MEDICAL PHARMACY & ONCOLOGY TREND REPORT™

2011 SECOND EDITION

ICORE HEALTHCARE
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A Benchmark for Medical Pharmacy

iCore HEALTHCARE
A Magellan Health Company

Medical Pharmacy — The Future of Specialty Drugs and Overall Pharmacy Benefit Management

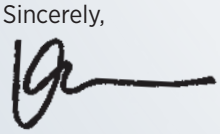
It is our pleasure to present you with ICORE Healthcare's 2011 Medical Pharmacy & Oncology Trend Report™. This is the second edition of this report, and it has been enhanced this year by showing year-over-year changes in costs, trends, and payor management tools for provider-administered specialty products, which are paid under the medical benefit. As in the past, various reports exist to describe specialty and oral chemotherapy products paid under the pharmacy benefit; however, no other source exists for 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 traditional oral pharmacy products associated with few U.S. Food and Drug Administration approvals when compared with specialty products. This finding will continue to prevail, in part due to the oncology pipeline, which is even more robust than it was in 2010 – specifically, there is a 16 percent increase in the number of phase 2 oncology agents, as well as a 10 percent increase in the number of phase 3 oncology agents year over year. With this continued growth, specialty drugs, and in particular those that are provider administered, will come to dominate the pharmacy market, so knowing the extent and impact of medical injectable costs and trends is more critical now than ever.

To understand these costs and trends, as well as the payor initiatives used this year compared with 2010, we surveyed 60 medical, pharmacy, and clinical directors, representing health plans that provide medical and pharmacy benefits to 153 million commercial members. We then evaluated the paid claim files of health plans' medical benefit injectables such that benchmarks and trends could be determined.

We want to offer special thanks to the payor executives who served on this year's ICORE Healthcare 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,



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A Benchmark for Medical Injectables

In 2011, nearly all payor executives identified provider-administered injectable drugs as a cost driver and concern, and the majority of these industry experts reported specific concerns related to the *overall cost* of medical benefit drugs, which is a threat to cost of care. As a result, and documented within this report, payors have implemented internal and external partnership cost management strategies to mitigate this threat.

This year, a key cost driver includes the transition from office-based to facility-based administration; in fact, during the past few years, consolidation and acquisition activities have had a tremendous impact on office-based providers, which serve as the largest site of service for provider-administered injectables. In addition, significant utilization increases were found in niche therapies such as Lucentis, Xolair, and Tysabri.

Offsetting these increases were lower utilization of Avastin for breast cancer and the introduction and expansion of generic Taxotere and Eloxatin. Erythropoiesis-stimulating agents (ESAs), such as Procrit and Aranesp, continued their downward utilization trend. As a result, per-member-per-month costs were consistent with 2009 at just over $12, although this flat trend is likely, in part, a result of the relatively aggressive cost-management efforts in place in many of the payors from whom the data were extracted. We expect to see modest trend increases this year, partly due to several new high-cost therapies entering the market. As a result, payors will have to continue to focus on cost and utilization management strategies to effectively manage this trend.

Our second issue of this Medical Pharmacy & Oncology Trend Report™ features two key sections. The first outlines our findings from the study of medical, pharmacy, and clinical directors at 60 payors across the United States ranging in size from 30,000 lives to more than 20 million lives. This section contemplates current and future cost-management techniques across six key medical injectable drug management drivers, as shown in the table. Note that our findings for this section are generally reported as percent of covered lives rather than percent of payors, since nearly two-thirds of covered lives are enrolled in the 10 largest payors, and a bias may thus be introduced.

Many of the benchmarks and statistics found in this report are not available elsewhere. Because of this, coupled with frequent requests from our customers and partners, you may access the report at **www.icorehealthcare.com/trends.aspx**

The second section of this report uses paid medical benefit claims from commercial payors to describe the spend, trend, and utilization of medical benefit injectables from 2009 and 2010, across all key sites of service. A review of the medical pharmacy pipeline and new regulations are also described within this report.

SIX KEY MEDICAL INJECTABLE DRUG MANAGEMENT DRIVERS

DRIVERS	HOW DO YOU KNOW IF YOUR STRATEGY IS WORKING?
Medical benefit drug formulary	Do you receive rebates? Are you encouraging the use of high-quality, lower-cost products?
Provider reimbursement	Does your approach improve drug mix and utilization?
Benefit design	What is your benefit plan for the next three years? Does it eclipse member contribution limits?
Distribution channel management	Does your strategy encourage provider-office administration?
Utilization management (UM)	Do your UM functions support standard of care prescribing and preferred products?
Operational improvements	What is your plan to correct payment errors and fraud?

2011 Survey Methodology and Demographics

The methodology for this second edition of ICORE Healthcare's 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 supportive care.

- 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 ICORE Healthcare.
- The second section of the report was derived from secondary analyses of health plan medical and pharmacy paid claims data. An exciting addition to this year's report is that the analyzed 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.

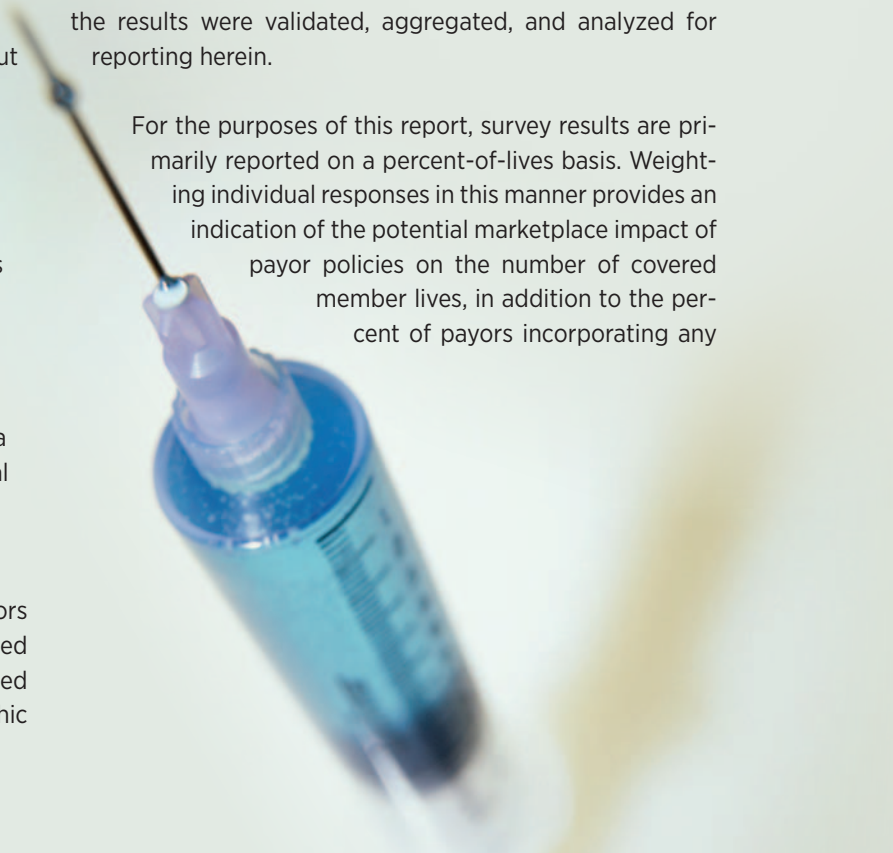
HEALTH PLAN SURVEY METHODOLOGY

As in our previous report 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 the payor advisory board and align 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 2010 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, ICORE Healthcare's parent company.

The period of data collection took place over a three-week period during June and July 2011. Following data collection, the results were validated, aggregated, and analyzed for reporting herein.

For the purposes of this report, survey results are primarily reported on a percent-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 percent 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.

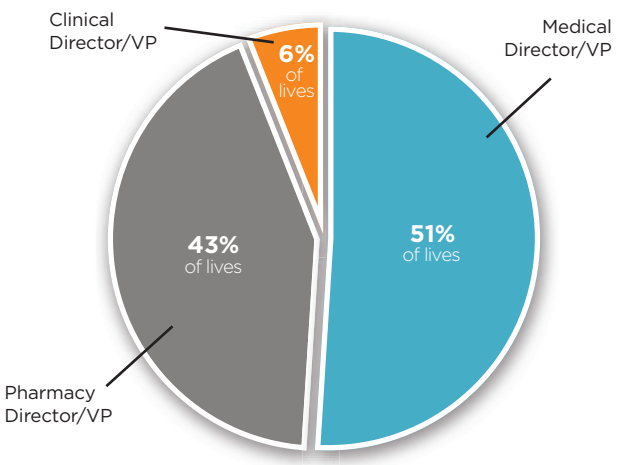
A total of 60 individual survey responses were received. As noted in the table below, these 60 health plans manage 153.2 million lives, a slight increase over the 146.3 million covered lives reported in 2010.

Seventy percent of the health plan organizations that responded in 2011 also provided responses to the 2010 survey. When evaluating year-to-year trends, the entire sample of 2011 respondents is compared with the respondents in 2010. The demographic composition of the year-to-year respondents is consistent; only slight differences exist in the composition of the base.

SURVEY RESPONDENT COMPOSITION

	COUNT	LIVES	% OF LIVES	% OF PLANS
Fewer than 500,000	23	5,452,100	4%	38%
500,000 to 999,999	16	10,538,000	7%	27%
1,000,000 to 4,999,999	15	32,970,500	21%	25%
5,000,000 or more	6	104,190,000	68%	10%
TOTAL	**60**	**153,150,600**	**100%**	**100%**

REPRESENTATION OF SURVEY RESPONDENTS



Current survey respondents tended to be very experienced with an average of 22 years in the field and nine years in their current positions. Year to year, there was a similar split between the lives represented by medical director respondents (51 percent) and those of pharmacy directors/clinical pharmacists (49 percent). Internal medicine, family practice, 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, 77 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 HMO/PPO products. Additionally, two-thirds of total covered lives reflect commercial product coverage.

Survey respondents from national plans reflect 20 percent of the respondents, yet they cover two-thirds (67 percent) of the total lives represented in this survey. Conversely,

regional plans have a larger percentage of payor respondents (80 percent), but reflect only 33 percent of the total covered lives.

The map below illustrates that geographically about half the covered lives of these regional payor respondents are located in the nation's heartland, with the balance divided across the East and West Coast states.

HEALTH PLAN CLAIMS DATA ANALYSES

ICORE Healthcare analyzed health plan paid claims data that included both paid medical and pharmacy claims for full year 2009 and 2010. These claims represent a 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 LOB, sites of service (SOS), and both the medical and pharmacy benefits. For example, the claims set is inclusive of:

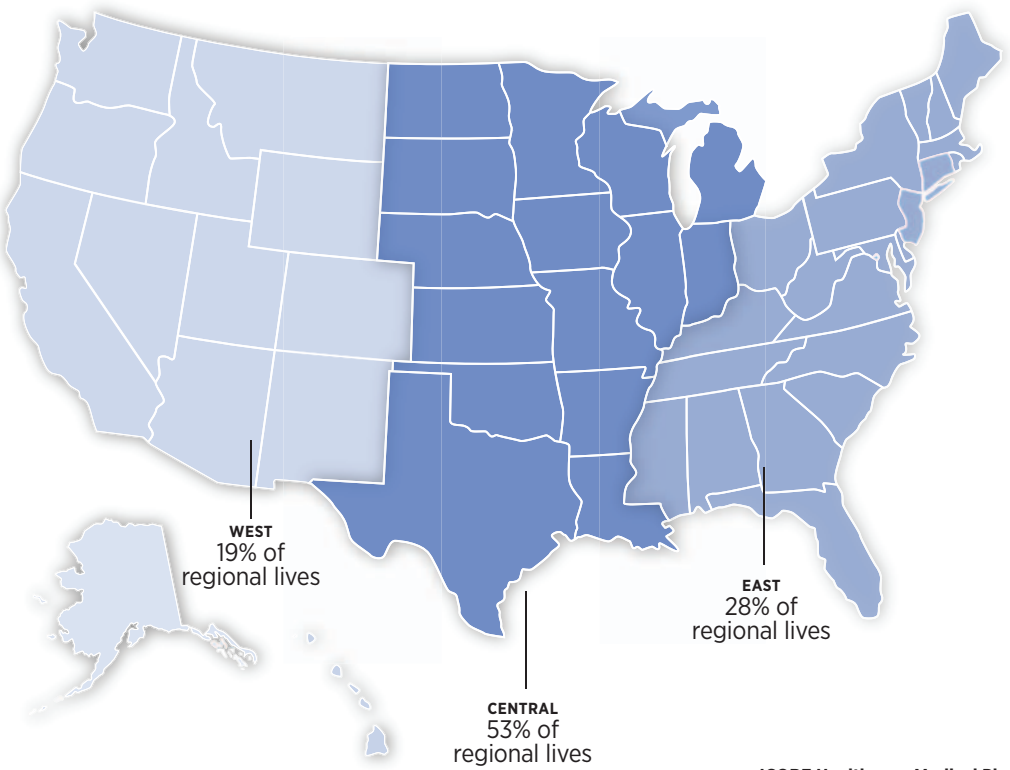
- Commercial, Medicare, and managed Medicaid products
- Multiple sites of service:
  - Medical claims – physician office, outpatient hospital, home infusion, specialty pharmacy
  - Pharmacy claims – retail, specialty pharmacy

Where appropriate, the current 2010 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 2011 over 2010 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 relies not on projections but represents allowed claims actually paid by health plans. We have included 24 months of claims data (2009 and 2010) where available to strengthen trending ability.

REGIONAL PLANS – GEOGRAPHIC DISTRIBUTION OF LIVES



Report Summary and Conclusions

ICORE Healthcare's 2011 Medical Pharmacy & Oncology Trend Report™ evaluated injectable quality and cost management tools and trends of senior leaders from commercial payors and paid claims across LOB, SOS, and both the medical and pharmacy benefit.

Key findings of this report include:

- Consistent with last year, at least some medical injectable formulary management occurs at the vast majority of payors, with supportive therapy, such as ESAs, being the most common target.
- Plans representing over three-fourths of the covered lives receive rebates for at least one injectable paid under the medical benefit. Biologic response modifiers (BRMs) are the most common source for these rebates.
- For the most part, average wholesale price (AWP)-based reimbursement has been replaced by average sales price (ASP) reimbursement.
- Less than half of commercial payors (41 percent) subject their members to a coinsurance for medical injectables, and the average coinsurance amount is 20 percent of the drug cost. Half of the payors also subject their members to a drug copay.
- Relatively few payors (18 percent) require only a copay for medical injectable products, and that copay averages $46.
- Genomic testing continues to play an increasingly important role in determining patient potential for positive therapeutic outcomes; the majority of lives, for instance, are subjected to HER2 (84 percent) or KRAS (82 percent) testing prior to specific chemotherapeutic selections.
- Most payors offer breast cancer, colorectal cancer, and prostate cancer screenings that aim to meet Healthcare Effectiveness Data and Information Set (HEDIS) measures; smoking cessation programs are offered to a lesser degree. Compliance with these screenings is variable, averaging 68 percent, 59 percent, 58 percent, and 35 percent, respectively.
- The cost of claims for medical injectables used to treat cancer account for about half of medical benefit injectable costs associated with the claims analyzed. Oral chemotherapies, which are generally paid under the pharmacy benefit at a health plan, account for about one-tenth of the total cost of drugs used to treat cancer.
- The top 10 medical injectable drugs accounted for over 55 percent of the overall medical injectable benefit spend in 2010.
- Cost per claim varies widely for these products depending on where the service to the patient occurs. Costs associated with medical injectables infused within a facility are about twice those of the same products when administered in a provider's office.
- Significantly less than 1 percent of total spend is paid under the classic "dump" code.
- The pipeline for cancer drugs is very robust; breast cancer continues to lead the clinical research field with over 100 agents in either phase 2 or 3 trials across all indications and lines of therapy.
- The legislative environment continues to be challenging and evolving at both the federal and state levels. This is especially true in oncology where legislation around off-label coverage, member contribution parity between oral and IV therapies, biosimilars, and marketplace dynamics shifting site of care out of the oncologist office to facilities is creating pressure. This will likely result in continued increases in the cost of care delivered across the health care system, if the trend continues unabated.

We know you will find this report novel and useful. Access the data at www.icorehealthcare.com/trends.aspx

PAYOR SURVEY DATA

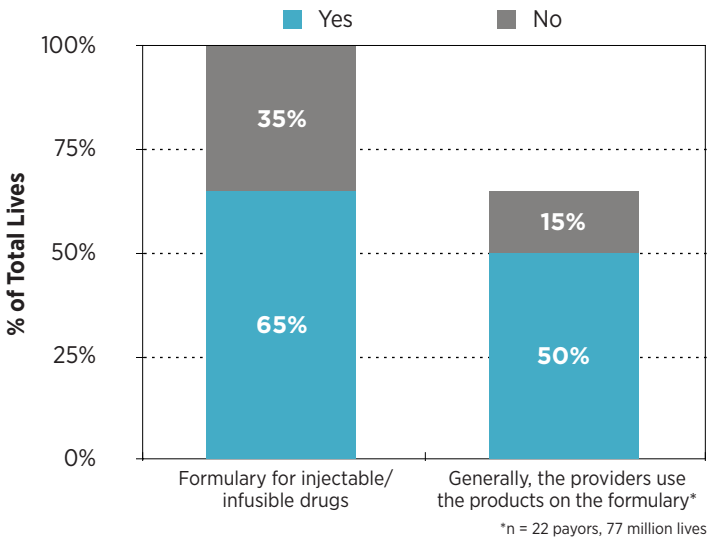
Medical Benefit Drug Formulary

In this year's study of commercial payors, health plans covering about two-thirds of lives (65 percent) operate with established medical benefit injectable drug formularies, which is not statistically different from the 75 percent of covered lives reported by payors in 2010. Consistent with 2010, payors report that their provider network generally complied with the plans' formularies. The likelihood of having a formulary was directionally greater among the smaller payors, as defined by less than 500,000 member lives. *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 100 million members most likely to be subjected to medical formulary requirements, almost all were for ESAs and intravenous immune globulin (IVIG) products. Further, we found that BRMs were under formulary management for two-thirds of the members. This year, we asked an additional question as to which BRMs are subjected to a medical formulary. A wide array of BRMs were included, specifically, Remicade, Orencia, Enbrel, Procrit, Humira, and Rituxan. *See Figure 3, Therapeutic Classes With a Medical Formulary Currently in Place.*

The portion of lives under a chemotherapy formulary was lower this year (57 percent versus 86 percent). While this was a significant reduction, it is likely due to an improved definition of chemotherapy in this second edition report.

