



**Milliman Specialty Medical Drug
2010 Commercial Benchmark Study**

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I. EXECUTIVE SUMMARY

The purpose of this study is to provide employers and health plans with specialty drug claim cost benchmarks to better understand the magnitude and distribution of specialty drug costs adjudicated under the medical benefit by:

- > Identifying specialty drugs and the percentage of total healthcare costs they represent,
- > Benchmarking or determining from historical data, the amount of specialty drug spend covered under the medical and pharmacy benefits,
- > Evaluating the amount of drug spend by therapeutic class and place of service under the medical benefit,
- > Quantifying the medical drug trend by therapeutic class and place of service of specialty drugs being administered under the medical benefit,
- > Identifying the distribution of cost for specialty drug utilizers, and
- > Providing detail cost information for oncology and inflammatory conditions.

This study also describes various opportunities for health care organizations to better manage the total specialty drug trend.

For purposes of this study we defined specialty medical drugs as specialty drugs administered by a healthcare professional in the home, a hospital outpatient facility, or a physician's office and typically covered under the medical benefit. We defined specialty pharmacy drugs as specialty drugs dispensed in a retail, mail, or specialty pharmacy, self-administered by the patient and typically covered under the pharmacy benefit.

This study was commissioned by Novologix, Inc. The information in this study was based on claims data from a commercial group population (i.e., primarily under age 65 commercial group members excluding Medicare, Medicaid, individually insured, and uninsured populations). The study was based on 2009 and 2010 claims data.

HIGHLIGHTS

2010 highlights from this study include:

- > This report is based on drug claim costs using the Truven Health MarketScan©2012 Research Database (MarketScan) for 2009 and 2010 claims data.
- > Total drug costs, including drugs adjudicated under the medical and pharmacy benefit, account for about 25% of total healthcare claim costs.
- > Approximately 50% of total specialty drug costs were paid as a medical benefit and 50% were paid as a pharmacy benefit.
- > The specialty drug cost trend exceeded the trend in total medical and pharmacy costs:
 - Specialty drug costs increased by 13.2%
 - Total drug costs increased by 6.7%

- Overall healthcare costs, including medical and pharmacy, increased by 5.1%
- > Specialty drug utilization differed significantly between the medical and pharmacy benefit:
 - Specialty medical drug costs composed about 54% of total medical drug costs
 - Specialty pharmacy costs composed about 15% of total pharmacy costs
- > The top 10 specialty drug therapeutic classes composed 95% of total specialty medical drug spend:
 - Oncology specialty drugs composed about 40% of total specialty medical drug spend
 - Hematopoietic Growth Factors, the second most costly specialty drug class, only composed 19% of total specialty medical drug spend
- > Forty-four percent (44%) of total specialty medical drug costs (excluding drugs provided during an inpatient admission) were provided in a physician's office, 34% were provided in a hospital outpatient department and 13% were provided in the patient's home. There was a noticeable shift in where specialty medical drugs were dispensed. Specialty medical drug costs provided in a hospital outpatient department increased by almost 20% while costs provided in a physician's office declined by 5%.
- > Specialty medical drug costs as a percentage of total specialty drug costs varied considerably by region of the country. The West region had much higher relative specialty medical drug costs than the South, Northeast and Midwest regions.
- > The average aggregate healthcare costs PMPM of patients who use specialty drugs was 8.5 times higher than the average aggregate healthcare costs PMPM of all members in the study.

CAVEATS AND LIMITATIONS

The information in this study is designed to describe and benchmark specialty drug costs. It may not be appropriate, and should not be used, for other purposes.

We relied on data obtained through proprietary and purchased data sources as the basis for our analysis and did not independently audit or verify the source of the information. If this information is incomplete or inaccurate, our observations and comments may not be appropriate. We performed general reasonableness tests on the underlying data.

II. BACKGROUND

Over \$30 billion in annual U.S. drug expenditures will be subject to generic competition in 2012¹. Patents have expired on several blockbuster brand drugs (e.g., Lipitor, Plavix, Seroquel, and Singulair), which is just the beginning of what should be rampant generic competition. Generic drug launches helped keep the inflationary trend for pharmacy expenditures in the low single digits in for the past several years.

In stark contrast are the inflationary drug trends for specialty drug products. Total 2011 per member per month (PMPM) specialty pharmacy drug cost trends reported by Pharmacy Benefit Managers (PBMs) ranged from 16% to 20%^{1 2}. Similar industry-reported medical drug cost and trend benchmarks have not been readily available.

Specialty drugs are typically associated with high-cost, complex, or rare health care conditions such as cancer, rheumatoid arthritis, and multiple sclerosis. Specialty drug products are expected to drive a significant portion of future drug costs and inflationary trends^{1 2}.

Although specialty drugs are often treated as a distinct class of medications, there is no universally accepted definition. Often the term “specialty drug” is a label that payers put on medications for the purpose of benefit management, cost sharing, and clinical oversight. A specialty drug may possess one or more of the following characteristics^{3 4 5}.

- > Significantly higher cost than non-specialty medications (e.g., Medicare Part D defines as any drug in which the negotiated monthly price is \$600 or more),
- > Developed using biotechnology and made from proteins, nucleic acids, or living organisms (i.e., biologic),
- > Specialized delivery, storage, handling, or administration requirements,
- > Administered via injection or infusion; however, can be inhaled or orally administered,
- > Intensive patient administration and compliance training,
- > Requires close patient monitoring for adverse events or drug requires patient be included in FDA mandated Risk Evaluation and Mitigation Strategy (REMS) program,
- > Available through limited distribution channels (e.g., a designated Specialty Pharmacy), or
- > Used for the treatment of uncommon health care conditions.

¹ Express Scripts. 2011 Pharmacy Trend Report. April 2012. Accessed September 24, 2012.

² CVS Caremark. Insights 2012 Advancing The Science of Pharmacy Care. 2012. Accessed September 24, 2012.

³ Baldini CB, Culley EJ. Estimated Cost Savings Associated with the Transfer of Office-Administered Specialty Pharmaceuticals to a Specialty Pharmacy Provided in a Medical Injectable Pharmacy Program. *J Manag Care Pharm.* 2011; 17(1):51-59.

⁴ Specialty Pharmacy, Presentation Developed for the Academy of Managed Care Pharmacy. December 2011. Available at www.amcp.org. Accessed September 24, 2012.

⁵ EMD Serono. EMD Serono Specialty Digest. 8th edition. 2012. Accessed September 24, 2012.

Payers do not classify specialty drug products similarly so it is important to define specialty drugs clearly in any type of cost analysis. For purposes of this study we developed a specific specialty drug list leveraging other publicly available specialty drug definitions. The therapeutic classes and examples of drugs defined as specialty drugs are provided in Appendix C.

In addition, we differentiate specialty drug claims adjudicated under the medical and pharmacy benefit by the following:

- > Specialty medical drugs are defined as those specialty drugs typically administered by a healthcare professional in the home, a hospital outpatient facility, or a physician's office and covered under the medical benefit.
- > Specialty pharmacy drugs as those specialty drugs typically dispensed in a retail, mail, or specialty pharmacy, self-administered by the patient and covered under the pharmacy benefit.

