



UNIVERSITY OF MICHIGAN
COLLEGE OF PHARMACY

Specialty Drug Whitepaper

Developed for the University of Michigan Benefits Office

By:

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EXECUTIVE SUMMARY

Specialty drugs are generally considered high-cost injectable, infused, oral or inhaled drugs that require close supervision and monitoring (Fontanez, 2005). To facilitate comparison of the University's experience with specialty drugs with that of the major national pharmacy benefit management companies, this report focuses on specialty drug products from eight therapeutic areas including, anticoagulants, antivirals, cancer, growth hormone deficiencies, hematopoietics, infertility, multiple sclerosis (MS), and rheumatoid arthritis.

Specialty drugs are the fastest-growing segment of pharmaceutical spending within the University of Michigan pharmacy benefit creating financial pressure to develop better methods to track and manage the use of these products. For the University of Michigan (UM) 2006 pharmacy benefit, the nearly \$6.5 million spent on specialty drugs accounted for 9.1% of the total drug ingredient cost up from 7.2% (\$4.8 million) in 2005. In 2006, the average ingredient cost per specialty drug prescription was \$1,538 a 10.4% increase over the 2005 average cost of \$1,393. This is in contrast to an average ingredient cost per nonspecialty drug prescription of \$73.63 in 2006 and \$72.09 in 2005.

Specialty drug trend under the UM pharmacy benefit is increasing at over thirteen times the rate of nonspecialty or traditional drug spend. Drug trends are reported as year over year increases in per member per year (PMPY) ingredient costs. Overall drug trend from 2005 to 2006 was only 4.4% compared to an 11.3% increase from 2004 to 2005. However, evaluating drug trend by product type revealed that traditional or nonspecialty medication PMPY costs rose only 2.3% in 2006, while specialty drug PMPY costs rose 31.8%. The 2006 UM specialty drug PMPY specialty drug trend is significantly higher than the 20.9% PMPY trend reported in the recent 2006 Express Scripts Drug Trend Report (Express Scripts 2006).

In comparison to the active and retiree eligible population, a higher percentage of the disabled eligibles (6.68%) are specialty drug utilizers with a higher average cost per prescription (\$1,796), and cost per utilizer per year (\$12,465). Specialty drugs within the multiple sclerosis category are the primary drivers for specialty drug utilization and costs for the disabled group. Specialty drugs within the anticoagulant category (primarily Lovenox at \$800 per prescription on average) are the primary drivers for utilization for the retiree group but total costs within the retiree group are driven by agents within the rheumatoid arthritis (\$1,525 average cost per prescription) and cancer categories (average cost per prescription \$2,525).

A 2006 survey by Pharmaceutical Research and Manufacturers of America (PhRMA) noted that there are 418 biotechnology drugs in the development pipeline (PhRMA, 2006). Many of these biotechnology drugs will be considered specialty drugs based on their cost, dosage form, distribution channel, storage requirements, side effect profile, and/or monitoring needs. Of the 418 biotechnology drugs in the development pipeline, cancer-related products dominate with 210 products, more than four times the number for the next category, infectious diseases with 50 products in development. The therapeutic categories for which specialty drugs are being developed include indications that are more common in the general population and particularly common in the aging population such as respiratory disorders, cancer, cardiovascular disorders, diabetes, and rheumatoid arthritis, among others, significantly expanding the financial exposure of the University.

When considering issues related to specialty drugs and benefit design, the two primary questions to consider relate to whether specialty drugs should be part of the medical or the pharmacy benefit and the level of member cost sharing required for these high cost medications. Working with UM's health plan vendors, the University of Michigan Benefits Office is ahead of most employer-sponsored pharmacy benefit programs in moving self-administered specialty drugs from the medical benefit to the pharmacy benefit. By taking this approach, the University has been able to benefit from pricing and utilization management controls available in the pharmacy benefit program and not the medical benefit. These controls include the negotiated product

discounts through the contracted specialty pharmacy vendor, prior authorization and step therapy certification prior to drug dispensing, and the 340B pricing discount program coordinated with the UMHHC Department of Pharmacy. The 340B drug pricing program was established by 1992 Public Health Service legislation and requires drug manufacturers to provide outpatient drugs at a reduced price for patients of eligible entities such as federally qualified health centers, disproportionate share hospitals, and certain clinics that focus on specific diseases such as AIDS or hemophilia. In 2006, the UM Benefits Office and UMHHC Pharmacy Department established a cost sharing arrangement to utilize 340B discounts for UM members obtaining select specialty drugs from UMHHC pharmacies and under the direct care of UM physicians. Under the cost sharing arrangement, the Benefits Office and UMHHC Pharmacy Department equally split the savings per claim.

With an average ingredient cost of \$1,538 for a 30 day supply of specialty medications and a \$12 to \$14 second tier monthly copayment, UM member cost sharing for these products is minimal ranging from a 0.78% to 0.91% of the cost of the product. Nonspecialty drug products average monthly ingredient cost is \$73.63 for an average member cost share range of 16%-19%. With the University's low cost sharing requirements for specialty pharmaceutical products and the catastrophic coverage for prescription drugs after an annual out-of-pocket maximum of \$2,500 per individual coverage or \$5,000 per family per year is met, the University has not shifted costs of the specialty drugs onto members. RAND researchers reported that increasing copayments may not be the best way to contain health care costs when it comes to specialty drugs (Goldman, 2006). Evaluating medical and pharmacy claims data from 55 health plans offered by 15 large employers covering 1.5 million members, the researchers determined that specialty drug use is largely insensitive to cost sharing. That is, for these high cost agents, members continue to use these medications even when their cost share increases. Furthermore, the researchers noted that these members can face extreme financial burden not just for their specialty drug products but across all health care services. The authors argue that increasing member cost share for these agents will do little to reduce overall health care spending. Instead, management of specialty drugs should focus on utilization management techniques making sure that only patients who will benefit the most receive the products.

With an average specialty drug ingredient cost per claim of \$1,538, for an annual cost of \$18,456, averting the inappropriate use of specialty drugs could potentially realize significant drug cost avoidance for the UM pharmacy benefit. Total cost avoidance would be dependent upon the cost of the substituted drug and duration of therapy. Developing a specialty drug utilization management plan and assigning staff resources to focus on this portion of the pharmacy benefit and to work with the medical vendors to monitor the specialty drug expenses on the medical plan side has the potential to provide significant cost avoidance.

The utilization plan should consider including initiatives in the following areas:

Benefit Design

- Maintaining the current member cost sharing requirements for specialty drugs
- Investigating the option of creating a specialty pharmacy formulary with preferred products and negotiating drug company rebate contracts for the products with consideration that those pharmacy claims filled through the 340B program will not qualify for rebates
- Enforcing a 30 day quantity limit per dispensing for specialty drugs
- Evaluating the feasibility of a starter pack quantity limit (7 to 14 days) for newly prescribed specialty drug therapy
- Assessing the specialty drug spend on the medical benefit side and working with the contracted health plans to better manage the utilization and costs on the medical benefit side inclusive of home infusion therapy

- Working with the medical benefit vendors to implement programs to prevent double billing for specialty drugs against both the pharmacy and medical benefit
- Assessing the value of shifting the non Medicare part-B products from the medical benefit to the pharmacy benefit to better utilize pharmacy benefit management techniques for these products if not adequately managed on the medical benefit side

Cost Management

- Expanding member and physician use of the preferred drug distribution channel or specialty pharmacy provider network by transitioning to mandatory use of these channels
- Expanding further the 340B specialty drug program for qualified members and drugs
- Evaluating the cost of generic ancillary products (e.g. diluents, syringes) dispensed by the specialty pharmacy vendors and developing and implementing a MAC list for those products
- Assessing the contractual agreement with the current specialty pharmacy vendor and completing a request for proposal process for specialty pharmacy vendors to benchmark the negotiated discounts and services offered
- Developing standard contract language for the retail and mail service pharmacy network to require matching of negotiated specialty drug discounts offered by the specialty pharmacy vendor and recontracting or amending the current contracts to include this wording
- Working with the contracted health plans to identify members who qualify for the Avastin cap program and applying for cap coverage through Genentech
- Tracking the development and implementation of other drug company sponsored programs capping the cost of care with high cost specialty drugs

Utilization Management

- Implementing the AMCP Format for Formulary Submissions to support the formulary decision making process, evaluation of new drug therapies, and establishment of utilization management parameters
- Implementing specialty drug prior authorization and/or step therapy programs with diagnostic and laboratory requirements along with recertification requirements
- Minimizing the use of specialty drugs for off-label, unproven, ineffective indications by enhancing prior authorization requirements and use of peer specialist review for off-label requests with no supporting documentation in the peer reviewed literature
- Developing a drop shipment program in conjunction with the specialty pharmacy vendor for drugs administered in the physician's office but covered under the pharmacy benefit
- Audit and perform ongoing monitoring of the specialty pharmacy provider network to assure quality services are provided and there is minimal to no waste of these high cost specialty drug products
- Developing adherence monitoring and member education programs for select specialty drug products with poor adherence rates due to patient side effects
- Monitoring the specialty drug pipeline and developing pro-active cost and utilization management programs directed towards members and prescribers
- Working with the contracted health plans to use and share the pharmacy claims data to identify members to participate in case management programs based on first fill of targeted specialty drugs

- Investigating the impact of specialty drugs on total health care costs and patient outcomes to assure that the products are providing the expected health benefits/outcomes in comparison to traditional, nonspecialty drug therapy

Staffing Resources/Collaborative Initiatives

- Hiring an additional pharmacist within the UM Benefits Office to focus on managing specialty drugs and implementing the recommendations within this report
- Working collaboratively with appropriate University units (such as the Center for Medication Use, Policy and Economics) to develop and implement adherence monitoring and other clinical programs, and to assess the outcomes of these programs as well as investigating the impact of specialty drugs on total health care costs and patient outcomes

INTRODUCTION

The definition of specialty drugs and what agents are included within this category is evolving and varies from health plan to health plan as well as across pharmacy benefit programs. Initially the term specialty drugs applied only to high cost injectable drugs. More recently the terms biologic, biological, biopharmaceutical and biotech have been used interchangeably with specialty drugs. However, not all specialty drugs are biologic in origin (Stern, 2006). Biologics are different from traditional or chemical synthetic drugs in that they are produced through biologic processes involving manipulation of genetic material and cultures of living mammalian, microbial, or yeast cells (Grabowski). Specialty drugs cannot be defined only at the therapeutic class level as not all drugs within a therapeutic class are considered specialty drugs. For example, within the Rheumatoid arthritis therapeutic class, Enbrel, Humira, Kineret, Orencia, Remicade, and Rituxan are considered specialty drugs but Methotrexate is not. This evolving nature of the definition of specialty drugs and what drugs are included within the specialty drug category across plans may affect between group comparisons and make benchmark comparisons difficult. For the purposes of this report, the following definition for specialty drugs will be used: specialty drugs are generally considered high-cost injectable, infused, oral or inhaled drugs that require close supervision and monitoring (Fontanez, 2005).

To facilitate comparison of the University's experience with specialty drugs with that of the major national pharmacy benefit management companies, this report focuses on specialty drug products from eight therapeutic areas including, anticoagulants, antivirals, cancer, growth hormone deficiencies, hematopoietics, infertility, multiple sclerosis (MS), and rheumatoid arthritis. The 2006 Drug Trend Report published by the pharmacy benefit manager (PBM), Express Scripts, Inc. was used as the primary benchmark for this report as the 2006 trend data were available at the time of the writing of this report, the financials were based on discounted ingredient costs alone, and per member per year costs were published at the individual specialty drug level. Drug trend reports from other PBMs were not used for the following reasons: the 2006 trend data were not available for Caremark; the Medco 2006 Drug Trend Report did not include sufficient per member per year cost detail at the individual specialty drug level and is based on net cost to the client after discounts, rebates, and member cost share have been deducted making comparisons difficult when member cost share for specialty drugs can vary significantly across plans; and the Walgreens 2006 Drug Trend Report focused only on clients using the Walgreens preferred medication list (formulary) and did not include sufficient per member per year cost detail at the individual specialty drug level.

Specialty drugs are the fastest-growing segment of pharmaceutical spending within the University of Michigan pharmacy benefit creating financial pressure to develop better methods to track and manage the use of these products. For the University of Michigan (UM) 2006 pharmacy benefit, the nearly \$6.5 million spent on specialty drugs accounted for 9.1% of the total drug ingredient cost up from 7.2% (\$4.8 million) in 2005.

Specialty drug trend under the UM pharmacy benefit is increasing at over thirteen times the rate of nonspecialty or traditional drug spend. Drug trends are reported as year over year increases in per member per year (PMPY) ingredient costs. Overall drug trend from 2005 to 2006 was only 4.4% compared to an 11.3% increase from 2004 to 2005. However, evaluating drug trend by product type revealed that traditional or nonspecialty medication PMPY costs rose only 2.3% in 2006, while specialty drug PMPY costs rose 31.8%. The UM specialty drug PMPY trends for 2006 are significantly higher than those reported in the recent 2006 Express Scripts Drug Trend Report (Table 1).

Table 1: Pharmacy Benefit Specialty and Nonspecialty Drug Trends

	University of Michigan		Express Scripts National Benchmark*	
	2005	2006	2005	2006
Percentage of Total Drug Ingredient Costs Attributed to Specialty Drugs	7.2%	9.1%	not reported	9.2%
PMPY Ingredient Cost Drug Trend – all Drugs	11.3%	4.4%	9.0%	7.2%
PMPY Ingredient Cost Drug Trend – Nonspecialty Drugs	9.6%	2.3%	7.9%	5.9%
PMPY Ingredient Cost Drug Trend – Specialty Drugs	38.9%	31.8%	not reported	20.9%

*Sources:

Express Scripts 2006 Drug Trend Report. St. Louis, MO: CuraScript Pharmacy; April 2007. Available at: <http://www.express-scripts.com>. Accessed April 30, 2007.

Express Scripts 2005 Drug Trend Report. St. Louis, MO: CuraScript Pharmacy; June 2006. Available at: <http://www.express-scripts.com>. Accessed April 30, 2007.

In 2006, for the UM pharmacy benefit, the average ingredient cost per specialty drug prescription was \$1,538 a 10.4% increase over the 2005 average cost of \$1,393. This is in contrast to an average ingredient cost per nonspecialty drug prescription of \$73.63 in 2006 and \$72.09 in 2005. The UM prescription claims ingredient costs are higher than those reported in the recent 2006 Express Scripts Drug Trend Report (Table 2).

Table 2: Average Ingredient Cost for Specialty and Nonspecialty Drugs

	University of Michigan		Express Scripts National Benchmark*	
	2005	2006	2005	2006
Average Ingredient Cost per Specialty Drug	\$1,393	\$1,538	\$1,307	\$1,454
Average Ingredient Cost per Nonspecialty Drug	\$72.09	\$73.63	\$51.78	\$53.64

*Express Scripts 2006 Drug Trend Report. St. Louis, MO: CuraScript Pharmacy; April 2007. Available at: <http://www.express-scripts.com>. Accessed April 30, 2007.

Initially, specialty drugs were developed and marketed for rare medical conditions such as Gaucher Disease. However, the therapeutic categories for which specialty drugs are available have expanded tremendously and now include indications that are more common in the general population and particularly common in the aging population such as anemia, cancer, cardiovascular disorders, diabetes, respiratory disorders, and rheumatoid arthritis, among others, significantly expanding the financial exposure of the University both in terms of use for United States Food and Drug Administration (FDA) approved indications (labeled) as well as non FDA approved or “off-label” indications. Reflecting the expansion in the number of specialty products available and the indications for which the products are used, the number of University of Michigan members utilizing specialty drugs and the total specialty drug claim count has increased 11.3% and 20.3% respectively between 2005 and 2006 (Table 3).

Table 3: UM Members Using Specialty Drugs and Claim Count under the Pharmacy Benefit

Year	*Number of UM Members Using Specialty Drugs	% Change from Previous Year	Number of Specialty Drug Claims	% Change from Previous Year
2004*	860	not assessed	2812	not assessed
2005*	1025	19.2%	3480	23.8%
2006	1141	11.3%	4198	20.6%

*Number does not reflect unique member counts. In 2006, there were 941 unique members utilizing specialty drugs; unique member counts are not available for 2004 and 2005.

Specialty Drug Spend by Therapeutic Class Under the UM Pharmacy Benefit

Selected products from the following eight therapeutic classes are included as part of the UM pharmacy benefit specialty drug program:

- Anticoagulants
- Antivirals
- Cancer agents
- Growth hormone
- Hematopoietics
- Infertility
- Multiple sclerosis
- Rheumatoid arthritis (anti-inflammatory)

Appendix A trends the utilization and total UM amount paid (with member cost sharing deducted) within the specialty drug therapeutic classes between 2004 and 2006. Appendix B trends the utilization and total costs by employment status. Appendix C provides the same information based on total ingredient costs (member cost sharing not deducted). And Appendix D includes the net costs and per member per year costs by therapeutic category after savings from the 340B drug pricing program with the UM Health System Pharmacies are deducted.

