MEDICAL PHARMACY & ONCOLOGY TREND REPORT™

2012 THIRD EDITION

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A Benchmark for Medical Pharmacy

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

It is our pleasure to present you with Magellan Pharmacy Solution's 2012 Medical Pharmacy & Oncology Trend Report™. This is the third edition of this report, and it has been enhanced this year by showing additional data regarding site of service, which is a significant threat to the cost of medications paid under the medical benefit. As we have discussed in the past, various reports exist to describe specialty and oral chemotherapy products paid under the pharmacy benefit; however, no other source exists for direct measures of injectables paid under a payor's medical benefit, where top drugs such as Neulasta, Remicade, Avastin, Rituxan, Procrit and Aranesp are almost entirely paid. We are excited to continue to be your sole source for these important benchmarking and trending statistics.

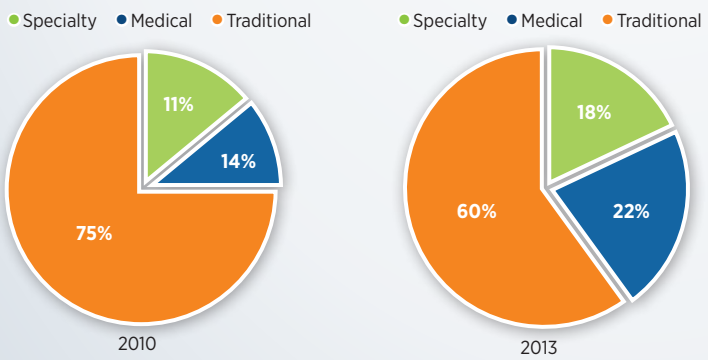
In recent years, we've seen the trend for traditional oral pharmacy products with essentially no trend (and, in fact, negative trends in well managed plans) when compared with specialty products, where trends are approximately 20 percent for self-administered injectables and double digits for provider-administered products. This finding will continue to prevail, in part due to the oncology pipeline, paired with traditional oral medications losing patents. According to a recent report, by the end of 2013 specialty products will be about 40 percent of total drug spend, and medical benefit injectables will comprise nearly a quarter of total spend, as shown in the illustration below.

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 50 top U.S. commercial health plans representing 157.2 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.

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

Sincerely,

Kjel A. Johnson, Pharm.D.
Senior Vice President, Strategy & Business Development, Magellan Pharmacy Solutions



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2012 Survey Methodology and Demographics

The methodology for this third edition of Magellan Pharmacy Solutions' Medical Pharmacy & Oncology 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 Pharmacy Solutions 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 (LOB) (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 2011 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 Pharmacy Solutions' parent company.

The data collection took place over a three-week period during June and July 2012. 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 to slightly more or less than 100 percent due to rounding effects.

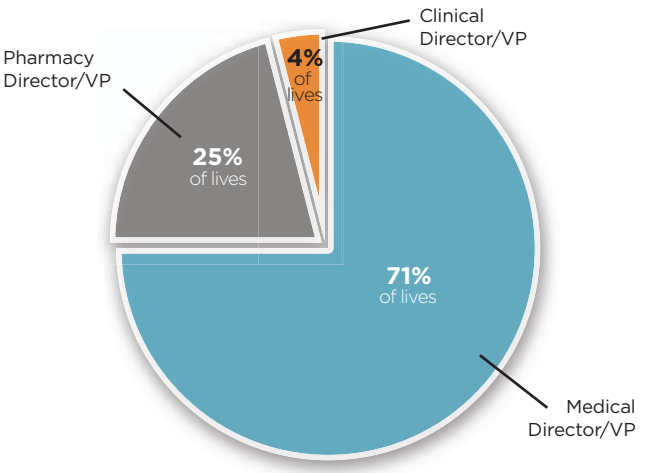
A total of 50 individual survey responses were received. As noted in the table below, these 50 health plans manage 157.2 million lives, a slight increase over the 153.2 million covered lives reported in 2011.

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 2012 respondents is compared with the respondents in

SURVEY RESPONDENT COMPOSITION

	COUNT	LIVES	% OF LIVES	% OF PLANS
Less than 500,000	16	3,816,000	2%	32%
500,000 to 999,999	13	8,393,000	5%	26%
1,000,000 to 4,999,999	13	30,620,000	20%	26%
5,000,000 or more	8	114,400,000	73%	16%
TOTAL	**50**	**157,229,000**	**100%**	**100%**

REPRESENTATION OF SURVEY RESPONDENTS



2011. The demographic composition of this year's respondents is not as consistent as the composition of the base in the prior two years.

Current survey respondents tended to be very experienced, with an average of 23 years in the field and eight years in their current position. Compared to last year, there was an increase of 20 percent in the lives represented by medical director respondents (71 percent) versus those of pharmacy directors/clinical pharmacists (29 percent). Internal medicine and emergency medicine are the leading specialties reported by these health plan medical directors.

Of the total lives covered by the payors completing the survey, 65 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 22 percent of the respondents, yet they cover nearly three-fourths (73 percent) of the total lives represented in this survey. Conversely, regional plans have a larger percentage of payor respondents (78 percent), but reflect only 27 percent of the total covered lives.

The map at right illustrates that geographically nearly half of the covered lives of these regional payor respondents are located in the west.

HEALTH PLAN CLAIMS DATA ANALYSES

Magellan Pharmacy Solutions analyzed health plan paid claims data that included paid medical claims for full year 2010 and 2011. These claims represent a large proprietary data set from a number of regional and national health plans. The data set is complete in that we are able to look at the paid claims across all LOB, sites of service (SOS) and medical benefits. For example, the claims set is inclusive of:

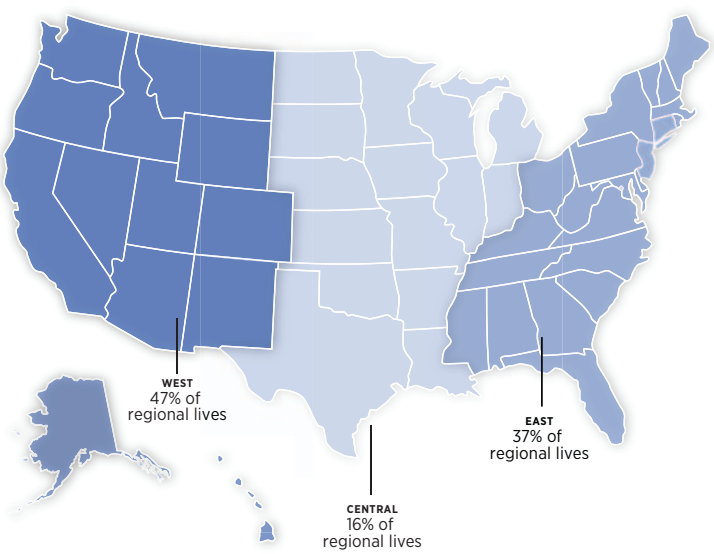
- Commercial, Medicare and managed Medicaid products
- Multiple sites of service:
  - Medical claims — physician office, outpatient hospital, home infusion, specialty pharmacy

Where appropriate, the current 2011 paid claims data are illustrated along with the key year-over-year trend comparisons within this data set.

LIMITATIONS OF THE DATA/DISCUSSION

As with any data set, there are limitations. Because the survey was conducted using self-selected survey responses, it does not have the characteristics of a randomly assigned sample. The responses were stratified based upon plan size, the respondents' medical versus pharmacy responsibilities and plan geography. The sample is reflective of general market dynamics, though care should be taken regarding its generalizability to the entire payor universe. Where appropriate, statistically significant differences in 2012 over 2011 have been noted. The claims analyses presented are subject to the same limitations as all claims data — specifically the limitations of coding accuracy and other factors. A strength of the claims data used in this report is that it does not rely on projections but represents allowed claims actually paid by health plans. We have included 24 months of claims data (2010 and 2011) where available to strengthen trending ability.

REGIONAL PLANS — GEOGRAPHIC DISTRIBUTION OF LIVES



Report Summary and Conclusions

Magellan Pharmacy Solutions' 2012 Medical Pharmacy & Oncology 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.

Key findings of this report include:

- A significant increase in trend was found when compared to the previous trend. This was due to several factors, most notably the lack of any top 25 drug losing patent protection. Increases in price and utilization are also drivers of this increased trend. The year-over-year cost increase per 1 million lives was 16 percent for the top 25 therapies.
- A significant increase in formulary management for metastatic breast cancer was measured; this is likely due to the change in U.S. Food and Drug Administration (FDA) labeling of Avastin and the approvals of some of the newer high-cost agents like Perjeta and Halavan. The significant increase in formulary management for prostate cancer drugs is a result of the approval of drugs such as Jevtana and Provenge, whose treatment cost is in excess of $90,000.
- Fewer plans are receiving rebates for medical benefit drugs today than in the past. This is thought to be a result of the restructuring of key rebate opportunities for biological response modifiers paid under this benefit.
- Nearly a doubling of lives under a variable fee schedule reimbursement scheme was seen compared to the previous year; such a strategy employs reference pricing rather than fixed increases or discounts to average sales price (ASP) or average wholesale price (AWP). For plans using ASP-based reimbursement, an increase from ASP + 11 to ASP + 18 percent was seen. We suspect this is in an effort to curb referrals of patients to higher-cost facility administration sites, and this is supported by the large number of changes to provider reimbursement that occurred during the measurement period.
- For newly approved drugs that have not yet been assigned a J code, about half of lives subject the drug to ASP pricing, which is wholesale acquisition price (WAC)-based; a quarter *hold*.
- Coinsurances increased from 20 to 26 percent and average copays increased from $46 to $75, demonstrating the plans' interests in increasing member cost contributions.
- Palliative care programs are increasing and are expected to continue to do so.
- A third of payors reported that network provider practices were being purchased by health systems in their service areas.
- Utilization management for medical injectables increased year over year from about 70 percent of covered lives to nearly all covered lives as payors attempt to better manage the quality and cost of oncology and rheumatology care. Most commonly, this was accomplished by requiring authorizations for use and by using criteria based upon FDALabel, compendia listing and appropriate use of concomitant medications. Criteria were generally developed internally and defended with external reviews.
- About half of payors use FDALabel to edit medical injectable claims, and nearly 40 percent use no edits whatsoever.
- Changes in the administration site of service were identified as a key threat, but this problem was largely unaddressed by payors last year.
- The top five diagnoses were responsible for a quarter of the total spend; orthopedic diagnoses were over half the top 10 diagnosis codes.
- As in the past, just over half of all medical benefit drug costs were related to the treatment of cancer.
- An eightfold increase in the use of unclassified ("dump") billing codes was found last year, which is likely the result of many new drug approvals.

We believe you will 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.icorehealthcare.com/trends.**

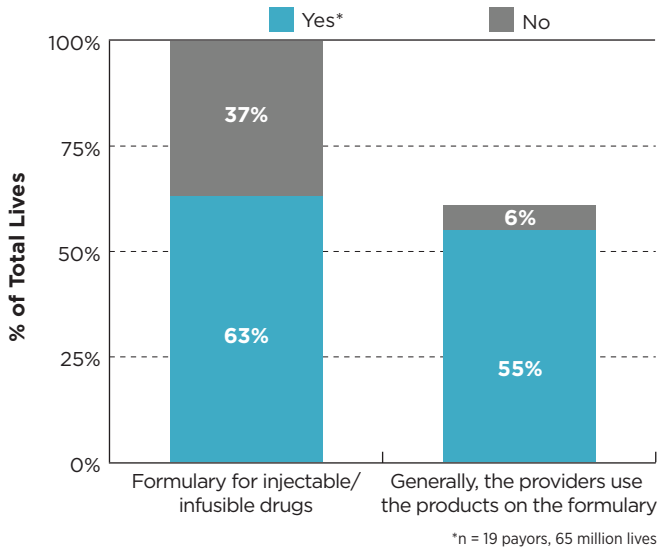
PAYOR SURVEY DATA

Medical Benefit Drug Formulary

In this year's study of commercial payors, health plans covering about two-thirds of lives (63 percent) operate with established medical benefit injectable drug formulary for at least some therapeutic classes, which is not statistically different from the 75 and 65 percent of covered lives reported by payors in 2010 and 2011, respectively. Among payors reporting formularies (n = 19, 65 million lives), the provider network generally complied with the plans' formulary, which is consistent with 2010 and 2011. The likelihood of having a formulary was the same for small and large payors. *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 95 million members most likely to be subjected to medical formulary requirements, most were for all products listed. Further, we found that formulary management increased when compared to 2011 for nearly 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 2011. *See Figure 3, Therapeutic Classes with a Medical Formulary Currently in Place.*

FIG. 1 FORMULARIES IN PLACE OVERALL



*n = 19 payors, 65 million lives

FIG. 2 FORMULARIES IN PLACE BY PLAN SIZE

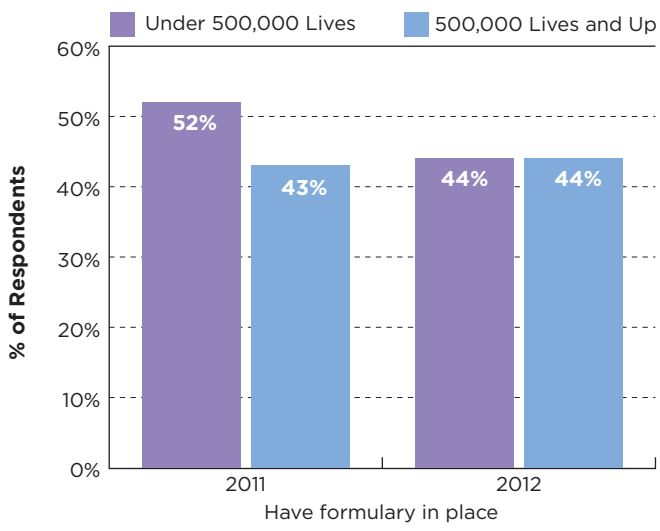
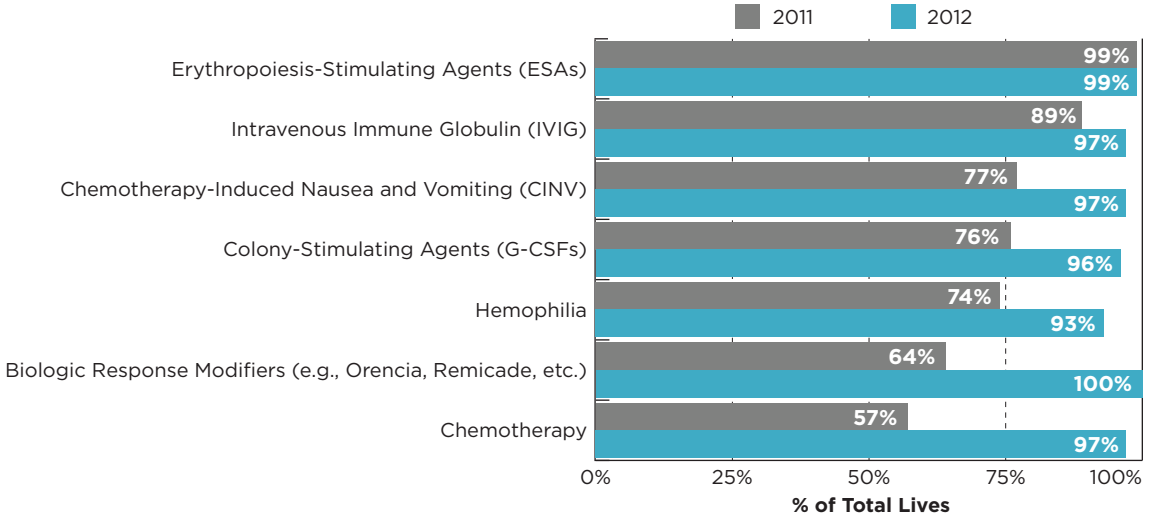


FIG. 3 THERAPEUTIC CLASSES WITH A MEDICAL FORMULARY CURRENTLY IN PLACE



n = 28 payors, 100 million lives (2011)
n = 21 payors, 95 million lives (2012)

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. The increase in the portion of lives under formulary for metastatic breast cancer is likely due to the FDA change in Avastin label, while the increase in the prostate cancer is likely due to the approval of Provenge, a costly therapy. *See Figure 4, Common Cancer Types Where Payors Have at Least Some Medical Drug Formulary in Place.*

FIG. 4 COMMON CANCER TYPES UNDER FORMULARY

CANCER TYPE	2010 % OF LIVES	2011 % OF LIVES	2012 % OF LIVES	% CHANGE FROM 2011
Non-small cell lung cancer	100%	100%	44%	-56%
Metastatic breast cancer	63%	49%	98%	100%
Prostate cancer	63%	49%	97%	98%
Non-Hodgkin's lymphoma	63%	46%	44%	-4%
Multiple myeloma	63%	46%	48%	4%
Renal-cell carcinoma	63%	46%	44%	-4%
Leukemia	63%	46%	45%	-2%

n = 12 payors, 94 million lives (2010)
n = 12 payors, 57 million lives (2011)
n = 13 payors, 58 million lives (2012)

Carrying forward the methodology used in Magellan Pharmacy Solutions' 2011 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 2012, plans covering 51 percent of the lives note receiving rebates on medical injectable products. This is similar to 2010 (56 percent) but down from 2011 (76 percent). This year, proportionally more smaller payors (fewer than 500,000 lives) have established a rebate contract for at least one medical injectable product, which is an increase from 2011 (57 percent versus 48 percent). *See Figure 5, Rebates Received from Drug Manufacturers That Are Mainly Paid on the Medical Benefit Overall, and Figure 6, Rebates Received from Drug Manufacturers That Are Mainly Paid on the Medical Benefit by Size of Health Plan.*

FIG. 5 REBATES RECEIVED OVERALL

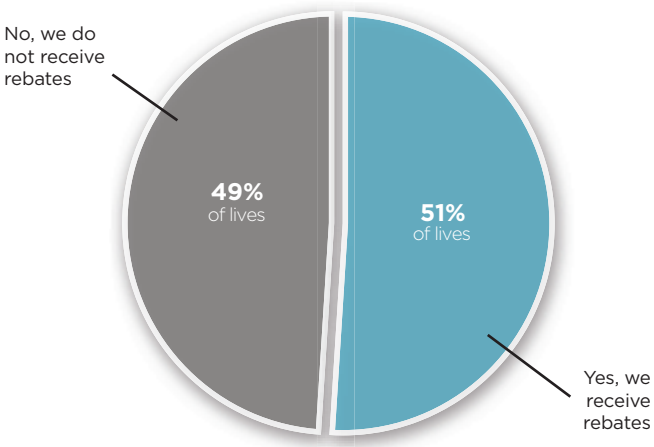
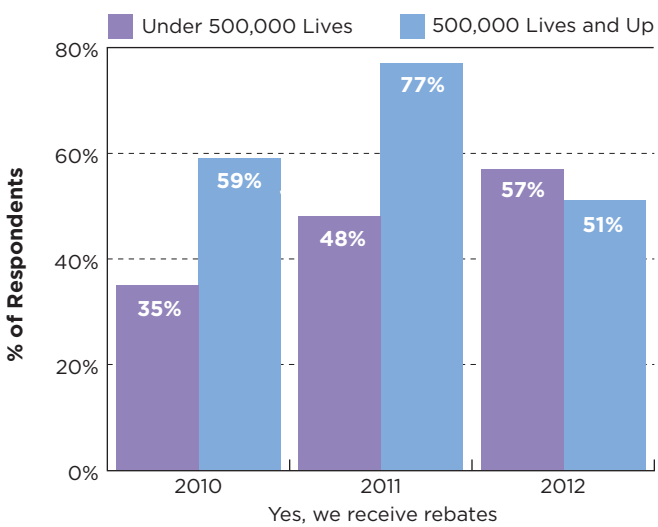
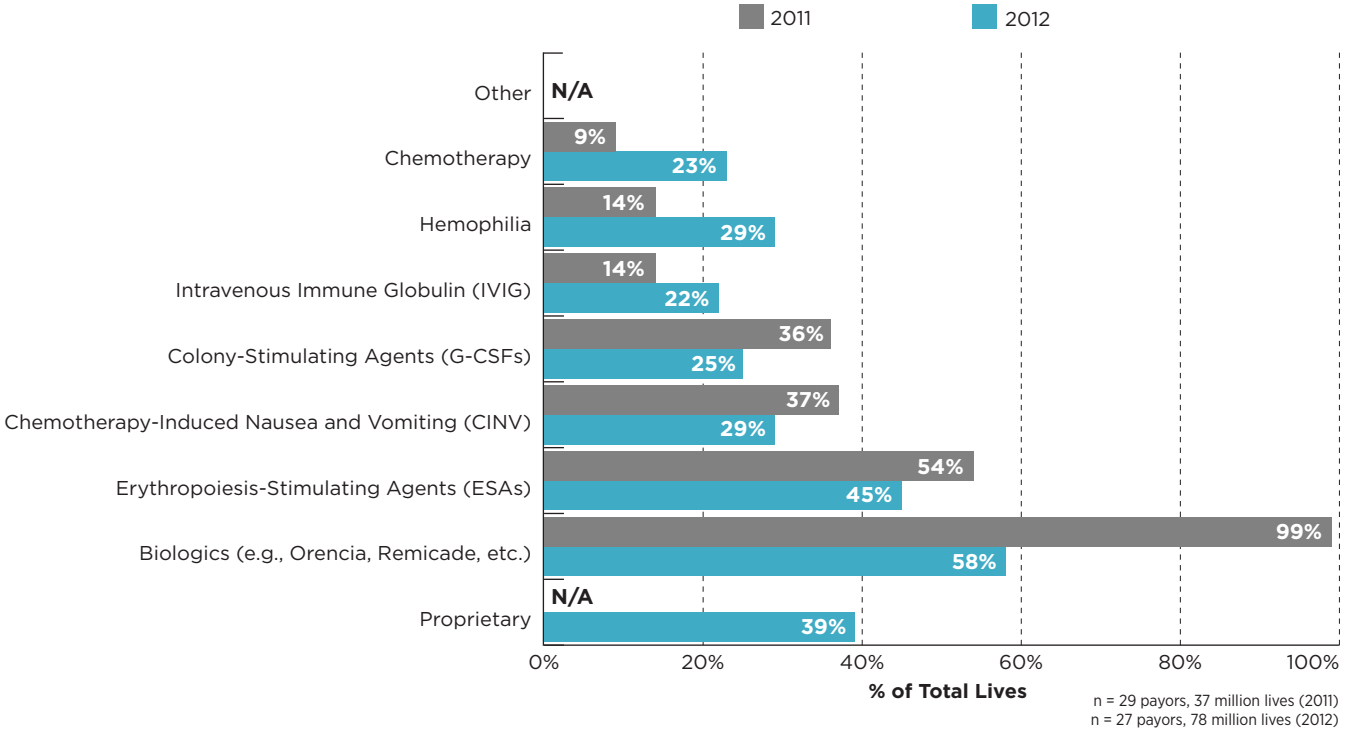