About 50% of specialty drug costs are administered by a healthcare professional and covered under the medical benefit and the other 50% are covered under the pharmacy benefit. This situation may lead to confusion among payers and providers as to how to best manage the patient and coordinate care in the most cost effective manner. In addition, it may also lead to confusion among patients on how and where to obtain specialty medications.

A specialty drug claim adjudicated under the medical benefit is processed differently than a claim adjudicated under the pharmacy benefit. When a claim is covered under the pharmacy benefit, a PBM is typically responsible for electronically capturing and processing that claim. The claim adjudication happens at the point of sale, which allows various drug utilization review (DUR) interventions and formulary controls to take place before any drugs are dispensed. Pharmacy drug claims are often clean with correct cost, number of units of dispensed and minimal payment lag time or run out. In contrast, medical drug claims are not adjudicated in real-time and may not have the correct number of units dispensed. This delay limits the DUR interventions and formulary controls that can take place.

The costs of drugs vary by the different types of contracts that may be in place between different types of medical and pharmacy providers. Medical drug claims are typically reimbursed on a discounted basis, fee schedule, average sales price (ASP) or other methods. Medical providers use the Level I and Level II Healthcare Common Procedural Coding System (HCPCS) to identify the claims, and the billed amount may be considerably higher than what the provider may have paid for the given drug. Providers may generate a profit from the drugs they administer. Health care organizations often pay higher costs for drugs that are adjudicated under the medical benefit versus the pharmacy benefit⁶.

Pharmacy claims are typically reimbursed as a discount from the average wholesale price (AWP), which is a published figure based on the National Drug Code (NDC) associated with each product.

This study includes the following benchmark information in Section III:

- > A per member per month (PMPM) claim cost summary of total healthcare spend by medical service category including separate claim cost summaries for total medical and pharmacy benefit spend and specialty medical drug and specialty pharmacy benefit spend
- > Specialty drug spend by therapeutic class
- > Specialty drug trend by therapeutic class
- > Specialty drug spend by place of service

⁶ Fein A. 2011-2012 Economic Report on Retail and Specialty Pharmacies. January 2012.

- > Specialty medical drug cost distribution by drug therapeutic class
- > Specialty medical drug trends for the top 10 HCPCS
- > Specialty drug spend by region
- > Average patient cost share by place of service

Additional background information is included in Section II. More detailed benchmark information on Oncology and Inflammatory Conditions is included in Section IV. Trend mitigation strategies for managing specialty medical drug costs are included in Section V. More detailed conclusions from the study are included in Section VI and a summary of the study data sources and methodology is included in Section VII.

The results of this study would be different for the Medicare, Medicaid, individual, or uninsured populations. In addition, the results in the study may not be representative of populations covered under state insurance exchanges or population changes brought about by the Patient Protection and Affordable Care Act.

III. RESULTS

This study was based on 2009 and 2010 drug claims for a commercially insured population as reported in the MarketScan database. We used this information to develop allowed cost and trend information and to illustrate changes in drug costs and utilization within the medical and pharmacy benefits. Allowed costs represent claim costs at contractual prices prior to reductions for patient cost sharing.

SUMMARY OF HEALTHCARE EXPENDITURES

Tables 1a (2009) and 1b (2010) provide an allocation of healthcare expenditures by type of service, total drug and specialty drug allowed cost components of those services.

Table 1a Summary of Healthcare Expenditures Per Member Per Month (PMPM) 2009								
Claim or Benefit Type	Hospital Outpatient	Hospital Inpatient	Home Health	Physician Office	Other Medical	Total Medical	Pharmacy Benefit Drugs	Total
All Services	\$94.71	\$80.25	\$5.89	\$75.11	\$23.23	\$279.19	\$63.25	\$342.44
Drugs Only*	\$8.85	N/A	\$1.33	\$7.31	\$1.60	\$19.09	\$63.25	\$82.34
Specialty Drugs Only*	\$3.07	N/A	\$1.17	\$5.00	\$0.97	\$10.21	\$8.53	\$18.74

*Medical drug components include only drug ingredient costs with no administrative fee or professional fee. Pharmacy Benefit Drug component includes drug ingredients costs plus dispensing fee.

Table 1b Summary of Healthcare Expenditures Per Member Per Month (PMPM) 2010								
Claim or Benefit Type	Hospital Outpatient	Hospital Inpatient	Home Health	Physician Office	Other Medical	Total Medical	Pharmacy Benefit Drugs	Total
All Services	\$101.16	\$82.73	\$6.45	\$76.04	\$25.55	\$291.93	\$67.87	\$359.80
Drugs Only*	\$9.74	N/A	\$1.54	\$7.02	\$1.71	\$20.01	\$67.87	\$87.88
Specialty Drugs Only*	\$3.68	N/A	\$1.36	\$4.76	\$1.03	\$10.83	\$10.38	\$21.21

*Medical drug components include only drug ingredient costs with no administrative fee or professional fee. Pharmacy Benefit Drug component includes drug ingredients costs plus dispensing fee.

In 2010, drug costs, including specialty and non-specialty drug costs, represented approximately 25% of total health care costs (\$87.88 vs. \$359.80 PMPM). Specialty drug costs represented about 6% of the overall total health care costs (\$21.21 vs. \$359.80 PMPM). Drug costs included in an inpatient hospital admission are not identified separately from other inpatient costs because of the bundling of inpatient ancillary services costs; therefore, inpatient drug costs are not included in our definition of drug costs (noted as N/A in Tables 1a and 1b).

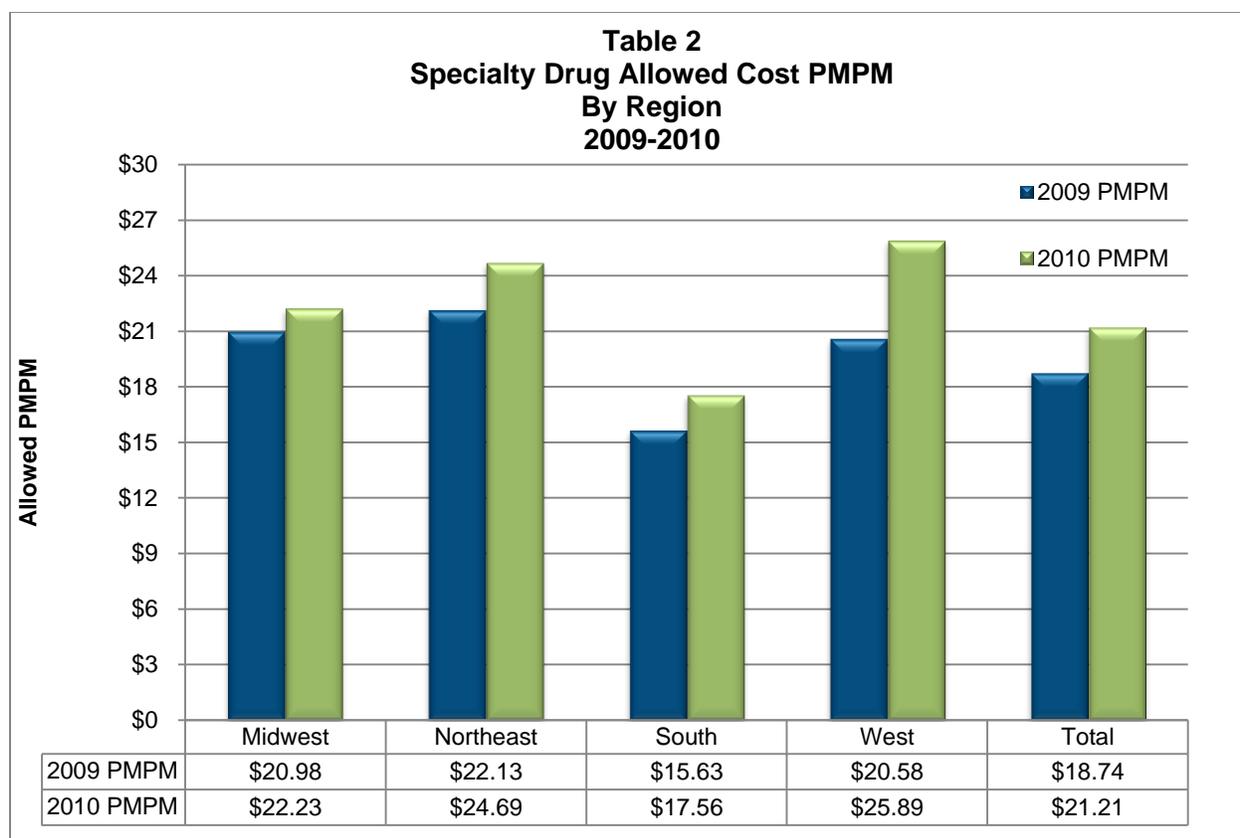
Approximately 51.1% of specialty drug costs were covered under the medical benefit in 2010 (\$10.83 vs. \$21.21 PMPM), which represented a decrease from 2009 (54.5% vs. 51.1%).