Two therapeutic classes represent over 52% of the total drug ingredient costs and have the highest per member per year costs: Multiple sclerosis (26.9% of total specialty drug ingredient costs and \$21.70 PMPY) and Rheumatoid arthritis (25.1% of total specialty drug ingredient costs and \$20.30 PMPY). Tumor necrosis factor (TNF) blocker agents included within the rheumatoid arthritis (anti-inflammatory) category recently received expanded indications to cover certain forms of psoriasis, ankylosing spondylitis, and Crohn's disease, hence this category of agents has realized the highest year over year trend in total number of utilizers as well as cost. The anticoagulant category has the highest number of total utilizers among all of the specialty drug therapeutic categories.

Table 4 includes specialty drug utilization by employment status for the UM pharmacy benefit. In comparison to the active and retiree eligible population, a higher percentage of the disabled eligibles (6.68%) are specialty drug utilizers with a higher average cost per prescription (\$1,796), and cost per utilizer per year (\$12,465). Specialty drugs within the multiple sclerosis category are the primary drivers for specialty drug utilization and costs for the disabled group (Appendix B). Retirees, on average, have a lower average cost per prescription (\$1,352) and cost per utilizer per year (\$4,502). Specialty drugs within the anticoagulant category (primarily Lovenox at \$800 per prescription on average) are the primary driver for utilization for the retiree group but total costs within the retiree group are driven by agents within the rheumatoid arthritis (\$1,525 average cost per prescription) and cancer categories (average cost per prescription \$2,525). Utilization management and prior authorization programs (discussed in a later section of this report) along with coordinated case management with health plans and providers are an effective approach to manage the appropriate utilization of specialty drugs for segments of the population.

Table 4: 2006 Aggregate Utilization and Cost Metrics by Employment Status for Select* Specialty Drug Classes Covered Under the UM Pharmacy Benefit

Metric	Employment Status		
	Active	Retiree	Disabled
Total Eligibles**	70,218	8,793	733
Total Utilizers	677	215	49
% Utilizers	0.96%	2.45%	6.68%
Total Prescriptions Filled	3142	716	340
Prescriptions Filled per 1000 Eligibles	44.7	81.4	463.8
Total Ingredient Cost	\$4,750,396.55	\$968,085.70	\$610,804.15
Cost per Prescription	\$1,511.90	\$1,352.08	\$1,796.48
Cost per Utilizer	\$7,016.83	\$4,502.72	\$12,465.39
Per Member per Year	\$67.65	\$110.10	\$833.30

* Includes the specialty drugs classes: rheumatoid arthritis, multiple sclerosis, cancer, growth hormone, antivirals, infertility, anticoagulants, and hematopoietics.

** Based on the average number of lives covered on the first day of every month over the twelve month calendar year

Appendix E includes the average total savings and average UM drug plan savings for only the specialty drugs filled under the 340B program in 2006. The 340B drug pricing program was established by 1992 Public Health Service legislation and requires drug manufacturers to provide outpatient drugs at a reduced price for patients of eligible entities such as federally qualified health centers, disproportionate share hospitals, and certain clinics that focus on specific diseases such as AIDS or hemophilia (US Department of Health and Human Services). In 2006, the UM Benefits Office and UMHC Pharmacy Department established a cost sharing arrangement to utilize 340B discounts for UM members obtaining select specialty drugs from UMHC pharmacies and under the direct care of UM physicians. Under the cost sharing

arrangement, the Benefits Office and UMHHC Pharmacy Department equally split the savings per claim. (See the Distribution Channels section of this report for more details on the 340B program.) Not all patients and prescription claims qualify for the 340B program due to the strict Public Health Service regulations around the program. However, only 44% of the prescriptions eligible for the 340B program were filled through the 340B program. As shown in Appendix E, the UM Benefit's Office realized an average per claim savings ranging from a low of \$102 per claim to a high of \$631 per claim. Increasing the utilization of the 340B program will help to bring down the average cost per claim and PMPY total amount paid by UM.

As noted in Table 5, when compared to the 2006 Express Scripts Drug Trend Report, total amount paid PMPY for the multiple sclerosis, infertility, anticoagulants and hematopoietic categories is much higher for UM (net of 340B savings in the rheumatoid arthritis, multiple sclerosis, and antiviral categories). However UM PMPY amount paid was lower for cancer agents, growth hormones, and antivirals. Additional complex, medical and pharmacy claims analysis is required to determine if the difference is due to prevalence and disease severity of the conditions within the UM covered beneficiaries or drug specific factors such as utilization rates, cost per prescription or mix of drug use. This additional analysis was beyond the scope of work of the current project.

Table 5: Specialty Drugs Per Member Per Year (PMPY) Net Total Amount Paid by UM in Comparison to National Benchmark

	*University of Michigan Net Amount Paid Per Member Per Year		**Express Scripts National Benchmark Per Member Per Year	
	2005	2006	2005	2006
Rheumatoid arthritis*	\$9.41	\$19.37	\$15.52	\$19.04
Multiple sclerosis*	\$16.88	\$19.20	\$11.43	\$13.60
Cancer	\$7.26	\$9.67	\$7.49	\$10.44
Growth hormone	\$3.38	\$4.36	\$3.74	\$4.59
Antivirals*	\$3.15	\$2.17	\$3.76	\$3.45
Infertility	\$3.09	\$3.44	\$2.62	\$2.58
Anticoagulants	\$6.96	\$6.90	\$2.63	\$3.34
Hematopoietics	\$8.96	\$9.60	\$4.81	\$5.01

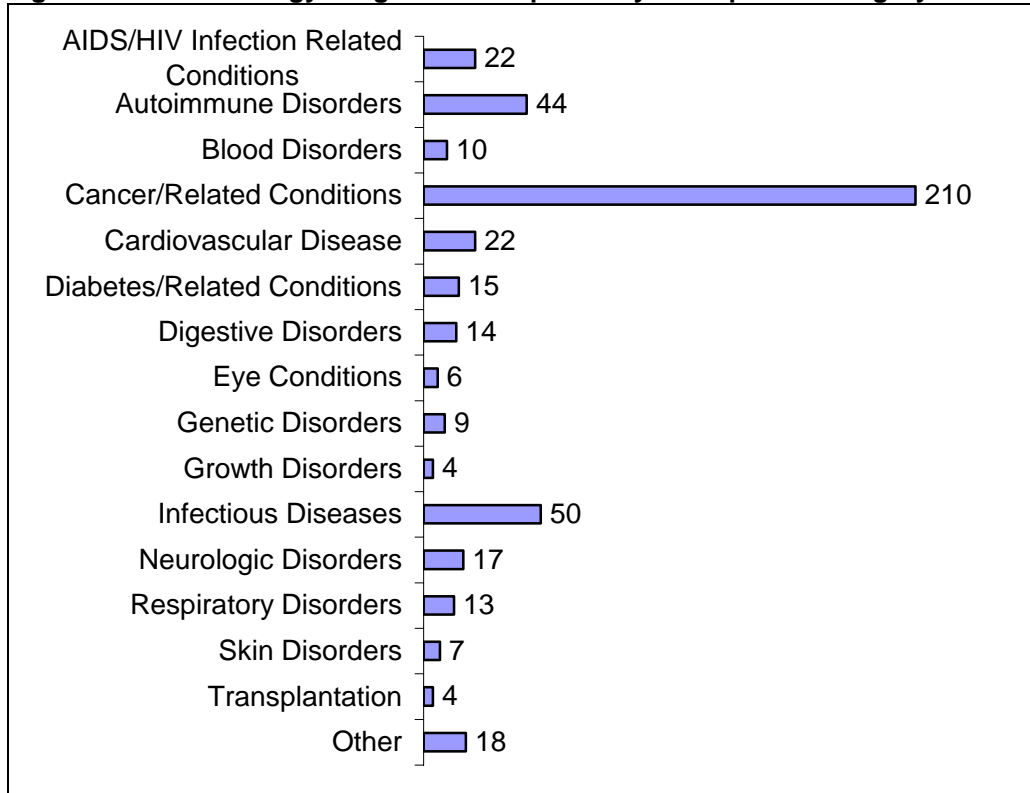
*UM PMPY net total drug paid is net of savings realized from the 340B program in the rheumatoid arthritis, multiple sclerosis, and antiviral categories.

**Express Scripts 2006 Drug Trend Report. St. Louis, MO: CuraScript Pharmacy; April 2007. Available at: <http://www.express-scripts.com>. Accessed April 30, 2007.

Specialty Drug Pipeline

A 2006 survey by Pharmaceutical Research and Manufacturers of America (PhRMA) noted that there are 418 biotechnology drugs in the development pipeline (PhRMA, 2006). Many of these biotechnology drugs will be considered specialty drugs based on their cost, dosage form, distribution channel, storage requirements, side effect profile, and/or monitoring needs. Of the 418 biotechnology drugs in the development pipeline, cancer-related products dominate with 210 products, more than four times the number for the next category, infectious diseases with 50 products in development (Figure 1).

Figure 1: Biotechnology Drugs in Development by Therapeutic Category* as of June 2006



*Some drugs are listed in more than one category.

Source: PhRMA, 2006 Report, Medicines in Development, Biotechnology. Washington DC, 2006. Available at: <http://www.phrma.org/files/Biotech%202006.pdf>. Accessed April 30, 2007.

Of the 418 drugs in development, 74 drugs are in phase III development and another 12 drugs are in phase II/III development stages. Phase III development focuses on drug safety and efficacy and is the point after which drug companies typically submit a new drug application to the FDA to seek approval for marketing. Some of the agents are currently FDA approved and marketed products seeking expanded indications. To assess the potential exposure to the UM pharmacy and medical benefit for the products in phase II/III and phase III development stages, 2006 M-CARE medical claims data were analyzed to determine the number of members whose records contained a diagnostic code for the indications. Member counts were calculated in cases where the indication was coded as a primary diagnosis or as secondary diagnosis. Appendix F includes the results of this analysis. Type II diabetes mellitus (2,150 members), cancer (1,196 members), and arthropathies/autoimmune inflammatory disorders (769 members) had the highest number of unique member counts. Not all of these members would be candidates for the drugs upon FDA approval; however, the analysis demonstrates the potential utilization exposure for these new products. Predicting financial exposure for the specialty drug pipeline is difficult as

potential marketing price points for specialty drugs are difficult to access prior to product launch and annual costs at the drug level can range from a few thousand dollars per patient per year of therapy for some products up to amounts exceeding \$200,000 per patient per year of therapy. Development of utilization management programs such as clinical guidelines, prior authorization criteria or step therapy requirements and having these programs ready at the time of FDA approval and product marketing will assist the UM pharmacy benefit in assuring that newly marketed specialty drugs are used appropriately in members who would benefit the most from the new therapies.

Summary

Specialty drug spend for the UM pharmacy benefit is an important component of the total cost of the program with \$6.6 million spent on specialty drugs in 2006 accounting for 9.1% of the total drug ingredient costs and representing a 31.8% specialty drug PMPY trend from 2005 experience. In developing a plan to manage the costs and utilization of specialty drugs for the University of Michigan Pharmacy Benefit, several issues need to be considered including:

- Benefit design
- Distribution channels
- Utilization management
- Peer academic and health systems handling of specialty drugs

This paper will address each of these issues identifying potential opportunities to manage the appropriate utilization and cost of specialty pharmaceutical products for the University of Michigan pharmacy benefit program.

BENEFIT DESIGN

When considering issues related to specialty drugs and benefit design, the two primary questions to consider relate to whether specialty drugs should be part of the medical or the pharmacy benefit and the level of member cost sharing required for these high cost medications.

Pharmacy vs. Medical Benefit Coverage

According to the 2006 Express Scripts Drug Trend Report, spending on specialty pharmaceuticals, combined across both the pharmacy and medical benefit, is expected to reach \$99 billion by 2010, nearly double the \$54 billion spent on the agents in 2006, or 20% of total drug spend across the pharmacy and medical benefits in 2006. By 2010, 25% of the dollars spent on medications across both the pharmacy and medical benefits will be spent on specialty pharmaceuticals (Express Scripts, 2006). The specialty drug spend on the medical benefit side for the University of Michigan was not evaluated as part of this project. Tracking specialty drug spend on the medical benefit side can be difficult due to limitations in the medical drug coding terminology (this issue will be discussed later in this section of the paper). A future initiative should include working with the medical vendors to track specialty drug spend on the medical benefit side. Differences in the benefit design and associated levels of patient cost-share requirements, clinical and utilization management programs, drug coding, and billing systems of the pharmacy and medical benefits result in challenges and inconsistencies in the cost and care management of specialty pharmaceuticals for payers, providers and members alike.

Managing specialty pharmaceutical utilization, particularly injectable specialty pharmaceuticals, is complicated by the split in benefit assignment between the pharmacy and medical benefits. Self-administered injectables (SAI) are typically administered at home by the patient or caregiver and may be assigned to either the pharmacy or medical benefit. According to the 2006 EMD Serono Specialty Injectable survey, 13% of responding HMOs and 10% of responding PPOs covered SAI only under the medical benefit in 2006. An additional 34% of HMOs and 32% of PPOs covered

SAI under both the pharmacy and medical benefit (EMD Serono, 2006). By providing dual coverage of SAI products under both the pharmacy and medical benefit, there is potential for double billing against the pharmacy and medical benefit.

For SAI covered under the pharmacy benefit, the plan payer/sponsor negotiates product price discounts and dispensing fees with the pharmacy dispensing the specialty drug. The prescription claim for the specialty medication is adjudicated through the pharmacy benefit in a real time basis using the National Drug Code (NDC), a unique identifying number that specifies the manufacturer, strength, dosage form, and package size. NDCs are available as soon as a product receives FDA approval and enters the market (Stern 2006). Since the prescription is adjudicated in a real time basis, member cost sharing requirements and utilization management tools (prior authorization, step therapy, dispensing quantity limits, duration of therapy limits, etc) can be applied prior to the member receiving the medication.

On the other hand, office-administered injectables (OAI) or home infusion therapy (HIT) must be administered in a doctor's office, infusion center, hospital, or at home under direct supervision by a healthcare professional and are traditionally assigned to the medical benefit with member cost sharing for the products integrated as part of the medical service fees. Physicians or the home infusion therapy provider are responsible for obtaining the medication, administering the product, and submitting a medical claim for reimbursement for both the drug and professional services. This process is commonly termed "buy and bill". Medical claims are rarely processed in a "real time" mode limiting the ability to determine member cost sharing requirements and apply utilization management tools. Furthermore, medical claims billing systems do not use the NDC code but instead use the Healthcare Common Procedure Coding System (HCPCS) "J" code to identify and bill medications under the medical benefit. J codes are limited in that they only identify the chemical name of the drug and do not provide the product manufacturer, strength, and package size detail contained within the NDC code. In addition, J codes are often assigned 6 to 18 months after a drug enters the market. During this initial phase when a specific J code is not available, providers typically use a nonspecific code such as J3590 (Unclassified Biologics) or J3490 (Unclassified Drugs) for billing purposes. This hinders the payer from accurately tracking specialty product utilization and enforcing product specific utilization management, member copayment determination, preferred pricing and negotiated discounts via drug company rebates (Stern, 2006). The limitations of the medical claims billing system and J codes also apply to SAI processed under the medical benefit.

Because of utilization management limitations within medical code billing systems attributed to the use of J codes, some health plans have revised their provider billing processes requiring submission of both the J code and NDCs. However, many health plans then must manually review and price these claims. According to a recent specialty injectable survey published by EMD Serono in 2006, 31% of the surveyed health plans were able to capture both the J code and the NDC for processing claims for injectable drugs covered under the medical benefit up from 26% in 2005 and 11% in 2004 (EMD Serono, 2006). The survey also noted that 13% of the health plans moved select office administered injectable products from the medical benefit to the pharmacy benefit. OAI specialty products that are best candidates for such a move include those products with stable, predictable dosage and administration cycles such as Remicade. However, infused oncology products have typically remain part of the medical benefit because of dosing variations and reluctance of many oncology practices to renegotiate terms of their administration fee schedules. Moving OAI to the pharmacy benefit typically requires renegotiating medical provider contracts through the health plan as often the administration fees are wrapped into the cost of the drug. See the section on Distribution Channels later in this report for further discussion of this issue.

Working with UM's health plan vendors, the University of Michigan Benefits Office is ahead of most employer-sponsored pharmacy benefit programs in moving self-administered specialty drugs from the medical benefit to the pharmacy benefit. By taking this approach, the University has been able to benefit from pricing and utilization management controls.

Member Cost Sharing

The University currently offers a generous pharmacy benefit with a three-tier copayment structure based on drug type: generic, brand-name, and non-preferred brand-name drugs. Copayment levels vary according to covered employee group type and are outlined in Table 6. Currently, specialty pharmaceutical products are available as brand name products only and, therefore, fall in the second tier cost sharing level for members with copayments ranging from \$12 to \$14 for a 34 day supply. There are no specialty products assigned to the third or nonpreferred tier. Catastrophic coverage for prescription drugs goes into effect after annual out-of-pocket medication expenditures reach \$2,500 per individual coverage or \$5,000 per family. Catastrophic coverage applies only to covered prescription drugs and does not include fertility medications. Fertility medications are limited to a lifetime \$5,000 family coverage.

