Magellan Rx Management

Medical Pharmacy Trend Report

2013 FOURTH EDITION

Magellan Rx MANAGEMENT℠

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Magellan Rx Management
6870 Shadowridge Dr., Suite 111
Orlando, FL 32812
Tel: 866-664-2673
Fax: 866-994-2673
www.magellanhealth.com

Publishing Staff

MEDIA DIRECTOR
Erika I. Ruiz-Colon

MEDIA MANAGER
Kayla Killian

Contributors

Robert Louie, R.Ph.
VICE PRESIDENT, CLINICAL MEDICAL PHARMACY

Jeanine Boyle, J.D., M.P.H.
VICE PRESIDENT, HEALTH CARE REFORM STRATEGY

Erika I. Ruiz-Colon
DIRECTOR, SALES AND STRATEGIC OPERATIONS

Mary Talberg
DIRECTOR, IT FINANCIAL INFORMATION MANAGEMENT

Michele Marsico
DIRECTOR, ANALYTICS

Kayla Killian
PROJECT MANAGER

Jason Peterson, R.Ph.
CLINICAL PHARMACIST

Payor Advisory Board

Mona Chitre, Pharm.D., CGP
VICE PRESIDENT, PHARMACY MANAGEMENT — EXCELLUS BLUE CROSS BLUE SHIELD

Mohamed Diab
VICE PRESIDENT, MEDICAL MANAGEMENT — EMBLEM HEALTH

Samir Mistry, Pharm.D.
PARTNER — HEALTHCARE AT COGNIZANT TECHNOLOGY SOLUTIONS

Scott McClelland, Pharm.D.
SENIOR DIRECTOR OF COMMERCIAL PHARMACY AND SPECIALTY PHARMACY MANAGEMENT — FLORIDA BLUE

Gary Tereso, Pharm.D., BCPS
DIRECTOR OF PHARMACY AND CASE MANAGEMENT SERVICES — HEALTH NEW ENGLAND

Medical Pharmacy — The Future of Specialty and Overall Pharmacy Drug Management

It is our pleasure to present you with the Magellan Rx Management Medical Pharmacy Trend Report™. This is the fourth edition of this report, and it has been enhanced this year by showing additional data regarding orphan indications for some key drugs. We have added a survey of employers to report key findings for this market segment. The survey reflected the current managed health care landscape regarding the coverage, reimbursement and management of medical injectable/infusible drugs, including oncology drugs (provider-administered, not self-injectables). The employer trend report will be available online. We will continue to build on employer data and surveys in future reports. In addition, our survey asked much more specific questions to drill into key areas like how plans implement a medical formulary and what medical drugs have rebates. We also spend some time commenting on the "other" buckets in our analysis and the implications these specialty medical drugs can have for an overall medical specialty strategy. As we have discussed in the past, various reports exist to describe specialty and oral chemotherapy products paid under the pharmacy benefit; however, this trend report remains the key source that exists for injectables paid under a payor's medical benefit, where top drugs such as Neulasta, Remicade, Avastin, Rituxan and Lucentis are almost entirely paid. We are excited to continue to be the leading source for these important benchmarking and trending statistics.

In recent years, we have experienced low increases in the costs of traditional oral pharmacy products (and, in fact, negative trends in well-managed plans) when compared with specialty products, where trends are approximately 20 percent for self-administered injectables and double digits for provider-administered products. This finding will continue to prevail, in part due to the oncology pipeline, paired with traditional oral medications losing patents. Specialty products are 25 to 30 percent of total drug spend, and medical benefit injectables comprise nearly 50 percent of the specialty spend, or 15 percent overall. The percentage of specialty drugs will continue to grow at a faster pace than traditional oral drugs and will represent 50 percent of total drug cost in the future.

To understand these costs and trends and the payor management initiatives used this year to improve the quality and cost of care compared with previous years, we surveyed 48 top U.S. commercial health plans representing 166 million lives. We then evaluated the paid claim files of health plans' medical benefit injectables such that benchmarks and trends could be determined over the past three years. It is important to note each year the universe of these health plans can change but the data used will represent a consistent data set over the three-year trend analysis.

We want to offer special thanks to the payor executives who served on this year's Magellan Rx Management Medical Pharmacy Trend Report™ advisory board. It was their input into the overall objective, content and design that allowed us to offer this comprehensive report.

Mostafa Kamal
SENIOR VICE PRESIDENT AND GENERAL MANAGER, SPECIALTY RX
Magellan Rx Management

John LaFreniere
VICE PRESIDENT, PHARMACY OPERATIONS
Magellan Rx Management

Casandra Stockman, Pharm.D.
VICE PRESIDENT, SPECIALTY RX ACCOUNT MANAGEMENT
Magellan Rx Management

Adam Wiatrowski
SENIOR VICE PRESIDENT, ACCOUNT MANAGEMENT
Magellan Rx Management

Robert Louie, R.Ph.
VICE PRESIDENT, CLINICAL MEDICAL PHARMACY
Magellan Rx Management

Amy Van Buren
VICE PRESIDENT, SPECIALTY RX ACCOUNT MANAGEMENT
Magellan Rx Management

2013 Survey Methodology and Demographics

The methodology for this fourth edition of Magellan Rx Management Medical Pharmacy Trend Report™ was developed with guidance from our payor advisory board.

This report employs a combination of primary and secondary research methodologies to deliver a comprehensive view of payor perceptions and health plan actions related to medical injectables, including those used for chemotherapy and cancer supportive care, rheumatology and immunotherapy.

The first section of the report was derived from a custom market research survey conducted among commercial health plan medical directors and pharmacy directors. The Web survey was designed to gather feedback about how managed care organizations operate around six key management drivers for medical injectable drugs identified by Magellan Rx Management and our payor advisory board.

The second section of the report was derived from secondary analyses of health plan medical paid claims data. An exciting enhancement to this year's report is that the claims data are from various sites of service, regardless of where the drug was infused or administered. In addition, this year's report evaluates multiple lines of business (LOBs) (i.e., commercial, Medicare, managed Medicaid) to provide a more comprehensive view of key oncology and medical injectable trends among health plans.

HEALTH PLAN SURVEY METHODOLOGY

As in our previous edition, the target list of payors consisted of the top 160 U.S. commercial health plans based on number of lives covered. The sample was stratified based on covered lives, national versus regional plans, geographic dispersion and medical versus pharmacy executives. Research topics were developed in conjunction with our payor advisory board and aligned with the six key medical injectable drug management drivers. The survey questions were defined, and some questions were revised to provide greater specificity over the 2012 survey version. The potential effect of the changes has been noted where appropriate in the results. The questions were pretested, and the survey was deployed to the sample audience via a secure browser-based software program hosted by Magellan Health Services, Magellan Rx Management's parent company.

The data collection took place over a three-week period during June and July 2013. Following data collection, the results were validated, aggregated and analyzed for reporting herein. For purposes of this report, survey results are primarily reported on a "percentage of lives" basis. Weighting individual responses in this manner provides an indication of the potential marketplace impact of payor policies on the number of covered member lives, in addition to the percentage of payors incorporating any one policy. Survey results are also reported, at times, with the health plans stratified into large- and small-sized plans, defined as 500,000 or more lives and fewer than 500,000 lives, respectively. In certain cases, base sizes are small and care should be used when interpreting the data. Rarely, some percentages may add up to slightly more or less than 100 percent due to rounding effects.

A total of 48 individual survey responses were received. As noted in the table below, these 48 health plans manage 166.3 million lives, a slight increase over the 157.2 million covered lives reported in 2012.

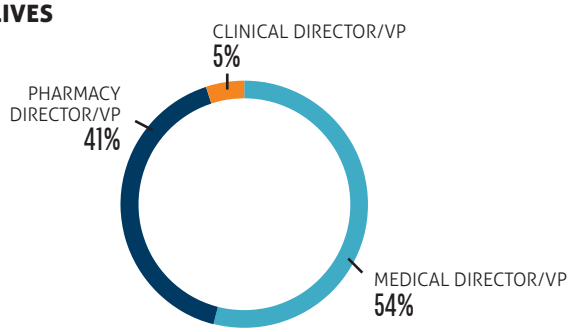
Sixty-four percent of the health plan organizations that responded in 2012 also provided responses to the 2011 survey. When evaluating year-to-year trends, the entire sample of 2013 respondents is compared with the respondents in 2012 and 2011. The demographic composition of this year's respondents is not as consistent as the composition of the base in the prior two years.

Survey Respondent Composition

	COUNT	LIVES	% OF LIVES	% OF PLANS
Less than 500,000	16	3,969,000	2%	33%
500,000 to 999,999	12	8,005,000	5%	25%
1,000,000 to 4,999,999	15	36,105,000	20%	31%
5,000,000 or more	5	118,246,487	73%	11%
Total	**48**	**166,325,487**	**100%**	**100%**

Representation of Survey Respondents

% OF LIVES

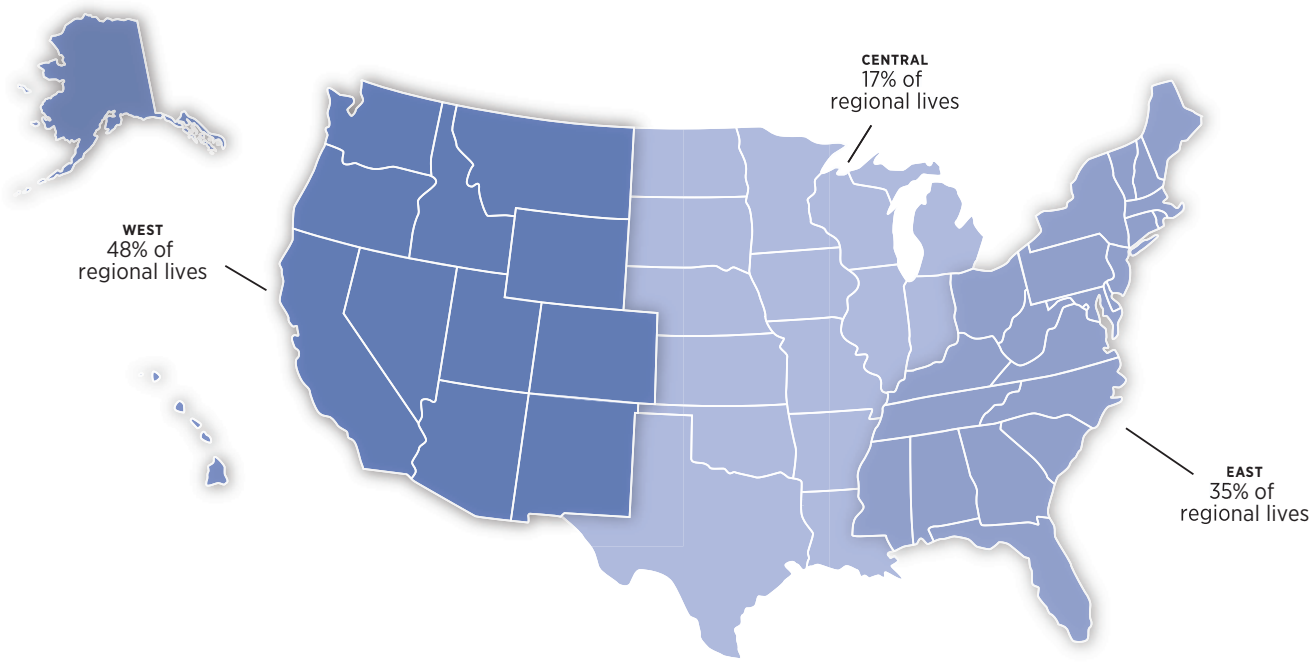


Current survey respondents tended to be very experienced, with an average of 22 years in the field and nine years in their current position. Compared to the previous year, there was a decrease of 17 percent in the lives represented by medical director respondents (54 percent) versus those of pharmacy directors/clinical pharmacists (41 percent). Internal medicine and family medicine are the leading specialties reported by these health plan medical directors.

Of the total lives covered by the payors completing the survey, 59 percent are fully insured lives, while the balance are provided only administrative services by the health plan. Survey respondents noted that the majority of their members (67 percent of lives) who receive coverage are covered under mixed health maintenance organization (HMO)/preferred provider organization (PPO) products. In addition, two-thirds (65 percent) of total covered lives reflect commercial product coverage.

Survey respondents from national plans reflect 21 percent of the respondents, yet they cover nearly three-fourths (72 percent) of the total lives represented in this survey. Conversely, regional plans have a larger percentage of payor respondents (79 percent), but reflect only 28 percent of the total covered lives. The map on this page illustrates that geographically nearly half of the covered lives of these regional payor respondents are located in the west.

Regional Plans – Geographic Dispersion of Lives



Report Summary and Conclusions

Magellan Rx Management 2013 Medical Pharmacy Trend Report™ evaluated injectable quality and cost management tools and trends of medical benefit injectables, defined as injectable drugs that are administered by providers at various sites of service and are paid under the medical benefit. The results of this study are a combination of findings from senior leaders at commercial payors as well as paid claims across key lines of business and sites of service.

In this year's report, we asked very specific questions in some key areas to try to really understand what health plans are doing to manage medical drugs. For example, we tried to get a sense of how each plan defined and implemented a medical drug formulary. Our analysis attempted to drill into the "other" bucket in many of our claims data analyses to uncover some insightful trends; we believe this category is where most of the opportunities and challenges will be found. As we continue to move our trend report forward, sometimes the responses do not seem to make sense and may represent more of what our health plan responders feel they should be doing rather than what truly is in place. We will continue to use this insight to craft new and critical questions to provide a trend report that you can use as a benchmark for your medical pharmacy needs.

Key findings of this report include:

- Drugs reimbursed on the medical benefit continue to trend 7 to 12 percent from last year's report. This trend was impacted by new drugs and new indications; specifically, a few drugs made the top 25 list, including Soliris and Xgeva. Site of service continues to impact unit cost with utilization shifting to the hospital, where drugs cost twice as much on average. Off-label use or use not supported by data remained consistent, at 6 percent for commercial and 5 percent for Medicare. These trends compared to low to negative trends for traditional pharmacy claims remain a major concern for payors.
- Twenty-two percent of plans indicated they had a medical formulary in place using tiered benefit structures (25 percent), prior authorization (94 percent), policy (25 percent), reimbursement strategies (31 percent) and pathways (31 percent). It is important to understand that when plans are referring to preferred products or formularies on the medical benefits, they use different techniques than what has been used on the pharmacy benefit. Only one out of four used a traditional benefit design to implement a formulary today. This area will continue to evolve in the future.
- Only 31 percent of plans responded yes to receiving rebates on the medical benefit, down from 57 percent, which seems to be a result of some key products moving away from this strategy. However, plans did respond yes to receiving rebates in some new categories like hemophilia, intravenous immunoglobulin (IVIG) and cancer.
- Genetic testing remains a critical component of medical drug management but plans are not developing sophisticated strategies including network strategies.
- This year we wanted to analyze if plans are implementing utilization review programs by drug or by therapy class. Ninety percent manage by drug, which may not be the ideal way to manage a patient's care but is the most realistic way plans can implement these complex prior authorizations.
- Thirty percent of plans are not performing any post-claim edits for these high-cost drugs. This is an area of opportunity for these plans.
- Fifty-six percent of plans implemented a fixed fee schedule to reduce the number of hospitals reimbursed for medical drugs as a percentage of charge. As we reported last year, shift to hospital site of service for medical drugs is a critical driver of trend. This effort to improve and fix the unit cost paid to hospitals is an important step, but our experience in the market shows that these programs may not have been as widely implemented successfully and this area remains a challenge for most payors.
- The top cancer medications increased in hospital utilization by 20 to 35 percent, with the majority of this utilization shifting from the physician's office. This continues to challenge payors, given the cost of these drugs in a hospital setting.

Looking back at the last three trend reports and reviewing the results of our fourth edition, we want to provide some perspective of the pharmacy benefit managers' understanding of and experience with medical pharmacy drug management and trends. Most of the large PBMs distribute an annual trend report of drugs covered under the pharmacy benefit. A few years ago, the largest PBM's trend report included a graph for autoimmune disorders that listed Remicade as having no utilization for a three-year period. As the readers of this report know, Remicade is the top drug reimbursed on the medical benefit, and when analyzed with the self-injected products that treat autoimmune disorders, Remicade has significant market share — thus, the PBM's analysis of this key therapy class was inaccurate. In the following year, the PBM's trend report did report medical drug utilization that is purchased from a consulting data company. In last year's report, the same PBM removed all medical drug utilization. We mention this to demonstrate how far the pharmacy benefit management industry has to go to analyze and provide real insights on and solutions to the most complex drug utilization on the medical benefit. We hope you continue to find this report useful and unique, as it is the only detailed drug trend report available for those medicines administered by providers and billed under the medical benefit. You may access the data and additional copies of this report at **www.magellanhealth.com**.

Payor Survey Data

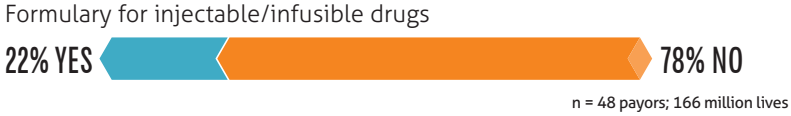
Medical Benefit and Drug Formulary

In this year's study of commercial payors, health plans covering about one-quarter of lives (22 percent) operate with established medical benefit injectable drug formulary for at least some therapeutic classes, which is substantially lower than the two-thirds of covered lives reported by payors the last three years (75, 65 and 63 percent in 2010, 2011 and 2012, respectively). This year large payors were less likely to have a formulary than small payors, which is inconsistent with last year. *See Figure 1, Medical Benefit Injectable Formularies in Place Overall, and Figure 2, Medical Benefit Injectable Formularies in Place by Size of Health Plan.*

Of the 36 million members subjected to medical formulary requirements, most were for all products listed. Further, we found that formulary management remained high in all categories of products listed. We asked which biologic response modifiers (BRMs) are subjected to a medical formulary. A wide array of BRMs were included, specifically Enbrel, Humira, Orencia, Procrit, Remicade and Rituxan, which was consistent with previous years. *See Figure 3, Therapeutic Classes with a Medical Formulary Currently in Place.*

FIGURE 1: Formularies in Place Overall

% OF LIVES



n = 48 payors; 166 million lives

FIGURE 2: Formularies in Place by Plan Size

% OF RESPONDENTS

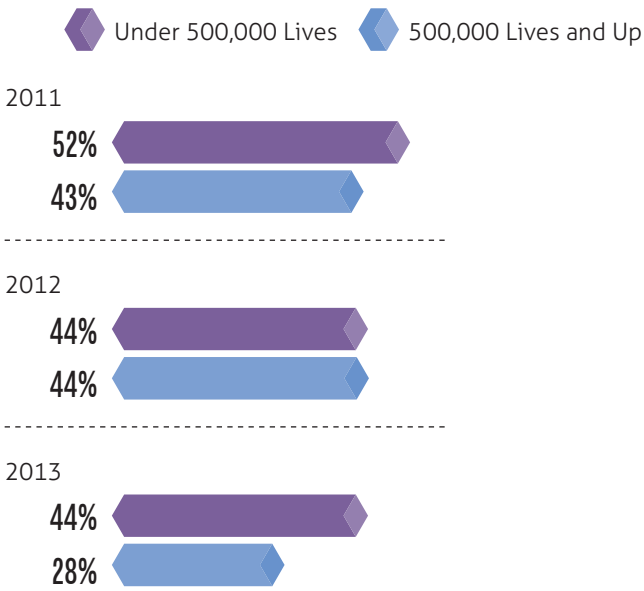
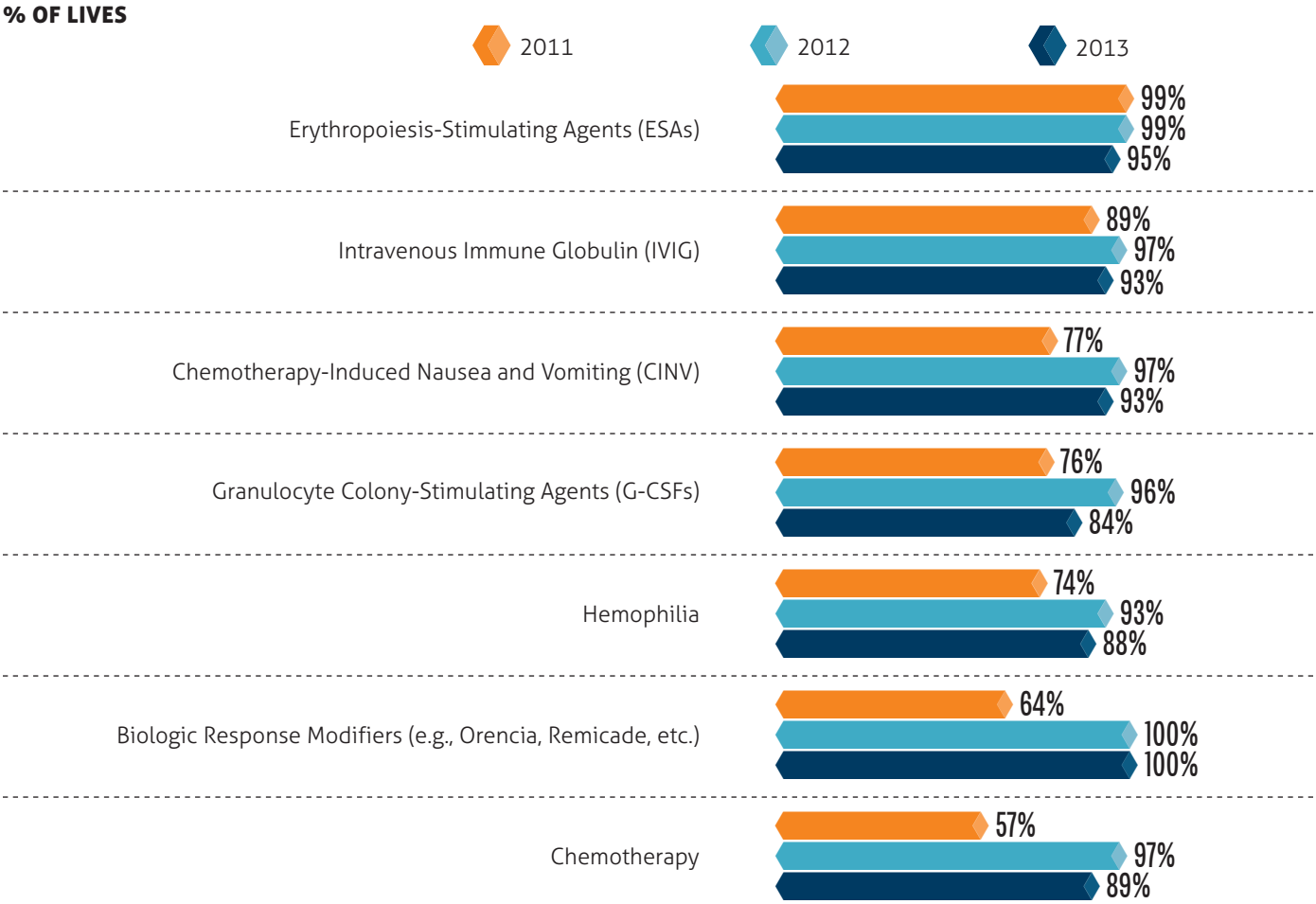


FIGURE 3: Therapeutic Classes with a Medical Formulary Currently in Place



n = 28 payors; 100 million lives (2011)
n = 21 payors; 95 million lives (2012)
n = 16 payors; 36 million lives (2013)

To better understand the extent to which formularies impact individual chemotherapeutics, we identified seven cancers whose treatments were commonly listed by payors as being under formulary management. Last year there was an increase in the portion of lives under formulary for metastatic breast cancer and prostate cancer, which remained high for 2013. In addition, this year there were substantial increases in the portion of lives under formulary for the other five cancers. *See Figure 4, Common Cancer Types Where Payors Have at Least Some Medical Drug Formulary in Place.*

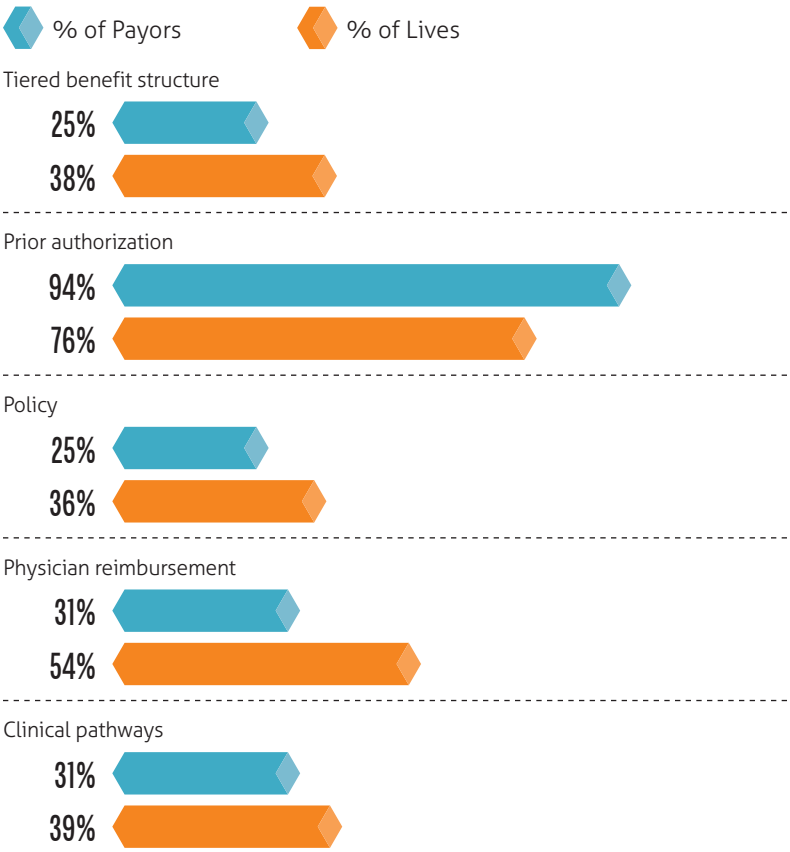
FIGURE 4: Common Cancer Types Under Formulary

Cancer Type	2010 % of lives	2011 % of lives	2012 % of lives	2013 % of lives	% change from 2012
Non-Small Cell Lung Cancer	100%	100%	44%	97%	120%
Metastatic Breast Cancer	63%	49%	98%	99%	1%
Prostate Cancer	63%	49%	97%	93%	-4%
Non-Hodgkin's Lymphoma	63%	46%	44%	90%	105%
Multiple Myeloma	63%	46%	48%	92%	92%
Renal Cell Carcinoma	63%	46%	44%	92%	109%
Leukemia	63%	46%	45%	92%	104%

n = 12 payors; 94 million lives (2010)
n = 12 payors; 57 million lives (2011)
n = 13 payors; 58 million lives (2012)
n = 11 payors; 32 million lives (2013)

This year we asked how payors implement their medical formulary. Prior authorization (PA) was used in three-quarters of covered lives (76 percent). Physician reimbursement was also used in over half of covered lives (54 percent). *See Figure 5, Implementation of Medical Formulary.*

FIGURE 5: Implementation of Medical Formulary



n = 16 payors; 36 million lives (2013)

Carrying forward the methodology used in the 2012 Medical Pharmacy & Oncology Trend Report™, the trend appears to demonstrate that payors are becoming more sophisticated in and likely to establish preferential pricing for drugs paid under the medical benefit. In addition, plans appear to be more capable of moving market shares to preferred medical benefit injectable products. In some cases, the preferred medical benefit injectable product has a manufacturer's rebate available to the health plan.

