RESEARCH

Health Plan Utilization and Costs of Specialty Drugs Within 4 Chronic Conditions

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ABSTRACT

BACKGROUND: Drugs are most typically defined as specialty because they are expensive; however, other criteria used to define a drug as specialty include biologic drugs, the need to inject or infuse the drug, the requirement for special handling, or drug availability only via a limited distribution network. Specialty drugs play an increasingly important role in the treatment of chronic conditions such as multiple sclerosis (MS), rheumatoid arthritis (RA), psoriasis, and inflammatory bowel disease (IBD), yet little is known regarding the comprehensive medical and pharmacy benefit utilization and cost trends for these conditions.

OBJECTIVE: To describe MS, RA, psoriasis, and IBD trends for condition prevalence, treatment with specialty drugs, specialty costs, nonspecialty costs, and total direct costs of care within the medical and pharmacy benefits.

METHODS: This was a descriptive analysis of a commercially insured population made up of 1 million members, using integrated medical and pharmacy administrative claims data from 2008 to 2010. Analyses were limited to continuously enrolled commercially insured individuals less than 65 years of age. Condition-specific cohorts for MS, RA, psoriasis, and IBD were defined using standardized criteria. Trends in condition prevalence, specialty drug use for the conditions, and direct total cost of care were analyzed. The direct costs were subcategorized into the following: medical benefit specialty drug costs, medical benefit all other costs, pharmacy benefit specialty drug costs, and pharmacy benefit all other costs. Trends and compound annual growth rates were calculated for the total cost of care and subcategory costs from 2008 through 2010.

RESULTS: Condition prevalence ranged from a low of 1,720 per million members for MS to a high of 4,489 per million members for RA. Psoriasis and MS condition prevalence rates were unchanged over the 3 years; however, IBD prevalence increased 7.0%, and RA prevalence increased 9.7%. The rate of specialty drug use was lowest for IBD (13.7%) and highest for MS (71.8%). The lowest total annual cost of care was for psoriasis ($14,815), and the highest total annual cost was for MS ($36,901). The most commonly used specialty drugs for each of the conditions were as follows: glatiramer (MS), etanercept (RA and psoriasis), and infliximab (IBD). The total annual costs were more than double for the specialty drug users for psoriasis compared with all the psoriasis members ($29,565 vs. $14,815). The total costs were only somewhat higher among MS members using specialty drugs ($41,760 vs. $36,901). Among specialty drug users for each of the cohorts, the annual costs of specialty drugs accounted for 50% or more of the total annual costs. The annual spending growth rate for specialty drugs ranged from 4.4% to 18.0%.

CONCLUSIONS: Although specialty drug utilization varied widely across the 4 chronic conditions analyzed, when specialty drugs were used they accounted for the majority of the annual total direct cost of care. Because specialty drugs are accounting for a growing portion of chronic disease total cost of care, health insurers will need to become more vigilant regarding specialty drug use and focus on 4 cost saving management opportunities: drug distribution channel, utilization management, contracting activities, and care coordination.

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What is already known about this subject

- In 2011, among U.S. privately insured individuals under aged 65 years, spending on specialty drugs accounted for 25% of the total spending for prescription drugs processed via the medical and pharmacy benefits and are forecasted to be 50% in 2018.
- Within the pharmacy benefit, specialty drugs account for 1% of all prescriptions but for 17% of the total spending. Specialty drug expenditures increased by 20.1% from 2010 to 2011.
- Specialty drugs play an increasingly important role in the treatment of such chronic conditions as multiple sclerosis (MS), rheumatoid arthritis (RA), psoriasis, and inflammatory bowel disease (IBD).
- Specialty drugs typically include biological products, are often administered as injections or infusions, sometimes require special handling and administration, and are substantially more expensive than the traditional small molecule drugs.

What this study adds

- As specialty drugs can be billed via both the medical and pharmacy benefits, integration of medical and pharmacy benefit claims data are required to obtain a comprehensive understanding of condition costs and specialty drug costs.
- In 2010, among persons treated with a specialty drug, the annual specialty drug costs were more than 50% of direct total cost of care.
  - MS specialty drug costs $28,152 (67.4%) of $41,760 per person per year (PPPY) total direct costs
  - RA specialty drug costs $18,098 (53.0%) of $34,163 PPPY total direct costs
  - IBD specialty drug costs $21,428 (50.3%) of $42,642 PPPY total direct costs
  - Psoriasis specialty drug costs $19,612 (66.3%) of $29,565 PPPY total direct costs
- The growth rate in expenditures for these conditions was 5.7% to 11.4%, which is much higher than the 4.3% national health consumption expenditure growth rate over the same time period.
- The specialty drug expenditure growth of 4.4% to 18.0% exceeded the national health consumption expenditure growth rate.
- These study findings, coupled with the forecast that specialty drugs will account for 50% of drug expenditures in the next 5 years, will necessitate health care payers to manage specialty drug costs and optimize value through drug management programs and policies. Specialty management programs and policies include drug distribution channels, utilization management, contracting activities, and care coordination.