With an average ingredient cost of \$1,538 for a 30 day supply of specialty medications and a \$12 to \$14 second tier monthly copayment, UM member cost sharing for these products is minimal ranging from a 0.78% to 0.91% of the cost of the product. Nonspecialty drug products average monthly ingredient cost is \$73.63 for an average member cost share range of 16%-19%. With the University's low cost sharing requirements for specialty pharmaceutical products and the catastrophic coverage for prescription drugs after an annual out-of-pocket maximum of \$2,500 per individual coverage or \$5,000 per family per year is met, the University has not shifted costs of the specialty drugs onto members. RAND researchers recently reported that increasing copayments may not be the best way to contain health care costs when it comes to specialty drugs (Goldman, 2006). Evaluating medical and pharmacy claims data from 55 health plans offered by 15 large employers covering 1.5 million members, the researchers determined that specialty drug use is largely insensitive to cost sharing. That is, for these high cost agents, members continue to use these medications even when their cost share increases. Furthermore, the researchers noted that these members can face extreme financial burden not just for their specialty drug products but across all health care services. The authors argue that increasing member cost share for these agents will do little to reduce overall health care spending. Instead, management of specialty drugs should focus on utilization management techniques making sure that only patients who will benefit the most receive the products.

Table 6: 2007 Prescription Drug Plan Copayments

Group	Drug Type	Retail Pharmacy Co-Pay^{1,2} (up to a 34-day supply)	Walgreens Mail Service Pharmacy Co-Pay¹ (up to a 90 day supply)
AFSCME Active or LTD members enrolled in any medical plan (per contract)	Generic Drugs/Tier 1	\$5	\$10
	Brand-Name Drugs/Tier 2	\$12	\$24
	Non-preferred Drugs (Brand-Name)/Tier 3	\$22	\$44
IUOE Active or LTD members enrolled in any medical plan (per contract)	Generic Drugs/Tier 1	\$6	\$12
	Brand-Name Drugs/Tier 2	\$12	\$24
	Non-preferred Drugs (Brand-Name)/Tier 3	\$18	\$36
Trades Active or LTD members enrolled in any medical plan (per contract)	Generic Drugs/Tier 1	\$7	\$14
	Brand-Name Drugs/Tier 2	\$14	\$28
	Non-preferred Drugs (Brand-Name)/Tier 3	\$24	\$48
All Faculty, Staff, Retirees and their dependents except as noted above	Generic Drugs/Tier 1	\$7	\$14
	Brand-Name Drugs/Tier 2	\$14	\$28
	Non-preferred Drugs (Brand-Name)/Tier 3	\$24	\$48

¹ Catastrophic coverage for prescription drugs goes into effect after the annual out-of-pocket maximum of \$2,500 per individual coverage or \$5,000 per family is met. Catastrophic coverage applies only to covered prescription drugs and does not include infertility medications, generic drug incentive or medical plan expenses such as doctor visits.

² If the retail price of a covered medication is less than the tier copayment, the member pays only the cost of the medication. If the cost of the covered medication is more than the copayment, the member pays only the copayment. The member always pays the full cost for prescriptions that are not covered by the plan.

Specialty Drugs Cost Sharing Trends

Currently there is limited published literature on member cost sharing requirements for specialty pharmacy products as pharmacy benefit plan sponsors are just starting to address this growing therapeutic segment. Table 7 details published surveys that included information on member cost sharing requirements for specialty drugs. Because of the disproportionate member cost share between traditional and specialty medications, some plans (inclusive of health plans and employer sponsored carved out pharmacy benefit offerings) have established a separate tier for specialty drugs with a higher copayment or coinsurance with minimum and maximum out of pocket thresholds on a per claim basis. At the same time, few plans have also established an annual maximum out of pocket threshold for pharmacy benefit-related expenditures leaving those members with a coinsurance cost sharing model for specialty drugs at significant financial risk if prescribed a high-cost specialty drug.

Table 7: Pharmacy Benefit Specialty Drug Member Cost Sharing

Source, Survey Year	Type of Plans	Average Specialty Drug Member Copayment(Preferred Brand/ Nonpreferred Brand)	Average Specialty Drug Member Coinsurance (Preferred Brand/ Nonpreferred Brand)	Average Out of Pocket Maximum per Prescription (% of Plans with a Maximum)	Annual Out of Pocket Maximum for Prescription Drugs (% of Plans with a Maximum)
EMD Serono, 2006	HMO	\$26 / \$44	22% / 29%	\$118 (10%)	\$2,278 (13%)
EMD Serono, 2006	PPO	\$24 / \$46	21% / 29%	\$138 (6%)	\$2,833 (4%)
Zitter, 2006	“Managed Care Decision Makers”	\$23 / \$42	27% / 50%	not reported	\$2,344
KFF/HRET, 2006	Employer Groups	\$63	42%	not reported	not reported

Notes:

EMD Serono specialty drug copayments reflect preferred and nonpreferred branded copayment tiers for injectable products only.

The surveys did not define annual out of pocket maximum as a per individual or per family requirement.

EMD Serono, a biotechnology company specializing in therapies for reproductive, neurologic (multiple sclerosis), and metabolic endocrinology (growth hormones), has sponsored an annual survey of health plans management of specialty injectable drugs (EMD Serono) over the past three years. The survey is seen as a benchmark for documenting trends in health plans management of specialty injectable products across both the pharmacy and medical benefit, but excludes monitoring trends for oral specialty products. The most recent survey included 69 health plans across the United States covering 133 million lives in total.

From a member cost sharing perspective for specialty injectable drugs, the EMD Serono survey is the only survey that has evaluated specialty drug cost sharing requirements across both the pharmacy and medical benefit. The EMD Serono survey noted that in 2006 for specialty injectable drugs covered under the pharmacy benefit, multi-tiered copayments were the primary mechanism for cost sharing for both HMO and PPO plans with preferred and non-preferred copayments averaging \$26 and \$44 respectively for HMO plans and \$24 and \$46 dollars for PPO plans. Tiered co-insurance averaged 22% and 29% for preferred and non-preferred products in the HMO plans and averaged 21% and 29% for preferred and non-preferred products for PPO plans. Only 10% of HMO plans and 6% of PPO plans had an out of pocket maximum per prescription averaging \$118 and \$138 respectively. Only 13% of HMO plans and 4% of PPO plans had an annual out of pocket maximum for pharmacy benefits averaging \$2,278 for HMO plans and \$2,833 for PPO plans (EMD Serono).

The EMD Serono survey noted that for specialty injectables covered under the medical benefit, less than one-third of the health plans surveyed had a member cost-sharing requirement. Flat copayments for specialty products covered under the medical benefit were used by 36% of the HMO plans and 29% of the PPO plans and averaged \$26 and \$30 respectively. Flat coinsurance was used in 36% of the HMO plans and 35% of the PPO plans with percentage co-insurance averaging 24% and 25% respectively. Annual out of pocket maximums for drugs covered under the medical benefit were more common than for drugs covered under the pharmacy benefit with

29% of HMO plans and 26% of PPO plans reporting annual out of pocket maximums of \$3,050 and \$3,111 respectively (EMD Serono).

In spring 2006, the Zitter Group reviewed the trends in specialty pharmaceutical management by interviewing managed care decision-makers (including both pharmacy and medical directors). The Zitter Group's web site provides a snapshot of member cost-sharing requirements for specialty pharmacy products (Zitter, 2006). Based on 102 survey responses, The Zitter Group indicated that this subset of managed care respondents have typically placed self-administered specialty pharmacy products in the second or third copayment tier.

Over the past 12 years, the Kaiser Family Foundation (KFF) and the Health Research and Educational Trust (HRET) have jointly conducted an annual survey of employer sponsored health benefits. This survey provides a detailed look at trends in employer-based health coverage, including changes in premiums, employee contributions, cost sharing policies and other relevant information related to both the medical and pharmacy benefit. The 2006 survey included 3,159 randomly selected public and private firms with three or more employees (2,122 of which responded to the full survey and 1,037 of which responded to a single question about offering coverage) (Kaiser 2006). The KFF/HRET report addressed member cost-sharing requirements in general, but did not perform a sub-analysis on the cost sharing burden for specialty drug products. The report did note that 5% of plans have created a fourth tier for lifestyle and/or specialty products with an average copayment of \$63 which would place member cost sharing at 4.1% for the average specialty drug product with a monthly ingredient cost of \$1,538. The average coinsurance for the fourth tier was 42%, exposing members to a possible copayment of \$646 for a \$1,538 specialty drug. The report also noted that 21% and 22% of the covered workers do not have an annual out of pocket maximum for single and family coverage, respectively. Among the covered workers with an annual out of pocket maximum, prescription drug cost sharing was frequently excluded from the expenditures counting towards the out of pocket maximum. This included 63% of covered workers in HMOs, 83% of covered workers in PPOs, and 73% of covered workers in POS plans. The exception was HDHP/HRA plans where out of pocket expenses for prescription drugs were excluded from annual out of pocket maximums for only 33% of covered workers.

Summary

Member cost sharing needs to be considered in light of the extreme expense of these agents as well as the medical evidence for the place in therapy and potential medical cost avoidance. RAND researchers reported that increasing copayments may not be the best way to contain health care costs when it comes to specialty drugs (Goldman, 2006). The researchers argue that increasing member cost share for these agents will do little to reduce overall health care spending. Instead, management of specialty drugs should focus on utilization management techniques making sure that only patients who will benefit the most receive the products. With the University's low cost sharing requirements for specialty pharmaceutical products and the catastrophic coverage for prescription drugs after an annual out-of-pocket maximum of \$2,500 per individual coverage or \$5,000 per family per year is met, the University has not unduly shifted costs of the specialty drugs onto members. UM efforts to contain specialty drug costs should continue to focus on seeking low cost distribution channels and implementing utilization management programs.

DISTRIBUTION CHANNELS

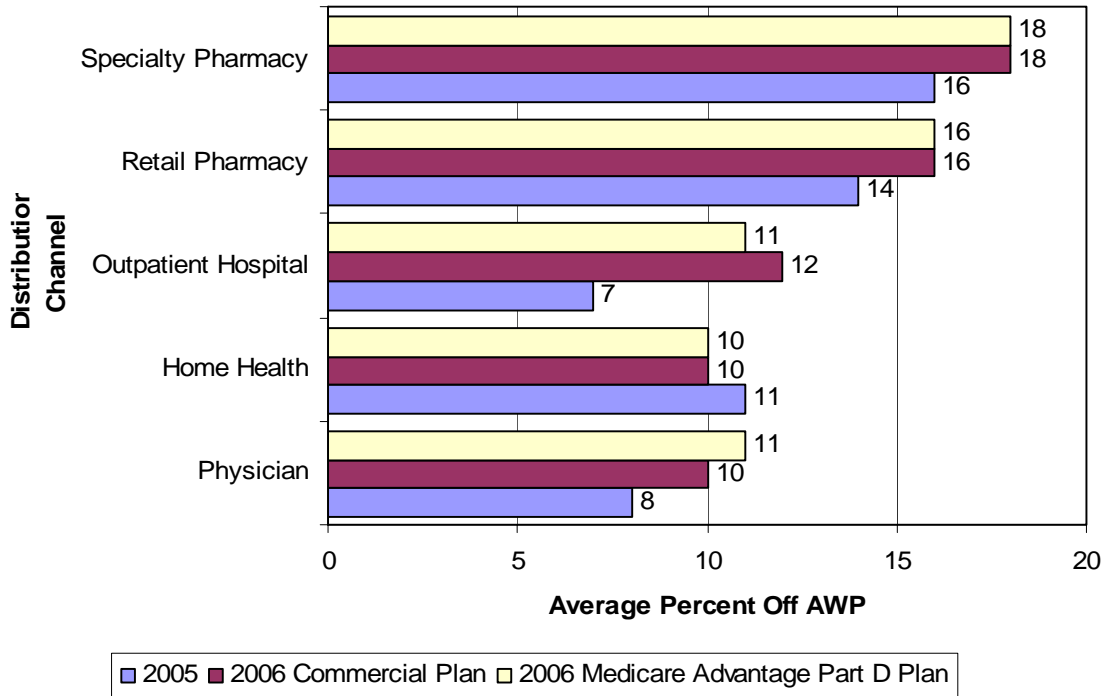
Specialty drug products are dispensed through a variety of distribution channels including specialty pharmacies, retail pharmacies, mail service pharmacies, outpatient hospital pharmacies and clinics, home health (infusion) agencies, and physician's offices. Each of these channels offers a different set of services associated with the distribution services ranging from patient counseling to product administration and full care/case management services with nursing assistance. The costs of additional services are frequently wrapped into the cost of the product

and not charged a la carte. This makes it difficult to compare net drug costs across distribution channels. Managed care has recognized this shortcoming and is working towards a model that segregates the cost of the drugs from the cost of additional services, particularly product administration/infusion services. However, this requires negotiating new contracts with the physician provider network, outpatient hospital network and home health network.

Specialty Product Discounts by Distribution Channel

Specialty product discount contract rates for drugs vary by distribution channel and provider specialty and are typically most aggressive within the specialty pharmacy distribution channel. According to the EMD Serono injectable drug survey and as shown in Figure 2, discount percentage points can vary as much as 8% points off of the product's Average Wholesale Price (AWP) between contracted rates for specialty drugs billed through physicians and specialty pharmacy providers (EMD Serono, 2006). An 8% differential on a specialty product with an average wholesale price of \$1,800 represents \$144 per claim, the accumulation of which would create significant savings over the benefit year.

**Figure 2
Average Negotiated Specialty Product Discounts
By Provider Distribution Channel**



Source: EMD Serono Injectables Digest. Managed Care Strategies for Management of Specialty Injectable Drugs, Third Edition.

In negotiating specialty product discounts with specialty pharmacy providers, product discounts at the individual ingredient and strength level should be defined instead of accepting a blended overall average product discount across all products. Specialty product discounts can range from a low of a few percentage points off of AWP to greater than 40%. As in the general retail and mail order pharmacy network, a maximum allowable cost list (MAC) should be used for any generic nonspecialty or ancillary product dispensed from the vendor.

Specialty Pharmacy Vendors

Specialty pharmacy vendors have evolved over the past decade as a result of the unique storage, shipping, reimbursement, inventory costs, refill management and patient education and care management needs associated with specialty drugs. The traditional retail pharmacy and mail service distribution channels have limitations in efficiently addressing and meeting many of these needs. Pharmacy Benefit Managers (PBM) have identified specialty pharmacy as a revenue and market growth opportunity resulting in several acquisitions of regional and smaller local specialty pharmacy service providers. Currently, there are 8 PBMs (Bioscrip, Medco, CVS/Caremark, Express Scripts, Prescription Solutions, Walgreens Health Initiative, WellDyneRx, and Wellpoint), 2 national health plans (Cigna and Aetna), and 3 drug wholesalers (McKesson, US Bioservices, and Cardinal) that own and operate specialty pharmacies (EMD Serono). In addition, there are many other regionally owned and operated specialty pharmacy vendors. Some specialty pharmacy vendors specialize in certain product and disease areas such as hemophilia, infertility, or oncology and bring a level of expertise and patient services not typically available via other non-specialized providers.

In February of 2007, independently owned community pharmacies and the National Community Pharmacists Association announced the launch of the Community Specialty Pharmacy Network (CSPN) in competitive response to PBMs expansion into and ownership of specialty pharmacies as well as PBMs', health plans' and insurers' demands that community pharmacies distributing specialty products match the product discounts available at the national PBM owned specialty pharmacies. All CSPN-affiliated stores will be accredited and trained in the targeted specialty drugs and diseases to standardize service across the independent stores within the network. CSPN has also implemented a web-based software system to uniformly collect and report utilization, adherence, disease progression, and side effect data (Perry, 2007). CSPN has arranged group purchasing to seek discounts and lower inventory costs for specialty products and compete against the PBM-owned specialty pharmacies. By having the option to obtain a specialty product directly from a local provider at a competitive rate, access, product waste associated with mis-shipments, and physician office administrative concerns associated with a regionalized distribution channel may be minimized.

Home health (infusion) providers are starting to expand their offering and provide specialty pharmacy services in addition to home infusion services. With an existing nursing case and care management service model and 24 hour access to pharmacists, expansion into the specialty pharmacy distribution channel is a logical extension of their business model. The challenge for these providers will be matching the product discounts available via specialty pharmacies and pricing the ancillary services a la carte. Home health (infusion) providers may offer a cost effective alternative for specialty drug infusions that must be administered directly by health professionals and which are typically covered under the medical benefit.

