.29 to $0.24. Soliris, used in the treatment of paroxysmal nocturnal hemoglobinuria and atypical hemolytic uremic syndrome, saw the largest increase in annual cost per patient of 38 percent, up to $449,911. Orencia and Sandostatin LAR saw the largest increases in ASP of 19 percent and 11 percent respectively. Orencia also saw the largest increase in AWP of 17 percent.

FIGURE 9

Commercial Top 25 Drugs by Spend 2014-2015

				Allowed Amount PMPM			Annual Cost per Patient			Reimbursement Trend	
RANK	HCPCS	BRAND	CATEGORY	2014	2015	% CHANGE	2014	2015	% CHANGE	ASP	AWP
1	J1745	Remicade	BDAID	$2.31	$2.56	11%	$27,529	$32,335	17%	8%	10%
2	J2505	Neulasta	Oncology Support: Colony-Stimulating Factors	$1.73	$1.84	7%	$19,231	$22,184	15%	10%	10%
3	J9035	Avastin	Oncology, Ophthalmic Injections	$1.27	$1.28	1%	$19,014	$21,121	11%	4%	5%
4	J9355	Herceptin	Oncology	$1.04	$1.20	15%	$41,771	$48,085	15%	6%	6%
5	J9310	Rituxan	Oncology, BDAID: Rheumatoid Arthritis	$1.09	$1.17	7%	$29,641	$33,186	12%	6%	6%
6	J1561	Gamunex-C/Gammaked	Immune Globulin	$0.47	$0.66	40%	$54,734	$58,493	7%	4%	1%
7	J1569	Gammagard Liquid	Immune Globulin	$0.50	$0.58	15%	$44,746	$49,936	12%	-3%	5%
8	J2323	Tysabri	Multiple Sclerosis, BDAID: Crohn's Disease/Ulcerative Colitis	$0.45	$0.51	15%	$41,714	$51,817	24%	10%	12%
9	J7192	Advate/Helixate FS/ Kogenate FS/Kovaltry/ Recombinate	Antihemophilic Factor	$0.51	$0.42	-17%	$167,206	$161,923	-3%	3%	12%
10	J9306	Perjeta	Oncology	$0.28	$0.42	47%	$37,291	$42,349	14%	2%	3%
11	J0897	Xgeva/Prolia	Oncology, Bone Resorption Inhibitors (Osteoporosis)	$0.34	$0.39	15%	$4,682	$4,861	4%	6%	8%
12	J9305	Alimta	Oncology	$0.37	$0.35	-5%	$32,922	$37,756	15%	2%	1%
13	J1300	Soliris	Rare Diseases	$0.25	$0.32	25%	$326,165	$449,911	38%	3%	2%
14	J0585	Botox	Botulinum Toxins	$0.23	$0.29	26%	$2,124	$2,580	21%	3%	3%
15	J2357	Xolair	Asthma/COPD	$0.21	$0.26	25%	$15,546	$15,931	2%	8%	8%
16	J9264	Abraxane	Oncology	$0.25	$0.24	-3%	$24,921	$26,738	7%	4%	8%
17	J9228	Yervoy	Oncology	$0.26	$0.25	-7%	$143,088	$157,531	10%	4%	3%
18	J9263	Eloxatin	Oncology	$0.29	$0.24	-18%	$9,352	$8,646	-8%	-35%	-5%
19	J2469	Aloxi	Oncology Support: Antiemetics	$0.24	$0.23	-2%	$2,173	$2,344	8%	7%	8%
20	J2353	Sandostatin LAR	Oncology Support: Gastrointestinal	$0.22	$0.23	7%	$41,848	$46,094	10%	11%	13%
21	J9041	Velcade	Oncology	$0.24	$0.23	-3%	$30,032	$30,993	3%	0%	2%
22	J0129	Orencia	BDAID	$0.19	$0.23	19%	$18,957	$25,413	34%	19%	17%
23	J9171	Taxotere	Oncology	$0.26	$0.22	-13%	$7,616	$7,669	1%	-35%	-15%
24	J9055	Erbitux	Oncology	$0.25	$0.21	-17%	$43,440	$44,844	3%	0%	2%
25	J0598	Cinryze	Hereditary Angioedema	$0.18	$0.19	4%	$391,907	$342,332	-13%	5%	5%
Top 25 Totals				$13.45	$14.54	8%	$22,529	$24,751	10%		
Total Medical Pharmacy				$20.95	$23.68	13%	$1,766	$1,988	13%	10%	14%

Please note that due to rounding, some column totals do not add up accurately.

In Medicare, 71 percent of medical benefit spend was spread across the top 25 drugs and among the top 10 categories. Of the top categories, 11 oncology drugs, three autoimmune agents, two ophthalmic injections, and two ESAs were included in the top 25. In addition, intravenous immune globulin, CSFs, rare diseases and multiple sclerosis had drugs in the top 25. One immune globulin agent, Gamunex-C/Gammaked, fell from the top 25 in 2015, replaced by unclassified spend for J9999 (**see figure 10**).

In 2015, Neulasta, at $4.02 PMPM, was the top spend drug for Medicare and Rituxan, at $3.69, was the second highest spend. Eylea quadrupled its PMPM and leaped from ranking 23rd in 2014, to fifth in 2015, with a 331 percent increase in PMPM from $0.52 in 2014 to $2.25 in 2015. This increase was primarily due to the first-year results of the Protocol T study in diabetic macular edema. Unclassified agents will be discussed in the next section, but the introduction of PD1 inhibitors Opdivo and Keytruda largely contributed to a more than 500 percent increase in the category. Erbitux saw a 40 percent decrease in PMPM from $0.78 in 2014 to $0.47 in 2015. Again, Soliris saw the largest change in annual cost per patient with a 77 percent increase to over $490,000.

FIGURE 10

Medicare Top 25 Drugs by Spend 2014-2015

				Allowed Amount PMPM			Annual Cost per Patient			Reimbursement Trend	
RANK	HCPCS	BRAND	CATEGORY	2014	2015	% Change	2014	2015	% Change	ASP	AWP
1	J2505	Neulasta	Oncology Support: Colony-Stimulating Factors	$3.70	$4.02	9%	$12,989	$13,408	3%	10%	10%
2	J9310	Rituxan	Oncology, BDAID: Rheumatoid Arthritis	$3.65	$3.69	1%	$23,448	$23,096	-2%	6%	6%
3	J2778	Lucentis	Ophthalmic Injections	$2.99	$2.71	-9%	$9,374	$9,938	6%	-2%	0%
4	J9035	Avastin	Oncology, Ophthalmic Injections	$2.41	$2.67	10%	$3,252	$3,942	21%	4%	5%
5	J0178	Eylea	Ophthalmic Injections	$0.52	$2.25	331%	$8,659	$8,690	0%	0%	0%
6	J1745	Remicade	BDAID	$2.03	$2.22	9%	$18,443	$22,218	20%	8%	10%
7	J0897	Xgeva/Prolia	Oncology, Bone Resorption Inhibitors (Osteoporosis)	$1.38	$1.46	6%	$2,811	$2,940	5%	6%	8%
8	J1569	Gammagard Liquid	Immune Globulin	$1.27	$1.42	11%	$39,406	$35,719	-9%	-3%	5%
9	J9305	Alimta	Oncology	$1.48	$1.37	-7%	$25,333	$26,437	4%	2%	1%
10	J9355	Herceptin	Oncology	$1.57	$1.29	-18%	$30,668	$31,666	3%	6%	6%
11	J9041	Velcade	Oncology	$1.18	$1.05	-11%	$23,979	$23,180	-3%	0%	2%
12	J9033	Treanda	Oncology	$1.03	$0.97	-6%	$24,921	$27,305	10%	8%	14%
13	J0881	Aranesp	Oncology Support: Erythropoiesis-Stimulating Agents	$0.67	$0.79	18%	$5,145	$5,665	10%	6%	5%
14	J2353	Sandostatin LAR	Oncology Support: Gastrointestinal	$0.63	$0.78	24%	$31,300	$33,613	7%	11%	13%
15	J9264	Abraxane	Oncology	$0.89	$0.71	-20%	$17,966	$15,655	-13%	4%	8%
16	J2323	Tysabri	Multiple Sclerosis, BDAID: Crohn's Disease/Ulcerative Colitis	$0.61	$0.69	15%	$36,555	$43,901	20%	10%	12%
17	J0129	Orencia	BDAID	$0.55	$0.67	22%	$16,170	$22,601	40%	19%	17%
18	J9217	Eligard/Lupron Depot	Oncology	$0.68	$0.67	-1%	$1,958	$1,974	1%	7%	10%
19	J1300	Soliris	Rare Diseases	$0.71	$0.62	-14%	$280,069	$494,873	77%	3%	2%
20	J9228	Yervoy	Oncology	$0.60	$0.52	-13%	$108,391	$101,694	-6%	4%	3%
21	J9025	Vidaza	Oncology	$0.57	$0.49	-14%	$25,802	$19,015	-26%	-18%	-2%
22	J9055	Erbitux	Oncology	$0.78	$0.47	-40%	$28,708	$28,016	-2%	0%	2%
23	J0885	Procrit	Oncology Support: Erythropoiesis-Stimulating Agents	$0.60	$0.43	-29%	$3,513	$3,781	8%	4%	5%
24	J9999	Unclassified	Unclassified	$0.07	$0.42	542%	$21,781	$28,801	32%	-	-
25	J2469	Aloxi	Oncology Support: Antiemetics	$0.47	$0.40	-15%	$1,186	$1,089	-8%	7%	8%
Top 25 Totals				$31.04	$32.79	6%	$10,411	$11,063	6%		
Total Medical Pharmacy				$45.23	$46.01	2%	$2,041	$2,285	12%	10%	14%

Please note that due to rounding, some column totals do not add up accurately.

Other Cost Drivers

As evidenced in the Medicare top 25 agents by spend, another segment that contributed to the overall medical pharmacy spend was the unclassified HCPCS codes. For commercial, individual unclassified codes did not have an impact on the top 25 drugs, but in total, as its own disease state or drug category, unclassified drugs accounted for $0.45 of total PMPM and would rank 11th as its own drug class. Unclassified code J3490 had the largest impact of $0.16 PMPM, and typically includes traditional injectable drugs, such as powders, solutions, anesthesia, antihistamines, cardiovascular agents, and antibiotics (**see figure 11**).

For Medicare, unclassified code J9999 contributed to the top 25 drugs, due to the introduction of PD1 inhibitors Opdivo and Keytruda, ranked 24th, and contributed $0.43 of PMPM spend. In total, 2015 unclassified Medicare codes accounted for $0.70 of spend.

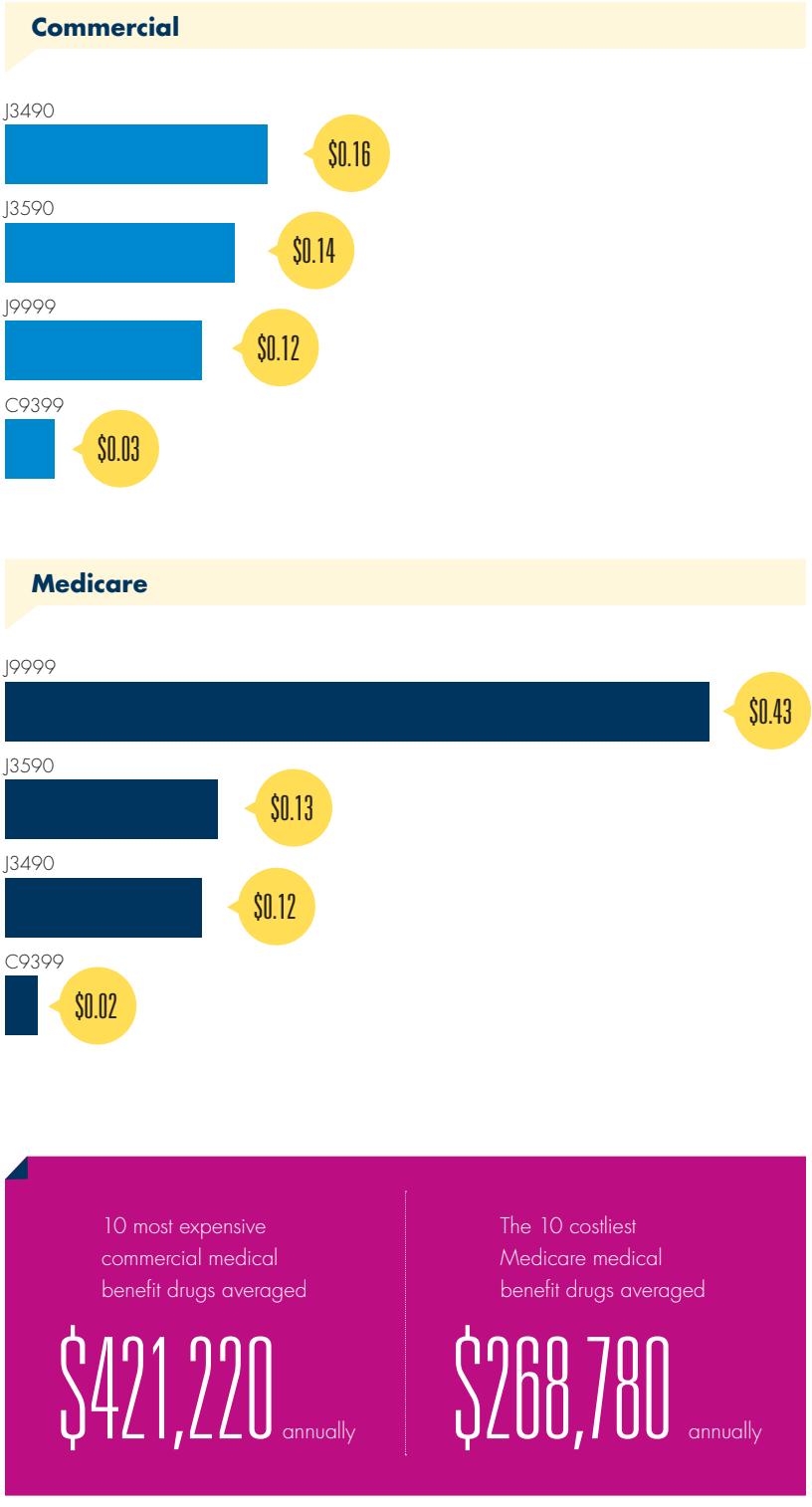
Cinryze, found in the top 25 commercial drugs, and Soliris, found in the top 25 commercial and Medicare drug listings, represented another expensive drug segment: highest cost medical benefit drugs by annual cost per patient. There are numerous other drugs that represent the highest annual cost per patient on the medical benefit; however, due to the limited population they impacted, many fell outside of the top 25 drugs by payer PMPM spend. The most expensive drug, Lumizyme, cost more than $600,000 per patient annually among commercial members and $896,000 per patient annually in Medicare members but only affected one in every 100,000 members (**see figures 12 and 13**).

Many of these disease states are genetic disorders and last over a patient's lifetime. With that in mind and not controlling for increases in cost of living, over a 10-year period, some of these medications may cost between $2.5 million and $6 million. For a drug such as Soliris, with disease onset at the age of 35 and overall survival the same as the normal population, payers can expect to incur more than $18 million in costs.[3]

On average, the 10 most expensive commercial medical benefit drugs averaged $421,220 annually per patient and affected 2 per 100,000 members. The 10 costliest Medicare medical benefit drugs averaged $268,780 and affected 8 per 100,000 members.

FIGURE 11

Unclassified Code by Allowed Amount PMPM



10 most expensive commercial medical benefit drugs averaged **$421,220** annually

The 10 costliest Medicare medical benefit drugs averaged **$268,780** annually

3. Johns Hopkins The Sidney Kimmel Comprehensive Cancer Center. Cancer Types: Paroxysmal Nocturnal Hemoglobinuria (PNH). http://www.hopkinsmedicine.org/kimmel_cancer_center/types_cancer/paroxysmal_nocturnal_hemoglobinuria_pnh.html. Accessed March 2017.

FIGURE 12

2015 Top 10 Highest Cost Commercial Medical Benefit Drugs by Cost per Patient and Allowed Amount PMPM

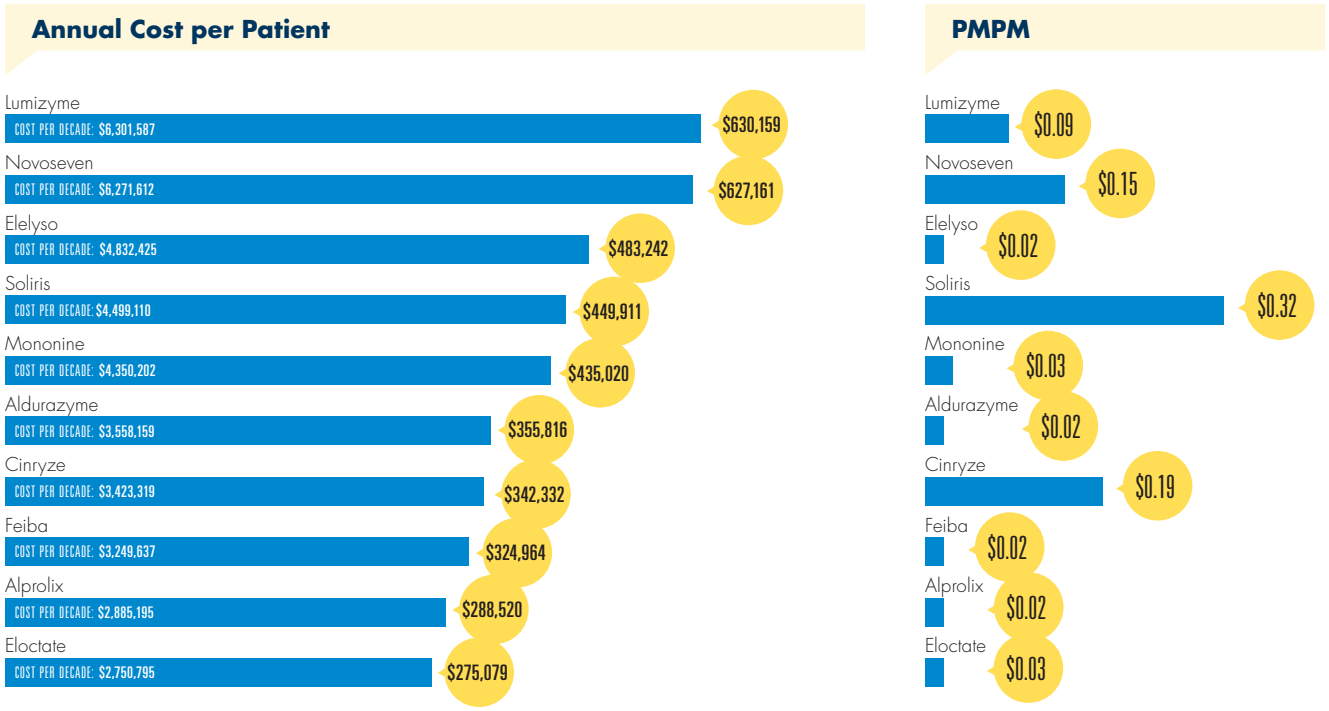
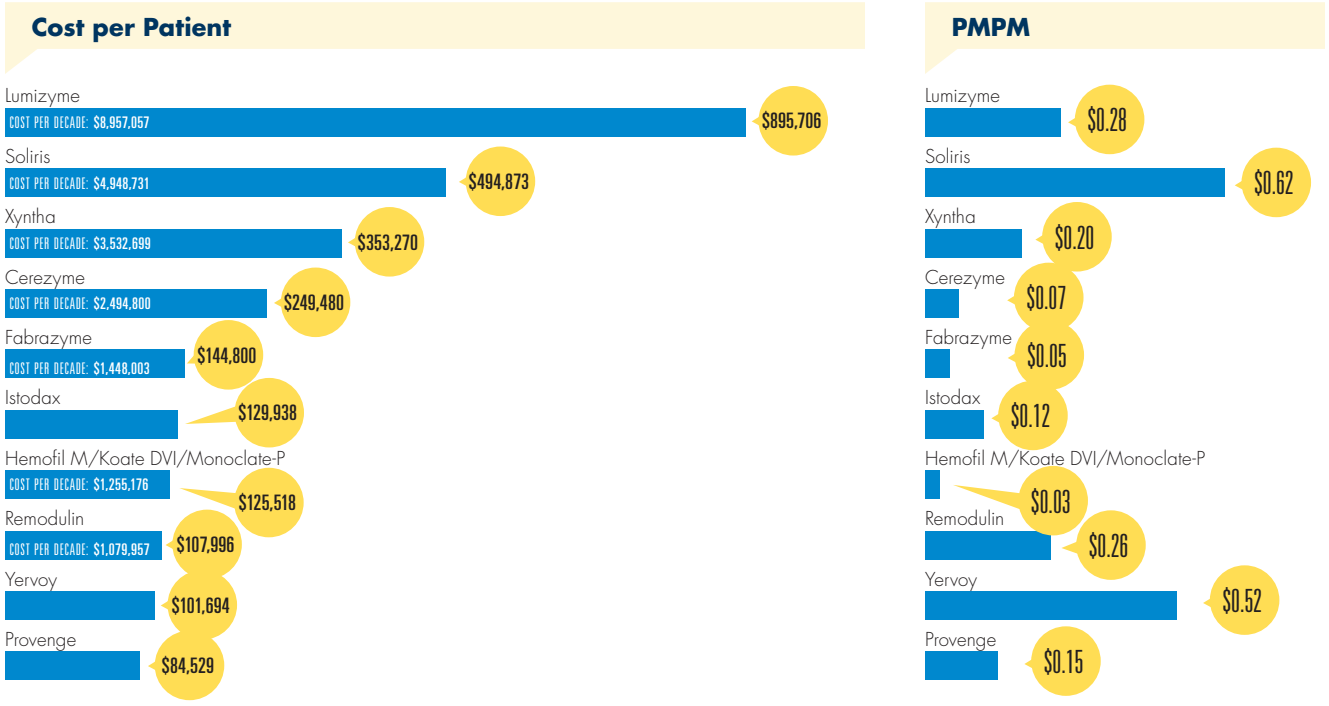


FIGURE 13

2015 Top 10 Highest Cost Medicare Medical Benefit Drugs by Cost per Patient and Allowed Amount PMPM

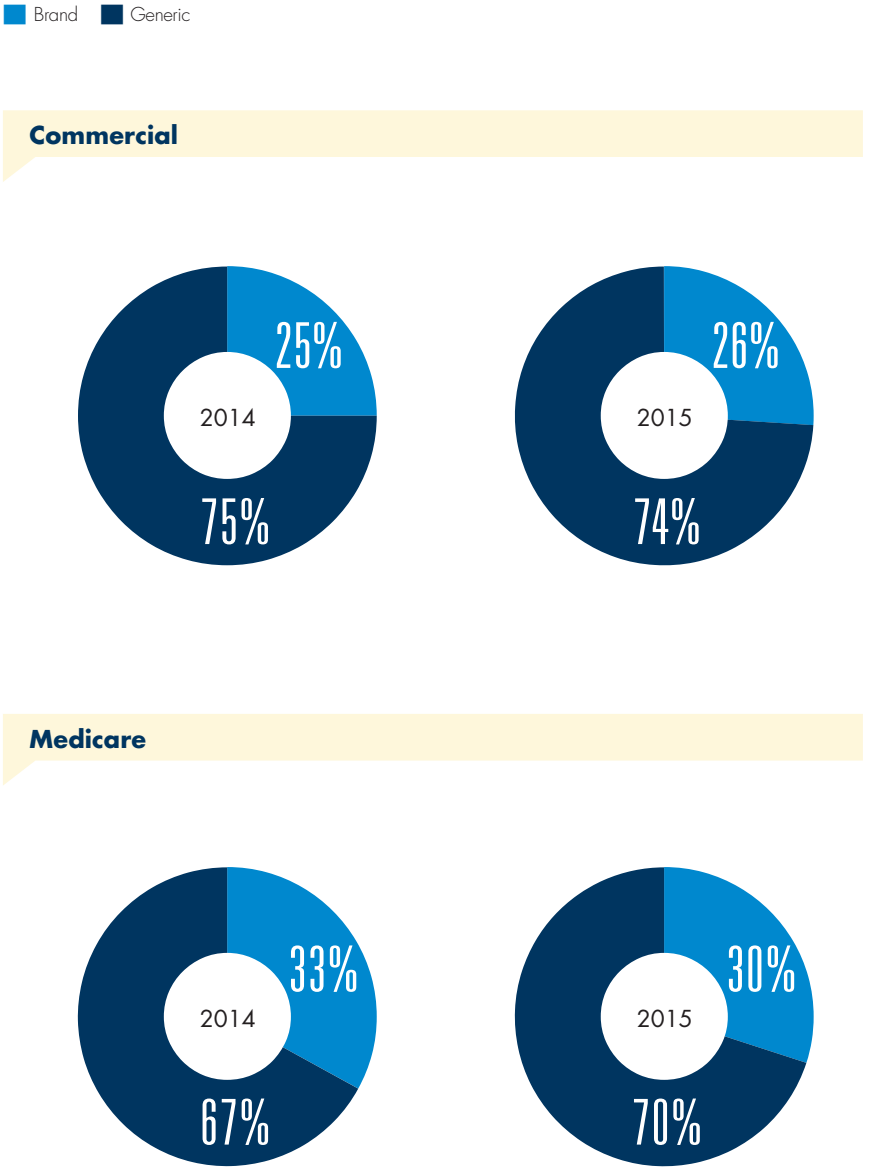


Medical Benefit Utilization

Earlier we noted the most utilized categories on the medical benefit were corticosteroids and pain management. With that in mind, when evaluating all medical benefit utilization in 2015 by HCPCS representing single source/branded drugs versus multiple source/generic agents, 74 percent of commercial and 70 percent of Medicare claims were billed with HCPCS representing generic NDC's (**see figure 14**).

FIGURE 14

Medical Benefit Use of Brand vs. Generic for Commercial and Medicare



Medical Benefit Category Profiles

New this year, we have included profiles of the seven highest spend categories for the medical benefit: oncology, oncology support, biologic drugs for autoimmune disorders, immune globulin, ophthalmic injections, rare diseases, and viscosupplementation.

ONCOLOGY

Oncology continues to be the leading payer expense on the medical benefit, with commercial utilization continuing to shift to hospital outpatient facilities for the costliest agents.

Oncology had a significant year in approvals of new drugs to the category with novel mechanisms of action (MOAs), as well as new indications for existing agents. Oncology immunotherapies saw the approval of atezolizumab (Tecentriq) in 2016 and received six additional FDA-approved indications for existing agents, including a non-small cell lung cancer (NSCLC) indication for PD-1 treatment nivolumab (Opdivo).

Most medical benefit oncology drugs are administered in the physician office with 57 percent of commercial members and 68 percent of Medicare members opting to receive chemotherapy in this setting vs. 39 percent and 28 percent in the hospital outpatient setting, respectively (**see figure 17**). As expected, the oncology category is the top medical benefit category in both commercial and Medicare. The PMPM cost in Medicare is more than double the cost in commercial lines of business at $19.07 and $8.45, respectively. The oncology category accounts for more than one-third of the medical benefit spend for both lines of business. The year-over-year trend for this category is 6 percent and 7 percent, respectively, but this is anticipated to increase in 2016 due to the PD1 inhibitors Keytruda and Opdivo receiving classified codes on 1/1/16 (**see figure 15**).

- Avastin in commercial and Rituxan in Medicare have the top spend in the category of $1.28 and $3.69 PMPM, respectively (**see figure 16**).
- Of the top 25 drugs by commercial and Medicare payer spend, there are 12 oncology agents. Of those, Yervoy has the highest annual cost per patient of nearly $160,000 and more than $100,000 per year, respectively, which is more than triple the next costliest agent (Herceptin) (**see figure 16**).
- Perjeta had the largest increase in commercial PMPM spend from 2014 to 2015, showing its continued impact on the breast cancer community first in the metastatic setting and then the later approved neoadjuvant setting (**see figure 16**).

FIGURE 15

2015 Commercial and Medicare PMPM of Oncology Agents

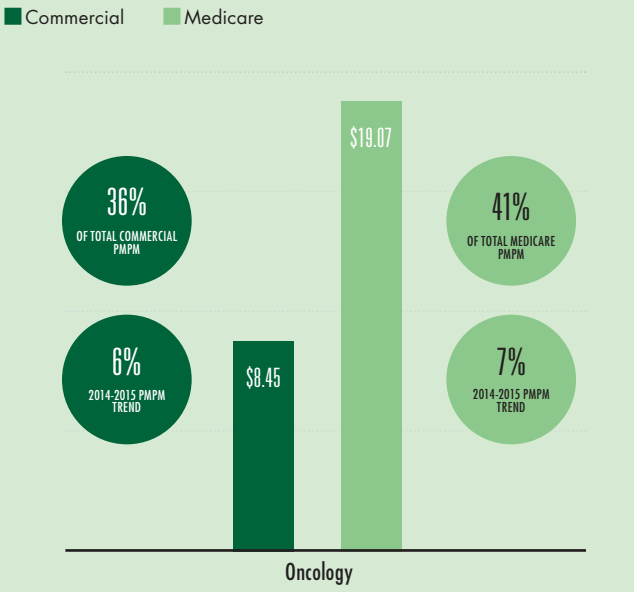


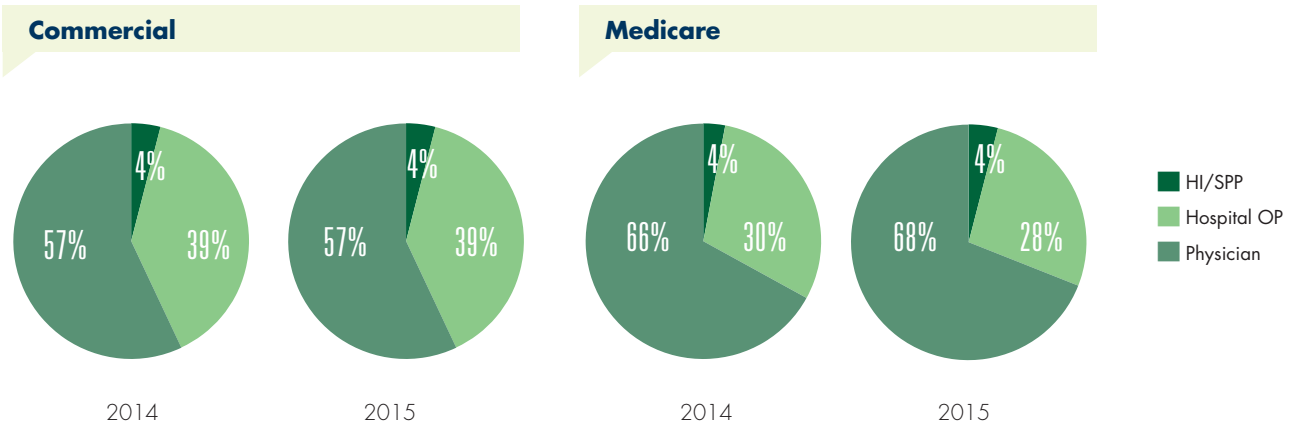
FIGURE 16

2015 Oncology Drugs in Top 25 Medical Pharmacy Agents

			ALLOWED AMOUNT PMPM			ANNUAL COST PER PATIENT		
RANK	HCPCS	BRAND	2014	2015	% CHANGE	2014	2015	% CHANGE
COMMERCIAL								
3	J9035	Avastin	$1.27	$1.28	1%	$19,014	$21,121	11%
4	J9355	Herceptin	$1.04	$1.20	15%	$41,771	$48,085	15%
5	J9310	Rituxan	$1.09	$1.17	7%	$29,641	$33,186	12%
10	J9306	Perjeta	$0.28	$0.42	47%	$37,291	$42,349	14%
11	J0897	Xgeva/Prolia	$0.34	$0.39	15%	$4,682	$4,861	4%
12	J9305	Alimta	$0.37	$0.35	-5%	$32,922	$37,756	15%
16	J9264	Abraxane	$0.25	$0.24	-3%	$24,921	$26,738	7%
17	J9228	Yervoy	$0.26	$0.25	-7%	$143,088	$157,531	10%
18	J9263	Eloxatin	$0.29	$0.24	-18%	$9,352	$8,646	-8%
21	J9041	Velcade	$0.24	$0.23	-3%	$30,032	$30,993	3%
23	J9171	Taxotere	$0.26	$0.22	-13%	$7,616	$7,669	1%
24	J9055	Erbitux	$0.25	$0.21	-17%	$43,440	$44,844	3%
MEDICARE								
2	J9310	Rituxan	$3.65	$3.69	1%	$23,448	$23,096	-2%
4	J9035	Avastin	$2.41	$2.67	10%	$3,252	$3,942	21%
7	J0897	Xgeva/Prolia	$1.38	$1.46	6%	$2,811	$2,940	5%
9	J9305	Alimta	$1.48	$1.37	-7%	$25,333	$26,437	4%
10	J9355	Herceptin	$1.57	$1.29	-18%	$30,668	$31,666	3%
11	J9041	Velcade	$1.18	$1.05	-11%	$23,979	$23,180	-3%
12	J9033	Treanda	$1.03	$0.97	-6%	$24,921	$27,305	10%
15	J9264	Abraxane	$0.89	$0.71	-20%	$17,966	$15,655	-13%
18	J9217	Eligard/Lupron Depot	$0.68	$0.67	-1%	$1,958	$1,974	1%
20	J9228	Yervoy	$0.60	$0.52	-13%	$108,391	$101,694	-6%
21	J9025	Vidaza	$0.57	$0.49	-14%	$25,802	$19,015	-26%
22	J9055	Erbitux	$0.78	$0.47	-40%	$28,708	$28,016	-2%

FIGURE 17

Oncology Member Utilization by Site of Service 2014-2015



Oncology agents Erbitux and Abraxane are close to double the cost in the hospital outpatient setting vs. the physician office. Those same drugs had the highest cost per claim in the home infusion/specialty pharmacy setting (**see figure 18**). Oncology drug categories experienced product preferencing strategies by both commercial and Medicare payers, namely bone resorption inhibitors used for the prevention of skeletal-related events in patients with bone metastases (36 percent commercial payers, 47 percent Medicare) and gonadotropin-releasing hormones agents (24 percent commercial payers, 47 percent Medicare) prescribed for the treatment of breast and prostate cancer (**see figure 19**).

FIGURE 18

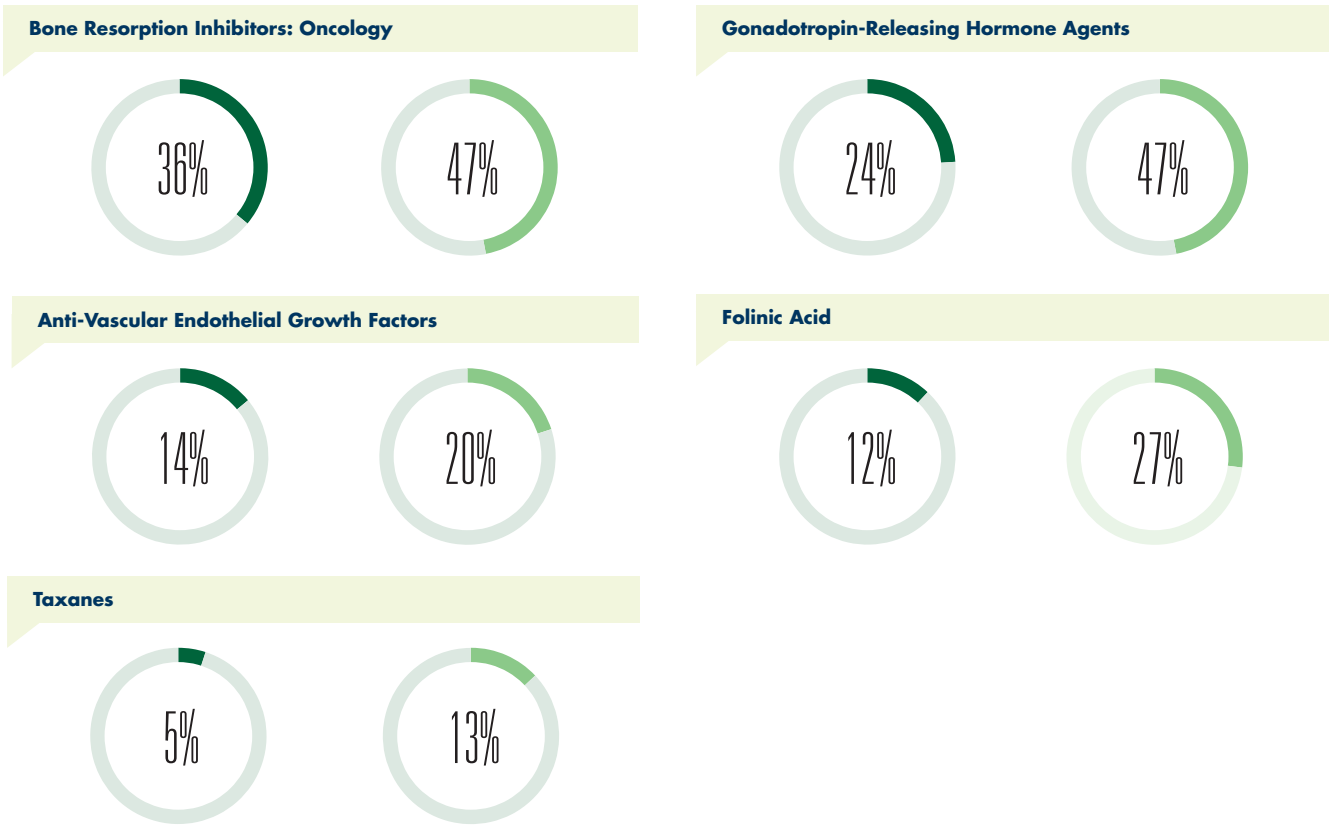
2015 Example Oncology Drugs by Cost per Claim and Unit by Site of Service

	COST PER CLAIM			COST PER UNIT		
	HOSPITAL OP	HI/SPP	PHYSICIAN	HOSPITAL OP	HI/SPP	PHYSICIAN
COMMERCIAL						
Alimta	$9,607	$10,648	$6,375	$119.61	$125.27	$70.64
Perjeta	$9,660	$4,445	$5,630	$21.78	$10.22	$12.10
Erbitux	$6,477	$12,835	$3,381	$116.69	$53.48	$60.06
Abraxane	$4,414	$9,970	$2,368	$25.07	$13.85	$11.27
MEDICARE						
Alimta	$4,626	—	$5,238	$63.64	—	$60.80
Perjeta	$5,019	—	$4,791	$10.42	—	$10.13
Erbitux	$2,657	—	$2,930	$57.03	—	$53.65
Abraxane	$1,928	—	$1,866	$10.44	—	$9.63

FIGURE 19

Oncology Product Preferencing (% of payers)

Commercial (n=42 payers; 101 million lives) Medicare (n=8 payers; 36 million lives)



Although some medical benefit drug utilization began to shift toward more cost-efficient sites of service in 2015, the same did not occur for certain commercial oncology agents. Perjeta, Abraxane, and Erbitux are examples of agents shifting toward hospital outpatient sites of service from the physician office. For these three drugs, the cost per claim and cost per unit in the hospital outpatient setting were higher compared to the corresponding costs in the physician's office, in some cases exceeding two times the cost. For Medicare, with higher cost per unit in the hospital outpatient setting, there was an increase in physician office use for Alimta, Perjeta and Erbitux, but not to the same degree as the commercial benefit. However, for Alimta and Erbitux, the cost per claim is less in the hospital outpatient setting but not for Perjeta, where it is $228 more. (**see figures 18 and 20**).

FIGURE 20

Example Oncology Drug Utilization by Site of Service 2014-2015

ONCOLOGY SUPPORT

Oncology support agents, used in the treatment and prevention of chemotherapy and cancer disease sequelae, represented 12 percent of total medical pharmacy costs for commercial and 15 percent for Medicare.

Oncology support drugs are used to treat disorders typically resulting from chemotherapy regimens including antiemetics to reduce chemotherapy-induced nausea and vomiting, colony-stimulating factors to prevent febrile neutropenia, erythropoiesis-stimulating agents to prevent anemia, and gastrointestinal agents to treat tumor-driven diarrhea.

The entry of the first biosimilar agent, Zarxio (filgrastim-sndz), in the CSF category represented a landmark event in the space. With additional biosimilars expected to be released for Neulasta, payers are now presented with more flexibility in terms of product preferencing and management opportunities.

Oncology support drugs accounted for 12 percent of commercial and 15 percent of Medicare spend. Overall, the category accounted for $2.78 of total commercial PMPM and $6.97 of Medicare PMPM. The annual trend for the oncology support agents was 1% in commercial and 4% in Medicare (**see figure 21**).

- In commercial and Medicare, CSF agents had the highest spend at $1.99 and $4.32 PMPM, respectively (**see figure 21**).
- Aloxi, Neulasta, and Sandostatin LAR ranked in the top 25 drugs for both commercial and Medicare. Additionally, Aranesp and Procrit made the top 25 drugs in Medicare (**see figure 22**).