The U.S. Food and Drug Administration (FDA) does not designate drugs as "specialty"; rather, the designation is internally defined within a health plan or pharmacy benefit manager (PBM) and, as such, can vary significantly. Although the definition of "specialty" will vary among health plans and PBMs, typically it is associated with a dollar amount cutoff and may include biologic drugs, drugs injected or infused, drugs requiring special handling, or drugs that are available only via a limited distribution network.[1] In addition, specialty drugs may be defined by the condition they are used to treat; for example, human immunodeficiency virus or growth hormone deficiencies. Specialty drugs have provided new treatment options for many chronic conditions, although they have historically been used as treatments for cancer as well as rare genetic conditions (e.g., Gaucher's disease). More recently, they have become the standard of care for common chronic diseases such as multiple sclerosis (MS) and rheumatoid arthritis (RA).[1]

In 2011, among U.S. privately insured individuals under 65 years of age, spending on specialty drugs accounted for 25% of the total spending for prescription drugs processed via the medical and pharmacy benefit and are forecasted to be 50% in 2018.[2,3] Specialty drugs processed via the medical benefit account for half of all specialty drug spending.[2] Among 7 million privately insured working age individuals, specialty drugs within the pharmacy benefit accounted for only 1% of the prescriptions but accounted for 17% of total spending; specialty drug spending increased by 20.1% from 2010 to 2011.[4] As a result of these costs, employers have instituted mechanisms such as prior authorization, drug supply restrictions, and limited distribution arrangements for managing spending for these agents.[5-7] Since spending on specialty drugs continues to rise faster than that of traditional therapies,[3] payers and policymakers must better understand the costs and clinical benefits of these drugs.

Relatively little is known about the utilization of and spending on specialty drugs to manage conditions such as MS, RA, inflammatory bowel disease (IBD), and psoriasis, particularly in the context of individuals' total health care costs. One reason for this knowledge gap is that the use of specialty drugs and the attribution of member spending across pharmacy and medical benefits is challenging. Access to integrated medical and pharmacy claims data is required in order to determine a member's specialty drug use and spending across both benefits. For example, some specialty drugs are captured through pharmacy benefit claims, while many more, predominantly those administered through infusions in clinics, are captured through medical benefit claims; data regarding medical and pharmacy benefits are often housed separately and utilize distinct drug coding systems.

We evaluated the specialty drug use and costs for 4 chronic conditions in which specialty drug costs have been increasing: MS, RA, IBD, and psoriasis.[2,4] These 4 chronic conditions were selected because specialty drugs used to treat these conditions represent the top expenditure specialty drug through the medical benefit (i.e., infliximab) and the top 4 expenditure specialty drugs through the pharmacy benefit (i.e., adalimumab, etanercept, interferon beta-1a, and glatiramer).[4] In addition to specialty drug use and costs, we were also interested in how these costs compared with costs for nonspecialty drugs and total health care costs, as well as the cost growth from 2008 through 2010.

Methods

Data

We used medical and pharmacy administrative claims data from a Midwest Blue Cross Blue Shield plan to assess prevalence and trends for the selected specialty conditions, costs, and specialty drug use. For study inclusion, we required individuals to have been commercially insured in a managed care plan, continuously enrolled during a given year of analysis, and less than or equal to age 64 during the entire time frame of the study period. We excluded members greater than age 64 because of the potential for incomplete data capture among Medicare beneficiaries. The analysis dataset included all medical and pharmacy claims with total paid amounts, defined as a total of plan paid, member paid, and any third-party payment, such as supplemental insurance.

Subjects

We identified 4 separate study cohorts, 1 for each condition of interest, using prespecified criteria. To be included in a condition cohort, we required members to have 1 of the following: (a) 2 separate medical claims with the *International Classification of Disease, Ninth Revision, Clinical Modification* (ICD-9-CM) diagnosis code of interest in any of 5 diagnosis code fields available on the medical claim, (b) 1 medical claim with an ICD-9-CM diagnosis code of interest in any of 5 diagnosis code fields and 1 drug claim used to treat the condition from the medical or pharmacy benefit, or (c) 2 separate drug claims from the pharmacy or medical benefit for drugs to treat the condition. Criteria "c," defined as drug presence indicates presence of the condition, was used when the drug had an indication for only 1 of the 4 conditions. Appendix A (available in online article) contains the drug list used to identify a plan member as having each condition and an indicator as to whether presence of the drug alone could qualify as having specialty drug treatment (i.e., drug presence indicates presence of the condition). We used the following ICD-9-CM diagnosis codes to define an individual as having a specialty condition: 340.xx for MS; 714.xx or 720.0x for RA; 555.xx or 556.xx for IBD; and 696.0x,