Specialty Product Discounts for Products Administered in Providers' Offices

Negotiating deeper discounts for medications covered under the medical benefit and typically provided by physicians in the "buy and bill model" can be difficult for health plans and insurers, and even more difficult for self-funded employers. First, the physician contractual relationship is held by the health plan/insurer and not the self-funded employer. In addition, in the physician "buy and bill model", the costs of product administration and patient monitoring services are often wrapped into the product cost as evidenced by the differential in the AWP discounts in comparison to other distribution channels. In negotiating deeper product discounts, the cost of the drug needs to be separated from the administration services fee and the administration service fee typically needs to be adjusted upward to better reflect the cost of the clinical services.

The Centers for Medicare and Medicaid Services (CMS) Competitive Acquisition Program (CAP) has established a precedent for separating product costs from administration fees and managing J-code reimbursement for part B drugs administered in physicians' offices. Launched in 2005,

the CAP program gives the physician the choice of obtaining products via a drop ship process from a specialty pharmacy vendor selected by CMS in a competitive bid process or to continue to use their own inventory in the traditional buy and bill mode. However, ceilings have been placed on product reimbursement using the average sales price (ASP) + 6% reimbursement model (CMS, CAP). ASP is the weighted average sales price to wholesalers by manufacturers after all discounts, rebates, charge-backs, and other price reductions are taken into consideration regardless of whether the discounts or rebates are paid to the wholesaler, the pharmacy, or the PBM. However, rebates for the Medicaid program and other “nominal sales” are not included in the ASP calculation. Because ASP takes into consideration discounts that may not be available to an individual provider, the intent of the program was to encourage providers to seek purchasing options to lower their product acquisition costs or to use the CAP option. An administrative benefit of the CAP option for physicians is the CAP vendor is responsible for billing Medicare for the product and collecting any cost sharing responsibilities from the member not the physician.

Commercial health plans are closely watching the CMS CAP program and ASP + 6% pricing model and some plans have already instituted the pricing model within their provider network. According to the EMD Serono survey, 38% of the 69 responding plans have implemented a variation of the ASP pricing. And, many of the plans that did implement the pricing increased the ASP reimbursement level to ASP + 7% to 8% (EMD Serono).

Other distribution and cost management tactics for products administered in the provider’s office include:

- Negotiating with wholesalers or group purchasing organizations to include their provider network as a qualified purchaser
- Contracting with specialty pharmacy vendors to include the option of provider inventory supply through the vendor
- Contracting with specialty pharmacy vendors and mandating the use of the vendor for some or all specialty drug products for both the pharmacy and medical benefit

If the goal is to move product acquisition to a lower cost distribution channel such as a specialty pharmacy vendor, and yet maintain product administration/infusion services within the provider’s office, the logistics of pre-ordering the product and having the product delivered (aka, “drop shipped”) to either the patient directly or the provider’s office must be taken into consideration. In some situations the patient must obtain a written prescription from the physician, contact or go to a pharmacy, purchase the product and bring it to the physician’s office for administration. Data are not readily available to determine how frequently this approach is used or whether it is perceived as an administrative hassle by the patients and physicians. Furthermore, product stability for those agents that require refrigeration and/or constant temperature control is an issue of concern as well. Health plans and insurers who fail to recognize the impact of moving the point of product distribution further away from the site of product administration risk disrupting the provider network and creating perverse incentives in which physicians send patients to other high cost distribution channels such as hospitals for specialty products and infusion services.

340B Pricing

Since 2005, the University of Michigan Benefits Office has pursued an alternative distribution channel taking advantage of 340B pricing available to disproportionate share facilities and select UMHC Pharmacies. The discounts typically available via 340B pricing are equal to or below what state Medicaid agencies pay for drugs but not necessarily as low as the prices available to the four major departments of the federal government including the Department of Defense, Department of Veterans Affairs, Coast Guard, and Public Health Service (US Department of Health and Human Services). It should be noted that drugs purchased through the 340B pricing program do not qualify for additional drug company rebates on top of the 340B pricing discounts. In addition, the program is dependent upon the health system’s status as a disproportionate

share facility and depending upon the patient mix the status could change. Only prescriptions written by physicians employed by the UM Health System qualify for the 340B pricing program. Senate Bill 1376 was introduced into the first session of the 110th Congress in 2007 and is aimed at revising and expanding the 340B discount program for certain providers and facilities (Senate Bill 1376). It is unclear at this point in time whether this bill when/if passed will benefit the UM pharmacy benefit program; but proposed changes to the 340B program should be monitored closely.

In this cost sharing arrangement between the UM Benefits Office and the UMHHC Pharmacy Department, the Benefits Office and the UMHHC Pharmacy Department equally split the ingredient cost savings realized through the 340B pricing discounts. Furthermore, in an effort to encourage utilization of the UMHHC Pharmacies and increase the number of claims with 340B savings, UM Pharmacy Benefit members obtaining services from University of Michigan physicians (at UM clinics) are encouraged via direct mailings and copayment waivers to obtain specialty drugs from the UMHHC Pharmacies. During 2006, 766 prescriptions were filled under the program for a total 340B savings of \$512,080 with the UM Benefits Office splitting 50% of the savings with the UMHHC Pharmacy Department. Appendix E provides average savings per claim for the drugs in the 340B program during 2006 with UM Drug Plan savings ranging from \$102 per Kineret claim to \$630 per Rebif Titration Pack claim. The program was expanded in 2007 to include additional specialty medications as outlined in Table 8. As of June 2007, an additional 93 letters were mailed to qualified UM members encouraging the members to obtain their specialty drugs from the UMHHC pharmacies. If these members obtain their specialty drugs through the UMHHC pharmacies, conservative estimates indicate that the UM Benefits Office may save in excess of \$100,000.

Table 8: Specialty Products Included in the UM 340B Pricing Program

Multiple Sclerosis	Hepatitis C	Rheumatoid Arthritis
Avonex	Ribaviran capsules	Enbrel
Betaseron	Peg-Intron	Humira
Copaxone	Pegasys	Kineret
Rebif	Intron A	
Hematopoietics	Oral Cancer Drugs	Growth Hormone
Aranesp	Gleevec	Genotropin
Epogen	Revlimid	Humatrope
Neulasta	Sutent	Norditropin
Neupogen	Tarceva	Nutropin
Procrit	Temodar	Tev-Tropin
	Xeloda	

Narrowing the Specialty Pharmacy Provider Network

Some health plans have opted to limit their specialty pharmacy network to a single specialty pharmacy provider as a mechanism to control costs and improve quality of services associated with specialty drugs. The EMD Serono survey noted that 56% of the responding health plans have contracted with a single specialty pharmacy provider (EMD Serono). It is difficult to limit the network to a single vendor as some drug companies have launched specialty products via closed distribution channels (either as a result of a FDA requirement for product approval or as a marketing business decision). Limiting the network to a single vendor does not necessarily address the need for a cost-effective backup vendor in cases of unforeseen catastrophic service disruptions at the selected vendor's site. Furthermore, 37 states, including Michigan, have Any Willing Provider laws prohibiting health insurers from excluding participation of qualified providers

in their geographic coverage areas willing to meet the terms and conditions of the organization (Stern, NCSL). Most of the state Any Willing Provider laws are limited to pharmacies or pharmacists. However, some states have adopted broader provisions applying to hospitals, physicians, chiropractors, podiatrists, therapists and nurses (NCSL). One approach to address Any Willing Provider laws is to establish standard pharmacy network contract language that requires the participating pharmacy to meet drug-specific and service-specific negotiated discounts and prices offered by the specialty pharmacy vendor.

At this point in time, the UM pharmacy benefit does not have a preferred or exclusive specialty pharmacy vendor network. Walgreens Specialty Pharmacy and Walgreens retail pharmacies have agreed to match the specialty pharmacy discount rates initially established with Caremark Specialty Pharmacy when Caremark was the PBM managing the pharmacy benefit. However, in 2006, 39.2% of the specialty claims representing 49.3% of total plan's specialty drug spend evaluated for this report were dispensed through one of the pharmacies with negotiated specialty discounts or through the UM 340B program. As of the first seven months of 2007, these numbers had increased to 42.4% of the claims representing 51.9% of the plan spend. Given the increase in market competition among specialty pharmacy vendors, the UM pharmacy benefit should consider doing a request for proposal for specialty pharmacy services and pricing. In addition, specialty pharmacy pricing in the retail network should be evaluated to assure competitive discount rates. Standard contract language for the retail and mail service pharmacy network should be developed to require matching of negotiated specialty drug discounts offered by the specialty pharmacy vendor. The current pharmacy network contracts should be amended (or renegotiated) to include the new specialty pharmacy pricing requirements. If the independent retail network provides the initial patient education and training, upward adjustments could be considered for either the product discount fee or the dispensing fee particularly if the future fills for specialty drugs are directed to other dispensing channels.

In selecting providers to participate in the specialty pharmacy network, partnerships should be established with vendors that will:

- Offer competitive specialty product discounts
- Be a reliable source for hard to find products with local backups for emergent issues and unforeseen problems with product shipments
- Provide cold-chain delivery for temperature sensitive products with packaging adjustments for seasonal variations
- Have a policy in place to immediately handle as well as cover the cost of lost packages including using insured deliveries
- Provide access to staff trained in the nuances of the products and disease states on a 24 hour basis
- Provide member reimbursement support
- Provide member education on how to store and administer the specialty medication, manage the disease, achieve desired outcomes and minimize or address side effects
- Provide member adherence monitoring and refill reminder services
- Participate in disease monitoring and management in conjunction with the medical providers

Summary

For the University of Michigan pharmacy benefit, the key is to assure that existing and newly marketed self-administered specialty drugs remain within the pharmacy benefit to take advantage of the most cost effective distribution channels. In terms of office administered injectable products covered under the medical benefit, the UM Benefits Office needs to work with the health plan vendors to assure that plans have put in place pricing, utilization management, and claims administration controls to track and manage the utilization of these products in a cost effective

manner that does not negatively impact patient services and the provider network. If the UM finds that the health plans have not put in place the necessary controls to manage the costs of office administered injectable products, the option exists to negotiate with the health plans to move these products to the pharmacy benefit and use a specialty pharmacy vendor to supply the product via drop shipments upon receipt of a prescription order. If this is to take place, UM will need to make sure the health plans have appropriately adjusted administration service fees, addressed administrative and pricing concerns brought up by the provider network, and have put in place mechanisms to prevent direct billing for the specialty product under the medical benefit.

In terms of seeking the most cost effective distribution channel for self-administered specialty products covered under the pharmacy benefit, the UM Benefits Office should continue to pursue the 340B distribution channel through the health system clinic pharmacies for those qualified members and medications. The UM Benefits Office should also review the specialty product contractual arrangement with the current specialty pharmacy vendor (Walgreen's Specialty Pharmacy) to make sure the contracted rates are competitive within the market (including a MAC program for generic ancillary products), and the vendor provides quality distribution and patient education, monitoring and management services. A formal request for proposal for specialty pharmacy services is the best approach to assess market competitiveness for specialty pharmacy services and pricing. Furthermore, the standard retail and mail service pharmacy network contracts should be reviewed to require these pharmacies to match the discounts negotiated with the specialty pharmacy vendor if they also want to participate in the specialty pharmacy network. If the independent retail pharmacy network provides the initial patient education and training, upward adjustments could be considered for either the product discount fee or the dispensing fee particularly if the future fills for specialty drugs are directed to other dispensing channels.

UTILIZATION MANAGEMENT

The work of Goldman and colleagues at RAND indicated that for high cost specialty drugs, members continue to use these medications even when their cost share increases (Goldman, 2006). Furthermore, the researchers noted that these members can face extreme financial burden not just for their specialty drug products but across all health care services. The authors argue that increasing member cost share for these agents will do little to reduce overall health care spending. Instead, management of specialty drugs should focus on utilization management techniques making sure that only patients who will benefit the most receive the products. This can be a difficult challenge as drug companies have already implemented direct to consumer advertising campaigns touting high cost specialty drugs for conditions such as anemia secondary to chemotherapy treatment, psoriasis and rheumatoid arthritis giving the impression that new products are better without addressing the cost-benefit of the agents or value of existing non-specialty products. Because of the high cost of specialty drugs, implementation of effective utilization management programs can result in large dividends associated with cost avoidance.

Effective specialty drug utilization management programs include the following components:

- Formulary development
- Clinical guidelines
- Prior authorization
- Step therapy
- Quantity limits
- Reporting and claims review
- Provider education
- Member education

Formulary Development

Establishing a standardized formulary drug review process is the foundation for effective utilization management. Many health plans, PBMs, and some large employer groups have

adopted the use of the Academy of Managed Care Pharmacy's Format for Formulary Submissions for the Pharmacy & Therapeutics Committee's use in formulary decision making process (AMCP). The format is also useful in reviewing the evidence to support establishing drug and disease specific utilization management guidelines. The AMCP Format for Formulary Submissions relies on evidence based medicine to assess a drug's safety, efficacy, as well as overall clinical and economic value relative to alternative therapies. Because of the Food and Drug Administration's accelerated review process for certain classes of drugs (including some specialty drugs), some agents have been approved without published randomized clinical trial evidence making it difficult to adhere to the AMCP Format. As such, some health plans such as Premera Blue Cross and Kaiser Permanente rely on available evidence as well as committees supported by specialists in diseases with emerging specialty drug products (Monroe and Watkins).

Generic Specialty and Biologic Drugs

While the Hatch-Waxman Act of 1984 created a clear path under the Federal Food, Drug, and Cosmetic Act (FD&C Act) for FDA approval of generic traditional (nonspecialty) drug products via the abbreviated new drug application process (ANDA), the approval pathway for generic biologic, biotechnology, and some specialty products remains undefined and hotly debated (Grabowski). Biologics are regulated under the Public Health Service Act (PHS Act) which does not have an equivalent provision to the Hatch-Waxman Act to permit expedited review of generic versions of approved biologic products. Biologics are different from traditional or chemical synthetic drugs in that they are produced through biologic processes involving manipulation of genetic material and cultures of living mammalian, microbial, or yeast cells (Grabowski). While not all specialty drugs are biologic drugs, many of the more commonly used specialty drugs are biologics such as the red blood cell stimulating agents (e.g., Procrit and Epogen), human growth hormones (e.g. Genotropin, Humatrope, and Nutropin AQ) and the breast cancer drug Herceptin. The argument against generic versions is that biologics made in different cell lines or manufacturing plants might behave differently than the patented or branded biologics and therefore should require full scale human studies similar to those used for the patented branded drug.

The issue of biosimilars (also referred to as biogenerics) is at the center of an intense debate between stakeholders seeking avenues to decrease the double digit drug trend associated with these products and the biotechnology manufacturers lobbying to preserve their revenue stream and block generic competition. The "Access to Life-Saving Medicine Act" (H.R. 1038/S. 623) was introduced in February 2007 and seeks to amend the Public Health Service Act to provide for the licensing of comparable and interchangeable biological products. Essentially, the act would establish an abbreviated Food and Drug Administration (FDA) pathway for biosimilars. A recent study by Express Scripts estimated the potential biosimilar savings in four therapeutic categories: multiple sclerosis, anemia, growth failure, and diabetes (Miller). The authors estimated \$3.5 billion in savings in the first year following approval of a biosimilar pathway. The assumptions of the study are questioned by the Biotechnology Industry Organization (BIO). Others argue that the capital investment required to manufacture biosimilar products will limit the total number of generic manufacturers creating less market competition and lower savings than anticipated. European regulators recently approved generic versions of Johnson & Johnson's Eprex, a red blood cell stimulating agent sold in the US as Procrit and as Amgen's Epogen (European Medicines Evaluation Agency). The economic impact of the European approval of these biosimilar agents will be watched closely by the US market as the "Access to Live-Saving Medicine Act" moves through the US legislative process.

The debate over a biosimilar pathway will take time to resolve, particularly given the need for legislation to define the pathway to biosimilar approval. In the meantime, one potential cost savings approach for purchasers of biologic and specialty products to consider is the development of preferred products. When there are multiple therapy options within a specialty drug class such as hematopoietics, growth hormone deficiency, hepatitis C, multiple sclerosis, psoriasis, and rheumatoid arthritis, some health plans are selecting preferred products (Stern, EMD Serono). By selecting preferred products and steering use to the preferred products, health

plans and payors have the ability to negotiate and receive modest market share rebates. According to the EMD Serono survey, 86% of the responding health plans had designated 1 or more preferred specialty products with 61% selecting preferred products in 5 or more therapeutic categories (EMD Serono).

