

MILLIMAN REPORT

Commercial specialty medication research: 2019 benchmark projections

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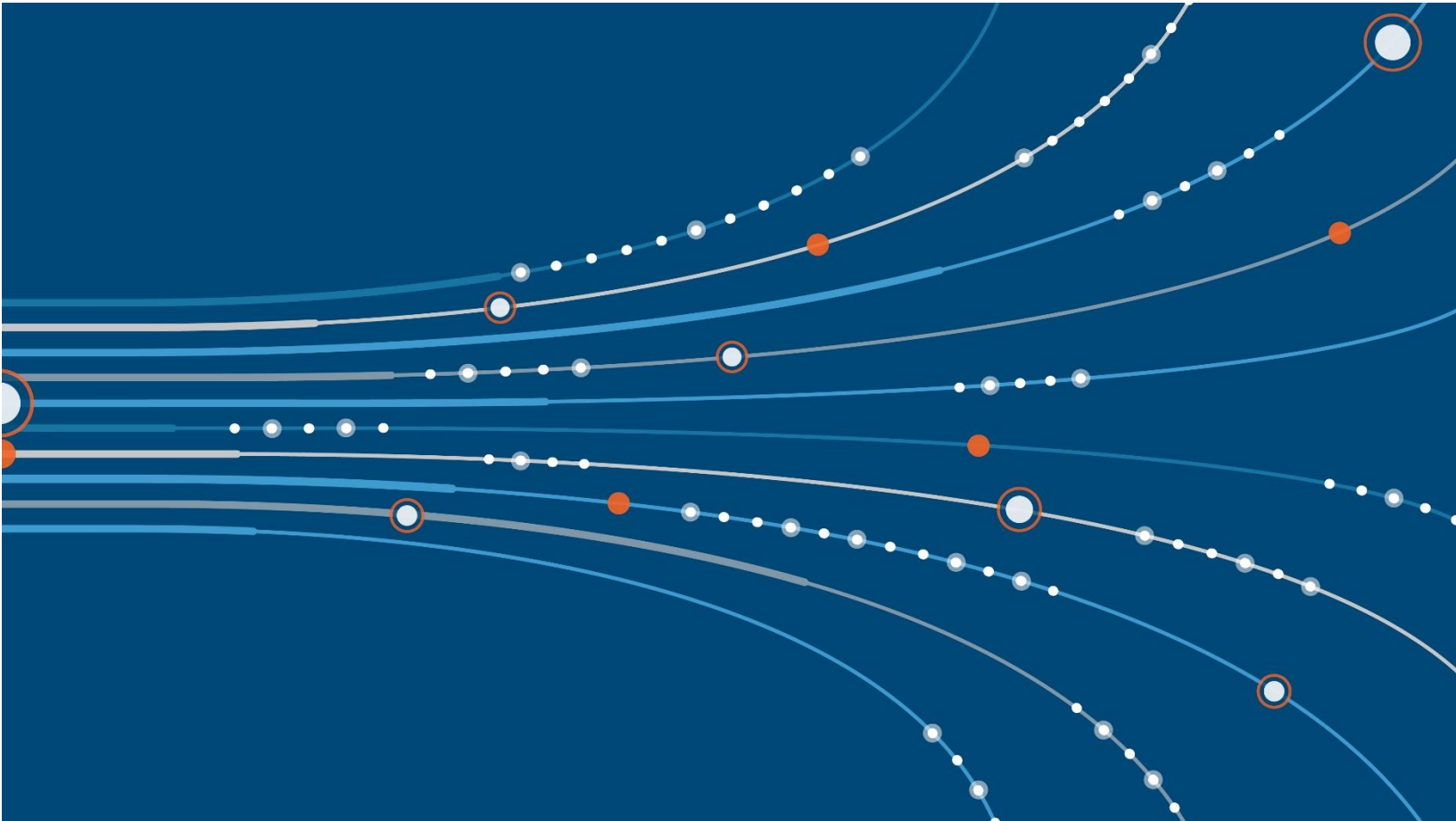




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Executive Summary

This study provides claim cost benchmarks to illustrate the magnitude and distribution of specialty medication costs adjudicated under both the pharmacy and medical benefit for a commercially insured population, defined as members covered by a group insurance plan that is not maintained by a government-run program. This is done by:

- Defining specialty medications, noting that there is no industry standard definition in the commercial space
- Identifying specialty medications in the claims data and calculating the percentage of total healthcare costs they represent
- Benchmarking, or determining from historical data, the amount of specialty spend covered by commercially insured medical and pharmacy benefits
- Evaluating the amount of medication spend by therapeutic class and place of service under the medical benefit
- Projecting specialty spend into the future by quantifying trends by therapeutic class and place of service for specialty medications

Specialty Medical Medications:

For the purposes of this study, we defined specialty medical medications as those 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 Medications:

We defined specialty pharmacy medications as those dispensed in retail, mail, or specialty pharmacies, which are typically self-administered by the patient and covered under the pharmacy benefit.

The findings of this report rely on these definitions. The information in this study was based on claims data from a commercially insured group population (i.e., primarily commercial group members under age 65, excluding Medicare and Medicaid beneficiary populations). Claims were categorized as specialty medical or specialty pharmacy based on how the claim was paid. This study was based on 2017 claims data, which we projected forward to 2019.

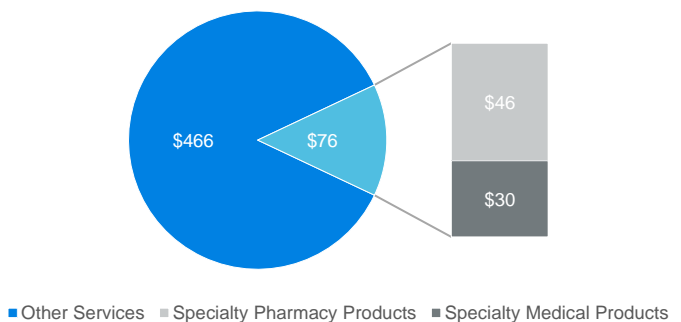
HIGHLIGHTS

The findings of this study suggest that understanding the complex and changing specialty landscape is important for payers to effectively manage specialty medication costs.

Highlights from this study include:

- Total specialty medication costs, including those adjudicated under both the medical and pharmacy benefits, are expected to account for nearly 15% of total healthcare claim costs in 2019. Note that our analysis does not account for any rebates, which offset a portion of medication costs (estimates vary but a 2018 report by Altarum estimated 2016 rebates in the private market at 12% of allowed costs¹ and a 2019 report by the Pew Charitable Trusts estimated 2016 rebates in the commercial health plan market at 16% of retail pharmacy benefit premiums²).