Specialty drug costs increased at a higher rate than overall healthcare costs and overall pharmacy costs between 2009 and 2010. Aggregate specialty drug costs increased by 13.2% (\$21.21 vs. \$18.74 PMPM) while overall medical costs increased by 5.1% (\$359.80 vs. \$342.44 PMPM) and overall drug costs increased by 6.7% (\$87.88 vs. \$82.34 PMPM). Specialty medical drug costs increased by 6.1% (\$10.83 vs. \$10.21 PMPM) while specialty pharmacy drug costs increased by 21.7% (\$10.38 vs. \$8.53 PMPM). Some reasons for the lower trend in the specialty medical drug component may be that several new specialty drugs became available orally or as a self-injectable, with these drugs primarily being dispensed through the pharmacy benefit⁷ and more health plans may have required certain specialty drugs to be dispensed in a retail or specialty pharmacy.

Specialty drug utilization is dramatically different under the medical and pharmacy benefits. Specialty drug costs compose about 54% of total medical drug costs, but only about 15% of total pharmacy drug costs.

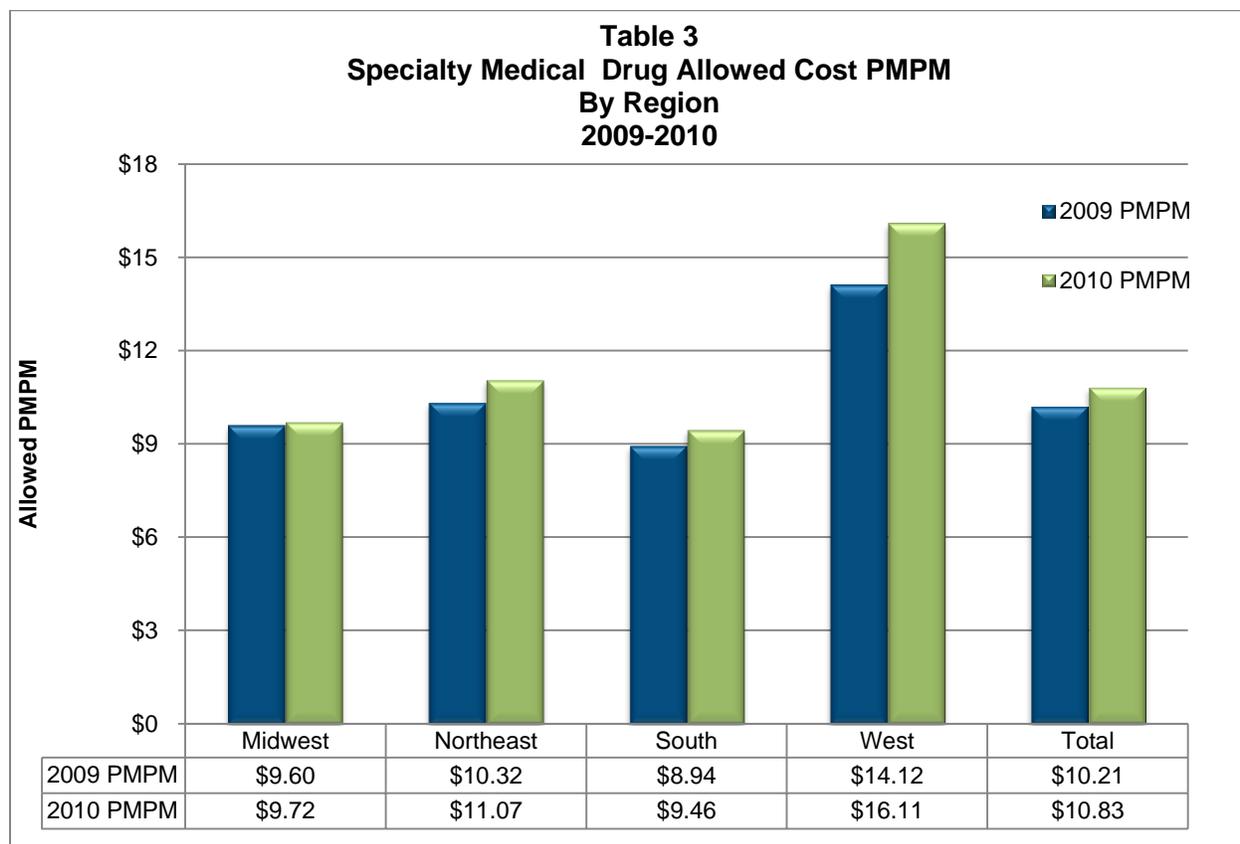
SPECIALTY DRUG COSTS BY REGION

Table 2 summarizes aggregate specialty drug costs, including both medical drug and pharmacy drug costs, for 2009 and 2010 by region of the country. The costs provided below are not normalized for population or plan design differences.



⁷ Specialty Pharmacy, Presentation Developed for the Academy of Managed Care Pharmacy. December 2011. Available at www.amcp.org. Accessed September 24, 2012.

Table 3 summarizes only specialty medical drug costs for 2009 and 2010 by region. The costs provided below are not normalized for population or plan design differences.



Specialty medical drug costs, as a percentage of total specialty drug costs, varied considerably by region with the West region having higher relative specialty medical drug costs than the other regions. The regional costs in Tables 2 and 3 may differ due to differences in population mix, average patient cost sharing, prescribing patterns and other factors. We did not standardize the costs to reflect a common population mix or the same average patient cost sharing.

SPECIALTY DRUG COSTS BY DRUG THERAPY CLASS

Table 4 summarizes 2009 and 2010 PMPM specialty drug costs separated between medical drug and pharmacy for the top ten specialty therapeutic classes in descending order by 2010 medical specialty drug spending.