Clinical Guidelines, Prior Authorization, and Step Therapy

As part of the formulary review process, health plans are developing clinical guidelines as the basis for appropriate utilization of specialty drugs. The clinical guidelines are used to support utilization management restrictions enforced via prior authorization, step therapy, and quantity limits. Many health plans and PBMs require prior authorization for all specialty drugs. Kaiser Permanente uses clinical guidelines for specialty drugs to model the safest, most effective, and most efficient use of the products in various settings. The clinical guidelines also support provider education initiatives. The guidelines are also used to identify the best candidates for therapy, define a step-therapy approach, provide recommendations for safe dosing or monitoring, and to offer risk-versus-benefit perspective on therapy (Monroe). For example, when Tysabri (natalizumab) was first marketed in the US for multiple sclerosis, Kaiser placed restrictions on the use of the product in patients whose condition was well controlled on other MS therapies. This was before the product was removed from the market due to the development of progressive multifocal leukoencephalopathy. Kaiser has further restricted the use of Xolair for Asthma, and Enbrel, Humira and Remicade for rheumatoid arthritis to assure that traditional therapy has been tried before the trial of newer specialty drugs. Checking of HCV genotypes and RNA titers at the start of treatment for Hepatitis C and repeat RNA titers after 12 weeks of treatment is another example of how some plans are attempting to assure that once started on therapy, continued therapy is monitored and appropriate for patients using high cost specialty drugs. There are many other examples of prior authorization and step therapy requirements to assure the appropriate utilization of these agents. The key is to develop the guidelines using the best evidence possible and seek specialist input from the provider network. Prior authorization and step therapy guidelines should include certification for initial treatment, dosing, monitoring as well as recertification requirements. The UM pharmacy benefit program through the Benefits Office has implemented prior authorization certification and recertification requirements for several specialty drugs.

Off-Label Use

In establishing clinical guidelines, prior authorization and step therapy criteria, one controversial area is off-label use of specialty drugs. Off-label use is using the product for a condition for which it has no FDA approved indication, varying the dosage or dosing schedule, or using the medication to address another aspect or symptom of the disease the drug is approved to treat (Adams). As broadly defined, such off-label use is common in medical practice and often very appropriate. Concerns with off-label use of specialty drugs, other than the obvious questions regarding unknown efficacy and safety, are the expense of the agents and the need to manage limited financial resources across the entire benefit and covered membership. Because of the Food and Drug Administration's accelerated review process for certain classes of drugs (including some specialty drugs), many agents have been approved initially for very narrow labeled indications. However, for certain areas, such as oncology, approaches to treatment and use of medications move much faster than published literature and FDA approved labeled indications; in these cases, off-label prescribing is an important part of the provision and evolution of care.

For the Medicare Part D drug benefit, CMS will only authorize payment for off-label use of a medication if it is cited in one of the approved compendia listed in the MMA (American Hospital Formulary Service Drug Information, US Pharmacopeia-Drug Information, and the DRUGDEX Information System). For Medicare Part B, by law, Medicare must cover off-label uses of cancer therapies when such uses are supported by citations in specified national cancer compendia or by clinical evidence in peer-reviewed literature. Likewise, 39 states have passed legislation requiring coverage of off-label drug use for cancer if the agent is cited in the national compendium noted above or in peer reviewed medical journals (Stern). While coverage

requirements for off-label use of medications are clearly defined for Medicare beneficiaries, there are no clear guidelines for beneficiaries covered under self-funded employer-sponsored pharmacy benefit programs. The National Council of State Legislatures (NCSL) and the Academy of Managed Care Pharmacy (AMCP) both track state and federal legislation related to pharmaceutical products. In their most recent updates available on their websites, neither organization lists proposed legislation related to mandated benefit coverage for off-label use of prescription drug products. However, the State of Michigan Office of Financial and Insurance Services does specify that traditional health insurance policies (defined as “fee for service” policies) providing prescription drug coverage must cover off-label use of FDA approved drugs (Office of Financial and Insurance Services). The citation does not specify whether the off-label use must be supported in the literature. One approach to manage off-label use of specialty medications is to develop utilization criteria sets listing FDA approved indications, off-label use supported by the literature or national compendia, and off-label use shown to be of no clinical benefit in the literature or national compendia. Requests for benefit coverage for off-label use shown to be of no clinical benefit would be denied. For those cases of off-label use where there is no published data, decisions should be made on a case by case basis using the medical center specialists and peer review assistance along with the established appeals process. Implementing clinically sound, step-therapy requirements with traditional drug therapy (demonstrated to be effective for the medical condition of concern) prior to coverage of specialty drugs for off-labeled indications is another mechanism to assure specialty drugs are used appropriately and costs are managed.

Once the guidelines are established, communicating the guidelines to the provider network and establishing prior authorization and step therapy review processes that are standardized and efficient are critical to the success of the program. Some plans rely on their specialty pharmacy vendor to develop and apply the prior authorization and step therapy criteria sets as well as manage the review and certification process. One risk in allowing the specialty pharmacy vendor to review and approve the prior authorization and step therapy requests is that the vendor has no financial incentive to deny certification for requests that do not meet the guidelines. On the contrary, a major source of the vendors’ revenue is based on the approval and dispensing of the specialty products. For this reason, many health plans and other payers have retained the responsibility for prior authorization and step therapy review for specialty drugs. If the specialty pharmacy vendor does manage the prior authorization process, it is important to audit the services to make sure the guidelines and criteria sets are appropriately applied.

Quantity Limits

Quantity limits for specialty drugs are an important and yet often over-looked aspect of utilization management for specialty drugs. Most specialty drugs are distributed via mail. Historically, quantity limits for drugs distributed through the mail have been set to a 90 day supply due to the stable dosages associated with chronic use medications. Specialty drugs on the other hand are less likely to have stable dosage regimens and a 90 day supply of an average specialty drug could cost \$4,500 or well above that amount depending upon the medication. Therefore, it is important that for these medications the quantity limit per dispensing generally be set to a maximum of 30 days supply. Another alternative to consider would be establishing a 7 to 14day “starter pack” for new prescription orders if appropriate. The cost of packaging and shipping for temperature sensitive drugs may be a financial barrier for limited quantity refills on a regular, ongoing basis. However, utilization of local retail pharmacies for such starter packs or refills may be another option to consider if the retail network can match the negotiated product discounts.

Reporting and Claims Review

An area that needs improvement across all drug and disease categories is patient level outcomes assessment and pharmaco-economic impact assessments. This is particularly important for specialty drugs where the cost of inappropriate or ineffective drug therapy is financially strenuous. Few health plans have the integrated reporting systems and technical expertise in house to efficiently track patient level outcomes and act upon that information at the point of care. Kaiser Permanente, as in integrated, relatively closed delivery system, has initiated projects to be able to

track and affect patient care (Monroe). As a carved out pharmacy benefit, the University of Michigan's challenge is to assure that the pharmacy benefit claims data is efficiently and timely shared with their medical plans so as not to delay identification of members for case and disease management programs. Currently, UM shares prescription claims history data with the medical plans on a weekly basis. Some carved out pharmacy benefit programs have implemented "early alert" reporting programs to identify and report patients newly started on target drug therapies. These early alert reports and accompanying drug claims data are shared with the health plans on a weekly, monthly or timelier basis. Other programs have included a component of integrated care management needs and reporting to the medical care management program as part of the prior authorization certification and review process.

Reporting and claims review are important components of an effective utilization management program. Tracking total spending by drug category, plan, and physician specialty can reveal usage trends and assist in developing and assessing the impact of a utilization management program. For Kaiser Permanente, analysis of claims data revealed that immunomodulatory specialty drugs for rheumatoid arthritis costing \$12,000 or more per patient per year were supplanting older traditional therapies that had cost a few hundred dollars per patient per year (Monroe). Implementing a step therapy program requiring the trial of methotrexate prior to the use of a more expensive specialty product is a common step therapy program for rheumatoid arthritis. High cost drug therapies with significant side effects that challenge even the most motivated patients can create the risk of noncompliance with prescribed therapies. Tracking refill patterns and implementing programs to educate patients on techniques to address side effects can potentially improve response to therapy. This is a particular issue for interferon therapies for hepatitis C where 27% of patients interrupt therapy and approximately one-third of patients reduce the dosage of the medication due to side effects of therapy (Mulhall). For the UM pharmacy benefit, integrating pharmacy and medical claims data analysis along with patient and provider education initiatives would create an effective mechanism to monitor and encourage appropriate utilization of these high cost drugs.

In a rare movement, two drug companies instituted caps on the cost of expensive, new cancer therapies. In October of 2006 when Amgen won approval for a new cancer drug, Vectibix, the company established a cap: the drug would cost \$8,000 a month, but patients would receive it free after co-payments (i.e. total out of pocket costs) exceeded 5% of their adjusted gross income. Shortly after Amgen's announcement, Genentech announced a cap program for Avastin. The company said it would impose a total drug cost cap of \$55,000 per patient annually, regardless of insurance or income (Anand). The average cost for a course of therapy is just under \$50,000. Tracking patient level cost and utilization of Avastin, an infused product typically covered under the medical benefit, and applying for cap coverage could potentially decrease the cost of therapy for those patients exceeding average courses of therapy.

Provider and Member Education

Provider and member education regarding the specialty pharmacy program, distribution channels, prior authorization, and step therapy requirements, appropriate utilization and monitoring of specialty drugs should not be overlooked. A proactive approach to educating providers and members regarding the program can set appropriate expectations and minimize disruptions in care and benefit coverage. Furthermore, integrating provider and member education initiatives as a part of an overall data analytic approach to specialty drug management will provide opportunities to address both quality as well as cost of care.

Summary

For the University of Michigan pharmacy benefit, utilization management initiatives should include using a standardized formulary drug review process such as the AMCPs Format for Formulary Submissions to support the formulary decision making process. Identifying preferred drugs and negotiating product discounts through drug company rebates is a viable approach to cost management for those therapeutic categories with multiple therapy options and should be pursued. Developing clinical guidelines, prior authorization criteria and step therapy programs to assure the appropriate utilization and place in therapy for specialty drugs should be a priority. A

defined decision making process for off-label use of specialty drugs is critical to assure appropriate and timely access to rapidly evolving approaches to therapy while at the same time limiting financial exposure for ineffective therapies. For carved out pharmacy benefit programs, an early alert reporting loop to the case and disease management groups within the medical plans is an important aspect to assure that members using high cost specialty drugs are appropriately monitored at the medical plan level. Working collaboratively with University units (such as the Center for Medication Use, Policy, and Economics) to develop and implement adherence monitoring and other clinical programs, and to assess the outcomes of these programs as well as investigating the impact of specialty drugs on total health care costs and patient outcomes is another option to consider. A proactive approach to educating providers and members regarding the specialty drug program and utilization management initiatives is critical to set appropriate expectations and minimize disruptions in care.

PEER INSTITUTIONS COST SHARING AND APPROACH TO SPECIALTY DRUGS

The University of Michigan Provost's Office has traditionally identified a select set of 17 academic institutions and 6 Michigan-based health systems as peers for benchmark comparison of a variety of key attributes including staff health care benefits. Benefit brochures available in the public domain for the peer academic institutions were reviewed to determine specialty drug pharmacy benefit cost sharing requirements for the 2006-2007 benefit year. Health benefit representatives at the Michigan-based health systems were contacted to determine benefit requirements for specialty drugs. Appendices F and G list the key pharmacy benefit characteristics including specialty pharmacy program characteristics (if available) for the peer academic institutions and health systems, respectively.

Eleven of the 17 peer academic institutions carve-out the administration of their pharmacy benefit to a single pharmacy benefit manager (Table 9). Four of the eleven are part of the University Rx Purchasing Coalition or PURPC (pronounced "purpose") and have combined their purchasing power with several other universities and selected a single PBM (Medco) along with Medco's specialty pharmacy subsidiary, Accredo. While the university members of PURPC use the same PBM, the pharmacy benefit plan design, membership and financial information for each of the universities participating in PURPC is kept separate and managed by the individual universities.

Table 9: Pharmacy Benefit Carve-Out Status and Specialty Pharmacy Vendor Use of 17 Peer Academic Institutions

Institution	Pharmacy Benefit Carve-Out	PBM Administering Carve-Out	Specialty Pharmacy Vendor(s)
Columbia University	Yes*	Medco*	Accredo
Cornell University	Yes*	Medco*	Accredo
Michigan State University	Yes	CVS Caremark	Caremark Specialty Pharmacy MSU Clinical Center Olin Pharmacy
Northwestern University	Yes	Walgreens Health Initiative	Walgreens Specialty Pharmacy
Princeton University	Yes*	Medco*	Accredo
University of Minnesota	Yes	RxAmerica	RxAmerica
University of North Carolina	Yes	Medco	Accredo
University of Pennsylvania	Yes	CVS Caremark	CareMark Specialty Pharmacy
University of Virginia	Yes	CVS Caremark	Caremark Specialty Pharmacy
University of Wisconsin	Yes	Navitus	Specialty Scripts
Yale University	Yes*	Medco*	Accredo
Indiana University	No	not applicable	PrecisionRx Specialty Solutions Prescription Solutions
Stanford University	No	not applicable	Managed by health plans
University of California	No	not applicable	Managed by health plans
University of Chicago	No	not applicable	Managed by health plans
University of Illinois	No	not applicable	Managed by health plans
University of Washington	No	not applicable	Managed by health plans

*Part of the University Rx Purchasing Coalition PURPC; all pharmacy benefits carved-out to Medco with specialty pharmacy services provided by Accredo, Medco's specialty pharmacy division. Other universities participating in PURPC include Boston University, Notre Dame, Seton Hall, and Rochester Institute of Technology.

As of the 2006-2007 benefit year, few of the peer academic institutions and their associated health plans have implemented utilization and cost management programs specific for specialty drugs. None of the institutions had any information available in the benefit brochures that suggested they have implemented a program to take advantage of 340B pricing. The University of Virginia was the only institution requiring mandatory use of a specialty pharmacy vendor for both patient administered and physician administered specialty drugs (Table 10). Only three institutions' pharmacy benefit plan descriptions specifically noted that all specialty drugs require prior authorization (Indiana University, Stanford University and University of Virginia). Two institutions placed lifetime benefit caps on fertility drugs (Columbia and Stanford University). Seven institutions had annual out of pocket maximums for all covered drugs under the prescription benefit ranging from \$700 to \$4,500 per year. Only 1 institution specifically set an annual out of pocket maximum for specialty drugs at \$5,000 per year. And 1 institution (Yale) established an annual pharmacy benefit cap of \$25,000 per person per year.

Table 10: Specialty Pharmacy Vendor Use, Restrictions and Cost Sharing Requirements of 17 Peer Academic Institutions

Institution	Specialty Pharmacy Vendor(s)	Specialty Drug Restrictions and or Caps	Per Prescription Cost-Sharing Maximums	Annual Out of Pocket Maximums for Prescriptions
Columbia University	Accredo	\$15,000 lifetime cap for fertility drugs	nr	nr
Cornell University	Accredo	nr	nr	nr
Indiana University*	PrecisionRx Specialty Solutions Prescription Solutions	20% coinsurance for specialty drugs. All specialty drugs require prior authorization. Limit to 30 day supply per prescription.	nr	\$2,400 maximum out of pocket expense per member per year
Michigan State University	Caremark Specialty Pharmacy MSU Clinical Center Olin Pharmacy	nr	nr	\$1,000 per member per year or \$2,000 per family per year
Northwestern University**	Walgreens Specialty Pharmacy	20% coinsurance with \$100 maximum per prescription	nr	\$5,000 annual out of pocket maximum for self-injectable drugs
Princeton University	Accredo	nr	nr	nr

Table 10: Specialty Pharmacy Vendor Use, Restrictions and Cost Sharing Requirements of 17 Peer Academic Institutions

Institution	Specialty Pharmacy Vendor(s)	Specialty Drug Restrictions and or Caps	Per Prescription Cost-Sharing Maximums	Annual Out of Pocket Maximums for Prescriptions
Stanford University	Managed by individual health plans	50% copayment for fertility drugs with \$5,000 lifetime cap. All specialty drugs require prior authorization.	nr	nr
University of California	Managed by individual health plans	nr	nr	nr
University of Chicago	Managed by individual health plans	nr	nr	nr
University of Illinois	Managed by individual health plans	nr	nr	nr
University of Minnesota	RxAmerica	nr	nr	Annual out of pocket maximum \$750 per person or \$1,500 per family
University of North Carolina	Accredo	nr	nr	\$2,500 annual out of pocket maximum per person
University of Pennsylvania	CareMark Specialty Pharmacy	nr	nr	\$1,500 annual out of pocket maximum per person and \$4,500 per family
University of Virginia	Caremark Specialty Pharmacy	Specialty drugs require prior authorization. Mandatory use of specialty pharmacy vendor inclusive of physician administered drugs.	nr	nr

Table 10: Specialty Pharmacy Vendor Use, Restrictions and Cost Sharing Requirements of 17 Peer Academic Institutions

Institution	Specialty Pharmacy Vendor(s)	Specialty Drug Restrictions and or Caps	Per Prescription Cost-Sharing Maximums	Annual Out of Pocket Maximums for Prescriptions
University of Washington****	Managed by individual health plans	Specialty drugs, Insulin and disposable diabetic supplies in Generic copayment tier with 10% coinsurance	Per prescription maximums based on days supply: Up to 30 day supply \$75 31-60 day supply \$150 61-90 day supply \$225;	nr
University of Wisconsin	Specialty Scripts	nr	nr	\$1,000 annual out of pocket maximum per person and \$2,000 per family for tier 1 and 2 drugs only. Tier 3 nonformulary drugs do not count towards out of pocket maximum
Yale University	Accredo	Annual benefit cap of \$25,000 per person.	nr	Annual \$700 out of pocket maximum

nr = not reported in pharmacy benefit description

*Specialty drug restrictions apply only to the MPlan HMO offering.