FIGURE 1: PROJECTED 2019 COMMERCIAL HEALTHCARE COSTS, PMPM



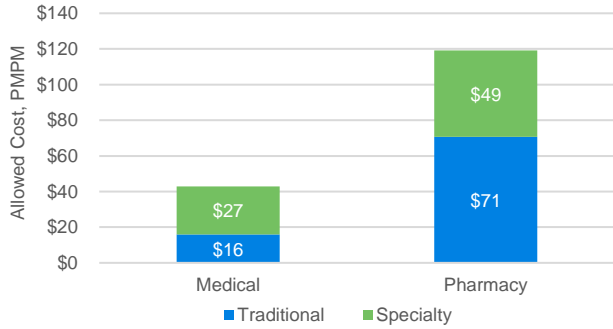
¹ Roehrig, Charles, PhD (April 2018). The impact of prescription drug rebates on health plans and consumers. *Altarum*.

² Coukell, Allan & Urah, Susan K. (March 2019). The Prescription Drug Landscape, Explored. The Pew Charitable Trusts.

- Approximately 40% of total specialty costs are expected to be paid as a medical benefit and 60% paid as a pharmacy benefit in 2019.
- Projected specialty cost trends exceed the trend in total medical and pharmacy costs.
- Use of specialty medications differed significantly between the medical and pharmacy benefits, both as a percentage of total spend under the benefit and by distribution of therapeutic classes:

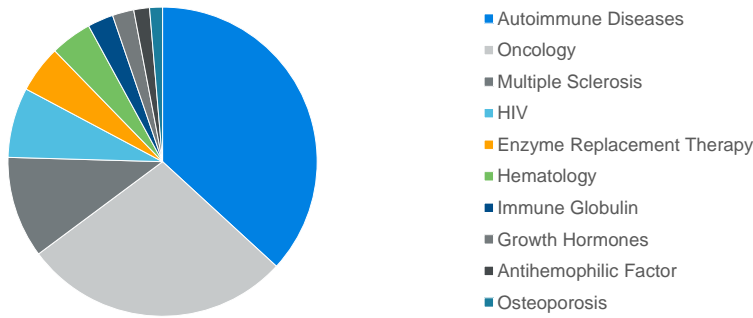
- Specialty medical costs are expected to comprise about 63% of total medication costs under the medical benefit and about 40% of total pharmacy costs in 2019.
- While many of the same therapeutic classes drive specialty spending under the medical and pharmacy benefits, specific medications within those classes are generally covered under one benefit (not both).

FIGURE 2: PROJECTED 2019 COSTS BY BENEFIT, PMPM



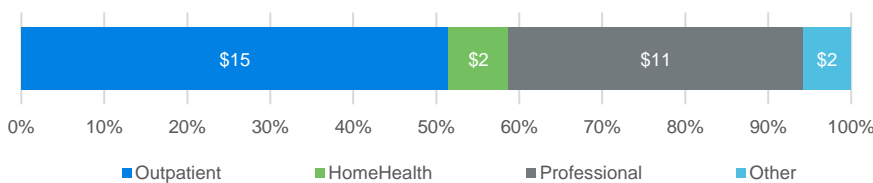
- The top 10 therapeutic classes for specialty medications comprise about 88% of total specialty spend under both the medical and pharmacy benefit. The chart in Figure 3 shows the distribution of spend among these top 10 classes for medical and pharmacy claims combined. The autoimmune disease class is projected to make up 32% of total specialty spend, the majority of which is under the pharmacy benefit.
- The oncology class is projected to make up 25% of total specialty spend, the majority of which is under the medical benefit.

FIGURE 3: DISTRIBUTION OF TOP 10 SPECIALTY CLASSES (MEDICAL AND PHARMACY)



- Hospital outpatient settings are the site for providing 51% of total specialty medical costs, 35% are provided in physician's offices, and 7% are provided in the patient's home.
- A payer's average charge for specialty medications varies by site of care, with the hospital outpatient setting being the most expensive and home health being the least expensive among medical benefit settings.

FIGURE 4: ALLOWED COST (PMPM) DISTRIBUTION OF MEDICAL PHARMACY SPENDING



Background

Payers closely manage their pharmacy benefit spending and many have experienced relatively low annual trends, particularly when accounting for rebates, which have grown in recent years and help offset gross claim costs. Some pharmacy benefit managers (PBMs) are even showing negative trends on traditional drug spend (i.e., non-specialty brand and generic), when accounting for both utilization and cost.³ Spend on specialty medications, however, continues to rise and is projected to continue rising.

The pharmacy landscape is constantly evolving as innovative and curative treatments are developed, competition from new brand or generic medications comes on the market, new technologies are developed, and regulations around pharmaceuticals continue to evolve. Specialty medications have become a large portion of healthcare spend, consuming over \$200 billion of a total estimated \$480 billion in pharmacy spend⁴ per year and have become an important component for payers to understand, measure, and manage.

WHAT IS A SPECIALTY MEDICATION?

Specialty medications are typically associated with high-cost, complex, or rare healthcare conditions such as cancer, rheumatoid arthritis, and multiple sclerosis. There are many specialty medications in manufacturers' pipelines, and these new entrants are expected to drive significant portions of future medication costs and inflationary trends.

Although specialty medications are often treated as a distinct class of medications, there is no universally accepted definition. Often the term "specialty" is a label that payers use for the purpose of benefit management, cost sharing, and clinical oversight. Medications may even change in classification over time; for example, some PBMs have moved HIV and PCSK9 treatments (with medications that help to lower a patient's LDL cholesterol level) from their specialty lists to their non-specialty lists due to changing therapeutic class dynamics (e.g., new medications coming to market, changes in price, increasing competition in the class, or new approved indications). The Methodology section below includes a summary of specialty medication characteristics.

For the purposes of this study, we developed a specific specialty medication list based largely on the definition used in Milliman's Health Cost Guidelines™ (HCG). The HCG list uses a variety of sources, including lists of medications typically dispensed through specialty pharmacies, definitions from the Centers for Medicare and Medicaid Services (CMS), and publicly available specialty medication lists provided by PBMs and health plans. A more detailed explanation is found in the Methodology section below and examples of medications defined as specialty are provided in Appendix A.

Some specialty medications are covered under the medical benefit while some are covered under the pharmacy benefit. While there are generally fewer management controls in place by payers for medical pharmacy, all pharmacy remains an important component of overall spend to a payer.

HOW DO COMMERCIAL PATIENTS GAIN ACCESS TO SPECIALTY MEDICATIONS?

We differentiate specialty claims adjudicated under the medical and pharmacy benefits by the following:

- Specialty medical medications are defined in this study as those covered under the medical benefit, which are typically administered by a healthcare professional in the home, a hospital outpatient facility, or a physician's office. Medications administered in an inpatient hospital setting are typically bundled with other ancillary services, and thus little inpatient specialty medication data is available through most sources of claims data.
- Specialty pharmacy medications are dispensed in a retail, mail, or specialty pharmacy, typically self-administered by the patient, and covered under the pharmacy benefit.

³ Express Scripts. 2018 Drug Trend Report and Prime Therapeutics Spring 2019 Focus on Trend.