Table 4
Specialty Drug Allowed Cost PMPM
Medical vs. Pharmacy Benefit
Top 10 Specialty Therapeutic Classes
2009-2010

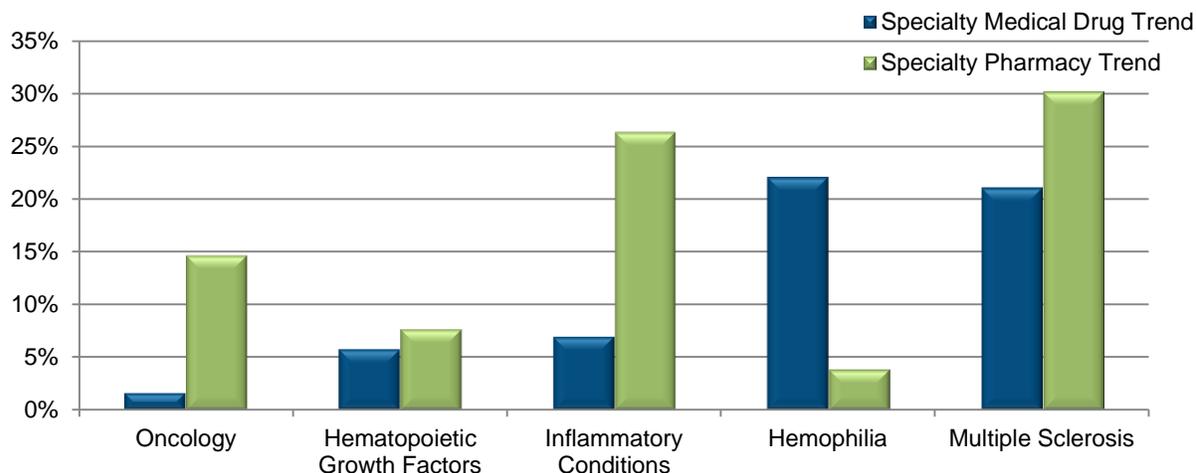
Therapeutic Class	2009			2010		
	Specialty Medical PMPM	Specialty Pharmacy PMPM	Total Specialty Drug PMPM	Specialty Medical PMPM	Specialty Pharmacy PMPM	Total Specialty Drug PMPM
Oncology	\$4.26	\$1.36	\$5.62	\$4.33	\$1.56	\$5.89
Hematopoietic Growth Factors	\$1.90	\$0.26	\$2.16	\$2.01	\$0.28	\$2.29
Inflammatory Conditions	\$1.29	\$2.31	\$3.60	\$1.38	\$2.92	\$4.30
Hemophilia	\$0.68	\$0.26	\$0.94	\$0.83	\$0.27	\$1.10
Immune Deficiency	\$0.78	\$0.03	\$0.81	\$0.78	\$0.09	\$0.87
Multiple Sclerosis	\$0.19	\$1.95	\$2.14	\$0.23	\$2.54	\$2.77
Osteoporosis	\$0.19	\$0.00	\$0.19	\$0.21	\$0.00	\$0.21
Viscosupplements	\$0.13	\$0.02	\$0.15	\$0.18	\$0.02	\$0.20
Respiratory Conditions	\$0.14	\$0.17	\$0.31	\$0.16	\$0.17	\$0.33
Acromegaly	\$0.13	\$0.04	\$0.17	\$0.16	\$0.05	\$0.21
Other	\$0.52	\$2.13	\$2.65	\$0.56	\$2.48	\$3.04
Total	\$10.21	\$8.53	\$18.74	\$10.83	\$10.38	\$21.21
% of Total	54.5%	45.5%	100.0%	51.1%	48.9%	100.0%

The top ten specialty therapeutic classes paid under the medical benefit accounted for about 95% of total specialty medical drug costs. The most expensive and highly utilized specialty medical drug therapeutic class is oncology, which accounted for about 40% of all specialty medical drug costs. The second largest class, hematopoietic growth factors only represents about 19% of all specialty medical drug costs. We discuss Oncology and Inflammatory Conditions in more detail in Section IV of this report.

In eight of the top ten therapeutic classes, more than 50% of specialty drug costs were covered under the medical benefit. Hematopoietic Growth Factors, osteoporosis, and viscosupplements are almost exclusively covered as a medical benefit. However, in almost all of the top ten therapeutic classes, and in aggregate, the percentage of drug costs covered under the medical benefit decreased in 2010, with acromegaly (i.e., too much growth hormone in the body) the one exception.

Table 5 shows the 2010 PMPM medical drug and pharmacy trends for the top five specialty therapeutic classes provided in Table 4.

**Table 5
Specialty Medical and Pharmacy PMPM Trend
Top 5 Specialty Therapeutic Classes
2009 vs 2010**



Note: Immune Deficiency is excluded from chart. Specialty Medical Drug Trend is 0% and Specialty Pharmacy Trend is 200%.

The top five specialty pharmacy therapeutic classes experienced a positive medical drug trend, ranging from 1.6% up to 30.3% from 2009 to 2010. In most of these classes, the specialty pharmacy trend was higher than the specialty medical drug trend. A possible explanation for the higher specialty pharmacy trends may be that some plan sponsors covered certain specialty drugs only through a specialty pharmacy as a way of controlling costs, resulting in a shift from medical drug to pharmacy. This coverage can be done through “white bagging”, where a specialty medication is dispensed at a specialty pharmacy and the drug is sent directly to the hospital pharmacy on behalf of a patient. The hospital takes possession of the medication and provides the administration to the patient. Another method is “brown bagging” which is where the patient is dispensed the specialty medication directly and brings the medication to the physician’s office or clinic for administration⁸.

⁸ Pembroke Consulting, 2012. Channels leading to dispensing of specialty products under the pharmacy benefit. http://4.bp.blogspot.com/-eV6Q-CK43xk/T_r65dQaULI/AAAAAAAAABZI/8BtU5sX4FO8/s1600/Channels_leading_to_dispensing_specialty_products_under_pharmacy_benefit.png. Accessed October 7, 2012.

MEDICAL DRUG DISTRIBUTION CHANNELS

Specialty medical drug drugs are dispensed in various settings or places of service (POS), such as a physician’s office, a home health encounter, or a hospital outpatient facility. Table 6 shows the distribution of specialty medical drug costs and changes in PMPM cost between 2009 and 2010 by place of service.

Table 6 Specialty Medical Drug Costs Trends by Place of Service 2009-2010			
	2009	2010	
Place of Service	Allowed Cost PMPM	Allowed Cost PMPM	Allowed Cost PMPM Trend
Physician Office	\$5.00	\$4.76	-4.8%
Home Health	\$1.17	\$1.36	16.2%
Hospital Outpatient	\$3.07	\$3.68	19.9%
Other	\$0.97	\$1.03	6.2%
Total	\$10.21	\$10.83	6.1%

Note: Other category includes end stage renal disease treatment facilities, emergency rooms, ambulatory surgical centers and skilled nursing facilities

A comparison between the cost per unit by place of service (or even between the medical benefit and pharmacy benefit) may be misleading since costs may not be on an ‘apples’ to ‘apples’ basis. Claims may be adjudicated differently with potentially different dosing and coding. In addition, the mix of drugs by place of service could vary. Therefore only PMPM costs are shown in Table 6.