In 2013, plans covering 50 percent of the lives note receiving rebates on medical injectable products. This is similar to 2012 (51 percent). Compared to 2012, proportionally fewer smaller payors (less than 500,000 lives) and more larger payors have established a rebate contract for at least one medical injectable product. *See Figure 6, Rebates Received from Drug Manufacturers That Are Mainly Paid on the Medical Benefit Overall, and Figure 7, Rebates Received from Drug Manufacturers That Are Mainly Paid on the Medical Benefit by Size of Health Plan.*

FIGURE 6: Rebates Received Overall

% OF LIVES

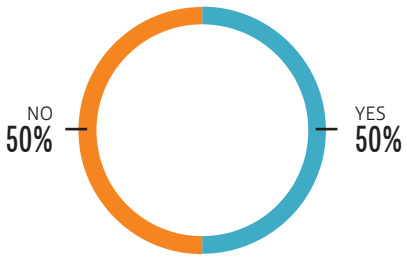
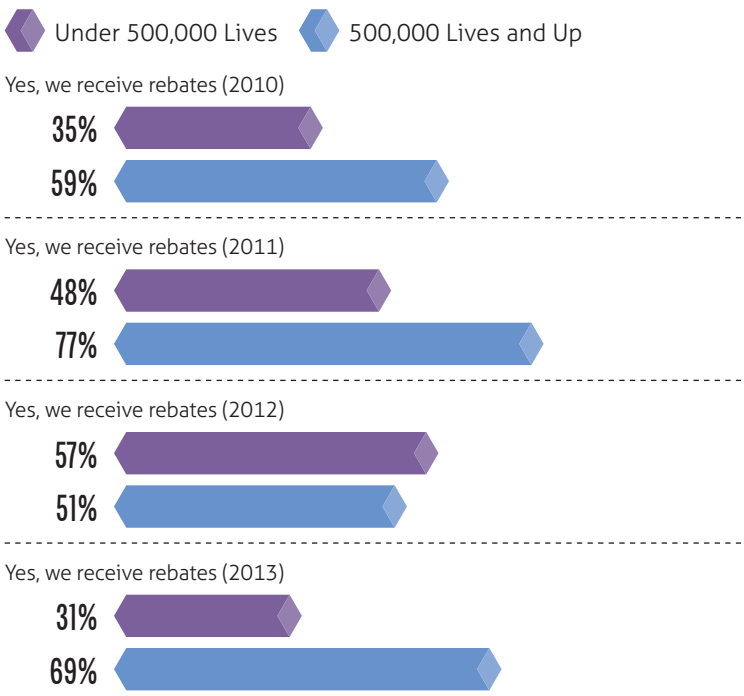


FIGURE 7: Rebates Received by Plan Size

% RESPONDENTS

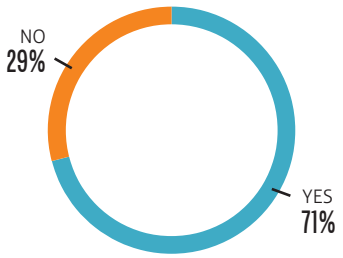


n = 29 payors; 82 million lives (2010)
n = 31 payors; 116 million lives (2011)
n = 27 payors; 78 million lives (2012)
n = 27 payors; 82 million lives (2013)

Nearly three-quarters of payors who reported receiving rebates for medical benefit injectables report receiving them for products other than Remicade. *See Figure 8, Rebates Other than Remicade.* This year the portion of lives affected by rebates increased for nearly every category listed. *See Figure 9, Therapeutic Classes Where Payors Receive Injectable/Infusible Product Rebates.*

FIGURE 8: Rebates Other than Remicade

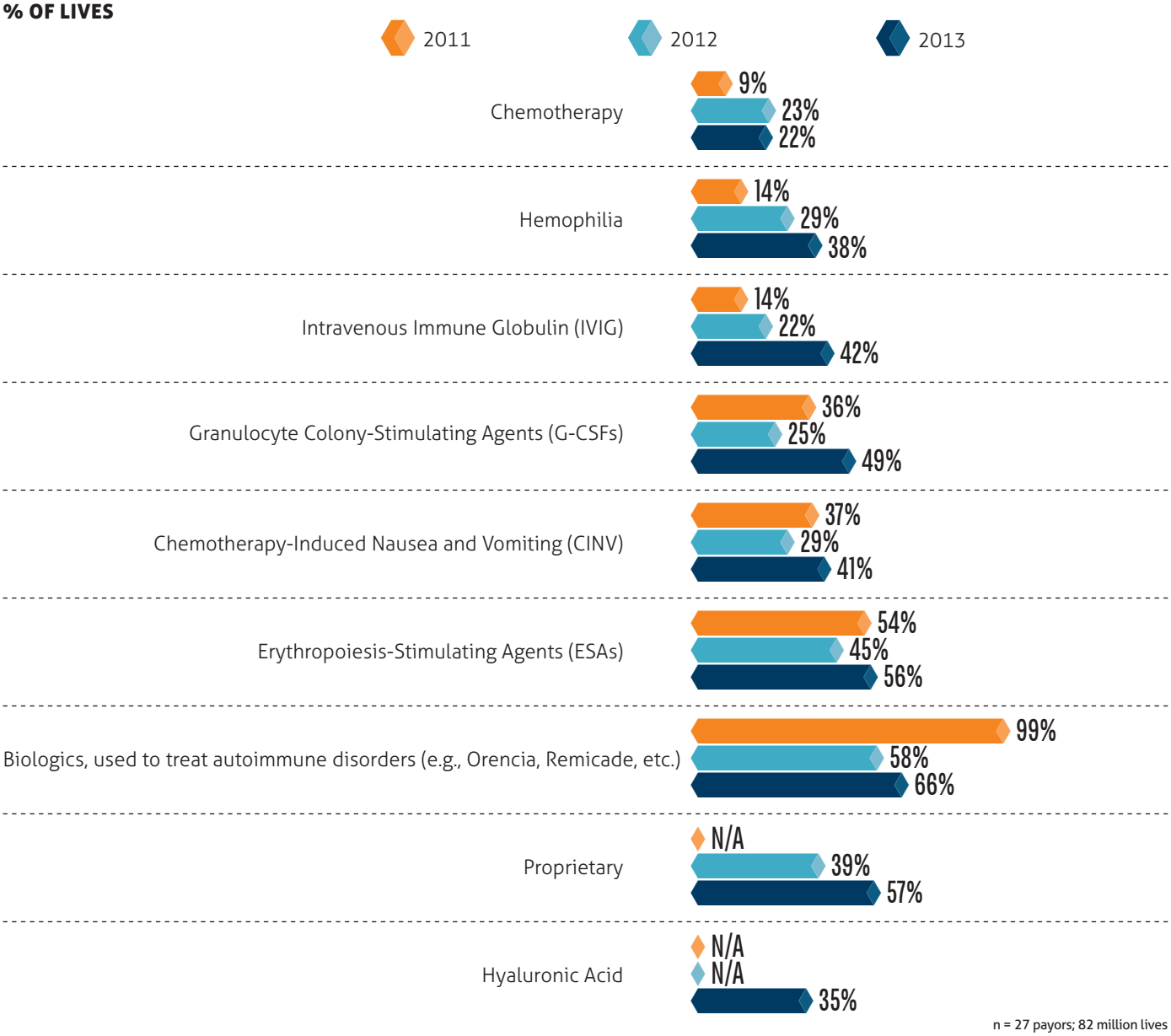
% OF LIVES



n = 27 payors; 76 million lives (2013)

FIGURE 9: Therapeutic Classes with Rebates

% OF LIVES

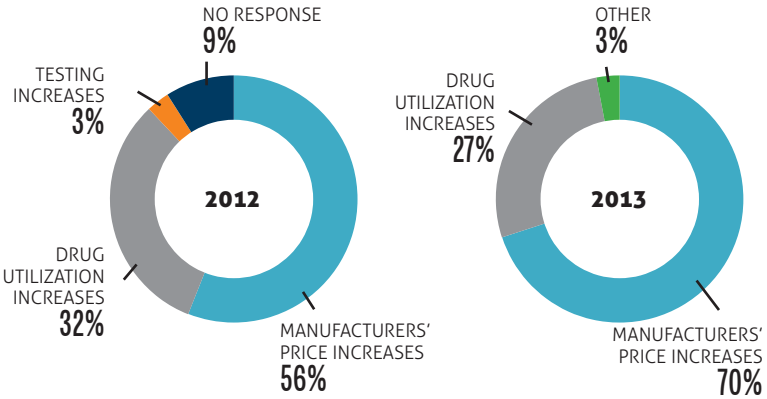


n = 27 payors; 82 million lives

We asked what payors think is the key driver of oncology costs. Plans covering 70 percent of lives reported manufacturers' price increases, which is an increase from 56 percent in 2012. Drug utilization increases were reported by plans covering 27 percent of lives. *See Figure 10, Key Driver of Oncology Costs.*

FIGURE 10: Key Driver of Oncology Costs

% OF LIVES



Provider Reimbursement

Typically, providers purchase oncolytics and other infusible/injectable agents from a distributor, administer the drug to patients in their offices and then bill the patient's insurance carrier for reimbursement of the drug and associated administration costs under the patient's medical benefit. This method of distribution is commonly referred to as "physician buy and bill." About eight of every 10 covered lives in the survey are covered by plans that reimburse providers for medical benefit injectables based upon a percentage higher than the average sales price (ASP) plus methodology. This is an increase from six of every 10 the last three years, supporting the hypothesis that many of the payors migrating to this method of reimbursement have done so following the Medicare Modernization Act (MMA) of 2005. *See Figure 11, Reimbursement Approach and the Extent of Discounts Used by Payors to Reimburse for Drugs Paid Under the Medical Benefit.*

The increase in the ASP plus methodology was offset by decreases this year for the average wholesale price (AWP) minus-based reimbursement methodology to about one in 10 covered lives and in the variable fee schedule (VFS)-based methodology for reimbursement to 3 percent of covered lives. The number of lives for which providers are reimbursed under an AWP plus has remained near zero. It is possible that payors using tight ASP-based reimbursement are realizing several unintended consequences of such an approach: namely, the selection of higher-cost products ("more cost, more plus") and referrals to hospital outpatient facilities for drug administration. This year the risk reimbursement methodology increased to 6 percent of covered lives, up from 3 percent last year and 0 percent in 2011 and 2012. *See Figure 12, Reimbursement Approach and the Extent of Discounts Used by Payors to Reimburse for Drugs Paid Under the Medical Benefit by Size of Health Plan.*

FIGURE 11: Reimbursement Approach Overall

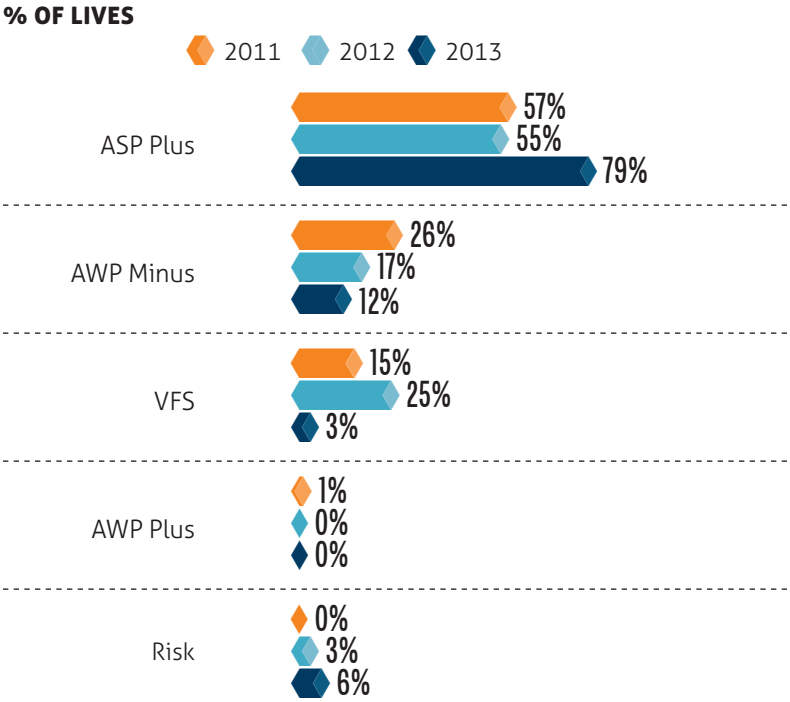
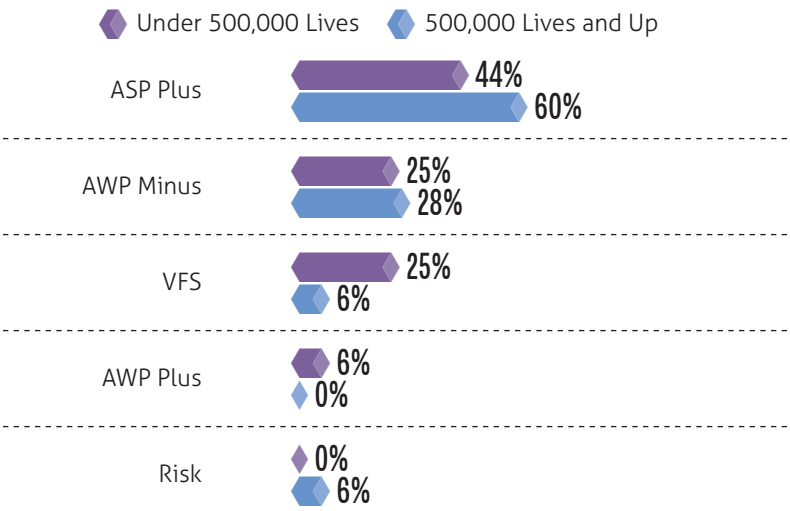


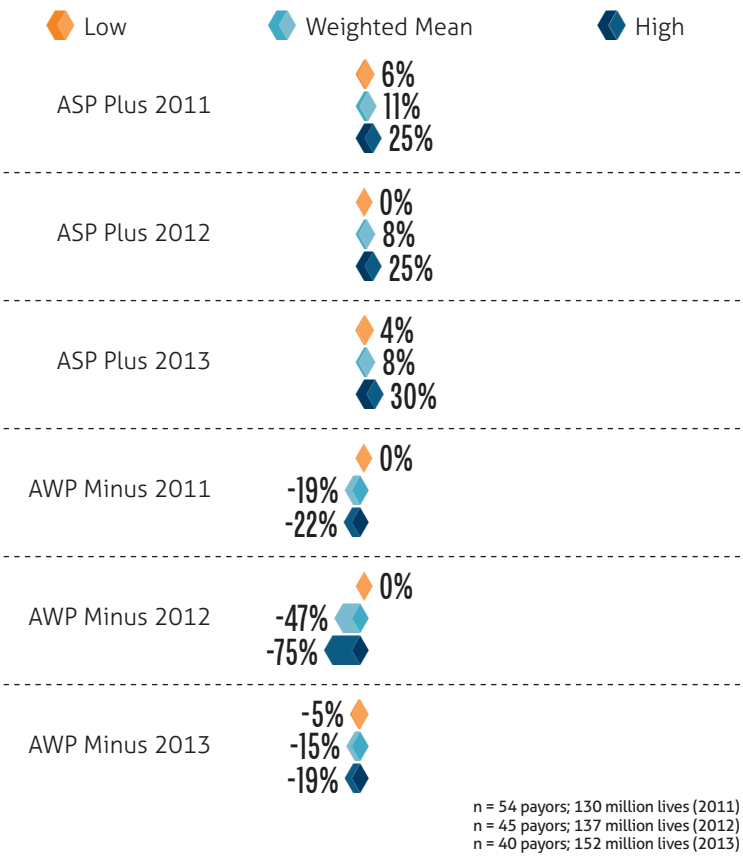
FIGURE 12: Reimbursement Approach by Plan Size



The weighted mean percentage reported this year for ASP plus is 8 percent. At the time the MMA reimbursement changes occurred for Medicare patients, the Community Oncology Alliance (COA), a nonprofit organization dedicated to community oncology practice, stated that ASP plus 12 percent would be the minimum reimbursement to cover provider-administered drugs and administration costs.[1] Today, the average ASP-based reimbursement appears to be well above that threshold. AWP-minus reimbursement, on average, is with a 15 percent discounting of AWP, substantially higher than 2012 and similar to what was reported in 2011. *See Figure 13, Range of Reimbursement Methodology Percentage in Place for Injectables Paid Under the Medical Benefit.*

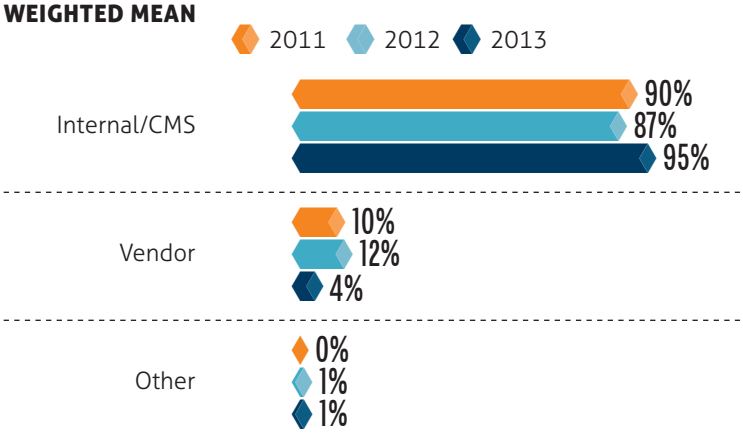
The survey required payors to divide 100 points across each of the sources they use to set reimbursement strategies. On a weighted average basis, commercial payors are relying more on their own internal resources than on vendors (weighted mean of 82 percent versus 4 percent), which is consistent with last year's report. Specifically, their provider contracting departments, medical and pharmacy directors, and finance teams are influential. Assistance from the Centers for Medicare & Medicaid Services (CMS) was listed as a separate source in the survey this year and was used to set reimbursement for a weighted mean of 13 percent. Other sources of influence in the development of payor reimbursement strategies include vendors, such as a health plan's reimbursement consultant, specialty pharmacy, pharmacy benefit manager (PBM) and other companies. *See Figure 14, How Payors Develop Their Medical Benefit Drug Reimbursement Strategies.*

FIGURE 13: Reimbursement Percentage in Place



n = 54 payors; 130 million lives (2011)
n = 45 payors; 137 million lives (2012)
n = 40 payors; 152 million lives (2013)

FIGURE 14: Development of Reimbursement Strategies



[1]Okon T, Coplon S, Kube D. Problems facing cancer care with Medicare's definition of average selling price. *Community Oncol.* 2004;1(1):59-63. http://www.oncologypractice.com/co/journal/articles/0101059a.pdf. Accessed February 6, 2014.

Further, payors who represent just under half of covered lives in 2013 have begun to explore pilot programs that look at bundled payments for services with large, in-network oncology groups, a small decrease from last year (46 percent versus 53 percent of covered lives). *See Figure 15, Payors That Initiated Pilot Programs.*

We asked what reimbursement strategies payors use for newly released injectable drugs (no J code assigned). This year payors reported for nearly half of covered lives a strategy other than ASP plus/minus percent, AWP plus/minus percent, and wholesale acquisition price (WAC) plus/minus percent was used, most commonly percent billed. This is a significant increase over last year (45 percent versus 6 percent), which may be due in part to a single large plan with this strategy. *See Figure 16, Reimbursement Method for Newly Approved Medical Benefit Injectables.*

FIGURE 15: Payors That Initiated Pilot Programs

% OF LIVES

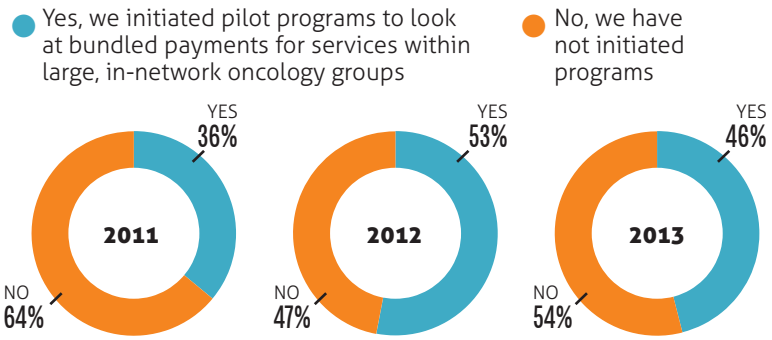
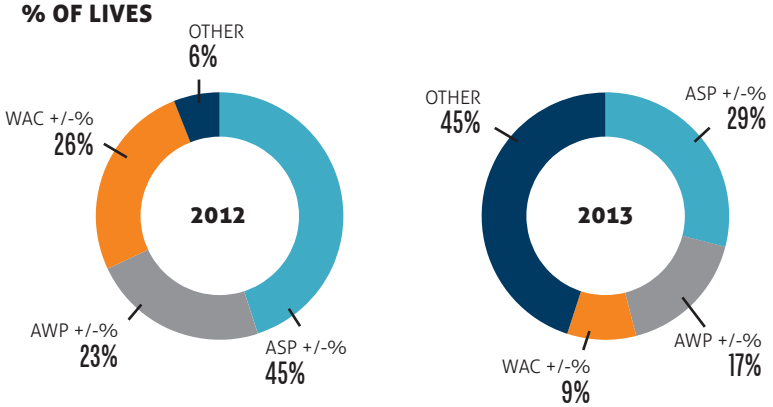


FIGURE 16: Reimbursement for Newly Approved Injectables

% OF LIVES



In 2013 plan requirements for drug coinsurance and copay were similar to the previous year, with approximately one-quarter of covered lives with neither requirement (26 and 27 percent in 2012 and 2013, respectively). While smaller plans were still less likely to require member contribution than larger plans, the percentage difference was smaller between plan sizes this year. This was a significant decrease from 2010 and 2011 (41 and 43 percent, respectively). Of those that do require member contribution, it looks to be for either a drug coinsurance only (29 percent) or a drug copay only (27 percent), with fewer payors requiring both a copay and a coinsurance (17 percent). This is similar to the proportions reported for 2012. *See Figure 17, Predominant Member Contribution for Injectables Paid Under the Medical Benefit Overall, and Figure 18, Predominant Member Contribution for Injectables Paid Under the Medical Benefit by Size of Health Plan.*