⁴ Reinke, Thomas (September 18, 2019). Specialty Drug Spend Soars. Can Formulary Management Bring It Down to Earth? Managed Care. Retrieved December 26, 2019, from <https://www.managedcaremag.com/archives/2019/9/specialty-drug-spend-soars-can-formulary-management-bring-it-down-earth>.

About 40% of specialty costs are projected to be under the medical benefit in 2019, and the other 60% are for medications covered under the pharmacy benefit. As specialty costs have grown, payers are putting more attention on the implications of covering these medications under the medical or pharmacy benefit as well as the site of care under the medical benefit. In particular, payers may shift away from covering specialty medications under the medical benefit due to various reasons (e.g., better transparency or contracted pricing) even though physician-administered drugs have demonstrated high adherence and quality of care for certain infused therapies. Despite this shift away from covering specialty medications under the medical benefit, the proportion of costs incurred under the medical benefit continues to grow because the costliest specialty medications are often paid under the medical benefit.

There are cases where it may be more advantageous to cover specialty medications under the medical benefit.

For example:

- A physician group or outpatient infusion clinic leveraging class of trade to secure lower pricing. "Class of trade" is defined as a group of pharmaceutical buyers who share similar purchasing characteristics and may be eligible for specific pricing discounts and rebates that are due to these shared attributes.⁵ (Examples include retail, long-term care, mail order, and institutional.)
- In the treatment of diseases where dosages are often changed and physicians are able to tailor the dose of the medication prior to administration, which would avoid waste of medication.
- If there are concerns about compliance or safety, a doctor can better monitor that a patient is actually taking a medication if it is administered in the office.

Competing dynamics of the optimal benefit coverage and site of care 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 about how and where to obtain specialty medications.

HOW IS A PAYER'S COST FOR A SPECIALTY MEDICATION DETERMINED?

A specialty medication adjudicated under the medical benefit is processed differently from a medication 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 the medication is dispensed. As a result, data sets containing pharmacy prescription claims are often considered highly accurate, with better information about allowed cost, number of units dispensed, and minimal lag time between claim adjudication and provider payment.
- In contrast, medical specialty claims are not adjudicated in real-time and may be submitted via Level I and Level II Healthcare Common Procedural Coding System (HCPCS). It is not uncommon for the number of units billed to not be the same amount administered to the patient. Furthermore, the manual adjudication of medical prescription claims limits the DUR interventions and formulary management programs that PBMs rely upon to control costs, though in recent years it is becoming more prevalent to implement real-time management programs on medical benefit drugs.

⁵ Academy of Managed Care Pharmacy (2009). AMCP Guide to Pharmaceutical Payment Methods, 2009 Update (Version 2.0). J Managed Care Pharm Vol 15, No. 6a. Retrieved April 7, 2019, from <https://www.jmcp.org/doi/pdf/10.18553/jmcp.2009.15.s6-a.1>.

The costs of medications vary by the types of contracts that may be in place between different types of medical and pharmacy providers.

- Prescriptions adjudicated under the pharmacy benefit are processed at the National Drug Code (NDC) level and pricing is determined at the point of sale based upon negotiated prices. Most (but not all) PBM contracts reimburse prescription medications in the commercial market using average wholesale price (AWP) minus a discount for brands and maximum allowable cost (MAC) lists for generics. Rebates may further lower the cost of the medication. Pharmacy benefit rebates, which may reduce spend for an individual medication up to 50% or more and have been estimated to reduce the retail pharmacy benefit share of premium up to 16%⁶) are usually collected after the point of sale and not reflected in claims databases. Therefore, they are not accounted for in our analysis.
- Medical pharmacy claims are typically reimbursed using a proprietary fee schedule that is based on average sales price (ASP), the submitted amount, or other methods. The provider reimbursement may vary by site of care. Because of the lack of granularity in the HCPCS billing system, payers may be charged different costs for medications that are adjudicated under the medical benefit versus the pharmacy benefit.

The remainder of this report discusses our primary results and conclusions, including the following benchmark information:

- A per member per month (PMPM) claim cost summary of total healthcare spend by service category, including separate claim cost summaries for total medical and pharmacy benefit spend and specialty medical and pharmacy benefit spend
- Specialty cost distribution by therapeutic class, in total and separately for medical and pharmacy
- Estimated specialty medical trends by place of service and for the top 10 HCPCS medications.

A discussion of the results and a description of our methodology follow the benchmarking results.

⁶ Coukell & Urah, op cit.

Results

APPROACH

This study was based on 2017 claims for a commercially insured population, as reported in Milliman's proprietary Consolidated Health Cost Guidelines Sources Database (CHSD), which we projected forward to 2019. We used this information to develop allowed cost and trend information and to illustrate changes in specialty medication costs and utilization within the medical and pharmacy benefits. Allowed costs represent total expenditures by both plans and members, and are calculated at contractual prices prior to rebates. It is important to note that rebates typically reflect a significant reduction to a payer's pharmacy benefit spend, though rebates on medical pharmacy spend are more limited.⁷ Additionally, rebates vary considerably based on a plan sponsor's contracts and utilization levels. Reporting benchmarks on an allowed cost basis, rather than a rebated basis, provides a better opportunity for comparative benchmarking purposes.

The specialty utilization under the medical benefit is likely underestimated in this analysis due to the lack of NDC-level data present in most medical claims data. As discussed in the Background section above, providers are reimbursed for medications administered under the medical benefit based on the HCPCS code assigned to the medication, which flows through the claims data. In some cases, multiple NDCs (i.e., multiple medications, not different dosages or strengths of the same medication) may fall under one HCPCS code but will be reimbursed at the same rate. As such, some HCPCS codes may include both specialty and non-specialty medications, in particular some of the general codes, such as J3490, Unclassified Drugs or J3590, Unclassified Biologics. They are not identified as specialty in this analysis.

Additionally, this analysis summarizes all pharmacy costs, including HCPCS codes used for administration, vaccines and immunizations, and radiopharmaceuticals that may be excluded from similar analyses that only focus on identifiable medical pharmacy claims. By nature of the definition of specialty medications (i.e., they may require special handling and storage, or administration by a professional), it follows that the majority of medications administered in a medical setting are specialty medications. Therefore, our estimate of the proportion of pharmacy costs under the medical benefit attributed to specialty medications may be lower than other studies, which exclude spend associated with these HCPCS codes.

The table in Figure 5 provides a breakdown of healthcare expenditures in total, for all medications, and for specialty medications, by type of service (refer to Appendix B for the observed 2017 benchmarks).

FIGURE 5: PROJECTED 2019 HEALTHCARE EXPENDITURES BY PLACE OF SERVICE PMPM

CLAIM TYPE	HOP	HIP	HOME HEALTH	PHYS OFC	OTHER	TOTAL MEDICAL	PHARM	TOTAL
All Services	\$180	\$106	\$10	\$102	\$27	\$425	\$117	\$542
Medications Only	\$24	N/A	\$2	\$17	\$3	\$47	\$117	\$164
Specialty Medications Only	\$15	N/A	\$2	\$11	\$2	\$30	\$46	\$76
Specialty % of Total Place of Service	9%	N/A	22%	10%	6%	7%	40%	14%

Note: Medical components include only ingredient costs with no administrative fee or professional fee. Pharmacy component includes ingredient costs plus dispensing fee.