For many drugs, the hospital outpatient facility is a higher cost distribution channel than the physician office. For example, based on a Walgreens study, infliximab injections (J1745) are over twice as expensive on average at an outpatient facility versus a physician’s office⁹.

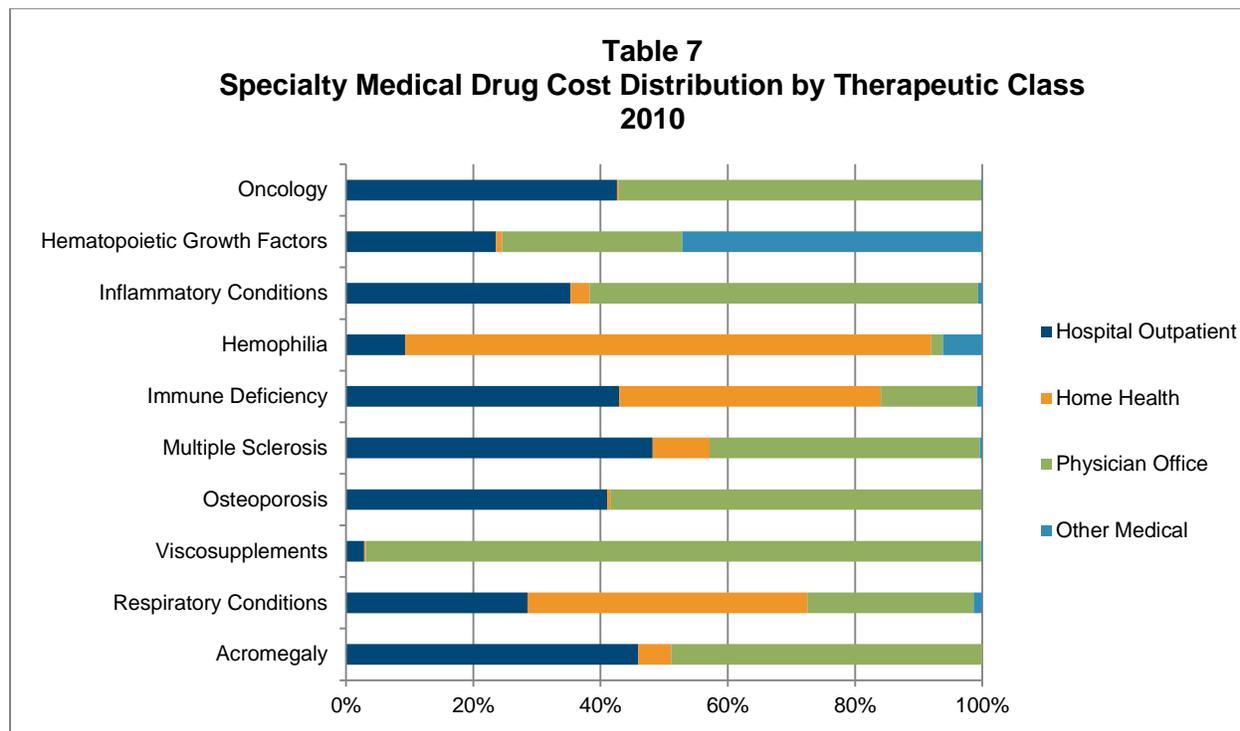
In 2010, 44% of the specialty medical drug spend was dispensed in an office setting, 12.5% in the home, and 34% in a hospital outpatient setting. There was a noticeable increase in the proportion of specialty medical drug spend in the hospital outpatient setting between 2009 and 2010 (i.e., 30.1% vs. 34.0%). The shift in the percentage of claims going to a hospital outpatient setting may be due to claims shifting from a physician’s office to a hospital outpatient setting, or possibly drugs shifting to the pharmacy benefit from the physician’s office, leaving fewer drugs in the medical benefit. Several self-injectable drugs that used to be administered in the physician’s office are now being dispensed by specialty pharmacies leaving predominantly infusion products for the physician’s office and other treatment settings. Since the hospital outpatient facility is typically more expensive than a physician’s office, this shift puts additional pressure on the unit cost trend.

Home Health specialty drug costs continue to rise. The home continues to provide a convenient alternative for a skilled healthcare professional to administer specialty medications to patients taking infusion based medications. The drug mix in the home health setting is quite different that other places of service. Hemophilia and immune deficiency medications represent a much higher proportion of drug cost within the home health setting, 50% and 24% of cost, respectively.

⁹ Specialty Drugs, Presentation Developed for Societies of Actuaries 2012 Health Meeting. June 2012.

The Other Medical place of service category includes specialty drug costs associated with end stage renal disease treatment facilities, emergency rooms, ambulatory surgical centers and skilled nursing facilities.

Table 7 shows the distribution of 2010 specialty medical drug costs by place of service and specialty drug therapeutic class.



About 45% of oncology specialty drug costs were delivered in a hospital outpatient setting with most of the remaining costs in a physician’s office. Several classes had a majority of their costs dispensed in the home (e.g., hemophilia and immune deficiency). Classes like viscosupplements (i.e., gel-like substances that mimic the properties of naturally occurring joint fluid for arthritis sufferers), which are usually injections, were almost exclusively administered in a physician’s office. Examples of drugs within each of these therapeutic classes are shown in Appendix C.

SPECIALTY MEDICAL DRUGS

Table 8 shows the top ten drugs (defined by Level I and Level II HCPCS) by 2010 allowed cost PMPM within specialty medical drug and the 2009 to 2010 PMPM trends in these drugs. Some drugs have more than one HCPCS code, like Epoetin, to account for different dosing or diagnosis. However, Table 8 is summarized by individual HCPCS codes.