**Specialty drug restrictions apply only to Unicare HMO offering.

****Specialty drug coinsurance levels apply only to PPO offering.

Four of the 6 health systems carve-out their pharmacy benefit to a single PBM (Beaumont, Henry Ford Health System, Oakwood, and St. John) (Appendix H). Detroit Medical Center and Trinity Health System do not carve-out the pharmacy benefit. Three of the health systems provided information on specialty pharmacy programs and current member cost sharing requirements for the entire pharmacy benefit (Beaumont, Trinity, and St. John). The other health systems did not respond to request for information on the pharmacy benefit or declined to share information. Of the three responding programs, St. John Health System has the most controls established for specialty drugs. St. John's requires prior authorization and mandatory use of a single specialty pharmacy (Bioscrip) for all specialty drugs including agents covered under both the pharmacy and medical benefit. Currently, St. John only process growth hormone as part of the pharmacy benefit; all other specialty drugs are processed under the medical benefit.

RECOMMENDATIONS

With nearly \$6.5 million spent on specialty drugs in 2006 (9.1% of the total drug ingredient cost) and a PMPY trend of 31.8%, specialty drugs are the fastest-growing segment of pharmaceutical spending within the University of Michigan pharmacy benefit creating financial pressure to develop better methods to track and manage the use of these products.

With an average specialty drug ingredient cost per claim of \$1,538, for an annual cost of \$18,456, averting the inappropriate use of specialty drugs could potentially realize significant drug cost avoidance for the UM pharmacy benefit. Total cost avoidance would be dependent upon the cost of the substituted drug and duration of therapy. Developing a specialty drug utilization management plan and assigning staff resources to focus on this portion of the pharmacy benefit and to work with the medical vendors to monitor the specialty drug expenses on the medical plan side has the potential to provide significant cost avoidance.

The utilization plan should consider including initiatives in the following areas:

Benefit Design

- Maintaining the current member cost sharing requirements for specialty drugs
- Investigating the option of creating a specialty pharmacy formulary with preferred products and negotiating drug company rebate contracts for the products with consideration that those pharmacy claims filled through the 340B program will not qualify for rebates
- Enforcing a 30 day quantity limit per dispensing for specialty drugs
- Evaluating the feasibility of a starter pack quantity limit (7 to 14 days) for newly prescribed specialty drug therapy
- Assessing the specialty drug spend on the medical benefit side and working with the contracted health plans to better manage the utilization and costs on the medical benefit side inclusive of home infusion therapy
- Working with the medical benefit vendors to implement programs to prevent double billing for specialty drugs against both the pharmacy and medical benefit
- Assessing the value of shifting the non Medicare part-B products from the medical benefit to the pharmacy benefit to better utilize pharmacy benefit management techniques for these products if not adequately managed on the medical benefit side

Cost Management

- Expanding member and physician use of the preferred drug distribution channel or specialty pharmacy provider network by transitioning to mandatory use of these channels
- Expanding further the 340B specialty drug program for qualified members and drugs
- Evaluating the cost of generic ancillary products (e.g. diluents, syringes) dispensed by the specialty pharmacy vendors and developing and implementing a MAC list for those products
- Assessing the contractual agreement with the current specialty pharmacy vendor and completing a request for proposal process for specialty pharmacy vendors to benchmark the negotiated discounts and services offered
- Developing standard contract language for the retail and mail service pharmacy network to require matching of negotiated specialty drug discounts offered by the specialty pharmacy vendor and recontracting or amending the current contracts to include this wording

- Working with the contracted health plans to identify members who qualify for the Avastin cap program and applying for cap coverage through Genentech
- Tracking the development and implementation of other drug company sponsored programs capping the cost of care with high cost specialty drugs

Utilization Management

- Implementing the AMCP Format for Formulary Submissions to support the formulary decision making process, evaluation of new drug therapies, and establishment of utilization management parameters
- Implementing specialty drug prior authorization and/or step therapy programs with diagnostic and laboratory requirements along with recertification requirements
- Minimizing the use of specialty drugs for off-label, unproven, ineffective indications by enhancing prior authorization requirements and use of peer specialist review for off-label requests with no supporting documentation in the peer reviewed literature
- Developing a drop shipment program in conjunction with the specialty pharmacy vendor for drugs administered in the physician's office but covered under the pharmacy benefit
- Audit and perform ongoing monitoring of the specialty pharmacy provider network to assure quality services are provided and there is minimal to no waste of these high cost specialty drug products
- Developing adherence monitoring and member education programs for select specialty drug products with poor adherence rates due to patient side effects
- Monitoring the specialty drug pipeline and developing pro-active cost and utilization management programs directed towards members and prescribers
- Working with the contracted health plans to use and share the pharmacy claims data to identify members to participate in case management programs based on first fill of targeted specialty drugs
- Investigating the impact of specialty drugs on total health care costs and patient outcomes to assure that the products are providing the expected health benefits/outcomes in comparison to traditional, nonspecialty drug therapy

Staffing Resources/Collaborative Initiatives

- Hiring an additional pharmacist within the UM Benefits Office to focus on managing specialty drugs and implementing the recommendations within this report
- Working collaboratively with appropriate University units (such as the Center for Medication Use, Policy and Economics) to develop and implement adherence monitoring and other clinical programs, and to assess the outcomes of these programs as well as investigating the impact of specialty drugs on total health care costs and patient outcomes

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Appendix A: Utilization and Total UM Amount Paid for Specialty Drugs Covered under the UM Pharmacy Benefit

Specialty Drug Class	Year	Total Utilizers	% Change From Previous Year	Total Prescriptions Filled	% Change From Previous Year	Total UM Amount Paid*	% Change From Previous Year	UM Paid PMPY*	% Change From Previous Year	% Spend for Specialty Drug Class of Total UM Amount Paid
<i>Rheumatoid Arthritis</i>	2004	32	—	123	—	\$ 162,016.35	—	\$ 2.05	—	4.8%
	2005	89	178.1%	539	338.2%	\$ 756,670.69	78.6%	\$ 9.57	365.9%	16.0%
	2006	154	73.0%	1043	93.5%	\$ 1,602,434.54	111.8%	\$ 20.05	109.5%	25.8%
<i>Multiple Sclerosis</i>	2004	112	—	830	—	\$ 1,120,613.49	—	\$ 14.20	—	33.2%
	2005	119	6.3%	869	4.7%	\$ 1,365,761.79	21.9%	\$ 17.27	21.6%	28.9%
	2006	138	16.0%	1057	21.6%	\$ 1,719,442.11	25.9%	\$ 21.51	24.6%	27.6%
<i>Cancer</i>	2004	77	—	309	—	\$ 457,670.15	—	\$ 5.80	—	13.6%
	2005	75	-2.6%	289	-6.5%	\$ 574,066.07	25.4%	\$ 7.26	25.1%	12.2%
	2006	81	8.0%	316	9.3%	\$ 772,783.49	34.6%	\$ 9.67	33.2%	12.4%
<i>Growth Hormone</i>	2004	16	—	118	—	\$ 215,590.34	—	\$ 2.73	—	6.4%
	2005	19	18.8%	134	13.6%	\$ 267,258.88	24.0%	\$ 3.38	23.7%	5.7%
	2006	19	0.0%	143	6.7%	\$ 348,508.15	30.4%	\$ 4.36	29.0%	5.6%
<i>Antivirals</i>	2004	45	—	251	—	\$ 279,468.36	—	\$ 3.54	—	8.3%
	2005	42	-6.7%	199	-20.7%	\$ 256,038.89	-8.4%	\$ 3.24	-8.6%	5.4%
	2006	26	-38.1%	159	-20.1%	\$ 184,188.87	-28.1%	\$ 2.30	-28.8%	3.0%
<i>Infertility</i>	2004	219	—	349	—	\$ 270,938.57	—	\$ 3.43	—	8.0%
	2005	226	3.2%	371	6.3%	\$ 244,077.77	-9.9%	\$ 3.09	-10.1%	5.2%
	2006	216	-4.4%	398	7.3%	\$ 274,774.20	12.6%	\$ 3.44	11.4%	4.4%
<i>Anticoagulants</i>	2004	264	—	512	—	\$ 349,030.82	—	\$ 4.42	—	10.4%
	2005	355	34.5%	732	43.0%	\$ 550,251.27	57.7%	\$ 6.96	57.3%	11.7%
	2006	397	11.8%	719	-1.8%	\$ 551,549.86	0.2%	\$ 6.90	-0.8%	8.9%
<i>Hematopoietics</i>	2004	95	—	320	—	\$ 516,399.07	—	\$ 6.55	—	15.3%
	2005	100	5.3%	347	8.4%	\$ 708,816.78	37.3%	\$ 8.96	36.9%	15.0%
	2006	110	10.0%	363	4.6%	\$ 767,508.34	8.3%	\$ 9.60	7.1%	12.3%
<i>All Specialty Drugs</i>	2004	860	—	2812	—	\$ 3,371,727.15	—	\$ 42.74	—	—
	2005	1025	19.2%	3480	23.8%	\$ 4,722,942.14	40.1%	\$ 59.72	39.7%	—
	2006	1141	11.3%	4198	20.6%	\$ 6,221,189.56	31.7%	\$ 77.83	30.3%	—

* This DOES NOT reflect savings due to 340B program

Appendix B: Specialty Drug Class-Specific 2006 Utilization and Cost Metrics by Employment Status

Specialty Drug Class	Employment Status	Total Utilizers	Total Prescriptions Filled	% of Class	% of Employment Status	Total Ingredient Costs	% of Class Total Costs	% of Employment Status Total Costs
Rheumatoid Arthritis	Active	133	766	73.4%	24.4%	\$1,188,784.06	73.3%	25.0%
	Retired	26	197	18.9%	27.5%	\$304,026.96	18.7%	31.4%
	Disabled	12	80	7.7%	23.5%	\$129,609.80	8.0%	21.2%
Rheumatoid Arthritis Total		171	1043			\$1,622,420.82		
Multiple Sclerosis	Active	117	847	80.1%	27.0%	\$1,407,455.80	81.2%	29.6%
	Retired	5	42	4.0%	5.9%	\$63,519.54	3.7%	6.6%
	Disabled	21	168	15.9%	49.4%	\$263,225.40	15.2%	43.1%
Multiple Sclerosis Total		143	1057			\$1,734,200.74		
Cancer	Active	61	173	54.7%	5.5%	\$378,522.31	48.1%	8.0%
	Retired	33	109	34.5%	15.2%	\$303,566.33	38.6%	31.4%
	Disabled	11	34	10.8%	10.0%	\$105,208.63	13.4%	17.2%
Cancer Total		105	316			\$787,297.27		
Growth Hormone	Active	17	122	85.3%	3.9%	\$334,931.21	94.7%	7.1%
	Retired	5	21	14.7%	2.9%	\$18,829.40	5.3%	1.9%
	Disabled	0	0	0.0%	0.0%	\$0.00	0.0%	0.0%
Growth Hormone Total		22	143			\$353,760.61		
Antivirals	Active	28	137	86.2%	4.4%	\$168,770.12	90.4%	3.6%
	Retired	2	13	8.2%	1.8%	\$6,193.61	3.3%	0.6%
	Disabled	3	9	5.7%	2.6%	\$11,801.02	6.3%	1.9%
Antivirals Total		33	159			\$186,764.75		
Infertility	Active	250	395	99.2%	12.6%	\$298,019.28	99.9%	6.3%
	Retired	1	3	0.8%	0.4%	\$195.00	0.1%	0.0%
	Disabled	0	0	0.0%	0.0%	\$0.00	0.0%	0.0%
Infertility Total		251	398			\$298,214.28		
Anticoagulants	Active	284	479	66.6%	15.2%	\$426,528.04	75.0%	9.0%
	Retired	151	223	31.0%	31.1%	\$126,744.38	22.3%	13.1%
	Disabled	10	17	2.4%	5.0%	\$15,411.10	2.7%	2.5%
Anticoagulants Total		445	719			\$568,683.52		
Hematopoietics	Active	74	223	61.4%	7.1%	\$547,385.73	70.4%	11.5%
	Retired	41	108	29.8%	15.1%	\$145,010.48	18.6%	15.0%
	Disabled	15	32	8.8%	9.4%	\$85,548.20	11.0%	14.0%
Hematopoietics Total		130	363			\$777,944.41		

Appendix C: Utilization and Total Ingredient Costs for Specialty Drugs Covered under the UM Pharmacy Benefit

Specialty Drug Class	Year	Total Utilizers	% Change From Previous Year	Total Prescriptions Filled	% Change From Previous Year	Total Ingredient Costs*	% Change From Previous Year	PMPY based on Total Ingredient Costs*	% Change From Previous Year	% Spend for Specialty Drug Class of Total Ingredient Costs
Rheumatoid Arthritis	2004	32	—	123	—	\$ 167,991.27	—	\$ 2.13	—	4.8%
	2005	89	178.1%	539	338.2%	\$ 770,929.91	78.2%	\$ 9.75	357.8%	15.9%
	2006	154	73.0%	1043	93.5%	\$ 1,622,420.82	110.4%	\$ 20.30	108.2%	25.1%
Multiple Sclerosis	2004	112	—	830	—	\$ 1,141,380.91	—	\$ 14.47	—	32.8%
	2005	119	6.3%	869	4.7%	\$ 1,383,487.75	21.2%	\$ 17.49	20.9%	28.5%
	2006	138	16.0%	1057	21.6%	\$ 1,734,200.74	25.3%	\$ 21.70	24.0%	26.9%
Cancer	2004	77	—	309	—	\$ 475,691.08	—	\$ 6.03	—	13.7%
	2005	75	-2.6%	289	-6.5%	\$ 586,258.24	23.2%	\$ 7.41	23.0%	12.1%
	2006	81	8.0%	316	9.3%	\$ 787,297.31	34.3%	\$ 9.85	32.9%	12.2%
Growth Hormone	2004	16	—	118	—	\$ 220,079.48	—	\$ 2.79	—	6.3%
	2005	19	18.8%	134	13.6%	\$ 271,494.33	23.4%	\$ 3.43	23.1%	5.6%
	2006	19	0.0%	143	6.7%	\$ 353,670.60	30.3%	\$ 4.42	28.9%	5.5%
Antivirals	2004	45	—	251	—	\$ 284,616.13	—	\$ 3.61	—	8.2%
	2005	42	-6.7%	199	-20.7%	\$ 259,913.31	-8.7%	\$ 3.29	-8.9%	5.4%
	2006	26	-38.1%	159	-20.1%	\$ 186,764.75	-28.1%	\$ 2.34	-28.9%	2.9%
Infertility	2004	219	—	349	—	\$ 305,343.67	—	\$ 3.87	—	8.8%
	2005	226	3.2%	371	6.3%	\$ 290,494.06	-4.9%	\$ 3.67	-5.1%	6.0%
	2006	216	-4.4%	398	7.3%	\$ 298,215.28	2.7%	\$ 3.73	1.6%	4.6%
Anticoagulants	2004	264	—	512	—	\$ 361,319.76	—	\$ 4.58	—	10.4%
	2005	355	34.5%	732	43.0%	\$ 568,204.75	57.3%	\$ 7.18	56.9%	11.7%
	2006	397	11.8%	719	-1.8%	\$ 568,683.52	0.1%	\$ 7.11	-1.0%	8.8%
Hematopoietics	2004	95	—	320	—	\$ 524,032.16	—	\$ 6.64	—	15.1%
	2005	100	5.3%	347	8.4%	\$ 716,622.42	36.8%	\$ 9.06	36.4%	14.8%
	2006	110	10.0%	363	4.6%	\$ 904,771.60	26.3%	\$ 11.32	24.9%	14.0%
All Specialty Drugs	2004	860	—	2812	—	\$ 3,480,454.46	—	\$ 44.11	—	—
	2005	1025	19.2%	3480	23.8%	\$ 4,847,404.77	39.3%	\$ 61.29	38.9%	—
	2006	1141	11.3%	4198	20.6%	\$ 6,456,024.62	33.2%	\$ 80.77	31.8%	—