FIG. 6 REBATES RECEIVED BY PLAN SIZE



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

FIG. 7 THERAPEUTIC CLASSES WITH REBATES

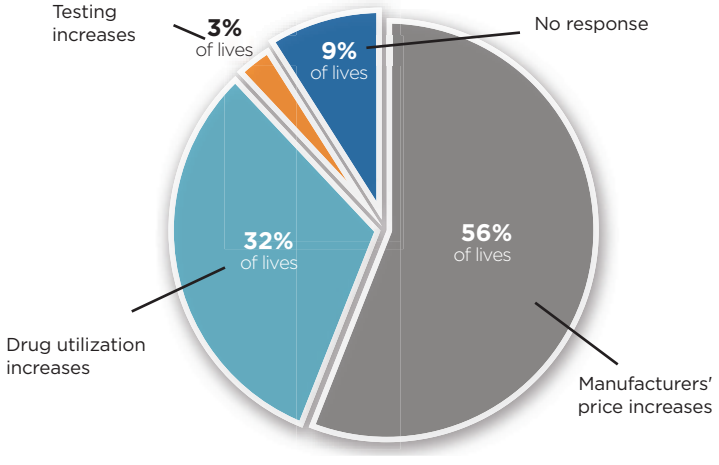


n = 29 payors, 37 million lives (2011)
n = 27 payors, 78 million lives (2012)

Nearly all payors (85 percent) who reported receiving rebates for medical benefit injectables report receiving them for BRM products. A wide array of BRMs were included, specifically Actemra, Cimzia, Humira, Orencia, Procrit and Remicade. *See Figure 7, Therapeutic Classes Where Payors Receive Injectable/Infusible Product Rebates.*

This year we asked what payors think is the key driver of oncology costs. Plans covering 56 percent of lives reported manufacturers' price increases, followed by drug utilization increases, reported by plans covering 32 percent of lives. *See Figure 8, Key Driver of Oncology Costs.*

FIG. 8 KEY DRIVER OF ONCOLOGY COSTS



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 six 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 fairly consistent with 2010 and 2011 findings, 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 9, Reimbursement Approach and the Extent of Discounts Used by Payors to Reimburse for Drugs Paid Under the Medical Benefit.*

There was a decrease this year for the average wholesale price (AWP) minus–based reimbursement methodology to about one in five covered lives. That decrease was offset by an increase in the variable fee schedule (VFS)-based methodology for reimbursement to about one in four covered lives. This appears to be partly due to experimental error resulting from a different sample of responders. The number of lives for which providers are reimbursed under an AWP plus has trended to 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 for drug administration. New this year was the emergence of the risk reimbursement methodology to 3 percent of covered lives, up from 0 percent the past two years for large plans (more than 500,000 lives). *See Figure 10, Reimbursement Approach and the Extent of Discounts Used by Payors to Reimburse for Drugs Paid Under the Medical Benefit by Size of Health Plan.*

FIG. 9 REIMBURSEMENT APPROACH OVERALL

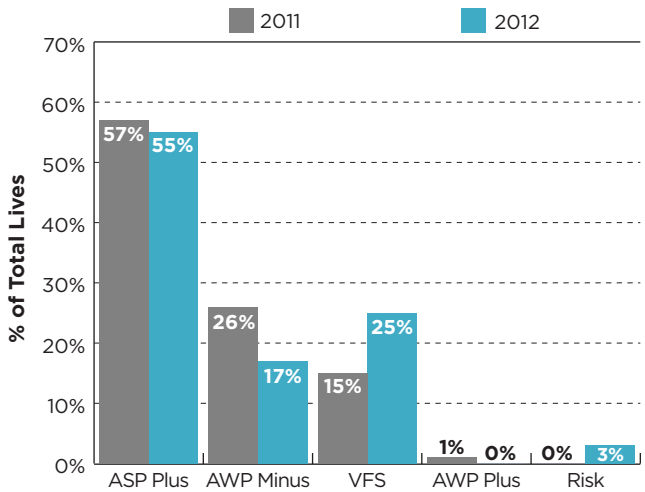


FIG. 10 REIMBURSEMENT APPROACH BY PLAN SIZE

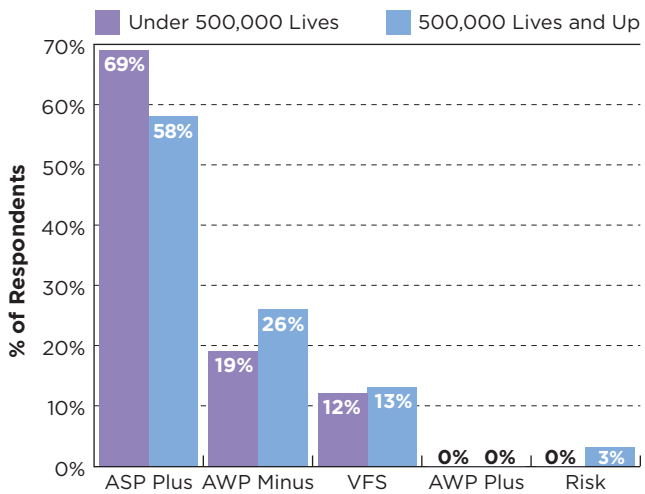
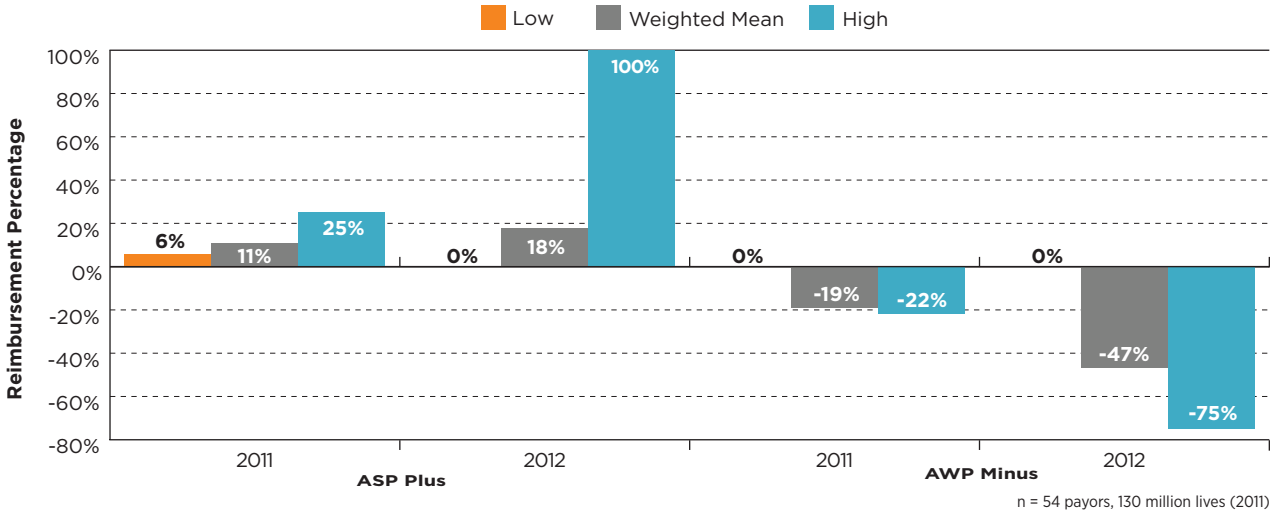


FIG. 11 REIMBURSEMENT PERCENTAGE IN PLACE

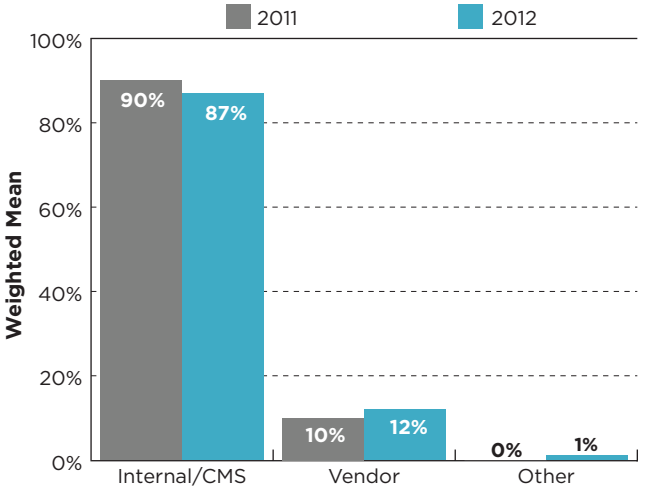


n = 54 payors, 130 million lives (2011)
n = 45 payors, 137 million lives (2012)

The weighted mean percentage higher than ASP reported this year was 18 percent, up from 11 percent last year. 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 cost.[1] Today, the average ASP-based reimbursement appears to be well above that threshold. AWP-minus reimbursement, on average, is with a 47 percent discounting of AWP, substantially lower than the previous year. It is difficult to imagine such discounts off AWP since (based largely upon drug mix) a 40 percent discount off AWP is approximately ASP plus zero. *See Figure 11, 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, which is consistent with last year's report. Specifically, their provider contracting departments, medical and pharmacy directors, and finance teams are influential, combined with assistance from the Centers for Medicare & Medicaid Services (CMS). 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 12, How Payors Develop Their Medical Benefit Drug Reimbursement Strategies.*

FIG. 12 DEVELOPMENT OF REIMBURSEMENT STRATEGIES



n = 47 payors, 142 million lives (2012)

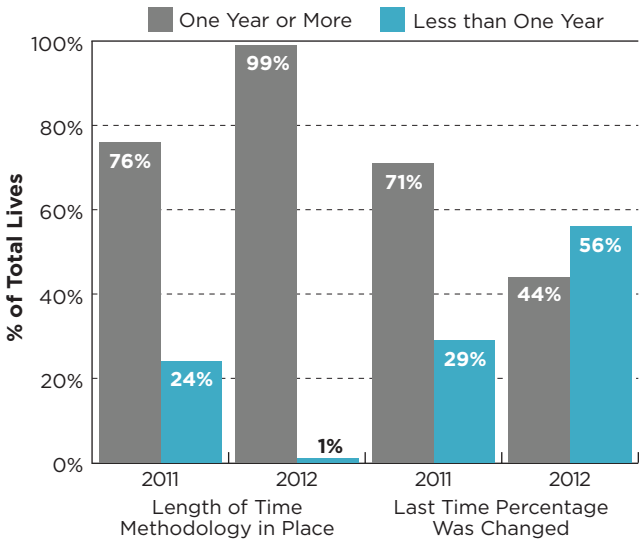
[1] Okon T., Coplon S. and Kube D. "Problems Facing Cancer Care with Medicare's Definition of Average Selling Price." *Community Oncol.* 2004;1(1):59-63. www.oncologypractice.com/co/journal/articles/0101059a.pdf. Accessed September 4, 2012.

In 2012, payors representing 1 percent of commercial managed care lives changed their medical benefit injectable reimbursement methodology, which is a substantial decrease from 2011 (24 percent). In addition, the percent modification to payor reimbursement strategies was changed within the past year for 56 percent of member lives, also a significant change from 2011 (29 percent). *See Figure 13, The Duration of Current Reimbursement Strategies at Health Plans.*

Payors reported several precipitating factors that led to making these changes. Namely, these were to address increased competitive market conditions and increased network pressures, along with a need to mimic CMS and demonstrate cost savings on medical injectables.

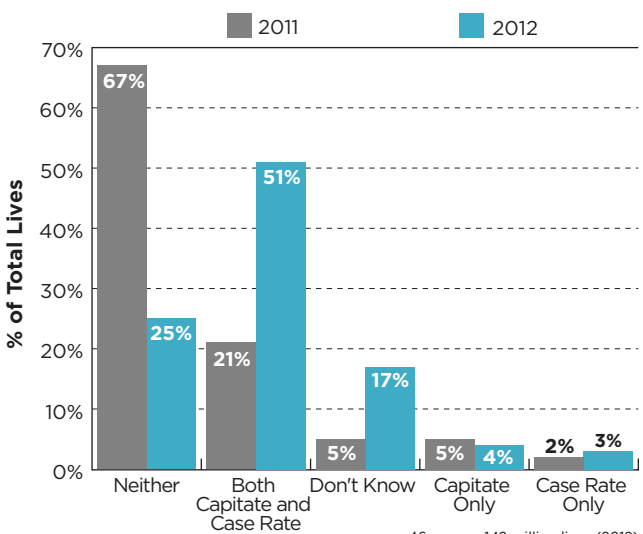
Payors representing half of the member lives have both capitated and case rate reimbursement arrangements with their providers, a significant increase for each of the past two years (51 percent versus 21 percent and 3 percent in 2011 and 2010, respectively). This is partly offset by a significant decrease for lives covered by payors with neither arrangement (25 percent versus 67 percent for 2011). *See Figure 14, Portion of Payor Lives That Capitate Reimbursement to Providers or Use Case Rates.*

FIG. 13 DURATION OF REIMBURSEMENT STRATEGIES



n = 46 payors, 142 million lives (2012)

FIG. 14 PAYORS WHO CAPITATE OR USE CASE RATES

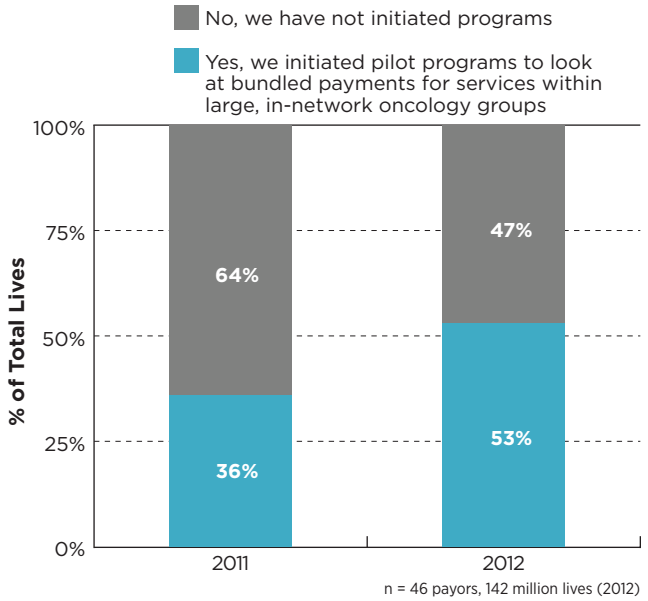


n = 46 payors, 142 million lives (2012)

Further, payors who represent more than half of covered lives in 2012 have begun to explore pilot programs that look at bundled payments for services with large, in-network oncology groups, an increase over last year of one-third of covered lives. *See Figure 15, Payors Who Initiated Pilot Programs.*

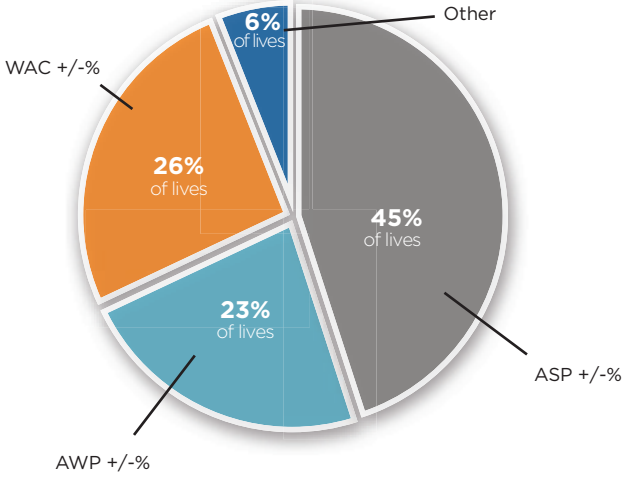
This year we asked what reimbursement strategies payors use for newly released injectable drugs (no J code assigned). Nearly half of covered lives are in plans with an ASP plus/minus percent strategy, and an additional one-quarter each for AWP plus/minus percent and WAC plus/minus percent strategies. *See Figure 16, Reimbursement Method for Newly Approved Medical Benefit Injectables.*

FIG. 15 PAYORS WHO INITIATED PILOT PROGRAMS



n = 46 payors, 142 million lives (2012)

FIG. 16 REIM. FOR NEWLY APPROVED INJECTABLES

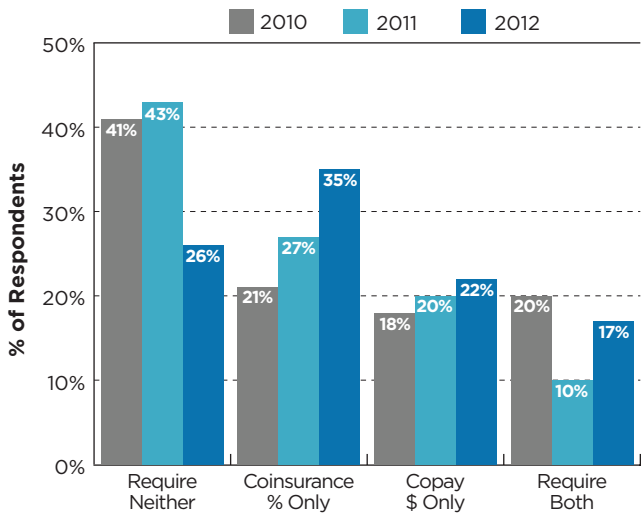


n = 46 payors, 142 million lives (2012)