Table 8
Specialty Medical Drug Cost and Trend
Top 10 HCPCS Summary

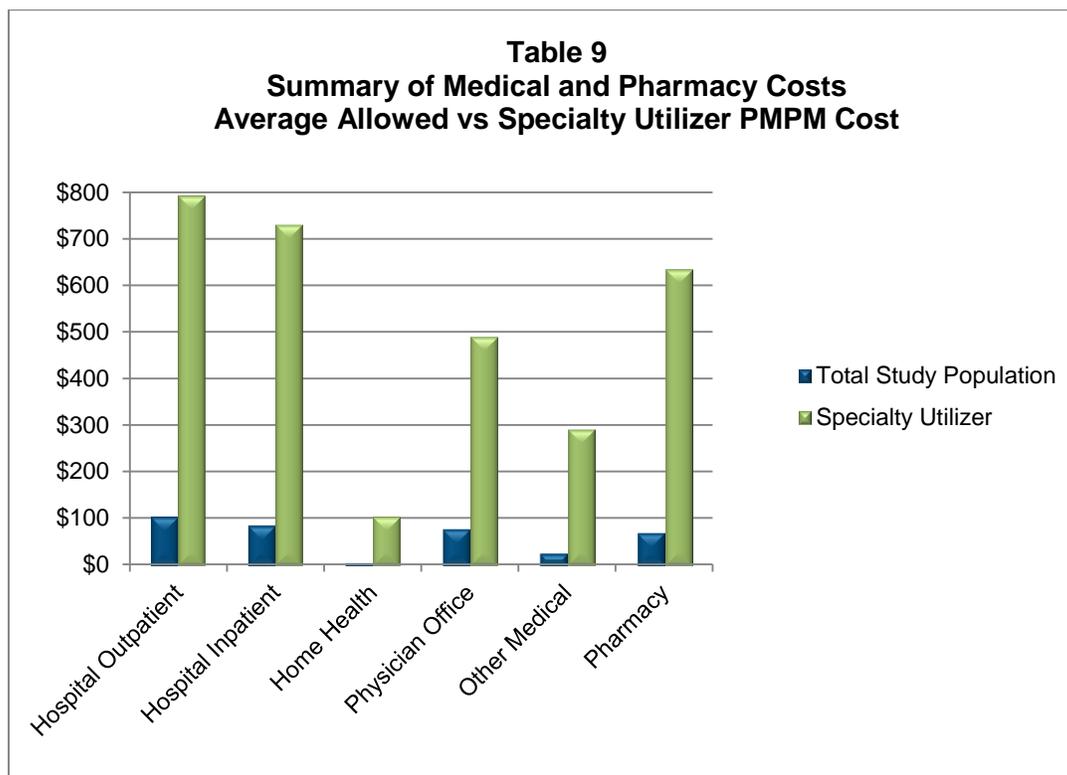
HCPCS	Drug Name	Therapeutic Class	2010 Allowed PMPM	Allowed Cost PMPM Trend*	Price Inflation	Utilization Trend
J1745	Infliximab injection	Inflammatory Conditions	\$1.18	4.81%	4.24%	0.55%
Q4081	Epoetin alfa, 100 units ESRD	Hematopoietic Growth Factors	\$1.01	17.32%	24.90%	-6.06%
J9035	Bevacizumab injection	Oncology	\$0.95	1.07%	-6.72%	8.36%
J2505	Injection, pegfilgrastim 6mg	Hematopoietic Growth Factors	\$0.71	1.35%	8.78%	-6.82%
J9310	Rituximab injection	Oncology	\$0.59	7.14%	9.10%	-1.79%
J9355	Trastuzumab injection	Oncology	\$0.59	6.54%	-1.86%	8.57%
J9170/J9171	Docetaxel injection	Oncology	\$0.36	0.62%	-10.22%	12.07%
J7192	Factor viii recombinant NOS	Hemophilia	\$0.35	9.71%	-13.51%	26.86%
J9263	Oxaliplatin	Oncology	\$0.32	-20.46%	-22.10%	2.13%
J1569	Gammagard Liquid injection	Immune Deficiency	\$0.27	-4.26%	3.42%	-7.42%

* From 2009 to 2010

There was very little rank variation between the top ten HCPCS in 2009 and 2010 and the top ten HCPCS represented almost 60% of the overall specialty medical drug spend (i.e., \$6.33 vs. \$10.83 PMPM) and 38% of the claims or utilization. The resulting trends by drug product differed considerably.

SPECIALTY UTILIZERS

Table 9 shows average allowed PMPM costs for the total study population versus the average allowed PMPM costs (i.e., discounted charges prior to reductions for member cost sharing) for those patients who had at least two specialty drug claims across any site of service during the 2010 study period.



As with other patients who have high cost conditions, the average 2010 healthcare costs for members who utilized specialty medications were almost eight and half times higher than the average healthcare costs for all members in the study. In addition, specialty drug utilizers had a very different distribution of medical and pharmacy costs. Specialty drug costs (medical and pharmacy combined) represented approximately 30% of their healthcare costs and 73% of their total drug costs versus 6% of healthcare cost and 24% of total drug cost for the total study population.

PATIENT COST SHARING

Average patient cost sharing or out of pocket costs vary by place of service. Under the medical benefit, the patient's financial responsibility is typically subject to deductibles and coinsurance with some maximum annual out-of-pocket limit. The deductible and out-of-pocket limits typically apply to all medical and pharmacy services combined. Under the pharmacy benefit, the patient's responsibility may include a separate pharmacy deductible with copayments and / or coinsurance, with potentially a separate out-of-pocket limit from the medical benefit. From the patient's perspective, it would be in the patient's best interests financially to avoid paying two separate out-of-pocket maximums. Therefore, the patient and the health plan may be at odds over the preferred specialty pharmacy distribution channel.

Table 10 shows the actual patient cost sharing realized and average patient cost share (i.e. out of pocket cost) per claim for specialty medications by place of service in 2010.

Table 10
Specialty Drug Patient Cost Sharing by Place of Service
2010

Place of Service	Average Allowed Cost per Claim	Average Patient Cost Share per Claim	Average Patient Cost Share Percent
Specialty Medical Drug	\$1,409	\$43	3.1%
Hospital Outpatient	\$2,365	\$50	2.1%
Home Health	\$3,898	\$69	1.8%
Physician Office	\$1,131	\$43	3.8%
Other Medical	\$656	\$31	4.7%
Specialty Pharmacy	\$1,716	\$63	3.7%
Total	\$1,544	\$52	3.4%

Average patient cost share for specialty medications is lower than for aggregate medical or pharmacy benefits (e.g., under 4%) due to the high cost of these drugs and the impact of annual maximum out-of-pocket limits under the medical benefit and the copay structure under the pharmacy benefit limiting the amount patients are required to pay.

UNDERLYING DATA DEMOGRAPHICS

Appendix A highlights the geographical area and gender composition of the data for the two years in the study period.

The MarketScan database had a large increase in the number of contributing entities from 2009 to 2010. To control for large population changes, only contributors that were present in every month of both 2009 and 2010 were included and whose membership counts did not change by more than 25% from year-to-year were included in the study.

The membership for this analysis was separated into four regional segments: Midwest, Northeast, South, and West (see Appendix B for states by region). The data is credible and broad enough to represent national average expenditures. In addition, the gender composition, which plays a big part in predicting healthcare expenditures, was fairly uniform by region and year.

IV. ONCOLOGY AND INFLAMMATORY CONDITIONS

In order to better understand the administration of specialty drug services covered under the medical benefit, we analyzed in more depth two of the largest areas of specialty medical drug cost, Oncology and Inflammatory Conditions.

ONCOLOGY

Oncology drug therapy costs represented approximately 30% of specialty medical and pharmacy drug costs in 2010. This drug class is the most expensive specialty therapeutic class, and growth in this therapeutic class is expected by a PBM industry source to increase by over 20% in the next two years¹⁰. Many oncology drugs are infusion based products that require a healthcare professional for administration. In addition, patients may require additional adjunctive therapy and close monitoring for adverse events. The growth in the oncology therapeutic class is driven by a combination of factors:

- > Technology that has led to earlier and higher diagnosis rates.
- > Research and development of new drug products enabling new treatment options for patients.

The overall 2010 PMPM specialty drug trend for the oncology drug therapeutic class was 4.8%, with a specialty medical drug trend of 1.6% and pharmacy trend of 14.7%. Overall utilization increased by 1.5%, but decreased slightly for medical drug. Medical drugs composed about 74% of the oncology spend and 52% of the utilization, a 2.3% and 1.3% decrease from 2009, respectively.

An increase in utilization led to the increase in PMPM trends in the pharmacy benefit, potentially due to oral cancer medications being introduced to the market along with white and brown bagging.

The top ten oncology Level I and Level II HCPCS and resulting trends from 2009 to 2010 are provided below in Table 11.