FIG. 1 FORMULARIES IN PLACE OVERALL



*n = 22 payors, 77 million lives

FIG. 2 FORMULARIES IN PLACE BY PLAN SIZE

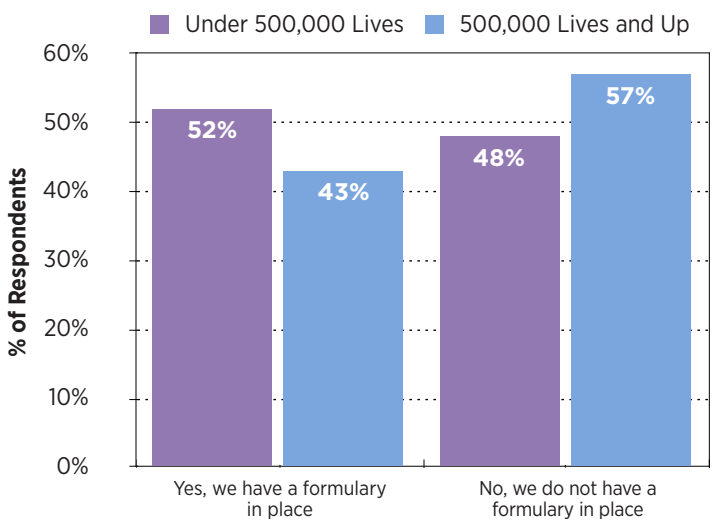
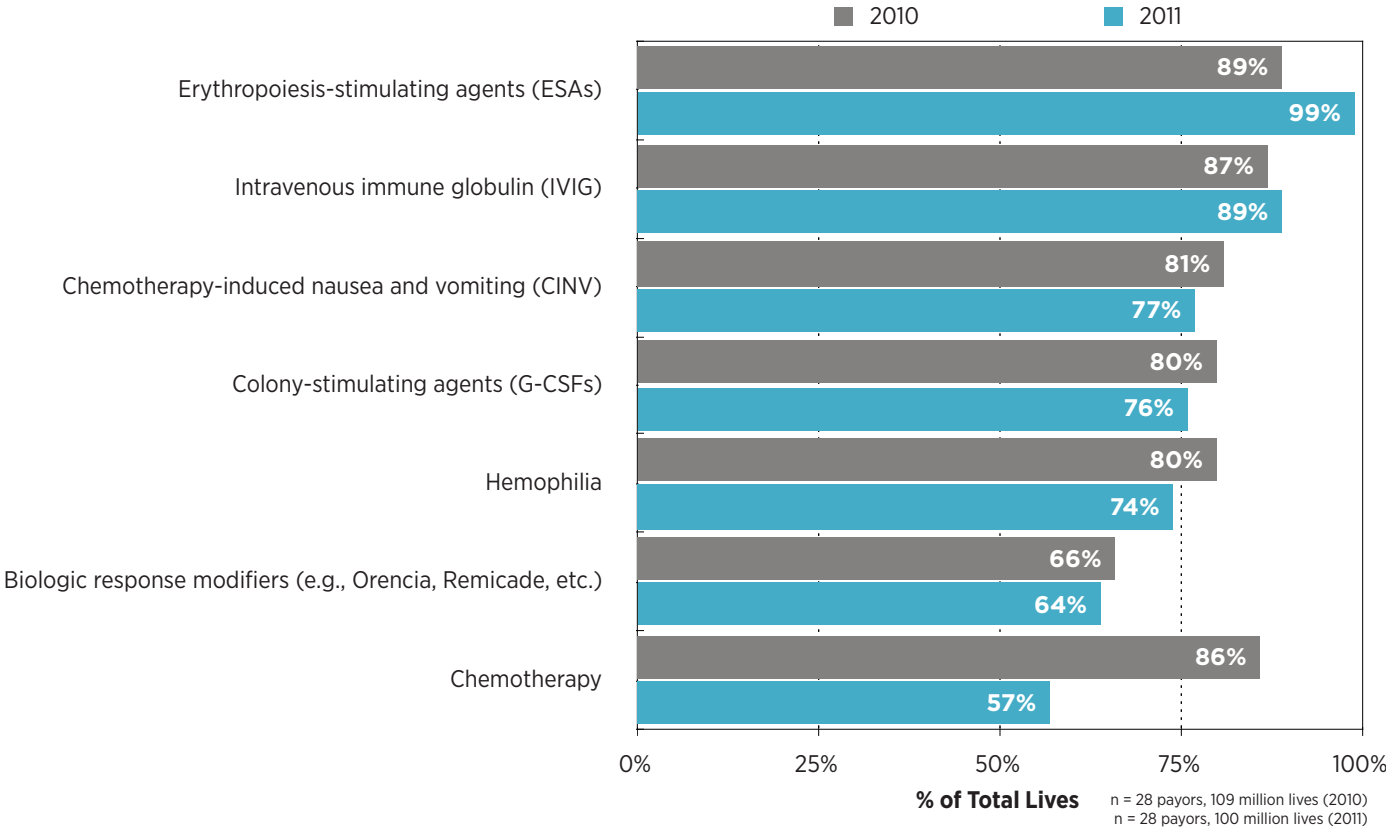


FIG. 3 THERAPEUTIC CLASSES WITH A MEDICAL FORMULARY CURRENTLY IN PLACE



n = 28 payors, 109 million lives (2010)
n = 28 payors, 100 million lives (2011)

We went a step further 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. Non-small cell lung cancer (NSCLC) was consistent at the top of the list in this 2011 second edition, while the others decreased from 2010. *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	% CHANGE FROM 2010
Non-small cell lung cancer	100%	100%	0%
Metastatic breast cancer	63%	49%	-22%
Prostate cancer	63%	49%	-22%
Non-Hodgkin lymphoma	63%	46%	-27%
Multiple myeloma	63%	46%	-27%
Renal cell carcinoma	63%	46%	-27%
Leukemia	63%	46%	-27%

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

Carrying forward the methodology used in ICORE Healthcare's 2010 Medical Pharmacy & Oncology Trend Report™, the trend appears to demonstrate that payors are becoming more sophisticated operationally to establish preferencing 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 2011, plans covering three-fourths of the lives note receiving rebates on medical injectable products, a statistically significant increase over the 56 percent reported a year ago. Compared with plans covering fewer than 500,000 lives, larger payors were 29 percent more likely to have established a rebate contract for at least one medical injectable product over smaller plans (77 percent versus 48 percent, respectively). *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.*

Nearly all payors who reported receiving rebates for medical benefit injectables report receiving them for BRM products. In contrast, reported rebates for ESAs were significantly lower in 2011 – 54 percent compared with 78 percent in 2010. *See Figure 7, Therapeutic Classes Where Payors Receive Injectable/Infusible Product Rebates.*

FIG. 5 REBATES RECEIVED OVERALL

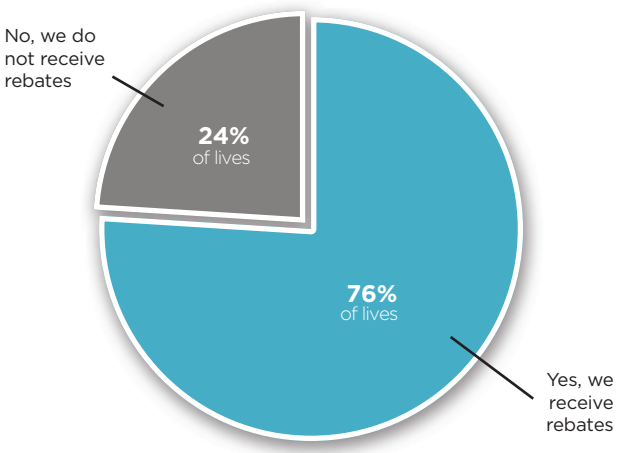
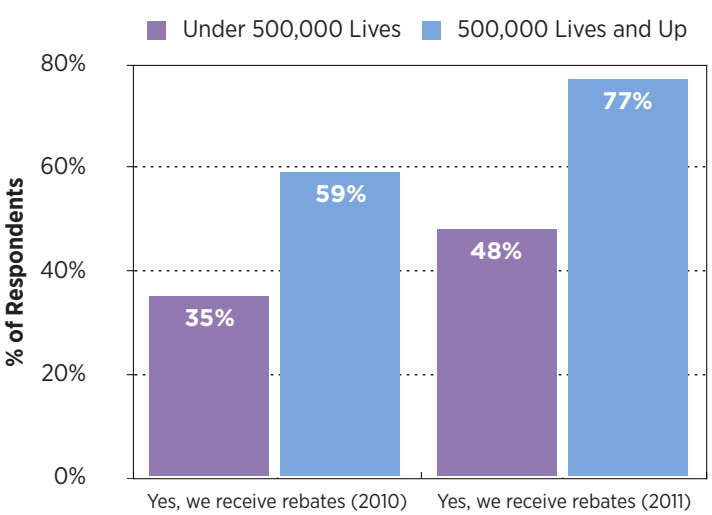
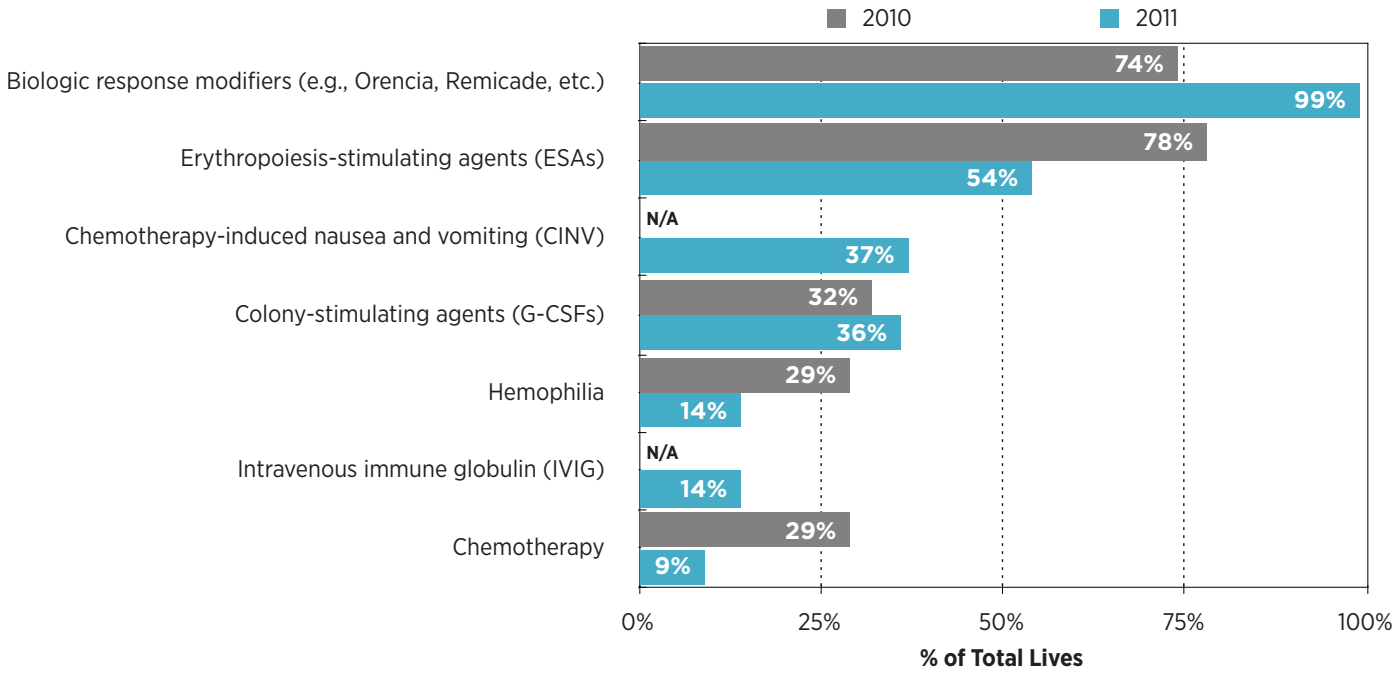


FIG. 6 REBATES RECEIVED BY PLAN SIZE



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

FIG. 7 THERAPEUTIC CLASSES WITH REBATES



n = 29 payors, 82 million lives (2010)
n = 29 payors, 37 million lives (2011)

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 above the average sales price (ASP plus) methodology. This is fairly consistent with 2010 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 8, Reimbursement Approach and the Extent of Discounts Used by Payors to Reimburse for Drugs Paid Under the Medical Benefit.*

There was crossover this year between average wholesale price minus-based (AWP minus) and variable fee schedule-based (VFS) reimbursement methodologies. About one in four covered lives has benefits that take the traditional AWP approach to provider reimbursement, with about 15 percent of the lives subject to variable fee schedules, or reference pricing. This appears to be partly due to experimental error resulting from a different sample of responders, and partly driven by more frequent reports of reimbursement under an AWP minus methodology versus other approaches among smaller plans in 2011. The number of lives where providers are reimbursed under an AWP plus, or risk arrangement, approaches 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. *See Figure 9, 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. 8 REIMBURSEMENT APPROACH OVERALL

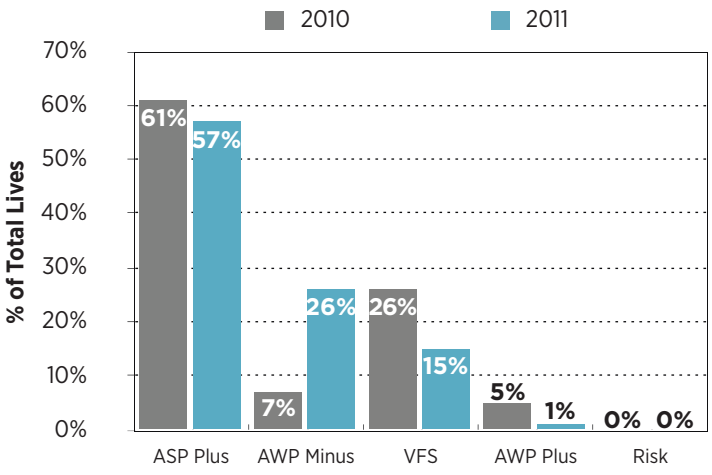


FIG. 9 REIMBURSEMENT APPROACH BY PLAN SIZE

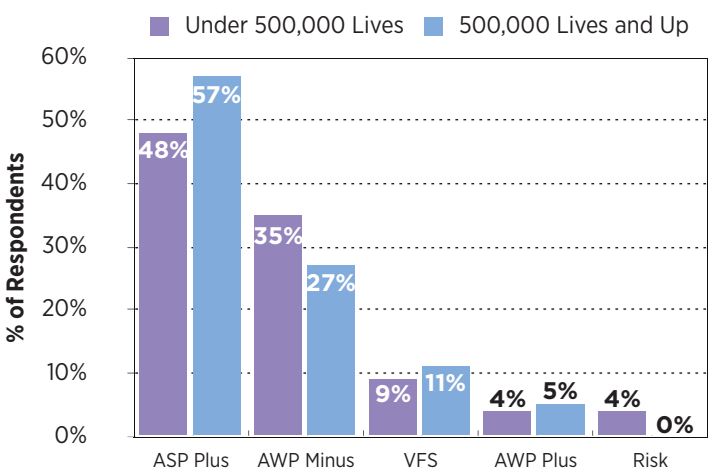
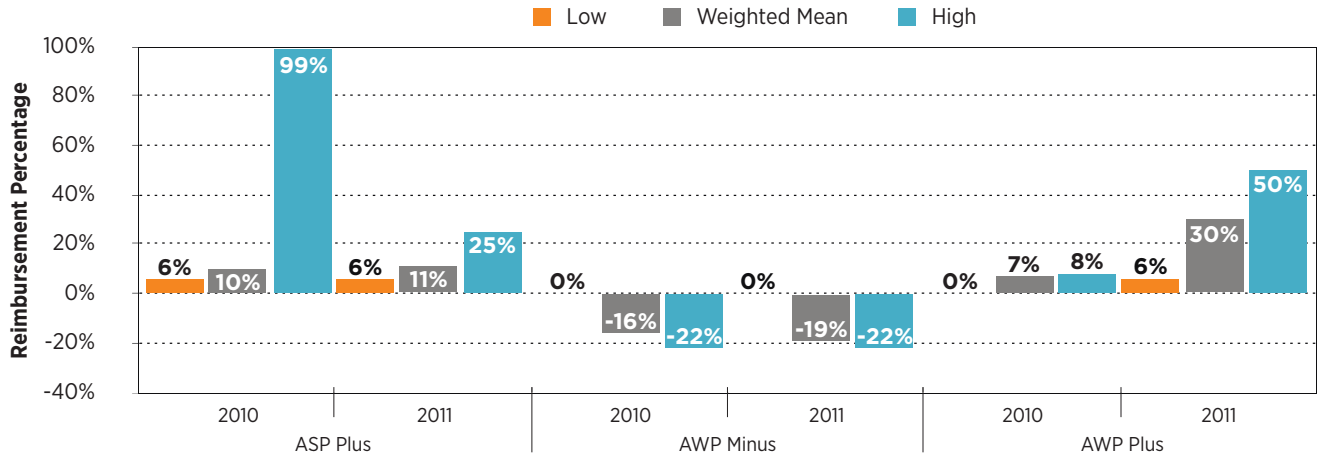


FIG. 10 REIMBURSEMENT PERCENTAGE IN PLACE



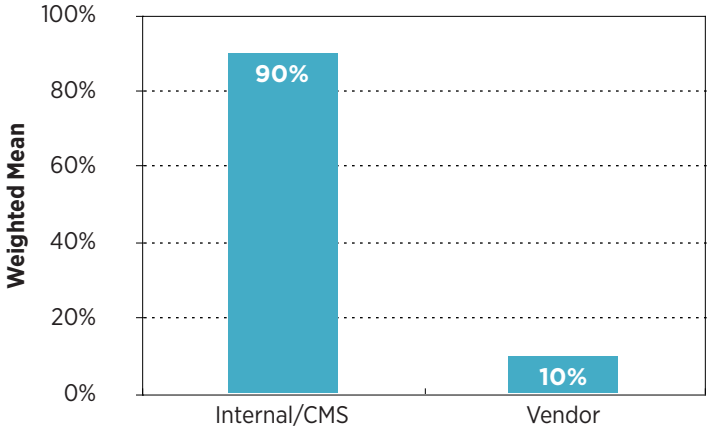
n = 37 payors, 107 million lives (2010)
n = 54 payors, 130 million lives (2011)

The weighted mean percentage above ASP reported this year was 11 percent, with the range from +6 percent (the Medicare allowance) to +25 percent. This is nearly exactly what was seen last year at ASP + 10 percent (p = ns). 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 + 12 percent would be the minimum reimbursement to cover provider-administered drugs and administration cost.[1] Today, the average ASP-based reimbursement continues to be just below that threshold. *See Figure 10, Range of Reimbursement Methodology Percentage in Place for Injectables Paid Under the Medical Benefit.*

AWP-minus reimbursement, on average, is with a 19 percent discount off of AWP, the range being consistent with what was found in the previous year. The AWP-plus base sizes are small and thus subject to significant year-over-year variances. The outliers could suggest that some health plan executives still do not have specific knowledge of this level of detail.

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. 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 11, How Payors Develop Their Medical Benefit Drug Reimbursement Strategies.*

FIG. 11 DEVELOPMENT OF DRUG REIMBURSEMENT STRATEGIES



[1]Okon T, Coplon S, et al. Problems Facing Cancer Care with Medicare's Definition of Average Selling Price. *Community Oncol.* 2004;1(1):59-63. www.communityoncology.net/co/journal/articles/0101059a.pdf. Accessed September 2, 2011.

