Arthur J. Gallagher & Co.

Industry Snapshot Newsletter

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Understanding the issue: The Threat of Rising Specialty Drug Costs to Student Health Insurance Plans (and possible strategies to help mitigate the burden)

Although there's virtually no avoiding the prevalent societal buzz dissecting President Trump's every move (and tweet) relating to the Patient Protection and Affordable Care Act (PPACA), we must not overlook other fundamental trends impacting higher education student health insurance policies. One such topic gaining industry attention is the dramatically increased specialty drug costs plaguing insurance companies and students.

The term "specialty drug" is used to describe prescription products with sensitive conditions for storage, handling, administration, and monitoring. Most commonly, this category of drug refers to biologics, injectables, or infused therapies (often administered in the patient's home). Specialty drugs are commonly used to treat complex and/or chronic conditions like cancer, rheumatoid arthritis, hepatitis C, and multiple sclerosis, and they are generally more costly than traditional medications like antibiotics or antidepressants. Sovaldi, a drug to treat the Hepatitis C virus, costs about $1,000 per day for the 12-week course of treatment amounting to $84,000. A drug like Sovaldi is often prescribed in conjunction with other drugs, significantly raising the total treatment cost for both the insurance company and the patient.

Why are specialty drugs so expensive, you ask? Research and development costs of these elite drugs are understandably high. As with any new drug, specialty drugs must meet all regulatory approval requirements put forth by the Food and Drug Administration (FDA). However, there are additional factors that may be influencing the rising cost of specialty drugs. Non-specialty brand medication patents eventually expire, and then become available as less expensive generic drugs. This shift undermines revenue for large drug manufacturers, who subsequently struggle to replace branded products made available as generic drugs because they typically have very sparse pipelines. As a result, we are seeing more large drug manufacturers buying other drug manufacturers (and hiking up the cost of the drugs they produce), in order to replenish/expand their pipelines and portfolio of marketable branded products. Health insurance companies, like drug manufacturers, must also continue to drive their revenue if they intend to thrive in the increasingly competitive PPACA-regulated insurance market.

Student access to affordable healthcare is obviously one of the highest priorities of college/university administrators, and we continue to hear a common voice of industry concern, as increased costs of specialty prescriptions have inevitably led to a rising frequency of high dollar claims within many schools' student health insurance plans (SHIPs). In previous years (prior to the implementation of PPACA regulations), students in need of specialty drugs

simply would not enroll in their school's SHIP, since prescription benefits were limited. Now, with PPACA guidelines in place, prescriptions are unlimited, meaning students seeking specialty drug treatment are much more likely to enroll in a SHIP. This means that high dollar specialty drug claims are not appearing merely as one-off occurrences within the SHIPs. Instead, they have become a consistent influence on plan performance for years at a time, again due to the fact that specialty medications are mainly used to treat chronic student conditions over extended periods. The concerning result is considerably increased benefit expenses for insurance carriers, resulting in an unavoidable rise in student premiums and other out-of-pocket costs over time.

On a larger scale, although used by a minimal number of patients, specialty drugs account for a significant portion of overall drug spend in the U.S., and represent the fastest growing sector of pharmacy spending. According to some reports, specialty drugs represent only 1% of all U.S. prescriptions, but 31.8% of the total drug spend. And as a result of price inflation and new drug approvals, that number is projected to grow to 50% in 2017, according to Express Scripts, one of the nation's leading pharmacy benefits managers. Experts predict that specialty drug use will surpass traditional drug spend by 2018. By 2020, it is predicted that specialty drugs will represent half of the total U.S. drug spend, at a cost of $400 billion.

"We are talking about a tsunami of expensive medicines that could literally bankrupt the health care system," says John Rother, President and CEO of the National Coalition on Health Care (NCHC), which launched the "Campaign for Sustainable Rx Pricing" in 2014.

Although some may argue that overall national statistics cannot be regarded as entirely relevant in the unique world of student healthcare, our recent client data seems to suggest otherwise. An analysis of the Gallagher Student Health & Special Risk national book of SHIP business over the last two full policy years revealed that the annual number of high dollar medical claims (over $25,000) dropped from 2014-15 to 2015-16. However, we saw the severity of high dollar medical claims increase overall. Very often our client's high dollar medical claims relate to pharmacy costs. Prescription cost was far and away the highest expense in our SHIP market, with an average of 22% increase year-over-year (much higher than the 5% increase in preventative services, and 0% in hospital costs). As illustrated in the below charts, eight out of the top ten specialty drugs being used by students attending our client institutions in 2016 also fell into the top ten overall commercial drugs released by Express Scripts. This seems to support the theory that student health pharmacy trends may not be much different after all, when compared to overall prescription drug use in our country.