PMPM = Per Member Per Month, HOP = Hospital Outpatient, HIP = Hospital Inpatient, PHYS OFC = Physician Office, PHARM = Pharmacy Benefit.

Pharmacy costs included in an inpatient hospital admission are not identified separately from other inpatient costs because of the bundling of inpatient services in claims data. Thus, inpatient medication costs are not included in our definition (and are noted as "N/A" in Figure 5), which likely understates the medication spend under the medical benefit.

⁷ IQVIA's 2019 "Medicine Use and Spending in the U.S." report estimates that discounts, rebates, and other price concessions on brands reduced absolute invoice spending by 28%. See <https://www.iqvia.com/>.

We note the following in Figure 5:

- Specialty costs represent approximately 14% of the overall total healthcare costs (\$76 out of \$542 PMPM), or nearly half of total medication costs.
- Approximately 40% of specialty costs are estimated to be covered under the medical benefit in 2019 (\$30 out of \$76 PMPM).

Specialty costs have been increasing at a higher rate than overall healthcare costs and overall pharmacy costs in recent years, and this trend is expected to continue into the future. Average annual trend in specialty costs from 2017 to 2019 is expected to be 12.6%, while overall medical costs (excluding specialty costs) are expected to increase by 7.1% per year on average and overall non-specialty medication costs by 8.3%. As noted, the increase in pharmacy costs is prior to the impact of rebates; increases in rebates help offset the net impact to plan sponsors, particularly for costs under the pharmacy benefit. Rebate levels vary significantly, especially among specialty medications. Some specialty medications may not have any rebates, such as certain oncology treatments without therapeutic alternatives, while others may have significant rebate levels near or exceeding half the list price of the medication.

Specialty costs are expected to comprise about 63% of total medication costs under the medical benefit in 2019, but only about 40% of total pharmacy benefit costs. Because specialty medication utilization is different between medical and pharmacy benefits, these percentages may continue to change. Some market forces will push higher costs and utilization under one or both benefits (e.g., the launching of new medications, shifting medications from one benefit to the other) with other forces pushing lower costs and utilization (e.g., tighter management controls, more competition from generics or biosimilars).

THE MAJORITY OF SPECIALTY COSTS ARE DRIVEN BY A HANDFUL OF THERAPEUTIC CLASSES

The table in Figure 6 summarizes 2019 PMPM specialty costs separated between medical and pharmacy for the top 10 specialty therapeutic classes by projected total specialty spending.

FIGURE 6: PROJECTED 2019 SPECIALTY SPENDING IN THE MEDICAL VS. PHARMACY BENEFITS

Therapeutic Class	Medical	Pharmacy	Total
Autoimmune Diseases	\$6.70	\$17.90	\$24.60
Oncology	\$12.40	\$6.30	\$18.70
Multiple Sclerosis	\$1.20	\$5.90	\$7.10
HIV	\$0.00	\$4.90	\$4.90
Enzyme Replacement Therapy	\$0.70	\$2.70	\$3.30
Hematology	\$2.60	\$0.30	\$2.90
Immune Globulin	\$1.60	\$0.20	\$1.80
Growth Hormones	\$0.00	\$1.50	\$1.50
Antihemophilic Factor	\$0.40	\$0.80	\$1.10
Osteoporosis	\$0.60	\$0.30	\$0.90
All Other	\$3.90	\$5.50	\$9.40
Total	\$30.10	\$46.30	\$76.40
% of Total	39%	61%	100%

The top 10 specialty therapeutic classes account for about 87% of total specialty medical costs and 88% of total specialty pharmacy costs.

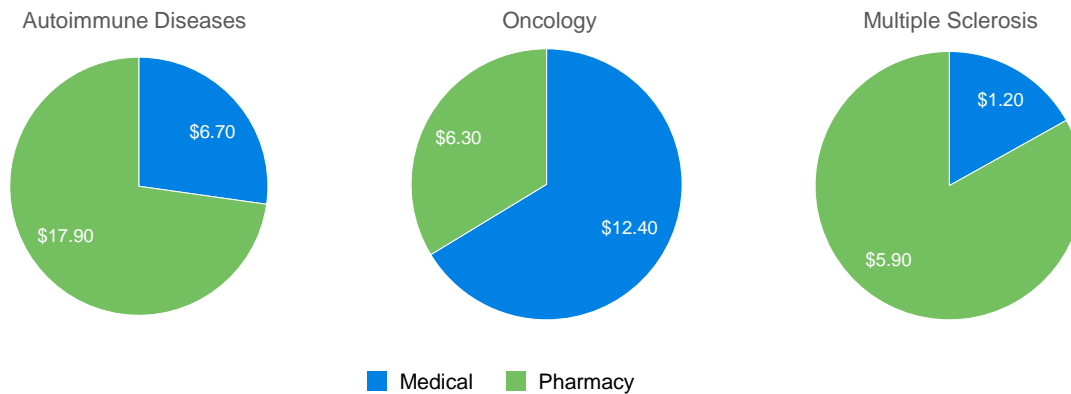
Autoimmune Diseases is the most expensive (in total) and highly utilized specialty therapeutic class, accounting for about 32% of all specialty costs. About 73% of specialty costs for autoimmune diseases are paid through the pharmacy benefit, with 27% paid through the medical benefit. This class includes a variety of chronic autoimmune diseases, such as rheumatoid arthritis, psoriasis, Crohn’s disease, ulcerative colitis, and others. Most medications in this class are indicated to treat one or several (but not all) of these diseases, which leads to complex competitive dynamics within the class. New medications have recently launched in this class and more are expected in the future. In addition, several biosimilars on the market are covered by the medical benefit, with biosimilars to pharmacy benefit medications expected in the next several years. Rebates are significant in this class due to the competitive nature.

Oncology is the largest class specific to specialty medical spending, which represents about 41% of all specialty medical costs and 25% of total specialty costs for medical and pharmacy combined. More than 15.5 million Americans have a history of cancer, with over 100 types of identified cancer. Treatment options include chemotherapy, targeted therapies, and an emerging treatment, immunotherapy.⁸ It is not surprising that there are over 1,000 medications in the pipeline for cancer.

Multiple Sclerosis is the third highest ranking class in total. Affecting approximately 1 million Americans, this disease attacks an individual’s myelin and nerve fibers, causing fatigue, numbness or tingling, walking difficulties, and cognitive and emotional changes, among other symptoms.⁹ A number of oral therapies exist, as well as biologics and immunomodulators.

Among the top 10 therapeutic classes, only Oncology, Hematology, Immune Globulin, and Osteoporosis medications had a majority (more than 50%) of specialty costs covered under the medical benefit. On the other hand, as shown in Figure 7, HIV and Growth Hormones are almost exclusively covered by the pharmacy benefit.