PAYOR SURVEY DATA

In 2011, payors representing 24 percent of commercial managed care lives recently changed their medical benefit injectable reimbursement methodology, which is an increase from 2010 (8 percent). In addition, the percent modification to payor reimbursement strategies was changed within the past year for 29 percent of member lives. *See Figure 12, 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 two-thirds of the member lives have neither capitated nor case rate reimbursement arrangements with their providers. Interestingly, a significant increase was seen in the percentage of covered lives where payors use both capitation and a case rate (21 percent versus 3 percent in 2010). *See Figure 13, Portion of Payor Lives That Capitate Reimbursement to Providers or Use Case Rates.*

Further, payors who represent a third of covered lives in 2011 have begun to explore pilot programs that look at bundled payments for services with large, in-network oncology groups. *See Figure 14, Payors Who Initiated Pilot Programs.*

FIG. 12 DURATION OF CURRENT REIMBURSEMENT STRATEGIES

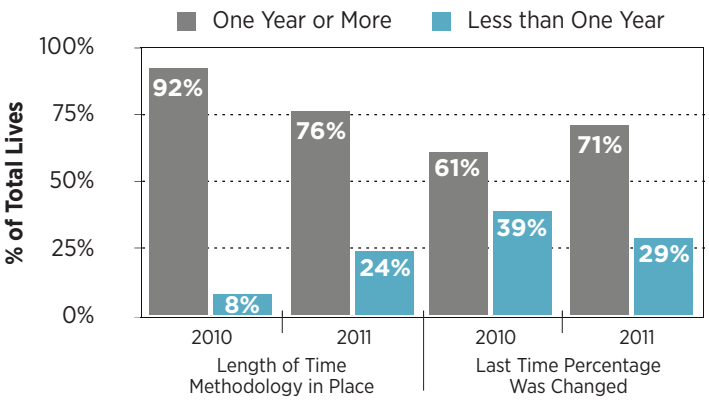


FIG. 13 PAYORS WHO CAPITATE OR USE CASE RATES

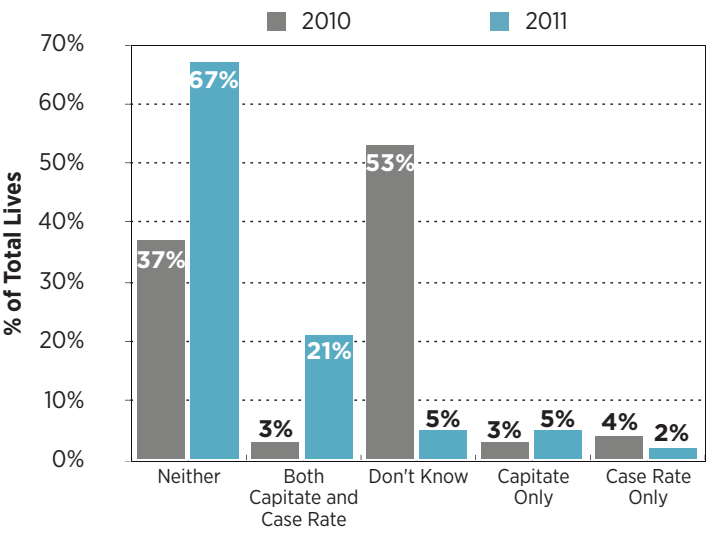
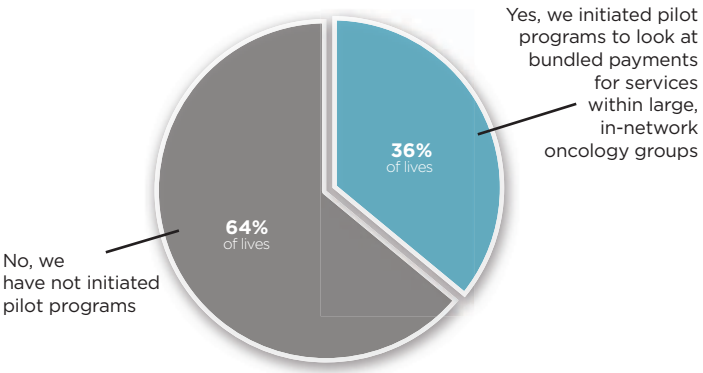


FIG. 14 PAYORS WHO INITIATED PILOT PROGRAMS



Benefit Design

Consistent with 2010, just under half the payors reported their plans do not require either a drug copay amount or drug coinsurance for medical injectables, which looks to be driven by the smaller plans. Of those that do require member contribution, it looks to be for either a drug coinsurance only (25 percent) or a drug copay only (20 percent). Very few payors in 2011 are requiring both a copay and a coinsurance as compared with 2010. *See Figure 15, Predominant Member Contribution for Injectables Paid Under the Medical Benefit Overall, and Figure 16, Predominant Member Contribution for Injectables Paid Under the Medical Benefit by Size of Health Plan.*

FIG. 15 PREDOMINANT MEMBER CONTRIBUTION REQUIREMENTS OVERALL

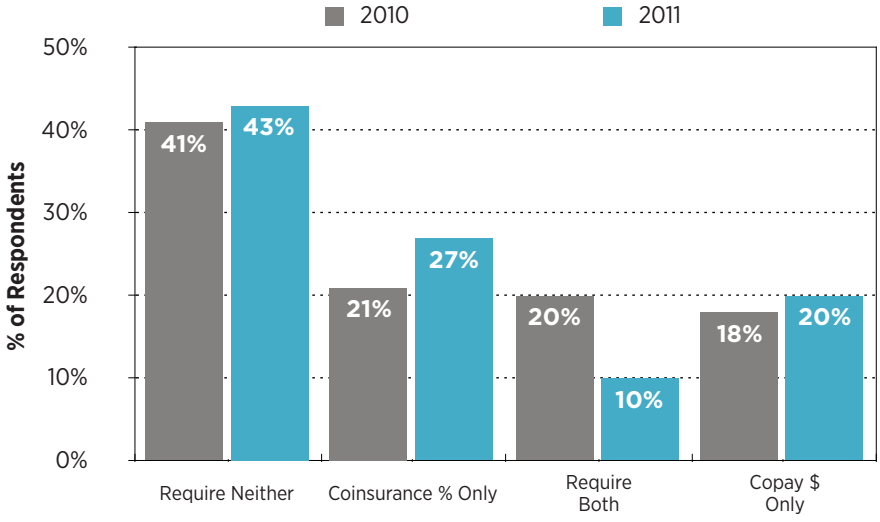
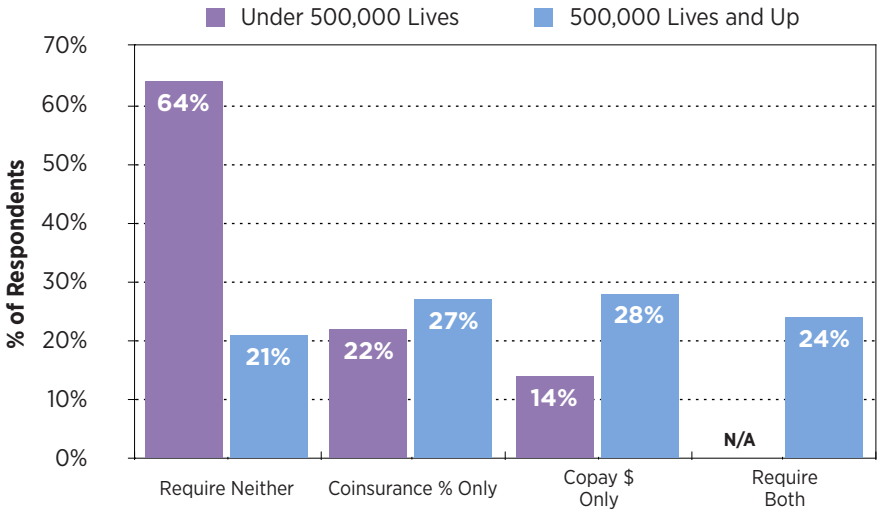


FIG. 16 PREDOMINANT MEMBER CONTRIBUTION REQUIREMENTS BY PLAN SIZE

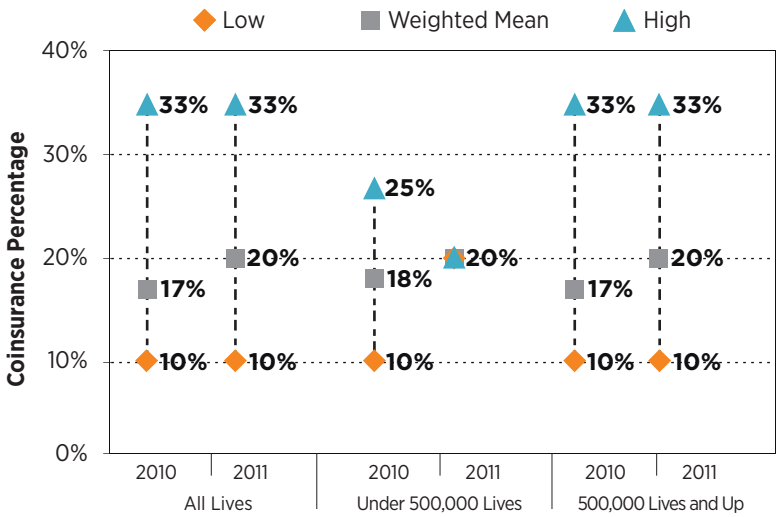


It appears members subject to coinsurances for medical benefit injectable drugs are being asked to slightly increase their share of contribution this year, with the average being 20 percent of the claim cost in 2011 versus 17 percent in 2010. The larger payors have a wider range at the upper end than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

There appears to be year-over-year consistency in copays for medical benefit injectable drugs. An average copay of $46 was reported in 2011, only a slight increase over the $43 average in 2010. The spread is greater for larger plans. A more narrow range exists for smaller payors who may have fewer plans to administer. Regarding copays for medical injectables, payors accounting for 88 percent of the covered lives studied stated they will maintain the current level of copay for the remainder of 2011. *See Figure 18, Reported Copay Amounts for Medical Benefit Injectables.*

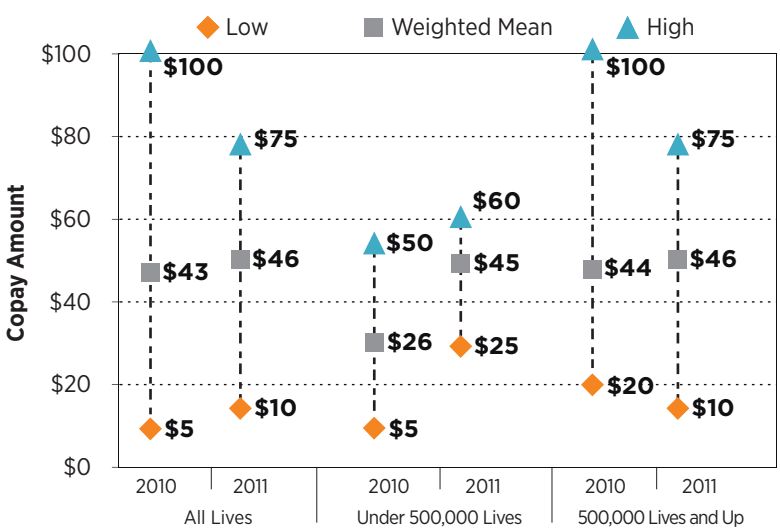
Many medical injectable benefit claims are in excess of $3,000. This is concerning due to the hypothesis that when the member contribution exceeds $2,500 per year out of pocket member medication compliance is impacted. A new design seems to be emerging where coinsurances are applied to a maximum capped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

FIG. 17 REPORTED COINSURANCE AMOUNTS



n = 25 payors, 91 million lives (2010)
n = 22 payors, 76 million lives (2011)

FIG. 18 REPORTED COPAY AMOUNTS



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

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

Of those payors reporting a difference, it is related to geographic competition, different insurance products, or each state's Department of Insurance requiring maximum coinsurance rates based on various lines of business. *See Figure 19, Variable Member Cost Share Requirements Across Different Plan Service Areas Overall, and Figure 20, Variable Member Cost Share Requirements Across Different Plan Service Areas by Size of Plan.*

FIG. 19 MEMBER COST REQUIREMENTS OVERALL

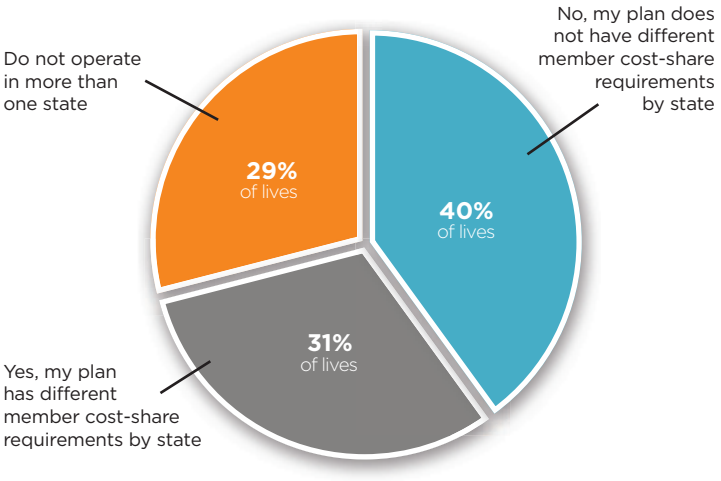
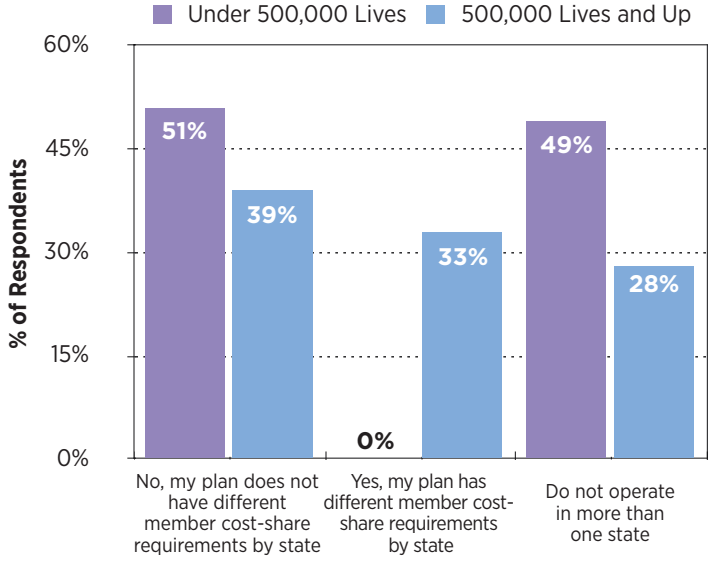


FIG. 20 MEMBER COST REQUIREMENTS BY PLAN SIZE



The survey asked payors to think ahead through the remainder of 2011 and into 2012 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 when compared with smaller payors. Looking forward, regardless of size, payors overall intend to increase the percentage of members with a coinsurance, although the increases are not statistically significant. *See Figure 21, Percentage of Member Lives Subject to a Coinsurance for Medical Injectables by Size of Plan.*

Further, among payors reporting coinsurances for 2012, the projected percentage assigned to medical benefit injectables is 22 percent, a slight increase from the 2011 reported coinsurance amount of 20 percent. *See Figure 22, Reported Coinsurance Amounts for Medical Benefit Injectables in 2012.*

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 53 percent of the lives have an annual cap on their members' coinsurance out of pocket, with the weighted mean at $2,076 per year.

FIG. 21 MEMBERS SUBJECT TO A COINSURANCE BY PLAN SIZE

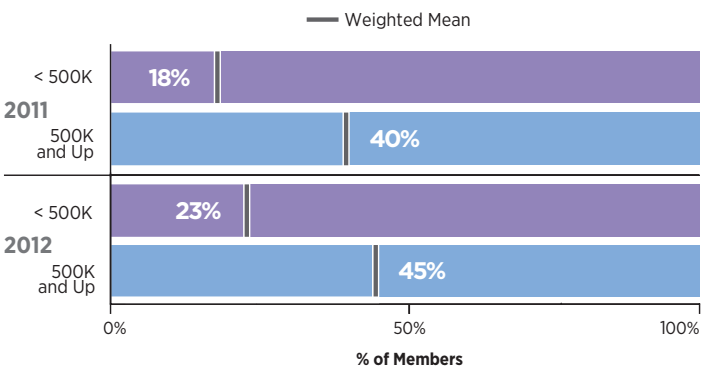
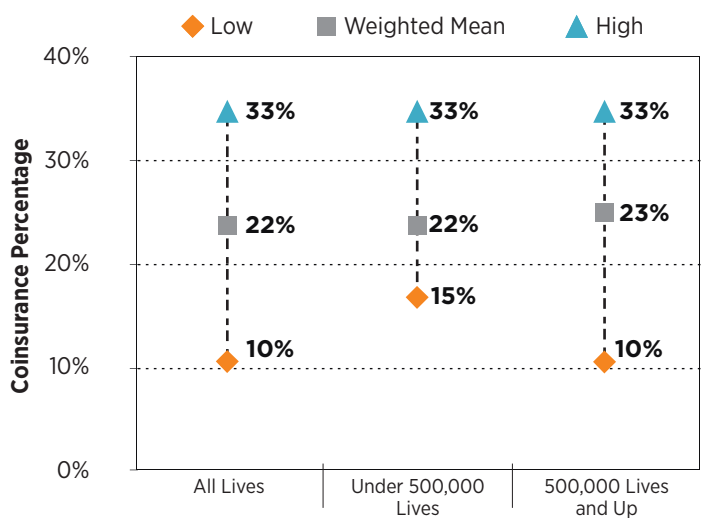


FIG. 22 COINSURANCE AMOUNTS PROJECTED FOR 2012



n = 46 payors, 135 million lives

Both small and large payors report that the portion of their membership that has a medical benefit injectable copay will remain about the same next year. Of note, the large payors reported a significantly higher percentage of members subject to a copay in 2011 (50 percent), as compared with their 2011 projections in last year's survey (24 percent). Larger payors report half of their members will be subjected to a medical benefit injectable copay. *See Figure 23, Percentage of Members Subject to a Copay for Medical Injectables by Size of Plan.*

Among payors anticipating copays for 2012, the average amounts range from $5 to $150, with $64 being the weighted mean. Of note, members within smaller health plans have a higher baseline level, though a narrower range than the larger health plans. This is consistent with larger plans having a greater number of employer contracts to manage and, thus, a greater spread in copay amounts. *See Figure 24, Reported Copay Amounts for Medical Benefit Injectables in 2012.*

FIG. 23 MEMBERS SUBJECT TO A COPAY BY PLAN SIZE

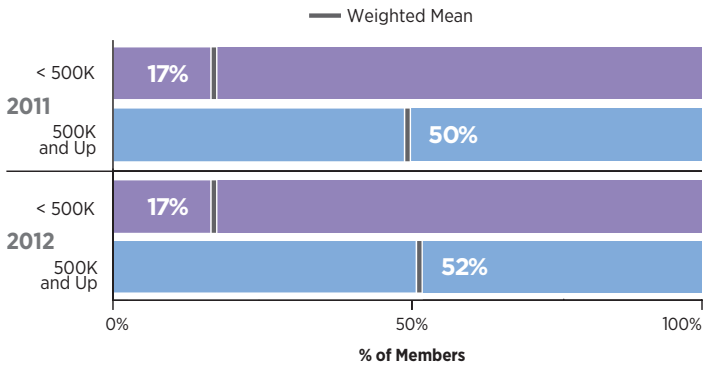
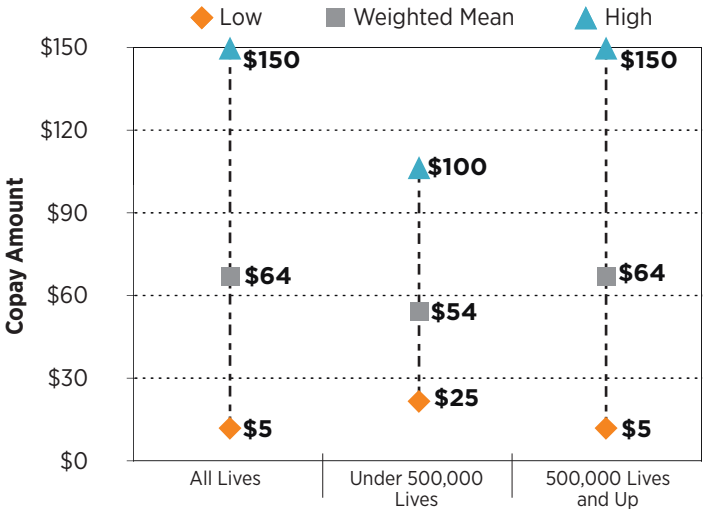


FIG. 24 COPAY AMOUNTS PROJECTED FOR 2012



n = 32 payors, 121 million lives

ORAL VERSUS INTRAVENOUS

About half the covered lives in the survey are subject to contribution parity, a statistically significant increase over the level reported last year (26 percent). Parity is noted primarily in relation to orals versus IV, Part B/Part D administered drugs, or self-administered options. 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 if the drug is paid under the medical or pharmacy benefit. *See Figure 25, Member Contribution Parity Between IV and Oral Products With Similar Indications.*

In 92 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 2012. 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 26, Member Contribution Parity Mandated by State Law.*

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 all 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 that 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 27, Genomic Test Requirements Before Chemotherapy.*

More information on these tests may be accessed at:
KRAS – www.kras-info.com
HER2 – www.herceptin.com/hcp/HER2-testing
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. 25 MEMBER CONTRIBUTION PARITY