Top 10 Specialty Drugs in 2016

Gallagher Student Health & Special Risk 2016 National Book of SHIP Business		
Brand Name	**Illness Treated**	**Amount Paid Per Member**
PROCYSBI	Nephropathic Cystinosis	$246,610
HARVONI	Hepatitis C	$50,143
XYREM	Narcolepsy	$32,172
COPAXONE	Multiple Sclerosis	$17,008
GILENYA	Multiple Sclerosis	$18,711
TECFIDERA	Relapsing Multiple Sclerosis	$21,443
CIMZIA	Crohn's Disease, Evere Rheumatoid Arthritis, and Ankylosing Spondylitis	$10,514
HUMIRA PEN	Rheumatoid Arthritis, Juvenile Idiopathic Arthritis, Psoriatic Arthritis, Ankylosing Spondylitis, Plaque Psoriasis, Hidradenitis Suppurativa, Crohn's Disease	$15,216
ENBREL SURECLICK	Rheumatoid Arthritis, Psoriatic Arthritis, or Ankylosing Spondylitis	$12,623
TRUVADA	HIV/AIDS	$2,479

Express Scripts 2016 (Commercial) Drug Trend Report

					Trend		
Rank	Drug Name	Therapy Class	PMPY Spend	% of Total Specialty Spend	Utilization	Unit Cost	Total
1	Humira Pen (adalimumab)	Inflammatory conditions	$45.11	11.3%	10.5%	17.9%	28.4%
2	Enbrel (etanercept)	Inflammatory conditions	$26.82	6.7%	-4.3%	10.9%	6.6%
3	Tecfidera (dimethyl fumarate)	Multiple Sclerosis	$13.49	3.4%	-2.1%	10.5%	8.4%
4	Copaxone (glatiramer)	Multiple Sclerosis	$12.42	3.1%	-12.3%	1.6%	-10.7%
5	Harvoni (ledipasvir/sofosbuvir)	Hepatitis C	$9.86	2.5%	-49.5%	-4.3%	-53.8%
6	Revlimid (lenalidomide)	Oncology	$9.78	2.5%	13.7%	10.6%	24.3%
7	Gilenya (fingolimod)	Multiple Sclerosis	$8.48	2.1%	5.6%	9.0%	14.6%
8	Truvada (emtricitabine/tenofovir disoproxil fumarate)	HIV	$8.44	2.1%	27.1%	10.7%	37.8%
9	Humira (adalimumab)	Inflammatory conditions	$8.15	2.1%	2.8%	16.0%	18.8%
10	Stelara (ustekinumab)	Inflammatory conditions	$8.13	2.0%	18.2%	3.7%	21.9%

This prominent industry trend of pharmacy spending spikes is understandably igniting fear among various SHIP stakeholders and insurance companies alike, as they recognize that the cost of prescription drugs is simply unsustainable if the market continues in this direction. In addition to student health administrators, insurance companies, and drug manufacturers, state and federal insurance regulators, marketplace officials, and lawmakers play a critical role in ensuring that consumers (including college/university students) have access to the affordable prescription drugs they need. That being said, it's important to explore the proposed cost management strategies being considered by the U.S. and global healthcare industries (including the student health market) to control costs and prevent industry bankruptcy.

One such strategy, referred to as utilization management by the insurance industry, describes a process implemented by both the U.S. government and commercial insurance carriers, modifying health insurance plan benefit designs to ensure appropriate medication utilization, increase drug effectiveness, and decrease incurred costs. The main concept of utilization management is a method of obstructionism - determining "medical necessity" through an evaluation of suggested patient pharmaceutical treatment, to decide whether the treatment is clinically justified. Utilization management is comprised of programs including step therapy and prior authorization.

As the term denotes, a step therapy program uses a "step" approach with drugs for certain conditions, meaning that patients must first try a safe, lower-cost drug alternative or one that may be more clinically effective, before "stepping up" to a different (more expensive) drug. The objective is to lower costs through safe, less expensive drugs.

Prior authorization, often also referred to as "pre-approval," refers to a set of policies requiring a healthcare professional to provide documentation validating a patient's need for a particular medication. Under most prior authorization criteria, clinical information is necessary to verify that a specialty drug is medically appropriate for a patient before coverage is granted by the insurance company.

Not surprisingly, many patients and providers are not happy with processes like step therapy and prior authorization, since they essentially require that patients first fail on what are commonly referred to as "preferred drugs," before they can be approved for others. Advocates argue that insureds should not be forced to try ineffective (albeit less expensive) treatments for their chronic ailments, when specialty drugs can offer them fewer side effects, improved quality of life, and the possibility of living a longer, more productive life. Some state legislatures agree, and have recently begun to intervene, attempting to speed up the prior authorization process and similar practices used by insurers. State officials in Colorado, Iowa, New Mexico and Texas are currently considering such legislation.