FIGURE 7: DISTRIBUTION OF THREE THERAPEUTIC CLASSES



⁸ American Cancer Society. Cancer Facts & Figures 2019. Retrieved December 26, 2019, from <https://www.cancer.org/research/cancer-facts-statistics/all-cancer-facts-figures/cancer-facts-figures-2019.html>

⁹ See the National Multiple Sclerosis Society website at <https://www.nationalmssociety.org/>.

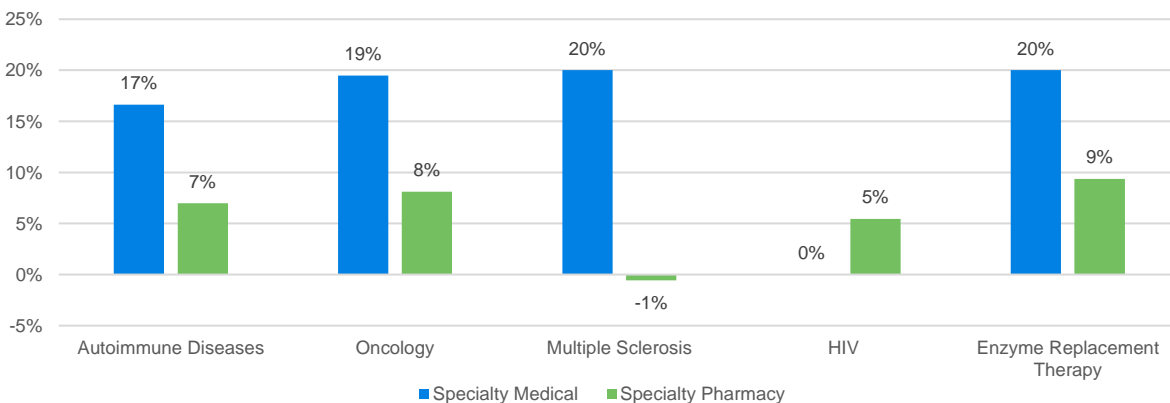
The table in Figure 8 summarizes actual 2017 PMPM and projected 2019 PMPM specialty medical costs for the top five therapeutic classes in the medical benefit. The top five specialty medical classes capture 79% of total specialty medical costs in 2017. The implied annual trend rate for each of these classes illustrates the rising costs associated with specialty medications.

FIGURE 8: PROJECTED SPECIALTY MEDICAL MEDICATION SPENDING, PMPM: TOP 5 SPECIALTY THERAPEUTIC CLASSES, 2017 TO 2019

THERAPEUTIC CLASS	2017	2019	AVERAGE ANNUALIZED TREND
Oncology	\$8.68	\$12.39	19%
Autoimmune Diseases	\$4.91	\$6.69	17%
Hematology	\$1.86	\$2.57	17%
Immune Globulin	\$1.36	\$1.57	8%
Multiple Sclerosis	\$0.82	\$1.17	20%
All Other	\$4.75	\$5.55	8%
Total	\$22.38	\$29.94	16%
Top 5, as % of Total	79%	81%	

The chart in Figure 9 shows the expected average annual medical and pharmacy PMPM trends from 2017 to 2019 for the top five specialty therapeutic classes provided.

FIGURE 9: PROJECTED SPECIALTY MEDICAL AND PHARMACY ANNUALIZED PMPM TREND, TOP 5 SPECIALTY THERAPEUTIC CLASSES, 2017 TO 2019



In some of the top specialty classes, the specialty pharmacy trend is expected to be higher than the specialty medical trend while in other classes the opposite is true. Overall, trends in specialty medical are projected to be higher than traditional classes of medications. Trends represent cost, utilization, and mix trend, resulting in total trend.

- Utilization of autoimmune diseases medications is expected to be high for both specialty medical and specialty pharmacy. Recent and future introduction of biosimilars in this class, as well as new biologics, may present interesting cost dynamics as the biosimilar has a lower unit cost; however, utilization of biosimilars is much lower than for traditional generics.
- Multiple sclerosis trends are expected to be high in the medical benefit and may be negative in the pharmacy benefit due to new medications launching in the medical benefit.

Although the projected specialty medical trend is higher, the majority of specialty spend is still projected to remain under the pharmacy benefit in 2019. Some plan sponsors are managing total specialty spend using strategies to shift utilization from the medical setting to the pharmacy setting, where they have greater control of costs and management.

- Plan sponsors may cover certain specialty medications only through a specialty pharmacy, a process known as “white bagging,” where a specialty medication is dispensed at a specialty pharmacy and the medication 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 administration.¹⁰

These strategies require not only considerations for the impact to plan costs but also to the impact on the patient and provider relationship because the provider may have preferences as to how the patient receives treatment. These strategies are not appropriate for all therapeutic classes but may be effective for some classes, such as hemophilia.¹¹

DISTRIBUTION CHANNELS ARE AN IMPORTANT DETERMINANT IN THE COST OF SPECIALTY MEDICAL MEDICATIONS TO A PAYER

Specialty medical medications are dispensed in various settings or places of service, such as a physician’s office, the patient’s home, or a hospital outpatient facility. The table in Figure 10 shows the distribution of specialty medical costs and changes in PMPM cost by place of service. The average annual trend is the result of the medication mix in the specific place of service—we did not assume a shift in place of service between 2017 and 2019.

FIGURE 10: PROJECTED SPECIALTY MEDICAL COST TRENDS BY PLACE OF SERVICE, 2017 TO 2019

Place of Service	2017	2019	2019	
	Allowed Costs PMPM		Avg Annual Trend	Distribution of Costs
Physician Office	\$7.92	\$10.60	16%	35%
Home Health	\$1.83	\$2.17	9%	7%
Hospital Outpatient	\$11.29	\$15.38	17%	51%
Other Medical	\$1.28	\$1.74	16%	6%
Total Medical	\$22.38	\$29.94	16%	100%

In Figure 10, 51% of the specialty medical spend is expected to be dispensed in a Hospital Outpatient setting, 35% in a Physician Office setting, and 7% in the home. Hospital Outpatient claims may be expected to grow at a faster rate than other medical settings, possibly because of medications shifting from the Physician Office to the pharmacy benefit, leaving fewer medications in the medical benefit and therefore proportionally more in Hospital Outpatient. For example, self-injectable medicines that used to be administered in the Physician Office are now dispensed mostly by specialty pharmacies, leaving predominantly infusion medications for the Physician Office and other treatment settings. Because a Hospital Outpatient facility is typically more expensive than a Physician Office, this shift puts additional pressure on the overall unit cost trend.

Specialty utilization in the Home Health setting may be an attractive option for both patient and payer. The home provides a convenient alternative for a skilled healthcare professional to administer specialty medications to patients taking infusion-based medications. The medication mix in the Home Health setting is quite different from other places of service. The Home Health setting represents a much higher proportion of specialty costs for Enzyme Replacement Therapy and Immune Globulin, 43% and 40% of cost, respectively.