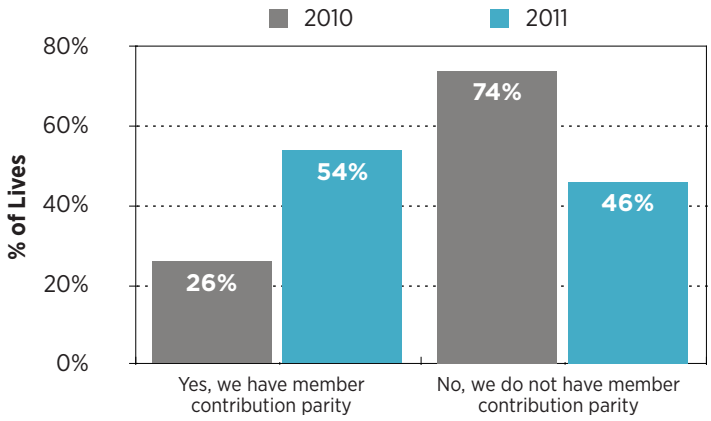
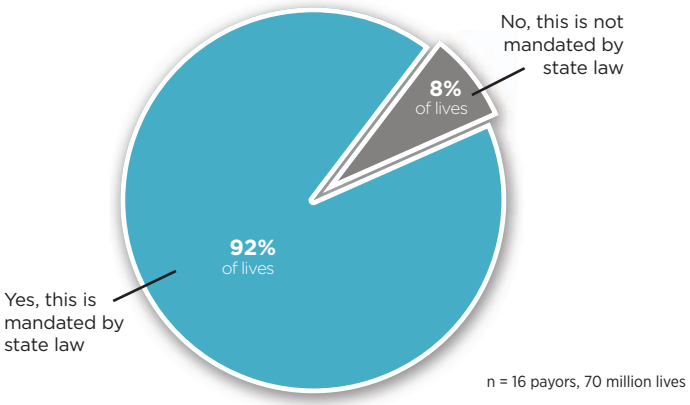
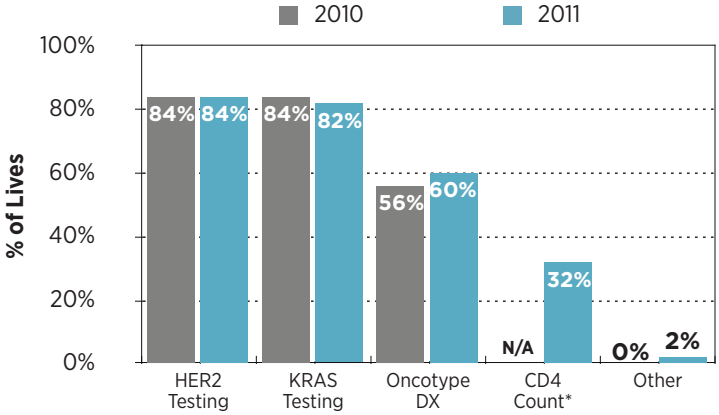


FIG. 26 PARITY MANDATED BY STATE LAW



n = 16 payors, 70 million lives

FIG. 27 MEMBERS SUBJECT TO GENOMIC TEST REQUIREMENTS



*new answer selection in 2011

Most members of commercial health plans (83 percent of covered lives) were enrolled in plans that featured established National Committee for Quality Assurance HEDIS cancer screening or prevention programs, a slight increase from last year. Breast and colorectal cancer screenings, along with medical assistance with smoking cessation, are part of the 2011 HEDIS measures. This is clearly driven by the large plans, as 38 percent of the payor respondents reported not having programs in place.

Breast cancer and colorectal cancer screening programs were most commonly available to members, with prostate cancer detection and smoking-cessation programs also offered to more than half the members. Prevention programs were nearly always developed internally at the health plans. *See Figure 28, HEDIS Cancer Screening or Prevention Programs in Place, and Figure 29, Specific HEDIS Prevention Programs Established.*

FIG. 28 SCREENING OR PREVENTION PROGRAMS IN PLACE

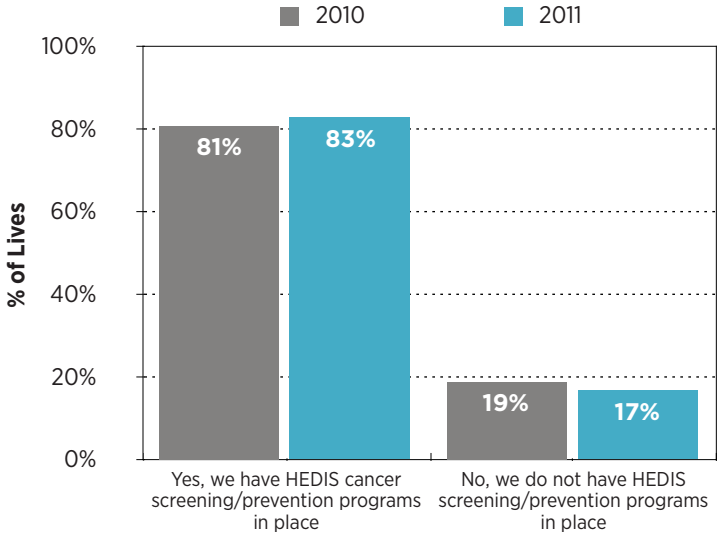
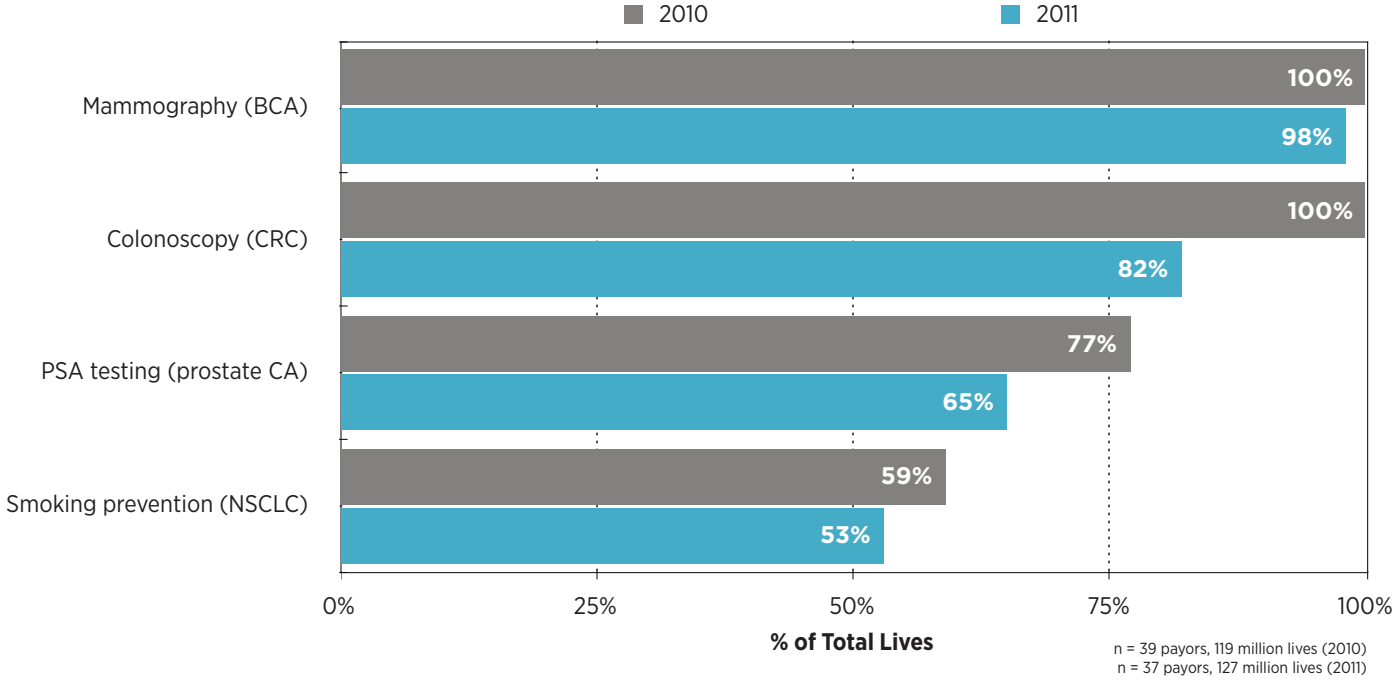


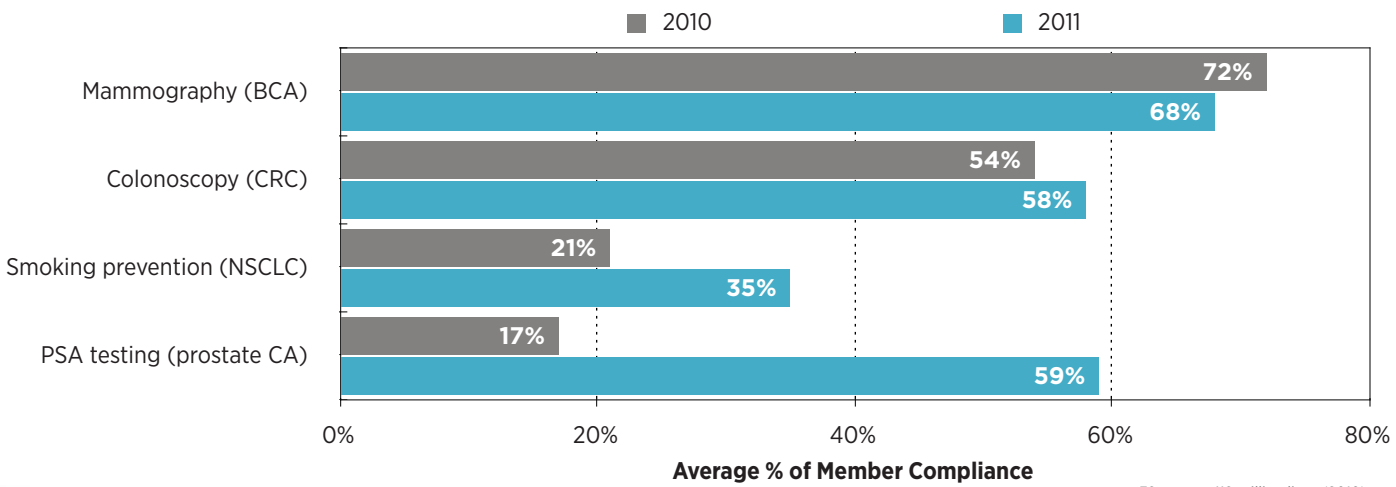
FIG. 29 HEDIS PREVENTION PROGRAMS ESTABLISHED



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

Changes in compliance with mammography and colonoscopy screening programs were consistent with results reported in 2010. Interestingly, we saw large increases in the percentage of members complying with prostate-specific antigen (PSA) testing (59 percent versus 17 percent in 2010) and smoking-cessation programs (35 percent versus 21 percent in 2010). *See Figure 30, Most Recent Percentage of Member Compliance by Cancer Screening Program.*

FIG. 30 MEMBER COMPLIANCE BY SCREENING PROGRAM



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

The 2011 survey noted an increase in the percentage of covered lives provided with an option for palliative care programs (55 percent versus 45 percent in 2010). Respondents offering such benefits report that their programs tend to include case management, care management, hospice, and other palliative care options. *See Figure 31, Palliative Care Programs Provided for Membership.*

This year, we saw a statistically significant increase in the number of members offered a separate benefit for these palliative care programs, where most were covered under the medical benefit last year. *See Figure 32, Palliative Care Program Coverage.*

For members receiving insurance from payors who have separate end-of-life benefits, 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 reported at about five to six months this year, where it was noted at about two to three months on average last year. We view this as a positive change over last year, as hospice should be offered when members have months to live, not days to live.

FIG. 31 PALLIATIVE CARE PROGRAMS PROVIDED

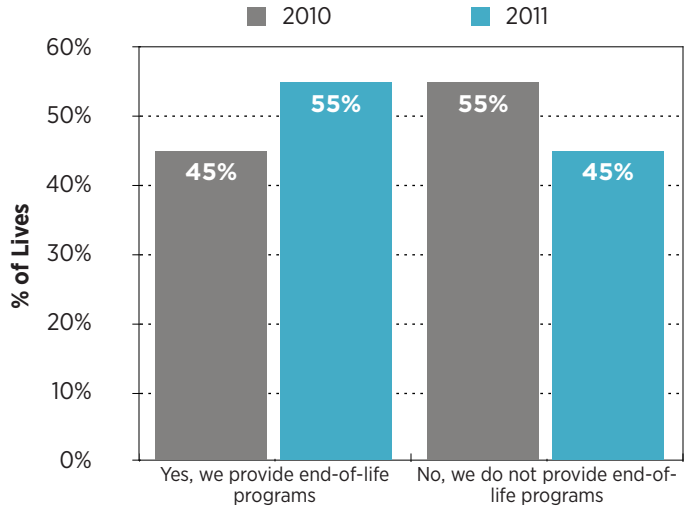
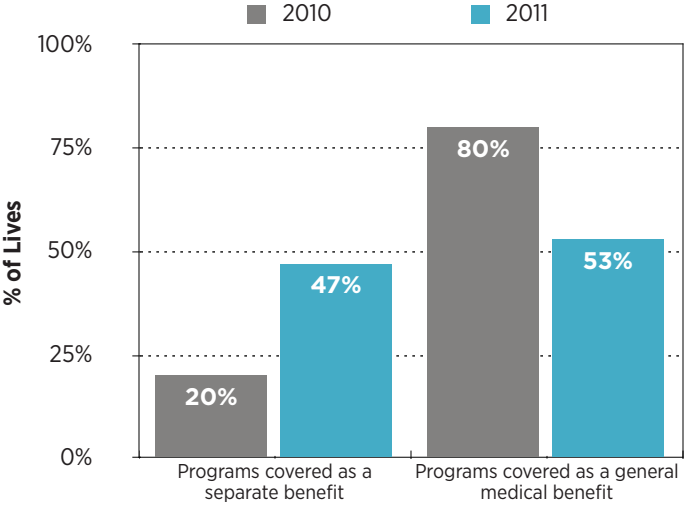


FIG. 32 PALLIATIVE CARE PROGRAM COVERAGE

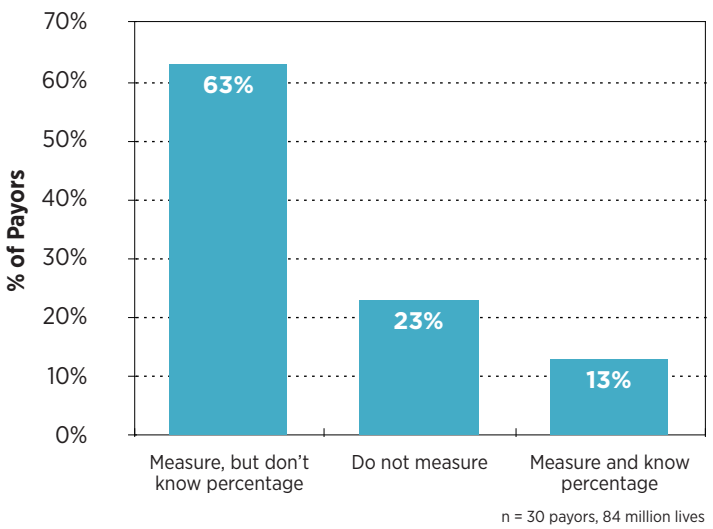


n = 25 payors, 65 million lives (2010)
n = 30 payors, 84 million lives (2011)

Of those plans that offer end-of-life/palliative care programs for their membership, 13 percent reported they measure member participation in this benefit and know the actual portion of members who qualify and participate, though these payors account for just 2 percent of covered lives. The self-reported weighted average percentage of participation was 10 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 33, Portion of Payors Who Know the Percentage of Eligible Members Who Actually Participated in These Palliative Care Programs in the Last Year.*

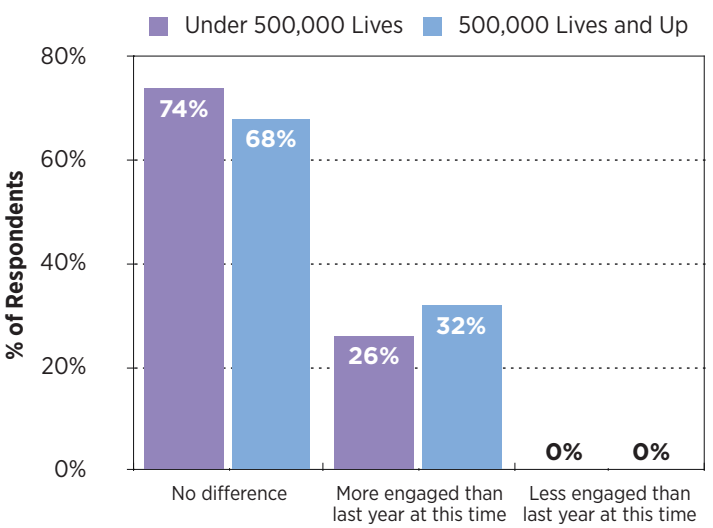
Last year, payors reported that their employer groups were becoming a significant driver in the development of future drug benefit designs; we see this effect continuing through 2011. In addition, this year, payors noted their employer groups are interested in learning about cancer management, medical management, curtailing growth in specialty spend, utilization data, and increased cost sharing. Specific to oncology, employers are requesting payors to provide cost-control initiative programs that ensure appropriate use and access and methods to provide more benefit with less cost. *See Figure 34, Level of Employer Engagement With Health Plans in Developing Benefit Designs by Size of Plan.*

FIG. 33 PAYORS MONITORING MEMBER PARTICIPATION



n = 30 payors, 84 million lives

FIG. 34 LEVEL OF EMPLOYER ENGAGEMENT BY PLAN SIZE



Distribution Channel Management

Consistent with the 2010 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 represents an average of one-quarter of the billed claims, and home infusion represents 15 percent of medical injectable billed claims. Inpatient administration increased slightly to 12 percent in 2011 from the 10 percent reported in 2010. This is likely to amplify in the future as payors continue to tighten reimbursement to mimic Medicare rates and as private practices are being purchased by hospital systems and then moving outpatient facility administration to leverage more favorable 340B pricing and higher payor reimbursement. In fact, a study by the COA last year found that over 300 oncology practices were bought by hospitals in the previous four years.[6] *See Figure 35, Average Percentage of Medical Injectable/Infusible Claims Billed From Each Site of Service.*

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, about two-thirds of the volume is billed through a buy-and-bill process, where the provider has purchased the drug and then invoices the payor for reimbursement under the patient medical benefit.

Specialty pharmacies provide approximately one-fourth 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, and higher costs, since partial vial use is not possible when billing NDC-11 codes to the pharmacy benefit.[7] *See Figure 36, Percentage of Medical Injectable/Infused Drug Volume Distributed to Members Through Various Billing Processes.*

FIG. 35 PERCENTAGE OF MEDICAL INJECTABLE CLAIMS BILLED

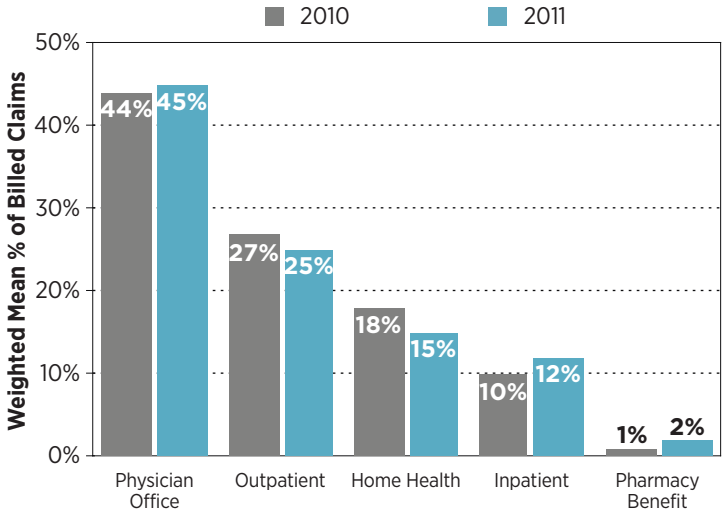


FIG. 36 DRUG VOLUME DISTRIBUTED IN PHYSICIAN OFFICE

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

[6] Community Oncology Cancer Care Practice Impact Report. Community Oncology Alliance website. http://communityoncology.org/UserFiles/files/87f3205e-ee73-4b03-85fb-094870cc430d/COA%20Community%20Oncology%20Practice%20Impact%20Report%203-31-11(1).pdf. Accessed October 17, 2011.