FIGURE 21

2015 Commercial and Medicare PMPM of Oncology Support Agents

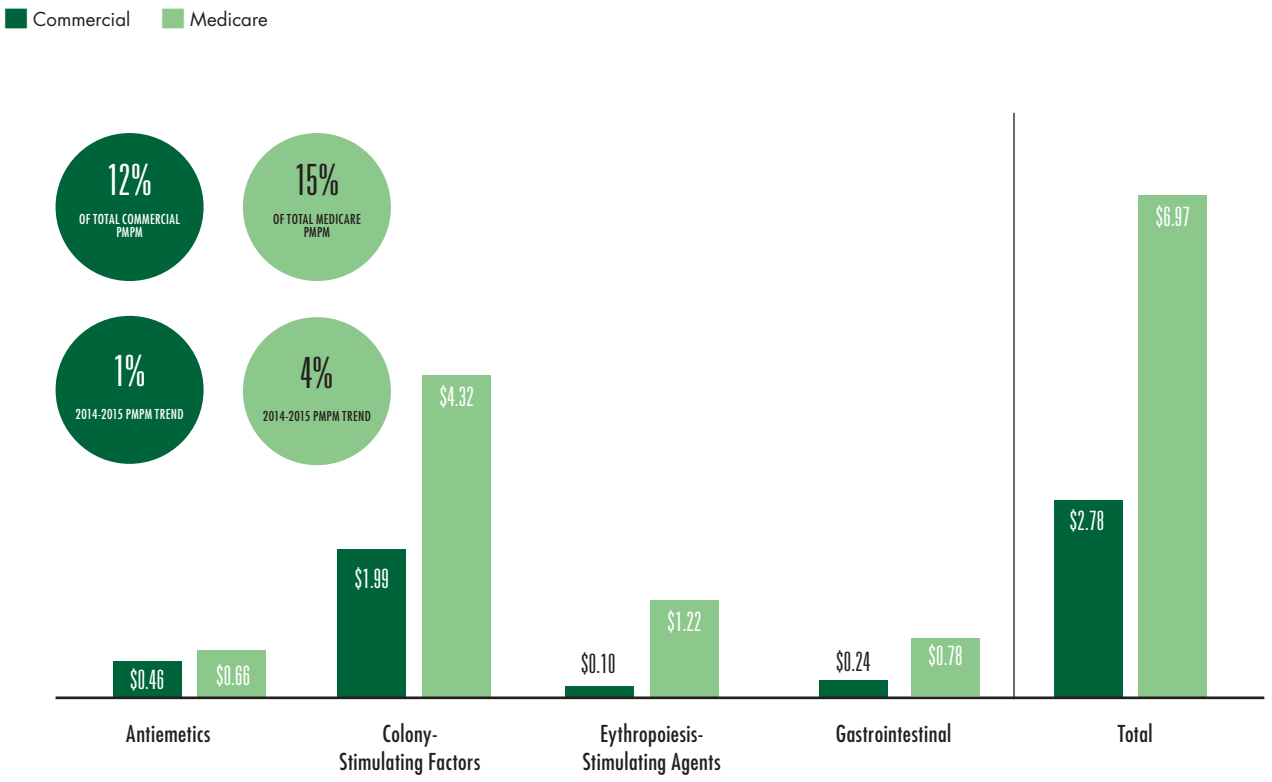


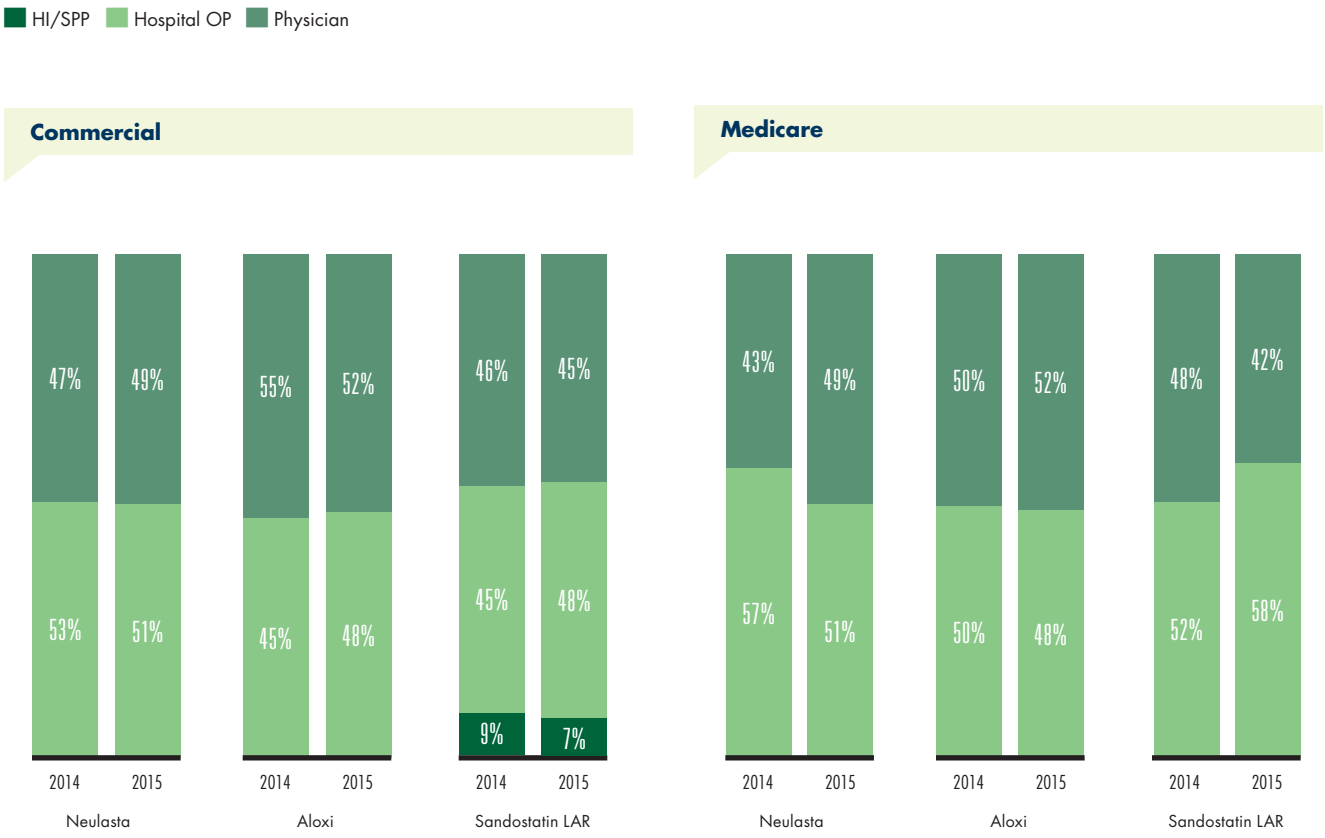
FIGURE 22

2015 Oncology Support Drugs in Top 25 Medical Pharmacy Agents

			ALLOWED AMOUNT PMPM			ANNUAL COST PER PATIENT		
RANK	HCPCS	BRAND	2014	2015	% CHANGE	2014	2015	% CHANGE
COMMERCIAL								
2	J2505	Neulasta	$1.73	$1.84	7%	$19,231	$22,184	15%
19	J2469	Aloxi	$0.24	$0.23	-2%	$2,173	$2,344	8%
20	J2353	Sandostatin LAR	$0.22	$0.23	7%	$41,848	$46,094	10%
MEDICARE								
1	J2505	Neulasta	$3.70	$4.02	9%	$12,989	$13,408	3%
13	J0881	Aranesp	$0.67	$0.79	18%	$5,145	$5,665	10%
14	J2353	Sandostatin LAR	$0.63	$0.78	24%	$31,300	$33,613	7%
23	J0885	Procrit	$0.60	$0.43	-29%	$3,513	$3,781	8%
25	J2469	Aloxi	$0.47	$0.40	-15%	$1,186	$1,089	-8%

FIGURE 23

Example Oncology Support Drug Utilization by Site of Service 2014-2015



Commercial member utilization of oncology support agents shifted slightly higher in the hospital outpatient setting. Medicare member utilization was more balanced, with 58 percent of members utilizing the hospital outpatient setting, up from 52 percent in 2014 (**see figure 24**).

Less than half of payers had some preferencing for antiemetics, while more than half and almost three-quarters (73 percent) of Medicare payers had preferencing for CSF use (**see figure 25**).

The costs per unit and per claim for Medicare are almost the same for hospital outpatient facilities versus physician office, while for commercial the costs are two to three times more expensive in the hospital outpatient setting (**see figure 26**).

FIGURE 24

Oncology Support Member Utilization by Site of Service 2014-2015

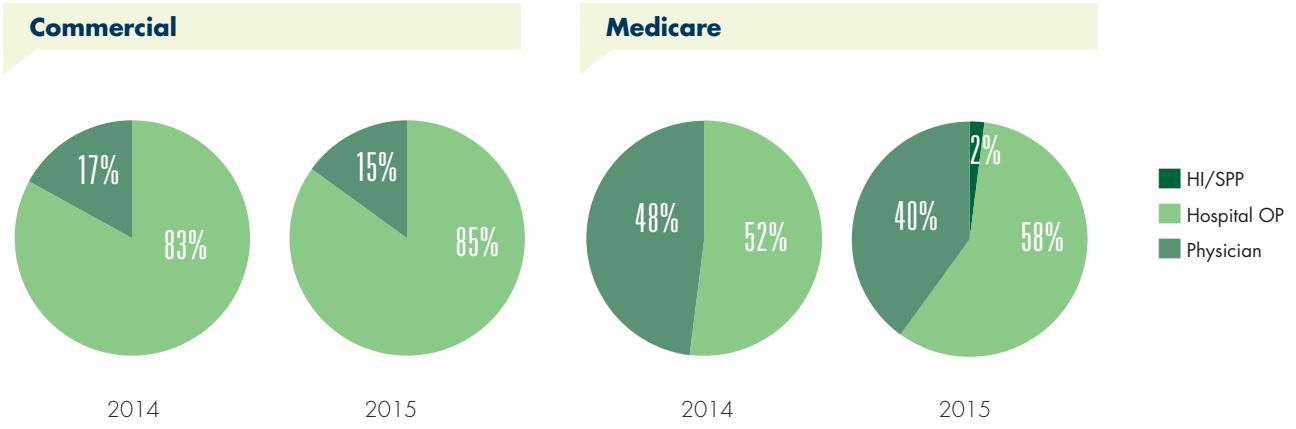
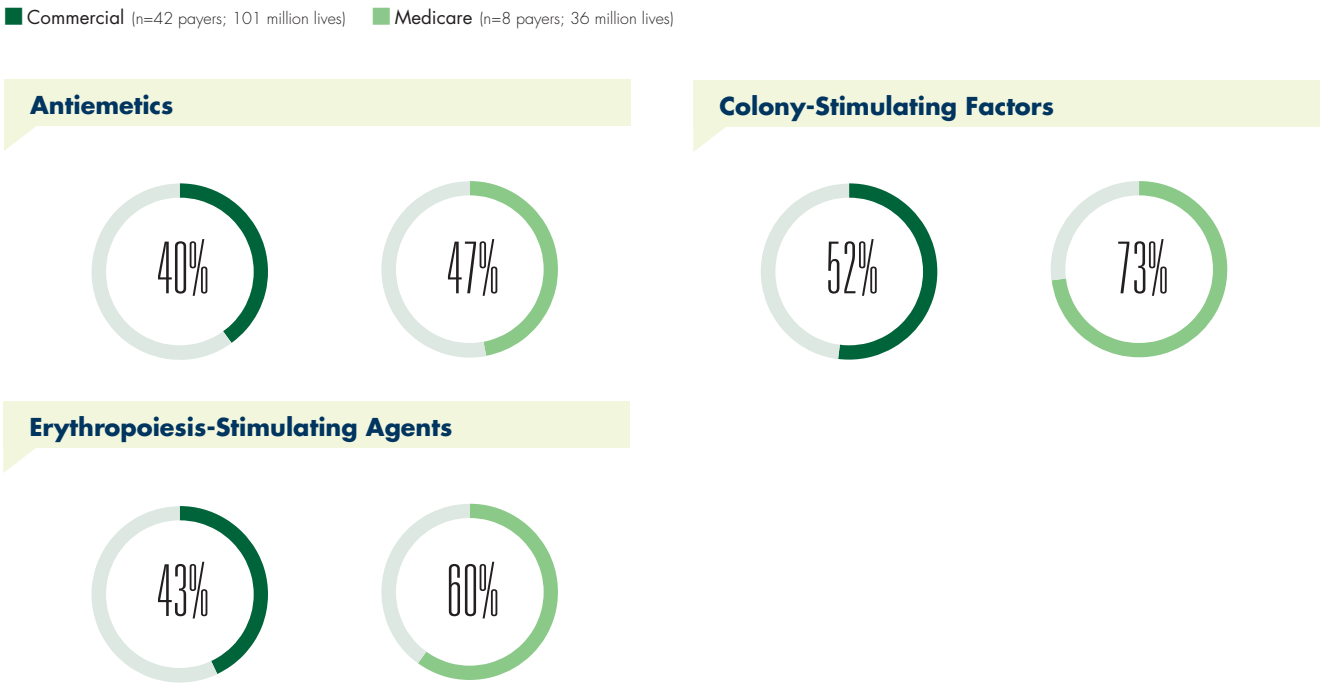


FIGURE 25

Oncology Support Product Preferencing (% of payers)



Aloxi is indicated for the prevention of acute nausea and vomiting associated with initial or repeat courses of highly emetogenic chemotherapy (HEC) and prevention of acute and delayed nausea and vomiting with initial and repeat courses of moderately emetogenic chemotherapy (MEC). Interestingly, 25 and 30 percent of Aloxi's spend was billed with low emetogenic chemotherapy (LEC) and minimally emetogenic chemotherapy (MinEC) regimens under the commercial and Medicare medical benefits, respectively. Zofran saw 29 percent of its spend billed with MinEC regimens in commercial and 19 percent in Medicare, although no routine prophylaxis is recommended for patients receiving regimens associated with less than 10 percent frequency of emesis (**see figure 27**).

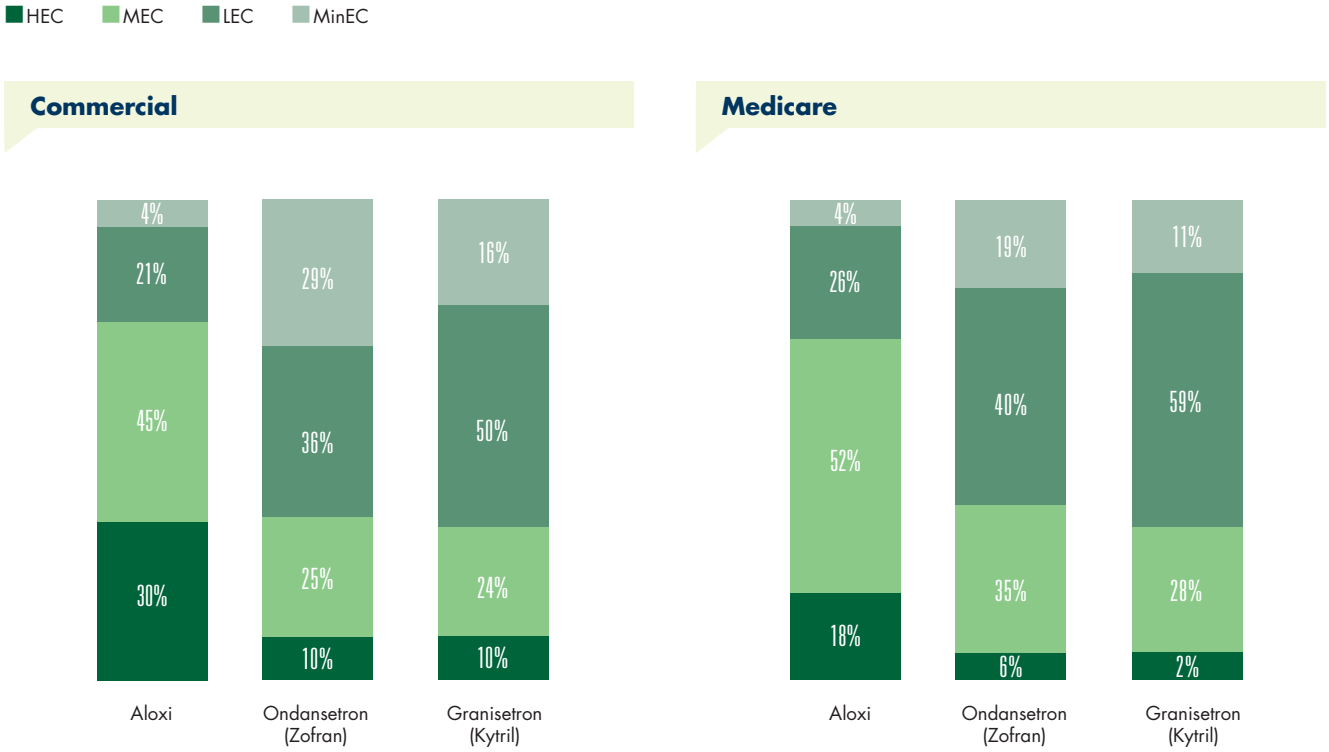
FIGURE 26

2015 Example Oncology Support Drugs by Cost per Claim and Unit by Site of Service

	COST PER CLAIM			COST PER UNIT		
	HOSPITAL OP	HI/SPP	PHYSICIAN	HOSPITAL	HI/SPP	PHYSICIAN
COMMERCIAL						
Neulasta	$8,433	$5,954	$4,134	$8,404.88	$4,871.77	$4,127.65
Aloxi	$693	$398	$252	$71.82	$27.83	$25.14
Sandostatin LAR	$8,676	$3,984	$5,169	$313.15	$151.61	$168.19
MEDICARE						
Neulasta	$3,792	—	$3,672	$3,787.21	—	$3,671.96
Aloxi	$220	—	$210	$22.62	—	$21.06
Sandostatin LAR	$4,745	—	$4,026	$155.52	—	$149.91

FIGURE 27

2015 Percentage of Allowed Amount PMPM by Emetogenic Potential of Chemotherapy Regimen



BIOLOGIC DRUGS FOR AUTOIMMUNE DISORDERS

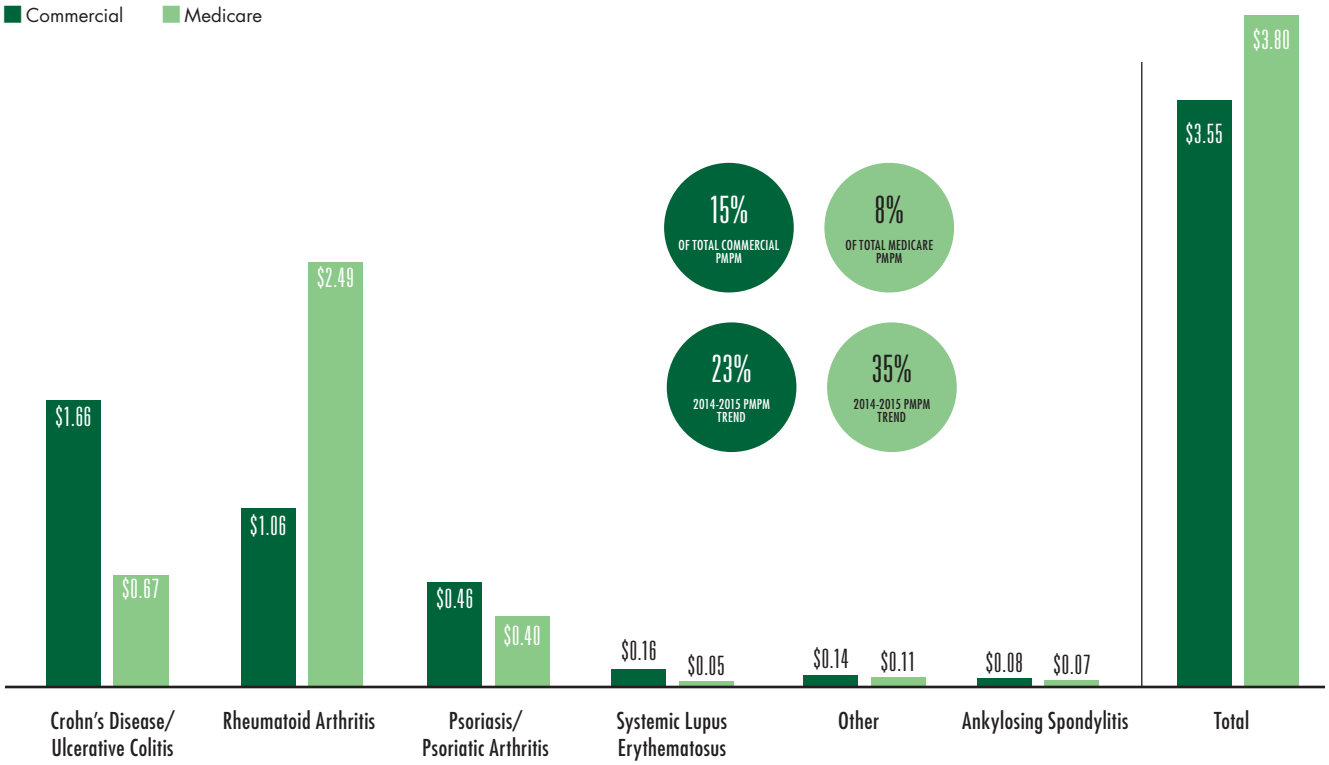
BDAIDs remained a significant spend driver for payers, but utilization by site of service experienced first time trend toward the most cost efficient provider, the physician office.

Biologic drugs for autoimmune disorders are used to treat a variety of disorders including therapies for ankylosing spondylitis, Crohn's disease/ulcerative colitis, psoriasis/psoriatic arthritis, rheumatoid arthritis, systemic lupus erythematosus, and several others. Over the last five years, the majority of members received their biologics for autoimmune diseases in the physician office setting. In 2015, 60 percent of commercial and 63 percent of Medicare members opted for this site of service, a 3 percentage point increase over the previous year in both lines of business (**see figure 30**). Overall, the category accounted for $3.55 of total commercial PMPM and $3.80 of Medicare PMPM spend, ranking 2nd after oncology for commercial and fourth in Medicare (**see figure 28**).

- In commercial, Crohn's disease/ulcerative colitis had had the highest spend at $1.66 PMPM. In Medicare, rheumatoid arthritis accounted for the largest spend at $2.49 PMPM (**see figure 28**).
- As expected, commercial claim and unit costs in the hospital outpatient setting were more than double the physician office for two frequently used BDAID agents, Remicade and Orencia. For Medicare, claim and unit costs were relatively similar across these three outpatient sites of service (**see figure 29**).
- For the first time ever captured in our Trend Report, Remicade saw increased use in the physician office, which shifted from the hospital outpatient setting. Orencia utilization is fairly consistent year-over-year with a small shift in trends among the three sites based on line of business (**see figure 31**).
- Of those payers who implemented product preferencing, 88 percent of commercial payers and 80 percent of Medicare payers had some form of preferencing for the BDAID category (**see figure 32**).
- For commercial, 92 percent of payers implemented a prior authorization for the use of BDAID treatments. When payers had a separate strategy for Medicare (n=8), 75 percent of them implemented a prior authorization and 25 percent offered care/case management programs (**see figures A30 and A31 in appendix**).
- When analyzing just rheumatoid arthritis utilization, Remicade consistently had the most utilization and Orencia had the second highest utilization (**see figures 33 and 35**).

FIGURE 28

2015 Commercial and Medicare PMPM of Biologics for Autoimmune Diseases



Please note that due to rounding, some column totals do not add up accurately.

FIGURE 29

2015 Example BDAID by Cost per Claim and Unit by Site of Service

	COST PER CLAIM			COST PER UNIT		
	HOSPITAL OP	HI/SPP	PHYSICIAN	HOSPITAL OP	HI/SPP	PHYSICIAN
COMMERCIAL						
Remicade	$10,159	$5,523	$4,560	$233.23	$105.60	$88.88
Orencia	$6,388	$2,651	$2,838	$92.29	$34.26	$35.97
MEDICARE						
Remicade	$4,203	$4,266	$3,397	$80.85	$94.99	$75.60
Orencia	$2,569	$2,446	$2,671	$35.43	$31.66	$34.61

FIGURE 30

BDAID Member Utilization by Site of Service 2014-2015

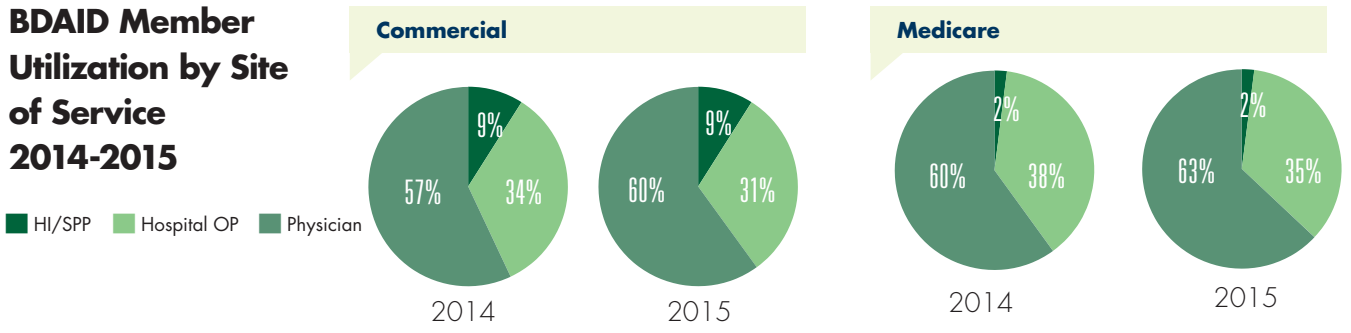


FIGURE 31

2015 Example BDAID Drug Utilization by Site of Service 2014-2015

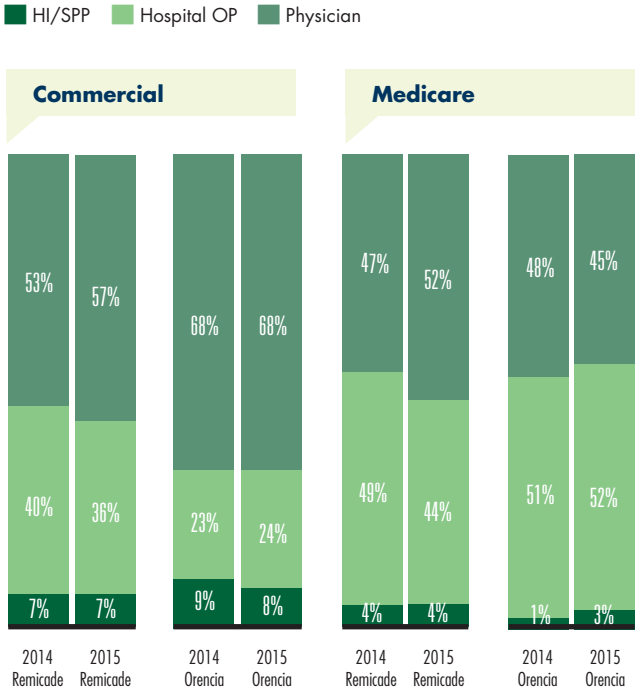


FIGURE 32

BDAID Product Preferencing (% of payers)

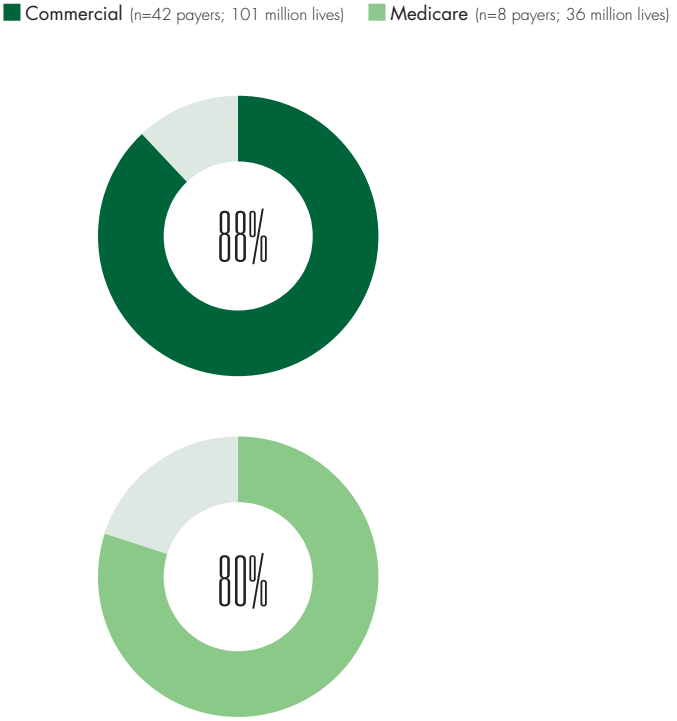


FIGURE 33

2015 Commercial BDAID: Rheumatoid Arthritis Utilization, PMPM, and Annual Cost per Patient 2014-2015

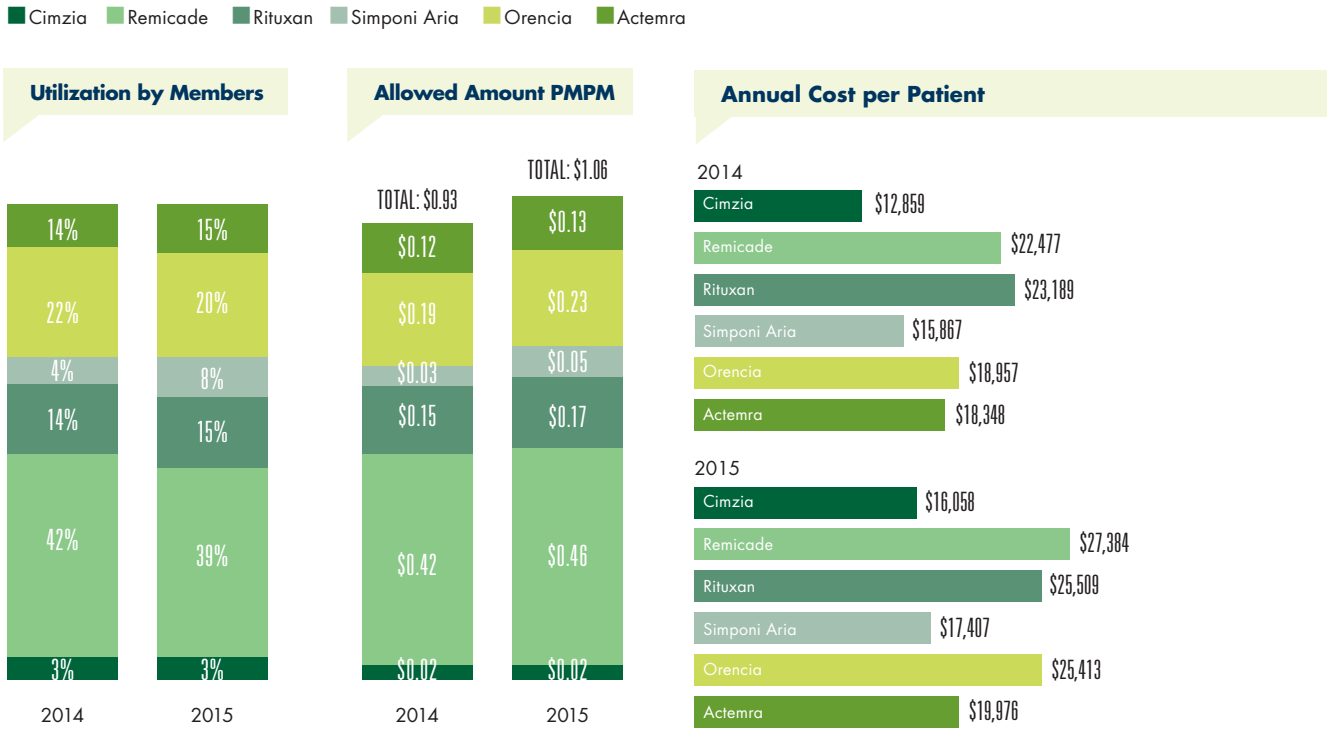
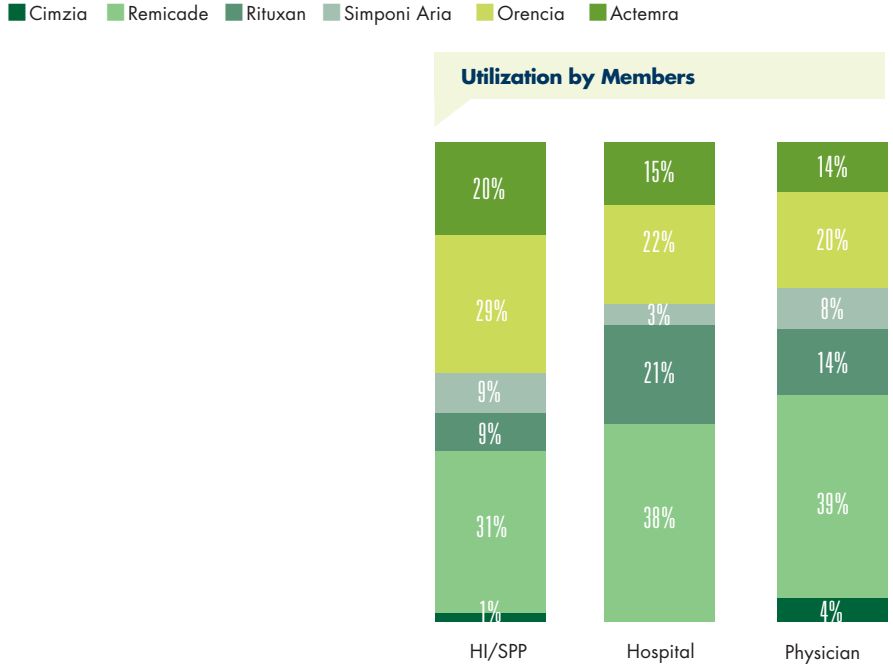


FIGURE 34

2015 Commercial BDAID: Rheumatoid Arthritis Utilization by Site of Service



Please note that due to rounding, some column totals do not add up accurately.

FIGURE 35

2015 Medicare BDAID: Rheumatoid Arthritis Utilization, PMPM, and Annual Cost per Patient 2014-2015

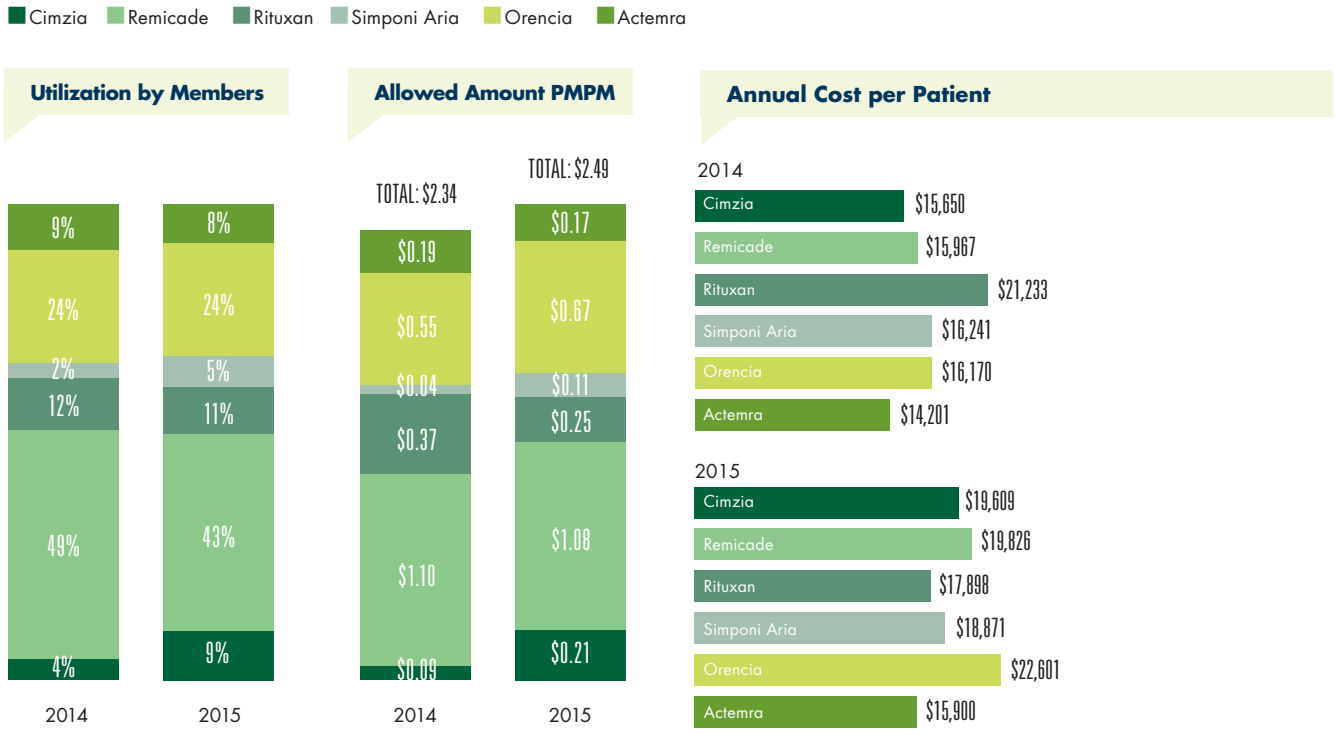
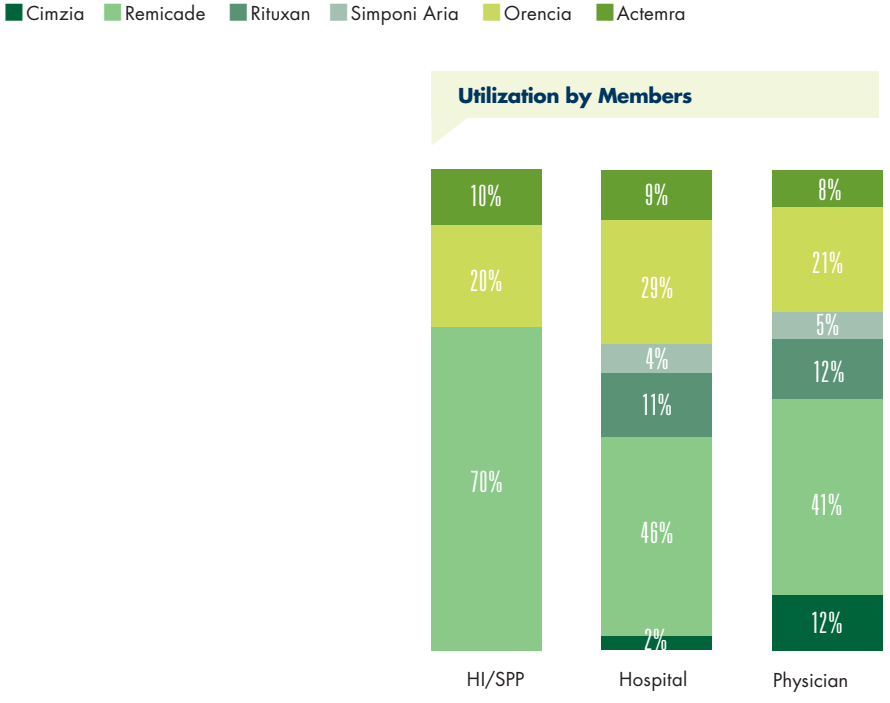


FIGURE 36

2015 Medicare BDAID: Rheumatoid Arthritis Utilization by Site of Service



Please note that due to rounding, some column totals do not add up accurately.

IMMUNE GLOBULIN (IG)

Immune Globulin product preferencing is visible by provider type/distribution channel, but it is a tactic only employed by a small percentage of commercial payers.

The top drugs utilized in the Immune Globulin (IG) category were Gamunex-C/Gammaked and Gammagard liquid. They were also the top immune globulin trend drivers for commercial, with their PMPM increasing 40 percent and 15 percent, respectively from 2014 to 2015 (**see figure 9**). Over the last five years, commercial administration of these drugs has been mainly in the home infusion/specialty pharmacy setting, although many members were treated in the hospital outpatient setting. Medicare administration has been more fluid and in 2015 was closely split between the home infusion/specialty pharmacy and physician office (**see figure 40**). Overall, the category (including both intravenous and subcutaneous products) accounted for $1.92 of total commercial PMPM and $2.98 of Medicare PMPM ranking as the fourth-highest spend category for commercial and the fifth-highest category in Medicare (**see figure 37**).

- Product preferencing tactics are typically not employed by commercial payers for immune globulin categories (31 percent for IVIG and 17 percent for SCIG); however, more than half (53 percent) of payers with Medicare Advantage lives took advantage of this management strategy for IVIG specifically (**see figure 38**).
- The disparity by place of service in commercial claim and unit costs was not as great as the BDAID category. In most cases, however, hospital outpatient facilities carried the highest claim and unit costs relative to other sites of care. Conversely, with Medicare, home infusion carries the greatest cost on a per claim basis. In most cases, cost per claim is actually lower in the hospital outpatient setting relative to home infusion and physician office (**see figure 39**).
- Just like BDAIDs, IG drugs for commercial showed an increased trend toward the physician office setting in 2015 with utilization shifting from both the hospital outpatient facility and home infusion/specialty pharmacy settings (**see figure 40**).
- For commercial and Medicare, Gammagard Liquid and Gamunex-C/Gammaked were utilized mostly in the home infusion/specialty pharmacy setting, while Gammagard and Privigen were utilized in the hospital outpatient setting (**see figure 41**).
- Both commercial and Medicare payers are most likely to use prior authorization as a management strategy in this category with disease or care management program as the second most common strategy (**see figures A30 and A31 in appendix**).