Benefit Design

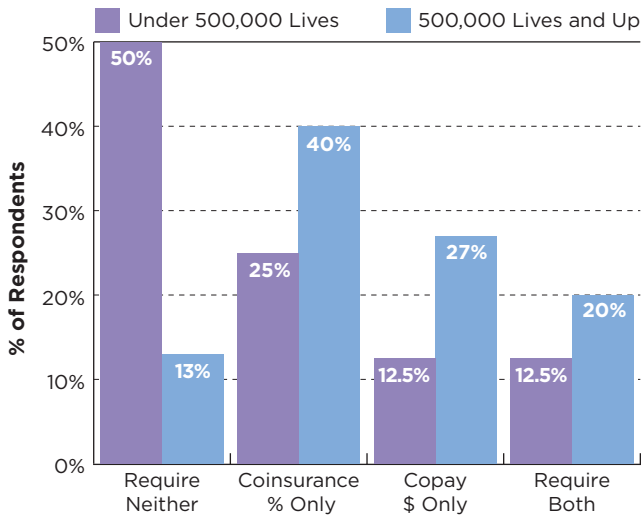
Compared with the past two years, there was a significant decrease in the proportion of plans (both small and large) that required neither a drug copay amount nor drug coinsurance for medical injectables, although smaller plans were far less likely to require member contribution. Of those that do require member contribution, it looks to be for either a drug coinsurance only (35 percent) or a drug copay only (22 percent), with fewer payors requiring both a copay and a coinsurance (17 percent). *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.*

FIG. 17 CONTRIBUTION REQUIREMENTS OVERALL



n = 46 payors, 142 million lives (2012)

FIG. 18 CONTRIBUTION REQUIREMENTS BY PLAN SIZE



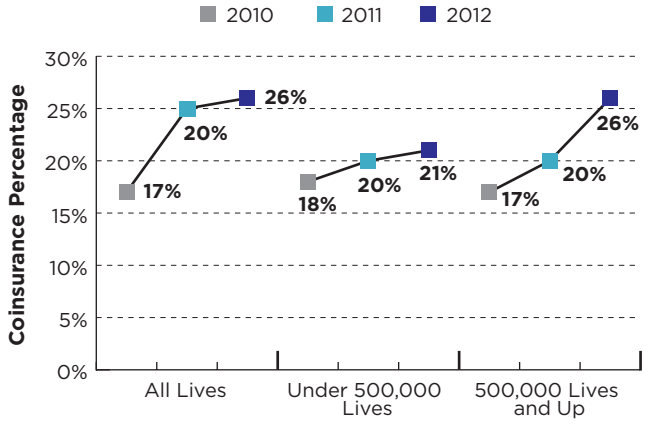
n = 46 payors, 142 million lives (2012)

Members subject to coinsurances for medical benefit injectable drugs are being asked to slightly increase their share of contribution this year, with the average being 26 percent of the claim cost in 2012 versus 20 percent in 2011 and 17 percent in 2010. The larger payors have a wider range at the upper end than the smaller plans. Most payors (75 percent) noted they would maintain the same coinsurance levels through the remainder of 2012. *See Figure 19, Reported Coinsurance Amounts for Medical Benefit Injectables.*

There appears to be an increase in copays for medical benefit injectable drugs. An average copay of $75 was reported in 2012, up from $46 in 2011, but this may be due in part to a high copay for a single large plan. Regarding copays for medical injectables, most payors (83 percent) stated they will maintain the current level of copay for the remainder of 2012. *See Figure 20, Reported Copay Amounts for Medical Benefit Injectables.*

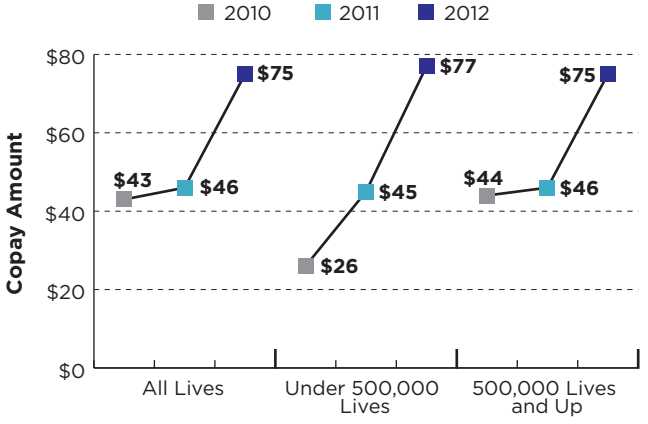
Many medical injectable benefit claims are in excess of $3,000 per dose. This is concerning because when the member contribution exceeds $2,500 per year, out-of-pocket member medication compliance is impacted. A new design seems to be emerging in which coinsurances are applied to a maximum capped amount,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

FIG. 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)

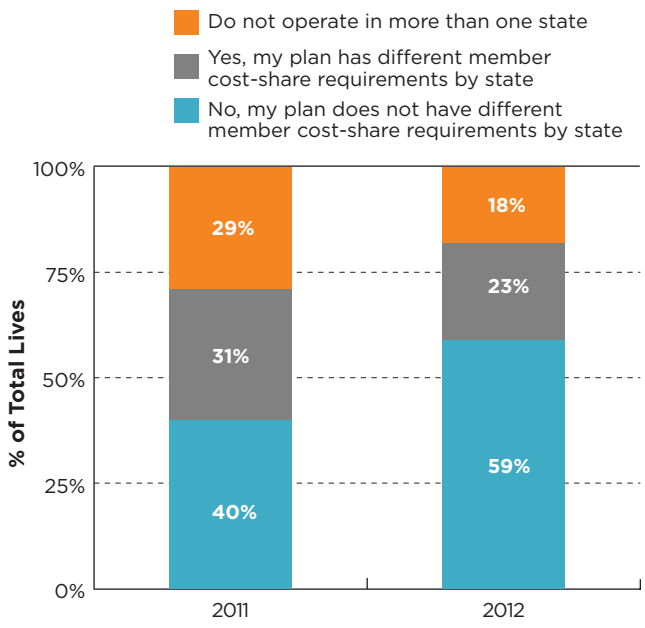
FIG. 20 REPORTED COPAY AMOUNTS



n = 23 payors, 64 million lives (2010)
n = 18 payors, 77 million lives (2011)
n = 18 payors, 105 million lives (2012)

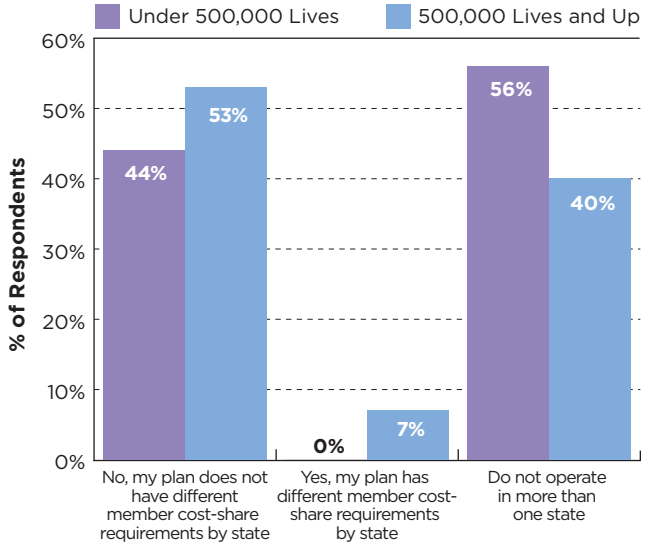
Looking across service areas, fewer than one in four covered lives is subject to different member cost-share requirements based on the state in which they are treated. This was seen only with plans larger than a half million lives because smaller payors either don't operate in more than one state or do not have different requirements across their service areas. *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.*

FIG. 21 MEMBER COST REQUIREMENTS OVERALL



n = 46 payors, 142 million lives (2012)

FIG. 22 MEMBER COST REQUIREMENTS BY PLAN SIZE



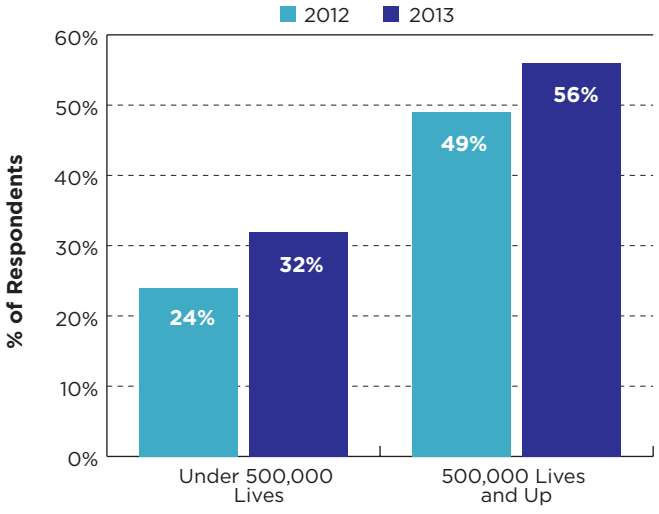
n = 46 payors, 142 million lives (2012)

The survey asked payors to think ahead through the remainder of 2012 and into 2013 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 2013, the projected percentage assigned to medical benefit injectables is 20 percent. In 2012, the reported coinsurance amount was 22 percent, and 20 percent for 2011. *See Figure 24, Reported Coinsurance Amounts Projected for Medical Benefit Injectables in 2013.*

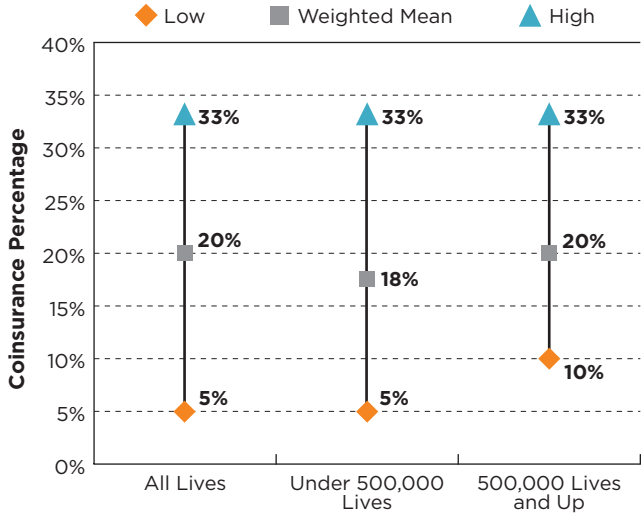
At times, payors employ coinsurances to put more "skin in the game" for their members for drugs covered under the medical benefit. However, the tactic loses some punch once maximum out-of-pocket annual contributions are reached. A weighted average of 74 percent of covered lives has an annual cap on members' coinsurance out of pocket, with the weighted mean at $3,003 per year. This is an increase from 2011 of 53 percent of the lives, with a cap on coinsurance out of pocket and an average of $2,076 per year.

FIG. 23 MEMBERS SUBJECT TO A COINSURANCE BY PLAN SIZE



n = 46 payors, 142 million lives (2012)

FIG. 24 COINSURANCE AMOUNTS PROJECTED FOR 2013

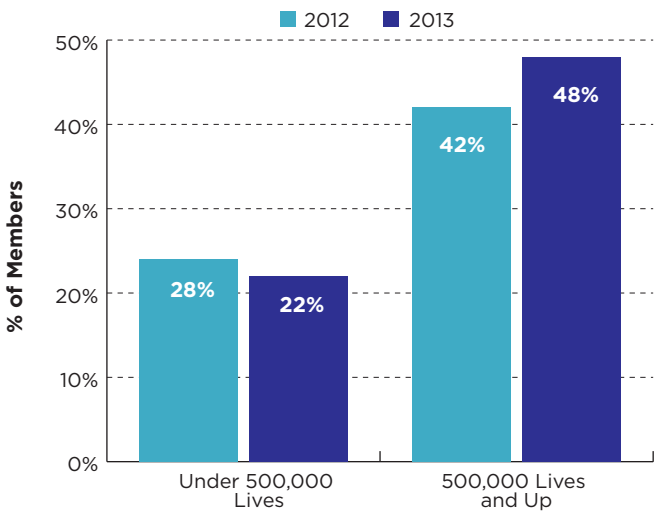


n = 34 payors, 104 million lives

Payors with more than 500,000 members report that the portion of their membership that has a medical benefit injectable copay will remain about the same in 2013. Payors with fewer than 500,000 members report that a smaller portion of their membership will have a copay in 2013. Of note, the large payors reported a lower percentage of members subject to a copay in 2012 (42 percent) as compared with their 2012 projections in last year's survey (50 percent). They project 48 percent of their members will be subjected to a medical benefit injectable copay in 2013. Small payors reported a much higher percentage of members subject to a copay in 2012 (28 percent) as compared with their 2012 projections (17 percent) in last year's survey. They project 22 percent will be subjected to copays in 2013. *See Figure 25, Percentage of Members Subject to a Copay for Medical Injectables by Size of Plan.*

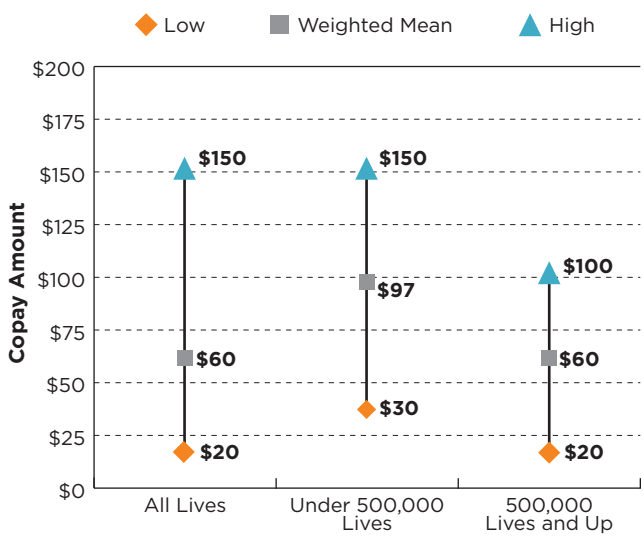
Among payors anticipating copays for 2013, the average amounts range from $20 to $150, with $60 being the weighted mean. Of note, members within smaller health plans have a higher copay on average. *See Figure 26, Reported Copay Amounts for Medical Benefit Injectables in 2013.*

FIG. 25 MEMBERS SUBJECT TO A COPAY BY PLAN SIZE



n = 46 payors, 142 million lives (2012)

FIG. 26 COPAY AMOUNTS PROJECTED FOR 2013



n = 22 payors, 82 million lives

ORAL VERSUS INTRAVENOUS

About half the covered lives in the survey are subject to contribution parity, which is similar to the level reported last year (54 percent). 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 72 percent of the lives in which member contribution parity exists, respondents noted it is due to state law. 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. *See Figure 28, Member Contribution Parity Mandated by State Law.*

FIG. 27 MEMBER CONTRIBUTION PARITY

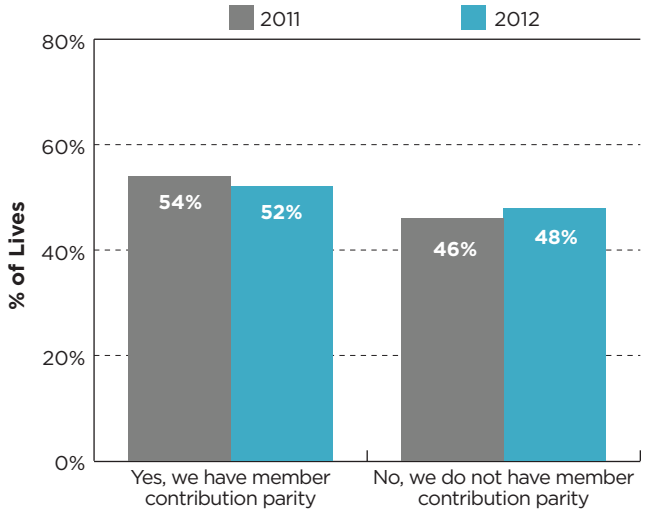
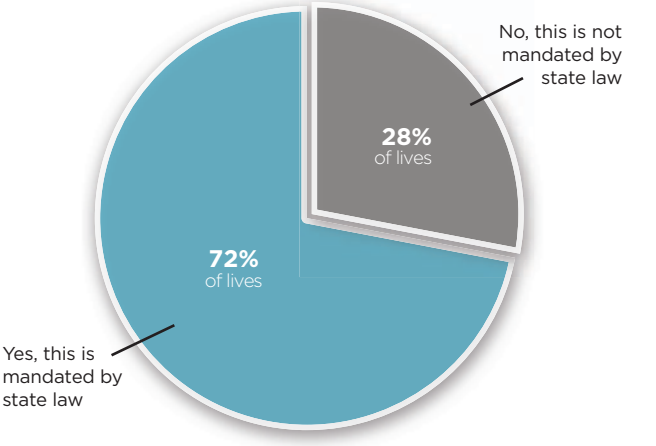


FIG. 28 PARITY MANDATED BY STATE LAW



n = 15 payors, 56 million lives

Genomic testing continues to play an important role in determining patient potential for positive treatment outcomes. HER2 testing[2] in advance of breast cancer therapy and KRAS testing[3] in advance of colorectal cancer therapy are the norm for four of every five members across health plans. Six in 10 members are subject to an Oncotype DX[4] test, should the need arise, but only about one in three would need a CD4 count[5] if receiving therapy for HIV. Other tests for which payors are contemplating coverage rules include those for the breast cancer susceptibility genes (BRCA) and epidermal growth factor receptor (EGFR). Since testing can vary significantly with these assays, fewer than half the payors reported having a relationship with a reference lab for these tests; the highest was reported at 49 percent for KRAS testing. *See Figure 29, Portion of Health Plans That Have a Relationship with a Reference Laboratory to Conduct Genomic Tests.*

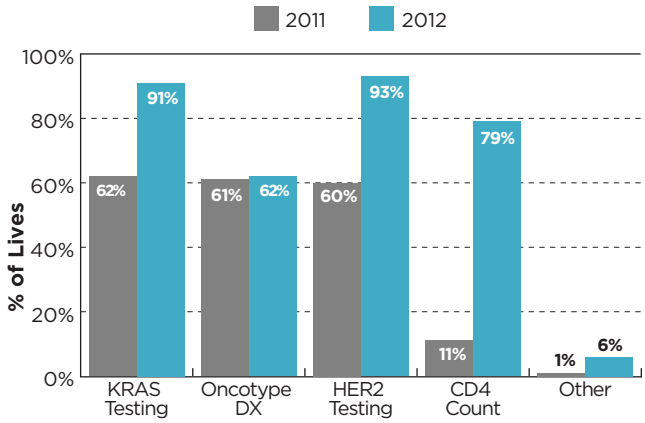
Most members of commercial health plans (78 percent of covered lives) were enrolled in plans that featured established National Committee for Quality Assurance HEDIS (Healthcare Effectiveness Data and Information Set) cancer screening or prevention programs, a slight but insignificant decrease from 2011. Breast and colorectal cancer screenings, along with medical assistance with smoking cessation, are part of the 2013 HEDIS measures. This is clearly driven by the large plans, as 22 percent of the payor respondents reported not having programs in place.