[7] Johnson K. Back to the Future. *Managed Care Onc.* 2011;2:5-6.

Utilization Management

Utilization management is a valuable tool that health plans employ to encourage appropriate use and dosing and to monitor site of service dynamics. About three-fourths of members are 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 37, Managing Utilization of Injectable/Infusible Products Administered by a Provider.*

Looking at selected classes of medical injectables, we found those with the most management (subjected to PA for at least 50 percent of members) appear to be IVIG, chemotherapies, ESAs, and BRMs. Guidelines developed by the National Comprehensive Cancer Network (NCCN) were the most commonly used tool to ensure appropriate use for chemotherapies; case management and disease management were also commonly employed. Only 8 percent of the lives were subjected to one or more chemotherapy pathway; for the most part, pathway programs were pilot studies and not implemented across the majority of the plans' membership. Drugs used for chemotherapy-induced nausea and vomiting (CINV) were least likely to be subjected to PAs, though formularies and differential reimbursement were used to manage utilization for nearly half of the lives studied. Colony-stimulating factors (G-CSFs) have the largest percentage of lives with none of the restrictions noted. *See Figure 38, Utilization Management Tools Used for Medical Injectable/Infusible Products in the Specific Therapeutic Classes.*

FIG. 37 MANAGING UTILIZATION OF PRODUCTS

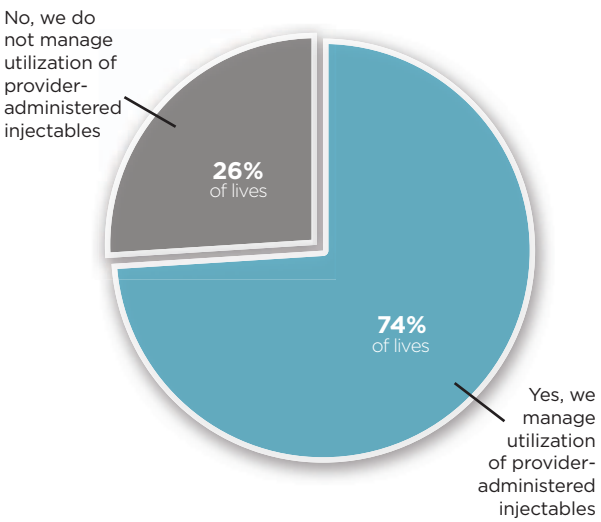


FIG. 38 UTILIZATION MANAGEMENT TOOLS BY CLASS

THERAPEUTIC CLASS	PRIOR AUTHORIZATION	CASE MANAGEMENT	DISEASE MANAGEMENT	CLINICAL PATHWAY GUIDELINES	DIFFERENTIAL REIMBURSEMENT	STEP EDIT REQUIREMENTS	FAILURE OF GENERIC FIRST	NCCN GUIDELINES	FORMULARY PRESENCE	NONE
Intravenous immune globulin (IVIG)	60%	46%	28%	30%	34%	4%	0%	29%	40%	3%
Chemotherapy	58%	41%	42%	8%	1%	3%	1%	61%	10%	2%
Erythropoiesis-stimulating agents (ESAs)	58%	37%	32%	36%	42%	5%	10%	42%	37%	3%
Colony-stimulating agents (G-CSFs)	49%	36%	30%	7%	42%	3%	0%	8%	36%	13%
Biologic response modifiers (e.g., Orencia, Remicade, etc.)	63%	28%	31%	30%	27%	21%	4%	28%	43%	3%
Hemophilia	49%	49%	34%	29%	27%	1%	0%	0%	36%	10%
Chemotherapy-induced nausea and vomiting (CINV)	23%	4%	1%	5%	43%	14%	10%	20%	43%	4%

n = 44 payors, 113 million lives

This year, we see that prostate cancer is the oncology therapy most commonly subjected to utilization management tools. The reason for this is twofold: 1) Luteinizing hormone-releasing hormone analogs (LHRHa) are also used for infertility treatments that are an infrequently covered benefit, and 2) the introduction of sipuleucel-T (Provenge), which has been reported to cost $93,000 per patient.[8] We also noted an increase in utilization management for drugs used to treat renal cell carcinoma, which is likely due to the increasing number of oral therapeutic options available. NSCLC also continues to be managed at a high level. 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 39, Cancer Types Most Commonly Subjected to Medical Utilization Tools.*

FIG. 39 CANCERS SUBJECTED TO MEDICAL UTILIZATION TOOLS

	2010 % OF LIVES	2011 % OF LIVES	YEAR-OVER-YEAR % CHANGE
Prostate cancer	59%	94%	59%
Non-small cell lung cancer	85%	83%	-2%
Renal-cell carcinoma	54%	75%	39%
Metastatic breast cancer	59%	70%	19%
Leukemia	48%	69%	44%
Non-Hodgkin lymphoma	49%	66%	35%
Multiple myeloma	56%	62%	11%

[8] Szabo L. FDA Approves $93K Prostate Cancer Vaccine. *USA Today.* April 30, 2010. www.usatoday.com/news/health/2010-04-30-prostatevaccine30_ST_N.htm. Accessed September 2, 2011.

Remicade, Rituxan, and Avastin are subject to PA for roughly half of the covered lives. As in the past, case management continues to be an important tool health plans employ to monitor utilization. Step edit requirements seem to be utilized along with case management for Alimta therapy. Avastin, Herceptin, and Erbitux reflect the largest percentage associated with pathways as a management tool, consistent with the use of genomic testing prior to therapy. Formularies are noted as a tool where oral and IV therapy alternatives coexist. Similar to 2010, few payors reported not using any medical injectable management tools or controls. *See Figure 40, Management Tools Used for Common Medical Injectable Therapies.*

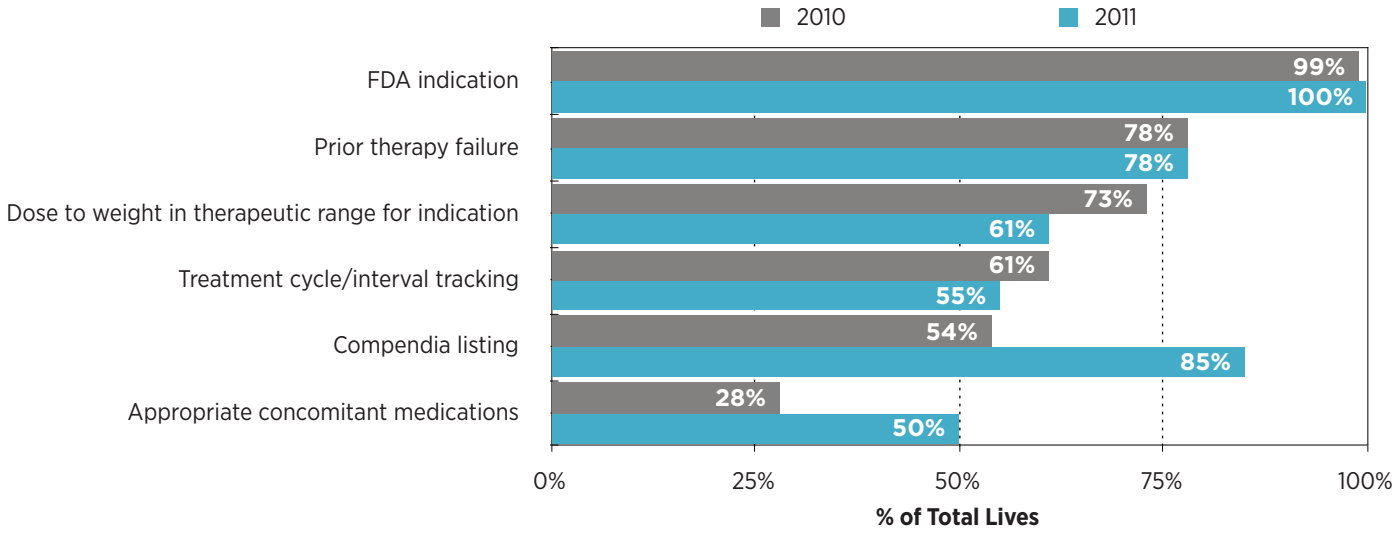
We asked payors whether they manage primarily to a specific drug or to cancer therapeutic categories. Payors representing 58 percent of the lives look to manage the drug entity itself. Payors still look to indication by the U.S. Food and Drug Administration (FDA) and compendia listing when developing PA criteria. Plans representing about three-fourths of the covered lives also have a policy to approve a medical injectable drug if the member has failed the medication in the past. This year, we see a jump in criteria looking for specific concomitant medications, which would be expected with so many therapies to treat increasingly required drug combinations. *See Figure 41, Specific Prior Authorization Criteria That May Be Required.*

FIG. 40 MANAGEMENT TOOLS FOR COMMON THERAPIES BY PERCENT OF LIVES

DRUGS	PRIOR AUTHORIZATION	CASE MANAGEMENT	DISEASE MANAGEMENT	CLINICAL PATHWAY GUIDELINES	DIFFERENTIAL REIMBURSEMENT	FORMULARY PRESENCE	STEP EDIT REQUIREMENTS	FAILURE OF GENERIC FIRST	NONE
Remicade	49%	42%	29%	18%	1%	14%	11%	1%	3%
Rituxan	48%	45%	27%	21%	1%	10%	3%	0%	1%
Avastin	47%	47%	27%	36%	1%	9%	2%	0%	1%
Herceptin	43%	20%	2%	36%	1%	9%	1%	0%	3%
Cerezyme	43%	46%	29%	13%	1%	36%	1%	0%	3%
Erbitux	42%	20%	1%	33%	1%	9%	1%	0%	7%
Aloxi	27%	44%	27%	18%	16%	37%	7%	1%	4%
Abraxane	25%	42%	29%	19%	16%	9%	8%	0%	5%
Taxotere	25%	17%	0%	18%	3%	9%	3%	0%	4%
Eloxatin	25%	46%	28%	16%	3%	36%	1%	0%	4%
Gemzar	25%	47%	28%	18%	1%	9%	1%	0%	7%
Zometa	24%	48%	27%	13%	3%	38%	1%	1%	8%
Alimta	20%	46%	28%	19%	16%	9%	46%	0%	9%

n = 44 payors, 113 million lives

FIG. 41 SPECIFIC PRIOR AUTHORIZATION CRITERIA



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

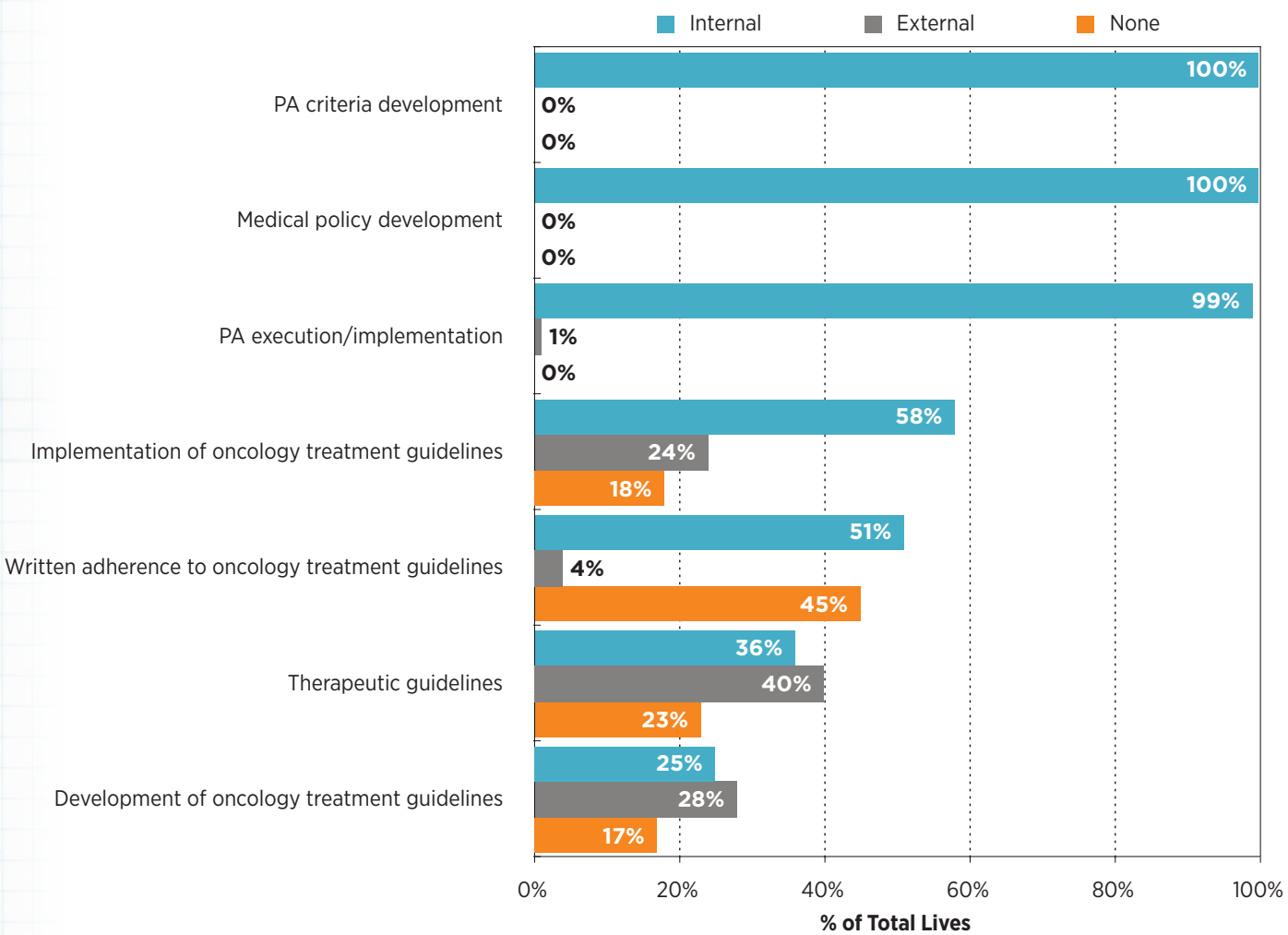
When asked about top concerns around medical injectables in 2011, over half the payors mentioned the overall cost of these agents. Appropriate utilization and new therapies were each mentioned by 17 percent of payors. We also asked payors to define the key driver of oncology cost increases. Manufacturer pricing action was noted by plans representing two-thirds of the lives; the balance believe the driver is related to increased drug utilization. *See Figure 42, Top Medical Injectable Concerns in 2011.*

FIG. 42 TOP MEDICAL INJECTABLE CONCERNS IN 2011

MEDICAL INJECTABLE CONCERN	% OF PAYORS
Overall cost	57%
Appropriate utilization	17%
New therapies	17%
Price increases	8%
Biologics	7%
Expansion on drug indications	5%
IVIG	5%
Fraud	2%

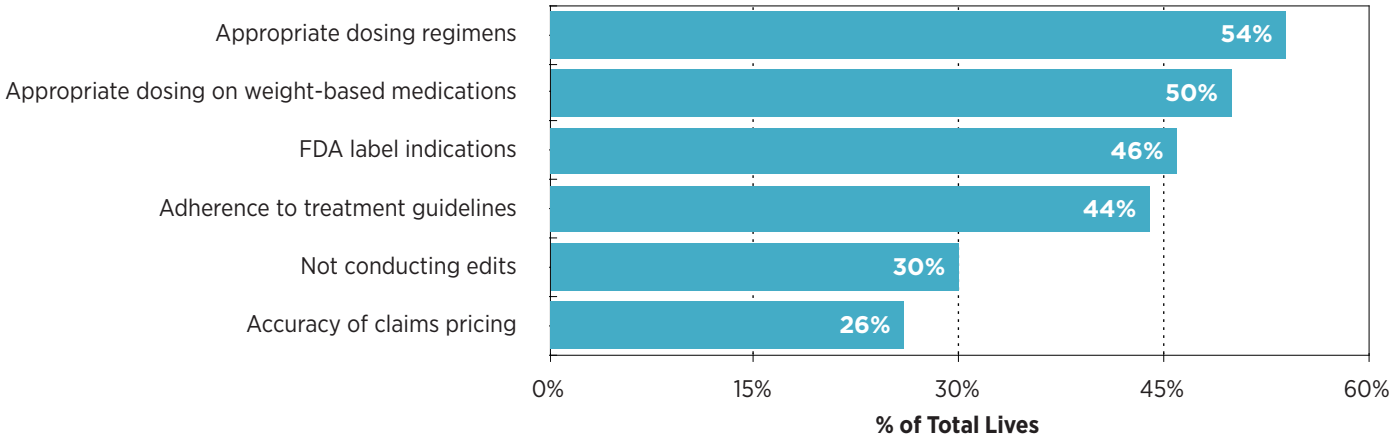
Virtually all payors noted their PA criteria and medical policy development and execution are created internally. When it comes to therapeutic or oncology treatment guidelines, these are frequently developed externally to the plan, often utilizing the expertise of the oncologist community. *See Figure 43, Where Management Services Are Developed at Health Plans.*

FIG. 43 WHERE MANAGEMENT SERVICES ARE DEVELOPED



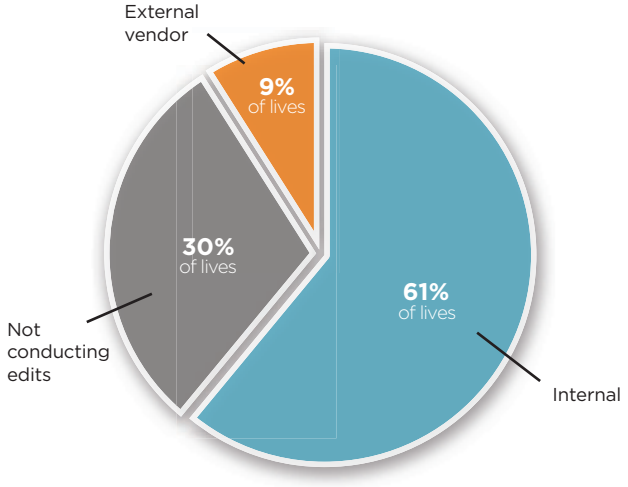
Operational Improvements

FIG. 44 POST-CLAIM EDITS CONDUCTED



Payors continue to use post-claim edits for provider-administered injectables paid under the member's medical benefit. 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 appropriate dosing regimens overall, as well as appropriate weight-based medications, are likely for over half the covered lives. Additional edits are designed to assess off-label or off-standard-of-care use and to mitigate claim pricing errors. Of those conducting reviews, almost all are developed and conducted by internal health plan staff. *See Figure 44, Post-Claim Edits Conducted on Medical Injectable Claims, and Figure 45, Implementation of Post-Claim Edits.*

FIG. 45 IMPLEMENTATION OF POST-CLAIM EDITS



Radiation oncology treatments generally fall within the medical benefit at most health plans. Figure 46 illustrates that radiation oncology, regardless of whether for diagnostic or treatment purposes, is being managed by health plans for the majority (51 percent) of the covered lives represented in the 2011 survey. *See Figure 46, Health Plans That Manage Radiation Oncology Benefits.*

About two-thirds 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 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, only 36 percent of members are subjected to a shift toward being treated at a hospital or infusion center. *See Figure 47, Programs to Encourage Site-of-Service Shift.*

Approximately two–thirds of payors' lives have a fee schedule for infusion centers or hospitals, although the robustness of these schedules is highly variable since they are commonly based upon a "percentage of charges" model where the center or hospital develops a charge master.