FIGURE 37

2015 PMPM of Immune Globulin Agents

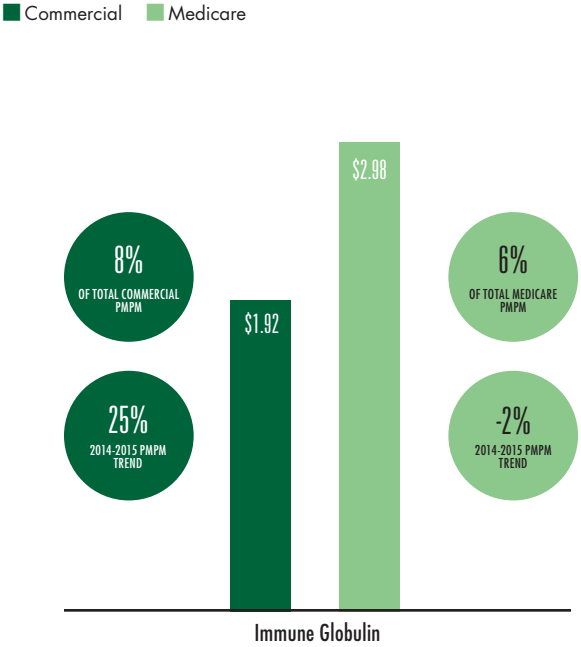


FIGURE 38

Immune Globulin Product Preferencing (% of payers)

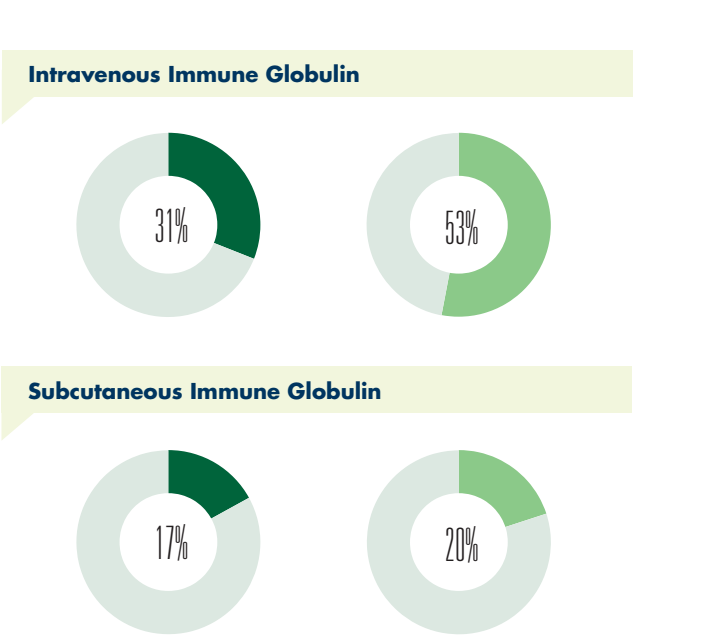


FIGURE 39

2015 Example IG Drugs by Cost per Claim and Unit by Site of Service

	COST PER CLAIM			COST PER UNIT		
	HOSPITAL OP	HI/SPP	PHYSICIAN	HOSPITAL OP	HI/SPP	PHYSICIAN
COMMERCIAL						
Gammagard Liquid	$6,718	$4,571	$4,202	$91.18	$61.51	$59.08
Gamunex-C/Gammaked	$7,759	$4,194	$5,600	$116.10	$60.06	$60.78
Gammagard	$4,833	$4,443	$5,777	$69.86	$63.68	$59.14
Privigen	$5,394	$3,909	$2,391	$95.24	$52.05	$49.84
MEDICARE						
Gammagard Liquid	$3,164	$5,014	$3,326	$42.47	$57.13	$47.95
Gamunex-C/Gammaked	$2,633	$3,918	$3,275	$48.63	$42.91	$41.21
Gammagard	$1,388	$2,871	$1,723	$35.59	$100.15	$43.07
Privigen	$3,118	$2,118	—	$49.11	$47.39	—

FIGURE 40

Immune Globulin Member Utilization by Site of Service 2014-2015

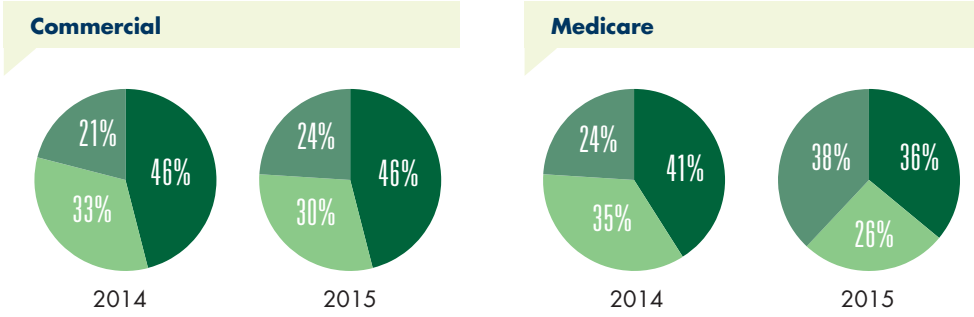


FIGURE 41

Example IG Drug Utilization by Site of Service 2014-2015

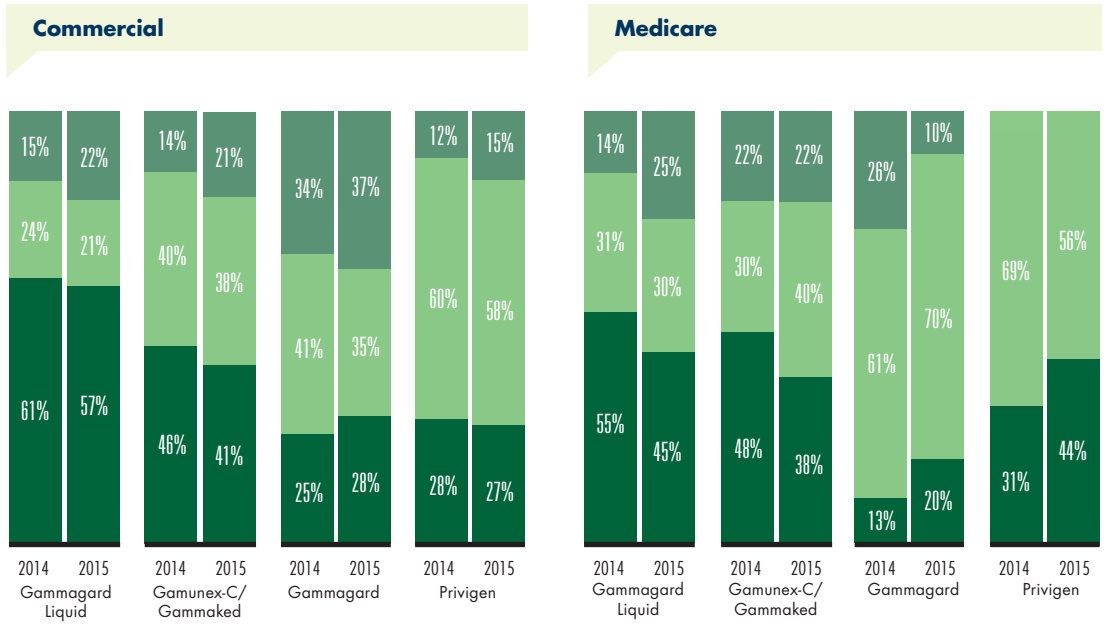


FIGURE 42

Commercial IG Utilization, PMPM, and Annual Cost per Patient 2014-2015

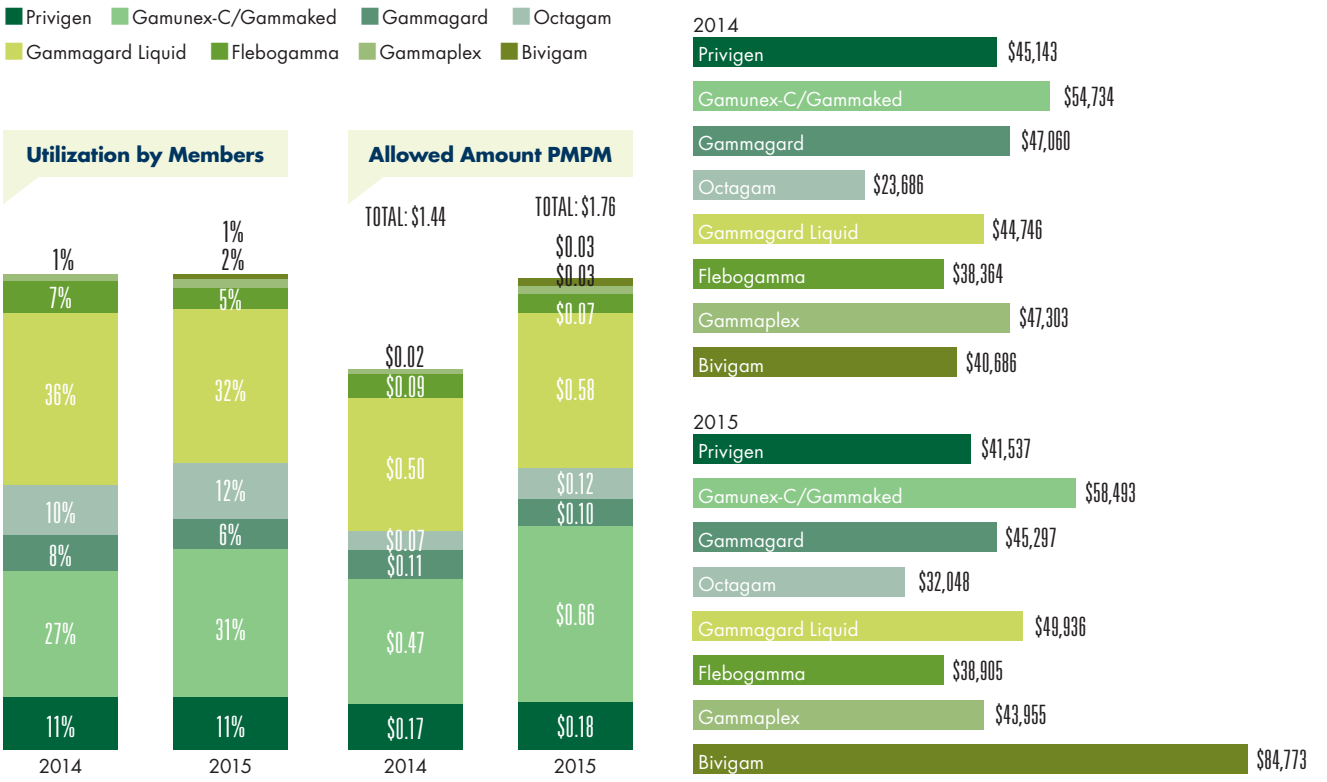
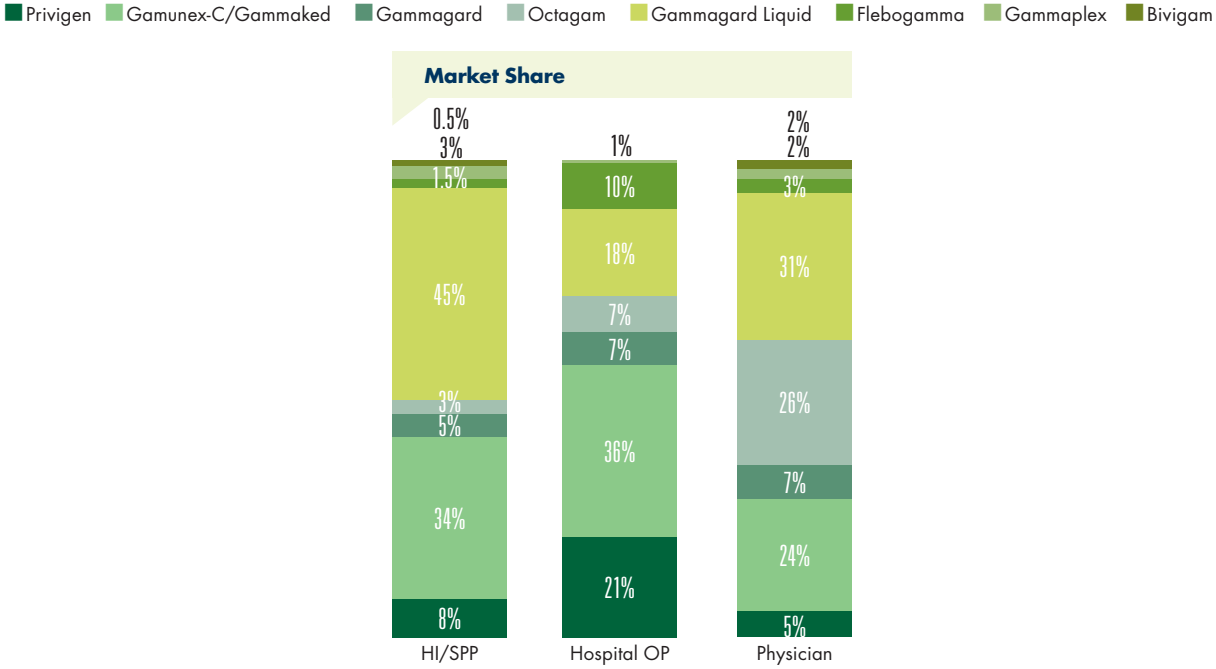


FIGURE 43

2015 Commercial IG Utilization by Site of Service



Please note that due to rounding, some column totals do not add up accurately.

FIGURE 44

Medicare IG Utilization, PMPM, and Annual Cost per Patient 2014-2015

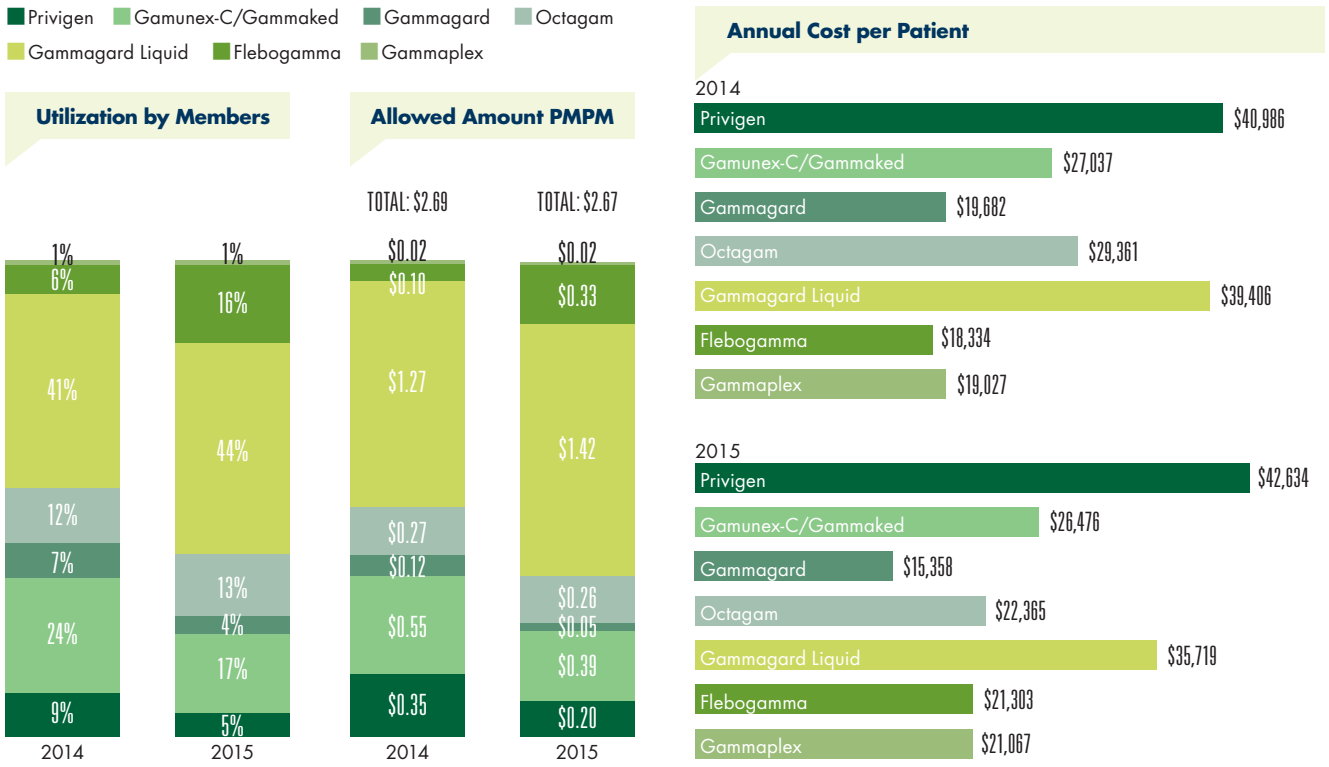
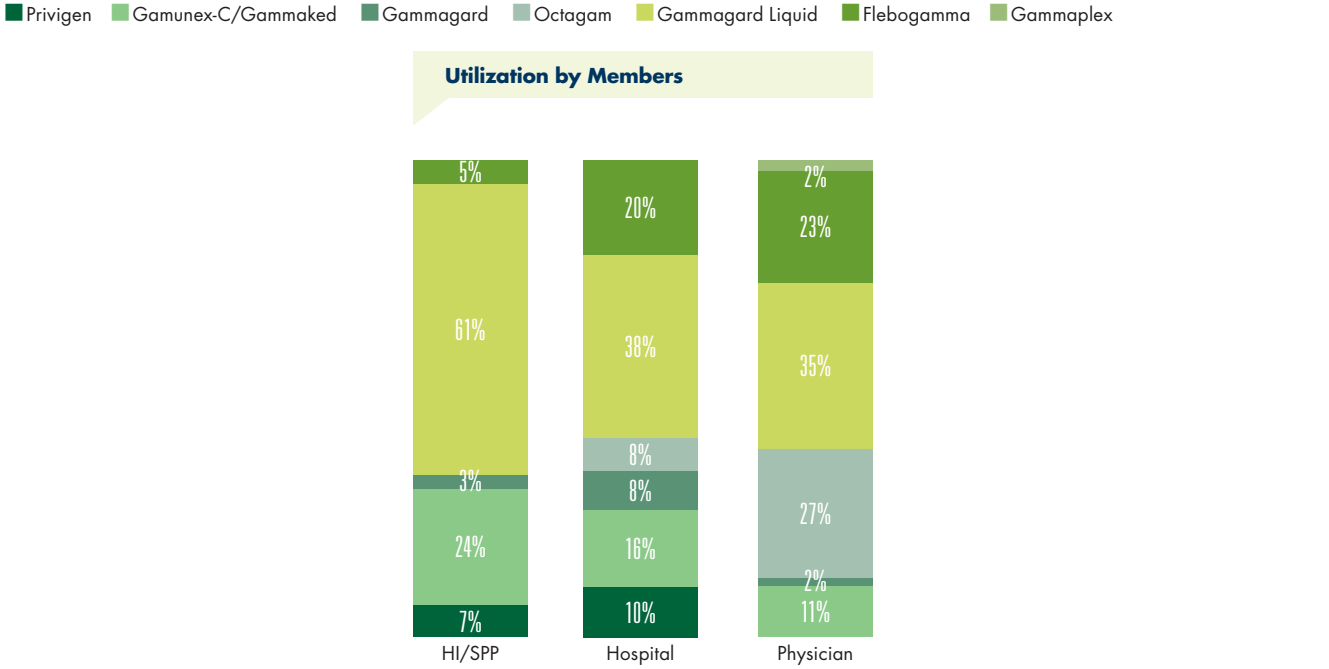


FIGURE 45

2015 Medicare IG Utilization by Site of Service



Please note that due to rounding, some column totals do not add up accurately.

OPHTHALMIC INJECTIONS

Ophthalmic injections had the largest annual trend of 30 percent and 39 percent for commercial and Medicare, respectively.

The significant PMPM trend in the category was a result of increased use based on positive results from the Protocol T study, confirming the efficacy of anti-VEGFs in the treatment of diabetic retinopathy.

Ophthalmic agents had a larger impact on the Medicare category at 11 percent of spend and only accounted for 1 percent of commercial PMPM. In Medicare, ophthalmic injections ranked as the second-highest spend category, equating to $5.25 of the total $46.01 PMPM spend. For both lines of business, ophthalmic agents were administered almost exclusively in the physician office (**see figures 46 and 49**).

- Medicare payers were more concerned with preferencing ophthalmic agents, mostly through prior authorization (**see figure 47**).
- Lucentis and Eylea are included in the top 25 drugs for Medicare (**see figure 48**).
- In looking at bevacizumab (Avastin) only for ophthalmic use, it accounted for the majority of market share in both commercial and Medicare. Eylea overtook Lucentis market share for commercial in 2015 but was 1 percent behind Lucentis in Medicare. However, the trend indicates that Eylea will surpass Lucentis in market share in 2016 (**see figures 50 thru 53**).
- What was most noteworthy for this category was the annual cost per patient for both commercial and Medicare which showed the cost of bevacizumab (Avastin) at 28 to 38 times lower than the higher cost agents (**see figures 50 and 52**).

FIGURE 46

2015 PMPM of Ophthalmic Agents

FIGURE 47

Ophthalmic Injections Product Preferencing (% of payers)

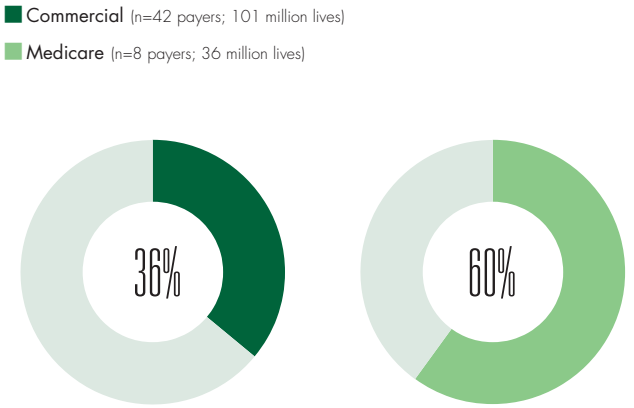


FIGURE 48

2015 Example Ophthalmic Drugs by Cost per Claim and Unit by Site of Service

	COST PER CLAIM			COST PER UNIT		
	HOSPITAL	HI/SPP	PHYSICIAN	HOSPITAL	HI/SPP	PHYSICIAN
COMMERCIAL						
Eylea	$3,969	$1,932	$2,221	$2,036.58	$965.92	$1,045.67
Lucentis	$2,680	$2,245	$1,791	$632.90	$431.79	$415.76
MEDICARE						
Eylea	$2,211	—	$2,089	$963.06	—	$939.55
Lucentis	$1,376	—	$1,941	$305.81	—	$396.01

FIGURE 49

Ophthalmic Member Utilization by Site of Service 2014-2015

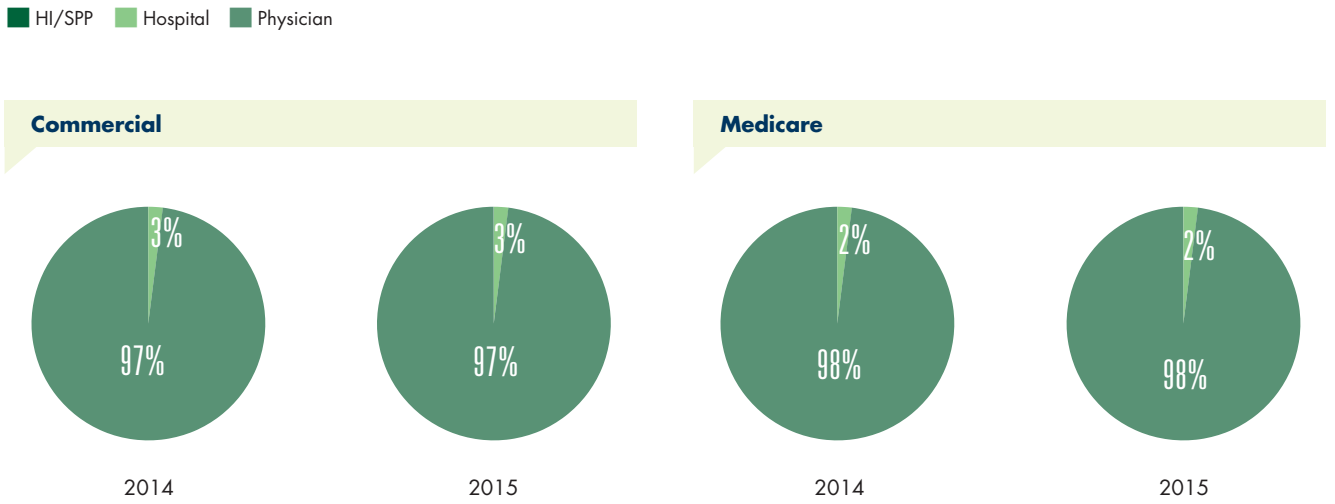


FIGURE 50

Commercial Ophthalmic Utilization, PMPM, and Annual Cost per Patient 2014–2015

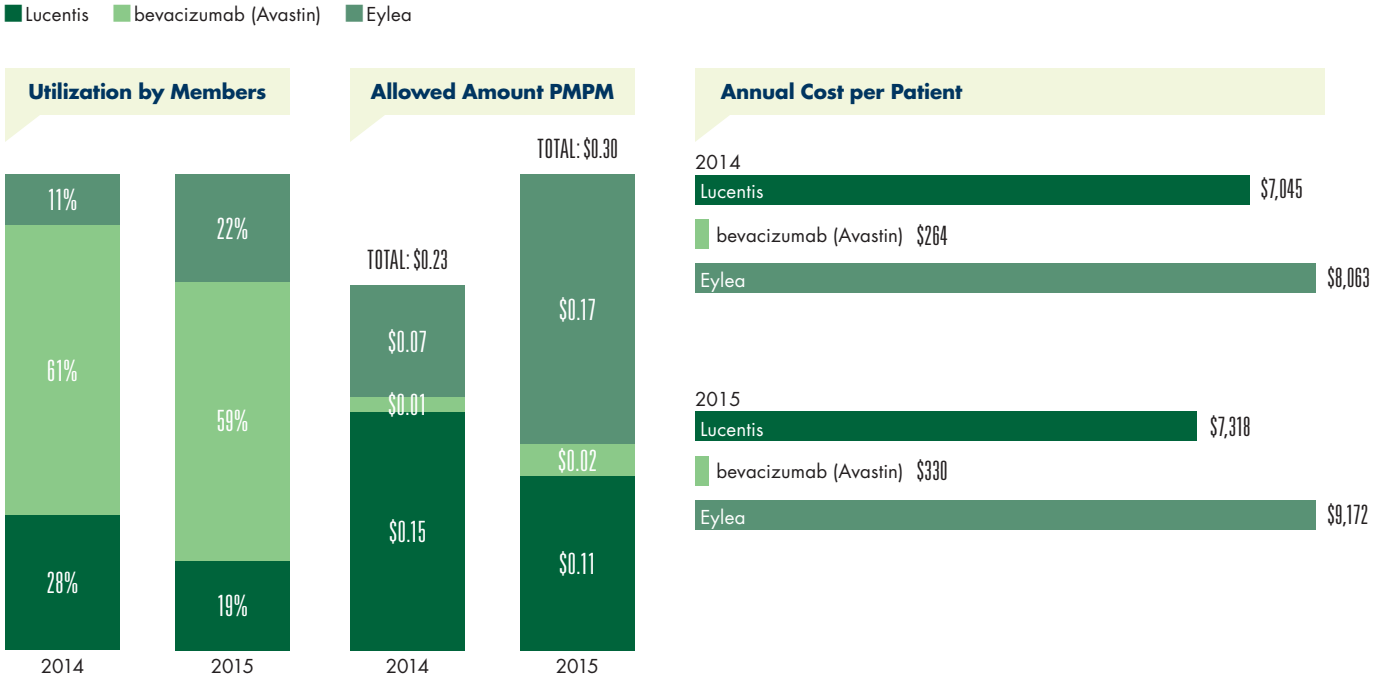
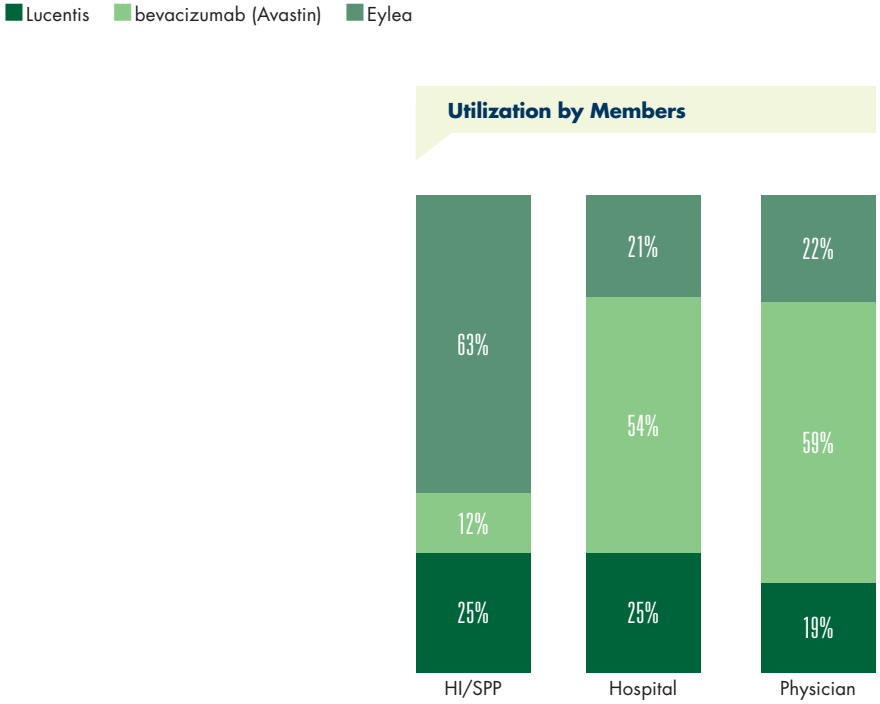


FIGURE 51

2015 Commercial Ophthalmic Utilization by Site of Service



Please note that due to rounding, some column totals do not add up accurately.

FIGURE 52

Medicare Ophthalmic Utilization, PMPM, and Annual Cost per Patient 2014–2015

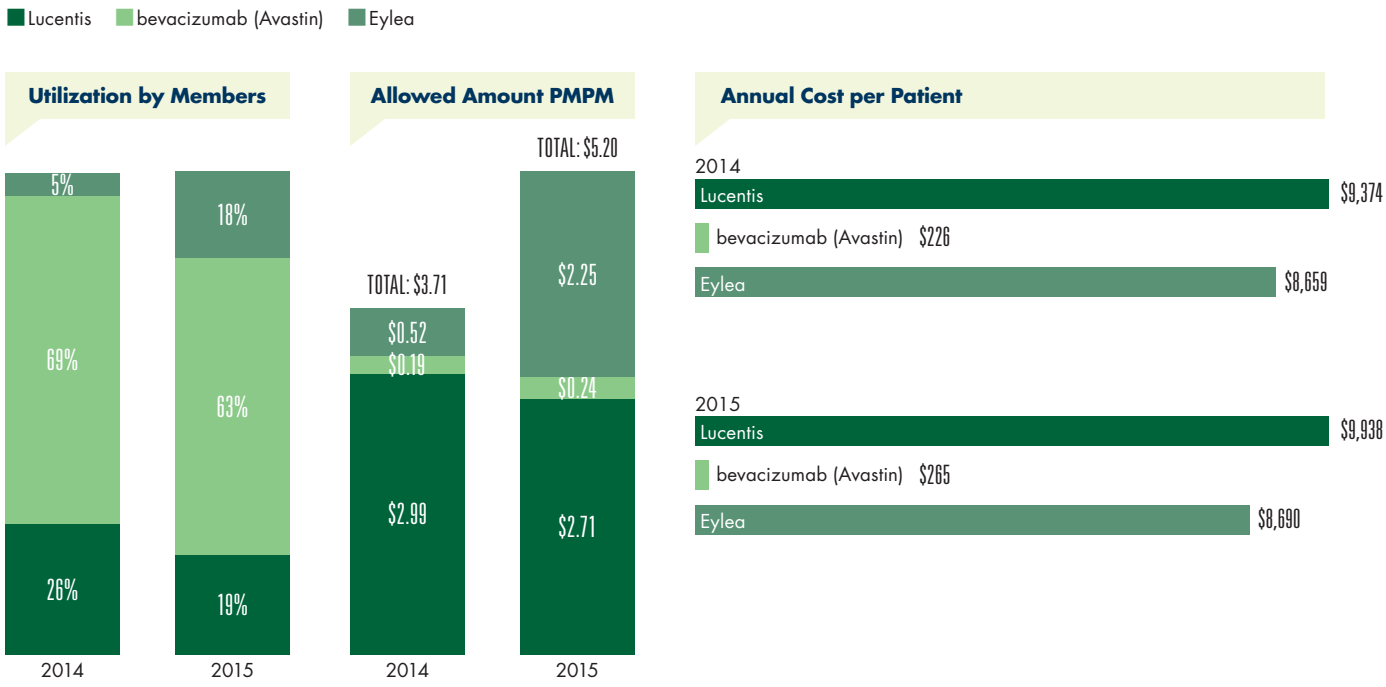
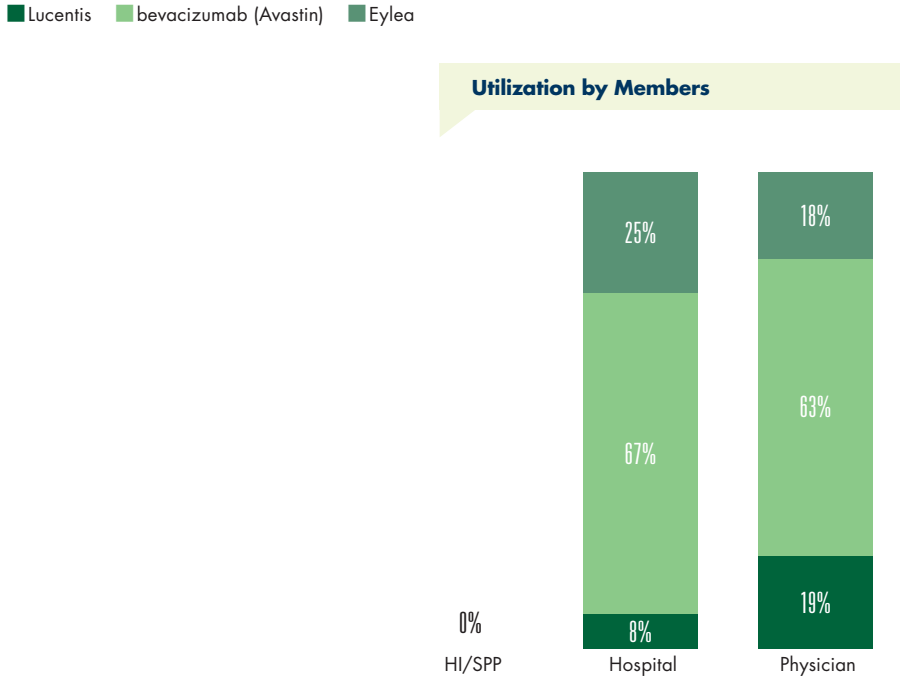


FIGURE 53

2015 Medicare Ophthalmic Utilization by Site of Service



Please note that due to rounding, some column totals do not add up accurately.

RARE DISEASES

Rare diseases only affect an average of two patients per 100,000, but constitute some of the most costly drugs on the medical pharmacy benefit.

Rare diseases, as defined in this report analysis, included antihemophilic factors (namely Factor VIII), enzyme-replacement therapy, Gaucher (Cerezyme), paroxysmal nocturnal hemoglobinuria (PNH) (Soliris), and Castleman disease (Sylvant). Although rare diseases covered multiple drugs across multiple categories, the leading drugs in this combined category included Soliris, Cerezyme, and Factor VIII agents (antihemophilic factor (Recombinant)). Soliris and Cerezyme were two of the most expensive medical benefit agents on the market contributing to 9 percent of total commercial PMPM and 3 percent of Medicare PMPM (**see figure 54**).

- Most rare disease agents were administered in the home infusion/specialty pharmacy setting in commercial and the hospital outpatient setting in Medicare. Over the last five years, this has been variable, most likely due to the introduction of new agents in this category with varying methods of administration (**see figure 57**).
- Year over year, Soliris and Cerezyme utilization decreased in the home infusion/specialty pharmacy setting for commercial. In commercial, Soliris utilization increased 14 percentage points in the physician office setting and Cerezyme utilization increased 9 percentage points in the hospital outpatient setting (**see figure 58**).
- In Medicare, Factor VIII agents shifted utilization from the home infusion/specialty pharmacy to the hospital outpatient setting, potentially as a result of increased access to, and utilization of, hemophilia treatment centers (HTCs), and Soliris shifted all utilization to the hospital outpatient setting (**see figures 59 and 61**).
- The factor VIII products, antihemophilic factor (Recombinant) and Cerezyme, had more than two-thirds of the market share in commercial. In 2015, Cerezyme had complete market share in Medicare (**see figures 59 thru 62**).

FIGURE 54

2015 PMPM of Example Rare Diseases

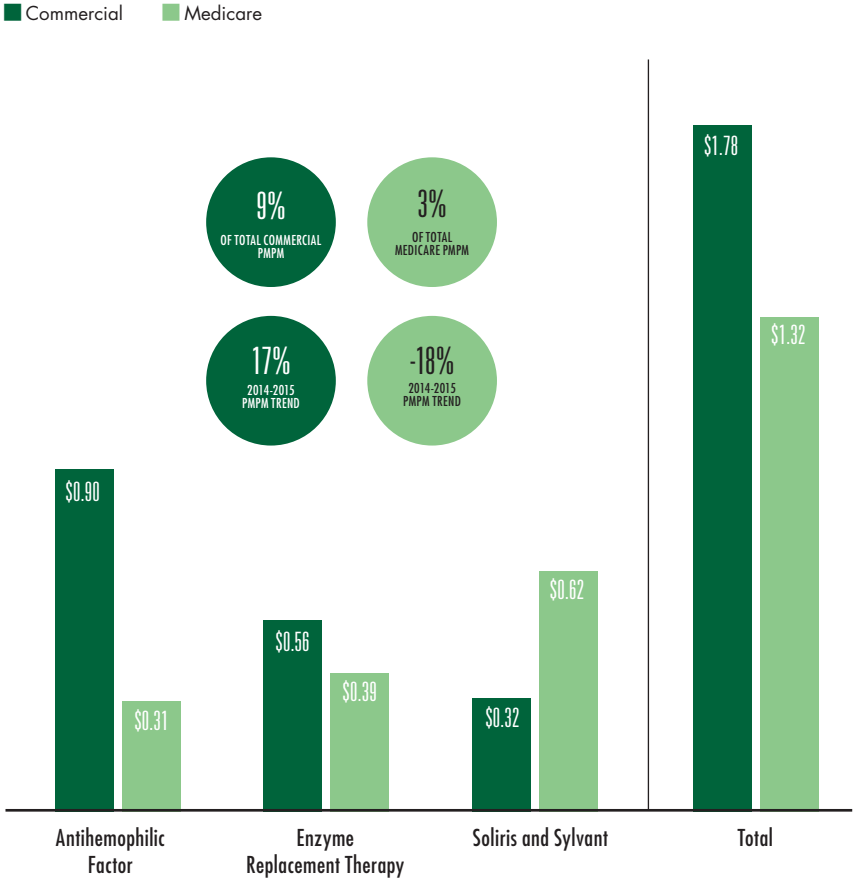


FIGURE 55

Example Rare Disease Product Preferencing

(% of payers)

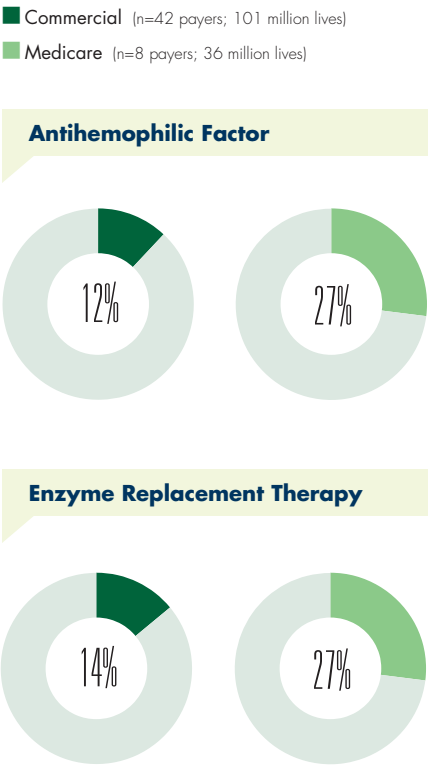


FIGURE 56

2015 Example Rare Diseases Drugs by Cost per Claim and Unit by Site of Service

	COST PER CLAIM			COST PER UNIT		
	HOSPITAL	HI/SPP	PHYSICIAN	HOSPITAL	HI/SPP	PHYSICIAN
COMMERCIAL						
Antihemophilic Factor (Recombinant)	$13,248	$19,463	$15,692	$1.39	$2.52	$1.72
Soliris (PNH)	$39,822	$23,141	$23,929	$434.44	$235.24	$231.48
Cerezyme (Gaucher)	$27,049	$22,434	$16,804	$76.88	$42.12	$42.01
MEDICARE						
Antihemophilic Factor (Recombinant)	$9,457	$8,394	—	—	$1.12	$0.91
Soliris (PNH)	$21,285	—	—	—	$214.93	—

FIGURE 57

Rare Diseases Member Utilization by Site of Service 2014–2015

FIGURE 58

Example Rare Diseases Drug Utilization by Site of Service 2014–2015

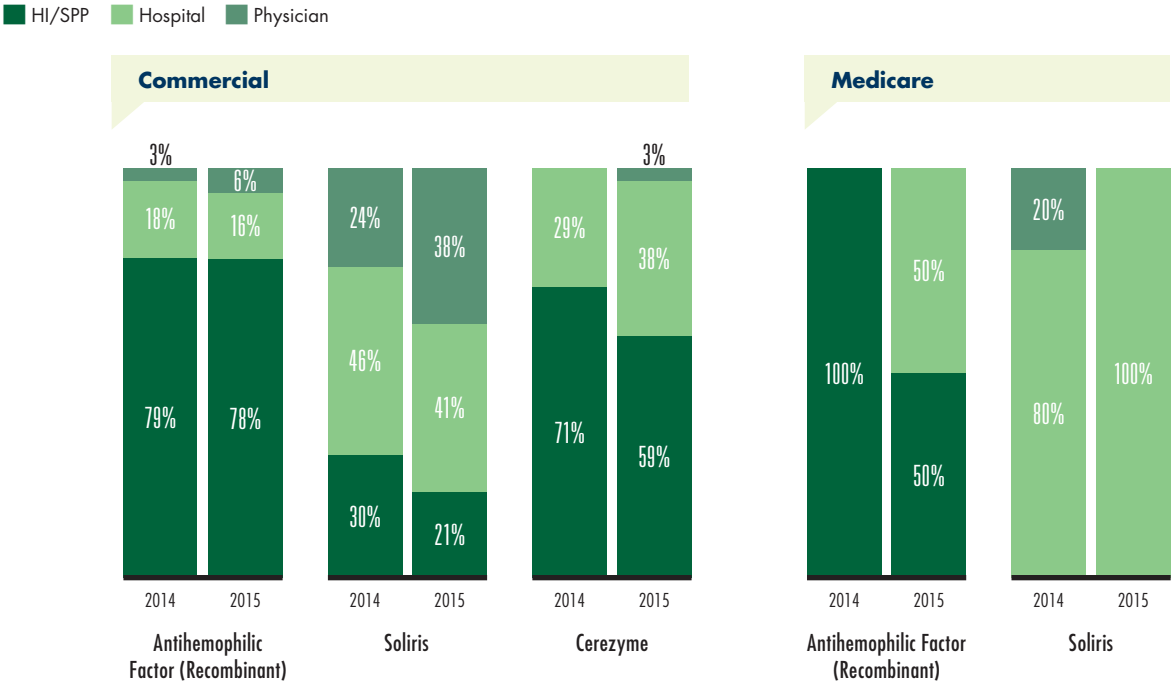


FIGURE 59

Commercial Factor VIII Utilization, PMPM, and Annual Cost per Patient PMPM 2014-2015

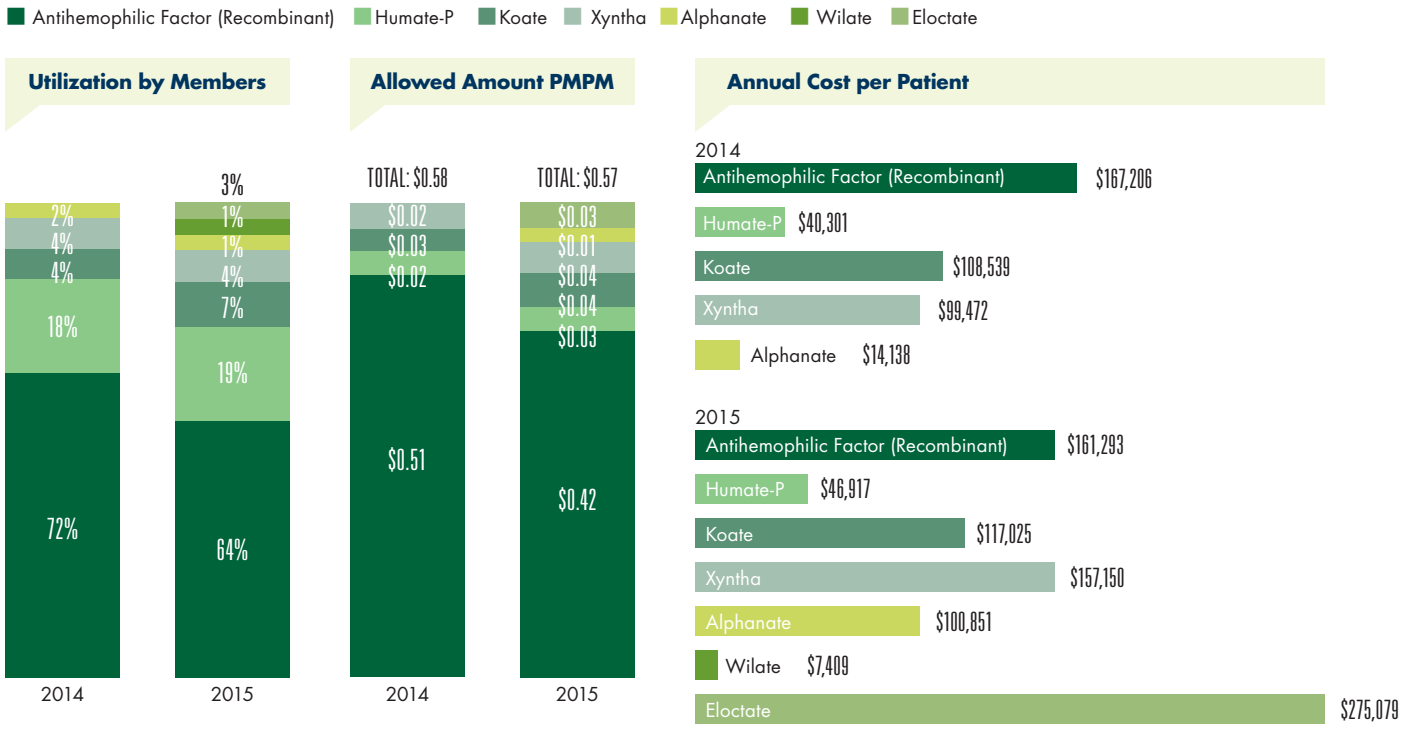
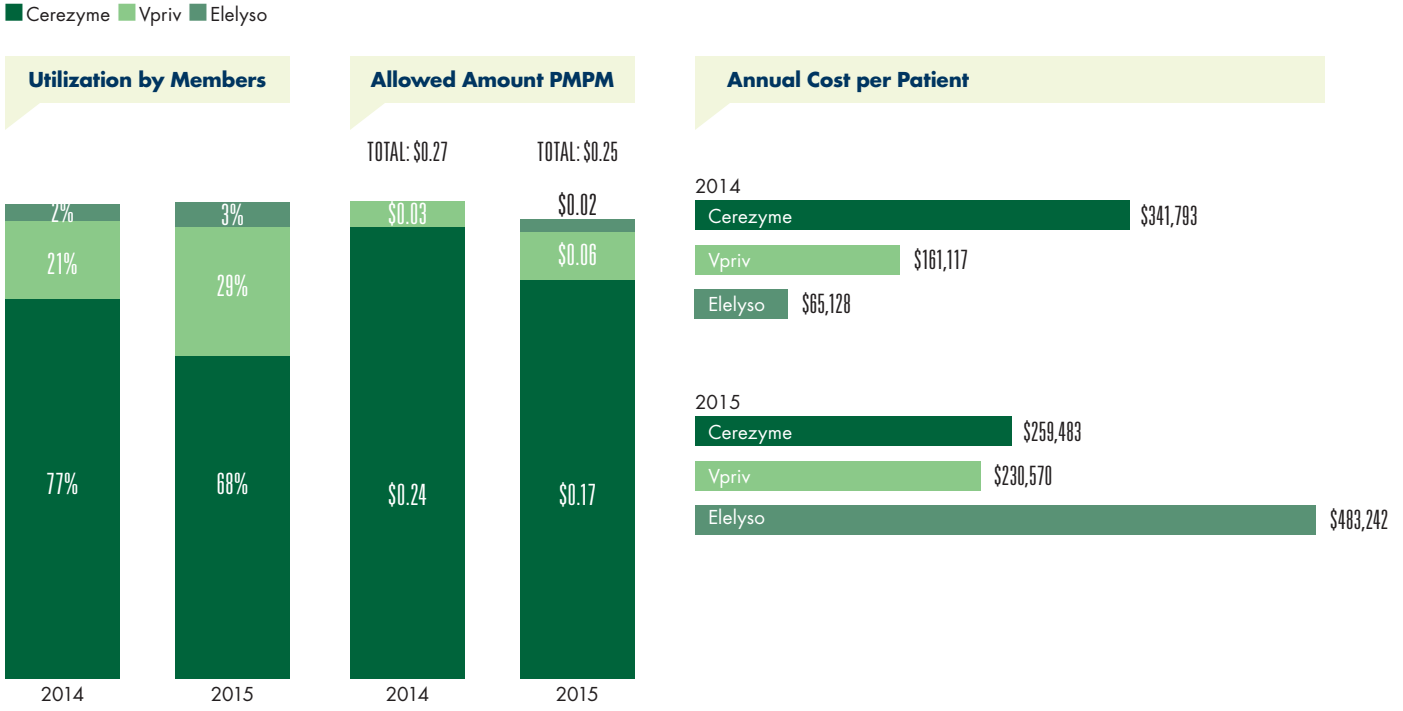


FIGURE 60

Commercial Gaucher Utilization, PMPM, and Annual Cost per Patient 2014-2015



Please note that due to rounding, some column totals do not add up accurately.