While breast cancer and colorectal cancer screening programs (54 percent of covered lives) continue as the most commonly available to members, this year's survey results were markedly different from previous years. Prostate cancer detection and smoking cessation programs were offered to slightly less than half the members. We are not aware of why this observation occurred. Prevention programs were nearly always developed internally at the health plans. *See Figure 30, HEDIS Cancer Screening or Prevention Programs in Place, and Figure 31, Specific HEDIS Prevention Programs Established.*

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.cd4.org

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

FIG. 29 RELATIONSHIPS WITH LABS ESTABLISHED



n = 109 million lives (2012)

FIG. 30 SCREENING OR PREVENTION PROGRAMS IN PLACE

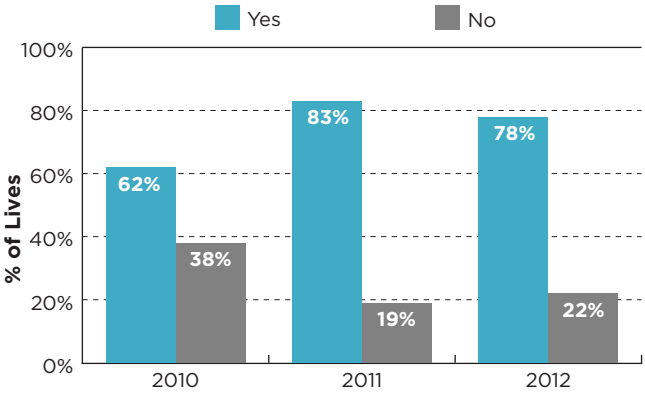
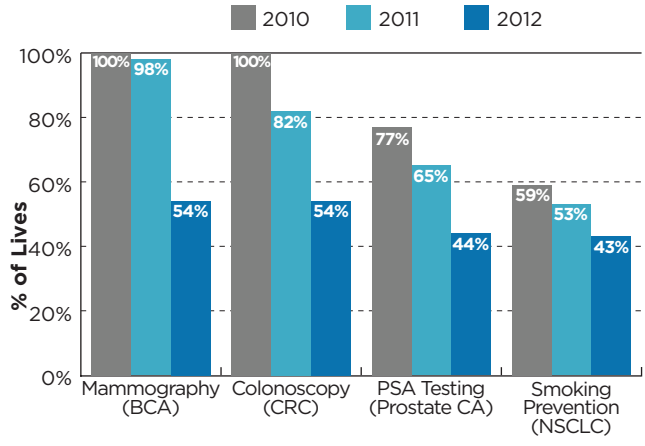


FIG. 31 HEDIS PREVENTION PROGRAMS ESTABLISHED

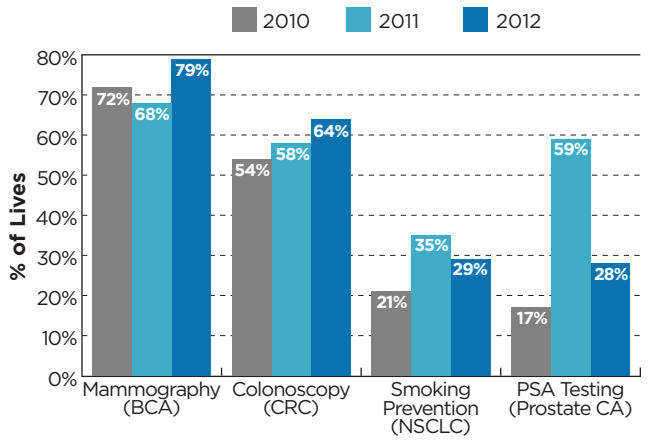


n = 39 payors, 119 million lives (2010)
n = 37 payors, 127 million lives (2011)
n = 26 payors, 85 million lives (2012)

Compliance with mammography and colonoscopy screening programs continued to show improvement over previous survey years. The large increase in the percentage of members complying with prostate-specific antigen (PSA) testing (59 percent in 2011) was not observed in the 2012 survey (28 percent). Year-over-year changes for mammography, colonoscopy and smoking cessation were within experimental error limits. *See Figure 32, Most Recent Percentage of Member Compliance by Cancer Screening Program.*

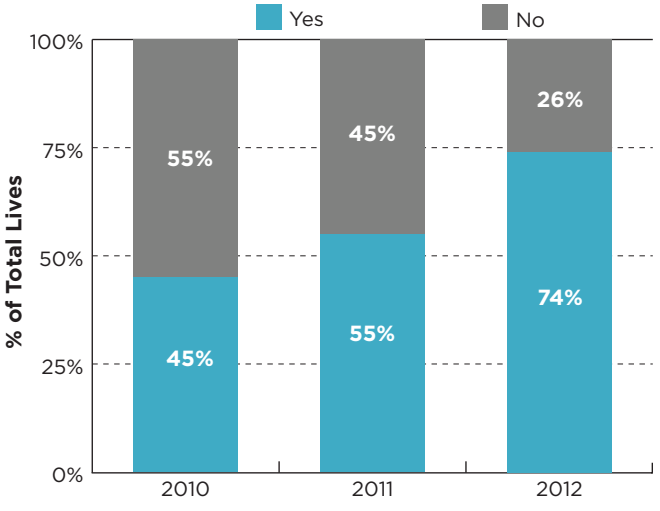
The 2012 survey noted a marked increase in the percentage of covered lives provided with an option for palliative care programs (74 percent versus 55 percent in 2011). Respondents offering such benefits report that their programs tend to include case management, care management, hospice and other palliative care options. *See Figure 33, Palliative Care Programs Provided for Membership.*

FIG. 32 MEMBER COMPLIANCE BY SCREEN PROGRAM



n = 39 payors, 119 million lives (2010)
n = 37 payors, 127 million lives (2011)
n = 26 payors, 85 million lives (2012)

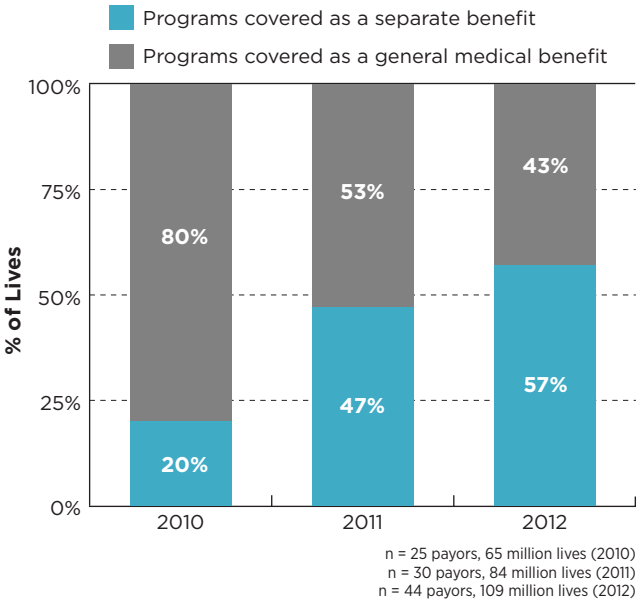
FIG. 33 PALLIATIVE CARE PROGRAMS PROVIDED



Again this year, we saw a statistically significant increase in the number of members offered a separate benefit for these palliative care programs, whereas most were covered under the medical benefit in previous years. *See Figure 34, Palliative Care Program Coverage.*

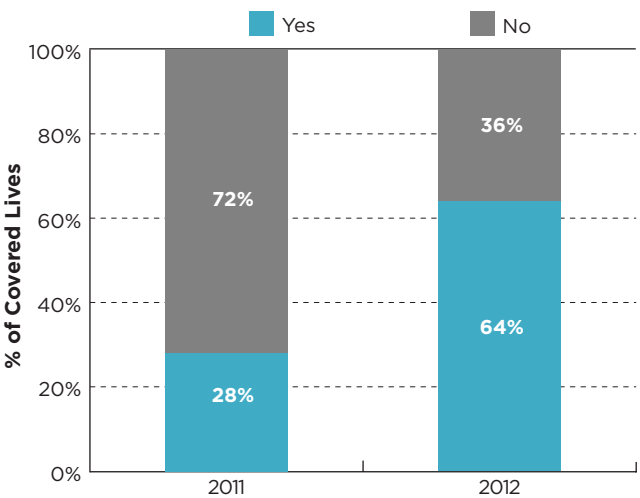
Although members receiving insurance from payors who have separate end-of-life benefits increased significantly this year, the results were skewed by one large payor. Again this year, few payors allow the plan sponsor to purchase a separate rider for this coverage. The most common number of days of hospice care included in this benefit was slightly less than three months, which was similar to that reported in 2010. *See Figure 35, Use of Rider for End-of-Life Benefit.*

FIG. 34 PALLIATIVE CARE PROGRAM COVERAGE



n = 25 payors, 65 million lives (2010)
n = 30 payors, 84 million lives (2011)
n = 44 payors, 109 million lives (2012)

FIG. 35 USE OF RIDER FOR END-OF-LIFE BENEFIT



Of those plans that offer end-of-life/palliative care programs for their membership, 10 percent reported they measure member participation in this benefit and know the actual portion of members who qualify and participate, although these payors account for just 4 percent of covered lives. The self-reported weighted average percentage of participation was 2 percent among membership. The vast majority of payors measure this; they just do not have a handle on the utilization of the benefit top of mind. *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.*

Consistent with previous years, approximately one-third of payors reported that their employer groups were becoming a significant driver in the development of future drug benefit designs; we see this effect continuing through 2012. In addition, this year, payors noted their employer groups are interested in learning about cancer management, medical management, curtailing growth in specialty spend, data utilization and increased cost sharing. Specific to oncology, employers are requesting payors to provide cost-control initiative programs that ensure appropriate use, access and methods to provide more benefit with less cost. *See Figure 37, Level of Employer Engagement with Health Plans in Developing Benefit Designs by Size of Plan.*

FIG. 36 PAYORS MONITORING MEMBER PARTICIPATION

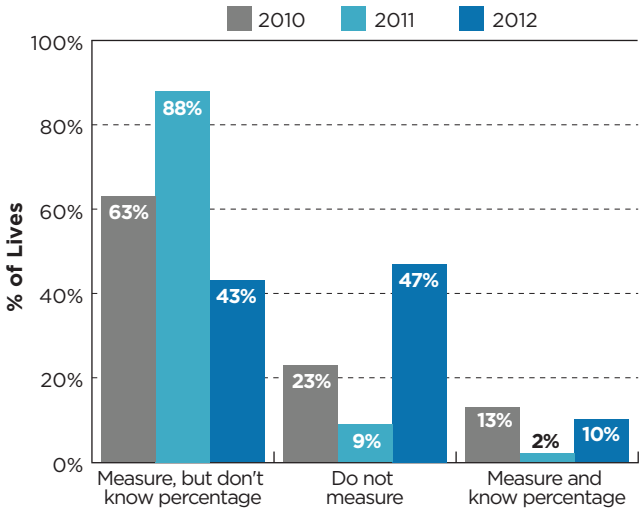
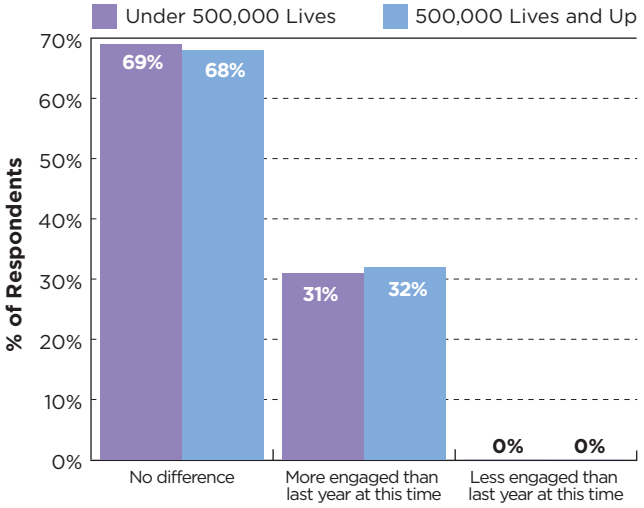


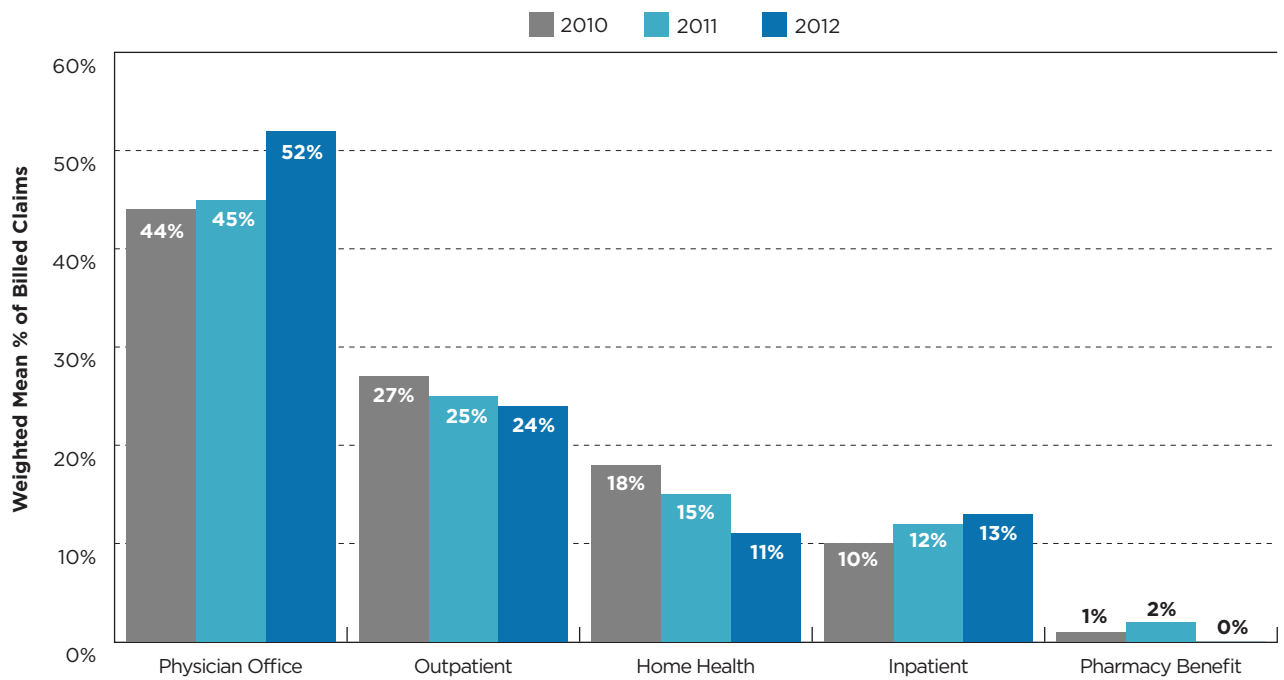
FIG. 37 LEVEL OF EMPLOYER ENGAGEMENT



Distribution Channel Management

Consistent with the 2011 survey results, payors tell us that about half 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 continues to represent an average of one-quarter of the billed claims, and home infusion represents 11 to 18 percent of medical injectable billed claims. Inpatient administration (13 percent) remained very similar to the 12 percent reported in 2011. This is likely to amplify in the future as payors build accountable care organizations (ACOs) and as private practices continue to be purchased by hospital systems, which then move outpatient facility administration to leverage more favorable 340B pricing and higher payor reimbursement. *See Figure 38, Average Percentage of Medical Injectable/ Infusible Claims Billed from Each Site of Service.*

FIG. 38 PERCENTAGE OF MEDICAL INJECTABLE CLAIMS BILLED



The survey asked payors to describe distribution channels for chemotherapies as well as other nonchemotherapy infused drugs billed under the medical benefit. When providers administer infused chemotherapies in their office, 60 percent 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.

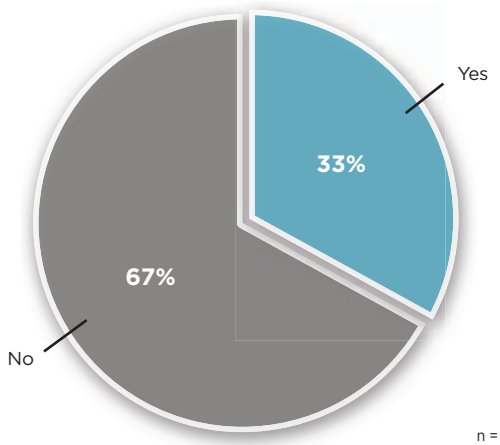
Specialty pharmacies provide approximately one-third of the chemotherapeutic drugs infused in the provider's office; this channel serves a minor portion of chemotherapy acquisition for good reason, as specialty pharmacy acquisition costs are 17 percent higher on a weighted average basis than in the provider's office. Moreover, approximately 20 percent of drugs shipped to a provider's office fail to be used due to, for example, changes in dose, therapy, duration of therapy, benefit changes or enrollment in palliative care programs. Finally, higher claim cost can occur as partial-vial use is not possible when billing the 11-digit National Drug Codes (NDCs) used by specialty pharmacies. *See Figure 39, Percentage of Medical Injectable/Infused Drug Volume Distributed to Members Through Various Billing Processes.*

FIG. 39 DRUG VOLUME DISTRIBUTED IN PHYSICIAN OFFICE

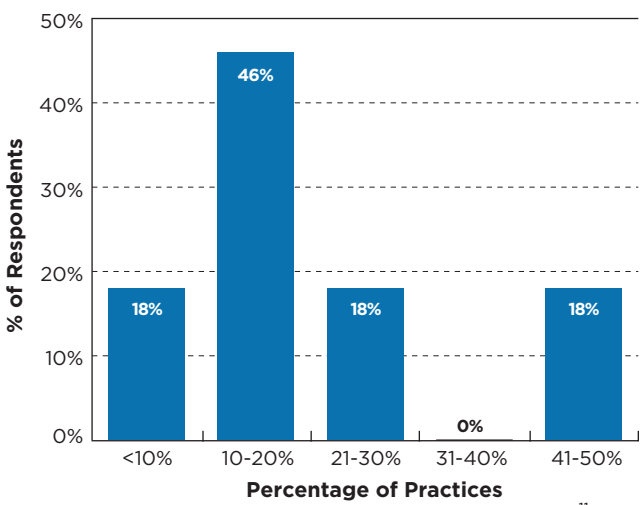
PRIMARY BILLING PROCESSES	WEIGHTED AVERAGE VOLUME 2011		WEIGHTED AVERAGE VOLUME 2012	
	INFUSED CHEMO DRUGS	INFUSED NONCHEMO DRUGS	INFUSED CHEMO DRUGS	INFUSED NONCHEMO DRUGS
Physician buy and bill (provider uses stock and bills plan)	64%	38%	60%	36%
Specialty pharmacy provider (SPP) (a pharmacy or distributor ships to provider's office and provider does not bill for the drug)	25%	44%	32%	51%
Other	6%	7%	6%	10%
Brown bag (member takes drug to the provider's office for administration)	5%	11%	1%	1%

One-third of survey respondents report they are seeing oncology practices in their service area being purchased by hospital systems. Of those, most said it is occurring in a relatively small percentage of oncology practices. The most common reason reported was practice financials. *See Figure 40, Practices Purchased by Hospital Systems.*

FIG. 40 PRACTICES PURCHASED BY HOSPITAL SYSTEMS



n = 43 payors



n = 11 payors

IF YES, WHY?	
Practice financials	50%
Hospital is building an accountable care organization	21%
Practice quality of life	21%

Utilization Management

Utilization management (UM) is a valuable tool that health plans employ to encourage appropriate use and dosing and to monitor site-of-service dynamics. In 2012, 92 percent of members were enrolled in plans that have implemented utilization management programs for provider-administered injectables. Most payors use prior authorization (PA) as the primary utilization management tool. *See Figure 41, Managing Utilization of Injectable/Infusible Products Administered by a Provider.*

Inspection of selected classes of medical injectables found that those with the most management (i.e., subjected to PA for at least 50 percent of members) included all the agents listed in Figure 42 except those for hemophilia treatments. Even more so than in previous years, guidelines developed by the National Comprehensive Cancer Network (NCCN) were the most commonly used tools to ensure appropriate use for chemotherapies; case management and disease management were also commonly employed. In 2012, use of clinical pathways for chemotherapy increased (17 percent of covered lives) versus only 8 percent in 2011; importantly, pathway programs were largely pilot studies and not implemented across the majority of the plans' membership. Drugs used for hemophilia were least likely to be subjected to PAs, although formularies and step edits were used to manage utilization for nearly half of the lives studied. Chemotherapy-induced nausea and vomiting accounted for the most lives in which no restrictions were noted, likely due to the low cost of generics coupled with coverage rules on Aloxi. *See Figure 42, Utilization Management Tools Used for Medical Injectable/Infusible Products in the Specific Therapeutic Classes.*