TABLE 1 Characteristics of Plan Members by Chronic Condition Cohort During 2010

	Multiple Sclerosis (n = 1,685)	Rheumatoid Arthritis (n = 4,398)	Inflammatory Bowel Disease (n = 4,377)	Psoriasis (n = 3,480)
Female, %	73.4	71.3	52.3	49.7
Age, %				
0-20 years	0.6	4.5	7.8	12.1
21-40 years	27.3	15.5	29.0	23.9
41-50 years	32.3	25.2	26.0	25.0
51-64 years	39.8	54.8	37.2	39.0
Treated with any drug for the condition,[a] %	71.8	86.8	81.6	94.1

[a]*See Appendix A (available in online article) for list of drugs indicating that the condition was treated with a drug (specialty or nonspecialty).*

696.1x, or 696.8x for psoriasis. For each year of the analysis, we required plan members to re-qualify as having the specialty condition to be included. Members could contribute to more than 1 condition during any given year of analysis.

Information About Specialty Drug Utilization and Expenditures

We collected the medical and pharmacy claims for individuals identified as having 1 of the chronic conditions during the calendar year. We divided each member's annual total costs of care into 4 mutually exclusive cost categories: medical benefit costs for specialty drugs used to treat the condition (Medical Specialty), all other medical benefit costs (Medical All Other), pharmacy benefit costs for specialty drugs used to treat the condition (Pharmacy Specialty), and all other pharmacy benefit costs (Pharmacy All Other). Appendix A (available in online article) depicts the drugs defined as specialty therapies for each condition of interest; we defined specialty drugs as those with a total paid of $1,000 or more per month. Utilization of each specialty drug chemical entity was quantified at the member level and defined as the presence of at least 1 claim during the analysis year.

Analysis

We performed a univariate analysis to describe the study cohorts. Once plan members were placed into their respective condition cohorts, we evaluated members' total health care costs in terms of the individual members' average per person per year (PPPY) costs. The PPPY was calculated by summing the costs for all members with the condition and dividing by the number of members with the condition. In addition, we calculated the per member per year (PMPY) costs for the condition by taking the same sum costs for all members with the condition; however, the denominator was the entire health plan enrollment. Over the 3 analysis years (2008 through 2010), we trended by condition: prevalence, prevalence of specialty drug use among members, per person total cost (i.e., PPPY) and cost for each of the 4 mutually exclusive cost categories, and per person total cost among members (i.e., PMPY) utilizing specialty drugs for a given condition. Lastly, we calculated the 3-year compound annual growth rate.[8]

Results

Subjects

In 2010, there were a total of 1,685, 4,398, 4,377, and 3,480 individuals identified in the MS, RA, IBD, and psoriasis cohorts, respectively (Table 1 and Appendix B [available in online article]). The cohort sizes were similar in 2008 and 2009. More than 70% of the cohort was female for MS and RA, while approximately 50% were female for the IBD and psoriasis cohorts. In 2010, the percentage of members treated with any drug (specialty or nonspecialty) was high across the 4 conditions, ranging from 71.8% for MS to 94.1% for psoriasis.

Prevalence of Conditions and Specialty Drug Use

Among the conditions of interest, the prevalence ranged from a low of 1,720 per million members for MS to a high of 4,489 per million members with RA (Table 2a). The rates of specialty drug utilization varied substantially across the 4 conditions. The rate of specialty drug use was lowest for IBD (13.7%), followed by psoriasis (24.3%), RA (35.4%), and highest for MS (71.8%) in 2010. Over the 3 years, the proportion of members with an MS condition utilizing a specialty drug increased from 70.8% to 71.8%, and for RA specialty drug utilization, the proportion of members increased from 34.6% to 35.4% (Appendix B, available in online article). The proportion of members with a psoriasis condition and specialty drug utilization increased over the 3 years from 20.3% to 24.3%, while specialty drug utilization among the IBD cohort increased from 10.8% to 13.7%.