FIGURE 61

Medicare Factor VIII Utilization, PMPM, and Annual Cost per Patient 2014-2015

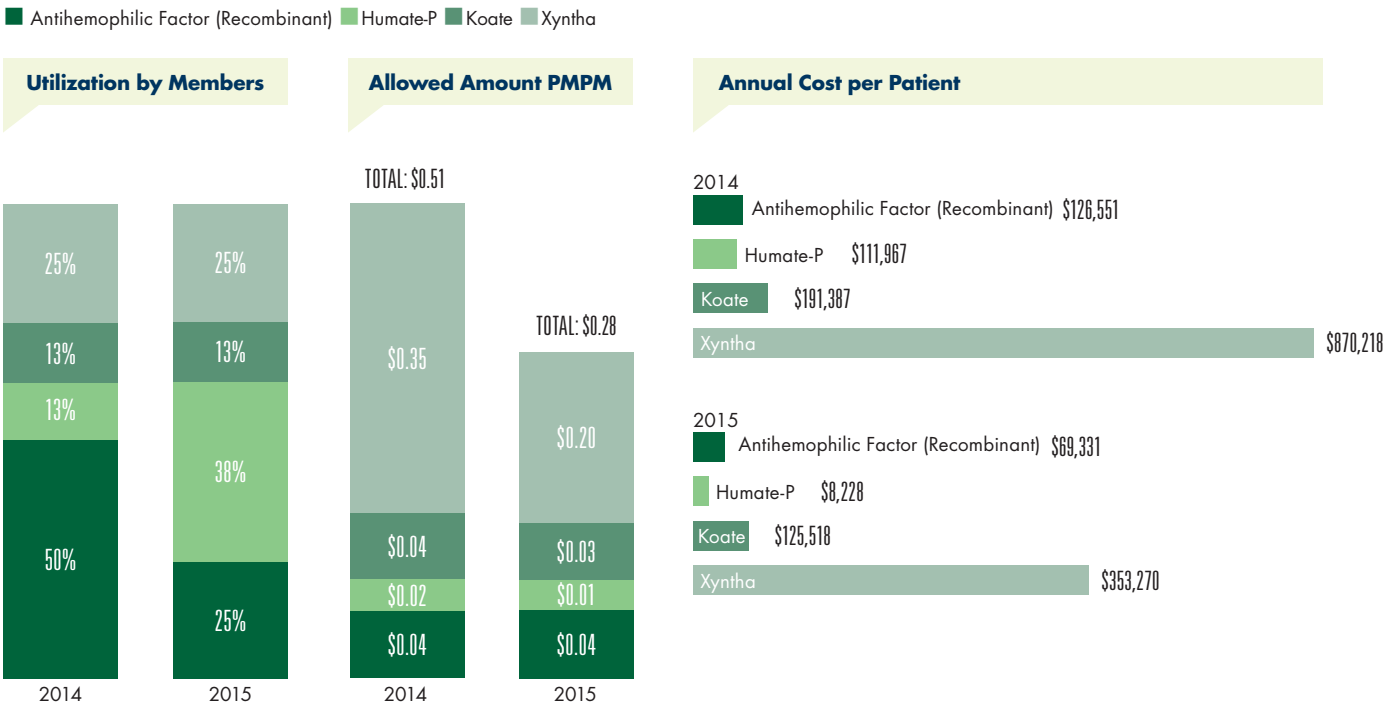
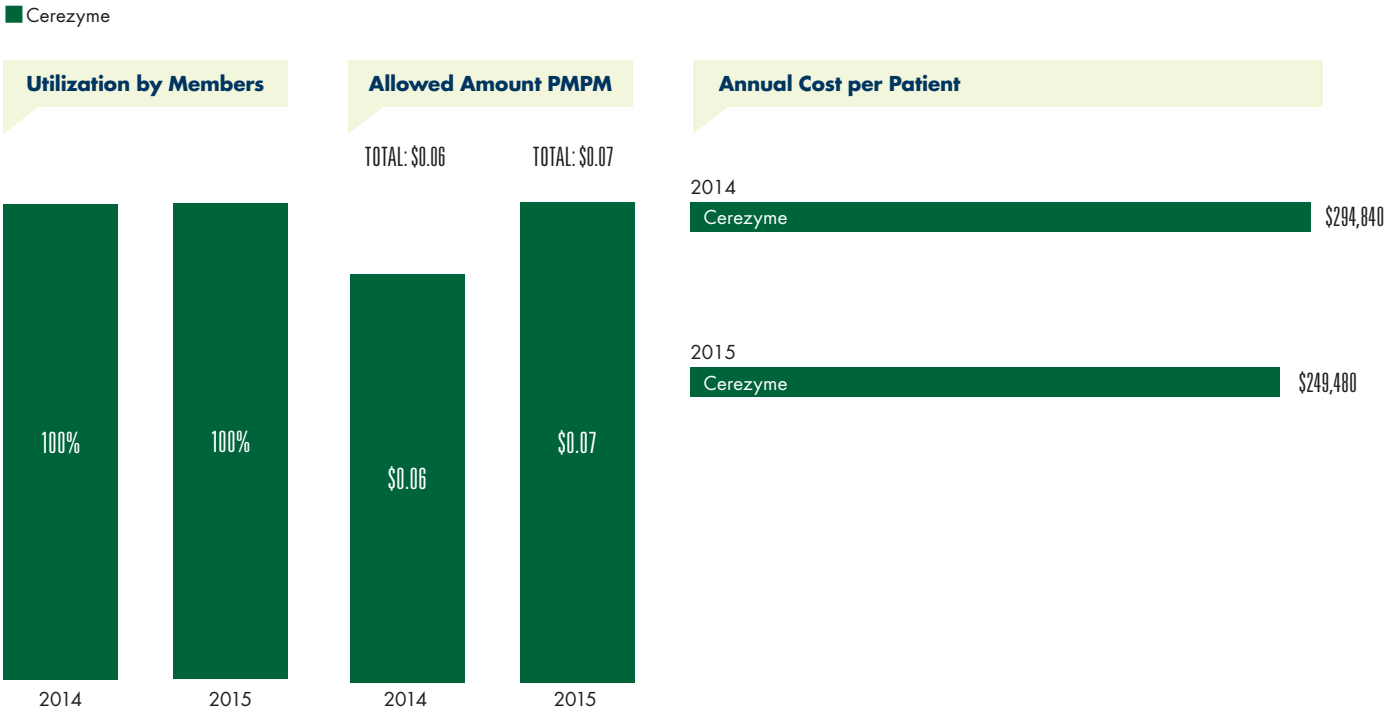


FIGURE 62

Medicare Gaucher Utilization, PMPM, and Annual Cost per Patient 2014-2015



Please note that due to rounding, some column totals do not add up accurately.

VISCOSUPPLEMENTATION

Despite recent questions regarding the clinical effectiveness of viscosupplementation, and the debate throughout the managed care community about whether or not to cover these agents, viscosupplementation continued to be a top spend category in both commercial and Medicare.

Viscosupplementation agents, or treatment with hyaluronic acids (HAs) for osteoarthritis of the knee, made up two percent of Medicare PMPM spend and ranked seventh on the Medicare medical pharmacy benefit spend categories. The trend was negative in this category most likely due to the 2013 American Academy of Orthopedic Surgeons Guidelines (**see figure 63**).

- Close to two-thirds (60 percent) of payers preferred products within this category (**see figure 64**).
- Viscosupplementation agents are most often administered in the physician office in both commercial and Medicare. Viscosupplementation agents are commonly dispensed through a specialty pharmacy in commercial but rarely done so in Medicare (**see figure 66**).
- Orthovisc had the largest market share in commercial, but Euflexxa and Synvisc/Synvisc-One had similar market share. In Medicare, Euflexxa had close to half (46 percent) of market share (**see figures 68 and 70**).

FIGURE 63

2015 PMPM of Viscosupplementation

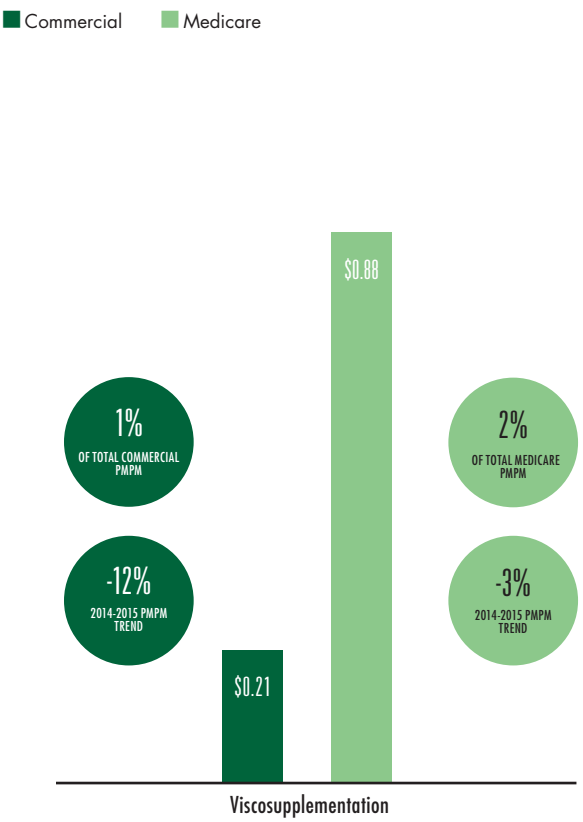


FIGURE 64

Viscosupplementation Product Preferencing (% of payers)

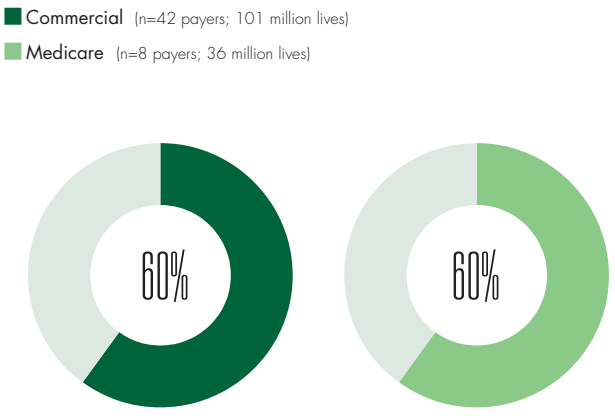


FIGURE 65

2015 Example Viscosupplementation Drugs by Cost per Claim and Unit by Site of Service

	COST PER CLAIM			COST PER UNIT		
	HOSPITAL	HI/SPP	PHYSICIAN	HOSPITAL	HI/SPP	PHYSICIAN
COMMERCIAL						
Euflexxa	$627	$1,059	$261	$498	$262	$179
Synvisc/Synvisc-One	$1,374	$1,452	$583	$40	$22	$15
Gel-One	$1,249	$1,218	$908	$1,124	$953	$705
MEDICARE						
Euflexxa	$204	$1,157	$275	$153	$331	$192
Synvisc/Synvisc-One	$542	$1,543	$548	$13	$24	$12
Gel-One	$1,117	$1,000	$725	$559	$1,000	$464

FIGURE 66

Viscosupplementation Member Utilization by Site of Service 2014-2015

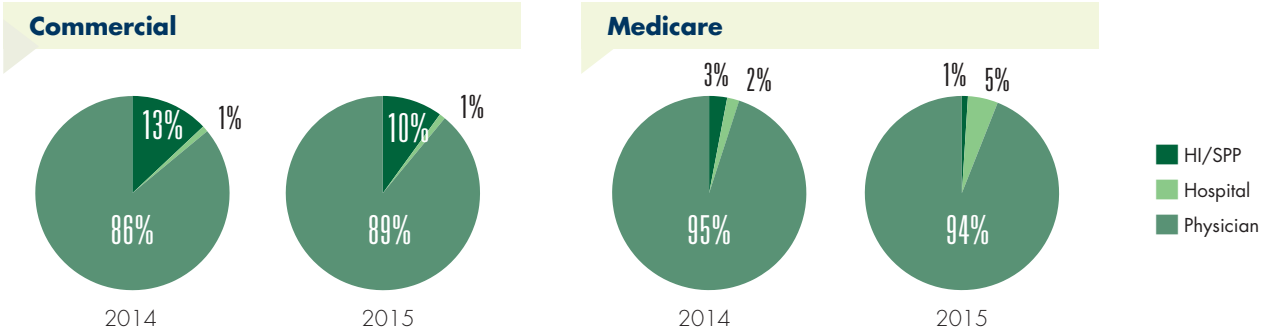


FIGURE 67

Example Viscosupplementation Drug Utilization by Site of Service 2014-2015

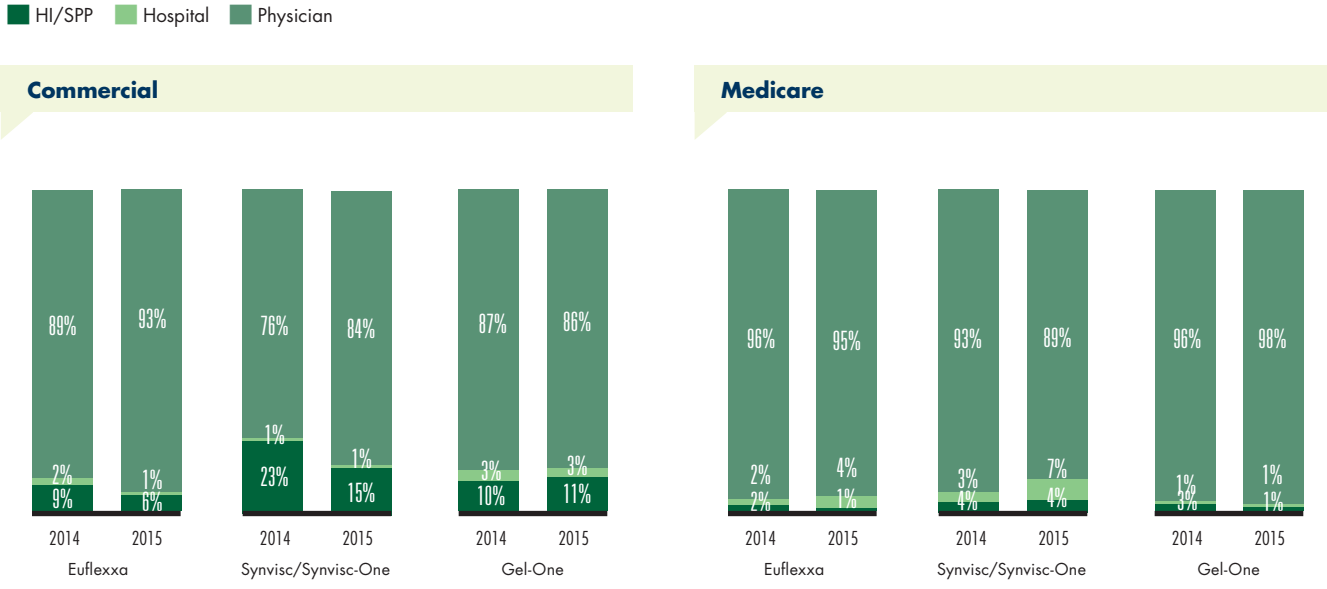


FIGURE 68

Commercial Viscosupplementation Utilization, PMPM, and Annual Cost per Patient 2014-2015

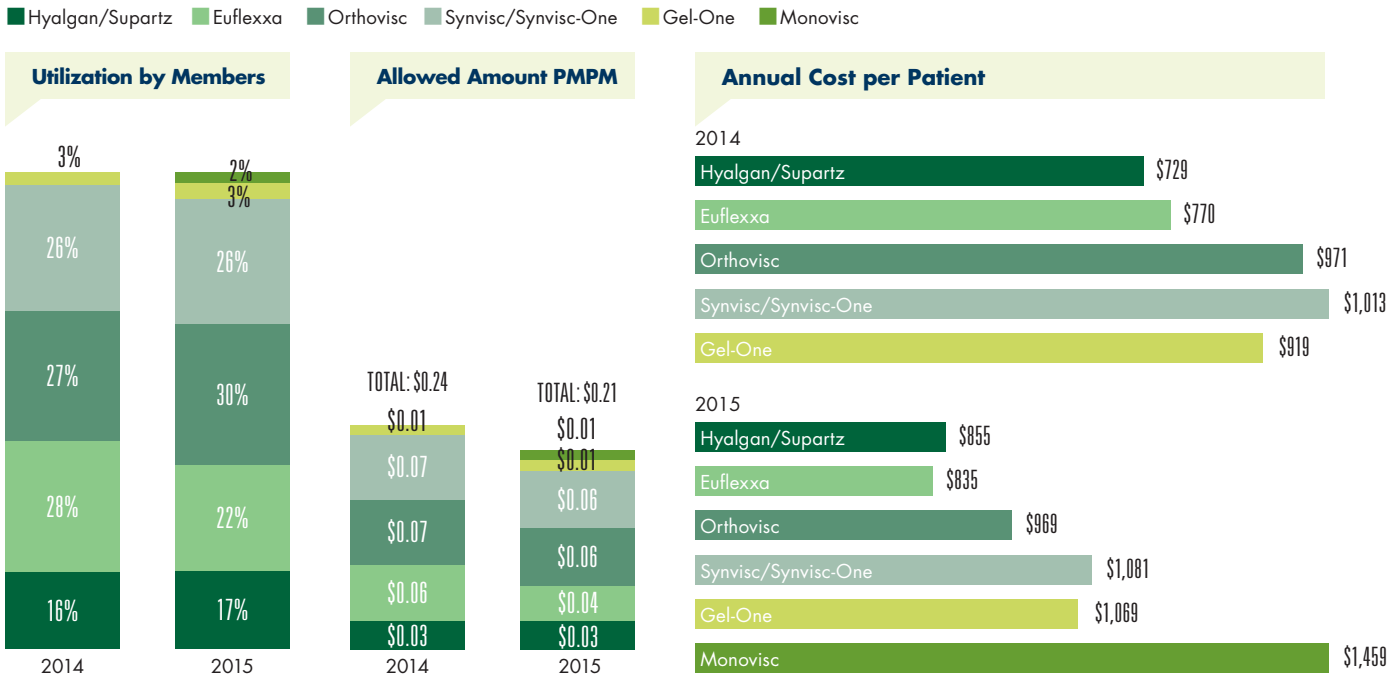
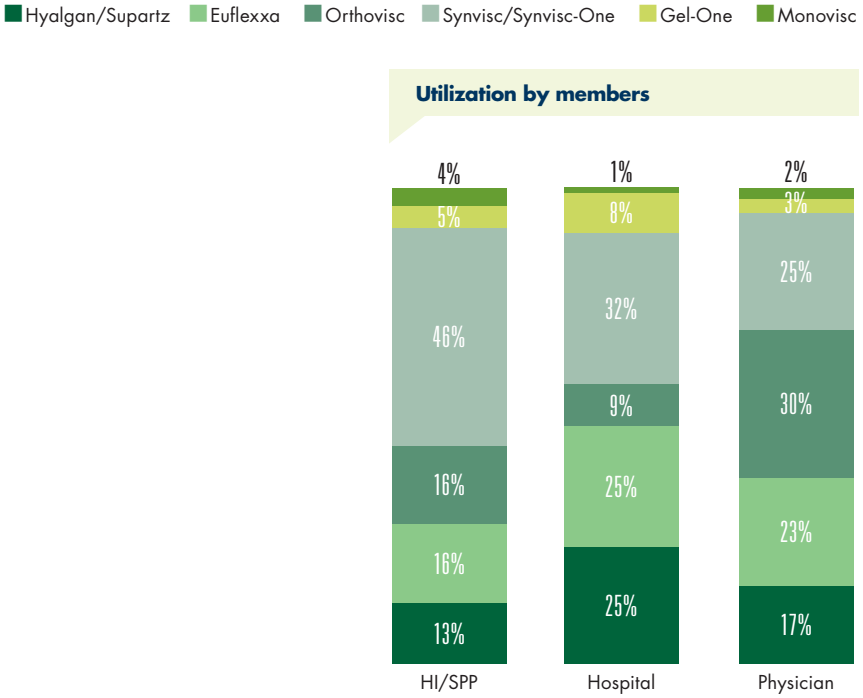


FIGURE 69

2015 Commercial Viscosupplementation Utilization by Site of Service



Please note that due to rounding, some column totals do not add up accurately.

FIGURE 70

Medicare Viscosupplementation Utilization, PMPM, and Annual Cost per Patient PMPM 2014-2015

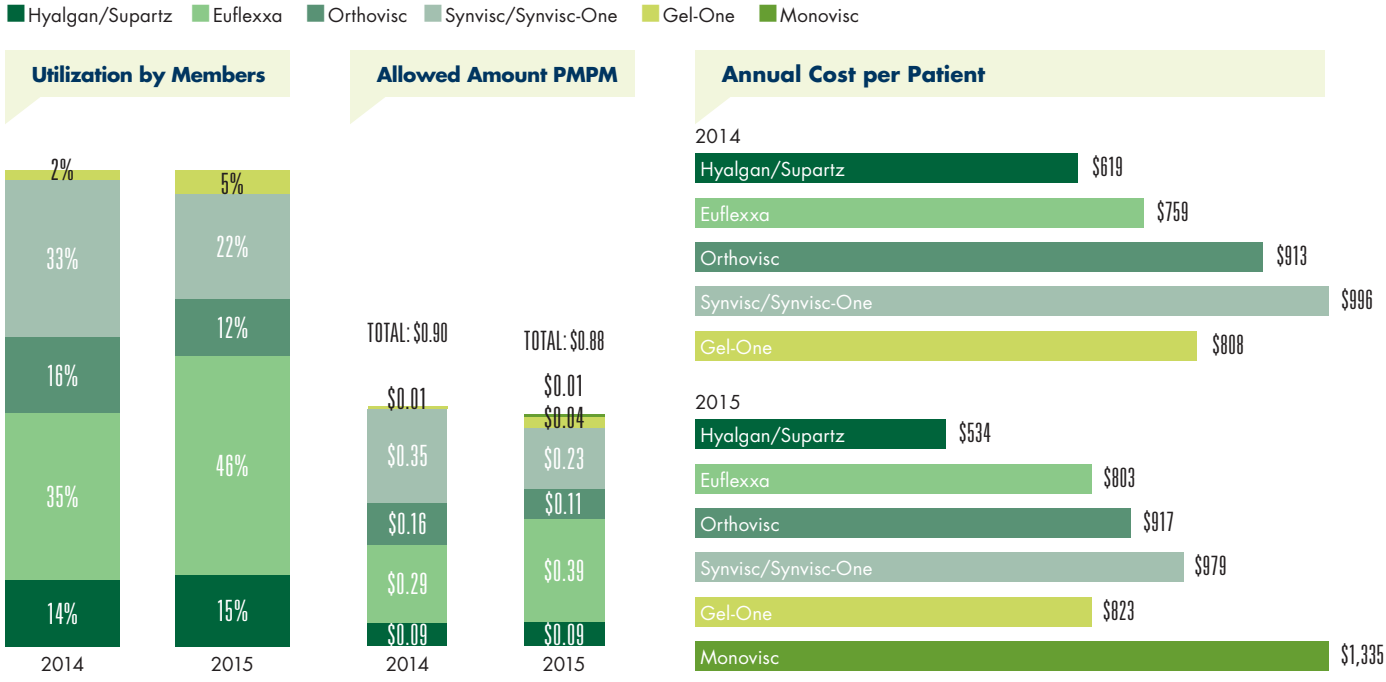
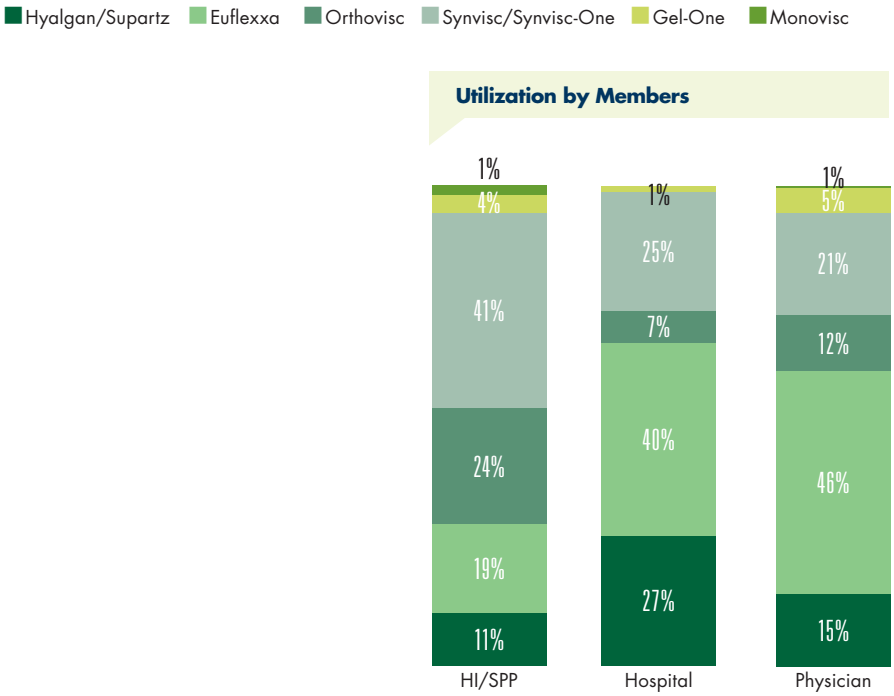


FIGURE 71

2015 Medicare Viscosupplementation Utilization by Site of Service



Please note that due to rounding, some column totals do not add up accurately.

Medical Benefit Drug Management

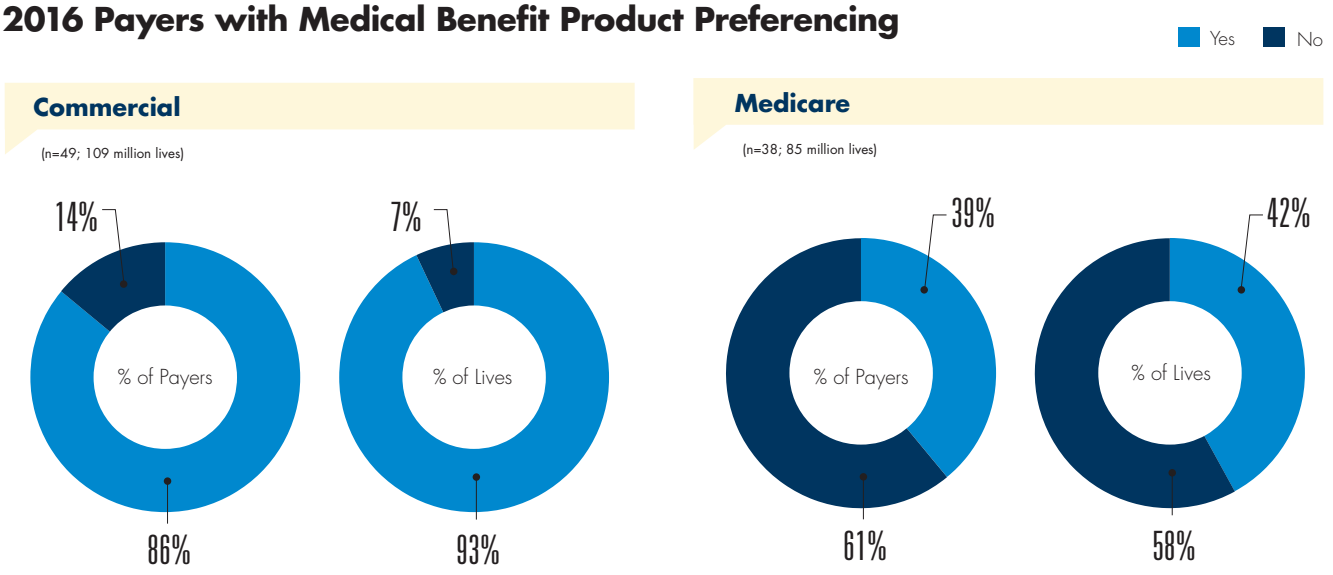
Controlling the cost of medical benefit drugs is a difficult task due to the ever-evolving landscape of specialty medications and continued influx of new drugs and indications. To control the costs of specialty drugs, in 2016, health plans implemented several methods of medical benefit drug management. Many of these methods mirrored that of the pharmacy benefit with step edits, prior authorization (PA), and rebating. Others differentiated themselves from the pharmacy benefit such as post-service, pre-payment claim edits (PSCE), clinical pathways, or care management programs. Commercial health plans were more easily able to preference products compared to Medicare.

Short of a drug formulary, health plans may preference a medical benefit product within a disease category through tools such as policy criteria, provider reimbursement, step edits, etcetera. In 2016, for commercial payers, 86 percent of health plans, which made up 93 percent of lives, had some form of product preferencing in place. For Medicare, product preferencing was less common. Only 39 percent of health plans, representing 42 percent of lives, engaged in product preferencing (**see figure 72**).

Product Preferencing

FIGURE 72

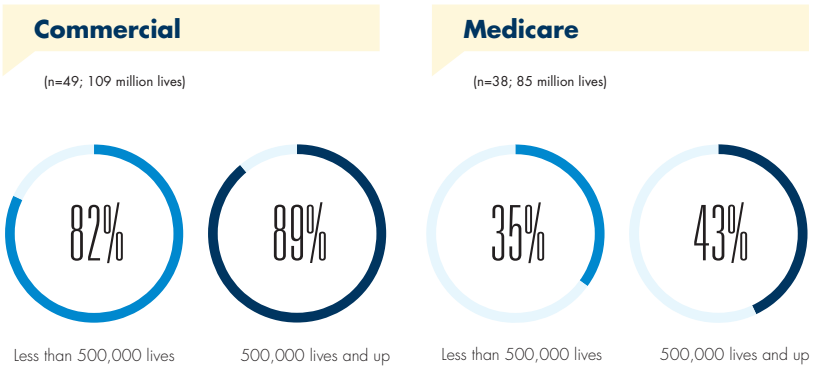
2016 Payers with Medical Benefit Product Preferencing



Plan size, regardless of line of business, was not as much of a factor in 2016 in the practice of product preferencing. In the commercial population, 82 percent of small (less than 500,000 lives) and 89 percent of large plans (more than 500,000 lives) engaged in this practice. In Medicare, there was a slight uptick in larger plans, but both segments were closely practiced in preferencing with 35 percent of small and 43 percent of large plans managing the benefit (**see figure 73**).

FIGURE 73

2016 Payers with Medical Benefit Product Preferencing by Plan Size (% of payers)

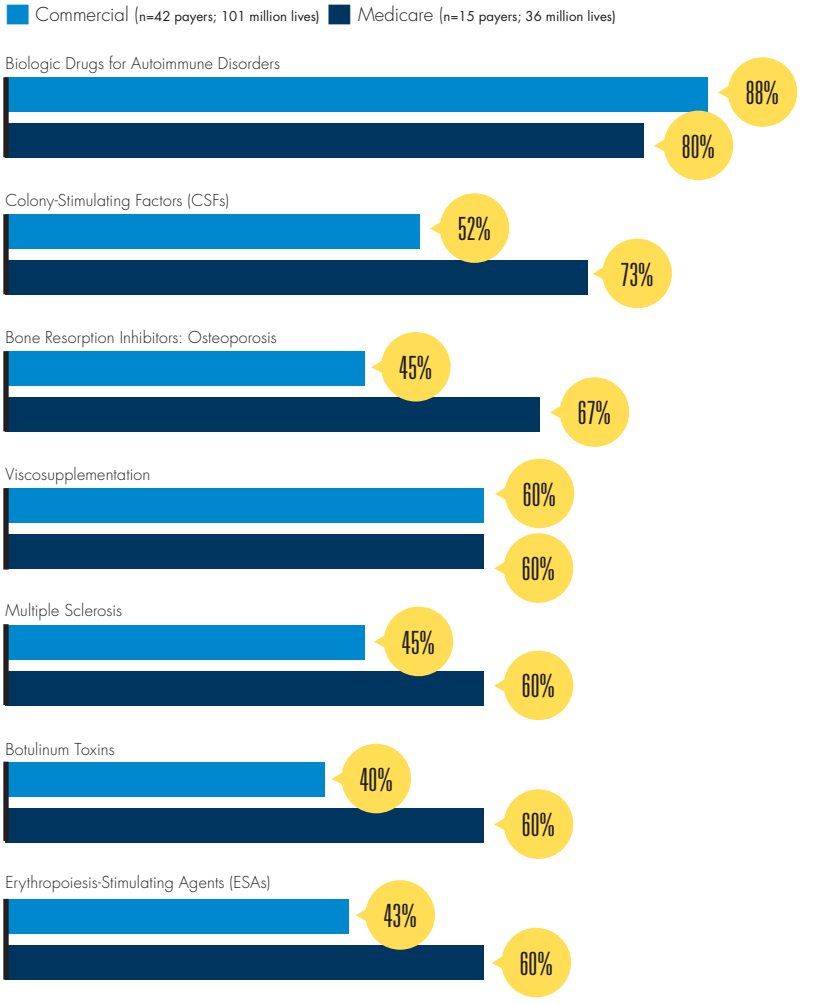


Across both commercial and Medicare payers, biologic drugs for autoimmune disorders were managed at the highest rates. Due to the breadth of this category and the introduction of a biosimilar for Remicade in 2016, health plans within commercial and Medicare lines of business were potentially able to control utilization of these drugs, and providers were able to choose lower cost options with similar results. Other top-five categories highly managed across both commercial and Medicare included colony-stimulating factors (52 percent in commercial and 73 percent in Medicare) and osteoporosis agents (45 percent in commercial and 67 percent in Medicare) (**see figure 74**).

Rounding out the top five for each line of business were viscosupplementation and multiple sclerosis in commercial, and botulinum toxins and erythropoiesis-stimulating agents (ESAs) in Medicare.

FIGURE 74

2016 Medical Benefit Top Disease States or Drug Categories With Product Preferencing



Utilization of Management Tools

Medical benefit product preferencing most often came in the form of prior authorization. Commercial payers indicated higher levels of management of the medical benefit with almost three-fourths (70 percent) of commercial payers versus little more than half (51 percent) of Medicare payers using prior authorization tools to manage the medical benefit, although it should be noted that 74 percent of respondents indicated they use the same management tools for Medicare as commercial (**see figure 75**).

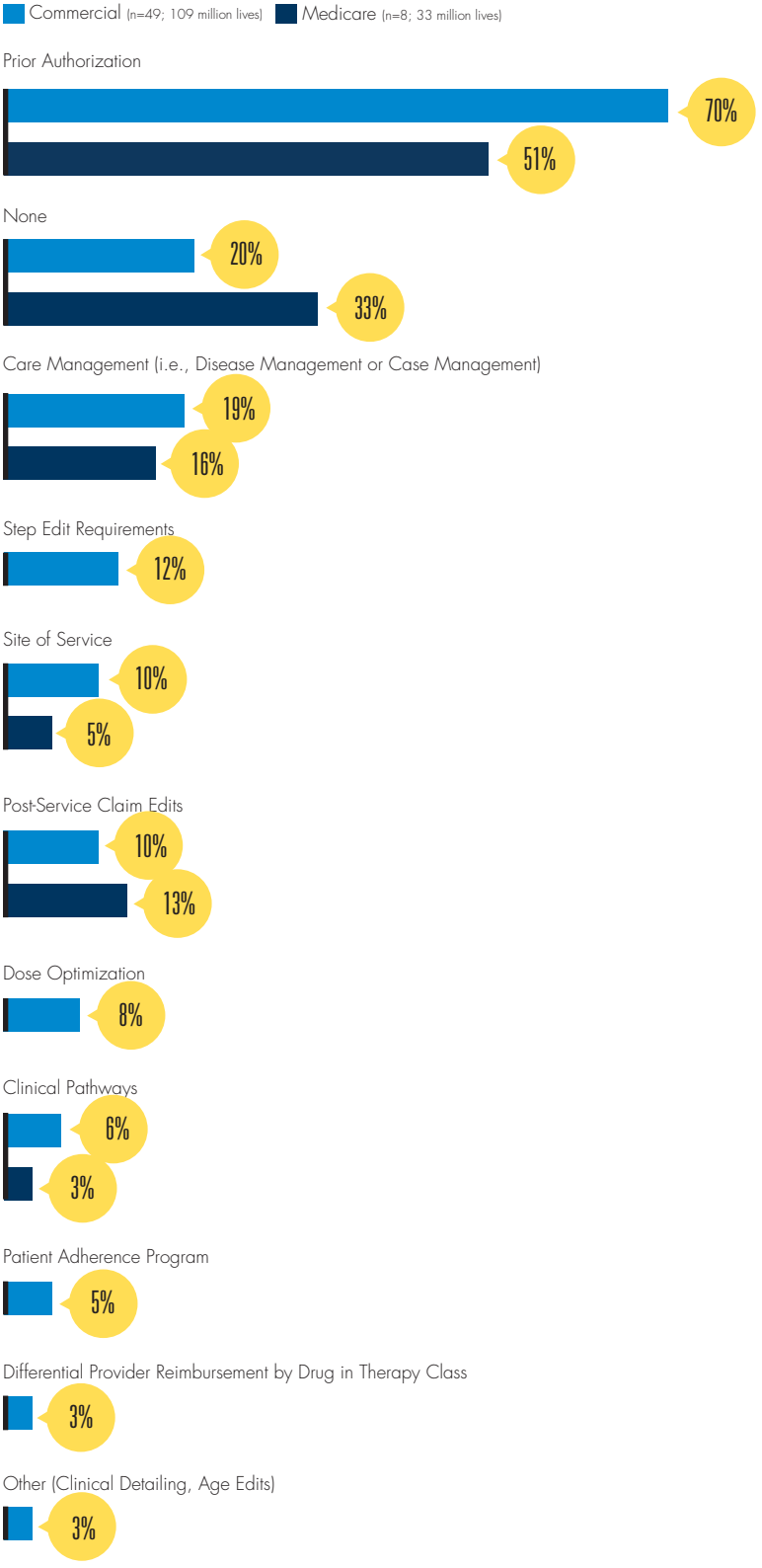
Even with the heavy use of prior authorization, some commercial payers take a "hands-off" approach to managing medical benefit drugs. Close to one-quarter (20 percent) of commercial payers used no management tools. For both commercial and Medicare payers, a secondary method of management was care/case management programs (19 percent and 16 percent, respectively). For those Medicare payers who did not use the same tools across the same disease states (n=8), use of claim edits occurred at a higher rate than in commercial.

