MarshMcLennan Agency

Your future is limitless.℠

Rx newsletter

In this issue

Market trends:

Mounting for transparency around prescription drug pricing

Pharmacy 101

Understanding Pharmacy Utilization and Plan Spend

Disease spotlight:

Sickle Cell Disease (SCD) in America

Clinical spotlight:

Future of Pharmacogenomics in the PBM Industry

Pipeline:

Pending drug approvals
Brands losing patent

Market trends

Pharmacy Benefit Managers feel the pressure mounting for transparency around prescription drug pricing.

Increased transparency claims have done little to quell outrage over drug pricing.

Pharmacy benefit managers, or PBMs, manage prescription drug benefits by acting as the third-party between drug manufacturers and health plans. PBMs often boast about their expertise in the industry, which allows them to negotiate lower prescription drug prices on behalf of health plans.[1]

As of late, many PBMs have come under scrutiny for their drug pricing strategies, as their benefits are rarely reaching consumers and drug prices have been adversely impacted. With drug manufacturers increasing out-of-pocket costs at the consumer level, the impact of the benefits of PBMs is significantly reduced.[1]

Investigations Heat Up

The frustration with PBMs' actions is at an all-time high as the government widens various investigations into the drug pricing system.

In June 2022, the Federal Trade Commission (FTC) launched inquiries into the largest PBMs in the industry, citing anti-competitive practices. While the FTC's investigation is ongoing, Congress has introduced the Pharmacy Benefit Manager Transparency Act.[2]

The bipartisan bill's goal is to increase pricing transparency and to hold PBMs accountable for deceptive practices. In March 2023, the Senate Committee on Commerce, Science, and Transportation approved the bipartisan bill to advance to the Senate.[3]

Pressure Builds on the State Level

Not only is the federal government stepping in, but two senators are creating a bipartisan framework to address the challenges PBMs are creating and proposing possible legislative solutions.

Senators Mike Crapo (R-Idaho) and Ron Wyden (D-Oregon) highlighted four main problems that PBMs have perpetuated – "misaligned incentives," a lack of transparency, the adverse impact of vertical integration, and anti-competitive practices such as spread pricing. Their most powerful solution is to "delink" drug pricing from PBMs' revenues so that there is no incentive to raise prices further.[4]

Sources:

1. *"Pharmacy benefit managers claim to lower drug costs. Congress isn't convinced," Harvard Public Health Magazine, accessed May 3, 2023, https://harvardpublichealth.org/health-policy-management/pbms-face-scrutiny-from-congress-over-drug-prices/*
2. *"Pharmacy Benefit Managers Are Again In The Crosshairs Of Congress and The FTC: Action To Reform Drug Pricing Increasingly Likely," Forbes, accessed May 3, 2023, https://www.forbes.com/sites/joshuacohen/2023/04/02/pharmacy-benefit-managers-are-again-in-the-crosshairs-of-congress-and-the-ftc-action-to-reform-drug-pricing-increasingly-likely/?sh=57d7245d447f*
3. *"Commerce Committee Approves Cantwell, Grassley Bipartisan Bill to Combat Rising Prescription Drug Prices," U.S. Senate Committee on Commerce, Science & Transportation, accessed May 4, 2023, https://www.commerce.senate.gov/2023/3/commerce-committee-approves-cantwell-grassley-bipartisan-bill-to-combat-rising-prescription-drug-prices*
4. *"2 Senator Release Framework Targeting PBMs," MedCity News, accessed May 4, 2023, https://medcitynews.com/2023/04/2-senators-release-framework-targeting-pbms/*

Pharmacy 101

Understanding Pharmacy Utilization and Plan Spend

Prescription drugs and their continued dominance.

Prescription drug benefits continue to make up a large amount of an employer's healthcare spend. It is estimated that 20% to 25% of healthcare spend is due to prescription medications, and that in 2023, specialty medication utilization will increase by 6.1%.

National trends in prescription drug cost

Over the past two years pharmaceutical expenditures have grown at a substantial rate growing in both utilization and cost.

In 2021, the total prescription drug expenditures for the United States were approximately $577 billion, up 7.7% over 2020. [1]

In 2022, overall pharmaceutical expenses in the U.S. grew 9.4% from 2021 to a total of $634 billion. [2]

For 2023, drug expenses are expected to increase again by another 6% to 8%, putting pharmaceutical costs close to $700 billion. [2]

Of the many factors that drive the overall increase in pharmaceutical spending, the major contributions stem from utilization, price, and the introduction of new drugs to the market.

For example, in 2021, utilization grew 4.8% over 2020 and then grew 5.9% in 2022 from 2021. [2] We may still be feeling the ramifications of the COVID-19 pandemic, which caused many individuals to put off healthcare visits, leading to drops in drug adherence and overall wellness.