FIG. 46 MANAGE RADIATION ONCOLOGY BENEFITS

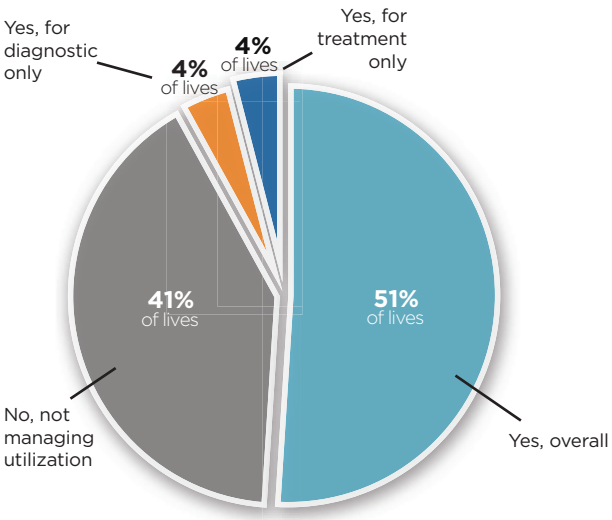
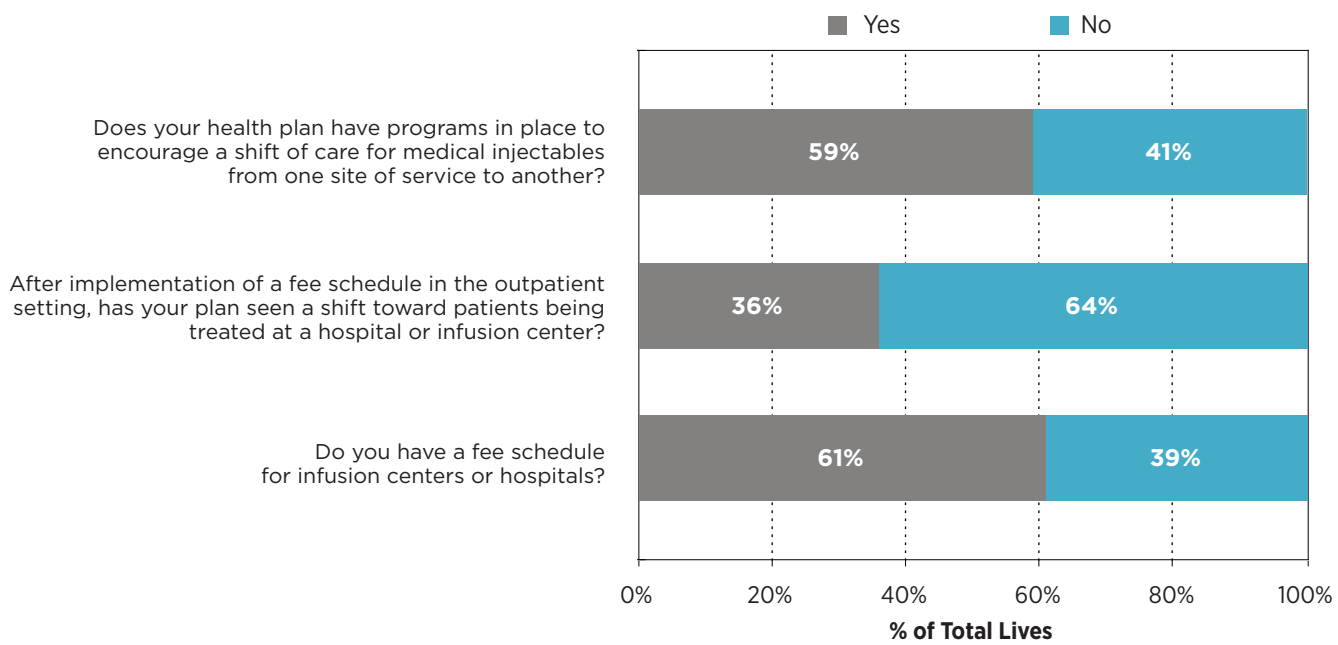


FIG. 47 PROGRAMS TO ENCOURAGE SITE-OF-SERVICE SHIFT



HEALTH PLAN CLAIMS DATA

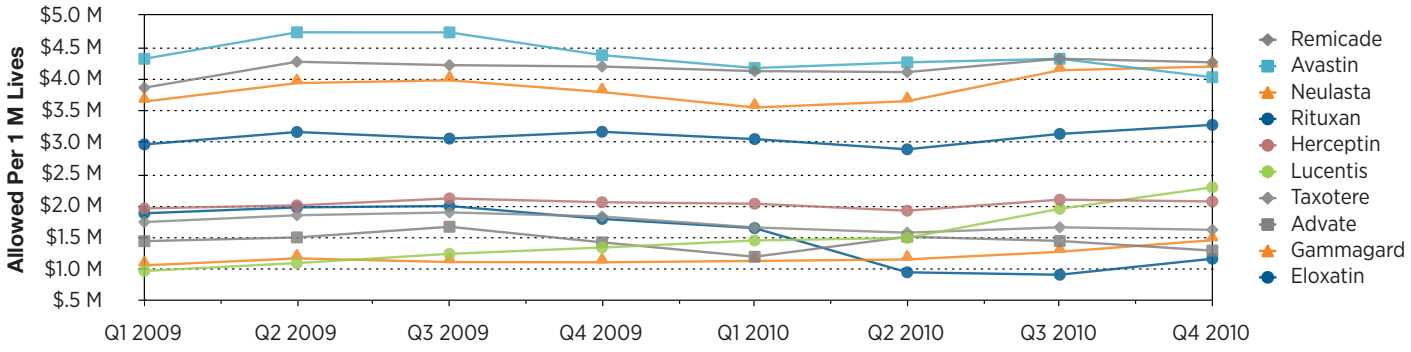
Trend Drivers

Based on analysis of 24 months of paid medical benefit injectable claims, a 1-million-life commercial plan will have averaged $178 million in medical benefit injectable costs in 2010 across all sites of service. Of that, the top 25 medical drugs comprised more than 82 percent of the total medical injectable spend, which is consistent with 2009 where the top 25 J codes represented 84 percent. In 2010, Remicade was the largest overall spend per 1 million insured lives, just edging Avastin, which saw a year-over-year decline of 7.6 percent in the paid claim amount. This is likely a reflection of decreased provider utilization of Avastin for metastatic breast cancer (mBC), as the uncertainty of the FDA's position regarding the mBC indication has unfolded over the last year. This, however, is likely to stabilize in 2011. Gammagard had an upward trend in spend during 2010, likely due to limitations in supply of other IVIG products. Lucentis had a significant upward trend as well; this is believed to be due to direct marketing to physicians and some plan preferencing for the product's use to treat wet macular degeneration. *See Figure 48, Top 25 Medical Injectable Drugs by Allowed Amount per 1 Million Lives.*

FIG. 48 TOP 25 MEDICAL BENEFIT SPECIALTY DRUGS (ALL LINES OF BUSINESS AND SITES OF SERVICE)

					2009	2010	
DRUG	RANKING	J CODE	UNITS PER 1 M LIVES	CALCULATED COST PER UNIT	ALLOWED PER 1 M LIVES	ALLOWED PER 1 M LIVES	% CHANGE
Remicade	1	J1745	198,733	$84.69	$16,565,188	$16,831,355	1.6%
Avastin	2	J9035	217,208	$77.33	$18,179,915	$16,797,540	-7.6%
Neulasta	3	J2505	4,796	$3,242.84	$15,370,300	$15,551,250	1.2%
Rituxan	4	J9310	18,392	$672.74	$12,379,824	$12,373,250	-0.1%
Herceptin	5	J9355	102,327	$79.60	$8,162,733	$8,145,277	-0.2%
Lucentis	6	J2778	18,446	$391.22	$4,680,999	$7,216,687	54.2%
Taxotere	7	J9171	285,171	$22.94	$7,347,321	$6,542,993	-10.9%
Advate	8	J7192	2,041,663	$2.68	$6,062,683	$5,474,438	-9.7%
Gammagard	9	J1569	66,516	$75.82	$4,480,838	$5,043,225	12.6%
Eloxatin	10	J9263	404,990	$11.62	$7,671,378	$4,705,059	-38.7%
Alimta	11	J9305	78,597	$58.09	$4,207,658	$4,565,757	8.5%
Gemzar	12	J9201	23,024	$183.52	$4,200,409	$4,225,284	0.6%
Gamunex	13	J1561	53,906	$75.48	$3,161,805	$4,068,691	28.7%
Procrit	14	Q4081	3,244,100	$1.10	$4,500,414	$3,573,004	-20.6%
Zometa	15	J3487	13,034	$270.73	$3,400,805	$3,528,521	3.8%
Aranesp	16	J0881	895,456	$3.74	$4,248,157	$3,351,996	-21.1%
Erbitux	17	J9055	46,852	$68.61	$3,599,703	$3,214,451	-10.7%
Procrit	18	J0885	235,821	$12.56	$3,027,376	$2,960,842	-34.2%
Aloxi	19	J2469	102,904	$27.61	$3,400,845	$2,841,468	-16.4%
Xolair	20	J2357	97,961	$28.22	$2,356,150	$2,764,605	17.3%
Velcade	21	J9041	58,370	$43.75	$2,175,737	$2,553,969	17.4%
Orencia	22	J0129	99,660	$23.82	$2,184,236	$2,374,323	8.7%
Tysabri	23	J2323	246,761	$9.52	$2,029,754	$2,349,569	15.8%
Gammagard S/D	24	J1566	30,966	$68.01	$2,641,719	$2,106,055	-20.3%
Abraxane	25	J9264	169,836	$12.25	$1,920,594	$2,079,944	8.3%
Total					**$147,956,540**	**$145,239,553**	**-1.8%**

FIG. 49 TOP 10 DRUGS BY QUARTER (2009 AND 2010)



The top 10 drugs are responsible for more than 55 percent of the overall medical injectable benefit spend at these plans. It appears 2010 was a relatively volatile period for these products, with some large swings in quarter-to-quarter claims. Lucentis, Rituxan, Neulasta, and Gammagard appear to be increasing in 2010. *See Figure 49, Top 10 Drugs by Quarter (2009 and 2010).*

When the diagnosis codes used for members receiving medical benefit injectable drugs were reviewed, about 25 diagnoses represent at least 1 percent of patients receiving medical injectables. The top 15 diagnoses accounted for 37 percent of total patients per million lives. Additionally, five of the top six ICD-9 codes are for rheumatologic disorders. *See Figure 50, Portion of Health Plan Members Who Received a Medical Injectable for Key Diagnoses.*

FIG. 50 PORTION OF MEMBERS WHO RECEIVED A MEDICAL INJECTABLE

			2009	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	5%	6%
2	726	Peripheral enthesopathies and allied syndromes	5%	5%
3	719	Other and unspecified disorders of joint	4%	5%
4	786	Symptoms involving respiratory system and other chest symptoms	4%	4%
5	724	Other and unspecified disorders of back	3%	3%
6	727	Other disorders of synovium, tendon, and bursa	2%	3%
7	789	Other symptoms involving abdomen and pelvis	3%	2%
8	414	Other forms of chronic ischemic heart disease	2%	2%
9	728	Disorders of muscle, ligament, and fascia	1%	1%
10	493	Asthma	1%	1%
11	466	Acute bronchitis and bronchiolitis	1%	1%
12	692	Contact dermatitis and other eczema	1%	1%
13	461	Acute sinusitis	1%	1%
14	477	Allergic rhinitis	1%	1%
15	780	General symptoms	1%	1%
16	266	Deficiency of B-complex components	1%	1%
17	281	Other deficiency anemias	1%	1%
18	V25	Encounter for contraceptive management	1%	1%
19	722	Intervertebral disk disorders	1%	1%
20	729	Other disorders of soft tissues	1%	1%
21	787	Symptoms involving digestive system	1%	1%
22	733	Other disorders of bone and cartilage	0%	1%
23	362	Other retinal disorders	0%	1%
24	285	Other and unspecified anemias	0%	1%
25	723	Other disorders of cervical region	0%	1%
Total			**41%**	**47%**

Management of Spend Drivers

Provider-infused or injected chemotherapy, as expected, represents the largest portion of medical benefit injectable costs at about one-third of the total costs; when chemotherapy support medicines are considered, injectables associated with cancer care represent about half of allowed medical injectable costs. The 2010 portion of total provider-administered injectable spend due to cancer and cancer support was nearly identical to 2009. Overall spend was flat year over year, likely due to certain cancer drugs losing patent, lower ESA utilization, and 340B pricing pressures on blood factors. Also, and very important, many payors have implemented medical injectable cost-control programs, as outlined earlier in this report. It is clear that some of these programs are effective at cost control. For reference purposes as depicted in Figure 51, a 1-million-life commercial payor in 2010 spent on average $18 million on oral chemotherapy, but spent nearly $82 million on injectable chemotherapies, suggesting that oral chemotherapy is approximately 18 percent of a payor's total chemotherapy spend. 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 and pharmacy benefits. 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 13 percent of total medical injectable costs. *See Figure 51, Spend by Key Therapeutic Class per 1 Million Lives.*

FIG. 51 SPEND BY KEY THERAPEUTIC CLASS (MEDICAL AND PHARMACY)

	2009		2010	
THERAPY	ALLOWED PER 1 M LIVES	% OF SPEND	ALLOWED PER 1 M LIVES	% OF SPEND
IV chemotherapy	$89,181,960	33%	$81,881,838	31%
Rheumatology	$32,666,943	12%	$35,510,361	13%
Granulocyte colony-stimulating factor	$20,472,358	8%	$20,652,866	8%
Oral chemotherapy	$17,911,263	7%	$18,181,125	7%
Intravenous immune globulin	$15,090,615	6%	$16,088,787	6%
Chemotherapy support – unspecified	$10,185,650	4%	$10,207,388	4%
Hemophilia	$9,396,503	4%	$8,477,727	3%
Erythropoiesis-stimulating agent	$9,611,659	4%	$8,227,824	3%
Antiemetics	$5,545,859	2%	$4,846,520	2%
Other	$57,434,542	21%	$63,147,583	24%
Total	**$267,497,351**	**100%**	**$267,222,020**	**100%**

National Provider Trends

Across all lines of business, oncologists order and administer the most medical benefit injectable drugs, representing 39 percent of the total spend. Hematologists and rheumatologists are also key medical specialties. Other provider specialties mentioned include internists, gastroenterologists, pediatricians, ophthalmologists, and various others. *See Figure 52, 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 2010 when compared with 2009, and this was absorbed by an increase in prescribing by radiation oncologists and hematologists. One factor for why this occurred is the increase in more hospital broad-specialty-based care for oncology in 2010. *See Figure 53, Claims per 1 Million Lives by Provider Specialty.*

FIG. 52 SPEND BY PROVIDER SPECIALTY

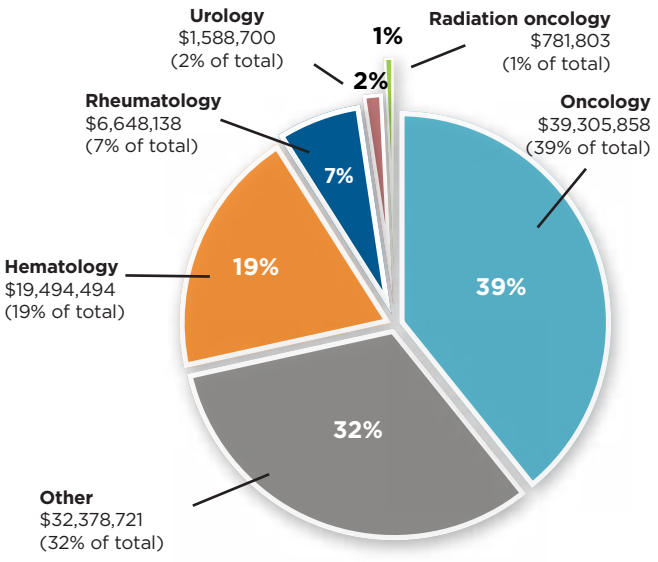


FIG. 53 CLAIMS BY PROVIDER SPECIALTY

SPECIALTY	2009 UNITS PER 1 M LIVES	2010 UNITS PER 1 M LIVES	% CHANGE	2009 CLAIMS PER 1 M LIVES	2010 CLAIMS PER 1 M LIVES	% CHANGE
Oncology	2,046,690	1,937,091	-5.4%	81,088	67,560	-16.7%
Other	3,631,554	3,512,842	-3.3%	253,875	232,749	-8.3%
Hematology	884,837	1,157,807	30.8%	35,407	39,258	10.9%
Rheumatology	147,611	166,082	12.5%	12,985	12,578	-3.1%
Urology	28,415	41,297	45.3%	6,367	6,338	-0.5%
Radiation oncology	41,173	50,650	23.0%	1,408	1,683	19.5%

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 at 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 2010, 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 potential to increase significantly costs of care over time as this continues. While most sites of service had no systematic change in cost per claim over time, stand-alone clinics and dialysis centers had a reduction in cost per claim for all these high-spend products. This is likely due to a focused effort of payors to control reimbursement costs at these centers, as a result of historically high reimbursement rates when compared with other administration sites. *See Figure 54, Spend and Utilization per 1 Million Lives by Site of Service.*

FIG. 54 SPEND AND UTILIZATION PER 1 MILLION LIVES BY SITE OF SERVICE

RANKING	J CODE	BRAND NAME	ALLOWED PER 1 M LIVES	2009 TOTAL $/CLAIM	2010 TOTAL $/CLAIM
1	J1745	Remicade	$16,831,355	$3,711	$3,765
2	J9035	Avastin	$16,797,540	$3,784	$3,248
3	J2505	Neulasta	$15,551,250	$3,405	$3,309
4	J9310	Rituxan	$12,373,250	$5,228	$5,218
5	J9355	Herceptin	$8,145,277	$2,562	$2,516
6	J2778	Lucentis	$7,216,687	$2,088	$2,071
7	J9171	Taxotere	$6,542,993	$2,622	$2,308
8	J7192	Advate	$5,474,438	$7,057	$4,970
9	J1569	Gammagard	$5,043,225	$4,779	$4,409
10	J9263	Eloxatin	$4,705,059	$3,888	$3,658

		PERCENT OF $/CLAIM											
		HOSPITAL			OTHER (I.E., ESRD AND CLINICS)			HOME INFUSION/SPP			MEDICAL OFFICE		
BRAND NAME	RANKING	2009	2010	% CHANGE	2009	2010	% CHANGE	2009	2010	% CHANGE	2009	2010	% CHANGE
Remicade	1	32%	34%	6%	32%	26%	-21%	18%	20%	7%	17%	18%	3%
Avastin	2	38%	40%	6%	40%	40%	1%	9%	8%	-16%	13%	12%	-9%
Neulasta	3	25%	26%	5%	39%	33%	-21%	20%	25%	18%	16%	17%	7%
Rituxan	4	26%	26%	0%	36%	32%	-10%	23%	24%	6%	16%	18%	11%
Herceptin	5	23%	24%	4%	36%	32%	-12%	30%	31%	4%	12%	13%	14%
Lucentis	6	17%	12%	-38%	37%	33%	-11%	23%	27%	14%	23%	28%	19%
Taxotere	7	28%	29%	2%	37%	29%	-28%	19%	24%	21%	15%	18%	18%
Advate	8	38%	50%	24%	37%	13%	-195%	15%	13%	-15%	10%	25%	145%
Gammagard	9	24%	29%	19%	26%	18%	-48%	28%	27%	-4%	22%	26%	17%
Eloxatin	10	26%	28%	9%	36%	29%	-25%	22%	24%	10%	16%	18%	14%

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 illustrates the top five diagnoses for Avastin, Herceptin, Remicade, Rituxan, Neulasta, and Taxotere in 2010. Additionally, the 2009 data are presented. Of concern, nonspecific ICD-9 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 55, Top Five Diagnosis Codes for Key Medical Benefit Drugs.*

FIG. 55 | TOP FIVE DIAGNOSIS CODES

	DESCRIPTION	CODE	ALLOWED PER 1 M LIVES			CLAIMS PER 1 M LIVES		
			2009	2010	% CHANGE	2009	2010	% CHANGE
AVASTIN	Encounter for other and unspecified procedures and aftercare	V58	$4,676,837	$4,029,285	-13.8%	659	553	-16.1%
	Malignant neoplasm of female breast	174	$3,210,006	$2,853,309	-11.1%	572	498	-13.0%
	Malignant neoplasm of trachea, bronchus, and lung	162	$3,143,141	$2,780,706	-11.5%	478	442	-7.6%
	Malignant neoplasm of colon	153	$3,166,199	$2,535,443	-19.9%	845	741	-12.4%
	Malignant neoplasm of brain	191	$1,142,004	$1,300,605	13.9%	162	226	39.5%