20%

of commercial payers and 33% of Medicare payers did not use any management strategies for medical benefit drugs.

FIGURE 75

2016 Utilization Management Tools for Commercial and Medicare (% of payers)



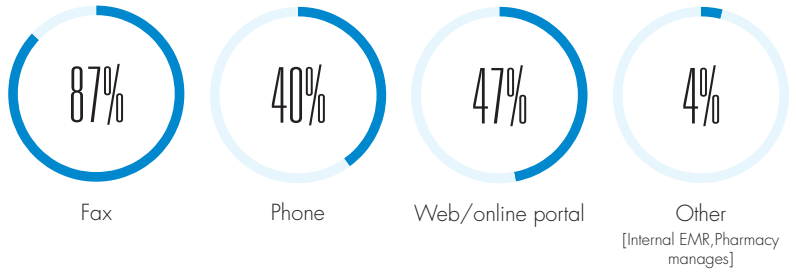
Prior Authorization and Post-Service Claim Edits

As indicated, two types of medical benefit management programs in use for medical pharmacy were prior authorization and post-service claim edits. Prior authorization occurs before the initiation of therapy, whereas post-service claim edits are an adjudication process occurring once the claim has been submitted. Over the last few years, web-based technologies have reshaped these approaches to be more-efficient cost-saving tools but they are still in transition. In 2016, 47 percent of payers took advantage of web-based online portals for their prior authorization programs but based on current practices, 87 percent of payers continued to accept faxed submissions (**see figure 76**).

FIGURE 76

2016 Prior Authorization Submission Types (% of payers)

(n=47; 10.3 million lives)



Payers most often (89 percent) made prior authorization coverage decisions by examining if the treatment met appropriate use conditions based on ICD-9 or ICD-10 diagnosis codes. Appropriate dosage was utilized with the same frequency at 89 percent. Almost equally important, 85 percent of payers required lab results while 83 percent required duration of therapy and the patient's history with previous therapies (**see figure 77**).

FIGURE 77

2016 Prior Authorization Submission Approval Criteria

(% of payers) (n=47; 99 million lives)

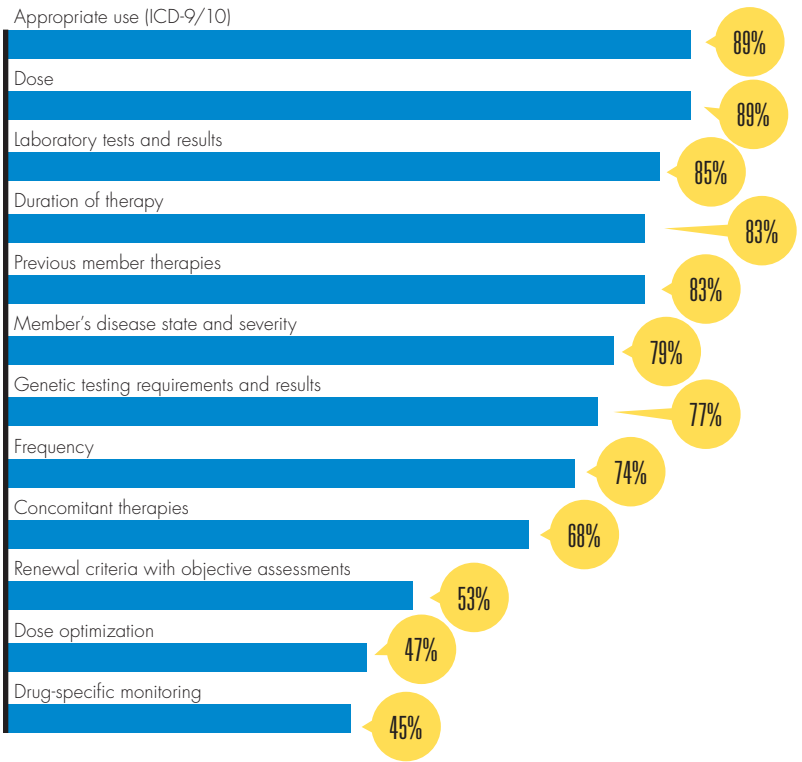


FIGURE 78

2016 Prior Authorization Denial Appeal Rate (% of payers)

(n=47; 99 million lives)

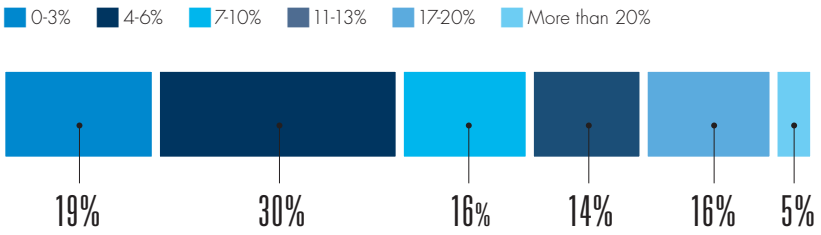
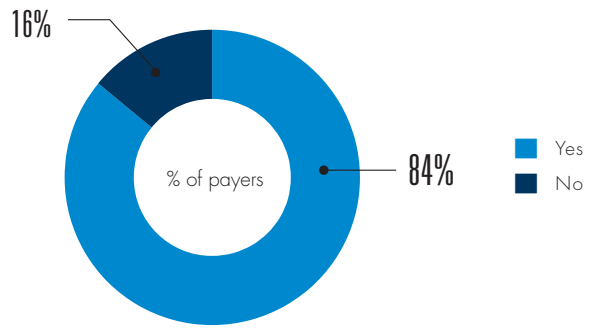


FIGURE 79

2016 Prior Authorization Submission Process and Timeline for Newly Released Medical Benefit Products

PA for Newly Released

(n=49; 109 million lives)



Payers indicated denial of a prior authorization results in appeal of that decision on average 9 percent of the time with 49 percent stating they have an appeal rate of 6 percent or less. Rarely (5 percent), health plans experienced an appeal rate higher than 20 percent (**see figure 78**).

Prior authorizations were not limited to existing therapies with classified HCPCS codes. Eighty-four percent of payers implemented a PA for newly released medical benefit drugs. This occured quickly for the majority of payers (56 percent) within 1 month of product launch (**see figure 79**).

When assessing post-service claim edits, 69 percent of payers evaluated the listed indication and 62 percent of payers evaluated claim to matching authorization when approving a claim. More than half of payers (54 percent) assured the dose and frequency matched, dose per day, and dose over time were accurate (**see figure 80**).

Although 53 percent of payer respondents representing both commercial and Medicare were unaware of the denial rate for post-service claim edits after criteria were reviewed, in total, 47 percent of payers indicated that, on average, 6.5 percent of claims are denied post submission (**see figure 81**).

As with prior authorizations, payers indicated that they would go through the process of a post-service claim edit with newly released medical benefit drugs, although at lower rates. Over one-third (39 percent) of payers performed a post-service claim edit on medical benefit drugs that did not have an assigned, classified J-code (**see figure 82**).

PA Implementation Time for Newly Released Drugs (% of payers)

(n=41; 71 million lives)

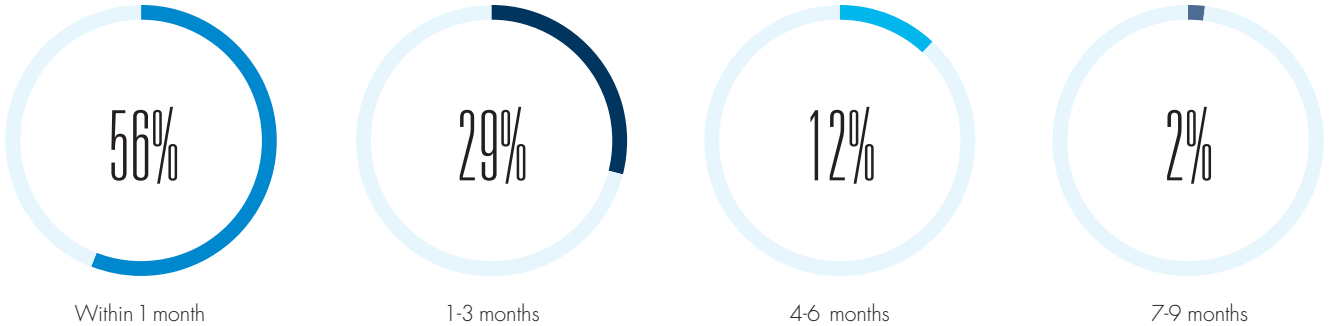


FIGURE 80

2016 Post-Service Claim Edits Reviewed Elements (% of payers) (n=13; 16 million lives)

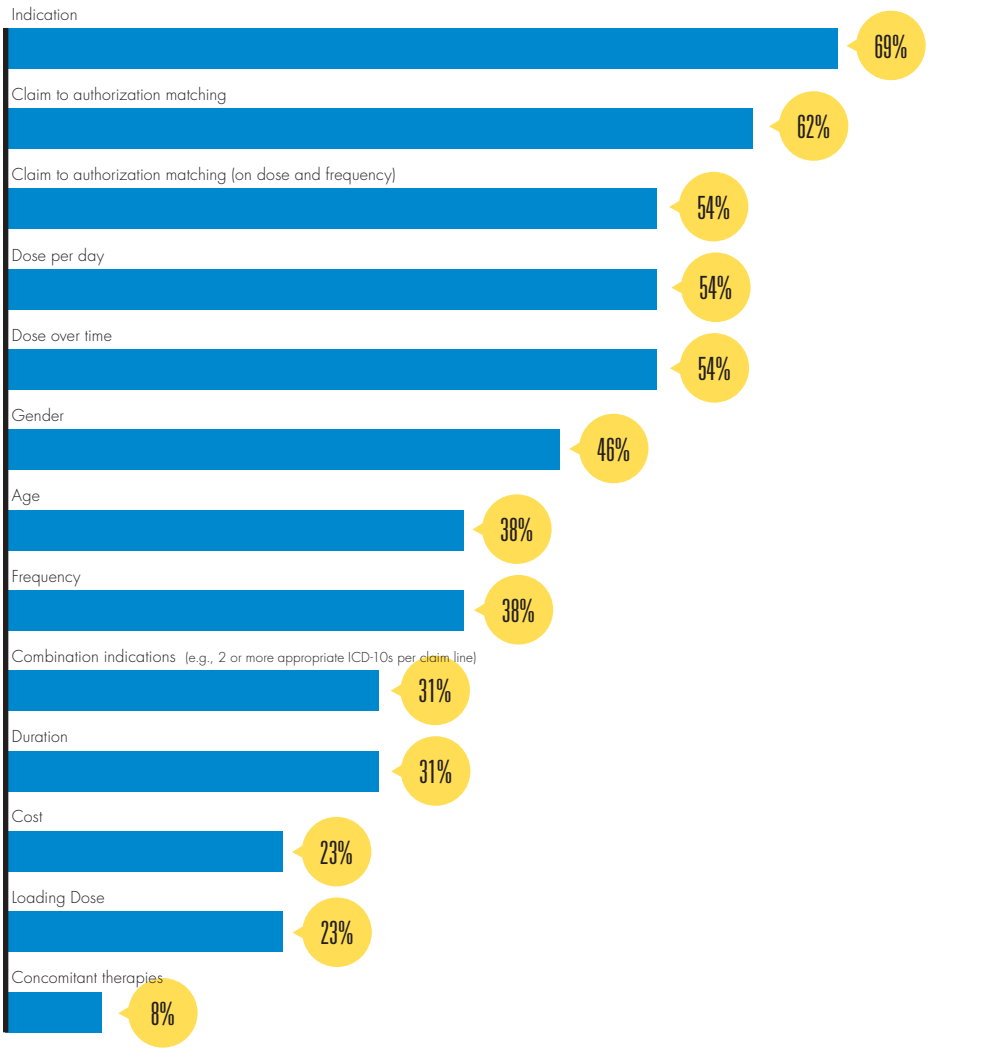


FIGURE 81

PSCE Net Denial Rate Commercial and Medicare (% of payers)

(n=13; 16 million lives)

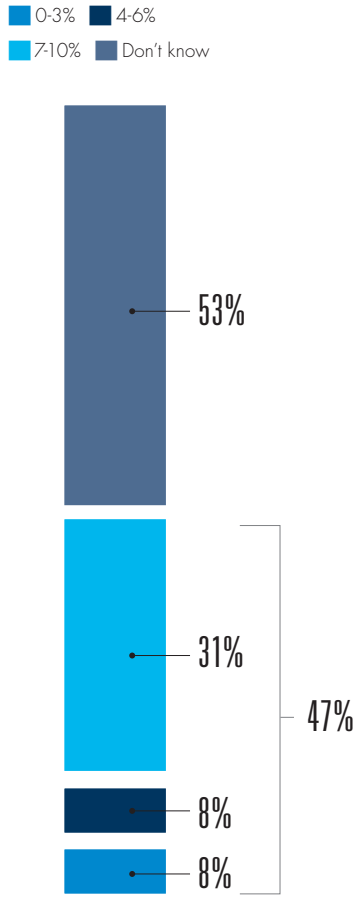
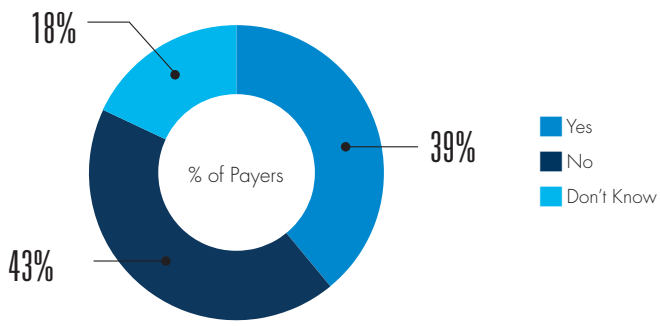


FIGURE 82

PSCE Performed on Newly Released Products

(n=49; 109 million lives)



31%

of payers had a 7-10% PSCE denial rate

Member Cost Share

Benefit Design

Payer management of medical benefit drugs includes member cost share for both commercial and Medicare. The majority of members were responsible for paying a coinsurance when obtaining their medical benefit treatment, but payers still utilized the copay model. In 2016, 51 percent of commercial payers required coinsurance to cover member cost share, an increase from 49 percent in 2015 and 46 percent in 2014. There was a slight decrease in payers requiring a copay from 34 percent in 2015 to 33 percent in 2016. Commercial payers have moved away from the option of no member cost share, decreasing this option by 9 percentage points (36 percent) since 2014. More than two-thirds of Medicare members (68 percent) are responsible for a coinsurance (**see figure 83**).

Total member cost share is not limited to a coinsurance or copay. Members are often responsible for a deductible that must be met before the payer starts remuneration. In total, taking into account coinsurance, copay, and deductible, members using a medical benefit drug paid 3 percent of total medical costs in commercial and 5 percent in Medicare (**see figure 84**).

51%

of commercial and 68% of Medicare payers required coinsurance in 2016

FIGURE 83

Medical Benefit Member Cost Share Type 2014-2016 (% of payers)

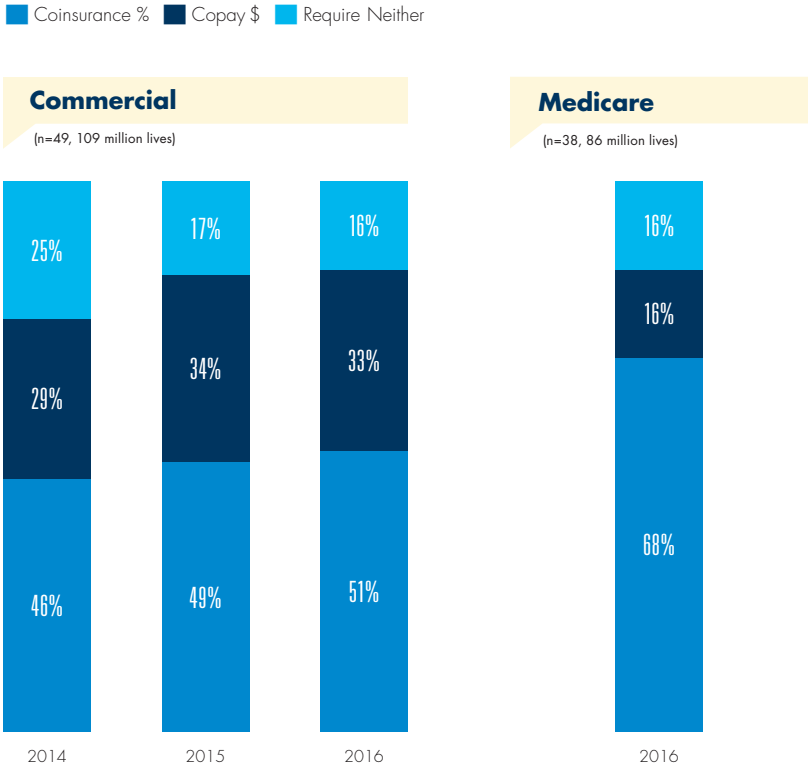
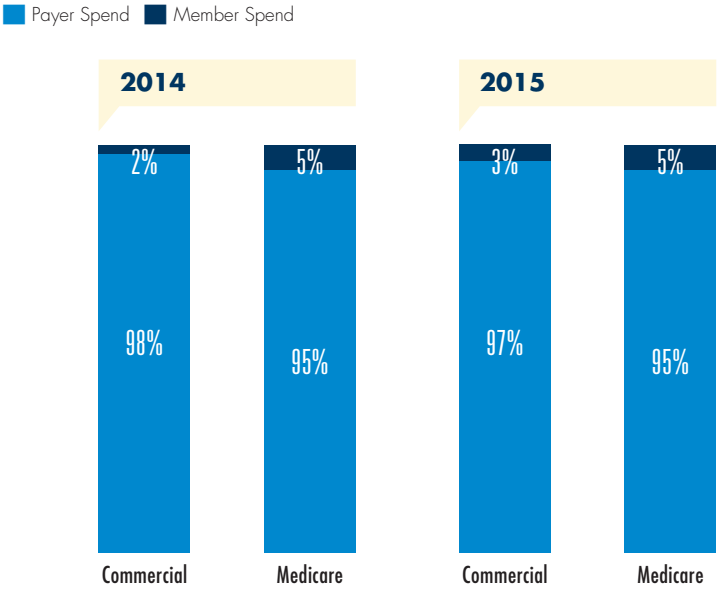


FIGURE 84

Medical Benefit Percentage of Spend for Member versus Payer 2014–2015



Aligning with payer survey responses, very little member responsibility is compromised from copays. For commercial, most member out-of-pocket spend occurs due to their deductible and coinsurance requirements. For Medicare Advantage plans, almost all member medical benefit drug expenses are from coinsurance requirements (**see figure 85**).

In addition to member cost share responsibility, narrowing of network providers was a potential cost-saving and quality-improvement strategy for payers. In 2016, this was not a strategy for the majority of payers with only one-quarter (25 percent) of health plans implementing a narrow network for their members. Of those who did not have this requirement in 2016, another quarter indicated that they planned to implement narrow networks within the next year (**see figure 86**).

FIGURE 85

2015 Member Cost Share Rates for Medical Benefit Drugs by Site of Service

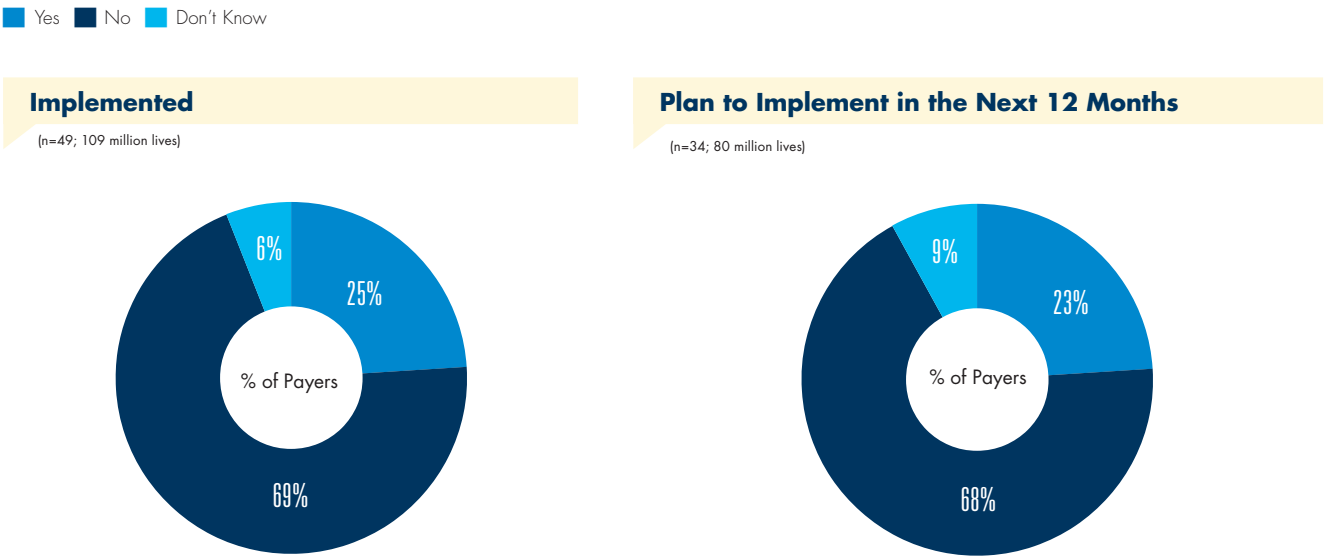
Commercial			
	COPAY PMPM	DEDUCTIBLE PMPM	COINSURANCE PMPM
HI/SPP	$0.00	$0.02	$0.04
HOSPITAL OP	$0.01	$0.10	$0.17
PHYSICIAN	$0.01	$0.16	$0.13
Total PMPM	$0.03	$0.28	$0.34

Medicare			
	COPAY PMPM	DEDUCTIBLE PMPM	COINSURANCE PMPM
HI/SPP	$0.00	$0.00	$0.07
HOSPITAL OP	$0.00	$0.01	$0.82
PHYSICIAN	$0.00	$0.03	$1.43
Total PMPM	$0.01	$0.04	$2.31

Please note that due to rounding, some column totals do not add up accurately.

FIGURE 86

Current and Anticipated Narrow Network Management Approach



Variable Member Cost Share

Although standard on the pharmacy benefit, payers do not typically vary member cost share requirements by drug to drive members to a preferred product under the medical benefit. Only 14 percent of payers varied cost share by drug. Even so, of the few payers engaging in this strategy, 57 percent experienced outcomes of more thoughtful prescribing and increased use of preferred drugs (**see figure 87**). For the 84 percent not engaging in this strategy, one-third (33 percent) knew their organization had the capability to implement variable cost share by drug.

More common, but still rare, was the payer's ability to vary cost share based on site of service (i.e., physician office, home via home infusion, and hospital outpatient facility). Close to one-quarter (24 percent) of payers varied member cost share based on the site of service. For those payers who did not vary cost share by provider type, or were unaware, more than half (51 percent) felt it was possible for their organization to undergo such a model (**see figure 88**). For payers who are varying by site of service, 75 percent cited outcomes including significant savings in IVIG home infusion and an overall increase in home infusion utilization.

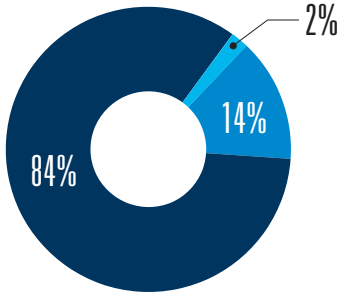
FIGURE 87

Landscape of Varying Cost Share by Drug (% of payers)

Yes No Don't Know

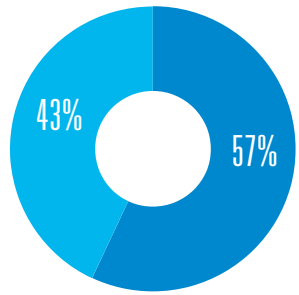
Varied Cost Share by Drug

(n=49; 109 million lives)



Experienced Outcomes

(n=7; 8 million lives)



Capability to Vary Cost Share by Drug

(n=42; 101 million lives)

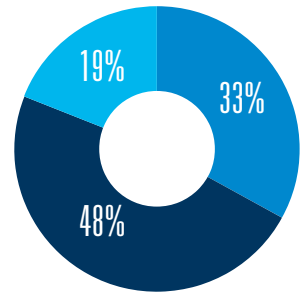


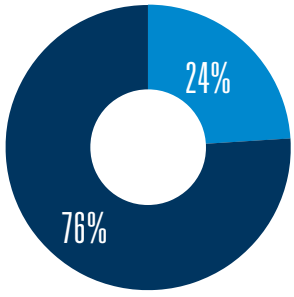
FIGURE 88

Landscape of Varying Cost Share by Site of Service (SOS) (% of payers)

Yes No Don't Know

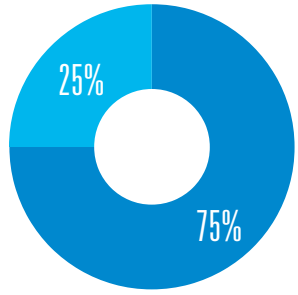
Varied Cost Share by SOS

(n=49; 109 million lives)



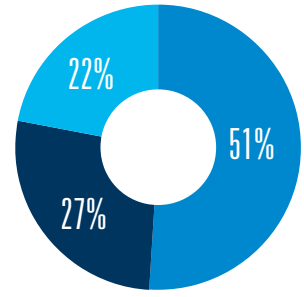
Experienced Outcomes

(n=12; 17 million lives)



Capability to Vary Cost Share by SOS

(n=37; 92 million lives)



Rebates

To complete the picture of medical benefit management, commercial rebates should also be considered. Overall, payers indicated a discount of 18 percent for most medical benefit drugs would be considered sufficient value to preference a product.

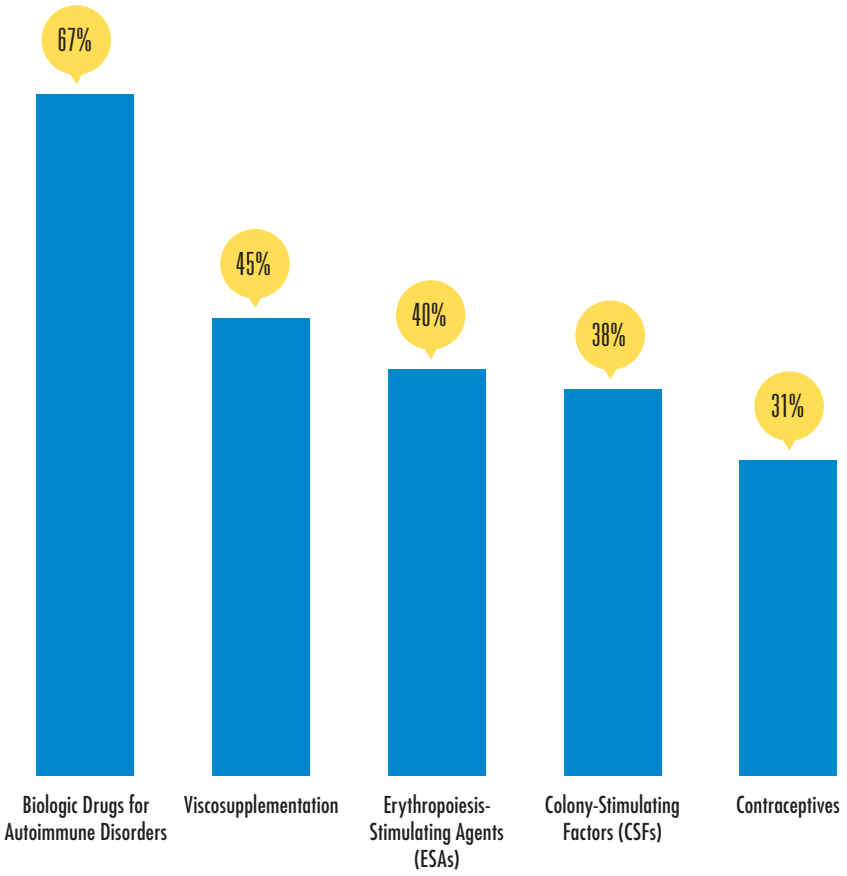
18% Average discount to consider preferring a medical benefit drug

When it comes to rebates, specifically by category, 67 percent of payers received a rebate for biologics used to treat autoimmune disorders. Less than half of payers received discounts for additional medical benefit drug categories, with discounts occurring most often within viscosupplementation, ESAs, CSFs, and contraceptives categories. For the remaining categories detailed in the appendix, one-quarter (26 percent) or less received rebates for a given category (**see figure 89 and appendix figure A32**).

FIGURE 89

Top Five Medical Benefit Rebated Categories (% of payers)

(n=49 payers; 109 million lives)



Medical Benefit Provider Landscape

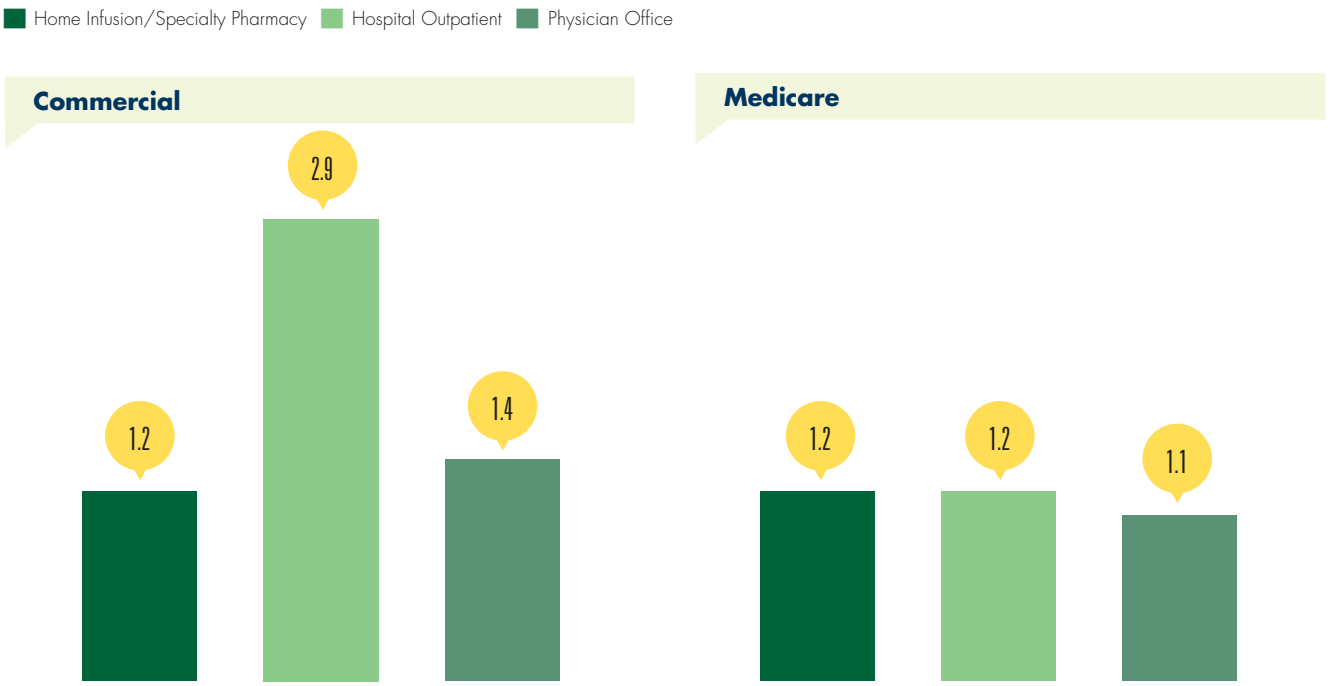
Our review of the medical benefit provider landscape includes all outpatient sites of service. Dependent on the treatment category or administration, each site of service can be the lowest cost option, but overall the hospital outpatient setting is typically the highest cost setting for administration of medical benefit drugs. Consistent with previous years' reports, we continue to see a trend of care shifting away from the physician office setting and toward hospital outpatient facilities. There are several reasons why this may be occurring including practice consolidation, decreased reimbursement to physician offices, and large health systems continuing to expand and acquire provider groups and services.

In 2015, as illustrated earlier in figures 3 and 4, 52 percent of commercial members received their provider-administered injectable or infused drug in the hospital outpatient setting, accounting for 52 percent of the overall spend. Higher trend in hospital outpatient drug spend is evidenced in the index to ASP (statistical measure of ASP change) by site of service. ASP index is two times higher in the hospital outpatient setting at 2.9 than in the physician office setting at 1.4 (**see figure 90**).

For Medicare, figures 3 and 4 show 74 percent of Medicare members received their provider-administered injectable or infused drug in the physician office setting, with their spend in that setting of 55 percent. The shift in utilization in the hospital outpatient setting, where 23 percent of members received care, was up from 17 percent in 2014. This shift has smaller spend consequences, however, as the index to ASP in Medicare is close to equal across all sites of service.

FIGURE 90

2015 Medical Pharmacy Index to ASP



Provider Reimbursement — Commercial

Reimbursement across these sites of service varies based on payer pricing structure and other industry practices. Typically, physician offices and home infusion sites are reimbursed under an ASP plus X percent methodology usually closely related to the Medicare allowable (ASP plus 6 percent). Specialty pharmacies are typically reimbursed under an AWP minus a discount model, and hospital outpatient facilities are typically reimbursed via percent of charges. The 2016 payer survey reflected the continuity of these reimbursement models.

In the physician office setting, 62 percent of covered lives were reimbursed under an ASP plus markup model. Although the markup varies from payer to payer, the weighted markup was in line with the Medicare allowable at 7 percent. While 23 percent of payers' covered lives were under an AWP minus model, the weighted rate was a discount of 15 percent most commonly; and the few payers (1 percent) who reimbursed under a percent of charges model, on average, reimbursed at a weighted 61 percent of the charges. Other reimbursement models, reflected across all sites of service, included capitated, ASP minus a discount, or a combination of both ASP and AWP models assumingly based on the drug (**see figure 91**).

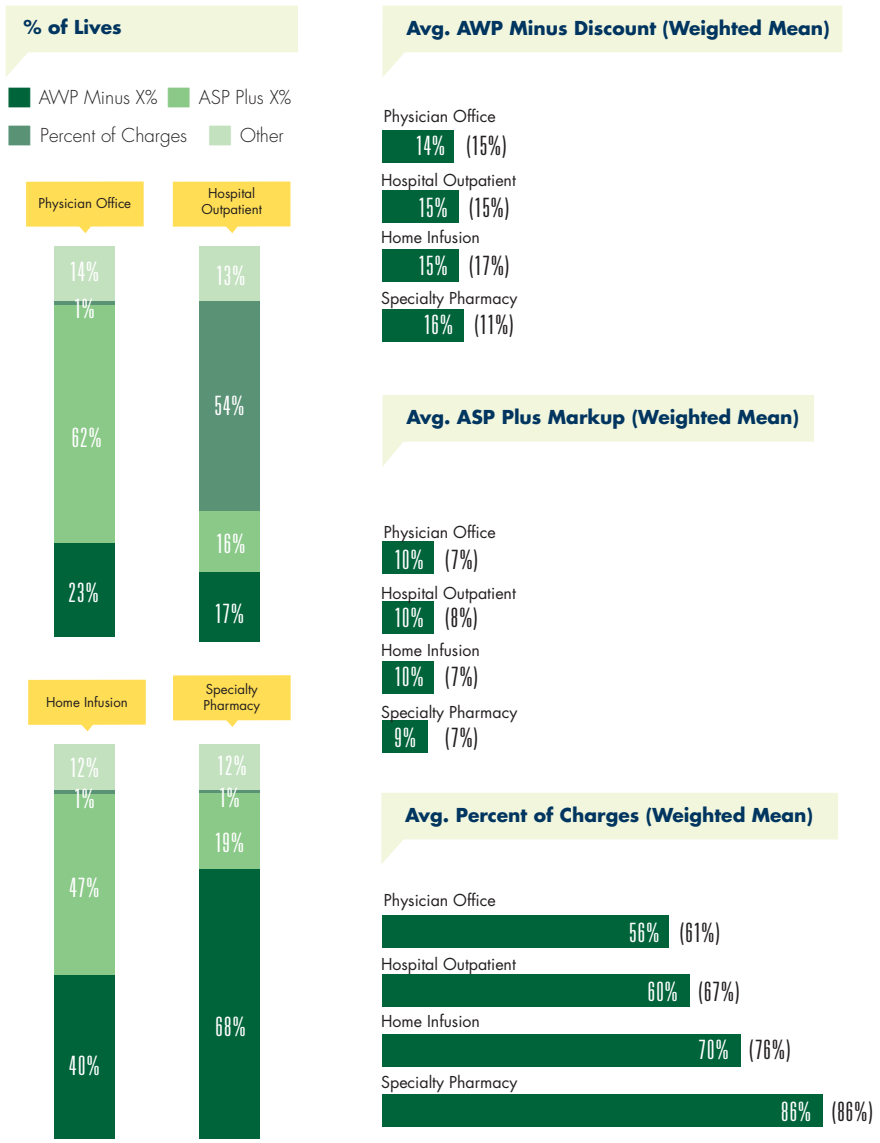
In the hospital outpatient setting, 54 percent of covered lives had their services reimbursed under a percent of charges model. This was down from 63 percent in 2015. The weighted percent of charges rate was slightly higher than that of the physician office at 67 percent. Although 13 percent of covered lives were under other reimbursement models, 17 percent were under an AWP minus and 16 percent were under an ASP plus model. The weighted percent discount averaged 15 percent, exactly that of the physician office; and the weighted ASP plus rate was higher than that of the physician office and the Medicare allowable at 8 percent (**see figure 91**).

In the home infusion setting, the model was more evenly split between AWP minus and ASP plus at 40 percent and 47 percent, respectively. For the rarely used percent of charges model, the weighted percent averaged 76 percent, much higher than either the hospital outpatient or physician office setting (**see figure 91**).

In the specialty pharmacy setting, the majority of covered lives (68 percent) were under an AWP minus model with an average weighted discount of 11 percent. Similar to the physician office setting, the 19 percent of covered lives under the ASP plus model averaged a weighted percent markup of 7 percent (**see figure 91**).

FIGURE 91

2016 Commercial Reimbursement Methodology (n=49 payers; 109 million lives)



Provider Reimbursement — Medicare

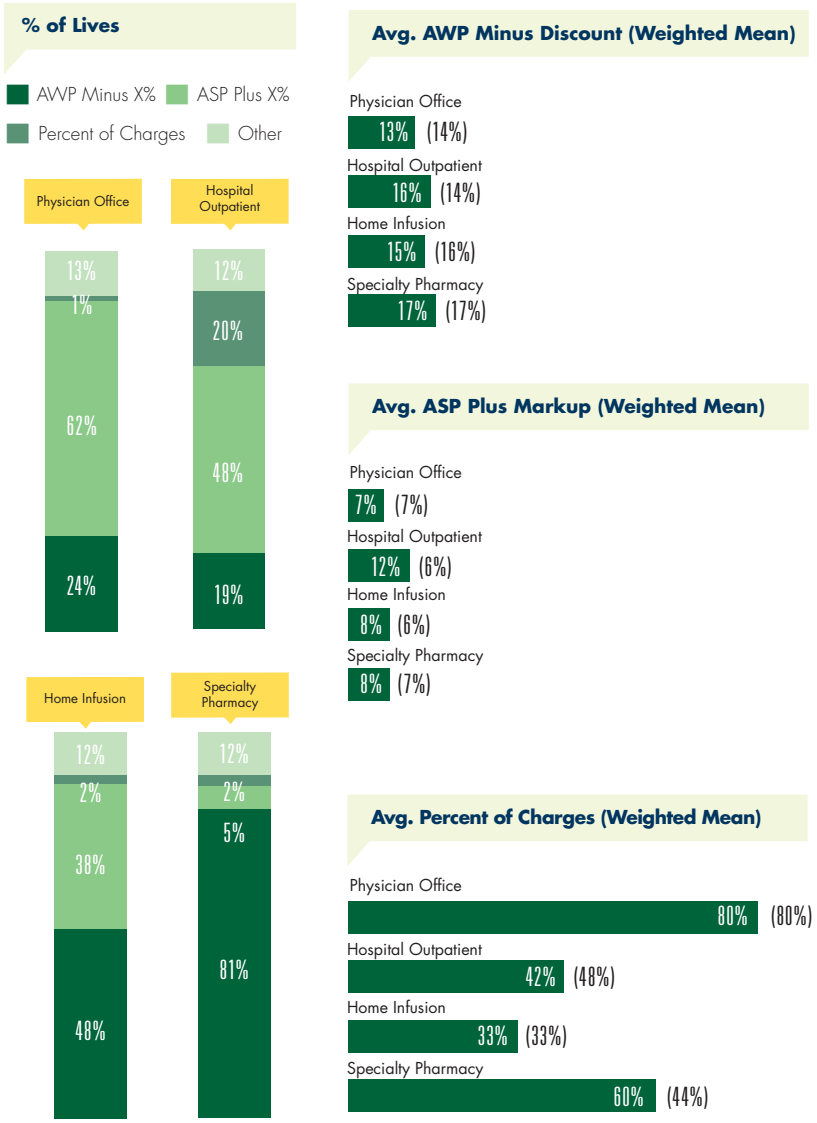
Although Medicare Advantage medical benefit lives are subject to rate fluctuation similar to commercial lives, Centers for Medicare and Medicaid Services (CMS) rules regarding Medicare allowable rates often dictated the reimbursement model and level across all sites of service. Medicare reimbursement in the physician office and hospital settings were more often an ASP plus model. Payers more often chose an AWP minus discount in the home infusion and specialty pharmacy settings.