* This DOES NOT reflect savings due to 340B program

Appendix D: Savings Realized under the 340B Specialty Drug Program

Specialty Drug Class	Year	Total UM Amount Paid	PMPY	Savings Realized from 340B Program	Net UM Amount Paid	Net UM PMPY
<i>Rheumatoid Arthritis</i>	2004	\$ 162,016.35	\$ 2.05	\$ -	\$ 162,016.35	\$ 2.05
	2005	\$ 756,670.69	\$ 9.57	\$ 12,743.76	\$ 743,926.93	\$ 9.41
	2006	\$ 1,602,434.54	\$ 20.05	\$ 54,131.53	\$ 1,548,303.01	\$ 19.37
<i>Multiple Sclerosis</i>	2004	\$ 1,120,613.49	\$ 14.20	\$ -	\$ 1,120,613.49	\$ 14.20
	2005	\$ 1,365,761.79	\$ 17.27	\$ 30,982.55	\$ 1,334,779.24	\$ 16.88
	2006	\$ 1,719,442.11	\$ 21.51	\$ 184,781.81	\$ 1,534,660.30	\$ 19.20
<i>Cancer</i>	2004	\$ 457,670.15	\$ 5.80	\$ -	\$ 457,670.15	\$ 5.80
	2005	\$ 574,066.07	\$ 7.26	\$ -	\$ 574,066.07	\$ 7.26
	2006	\$ 772,783.49	\$ 9.67	\$ -	\$ 772,783.49	\$ 9.67
<i>Growth Hormone</i>	2004	\$ 215,590.34	\$ 2.73	\$ -	\$ 215,590.34	\$ 2.73
	2005	\$ 267,258.88	\$ 3.38	\$ -	\$ 267,258.88	\$ 3.38
	2006	\$ 348,508.15	\$ 4.36	\$ -	\$ 348,508.15	\$ 4.36
<i>Antivirals</i>	2004	\$ 279,468.36	\$ 3.54	\$ -	\$ 279,468.36	\$ 3.54
	2005	\$ 256,038.89	\$ 3.24	\$ 6,776.61	\$ 249,262.28	\$ 3.15
	2006	\$ 184,188.87	\$ 2.30	\$ 10,842.94	\$ 173,345.93	\$ 2.17
<i>Infertility</i>	2004	\$ 270,938.57	\$ 3.43	\$ -	\$ 270,938.57	\$ 3.43
	2005	\$ 244,077.77	\$ 3.09	\$ -	\$ 244,077.77	\$ 3.09
	2006	\$ 274,774.20	\$ 3.44	\$ -	\$ 274,774.20	\$ 3.44
<i>Anticoagulants</i>	2004	\$ 349,030.82	\$ 4.42	\$ -	\$ 349,030.82	\$ 4.42
	2005	\$ 550,251.27	\$ 6.96	\$ -	\$ 550,251.27	\$ 6.96
	2006	\$ 551,549.86	\$ 6.90	\$ -	\$ 551,549.86	\$ 6.90
<i>Hematopoetics</i>	2004	\$ 516,399.07	\$ 6.55	\$ -	\$ 516,399.07	\$ 6.55
	2005	\$ 708,816.78	\$ 8.96	\$ -	\$ 708,816.78	\$ 8.96
	2006	\$ 767,508.34	\$ 9.60	\$ -	\$ 767,508.34	\$ 9.60
<i>All Specialty Drugs</i>	2004	\$ 3,371,727.15	\$ 42.74	\$ -	\$ 3,371,727.15	\$ 42.74
	2005	\$ 4,722,942.14	\$ 59.72	\$ 50,502.92	\$ 4,672,439.22	\$ 59.08
	2006	\$ 6,221,189.56	\$ 77.83	\$ 249,756.28	\$ 5,971,433.28	\$ 74.71

Appendix E: Average Total Savings and Average U-M Drug Plan Share of Savings for Specialty Drugs Filled under the 340B Program in 2006

Specialty Drug	Therapeutic Category	Number of 340B Prescriptions Filled in 2006	Average Ingredient Cost Paid per Claim	Average PHS Cost per Claim	Average Total 340B Savings per Claim*	Average U-M Drug Plan Savings per Claim**
Enbrel	Rheumatoid Arthritis	160	\$1,516.17	\$1,022.01	\$494.15	\$239.08
Enbrel Sureclick	Rheumatoid Arthritis	9	\$1,321.49	\$956.73	\$364.77	\$174.38
Humira	Rheumatoid Arthritis	65	\$1,976.64	\$1,523.48	\$453.16	\$218.58
Kineret	Rheumatoid Arthritis	1	\$631.81	\$411.59	\$220.22	\$102.11
Avonex	Multiple Sclerosis	35	\$1,395.63	\$711.56	\$684.07	\$334.04
Betaseron	Multiple Sclerosis	43	\$1,532.77	\$784.70	\$748.07	\$366.03
Copaxone	Multiple Sclerosis	232	\$1,512.90	\$746.47	\$766.42	\$375.21
Rebif	Multiple Sclerosis	188	\$1,706.53	\$949.35	\$757.18	\$370.59
Rebif Titration Pack	Multiple Sclerosis	1	\$1,620.28	\$341.95	\$1,278.33	\$631.17
Pegasys	Antivirals	9	\$1,549.75	\$810.58	\$739.17	\$361.58
Peg-Intron	Antivirals	8	\$1,578.86	\$581.67	\$997.19	\$490.59
Peg-Intron Redipen	Antivirals	4	\$1,597.87	\$1,029.09	\$568.79	\$276.39
Ribasphere	Antivirals	11	\$722.43	\$241.27	\$481.16	\$232.58

* Shared between UMHS Pharmacy and U-M Drug Plan

** 50% of Total 340B savings less the standard \$8 specialty drug dispensing fee

Appendix F: Specialty Drug Pipeline Analysis

Specialty Drugs in Phase III Clinical Studies and the Number of UM M-CARE Members with Diagnostic Codes Meeting the Targeted Indications for the Pipeline Specialty Drugs (Diagnostic Code Counts Based on M-CARE 2006 Medical Claims Data)

Diag Code	Diagnosis Description	Primary Dx Mbr Count	% of Distinct Mbrs	Tot Mbr Count	% of Distinct Mbrs	Spec Drug	Phase of study	Notes
Diabetes Mellitus								
25000	TYPE II DIABETES MELLITUS WITHOUT MENTION OF COMPLICATION	1,766	2.49%	3,915	5.51%	liraglutide (NN2211)	III	adjunct to diet and exercise to improve glycemic control in type 2 diabetes
250x	Combined DIABETES MELLITUS with complications*	384	0.54%	872	1.23%	liraglutide (NN2211)	III	adjunct to diet and exercise to improve glycemic control in type 2 diabetes
Cancers								
174/1749	MALIGNANT NEOPLASM OF BREAST (FEMALE), UNSPECIFIED	489	0.69%	716	1.01%	Tykerb	III	breast cancer
						Avastin® bevacizumab	III completed	first-line metastatic breast
						Herceptin® trastuzumab	III completed	first-line metastatic HER2 completed positive breast cancer in combination with Taxotere®
185	MALIGNANT NEOPLASM OF PROSTATE	133	0.19%	240	0.34%	GVAX® Prostate cancer vaccine	III	hormone refractory prostate cancer
						sipuleucel-T	II/III	prostate cancer
202	OTHER MALIGNANT NEOPLASMS OF LYMPHOID AND HISTIOCYTIC TISSUE	131	0.18%	209	0.29%	BIOVAXID™ FNHL1d1	III	indolent (slow-growing) follicular non-Hodgkin's lymphoma
						interleukin-4	III	
191	MALIGNANT NEOPLASM OF BRAIN	69	0.10%	126	0.18%	IL13-PE38QQR (Orphan Drug)	III	glioblastoma multiforme (50% of all brain cancers ICD-9 :191)
172	MALIGNANT MELANOMA OF SKIN	63	0.09%	100	0.14%	PEG-Intron® peginterferon	III	malignant melanoma
						GMK	III	prevention of recurrence following surgery to remove primary melanoma in high-risk patients
						gp100 peptide vaccine	II/III	melanoma
						ipilimumab (MDX-010)	III	melanoma (MCX-010 +/- DTIC)
						ipilimumab (MDX-010)	III	melanoma monotherapy; second-line metastatic melanoma (MDX-010 disomotide overmotide MDX-1379)

Cancers (con't)								
						Oncophage™ vitespen (Orphan Drug)	III	metastatic melanoma,
						ticilimumab	III	metastatic melanoma
153	MALIGNANT NEOPLASM OF COLON	53	0.07%	102	0.14%	Erbitux™ cetuximab (IMC-C225)	III	first line colorectal, second-line colorectal cancers
201	HODGKIN'S DISEASE	51	0.07%	94	0.13%	interleukin-3	III	
154	MALIGNANT NEOPLASM OF RECTUM, RECTOSIGMOID JUNCTION, AND ANUS	41	0.06%	79	0.11%	Erbitux™ cetuximab (IMC-C225)	III	
162	MALIGNANT NEOPLASM OF TRACHEA, BRONCHUS, AND LUNG	36	0.05%	83	0.12%	Avastin® bevacizumab	III completed	first-line non-squamous NSCLC cancers
						CA4P	III	stage III/IV NSCLC
						CPG 7909	III	NSCLC
						Erbitux™ cetuximab (IMC-C225)	III	first-line NSCLC,- second-line NSCLC,
						IGN101	II/III	NSCLC
1830	MALIGNANT NEOPLASM OF OVARY	31	0.04%	50	0.07%	Telcyta®	III	NSCLC (3rd line), ovarian
183	MALIGNANT NEOPLASM OF OVARY AND OTHER UTERINE ADNEXA	28	0.04%	64	0.09%	OvaRex®	III	ovarian cancer
141	MALIGNANT NEOPLASM OF TONGUE	19	0.03%	31	0.04%	Advexin®	III completed	Head and neck cancer
1950	MALIGNANT NEOPLASM OF HEAD, FACE, AND NECK	18	0.03%	41	0.06%	Advexin®	III completed	Head and neck cancer
2041	CHR LYMPHOID LEUKEMIA	17	0.02%	36	0.05%	rituximab	III	relapsed or refractory CLL
157	MALIGNANT NEOPLASM OF PANCREAS	17	0.02%	36	0.05%	Insegia™ anti- gastrin 17	III	advanced pancreatic cancer
						PANVAC™-VF	III	refractory pancreatic
Infertility								
628	INFERTILITY, FEMALE	542	0.76%	764	1.08%			
Arthropathies / Autoimmune Inflammatory Disorders								
714	RHEUMATOID ARTHRITIS AND OTHER INFLAMMATORY POLYARTHRPATHIES	305	0.43%	568	0.80%	Cimzia™ certolizumab pegol	III	
						golimumab	III	

Arthropathies / Autoimmune Inflammatory Disorders (con't)							
						Orencia™ abatacept	III
						Rituxan® rituximab	III
6961	OTHER PSORIASIS AND SIMILAR DISORDERS	206	0.29%	363	0.51%	CNTO 1276	II/III
						Humira®	III
7100	SYSTEMIC LUPUS ERYTHEMATOSUS	134	0.19%	264	0.37%	Orencia™ abatacept	III
						Rituxan® rituximab	III
6960	PSORIATIC ARTHROPATHY	61	0.09%	97	0.14%	CNTO 1275	II/III
						Humira®	III
7143	JUVENILE CHRONIC POLYARTHRITIS	43	0.06%	63	0.09%	Humira® adalimumab	III
						Actemra, tocilizumab	III
						Orencia™ abatacept	III
						Orencia™ abatacept	III
7102	SICCA SYNDROME	20	0.03%	49	0.07%	interferon alpha	III
Hepatitis							
07054	CHRONIC HEPATITIS C WITHOUT MENTION OF HEPATIC COMA	71	0.10%	128	0.18%		
0703	VIRAL HEPATITIS B WITHOUT MENTION OF HEPATIC COMA	66	0.09%	100	0.14%		
07051	OTHER SPECIFIED VIRAL HEPATITIS	14	0.02%	39	0.05%		Other Hep C
0707	UNSPECIFIED VIRAL HEPATITIS C	6	0.01%	33	0.05%		
Cardiovascular							
410	ACUTE MYOCARDIAL INFARCTION	144	0.20%	250	0.35%	pexelizumab	III
4139	OTHER AND UNSPECIFIED ANGINA PECTORIS	105	0.15%	223	0.31%	GENERX™	II/III stable exertional angina due to coronary artery disease
43491	CEREBRAL ARTERY OCCLUSION W/ CEREBRAL ARTERIES	39	0.05%	65	0.09%	desmoteplase	II/III acute stroke

Gastrointestinal								
556	IDIOPATHIC PROCTOCOLITIS	227	0.32%	360	0.51%	Nuvion® visilizumab	II/III	I.V. steroid-refractory ulcerative colitis
555	REGIONAL ENTERITIS	204	0.29%	332	0.47%	Humira® Tysarbi® natalizumab	III III	Crohn's Disease Crohn's Disease
Other Conditions								
4770	ALLERGIC RHINITIS DUE TO POLLEN	653	0.92%	1,256	1.77%	Tolamba™	II/III	ragweed allergy
487	INFLUENZA	182	0.26%	265	0.37%	FluBIOk™ derived from recombinant hemagglutinin (rHA) CAIV-T	II/III III	influenza vaccine prevention of influenza
60889	OTHER SPECIFIED DISORDERS OF MALE GENITAL ORGANS	86	0.12%	105	0.15%			
042	HUMAN IMMUNODEFICIENCY VIRUS (HIV) INFECTION WITH SPECIFIED CONDITIONS	58	0.08%	84	0.12%	ALVAC E120TMG	III	HIV infection (Thailand)
332	PARKINSON'S DISEASE	48	0.07%	103	0.15%	Altropane® E- IACFT	III	
0794	HUMAN PAPILLOMA VIRUS	45	0.06%	127	0.18%	Cervarix™ HPV vaccine	III	prevention of human papillomavirus infection
5282	ORAL APHTHAE	45	0.06%	73	0.10%			
78071	CHRONIC FATIGUE SYNDROME	57	0.08%	172	0.24%	Ampligen®	III completed	
0541	GENITAL HERPES	38	0.05%	82	0.12%	Simplirix	III	genital herpes prophylaxis
3310	ALZHEIMER'S DISEASE	34	0.05%	65	0.09%	Alzhemed™	III	

Appendix G: Key Characteristics of Pharmacy Benefit Offerings for Peer Academic Institutions

2006-2007 Benefit Year

Institution	Carve Out Pharmacy to Single PBM? (Vendor) {Specialty Pharmacy Vendor(s)}	Health Plan Offering (PBM administrator if known) {Specialty Pharmacy vendor if known}	Pharmacy Benefit Type of Cost-Sharing	Number of Pharmacy Cost-sharing Tiers	Cost-sharing Tier Grouping (See Key Below)	*Retail Cost-Sharing Levels	*Mail Order Cost-Sharing Levels	Other Pharmacy Benefit Limits
Columbia University	Yes ¹ {Medco} {Accredo}	All Plans	Copayment	2	G/B	\$10/\$20	\$15/\$40	\$15,000 lifetime cap for fertility drugs
Cornell University	Yes ¹ {Medco} {Accredo}	All Plans	Copayment	3	G/SSB/MSB	\$5/\$20/\$40	\$10/\$40/\$60	
Indiana University	No	Anthem PPO {PrecisionRx Specialty}	Copayment	3	G/LCB/HCB	\$6/\$17/\$35	\$12/\$36/\$75	Out of pharmacy network: 50% of U&C
		MPlan HMO {Prescription Solutions}	Copayment and Coinsurance	4	O/G/SB/NSB	\$4/\$7/\$20/\$50 Specialty Drugs: All require prior authorization with a 20% coinsurance up to \$2,400 out of pocket maximum PMPY; limit to 30 day supply	G/SB \$14/\$40	Out of pharmacy network: no coverage
		Blue Preferred {PrecisionRx Specialty}	Copayment	3	G/FB/NF	\$8/\$20/\$40	\$16/\$40/\$80	Out of pharmacy network: 50% of U&C

Institution	Carve Out Pharmacy to Single PBM? (Vendor) {Specialty Pharmacy Vendor(s)}	Health Plan Offering (PBM administrator if known) {Specialty Pharmacy vendor if known}	Pharmacy Benefit Type of Cost-Sharing	Number of Pharmacy Cost-sharing Tiers	Cost-sharing Tier Grouping (See Key Below)	*Retail Cost-Sharing Levels	*Mail Order Cost-Sharing Levels	Other Pharmacy Benefit Limits
Michigan State University	Yes (CVS Caremark) {MSU Clinical Pharmacy, Caremark Specialty Pharmacy, Olin Pharmacy}	All Plans	Copayment	3	G/FB/NFB	\$10/\$15/\$30	\$20/\$30/\$60	Out of pocket maximums: \$1,000 PMPY or \$2,000 per family per year
		Pharmacies Operated by MSU	Copayment	3	G/FB/NFB	\$8/\$13/\$28 (1-34 days)	\$16/\$26/\$56 (35-90 days)	Out of pocket maximums: \$1,000 PMPY or \$2,000 per family per year
Northwestern University	Yes (Walgreens Health Initiative) {Walgreens Specialty Pharmacy}	Value PPO Aetna HMO HMO Illinois	Copayment	3	G/PB/NPB	\$5/\$25/\$45	\$10/\$45/\$65	Out of pocket maximum: \$1,250 per family per year
		Unicare HMO	Copayment and Coinsurance	3	G/PB/NPB	\$5/\$25/\$45 Self-injectables 20% coinsurance with per Rx maximum of \$100 and \$5,000 annual out of pocket maximum for self-injectables	\$10/\$45/\$65	