¹⁰ National Association of Boards of Pharmacy (April 2018). White and Brown Bagging Emerging Practices, Emerging Regulation. Retrieved December 26, 2019, from https://nabp.pharmacy/wp-content/uploads/2018/04/White-Bagging-and-Brown-Bagging-Report-2018_Final.pdf.

¹¹ Academy of Managed Care Pharmacy (2018). Market Insights: Summit on Hemophilia. Retrieved December 26, 2019, from http://www.amcp.org/uploadedFiles/Production_Menu/Publications/AMCP_Publications/MarketInsights_Sept2018.pdf (requires login).

The Other Medical place of service category includes specialty costs associated with end-stage renal disease (ESRD) treatment facilities, ambulatory surgical centers, and other miscellaneous and less common settings. It also includes a small number of claims identified as hospital inpatient or skilled nursing facility. Hospital inpatient was otherwise excluded from our data, due to bundling of services.

A comparison of costs by place of service (or even between the medical benefit and pharmacy benefit) is challenging because costs may be adjudicated differently, with potentially different dosing and coding, and they may be based on different mixes of medications. Additionally, patients may require treatment in specific sites of care. Some medications may have a loading dose that varies from the maintenance dose (i.e., is higher) and requires more extensive oversight, thus leading to a higher cost. For many medications, though, the hospital outpatient facility is a higher-cost distribution channel than the physician office. The table in Figure 11 summarizes the projected costs by place of service for the top 10 specialty medical HCPCS codes. Figure 11 shows a graphical representation of the Physician Office allowed cost per claim compared to the Hospital Outpatient cost per claim. *Across all 10 HCPCS codes, the cost per claim in the Hospital Outpatient setting is at least 50% higher than the Physician Office.*

FIGURE 11: PROJECTED 2019 SPECIALTY MEDICAL SPENDING BY PLACE OF SERVICE TOP 10 HCPCS CODES, SUMMARY

HCPCS	Primary Brand Name	2017 Total PMPM	2019 Total PMPM	2019 Allowed Cost per Claim				
				Total	Physician Office	Home Health	Hospital Outpatient	Other Medical
J1745	Remicade	\$3.16	\$4.29	\$8,227	\$6,212	\$6,162	\$11,221	\$9,887
J2505	Neulasta*	\$1.52	\$2.10	\$7,826	\$5,418	\$6,362	\$9,938	\$8,868
J9355	Herceptin	\$1.32	\$1.88	\$8,999	\$6,607	N/A	\$11,175	\$8,162
J9310	Rituxan	\$1.23	\$1.76	\$13,619	\$10,461	N/A	\$15,893	\$16,365
J9035	Avastin	\$0.94	\$1.34	\$5,539	\$2,407	N/A	\$12,339	\$8,150
J2323	Tysabri	\$0.79	\$1.13	\$8,205	\$6,528	\$6,499	\$9,899	\$8,365
J9299	Opdivo	\$0.65	\$0.92	\$12,328	\$9,051	N/A	\$15,081	\$12,290
J3380	Entyvio	\$0.67	\$0.91	\$9,312	\$7,088	\$6,760	\$12,042	\$12,544
J9306	Perjeta	\$0.50	\$0.71	\$12,086	\$8,300	N/A	\$15,000	\$11,711
J9271	Keytruda	\$0.45	\$0.64	\$19,363	\$14,156	\$0	\$23,241	\$18,465

Shaded cells indicate the highest-cost place of service for each medication.

* Neulasta Delivery Kit

FIGURE 12: PROJECTED 2019 AVERAGE COST PER CLAIM AT PHYSICIAN OFFICE VS. HOSPITAL OUTPATIENT, TOP 10 HCPCS CODES

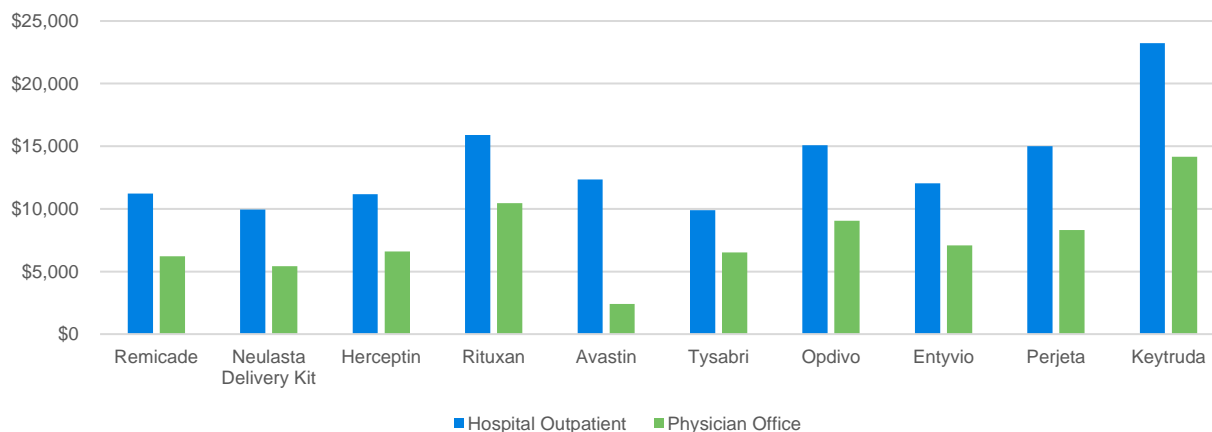
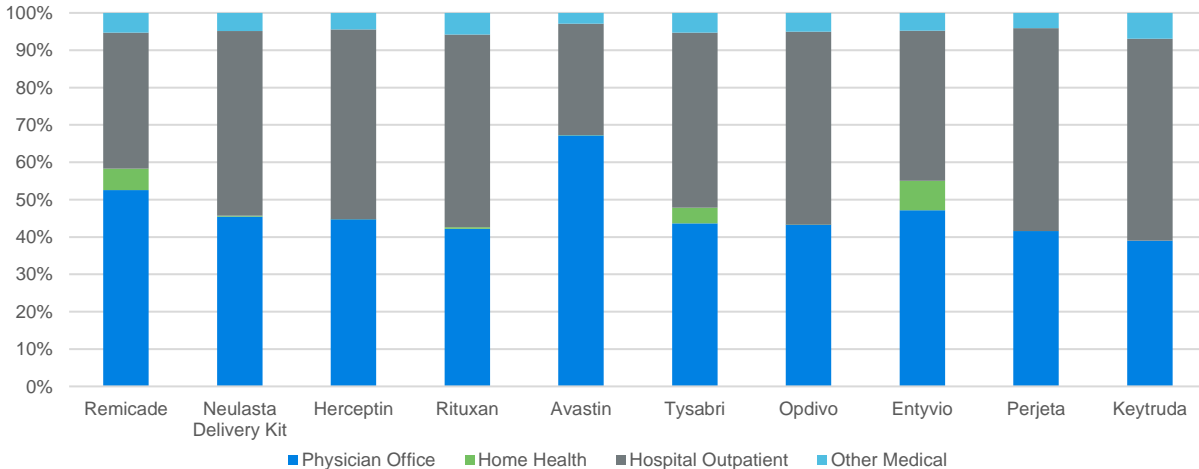


Figure 13 summarizes the projected distribution of utilization by place of service for the top 10 HCPCS codes. Most utilization occurs in the Physician Office setting, followed by the Hospital Outpatient setting, with minimal utilization under Home Health or Other Medical. Utilization is measured by count of claims.