Again, consistent with CMS Medicare reimbursement rules, the average weighted reimbursement was close to ASP plus 6 percent across all sites of service. (**see figure 92**).

FIGURE 92

2016 Medicare Reimbursement Methodology

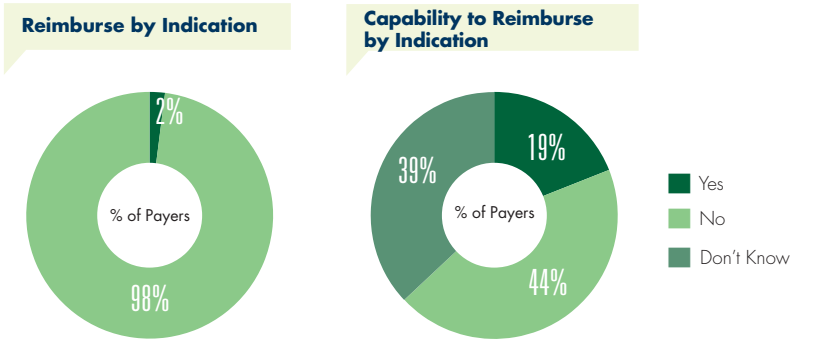
(n=38 payers; 85 million lives)



Although possible as technology progresses and more biosimilars emerge in the market, payers did not reimburse by indication. Only 2 percent of payers reimbursed medical benefit drugs by indication with 19 percent of payers having the capability to implement this form of reimbursement (**see figure 93**).

FIGURE 93

Reimbursement by Indication (% of payers)



Administrative Code Reimbursement

Medical pharmacy provider reimbursement consists of drug reimbursement as well as the cost to administer the drug. In commercial and Medicare, the most costly administration was the administration of intravenous chemotherapy infusion for up to one hour. (**see figures 94 and 95**). For medical benefit drug administration, the hospital outpatient setting was again typically the most costly. For chemotherapy administration, the PMPM and unit cost in the hospital outpatient was more than double that of the physician office. Unit cost in the hospital outpatient setting was overall higher than in the physician office (**See appendix A33 thru A35 for full chart**).

FIGURE 94

2015 Top Five Commercial Administrative Codes by Allowed Amount PMPM and Unit Cost

		ALLOWED AMOUNT PMPM			UNIT COST	
CPT CODE	CPT DESCRIPTION	HOSPITAL OUTPATIENT	PHYSICIAN OFFICE	TOTAL PMPM	HOSPITAL OUTPATIENT	PHYSICIAN OFFICE
96413	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug	$0.60	$0.24	$0.85	$608.58	$209.78
96375	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); each additional sequential intravenous push of a new substance/drug	$0.34	$0.03	$0.37	$142.03	$35.28
96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour	$0.33	$0.08	$0.41	$402.48	$91.76
96374	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); intravenous push, single or initial substance/drug	$0.24	$0.01	$0.26	$209.35	$75.85
96361	Intravenous infusion, hydration; each additional hour	$0.21	$0.01	$0.21	$114.98	$22.46

Due to rounding to the nearest cent, the Total PMPM coulumn may not add up accurately.

FIGURE 95

2015 Top Five Medicare Administrative Codes by Allowed Amount PMPM and Unit Cost

		ALLOWED AMOUNT PMPM			UNIT COST	
CPT CODE	CPT DESCRIPTION	HOSPITAL OUTPATIENT	PHYSICIAN OFFICE	TOTAL PMPM	HOSPITAL OUTPATIENT	PHYSICIAN OFFICE
96413	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug	$0.87	$0.37	$1.23	$295.33	$146.09
96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour	$0.34	$0.09	$0.43	$179.82	$72.24
96372	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular	$0.17	$0.23	$0.40	$52.62	$24.23
96367	Intravenous infusion,for therapy, prophylaxis, or diagnosis (specify substance or drug); additional sequentialinfusion of a new drug/substance, up to 1 hour	$0.15	$0.09	$0.25	$55.52	$31.58
96375	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); each additional sequential intravenous push of a new substance/drug	$0.14	$0.05	$0.18	$40.99	$22.72

Due to rounding to the nearest cent, the Total PMPM coulumn may not add up accurately.

Biosimilar Reimbursement Strategy

As of January 2017, two biosimilars were available on the market. Payers started to implement strategies to reimburse the use of current biosimilars and biosimilars not yet on the market. Close to one-quarter of payers (24 percent), representing 31 percent of lives, had a defined biosimilar strategy in 2016. Of the payers with a current biosimilar strategy, 25 percent used an ASP plus markup model or a comparable drug profit to reference product. At the lives level, closer to half (46 percent) of lives were settled under a model that reimbursed based on comparable drug profit to the reference product (**see figures 96 and 97**).

FIGURE 96

2016 Defined Biosimilar Strategy

(n=49; 109 million covered lives)

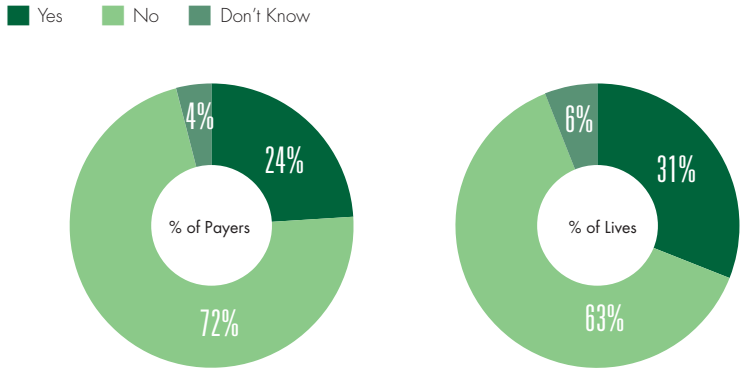
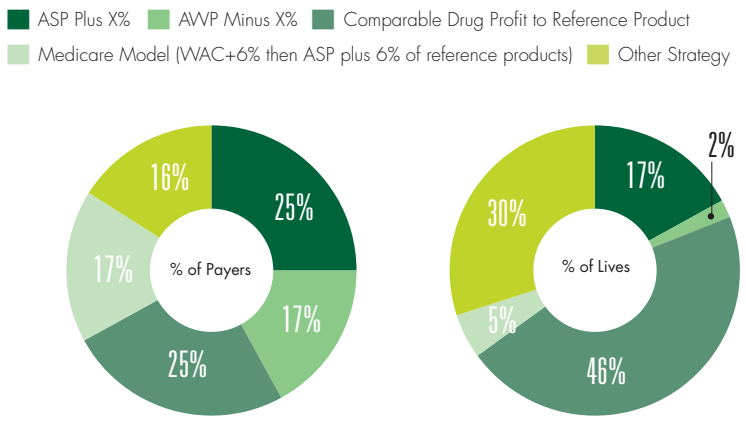


FIGURE 97

2016 Biosimilar Reimbursement Methodology

(n=12; 33 million covered lives)

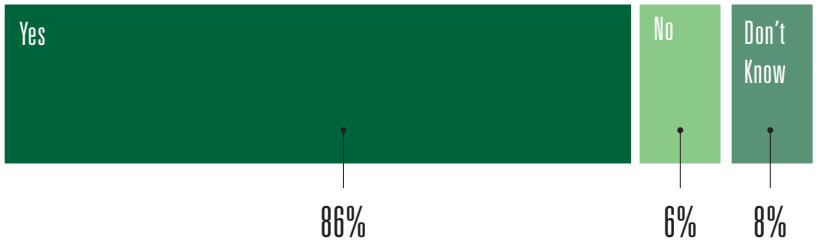


The majority of payers (86 percent) indicated that if a biosimilar was available and had the same FDA-labeled indication as the reference drug, they would consider preferring the product whether the FDA deemed it interchangeable or not (**see figure 98**).

FIGURE 98

2016 Biosimilar Interchangeability (% of payers)

(n=49; 109 million covered lives)



Alternative Payment Models

With the advent of the Oncology Care Model (OCM) to reduce the cost of specialty drugs, payers continued to implement alternative payment models to manage this spend. On average, 24 percent of a payer's provider network utilized alternative payment models in their practices (**see figure 99**).

Although 46 percent of payers indicated it was too early in the process to understand any savings they may have experienced from alternative payment models, 40 percent of payers indicated they had experienced some level of savings from the use of alternative payment models (**see figure 100**).

In 2016, 43 percent of payers had not yet implemented any type of alternative payment models, although one-third (33 percent) implemented bundled payments or value based contracting models for their providers (**see figure 101**).

FIGURE 99

Average Percent of Providers Using Alternative Payment Models

(n=28; 66 million lives)

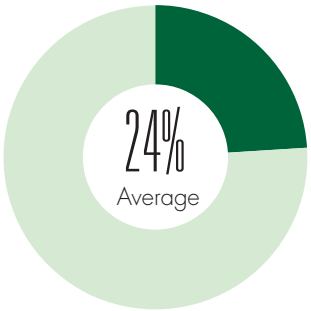


FIGURE 100

Savings From Alternative Payment Models Implemented in the Last 12 Months (% of payers)

(n=28; 66 million lives)

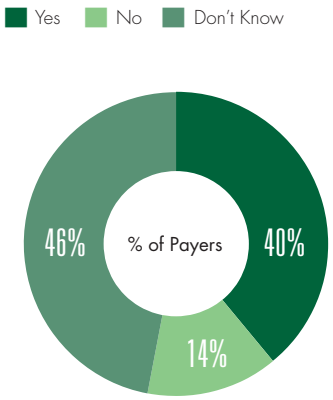
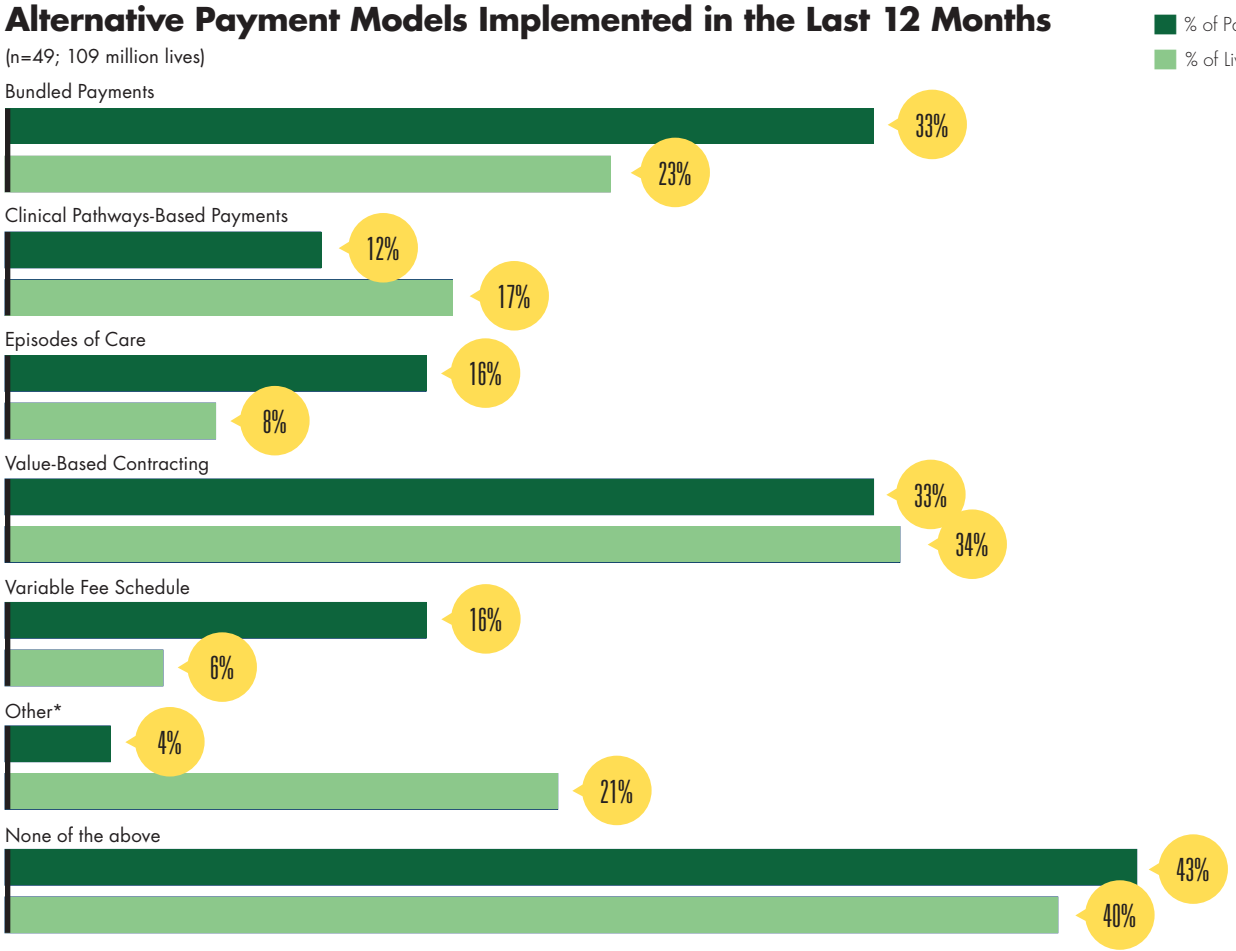


FIGURE 101

Alternative Payment Models Implemented in the Last 12 Months

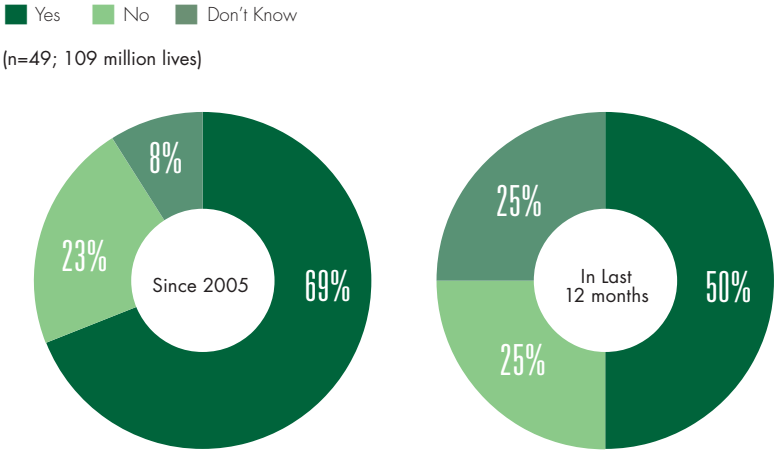
(n=49; 109 million lives)



*Risk-based payments for total cost of care performance; capitation

FIGURE 102

Office Based Practices in Payer's Network Purchased by Hospital Systems (% of payers)



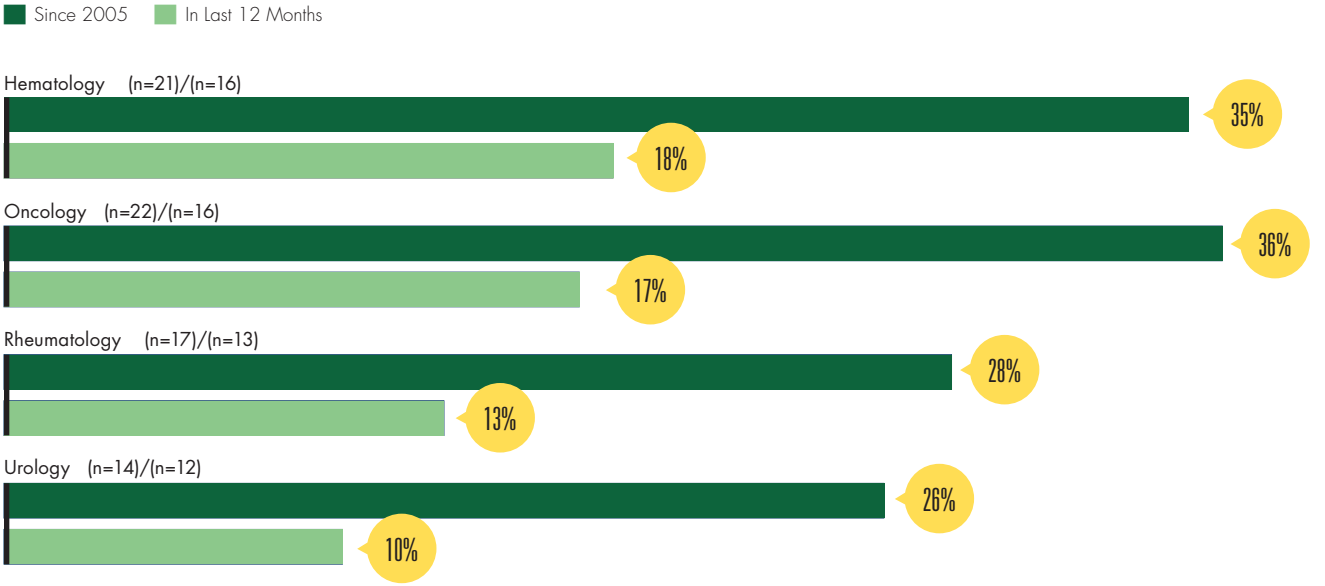
Hospital Acquisitions of Office-Based Practices

More than 10 years since the implementation of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), 50 percent of payers were still seeing the purchase of practices by hospital systems. This number was down from the overall previous 10 years, when 69 percent of payers indicated office-based purchases by hospitals (**see figure 102**).

Payers indicated that since 2005, 36 percent of their network oncology practices, and 35 percent of their network hematology practices, had been purchased by hospitals. Closer to one-quarter of rheumatology and urology practices, 28 percent and 26 percent, respectively, were purchased since 2005. More hematology practices within a provider network were purchased over the last year than oncology practices, 18 versus 17 percent (**see figure 103**).

FIGURE 103

Percentage of Office-Based Practices Purchased by Hospital Systems (% of lives)



Oncology Landscape

One-third (35 percent) of commercial payers had oncology specific medical benefit programs. The most common management strategy in 2015 was prior authorization, with 82 percent of payers reporting this as a strategy they used. The second most common, at 41 percent, was a clinical pathways program (**see figure 104**).

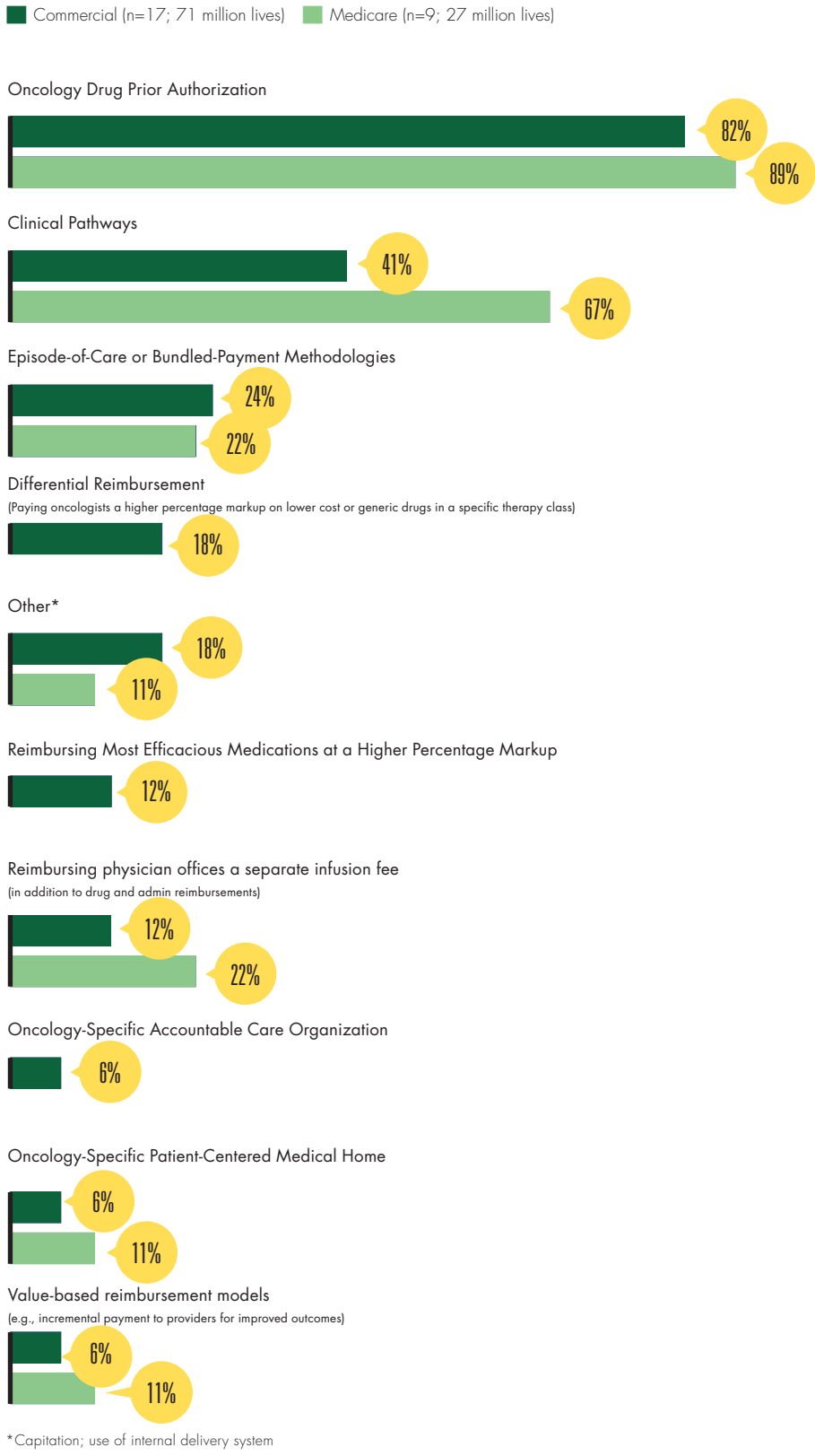
Close to one-quarter (24 percent) of payers with Medicare lives provided oncology specific medical benefit programs. For the few payers providing these programs, 89 percent had an oncology prior authorization program and 67 percent had a clinical pathways program (**see figure 104**).

35% of commercial payers had oncology specific programs.

24% of medicare payers had oncology specific programs.

FIGURE 104

2016 Oncology-Specific Pilot Programs Initiated by Payers (% of payers)



*Capitation; use of internal delivery system

Health Information Data

New for 2016, we asked payers if they were planning to increase the use and collection of National Drug Code (NDC) data over the next 12 to 18 months for medical benefit drugs. Close to two-thirds (64 percent) planned to capture NDC data and more than one-quarter (28 percent) planned to report utilization data (**see figure 105**).

In 2016, 57 percent of payers also had providers collecting and sharing quality and outcomes data from their medical records (**see figure 106**). For those whose providers were collecting and sharing this data, 29 percent were able to implement changes based on the outcomes data they were given (**see figure 107**).

FIGURE 105

NDC Data Collection in the Next 12-18 Months (% of payers)

(n=25; 45 million lives)

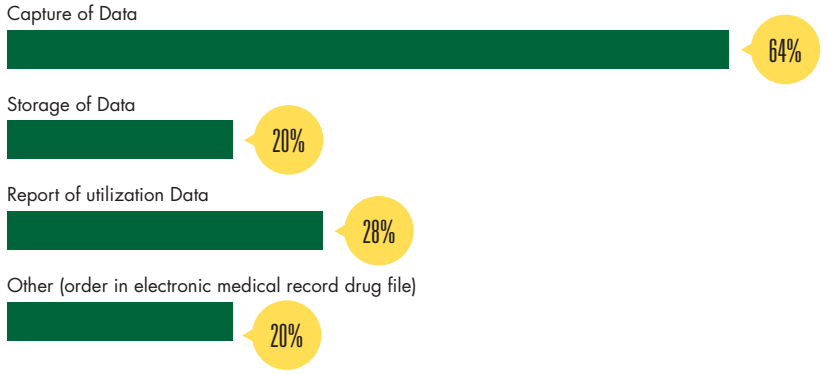


FIGURE 106

Network Provider Sharing of Quality and Outcomes Data (% of payers)

(n=49; 109 million lives)

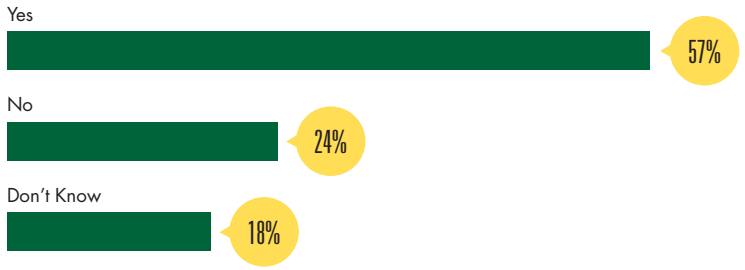
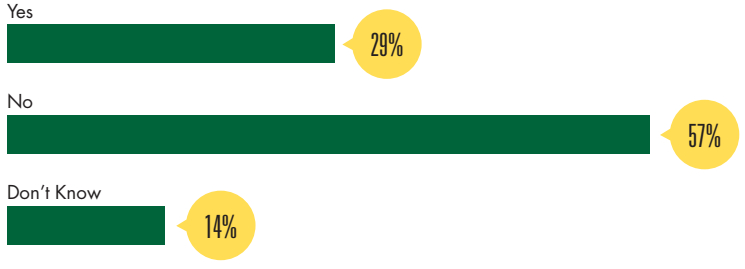


FIGURE 107

Network Provider Changes Based on Outcomes Data

(% of payers)

(n=28; 62 million lives)



For your convenience, a downloadable PDF version of this 2016 Magellan Rx Medical Pharmacy Trend Report as well as previous reports and other Magellan Rx publications are available at **magellanrx.com**.

Medical Benefit Drug Pipeline

2016 Drug Approvals

In 2016, 13 new medical pharmacy drugs were approved, including four oncology/oncology support agents and three agents for the treatment of hemophilia, most of which allowed for a decreased number and frequency of infusions. Pediatric and rare diseases are another area which is evolving. Exondys 51 was the first agent approved to treat Duchenne muscular dystrophy, and Spinraza was the first approved drug for Spinal Muscular Atrophy (SMA). In 2016, Inflectra was the first monoclonal antibody(mAb) and infused biosimilar to be approved by the FDA for the treatment of autoimmune diseases (**see figure 108**).

FIGURE 108

Medical Benefit Drugs Approved in 2016

BRAND NAME	GENERIC NAME	APPROVAL DATE	ROUTE OF ADMINISTRATION	INDICATION	DISEASE STATE PREVALENCE	ESTIMATED COST (AWP)	COMMENT
Idelvion	albutrepenonacog alfa	3/4/2016	IV Infusion	Hemophilia B	Estimated 5,000 cases in the U.S.	Variable by weight; approximately $450,000 to $500,000 annually	Orphan drug designation. Long acting recombinant Factor IX.
Evomela	melphalan	3/10/2016	IV Infusion	Multiple Myeloma (MM) in patients who cannot tolerate oral therapy	Estimated 30,330 new cases of MM were forecasted to be diagnosed (17,900 in men and 12,430 in women) in 2016.	Estimated $15,500 annually	Orphan drug designation for its use as a high-dose conditioning regimen for MM patients undergoing autologous stem cell transplantation. This is the first approved new formulation of melphalan since its initial approval in 1964.
Kovaltry	octocog alfa	3/17/2016	IV Infusion	Hemophilia A	Estimated 15,000 cases in the U.S.	Variable by weight and dosage; annual cost range for adult dosage is $185,000 to $555,000.	Also sold as Iblias in some markets. Offers twice to three-times weekly dosing.
Cinqair	reslizumab	3/23/2016	IV Infusion	Add-on maintenance treatment of patients with severe asthma in adults 18 and older and with eosinophilic phenotype	22.6 million Americans with asthma. 20% comprises severe cases and up to half of the severe cases are eosinophilic subtypes.	Estimated $28,860 annually	Humanized interleukin-5 antagonist monoclonal antibody.
Defitelio	defibrotide sodium	3/30/2016	IV Infusion	Hepatic veno-occlusive disease (VOD) with renal or pulmonary dysfunction following hematopoietic stem cell transplantation (HSCT)	Mean prevalence of hepatic VOD after HSCT estimated at 14% (rates ranging from 5% to 60%)	Estimated cost for 21 days of therapy is $208,000; max of 60 days estimated cost is $594,000.	Potentially curative treatment. Previously no approved options for hepatic VOD.
Inflectra	infliximab-dyyb (Remicade biosimilar Hospira)	4/5/2016	IV Infusion	Crohn's disease, ulcerative colitis, RA, ankylosing spondylitis, PsA, plaque psoriasis	Varies	Approximately $35,000 to $50,000 annually	First monoclonal antibody biosimilar approved; second biosimilar approved in the U.S. Not approved as interchangeable product. Boxed warning regarding risk of serious infections and malignancy.
Tecentriq	atezolizumab	5/18/2016	IV Infusion	Locally advanced or metastatic urothelial carcinoma (bladder cancer). Additional approval 10/16 for metastatic NSCLC.	There are over 580,000 Americans with bladder cancer in the U.S., with 77,000 new cases estimated in 2016. Urothelial carcinoma accounts for 90% of all bladder cancers.	Approximately $150,000 annually	Granted breakthrough therapy designation, priority review, and accelerated approval. First and only PD-L1 inhibitor approved. Also subsequently approved for metastatic NSCLC.
Afstyla	antihemophilic Factor VIII (recombinant) single chain, or rVIII – single chain	5/26/2016	IV Infusion	Hemophilia A	Estimated 15,000 cases in the U.S.	Variable by patient weight. Approximately $330,000 to $1.2 million annually	First single-chain product for hemophilia A specifically designed for extended dosing (two to three times weekly).
Sustol	granisetron	8/10/2016	SQ Injection	Chemotherapy-induced nausea/ vomiting	Occurs in up to 80% of chemotherapy patients	Approximately $600 per 10 mg syringe	First extended release 5-HT3 antagonist, maintaining therapeutic levels for ≥5 days. Health-provider administered.
Cuvitru	immune globulin SQ (human) 20% solution	9/14/2016	SQ Infusion	Primary immunodeficiency	Estimated 38.9 to 50.5 per 100,000 in the U.S.; 6 million worldwide	Approximately $77,500 to $155,000 annually	SQ infusion only. Approved in adults and children ≥2 yo. Formulation allows for fewer infusion sites and shorter infusion durations compared to conventional SQ IG treatments.
Exondys 51	eteplirsen	9/19/2016	IV Infusion	Duchenne muscular dystrophy (DMD) with confirmed mutation of dystrophin gene amenable to exon 51 skipping	Affects 1 out of 3,600 male infants worldwide; approx. 2,000 patients in US	Approximately $300,000 annually	Priority review and fast track/orphan designations. Clinical benefit has not been established, and continued approval is contingent upon verification of clinical benefit in further trials.
Lartruvo	olaratumab	10/19/2016	IV Infusion	Soft tissue sarcoma (STS)	Estimated 12,310 new cases of STS in 2016	Approximately $109,000 per six months	Accelerated approval, orphan drug designation, fast track designation, breakthrough therapy designation, and priority review. Phase III confirmatory study in progress.
Spinraza	nusinersen	12/23/16	IV Infusion	Spinal Muscular Atrophy (SMA)	Affects 1 in 10,000 live births in the U.S. Approximately 9,000 patients in the U.S.	Approximately $750,000 for year one and $375,000 for subsequent years of therapy	SMA is the leading heritable cause of infant mortality. First drug approved to treat children and adults with SMA. Fast track designation, priority review, and orphan drug designation.

List above may not be inclusive of all new medical specialty drug approvals in 2016; based on varying specialty definitions and date of update.

Medical Benefit Pipeline

A large portion of the new therapies in the medical pharmacy pipeline are agents with unique mechanisms of action to treat cancer. Immunotherapies, including the checkpoint inhibitors of the programmed cell death protein 1 (PD1) and programmed death-ligand 1 (PD-L1) inhibitors, continued to be approved and approved for expanded indications. In 2016, they were approved for six additional indications beyond their original FDA approvals. These agents are being studied individually and in numerous different combinations with each other and other chemotherapies to treat a variety of cancers including multiple myeloma, breast, pancreatic, ovarian, hepatocellular carcinoma, non-small cell lung cancer, renal cell carcinoma, lymphoma, bladder cancer, and head and neck cancer.

On the horizon, moving into 2018 and beyond, the adoptive cell transfer (ACT) therapies are thought to be revolutionary. The majority of these agents are currently in Phase I trials and research is continuing. Utilizing chimeric antigen receptor (CAR) T cell therapies that can target the CD19 antigen could become the standard of care for many lymphomas and leukemias including acute lymphoblastic leukemia (ALL) and chronic lymphocytic leukemia (CLL). Treatments using these engineered immune cells have generated preliminary responses in patients with advanced cancers and have proven to be an area to watch for rapid advancement.

The category of autoimmune disorders saw the first approval of a biosimilar to Remicade with Inflectra in 2016, although it experienced a delay in market launch of several months. There is another biosimilar to Remicade in the pipeline for 2017. There are also several other biosimilar hematologic agents expected for approval in 2017 with biosimilars for Neupogen, Neulasta, and Epogen/Procrit.

There are several orphan agents in the pipeline for pediatric and rare disease states that have been identified as breakthrough therapies and received fast track designation by the FDA. This allows for expedited development and review of these agents due to the serious conditions they treat and to fill an unmet medical need (**see figure 109**).

FIGURE 109

Medical Benefit Pipeline

THERAPEUTIC CATEGORY	DRUG	MECHANISM OF ACTION	INDICATION	ROUTE OF ADMINISTRATION	DISEASE STATE PREVALENCE	EXPECTED APPROVAL	ADDITIONAL COMMENTS
Alzheimer's Disease	solanezumab	Amyloid beta protein inhibitor	Alzheimer's Disease	IV infusion	5.4 million Americans	2018	Did not meet its desired end point from EXPEDITION-3
Autoimmune Disorders	infliximab	TNF-alpha inhibitor	RA, Crohn's, UC, ankylosing spondylitis, PsA, plaque psoriasis	IV infusion	Varies by disease state	4Q 2017	Second biosimilar to Remicade (Samsung Bioepis with Merck)
Hematological	N9-GP nonacog beta pegol	Coagulation Factor IX (Recombinant)	Hemophilia B	IV infusion	Estimated 5,000 cases in the U.S.	5/16/2017	Long-acting Factor IX
Hematological	epoetin alfa (Retacrit)	Erythropoiesis-stimulating agent (ESA)	Treatment of anemia	IV infusion/SQ injection	Varies with cause	2H 2017	Biosimilar to Epogen/Procrit (Pfizer)
Hematological	pegfilgrastim	Granulocyte colony-stimulating factor	Treatment of neutropenia	SQ injection	Varies with cause	2017	Biosimilar to Neulasta (Apotex)
Hematological	filgrastim (Grastofil)	Granulocyte colony-stimulating factor	Treatment of neutropenia	SQ injection	Varies with cause	2017	Biosimilar to Neupogen (Apotex)
Hematological	pegfilgrastim	Granulocyte colony-stimulating factor	Treatment of neutropenia	SQ injection	Varies with cause	June 2017	Second biosimilar to Neulasta (Coherus)
HIV	Remune	HIV vaccine	Human Immunodeficiency Virus (HIV)-1	Intramuscular injection	Estimated 1.2 million cases in the U.S.	2017	First-in-class rescue vaccine
Immune Globulin	Intravenous immune globulin (RI-002)	Immunoglobulin	Primary immunodeficiency (PI)	IV infusion	Estimated 38.9 to 50.5 per 100,000 in the U.S.; six million worldwide	Delayed	ADMA Biologics' specialty plasma-derived IVIG. Contains polyclonal antibodies and RSV antibodies.
Multiple Sclerosis	ocrelizumab (Ocrevus)	CD20 antibody	Primary progressive and relapsing multiple sclerosis	IV infusion	Approximately 400,000 Americans with MS; relapsing MS is the most common form of MS – 85% of cases. Primary progressive MS is diagnosed in 10% of MS patients at onset.	3/28/2017	Fast track and breakthrough therapy designations
Oncology	axalimogene filolisbac, or AXAL	Immunotherapy	Cervical cancer	Intramuscular injection	7.5 new cases per 100,000 women per year. Estimated 248,920 women with cervical cancer in 2013.	TBD	Orphan drug designation for invasive cervical cancer, head and neck cancer, and anal cancer – all in Phase III. Fast track designation for cervical cancer. Listeria monocytogenes vaccine used to elicit immune response against cancer.

FIGURE 109, CONTINUED

Medical Benefit Pipeline, cont.

THERAPEUTIC CATEGORY	DRUG	MECHANISM OF ACTION	INDICATION	ROUTE OF ADMINISTRATION	DISEASE STATE PREVALENCE	EXPECTED APPROVAL	ADDITIONAL COMMENTS
Oncology	lutetium Lu 177 dotate (Lutathera)	Lu-177-labeled somatostatin analogue peptide	Gastroenteropancreatic neuroendocrine tumors (GEP-NETs)	IV infusion	Incidence of 3.65 per 100,000 individuals per year	Delayed	Part of emerging form of treatments called peptide receptor radionuclide therapy (PRRT). Orphan drug and fast track designations.
Oncology	durvalumab	Programmed death ligand-1(PD-L1) inhibitor	Squamous cell carcinoma of the head and neck (SCCHN)	IV infusion	Estimated 62,000 individuals will develop head and neck cancer each year.	TBD	Fast track designation for SCCHN. In Phase III trials for NSCLC with expected filing in 2017. Also in trials for gastric, pancreatic, and bladder cancers and in multiple combinations.
Oncology	inotuzumab ozogamicin	Anti-cluster of differentiation 22 (CD22) antibody	Acute lymphocytic leukemia (ALL)	IV infusion	1.7 new cases per 100,000 individuals annually. Estimated 78,000 Americans with ALL in the U.S. in 2013.	TBD	Breakthrough therapy designation
Oncology	TT10 EB-VST	Immunomodulator	Nasopharyngeal cancer	IV infusion	Less than one case per 100,000 each year. In 2015, estimated new 3,200 cases in the U.S.	TBD	Orphan/fast track designation. Virus-driven cancer T-cell therapy —Epstein-Barr virus specific T cells
Oncology	copanlisib	Phosphoinositide 3-kinase (PI3K) inhibitor	Non-Hodgkin lymphoma (NHL)	IV infusion	19.5 per 100,000 individuals annually. Estimated 570,000 people with NHL in the U.S. in 2013.	TBD	Orphan drug designation for follicular lymphoma, a histologic subtype of NHL
Oncology	avelumab	Programmed death ligand-1(PD-L1) inhibitor	Non-small cell lung cancer (NSCLC)	IV infusion	Over 188,000 NSCLC patients diagnosed each year	TBD	In Phase III trials for NSCLC, renal cell carcinoma, and gastric, bladder, and ovarian cancers. Breakthrough therapy designation for metastatic Merkel cell carcinoma (MCC), currently in Phase II.
Oncology	imetelstat	Telomerase inhibitor	Myelodysplastic Syndrome (MDS)	IV infusion	Incidence of 3-4 cases per 100,000 per year; 30 cases per 100,000 per year in pts > 70. Estimated 10-15K new cases diagnosed annually in the U.S.	TBD	Orphan drug designation
Oncology	aldoxorubicin	Albumin-binding cytotoxic agent	Soft tissue sarcoma	IV infusion	Estimated 12,310 new cases will be diagnosed in 2016.	TBD	Phase III trial conducted under a special protocol assessment (SPA)
Oncology	volasertib	Polo-like kinase-1 (Plk1) inhibitor	Acute myeloid leukemia (AML)	IV infusion/Oral	Estimated 19,950 new cases of AML in the U.S. in 2016.	TBD	Orphan/breakthrough therapy designation. Currently in phase III clinical trials for previously untreated AML ineligible for intensive remission induction therapy.
Oncology	rilimogene galvacirepvec	Immunotherapy	Prostate cancer	SQ injection	129.4 per 100,000 men annually. Estimated 2.8M men with prostate cancer in the U.S. in 2013.	TBD	Fast track designation
Oncology	eltrapuldencel-T	Autologous dendritic cell therapy	Melanoma	SQ injection	21.8 new cases per 100,000 individuals per year. Estimated 1.03 million people with melanoma in the U.S.	TBD	Fast track and orphan drug designations
Oncology	aglatimagene besadenovec (ProstAtak)	Immunomodulator	Prostate cancer	Trans-rectal ultrasound-guided injection	129.4 per 100,000 men annually. Estimated 2.8 million men with prostate cancer in the U.S. in 2013.	TBD	In Phase III trial with valacyclovir for newly diagnosed prostate cancer. Orphan drug designation. Trial conducted under a special protocol assessment (SPA) agreement with the FDA.
Rare Diseases	cerliponase alfa (Brineura)	Enzyme replacement therapy	Late-infantile neuronal ceroid lipofuscinosis (CLN2) disease, a form of Batten Disease	Intracerebro-ventricular injection	Affects two to four of every 100,000 live births in the U.S.	4/27/2017	Priority review, orphan drug designation, and breakthrough therapy designation
Rare Diseases	edaravone (Radicava)	Neuroprotective agent	Amyotrophic Lateral Sclerosis (ALS)	IV infusion	Estimated 3.9 cases per 100,000 people in the U.S.	6/16/2017	Orphan drug designation
Viscosupplementation	sodium hyaluronate; triamcinolone hexacetonide (Cingal)	Hyaluronic acid; corticosteroid	Osteoarthritis of the knee	Intra-articular injection	An estimated 30.8 million adults had osteoarthritis from 2008 to 2011; symptomatic knee OA occurs in 10 percent of men and 13 percent of women aged 60 years or older.	TBD	This proprietary cross-linked sodium hyaluronate is currently marketed by the same manufacturer, Anika, as Monovisc. Cingal is approved as a medical device in Canada and was recently approved in Europe.