Costs of Specialty Drugs and Total Health Care

In 2010, the average PPPY total health care cost for individuals across the 4 conditions varied by a factor of almost 2.5 times (Table 2a). The lowest total annual health care cost was for psoriasis ($14,815) and highest for MS ($36,901). Across the entire population enrolled in 2010 (n = 979,735), the PMPY

TABLE 2a Prevalence, Treatment, Rates, and Costs by Chronic Condition Cohort Among All Members During 2010

	Diagnosed per Million Members	Treated with Specialty Drug[a] (%)	Average PPPY Total Health Care Cost[b] ($)	Annual PPPY Growth in Cost of Care 2008-2010[c] (%)	Condition PMPY Total Health Care Cost[d] ($)	Specialty Drug PMPY Total Health Care Cost[e] ($)
Multiple sclerosis	1,720	71.8	36,901	11.4	63.46	34.74
Rheumatoid arthritis	4,489	35.4	19,830	8.0	103.82	28.74
Inflammatory bowel disease	4,468	13.7	22,070	5.7	98.60	13.09
Psoriasis	3,552	24.3	14,815	7.5	52.62	16.91

[a]*Specialty drugs are defined in Appendix A (available in online article).*
[b]*PPPY = per person per year; costs reflected the total allowed amount defined as the sum of member paid, plan paid, and coordination of benefits paid to the provider.*
[c]*Growth derived using the compound annual growth rate.*
[d]*PMPY = per member per year; condition attributable costs as described in the Methods section of this article.*
[e]*Specialty drug costs included medical and pharmacy spending.*

TABLE 2b Prevalence, Treatment, Rates, and Costs by Chronic Condition Among Specialty Drug Users During 2010

	Average PPPY Total Health Care Cost[a] ($)	Average PPPY Specialty Drug Cost[b] ($)	Specialty Drug Cost as Percent of Total Cost of Care (%)	Annual Growth in Specialty Drug Cost PPPY 2008-2010[c] (%)
Multiple sclerosis (n = 1,209)	41,760	28,152	67.4	18.0
Rheumatoid arthritis (n = 1,556)	34,163	18,098	53.0	5.6
Inflammatory bowel disease (n = 598)	42,642	21,438	50.3	8.5
Psoriasis (n = 845)	29,565	19,612	66.3	4.4

[a]*PPPY = per person per year; costs reflected the total allowed amount defined as the sum of member paid, plan paid, and coordination of benefits paid to the provider.*
[b]*Specialty drugs are defined in Appendix A (available in online article).*
[c]*Growth derived using the compound annual growth rate.*

costs were highest for RA ($103.82) and lowest for psoriasis ($52.62). However, the PMPY costs for specialty drugs across the entire population were highest for MS ($34.74) and lowest for IBD ($13.09). The most commonly used specialty drugs for each of the conditions were glatiramer (MS), etanercept (RA and psoriasis), and infliximab (IBD).

Among specialty drug users for each of the cohorts, the annual costs of specialty drugs accounted for 50% or more of the total annual direct cost of care (Table 2b). For psoriasis patients, costs were more than double among specialty drug users compared with all the psoriasis members ($29,565 vs. $14,815). By contrast, the total costs were only somewhat higher among MS members using specialty drugs ($41,760 vs. $36,901). In addition, the annual spending growth for specialty drug costs ranged from 4.4% for psoriasis up to 18.0% for MS between 2008 and 2010.

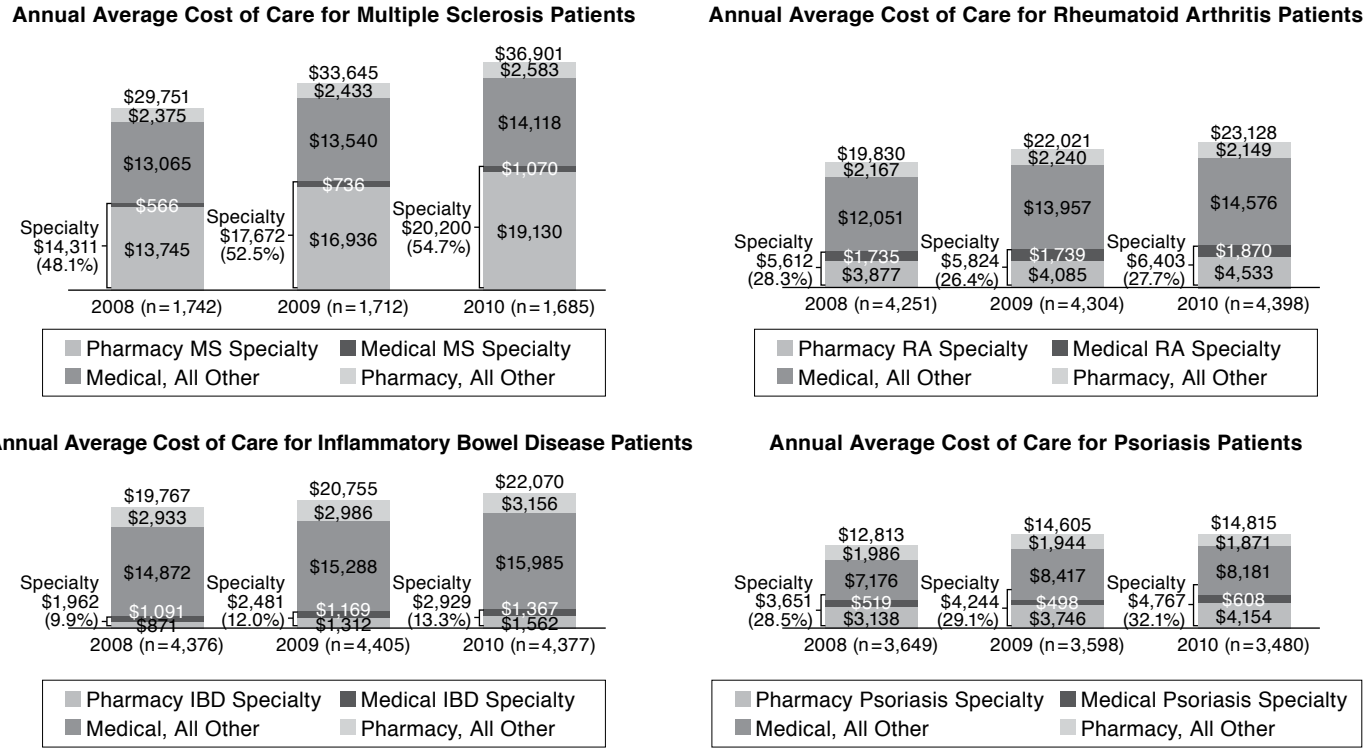
Proportion and Spending Growth by Category