FIG. 41 MANAGING UTILIZATION OF PRODUCTS

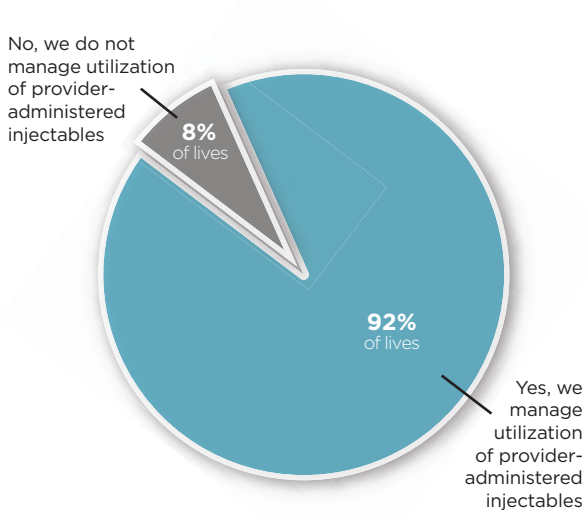


FIG. 42 UTILIZATION MANAGEMENT TOOLS BY CLASS

THERAPEUTIC CLASS	PRIOR AUTHORIZATION	DISEASE MANAGEMENT	STEP EDIT REQUIREMENTS	CLINICAL PATHWAY GUIDELINES	CASE MANAGEMENT	DIFFERENTIAL REIMBURSEMENT	FAILURE OF GENERIC FIRST	NCCN GUIDELINES	FORMULARY PRESENCE	NONE
Intravenous immune globulin (IVIG)	83%	53%	37%	15%	38%	9%	8%	50%	46%	0%
Chemotherapy	82%	67%	57%	17%	39%	22%	8%	84%	11%	8%
Erythropoiesis-stimulating agents (ESAs)	81%	50%	44%	18%	35%	11%	8%	56%	47%	1%
Colony-stimulating agents (G-CSFs)	79%	63%	44%	17%	34%	9%	8%	55%	11%	3%
Biologic response modifiers (e.g., Orencia, Remicade, etc.)	94%	64%	57%	18%	35%	51%	12%	49%	51%	1%
Hemophilia	83%	67%	58%	3%	36%	8%	8%	44%	49%	9%
Chemotherapy-induced nausea and vomiting (CINV)	31%	64%	44%	16%	38%	46%	13%	56%	13%	11%

n = 35 payors, 99.5 million lives

Payors in 2012 reported markedly increased use of utilization management tools for all major cancer types (95 percent of covered lives were reported for all other surveyed cancer therapies). As noted earlier, PA, NCCN guideline adherence, edits, genetic tests prior to initial therapy, claims edits for appropriate diagnosis and retrospective drug utilization review continue to be common methods that payors employ. *See Figure 43, Cancer Types Most Commonly Subjected to Medical Utilization Tools.*

Avastin, Remicade and Rituxan continue to be the most commonly reported agents subjected to PA (nearly half of covered lives). As in the past, case management continues to be a smaller, but important, tool health plans employ to monitor utilization. Interestingly, use of disease management and differential reimbursement was limited to only four large payors (35 to 50 percent of lives covered). Aloxi, Cerezyme, Eloxatin, Gemzar and Herceptin were associated with the highest use of clinical pathways as a management tool, consistent with the use of genomic testing prior to therapy. Similar to 2010 and 2011, few payors reported not using any medical injectable management tools or controls. *See Figure 44, Management Tools Used for Common Medical Injectable Therapies.*

FIG. 43 CANCERS SUBJECTED TO MEDICAL UTILIZATION TOOLS

	2010 % OF LIVES	2011 % OF LIVES	2012 % OF LIVES	YEAR-OVER-YEAR % CHANGE
Metastatic breast cancer	59%	70%	97%	39%
Prostate cancer	59%	94%	97%	3%
Multiple myeloma	56%	62%	95%	53%
Non-Hodgkin's lymphoma	49%	66%	95%	44%
Leukemia	48%	69%	95%	38%
Renal-cell carcinoma	54%	75%	95%	27%
Non-small cell lung cancer	85%	83%	95%	14%

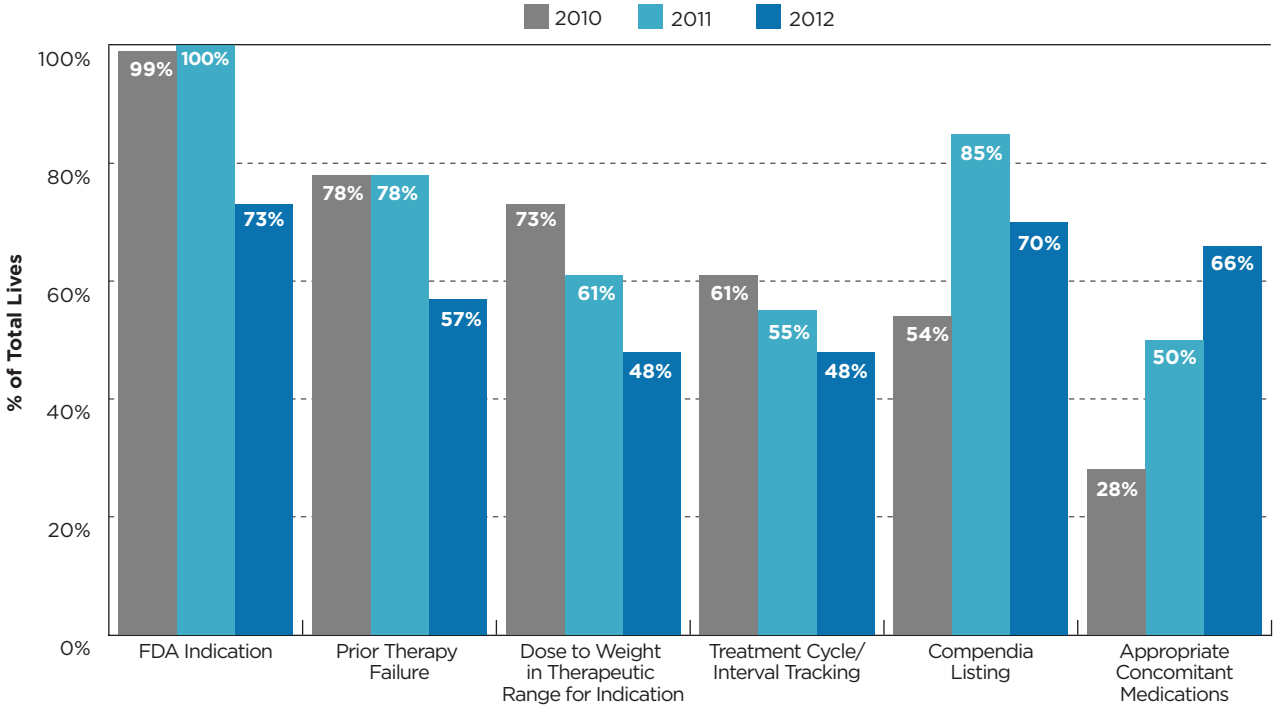
FIG. 44 MANAGEMENT TOOLS FOR COMMON THERAPIES BY PERCENT OF LIVES

DRUGS	PRIOR AUTHORIZATION	CASE MANAGEMENT	DISEASE MANAGEMENT	CLINICAL PATHWAY GUIDELINES	DIFFERENTIAL REIMBURSEMENT	STEP EDIT REQUIREMENTS	FAILURE OF GENERIC FIRST	NCCN GUIDELINES	NONE
# RESPONDENTS	N = 31	N = 8	N = 4	N = 10	N = 4	N = 10	N = 9	N = 19	N = 11
Remicade	90%	39%	49%	9%	35%	51%	7%	45%	1%
Rituxan	88%	40%	49%	3%	35%	46%	7%	60%	3%
Avastin	87%	40%	49%	3%	35%	8%	3%	85%	3%
Erbitux	87%	40%	49%	3%	35%	8%	2%	85%	3%
Herceptin	86%	40%	49%	16%	35%	9%	2%	72%	3%
Abraxane	76%	40%	49%	10%	35%	8%	4%	85%	8%
Gemzar	75%	40%	49%	16%	35%	8%	3%	75%	8%
Cerezyme	55%	43%	49%	20%	35%	8%	3%	46%	1%
Alimta	47%	39%	49%	3%	35%	10%	2%	62%	8%
Aloxi	46%	40%	49%	17%	35%	9%	3%	55%	8%
Zometa	43%	39%	49%	4%	35%	8%	2%	56%	8%
Eloxatin	41%	40%	49%	16%	35%	8%	2%	62%	9%
Taxotere	41%	40%	50%	3%	35%	8%	3%	70%	9%

n = 31 payors, 99 million lives (2012)

When asked whether they manage primarily to a specific drug or by cancer therapeutic categories, nearly all payors (97 percent of covered lives) look to manage the drug entity itself. Payors still look to indication by the FDA and compendia listings when developing PA criteria. Large increases in concomitant medications being reviewed were seen this year, included as part of specific prior authorization criteria, perhaps reflecting the increased utilization of specific drug combinations. Overall, it is clear that inconstancy exists in how criteria are being created. *See Figure 45, Specific Prior Authorization Criteria That May Be Required.*

FIG. 45 SPECIFIC PRIOR AUTHORIZATION CRITERIA



n = 39 payors, 85 million lives (2010)
n = 38 payors, 57 million lives (2011)
n = 31 payors, 90 million lives (2012)

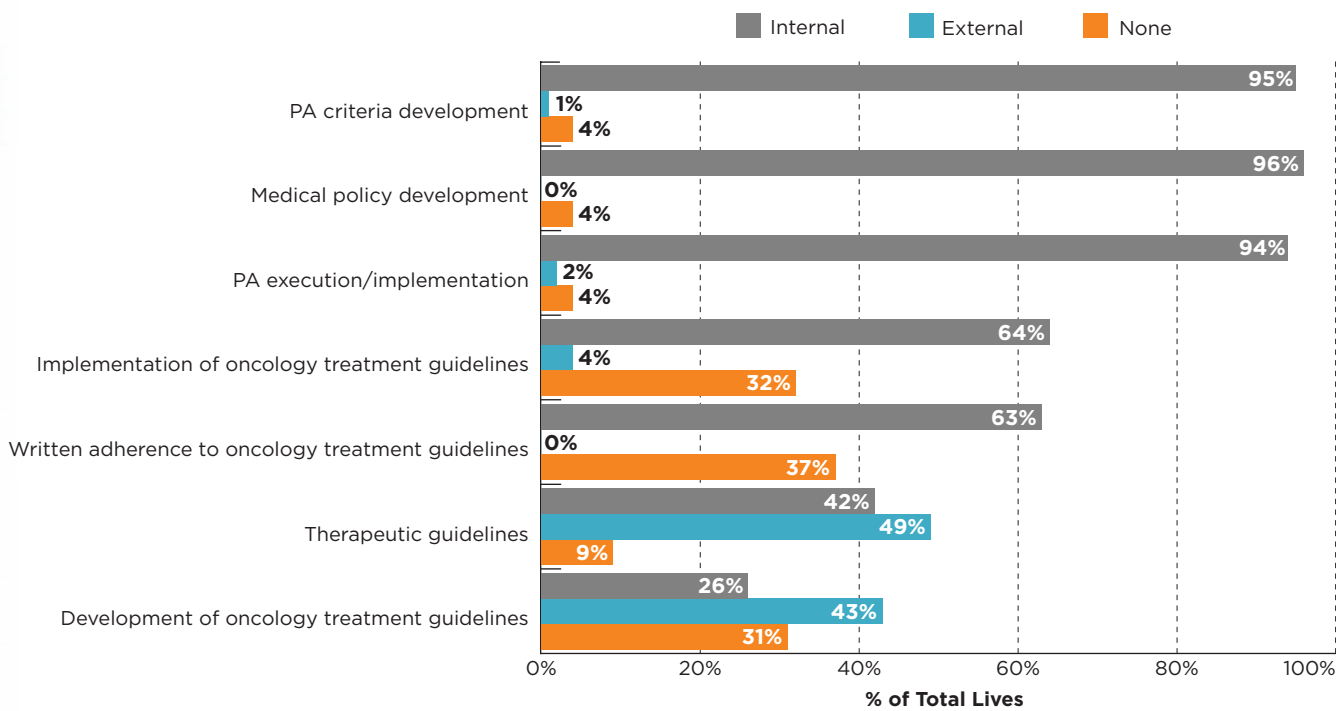
When asked about top concerns regarding medical injectables in 2012, more than one-third of payors mentioned the overall cost as the most significant concern. Benefit coverage was the next most commonly mentioned concern (21 percent). Also, we asked payors to define the key driver of oncology cost increases. Manufacturer pricing action was noted by plans representing two-thirds of the lives; the balance believe the driver is related to increased drug utilization, as described earlier in this report. *See Figure 46, Top Medical Injectable Concerns in 2012.*

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 frequently developed externally to the plan, often utilizing the expertise of the oncologist community. *See Figure 47, Where Management Services Are Developed at Health Plans.*

FIG. 46 TOP MEDICAL INJECTABLE CONCERNS IN 2012

MEDICAL INJECTABLE CONCERN	% OF PAYORS
Overall, increased costs	37%
Appropriate utilization	21%
New biologics	12%
Oncologics	12%
Integration of medical injectables with oral pharmacy management	4%

FIG. 47 WHERE MANAGEMENT SERVICES ARE DEVELOPED



Operational Improvements

Payors continue to use post-claim edits for provider-administered injectables paid under the member's medical benefit. Such edits are recommended to mitigate fraud, waste, billing errors, and off-standard-of-care use. We continue to see the portion of payors with medical pharmacy edits to be low. Payors have commented that while existing edit tools may capture severe outliers, detailed content is needed to optimize the opportunity. Claims reviews conducted to monitor FDA label indications are performed for more than half of covered lives. Appropriate dosing regimens overall, as well as appropriate weight-based medications, were monitored in 43 and 39 percent of covered lives, respectively. Additional edits are designed to assess off-label or off-standard-of-care use and to mitigate claim pricing errors. Of those conducting reviews, nearly all are developed and conducted by internal health plan staff. *See Figure 48, Post-Claim Edits Conducted on Medical Injectable Claims, and Figure 49, Implementation of Post-Claim Edits.*

FIG. 48 POST-CLAIM EDITS CONDUCTED

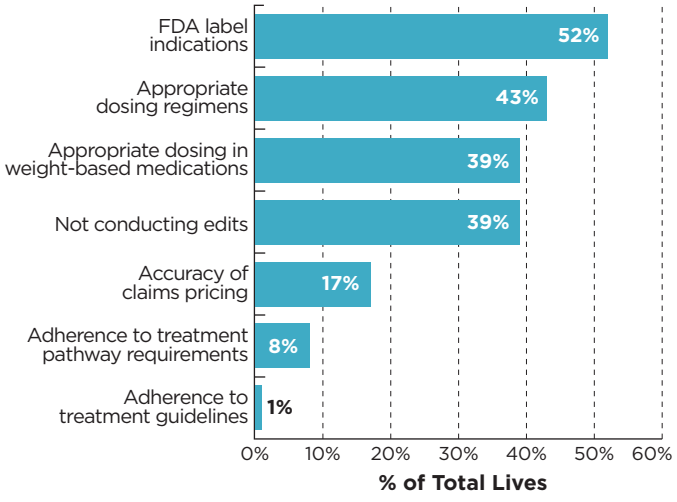
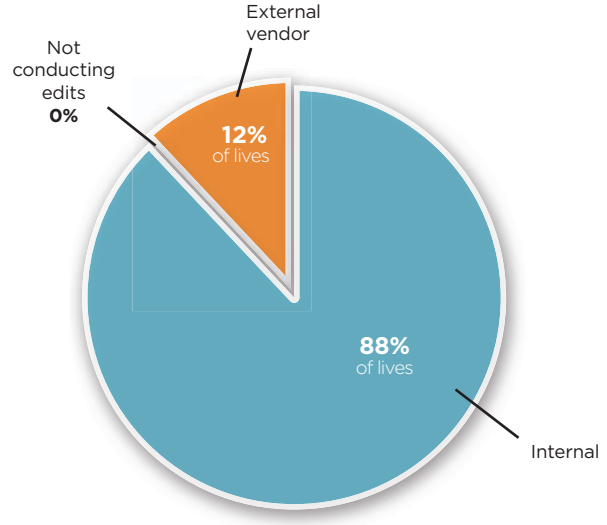
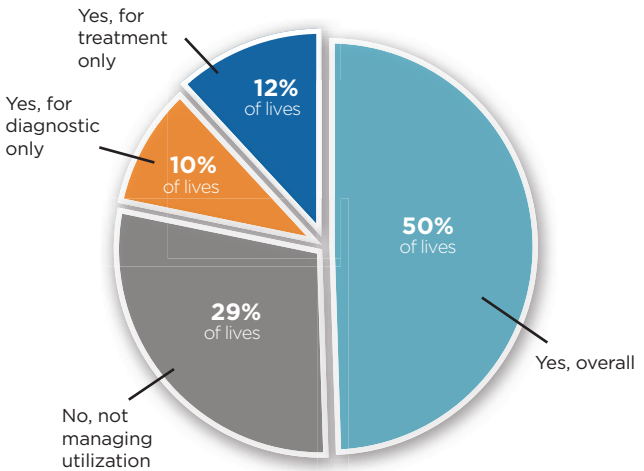


FIG. 49 IMPLEMENTATION OF POST-CLAIM EDITS



Radiation oncology treatments generally fall within the medical benefit at health plans. Figure 50 illustrates that radiation oncology, regardless of whether for diagnostic or treatment purposes, is being managed by health plans for half (50 percent) of the covered lives represented in the 2012 survey. *See Figure 50, Health Plans That Manage Radiation Oncology Benefits.*

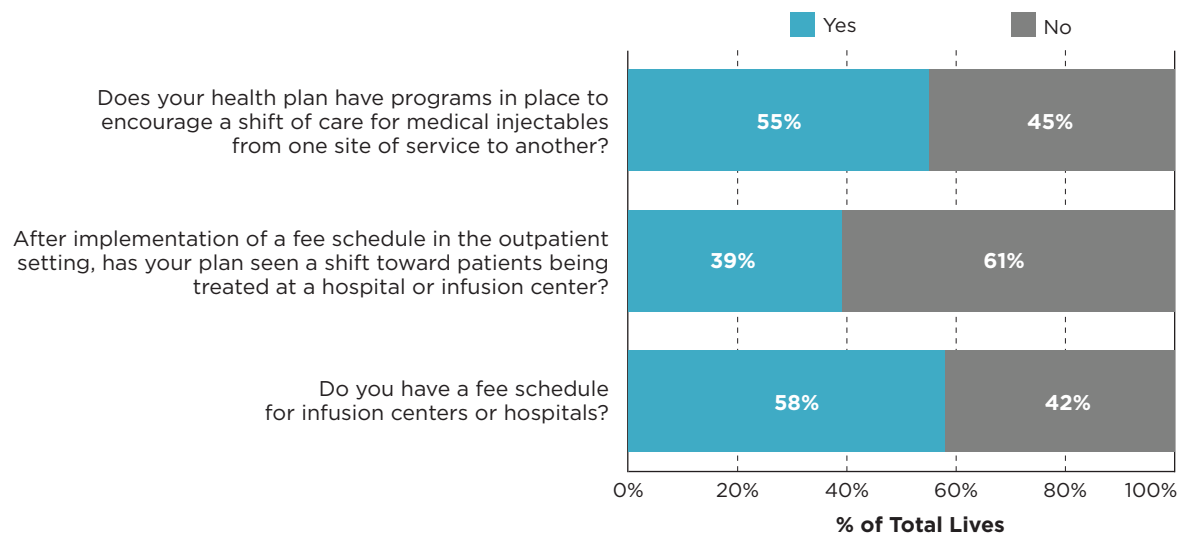
FIG. 50 MANAGE RADIATION ONCOLOGY BENEFITS



More than half of members were enrolled in payors who have implemented programs to manage untoward site of service shifts, although the success of these programs is generally not known. Programs such as differential reimbursement or mandated specialty pharmacy use have been implemented to encourage the provision of care in the provider or home setting and away from the inpatient or outpatient hospital setting. After implementation of a fee schedule in the outpatient setting, nearly one-quarter of members were subjected to a shift toward being treated at a hospital or infusion center. *See Figure 51, Programs to Encourage Site of Service Shift.*

Approximately 58 percent of payors' lives have a fee schedule for infusion centers or hospitals, although the robustness of these schedules is highly variable because they are commonly based upon a "percentage of charges" model in which the center or hospital develops a charge master.