FIGURE 17: Contribution Requirements Overall

% OF RESPONDENTS

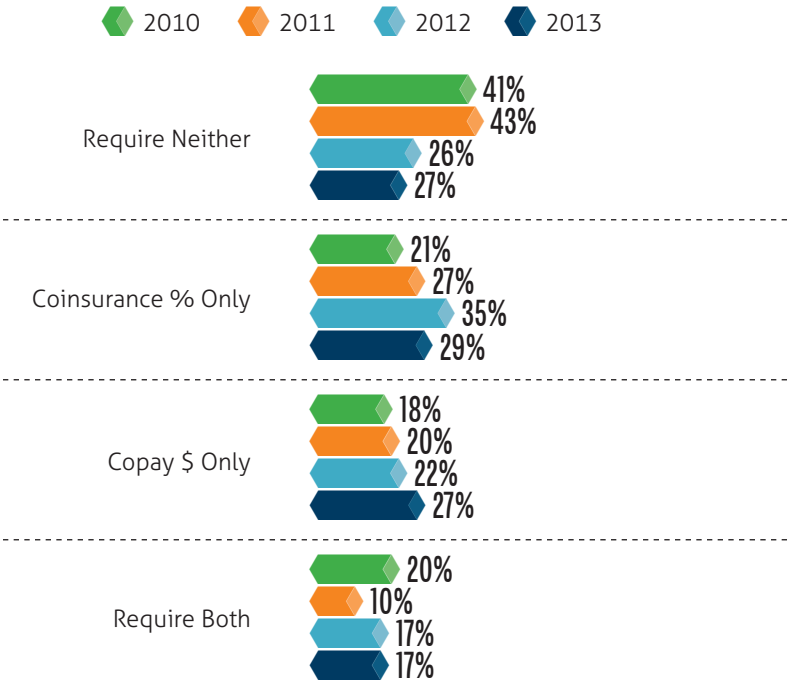
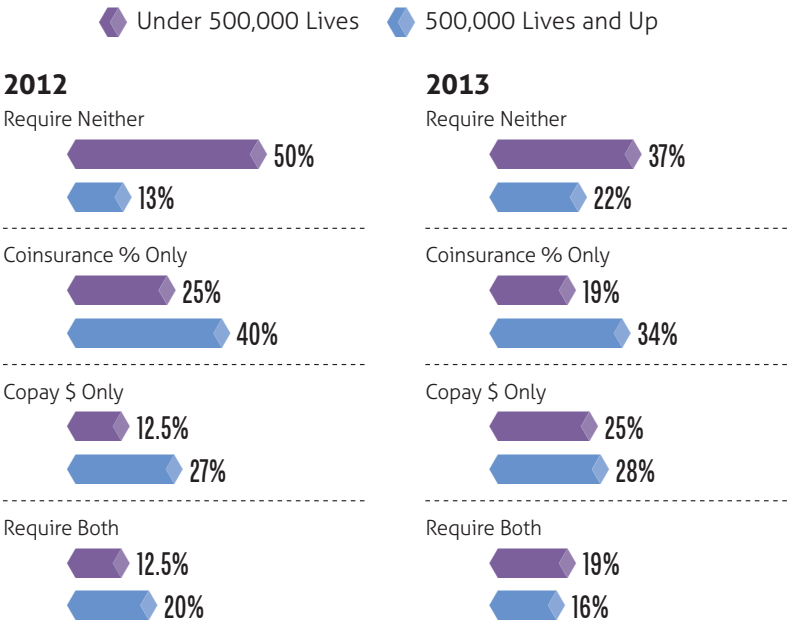


FIGURE 18: Contribution Requirements by Plan Size

% OF RESPONDENTS

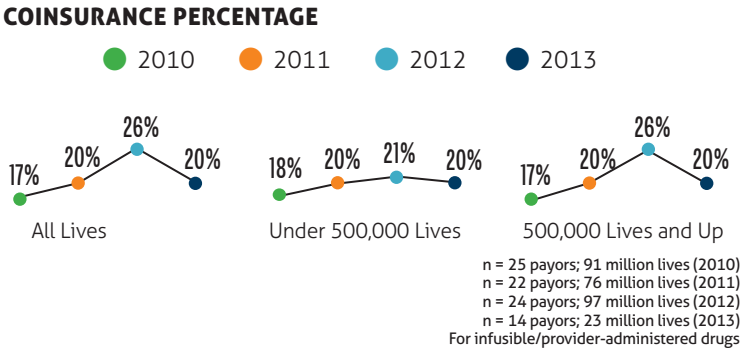


Benefit Design

Members subject to coinsurances for medical benefit injectable drugs are being asked to contribute 20 percent of the claim cost on average in 2013, which is a slight decrease in their share of contribution for the first time in three years (26 percent, 20 percent and 17 percent in 2012, 2011 and 2010, respectively). Most payors (77 percent) noted they would maintain the same coinsurance levels through the remainder of 2013. *See Figure 19, Reported Coinsurance Amounts for Medical Benefit Injectables.*

There appears to be a sharp decrease in copays for medical benefit injectable drugs. An average copay of $25 was reported in 2013, down from $75 in 2012, which was likely high in part due to a high copay for a single large plan last year. Regarding copays for medical injectables, most payors (90 percent) stated they would maintain the current level of copay for the remainder of 2013. *See Figure 20, Reported Copay Amounts for Medical Benefit Injectables.*

FIGURE 19: Reported Coinsurance Amounts



n = 25 payors; 91 million lives (2010)
n = 22 payors; 76 million lives (2011)
n = 24 payors; 97 million lives (2012)
n = 14 payors; 23 million lives (2013)
For infusible/provider-administered drugs

FIGURE 20: Reported Copay Amounts

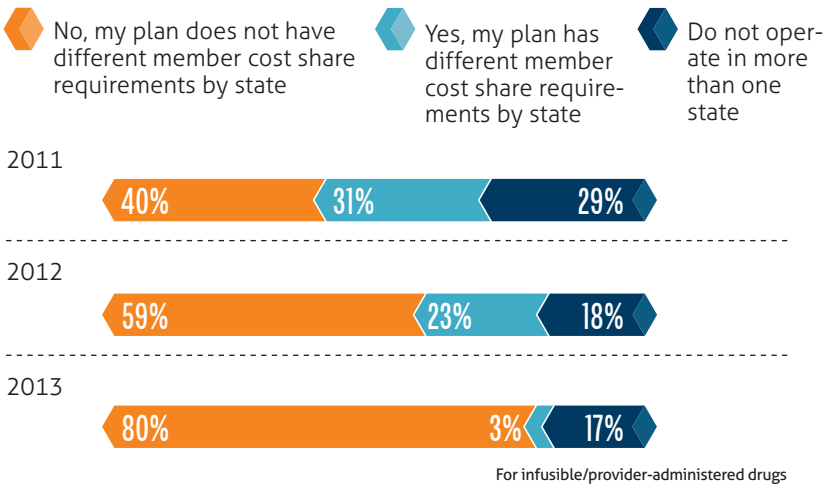
n = 13 payors; 35 million lives (2013)
For infusible/provider-administered drugs

Many medical injectable benefit claims are in excess of $3,000 per dose. This is concerning because when the member contribution exceeds $2,500 per year, out-of-pocket member medication compliance is impacted. A new design seems to be emerging in which coinsurances are applied to a maximum capped amount, generally between $2,500 and $3,000 annually.

Looking across service areas, 3 percent of covered lives are subject to different member cost-share requirements based on the state in which they are treated, which is a substantial decrease from 23 percent in 2012. The remainder either don't operate in more than one state (17 percent) or do not have different requirements across their service areas (80 percent). *See Figure 21, Variable Member Cost Share Requirements Across Different Plan Service Areas Overall, and Figure 22, Variable Member Cost Share Requirements Across Different Plan Service Areas by Size of Plan.*

FIGURE 21: Member Cost Share Requirements Overall

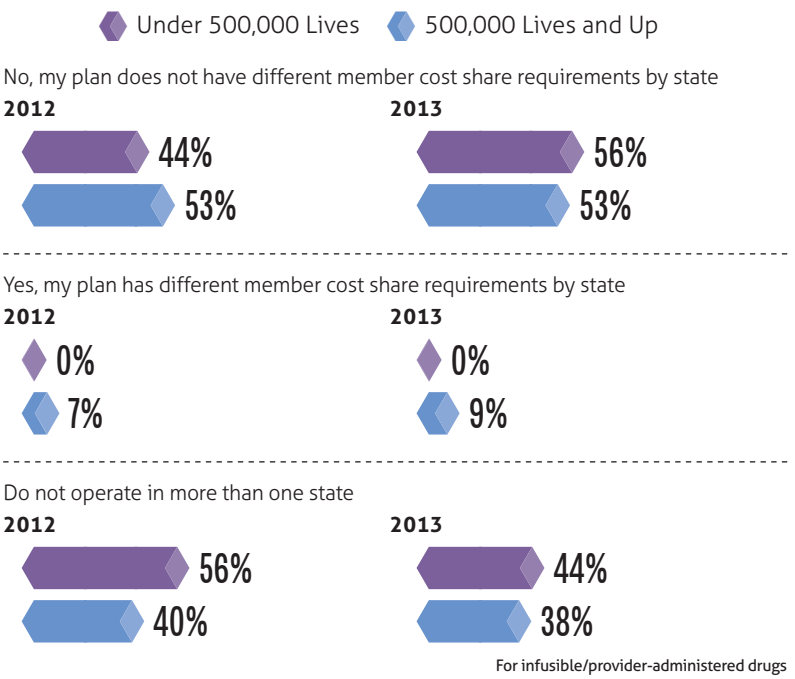
% OF LIVES



For infusible/provider-administered drugs

FIGURE 22: Member Cost Share Requirements by Plan Size

% OF RESPONDENTS

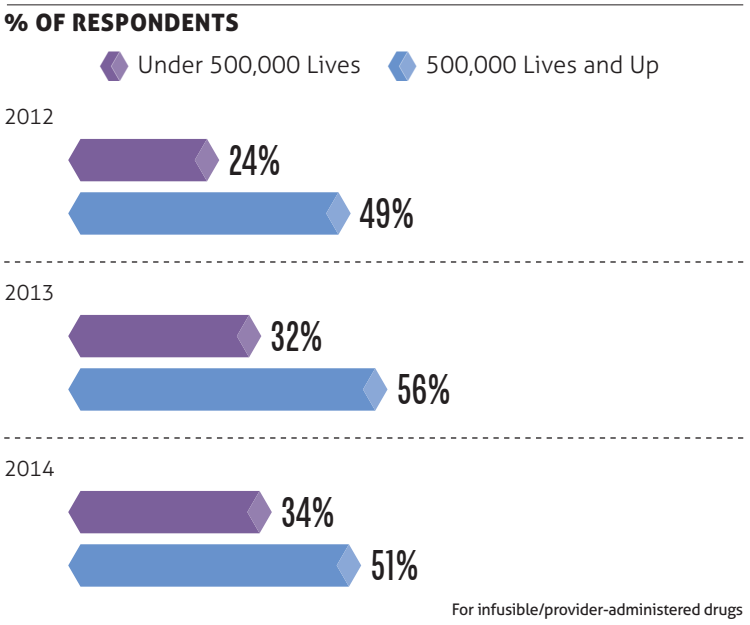


For infusible/provider-administered drugs

The survey asked payors to think ahead through the remainder of 2013 and into 2014 and to consider the likelihood of change to coinsurance responsibility for their membership. Larger payors continue to be more likely to have members with a medical benefit injectable coinsurance compared with smaller payors. Both small and large payors reported the percentage of their membership with coinsurance responsibility in 2012 was consistent with projections reported from the 2011 survey, suggesting projections of changes to benefits are robust. Looking forward, regardless of size, payors overall intend to increase the percentage of members with a coinsurance. *See Figure 23, Percentage of Member Lives Subject to a Coinsurance for Medical Injectables by Size of Plan.*

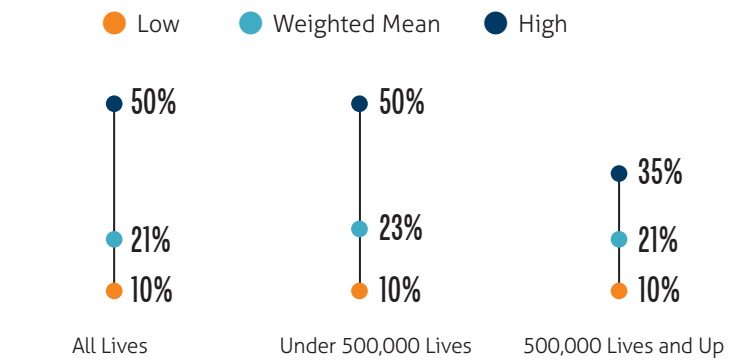
Further, among payors reporting coinsurances for 2014, the projected percentage assigned to medical benefit injectables is 21 percent, which is consistent with the last three years. *See Figure 24, Reported Coinsurance Amounts Projected for Medical Benefit Injectables in 2014.*

FIGURE 23: Members Subject to a Coinsurance by Plan Size



For infusible/provider-administered drugs

FIGURE 24: Coinsurance Amounts Projected for 2014



n = 37 payors; 142 million lives
For infusible/provider-administered drugs

At times, payors employ coinsurances to put more "skin in the game" for their members for drugs covered under the medical benefit. However, the tactic loses some punch once maximum out-of-pocket annual contributions are reached. A weighted average of 65 percent of covered lives has an annual cap on members' coinsurance out of pocket, with the weighted mean at $3,817 per year. This is a decrease from 2012 of 74 percent of the lives, with a cap on coinsurance out of pocket and a similar average of $3,003 per year.

Payors with more than 500,000 members report that the portion of their membership that has a medical benefit injectable copay will increase slightly in 2014. Payors with fewer than 500,000 members report that a slightly smaller portion of their membership will have a copay in 2014. Of note, the large payors reported the percentage of members subject to a copay in 2013 (52 percent) consistent with their 2013 projections in last year's survey (48 percent). They project 56 percent of their members will be subjected to a medical benefit injectable copay in 2014. Similarly, small payors reported the percentage of members subject to a copay in 2013 (24 percent) consistent with their 2013 projections (22 percent) in last year's survey. They project 22 percent will be subjected to copays in 2014. *See Figure 25, Percentage of Members Subject to a Copay for Medical Injectables by Size of Plan.*

Among payors anticipating copays for 2014, the average amounts range from $5 to $250, with $48 being the weighted mean. Of note, members within smaller health plans have a higher copay on average. *See Figure 26, Reported Copay Amounts for Medical Benefit Injectables in 2014.*

FIGURE 25: Members Subject to a Copay by Plan Size

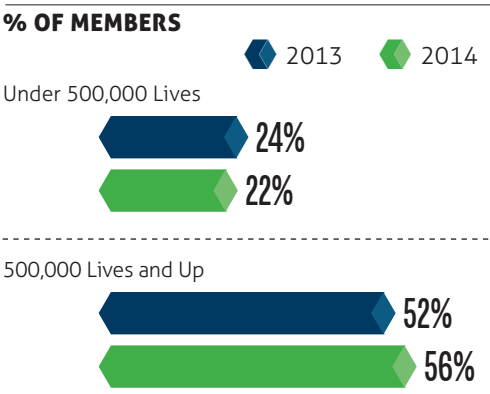
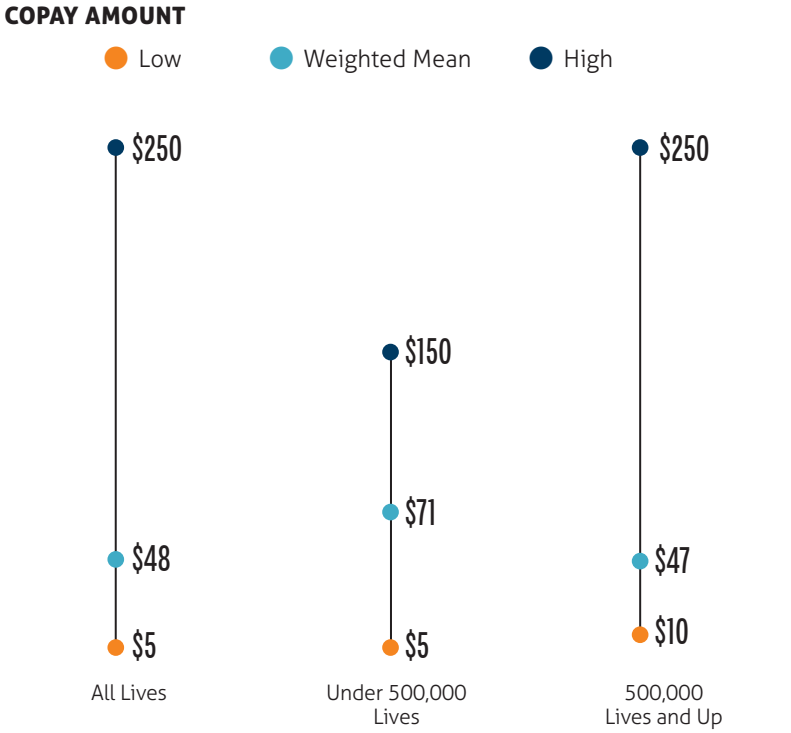


FIGURE 26: Copay Amounts Projected for 2014



n = 31 payors; 65 million lives

ORAL VERSUS INTRAVENOUS

Nearly two-thirds of the covered lives in the survey are subject to contribution parity, which is higher than the levels reported in 2012 and 2011 (about half). Parity is noted primarily in relation to oral versus Part B/Part D intravenously administered. This is likely a result of states that have enacted or have pending legislation looking to equalize member contributions for oral and IV products. States and employers alike are looking to equalize the member contribution regardless of whether the drug is paid under the medical or pharmacy benefit. *See Figure 27, Member Contribution Parity Between IV and Oral Products with Similar Indications.*

In 75 percent of the lives in which member contribution parity exists, respondents noted it is due to state law, similar to the 72 percent of lives reported for 2012. Those payors who do not currently report contribution parity commonly indicated that they were working toward oral versus IV contribution parity for 2013. Moreover, plans that were most interested in this parity are the same plans that are looking to establish medical homes and accountable care organizations (ACOs). *See Figure 28, Member Contribution Parity Mandated by State Law.*

FIGURE 27: Member Contribution Parity

% OF LIVES

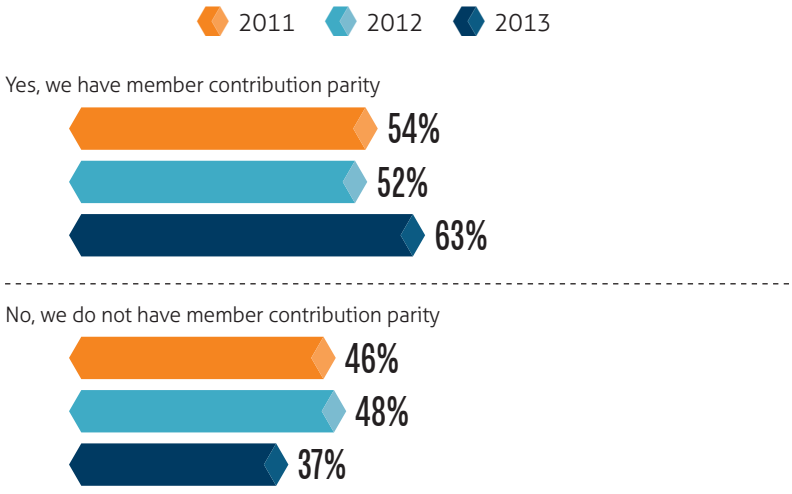
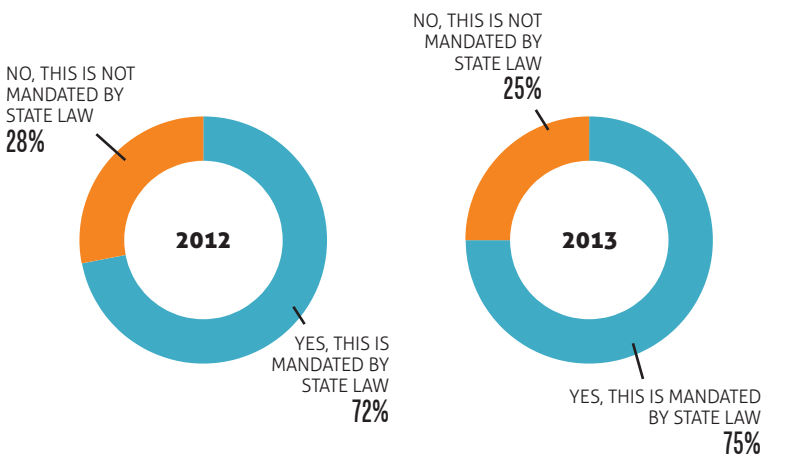


FIGURE 28: Parity Mandated by State Law

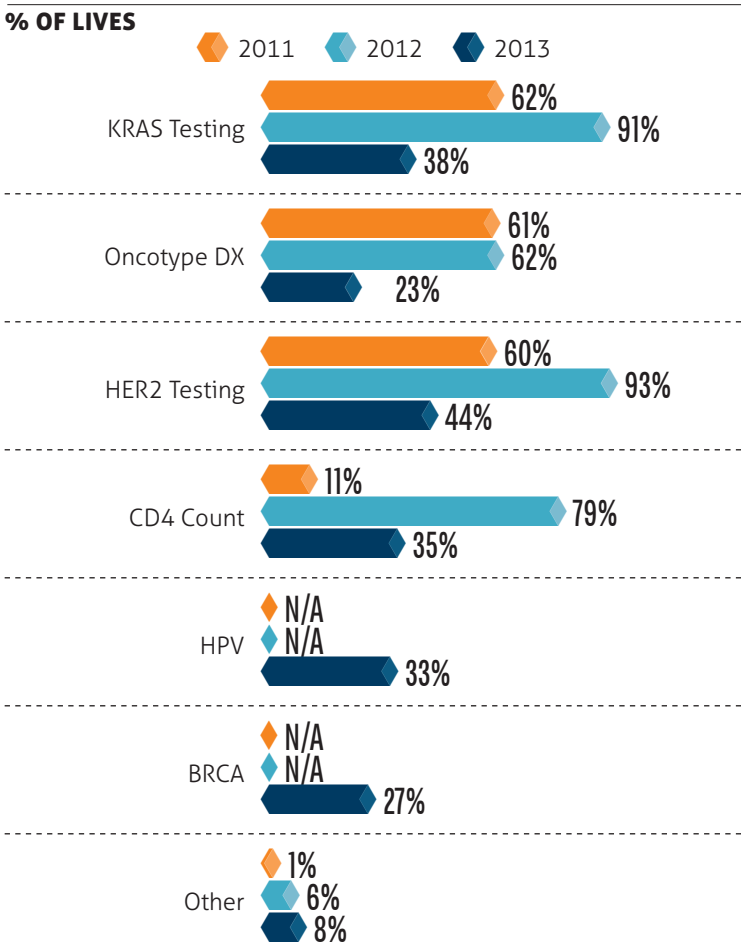
% OF LIVES



n = 23 payors; 105 million lives

Genomic testing continues to play an important role in determining treatment choices and potentially improving treatment outcomes. HER2 testing[2] in advance of breast cancer therapy was covered for nearly all patients (94 percent) and KRAS testing[3] in advance of colorectal cancer therapy is provided for 41 percent of members across all health plans. In 2013, only 16 percent of covered lives were provided Oncotype DX[4] testing, should the need arise, and nearly four of 10 members have CD4 counts[5] provided if receiving therapy for HIV. BRCA testing for breast cancer susceptibility genes was not provided by any health plans in this survey, and no other genomic test requirements were under consideration. Although testing can vary significantly with these assays, only about a third of payors reported having a relationship with a reference lab for these tests; the highest was reported at 44 percent for HER2 testing. *See Figure 29, Genomic Test Requirements Before Chemotherapy and Portion of Health Plans That Have a Relationship with a Reference Laboratory to Conduct Genomic Tests.*

FIGURE 29: Relationships with Labs Established

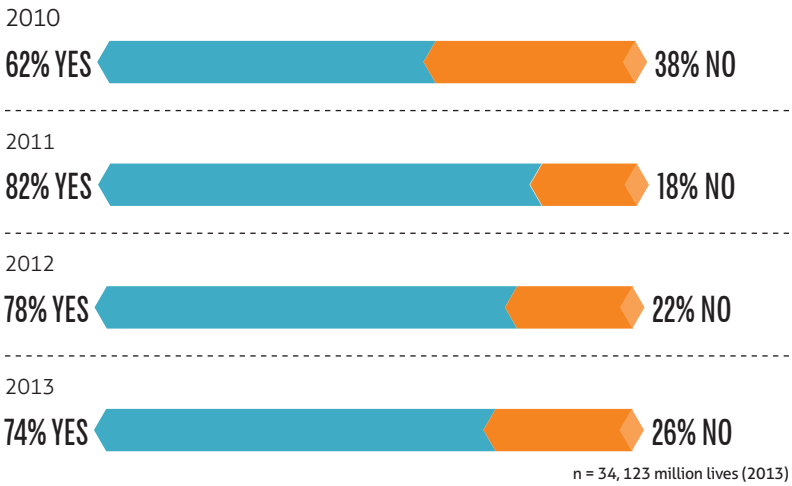


n = 109 million lives (2012)
n = 166 million lives (2013)

Most members of commercial health plans (74 percent of covered lives) were enrolled in plans that featured established National Committee for Quality Assurance HEDIS (Healthcare Effectiveness Data and Information Set) cancer screening or prevention programs. This has remained fairly consistent since 2011 (range 74–82 percent).

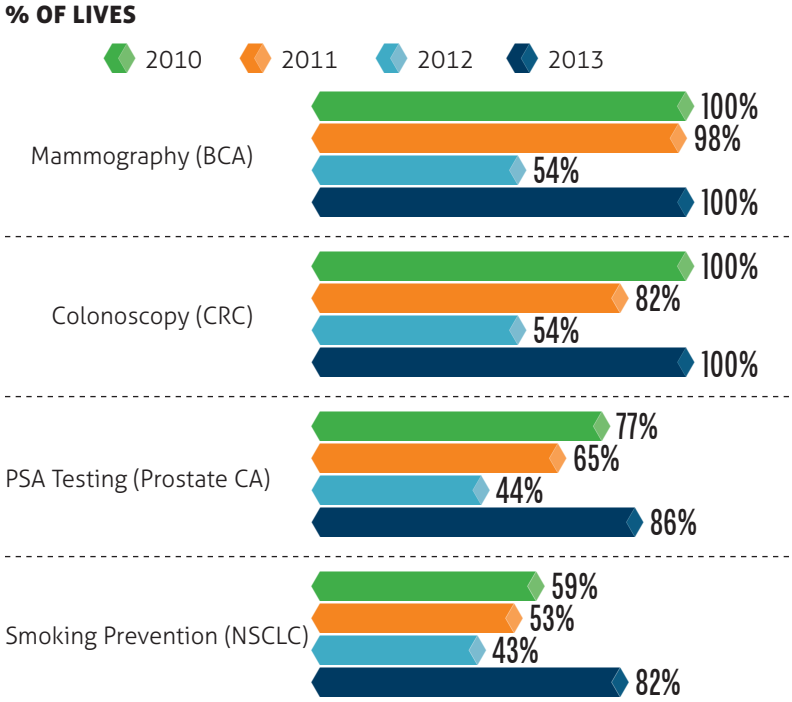
Breast cancer and colorectal cancer screening programs (100 percent of covered lives) are the most commonly available to members. Prostate cancer detection and smoking cessation programs were offered to less than two out of 10 members. The majority of prevention programs were developed externally at the health plans. *See Figure 30, HEDIS Cancer Screening or Prevention Programs in Place, and Figure 31, Specific HEDIS Prevention Programs Established.*

FIGURE 30: Screening or Prevention Programs in Place



n = 34, 123 million lives (2013)

FIGURE 31: HEDIS Prevention Programs Established



n = 34; 123 million lives (2013)

More information on these tests may be accessed at:

KRAS – www.kras-info.com

HER2 – www.herceptin.com/hcp/testing/index.html

Oncotype DX – www.oncotypedx.com

CD4 count – www.aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv-guidelines/4/cd4-t-cell-count

[2]HER2 (human epidermal growth factor receptor 2) testing is an important predictive and prognostic factor in breast cancer.