Rising specialty medication cost and what to expect

In 2021, the United States spent $577 billion on prescription drugs, with specialty medications alone accounting for approximately half of this total ($285 billion). [3]

Even with the cost of specialty medications being as great as it is, which accounts for about half of all medication spend, its utilizers only encompass approximately 1%-2% of patients. [3]

Increases in the overall trend will continue for specialty medications that includes conditions such as: [4]

- Inflammatory Conditions
  - Psoriasis, psoriatic arthritis, Crohn's disease, and ulcerative colitis.
- Rare Conditions
  - Muscular Dystrophy, sickle cell disease, amyloidosis, and hemophilia.
- Cancer

There is help on the way as several biosimilars* are coming to market in 2023 for Humira (adalimumab), which was the top drug in terms of cost in 2021 and 2022. This may help mitigate rising prices in categories with little or no competition, but it remains to be seen how impactful this will be compared to the PBM's biosimilar and brand strategy.

Since the cost of specialty medications is significant to both the plan and member, it is important that these medications are used and managed properly. It is in every plan sponsors best interest to contact their PBM partner to try and mitigate these costs as best as possible.

*A biosimilar product is a biologic product that is approved based on demonstrating that it is very similar to an FDA-approved biologic product and has no clinically meaningful differences in terms of safety and effectiveness.[5]

Sources:

1. *"National trends in prescription drug expenditures and projections for 2023," National Institute Library of Medicine, accessed May 05, 2023, https://pubmed.ncbi.nlm.nih.gov/37094296/*
2. *"National trends in prescription drug expenditures and projections for 2022," National Institute Library of Medicine, accessed May 05, 2023, https://pubmed.ncbi.nlm.nih.gov/37094296/*
3. *"A Primer for Medical Specialty Drug Utilization Management Strategies," Pharmacy Times, accessed May 05, 2023, https://www.pharmacytimes.com/view/a-primer-for-medical-specialty-drug-utilization-management-strategies*
4. *"2021 + Onward," Evernorth.com, accessed May 05, 2023, https://www.evernorth.com/drug-trend-report/2021-and-onward*
5. *"LET'S TAKE A CLOSER LOOK AT THE CHARACTERISTICS OF BIOSIMILARS," Pfizer, accessed May 26, 2023, https://www.pfizerbiosimilars.com/characteristics-of-biosimilars*

Disease Spotlight

Sickle Cell Disease (SCD) in America

According to the CDC, 100,000 Americans are suffering from Sickle Cell Disease (SCD).

What is Sickle Cell Disease (SCD)?

Sickle Cell Disease (SCD) is a group of inherited red blood cell disorders, which results in a lack of red blood cells. Infection, acute chest syndrome, stroke, and other severe consequences including discomfort are all possible side effects.[1]

The risks of SCD are not equal among all populations, unfortunately there is a significantly higher risk among certain minorities due to genetic heritage.

- "SCD occurs among about 1 out of every 365 Black or African-American births." [2]
- "SCD occurs among about 1 out of every 16,300 Hispanic-American births." [2]

Due to the variety of types of SCD, there are a range of complications that can result from SCD. Including, but not limited to:

- Acute Chest Syndrome, Anemia, Blood Clots, Fever, Infection, Kidney Problems, Organ Damage Pulmonary Hypertension, and Stroke.

Treatments, Cures, and Costs

As of 2022, researchers concluded that "privately insured individuals with SCD spend approximately $1.7 million on disease related expenses over their lifetime."[3]

- This figure only takes into consideration out-of-pocket costs of medical care. When factoring in premiums and total plan paid amounts the numbers would be dramatically higher.

Currently, SCD can only be cured via bone marrow transplant or stem cell transplants which are not without their own risks.

- While there are a multitude of drugs to treat the symptoms of SCD, none are curative at this moment.
- However, with the explosion of gene therapies, there are promising new candidates for curing SCD. They are expected to carry significant price tags.
  - A variety of organizations and companies are already working on SCD cures such as UCLA, Bluebird Bio, and Crispr Therapeutics.[4]
- As the U.S. population continues to age and live longer than prior generations, the amount of people living with SCD will continue to rise. As such, SCD will continue to garner attention and efforts towards curative therapies. However, with almost all revolutionary therapies currently, the price tag might be equally astronomical.

Sources:

1. *"What is Sickle Cell Disease" Center for Disease Control, accessed May 2, 2023, https://www.cdc.gov/ncbddd/sicklecell/facts.html*
2. *"Data & Statistics on Sickle Cell Disease" Center for Disease Control, accessed May 2, 2023, https://www.cdc.gov/ncbddd/sicklecell/data.html*
3. *"The Cost of Living with Sickle Cell Disease" American Society of Hematology accessed May 2, 2023, https://www.hematology.org/newsroom/press-releases/2022/the-cost-of-living-with-sickle-cell-disease*
4. *"A Gene Therapy Cure for Sickle Cell is on the Horizon" WIRED accessed May 2, 2023, https://www.wired.com/story/a-gene-therapy-cure-for-sickle-cell-is-on-the-horizon/*

Clinical Spotlight

Future of Pharmacogenomics in the PBM Industry

What is Pharmacogenomics?