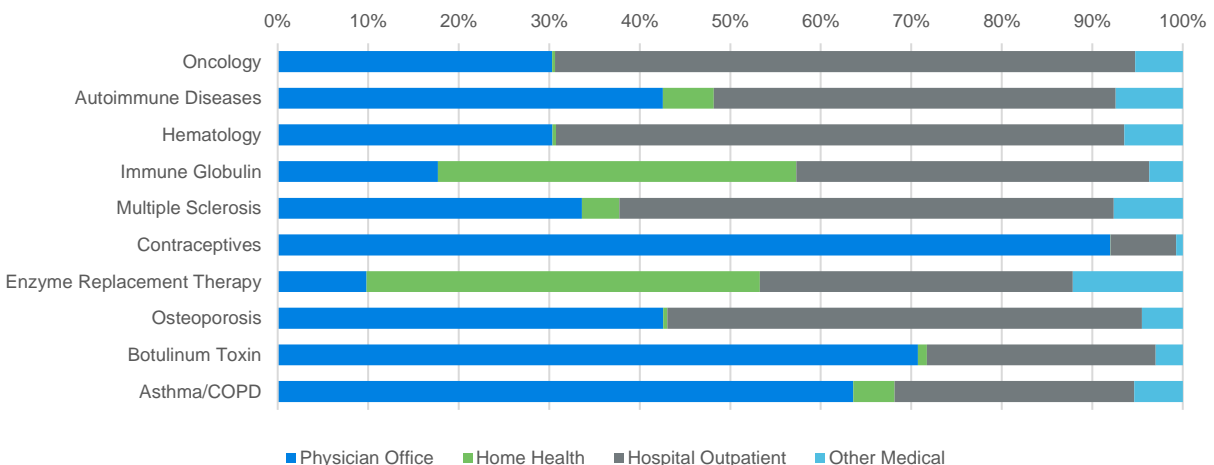
FIGURE 13: PROJECTED 2019 SPECIALTY MEDICAL UTILIZATION BY PLACE OF SERVICE TOP 10 HCPCS CODES SUMMARY



The 10 HCPCS codes listed above represent approximately 50% of the overall projected specialty medical spend. Note, however, that we projected 2017 experience at a class level, rather than medication-specific. As such, Figure 13 does not account for changing market share for certain medications between the experience period and the projection period and does not attempt to anticipate medication-specific price changes. When projecting from 2017 to 2019, cost and utilization were trended at the therapeutic class level, and not at the place of service or medication level. The distributions by place of service in Figures 13 and 14 are reflective of 2017 distributions.

The chart in Figure 14 shows the distribution of 2019 specialty medical costs by place of service and specialty therapeutic class, for the top 10 specialty medical classes.

FIGURE 14: PROJECTED 2019 SPECIALTY MEDICAL SPENDING DISTRIBUTION BY THERAPEUTIC CLASS



About 64% of oncology specialty costs were delivered in a Hospital Outpatient setting, with most of the remaining costs in a Physician Office. Several classes had notable amounts of costs dispensed in the home (e.g., Immune Globulin and Enzyme Replacement Therapy). Contraceptives were almost exclusively administered in a physician's office. Examples of medications within each of these therapeutic classes are shown in Appendix A.

COMPLEX PROBLEMS MAY REQUIRE COMPLEX SOLUTIONS

Specialty medications are at the forefront of pharmacy management, due in part to the many new medications launching in recent years and many more expected to launch in the future. This, coupled with the high cost associated with these medications, has caused concern from payers wanting to ensure their members with the most sensitive healthcare needs maintain access to necessary care while still managing costs. Specialty costs are expected to continue to rise and to become a more significant proportion of pharmacy and overall healthcare expenditures. In the future, the availability of biosimilars, drugs to treat rare diseases, and gene therapies may be additional forces transforming the specialty landscape.

One of the greatest challenges to managing specialty spend is their complex distribution systems, with medications covered under both the pharmacy and medical benefits 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 unique pricing schedules for these medications. Additionally, specialty medications generally treat patients with complex medical problems, making plan sponsors hesitant to intervene in the patient/physician relationship. Plan sponsors must understand the best strategy for each therapeutic class, such as:

- Renegotiating contracts with provider networks to provide similar reimbursement for specialty medical claims regardless of place of service.
- Shifting place of service to the most cost-effective channel.
- Managing financial incentives for physicians and hospitals to dispense medications that are more expensive. Current reimbursement is based on ASP plus methodology, which may create higher profit incentives for dispensing a higher-cost therapy.
- Covering medications only through a specialty pharmacy when there are tighter controls for pricing and pharmacy management.
- Aligning patient financial incentives to be delivery-channel-neutral.
- Implementing traditional PBM utilization management techniques, such as step therapies, preferred medication lists, quantity limits, and prior authorizations.
- Developing systems to consolidate and coordinate specialty utilization through the medical and pharmacy benefit.
- Timely and accurate reporting and analysis of specialty medication across both the medical and pharmacy benefit.

Provider choice of place of service and the changes in utilization by place of service have a large impact on specialty trends. Specialty costs will likely increase as delivery continues to shift from the physician's office setting to an outpatient hospital setting. As more self-injectables potentially move out of the medical benefit, in particular out of the physician's office, the pharmacy mixes remaining in the medical benefit dramatically change. In addition, the unit cost of these specialty medications can vary 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 more comprehensive views of specialty cost management across both the medical and pharmacy benefits.

Methodology

This report was based on an analysis of Milliman's Consolidated Health Cost Guidelines Sources Database (CHSD) for 2017 claims data. The database includes allowed cost and utilization for inpatient, outpatient, professional, and retail and mail pharmacy services for a commercial population, including small and large group employer-sponsored plans. The CHSD is similar source data as that underlying Milliman's 2019 Health Cost Guidelines (HCG) but our values may differ due to differences in assumed trends, provider reimbursement, and other assumptions.

Medication costs and utilization were studied in the following settings, which are assigned using the HCG methodology:

- Hospital outpatient facility
- Physician's office
- Home health
- Outpatient retail and mail pharmacy

This study focused on pharmacy claims that are not associated with an inpatient hospital admission, which tend to be less significant than other settings and are also difficult to measure. Inpatient ancillary services are often subject to bundled reporting, making it nearly impossible to separate out pharmacy costs. A pharmacy claim line was defined as the unit of measure.