FIG. 51 PROGRAMS TO ENCOURAGE SITE OF SERVICE SHIFT



HEALTH PLAN CLAIMS DATA

Trend Drivers

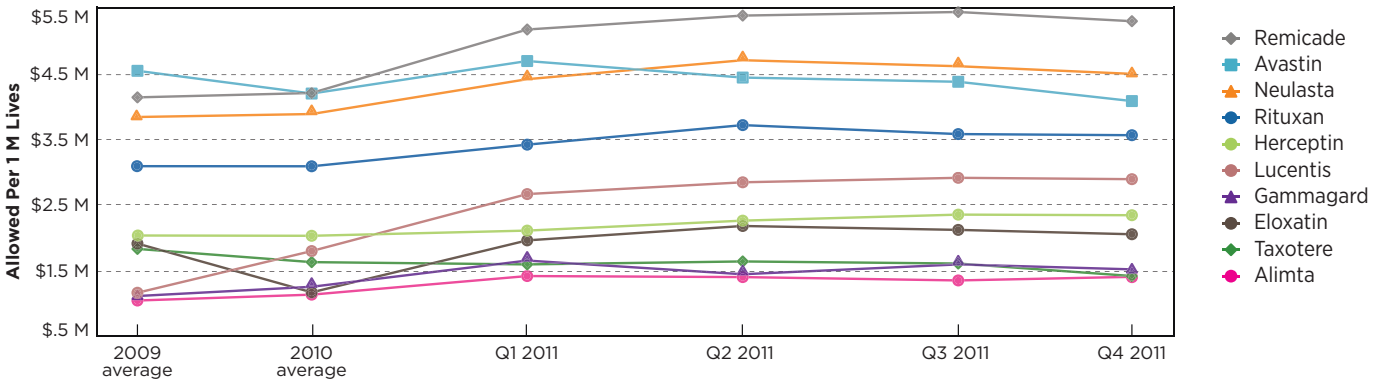
Based on analysis of paid medical benefit injectable claims from 2011, a 1-million-life commercial plan will have averaged $251 million in medical benefit injectable costs in 2011 across all sites of service. Of that, the top 25 medical drugs comprised more than 69 percent of the total medical injectable spend. Total medical pharmacy cost increased by 7 percent. In 2011, Remicade was the largest overall spend per 1 million insured lives, and had a year-over-year increase of 27 percent.

There was a continued decrease in provider utilization trend of Avastin for metastatic breast cancer (mBC). Lucentis again had a significant upward trend due to continued marketing to physicians. Eloxitan, Tysabri and Synvisc had greater than 50 percent increases in spend while Taxotere, Gemzar, Advate, Zometa and all ESAs had negative cost trends. *See Figure 52, Top 25 Medical Benefit Specialty Drugs by Allowed Amount per 1 Million Lives (All Lines of Business and Sites of Service).*

FIG. 52 TOP 25 MEDICAL BENEFIT SPECIALTY DRUGS (ALL LINES OF BUSINESS AND SITES OF SERVICE)

DRUG	RANKING	J CODE	UNITS PER 1 M LIVES	CALCULATED COST PER UNIT	2011 ALLOWED PER 1 M LIVES	2010 ALLOWED PER 1 M LIVES	% CHANGE
Remicade	1	J1745	249,815	$85.25	$21,297,483	$16,831,355	27%
Neulasta	2	J2505	5,874	$3,104.59	$18,237,283	$15,551,250	17%
Avastin	3	J9035	222,317	$79.16	$17,599,624	$16,797,540	5%
Rituxan	4	J9310	21,296	$671.05	$14,290,797	$12,373,250	15%
Lucentis	5	J2778	27,843	$407.13	$11,335,601	$7,216,687	57%
Herceptin	6	J9355	115,398	$78.76	$9,089,341	$8,145,277	12%
Eloxatin	7	J9263	756,958	$11.01	$8,337,577	$4,705,059	77%
Taxotere	8	J9171	274,058	$22.94	$6,286,493	$6,542,993	-4%
Gammagard	9	J1569	82,693	$75.43	$6,237,738	$5,043,225	24%
Alimta	10	J9305	96,918	$57.80	$5,601,882	$4,565,757	23%
Advate	11	J7192	1,005,650	$4.52	$4,541,021	$5,474,438	-17%
Gamunex	12	J1561	52,334	$81.52	$4,266,216	$4,068,691	5%
Gemzar	13	J9201	26,653	$151.47	$4,037,249	$4,225,284	-4%
Tysabri	14	J2323	267,670	$14.67	$3,925,521	$2,349,569	67%
Aloxi	15	J2469	139,470	$25.17	$3,510,232	$2,841,468	24%
Erbitux	16	J9055	53,051	$63.11	$3,347,783	$3,214,451	4%
Zometa	17	J3487	12,402	$258.09	$3,200,741	$3,528,521	-9%
Velcade	18	J9041	69,772	$43.93	$3,065,380	$2,553,969	20%
Procrit	19	Q4081 - ESRD	1,682,534	$1.79	$3,005,084	$3,573,004	-16%
Orencia	20	J0129	118,427	$25.11	$2,973,499	$2,374,323	25%
Aranesp	21	J0881	849,327	$3.48	$2,956,802	$3,351,996	-12%
Xolair	22	J2357	80,550	$34.47	$2,776,283	$2,764,605	0%
Procrit	23	J0885 - Non-ESRD	236,246	$11.57	$2,733,007	$2,960,842	-8%
Synvisc-One	24	J7325	148,521	$16.50	$2,450,895	$1,603,979	53%
Treanda	25	J9033	108,234	$22.15	$2,396,887	$1,327,114	81%
Total					**$167,500,416**	**$143,984,647**	**16%**

FIG. 53 TOP 10 DRUGS BY YEARLY AVERAGE (2009 AND 2010) AND QUARTER (2011)



The top 10 drugs are responsible for more than 49 percent of the overall medical injectable benefit spend at these plans. When compared to last year, top-costing drugs had a stable quarter-to-quarter spend. *See Figure 53, Top 10 Drugs by Yearly Average (2009 and 2010) and Quarter (2011).*

When the diagnosis codes used for members receiving medical benefit injectable drugs were reviewed, about 23 diagnoses represented at least 1 percent of patients receiving medical injectables, with osteoarthrosis and allied disorders being the top diagnosis and responsible for about 7 percent of the total medical pharmacy spend. The top five diagnoses were responsible for about a quarter of the total spend. There the top ICD9 codes are for rheumatologic disorders. *See Figure 54, Portion of Health Plan Members Who Received a Medical Injectable for Key Diagnoses.*

FIG. 54 PORTION OF MEMBERS WHO RECEIVED A MEDICAL INJECTABLE

			2011	2010
RANKING	PRIMARY DIAGNOSIS CODE	PRIMARY DIAGNOSIS CODE DESCRIPTION	% OF TOTAL PATIENTS PER 1 M LIVES	% OF TOTAL PATIENTS PER 1 M LIVES
1	715	Osteoarthrosis and allied disorders	6.6%	6.4%
2	726	Peripheral enthesopathies and allied syndromes	5.1%	5.4%
3	719	Other and unspecified disorders of joint	4.4%	4.7%
4	786	Symptoms involving respiratory system and other chest symptoms	4.2%	3.9%
5	724	Other and unspecified disorders of back	2.8%	3.0%
6	789	Other symptoms involving abdomen and pelvis	2.6%	2.4%
7	727	Other disorders of synovium, tendon and bursa	2.5%	2.5%
8	414	Other forms of chronic ischemic heart disease	1.9%	2.0%
9	V04	Need for prophylactic vaccination and inoculation	1.9%	0.1%
10	493	Asthma	1.5%	1.4%
11	466	Acute bronchitis and bronchiolitis	1.4%	1.4%
12	728	Disorders of muscle, ligament and fascia	1.3%	1.5%
13	780	General symptoms	1.3%	1.2%
14	281	Other deficiency anemias	1.3%	1.2%
15	266	Deficiency of B-complex components	1.2%	1.2%
16	477	Allergic rhinitis	1.1%	1.2%
17	461	Acute sinusitis	1.1%	1.2%
18	787	Symptoms involving digestive system	1.1%	1.0%
19	692	Contact dermatitis and other eczema	1.1%	1.3%
20	362	Other retinal disorders	1.1%	0.9%
21	729	Other disorders of soft tissues	1.0%	1.1%
22	722	Intervertebral disc disorders	1.0%	1.1%
23	V58	Encounter for other and unspecified procedures and aftercare	1.0%	0.8%
24	784	Symptoms involving head and neck	0.9%	0.8%
25	733	Other disorders of bone and cartilage	0.9%	0.9%
Total			**50.3%**	**48.6%***

*Slightly different than last year due to rounding effects

Management of Spend Drivers

Provider-infused or injected chemotherapy, as expected, represents the largest portion of medical benefit injectable costs at about 38 percent of the total costs; when chemotherapy support medicines are considered, injectables associated with cancer care represent just over half of allowed medical injectable costs (55 percent). The 2011 portion of total provider-administered injectable spend due to cancer was identical to the previous year, and colony-stimulating factors (CSFs), ESAs, and antiemetics had modest cost increases. However, the cost of other oncology support drugs increased by 20 percent. Overall spend was up year over year, likely due to manufacturer price increases.

It is 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 more comprehensive analysis, these paid amounts are likely larger than other available benchmarks that measure only provider office-based administrations. Provider-administered injectables used to treat rheumatologic disorders represent the second largest therapeutic area by spend – about 6 percent of total medical injectable costs in 2011, a much lower portion of the total than in the past, and just edging out IVIG and gastroenterology. *See Figure 55, Spend by Key Therapeutic Class per 1 Million Lives.*

FIG. 55 SPEND BY KEY THERAPEUTIC CLASS*

	2011		2010	
THERAPY	ALLOWED PER 1 M LIVES	% OF SPEND	ALLOWED PER 1 M LIVES	% OF SPEND
Oncology	$95,951,319	38%	$88,111,943	37%
Other	$60,805,348	24%	$50,694,864	22%
Colony-stimulating factor	$21,869,186	9%	$19,920,607	8%
Intravenous immune globulin	$15,729,028	6%	$16,625,591	7%
Gastroenterology	$14,863,165	6%	$13,169,318	6%
Rheumatology**	$11,174,638	4%	$10,811,282	5%
Oncology: support	$10,301,922	4%	$4,292,446	2%
Hemophilia	$7,668,098	3%	$9,291,609	4%
Erythropoiesis-stimulating agent	$6,143,347	2%	$6,605,204	3%
Antiemetics	$5,719,792	2%	$4,968,419	2%
Osteoarthritis	$5,105,485	2%	$10,565,653	4%
Total	**$255,331,325**	**100%**	**$235,056,935**	**100%**

* Pharmacy benefit injectables not available for 2011
** Osteoarthritis has been segmented

National Provider Trends

Across all lines of business, hematologists and oncologists together order and administer the most medical benefit injectable drugs, representing just less than 50 percent of the total spend. Rheumatology is also a key medical specialty. Other provider specialties mentioned include urology and various others. *See Figure 56, Spend per 1 Million Lives by Provider Specialty.*

In a year-over-year assessment of claims to determine what specialties are ordering medical benefit injectables, a lower portion appears to be ordered by oncologists in 2011 when compared with 2010. This is consistent with previous years and was absorbed by an increase in prescribing by rheumatologists, radiation oncologists and hematologists. *See Figure 57, Claims per 1 Million Lives by Provider Specialty.*

FIG. 56 SPEND BY PROVIDER SPECIALTY

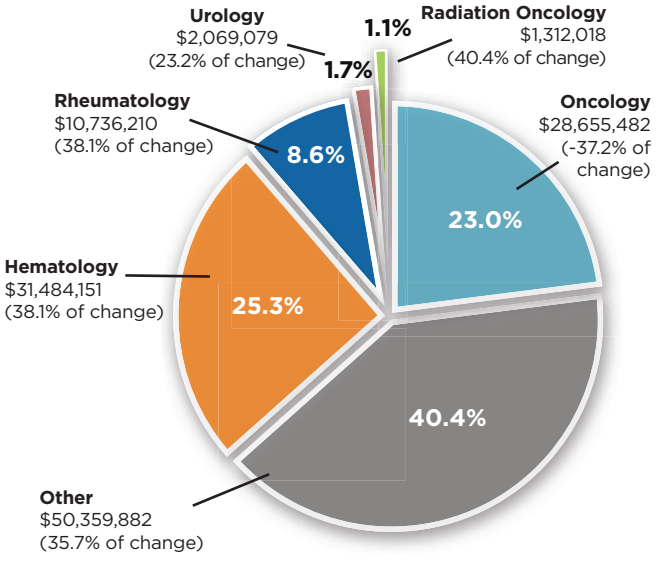


FIG. 57 CLAIMS BY PROVIDER SPECIALTY

SPECIALTY	2011 UNITS PER 1 M LIVES	2010 UNITS PER 1 M LIVES	% CHANGE	2011 CLAIMS PER 1 M LIVES	2010 CLAIMS PER 1 M LIVES	% CHANGE
Other	4,278,967	3,512,842	-16.1%	289,710	232,749	-21.7%
Oncology	1,625,971	1,937,091	21.8%	52,910	67,560	24.5%
Hematology	2,066,931	1,157,807	78.5%	58,465	39,258	48.9%
Rheumatology	350,190	166,082	110.9%	18,234	12,578	45.0%
Urology	58,508	41,297	41.7%	9,010	6,338	42.2%
Radiation oncology	89,631	50,650	77.0%	2,235	1,683	32.8%
Total	**8,470,198**	**6,865,768**		**430,565**	**360,165**	

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 2011, 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. While top 10 medications such as Remicade, Avastin, Lucentis and Gammagard were relatively stable in site of service mix, cancer drugs such as Neulasta, Rituxan, Herceptin, Eloxatin, Taxotere and Alimta had material increases in portions of drug administered in the hospital, and this was a result of the cannibalization of office administration. *See Figure 58, Spend and Utilization per 1 Million Lives by Site of Service.*

FIG. 58 SPEND AND UTILIZATION PER 1 MILLION LIVES BY SITE OF SERVICE*

RANKING	J CODE	BRAND NAME	ALLOWED PER 1 M LIVES	2011 TOTAL $/CLAIM	2010 TOTAL $/CLAIM	2009 TOTAL $/CLAIM
1	J1745	Remicade	$24,052,942	$3,943	$3,765	$3,711
2	J2505	Neulasta	$19,820,310	$3,306	$3,309	$3,405
3	J9035	Avastin*	$19,544,584	$2,297	$3,248	$3,784
4	J9310	Rituxan	$15,862,675	$5,411	$5,218	$5,228
5	J2778	Lucentis	$12,958,535	$2,045	$2,071	$2,088
6	J9355	Herceptin	$9,678,854	$2,939	$2,516	$2,562
7	J9263	Eloxatin	$9,125,364	$3,591	$3,658	$3,888
8	J1569	Gammagard	$7,021,631	$4,049	$4,409	$4,779
9	J9171	Taxotere	$6,779,615	$2,398	$2,308	$2,622
10	J9305	Alimta	$6,201,325	$5,019	$5,044	$5,338

		PERCENT OF CLAIM											
		HOSPITAL			HOME INFUSION/SPP			OTHER (ESRD, CLINICS, ETC.)			MEDICAL OFFICE		
BRAND NAME	RANKING	2009	2010	2011	2009	2010	2011	2009	2010	2011	2009	2010	2011
Remicade	1	23%	20%	23%	12%	8%	7%	1%	0%	0%	64%	71%	69%
Neulasta	2	24%	30%	31%	2%	1%	1%	1%	1%	2%	72%	68%	67%
Avastin	3	20%	18%	18%	3%	2%	1%	1%	1%	1%	76%	79%	81%
Rituxan	4	25%	32%	36%	2%	1%	1%	1%	1%	1%	71%	66%	63%
Lucentis	5	1%	0%	1%	8%	4%	3%	0%	0%	0%	91%	96%	95%
Herceptin	6	23%	28%	36%	1%	0%	0%	2%	2%	1%	74%	70%	63%
Eloxatin	7	28%	29%	38%	2%	0%	0%	2%	1%	2%	68%	69%	59%
Gammagard	8	22%	19%	18%	63%	66%	65%	1%	0%	0%	14%	15%	17%
Taxotere	9	22%	28%	31%	2%	1%	0%	1%	1%	1%	75%	71%	68%
Alimta	10	30%	38%	42%	2%	0%	0%	2%	2%	2%	66%	60%	56%

*$ per claim drop was a result of shift in sight of service, off-label use and the FDA decision to revoke the approval of the breast cancer indication for Avastin.

Medical benefit injectable drugs are commonly used for multiple indications, and we found wide variations in the indications of high-spend medical benefit injectable products. The data listed illustrate the top five diagnoses for the top six highest-cost drugs to payors: Remicade, Neulasta, Avastin, Rituxan, Lucentis and Herceptin. For comparison, the 2010 data are presented as well. 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 drugs are being used for their members. *See Figure 59, Top Six Diagnosis Codes for Key Medical Benefit Drugs.*

FIG. 59 TOP SIX DIAGNOSIS CODES

REMICADE

DESCRIPTION	CODE	ALLOWED PER 1 M LIVES			CLAIMS PER 1 M LIVES		
		2011	2010	% CHANGE	2011	2010	% CHANGE
Regional enteritis	555	$7,285,402	$5,787,732	26%	1,614	1,261	28%
Rheumatoid arthritis and other inflammatory polyarthropathies	714	$6,460,182	$5,699,470	13%	2,117	1,895	12%
Ulcerative colitis	556	$3,001,320	$1,919,806	56%	625	455	37%
Psoriasis and similar disorders	696	$2,470,860	$2,093,268	18%	612	537	14%
Ankylosing spondylitis and other inflammatory spondylopathies	720	$739,626	$534,229	38%	210	156	34%

NEULASTA

DESCRIPTION	CODE	ALLOWED PER 1 M LIVES			CLAIMS PER 1 M LIVES		
		2011	2010	% CHANGE	2011	2010	% CHANGE
Diseases of white blood cells	288	$5,032,150	$3,298,293	53%	1,792	1,176	52%
Encounter for other and unspecified procedures and aftercare	V58	$3,403,913	$2,402,215	42%	951	606	57%
Malignant neoplasm of female breast	174	$3,274,479	$3,356,197	-2%	930	923	1%
Convalescence	V66	$1,135,374	$918,824	24%	337	291	16%
Malignant neoplasm of trachea, bronchus and lung	162	$1,095,074	$1,214,710	-10%	383	390	-2%

AVASTIN

DESCRIPTION	CODE	ALLOWED PER 1 M LIVES			CLAIMS PER 1 M LIVES		
		2011	2010	% CHANGE	2011	2010	% CHANGE
Encounter for other and unspecified procedures and aftercare	V58	$5,358,521	$4,029,285	33%	777	553	40%
Malignant neoplasm of trachea, bronchus and lung	162	$3,094,423	$2,780,706	11%	447	442	1%
Malignant neoplasm of colon	153	$2,961,138	$2,535,443	17%	823	741	11%
Malignant neoplasm of brain	191	$2,119,552	$1,300,605	63%	314	226	39%
Malignant neoplasm of female breast	174	$1,780,998	$2,853,309	-38%	240	498	-52%

RITUXAN

DESCRIPTION	CODE	ALLOWED PER 1 M LIVES			CLAIMS PER 1 M LIVES		
		2011	2010	% CHANGE	2011	2010	% CHANGE
Other malignant neoplasms of lymphoid and histiocytic tissue	202	$6,145,634	$5,442,542	13%	1,210	1,135	7%
Encounter for other and unspecified procedures and aftercare	V58	$2,867,759	$2,128,068	35%	469	327	44%
Rheumatoid arthritis and other inflammatory polyarthropathies	714	$1,590,571	$1,324,958	20%	236	200	18%
Lymphoid leukemia	204	$1,295,580	$1,018,095	27%	269	234	15%
Lymphosarcoma and reticulosarcoma	200	$1,071,189	$826,271	30%	224	190	18%

LUCENTIS

DESCRIPTION	CODE	ALLOWED PER 1 M LIVES			CLAIMS PER 1 M LIVES		
		2011	2010	% CHANGE	2011	2010	% CHANGE
Other retinal disorders	362	$12,287,640	$7,166,424	71%	6,052	3,460	75%
Diabetes mellitus	250	$232,614	$20,646	1,027%	114	10	1,061%
Osteoarthrosis and allied disorders	715	$5,656	$2,832	100%	3	1	174%
Glaucoma	365	$4,736	$4,621	2%	3	2	22%
Other disorders of eye	379	$4,490	$6,219	-28%	2	3	-29%

HERCEPTIN

DESCRIPTION	CODE	ALLOWED PER 1 M LIVES			CLAIMS PER 1 M LIVES		
		2011	2010	% CHANGE	2011	2010	% CHANGE
Malignant neoplasm of female breast	174	$6,376,438	$6,277,958	2%	2,415	2,659	-9%
Encounter for other and unspecified procedures and aftercare	V58	$2,757,859	$1,601,429	72%	711	467	52%
Malignant neoplasm of esophagus	150	$108,954	$14,756	638%	28	4	592%
Secondary malignant neoplasm of other specified sites	198	$79,010	$51,087	55%	32	24	29%
Malignant neoplasm of stomach	151	$55,312	$27,449	102%	25	13	95%

Other Analyses for 2012

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), 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 the 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 who 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 60, Oncology Support Drug Utilization – Medical Benefits (2011).*

FIG. 60 ONCOLOGY SUPPORT DRUG UTILIZATION — MEDICAL BENEFITS (2011)*

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

	G-CSF — % of $/MM								
REGIMEN	NEULASTA			NEUPOGEN			LEUKINE		
	2009	2010	2011	2009	2010	2011	2009	2010	2011
Nonmyelosuppressive	16%	20%	25%	38%	39%	50%	30%	29%	43%
Myelosuppressive	84%	80%	75%	62%	61%	50%	70%	71%	57%

*Pharmacy benefit injectables not available for 2011

Two years of paid claims across all lines of business were also analyzed to compare the portion of classified and unclassified codes paid at commercial payors. Included in this comparison were the classic "dump" codes, such as J3490, J3535, J3590, J7699, J7199, J7599, J7799, J8498, J8499, J8597, J8999 and J9999. In fact, significant increases in drugs paid under these codes were seen in 2011. This may have been the result of a larger number of cancer drug approvals in 2011 than 2010. We believe this is in line with what is to be expected, as these codes were established for drugs newly approved that do not yet have a Medicare HCPCS code assigned.[6] *See Figure 61, Unclassified Codes – Medical Benefit.*

FIG. 61 UNCLASSIFIED CODES — MEDICAL BENEFIT

	UNCLASSIFIED	CLASSIFIED
2010		
Allowed per 1 M lives	$690,094	$228,338,685
Claims per 1 M lives	3,528	776,273
% of total spend	0.3%	99.7%
2011		
Allowed per 1 M lives	$6,605,245	$255,496,357
Claims per 1 M lives	17,821	693,881
% of total spend	2.5%	97.5%

[6] FDA Approved Drugs. CenterWatch website. www.centerwatch.com/drug-information/fda-approvals/default.aspx?DrugYear=2010. Accessed January 8, 2013.