[3] KRAS (Kirsten RNA associated rat sarcoma 2 virus gene) testing is a new biomarker being used to select the best treatment for individual colorectal patients.

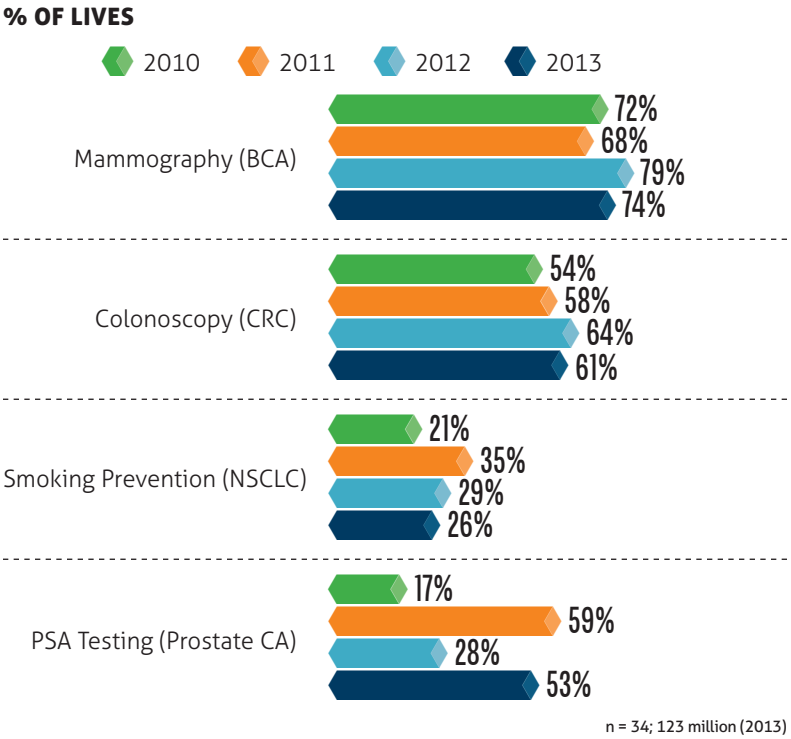
[4]Oncotype DX testing is a unique diagnostic test available to both breast cancer and colon cancer patients to help with treatment decisions.

[5]CD4 testing measures the number of helper T cells to analyze the prognosis of patients infected with HIV.

Compliance with mammography and colonoscopy screening programs continued to report similar rates with previous survey years. Prostate-specific antigen (PSA) testing compliance (53 percent) continues to vary widely depending on survey year (17 percent in 2010 to 59 percent in 2011). Smoking cessation programs remained relatively consistent (at 26 percent versus 29 percent in 2012). *See Figure 32, Most Recent Percentage of Member Compliance by Cancer Screening Program.*

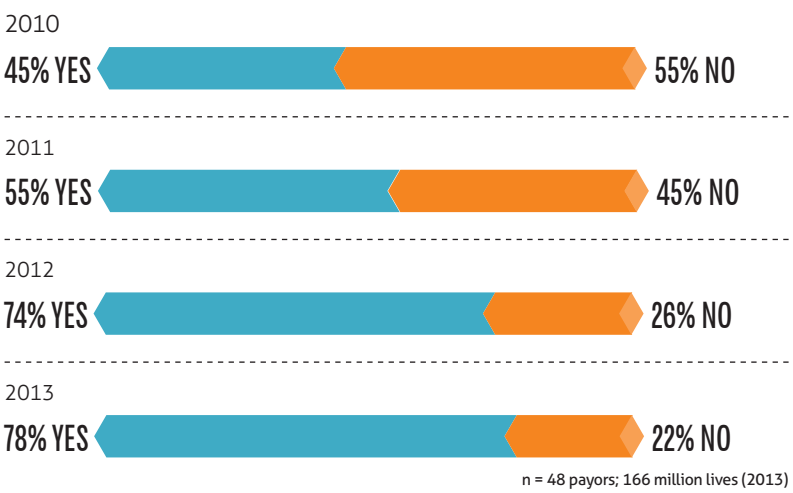
The percentage of covered lives provided with an option for a palliative care program (78 percent) was similar to 2012 and represents a slight departure from the substantial increases observed in previous survey years. Respondents offering such benefits report that their programs tend to include nurse case management, hospice and other palliative care options. *See Figure 33, Palliative Care Programs Provided for Membership.*

FIGURE 32: Member Compliance by Screening Program



n = 34; 123 million (2013)

FIGURE 33: Palliative Care Programs Provided

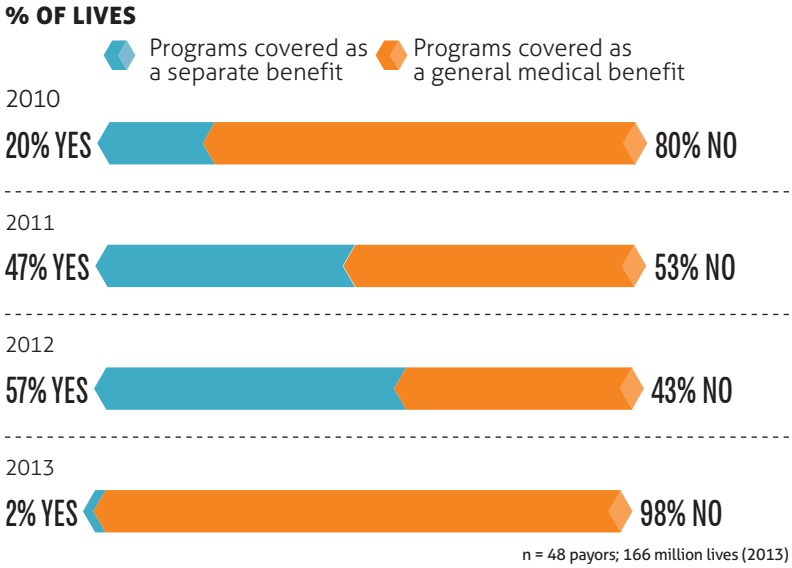


n = 48 payors; 166 million lives (2013)

Contrary to previous years, survey respondents reported a significant decrease in the number of members offered a separate benefit for end-of-life/palliative care programs (2 percent). Ninety-eight percent of plans are offering this as part of the medical benefit. *See Figure 34, Palliative Care Program Coverage.*

Similarly, the trend toward offering members the option of purchasing a separate rider for palliative care coverage declined in 2013 (43 percent versus 64 percent in 2012). The most common amount of hospice care allowed in this benefit was three months, with an average of 105 days. *See Figure 35, Use of Rider for End-of-Life Benefit.*

FIGURE 34: Palliative Care Program Coverage



n = 48 payors; 166 million lives (2013)

FIGURE 35: Use of Rider for End-of-Life Benefit

n = 6; 5.5 million lives (2013)

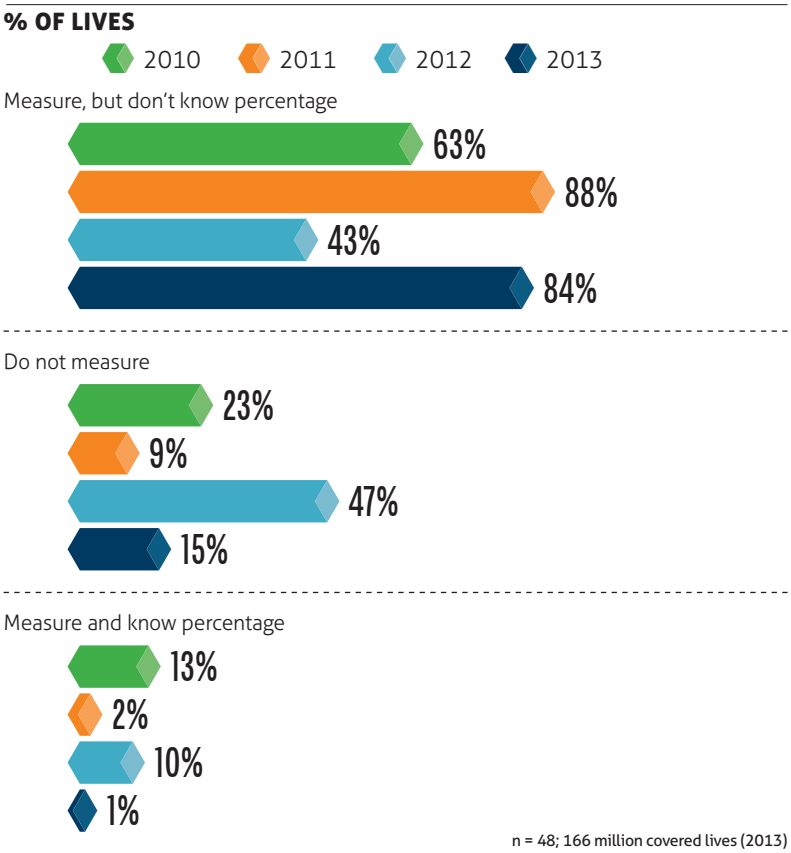
The vast majority of plans reported they measure participation in end-of-life programs but do not know the percentage of eligible members who utilize the benefit. *See Figure 36, Portion of Payors Who Know the Percentage of Eligible Members Who Actually Participated in These Palliative Care Programs in the Last Year.*

Unlike previous years, a major shift in employer involvement was reported depending on the relative size of the payor. Large payors continue to note a high level of engagement from employer groups to control costs, whereas smaller groups tended to report no differences from last year.

With respect to medical injectable benefits, payors noted their employer groups want increased cost sharing/higher member cost share, risk exposure caps, clinical management programs, justification for cost drivers and health outcomes reporting.

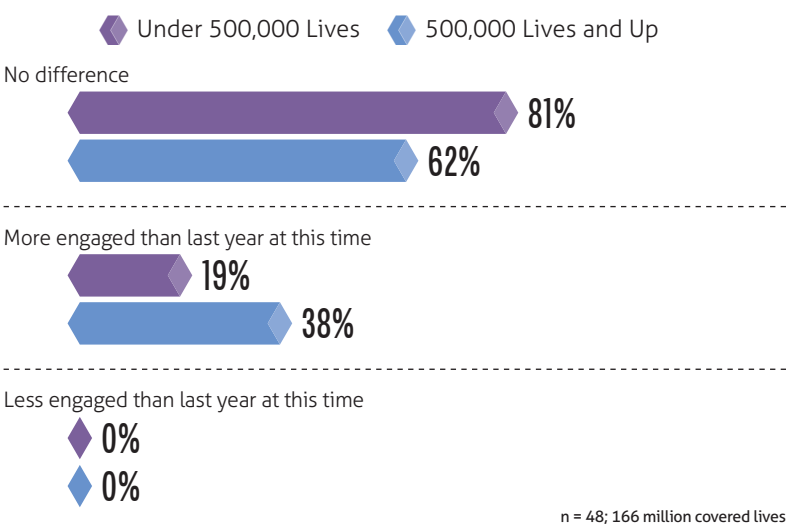
Specific to oncology, employers are requesting payors to provide cost-control initiatives (e.g., prior authorization, clinical pathways, etc.) that ensure appropriate use, better access and quality care. Several payors noted the desire to limit coverage (e.g., limit coverage of third- and fourth-line therapies of unproven value). *See Figure 37, Level of Employer Engagement with Health Plans in Developing Benefit Designs by Size of Plan.*

FIGURE 36: Payors Monitoring Member Participation



n = 48; 166 million covered lives (2013)

FIGURE 37: Level of Employer Engagement



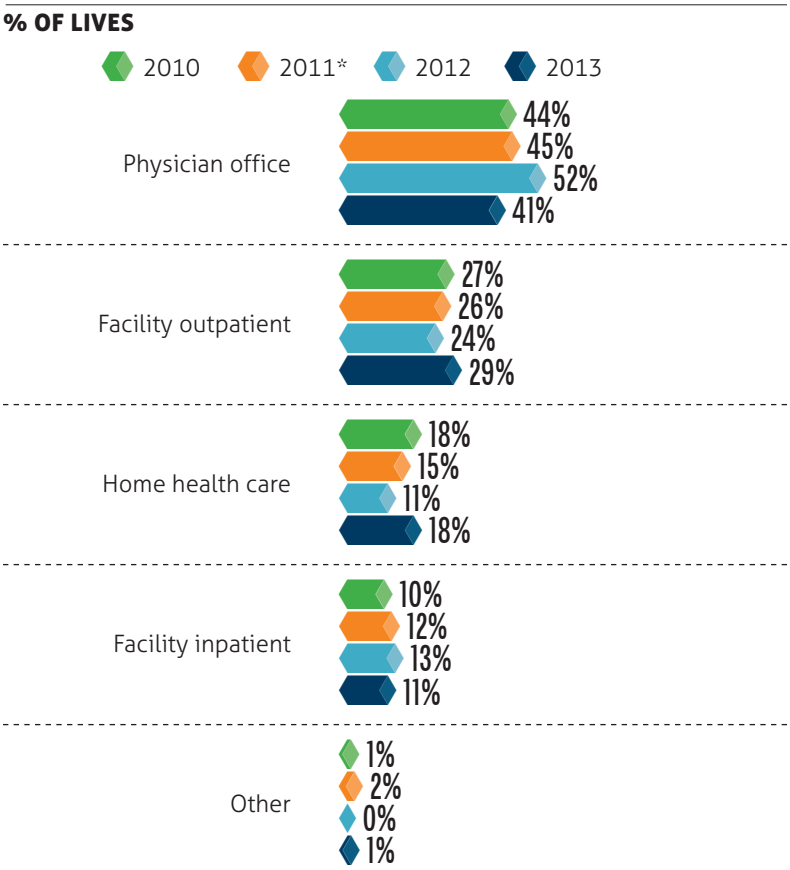
n = 48; 166 million covered lives

Distribution Channel Management

The increasing trend observed in previous years changed substantially in 2013. Payors tell us that about 40 percent of all medical injectables are administered to members in their providers' offices and submitted for reimbursement under the traditional buy-and-bill process. Outpatient administration increased over previous years to average just less than 30 percent of billed claims, and home infusion represented 18 percent of medical injectable billed claims. Inpatient administration (11 percent) remained similar to previous years.

As payors continue to lower reimbursements to mimic Medicare rates, the purchase of private practices by hospital systems in order to take advantage of outpatient facility administration using 340B pricing is a trend that seems likely to continue. Indeed, in a recent study conducted by the Community Oncology Alliance, more than 300 oncology practices were purchased by hospitals over a recent four-year period.[6] *See Figure 38, Average Percentage of Medical Injectable/Infusible Claims Billed from Each Site of Service.*

FIGURE 38: Percentage of Medical Injectable Claims Billed



n = 48; 166 million lives (2013)

*Slightly different than last year due to rounding effects.

[6] Community Oncology Alliance. *Community Oncology Cancer Care Practice Impact Report.* http://www.communityoncology.org/UserFiles/Community_Oncology_Practice_Impact_Report_6-25-13F.pdf. Accessed March 18, 2014.

The survey asked payors to describe distribution channels for chemotherapies as well as other non-chemotherapy infused drugs billed under the medical benefit. When providers administer infused chemotherapies in their offices, three-quarters of the volume is billed through a buy-and-bill process, in which the provider purchases the drug and then invoices the payor for reimbursement under the patient medical benefit. In 2013, payors reported a smaller proportion of chemotherapeutic drugs (15 percent) billed through specialty pharmacies for administration in the provider's office when compared to the previous year. See *Figure 39, Percentage of Medical Injectable/Infused Drug Volume Distributed to Members Through Various Billing Processes.*

FIGURE 39: Drug Volume Distributed in Physician Office

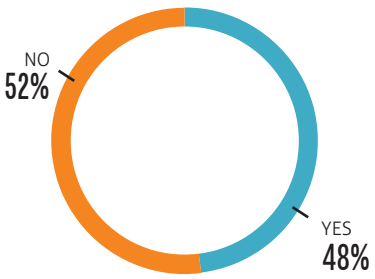
PRIMARY BILLING PROCESSES	WEIGHTED AVERAGE VOLUME 2011*		WEIGHTED AVERAGE VOLUME 2012		WEIGHTED AVERAGE VOLUME 2013	
	Infused Chemo Drugs	Infused Nonchemo Drugs	Infused Chemo Drugs	Infused Nonchemo Drugs	Infused Chemo Drugs	Infused Nonchemo Drugs
Physician buy and bill (provider uses his stock and bills plan)	64%	38%	60%	37%	75%	70%
Specialty pharmacy provider (a pharmacy or distributor ships to provider's office and provider does not bill for the drug)	25%	44%	32%	51%	15%	18%
Brown bag (member takes drug to the provider's office for administration)	6%	7%	6%	10%	7%	9%
Other	5%	11%	2%	2%	3%	3%

n = 48; 166 million lives (2013)

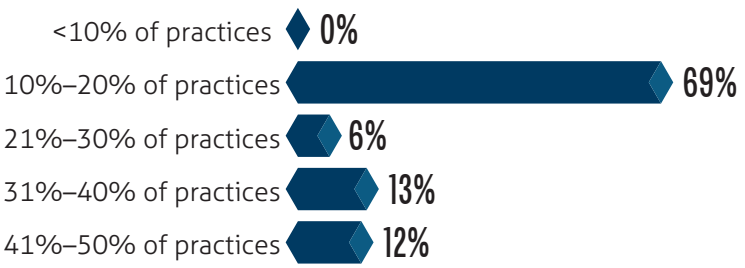
*Slightly different than last year due to rounding effects.

Nearly half of all payors reported that hospitals were seeking to purchase oncology practices, and for a large majority of respondents this represented approximately 10 to 20 percent of oncology practices in their area. The reasons hypothesized for this observed trend included 340B pricing available to hospitals, vertical integration and strengthening the ACO model. *See Figure 40, Hospital Systems Purchasing Oncology Practices.*

FIGURE 40: Hospital Purchasing Oncology Practices



% OF RESPONDENTS



IF YES, WHY?	
Hospital can generate significant revenue through chemotherapy infusions and diagnostic imaging	55%
Take advantage of 340B pricing	18%
Attempts to strengthen ACO models	14%

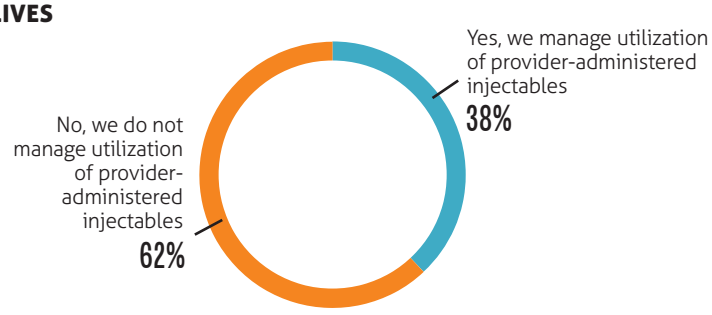
Utilization Management

Utilization management is a valuable tool that health plans employ to encourage appropriate use and dosing and to monitor site of service dynamics. In 2013, slightly more than one-third of members were enrolled in plans that have implemented utilization management programs for provider-administered injectables. While this is a marked departure from previous years, this likely represents differences reported by a small number of large plans. *See Figure 41, Managing Utilization of Injectable/Infusible Products Administered by a Provider.*

Overall, utilization of management tools reported in Figure 43 was noticeably different this year for many drug classes, perhaps reflecting a different mix of survey respondents this year. Nevertheless, prior authorization continued as a favored management tool being used in at least 50 percent of all covered lives for all drug classes. Guidelines developed by the National Comprehensive Cancer Network (NCCN) were not as prominently featured as in previous years. Similarly, case management and disease management were not utilized as commonly this year. See *Figure 42, Utilization Management Tools Used for Medical Injectable/Infusible Products in the Specific Therapeutic Classes.*

FIGURE 41: Managing Utilization of Products

% OF LIVES



n = 48; 166 million lives

FIGURE 42: Utilization Management Tools by Class

	PRIOR AUTHORIZATION	CASE MANAGEMENT	FORMULARY	STEP EDIT	CLINICAL PATHWAY	DISEASE MANAGEMENT	NCCN GUIDELINES	NONE	DIFFERENTIAL REIMBURSEMENT	GENERIC FIRST
Intravenous Immune Globulin (IVIG)	85%	20%	18%	10%	5%	4%	3%	0%	0%	0%
Chemotherapy	67%	37%	24%	15%	31%	3%	41%	1%	8%	5%
ESAs	66%	18%	33%	10%	16%	3%	15%	3%	0%	0%
CSFs	65%	17%	24%	9%	30%	3%	31%	3%	1%	0%
CINV	59%	19%	38%	13%	10%	3%	28%	8%	3%	10%
Biologics	83%	21%	39%	50%	6%	9%	3%	2%	2%	5%
Hemophilia	58%	30%	17%	0%	4%	11%	3%	9%	7%	0%

n = 39; 62 million lives (2013)

Again in 2013, metastatic breast and prostate cancers were the oncology therapies most commonly subjected to utilization management tools. However, payors reported less utilization of management tools for other common cancers this year. *See Figure 43, Cancer Types Most Commonly Subjected to Medical Utilization Tools.*

Again this year, Remicade and Rituxan were the most commonly reported agents subjected to PA. Additionally, PA was used in over 50 percent of covered lives for all surveyed drugs. As in the past, case management continues to be a smaller, but important, tool health plans employ to monitor utilization. As noted previously, guidelines developed by the National Comprehensive Cancer Network (NCCN) were the next most commonly employed tool across most drugs. Apparently, case management is being utilized by a small number of relatively large payors. As in previous years, very few payors reported no use of any medical injectable management tools or controls. *See Figure 44, Management Tools Used for Common Medical Injectable Therapies.*

FIGURE 43: Cancers Subjected to Medical Utilization Tools

CANCER TYPE	2010 % OF LIVES	2011 % OF LIVES	2012 % OF LIVES	2013 % OF LIVES
Metastatic Breast Cancer	59%	70%	97%	80%
Prostate Cancer	59%	94%	97%	96%
Multiple Myeloma	56%	62%	95%	76%
Non-Hodgkin's Lymphoma	49%	66%	95%	76%
Leukemia	48%	69%	95%	76%
Renal-Cell Carcinoma	54%	75%	95%	77%
Non-Small Cell Lung Cancer	85%	83%	95%	76%

n = 39; 62 million lives (2013)

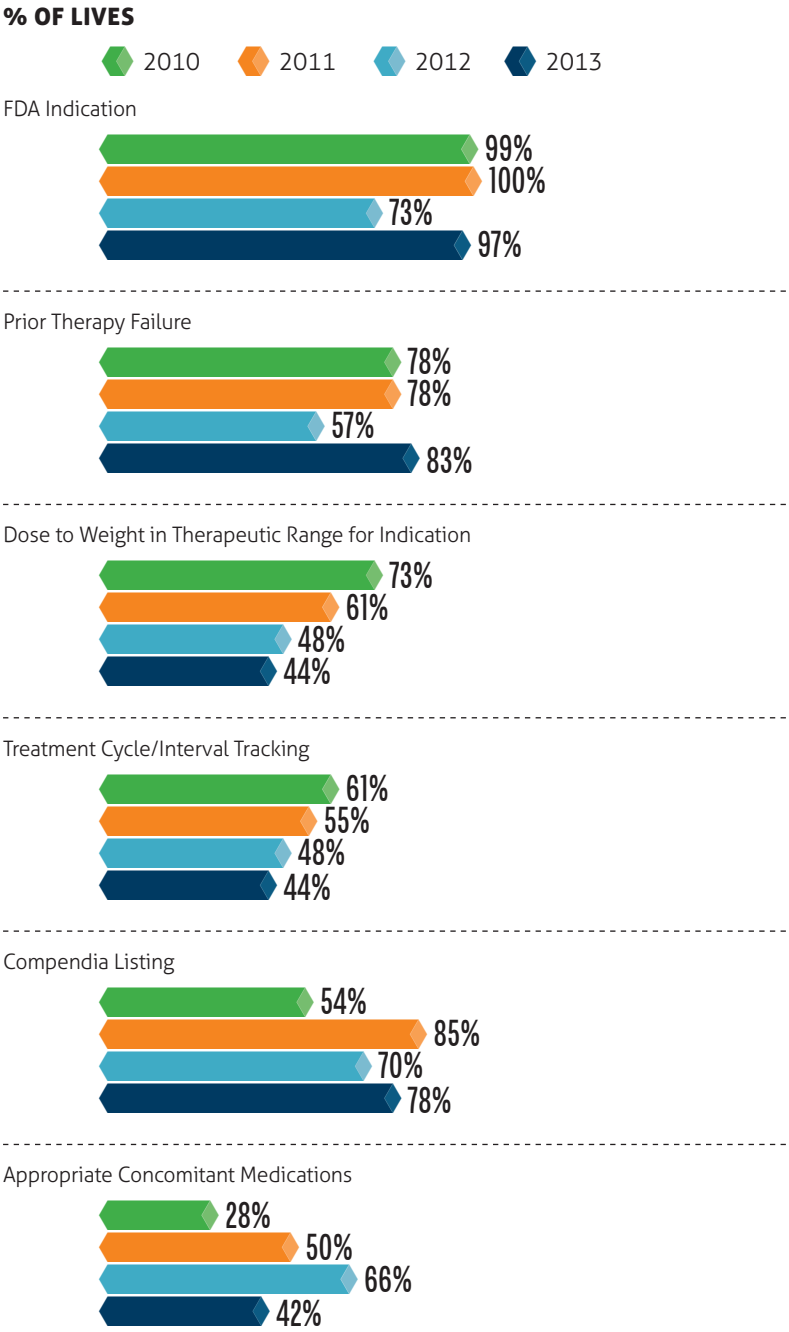
FIGURE 44: Management Tools for Common Therapies by Percent of Lives