	DESCRIPTION	CODE	ALLOWED PER 1 M LIVES			CLAIMS PER 1 M LIVES		
			2009	2010	% CHANGE	2009	2010	% CHANGE
HERCEPTIN	Malignant neoplasm of female breast	174	$6,018,739	$6,277,958	4.3%	2,606	2,659	2.0%
	Encounter for other and unspecified procedures and aftercare	V58	$1,923,343	$1,601,429	-16.7%	484	467	-3.4%
	Secondary malignant neoplasm of other specified sites	198	$61,667	$51,087	-17.2%	25	24	-3.4%
	Malignant neoplasm of stomach	151	N/A	$27,449	N/A	N/A	13	N/A
	Malignant neoplasm of male breast	175	N/A	$21,681	N/A	N/A	6	N/A

	DESCRIPTION	CODE	ALLOWED PER 1 M LIVES			CLAIMS PER 1 M LIVES		
			2009	2010	% CHANGE	2009	2010	% CHANGE
REMICADE	Regional enteritis	555	$5,511,584	$5,787,732	5.0%	1,218	1,261	3.5%
	Rheumatoid arthritis and other inflammatory polyarthropathies	714	$5,973,788	$5,699,470	-4.6%	2,011	1,895	-5.8%
	Psoriasis and similar disorders	696	$2,001,111	$2,093,268	4.6%	511	537	5.1%
	Ulcerative colitis	556	$1,707,740	$1,919,806	12.4%	393	455	15.8%
	Ankylosing spondylitis and other inflammatory spondylopathies	720	$579,823	$534,229	-7.9%	157	156	-0.4%

	DESCRIPTION	CODE	ALLOWED PER 1 M LIVES			CLAIMS PER 1 M LIVES		
			2009	2010	% CHANGE	2009	2010	% CHANGE
RITUXAN	Other malignant neoplasms of lymphoid and histiocytic tissue	202	$5,407,535	$5,442,542	0.6%	1,129	1,135	0.5%
	Encounter for other and unspecified procedures and aftercare	V58	$2,280,476	$2,128,068	-6.7%	328	327	-0.5%
	Rheumatoid arthritis and other inflammatory polyarthropathies	714	$1,020,757	$1,324,958	29.8%	167	200	19.7%
	Lymphoid leukemia	204	$1,092,669	$1,018,095	-6.8%	236	234	-0.5%
	Lymphosarcoma and reticulosarcoma	200	$905,996	$826,271	-8.8%	194	190	-1.8%

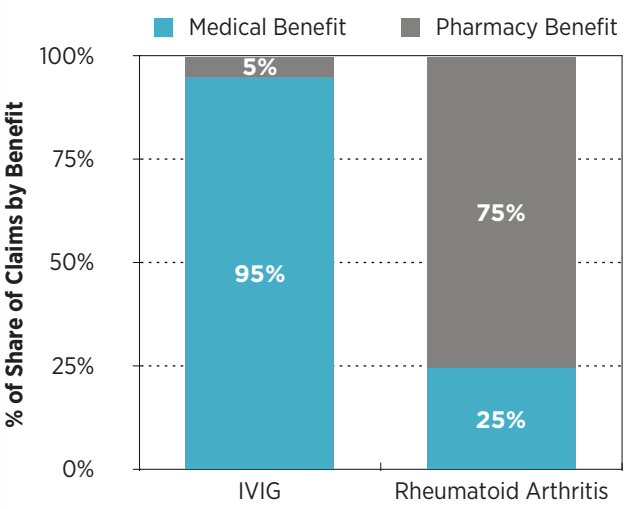
	DESCRIPTION	CODE	ALLOWED PER 1 M LIVES			CLAIMS PER 1 M LIVES		
			2009	2010	% CHANGE	2009	2010	% CHANGE
NEULASTA	Malignant neoplasm of female breast	174	$3,339,731	$3,356,197	0.5%	942	923	-2.0%
	Diseases of white blood cells	288	$2,799,542	$3,298,293	17.8%	990	1,176	18.8%
	Encounter for other and unspecified procedures and aftercare	V58	$2,635,785	$2,402,215	-8.9%	602	606	0.7%
	Malignant neoplasm of trachea, bronchus, and lung	162	$1,182,466	$1,214,710	2.7%	357	390	9.2%
	Other malignant neoplasms of lymphoid and histiocytic tissue	202	$803,072	$842,486	4.9%	241	254	5.3%

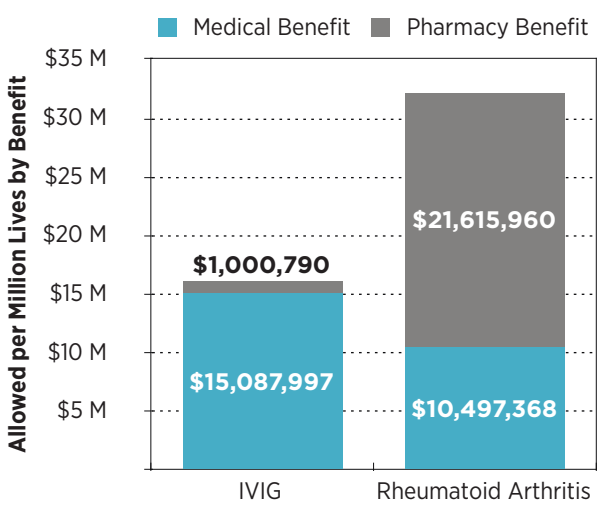
	DESCRIPTION	CODE	ALLOWED PER 1 M LIVES			CLAIMS PER 1 M LIVES		
			2009	2010	% CHANGE	2009	2010	% CHANGE
TAXOTERE	Malignant neoplasm of female breast	174	$2,933,734	$2,870,075	-2.2%	1,142	1,108	-3.0%
	Encounter for other and unspecified procedures and aftercare	V58	$1,992,836	$1,237,415	-37.9%	408	517	26.8%
	Malignant neoplasm of prostate	185	$674,833	$739,170	9.5%	377	303	-19.8%
	Malignant neoplasm of trachea, bronchus, and lung	162	$574,370	$608,623	6.0%	342	311	-9.1%
	Malignant neoplasm of ovary and other uterine adnexa	183	$204,480	$223,003	9.1%	106	91	-14.3%

New Analyses for 2011

There are several key specialty drugs commonly paid on both the medical and pharmacy benefits. To address this, we looked at two such classes, IVIG and rheumatoid arthritis (RA). The results are consistent year over year: By and large, claims for IVIG are paid under the medical benefit and claims for RA are paid under the pharmacy benefit. *See Figure 56, Self-Injectable Versus Physician-Administered Claims by Benefit (All Lines of Business, 2010).*

FIG. 56 SELF-INJECTABLE VS. PHYSICIAN-ADMINISTERED CLAIMS BY BENEFIT (ALL LINES OF BUSINESS, 2010)





Two common oncology supportive care therapeutic areas that receive payor attention for management were also 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 still 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.

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 that 40 percent of the Neupogen spend is for nonmyelosuppressive chemotherapy and slightly less for Leukine. 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 57, Oncology Support Drug Utilization – Medical and Pharmacy Benefits (2010).*

FIG. 57 ONCOLOGY SUPPORT DRUG UTILIZATION — MEDICAL AND PHARMACY BENEFITS (2010)

	CINV – % of $/MM		
REGIMEN	ALOXI	ZOFRAN	KYTRIL
LEC	37%	41%	47%
MEC	36%	27%	29%
HEC	22%	14%	10%
Unknown	5%	18%	14%

	G-CSF – % of $/MM		
REGIMEN	NEULASTA	NEUPOGEN	LEUKINE
Nonmyelosuppressive	19%	40%	32%
Myelosuppressive	81%	60%	68%

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, significantly less than 1 percent of total spend in each of the last two years was paid under these codes. 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. *See Figure 58, Unclassified Codes – Medical Benefit.*

FIG. 58 UNCLASSIFIED CODES — MEDICAL BENEFIT

	CLASSIFIED	UNCLASSIFIED
2009		
Allowed per 1 M lives	$227,049,357	$882,851
Claims per 1 M lives	743,151	3,607
% of total spend	99.6%	0.4%
2010		
Allowed per 1 M lives	$228,338,685	$690,094
Claims per 1 M lives	776,273	3,528
% of total spend	99.7%	0.3%

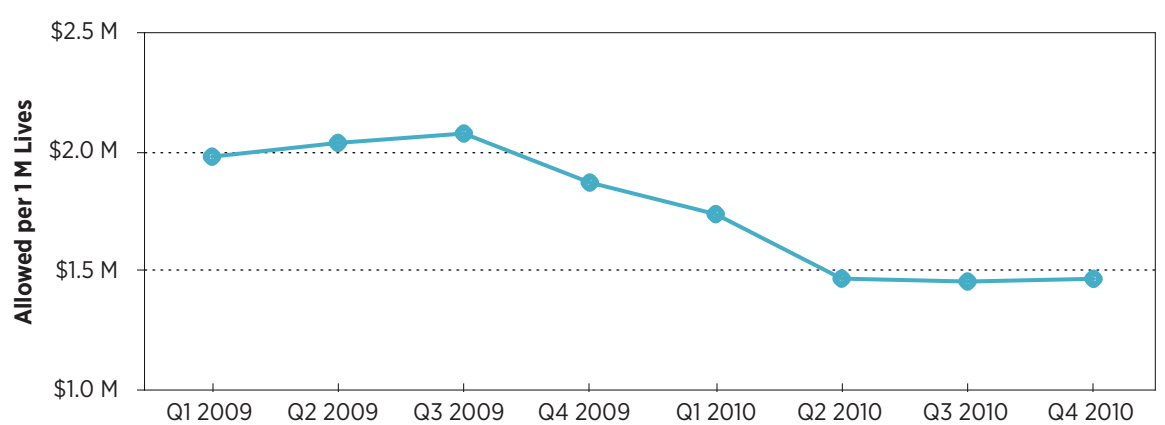
An analysis of label (FDA and NCCN guidelines) and off-label uses of medical injectables across all lines of business was conducted to see if there were any differences by service line. Label and off-label use was found to be consistent across all lines of business, with on-label claims representing 93 percent of the allowed spend per 1 million lives and 95 percent of the claims per 1 million lives. *See Figure 59, Off-Label Utilization for the Top 25 Drugs (2010).*

FIG. 59 OFF-LABEL UTILIZATION FOR THE TOP 25 DRUGS (2010)

	ALL LOB		COMMERCIAL		MEDICARE		MEDICAID	
	ALLOWED PER 1 M LIVES (% OF TOTAL)	CLAIMS PER 1 M LIVES (% OF TOTAL)	ALLOWED PER 1 M LIVES (% OF TOTAL)	CLAIMS PER 1 M LIVES (% OF TOTAL)	ALLOWED PER 1 M LIVES (% OF TOTAL)	CLAIMS PER 1 M LIVES (% OF TOTAL)	ALLOWED PER 1 M LIVES (% OF TOTAL)	CLAIMS PER 1 M LIVES (% OF TOTAL)
On-Label	$137,075,407 (93%)	62,786 (95%)	$138,176,959 (93%)	62,468 (94%)	$329,178,938 (95%)	177,285 (96%)	$20,503,840 (98%)	9,673 (95%)
Off-Label	$10,656,434 (7%)	3,586 (5%)	$11,118,355 (7%)	3,646 (6%)	$15,705,199 (5%)	7,725 (4%)	$318,500 (2%)	462 (5%)

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 60, Generic Introduction Spend Impact.*

FIG. 60 GENERIC INTRODUCTION SPEND IMPACT



PRODUCT PIPELINE AND LEGISLATIVE TRENDS

Product Pipeline

In 2010, a number of very costly medical injectables received approval for marketing in the U.S., and 2011 continues the trend with 11 new entrants approved by the FDA in the first half of the year. Yervoy created a stir in the market not only for the clinical data showing survival in metastatic melanoma, but also for its $30,000 per dose price tag. Although metastatic melanoma has a poor prognosis, Yervoy is the first drug shown to extend life in metastatic melanoma with a median survival of 10.1 months. However, as with the other agents, Yervoy is associated with severe side effects. Severe or fatal autoimmune reactions occurred in 12.9 percent of patients treated with Yervoy. Because of these severe adverse events, Yervoy is approved with a risk evaluation and mitigation strategy to inform providers of these severe risks. *See Figure 61, 2011 FDA-Approved Injectable Drugs/Indications – Specialty and Oncology.*

FIG. 61 2011 FDA–APPROVED INJECTABLE DRUGS

DRUG	MANUFACTURER	INDICATION	APPROVAL
Makena (hydroxyprogesterone caproate injection)	Hologic	Prevention of risk of preterm birth	February
Yervoy (ipilimumab)	Bristol-Myers Squibb	Metastatic melanoma	March
Benlysta (belimumab)	Human Genome Sciences	Systemic lupus erythematosus	March
Zytiga (abiraterone acetate)	Centocor Ortho Biotech	Prostate cancer	March
Sylatron (peginterferon alfa-2b)	Merck	Melanoma	April
Actemra (tocilizumab)	Genentech	Systemic juvenile idiopathic arthritis	April
Nulojix (belatacept)	Bristol-Myers Squibb	Prevention of organ rejection following kidney transplant	June
Firazyr (icatibant)	Shire	Acute attacks of hereditary angioedema	August
Adcetris (brentuximab vedotin)	Seattle Genetics	Hodgkin lymphoma and analplastic large-cell lymphoma	August
Soliris (eculizumab)	Alexion	Atypical hemolytic uremic syndrome	September
Onfi (clobazam)	Lundbeck	Lennox-Gastaut syndrome	October

Source: FDA-Approved Drugs. CenterWatch website. www.centerwatch.com/drug-information/fda-approvals. Accessed October 31, 2011.

Other than Teva's lipegfilgrastim (Neutroval), which is being held from its previous September 30, 2010 launch due to an agreement with Amgen until after 2013, there are few biosimilar therapies past phase 1 or phase 2 in the pipeline other than ESAs and G-CSFs. *See Figure 62, Biosimilar Pipeline.*

FIG. 62 BIOSIMILAR PIPELINE

PRODUCT NAME	PROPOSED INDICATION	COMPANY	PHASE OF FDA STUDY	COMMENTS
MK-2578 (pegylated erythropoietin)	Anemia, chronic kidney disease	Merck	N/A	Merck has discontinued development of this biosimilar product.
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	Teva entered into a settlement with Amgen that will prohibit it from launching Neutroval until November 2013.
Lipegfilgrastim	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	Phase 3 study of lipegfilgrastim achieved its primary endpoint of reducing the duration of severe neutropenia in patients receiving myelosuppressive chemotherapy. Initial study results showed the duration of severe neutropenia was similar to Neulasta in breast cancer patients. Teva entered into a settlement with Amgen that will prohibit it from launching lipegfilgrastim until November 2013.
Erythropoietin (EPO)	Treat anemia caused by chronic kidney disease	Hospira	Phase 2	Hospira already sells a biosimilar EPO, Retacrit, in Europe.
Rituximab	Rheumatoid arthritis	Sandoz	Phase 2	Sandoz initiated a phase 2 trial of biosimilar rituximab in January 2011.

In 2011, more agents are advancing to phase 2/3 trials than in 2010. Specifically, there is a 16 percent increase in the number of phase 2 agents, as well as a 10 percent increase in the number of phase 3 agents. Breast cancer continues to lead the clinical research field with over 100 agents in either phase 2/3 trials across all indications and lines of therapy. Many trials are associated with genomic markers, which continue to be an increasingly important tool to match therapeutic effect with the genetic makeup of patients. NSCLC is also heavily researched. Colorectal, prostate, melanoma, ovarian, and non-Hodgkin lymphoma each have at least 40 products under study. *See Figure 63, Pipeline Drugs in Various Phases of Study for Key Cancer Types, and Figure 64, Selected Phase 3 Products by Key Cancer Type.*

FIG. 63 PIPELINE DRUGS IN VARIOUS PHASES OF STUDY FOR KEY CANCER TYPES

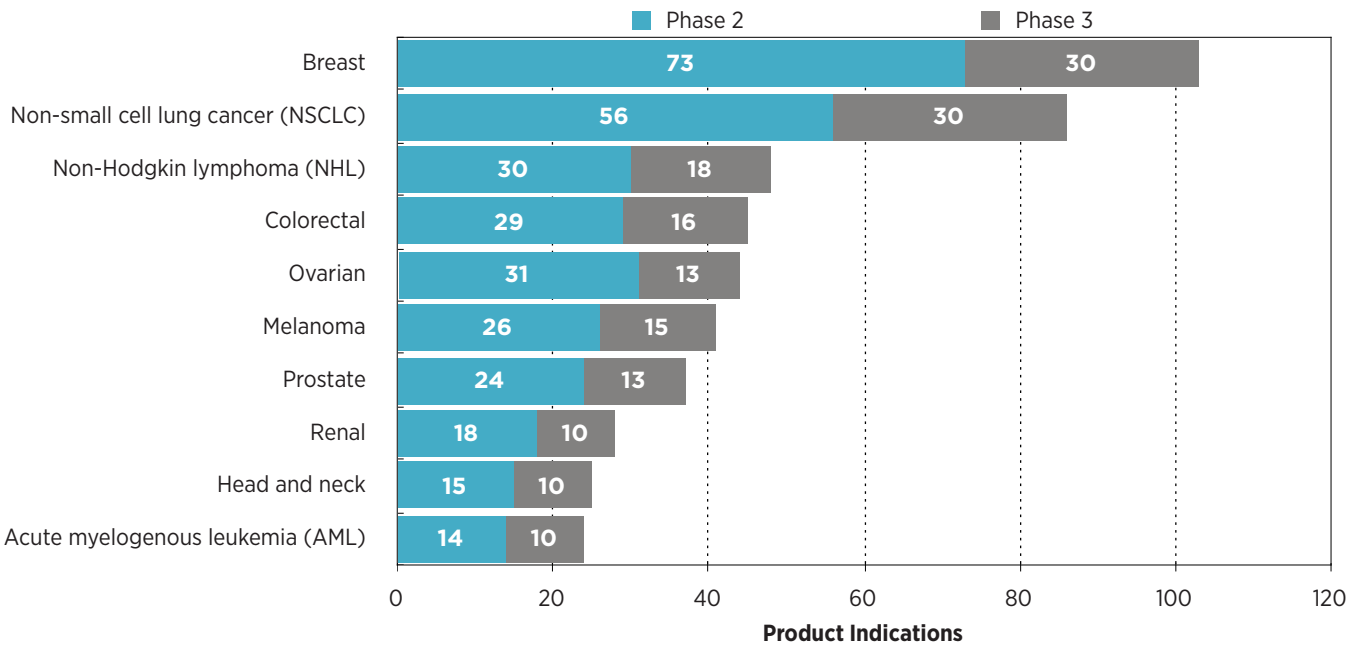


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FIG. 64 SELECTED PHASE 3 PRODUCTS BY CANCER TYPE

BREAST		
PRODUCT NAME	**CLASS**	**AREA(S) OF STUDY**
Afinitor	mTOR inhibitor	locally advanced or 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	first-line metastatic breast cancer (HER2- and HER2+); second-line metastatic breast cancer; adjuvant (HER2- and HER2+)
Doxil	anthracycline antibiotic	metastatic 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	metastatic breast cancer (triple negative)
Ixempra	epothilone	adjuvant breast cancer
neratinib	ErbB1 and ErbB2 inhibitor	advanced breast cancer (HER2+)
NeuVax	immunotherapy (peptide-based)	adjuvant breast cancer (HER2+)
Omnitarg	human EGF receptor (HER) dimerization inhibitor	first-line metastatic breast cancer (HER2+)
Orazol	bisphosphonate (oral)	adjuvant breast cancer
ramucirumab	anti-VEGFR-2 monoclonal antibody	second-line metastatic breast cancer
Stimuvax	immunotherapy	second-line metastatic breast cancer
Tavocept	chemoprotective agent	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
Alimta	antimetabolite (a folic acid antagonist)	NSCLC
ARQ 197 (+ erlotinib)	c-Met kinase inhibitor	second-line metastatic
Avastin	anti-VEGF monoclonal antibody	NSCLC with previously treated central nervous system metastases; adjuvant
crizotinib	anaplastic lymphoma kinase (ALK) inhibitor (oral)	advanced NSCLC
Erbitux	anti-EGFR monoclonal antibody	NSCLC; second-line metastatic
iniparib	PARP inhibitor	squamous cell lung cancer
Iressa	EGFR tyrosine kinase inhibitor	NSCLC
Lucanix	immunotherapy	NSCLC
motesanib diphosphate	anti-VEGF receptors 1, 2, and 3 (VEGFR 1-3) (oral)	first-line metastatic NSCLC
necitumumab	EGFR inhibitor	NSCLC
Nexavar	multiple tyrosine kinase inhibitor	first-line metastatic
Opaxio	microtubule inhibitor	NSCLC
Ostarine	selective androgen receptor modulator (SARM)	NSCLC
PF-00299804	pan-HER inhibitor	metastatic
Stimuvax	immunotherapy	NSCLC
Sutent	multiple tyrosine kinase inhibitor	NSCLC
talactoferrin	dendritic cell activator (DCA)	locally advanced or metastatic NSCLC
Tarceva	HER1/EGFR inhibitor	adjuvant
Tovok	EGFR/HER2 inhibitor	NSCLC
Vargatef	multiple tyrosine kinase inhibitor (VEGFR; fibroblast growth factor receptor, FGFR; platelet-derived growth factor receptor, PDGFR)	NSCLC
Zaltrap	VEGF-A inhibitor	second-line metastatic