Figure 1 shows the proportion of spending by each of the 4 mutually exclusive cost categories for each condition from 2008 through 2010. For MS, specialty drugs accounted for 48.1% of annual spending in 2008. This increased to almost 54.7% of total spending in 2010. For RA, the proportion of total health care spending on specialty drugs stayed stable (28.3% in 2008 and 27.7% in 2010). For IBD, the proportion of total health care spending on specialty drugs increased from 9.9% in 2008 to 13.3% in 2010. The proportion of spending on specialty drugs for psoriasis increased from 28.5% in 2008 to 32.1% in 2010. As shown in Table 2a, the annual growth rate for total annual health care costs from 2008 to 2010 ranged from 5.7% (IBD) to 11.4% (MS).

Discussion

In this study of commercially insured members from a midwestern state, we examined trends in condition prevalence, treatment, and spending for specialty drugs among those with MS, RA, IBD, or psoriasis. There was a gradual increase in use of specialty drugs for the management of these chronic conditions between 2008 and 2010. In addition, specialty therapies accounted for an increasing share of all health care costs for the conditions examined. These findings are important given the magnitude of spending on specialty therapies that was documented and the increasing pressure on insurers to optimize the value that these therapies can provide.

FIGURE 1 *Annual Average Cost of Care Trends from 2008-2010 for Patients[a] with Multiple Sclerosis, Rheumatoid Arthritis, Inflammatory Bowel Disease, and Psoriasis*



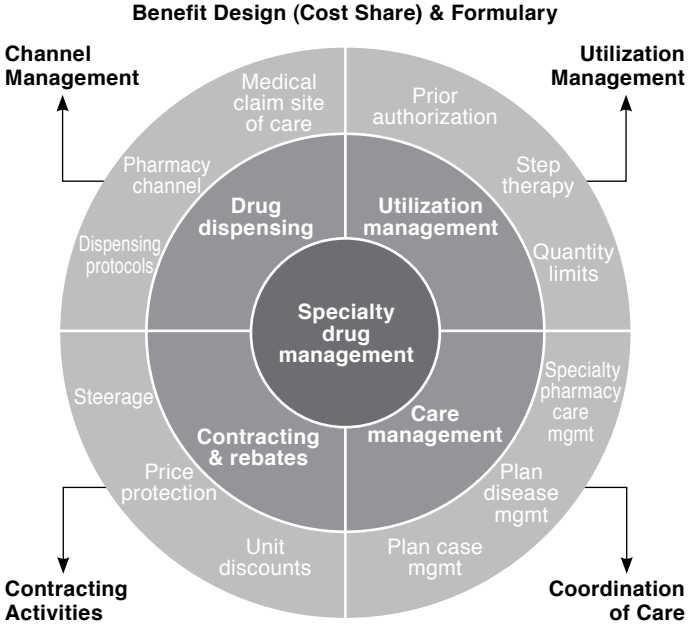
[a]*Commercially insured members continually enrolled during analysis year.*

The importance of the chronic conditions studied is exemplified in the finding that fewer than 1.5% of enrollees in the health plan we examined had 1 of the 4 conditions of interest, but they accounted for 7.2% of the entire plan membership health care expenditures. In addition, the growth rate in expenditures for the conditions was 5.7% to 11.4%, which is 32.6% to 165.1% higher than the 4.3% national health consumption expenditure growth rate over the same time period.[9] The specialty drug expenditure growth of 4.4% to 18.0% also exceeded the national health consumption expenditure growth rate.