Table 11
Oncology Specialty Medical Drug Costs
Oncology Top 10 HCPCS Summary
2009-2010

HCPCS	Drug Name	2009 Allowed PMPM	2010 Allowed PMPM	2009 Cost per Claim	2010 Cost per Claim
J9035	Bevacizumab injection	\$0.94	\$0.95	\$4,407	\$4,111
J9310	Rituximab injection	\$0.55	\$0.59	\$5,754	\$6,278
J9355	Trastuzumab injection	\$0.55	\$0.59	\$2,880	\$2,826
J9170/J9171	Docetaxel injection	\$0.36	\$0.36	\$3,116	\$2,797
J9263	Oxaliplatin	\$0.41	\$0.32	\$4,423	\$3,445
J9305	Pemetrexed injection	\$0.15	\$0.20	\$6,516	\$6,490
J9201	Gemcitabine hcl injection	\$0.15	\$0.18	\$1,620	\$1,951
J9055	Cetuximab injection	\$0.21	\$0.16	\$3,775	\$3,855
J9041	Bortezomib injection	\$0.10	\$0.10	\$1,530	\$1,749
J9264	Paclitaxel protein bound	\$0.10	\$0.10	\$2,724	\$2,822

¹⁰ Express Scripts. 2011 Pharmacy Trend Report. April 2012. Accessed September 24, 2012.

The top ten oncology drugs accounted for 82% of oncology specialty medical drug costs. Overall PMPM trend for these ten drugs was 0.8% in 2010; however, there was little trend uniformity by drug product. The top ten ranked drugs were fairly consistent in 2009 and 2010. Docetaxel was in the top ten prescribed oncology drugs for 2009 and 2010, but had different J-codes in each year. Bevacizumab is also used in treatment of macular degeneration and proliferative diabetic retinopathy and utilization for these purposes may be included in Table 11.

Oncology specialty medical drug trends by place of service are provided in Table 12.

Table 12 Oncology Specialty Medical Drug Trends by Selected Place of Service 2009-2010							
Place of Service	2009 Allowed PMPM	2010 Allowed PMPM	2009 Cost per Claim	2010 Cost per Claim	PMPM Trend	Price Inflation	Utilization Trend
Physician Office	\$2.71	\$2.47	\$1,095	\$1,073	-8.9%	-2.0%	-7.0%
Hospital							
Outpatient	\$1.54	\$1.84	\$2,284	\$2,281	19.5%	-0.1%	19.7%

Fifty-seven percent (57%) of oncology specialty medical drug costs were administered in a physician's office and 43% at a hospital outpatient facility. The medical drug price inflation trend was minimal in both places of service. There was a decline in the rate of oncology drugs administered in the physician office and a significant increase in the use of a hospital outpatient department for drug administration. Only a small portion of oncology spend (less than 2%) was administered in home health or other medical settings, therefore these settings are not included in Table 12.

INFLAMMATORY CONDITIONS

The inflammatory conditions drug therapy class includes drugs used for the treatment of diseases including Rheumatoid Arthritis, Psoriasis, and Inflammatory Bowel Disease. The increased use of these drugs can be attributable to recent drug launches and expanded FDA approved indications for current drugs. These drugs include numerous self-injectable and infusion based products. Although this therapeutic class includes a wide range of diseases, only a small number of unique HCPCS were utilized under the medical benefit.

The overall specialty drug trend within this class was 19.4% and 7.0% within medical drug. Utilization increased 2.7% and the cost per claim increased 4.2% within specialty medical drug. Approximately 32% of total specialty drug costs were covered under the medical benefit in 2010, a 3.7 percentage point decrease from 2009.

The top two Inflammatory Conditions HCPCS and resulting trends are provided below in Table 13.

Table 13 Inflammatory Conditions Specialty Medical Drug Costs Inflammatory Conditions Top 2 HCPCS Summary 2009-2010					
HCPCS	Drug Name	2009 Allowed PMPM	2010 Allowed PMPM	2009 Cost per Claim	2010 Cost per Claim
J1745	Infliximab injection	\$1.12	\$1.18	\$3,880	\$4,044
J0129	Abatacept injection	\$0.16	\$0.18	\$1,888	\$2,087

The top two drugs were the same in 2009 and 2010. These two drugs experienced positive price inflation and utilization in 2010.

Inflammatory Conditions specialty medical drug trends by place of service are provided in Table 14.

Table 14 Inflammatory Conditions Specialty Medical Drug Trends by Selected Place of Service 2009-2010							
Place of Service	2009 Allowed PMPM	2010 Allowed PMPM	2009 Cost per Claim	2010 Cost per Claim	PMPM Trend	Price Inflation	Utilization Trend
Physician Office	\$0.84	\$0.84	\$2,882	\$2,921	0.0%	1.4%	-1.3%
Home Health	\$0.03	\$0.04	\$2,592	\$2,742	33.3%	5.8%	26.0%
Hospital Outpatient	\$0.41	\$0.49	\$5,692	\$5,932	19.5%	4.2%	14.7%

Sixty-one percent (61%) of the specialty medical drug costs were administered in a physician's office and 35% in a hospital outpatient facility in 2010. The medical price inflation trend was highest in the home health setting, however, only a small portion of claims (less than 1%) were administered in that setting. A higher price inflation trend was observed in the hospital outpatient setting than in the physician's office setting. Overall PMPM trend and utilization remained flat for physician's office. While the utilization decreased in the medical benefit, it increased in the pharmacy benefit. Less than 1% of costs was administered in another place of service and therefore was excluded from Table 14.

V. TREND MITIGATION STRATEGIES

Controlling specialty drug spend within the medical benefit has proved difficult or has not received as much attention as within the pharmacy benefit. Many health plans do not monitor specialty medical drug spend separately within their plans¹¹. Besides the difficulty in tracking medical drug expenditures, the strategies for trend mitigation can be complex. Some of these strategies include:

- > Re-contracting with provider networks to provide similar reimbursement for specialty medical drug claims no matter the dispensing delivery channel or place of service,
- > Shifting place of service to most cost-effective channel,
- > Re-contracting with provider networks to eliminate financial incentives for physicians and hospitals to dispense more expensive drugs,
- > Covering medications through a specialty pharmacy only when there are tighter controls for pricing and pharmacy management (not necessarily patient co-morbid condition management),
- > Aligning member financial incentives to be delivery channel neutral,
- > Implementing traditional PBM utilization management techniques, like step therapies, preferred drug lists, quantity limits and prior authorizations,
- > Separating the specialty drug benefit from both the non-specialty pharmacy benefit and the medical benefit,
- > Development of systems to consolidate and coordinate specialty drug utilization through the medical and pharmacy benefit, and
- > Timely and accurate specialty drug reporting and analytics across both the medical and pharmacy benefit.

¹¹ EMD Serono. EMD Serono Specialty Digest. 8th edition. 2012. Accessed September 24, 2012.

VI. CONCLUSIONS

Specialty drug costs are expected to continue to rise and become a more significant proportion of pharmacy and overall healthcare expenditures. Numerous factors have contributed to the rise in specialty drug costs. Although there is an inconsistency in the specialty drug definition, specialty drugs can be defined by cost, route of delivery (e.g., injectable, infusion or oral), and therapeutic class. Specialty medications are distributed via a complex system with the drug covered under both the pharmacy and medical benefit and available via various delivery channels (i.e., physician's office, home health setting, hospital outpatient facility, pharmacy, mail-order pharmacy, and specialty pharmacy). This variation results in differing and sometimes complex pricing schedules for these products.