A specialty medication may possess one or more of the following characteristics:

- Significantly higher cost than non-specialty medications.
 - For example, Medicare Part D defines "specialty" as any medication in which the negotiated monthly price is \$670 or more. Note that this cost threshold rarely changes and, as such, medications traditionally considered non-specialty now have point-of-sale costs nearing this limit.
- Developed from biological natural sources, such as human, animal, protein-based, nucleic acid-based, living cells, tissue, and microorganisms, rather than conventional chemical processing (i.e., biologic).
 - This definition becomes increasingly important as biosimilars, which are intended to be copies of biologics, are approved.
- Specialized delivery, storage, handling, or administration requirements.
- Administered via injection or infusion; however, specialty medications can also be inhaled or orally administered.
- Intensive patient administration and compliance training.
- Requires close patient monitoring for adverse events, or the medication requires patient to be included in the Risk Evaluation and Mitigation Strategy (REMS) program mandated by the U.S. Food and Drug Administration (FDA).
- Available through limited distribution channels (e.g., a designated specialty pharmacy).
- Used for the treatment of uncommon healthcare conditions, or orphan diseases, which are defined as conditions that affect fewer than 200,000 people nationwide.¹²

For this analysis, specialty pharmacy claims were identified using Milliman's proprietary Health Cost Guidelines definition of specialty pharmacy medications. Many sources are used to determine the Health Cost Guidelines specialty medication list, including lists of medications typically dispensed through specialty pharmacies, definitions from the Centers for Medicare and Medicaid Services (CMS), and publicly available specialty medication lists provided by PBMs and health plans. There are no universally accepted criteria or lists for specialty identification. Specialty medical claims were identified using all HCPCS codes associated with a medication on Milliman's Health Cost Guidelines specialty pharmacy medication list, as well as additional HCPCS codes identified as specialty by a clinician.

¹² FDA (December 2017). Clarification of Orphan Designation of Drugs and Biologics for Pediatric Subpopulations of Common Diseases. Retrieved December 26, 2019, from <https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM589710.pdf>.

We projected 2017 claims data to 2019 using detailed trend projections. Our trend assumptions varied by year and therapeutic class, separately for specialty medical and specialty pharmacy claims, and separately for utilization and unit cost. The trend assumptions were based on a variety of sources, including internal Milliman trend research, published PBM trend reports, and historical AWP price trends. Actual trends are volatile and will vary from our assumptions. We did not apply separate trends by region or by place of service for medical claims, though trends will likely vary by these factors. We attempted to account for the impact of new medications within each therapeutic class as a whole but did not vary trends at a medication-specific level.

Caveats, limitations, and qualifications

The information in this study is intended to describe specialty cost trends in the commercial market and provide a benchmark for the specialty drug experience of health plans. 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.

Actual results will differ from these estimates, due to differences in population, mix of therapies used, distributions of medications by places of service, and medication prices, among other factors. The authors are not required to update this report when new information emerges.

The results of this study would be different for the Medicare, Medicaid, 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 (ACA).

Anna Bungler and Katie Holcomb are members of the American Academy of Actuaries and meet the qualification standards of the American Academy of Actuaries to render the actuarial opinion contained herein.

Appendices

APPENDIX A: SPECIALTY THERAPEUTIC CLASS DEFINITION

Specialty Therapeutic Class	Examples of Medications in Class
Alpha-1 Proteinase Inhibitor	Aralast NP, Glassia, Zemaira
Anticoagulants	Lovenox, Angiomax, Argatroban
Anticonvulsants	Epidiolex, Sabril
Antiemetics	Aloxi, Anzemet, Emend
Antihemophilic Factor	Advate, Eloctate, Alprolix
Antipsychotics	Invega Sustenna, Risperdal Consta, Abilify Maintena
Asthma/COPD	Xolair, Nucala, Cinqair
AutoImmune Diseases	Remicade, Entyvio, Stelara
Botulinum Toxin	Botox, Xeomin, Dysport
Cardiovascular Agents	Praluent, Repatha
CNS Agents	Duopa, Apokyn, Neupro
CNS: Skeletal Muscle Relaxants	Gablofen, Lioresal Intrathecal, Flexeril
Contraceptives	Mirena, Implanon, Skyla
Corticosteroids	Deltasone, Kenalog, Solu-Medrol
Corticotropin	Cosyntropin, Acthrel, Acthar
Diabetes	Lantus, Humalog, Novolog
Endocrine and Metabolic Conditions - Misc	Sandostatin Lar Depot, Somatuline Depot, Desmopressin Acetate
Enzyme Replacement Therapy	Fabrazyme, Lumizyme, Elaprase
Gastrointestinal Conditions	Gattex, Ocaliva, Solesta
Gastrointestinal: chemoprotectant/hormonal	Supprelin La, Gonal-F Rff, Ganirelix Acetate
Gout	Zyloprim, Uloric, Krystexxa
Growth Hormones	Zomacton, Norditropin, Humatrope, Genotropin
Hematology	Neulasta Delivery Kit, Nplate, Aranesp Albumin Free
Hepatitis	Sovaldi, Harvoni, Eplclusa, Zepatier
Hereditary Angioedema	Soliris, Cinryze, Berinert
HIV	Genvoya, Triumeq, Truvada
Immune Globulin	Gammaked, Gammagard Liquid, Privigen
Infectious Disease	Dalvance, Orbactiv, Zyvox
Multiple Sclerosis	Tysabri, Glatopa, Avonex
Oncology	Herceptin, Rituxan, Avastin
Ophthalmic Conditions	Eylea, Lucentis, Iluvien
Opioid Antagonists and Partial Agonists	Vivitrol, Zubsolv, Suboxone
Osteoporosis	Xgeva, Zoledronic Acid, Forteo
Other	Thyrogen, Mozobil, Sylvant
Pain Management	Prialt, Qutenza
Progestins	Makena, Mirena, Skyla
Pulmonary Arterial Hypertension	Remodulin, Tyvaso Starter, Epoprostenol Sodium
Pulmonary Fibrosis	Esbriet, Ofev
Sedatives/Anesthesia	Versed, Diprivan, Precedex
Transplant	Tacrolimus, Azathioprine, Cyclosporine
Viscosupplements	Euflexxa, Synvisc, Orthovisc

APPENDIX B: 2017 HEALTHCARE EXPENDITURES BY PLACE OF SERVICE PMPM

CLAIM TYPE	HOP	HIP	HOME HEALTH	PHYS OFC	OTHER	TOTAL MEDICAL	PHARM	TOTAL
All Services	\$153	\$93	\$9	\$90	\$24	\$369	\$98	\$466
Medications Only	\$18	N/A	\$2	\$14	\$2	\$38	\$98	\$135
Specialty Medications Only	\$11	N/A	\$2	\$8	\$1	\$22	\$38	\$60
Specialty % of Total POS	7%	N/A	21%	9%	5%	6%	39%	13%

Note: Medical components include only ingredient costs with no administrative fee or professional fee. Pharmacy component includes ingredient costs plus dispensing fee.

PMPM = Per Member Per Month, HOP = Hospital Outpatient, HIP = Hospital Inpatient, PHYS OFC = Physician Office, PHARM = Pharmacy Benefit.



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