Although we did not find any change in the psoriasis or MS condition prevalence rates, over the 3 years we found increased prevalence of IBD (7.0%) and RA (9.7%). Our findings demonstrated that specialty drug utilization increased almost 30% over 3 years for members with IBD; however, utilization of specialty drugs to treat RA remained relatively stable. Increased use of specialty drugs may not be associated with changes in disease prevalence, and specialty drug use trends appear to be condition specific. In addition, new specialty drugs for these conditions continue to be approved by the FDA. For example, tofacitinib (Xeljanz) was recently approved by the FDA for treatment of moderate to severe RA and is expected to cost approximately $25,000 per year of treatment.[10] This will require both payers and providers to determine the comparative effectiveness of the new agents and their appropriate place in therapy.

Both payers and employers are expecting high-cost specialty drugs to prevent disability, which will then lead to improved quality of life and work productivity. Unfortunately, the evidence supporting long-term disability prevention is lacking for MS specialty drugs.[11,12] By contrast, specialty drugs used to treat RA and IBD conditions have clinical trial data suggesting significantly delayed disability or disease remission; however, the incremental benefit over traditional generic disease-modifying agents such as methotrexate is not clear.[13-15] As insurers develop chronic disease care management programs, a key goal of the programs is to improve medication adherence. Increasing specialty drug adherence for chronic conditions will increase costs and may increase them substantially; however, this may be of greater value than partial use due to nonadherence, which may be less likely to translate into meaningful outcomes. We did not find evidence to suggest that the increases in specialty drug costs have been offset by reductions in expenditures from

FIGURE 2 Specialty Drugs—Management Opportunities



mgmt = management.

other types of health care utilization. For example, among members treated with specialty drugs, more than half their total cost of care was attributed to specialty drug expenditures. The specialty drugs would need to eliminate all other medical costs to become cost neutral, which is unforeseeable.

These study findings, coupled with the forecast that specialty drugs will account for 50% of all drug expenditures in the next 5 years,[2] will necessitate that health care payers manage specialty drug costs and optimize value through drug management programs. As shown in Figure 2, specific specialty management programs and policies include the following: (a) channel management that may result in narrowing the specialty drug pharmacy provider network to a limited number of dispensing pharmacies in order to obtain greater unit cost discounts; (b) contracting and rebates that may result in pharmaceutical manufacturer inflationary price protection and rebate optimization via formulary preferred product(s) steerage; (c) implementing utilization management or medical policy pre-authorization to prevent unsafe use or investigational use including requirements to try the preferred formulary product(s) prior to the nonpreferred product(s); and (d) coordination of care between the medical and pharmacy benefit clinical care teams, for example, disease management and specialty pharmacy care management.[7,16-19] The goals of these programs include helping members understand and manage their conditions; providing guidance in using health care resources judiciously; maintaining or improving adherence to the member's care plan, including specialty drug therapy; and obtaining best pricing.

To obtain improved management and cost containment for specialty drugs billed through the medical benefit, payers may consider the following: (a) forcing billing to the pharmacy benefit to allow for greater transparency and less erroneous or fraudulent billing, (b) recontracting with the medical billing provider for specific drug discounts, and (c) limiting the provider site of care specialty drug channel delivery. Examples of medical provider sites of care include the free-standing physician clinic (professional office) unaffiliated with a hospital, outpatient hospital (facility) clinics, inpatient hospital (facility), or the patient's home. Because these sites of care are generally associated with their own provider contracts, the specialty drug discounts may vary widely.[19]

Limitations

Our analysis has several limitations. First, we examined the utilization and cost patterns of a population of privately insured individuals from 1 health plan that was confined to 1 state. Utilization and expenditure patterns may differ among other populations, such as older adults and those in different regions of the country. Second, we did not have information regarding members' disease severity or clinical outcomes. Further work is needed to characterize the clinical stage at which specialty drugs are used and their effect on clinical and patient-reported outcomes. Finally, this was a descriptive, observational study, rather than one to characterize predictors of specialty drug use.

Conclusions

The use of specialty drugs to treat chronic conditions has increased gradually over the last few years. When specialty drugs are used for chronic conditions such as MS, RA, psoriasis, and IBD, they now account for more than 50% of the total cost of care. The agents have resulted in significant increases in treatment costs with limited published evidence of a direct medical cost offset. As specialty drugs fuel the rise in total cost of care for these conditions, it will be important for policymakers and payers to vigilantly analyze their medical and pharmacy benefit specialty drug cost trends and focus management activities on specialty drugs. These management activities include coordinated medical and pharmacy benefit formularies; specialty benefit designs; and specialty drug management programs, which include optimizing the drug distribution channel, utilizing management programs, contracting with pharmaceutical manufacturers for rebates and inflationary price protection, and coordinating care management through the medical and pharmacy benefits to maximize the value specialty drugs can provide.