	PRIOR AUTHORIZATION	CASE MANAGEMENT	FAIL GENERIC FIRST	STEP EDITS	NCCN	DISEASE MANAGEMENT	OTHER	CLINICAL PATHWAY	NONE	DIFFERENTIAL REIMBURSEMENT
# Respondents	n = 22	n = 4	n = 2	n = 2	n = 16	n = 4	n = 1	n = 6	n = 2	n = 1
Remicade	84%	19%	15%	12%	8%	6%	5%	5%	2%	1%
Rituxan	73%	19%	8%	2%	28%	4%	0%	12%	3%	0%
Cerezyme	68%	19%	17%	14%	4%	6%	0%	2%	0%	0%
Avastin	67%	21%	17%	0%	44%	4%	0%	15%	3%	0%
Erbitux	64%	21%	5%	0%	43%	4%	0%	15%	3%	0%
Alimta	64%	19%	17%	0%	35%	4%	1%	14%	3%	0%
Herceptin	61%	21%	5%	0%	29%	4%	0%	14%	3%	0%
Abraxane	61%	19%	17%	15%	42%	4%	14%	14%	3%	0%
Zometa	59%	19%	18%	1%	28%	5%	8%	12%	3%	0%
Aloxi	57%	19%	19%	1%	31%	4%	4%	13%	3%	1%
Eloxatin	57%	19%	17%	0%	39%	4%	0%	14%	1%	0%
Gemzar	56%	19%	5%	0%	26%	4%	14%	13%	1%	0%
Taxotere	53%	19%	17%	0%	42%	5%	14%	13%	3%	8%

n = 31 payors; 99 million lives (2012)
n = 39; 62 million lives (2013)

When asked about specific criteria used for prior authorization, nearly all payors still focus on indication by the U.S. Food and Drug Administration (FDA) (97 percent) and compendia listings (78 percent) when developing PA criteria. Again, this year specific concomitant medications (42 percent) are included as part of specific prior authorization criteria, perhaps reflecting the increased utilization of specific drug combinations. *See Figure 45, Specific Prior Authorization Criteria That May Be Required.*

FIGURE 45: Specific Prior Authorization Criteria



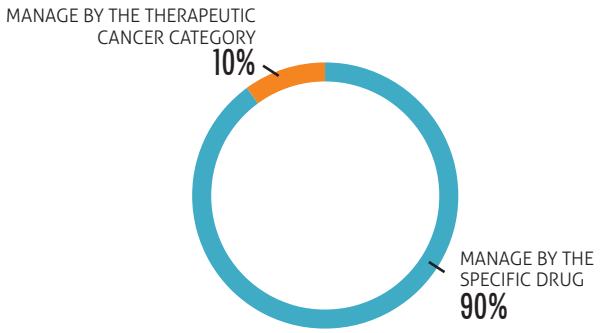
n = 36; 52,303,900 covered lives (2013)

When asked if payors' management strategies were targeted more toward specific drugs or cancer therapeutic category (e.g., breast cancer, lung cancer), the overwhelming majority of payors (90 percent) were focused on specific drugs. *See Figure 46, Management by Specific Drug or Cancer Category.*

When asked about top concerns regarding medical injectables in 2013, more than half of payors, a much larger proportion than last year, mentioned the overall cost as the most significant concern. Notably this year, payors identified a number of specific drugs and specific disease entities that were important concerns. *See Figure 47, Top Medical Injectable Concerns in 2013.*

FIGURE 46: Management by Specific Drug or Cancer Category

% OF LIVES



n = 39; 62, 569, 487 covered lives (2013)

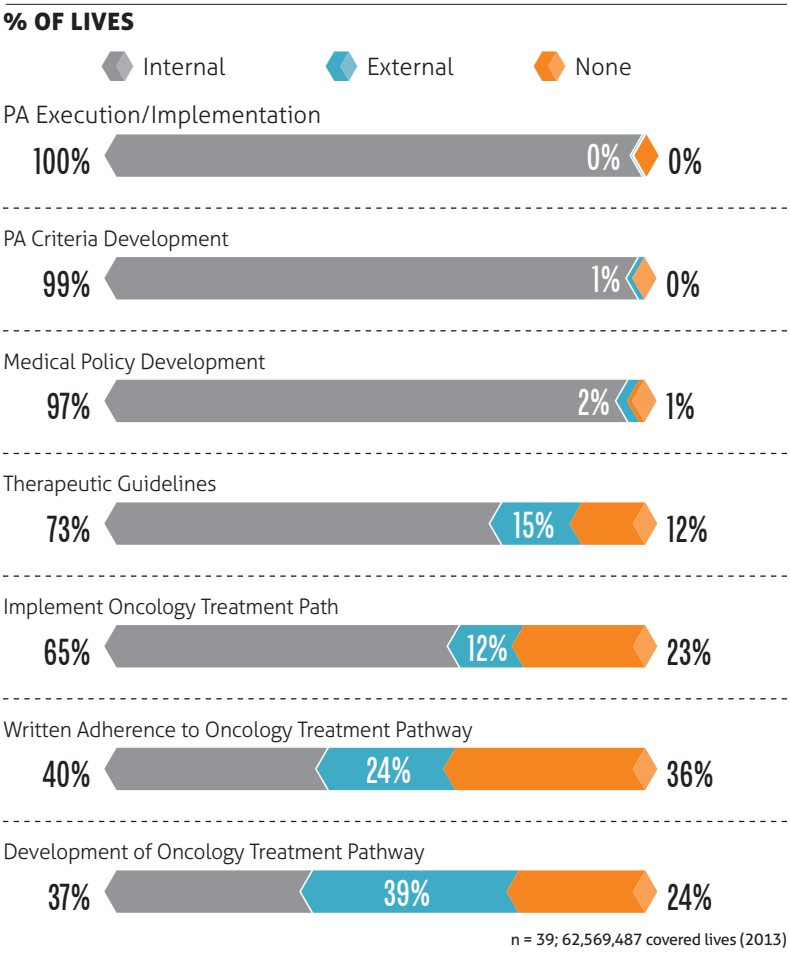
FIGURE 47: Top Medical Injectable Concerns in 2013

MEDICAL INJECTABLE CONCERN	% OF PAYORS
Increasing cost trends	56%
Other	26%
Specific drugs including: Avastin, Rituxan, Oxaplatin, Hizentra, Neulasta, Herceptin, RA/MS drugs, anti-TNFs	10%
Specific disease management including: Oncology, Hep C, RA, MS, melanoma, metastatic prostate CA	8%

Virtually all payors noted their PA criteria, as well as medical policy development and execution, are created internally. Similar to previous years, therapeutic or oncology treatment guidelines are slightly more likely to be developed externally to the plan, often utilizing the expertise of the oncologist community. *See Figure 48, Where Management Services Are Developed at Health Plans.*

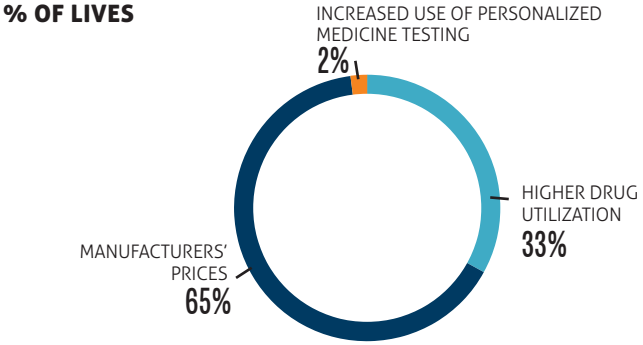
When asked to identify the key driver of oncology cost increases, two-thirds of survey respondents indicated manufacturers' prices, although higher utilization was also a prominent factor (one-third of respondents). *See Figure 49, Key Driver of Oncology Cost Increases.*

FIGURE 48: Where Management Services Are Developed



n = 39; 62,569,487 covered lives (2013)

FIGURE 49: Key Driver of Oncology Cost Increases

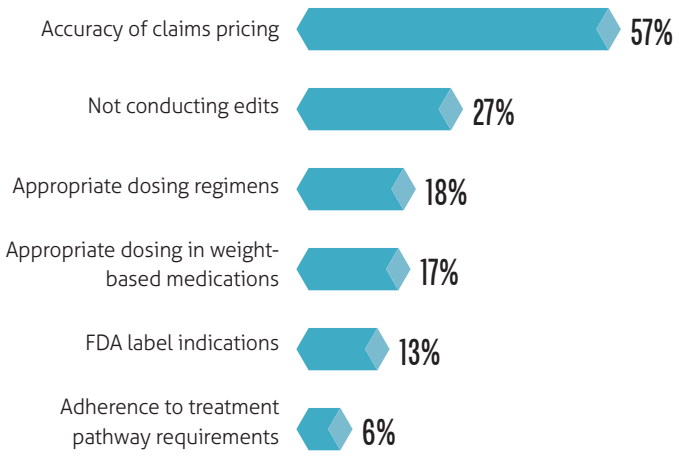


Operational Improvements

Payors continue to use post-claim edits for provider-administered injectables paid under the member's medical benefit. Claims edits were used in more than half of all covered lives in 2013 to mitigate claims pricing errors. Appropriate dosing regimens overall, as well as appropriate weight-based medications, were monitored in 18 and 17 percent of covered lives, respectively. Edits to check for appropriate FDA indications (13 percent) and adherence to treatment pathway (6 percent) were used infrequently. Of those conducting reviews, nearly all are developed and conducted by internal health plan staff. *See Figure 50, Post-Claim Edits Conducted on Medical Injectable Claims, and Figure 51, Implementation of Post-Claim Edits.*

FIGURE 50: Post-Claim Edits Conducted

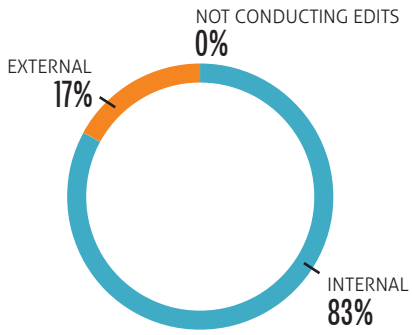
% OF LIVES



n = 48; 166,325,487 lives

FIGURE 51: Implementation of Post-Claim Edits

% OF LIVES



n = 27; 121,517,487 lives covered (2013)

Although becoming increasingly more prevalent, the overall management of radiology oncology services is limited to one in five members. Nearly half of all covered lives are subject to management of radiologic treatment only, while diagnostic-only use is relatively uncommon (5 percent). *See Figure 52, Managing Utilization of Radiology Oncology Benefits.*

A consensus regarding the use of oncology pathways appears to be emerging among payors. When asked about their current use, nearly all respondents were more likely to believe oncology pathways improved costs and quality today than they did three years ago, suggesting that these are continuing to evolve as effective management tools. *See Figure 53, Oncology Pathways.*

When asked about what programs have been implemented to manage the site of service, a third of respondents reported nothing was being done. A variety of prior authorization activities (17 percent) and contracting initiatives (15 percent) were most commonly identified.

More than half of respondents have implemented a fixed fee schedule for reducing the number of hospitals on a percentage reimbursement basis. *See Figure 54, Fixed Fee Schedule Implementation.*

FIGURE 52: Managing Radiology Oncology Benefits

% OF LIVES

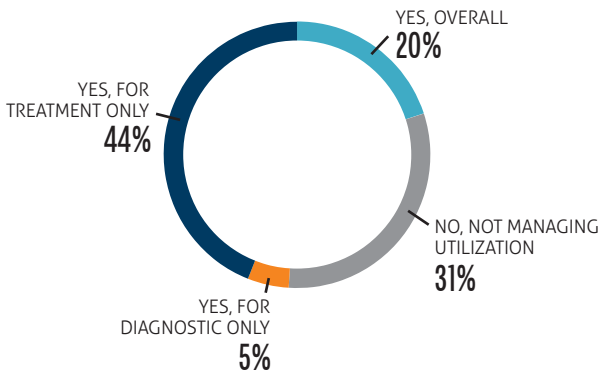
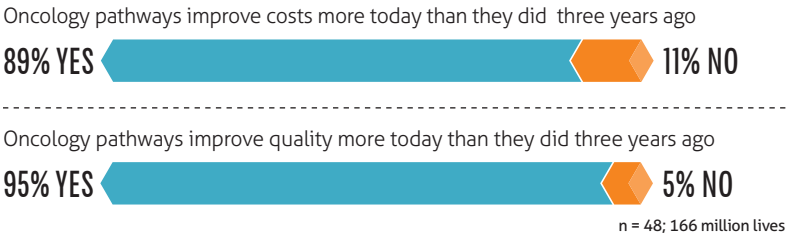


FIGURE 53: Oncology Pathways

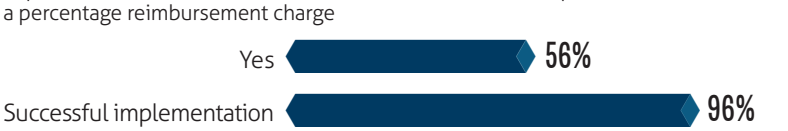
% OF LIVES



n = 48; 166 million lives

FIGURE 54: Fixed Fee Schedule Implementation

% OF LIVES

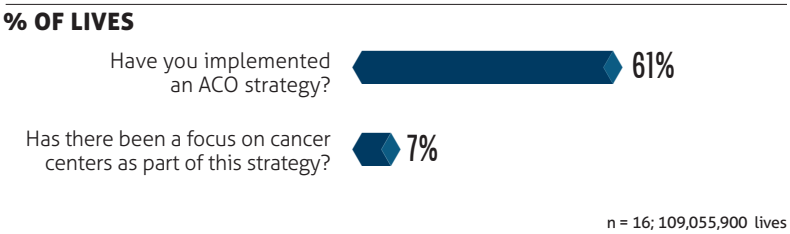


n = 48; 166 million lives

Only a third of survey respondents indicated they had implemented an ACO strategy. The large proportion of covered lives (61 percent) represented by these plans suggests this is occurring primarily in larger plans. Incorporating cancer centers does not appear to be a major focus of ACO implementation at this time. *See Figure 55, Implemented ACO Strategy.*

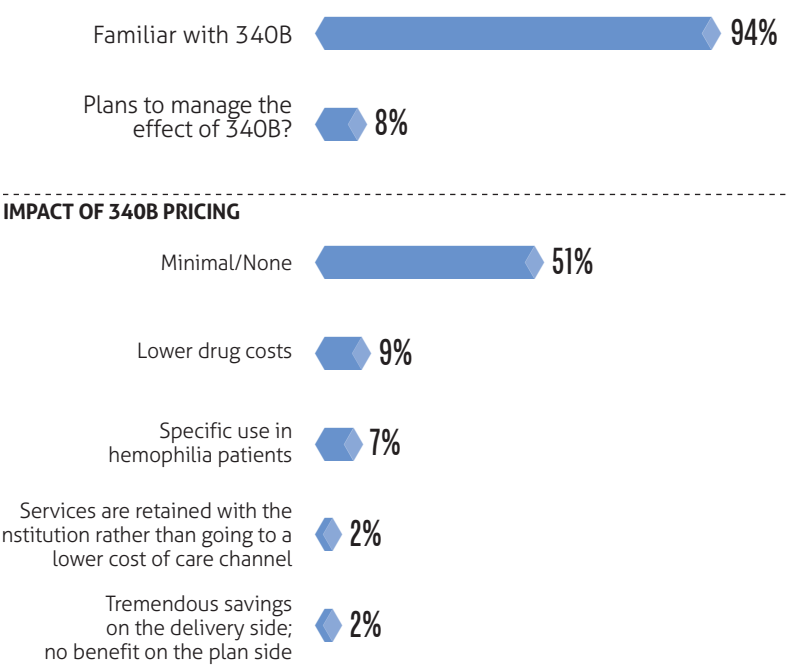
Nearly all respondents are familiar with 340B pricing and have no plans for managing it in the future. Over half of respondents believe 340B pricing has had minimal impact for their plans. *See Figure 56, 340B Pharmacy Pricing Impact.*

FIGURE 55: Implemented ACO Strategy



n = 16; 109,055,900 lives

FIGURE 56: 340B Pharmacy Pricing



Health Plan Claims Data

Trend Drivers

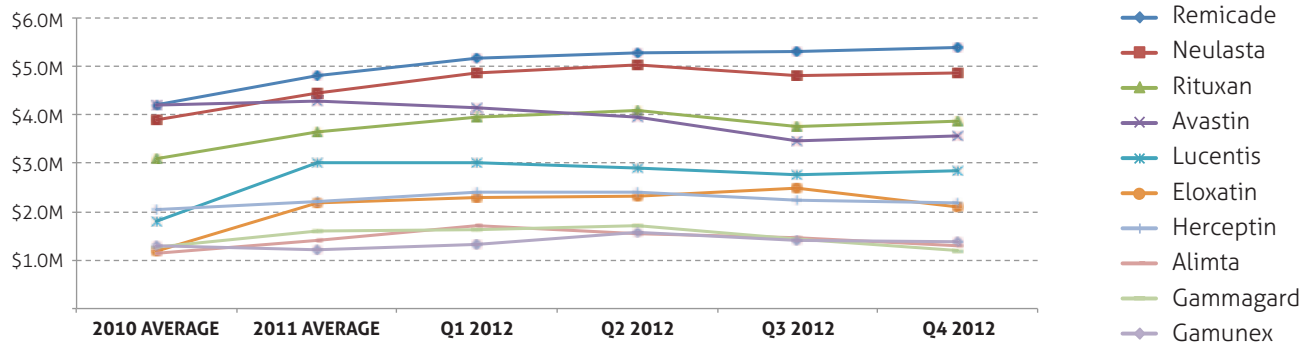
Based on the analysis of paid medical benefit claims from 2012, a 1-million-life commercial plan will have averaged $245 million in medical benefit costs in 2012. This represents an increase of 6.3 percent. Of that, the top 25 medical drugs comprised more than 69 percent of the total medical injectable spend. Remicade and Neulasta continue to hold the top two positions on the top 25 medical drug spend list, with 10 percent increases mostly driven by site of service shifts to the hospital. Avastin use declined related to use for metastatic breast cancer. There were two new additions of note to the top 25 list, Xgeva and Soliris. Xgeva represents a new top 25 drug for supportive care for chemotherapy that we have not seen in many years. Interestingly, as Xgeva made the top 25 list at 14, Aranesp is no longer on our list. This continues to show the importance of managing supportive care for chemotherapy as an area with significant complexity and cost. Soliris is used to treat a couple of very rare conditions: atypical hemolytic uremic syndrome (aHUS) and paroxysmal nocturnal hemoglobinuria (PNH). These are non-oncologic blood disorders. PNH is an acquired disease that leads to destruction of red blood cells. Soliris costs approximately $400,000 per year and the patient needs the drug for life. *See Figure 57, Top 25 Medical Benefit Specialty Drugs by Amount Allowed per 1 Million Lives.*

FIGURE 57: Top 25 Medical Benefit Specialty Drugs by Allowed Amount per 1 Million Lives

DRUG	RANK	J CODE	UNITS PER 1M LIVES	CALCULATED COST PER UNIT	ALLOWED PER 1M LIVES 2012	ALLOWED PER 1M LIVES 2011	% CHANGE
Remicade	1	J1745	226,809	$93.30	$21,160,843	$21,297,483	-1%
Neulasta	2	J2505	5,326	$3,672.85	$19,563,323	$18,237,283	7%
Rituxan	3	J9310	21,117	$741.59	$15,660,335	$14,290,797	10%
Avastin	4	J9035	189,940	$79.70	$15,138,979	$17,599,624	-14%
Lucentis	5	J2778	28,727	$401.05	$11,521,024	$11,335,601	2%
Eloxatin	6	J9263	767,492	$12.01	$9,220,983	$8,337,577	11%
Herceptin	7	J9355	104,263	$88.40	$9,216,387	$9,089,341	1%
Alimta	8	J9305	101,772	$58.99	$6,003,870	$5,601,882	7%
Gammagard	9	J1569	120,483	$49.64	$5,980,608	$6,237,738	-4%
Gamunex	10	J1561	94,567	$60.04	$5,678,156	$4,266,216	33%
Advate	11	J7192	937,478	$6.00	$5,623,680	$4,541,021	24%
Tysabri	12	J2323	310,394	$15.01	$4,658,058	$3,925,521	19%
Taxotere	13	J9171	246,801	$18.33	$4,523,014	$6,286,493	-28%
Xgeva	14	J0897	240,086	$16.31	$3,916,584	$0	100%
Velcade	15	J9041	79,610	$48.34	$3,848,161	$3,065,380	26%
Aloxi	16	J2469	126,935	$27.23	$3,455,882	$3,510,232	-2%
Erbitux	17	J9055	53,329	$57.97	$3,091,367	$3,347,783	-8%
Procrit	18	J0885	264,225	$10.67	$2,818,709	$3,005,084	3%
Soliris	19	J1300	10,552	$251.73	$2,656,111	$1,041,089	155%
Zometa	20	J3487	10,008	$259.89	$2,600,926	$3,200,741	-19%
Privigen	21	J1459	56,148	$46.23	$2,595,574	$1,369,634	90%
Synvisc-One	22	J7325	178,524	$14.40	$2,570,734	$2,450,895	5%
Orencia	23	J0129	103,698	$24.47	$2,537,581	$2,973,499	-15%
Sandostatin	24	J2353	18,723	$132.23	$2,475,720	$2,317,484	7%
Abraxane	25	J9264	202,764	$12.19	$2,471,145	$2,077,085	19%
TOTAL					**$168,987,753**	**$159,133,403**	**6%**

FIGURE 58: Top 10 Drugs by Yearly Average (2010 and 2011) and Quarter (2012)

ALLOWED PER 1 M LIVES



The top 10 drugs represent 49 percent of the overall medical drug spend for these plans. The top spending drugs had a stable quarter-to-quarter trend with only Avastin showing a decline in the second half of 2012. *See Figure 58, Top 10 Drugs by Yearly Average (2010 and 2011) and Quarter (2012).*

Our review of diagnosis codes in 2012 for members receiving medical benefit drugs demonstrated results consistent with 2011, with the top 25 codes representing 53 percent of the overall diagnosis codes for patients being treated with drugs paid on the medical benefit. The top ICD9 codes remain for conditions that treat autoimmune disorders. Other retinal disorders increased from 20th in 2011 to 13th in 2012, correlating with the increased treatment of macular degeneration. Our favorite codes, 780 for general symptoms and V58 for encounter of unspecified procedures, dropped a few spots respectively, showing minor improvements in coding for very expensive medications. *See Figure 59, Portion of Members Who Received a Medical Injectable.*

FIGURE 59: Portion of Members Who Received a Medical Injectable

RANK	PRIMARY DIAGNOSIS CODE	DESCRIPTION	% OF TOTAL PATIENTS PER 1M LIVES 2012	% OF TOTAL PATIENTS PER 1M LIVES 2011
1	715	Osteoarthrosis and allied disorders	8.1%	6.6%
2	726	Peripheral enthesopathies and allied syndromes	5.6%	5.1%
3	719	Other and unspecified disorders of joint	4.7%	4.4%
4	786	Symptoms involving respiratory system and other chest symptoms	4.3%	4.2%
5	724	Other and unspecified disorders of back	2.9%	2.8%
6	727	Other disorders of synovium, tendon and bursa	2.6%	2.5%
7	789	Other symptoms involving abdomen and pelvis	2.1%	2.6%
8	414	Other forms of chronic ischemic heart disease	1.9%	1.9%
9	V04	Need for prophylactic vaccination and inoculation	1.7%	1.9%
10	493	Asthma	1.5%	1.5%
11	466	Acute bronchitis and bronchiolitis	1.4%	1.4%
12	728	Disorders of muscle, ligament and fascia	1.4%	1.3%
13	362	Other retinal disorders	1.4%	1.1%
14	266	Deficiency of B-complex components	1.3%	1.2%
15	692	Contact dermatitis and other eczema	1.3%	1.1%
16	281	Other deficiency anemias	1.3%	1.3%
17	780	General symptoms	1.3%	1.3%
18	461	Acute sinusitis	1.2%	1.1%
19	477	Allergic rhinitis	1.2%	1.1%
20	729	Other disorders of soft tissues	1.1%	1.0%
21	733	Other disorders of bone and cartilage	1.0%	0.9%
22	722	Intervertebral disc disorders	1.0%	1.0%
23	787	Symptoms involving digestive system	0.9%	1.1%
24	V58	Encounter for other and unspecified procedures and aftercare	0.9%	1.0%
25	706	Diseases of sebaceous glands	0.9%	0.9%
TOTAL			53.0%	50.3%

Management of Spend Drivers

Provider-infused or injected chemotherapy and supportive care related to cancer treatment represents the largest portion of medical drug costs. It remains important to note that these data reflect all sites of service, and so provide a more complete picture of the overall spend across the medical benefit. Because of this comprehensive approach to the analysis, these allowed amounts are likely larger than other available benchmarks that measure only provider office-based administrations. One consistent data point in this year's report as well as in the past, the "other" bucket continues to represent a high percentage of any specific analysis of medical drug data. This is different from the traditional pharmacy benefit where specific information is required to process each claim and, therefore, data analysis can give a more complete picture. With 23 percent or $60 million per million lives of drug cost (compared with 24 percent the previous year) categorized in the "other" bucket, this should continue to represent opportunity not only to understand this data better in the future but in all likelihood manage the cost more effectively. *See Figure 60, Spend by Key Therapeutic Class.*

FIGURE 60: Spend by Key Therapeutic Class

THERAPY	ALLOWED PER 1M LIVES 2012	% OF TOTAL SPEND	ALLOWED PER 1M LIVES 2011*	% OF TOTAL SPEND
Oncology	$96,940,281	37%	$95,951,319	38%
Other	$60,373,878	23%	$60,805,348	24%
CSF	$22,027,714	8%	$21,869,186	9%
IVIG	$18,790,997	7%	$15,729,028	6%
Gastroenterology	$15,640,433	6%	$14,863,165	6%
RA	$11,761,576	5%	$11,174,638	4%
Oncology: Support	$8,905,197	5%	$10,301,922	4%
Hemophilia	$8,876,398	3%	$7,668,098	3%
ESA	$4,737,843	2%	$6,143,347	2%
Antiemetics	$5,841,154	2%	$5,719,792	2%
Osteoarthritis	$5,866,556	2%	$5,105,485	2%
TOTALS	**$259,762,027**	**100%**	**$255,331,325**	**100%**

*Slightly different than last year due to rounding effects.