Continued price increases for these products are a concern for both providers and patients. In 2010, the overall specialty pharmacy annual trend from 2009 was 13.2%, with specialty medical drug trend at 6.1% and specialty pharmacy trend at 21.7%. There was a shift in cost and utilization to the hospital outpatient and home health setting with a decline in physician's office administration of specialty pharmacy products. Approximately half of all specialty drug costs were adjudicated under the medical benefit, which represented up to 60% of the total medical drug spend. The top ten specialty therapy classes represented 95% of total specialty medical drug cost. In eight of top ten therapy classes, more than 50% of the specialty drug spend was adjudicated under the medical benefit.

The specialty drug landscape continues to change and evolve and these changes are reflected in this benchmarking study. There was an overall increase in cost within specialty medical drugs due to numerous factors. The introduction of new infusion and injectable specialty medications, the expansion of indications for existing drugs, along with expected drugs in the pipeline, have the ability to change prescribing patterns and impact medical drug trends in the future. These specialty medications along with drugs in the pipeline are specialized and unique therapies with unpredictable cost and utilization expectations¹². In addition, utilization and availability of self-injectable and oral agents may continue to drive current and new drugs to be administered and adjudicated under the pharmacy benefit.

Provider choice of place of service and the changes in utilization by place of service have a large impact on specialty drug trends. Specialty drug costs will likely increase as delivery shifts from the office setting to an outpatient hospital setting. As more self-injectable drugs potentially move out of the medical benefit, in particular the physician's office, the pharmacy mix remaining in the medical benefit dramatically changes. In addition, the unit cost of these specialty medications can vary dramatically under both medical and pharmacy benefit and place of service. These factors along with the historical cost and utilization trends demonstrate the need for health plans and employers to take a more comprehensive view of specialty drug cost management across the medical and pharmacy benefits.

¹² Doloresco F, Fominaya C, Schumock GT et al. Projecting future drug expenditures – 2011. *Am J Health-Syst Pharm.* 2011;68:e1-12

VII. METHODOLOGY

This report is a result of Milliman research and cost modeling analysis, using the MarketScan database for 2009 and 2010 claims data. The database includes administrative allowed cost and utilization for inpatient, outpatient, professional, and retail / mail pharmacy services for a commercial population. .

Drug cost and utilization was studied in the following settings: hospital outpatient facility, physician's office, home health, and outpatient retail / mail pharmacy. This study only focused on pharmacy claims that are not associated with an inpatient hospital admission. Inpatient ancillary services are often subject to bundled reporting making it all but impossible to separate out pharmacy costs. A pharmacy claim line was defined as the unit of measure.

The assumptions in this report include identifying pharmacy claims in the medical benefit and determining which of those claims were for specialty drugs. Pharmacy claims were identified by leveraging Milliman's proprietary *Health Cost Guidelines* definitions. Within the pharmacy claims, a variety of sources were used in order to determine the specialty drug list, including lists of drugs typically dispensed through specialty pharmacies, definitions from the Centers for Medicare and Medicaid Services (CMS), and publically available specialty drug lists provided by PBMs and health plans. Unfortunately, there are no universally accepted criteria or list for specialty drug identification. For this report, certain therapeutic classes like HIV and vaccines were not included in the definition for specialty drugs. The complete list can be viewed in Appendix C.

An additional cohort was developed to identify and analyze medical and pharmacy cost for specialty utilizers. A specialty utilizer was defined as a member having at least two specialty drug claims across any place of service in the study period.

APPENDICES

Appendix A: Study Demographic Summary

Appendix A Study Demographic Summary

Region	2009		2010	
	Member Months	% of Total	Member Months	% of Total
Midwest	6,818,126	24.9%	6,717,261	26.5%
Northeast	3,865,151	14.0%	3,889,107	15.3%
South	12,000,764	43.6%	10,723,370	42.3%
West	4,825,952	17.5%	4,025,849	15.9%
Total	27,509,993	100%	25,355,587	100%
Region	% Male	% Female	% Male	% Female
Midwest	49%	51%	49%	51%
Northeast	48%	52%	48%	52%
South	50%	50%	50%	50%
West	49%	51%	49%	51%
Total	49%	51%	49%	51%

Appendix B: Region Definition

Appendix B Region Definition			
Region	State	Region	State
Midwest	Illinois	South	Alabama
	Indiana		Arkansas
	Iowa		Delaware
	Kansas		District of Columbia
	Michigan		Florida
	Minnesota		Georgia
	Missouri		Kentucky
	Nebraska		Louisiana
	North Dakota		Maryland
	Ohio		Mississippi
	South Dakota		North Carolina
West	Wisconsin	Oklahoma	
	Alaska	South Carolina	
	Arizona	Tennessee	
	California	Texas	
	Colorado	Virginia	
	Hawaii	West Virginia	
	Idaho	Northeast	Connecticut
	Montana		Maine
	Nevada		Massachusetts
	New Mexico		New Hampshire
	Oregon		New Jersey
	Utah		New York
	Washington		Pennsylvania
	Wyoming	Rhode Island	
	Vermont		

Appendix C: Specialty Therapeutic Class Definition

Appendix C Specialty Therapeutic Class Definition

Specialty Therapeutic Class	Examples of Drug In Class
Acromegaly	Octreotide, Sandostatin
Anticoagulants	Lovenox, Arixtra, Enoxaparin, Fragmin
Corticotropin	Acthar HP
Cystic Fibrosis	Pulmozyme, TOBI, Cayston
Fertility Regulatory	Follistim AQ, Gonal-F, Menopur, Bravelle
Growth Hormone	Nutropin, Humatrope, Genotropin, Norditropin
Hematopoietic Growth Factors	Epogen, Neulasta, Neupogen, Procrit, Aranesp
Hemophilia	Advate, NovoSeven RT, Mononine, Benefix
Hepatitis Agents	Pegasys, Baraclude, Peg-Intron, Hepsera
Hereditary Angioedema	Cinryze, Soliris
IGF-1 Deficiency	Increlex
Immune Deficiency	Gammagard, Gamunex, Vivaglobin
Inflammatory Conditions	Humira, Enbrel, Remicade, Simponi
Metabolic Modifiers	Kuvan, Sensipar, Fabrazyme, Elaprase
Multiple Sclerosis	Copaxone, Avonex, Rebif, Betaseron
Neuromuscular Blocking Agent - Neurotoxins	Botox, Myobloc
Oncology	Gleevec, Avastin, Revlimid, Arimidex, Femara
Ophthalmic Conditions	Lucentis, Visudyne
Osteoporosis	Reclast, Prolia, Zometa
Other	Cerezyme, Sabril, VPRIV, Apokyn
Plasma Proteins	Thrombate III, Alburx, Plasbumin, Kedbumin
Platelet Aggregation Inhibitors	Integrilin, Reopro, Aggrastat
Pulmonary Hypertension	Tracleer, Revatio, Letairis, Remodulin
Respiratory Conditions	Xolair, Prolastin, Aralast
Respiratory Syncytial Virus	Synagis
Stem Cell Mobilizers	Mozobil
Thrombin Inhibitors	Angiomax, Pradaxa, Argatroban
Viscosupplements	Synvisc, Orthovisc, Hyalgan