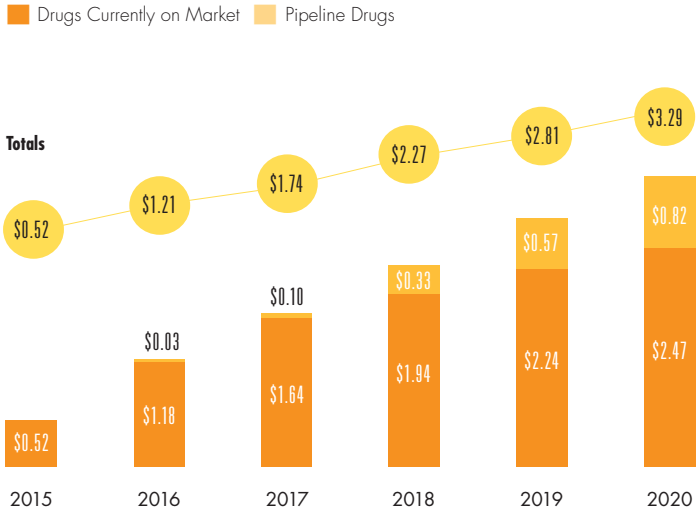
Specialty Pipeline Forecasting

Innovation continues to advance treatment each year as we consistently see new specialty therapies approved by the FDA aimed at treating complex diseases. Consequently, this has contributed to the increasing specialty spend for payers and heightened the importance of understanding the future financial impact and how to manage utilization. These large-molecule therapies, such as monoclonal antibody drugs, are commonly reimbursed on the medical benefit. One such example is the antineoplastic immunotherapy class, which has had several recent market entrants and FDA label expansions (**see figure 110**). There are more of these medications in the pipeline and further potential label expansions, which could increase their utilization and spend significantly. The estimated national 2015 PMPM for anti neoplastic immunotherapies could increase six-fold by 2020.

Beyond antineoplastic immunotherapies, other medical benefit drugs are expected to have an increased impact on payers going forward, with the amount of billion-dollar medical pharmacy drugs increasing from 18 to 28 by 2020 (**see figure 111**). As this list continues to expand, payers will need to expand their focus beyond only a handful of top-spend medical drugs and find solutions to evolve their medical drug management practices across many different therapeutic categories including autoimmune conditions, oncology, immune globulin, multiple sclerosis, asthma, migraine, etc. With a growing pipeline and the introduction of biosimilars into the U.S. market, medical pharmacy is more complex than ever and will continue to be increasingly significant in the management of overall drug spend.

FIGURE 110

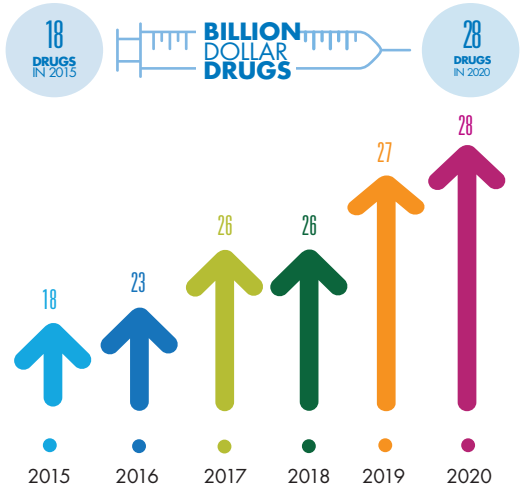
Oncology Immunotherapy Drugs Forecast by PMPM*



*Analysis for current drugs on the market included Opdivo (nivolumab), Keytruda (pembrolizumab), and CTLA-4 inhibitor Yervoy (ipilimumab). Tecentriq (atezolizumab) was approved starting in 2016 and therefore included in the market starting with that date. Pipeline drugs include: durvalumab, avelumab, and tremelimumab. All are expected to be approved in 2017 or 2018. The figures represent predictive values and have been provided for information and educational purposes only.

FIGURE 111

Number of Billion Dollar Drugs 2015-2020



Source: EvaluateLTD. EvaluatePharma®. Accessed: November 2016
http://www.evaluategroup.com/public/EvaluatePharma-Overview.aspx

Legislative Trends

Federal and state elected leaders and regulators have focused more intensely on healthcare reform in recent years, raising questions of cost, coverage, access, and quality increasingly to the forefront of the national dialogue. The Affordable Care Act (ACA) of 2010 focused on three main areas: insurance reforms and consumer protections, coverage expansion and improvement, and cost containment and payment reform, including shifting reimbursement methodologies from paying for volume to paying for value. The inauguration of President Donald Trump on January 20, 2017, introduced a new administration with different priorities and perspectives on healthcare, including the potential for repealing and replacing the ACA. National debate continues on the high prices charged for prescription drugs and biologics[1], and there remains significant interest in payment reform, reforming the Medicare and Medicaid programs, and exploring models of innovation—especially at the state level. In the context of these environmental changes, potential for new policy recommendations and regulatory changes is high as the new administration, the 115th Congress, and state executives begin new dialogue to address these questions.

The New Administration

The new administration entered the White House on a platform of repealing and replacing the ACA. The administration has proposed a number of healthcare-reform options to replace the law's components, including:

- The purchase of health insurance (favoring high-deductible health plans and tax-free health savings accounts (HSAs)) outside the exchanges
- Turning Medicaid into a state block grant program
- Deductibility of premium costs from personal income tax returns
- Reforming mental health programs and institutions
- The sale of insurance policies across state lines to boost competition
- Making HSAs inheritable

Beyond these replacement proposals, it has been suggested[2] that executive and congressional action on drug prices may be a larger and more immediate priority: An October Kaiser Family Foundation survey showed 74 percent[3] of respondents stated that making drugs for chronic conditions affordable should be a top healthcare priority, while 64 percent[4] of those surveyed believed the federal government should have the authority to limit pharmaceutical companies' ability to raise the price of prescription drugs. The new administration suggested allowing Medicare to negotiate prices, making it easier for consumers to import prescription drugs from other developed countries where they sell for less, and providing extra funding to the U.S. Food and Drug Administration (FDA) to speed approval of generic drugs. Conservative health policy proposals — including the proposed Fair Accountability and Innovative Research (FAIR) Drug Pricing Act of 2016[5] (McCain-R, Arizona, and Baldwin-D, Wisconsin), which would require manufacturers to explain annual price increases of more than 10 percent, and more disclosure of pricing details and pricing drugs based on their relative health benefit — will be under review by the new administration.

Health Insurance Marketplace in 2017

As marketplace enrollees began to shop for coverage in November 2016, the number of insurance choices available to them changed in many parts of the country. After remaining relatively stable between the 2015 and 2016 plan years, and seeing gains from 2014 to 2015, the number of issuers dropped significantly heading into the 2017 plan year: 228 issuers in 2017 as compared to 298 in 2016.[6] In late 2015, approximately nine out of 10 (87 percent) consumers lived in counties with three or more insurers; for 2016, this proportion fell to 56 percent.[7] Throughout 2016, insurers announced reduced participation or multi-state withdrawals from the marketplace, most notably the withdrawal of UnitedHealth and Aetna, which accounted for 43 of the total 83 issuer exits.[8] A majority of the original 23 nonprofit consumer operated and oriented plans (CO-OPs) have shuttered, including those in Connecticut, Illinois, Ohio, and Oregon; only seven are anticipated for plan year 2017.[9]

The third open enrollment under the ACA enrolled 11.1 million people (i.e., whom had signed up, paid their premiums, and held an active purchased policy) through the exchanges, with 2016 year-end effectuated enrollment at approximately 10 million[10] ; this initial post-enrollment period figure for 2016 was up from 10.2 million in 2015[11] and more than eight million in 2014.[12] For 2017, open enrollment ended with more than 9.2 million plan selections in states using HealthCare.gov for eligibility and enrollment, including approximately 3 million new

1. Ashley Kirzinger, Elise Sugarman, and Mollyann Brodie, Kaiser Family Foundation, "Kaiser Health Tracking Poll: October 2016" (Oct. 27, 2016), http://www.kff.org/health-costs/poll-finding/kaiser-health-tracking-poll-october-2016.
2. Reuters, "U.S. Consumers Will Want Trump, Congress to Take on Drug Prices" (Nov. 11, 2016), http://www.reuters.com/article/us-usa-election-pharmaceuticals-analysis-idUSKBN13622E.
3. Ibid., Kaiser Family Foundation (Oct. 27, 2016).
4. POLITICO and the Harvard T.H. Chan School of Public Health, "The 2016 Election: Clinton vs. Trump Voters on American Health Care" (October 2016), http://www.politico.com/f/?id= 00000158-039b-d881-adda-77db04b70000.
5. Senators Tammy Baldwin and John McCain, 114th Congress, second session, "Fair Accountability and Innovative Research Drug Pricing Act of 2016," http://www.baldwin.senate.gov/imo/media/doc/Text%20-%20FAIR%20Drug%20Pricing%20Act.pdf.
6. Reflects HealthCare.gov states and states with state-based marketplaces, where data were made available. See Office of the Assistant Secretary for Planning and Evaluation (ASPE), HHS, "Health Plan Choice and Premiums in the 2017 Health Insurance Marketplace," ASPE Research Brief (Oct. 24, 2016), table 10, "Number of Marketplace Issuers by State, 2016-2017 in HealthCare.gov States & State-Based Marketplaces for Which Data Are Available" (page 27), http://aspe.hhs.gov/sites/default/files/pdf/212721/2017MarketplaceLandscapeBrief.pdf.
7. Ibid., ASPE (Oct. 24, 2016), page 12.
8. Ibid., ASPE, page 13.
9. Peter Sullivan, The Hill, "Frustration Mounts Over ObamaCare Co-Op Failures" (Aug. 1, 2016), http://thehill.com/policy/healthcare/289847-frustration-mounts-over-obamacare-co-op-failures.

marketplace consumers and 6.2 million returning.[13] While these are in line with Health and Human Services (HHS) targets, it is short of earlier projections by the Congressional Budget Office (CBO), which continues to serve as an implicit yardstick for the ACA. In March 2016, CBO projected marketplace enrollment of 15 million for 2017, down from 21 and 13 million in earlier forecasts.[14]

Physician Payment and Payment Reform Updates

WITHDRAWN MEDICARE PART B PAYMENT REFORM DEMONSTRATION

In March 2016, the Centers for Medicare and Medicaid Services (CMS) announced a proposed rule to test a new model for how Medicare Part B pays for physician-administered prescription drugs[15]. Similar to an approach advanced by the independent Medicare Payment Advisory Commission (MedPAC) in its June 2015 report to Congress, Phase 1 of the new model would test whether changing today's ASP of a drug plus six percent add-on to 2.5 percent plus a flat fee payment of $16.80 per drug per day would change prescribing incentives (i.e., eliminating financial incentives for providers to prescribe more expensive drugs). [16] The new model was slated to begin in late 2016 with Phase 2 beginning in winter 2017. In response to significant public comment[17], opposition from congressional lawmakers on both sides of the aisle[18], physicians and physician specialty societies[19], and patient advocacy groups[20], the proposed demonstration was withdrawn in December 2016. It remains to be seen whether CMS, which was working under "limited time" to address stakeholders concerns, will revisit the the model in future rule-making[21].

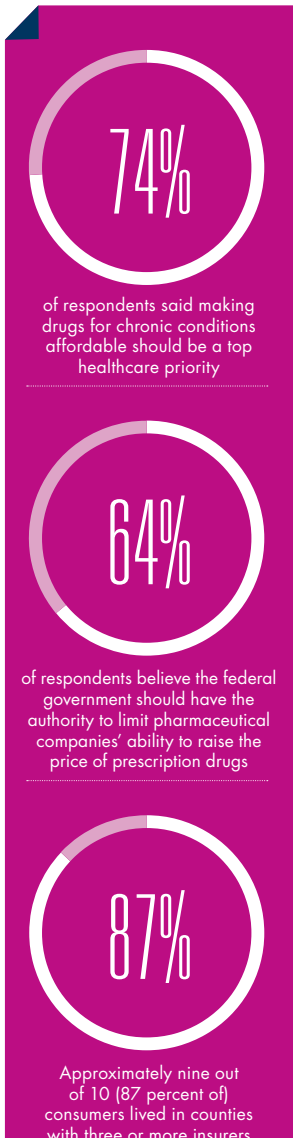
ONCOLOGY CARE MODEL UPDATE

The Oncology Care Model (OCM) is one of the first physician-led specialty care models and builds on lessons learned from other CMS Innovation Center programs and private-sector models. Through the new, five-year OCM, physician practices may receive performance-based payments for episodes of care surrounding chemotherapy administration to Medicare patients with cancer, as well as a monthly care management payment for each beneficiary. The two-sided risk track of this model will be an advanced alternative payment model (APM) under the newly final Quality Payment Program (QPP).

In late June 2016, HHS announced the selection of approximately 200 physician group practices and 17 health insurance companies to participate in the OCM. Aiming to support and encourage higher quality and more coordinated cancer care, the Medicare arm of the OCM includes more than 3,200 oncologists and will cover approximately 155,000 Medicare beneficiaries nationwide.[22] The OCM began July 1, 2016, and runs through June 30, 2021.

PATIENT-CENTERED ONCOLOGY CARE MODEL

The American Society of Clinical Oncology (ASCO) has developed a payment reform model designed to improve the quality and affordability of care for patients with cancer. The ASCO model will allow oncology practices to successfully navigate the transforming healthcare environment and transition to alternative payment models. Based on extensive feedback from ASCO members, other stakeholders across the oncology community, and policymakers, ASCO has developed a significantly enhanced proposal called Patient-Centered Oncology Payment: Payment Reform to Support Higher Quality, More Affordable Cancer Care (PCOP). PCOP was developed by an ASCO volunteer work group of leading medical oncologists, seasoned practice administrators, and experts in physician payment and business analysis. The basic PCOP system was designed to provide supplemental, non-visit-based payments to oncology practices to support diagnosis, treatment planning, and care management. Oncology practices would be able to bill payers for four new service codes: 1) New patient treatment planning: $750 payment for each new patient; 2) Care management during treatment: $200 payment each month for each patient



10. CMS, "March 31, 2016 Effectuated Enrollment Snapshot" (June 30, 2016), http://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-06-30.html.
11. CMS, "March 31, 2015 Effectuated Enrollment Snapshot" (June 2, 2015), http://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2015-Fact-sheets-items/2015-06-02.html.
12. ASPE, HHS, "Health Insurance Marketplace: Summary Enrollment Report for the Initial Annual Open Enrollment Period," ASPE Issue Brief (May 1, 2014), http://aspe.hhs.gov/sites/default/files/pdf/76876/ib_2014Apr_enrollment.pdf.
13. CMS, "Biweekly Enrollment Snapshot: Weeks 10 and 11, Jan. 1-Jan. 14, 2017" (Jan. 18, 2017), http://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-01-18.html.
14. Congressional Budget Office, "Federal Subsidies for Health Insurance Coverage for People Under Age 65: Tables From CBO's March 2016 Baseline" (March 2016, table 1, "Health Insurance Coverage for People Under Age 65," https://www.cbo.gov/sites/default/files/51298-2016-03-HealthInsurance.pdf.
15. CMS, "Proposed rule: Medicare Program; Part B Drug Payment Model," Federal Register 81 (March 11, 2016): 13229-13261, agency/docket no. CMS-1670-P (RIN 0938-AS85), https://www.gpo.gov/fdsys/pkg/FR-2016-03-11/pdf/2016-05459.pdf.
16. Medicare Payment Advisory Commission, "Report to the Congress: Medicare and the Health Care Delivery System" (June 2015), http://www.medpac.gov/docs/default-source/reports/june-2015-report-to-the-congress-medicare-and-the-health-care-delivery-system.pdf.
17. Shannon Muchmore, "CMS Defends Medicare Part B Proposal," Modern Healthcare (June 28, 2016), http://www.modernhealthcare.com/article/20160628/NEWS/160629905.
18. Representatives Tom Price, John Shimkis, Charles Boustany Jr., Kevin Brady, et al., U.S. House of Representatives, "Letter to The Honorable Andy Slavitt, Acting Administrator, Centers for Medicare & Medicaid Services" (May 2, 2016), http://tomprice.house.gov/sites/tomprice.house.gov/files/assets/Medicare%20Part%20B%20Demo%20Letter%5b4%5d.pdf.
19. For example, American Cancer Society, Cancer Action Network, "Letter to the Honorable Sylvia Burwell re: CMS-1670-P – Medicare Program; Part B Drug Payment Model; Proposed Rule, 81 Fed. Reg. 13230 (March 11, 2016)" (May 9, 2016), http://docs.house.gov/meetings/IF/IF14/20160517/104931/HHRG-114-IF14-20160517-SD005.pdf.
20. For example, Community Oncology Alliance, "Letter to Mr. Andy Slavitt re: Medicare Program; Part B Drug Payment Model [CMS-1670-P],"

3) Care management during active monitoring: $50 payment each month for each patient during treatment holidays and for up to six months following the end of treatment; 4) Participation in clinical trials: $100 per month payment for each patient while treatment is underway and for six months afterward.

Biosimilars Payment Policy Update

Biosimilars are biological products approved on the basis of comparability to a biologic previously approved by the U.S. FDA. Biologics and biosimilars consist of large, complex molecules manufactured in living cells and then extracted and purified. Because these products are produced in living cells (unlike generics), biosimilars are highly similar – but not identical – to their reference product; they also may not serve the full set of clinical indications as the original brand-name biologic product. Due to these differentiating factors, the regulatory pathway for biosimilars is different from that for generic drugs.

In the 2016 Medicare Physician Fee Schedule Final Rule, effective January 1, 2016, CMS updated the payment rule for biosimilars to clarify that the payment amount for a biosimilar is based on the ASP of all national drug codes assigned to the biosimilar biological products included within the same billing and payment code (or J code). In general, CMS will group biosimilar products to the same reference product into the same payment calculation; and these products will share a common payment limit and healthcare common procedure coding system (HCPCS) code.[23]

Under the Medicare Prescription Drug Program (Part D), biosimilars may be added to a plan formulary at any time as a formulary enhancement but are not considered interchangeable with the reference product. Biosimilars are not subject to the Medicare Coverage Gap Discount Program; because they are not generics, biosimilars are subject to higher maximum copayments for individuals eligible for low-income subsidies or who have entered catastrophic coverage. Separately, CMS restated its March 2015 guidance on the classification of biosimilars under the Medicaid program, confirming biosimilars are "single source drugs" and subject to higher rebates under the Medicaid Drug Rebate Program, already the highest rebates in healthcare.[24]

Despite biosimilars being single-source drugs and differing in other ways from generics, the Final Rule follows the reimbursement model of multi-source generic drugs; as a result, CMSs grouping of biosimilars that do not share clinical indications may result in confusion for providers or pose administrative challenges within medical practices. Such potential for confusion may extend beyond the clinical setting to patients' claim coding and payment, and may create an opportunity for future rule-making to encourage biosimilar development and uptake.[25]

340B

OVERVIEW OF THE 340B PROGRAM

Congress established the 340B Drug Pricing Program in 1992, which requires manufacturers to provide substantial discounts on outpatient drugs as a condition of receiving Medicaid and Medicare Part B payments.[26] Eligible providers ("340B-covered entities," or CEs) include hospitals, community health centers, and HIV/AIDS, diabetes, cancer, dental, and primary care clinics serving the underserved and/or providing uncompensated or undercompensated care. In addition, drugs purchased by 340B-covered entities at a discount can be sold to all individuals who meet the program's definition of a "patient" regardless of their insurance status.

Since 1992, the program has largely been implemented through guidance instead of formal rule-making and regulation like most federal statutory programs. In 2014, the D.C. Circuit Court held that the Health Resources and Services Administration (HRSA) does not have rule-making authority for the 340B program outside of civil monetary penalties, dispute resolution, and ceiling prices.[27] Due to this ruling, HRSA converted its omnibus regulation — intended to establish uniform clear and enforceable policies — into proposed guidance[28] because it lacks explicit rulemaking authority.

> The 340B program remains an area of focus for federal policymakers.

2016 REGULATORY LOOK BACK

The 340B program remains an area of focus for federal policymakers, and federal-level activity and publications from 2016 indicate it would have been a year of new guidance for the program. Below is a breakdown of recent regulatory initiatives related to 340B.

- Through release of its May 2015 regulatory agenda, the HRSA stated it would delay the final 340B program Omnibus Guidance until the end of 2016.[29] The August 2015 proposed version of this guidance received more than 800 comments, many of which raised legal and operational concerns the agency is expected to address in the final guidance. The Office of Management and Budget (OMB) received the agency's wide-ranging "mega-guidance" September 1, 2016, which had been scheduled to be published in December 2016.[30] It now appears unlikely the omnibus guidance will be published as sent to the OMB; the new administration has directed heads of federal agencies to conduct a full review of items unpublished, pending publication, and recently published (i.e., on or around the

(May 9, 2016), http://www.communityoncology.org/pdfs/COA_CMS_PartBModelLetter_5-9-16_FINAL.pdf.
21. Tom Howell Jr., "Obama Admin. Drops Contentious Medicare Part B Proposal," The Washington Times (Dec. 16, 2016), http://www.washingtontimes.com/news/2016/dec/16/obama-admin-drops-contentious-medicare-part-b-prop/.
22. HHS, "HHS Announces Physician Groups Selected for an Initiative Promoting Better Cancer Care" (June 29, 2016), http://www.hhs.gov/about/news/2016/06/29/hhs-announces-physician-groups-selected-initiative-promoting-better-cancer-care.html.
23. CMS, "Part B Biosimilar Biological Product Payment and Required Modifiers," (November 22, 2016), http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/Part-B-Biosimilar-Biological-Product-Payment.html
24. Esther Scherb and Kassie Maldonado, Covington & Burling LLP, https://www.cov.com/-/media/files/corporate/publications/2016/04/10_things_to_know_about_us_biosimilar_reimbursement.pdf.
25. Molly Burich, "Potential Unintended Consequences of CMS' Policy for Biosimilars Reimbursement" (June 6, 2016), http://www.biosimilardevelopment.com/doc/potential-unintended-consequences-of-cms-policy-for-biosimilars-reimbursement-0001.
26. Public Health Service Act, Pub. L. 78-410, 58 Stat. 682/42 U.S.C. Sec. 256b.

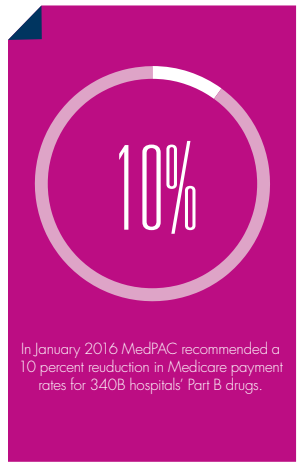
inauguration date of January 20) in the Federal Register, which may include the OMB-pending omnibus guidance.[31]

- Originally scheduled to be issued in 2015, the agency published a Notice of Proposed Rulemaking on the 340B program's administrative dispute resolution process in August 2016.[32] The proposed rule reflects an ACA requirement to implement an enhancement to the 340B program by establishing a binding administrative dispute resolution (ADR) process to resolve certain disputes between CEs and manufacturers arising under the program.
- Also required by the ACA, a final rule imposing monetary sanctions (not to exceed $5,000 per instance) on drug manufacturers "who intentionally charge a CE a price above the ceiling price established under the" program, plus standards and methodology for the calculation of ceiling prices, was published in the Federal Register January 5, 2017 following a delay from the May 2016 release estimate.[33]

Separate from HRSA's regulatory agenda, CMS issued two regulations in 2016 affecting the 340B program:

- The Medicaid Managed Care Final Rule[34], which requires Medicaid managed care organizations (Medicaid plans) to exclude utilization data for drugs subject to discounts under the 340B program so manufacturers will not be subject to a duplicate discount. State Medicaid agencies must implement this and other requirements in their managed care programs with Medicaid plan contracts beginning on or after July 1, 2017.
- The proposed rule updating the Medicare outpatient prospective payment schedule implements Sec. 603 of the Bipartisan Budget Act of 2015's site neutrality requirements, which change the way certain off-campus hospital outpatient departments will be paid.[35]

In addition, a pair of independent agencies also reviewed the 340B program in 2016: the HHS Office of the Inspector General (OIG) and MedPAC. For its part, the OIG addressed the aforementioned issue of Medicaid managed care rebates and 340B drugs in a June 2016 report.[36] In the report, the OIG concluded that many states use methods (i.e., often at the provider level or using the HRSA Medicaid Exclusion File) that may inaccurately identify 340B drug claims when calculating manufacturer rebates for drugs paid through Medicaid plans. While fewer states use claim-level methods, this level of methodology was found to be more accurate because it permits CEs to differentiate among specific claims. Consistent with its position in the Medicaid managed care final rule, CMS disagreed with the OIG's claim-level recommendation. Separately and relevant to the forthcoming final 340B Program Omnibus Guidance, HRSA agreed with OIG's recommendation that, for Medicaid plan drugs, the agency specified that CEs must follow state instructions to facilitate claim-level identification of drugs purchased through the program. In further comment, HRSA stated how this will be incorporated in the forthcoming final guidance and will be married with public comments received.



In addition, MedPAC voted in January 2016 to recommend reducing the Medicare payment rates for a 340B hospital's separately payable Part B drugs by a rate of 10 percent and to use the savings for Medicare beneficiaries and the uncompensated care pool—a recommendation released in MedPAC's March 2016 Report to the Congress.[37] In response to MedPAC's recommendation, the program received public support in February in the form of a letter signed by more than 4,700 physicians requesting Congress not make such modifications.[38]

27. Pharmaceutical Research and Manufacturers of America (PhRMA) v. HHS, 43 F. Supp. 3d 28 (D.D.C. 2014).
28. HRSA, HHS, "Notice: 340B Drug Pricing Program Omnibus Guidance," Federal Register 80 (Aug. 28, 2015): 52300-52324, agency/docket no. 2015-21246 (RIN 0906-AB08), http://www.gpo.gov/fdsys/pkg/FR-2015-08-28/pdf/2015-21246.pdf.
29. Office of Information and Regulatory Affairs, Office of Management and Budget, Executive Office of the President, "Agency Rule List – Spring 2016: Department of Health and Human Services" (accessed Nov. 15, 2016), http://www.reginfo.gov/public/do/eAgendaMain?operation=OPERATION_GET_AGENCY_RULE_LIST&currentPub=true&agencyCode=&showStage=active&agencyCd=0900.
30. Inside Health Policy, "OMB Reviews Wide-Ranging 340B 'Mega-Guidance'" (Sep. 2, 2016), https://insidehealthpolicy.com/daily-news/omb-reviews-wide-ranging-340b-mega-guidance.
31. Office of the Press Secretary, The White House, Assistant to the President and Chief of Staff Reince Priebus, "Memorandum for the Heads of Executive Departments and Agencies; Subject: Regulatory Freeze Pending Review" (Jan. 20, 2017), https://www.whitehouse.gov/the-press-office/2017/01/20/memorandum-heads-executive-departments-and-agencies.
32. HRSA, HHS, "Notice of Proposed Rulemaking: 340B Drug Pricing Program; Administrative Dispute Resolution," Federal Register 81 (Aug. 12, 2016): 53381-53388 (RIN 0906-AA90), https://www.gpo.gov/fdsys/pkg/FR-2016-08-12/pdf/2016-18969.pdf.
33. HRSA, HHS, "Notice of Proposed Rulemaking: 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation," Federal Register 80 (June 17, 2015): 34583-34588 (RIN 0906-AA89), https://www.gpo.gov/fdsys/pkg/FR-2015-06-17/pdf/2015-14648.pdf; and, HRSA, HHS, "340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation," Federal Register 82, no. 3 (Jan. 5, 2017): 1210-1230 (RIN 0906-AA89), https://www.gpo.gov/fdsys/pkg/FR-2017-01-05/pdf/2016-31935.pdf.
34. CMS, HHS, "Final Rule: Medicaid and Children's Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, and Revisions Related to Third Party Liability," Federal Register 81 (May 6, 2016): 27497-27901, agency/docket no. CMS-2390-F (RIN 0938-AS25), https://www.gpo.gov/fdsys/pkg/FR-2016-05-06/pdf/2016-09581.pdf.
35. CMS, HHS, "Proposed rule: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Procurement Organization Reporting and Communication; Transplant Outcome Measures and Documentation Requirements; Electronic Health Record (EHR) Incentive Programs; Payment to Certain Off-Campus Outpatient Departments of a Provider; Hospital Value-Based Purchasing (VBP) Program" Federal Register 81 (July 14, 2016): 45603-45788, agency/docket no. CMS-1656-P (RIN 0938-AS82), https://www.gpo.gov/fdsys/pkg/FR-2016-07-14/pdf/2016-16098.pdf.
36. Suzanne Murrin, Deputy Inspector General for Evaluation and Inspections, Office of Inspector General, HHS, "State Efforts to Exclude 340B Drugs from Medicaid Managed Care Rebates" (June 2016), no. OEI-05-14-00430, https://oig.hhs.gov/oei/reports/oei-05-14-00430.pdf.
37. Medicare Payment Advisory Commission, "Report to the Congress: Medicare Payment Policy" (March 2016), http://www.medpac.gov/docs/default-source/reports/march-2016-report-to-the-congress-medicare-payment-policy.pdf.
38. 340B Health, "Letter to the Honorables Paul Ryan, Mitch McConnell, Nancy Pelosi, and Harry Reid re: the 340B program" (Feb. 10, 2016), http://www.340bhealth.org/files/Physician_Letter.pdf.

Appendix

2016 Report Methodology and Demographics

The methodology for the seventh edition of the Magellan Rx Management Medical Pharmacy Trend Report™ was developed with original guidance from our payer 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 payer perceptions and health plan actions related to provider-administered infused or injected drugs paid under the medical benefit, also referred to as medical pharmacy 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 a survey of medical, pharmacy, and network directors at commercial health plans, as well as medical benefit paid claims data across key lines of business (i.e., commercial and Medicare Advantage) and outpatient sites of service and provider types (i.e., physician offices, homes via home infusion, specialty pharmacies, and hospital outpatient facilities). In a shift from previous years, payer survey responses and paid claims data are distributed throughout all six sections of the report. In light of this shift in reporting, full reports and exhibits will be available in the appendix.

Payer Survey

The 2016 Medical Pharmacy Trend Report™ payer survey included insights from U.S. health plans representing more than 109 million medical pharmacy lives. Data collection took place over two months in summer 2016 through a custom market research survey consisting of topics ranging from utilization and management trends to benefit design and provider network landscape. Validated results were analyzed based on percentage of payers or lives. Methodology for survey data analyses included stratification of payer sample by covered lives, small versus large plans, geographic dispersion, and respondent type (i.e., medical, pharmacy or network directors).

Survey Respondent Sample

The payer survey included insights from a total of 49 U.S. payers representing more than 109 million medical pharmacy lives. Of the total number of respondents, 38 payers indicated they were responsible for managing Medicare Advantage lives in addition to their commercial population. Throughout the survey, these respondents were asked questions for their Medicare lines of business in addition to their commercial lines of business.

Respondents represented an array of plan sizes as defined in **figure 112**. The respondent sample was split close to even with small plans, defined as less than 500,00 lives, representing close to half (45 percent) of the respondent sample. Larger plans represented the remaining 55 percent. Health plan respondents were mainly pharmacy directors (82 percent) and medical directors (12 percent). The remaining respondents were provider network directors (six percent).

FIGURE 112

2016 Respondent Sample

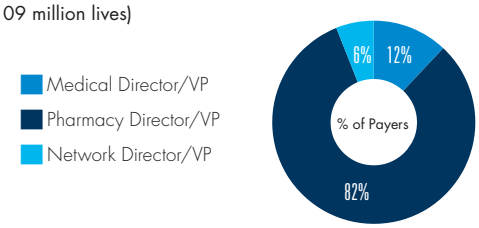
(n=49; 109 million covered lives)

COVERED LIVES	TOTAL COUNT	TOTAL LIVES	TOTAL LIVES (%)
Less than 500,000	22 (45%)	5,434,218	5%
500,000 to 999,999	5 (10%)	3,546,477	3%
1,000,000 to 4,999,999	16 (33%)	31,902,300	29%
5,000,000 or more	6 (12%)	68,120,928	63%
Total	49	109,003,923	100%

FIGURE 113

2016 Payer Respondent Positions

(n=49; 109 million lives)

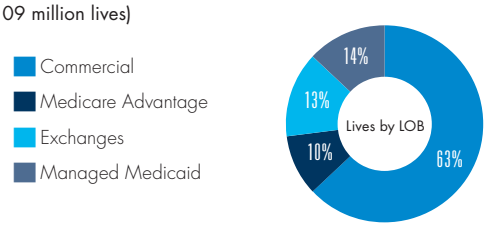


Survey participants represented all major lines of business beyond commercial and Medicare Advantage, including managed Medicaid and Health Insurance Exchange. Most respondents (68 percent) indicated an increase in health insurance exchange lives in 2016, in line with the national marketplace, although this may shift again in 2017 with various large insurers leaving the healthcare exchange marketplace (see Legislative Trends section). Overall, the largest line of business was commercial, representing 63 percent of the lives, while 10 percent of lives were attributed to Medicare Advantage (**see figure 114**).

FIGURE 114

2016 Lives by Line of Business

(n=49, 109 million lives)



Survey respondents from national plans constituted 12 percent of payers but represented 47 percent of total lives. Regional plans accounted for the other 53 percent of covered lives. The map in **figure 115** illustrates the geographic distribution of regional plan lives showing an almost equal split on the east and west coasts; 45 percent were located in the east and 46 percent of lives were located in the west. This represents a more balanced sample from 2015 when 60 percent of lives were located in the east.

Therapeutic Classes Represented

Therapeutic classes represented in the survey were inclusive of current medical benefit drugs. To ensure accuracy of responses, payer respondents were provided with examples of drugs for each of the categories presented (**see figure 116**).

Health Plan Claims Data

Medical benefit drug utilization and trend data were collected through secondary analyses of commercial and Medicare Advantage health plan medical paid claims data for the most recent calendar years. Claims data were analyzed for medical pharmacy utilization across 925 HCPCS codes and several outpatient sites of service, including the physician office, home infusion, 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 figures 94, 95, A33 thru A35**); their utilization was not included in any other analysis. Most analyses compared calendar years 2014 and 2015. In some cases, the past three to five years were analyzed to show a longer period of year over year spend and trend. Year over year, shifts in claims data information have occurred due to adjustments. In addition, the report previously evaluated medical pharmacy utilization across all outpatient sites of care, including "other." This report was focused solely on physician office, hospital outpatient, home infusion, and specialty pharmacy due to inconsistencies in volume and utilization patterns across the portfolio.

FIGURE 115

Regional Plans – Geographic Dispersion of Lives

(n=43; 58 million lives) National plans represented across all 50 states and D.C. were not included in this analysis.

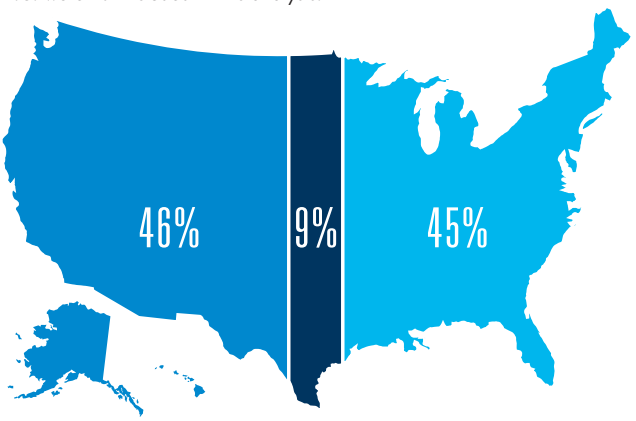


FIGURE 116

Medical Benefit Drug Examples for Therapeutic Categories in Payer Survey

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	Avastin, Vectibix, Erbitux, Zaltrap
Biologic Drugs for Autoimmune Disorders	Remicade, Orencia, Cimzia, Actemra, Simponi ARIA, Stelara, Entyvio
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, Zarxio
Contraceptives	Mirena, Skyla, Liletta
Enzyme Replacement Therapy	Vpriv, Cerezyme, Elelyso
Erythropoiesis-Stimulating Agents (ESAs)	Aranesp, Procrit, Epogen
Folinic Acid	Fusilev, leucovorin
Gonadotropin-Releasing Hormone Agents	Eligard, Lupron, Trelstar, Zoladex
Hereditary Angioedema Agents	Cinryze, Berinert, Kalbitor
Intravenous Immune Globulin (IVIG)	Gamunex, Gammagard
Intravenous Irons	Feraheme, Ferrlecit, Injectafer, Venofer
Multiple Sclerosis	Tysabri, Lemtrada
Ophthalmic Injections	Lucentis, Eylea, Macugen, bevacizumab
Pulmonary Arterial Hypertension Agents	Flolan, Remodulin, Revatio IV, Veletri, Tyvaso, Ventavis
Subcutaneous Immune Globulin (SCIG)	Hizentra, HyQvia
Taxanes	Taxol, Abraxane
Viscosupplementation	Orthovisc, Synvisc, Supartz, Hyalgan, Euflexxa, Gel-One, Monovisc

Appendix

Medical Benefit Drug Trends Supplement

A1

Medical Pharmacy Allowed Amount PMPM by LOB by Site of Service 2011-2015

	2011	2012	2013	2014	2015
Commercial					
Home Infusion/Specialty Pharmacy	$2.58	$2.73	$3.10	$3.24	$3.82
Hospital Outpatient	$7.12	$8.13	$9.69	$10.94	$12.23
Physician Office	$5.57	$5.72	$5.92	$6.77	$7.62
Total	$15.27	$16.57	$18.71	$20.95	$23.68
Medicare					
Home Infusion/Specialty Pharmacy	$3.07	$2.87	$3.92	$4.04	$3.42
Hospital Outpatient	$14.65	$18.44	$18.38	$19.06	$17.23
Physician Office	$25.90	$22.54	$23.96	$22.13	$25.36
Total	$43.63	$43.85	$46.26	$45.23	$46.01

Please note that due to rounding, some column totals do not add up accurately.

A2

Medical Pharmacy Percentage Spend by LOB by Site of Service 2011-2015

	2011	2012	2013	2014	2015
Commercial					
Home Infusion/Specialty Pharmacy	17%	16%	17%	15%	16%
Hospital Outpatient	47%	49%	52%	52%	52%
Physician Office	36%	34%	32%	32%	32%
Medicare					
Home Infusion/Specialty Pharmacy	7%	7%	8%	9%	7%
Hospital Outpatient	34%	42%	40%	42%	37%
Physician Office	59%	51%	52%	49%	55%

A3

Commercial Top 100 Medical Benefit Drugs by PMPM

						% Change				
	2011	2012	2013	2014	2015	2011-2012	2012-2013	2013-2014	2014-2015	2011-2015
Top 10	$7.59	$7.95	$8.79	$9.74	$10.65	5%	11%	11%	9%	40%
Top 25	$10.37	$10.91	$12.07	$13.51	$14.54	5%	11%	12%	8%	40%
Top 50	$12.66	$13.49	$14.95	$16.71	$18.19	7%	11%	12%	9%	44%
Top 100	$14.23	$15.37	$17.22	$19.27	$21.31	8%	12%	12%	11%	50%
Total (All Medical Benefit Drugs)	$15.27	$16.57	$18.71	$20.95	$23.68	8%	13%	12%	13%	55%

A4

Medicare Top 100 Medical Benefit Drugs by PMPM

						% Change				
	2011	2012	2013	2014	2015	2011-2012	2012-2013	2013-2014	2014-2015	2011-2015
Top 10	$21.81	$22.15	$22.09	$21.68	$23.11	2%	0%	-2%	7%	6%
Top 25	$32.33	$31.87	$31.81	$31.53	$32.79	-1%	0%	-1%	4%	1%
Top 50	$38.79	$38.75	$39.53	$39.19	$39.83	0%	2%	-1%	2%	3%
Top 100	$42.38	$42.39	$44.44	$43.40	$44.21	0%	5%	-2%	2%	4%
Total	$43.63	$43.85	$46.26	$45.23	$46.01	1%	5%	-2%	2%	5%

A5

2015 Commercial Allowed Amount PMPM by Disease State or Drug Category

Rank	Disease or Drug Category	PMPM	% of Allowed Amount PMPM	% of Members	Members per 1,000*
1	Oncology	$8.45	36%	2%	4.7
2	Oncology Support: Colony-Stimulating Factors	$1.99	8%	1%	1.2
3	Immune Globulin	$1.92	8%	0.18%	0.44
4	BDAID: Crohn's Disease/Ulcerative Colitis	$1.66	7%	0.25%	0.58
5	BDAID: Rheumatoid Arthritis	$1.06	4%	0.22%	0.47
6	Antihemophilic Factor	$0.90	4%	0.02%	0.06
7	Enzyme Replacement Therapy	$0.56	2%	0.01%	0.02
8	Multiple Sclerosis	$0.52	2%	0.05%	0.12
9	Oncology Support: Antiemetics	$0.46	2%	6%	17.0
10	BDAID: Psoriasis/Psoriatic Arthritis	$0.46	2%	0.08%	0.17
11	Unclassified	$0.45	2%	3%	6.5
12	Infectious Disease	$0.42	2%	7%	16.3
13	Other	$0.42	2%	12%	27.6
14	Rare Diseases	$0.32	1%	0.004%	0.01
15	Ophthalmic Injections	$0.31	1%	0.44%	0.86
16	Botulinum Toxins	$0.31	1%	1%	1.4
17	Contraceptives	$0.29	1%	3%	5.4
18	Asthma/COPD	$0.27	1%	3%	6.2
19	Oncology Support: Gastrointestinal	$0.24	1%	0.03%	0.07
20	Hereditary Angioedema	$0.22	1%	0.004%	0.01
21	Viscosupplementation	$0.21	1%	1%	2.5
22	Pain Management	$0.19	1%	12%	29.5
23	BDAID: Systemic Lupus Erythematosus	$0.16	1%	0.02%	0.05
24	Iron, Intravenous	$0.14	1%	1%	1.4
25	BDAID: Other	$0.14	1%	0.04%	0.10
26	Fluids	$0.13	1%	7%	17.5
27	Pulmonary Arterial Hypertension	$0.13	1%	0.005%	0.01
28	Hematology	$0.12	1%	0.01%	0.03
29	Alpha-1 Proteinase Inhibitor (for Emphysema)	$0.12	1%	0.01%	0.02
30	Anticoagulants	$0.11	0.5%	1%	3.9
31	Corticosteroids	$0.11	0.4%	29%	58.6
32	Sedatives/Anesthesia	$0.10	0.4%	7%	18.6
33	Oncology Support: Erythropoiesis-Stimulating Agents	$0.10	0.4%	0.10%	0.22
34	End-Stage Renal Disease: Erythropoiesis-Stimulating Agents	$0.09	0.4%	0.03%	0.09
35	Thyroid Agents	$0.08	0.4%	0.07%	0.18
36	Corticotropin, ACTH	$0.08	0.3%	0.07%	0.16
37	Cardiovascular Agents	$0.08	0.3%	2%	5.2
38	BDAID: Ankylosing Spondylitis	$0.08	0.3%	0.02%	0.03
39	Bone Resorption Inhibitors (Osteoporosis)	$0.36	2%	0.44%	0.96
40	Rare Autoinflammatory Conditions, Cryopyrin-Associated Periodic Syndromes	$0.04	0.2%	0.002%	0.004
41	Progestins	$0.04	0.2%	0.04%	0.08
42	Testosterone	$0.03	0.1%	1%	1.1
43	Skeletal Muscle Relaxants	$0.03	0.1%	0.12%	0.29
44	Diabetes	$0.02	0.1%	0.28%	0.72
45	Gout	$0.02	0.1%	0.001%	0.003
46	Rho (D) Immune Globulin	$0.01	0.1%	0.40%	0.87
47	Antipsychotics	$0.01	0.05%	0.05%	0.60
48	Transplant Agents	$0.01	0.02%	0.02%	0.05
49	Growth Hormone	$0.01	0.02%	0.001%	0.003

*Members per thousand includes overlap with other therapies and not unique members.