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 93 percent of the allowed spend per 1 million lives and 94 percent of the claims per 1 million lives, the nearly exact finding in our previous report. *See Figure 62, Off-Label Utilization for the Top 25 Drugs (2011).*

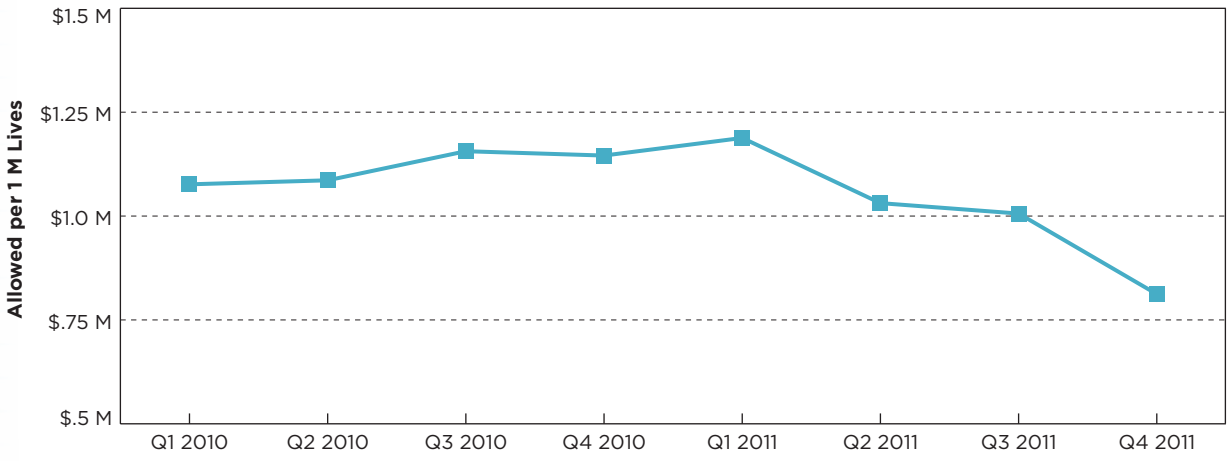
FIG. 62 OFF-LABEL UTILIZATION FOR THE TOP 25 DRUGS (2011)

	ALL LOBs*		COMMERCIAL		MEDICARE		MEDICAID	
	ALLOWED PER 1 M LIVES	CLAIMS PER 1 M LIVES	ALLOWED PER 1 M LIVES	CLAIMS PER 1 M LIVES	ALLOWED PER 1 M LIVES	CLAIMS PER 1 M LIVES	ALLOWED PER 1 M LIVES	CLAIMS PER 1 M LIVES
2010								
On-Label	$137,075,407	62,786	$138,176,959	62,468	$329,178,938	177,285	$20,503,840	9,673
Off-Label	$10,656,434	3,586	$11,118,355	3,646	$15,705,199	7,725	$318,500	462
2011								
On-Label	$156,643,003	72,188	$150,612,771	67,869	$340,324,019	203,752	N/A	N/A
Off-Label	$11,601,918	4,213	$11,346,161	4,057	$19,392,293	8,964	N/A	N/A
% OF TOTAL								
Off-Label 2010	7%	5%	7%	6%	5%	4%	2%	5%
Off-Label 2011	7%	6%	7%	6%	5%	4%	N/A	N/A

*This data includes only nonmanaged plans

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. The data show roughly a 25 percent drop over a 12-month period. Generic sales were put on hold while a challenge lawsuit was resolved, though much inventory flooded the market prior to that situation. *See Figure 63, Generic Introduction Spend Impact.*

FIG. 63 GENERIC INTRODUCTION SPEND IMPACT



PRODUCT PIPELINE AND LEGISLATIVE TRENDS

Drug Pipeline

Although 2011 proved to be a big year, with more than 11 new injectables receiving approval by the FDA, only seven new entities were approved in the first half of 2012. Among the most anticipated was Genentech's Perjeta, which was approved to treat HER2+ breast cancer. The FDA surprised many by making a decision on Perjeta in six months rather than the standard 10 months. Perjeta, approved to work in combination with Herceptin and Taxotere, appears to prolong the time before the aggressive HER2+ cancer worsens compared with Herceptin and chemotherapy alone. In the study upon which the FDA based its approval, patients treated with Perjeta, Herceptin and Taxotere exhibited an increase in median progression-free survival time of 6.1 months compared with those treated with just Herceptin and Taxotere. Overall survival rates are not yet available, but those who received the combination with Perjeta experienced a 38 percent reduction in the risk of their disease worsening or death. *See Figure 64, 2012 FDA-Approved Injectable Drugs/Indications – Specialty and Oncology.*

FIG. 64 2012 FDA-APPROVED INJECTABLE DRUGS

DRUG	MANUFACTURER	INDICATION	APPROVAL
Voraxaze (glucarpidase)	BTG International	Treatment of toxic plasma methotrexate concentrations	January
Bydureon (exenatide)	Amlin	Type 2 diabetes mellitus	January
Omontys (peginesatide)	Affymax	Anemia due to chronic kidney disease	March
Elelyso (taliglucerase alfa)	Pfizer	Gaucher disease	May
Perjeta (pertuzumab)	Genentech	Breast cancer	June
Kyprolis (carfilzomib)	Onyx	Multiple myeloma	July
Zaltrap (ziv-aflibercept)	Sanofi	Colorectal cancer	August

Source: FDA-approved drugs. CenterWatch website. www.centerwatch.com/drug-information/fda-approvals. Accessed August 31, 2012.

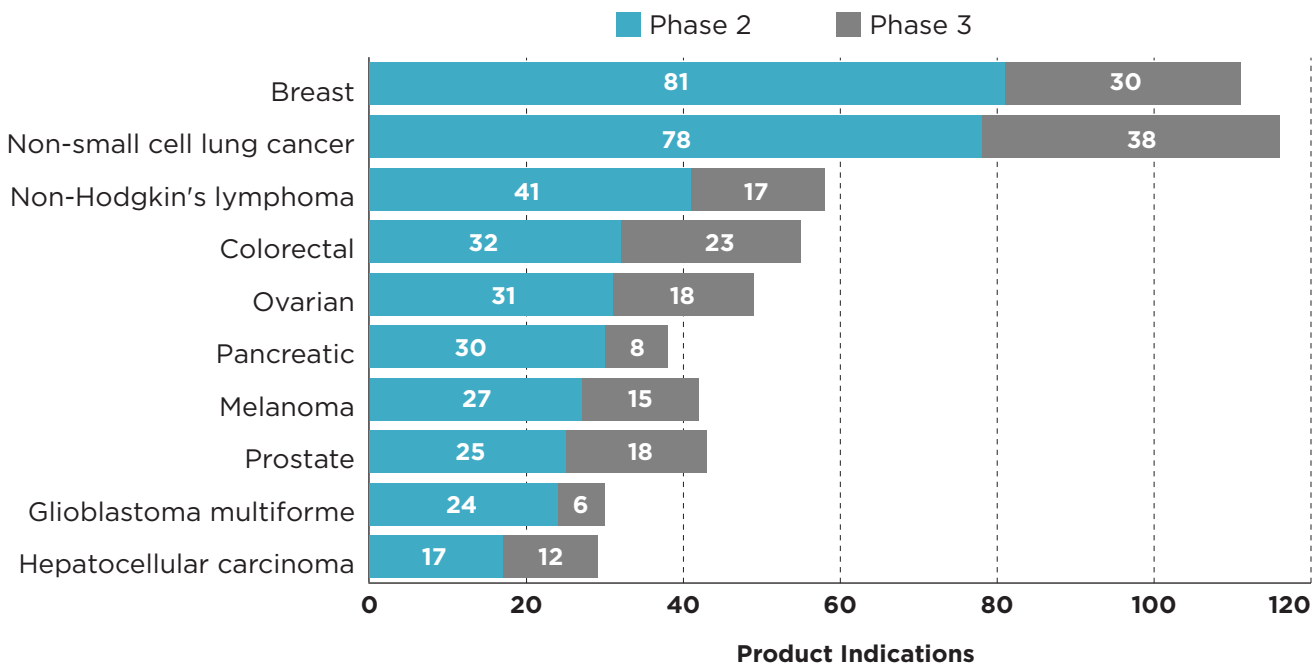
Until recently, there has not been much movement by the FDA since the Biologics Price Competition and Innovation Act (BPCI Act) of 2009 was passed in 2010. However, in February 2012, the FDA issued three draft guidance documents for the approval of biosimilars. Although these guidance documents add clarity to the abbreviated pathway for biosimilar approvals, there remain considerable challenges and questions for companies trying to bring biosimilars to market. *See Figure 65, Biosimilar Pipeline.*

FIG. 65 BIOSIMILAR PIPELINE

PRODUCT NAME	PROPOSED INDICATION	COMPANY	PHASE OF FDA STUDY	COMMENTS
Neutroval	Reduction in the duration of severe neutropenia and the incidence of febrile neutropenia in patients treated with established myelosuppressive chemotherapy for cancer	Teva	Phase 3 (completed)	Follow-on biologic for Neupogen (Amgen)
Lipegfilgrastim	Long-acting granulocyte colony-stimulating factors 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 Neulasta (Amgen)
Balugrastim	Long-acting granulocyte colony-stimulating factors 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 Neulasta (Amgen)
TL011	Rheumatoid arthritis	Teva	Phase 2	Follow-on biologic for Rituxan (Roche)
Filgrastim	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 Neupogen (Amgen). Sandoz's filgrastim biosimilar is already marketed under the brand name Zarzio in more than 30 countries outside the United States.
Pegfilgrastim	Long-acting granulocyte colony-stimulating factors 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 Neulasta (Amgen)
Rituximab	Rheumatoid arthritis	Sandoz	Phase 2	Follow-on biologic for Rituxan (Roche)
PF-05280586	Rheumatoid arthritis	Pfizer	Phase 1/2	Follow-on biologic for Rituxan (Roche)
Erythropoietin	Treatment of anemia associated with chronic renal failure	Hospira	Phase 3	Follow-on biologic for Epogen (Amgen)
Trastuzumab	Breast cancer and gastric cancer	Synthon	Preparing for phase 3	Follow-on biologic for Herceptin (Genentech). Synthon entered into a global license agreement with Amgen and Watson Pharmaceuticals.
BI 695501	Rheumatoid arthritis	Boehringer Ingelheim	Phase 1	Follow-on biologic for Humira (Abbott)

In 2012, non-small cell lung cancer (NSCLC) overtook breast cancer in the clinical research field with close to 120 agents in either phase 2 or 3 trials. New agents, as well as new indications, for existing drugs are being developed across all indications and lines of therapy. There has also been an increase in the number of clinical trials for agents used to treat breast cancer and non-Hodgkin's lymphoma. Personalized medicine has become an important focus in the development of these new drugs used to treat cancer. Many of the targeted agents in the pipeline will require accompanying genetic tests to ensure the medicine is tailored to the patient's specific genetic makeup. This will result in greater efficacy with less toxicity to the patient. *See Figure 66, Pipeline Drugs in Various Phases of Study for Key Cancer Types, and Figure 67, Selected Phase 3 Products by Key Cancer Type.*

FIG. 66 PIPELINE DRUGS IN VARIOUS PHASES OF STUDY FOR KEY CANCER TYPES



Adapted with permission from *Oncology Business Review.* Pipeline Online™. www.oncbiz.com. Accessed August 31, 2012.

FIG. 67 SELECTED PHASE 3 PRODUCTS BY CANCER TYPE

BREAST		
PRODUCT NAME	**CLASS**	**AREA(S) OF STUDY**
Afinitor	mTOR inhibitor	first-line metastatic breast cancer
Aromasin	aromatase inhibitor	breast cancer
arzoxifene	selective estrogen receptor modulator (SERM)	breast cancer
Avastin	antivascular endothelial growth factor (anti-VEGF) monoclonal antibody	adjuvant breast cancer (HER2+); adjuvant breast cancer (HER2-); second-line metastatic breast cancer; first-line metastatic breast cancer (HER2+); first-line metastatic breast cancer (HER2-)
denosumab	antireceptor activator of nuclear factor kappa-B ligand (RANKL) antibody	adjuvant breast cancer
Faslodex	oestrogen receptor antagonist	first-line metastatic breast cancer
Herceptin	antibody drug conjugate	adjuvant breast cancer (HER2+)
iniparib	poly (ADP-ribose) polymerase (PARP) inhibitor	first-line metastatic breast cancer (triple negative)
Ixempra	epothilone	adjuvant breast cancer
Myocet	nonpegylated liposomal doxorubicin	first-line metastatic breast cancer (HER2+)
neratinib	ErbB1 and ErbB2 inhibitor	first-line metastatic breast cancer (HER2+)
NeuVax	immunotherapy (peptide-based)	adjuvant breast cancer (HER2+)
Orazol	bisphosphonate (oral)	adjuvant breast cancer
ramucirumab	anti-VEGF monoclonal antibody	second-line metastatic breast cancer
Stimuvax	immunotherapy	second-line metastatic breast cancer
Tavocept	chemoprotective agent	first-line metastatic breast cancer
Tovok	epidermal growth factor receptor (EGFR)/ HER2 inhibitor	first-line metastatic breast cancer
trastuzumab emtansine	antibody drug conjugate	second-line metastatic breast cancer (HER2+)
Tykerb	ErbB2 and EGFR dual kinase inhibitor	adjuvant breast cancer; first-line metastatic breast cancer
Votrient (+ Tykerb)	multiple tyrosine kinase inhibitor	inflammatory breast cancer
Xeloda	fluoropyrimidine (oral)	adjuvant breast cancer
Zometa	bisphosphonate	breast cancer

NON-SMALL CELL LUNG CANCER (NSCLC)		
PRODUCT NAME	CLASS	AREA(S) OF STUDY
Abraxane	microtubule inhibitor	second-line metastatic NSCLC
Alimta	antimetabolite (a folic acid antagonist)	NSCLC
ARQ 197 (+ erlotinib)	c-Met kinase inhibitor	second-line metastatic NSCLC
Avastin	anti-VEGF monoclonal antibody	adjuvant NSCLC; NSCLC with previously treated central nervous system metastases
custirsen	clusterin inhibitor	first-line metastatic NSCLC
Erbitux	anti-EGFR monoclonal antibody	NSCLC; second-line metastatic NSCLC
erlotinib tablets	HER1/EGFR tyrosine kinase inhibitor	second-line metastatic NSCLC
GSK1572932A	immunotherapy	NSCLC
iniparib	poly (ADP-ribose) polymerase inhibitor	squamous NSCLC
Iressa	EGFR tyrosine kinase inhibitor	NSCLC
Lucanix	immunotherapy	NSCLC
MAGE-A3	antigen-specific cancer immunotherapeutic	first-line metastatic NSCLC
motesanib diphosphate	anti-VEGF receptors 1, 2 and 3 (VEGFR 1-3) (oral)	first-line metastatic NSCLC
motesanib diphosphate	VEGFR 1-3, platelet-derived growth factor receptor (PDGFR), c-Kit inhibitor (oral)	first-line metastatic NSCLC
necitumumab	EGFR inhibitor	NSCLC
Nexavar	multiple tyrosine kinase inhibitor	first-line metastatic NSCLC
Opaxio	microtubule inhibitor	NSCLC
Ostarine	selective androgen receptor modulator (SARM)	NSCLC
PF-00299804	pan-HER inhibitor	first-line metastatic NSCLC
ramucirumab	anti-VEGFR-2 monoclonal antibody	NSCLC
Stimuvax	immunotherapy	NSCLC
Sutent	multiple tyrosine kinase inhibitor	NSCLC
talactoferrin	dendritic cell-mediated immunotherapy (DCMI)	third-line metastatic NSCLC; first-line metastatic NSCLC
Tarceva	HER1/EGFR inhibitor	adjuvant NSCLC
Tavocept	chemoprotective agent	NSCLC
Telcyta	glutathione S-transferase P1-1 (GST P1-1) agonist	NSCLC (platinum resistant)
tivantinib (+ erlotinib)	c-Met inhibitor	second-line metastatic NSCLC
Tovok	EGFR/HER2 inhibitor	NSCLC
Vargatef	multiple tyrosine kinase inhibitor (VEGFR; fibroblast growth factor receptor, FGFR; PDGFR)	NSCLC
Zaltrap	VEGF-A inhibitor	second-line metastatic NSCLC

NON-HODGKIN'S LYMPHOMA (NHL)		
PRODUCT	**CLASS**	**AREA(S) OF STUDY**
Adcetris	antibody drug conjugate (anti-CD30)	cutaneous T-cell lymphoma (CTCL)
Afinitor	mTOR inhibitor	diffuse large B-cell lymphoma (DLBCL)
afutuzumab (GA101/RG7159)	anti-CD20 monoclonal antibody (humanized)	NHL
Arzerra	anti-CD20 monoclonal antibody (humanized)	second-line f-NHL
Avastin	anti-VEGF monoclonal antibody	DLBCL
belinostat	histone deacetylase (HDAC) inhibitor	second-line metastatic peripheral T-cell lymphoma (PTCL)
BiovaxID	immunotherapy	follicular non-Hodgkin's lymphoma (f-NHL)
enzastaurin	serine/therenine kinase inhibitor	DLBCL
Folotyn	antifolate	PTCL; CTCL
Marqibo	liposomal vincristine	NHL
pixantrone	anthracycline	second-line diffuse large B-cell NHL
Revlimid	immune system modulator	NHL
Treanda	alkylating agent	first-line metastatic PTCL
Velcade	proteasome inhibitor	second-line f-NHL
Zevalin	CD20-directed radiotherapeutic antibody	f-NHL

COLORECTAL		
PRODUCT NAME	**CLASS**	**AREA(S) OF STUDY**
Aptocine	light-activated drug treatment	first-line metastatic colorectal cancer
axitinib	multiple tyrosine kinase inhibitor (VEGFR 1, 2 and 3; PDGFR; c-KIT)	second-line metastatic colorectal cancer
brivanib	VEGFR-2 inhibitor	first-line metastatic colorectal cancer
Erbitux	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)	AKT inhibitor	second-line metastatic colorectal cancer
ramucirumab	anti-VEGFR-2 monoclonal antibody	first-line metastatic colorectal cancer
Recentin	multiple tyrosine kinase inhibitor (VEGFR 1, 2 and 3)	colorectal cancer
S-1	fluoropyrimidine (oral)	colorectal cancer
Tarceva	HER1/EGFR inhibitor	colorectal cancer
TheraSphere	yttrium-90 microspheres	liver metastases in colorectal patients
Vectibix	anti-EGFR monoclonal antibody (humanized)	first-line metastatic colorectal cancer
Xeloda	fluoropyrimidine (oral)	first-line metastatic colorectal cancer; second-line metastatic colorectal cancer; adjuvant colorectal cancer
Zaltrap	VEGF-A inhibitor	second-line metastatic colorectal cancer