National Provider Trends

Across all lines of business, hematologists and oncologists together order and administer the most medical benefit drugs, representing 44 percent of the total units ordered. As with other analyses in this trend report, the most telling statistic is that 50 percent of the units billed are categorized in the "other" bucket. As we review the "other" bucket, internal medicine represents 13 percent, orthopedic surgeons 3 percent, and ophthalmology and gastroenterology <1 percent. This data shows us that many physician specialties are incorporating specialty drugs into care of their patients. Some of the internal medicine physicians may have additional training and credentials to use these medications. It is apparent that health plans need to understand and manage physician specialties that are not as familiar with all the administration aspects of medical pharmacy including drug purchasing, administration, billing and reimbursement. *See Figure 61, Spend by Provider Specialty, and Figure 62, Claims by Provider Specialty.*

FIGURE 61: Spend by Provider Specialty

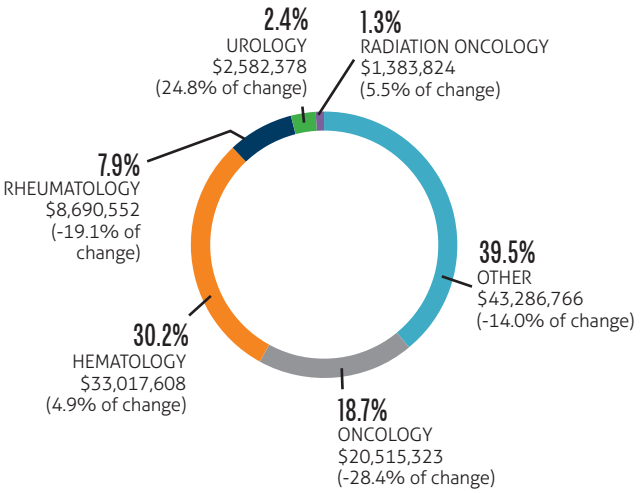


FIGURE 62: Claims by Provider Specialty

SPECIALTY	UNITS/MILLION 2012	UNITS/MILLION 2011	% OF CHANGE	CLAIMS/MILLION 2012	CLAIMS/MILLION 2011	% OF CHANGE
Other	3,890,064	4,278,967	-9.1%	267,742	289,710	-7.6%
Oncology	1,325,409	1,625,971	-18.5%	39,287	52,910	-25.7%
Hematology	2,058,771	2,066,931	-0.4%	57,637	58,465	-1.4%
Rheumatology	333,921	350,190	-4.7%	13,735	18,234	-24.7%
Urology	70,673	58,508	20.8%	7,647	9,010	-15.1%
Radiation Oncology	71,391	89,631	-20.4%	2,269	2,235	1.5%
TOTAL	**7,750,229**	**8,470,198**	**-8.5%**	**388,316**	**430,565**	**-9.8%**

Injectable therapies billed under the patient's medical benefit are typically administered through one of four main channels: the hospital, facility outpatient, home infusion or the provider's office. Additional infusions are given in other sites of service, with ESAs administered at dialysis centers serving as a key example. Looking at the top 10 drugs by annual allowed amount per 1 million lives in 2012, administration in the hospital setting generally results in twice the amount of what a provider-administered injectable delivered in the provider's office would cost. There has been some migration in the market with provider groups beginning to send patients to hospitals for their therapy administration, which has the potential to increase costs of care significantly over time as this continues. In 2012, seven of the top 10 drugs showed significant increases in utilization in the hospital setting directly reducing the use in the physician office. Figure 64 validates the increased cost due to site of service shift and the need for additional attention and strategies to mitigate this impact to cost for essentially the same drugs and services. *See Figure 63, Spend and Utilization per 1 Million Lives by Site of Service.*

FIGURE 63: Spend and Utilization per 1 Million Lives by Site of Service

RANKING	J CODE	BRAND NAME	ALLOWED PER 1 M LIVES	2012 TOTAL $/CLAIM	2011 TOTAL $/CLAIM	2010 TOTAL $/CLAIM	2009 TOTAL $/CLAIM
1	J1745	Remicade	$21,160,843	$4,389	$3,943	$3,765	$3,711
2	J2505	Neulasta	$19,563,323	$3,680	$3,306	$3,309	$3,405
3	J9310	Rituxan	$15,660,335	$5,584	$5,411	$5,218	$5,228
4	J9035	Avastin*	$15,138,979	$5,273	$2,297	$3,248	$3,784
5	J2778	Lucentis	$11,521,024	$1,985	$2,045	$2,071	$2,088
6	J9263	Eloxatin	$9,220,983	$3,717	$3,591	$3,658	$3,888
7	J9355	Herceptin	$9,216,387	$3,301	$2,939	$2,516	$2,562
8	J9305	Alimta	$6,003,870	$5,151	$5,019	$5,044	$5,338
9	J1569	Gammagard	$5,980,608	$3,945	$4,049	$4,409	$4,779
10	J1561	Gamunex	$5,678,156	$4,045	$3,834	$4,166	$4,349

		HOSPITAL				HOME INFUSION/SPP				OTHER (ESRD, CLINICS, ETC.)				MEDICAL OFFICE			
BRAND	RANK	2009	2010	2011	2012	2009	2010	2011	2012	2009	2010	2011	2012	2009	2010	2011	2012
Remicade	1	23%	20%	23%	32%	12%	8%	7%	7%	1%	0%	0%	0%	64%	71%	69%	61%
Neulasta	2	25%	30%	31%	41%	2%	1%	1%	0%	1%	1%	2%	1%	72%	68%	67%	58%
Rituxan	3	26%	32%	36%	44%	2%	1%	1%	0%	1%	1%	1%	1%	71%	66%	63%	55%
Avastin	4	20%	18%	18%	19%	3%	2%	1%	0%	1%	1%	1%	1%	76%	79%	81%	80%
Lucentis	5	1%	0%	1%	1%	8%	4%	3%	0%	0%	0%	0%	0%	91%	96%	95%	98%
Eloxatin	6	28%	29%	38%	46%	2%	0%	0%	0%	2%	1%	2%	1%	68%	69%	59%	53%
Herceptin	7	23%	28%	36%	49%	1%	0%	0%	0%	2%	2%	1%	1%	74%	70%	63%	50%
Alimta	8	30%	38%	42%	48%	2%	0%	0%	1%	2%	2%	2%	2%	66%	60%	56%	50%
Gammagard	9	22%	19%	18%	20%	63%	66%	65%	61%	1%	0%	0%	0%	14%	15%	17%	19%
Gamunex	10	21%	21%	19%	24%	55%	56%	58%	52%	1%	0%	0%	0%	23%	23%	23%	24%

*2011 and 2012 allow/claim exclude AMD ICD9 code claims.

Percentages are based on claim counts.

The data listed illustrate the top five diagnoses for the top six highest-cost drugs to payors. Nonspecific ICD9 codes continue to be used by providers for high-cost medications. As a result, this continues to drive the need to have claim systems with sophisticated edits and utilization review because these nondescript codes are not providing payors with the data needed to validate how these are being used for their members. Specifically, 11 percent of the allowed dollars spent per million lives would not be approved according to our industry standard claim edits for appropriate diagnosed codes, with V58 and some of the indications for Lucentis representing the majority of this 11 percent. V58 represents 31 percent of the Avastin use, which is an opportunity to improve the coding for this drug specifically. *See Figure 64, Top Five Diagnosis Codes for Key Medical Benefit Drugs.*

FIGURE 64: Top Five Diagnosis Codes for Key Medical Benefit Drugs

BRAND	DESCRIPTION	CODE	ALLOWED PER 1M LIVES 2012	ALLOWED PER 1M LIVES 2011	% CHANGE	CLAIMS PER 1M LIVES 2012	CLAIMS PER 1M LIVES 2011	% CHANGE
Remicade	Regional enteritis	555	$7,477,223	$7,285,402	3%	1,394	1,614	-14%
Remicade	Rheumatoid arthritis and other inflammatory polyarthropathies	714	$5,975,318	$6,460,182	-8%	1,811	2,117	-14%
Remicade	Ulcerative colitis	556	$3,219,010	$3,001,320	7%	637	625	2%
Remicade	Psoriasis and similar disorders	696	$2,468,942	$2,470,860	0%	578	612	-5%
Remicade	Ankylosing spondylitis and other inflammatory spondylopathies	720	$691,900	$739,626	-6%	173	210	-18%
Neulasta	Diseases of white blood cells	288	$5,104,123	$5,032,150	1%	1,630	1,792	-9%
Neulasta	Encounter for other and unspecified procedures and aftercare	V58	$3,822,786	$3,403,913	12%	822	951	-14%
Neulasta	Malignant neoplasm of female breast	174	$3,011,115	$3,274,479	-8%	770	930	-17%
Neulasta	Malignant neoplasm of trachea, bronchus and lung	162	$1,037,646	$1,095,074	-5%	307	383	-20%
Neulasta	Convalescence	V66	$871,843	$1,135,374	-23%	200	337	-41%
Rituxan	Other malignant neoplasms of lymphoid and histiocytic tissue	202	$5,941,350	$6,145,634	-3%	1,167	1,210	-4%
Rituxan	Encounter for other and unspecified procedures and aftercare	V58	$2,797,931	$2,867,759	-2%	478	469	2%
Rituxan	Rheumatoid arthritis and other inflammatory polyarthropathies	714	$1,668,197	$1,590,571	5%	231	236	-2%
Rituxan	Lymphosarcoma and reticulosarcoma	200	$1,322,552	$1,071,189	23%	265	224	18%
Rituxan	Lymphoid leukemia	204	$1,241,096	$1,295,580	-4%	245	269	-9%
Avastin	Encounter for other and unspecified procedures and aftercare	V58	$3,699,782	$5,358,521	-31%	595	777	-23%
Avastin	Malignant neoplasm of colon	153	$2,729,938	$2,961,138	-8%	785	823	-5%
Avastin	Malignant neoplasm of trachea, bronchus and lung	162	$2,484,173	$3,094,423	-20%	353	447	-21%
Avastin	Malignant neoplasm of brain	191	$1,549,342	$2,119,552	-27%	231	314	-26%
Avastin	Malignant neoplasm of ovary and other uterine adnexa	183	$1,411,933	$1,464,216	-4%	217	214	2%
Lucentis	Other retinal disorders	362	$11,253,711	$12,287,640	-8%	5,646	6,052	-7%
Lucentis	Diabetes mellitus	250	$228,178	$232,614	-2%	138	114	21%
Lucentis	Other disorders of eye	379	$12,361	$4,490	175%	7	2	201%
Lucentis	Glaucoma	365	$12,067	$4,736	155%	6	3	111%
Lucentis	Cataract	366	$4,757	$3,384	41%	2	2	49%
Eloxatin	Malignant neoplasm of colon	153	$3,585,112	$3,763,257	-5%	1,000	1,044	-4%
Eloxatin	Encounter for other and unspecified procedures and aftercare	V58	$2,199,169	$2,079,416	6%	528	566	-7%
Eloxatin	Malignant neoplasm of rectum, rectosigmoid junction and anus	154	$1,413,696	$1,309,334	8%	373	358	4%
Eloxatin	Malignant neoplasm of pancreas	157	$686,425	$611,451	12%	221	171	29%
Eloxatin	Malignant neoplasm of stomach	151	$404,158	$244,416	65%	109	56	95%

Insights for 2013

Two common oncology supportive care therapeutic areas that receive payor attention for management were evaluated, but for different reasons: CINV, which is believed to be easy to manage, and white blood cell stimulants (granulocyte colony-stimulating factors, or G-CSFs), because it is a high-cost line item. In CINV, we see the larger percentage of paid claims for Kytril and Zofran for use in combination with low emetogenic chemotherapy (LEC) regimens, followed by use in combination with moderate emetogenic chemotherapies (MECs). With Aloxi, we continue to see a little over one-third of the dollars associated with LEC regimens, even though the label is for use principally with highly emetogenic chemotherapies (HECs) or MEC regimens. This is consistent with our previous study. Looking at G-CSFs, we see that the vast majority of spend per million lives for Neulasta is for use in conjunction with myelosuppressive chemotherapy. The claims data show a significantly higher use of Neupogen and Leukine for nonmyelosuppressive chemotherapy. Further supporting the appropriate use of these products is the fact that payors that reported requiring authorization for G-CSFs found small to no denial rates, likely as a result of the complicated patient profile beyond simply the diagnosis code to Healthcare Common Procedure Coding System (HCPCS) code match. *See Figure 65, Oncology Support Drug Utilization – Medical Benefits (2012).*

FIGURE 65: Oncology Support Drug Utilization – Medical Benefits (2012)

CINV – % of Claims/MM	ALOXI				ZOFRAN				KYTRIL			
REGIMEN	2012	2011	2010	2009	2012	2011	2010	2009	2012	2011	2010	2009
LEC	40%	40%	38%	39%	40%	41%	40%	40%	47%	48%	50%	48%
MEC	39%	37%	37%	35%	22%	25%	23%	22%	26%	30%	29%	30%
HEC	16%	18%	21%	22%	9%	10%	10%	11%	12%	8%	10%	12%
Unknown	6%	6%	5%	4%	29%	24%	27%	27%	15%	14%	11%	10%

G-CSF – % of Claims/MM	NEULASTA				NEUPOGEN				LEUKINE			
REGIMEN	2012	2011	2010	2009	2012	2011	2010	2009	2012	2011	2010	2009
Nonmyelosuppressive	24%	25%	20%	16%	49%	50%	39%	38%	54%	43%	29%	30%
Myelosuppressive	76%	75%	80%	84%	51%	50%	61%	62%	46%	57%	71%	70%

Three years of paid claims across all lines of business were also analyzed to compare the portion of classified and unclassified codes paid. Included in this comparison were the classic "dump" codes, such as J3490, J3535, J3590, J7199, J7599, J7699, J7799, J8498, J8499, J8597, J8999 and J9999. There was a slight decrease in the amount allowed per 1 million lives in 2012 but these "dump" codes still represent $5 million in medical drug spend that needs to be reimbursed and managed. Some of the key drugs paid with a miscellaneous drug code in 2012 were Yervoy, Erwinaze and Jevtana. A sample of these drugs in our data set showed an average payment of $30,000 plus, which outlines a trend that most miscellaneous J codes related to drugs newly approved by the FDA will have a significant cost. *See Figure 66, Unclassified Codes – Medical Benefit.*

The analysis of orphan indication utilization for the top 25 drugs is new to our Medical Pharmacy Trend Report. The purpose of this analysis was to track and educate the market on the actual use of some key drugs for orphan indications. Some industry experts probably did not realize a drug like Avastin had an orphan indication. Our data shows that 31 percent of Avastin's use is for is for orphan indications. This drug is usually associated with treating major cancer indications. Why does this matter? Orphan indications drive many aspects of how a drug is classified from a legal and regulatory perspective. It impacts drug patents, and it impacts whether or not a drug can be included in 340B programs. According to a rule implemented by the Health Resources and Services Administration (HRSA) in 2013, drugs carrying an orphan designation are excluded from 340B programs for certain hospitals (including some cancer hospitals) if the drug is used to treat the orphan condition. For Avastin, that includes eight cancer types, some of which are relatively common. This is important because certain drugs like Alimta, Orencia or Herceptin that are used for non-orphan indications more than 95 percent of the time will be impacted significantly by these changes. It is important for plans to start to understand this level of complexity with 340B and other key regulatory drivers of specialty drug trends. This information and changes to this legislation could impact trend and management strategies in the future. *See Figure 67, Orphan Indication Impact on Drug Spend.*

FIGURE 66: Unclassified Codes – Medical Benefit

2012	UNCLASSIFIED	CLASSIFIED
Allowed per 1M lives	$4,498,437	$430,288,664
Claims per 1M lives	19,661	2,323,768
% of total spend	**1.0%**	**99.0%**
2011		
Allowed per 1M lives	$6,605,245	$255,496,357
Claims per 1M lives	17,821	693,881
% of total spend	**2.5%**	**97.5%**
2010		
Allowed per 1M lives	$690,094	$228,338,685
Claims per 1M lives	3,528	776,273
% of total spend	**0.3%**	**99.7%**

FIGURE 67: Orphan Indication Impact on Drug Spend

RANK	PROCEDURE CODE	BRAND	ORPHAN UTILIZATION	NON-ORPHAN UTILIZATION
1	J1745	Remicade	53%	47%
3	J9310	Rituxan	58%	42%
4	J9035	Avastin	31%	69%
7	J9355	Herceptin	3%	97%
8	J9305	Alimta	4%	96%
9	J1569	Gammagard	0%	100%
10	J1561	Gamunex	42%	58%
14	J0897	Xgeva	0%	100%
15	J9041	Velcade	92%	8%
17	J9055	Erbitux	36%	64%
18	J0885	Procrit	0%	100%
19	J1300	Soliris	76%	24%
20	J3487	Zometa	1%	99%
23	J0129	Orencia	0%	100%
24	J2353	Sandostatin	70%	30%
25	J9264	Abraxane	15%	85%
Grand Total			**35%**	**65%**

An analysis of label (FDA and NCCN guidelines) and off-label uses of medical injectables across all lines of business was conducted to see if there were any differences in appropriateness of use across service lines. Label and off-label use was found to be consistent across all lines of business, with on-label claims representing 92 percent of the allowed spend per 1 million lives and 94 percent of the claims per 1 million lives. This represents a slight change from the previous year of 1 percent, which represents an additional $1.4 million per 1 million lives of potential use not supported by data and approved by the FDA. This trend may not be significant but it continues to demonstrate the need to understand what drugs paid for on the medical benefit are being used for, whether they are being billed correctly and ultimately if they are safe and appropriate for the patient and covered by their benefits. *See Figure 68, Off-Label Utilization for the Top 25 Drugs (2012).*

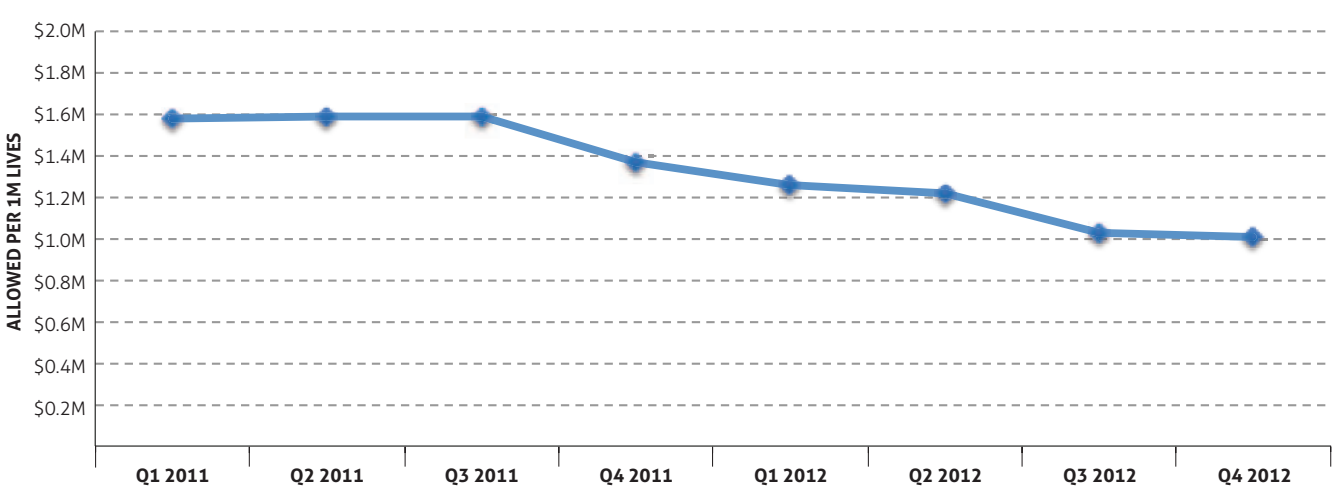
FIGURE 68: Off-Label Utilization for the Top 25 Drugs (2012)

	*ALL LOBs		COMMERCIAL		MEDICARE	
	ALLOWED/1M LIVES	CLAIMS/1M LIVES	ALLOWED/1M LIVES	CLAIMS/1M LIVES	ALLOWED/1M LIVES	CLAIMS/1M LIVES
2012						
On Label	$130,742,195	61,735	$125,616,771	58,695	$343,927,584	188,207
Off Label	$10,627,147	4,029	$10,292,982	3,866	$24,526,314	10,814
2011						
On Label	$156,643,003	72,188	$150,612,771	67,869	$340,324,019	203,752
Off Label	$11,601,918	4,213	$11,346,161	4,057	$19,392,293	8,964
% OF TOTAL						
2012						
On Label	92%	94%	92%	94%	93%	95%
Off Label	8%	6%	8%	6%	7%	5%
2011						
On Label	93%	94%	93%	94%	95%	96%
Off Label	7%	6%	7%	6%	5%	4%

*No Medicaid payor included in report.

In an effort to evaluate what happens to payor spend under a specific J code after a drug loses patent protection, essentially monetizing the value to payors of price erosion over time, we studied Eloxatin, which went generic in quarter four of 2009. In our report last year, the data showed roughly a 25 percent drop over a 12-month period. In the next 12 months, the allowed dollars per 1 million lives dropped an estimated additional 23 percent. It will continue to be of interest to understand how generic introduction and potential biosimilar introduction on drugs reimbursed on the medical benefit with a predominantly ASP-based reimbursement will be impacted by generic competition. This analysis over two years demonstrates a much slower decline in price compared to traditional pharmaceuticals paid on the pharmacy benefit after a generic introduction. *See Figure 69, Generic Introduction Spend Impact.*

FIGURE 69: Generic Introduction Spend Impact



Product Pipeline and Legislative Trends

Drug Pipeline

Two notable injectables, Kadcyla and Xofigo, were approved in 2013 under the FDA's priority review program. Both products are examples of a new trend of targeted therapy in oncology, which delivers a potent antineoplastic agent to a targeted area of the body, sparing other areas of the body from being exposed unnecessarily.

One of the most anticipated approvals occurred in February 2013 with Kadcyla (ado-trastuzumab emtansine), a new therapy for patients with HER2-positive, late-stage (metastatic) breast cancer. Kadcyla is an antibody-drug conjugate consisting of the monoclonal antibody trastuzumab connected to a cytotoxic drug called DM1 (mertansine) that interferes with cancer cell growth. Kadcyla works by delivering the drug to the specific cancer site, binding to the HER2 receptor, shrinking the tumor, slowing disease progression and prolonging survival. The safety and effectiveness of Kadcyla were evaluated in a clinical study of 991 patients with results that showed patients treated with Kadcyla had a median progression-free survival of 9.6 months compared to 6.4 months in patients treated with lapatinib plus capecitabine. The median overall survival was 30.9 months in the Kadcyla group and 25.1 months in the lapatinib plus capecitabine group.

In May 2013, Xofigo (radium Ra 223 dichloride) was approved by the FDA to treat men with symptomatic late-stage (metastatic) castration-resistant prostate cancer that has spread to bones but not to other organs. It is intended for men whose cancer has spread after receiving medical or surgical therapy to lower testosterone. Xofigo binds with minerals in the bone to deliver radiation directly to bone tumors, limiting the damage to the surrounding normal tissues. Xofigo's safety and effectiveness were evaluated in a single clinical trial of 809 men designed to measure overall survival. The FDA approval was based on results from the preplanned interim analysis, which showed men receiving Xofigo lived a median of 14 months compared to a median of 11.2 months for men receiving placebo.

Both products were approved under the FDA's priority review program, which provides for an expedited review of drugs that appear to provide safe and effective therapy when no satisfactory alternative therapy exists, or offer significant improvement compared to marketed products.