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DISCLOSURES

Alexander is an ad hoc member of the U.S. Food and Drug Administration's Drug Safety and Risk Management Advisory Committee and is a consultant for IMS Health. Starner, Gunderson, and Gleason are employees of Prime Therapeutics. Ritter is an employee of Blue Cross Blue Shield of Minnesota. Alexander is supported by the Agency for Healthcare Research and Quality (RO1 HS0189960). The funding source had no role in the design and conduct of the study, analysis or interpretation of the data, and preparation or final approval of the manuscript prior to publication.

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REFERENCES

1. Sullivan SD. The promise of specialty drugs: are they worth the price? *J Manag Care Pharm*. 2008;14(4 Suppl):S3-S6. Avaiable at: http://www.amcp.org/data/jmcp/JMCPSupp_S3-S6.pdf.

2. Johnson S, Gunderson B, Bowen KL, Starner CI, Gleason PP. Specialty drugs are forecasted to be 50% of all drug expenditures in 2018 [abstract]. *J Manag Care Pharm*. 2013;19(2):187. Available at: http://www.amcp.org/WorkArea/DownloadAsset.aspx?id=16216.

3. IMS Insitute for Healthcare Informatics. Healthcare spending among privately insured individuals under age 65. February 2012. Available at: http://www.imshealth.com/deployedfiles/ims/Global/Content/Insights/IMS%20Institute%20for%20Healthcare%20Informatics/Healthcare%20Spending/IHII_Spending_Report.pdf. Accessed May 24, 2013.

4. Prime Therapeutics. 2012 drug trend insights. Available at: http://www.primetherapeutics.com/pdf/2012PrimeDrugTrendInsights.pdf. Accessed May 24, 2013.

5. Stern D. Benefit design innovations to manage specialty drugs. *J Manag Care Pharm*. 2008;14(4 Suppl):S12-S16. Available at: http://www.amcp.org/data/jmcp/JMCPSupp_S12-S16.pdf.

6. Goldman DP, Joyce GF, Lawless G, Crown WH, Willey V. Benefit design and specialty drug use. *Health Aff (Millwood)*. 2006;25(5):1319-31.

7. Tu HT, Samuel DR. Limited options to manage specialty drug spending. Center for Studying Health System Change. HSC Research Brief No. 22. April 2012. Available at: http://www.hschange.com/CONTENT/1286/. Accessed May 24, 2013.

8. Larson DB, Johnson LW, Schnell BM, Salisbury SR, Forman HP. National trends in CT use in the emergency department: 1995-2007. *Radiology*. 2011;258(1):164-73. Available at: http://radiology.rsna.org/content/258/1/164.long. Accessed May 24, 2013.

9. Martin AB, Lassman D, Washington B, Catlin A; National Health Expenditure Accounts Team. Growth in U.S. health spending remained slow in 2010; health share of gross domestic product was unchanged from 2009. *Health Aff (Millwood)*. 2012;31(1):208-19.

10. Pfizer receives big boost as FDA approves rheumatoid arthritis drug. *Trefis*. November 8, 2012. Available at: http://www.trefis.com/stock/pfe/articles/152986/pfizer-receives-big-boost-as-fda-approves-rheumatoid-arthritis-drug/2012-11-08. Accessed May 24, 2013.

11. Alonso A, Hernan MA. Temporal trends in the incidence of multiple sclerosis: a systematic review. *Neurology*. 2008;71(2):129-35.

12. Ropper AH. The "poison chair" treatment for multiple sclerosis. *N Engl J Med*. 2012;367(12):1149-50.

13. Chen YF, Jobapurtra P, Barton P, et al. A systematic review of the effectiveness of adalimumab, etanercept and infliximab for the treatment of rheumatoid arthritis in adults and an economic evaluation of their cost-effectiveness. *Health Technol Assess*. 2006;10(42):iii-iv, xi-xiii, 1-229. Available at: http://www.hta.ac.uk/execsumm/summ1042.htm. Accessed May 24, 2013.

14. Bejarano V, Quinn M, Conaghan PG, et al. Effect of the early use of anti-tumor necrosis factor adalimumab on the prevention of job loss in patients with early rheumatoid arthritis. *Arthritis Rheum*. 2008;59(10):1467-74. Available at: http://onlinelibrary.wiley.com/doi/10.1002/art.24106/abstract;jsessionid=E01DC338C89791E31067934F792DB0A0.d03t02. Accessed May 24, 2013.

15. Behm BW, Bickston SJ. Tumor necrosis factor-alpha antibody for maintenance of remission in Crohn's disease. *Cochrane Database Syst Rev*. 2008;23(1):CD006893. Available at: http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD006893/abstract. Accessed May 24, 2013.