OVARIAN		
PRODUCT	CLASS	AREA(S) OF STUDY
alkeran	alkylating agent	ovarian cancer
AMG 386 (paclitaxel)	Fc-peptide fusion protein targeting angiopoietins (peptibody)	second-line metastatic ovarian cancer
Avastin	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	IgG1 monoclonal antibody (humanized)	second-line metastatic ovarian cancer
Hycamtin	topoisomerase inhibitor	first-line metastatic ovarian cancer
iniparib	PARP inhibitor	platinum-sensitive and platinum-resistant ovarian cancer
Karenitecin	highly lipophilic camptothecin	ovarian cancer
Opaxio	microtubule inhibitor	ovarian cancer
patupilone	epothilone	ovarian cancer
phenoxodiol	multiple signal transduction regulator	ovarian cancer
Tarceva	HER1/EGFR inhibitor	ovarian cancer
Vargatef	multiple tyrosine kinase inhibitor (VEGFR, FGFR, PDGFR)	ovarian cancer
Yondelis	marine-derived antitumoral agent	second-line metastatic ovarian cancer

PANCREATIC		
PRODUCT	CLASS	AREA(S) OF STUDY
ganitumab	insulin-like growth factor-1 receptor (IGF-1R) inhibitor (monoclonal antibody)	pancreatic cancer
larotaxel	taxane (semi-synthetic)	pancreatic cancer
mastinib	multiple tyrosine kinase inhibitor	pancreatic cancer
PN401 (formerly vistonuridine)	uridine prodrug	pancreatic cancer
S-1	fluoropyrimidine (oral)	pancreatic cancer

MELANOMA		
PRODUCT	CLASS	AREA(S) OF STUDY
Abraxane	microtubule inhibitor	first-line metastatic melanoma
Allovectin	immunotherapy	first-line metastatic melanoma
BRF113683	BRAF inhibitor	first-line metastatic melanoma
Delcath system	drug delivery platform	first-line metastatic melanoma in the liver
GSK1120212	MEK inhibitor	first-line metastatic melanoma
GSK2118436	BRAF inhibitor	first-line metastatic melanoma
MAGE-A3	antigen-specific cancer immunotherapeutic	first-line metastatic melanoma
Nexavar	multiple tyrosine kinase inhibitor	melanoma
Oncophage	immunotherapy	first-line metastatic melanoma
Pegintron	PEG recombinant alpha-2b interferon	melanoma
talimogene laherparepvec (formerly OncoVEX GM-CSF)	modified herpes-simplex 1 virus injected directly into tumor	first-line metastatic melanoma
Yervoy	anti-CTLA4 monoclonal antibody (humanized)	adjuvant melanoma; second-line metastatic melanoma
Zedaxin	immune system modulator	melanoma

PROSTATE		
PRODUCT NAME	**CLASS**	**AREA(S) OF STUDY**
Alpharadin	alpha-emitting radiopharmaceutical	treatment of bone metastases in hormone refractory prostate cancer (HRPC)
Avastin	anti-VEGF monoclonal antibody	HRPC
custirsen	clusterin inhibitor	first-line metastatic castration-resistant prostate cancer (CRPC)
custirsen (+ cabazitaxel)	clusterin inhibitor	second-line metastatic CRPC
DCVax	immunotherapy	prostate cancer
enzalutamide (formerly MDV3100)	oral androgen receptor antagonist	first-line metastatic prostate cancer
Jevtana	taxane	first-line HRPC
MDV3100	SARM	HRPC
OGX-427	Hsp27 inhibitor	first-line metastatic prostate cancer
orteronel	nonsteroidal androgen synthesis inhibitor (oral)	first-line metastatic CRPC
phenoxodiol	multiple signal transduction regulator	prostate cancer
Revlimid	immune system modulator	prostate cancer
Sutent	multiple tyrosine kinase inhibitor	HRPC
Zaltrap	VEGF-A inhibitor	first-line metastatic HRPC
Zytiga	inhibitor of the steroidal enzyme 17 alpha-hydroxylase/C17,20 lyase (oral)	first-line metastatic HRPC

GLIOBLASTOMA MULTIFORME (GBM)		
PRODUCT NAME	**CLASS**	**AREA(S) OF STUDY**
Avastin	anti-VEGF monoclonal antibody	GBM; second-line metastatic GBM
cintredekin besudotox IL-13	interleukin-13 (IL-13) and PE38 recombinant protein	GBM
NovoTTF-100A System	tumor treating fields therapy	first-line metastatic GBM
Recentin	multiple tyrosine kinase inhibitor (VEGF 1, 2 and 3)	second-line metastatic GBM
Temodar	alkylating agent	first-line metastatic GBM

SARCOMA		
PRODUCT NAME	**CLASS**	**AREA(S) OF STUDY**
AVE8062	vascular disrupting agent	sarcoma
Mepact	macrophage activator	osteosarcoma
ridaforolimus	mTOR inhibitor	soft tissue or bone sarcoma
TH-30	hypoxia-activated prodrug	first-line metastatic soft tissue sarcoma
Yondelis	marine-derived antitumoral agent	second- and third-line metastatic soft tissue sarcoma; first-line metastatic soft tissue sarcoma
Zymafos	ifosfamide metabolite	first-line metastatic soft tissue sarcoma

Key Legislative Outcomes — 2012

2012 ONCOLOGY POLICY UPDATES

Legislative, regulatory and marketplace changes continue to affect oncology care and practice management. At the eleventh hour, Congress once again prevented the double-digit sustainable growth rate (SGR) reductions. The American Tax Relief Act (ATRA) held the 2012 conversion factor the same in 2013 and for the short term avoided the 2 percent across-the-board cut that would affect physician payments required by sequestration. Congress must act to prevent the 2 percent across-the-board cuts in March 2013.

As in years past, Congress avoided the significant physician fee schedule cuts for the short term, one year, but did nothing to address the longer term problems with the sustainable growth rate formula. However, some Congressional members continue to pursue a longer term fix.

While states scramble to make critical decisions related to health care reform, federal issues, such as the physician payment fix and sequestration, further the uncertainty under which oncologists must practice. Uncertainty will continue throughout 2013 and 2014 as states prepare for health care reform and/or expand state Medicaid eligibility. The following is a review of significant policy and marketplace trends facing oncology providers today, including health care reform, molecular diagnostics and biosimilars, and experimental payment models.

HEALTH CARE REFORM STATUS: 2012

SUPREME COURT DECISION

On June 28, 2012, the Supreme Court upheld the Affordable Care Act (ACA), with the exception of the mandated Medicaid expansion. The court found that 1) the individual mandate is constitutional under Congress's taxing authority and 2) Medicaid expansion is constitutional only if states are not penalized or do not have existing Medicaid funding threatened if they choose not to comply with the expansion requirements. This converts the mandated health care reform Medicaid expansion (to 133 percent of the federal poverty level [FPL] for all individuals, including able-bodied adults) to an optional state expansion.

Since the Court generally upheld the ACA, attention turns to the states for key decisions regarding Medicaid expansion and implementation of the health benefit exchanges. Late in 2012, the Department of Health and Human Services finally issued proposed rules related to the essential health benefits and other operating details for the health exchanges. Final regulations are expected early in 2013. As open enrollment in October of 2013 draws near, states are scrambling to implement plans for health benefit exchanges. For the initial years of the state exchanges, more than half of states are anticipated to rely on federally run state health exchanges. While the exchanges will be run federally, the benchmarks which guide the essential health benefits in the state will be based on state-selected benchmarks.

MEDICAID EXPANSION

In August 2012, HHS announced that there is no deadline for states to make a decision regarding the Medicaid expansion — states may expand Medicaid eligibility at any time. Further, states may drop the expansion population at any time, providing flexibility for states and uncertainty for providers.

Late in 2012, HHS clarified the statute does not allow for the enhanced Federal Medical Assistance Percentage (FMAP), not offered to states for the newly eligible population, will not be available if a state expands its Medicaid program to a level below the 133 percent threshold. Depending on the federal policies and state action, the end result could be a scenario in which a group of the most vulnerable patients could fall in a gap between state Medicaid eligibility and federal subsidies through the exchange.

Governors from conservative Southern states (Florida, Louisiana, Mississippi, South Carolina and Texas) have publicly announced they do not intend to participate in the expansion. However, these announcements are largely political in nature. Medicaid expansion will likely be debated in state legislatures throughout the end of 2012 and 2013.

EXCHANGE IMPLEMENTATION

Exchange Structure and Requirements

Under the ACA, as upheld by the Supreme Court, all states must have a Health Insurance Exchange (Exchange) operating by January 1, 2014. There are three options for states: 1) state-based Exchange, 2) federal-state partnership Exchange or 3) federally facilitated Exchange. Each Exchange will offer coverage to two separate groups — individuals and employees of qualifying small businesses.

States must submit an Exchange blueprint to HHS by November 16, 2012, if they intend to operate a state-based Exchange or enter into a partnership Exchange with the federal government. HHS will then provide states with approval if the Exchange meets the requirements and will be ready for enrollment starting in October 2013. If states do not submit a blueprint, HHS will begin preparations for a federally facilitated Exchange.

For HHS to provide approval, an Exchange must be able to do the following:

- Provide consumer support for coverage decisions
- Facilitate eligibility determinations for individuals
- Provide for enrollment in qualified health plans (QHPs)
- Certify health plans as QHPs
- Operate a Small Business Health Options Program (SHOP)

Benchmarks and Essential Health Benefits

In order for a health plan to be a QHP, it must meet or exceed the state essential health benefit (EHB) benchmark. States have the following four options in choosing a coverage benchmark:*

1. The largest plan by enrollment in any of the three largest small group insurance products in the state's small group market
2. Any of the largest three state employee health benefit plans by enrollment
3. Any of the largest three national federal employee health benefits programs by enrollment
4. The largest insured commercial non-Medicaid HMO operating in the state

*Note: If a state does not choose a benchmark, the benchmark will default to the largest small group insurance product by enrollment. There will be no federal benchmark; each state will have its own based on choice or default.

Given this model outlined by HHS, providers are likely to be familiar with the benefits of the state exchange QHPs as they will be similar to a plan with significant enrollment in the state.

HEALTH CARE REFORM AND ANTICANCER COMPENDIA IMPLICATIONS

As they stand, existing federal statute and current Centers for Medicare & Medicaid Services (CMS) guidelines on the Exchanges and the EHB benchmarks do not explicitly

STATE-BASED EXCHANGE

State operates all Exchange activities; however, the state may use federal government services for the following:

- Premium tax credit and cost-sharing reduction determination
- Exemptions
- Risk-adjustment program
- Reinsurance program

STATE PARTNERSHIP EXCHANGE

State operates activities for:

- Plan management
- Consumer assistance
- Both

State may elect to perform or can use federal government services for the following activities:

- Reinsurance program
- Medicaid and CHIP eligibility: assessment or determination

FEDERALLY FACILITATED EXCHANGE

HHS operates; however, state may elect to perform or can use federal government services for the following activities:

- Reinsurance program
- Medicaid and CHIP eligibility: assessment or determination

address compendia protections in oncology. The lack of clarity regarding compendia coverage could put access to compendia-listed oncology care at risk for the health exchange benefit population.

Federal Medicare/Medicaid Compendia Standard: At this time, no policy at the federal level, as currently defined, compels the plans in the Exchanges to apply the Medicare/Medicaid anticancer compendia coverage standards to the EHB package in the qualified health plans. It is unclear at this time the extent to which CMS has the authority to require the state exchange plans to extend coverage for compendia-listed therapeutics if they are not included in the selected state benchmark plan.

State Mandates for Anticancer Compendia Coverage: States operating a state-based Exchange could follow two paths to cover compendia-listed oncolytics. The first and most expedient would be for the state to select a benchmark plan that currently includes mandated coverage for compendia-listed anticancer uses. CMS could further address this issue in the context of state mandates in subsequent guidance.

The second path would be for the state legislature to apply existing or new compendia language to the state benchmark. State legislatures could apply the same language to state health benefit exchange laws during the upcoming legislative session in January 2013. Through this route, the legislative mandates may not apply in the initial 2014/2015 plan years based on the existing HHS direction regarding state mandates. However, it is unclear whether compendia coverage considerations are considered a mandate in this sense. Further clarification regarding state mandates is expected in subsequent CMS guidance late in 2012 or 2013.

NEW FRONTIERS: MOLECULAR DIAGNOSTICS AND BIOSIMILARS

EVOLUTION OF 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. Companion diagnostics are molecular laboratory tests that typically screen certain patient types as candidates for targeted therapeutics. Increased knowledge of the human genome is one main reason for the growth in this area. As knowledge of the human genome is translated into clinical applications — identifying patients who have a clinically significant genetic marker or mutation — therapy can be effectively targeted, resulting in more efficient treatment practices and an increase in the significance of molecular diagnostics.

Use of genetic/genomic testing has rapidly increased in recent years, and consequently, payors and providers have begun to question the coding, coverage and reimbursement of genetic testing, as well as the overall management of molecular diagnostics and the related companion therapeutics. Over the past two years, the American Medical Association (AMA) created a new section of current procedural terminology (CPT) codes to better identify molecular diagnostic tests. The AMA will implement the new specific code section in 2013, but it is unclear how reimbursement of molecular diagnostics will change. Due to the coding changes, payors, including CMS, have begun to reevaluate how they cover and pay for these tests.

Further clarification of the CMS plan regarding molecular diagnostics is expected toward the end of 2012. The decisions by CMS regarding these tests could affect provider reimbursement as well as patient coinsurance obligations. Furthermore, as these tests are more clearly identified by payors, payors will likely begin to specify more management of the molecular testing, as well as the related therapeutics.

In 2013, providers should look for more payor management regarding molecular diagnostics. Likewise, treatment guidelines and recommendations regarding molecular testing are expected in 2013.

BIOSIMILARS POLICY DEVELOPMENT

The Biologics Price Competition and Innovation Act of 2009 amended the Public Health Service Act to create an abbreviated licensure pathway for products that are biosimilar to a biological reference product licensed by the FDA. Biosimilars are also referred to as follow-on biologics. In early 2012, the FDA released three draft guidance documents on the regulation of biosimilars and the interchangeability of follow-on biologics. The guidance documents begin to define terms such as “biosimilar” and “interchangeability.” These terms will be important as stakeholders look to develop policies for management of follow-on biologics and their reference products. To date, the FDA has not finalized these draft guidance documents.

On a related note, CMS does not make distinctions between biosimilars and biosimilars that are interchangeable in its policies to date. CMS policies to date indicate that the pay-

ment amount for physician-administered biosimilar products will be determined based on the average sales price (ASP) of all the national drug codes (NDCs) assigned to the Healthcare Common Procedure Coding System (HCPCS) code for the reference product (original product) and the new biosimilar product, regardless of interchangeability.

MARKETPLACE: EXPERIMENTAL PAYMENT SYSTEMS

Commercial payors, most notably United Health Care (UHC) in oncology, have been experimenting for a number of years with payment reform concepts to manage costs such as gain sharing, risk sharing, shared savings, bundled payments, global capitation and newer arrangements like care coordination through medical homes. In 2012, under authority granted through the Affordable Care Act, CMS has gotten into the game as well. Such initiatives are directed through the CMS Center for Medicare & Medicaid Innovation (CMMI).

CMMI is engaged in a number of different types of payment reform programs and demonstrations, including, but not limited to, accountable care organizations (ACOs) with shared savings, bundled payments currently focusing on post-acute care and other financial alignment initiatives (e.g., state demonstrations to integrate care for the dual eligible population), care coordination and Medicaid incentives for the prevention of chronic diseases. Under each type of program or demonstration, there are various stakeholders engaged in ongoing activities to improve quality of care and health outcomes, while controlling increasing costs. Among the numerous CMMI demonstrations, pilots and grants, CMMI has awarded only one oncology-related grant. While Medicare has not focused on oncology initially, CMS is sure to expand in oncology in the coming years.

The initial oncology grant was awarded for a national oncology medical home pilot project, the first of many such projects in Medicare, and continued experimentation commercially. Payment experimentation across the health care system and specifically in oncology continues to evolve and move beyond chemotherapeutics. In August 2012, 21st Century Oncology announced a radiation oncology bundled payment agreement with one of the nation's largest oncology group practices and Humana Inc., one of the nation's largest payors.

ONCOLOGY MEDICAL HOME GRANT

CMMI awarded a $19.7 million grant to a group of oncology practices organized as Innovative Oncology Business Solutions. The practices are some of the largest in the country, including Florida Infusion, Tennessee Oncology and practices in Georgia, Maine, New Mexico and Pennsylvania. The goal of the project is to test a model of care delivery focused on the medical home, or gatekeeper, for newly diagnosed or relapsed Medicare and Medicaid beneficiaries and commercially insured patients with breast, lung or colorectal cancer. The idea of the medical home has been studied by John Sprandio in Pennsylvania and modeled in demonstration in commercial plans, such as Blue Cross and Blue Shield of Michigan and United. The goal is to reduce unnecessary and avoidable hospitalizations and emergency room visits, seek a reduction in unnecessary diagnostic or radiation/imaging testing, and provide patient education on treatment protocols, treatment plan choices and end of life. Interestingly, the project is seen as a business driver in that the demonstration aims to hire 115 new positions across the seven practices.

RADIATION ONCOLOGY DEMONSTRATION

Recently, 21st Century Oncology, a Florida-based radiation group, reached an agreement with Humana Inc. to provide the first bundled payment methodology for radiation oncology treatments. The contract covers more than 130 employed radiation oncologists in 16 states and uses the same methodology the Radiation Therapy Alliance is proposing to CMS. Bundled payments will be used for 13 cancer types, including prostate, breast and lung, with an ultimate goal of having episode-based payments in place for all major cancer types. The bundles are based on diagnosis codes for ICD-9 (International Statistical Classification of Diseases and Related Health Problems), and the payment encompasses patient consultation, computed tomography scans and other imaging needed to plan the patient's radiation therapy, radiation dosimetry, treatment delivery and follow-up for 90 days.

As one of the nation's leading authorities in the management of specialty pharmaceuticals, including high-cost oral and infused/injected anticancer therapies, Magellan Pharmacy Solution has been closely following these demonstrations, as well as several high-profile commercial pathway projects, including those focused on the bundling of cancer care products and services. All these initiatives occur at a time when ACOs continue to evolve with public and private payors alike. All the payment experimentation may lead to significant changes in the payment and structure of payor-provider relationships across payment settings. This payor experimentation is context for Medicare debates set to begin following the November elections, given the physician fee fix and sequestration; some stakeholders are arguing that bigger changes than a temporary "physician fix" to the Medicare physician-fee schedule is needed.

Glossary

ACA	Affordable Care Act
ACO	accountable care organization
AMA	American Medical Association
ASP	average sales price
AWP	average wholesale price
BCA	breast cancer
BPCI Act	Biologics Price Competition and Innovation Act
BRCA	breast cancer susceptibility gene
BRM	biologic response modifier
CA	cancer
CHIP	Children's Health Insurance Program
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
DCMI	dendritic cell mediated immunotherapy
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
FMAP	Federal Medical Assistance Percentage
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
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
HMO	health maintenance organization
HRPC	hormone refractory prostate cancer
ICD	International Classification of Diseases
IGF-1R	insulin-like growth factor-1 receptor
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
mBC	metastatic breast cancer
MEC	moderate emetogenic chemotherapy

MMA . . . . . Medicare Modernization Act
NCCN . . . . . National Comprehensive Cancer Network
NDC . . . . . national drug code
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
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
SARM . . . . . selective androgen receptor modulator
SERM . . . . . selective estrogen receptor modulator
SGR . . . . . sustainable growth rate
SHOP . . . . . small business health options program
SOS . . . . . site of service
SPP . . . . . specialty pharmacy provider
UM . . . . . utilization management
VEGF . . . . . vascular endothelial growth factor
VFS . . . . . variable fee schedule
WAC . . . . . wholesale acquisition price

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