FIGURE 70: 2013 FDA-Approved Specialty Injectable Drugs

DRUG	MANUFACTURER	INDICATION	APPROVAL
Kynamro (mipomersen sodium)	Genzyme	Homozygous familial hypercholesterolemia	January
Kadcyla (ado-trastuzumab emtansine)	Genentech	Breast cancer	February
Xofigo (radium Ra 223 dichloride)	Bayer Healthcare Pharmaceuticals	Prostate cancer	May
Kcentra (Prothrombin Complex Concentrate)	CSL Behring	Anticoagulation reversal	May
Rixubis (Coagulation Factor IX [Recombinant])	Baxter International	Hemophilia B	June

Source: FDA website. www.fda.gov. Accessed September 17, 2013.

FIGURE 71: Biosimilar Pipeline

PRODUCT NAME	PROPOSED INDICATION	COMPANY	PHASE OF FDA STUDY	COMMENTS
Granix (tbo-filgrastim)	Indicated for reduction in the duration of severe neutropenia in patients with nonmyeloid malignancies receiving myelosuppressive anticancer drugs associated with a clinically significant incidence of febrile neutropenia	Teva	Product has launched	Follow-on biologic for filgrastim
Lipegfilgrastim	Long-acting granulocyte colony-stimulating factors (G-CSFs) being evaluated for their ability to reduce the duration of severe neutropenia in breast cancer patients undergoing chemotherapy	Teva	Phase 3 (Completed)	Follow-on biologic for pegfilgrastim. Lipegfilgrastim is a glycopegylated, recombinant form of filgrastim.
TL011	Rheumatoid arthritis	Teva	Phase 3 trial suspended	Follow-on biologic for rituximab. Phase 3 trial was suspended by Teva.
EP2006	Reduction in the duration of severe neutropenia and the incidence of febrile neutropenia in patients treated with established myelosuppressive chemotherapy for cancer	Sandoz	Phase 3	Follow-on biologic for filgrastim. Sandoz's filgrastim biosimilar is already marketed under the brand name Zarzio in more than 30 countries outside the United States.
LA EP2006	Long-acting granulocyte colony-stimulating factors (G-CSFs) being evaluated for their ability to reduce the duration of severe neutropenia in breast cancer patients undergoing chemotherapy	Sandoz	Phase 3	Follow-on biologic for pegfilgrastim
GP2013	• Rheumatoid arthritis • Advanced-stage follicular lymphoma	Sandoz	• Phase 2 • Phase 3	Follow-on biologic for rituximab
HX575	Treatment of anemia associated with chronic renal failure	Sandoz	Phase 3	Follow-on biologic for epoetin alfa
Epoetin	Treatment of anemia associated with chronic renal failure	Hospira	Phase 3	Follow-on biologic for epoetin alfa
BCD-020	Rheumatoid arthritis	Biocad	Phase 3	Follow-on biologic for rituximab
BI 695501	Rheumatoid arthritis	Boehringer Ingelheim	Phase 1	Follow-on biologic for adalimumab
BI 695500	Rheumatoid arthritis	Boehringer Ingelheim	Phase 1	Follow-on biologic for rituximab
HD203	Rheumatoid arthritis	Merck/ Hanwha	Phase 3	Follow-on biologic for etanercept
PF-05082566	Non-Hodgkin's lymphoma	Pfizer	Phase 1	Follow-on biologic for rituximab
PF-05280586	Rheumatoid arthritis	Pfizer	Phase 1/2	Follow-on biologic for rituximab

FIGURE 72: Pipeline Drugs in Various Phases of Study for Key Cancer Types

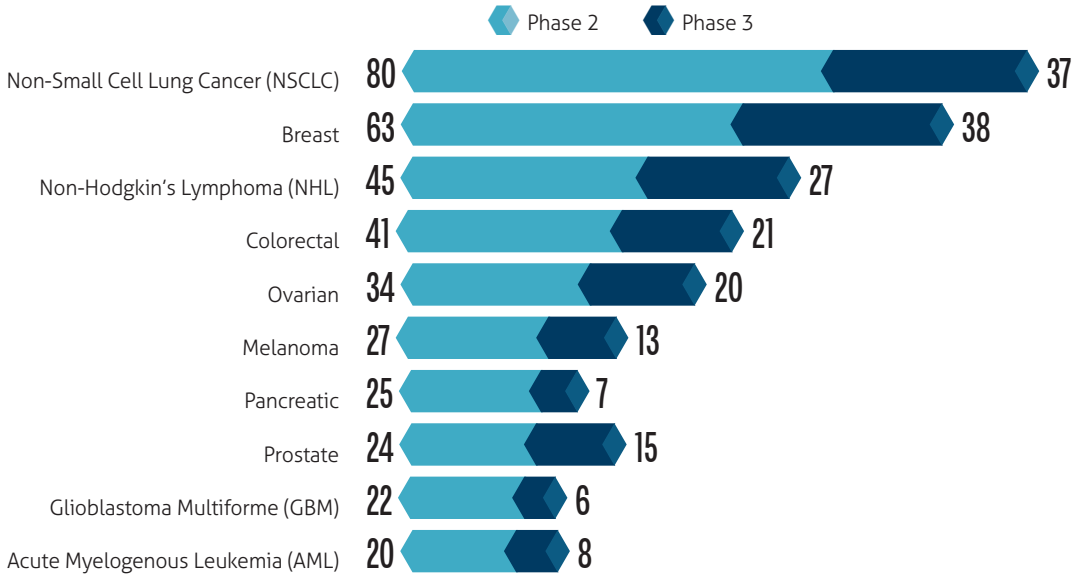


FIGURE 73: Selected Phase 3 Products by Key Cancer Type

BREAST		
PRODUCT	CLASS	AREA OF STUDY
Afinitor; everolimus; RAD001	mTOR inhibitor	first line metastatic breast cancer
APA-1000	adaptive phased array (APA)	breast cancer
arzoxifene	selective estrogen receptor modulator (SERM)	breast cancer
Avastin; bevacizumab	anti-VEGF monoclonal antibody	adjuvant breast cancer (HER2+), first line metastatic breast cancer (HER2-), first line metastatic breast cancer (HER2+), second line metastatic breast cancer, adjuvant breast cancer (HER2-)
BKM120	PI3K inhibitor	breast cancer
entinostat; SNDX-275	HDAC inhibitor	first line metastatic breast cancer
Faslodex; fulvestrant	oestrogen receptor antagonist	first line metastatic breast cancer
Gilotrif; afatinib; BIBW 2992	EGFR/HER2 inhibitor	first line metastatic breast cancer
Halaven; eribulin mesylate; E7389	halichondrin B analog (synthetic)	second line metastatic breast cancer
Herceptin; trastuzumab	antibody-drug conjugate	adjuvant breast cancer (HER2+), breast cancer (HER2+)
Ixempra; ixabepilone	epothilone	adjuvant breast cancer
Kadcyla; ado-trastuzumab emtansine; T-DM1	antibody-drug conjugate	third line metastatic breast cancer (HER2+), first line metastatic breast cancer (HER2+), third line metastatic breast cancer (HER2+)
Myocet (+ paclitaxel and trastuzumab)	non-pegylated liposomal doxorubicin	first line metastatic breast cancer (HER2+)
NeuVax; nelipepimut-S (+ trastuzumab); E75	immunotherapy (peptide-based)	adjuvant breast cancer (HER2+)
niraparib	PARP inhibitor	breast cancer
NKTR-102	topoisomerase 1 inhibitor	first line metastatic breast cancer
Orazol; MER-101	bisphosphonate (oral)	adjuvant breast cancer
palbociclib; PD-0332991	CDK 4,6 kinase inhibitor	first line metastatic breast cancer
Perjeta; pertuzumab; R1273	HER dimerization inhibitor	early-stage breast cancer (HER2+)
ramucirumab; IMC-1121B	anti-VEGFR-2 monoclonal antibody	second line metastatic breast cancer
Stimuvax; BLP25 liposome vaccine	immunotherapy	second line metastatic breast cancer
Tavocept; dimesna; BNP7787	chemoprotective agent	first line metastatic breast cancer
Tykerb; lapatinib	ErbB-2 and EGFR dual kinase inhibitor	first line metastatic breast cancer, adjuvant breast cancer
Votrient (+ Tykerb); pazopanib (+ lapatinib)	multiple tyrosine kinase inhibitor	inflammatory breast cancer
Xeloda; capecitabine	fluoropyrimidine (oral)	adjuvant breast cancer
Xgeva; denosumab; AMG 162	anti-RANKL antibody	adjuvant breast cancer
Zometa; zoledronic acid	bisphosphonate	breast cancer

NON-SMALL CELL LUNG CANCER		
PRODUCT	CLASS	AREA OF STUDY
Alimta; pemetrexed	antimetabolite (a folic acid antagonist)	non-small cell lung cancer (NSCLC)
Avastin; bevacizumab	anti-VEGF monoclonal antibody	adjuvant NSCLC, NSCLC with previously treated CNS metastases
custirsen; OGX-011/TV-1011	clusterin inhibitor	first line metastatic NSCLC
dacomitinib; PF-00299804	pan-HER inhibitor	second line metastatic NSCLC
Erbitux; cetuximab	anti-EGFR monoclonal antibody	NSCLC, second line metastatic NSCLC, first line metastatic NSCLC
erlotinib tablets	HER1/EGFR tyrosine kinase inhibitor	second line metastatic NSCLC
ganetespib (+ docetaxel); STA-9090	Hsp90 inhibitor	second line metastatic NSCLC
GSK1572932A	immunotherapy	NSCLC
Halaven; eribulin mesylate; E7389	halichondrin B analog (synthetic)	NSCLC
Iressa; gefitinib	EGFR tyrosine kinase inhibitor	NSCLC
Lucanix; belagenpumatucel-L	immunotherapy	NSCLC
MAGE-A3	antigen-specific cancer immunotherapeutic	first line metastatic NSCLC
motesanib diphosphate; AMG 706	VEGFR1-3, PDGFR, c-Kit inhibitor (oral)	first line metastatic NSCLC
necitumumab; IMC-11F8	EGFR inhibitor	NSCLC
Nexavar; sorafenib	multiple tyrosine kinase inhibitor	first line metastatic NSCLC
nintedanib	multiple tyrosine kinase inhibitor (VEGFR, FGFR, PDGFR)	NSCLC
onartuzumab; MetMAb (+ erlotinib)	c-Met inhibitor (monovalent antibody)	first line metastatic NSCLC
Opaxio; paclitaxel poliglumex; CT-2103	microtubule inhibitor	NSCLC
ramucirumab; IMC-1121B	anti-VEGFR-2 monoclonal antibody	NSCLC
Stimuvax; BLP25 liposome vaccine	immunotherapy	NSCLC
Tarceva; erlotinib	HER1/EGFR inhibitor	first line metastatic NSCLC, adjuvant NSCLC
Tavocept; dimesna; BNP7787	chemoprotective agent	NSCLC
Telcyta; canfosfamide HCl; TLK286	glutathione S-transferase P1-1 (GST P1-1) agonist	NSCLC (platinum-resistant)
Vargatef; BIBF 1120	multiple tyrosine kinase inhibitor (VEGFR, FGFR, PDGFR)	NSCLC
Xalkori; crizotinib; PF-02341066	ALK inhibitor (oral)	first line metastatic NSCLC, second line metastatic NSCLC
Zaltrap; aflibercept; VEGF Trap	VEGF-A inhibitor	second line metastatic NSCLC

NON-HODGKIN'S LYMPHOMA		
PRODUCT	CLASS	AREA OF STUDY
Adcetris; brentuximab vedotin; SGN-35	antibody-drug conjugate (anti-CD30)	first line metastatic non-Hodgkin's lymphoma (NHL), second line metastatic cutaneous T-cell lymphoma (CTCL)
Afinitor; everolimus; RAD001	mTOR inhibitor	diffuse large B-cell lymphoma (DLBCL)
afutuzumab (GA101/RG7159)	anti-CD20 monoclonal antibody (humanized)	NHL
Arzerra; ofatumumab	anti-CD20 monoclonal antibody (humanized)	second line follicular non-Hodgkin's lymphoma (f-NHL)
Avastin; bevacizumab	anti-VEGF monoclonal antibody	DLBCL
belinostat; PXD 101	HDAC inhibitor	second line metastatic peripheral T-cell lymphoma (PTCL)
BiovaxID	immunotherapy	f-NHL
enzastaurin	serine/threonine kinase inhibitor	DLBCL
Folotyn; pralatrexate	antifolate	PTCL, CTCL
ibrutinib; PCI-32765	Bruton's tyrosine kinase (BTK) inhibitor	second line metastatic mantle cell lymphoma (MCL)
inotuzumab ozogamicin; PF-5208773	antibody-drug conjugate (anti-CD22 monoclonal antibody linked to CalichDMH – humanized)	aggressive NHL
Marqibo; vincristine OPTISOME	liposomal vincristine	NHL
moxetumomab pasudotox; CAT-8015	anti-CD22 monoclonal antibody	NHL
obinutuzumab; GA101 (RG7159)	anti-CD20 monoclonal antibody (humanized)	first line indolent NHL, DLBCL, refractory indolent NHL
Pixuvri (+ Rituxan); pixantrone (+ rituximab); BBR 2778	anthracycline	second line metastatic B-cell NHL
Revlimid; lenalidomide	immune system modulator	NHL
Rituxan; rituximab	anti-CD20 monoclonal antibody	NHL
Treanda; bendamustine	alkylating agent	first line metastatic NHL
Velcade; bortezomib	proteasome inhibitor	second line f-NHL
Zevalin; ibritumomab tiuxetan	CD20-directed radiotherapeutic antibody	DLBCL

COLORECTAL		
PRODUCT	CLASS	AREA OF STUDY
Aptocine	light-activated drug treatment	first line metastatic colorectal cancer
Avastin; bevacizumab	anti-VEGF monoclonal antibody	first line metastatic colorectal cancer
brivanib	VEGFR-2 inhibitor	first line metastatic colorectal cancer
Erbitux; cetuximab	anti-EGFR monoclonal antibody	first line metastatic colorectal cancer, adjuvant colorectal cancer
erlotinib tablets	HER1/EGFR tyrosine kinase inhibitor	colorectal cancer
Imprime PGG (+ cetuximab)	immunomodulator	second line metastatic colorectal cancer, third line metastatic colorectal cancer
perifosine (+ capecitabine); KRX-0401	AKT inhibitor	second line metastatic colorectal cancer
ramucirumab; IMC-1121B	anti-VEGFR-2 monoclonal antibody	first line metastatic colorectal cancer
Recentin; cediranib	multiple tyrosine kinase inhibitor (VEGF 1, 2, 3)	colorectal cancer
S-1	fluoropyrimidine (oral)	colorectal cancer
Tarceva; erlotinib	HER1/EGFR inhibitor	colorectal cancer
TAS-102	antimetabolite	colorectal cancer
TheraSphere	yttrium-90 microspheres	liver metastases in colorectal patients
Vectibix; panitumumab	anti-EGFR monoclonal antibody (humanized)	first line metastatic colorectal cancer, second line metastatic colorectal cancer
Xeloda; capecitabine	fluoropyrimidine (oral)	adjuvant colorectal cancer, first line metastatic colorectal cancer, second line metastatic colorectal cancer

OVARIAN		
PRODUCT	CLASS	AREA OF STUDY
AMG 386 (+ paclitaxel)	Fc-peptide fusion protein targeting angiopoietins (peptibody)	second line metastatic ovarian cancer
Avastin; bevacizumab	anti-VEGF monoclonal antibody	first line metastatic ovarian cancer, second line metastatic platinum-sensitive ovarian cancer
erlotinib tablets	HER1/EGFR tyrosine kinase inhibitor	ovarian cancer
farletuzumab; MORAb-003	IgG1 monoclonal antibody (humanized)	second line metastatic ovarian cancer
Hycamtin; topotecan hydrochloride	topoisomerase inhibitor	first line metastatic ovarian cancer
Karenitecin; BNP1350	highly lipophilic camptothecin	ovarian cancer
nintedanib	multiple tyrosine kinase inhibitor (VEGFR, FGFR, PDGFR)	ovarian cancer
niraparib	PARP inhibitor	platinum-sensitive ovarian cancer
olaparib; AZD2281	PARP inhibitor	first line metastatic ovarian cancer
Opaxio; paclitaxel poliglumex; CT-2103	microtubule inhibitor	ovarian cancer
patupilone; EPO906	epothilone	ovarian cancer
phenoxodiol	multiple signal transduction regulator	ovarian cancer
Provenge; sipuleucel-T	immunotherapy	second line metastatic castrate-resistant prostate cancer (CRPC)
Tarceva; erlotinib	HER1/EGFR inhibitor	ovarian cancer
Telcyta (+ Doxil); canfosfamide HCl; TLK286	glutathione S-transferase P1-1 (GST P1-1) agonist	third line platinum-resistant ovarian cancer
Vargatef; BIBF 1120	multiple tyrosine kinase inhibitor (VEGFR, FGFR, PDGFR)	ovarian cancer
vintafolide; EC145	vinca alkaloid	platinum-sensitive ovarian cancer
Yondelis; trabectedin	marine-derived antitumoral agent	second line metastatic ovarian cancer

MELANOMA		
PRODUCT	CLASS	AREA OF STUDY
Abraxane; nab-paclitaxel	microtubule inhibitor	first line metastatic melanoma
GSK1120212	MEK inhibitor	first line metastatic melanoma
MAGE-A3	antigen-specific cancer immunotherapeutic	first line metastatic melanoma
Nexavar; sorafenib	multiple tyrosine kinase inhibitor	melanoma
Oncophage; vitespen	immunotherapy	first line metastatic melanoma
talimogene laherparepvec (formerly OncoVEX GM-CSF); T-Vec	oncolytic immunotherapy (derived from HSV-1)	first line metastatic melanoma
The Delcath system	drug delivery platform	first line metastatic melanoma in the liver
Yervoy; ipilimumab; MDX-010	anti-CTLA4 monoclonal antibody (humanized)	second line metastatic melanoma, adjuvant melanoma
Zadaxin; thymalfasin	immune system modulator	melanoma
Zelboraf (+ Yervoy); vemurafenib (+ ipilimumab); PLX4032 (RG7204)	BRAF-selective kinase inhibitor	adjuvant melanoma

PANCREATIC		
PRODUCT	CLASS	AREA OF STUDY
larotaxel; XRP9881	taxane (semi-synthetic)	pancreatic cancer
masitinib; AB1010	multiple tyrosine kinase inhibitor	pancreatic cancer
PN401 (formerly vistonuridine)	uridine prodrug	pancreatic cancer
S-1	fluoropyrimidine (oral)	pancreatic cancer

PROSTATE		
PRODUCT	CLASS	AREA OF STUDY
Avastin; bevacizumab	anti-VEGF monoclonal antibody	hormone refractory prostate cancer (HRPC)
Cometriq; cabozantinib; XL184	multiple tyrosine kinase inhibitor (MET and RET)	second line metastatic castrate-resistant prostate cancer (CRPC)
custirsen (+ cabazitaxel); OGX-011/TV-1011	clusterin inhibitor	second line metastatic CRPC, first line metastatic CRPC
DCVax	immunotherapy	prostate cancer
Jevtana; cabazitaxel; XRP6258	taxane	first line metastatic HRPC
orteronel; TAK-700	non-steroidal androgen synthesis inhibitor (oral)	first line metastatic CRPC
phenoxodiol	multiple signal transduction regulator	prostate cancer
triptorelin; Debio 8206	GnRH antagonist (oral)	first line metastatic prostate cancer
Zaltrap; aflibercept; VEGF Trap	VEGF-A inhibitor	first line metastatic HRPC
Zytiga; abiraterone acetate; CB-7630	inhibitor of the steroidal enzyme 17 alpha-hydroxylase/C17,20 lyase (oral)	first line metastatic HRPC

GLIOBLASTOMA MULTIFORME (GBM)		
PRODUCT	CLASS	AREA OF STUDY
Avastin; bevacizumab	anti-VEGF monoclonal antibody	first line metastatic glioblastoma multiforme (GBM), second line metastatic GBM
cintredekin besudotox IL-13	interleukin-13 (IL-13) and PE38 recombinant protein	GBM
DCVax	immunotherapy	GBM
NovoTTF-100A System (+ temozolomide)	tumor treating fields (TTF) therapy	first line metastatic GBM
Recentin; cediranib	multiple tyrosine kinase inhibitor (VEGF 1, 2, 3)	second line metastatic GBM

ACUTE MYELOGENOUS LEUKEMIA (AML)		
PRODUCT	CLASS	AREA OF STUDY
Ceplene; histamine dihydrochloride	histamine H2 receptor agonist	acute myelogenous leukemia (AML)
Clolar; clofarabine	antimetabolite	AML
Dacogen; decitabine	antimetabolite (cytidine analog)	AML
elacytarabine; CP-4055	antimetabolite	AML
midostaurin; PKC412	multiple tyrosine kinase inhibitor	AML
sapacitabine; CYC682	antimetabolite (oral)	first line metastatic AML
Trisenox; arsenic trioxide	taxane (a synthetic retinoid)	AML
vosaroxin; SNS-595	topoisomerase 2 inhibitor	AML

Key Legislative Outcomes — 2013

2013 ONCOLOGY POLICY UPDATES

Over the next 10 years, the Affordable Care Act (ACA) has the potential to expand health care coverage to approximately 30 million Americans. With more individuals entering the health care system, we can mostly likely expect a rise in the number of individuals being screened, diagnosed and treated for cancer.

In October 2013, the ACA Health Exchange implementation coincided with a budget standoff resulting in the first government shutdown since the winter of 1995/1996. Moving into 2014, Congress continues to grapple with the ever increasing mandatory spending as well as the growing federal debt. Should Congress be successful with a long-term fix, it is expected to provide 0.5 percent updates to physician fees for 5 years while phasing in value-based payments and alternative payment models (e.g. risk-bearing arrangements like accountable care organizations and medical homes). Alongside the potential for a sustainable growth rate (SGR) fix and continued discussions regarding alternative payment methodologies, the ACA has prompted continued experimentation in alternative payment methodologies. While the focus has been more on chronic care and inpatient hospitalizations, continued debate about payment methodologies and experimentation in oncology is expected throughout 2014. Oncology specialty societies continue to raise concern and propose alternatives to better account for cognitive services provided by oncologists in managing anticancer regimens in exchange for reduced drug reimbursement.

Below is a review of significant policy and marketplace trends facing oncology providers today: health care reform, molecular diagnostics and biosimilars and experimental payment models.

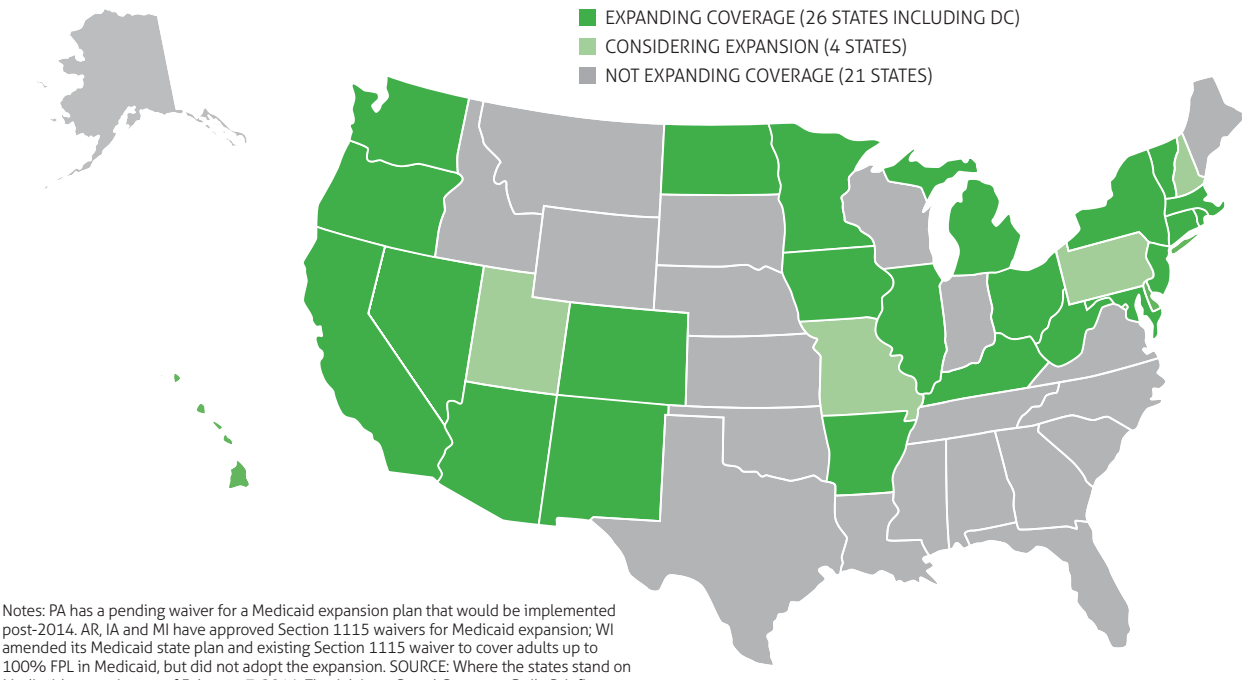
HEALTH CARE REFORM STATUS: 2013

Medicaid Expansion

As part of the ACA's effort to expand health insurance coverage, the federal government will fund an expansion in Medicaid eligibility up to 133 percent* of the federal poverty level (FPL) in every U.S. state beginning in January 2014. From 2014 to 2016, the federal government will pay for 100 percent of the difference between a state's current Medicaid eligibility level and the ACA minimum. Federal contributions to the expansion will drop to 95 percent in 2017 and remain at 90 percent after 2020. However, as a result of the Supreme Court ruling in June 2012 that upheld the ACA, it was also determined that the

*Given a 5 percent income disregard, for practical purposes, this is actually an expansion to 138 percent of the FPL.