Insurance companies continue to defend utilization management procedures, insisting that they can help ensure patient awareness of treatments that may be just as effective, and less expensive, than specialty drugs. This would mean immediately lower out-of-pocket costs for the patient/student being treated.

Another strategy designed to alleviate the financial strain of specialty drugs is the attempt to implement increased cost sharing options within health insurance plans. Traditionally, pharmacy benefits have had a steerage design, placing brand name/specialty drugs in a health plan's highest drug formulary tier, where out-of-pocket costs are most expensive. Patients are generally required to pay higher coinsurance for higher tier medications, since past research has shown that requiring patients to pay more out-of-pocket reduces their use of higher tier prescription drugs. However, if a patient truly needs the high tier drugs (i.e., specialty drugs) to lead a healthy life, then they will still find themselves paying high out-of-pocket costs, and the insurance company is still left with their share of the hefty expense.

For that reason, one of the widespread goals in the healthcare industry at this time remains to find more effective cost sharing options, since the aforementioned strategies have stakeholders skeptical that these initial methods are bringing any significant relief.

Along with some U.S. state legislatures and insurance carriers, Gallagher Student Health & Special Risk is exploring ways to reduce cost sharing, without increasing premiums, in the following ways:

1. Analyzing utilization data/patterns
2. Educating on-campus providers on cost-effective prescription alternatives
3. Implementing a separate deductible for pharmacy expenditures, with a proportionate deductible reduction for other (medical) expenditures
4. Enforcing a requirement that at least one specialty drug in each category be exempt from coinsurance
5. Applying a maximum $250 per month cost sharing on drugs
6. Implementing varying levels of pharmacy formularies, with varying levels of usage management/steerage (for example, formularies that may save a SHIP more in annual premium could implement pre-certification for more drug categories, introduce step therapy, and change drug lists to exclude certain drugs; the more cost-sharing to the patient, the greater the premium/pharmacy claims savings to the SHIP).
7. Moving to a percentage-based (vs. copayment-based) pharmacy model, to create more cost-sharing for expensive drugs

As with all complex issues addressed in our industry analysis pieces, there is no crystal ball to reveal what cost containment strategies will prove to be most effective. And there are undoubtedly more new ideas on the horizon that offer the possibility of more affordable pharmacy benefits for our students and the greater U.S. population. First and foremost, it is our (and your) responsibility to recognize and become educated on these vital issues impacting student healthcare, so we can all work together towards better healthcare, a sustainable market, and an improved quality of life for all.

We strongly encourage all industry partners to familiarize themselves with this topic, and to contact us with any outstanding questions for further clarification.

Additional Relevant Publications

As research best practices indicate, multiple sources/opinions should be evaluated in any major change or decision-making process. To this end, below is a list of scholastic and media publications examining the issue of increased specialty drug cost, and the potential impact on the healthcare industry:

- Harvard Business Review: We Need More Transparency on the Cost of Specialty Drugs
- CVS Health: Specialty Costs: Can They be Contained?
- Congressional Research Service: Specialty Drugs: Background and Policy Concerns
- Consumer Reports: Is There a Cure for High Drug Prices?
- Health Affairs Blog: Rising Cost Of Drugs: Where Do We Go From Here?

Appendix:

- Barlas, Stephen. "Are Specialty Drug Prices Destroying Insurers and Hurting Consumers?: A Number of Efforts Are Under Way to Reduce Price Pressure." Pharmacy and Therapeutics 39.8 (2014): 563–566. Print.
- Express Scripts Holding Company. "2016 Drug Trend Report." Express Scripts (2017) Print.
- Avalere Health. "Dimensions Specialty Management Solutions, Specialty Pharmacy Benefit Designs: Considerations for Shifting from the Medical to Pharmacy Benefit." Janssen Biotech, Inc. (2016) Print.
- "Specialty Drugs and Health Care Costs." The Pew Charitable Trusts. 16 Nov. 2015. Web.
- "2017 Market Update: Student Health & Special Risk, National Book of SHIP Business." Gallagher Student Health & Special Risk. 2017. Print.
- Patrick P. Gleason, G. Caleb Alexander, Catherine I. Starner, Stephen T. Ritter, Holly K. Van Houten, Brent W. Gunderson, and Nilay D. Shah. "Health Plan Utilization and Costs of Specialty Drugs Within 4 Chronic Conditions." Journal of Managed Care Pharmacy. 19:7 (2013): 542-548.
- "Issue Brief: Specialty Drugs: Issues and Challenges." America's Health Insurance Plans. July 2015. Web.
- "THE GROWTH OF SPECIALTY PHARMACY Current Trends and Future Opportunities." UnitedHealth Group. UnitedHealth Center for Health Reform & Modernization, April 2014. Web.
- Dolan, Rachel. "From The Archives: Pharmaceutical Pricing." Health Affairs Blog. 24 Nov. 2015. Web.