A6

2015 Medicare Allowed Amount PMPM by Disease State or Drug Category

Rank	Disease or Drug Category	PMPM	% of Allowed Amount PMPM	% of Members	Members per 1,000*
1	Oncology	$19.07	41%	6%	22.1
2	Ophthalmic Injections	$5.25	11%	4%	14.6
3	Oncology Support: Colony-Stimulating Factors	$4.32	9%	1%	4.3
4	Immune Globulin	$2.98	6%	0.32%	1.1
5	BDAID: Rheumatoid Arthritis	$2.49	5%	0.42%	1.5
6	Oncology Support: Erythropoiesis-Stimulating Agents	$1.22	3%	1%	3.0
7	Viscosupplementation	$0.88	2%	4%	12.6
8	Oncology Support: Gastrointestinal	$0.78	2%	0.08%	0.29
9	Multiple Sclerosis	$0.70	2%	0.06%	0.20
10	Infectious Disease	$0.70	2%	4%	15.2
11	Unclassified	$0.70	2%	1%	4.1
12	BDAID: Crohn's Disease/Ulcerative Colitis	$0.67	1%	0.10%	0.35
13	Oncology Support: Antiemetics	$0.66	1%	4%	12.9
14	Rare Diseases	$0.62	1%	0.004%	0.01
15	Asthma/COPD	$0.54	1%	2%	8.2
16	Other	$0.40	1%	12%	40.46
17	BDAID: Psoriasis/Psoriatic Arthritis	$0.40	1%	0.05%	0.18
18	Enzyme Replacement Therapy	$0.39	1%	0.003%	0.01
19	Pulmonary Arterial Hypertension	$0.39	1%	0.02%	0.06
20	Botulinum Toxins	$0.34	1%	1%	2.1
21	Bone Resorption Inhibitors (Osteoporosis)	$0.32	1%	1%	4.3
22	Antihemophilic Factor	$0.31	1%	0.01%	0.03
23	Hematology	$0.30	1%	0.03%	0.10
24	Alpha-1 Proteinase Inhibitor (for Emphysema)	$0.25	1%	0.01%	0.04
25	Iron, Intravenous	$0.23	1%	1%	3.5
26	Cardiovascular Agents	$0.19	0.4%	3%	9.7
27	Corticosteroids	$0.18	0.4%	38%	126.9
28	BDAID: Other	$0.11	0.2%	0.03%	0.10
29	Pain Management	$0.09	0.2%	6%	20.6
30	End-Stage Renal Disease: Erythropoiesis-Stimulating Agents	$0.09	0.2%	0.07%	0.28
31	Anticoagulants	$0.09	0.2%	1%	5.1
32	BDAID: Ankylosing Spondylitis	$0.07	0.2%	0.01%	0.05
33	BDAID: Systemic Lupus Erythematosus	$0.05	0.1%	0.01%	0.03
34	Fluids	$0.05	0.1%	4%	13.0
35	Thyroid Agents	$0.04	0.1%	0.06%	0.21
36	Sedatives/Anesthesia	$0.04	0.1%	3%	11.3
37	Transplant Drugs or Agents	$0.03	0.1%	0.04%	0.15
38	Skeletal Muscle Relaxants	$0.03	0.1%	0.11%	0.36
39	Antipsychotics	$0.02	0.1%	0.07%	0.26
40	Diabetes	$0.01	0.03%	0.27%	1.0
41	Testosterone	$0.01	0.03%	0.25%	0.85
42	Gout	$0.01	0.01%	0.001%	0.003

*Members per thousand includes overlap with other therapies and not unique members.

A7

2015 ASP and AWP Reimbursement Trends by Selected Disease State or Drug Category

Disease or Drug Category	ASP	AWP
Alpha-1 Proteinase Inhibitor (For Emphysema)	8%	5%
Antihemophilic Factor	5%	25%
BDAID: Psoriasis/Psoriatic Arthritis	7%	5%
BDAID: Rheumatoid Arthritis	12%	13%
BDAID: Systemic Lupus Erythematosus	4%	5%
Bone Resorption Inhibitors (Osteoporosis)	-13%	11%
Botulinum Toxins	4%	4%
Contraceptives	20%	2%
Corticotropin, ACTH	1%	1%
Cystic Fibrosis	-14%	5%
End Stage Renal Disease: Erythropoiesis-Stimulating Agents	5%	2%
Enzyme Replacement Therapy	2%	2%
Gout	35%	17%
Growth Hormone	n/a	12%
Hematology	29%	19%
Hereditary Angioedema	11%	9%
Human Immunodeficiency Virus	0%	2%
Immune Globulin	9%	4%
Infectious Disease	15%	7%
Infertility	10%	11%
Iron, Intravenous	5%	4%
Multiple Sclerosis	14%	7%
Oncology	6%	7%
Oncology Support: Antiemetics	-4%	4%
Oncology Support: Colony-Stimulating Factors	5%	4%
Oncology Support: Erythropoiesis-Stimulating Agents	5%	3%
Oncology Support: Gastrointestinal	9%	7%
Ophthalmic Injections	0%	1%
Other	23%	59%
Pain Management	1%	7%
Pulmonary Arterial Hypertension	4%	12%
Rare Autoinflammatory Conditions, Cryopyrin-Associated Periodic Syndromes	1%	0%
Viscosupplementation	-1%	5%

Medical Benefit Market Share Supplement

Bone Resorption Inhibitors (Oncology)

A8

Commercial Bone Resorption Inhibitors (Oncology) Market Share, Annual Cost per Patient and Allowed Amount PMPM 2014-2015

Brand	Market Share		Annual Cost per Patient		Allowed Amount PMPM	
	2014	2015	2014	2015	2014	2015
Pamidronate (Aredia)	3%	3%	$541	$582	$0.00	$0.00
Zoledronic Acid (Zometa)	36%	33%	$2,872	$2,589	$0.07	$0.06
Xgeva	60%	64%	$7,090	$7,131	$0.31	$0.34
TOTAL					$0.38	$0.41

A9

Medicare Bone Resorption Inhibitors (Oncology) Market Share, Annual Cost per Patient and Allowed Amount PMPM 2014-2015

Brand	Market Share		Annual Cost per Patient		Allowed Amount PMPM	
	2014	2015	2014	2015	2014	2015
Pamidronate (Aredia)	3%	2%	$387	$369	$0.00	$0.00
Zoledronic Acid (Zometa)	21%	23%	$1,651	$949	$0.16	$0.09
Xgeva	76%	75%	$3,455	$3,760	$1.18	$1.19
TOTAL					$1.34	$1.29

Bone Resorption Inhibitors (Osteoporosis)

A10

Commercial Bone Resorption Inhibitors (Osteoporosis) Market Share, Annual Cost per Patient and Allowed Amount PMPM 2014-2015

Brand	Market Share		Annual Cost per Patient		Allowed Amount PMPM	
	2014	2015	2014	2015	2014	2015
Ibandronate (Boniva)	3%	3%	$1,504	$1,374	$0.00	$0.00
Prolia	0%	0%	$828	—	$0.03	$0.05
Zoledronic Acid (Reclast)	62%	67%	$1,285	$1,391	$0.01	$0.01
TOTAL					$0.05	$0.06

A11

Medicare Bone Resorption Inhibitors (Osteoporosis) Market Share, Annual Cost per Patient and Allowed Amount PMPM 2014-2015

Brand	Market Share		Annual Cost per Patient		Allowed Amount PMPM	
	2014	2015	2014	2015	2014	2015
Ibandronate (Boniva)	3%	2%	$1,238	$1,131	$0.01	$0.01
Prolia	0%	0%	—	—	$0.20	$0.27
Zoledronic Acid (Reclast)	67%	64%	$1,200	$1,173	$0.04	$0.04
TOTAL					$0.25	$0.32

Botulinum Toxins

A12

Commercial Botulinum Toxins Market Share and Allowed Amount PMPM 2014-2015

Brand	Market Share		Annual Cost per Patient		Allowed Amount PMPM	
	2014	2015	2014	2015	2014	2015
Botox	95%	94%	$2,124	$2,580	$0.23	$0.29
Dysport	3%	3%	$1,403	$1,490	$0.00	$0.01
Myobloc	1%	1%	$1,668	$2,530	$0.00	$0.00
Xeomin	1%	2%	$1,412	$1,668	$0.00	$0.00
TOTAL					$0.24	$0.31

A13

2015 Commercial Botulinum Toxins Market Share and Allowed Amount PMPM by Site of Service

Brand	Market Share			Allowed Amount PMPM		
	HI/ SPP	Hospital OP	Physician	HI/ SPP	Hospital OP	Physician
Botox	99%	94%	92%	$0.06	$0.06	$0.17
Dysport	0%	0%	5%	—	$0.00	$0.01
Myobloc	0%	4%	1%	$0.00	$0.00	$0.00
Xeomin	1%	1%	3%	$0.00	$0.00	$0.00
TOTAL				$0.06	$0.06	$0.18

Please note that due to rounding, some column totals do not add up accurately.

A14

Medicare Botulinum Toxins Market Share and Allowed Amount PMPM 2014-2015

Brand	Market Share		Annual Cost per Patient		Allowed Amount PMPM	
	2014	2015	2014	2015	2014	2015
Botox	94%	95%	$1,890	$1,900	$0.33	$0.32
Dysport	2%	2%	$1,855	$3,277	$0.01	$0.01
Myobloc	2%	2%	$2,182	$2,911	$0.01	$0.01
Xeomin	2%	2%	$1,557	$1,564	$0.01	$0.01
TOTAL					$0.35	$0.34

A15

2015 Medicare Botulinum Toxins Market Share and Allowed Amount PMPM by Site of Service

Brand	Market Share			Allowed Amount PMPM		
	HI/SPP	Hospital OP	Physician	HI/SPP	Hospital OP	Physician
Botox	100%	97%	94%	$0.01	$0.05	$0.26
Dysport	0%	0%	2%	—	—	$0.01
Myobloc	0%	3%	2%	—	$0.00	$0.01
Xeomin	0%	0%	2%	—	—	$0.01
TOTAL				$0.01	$0.06	$0.28

Folinic Acid

A16

Commercial Folinic Acid Market Share, Annual Cost per Patient and Allowed Amount PMPM 2014-2015

Brand	Market Share		Annual Cost per Patient		Allowed Amount PMPM	
	2014	2015	2014	2015	2014	2015
Leucovorin	73%	85%	$778	$927	$0.02	$0.02
Fusilev	27%	15%	$13,752	$11,139	$0.10	$0.04
TOTAL					$0.12	$0.07

A17

2015 Commercial Folinic Acid Market Share and Allowed Amount PMPM by Site of Service

Brand	Market Share		Allowed Amount PMPM	
	Hospital OP	Physician	Hospital OP	Physician
Leucovorin	95%	79%	$0.02	$0.01
Fusilev	5%	21%	$0.01	$0.03
TOTAL			$0.03	$0.04

A18

Medicare Folinic Acid Market Share, Annual Cost per Patient and Allowed Amount PMPM 2014-2015

Brand	Market Share		Annual Cost per Patient		Allowed Amount PMPM	
	2014	2015	2014	2015	2014	2015
Leucovorin	73%	81%	$426	$434	$0.02	$0.02
Fusilev	27%	19%	$8,180	$9,207	$0.15	$0.10
TOTAL					$0.17	$0.12

Please note that due to rounding, some column totals do not add up accurately.

A19

2015 Medicare Folinic Acid Market Share and Allowed Amount PMPM by Site of Service

Brand	Market Share		Allowed Amount PMPM	
	Hospital OP	Physician	Hospital OP	Physician
Leucovorin	85%	80%	$0.01	$0.02
Fusilev	15%	20%	$0.01	$0.10
TOTAL			$0.01	$0.11

Oncology Support

The antiemetics market share report reflects utilization of intravenous serotonin antagonists indicated for chemotherapy-induced nausea and vomiting treatment and prevention; however, all utilization for these three agents is captured and is not limited to its oncology use only. The Oncology: Antiemetics category previously reported includes additional oral and IV antiemetic agents and explains the higher PMPM spend seen previously in the disease state/drug category analyses.

A20

Commercial Antiemetics Market Share, Annual Cost per Patient and Allowed Amount PMPM 2014-2015

Brand	Market Share		Annual Cost per Patient		Allowed Amount PMPM	
	2014	2015	2014	2015	2014	2015
Granisetron (Kytril)	3%	2%	$275	$301	$0.01	$0.01
Ondansetron (Zofran)	86%	89%	$47	$41	$0.05	$0.05
Aloxi	11%	9%	$2,173	$2,344	$0.24	$0.24
TOTAL					$0.30	$0.30

A21

2015 Commercial Antiemetics Market Share and Allowed Amount PMPM by Site of Service

Brand	Market Share		Allowed Amount PMPM	
	Hospital OP	Physician	Hospital OP	Physician
Granisetron (Kytril)	1%	9%	$0.01	$0.00
Ondansetron (Zofran)	96%	57%	$0.05	$0.00
Aloxi	3%	35%	$0.14	$0.10
TOTAL			$0.19	$0.10

A22

Medicare Antiemetics Market Share, Annual Cost per Patient and Allowed Amount PMPM 2014-2015

Brand	Market Share		Annual Cost per Patient		Allowed Amount PMPM	
	2014	2015	2014	2015	2014	2015
Granisetron (Kytril)	12%	7%	$90	$72	$0.01	$0.00
Ondansetron (Zofran)	40%	56%	$58	$36	$0.02	$0.02
Aloxi	47%	37%	$1,186	$1,089	$0.47	$0.40
TOTAL					$0.50	$0.42

A23

2015 Medicare Antiemetics Market Share and Allowed Amount PMPM by Site of Service

Brand	Market Share		Allowed Amount PMPM	
	Hospital OP	Physician	Hospital OP	Physician
Granisetron (Kytril)	1%	16%	$0.00	$0.00
Ondansetron (Zofran)	74%	29%	$0.02	$0.00
Aloxi	25%	55%	$0.15	$0.25
TOTAL			$0.17	$0.26

A24

Commercial Colony-Stimulating Factors Market Share, Annual Cost per Patient and Allowed Amount PMPM 2014-2015

Brand	Market Share		Annual Cost per Patient		Allowed Amount PMPM	
	2014	2015	2014	2015	2014	2015
Neupogen	24%	23%	$4,450	$4,480	$0.13	$0.11
Neulasta	72%	71%	$19,231	$22,184	$1.73	$1.84
Leukine	1%	1%	$3,830	$4,375	$0.00	$0.00
Granix	3%	5%	$5,274	$5,602	$0.02	$0.04
Zarxio	0%	0%	–	$1,558	–	$0.00
TOTAL					$1.88	$1.99

A25

2015 Commercial Colony-Stimulating Factors Market Share and Allowed Amount PMPM by Site of Service

Brand	Market Share			Allowed Amount PMPM		
	HI/SPP	Hospital	Physician	HI/SPP	Hospital	Physician
Neupogen	69%	16%	27%	$0.01	$0.05	$0.06
Neulasta	27%	72%	71%	$0.00	$1.15	$0.68
Leukine	4%	0%	1%	$0.00	$0.00	$0.00
Granix	0%	11%	2%	—	$0.03	$0.00
Zarxio	0%	0%	0%	—	$0.00	$0.00
TOTAL				$0.01	$1.24	$0.75

Please note that due to rounding, some column totals do not add up accurately.

A26

Medicare Colony-Stimulating Factors Market Share, Annual Cost per Patient and Allowed Amount PMPM 2014-2015

Brand	Market Share		Annual Cost per Patient		Allowed Amount PMPM	
	2014	2015	2014	2015	2014	2015
Neupogen	17%	16%	$3,416	$3,246	$0.22	$0.20
Neulasta	78%	77%	$12,989	$13,408	$3.70	$4.02
Leukine	3%	0%	$2,965	$1,485	$0.03	$0.00
Granix	2%	7%	$3,357	$3,437	$0.03	$0.09
Zarxio	0%	0%	–	$1,998	–	$0.00
TOTAL					$3.98	$4.32

Please note that due to rounding, some column totals do not add up accurately.

A27

2015 Medicare Colony-Stimulating Factors Market Share and Allowed Amount PMPM by Site of Service

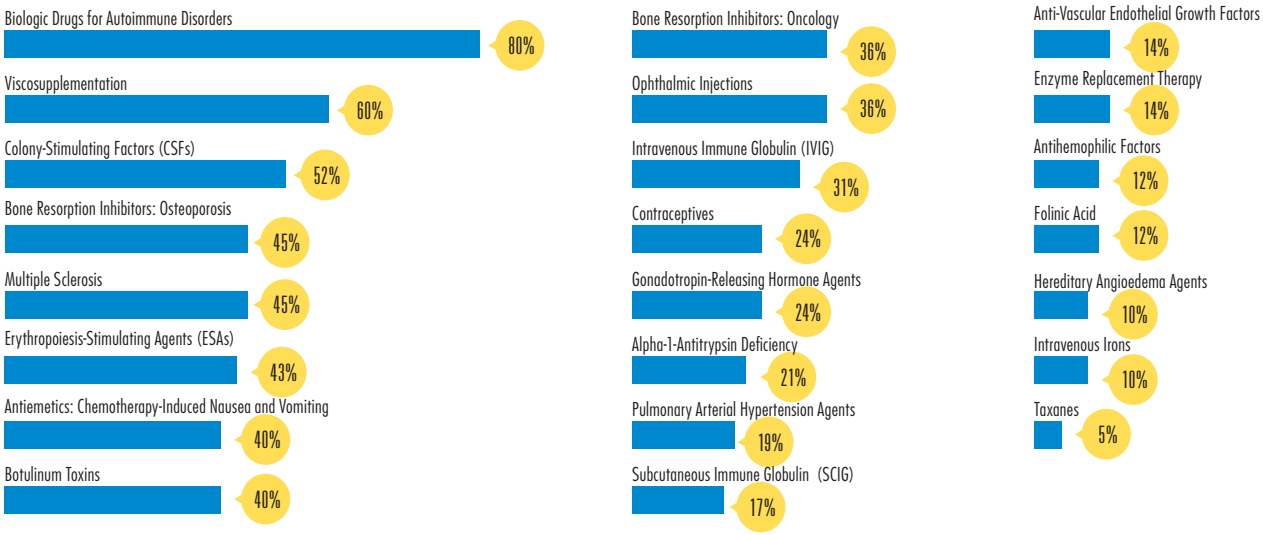
Brand	Market Share		Allowed Amount PMPM	
	Hospital OP	Physician	Hospital OP	Physician
Neupogen	15%	16%	$0.09	$0.11
Neulasta	77%	77%	$1.92	$2.10
Leukine	0%	0%	—	$0.00
Granix	8%	6%	$0.05	$0.04
Zarxio	0%	1%	$0.00	$0.00
TOTAL			$2.06	$2.26

Medical Benefit Landscape Trends Supplement

A28

2016 Commercial Medical Benefit Product Preferencing in Place by Drug Category

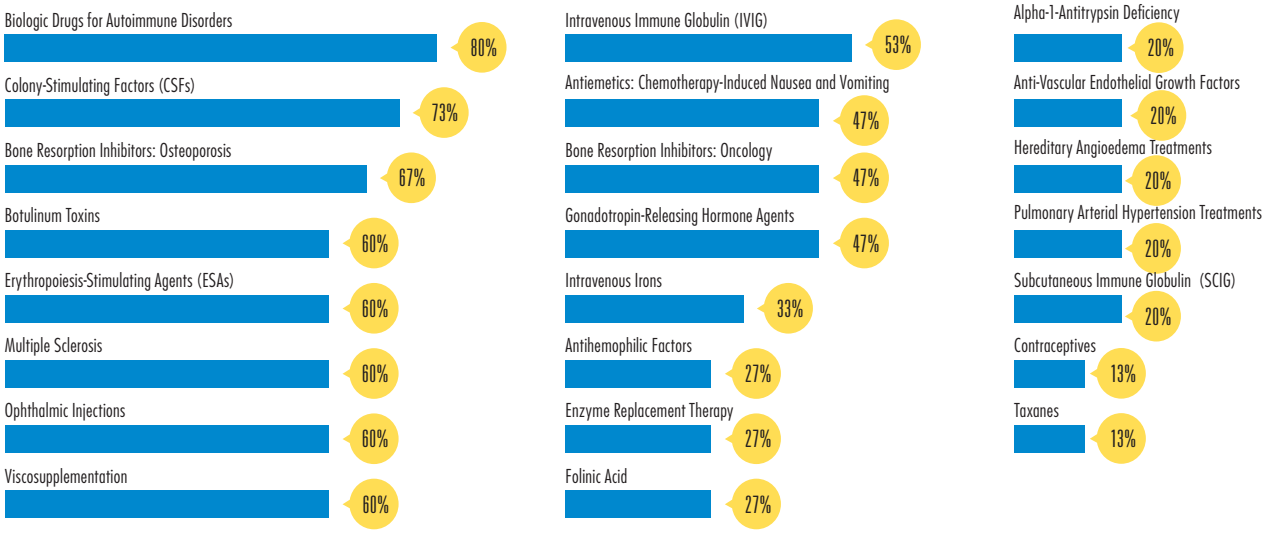
(n=42; 101 million covered lives) % of Payers



A29

2016 Medicare Medical Benefit Product Preferencing in Place by Drug Category

(n=8; 36 million covered lives) % of Payers



2016 Commercial Utilization Management Tools for Medical Benefit Drugs by Disease State or Drug Category (% of payers) (n=49; 109 million covered lives)

Disease State or Drug Category	Care Management (i.e., Disease Management or Case Management)	Clinical Pathways	Differential Provider Reimbursement by Drug in Therapy Class	Dose Optimization	Patient Adherence Program	Post-Service Claim Edits	Prior Authorization	Site of Service	Step Edit Requirements	None	Other	Average
Alpha-1-Antitrypsin Deficiency	31%	2%	2%	8%	6%	12%	69%	14%	4%	22%	2%	16%
Antiemetics: Chemotherapy-Induced Nausea and Vomiting	20%	12%	6%	10%	4%	14%	59%	6%	14%	27%	2%	16%
Antihemophilic Factors	31%	2%	2%	16%	6%	10%	55%	22%	2%	22%	6%	16%
Anti-Vascular Endothelial Growth Factors	24%	10%	10%	10%	4%	16%	69%	8%	6%	16%	2%	16%
Biologic Drugs for Autoimmune Disorders	31%	8%	8%	16%	10%	14%	92%	18%	33%	4%	2%	22%
Bone Resorption Inhibitors: Oncology	16%	12%	2%	10%	4%	6%	84%	10%	16%	12%	2%	16%
Bone Resorption Inhibitors: Osteoporosis	10%	8%	2%	8%	4%	6%	80%	12%	18%	18%	2%	15%
Botulinum Toxins	10%	6%	8%	10%	4%	12%	88%	12%	22%	2%	2%	16%
Colony-Stimulating Factors (CSFs)	16%	8%	2%	12%	4%	10%	71%	16%	14%	16%	4%	16%
Contraceptives	8%	2%	2%	6%	4%	6%	24%	8%	8%	61%	6%	12%
Enzyme Replacement Therapy	14%	2%	2%	6%	4%	8%	71%	16%	4%	24%	2%	14%
Erythropoiesis-Stimulating Agents (ESAs)	16%	10%	4%	6%	4%	12%	76%	8%	18%	18%	2%	16%
Folinic Acid	10%	4%	2%	4%	4%	6%	47%	0%	8%	47%	2%	12%
Gonadotropin-Releasing Hormone Agents	16%	4%	2%	8%	4%	8%	71%	8%	10%	18%	6%	14%
Hereditary Angioedema Treatments	22%	4%	2%	6%	6%	10%	80%	8%	6%	14%	2%	15%
Intravenous Immune Globulin (IVIG)	24%	8%	4%	16%	4%	14%	88%	22%	6%	2%	4%	18%
Intravenous Irons	16%	4%	0%	4%	4%	8%	55%	4%	4%	33%	4%	12%
Multiple Sclerosis	33%	6%	2%	4%	10%	12%	84%	12%	20%	8%	2%	18%
Ophthalmic Injections	14%	6%	4%	4%	4%	8%	57%	4%	14%	20%	2%	13%
Pulmonary Arterial Hypertension Agents	33%	4%	2%	4%	4%	10%	84%	4%	6%	8%	4%	15%
Subcutaneous Immune Globulin (SCIG)	16%	4%	0%	8%	4%	12%	84%	12%	4%	14%	2%	15%
Taxanes	14%	6%	2%	4%	4%	6%	55%	2%	6%	35%	2%	12%
Viscosupplementation	12%	6%	4%	4%	4%	10%	76%	6%	18%	18%	8%	15%
Average	19%	6%	3%	8%	5%	10%	70%	10%	12%	20%	3%	

A31

2016 Medicare Utilization Management Tools for Medical Benefit Drugs by Disease State or Drug Category (% of payers)

(n=8; 32 million covered lives)

Disease State or Drug Category	Care Management (i.e., Disease Management or Case Management)	Clinical Pathways	Post-Service Claim Edits	Prior Authorization	Site of Service	None	Average
Alpha-1-Antitrypsin Deficiency	25%	0%	13%	50%	0%	25%	19%
Antiemetics: Chemotherapy-Induced Nausea and Vomiting	13%	13%	13%	38%	0%	38%	19%
Antihemophilic Factors	25%	0%	13%	25%	13%	50%	21%
Anti-Vascular Endothelial Growth Factors	13%	13%	13%	38%	0%	50%	21%
Biologic Drugs for Autoimmune Disorders	25%	0%	13%	75%	13%	13%	23%
Bone Resorption Inhibitors: Oncology	13%	13%	13%	50%	13%	38%	23%
Bone Resorption Inhibitors: Osteoporosis	13%	0%	13%	38%	13%	50%	21%
Botulinum Toxins	13%	0%	13%	75%	0%	13%	19%
Colony-Stimulating Factors (CSFs)	13%	0%	13%	38%	13%	38%	19%
Contraceptives	13%	0%	13%	25%	0%	50%	17%
Enzyme Replacement Therapy	25%	0%	13%	50%	0%	25%	19%
Erythropoiesis-Stimulating Agents (ESAs)	13%	13%	25%	63%	13%	25%	25%
Folinic Acid	13%	0%	13%	38%	0%	38%	17%
Gonadotropin-Releasing Hormone Agents	13%	0%	13%	38%	13%	38%	19%
Hereditary Angioedema Agents	25%	0%	13%	63%	0%	25%	21%
Intravenous Immune Globulin (IVIG)	25%	0%	13%	75%	13%	25%	25%
Intravenous Irons	13%	0%	13%	25%	0%	50%	17%
Multiple Sclerosis	13%	0%	13%	63%	0%	25%	19%
Ophthalmic Injections	13%	0%	13%	50%	0%	38%	19%
Pulmonary Arterial Hypertension Treatments	25%	0%	13%	75%	0%	13%	21%
Subcutaneous Immune Globulin (SCIG)	13%	0%	13%	75%	13%	25%	23%
Taxanes	13%	13%	13%	25%	0%	50%	19%
Viscosupplementation	13%	0%	13%	75%	0%	25%	21%
Average	16%	3%	13%	51%	5%	33%	

A32

2016 Commercial Rebates Received by Disease State or Drug Category (% of payers)

(n=49; 109 million covered lives)

Disease State or Drug Category	% of Payers	% of Lives
Biologic Drugs for Autoimmune Disorders	67%	55%
Viscosupplementation	45%	40%
Erythropoiesis-Stimulating Agents (ESAs)	40%	70%
Colony-Stimulating Factors (CSFs)	38%	51%
Contraceptives	31%	27%
Botulinum Toxins	26%	58%
Multiple Sclerosis	24%	18%
Enzyme Replacement Therapy	19%	40%
Gonadotropin-Releasing Hormone Agents	19%	17%
Intravenous Immune Globulin (IVIG)	19%	32%
Pulmonary Arterial Hypertension Treatments	19%	18%

Disease State or Drug Category	% of Payers	% of Lives
Bone Resorption Inhibitors: Osteoporosis	17%	18%
No Rebates	14%	5.9%
Bone Resorption Inhibitors: Oncology	12%	18%
Antihemophilic Factors	10%	12%
Ophthalmic Injections	10%	20%
Subcutaneous Immune Globulin (SCIG)	10%	23%
Anti-Vascular Endothelial Growth Factors	7%	10%
Alpha-1-Antitrypsin Deficiency	5%	10%
Antiemetics: Chemotherapy-Induced Nausea and Vomiting (CINV)	5%	20%
Hereditary Angioedema Treatments	5%	10%

A32 CONTINUED

2016 Commercial Rebates Received by Disease State or Drug Category, cont.

(% of payers) (n=49; 109 million covered lives)

Disease State or Drug Category	% of Payers	% of Lives
Folinic Acid	2%	10%
Intravenous Irons	2%	10%
Taxanes	2%	10%

A33

Commercial Top Hospital and Physician Office Administration Codes by Allowed Amount PMPM, Unit Cost, and Site of Service

		Allowed Amount PMPM			Unit Cost	
CPT CODE	CPT DESCRIPTION	HOSPITAL OP	PHYSICIAN OFFICE	TOTAL PMPM	HOSPITAL OP	PHYSICIAN OFFICE
96413	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug	$0.60	$0.24	$0.85	$608.58	$209.78
95165	Supervision of preparation and provision of antigens for allergen immunotherapy; single or multiple antigens (specify number of doses)	$0.01	$0.45	$0.46	$24.72	$13.57
96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour	$0.33	$0.08	$0.41	$402.48	$91.76
96375	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); each additional sequential intravenous push of a new substance/drug	$0.34	$0.03	$0.37	$142.03	$35.28
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	$0.33	$0.33	$22.99	$22.37
90471	Immunization administration (includes percutaneous, intradermal, subcutaneous, or intramuscular injections); 1 vaccine (single or combination vaccine/toxoid)	$0.03	$0.28	$0.32	$77.42	$24.79
96372	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular	$0.12	$0.18	$0.30	$111.10	$28.58
96374	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); intravenous push, single or initial substance/drug	$0.24	$0.01	$0.26	$209.35	$75.85
96361	Intravenous infusion, hydration; each additional hour	$0.21	$0.01	$0.21	$114.98	$22.46
96367	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); additional sequential infusion of a new drug/substance, up to 1 hour	$0.10	$0.05	$0.15	$186.02	$44.36
96415	Chemotherapy administration, intravenous infusion technique; each additional hour	$0.09	$0.03	$0.13	$200.31	$45.97
96417	Chemotherapy administration, intravenous infusion technique; each additional sequential infusion (different substance/drug), up to 1 hour	$0.09	$0.03	$0.12	$310.71	$104.45
90461	Immunization administration each additional component	$0.00	$0.12	$0.12	$14.31	$11.40
96360	Intravenous infusion, hydration; initial, 31 minutes to 1 hour	$0.08	$0.01	$0.10	$295.48	$82.73
95117	Immunotherapy injections	$0.00	$0.08	$0.09	$70.89	$14.11
99601	Home infusion/specialty drug administration, per visit (up to 2 hours)	$0.00	$0.00	$0.09	$160.99	$118.05
96366	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); each additional hour	$0.07	$0.01	$0.09	$132.34	$32.77
96411	Chemotherapy administration; intravenous, push technique, each additional substance/drug	$0.06	$0.02	$0.07	$300.40	$91.81
96416	Chemotherapy administration, intravenous infusion technique; initiation of prolonged chemotherapy infusion (more than 8 hours), requiring use of a portable or implantable pump	$0.05	$0.02	$0.07	$625.71	$230.54
96401	Chemotherapy administration, subcutaneous or intramuscular; nonhormonal antineoplastic	$0.02	$0.04	$0.06	$256.01	$87.71

Please note that due to rounding, some column totals do not add up accurately.

A33 CONTINUED

Commercial Top Hospital and Physician Office Administration Codes by Allowed Amount PMPM, Unit Cost, and Site of Service (cont.)

		Allowed Amount PMPM			Unit Cost	
CPT CODE	CPT DESCRIPTION	HOSPITAL OP	PHYSICIAN OFFICE	TOTAL PMPM	HOSPITAL OP	PHYSICIAN OFFICE
96409	Chemotherapy administration; intravenous, push technique, single or initial substance/drug	$0.04	$0.01	$0.05	$400.57	$164.50
90472	Immunization administration; each additional	$0.00	$0.04	$0.04	$26.68	$15.76
96376	Intravenous push, single or initial substance/drug; each additional sequential intravenous push of the same substance/drug provided in a facility	$0.04	$0.00	$0.04	$100.83	$108.09
99602	Home infusion/specialty drug administration, per visit (up to 2 hours); each additional hour	$0.00	$0.00	$0.03	$55.44	$59.89
96402	Chemotherapy administration, subcutaneous or intramuscular; hormonal antineoplastic	$0.02	$0.00	$0.02	$232.87	$50.96
95115	Immunotherapy; one injection	$0.00	$0.02	$0.02	$39.57	$12.99
96523	Irrigation of implanted venous access device for drug delivery systems	$0.01	$0.00	$0.02	$134.55	$38.51
96368	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); concurrent infusion	$0.01	$0.00	$0.02	$140.52	$28.08
96450	Chemotherapy administration, into CNS (e.g., intrathecal), requiring and including spinal puncture	$0.01	$0.00	$0.01	$553.37	$334.61
90473	Immune administration oral/nasal	$0.00	$0.01	$0.01	$26.56	$25.50
96521	Refilling and maintenance of portable pump	$0.00	$0.01	$0.01	$406.44	$185.35
G0008	Administration of influenza virus vaccine	$0.00	$0.01	$0.01	$41.89	$22.60
	TOTAL (96413-G0008)	**$2.59**	**$2.17**	**$4.89**		

Please note that due to rounding, some column totals do not add up accurately.

A34

Medicare Top Hospital and Physician Office Administration Codes by Allowed Amount PMPM, Unit Cost, and Site of Service

		Allowed Amount PMPM			Unit Cost	
CPT CODE	CPT DESCRIPTION	HOSPITAL OP	PHYSICIAN OFFICE	TOTAL PMPM	HOSPITAL OP	PHYSICIAN OFFICE
96413	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug	$0.87	$0.37	$1.23	$295.33	$146.09
96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour	$0.34	$0.09	$0.43	$179.82	$72.24
96372	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular	$0.17	$0.23	$0.40	$52.62	$24.23
96367	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); additional sequential infusion of a new drug/substance, up to 1 hour	$0.15	$0.09	$0.25	$55.52	$31.58
90471	Immunization administration (includes percutaneous, intradermal, subcutaneous, or intramuscular injections); 1 vaccine (single or combination vaccine/toxoid)	$0.01	$0.19	$0.20	$57.24	$21.92
96375	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); each additional sequential intravenous push of a new substance/drug	$0.14	$0.05	$0.18	$40.99	$22.72
96374	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); intravenous push, single or initial substance/drug	$0.13	$0.01	$0.14	$115.01	$57.26
96415	Chemotherapy administration, intravenous infusion technique; each additional hour	$0.09	$0.05	$0.13	$56.79	$31.03
96361	Intravenous infusion, hydration; each additional hour	$0.12	$0.01	$0.13	$38.40	$15.46

Please note that due to rounding, some column totals do not add up accurately.

A34 CONTINUED

Medicare Top Hospital and Physician Office Administration Codes by Allowed Amount PMPM, Unit Cost, and Site of Service (cont.)

		Allowed Amount PMPM			Unit Cost	
CPT CODE	CPT DESCRIPTION	HOSPITAL OP	PHYSICIAN OFFICE	TOTAL PMPM	HOSPITAL OP	PHYSICIAN OFFICE
96401	Chemotherapy administration, subcutaneous or intramuscular; non-hormonal anti-neoplastic	$0.05	$0.07	$0.12	$112.81	$76.65
96417	Chemotherapy administration, intravenous infusion technique; each additional sequential infusion (different substance/drug), up to 1 hour	$0.06	$0.05	$0.11	$63.47	$67.89
96360	Intravenous infusion, hydration; initial, 31 minutes to 1 hour	$0.06	$0.01	$0.08	$126.44	$58.79
G0008	Administration of influenza virus vaccine	$0.00	$0.07	$0.07	$31.83	$22.20
96366	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); each additional hour	$0.05	$0.01	$0.07	$36.00	$20.35
96416	Chemotherapy administration, intravenous infusion technique; initiation of prolonged chemotherapy infusion (more than 8 hours), requiring use of a portable or implantable pump	$0.04	$0.03	$0.06	$317.89	$152.77
96409	Chemotherapy administration; intravenous, push technique, single or initial substance/drug	$0.04	$0.02	$0.05	$182.96	$117.90
96523	Irrigation of implanted venous access device for drug delivery systems	$0.04	$0.01	$0.05	$76.28	$26.74
96411	Chemotherapy administration; intravenous, push technique, each additional substance/drug	$0.03	$0.02	$0.05	$61.76	$64.00
95165	Supervision of preparation and provision of antigens for allergen immunotherapy; single or multiple antigens (specify number of doses)	—	$0.04	$0.04	—	$13.09
G0009	Administration of pneumococcal vaccine	$0.00	$0.04	$0.04	$41.69	$22.92
96402	Chemotherapy administration, subcutaneous or intramuscular; hormonal antineoplastic	$0.01	$0.02	$0.03	$65.99	$34.20
90472	Immunization administration; each additional	$0.00	$0.01	$0.01	$23.93	$12.18
95117	Immunotherapy injections	$0.00	$0.01	$0.01	$31.48	$11.79
96376	Intravenous push, single or initial substance/drug; each additional sequential intravenous push of the same substance/drug provided in a facility	$0.01	—	$0.01	$45.95	—
96521	Refilling and maintenance of portable pump	$0.00	$0.00	$0.01	$143.55	$136.51
96368	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); concurrent infusion	$0.00	$0.01	$0.01	$59.82	$19.45
	TOTAL (96413-96368)	**$2.40**	**$1.52**	**$4.01**		

Please note that due to rounding, some column totals do not add up accurately.

A35

Commercial and Medicare Top Home Infusion Administration Codes by Allowed Amount PMPM, Unit Cost, and Line of Business

		Commercial	Medicare	Commercial	Medicare
CPT CODE	CPT DESCRIPTION	ALLOWED AMOUNT PMPM		UNIT COST	
99601	Home infusion/specialty drug administration, per visit (up to 2 hours)	$0.08	$0.06	$117.75	$103.34
99602	Home infusion/specialty drug administration, per visit (up to 2 hours); each additional hour	$0.03	$0.02	$52.59	$49.84
	TOTAL	**$0.11**	**$0.08**		

Please note that due to rounding, some column totals do not add up accurately.

ACA ..... Affordable Care Act
ACO ..... accountable care organization
ACT ..... adoptive cell transfer
ADR ..... administrative dispute resolution
ALL ..... acute lymphoblastic 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
CBO ..... Congressional Budget Office
CD ..... Crohn's disease
CINV ..... chemotherapy-induced nausea and vomiting
CLL ..... chronic lymphocytic leukemia
CMS ..... Centers for Medicare & Medicaid Services
CMS Innovation Center .. Center for Medicare & Medicaid Innovation
CPT ..... Current Procedural Terminology
CSF ..... colony-stimulating factor
EHR ..... electronic health record
ESA ..... erythropoiesis-stimulating agent
FAIR ..... Fair Accountability and Innovative Research
FDA ..... U.S. Food and Drug Administration
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
HI/SPP ..... home infusion/specialty pharmacy
Hospital OP ..... hospital outpatient
HRSA ..... Health Resources and Services Administration
ICD ..... International Classification of Diseases
IDN ..... integrated delivery network
IG ..... immune globulin
IL ..... interleukin
IV ..... intravenous
IVIG ..... Intravenous immune globulin
LEC ..... low emetogenic chemotherapy
LOB ..... line of business
mAb ..... monoclonal antibody
MACRA ..... Medicare Access and CHIP Reauthorization Act of 2015
MEC ..... moderately emetogenic chemotherapy
MedPAC ..... Medicare Payment Advisory Commission
MinEC ..... minimal emetogenic chemotherapy
MIPS ..... Merit-Based Incentive Payment System
MOA ..... mechanism of action
NDC ..... National Drug Code
NK ..... natural killer
NSCLC ..... non-small cell lung cancer
OCM ..... Oncology Care Model
OIG ..... HHS Office of the Inspector General
OMB ..... Office of Management and Budget
PA ..... prior authorization
Part D ..... Medicare Prescription Drug Program
PCOP ..... Patient-Centered Oncology: Payment
PD1 ..... programmed cell death 1
PD-L1 ..... programmed death-ligand 1
PI3K ..... phosphoinositide 3-kinase inhibitor
PLK1 ..... polo-like kinase-1
PMPM ..... per member per month
PPPY ..... per patient per year
PSCE ..... post-service claim edits
QPP ..... Quality Payment Program
SCIG ..... Subcutaneous immune globulin
SLAMF7 .. signaling lymphocytic activation molecule family member 7
SMA ..... spinal muscular atrophy
SQ ..... subcutaneous
UC ..... ulcerative colitis
VEGF ..... vascular endothelial growth factor
WAC ..... wholesale acquisition cost

Notes