NON-HODGKIN LYMPHOMA (NHL)		
PRODUCT NAME	**CLASS**	**AREA(S) OF STUDY**
Arzerra	anti-CD20 monoclonal antibody (humanized)	second-line follicular
Avastin	anti-VEGF monoclonal antibody	diffuse large B-cell lymphoma (DLBCL)
BiovaxID	immunotherapy	follicular
enzastaurin	serine/threonine kinase inhibitor	DLBCL
Folotyn	antifolate	peripheral T-cell lymphoma (PTCL)
galiximab	anti-CD80 monoclonal antibody	B cell
pixantrone	anthracycline	second-line diffuse large B cell
Revlimid	immune system modulator	NHL
Velcade	proteasome inhibitor	second-line follicular
Zevalin	CD20-directed radiotherapeutic antibody	follicular

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

OVARIAN		
PRODUCT NAME	CLASS	AREA(S) OF STUDY
alkeran	alkylating agent	ovarian cancer
AMG 386 (+ paclitaxel)	Fc-peptide fusion protein targeting angiopoietins (peptibody)	second-line metastatic
Avastin	anti-VEGF monoclonal antibody	first-line metastatic; second-line metastatic platinum-sensitive
farletuzumab; MORAb-003	IgG1 monoclonal antibody (humanized)	second-line metastatic
Hycamtin	topoisomerase inhibitor	first-line metastatic
iniparib	PARP inhibitor	platinum-sensitive and platinum-resistant
Karenitecin	highly lipophilic camptothecin	ovarian cancer
Opaxio; paclitaxel poliglumex; CT-2103	microtubule inhibitor	ovarian cancer
patupilone	epothilone	ovarian cancer
phenoxodiol	multiple signal transduction regulator	ovarian cancer
Tarceva; erlotinib	HER1/EGFR inhibitor	ovarian cancer
Vargatef; BIBF 1120	multiple tyrosine kinase inhibitor (VEGFR, FGFR, PDGFR)	ovarian cancer

MELANOMA		
PRODUCT NAME	CLASS	AREA(S) OF STUDY
Abraxane	microtubule inhibitor	first-line metastatic
BRF113683	BRAF inhibitor	advanced; metastatic
Delcath System	drug delivery platform	metastatic in the liver
GSK1120212	MEK inhibitor	advanced; metastatic
GSK2118436	BRAF inhibitor	advanced; metastatic
Nexavar	multiple tyrosine kinase inhibitor	melanoma
Oncophage	immunotherapy	metastatic
OncoVEX granulocyte-macrophage colony-stimulating factor (GM-CSF)	modified herpes-simplex 1 virus injected directly into tumor	metastatic
Pegintron	PEG recombinant alpha-2b interferon	melanoma
Yervoy	anti-CTLA4 monoclonal antibody (humanized)	adjuvant; second-line metastatic
Zadaxin	immune system modulator	melanoma
Zelboraf	BRAF-selective kinase inhibitor	melanoma

PROSTATE		
PRODUCT NAME	**CLASS**	**AREA(S) OF STUDY**
Alpharadi	alpha-emitting radiopharmaceutical	treatment of bone metastases in hormone refractory prostate cancer (HRPC)
Avastin	anti-VEGF monoclonal antibody	HRPC
cabazitaxel	taxane	first-line HRPC
DCVax	immunotherapy	prostate cancer
MDV3100	SARM	HRPC
OGX-011/TV-1011 (+ docetaxel)	clusterin inhibitor	second-line metastatic hormone refractory
phenoxodiol	multiple signal transduction regulator	prostate cancer
Revlimid	immune system modulator	prostate cancer
satraplatin	platinum chemotherapy agent (oral)	second-line metastatic hormone refractory (docetaxel refractory)
Sutent	multiple tyrosine kinase inhibitor	HRPC
Zytiga	inhibitor of the steroidal enzyme 17 alpha-hydroxylase/C17,20 lyase (oral)	first-line metastatic HRPC

RENAL		
PRODUCT NAME	**CLASS**	**AREA(S) OF STUDY**
axitinib	multiple tyrosine kinase inhibitor (VEGFR 1, 2, and 3; PDGFR; cKIT)	second-line metastatic
Nexavar	multiple tyrosine kinase inhibitor	adjuvant
Oncophage	immunotherapy	metastatic
Sutent	multiple tyrosine kinase inhibitor	first-line metastatic; adjuvant; cytokine-refractory metastatic
tivozanib	VEGF receptors 1, 2, and 3 inhibitor	first-line metastatic
Torisel	mTOR inhibitor	renal cell carcinoma
Votrient	multiple tyrosine kinase inhibitor	adjuvant

HEAD AND NECK		
PRODUCT NAME	**CLASS**	**AREA(S) OF STUDY**
Alimta (+ cisplatin)	antimetabolite (a folic acid antagonist)	recurrent or metastatic (squamous)
Avastin	anti-VEGF monoclonal antibody	metastatic
Multikine	immunotherapy	first line
OncoVEX GM-CSF	modified herpes-simplex 1 virus injected directly into tumor	first line
selective electrochemical tumor ablation (SECTA) + bleomycin	electroporation therapy	head and neck cancer
Tykerb	ErbB2 and EGFR dual kinase inhibitor	head and neck cancer (squamous)
Vectibix	anti-EGFR monoclonal antibody (humanized)	metastatic; recurrent
zalutumumab (+ radiotherapy); HuMax-EGFR	anti-EGFR monoclonal antibody (humanized)	first line

ACUTE MYELOGENOUS LEUKEMIA (AML)		
PRODUCT NAME	**CLASS**	**AREA(S) OF STUDY**
Ceplene	histamine H2 receptor agonist	AML
Clolar	antimetabolite	AML
Dacogen	antimetabolite (cytidine analog)	AML
elacytarabine	antimetabolite	AML
midostaurine	multiple tyrosine kinase inhibitor	AML
Onrigin	alkylating agent	AML
sapacitabine	antimetabolite (oral)	first-line metastatic
Trisenox	taxane (a synthetic retinoid)	AML
Vidaza	antimetabolite (cytidine analog)	AML
vosaroxin	topoisomerase 2 inhibitor	AML

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Key Legislative Outcomes – 2011

Given the difficult economy, current budgetary challenges, and the call for deficit reduction, health care spending is and will likely remain a focal point for the states and federal government in the foreseeable future. In the U.S. this year, the government has paid over half of the nation's health care bills.

ONCOLOGY HEALTH POLICY UPDATES

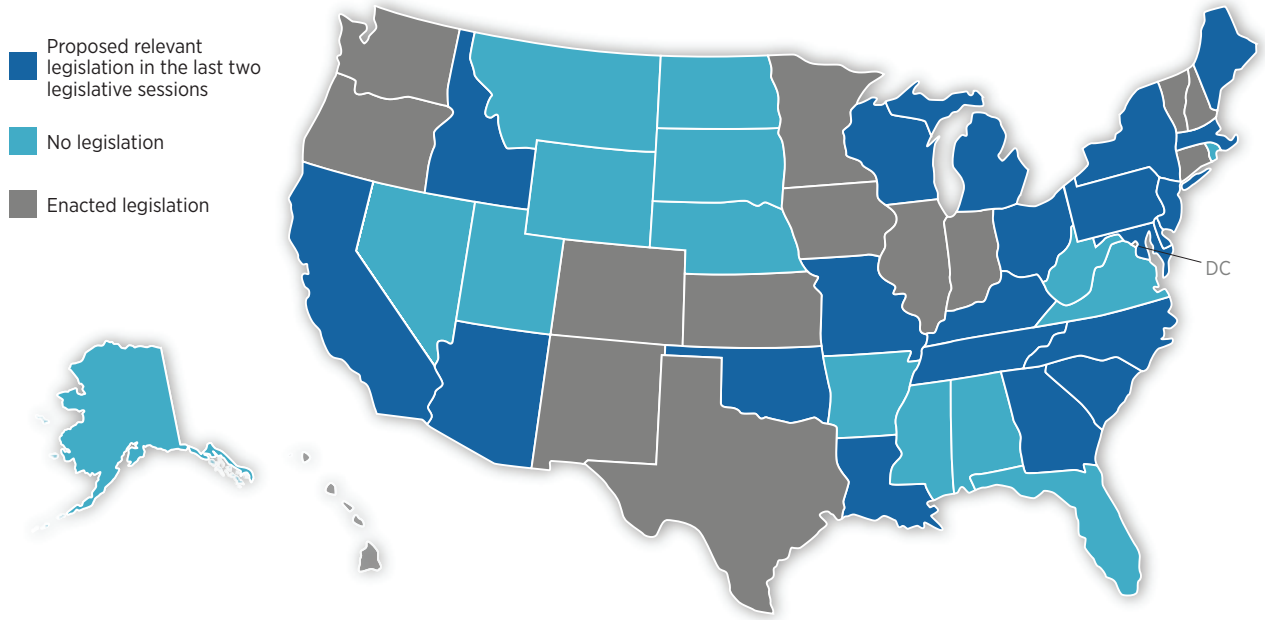
Since the passage of the Patient Protection and Affordable Care Act (ACA) in 2010, CMS has been actively engaged in the rule-making process, asking for comments to proposed rules, as well as issuing some final regulations and guidance. Some important developments related to ACA and oncology include:

- Provisions related to the increased Medicaid rebate amount for drugs dispensed or administered to fee-for-service Medicaid and Medicaid managed care beneficiaries
- Initial phasing in of coverage in the Medicare Part D coverage gap for brand-name and generic drugs, helping to reduce the beneficiary coinsurance amounts, as well as implementation of the manufacturer-required 50 percent rebate for drugs in the coverage gap

STATE ORAL AND IV PARITY LEGISLATION

Another important issue impacting oncology this year has been the efforts to secure cost-sharing parity between oral, injected, and infused products. The aim of supporters, led by the American Cancer Society, is to have parity in patient coinsurance responsibility between settings of care (ultimately, through medical and pharmacy benefit parity). A map below provides an overview of state policies related to oral and injected/infused parity. *See Figure 65, Oral and IV Parity Legislation.*

FIG. 65 | ORAL AND IV PARITY LEGISLATION



Source: HillCo HEALTH review of 50 state policies related to oral and IV parity as of 7/27/2011.

While not included in the chart, a number of other states, for example, North Carolina and Virginia, proposed legislation to study the issues of access related to oral versus IV oncolytics. The issue of oral versus IV parity continues to build at the state level each year, as demonstrated by the map.

OFF-LABEL-COVERAGE CANCER DRUGS AND BIOLOGICS

Under the Omnibus Budget and Reconciliation Act of 1990, states cover most prescription drugs, including cancer drugs and biologics, as well as supportive products, in their Medicaid programs (OBRA-90, Pub. L. 101-508, 104 Stat. 1388, enacted November 5, 1990). Coverage of off-label uses of anticancer medications are allowed under compendia approved by CMS (SSA 1861 (t)(2)(B), 42 USC 1395x, and 1927 (g)(I)(B)(II) as amended by DRA 2005, Pub. L. 109-171).

Many states also cover the same off-label uses for non-ERISA (Employee Retirement Income Security Act) employers and state-funded health care programs, such as for state employees. *See Figure 66, States That Also Require Coverage for Uses in Medical Literature.*

FIG. 66 STATES THAT ALSO REQUIRE COVERAGE FOR USES IN MEDICAL LITERATURE

YES		NO	NO STATUTORY CITATION	UNKNOWN
Alabama	Missouri	Connecticut	Alaska	Idaho
Arizona	Nebraska	New Mexico	Colorado	Kentucky
Arkansas	Nevada	North Carolina	District of Columbia	
California	New Hampshire	Oklahoma	Iowa	
Delaware	New Jersey		Montana	
Florida	New York		Pennsylvania	
Georgia	North Dakota		Utah	
Hawaii	Ohio		West Virginia	
Illinois	Oregon		Wisconsin	
Indiana	Rhode Island		Wyoming	
Kansas	South Carolina			
Louisiana	South Dakota			
Maine	Tennessee			
Maryland	Texas			
Massachusetts	Vermont			
Michigan	Virginia			
Minnesota	Washington			
Mississippi				

Source: Association of Community Cancer Centers report on off-label use of anticancer therapies, 2009.

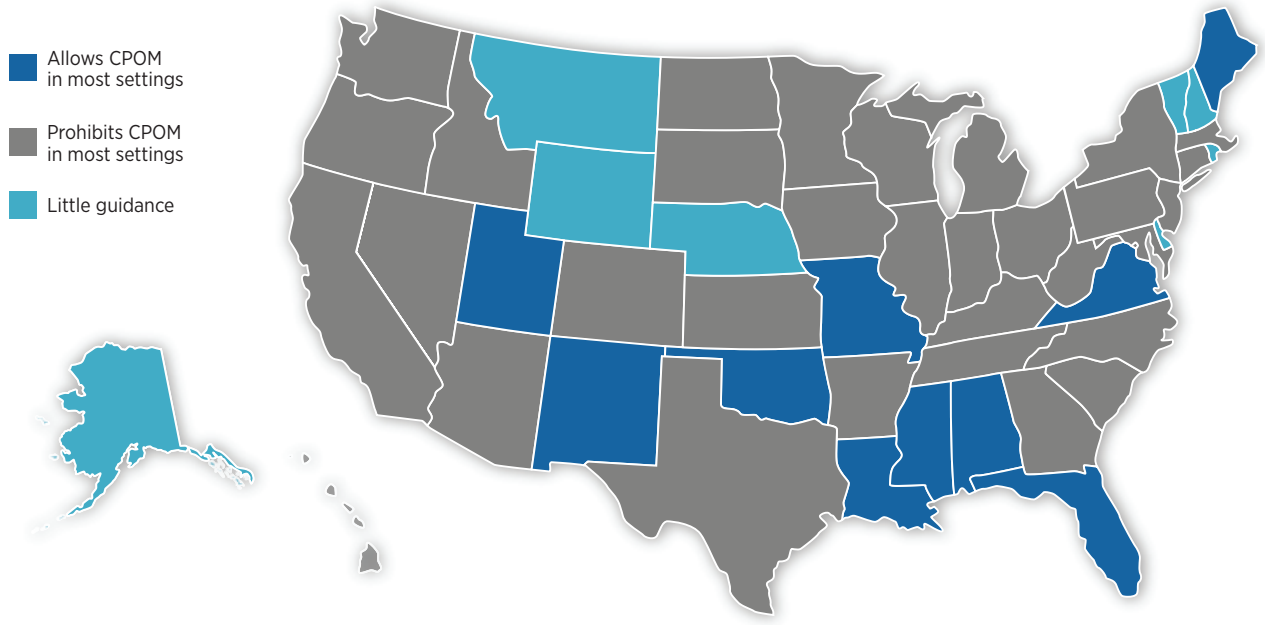
MARKETPLACE

There is some evidence to suggest that there is pressure in the market on oncology products in the physician office setting as compared with the hospital setting. This change appears focused around three dynamics:

1. Hospitals appear to be buying up large oncology practices and shifting the site of care to hospitals where more favorable contract pricing is usually present for chemotherapies than in the physician office buy-and-bill model. One reason this change is made possible is by certain state laws allowing for the corporate practice of medicine (CPOM). In states with a CPOM prohibition, a business corporation is prohibited from practicing medicine or employing a physician to provide professional medical services. Some prohibitions include exceptions, such as for rural or public hospitals or to allow physicians to provide medical services through some form of a professional corporation or service corporation.

   With regard to caring for cancer, it is important that hospices and palliative care programs understand their CPOM laws, since these laws determine what type of relationship they may have with physicians. For example, a hospice program that employs, as a W-2 worker, a physician to provide medical services in a state that has a CPOM prohibition may be placing the physician at risk. The map below summarizes each state's CPOM laws. *See Figure 67, Corporate Practice of Medicine (CPOM) Across States.*
2. Given the increasing pressures of managing a small practice and the increasingly higher cost of providing drugs and biologics, many smaller practices are shifting patients to the hospital and not providing drugs or biologics in the physician office setting.
3. The incentive for 340B pricing in the hospital setting, or a satellite facility, is not available in the physician office setting.

FIG. 67 | CORPORATE PRACTICE OF MEDICINE (CPOM) ACROSS STATES



Source: HillCo HEALTH 50-state overview of corporate practice of medicine as of 7/28/2011.

Glossary

ACA	Accountable Care Act
ALK	anaplastic lymphoma kinase
AML	acute myelogenous leukemia
ASP	average sales price
AWP	average wholesale price
BCA	breast cancer
BRCA	breast cancer susceptibility gene
BRM	biologic response modifier
CA	cancer
CINV	chemotherapy-induced nausea and vomiting
CMS	Centers for Medicare & Medicaid Services
COA	Community Oncology Alliance
CPOM	corporate practice of medicine
CRC	colorectal cancer
DCA	dendritic cell activator
DLBCL	diffuse large B-cell lymphoma
EGFR	epidermal growth factor receptor
EPO	erythropoietin
ERISA	Employee Retirement Income Security Act
ESA	erythropoiesis-stimulating agent
ESRD	end-stage renal disease
FDA	U.S. Food and Drug Administration
FGFR	fibroblast growth factor receptor
G-CSF	granulocyte colony-stimulating agent or colony-stimulating factor
GM-CSF	granulocyte-macrophage colony-stimulating factor
HCPCS	Healthcare Common Procedure Coding System
HEC	highly emetogenic chemotherapy
HEDIS	Healthcare Effectiveness Data and Information Set
HER	human EGF receptor
HMO	health maintenance organization
HRPC	hormone refractory prostate cancer

IV . . . . . intravenous
IVIG . . . . . intravenous immune globulin
KRAS . . . . . Kirsten RNA associated rat sarcoma 2 virus gene
LEC . . . . . low emetogenic chemotherapy
LHRHa . . . . . luteinizing hormone-releasing hormone analog
LOB . . . . . lines of business
mBC . . . . . metastatic breast cancer
MEC . . . . . moderate emetogenic chemotherapy
MMA . . . . . Medicare Modernization Act
NCCN . . . . . National Comprehensive Cancer Network
NHL . . . . . non-Hodgkin 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
RA . . . . . rheumatoid arthritis
SARM . . . . . selective androgen receptor modulator
SECTA . . . . . selective electrochemical tumor ablation
SERM . . . . . selective estrogen receptor modulator
SOS . . . . . site of service
SPP . . . . . specialty pharmacy providers
UM . . . . . utilization management
VEGF . . . . . vascular endothelial growth factor
VFS . . . . . variable fee schedule

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