Institution	Carve Out Pharmacy to Single Vendor? (Vendor) {Specialty Pharmacy Vendor(s)}	Health Plan Offering (PBM administrator if known)	Pharmacy Benefit Type of Cost-Sharing	Number of Pharmacy Cost-sharing Tiers	Cost-sharing Tier Grouping (See Key Below)	*Retail Cost-Sharing Levels	*Mail Order Cost-Sharing Levels	Other Pharmacy Benefit Limits
Princeton University	Yes ¹ (Medco) {Accredo}	All Plans	Copayment	3	G/SSB/MSB	\$5/\$20/\$30	\$10/\$40/\$60	
Stanford University	No	Kaiser	Copayment	2	G/B	\$10/\$20	\$10/\$20	100 day supply permitted at retail for single copayment.
		BlueShield CDHP High deductible PPO	Coinsurance	1	Not applicable	After deductible met, 20% coinsurance	After deductible met, 20% coinsurance	\$2,700 individual and \$5,000 family deductible. 50% copayment for fertility drugs with a \$5,000 lifetime cap
		All other health plans (Express Scripts) {CuraScript}	Copayment	3	G/FB/NFB	\$10/\$25/\$50 Specialty drugs require prior authorization.	\$20/\$50/\$100	\$500 individual and \$1,000 family deductible. Infertility drugs covered at 50% with \$5,000 lifetime maximum cap

Institution	Carve Out Pharmacy to Single Vendor? (Vendor) {Specialty Pharmacy Vendor(s)}	Health Plan Offering (PBM administrator if known)	Pharmacy Benefit Type of Cost-Sharing	Number of Pharmacy Cost-sharing Tiers	Cost-sharing Tier Grouping (See Key Below)	*Retail Cost-Sharing Levels	*Mail Order Cost-Sharing Levels	Other Pharmacy Benefit Limits
University of California	No	HealthNet (Caremark)	Copayment	4	G/PB/NPB	\$10/\$20/\$35	\$20/\$40/\$70	
		BlueCross CA	Copayment	3	G/FB/NFB	\$15/\$25/\$40	\$30/\$50/\$80	UC pharmacies can dispense mail order quantities
		Kaiser	Copayment	3	G/B	\$10/\$20	\$10/\$20	100 day supply for single copay at retail
		PacifiCare	Copayment	3	G/B/NF	\$10/\$20/\$35	\$20/\$40/\$70	
University of Chicago	No	Maroon Plan (Caremark)	Copayment	3	G/PB/NPB	\$8/\$20/\$35	\$16/\$40/\$70	
		All other health plans- Humana, UC Health Plan, HMO Illinois	Copayment	3	G/PB/NPB	\$5/\$15/\$30	\$10/\$30/\$60	

Institution	Carve Out Pharmacy to Single Vendor? (Vendor) {Specialty Pharmacy Vendor(s)}	Health Plan Offering (PBM administrator if known)	Pharmacy Benefit Type of Cost-Sharing	Number of Pharmacy Cost-sharing Tiers	Cost-sharing Tier Grouping (See Key Below)	*Retail Cost-Sharing Levels	*Mail Order Cost-Sharing Levels	Other Pharmacy Benefit Limits
University of Illinois	No	Quality Care Indemnity Health Plan (Medco) {Accredo}	Copayment	3	G/F/NF	\$10/\$20/\$40	\$20/\$40/\$80	Mandatory mail order for maintenance meds
		Open Access Plan (Medco) {Accredo}	Copayment	3	G/F/NF	\$10/\$20/\$40	\$20/\$40/\$80	Mandatory mail order for maintenance meds
		All HMO offerings	Copayment	3	G/F/NF	\$10/\$20/\$40	\$20/\$40/\$80	Mandatory mail order for maintenance meds at some HMOs; mail order not offered by some HMOs

Institution	Carve Out Pharmacy to Single Vendor? (Vendor) {Specialty Pharmacy Vendor(s)}	Health Plan Offering (PBM administrator if known)	Pharmacy Benefit Type of Cost-Sharing	Number of Pharmacy Cost-sharing Tiers	Cost-sharing Tier Grouping (See Key Below)	*Retail Cost-Sharing Levels	*Mail Order Cost-Sharing Levels	Other Pharmacy Benefit Limits
University of Minnesota	Yes (RxAmerica) {RxAmerica}	All Plans	Copayment	3	G-P/B/NFB	\$10/\$20/\$35	\$20/\$40/\$70	Annual out of pocket maximum \$750 per person or \$1,500 per family
		HRA	Coinsurance	1	Not applicable	HRA – 0% Then for Traditional Coverage portion – 10%	HRA – 0% Then for Traditional Coverage portion – 20%	HRA deductible \$2,500 individual \$5,000 family. No separate pharmacy out of pocket maximum but pharmacy costs count towards HRA total out of pocket maximum.

Institution	Carve Out Pharmacy to Single Vendor? (Vendor) {Specialty Pharmacy Vendor(s)}	Health Plan Offering (PBM administrator if known)	Pharmacy Benefit Type of Cost-Sharing	Number of Pharmacy Cost-sharing Tiers	Cost-sharing Tier Grouping (See Key Below)	*Retail Cost-Sharing Levels	*Mail Order Cost-Sharing Levels	Other Pharmacy Benefit Limits
University of Minnesota (continued)	Yes (RxAmerica) {RxAmerica}	HSA	Coinsurance	1	Not applicable	HSA – 0% Then for Traditional Coverage portion – 20%	HSA – 0% Then for Traditional Coverage portion – 20%	HSA deductible \$2,000 individual \$4,000 family. No separate pharmacy out of pocket maximum but pharmacy costs count towards HSA total out of pocket maximum.
University of North Carolina	Yes (Medco) {Accredo}	All Plans	Copayment	4	G/PSSB/PMSB/NPB	\$10/\$25/\$40/\$50	\$30/\$75/\$105/\$120	90 day supply permitted at retail or mail order; \$2,500 annual out of pocket maximum per person

Institution	Carve Out Pharmacy to Single Vendor? (Vendor) {Specialty Pharmacy Vendor(s)}	Health Plan Offering (PBM administrator if known)	Pharmacy Benefit Type of Cost-Sharing	Number of Pharmacy Cost-sharing Tiers	Cost-sharing Tier Grouping (See Key Below)	*Retail Cost-Sharing Levels	*Mail Order Cost-Sharing Levels	Other Pharmacy Benefit Limits
University of Pennsylvania	Yes (CVS Caremark) {Caremark Specialty Pharmacy}	All Plans	Coinsurance with minimum per claim	2	G/B	10% (\$5 minimum)/ 30% (\$15 minimum)	10% (\$10 minimum)/ 30% (\$30 minimum) If brand with no generic equivalent 20% (\$20 minimum)	\$1,500 annual out of pocket maximum per person and \$4,500 per family
University of Virginia	Yes (CVS Caremark) {Caremark Specialty Pharmacy}	All Plans	Copayment	3	G/FB/NFB	\$9/\$20/\$40 Specialty drugs require prior authorization. Mandatory use of specialty pharmacy vendor inclusive of physician administered drugs.	\$21/\$47/\$93	

Institution	Carve Out Pharmacy to Single Vendor? (Vendor) {Specialty Pharmacy Vendor(s)}	Health Plan Offering (PBM administrator if known)	Pharmacy Benefit Type of Cost-Sharing	Number of Pharmacy Cost-sharing Tiers	Cost-sharing Tier Grouping (See Key Below)	*Retail Cost-Sharing Levels	*Mail Order Cost-Sharing Levels	Other Pharmacy Benefit Limits
University of Washington	No	Group Health	Copayment	2	G/B	\$10/\$30	\$20/\$40	
		Kaiser	Copayment	2	G/B	\$10/\$25	\$20/\$50	
		All other managed care plans	Copayment	3	G/FB/NF	\$10/\$25/\$40	\$20/\$50/\$80	Insulin and disposable diabetic supplies in Generic copayment tier
		PPO (Express Scripts)	Retail Coinsurance with maximum per claim Mail Order Copayment	3	G-S/PB/NPB	10%/30%/50% G-S and PB maximums based on days supply: Up to 30 day supply \$75 31-60 day supply \$150 61-90 day supply \$225; no maximum for NPB products Specialty drugs, Insulin and disposable diabetic supplies in Generic copayment tier.	\$10/\$50/\$100	Annual deductible: \$100 per person or \$300 per family. 90 day supply allowed at retail

Institution	Carve Out Pharmacy to Single Vendor? (Vendor) {Specialty Pharmacy Vendor(s)}	Health Plan Offering (PBM administrator if known)	Pharmacy Benefit Type of Cost-Sharing	Number of Pharmacy Cost-sharing Tiers	Cost-sharing Tier Grouping (See Key Below)	*Retail Cost-Sharing Levels	*Mail Order Cost-Sharing Levels	Other Pharmacy Benefit Limits
University of Wisconsin	Yes (Navitus) {Specialty Scripts}	All Plans	Copayment	3	G-P/FB-HCG/NFB	\$5/\$15/\$35	not offered	\$1,000 annual out of pocket maximum per person and \$2,000 per family for tier 1 and 2 drugs only Tier 3 drugs do not count towards out of pocket maximum

Institution	Carve Out Pharmacy to Single Vendor? (Vendor) {Specialty Pharmacy Vendor(s)}	Health Plan Offering (PBM administrator if known)	Pharmacy Benefit Type of Cost-Sharing	Number of Pharmacy Cost-sharing Tiers	Cost-sharing Tier Grouping (See Key Below)	*Retail Cost-Sharing Levels	*Mail Order Cost-Sharing Levels	Other Pharmacy Benefit Limits
Yale University	Yes ¹ (Medco)	Yale Health Plan	Coinsurance	1	Not applicable	20%		Annual deductible \$200 individual and \$600 family with \$700 out of pocket maximum. Annual benefit cap of \$25,000 per person.
		Aetna POS	Copayment	2	G/B	\$10/\$15 (includes 90 day at retail for 1 copayment)	Brand \$8	
		Aetna POS with HSA	Coinsurance	1	Not Applicable	20% after annual deductible met	20% after annual deductible met	No separate pharmacy deductible but pharmacy costs count towards annual HSA deductible of \$1,500 per person or \$3,000 per family.

Notes:

¹: Part of University Rx Purchasing Coalition (PURPC, "purpose"); all Rx carved out to Medco

***Retail:** reflects 30 day supply unless otherwise noted.

***Mail Order:** reflects 90 day supply unless otherwise noted.

Cost Sharing Tier Grouping Key for Appendix G:	
FB = formulary brand; NF = nonformulary	NPB = nonpreferred brand
FB-HCG = formulary brand and select high cost generic drugs	NSB = nonselect brand
G = generic	O = select over the counter nonprescription drugs
G-P = generic plus select low cost brand drugs if no generic equivalent	PB = preferred brand
G-S = generic and specialty drugs	PMSB = preferred multisource brand
HCB = high cost brand (\$65 or more)	PSSB = preferred single source brand
LCB = low cost brand (up to \$65)	SB = select brand
LS = lifestyle drugs	SSB = single source brand
MSB = multisource brand	SX = sexual dysfunction drugs
NFB = nonformulary brand	U&C = usual and customary cash price for prescription drugs

Appendix H: Key Characteristics of Pharmacy Benefit Offerings for Michigan-Based Peer Health Systems

2006-2007 Benefit Year (unless otherwise noted)

Institution	Carve Out Pharmacy to Single Vendor? (Vendor) {Specialty Pharmacy Vendor(s)}	Health Plan Offering (PBM administrator if known)	Pharmacy Benefit Type of Cost-Sharing	Number of Pharmacy Cost-sharing Tiers	Cost-sharing Tier Grouping (See Key Below)	*Retail Cost-Sharing Levels	*Mail Order Cost-Sharing Levels	Other Pharmacy Benefit Limits
Beaumont Hospital	Yes (Caremark) {Caremark Specialty Pharmacy}	All Plans	Coinsurance with minimum and maximum	3	G/F/NF	25% all tiers \$7.50 per claim minimum \$150 per claim maximum	\$10/\$50/\$150	For retail: \$50 per person or \$100 per family annual deductible
		Beaumont Pharmacies	Copayment and coinsurance	3	Based on Beaumont Pharmacy Cost	If Beaumont cost is less than \$7.50, patient pays Beaumont Pharmacy cost + 10%. If Beaumont cost is \$7.50, patient pays \$7.50. If Beaumont cost is more than \$7.50, patient pays 25% of cost.	Not applicable	No annual deductible

Institution	Carve Out Pharmacy to Single Vendor? (Vendor) {Specialty Pharmacy Vendor(s)}	Health Plan Offering (PBM administrator if known)	Pharmacy Benefit Type of Cost-Sharing	Number of Pharmacy Cost-sharing Tiers	Cost-sharing Tier Grouping (See Key Below)	Retail Cost-Sharing Levels	Mail Order Cost-Sharing Levels	Other Pharmacy Benefit Limits
*Detroit Medical Center	No	DMC Pharmacies	Copayment and Coinsurance with tier 2 and 3 maximums	4	G/FB/NFB/Infertility	\$2/\$10/\$20/50% FB maximum: \$30 NFB maximum: \$50	\$4/\$20/\$40 FB maximum: \$60 NFB maximum: \$100	Infertility drugs only covered at DMC pharmacies for 50% coinsurance
		All other pharmacies	Copayment and Coinsurance with tier 2 and 3 minimums and maximums	3	G/FB/NFB	\$10/30%/40% FB minimum: \$25 FB maximum: \$40 NFB minimum: \$50 NFB maximum: \$90	Mail order available, copayment description not clear	
*Henry Ford Health System (HFHS)	Yes (Medco) {Accredo}	HAP	Copayment	3	G/PB/NPB	\$7/\$15/\$30	Mail order not offered	
		HFHS Pharmacies	Copayment	1	Any drug	\$5	Mail order not offered	
Trinity Health System	No (Medco) {Accredo}	CareChoices HMO & PPO (Medco)	Copayment	3	G/F/NF	\$10/\$20/\$40	Two retail copayments for 90 day supply	50% coinsurance for infertility agents

Institution	Carve Out Pharmacy to Single Vendor? (Vendor) {Specialty Pharmacy Vendor(s)}	Health Plan Offering (PBM administrator if known)	Pharmacy Benefit Type of Cost-Sharing	Number of Pharmacy Cost-sharing Tiers	Cost-sharing Tier Grouping (See Key Below)	Retail Cost-Sharing Levels	Mail Order Cost-Sharing Levels	Other Pharmacy Benefit Limits
*Oakwood Healthcare System	Yes (HealthTrans)	All Plans	Copayment and Coinsurance	3	G/PB/NPB	\$7/\$15/>50% or \$35	\$14/\$30/>50% or \$70	No out of pocket cap for NPB. Cover OTC Claritin and Prilosec for generic copay.
		Oakwood Pharmacies	Copayment and Coinsurance	4	G/PB/NPB/LS	\$5/\$10/>50% or \$35/100% pharmacy cost Five drugs available at nominal price at Oakwood pharmacies	90 day supply at Oakwood Pharmacies, pick up only: \$10/\$20/>50% or \$70	No out of pocket cap for NPB. However, if member meets with Oakwood pharmacist to review drug regimen and consults with prescriber, copayment for NPB products reduced to 50% or maximum of \$40.

Institution	Carve Out Pharmacy to Single Vendor? (Vendor) {Specialty Pharmacy Vendor(s)}	Health Plan Offering (PBM administrator if known)	Pharmacy Benefit Type of Cost-Sharing	Number of Pharmacy Cost-sharing Tiers	Cost-sharing Tier Grouping (See Key Below)	Retail Cost-Sharing Levels	Mail Order Cost-Sharing Levels	Other Pharmacy Benefit Limits
		Specialty Pharmacy Rider (In place for all employees with exception of 1 group.)	Coinsurance	1	Specialty Drugs	Specialty Drugs Offered thru Oakwood Pharmacies or Specialty/Mail Order Pharmacy Only 20%coinsurance		\$1,000 annual out of pocket maximum per person for specialty drugs.
St. John Health	Yes (MedImpact) {Bioscrip}	St. John Health PPOM	Copayment	3	G/PB/NPB	\$20/\$25/\$40	Mail order not offered	
		St. John's Health Smart Plan	Copayment	3	G/PB/NPB	\$4/\$12/\$23 Infertility @50% with no cap	Mail order not offered	Prior authorization and mandatory use of specialty pharmacy vendor for all specialty drugs including agents covered under medical benefit.

*Plan details for 2005-2006 as institution would not share updates to 2006-2007 pharmacy benefit.

Retail: reflects 30 day supply unless otherwise noted.

Mail Order: reflects 90 day supply unless otherwise noted.

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G-S = generic and specialty drugs	PMSB = preferred multisource brand
HCB = high cost brand (\$60 or more)	PSSB = preferred single source brand
LCB = low cost brand (up to \$60)	SB = select brand
LS = lifestyle drugs	SSB = single source brand
MSB = multisource brand	SX = sexual dysfunction drugs
NFB = nonformulary brand	U&C = usual and customary cash price for prescription drugs