Current Status of State Medicaid Expansion Decisions, as of February 7, 2014



Notes: PA has a pending waiver for a Medicaid expansion plan that would be implemented post-2014. AR, IA and MI have approved Section 1115 waivers for Medicaid expansion; WI amended its Medicaid state plan and existing Section 1115 waiver to cover adults up to 100% FPL in Medicaid, but did not adopt the expansion. SOURCE: Where the states stand on Medicaid expansion, as of February 7, 2014, The Advisory Board Company, Daily Briefing, http://www.advisory.com/daily-briefing/resources/primers/medicaidmap.

federal government could not withhold Medicaid funding for states that chose not to expand their Medicaid programs. This effectively allowed states to decide whether they wanted to accept the government funding.

The map on page 60 shows the state decisions regarding Medicaid expansion.

A subset of states, following the example set by Arkansas, are exploring an approach to Medicaid expansion likely to require a waiver from the Department of Health and Human Services (HHS) (Pennsylvania, Iowa and Michigan). Below are three models that illustrate the approaches states are experimenting with for Medicaid expansion.

Arkansas

Arkansas Governor Mike Beebe announced in February 2013 that the federal government would pay for Arkansas to expand health coverage to low-income residents through the state's insurance exchange, rather than its Medicaid program (the waiver was federally approved on September 27, 2013). Like the ACA Medicaid expansion, the plan will extend insurance coverage to all residents below 138 percent of the FPL. Although newly insured residents may face some copayments, the federal government has agreed to cover the entirety of their premiums for the first three years. As with the Medicaid expansion, the state will then begin increasingly covering a share of the costs, until it reaches 10 percent of the costs in 2020.

Pennsylvania

Instead of using federal money to expand Medicaid to uninsured residents, Pennsylvania plans to direct those dollars to the private market. A person who earns less than 138 percent of the poverty limit could, similar to a resident of Arkansas, use federal funds to purchase a health care plan through the health insurance exchange programs.

Pennsylvania currently has approximately 520,000 residents who stand to gain coverage under the system. Governor Tom Corbett has publicly stated that an expansion, as outlined in the Affordable Care Act, is simply too expensive for Pennsylvania, and that this private option would mean that no new enrollees would join the existing Medicaid program. The only exception would be those who are considered to be medically frail.

Michigan

Michigan's recently passed bill (HB 4714) would allow the state to use more than a billion dollars in federal funding next fiscal year to expand Medicaid access to individuals earning up to 138 percent of the poverty level, or around $15,000 for an individual, or $31,000 for the average family of four.

The legislation includes several unique revisions that were designed as a sort of "hand up" for disadvantaged residents, as opposed to a "handout," including copays and income-based premiums that could potentially be reduced through healthy lifestyle choices, or increased if an individual stays on Medicaid for more than four years. Michigan can still opt out of the expansion, according to the legislation, if state costs increase or if the federal government denies waivers for the proposed reforms.

The Michigan governor's office recently estimated that 320,000 Michiganders will be covered in the first year, 470,000 will be covered by 2021, and that Michigan's uninsured population will eventually drop by about 46 percent following implementation. Legislators also hope that the measure will help reduce state spending and improve the economy by curtailing expensive emergency room visits in favor of increased primary care visits.

The legislature delayed the effective date of the bill until the end of the session — January 1, 2014 — which means Michigan will have to delay implementation, likely until April 1, 2014, despite the availability of federal funds beginning January 1. An additional hurdle to implementation is that Michigan must submit a 1115 waiver request to the Centers for Medicare & Medicaid Services (CMS), and CMS must approve the waiver before coverage can begin.

Exchange Implementation

On October 1, 2013, the state health care exchanges (also known as "marketplaces") — often considered the cornerstone of the ACA — began their open enrollment period. Existing online, the exchanges provide a central site for individuals and small groups to compare and purchase health insurance plans. As of the first day of open enrollment, 27 states have elected or defaulted to a federally run exchange; six states will have a federal-state partnership exchange in which the Department of Health and Human Services will have significant operational and legal responsibility over the state activity; 15 states and the District of Columbia will run their own exchanges in 2014; and Utah and New Mexico will run their own small business exchange, but will default to a federally funded individual exchange.

Coverage Issues — Benchmarks and Essential Health Benefits

Essential health benefits (EHBs), which are required in all qualified health plans (QHPs) sold in the exchanges, define the coverage available to the newly insured population and could develop new definitions and standards for medical necessity.

Under the ACA, the Secretary of the Department of Health and Human Services was tasked with developing essential health benefits, which she decided should be determined by the states by drawing on benefits packages of existing plans plus specific substitutions and additions that individual and small group market plans typically omit (e.g., maternity, rehabilitative and habilitative benefits). This state-by-state approach to essential health benefits has generally been well received by states, health plans and the business community because it has minimized the need for insurers to make changes, and allows small employers to continue coverage that is similar to what they already offer. However, patient advocates are concerned that the benefit packages may not be generous or cost sharing

may be too high. Below is a figure that shows how oncolytics are or will be covered in each of the government-funded programs.

Medicare (Part B and Part D) and Medicaid provide the best access and most protections for oncology drugs. Medicare Part D provisions include six protected classes for which all or substantially all drugs must be covered; self-administered oncolytics is one of the six protected classes. For Part B, Medicare Administrative Contractors may create local coverage determinations to restrict the coverage of the drug for labeled and compendia indications, but cannot place further restrictions on coverage. The federal Medicare/Medicaid compendia standard requires coverage of all off-label indications for which there is evidence supporting efficacy. For Medicaid, all drugs are covered as long as the manufacturer provides the statutory rebates under Section 1927 of the Social Security Act (SSA).

Coverage protections for oncolytics in the exchange are less than what are currently covered under the Medicare and Medicaid programs. Additionally, it is anticipated that the out-of-pocket costs will be higher compared to other private insurance (commercial, employer-sponsored insurance) that oncologists may be familiar with; however, exchange patients are protected by maximum out-of-pocket costs of $6,350 in 2014, although how plans will implement this maximum differs (combined or separate medical and pharmacy benefits).

Medicaid expansion plan benefits are governed by state-defined alternative benefit plan (ABP) benchmarks and exchange plans/qualified health plans are governed by state-defined EHB benchmarks. ABP and EHB benchmarks define prescription drug benefits in the same way — the Medicaid expansion plan and the exchange plans must cover the greater of:

- One drug per USP class or category, or
- The same number of drugs per USP category and class as the ABP or EHB benchmark plan covered, respectively.

HHS requires all plans to make all clinically appropriate drugs available to beneficiaries. However, it is likely that cost sharing would be higher for a nonpreferred drug, even if it was the only clinically appropriate drug available for the beneficiary. As noted, HHS requires all plans to make clinically appropriate drugs available to beneficiaries and these provisions apply to physician-administered drugs; however, unlike the pharmacy/formulary benefits, there are no specific protections for physician-administered drugs.

Compared to Medicare and Medicaid, access to oncology drugs and biologics will be more limited and come at a higher expense to the patient. The chart on page 63 documents the number of oral/self-administered oncology drugs based on the state-selected EHB benchmark plans.

Health Reform, Oral Parity and Anticancer Compendia Implications

Oral/IV parity and off-label coverage (compendia coverage) will be applied to the exchanges only when these policies are state law. There are no federal protections for oral parity or off-label drug coverage like there are for Medicare and Medicaid programs. Table 3 summarizes the states with laws governing these areas.

NEW FRONTIERS: MOLECULAR DIAGNOSTICS AND BIOSIMILARS

Evolution Payor Policies in Molecular Diagnostics

Given the continued advancements in molecular diagnostics and the explosion of new targeted therapeutics, policy making related to molecular diagnostics continues to evolve. Use of genetic/genomic testing has rapidly increased in recent years, and consequently payors and providers have begun to reexamine the coding, coverage and reimbursement of genetic testing, as well as the overall management of molecular diagnostics and the related companion therapeutics.

LEAST PROTECTIONS → MOST PROTECTIONS

MEDICAID EXPANSION	ESSENTIAL HEALTH BENEFITS	MEDICAID	MEDICARE
• Alternative Medicaid benchmark • Medicaid rebates and Medicaid-covered outpatient drug standards • Proposed cost sharing increases from historic nominal cost sharing	• State benchmark defines benefits (applies to plans sold inside and outside of the exchange) • EHB formulary standards (greater than one per class/category or benchmark) • Formulary reviewed by exchange • Cost sharing limits ($6,250/index for 2013)	• Covered outpatient drug rebates, Sec. 1927 of SSA • Preferred drug lists — nonpreferred drug lists may see higher cost sharing • Specialty pharmacy	• Six protected classes • Oncolytics included as protected class • Infusion and IV drugs paid at ASP + 6% • Local policies cannot restrict coverage of labeled and compendia-supported indications

TABLE 1. Benchmark Coverage of Antineoplastics

CLASS	EXAMPLE DRUGS	RANGE	AVERAGE	MOST COMMON
Alkylating agents	altremine, chlorambucil, melphalan, lomustine cyclophosphamide	0–8	6.2	8
Antiangiogenic agents	lenalidomide, thalidomide	0–2	1.8	2
Antiestrogens/modifiers	estramustine, tamoxifen	0–3	2.6	3
Antimetabolites	mercaptopurine	0–2	1.8	2
Antineoplastics	not listed	0–52	29.5	52
Antineoplastics, other	fludarabine, leucovorin mitoxantrone	0–6	4.0	6
Aromatase inhibitors, third generation	anastrozole, letrozole	0–3	2.9	3
Enzyme inhibitors	etoposide, topotecan	0–3	2.0	3
Molecular target inhibitors	erlotinib, gefitinib, everolimus, dasatinib, imatinib, nilotinib, lapatinib, pazopanib, sorafenib, sunitinib	0–11	9.5	11
Monoclonal antibodies	rituximab	0–3	1.5	3
Retinoids	alitretinoin	0–3	2.5	3

Source: Aggregated from supplemental information regarding state EHB benchmark selection, provided from the Center for Consumer Information and Insurance Oversight (CCIIO) regarding the EHB proposed rule.[1]

Over the last three years, the American Medical Association (AMA) created a new section of Current Procedural Terminology (CPT) codes to better identify molecular diagnostic tests. In 2013, the AMA implemented the new specific CPT code section, but reimbursement for the new codes continues to be in flux. CMS decided to "gapfill" the new codes, whereby rates are set by the individual Medicare Administrative Contractors (MACs) for 2013 and a national rate is set for 2014. This process has caused some concerns for stakeholders and possibly access issues for beneficiaries, as the rates have been set lower than believed appropriate and in some cases, reflect a significant decrease from previous Medicare reimbursement.

CMS has finalized both the physician fee schedule and clinical laboratory fee schedule for 2014. The cuts anticipated in the PFS were not finalized; CMS made only minor adjustments. For the new molecular pathology codes on the CLFS, fees were set for most of the tier 1 codes and the tier 2 codes will be contractor priced. Additionally, tests with algorithms (Multi-Analyte Assays with Algorithmic Analyses – MAAA codes) will be contractor priced. If CMS moves forward with the cuts it initially proposed to the PFS, those cuts could create negative repercussions to patient access, particularly within oncology care.

MARKETPLACE: EXPERIMENTING WITH PAYMENT SYSTEMS

Payment models to manage costs such as gain sharing, risk sharing and global capitation have been in place for a number of years. In the first round of Center for Medicare & Medicaid Innovation (CMMI) grants, CMS funded a number of oncology-related products, most notably a test model for the "oncology medical home" coined and created by Dr. John Sprandio. This pilot comprises a handful of the largest oncology practices in the country, united in an effort to reduce costs and improve care; it includes practices in New Mexico, Georgia and Tennessee. CMMI accepted several oncology-related applications for the second round of CMMI grants, including some that could include provisions for bundling of certain oncology products. As of this writing, CMMI has not announced the results for the round two grants.

Accountable Care Organizations (ACOs)

ACOs are groups of doctors, hospitals and other health care providers who come together voluntarily to give coordinated high-quality care to their Medicare patients. The goal of coordinated care is to ensure that patients, especially the chronically ill, get the right care at the right time, while avoiding unnecessary duplication of services and preventing medical errors. A study completed by Ron Barkley, president of the Cancer Center Business Development Group, indicates that ACOs have proliferated in Medicare but to date none significantly focus on oncology and none are oncology specialty ACOs. In the commercial setting, ACOs do have a presence in oncology, but more likely have risk-sharing arrangements and use a shared savings approach with limited use of bundled services.

Perhaps the best examples of an ACO succeeding in the oncology space are in Florida. In May 2012, Blue Cross and Blue Shield of Florida announced an agreement with Baptist Health South Florida and Advanced Medical Specialties, which provides oncology services in Miami, to form an oncology ACO. Following that, in December 2012, BCBS of Florida unveiled an oncology ACO with Moffitt Cancer Center in Tampa. The collaboration, started in early 2013, has reported modest but positive shared savings for both BCBS of Florida and Moffitt. They are continuing with the arrangement with some tweaks to the contracting to fine tune the financial incentives and institute

TABLE 2. Round One CMMI Health Innovation Award Recipients – Oncology Focus

CMMI ROUND 1 AWARDEES IN ONCOLOGY	MODEL DESCRIPTION
Innovative Oncology Business Solutions, Inc.	Innovative Oncology Business Solutions, Inc., representing seven community oncology practices across the United States, received an award to test a medical home model of care delivery for newly diagnosed or relapsed Medicare and Medicaid beneficiaries and commercially insured patients with breast, lung or colorectal cancer.
The Trustees of the University of Pennsylvania	The Trustees of the University of Pennsylvania received an award to test a comprehensive set of home care services for Medicare and/or Medicaid beneficiaries with advanced cancer who are receiving skilled home care and have substantial palliative care needs, but are not yet eligible for hospice care.
University of Alabama at Birmingham	The University of Alabama at Birmingham (UAB) and the UAB Comprehensive Cancer Center received an award extending a regional network of lay health workers to expand comprehensive cancer care support services through a five-state region.
The Rector and Visitors of the University of Virginia	The Rector and Visitors of the University of Virginia received an award to improve care for patients with advanced cancer. The program will integrate data from multiple sources to help providers proactively identify opportunities for evidence-based care interventions that have been shown to improve quality of care, increase survival and reduce costs.
University of Iowa	The University of Iowa, in partnership with the 11 hospitals comprising its Critical Access Hospital Network, received an award to improve care coordination and communication with practitioners in 10 rural Iowa counties.

additional quality metrics. Ultimately, they are hoping to incorporate a value-based reimbursement system.

Other Payment Systems

Given the cost of cancer care (roughly 5 percent of U.S. health care spending), several commercial payors continue to experiment with shared savings or other risk-convening relationships. For instance, some have implemented care bundles in specific tumor types, such as adjuvant colon, lung or breast. Other programs are focused on guideline adherence and adherence to pathways unique to the practice, in an effort to further regiment care and thereby optimize costs. One of the best and most successful examples is the Aetna/US Oncology/Innovent Oncology program, which is in both Aetna's commercial and Medicare Advantage plans. The program helps doctors more effectively use clinically proven care guidelines and provides members with nurse support throughout treatment, including outreach between treatment visits, when complications are most likely to occur. The combination helps cancer patients receive effective, safe treatment with reduced side effects and lower overall costs. According to a press release issued by Aetna, the US Oncology Network and Texas Oncology, the demonstration has delivered impressive numbers and shared savings along with same or better health outcomes and a significant reduction in ER visits and hospital admissions, ultimately resulting in an impressive 12 percent cost savings among patients with lung, breast and colorectal cancers.

Another often discussed program is United Healthcare's multi-practice pilot project, first launched across five practices and then expanded to include 15 sites across the United States. The United pilot program bundles payments for an episode of care, freezes the margins formerly earned on oncology drugs and collects patient outcome data to help physicians drive the best clinical decision making. The goal is to debunk the idea that drug price drives therapeutic choice in oncology.

Academic centers like MD Anderson Cancer Center are studying oncology bundles in conjunction with academic centers like Harvard Business School to develop a responsible model for care delivery. The same is occurring at Regional Cancer Care Associates in New York and New Jersey in coordination with Horizon BCBS and again in Florida with BCBS Florida and the aforementioned ACOs. Continued experimentation in oncology payment approaches that align incentives across payors and providers, and include guidelines and other consistent therapeutic approaches, are expected to continue in 2014, and we could see additional Medicare experimentation through the CMMI round two grants awarded in 2014.

TABLE 3. Oncology-Related State-Specific Benefits – Off-Label Drug Coverage

STATE	OFF-LABEL USE		ORAL ANTICANCER MEDICATION (ORAL/IV PARITY)	
	STATE-REQUIRED BENEFIT	APPLICABLE MARKETS	STATE-REQUIRED BENEFIT	APPLICABLE MARKETS
Alabama	Insurance coverage for drugs to treat life-threatening illnesses	Individual, small group, large group	N/A	N/A
Arizona	Off-label prescription drugs for cancer	Individual and group disability, HCSO/HMO, HMDO	N/A	N/A
Arkansas	Off-label drug use	Individual, small group, large group (including HMOs)	N/A	N/A
Colorado	Off-label use of cancer drugs	Individual, group	Oral anticancer medication	Individual, group
Connecticut	Off-label use of cancer drugs	Individual, group	N/A	N/A
District of Columbia	N/A	N/A	Chemotherapy pill coverage	Individual, small group, large group, HMO
Florida	Coverage for use of drugs in treatment of cancer	Individual, small group, large group	N/A	N/A
Georgia	Off-label drug use	Individual, small group, large group	N/A	N/A
Illinois	N/A	N/A	Cancer drug parity	Individual and group
Indiana	Prescription drugs: Off-label use of certain drugs if Rx coverage provided	Individual, small group and employer association, large group and employer association, HMOs	N/A	N/A
Iowa	N/A	N/A	Oral cancer medication	Individual, small group, large group
Kansas	Off-label prescription drugs	Individual, small group, large group	Off-label prescription drugs	Individual, small group, large group
Maine	Off-label use of prescription drugs for cancer, HIV or AIDS	All contracts; the mandate applies to certificates issued in Maine through group policies that are issued outside of Maine	N/A	N/A
Massachusetts	Off-label uses of prescription drugs to treat cancer; off-label uses of prescription drugs to treat HIV/AIDS	Individual, small group, large group	N/A	N/A
Minnesota	Coverage for off-label drugs to treat cancer in certain circumstances	Individual, group, HMO	N/A	N/A
Mississippi	Coverage of drugs not approved by FDA; drugs used in treatment of cancer	Individual, group or blanket policy	N/A	N/A
Nebraska	Off-label drugs for cancer and HIV/AIDS	Individual, small group, large group	N/A	N/A
Nevada	Off-label drugs for cancer and HIV/AIDS	Individual, small group, large group	N/A	N/A
New Hampshire	Off-label prescription drugs	All fully insured insurance policies and certificates that include coverage for prescription drugs	N/A	N/A
New Jersey	Off-label drugs	Individual, small group, large group	Oral anticancer medications	Individual, small group, large group

TABLE 3. Oncology-Related State-Specific Benefits – Off-Label Drug Coverage (continued)

STATE	OFF-LABEL USE		ORAL ANTICANCER MEDICATION (ORAL/IV PARITY)	
	STATE-REQUIRED BENEFIT	APPLICABLE MARKETS	STATE-REQUIRED BENEFIT	APPLICABLE MARKETS
New Mexico	N/A	N/A	Coverage for orally administered anticancer medications; limits on patient costs	All
North Carolina	Coverage for certain off-label drug use for the treatment of cancer	Individual, small group, large group	N/A	N/A
North Dakota	Coverage for off-label uses of drugs	Individual, group plans (including HMOs)	N/A	N/A
Ohio	Off-label prescription drugs	Individual, group	N/A	N/A
Oregon	Prescription drugs — prohibits excluding a particular drug coverage solely because it is not FDA-approved for a medical condition	Individual and group	Oral anticancer medications	Individual and group plans, including HMOs
Rhode Island	Off-label prescription cancer drugs	Individual or group health insurance contracts; this section shall not apply to insurance coverage providing benefits for: (1) hospital confinement indemnity; (2) disability income; (3) accident only; (4) long-term care; (5) Medicare supplement; (6) limited benefit health; (7) specified disease indemnity; (8) sickness or bodily injury or death by accident or both; and (9) other limited benefit policies	N/A	N/A
South Carolina	Off-label drug use	All policies that provide coverage for prescription drugs	N/A	N/A
South Dakota	Off-label drug use	Individual, small group, large group	N/A	N/A
Tennessee	Coverage for off-label use of approved drugs	All insurers	N/A	N/A
Texas	Off-label drugs	Individual, large group plans (including HMOs)	Oral anticancer medications	Individual, small group, large group (including HMOs for all three)
Vermont	Coverage for off-label use	A health benefit plan offered, administered or issued by a health insurer doing business in Vermont	Orally administered anticancer medication	All health insurance plans, nonprofit hospital and medical services corporations, and HMOs; the term does not apply to coverage for specified disease or other limited benefit coverage

Source: Aggregated from supplemental information regarding state-required mandates, provided from CCIIO regarding the EHB proposed rule.[2]

[1]Center for Consumer Information and Insurance Oversight. Additional Information on Proposed State Essential Health Benefits Benchmark Plans (Summary of proposed EHB benefits, limits, and prescription drug coverage per state). Accessed February 6, 2014: http://cciio.cms.gov/resources/data/ehb.html.

[2]Center for Consumer Information and Insurance Oversight. Additional Information on Proposed State Essential Health Benefits Benchmark Plans (State required benefits). Accessed February 6, 2014. http://cciio.cms.gov/resources/data/ehb.html.

Glossary

ABP . . . . . alternative benefit plan
ACA . . . . . Affordable Care Act
ACO . . . . . accountable care organization
aHUS . . . . . atypical hemolytic uremic syndrome
ALK . . . . . anaplastic lymphoma kinase
AMA . . . . . American Medical Association
AMD . . . . . age-related macular degeneration
AML . . . . . acute myelogenous leukemia
APA . . . . . adaptive phased array
ASP . . . . . average sales price
AWP . . . . . average wholesale price
BCA . . . . . breast cancer
BTK . . . . . Bruton's tyrosine kinase
BRCA . . . . . breast cancer susceptibility gene
BRM . . . . . biologic response modifier
CA . . . . . cancer
CCIIO . . . . . Center for Consumer Information and Insurance Oversight
CINV . . . . . chemotherapy-induced nausea and vomiting
CMMI . . . . . Center for Medicare & Medicaid Innovation
CMS . . . . . Centers for Medicare & Medicaid Services
COA . . . . . Community Oncology Alliance
CPT . . . . . Current Procedural Terminology
CRC . . . . . colorectal cancer
CRPC . . . . . castrate-resistant prostate cancer
CSF . . . . . colony-stimulating factor
CTCL . . . . . cutaneous T-cell lymphoma
CTLA4 . . . . . cytotoxic T-lymphocyte antigen 4
DLBCL . . . . . diffuse large B-cell lymphoma
EGFR . . . . . epidermal growth factor receptor
EHB . . . . . essential health benefit
ESA . . . . . erythropoiesis-stimulating agent
ESRD . . . . . end-stage renal disease
FDA . . . . . U.S. Food and Drug Administration
FGFR . . . . . fibroblast growth factor receptor
f-NHL . . . . . follicular non-Hodgkin's lymphoma
FPL . . . . . Federal Poverty Level
GBM . . . . . glioblastoma multiforme
G-CSF . . . . . granulocyte colony-stimulating agent or colony-stimulating factor
GM-CSF . . . granulocyte-macrophage colony-stimulating factor
GST . . . . . glutathione S-transferase
HCPCS . . . . . Healthcare Common Procedure Coding System
HCSO . . . . . health care services organization
HDAC . . . . . histone deacetylase
HEC . . . . . highly emetogenic chemotherapy
HEDIS . . . . Healthcare Effectiveness Data and Information Set
HER . . . . . human EGF receptor
HHS . . . . . Department of Health and Human Services
HMDO . . . . . hospital, medical, dental and optometric service corporation
HMO . . . . . health maintenance organization
HRPC . . . . . hormone refractory prostate cancer
HRSA . . . . . Health Resources and Services Administration
ICD . . . . . International Classification of Diseases
IL-13 . . . . . interleukin-13
IV . . . . . intravenous
IVIG . . . . . intravenous immune globulin
KRAS . . . . . Kirsten RNA associated rat sarcoma 2 virus gene
LEC . . . . . low emetogenic chemotherapy
LOB . . . . . lines of business
MAC . . . . . Medicare Administrative Contractors
MCL . . . . . mantle cell lymphoma
MEC . . . . . moderate emetogenic chemotherapy
MMA . . . . . Medicare Modernization Act
NCCN . . . . . National Comprehensive Cancer Network
NHL . . . . . non-Hodgkin's lymphoma
NSCLC . . . . . non-small cell lung cancer
PA . . . . . prior authorization
PARP . . . . . poly (ADP-ribose) polymerase
PBM . . . . . pharmacy benefit manager
PDGFR . . . . . platelet-derived growth factor receptor
PNH . . . . . paroxysmal nocturnal hemoglobinuria
PPO . . . . . preferred provider organization
PSA . . . . . prostate-specific antigen
PTCL . . . . . peripheral T-cell lymphoma
QHP . . . . . qualified health plans
RANKL . . . . receptor activator of nuclear factor kappa-B ligand
SERM . . . . . selective estrogen receptor modulator
SGR . . . . . sustainable growth rate
SPP . . . . . specialty pharmacy provider
SSA . . . . . Social Security Act
TTF . . . . . tumor treating fluids
USP . . . . . U.S. Pharmacopeial Convention
VEGF . . . . . vascular endothelial growth factor
VFS . . . . . variable fee schedule
WAC . . . . . wholesale acquisition price

Magellan Rx Management
6870 Shadowridge Dr., Suite 111
Orlando, FL 32812

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