16. Baldini CG, Culley EJ. Estimated cost savings associated with the transfer of office-administered specialty pharmaceuticals to a specialty pharmacy provider in a medical injectable drug program. *J Manag Care Pharm*. 2011;17(1):51-59. Available at: http://www.amcp.org/data/jmcp/51-59.pdf.

17. Motheral BR. Pharmaceutical step-therapy interventions: a critical review of the literature. *J Manag Care Pharm*. 2011;17(2):143-55. Available at: http://www.amcp.org/JMCP/2011/March/9012/1033.html.

18. Navarro RP, Johnson KA. Opportunities and challenges of specialty pharmaceuticals. *J Manag Care Pharm*. 2013;19(1):70-71. Available at: http://www.amcp.org/WorkArea/DownloadAsset.aspx?id=16081.

19. Jacobs MS, Johnson KA. Curbing the costly trend: exploring the need for a progressive approach to the management of specialty pharmaceuticals under the medical benefit. *Am Health Drug Benefits*. 2012;5(5):280-89. Available at: http://www.ahdbonline.com/feature/curbing-costly-trend-exploring-need-progressive-approach-management-specialty-pharmaceutical. Accessed May 24, 2013.

APPENDIX A Drugs Used in the Analysis to Identify Condition Presence, Treatment, and Specialty Classification

Drugs Used to Treat Condition	Generic Product Identifier (Medi-Span) Beginning with	Healthcare Common Procedure Coding System	Drug Presence Indicates Presence of Condition	Specialty Drug
Inflammatory bowel disease				
certolizumab (Cimzia)	52505020	C9249, J0718	No	Yes
infliximab (Remicade)	52505040	J1745	No	Yes
golimumab (Simponi)	66270040	none	No	Yes
adalimumab (Humira)	66270015	J0135	No	Yes
etanercept (Enbrel)	6629	J1438	No	Yes
natalizumab (Tysabri)	624050	J2323, Q4079	No	Yes
aminosalicylates (balsalazide, mesalamine, olsalazine, sulfasalazine)	525000	none	Yes	No
corticotropin (Acthar gel)	303000100040	J0800	No	Yes
Psoriasis				
acitretin (Soriatane)	902500	none	Yes	No
alefacept (Amevive)	90250515	J0215	Yes	Yes
ustekinumab (Stelara)	90250585	C9261, J3357	Yes	Yes
certolizumab (Cimzia)	52505020	C9249, J0718	No	Yes
infliximab (Remicade)	52505040	J1745	No	Yes
golimumab (Simponi)	66270040	none	No	Yes
adalimumab (Humira)	66270015	J0135	No	Yes
etanercept (Enbrel)	6629	J1438	No	Yes
coal tar products	9052	none	Yes	No
anthralin, calcipotriene. calcitriol, tazarotene (other topicals for psoriasis)	902500	none	Yes	No
corticotropin (Acthar gel)	303000100040	J0800	No	Yes
Multiple sclerosis				
glatiramer (Copaxone)	62400030	J1595, Q2010	Yes	Yes
interferon beta-1a (Rebif)	624030604520	C9399, Q3026	Yes	Yes
interferon beta-1a (Avonex)	624030604564	J1825, J1826, Q3025	Yes	Yes
interferon beta-1b (Betaseron)	6240306050	J1830	Yes	Yes
natalizumab (Tysabri)	624050	J2323, Q4079	Yes	Yes
dalfampridine (Ampyra)	624060	none	Yes	Yes
fingolimod (Gilenya)	624070	none	Yes	Yes
mitoxantrone (Novantrone)	21200055	J9293	Yes	No
corticotropin (Acthar gel)	303000100040	J0800	No	Yes
Rheumatoid arthritis				
rituximab (Rituxan)	21353060	J9310	No	Yes
certolizumab (Cimzia)	52505020	C9249, J0718	No	Yes
infliximab (Remicade)	52505040	J1745	No	Yes
anakinra (Kineret)	6626	none	Yes	Yes
adalimumab (Humira)	66270015	J0135	No	Yes
golimumab (Simponi)	66270040	none	No	Yes
leflunomide (Arava)	6628	none	Yes	No
etanercept (Enbrel)	6629	J1438	No	Yes
abatacept (Orencia)	6640	C9230, J0129	Yes	Yes
tocilizumab (Actemra)	6650	C9264, J3262	Yes	Yes
auranofin, aurothioglucose, gold sodium thiomalate (gold salts)	6620	J1600, X6262, X6264	Yes	No
corticotropin (Acthar gel)	303000100040	J0800	No	Yes

APPENDIX B Flowchart of Member Identification, Condition Prevalence, Total Health Care Cost, and Specialty Costs