Pharmacogenomics (PGx) is based on studying a person's genetic profile. This has become increasingly common in the PBM industry as the studying of one's genetics helps to determine if a person may have adverse effects to medications they are prescribed. Over 90% of patients have some form of DNA variants that impacts their reactions to medicines that they are prescribed.[1]

PGx testing is significant when it comes to personalized medicine as it quickly diminishes the need for trial and failure with medications. The cost of care then decreases because of patients not having to take a medication for several weeks and then needing to take an alternative until the patient finds the right drug that works for them.

There are currently over 300 drugs that can be tested through a PGx program and the list continues to grow each year. Drug labeling can contain information on genomic biomarkers with some of the following: [2]

- Drug exposure and clinical response variability
- Risk for adverse events
- Mechanisms of drug action

A few examples of drugs on this list are Aripipazole, Bupropion, Citalopram, and Escitalopram. Oncology is the top specialty with over 100 drugs listed that meet the criteria. Second would be psychiatry and mental health.

Cost Barriers for PGx Testing

The concept of PGx testing has been favored amongst the medical and pharmacy field. With that said, costs are a huge factor that has come to play in determining if PGx testing should be completed on the medical or pharmacy side of insurance.

The average cost for PGx testing through the medical insurance is around $5,000 while the average cost through the pharmacy insurance is $500. Precision medicine program fees can typically be built into the PMPM calculations for clients.

PBM's approach on Pharmacogenomics

Majority of the PBM's in the pharmacy industry are launching clinical programs that provide PGx testing to help lower costs for the plan, and to assist patients with finding the correct medications that work best for them. Over $528 billion is spent on drugs that patients have adverse drug effects.

PBM's are carving out the PGx testing by partnering with major data software and laboratories to provide precision medicine care to their clients. FlexHealth is a laboratory that focuses on DNA testing to assist health systems with PGx testing. Another company with a focus on PGx testing is GenXys which provides guidance on a data level. They have a software with PGx data that can then identify drug and gene interactions for patients.

Sources:

1. *"Pharmacists Play Role in Pharmacogenomics Clinical Services," Pharmacy Times, accessed May 19, 2023, https://www.pharmacytimes.com/view/pharmacists-play-role-in-pharmacogenomics-clinical-services*
2. *"Table of Pharmacogenomic Biomarkers in Drug Labeling," FDA, accessed April 27, 2023, https://www.fda.gov/drugs/science-and-research-drugs/table-pharmacogenomic-biomarkers-drug-labeling*

Pipeline

Pending drug approvals

Drug name	Manufacturer	Indication/use	Expected FDA decision date
natalizumab (biosimilar to Biogen's Tysabri)	Polypharma Biologics/ Novartis	CD; MS	May – Jun 2023
foscarbidopa/ foslevodopa	Abbvie	Parkinson's disease	5/20/2023
epcoritamab	Genmab/Abbvie	Relapsed/refractory large B cell lymphoma	5/21/2023
nogapendekin alfa inbakicept	Immunitybio	Bladder cancer	5/23/2023
momelotinib	Sierra Oncology/ Gilead	Myelofibrosis	6/16/2023
olorofim	F2G	Fungal infections	6/17/2023
efgartigimod/ hyaluronidase	Argenx	Myasthenia gravis	6/20/2023
quizartinib	Daiichi Sankyo	AML	7/24/2023
risperidone (once monthly)	Laboratorios Farmacéuticos Rovi	Schizophrenia	7/27/2023
remestemcel-L	Mesoblast	GVHD	7/31/2023
zuranolone	Sage/Biogen	Major depressive disorder; postpartum depression	8/5/2023
avacincaptad pegol	Iveric Bio	Dry AMD-related geographic atrophy	8/19/2023
lotilaner	Tarsus	Demodex blepharitis	8/25/2023
lebrikizumab	Eli Lilly	Atopic dermatitis	Sept 2023
nedosiran	Novo Nordisk	Hyperoxaluria	Sept 2023

Brands Losing Patent

Drug name	Manufacturer	Indication/use	Expected FDA decision date
Amturnide	aliskiren hemifumarate; amlodipine besylate; hydrochlorothiazide	Hypertension	May 2023
Lucemyra	lofexidine hydrochloride	Mitigation of opioid withdrawal symptoms	5/1/2023
Vistogard	uridine triacetate	Emergency treatment following a fluorouracil or capecitabine overdose	7/1/2023
Mozobil	plerixafor	Mobilize hematopoietic stem cells for collection	7/1/2023
Cystadrops	cysteamine hydrochloride	Corneal cystine crystal deposits	8/1/2023
Vyvanse	lisdexamfetamine dimesylate	ADHD	8/1/2023
Tyzeka	telbivudine	Hepatitis B	Sept 2023

For more information about Rx and other solutions from MMA, visit www.mmaeast.com, or contact your local representative.

Shannon LaBarre, CPhT
+215-530-8118
Shannon.LaBarre@MarshMMA.com

Contributors:
Jenna Berger
Ellen Butcher
Shannon LaBarre, CPhT
Greg Schanck

A business of Marsh McLennan