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Rx newsletter

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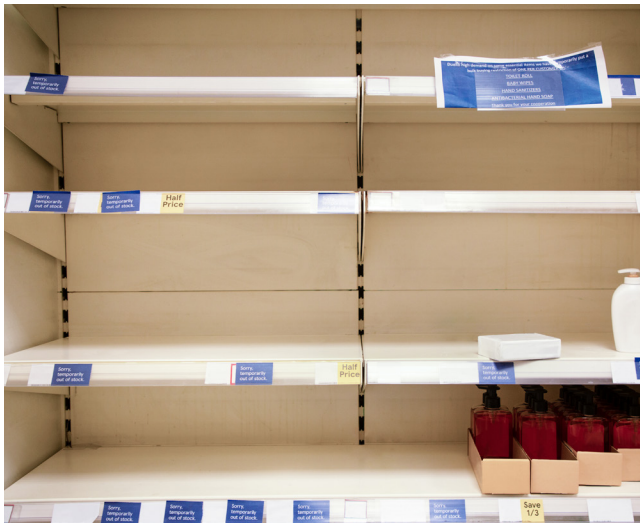
Monitoring Recent Trends: Drug Supply Shortages and Prescription Drug Transparency



Drug Shortages Continue to Make Headlines

Drug shortages are not resolving, and the FDA expects an increase in demand-related shortages.

Within the past few weeks, the FDA reported demand-related shortages for the antibiotic amoxicillin due to a spike in respiratory infections. [1]

Adderall, used to treat ADHD, has also been in shortage for months. Shortages for this drug can be more difficult to combat because it is classified as a Class 2 controlled substance, which means companies are limited on how much they can make. Demand has also bolstered shortages, driven by increased awareness of the condition and emergence of telehealth services.[2]

When surges in demand occur, manufacturers are unequipped to immediately respond with increased capacity. Mark Cuban's Cost Plus Drugs is taking a proactive approach in addressing the supply chain issues. The company recently opened a robotics-driven manufacturing site in Texas. The advanced technology at the site is equipped to rapidly respond and address drug shortages in hospitals.[3]

Legislative Updates to Prescription Drug Transparency

Section 204 of the Consolidated Appropriations Act (CAA) established new transparency reporting requirements for prescription drug data collection (RxDC). Enforcement of the RxDC reports were scheduled to go into effect on December 27, 2022. However, days before the enforcement date, the U.S. Departments of Labor, Health and Human Services, and Treasury (collectively, the Departments) released an FAQ with additional updates for the 2020 and 2021 data, including:

- The Departments will not take enforcement action against any plan or issuer that makes a "good faith, reasonable interpretation" of the requirements and RxDC reporting instructions for the 2020 and 2021 submissions.[4]
- A non-enforcement grace period is being provided through January 31, 2023, which means plans and issuers will not be considered out of compliance if the data is submitted by January 31.[4]

As we move into 2023, employers are focused on applying lessons learned from the first round of submissions and remaining compliant with the reporting requirements. All subsequent RxDC reports are due June 1st of the following year. Additional clarifying guidance from the Departments is expected to be released prior to the next reporting deadline on June 1, 2023.

Sources:

1. *"Drug shortages aren't going away any time soon, supply chain expert warns," Fierce Pharma, accessed January 23, 2023, https://www.fiercepharma.com/manufacturing/drug-shortages-arent-going-away-any-time-soon-supply-chain-expert-warns*
2. *"After Adderall, common antibiotic amoxicillin runs into shortage amid demand spikes and manufacturing woes," Fierce Pharma, accessed January 23, 2023, https://www.fiercepharma.com/manufacturing/after-adderall-common-antibiotic-amoxicillin-runs-shortage-amid-demand-spikes-and*
3. *"Mark Cuban in talks with hospitals to solve drug shortages," Becker's Healthcare, accessed January 23, 2023, https://www.beckershospitalreview.com/pharmacy/mark-cuban-in-talks-with-hospitals-to-solve-drug-shortages*
4. *"AFFORDABLE CARE ACT AND CONSOLIDATED APPROPRIATIONS ACT, 2021 IMPLEMENTATION PART 56," CMS, accessed January 23, 2023, https://www.cms.gov/files/document/aca-part-56.pdf*

Pharmacy 101

Is this the Beginning of the End for Specialty Coupon Maximizers

What are specialty coupon maximizers?

To answer that question, it's important to know what a specialty coupon is. When most people think of a specialty coupon, they think of the commercial stating if you cannot afford your prescription, to call the number provided. This is only partially true. There are normally two programs provided by the manufacturer, a patient assistant program, which is income based for uninsured patients, and the manufacture coupon for those with commercial insurance. The coupon helps members by covering their copay or coinsurance up to a certain amount. As specialty medications became more common and more expensive, coupons became more popular. The original purpose of the specialty coupon maximizer programs was to maximize how much of the coupon was used each time the patient filled the medication by creating a variable copay process in which the members cost share changed to closely align with the coupon value, therefore decreasing the plans share of the medication. The programs are normally paired with a true out of pocket program to make sure the coupons were not counting towards member accumulator amounts and members only get credit for their true out of pocket costs.

Coupon Program Concerns and Manufacture Updates

There has been an increase in drug manufacturers such as AbbVie and Johnson & Johnson (J&J) who have informed PBM's with these programs that they have updated their terms to where the employers are not benefiting from coupons. These drug manufacturers created coupons for members who need financial assistance and not for the financial benefit of employers and PBM's.

While it seems like the manufacturer is doing something kind for patients, there is a downside of these coupons. Whether driven by the PBM Program or the incentive provided by the manufacturer, members continue to lean towards medications that provide assistance without understanding the high cost the plan is picking up for these medications. There could potentially be less costly drug alternatives for members to utilize versus the more costly drugs that have coupons.

In May 2022, J&J filed a lawsuit against SaveOnSP based on their claim that they have lost over $100 million in revenue due to coupon maximizers.[1] They believe that members are being influenced by the PBM's and pushed to use the more costly drugs that would allow employers to benefit from the coupon savings.

In response to the lawsuit, SaveOnSP advised that the drug manufacturers can change how much they allow for the coupon amounts. J&J does not feel this makes much of a difference to their loss of revenue as they have tried this approach with Tremfya and Stelara to no avail.

As of 11/1/2022, AbbVie has announced they will be making changes to their terms and conditions with co-pay assistance programs.[2] Members whose plans are enrolled in the co-pay maximizer programs will no longer be able to use copay assistance coupons. On top of making this update, AbbVie will also be conducting internal audits to identify the members who will be impacted by this change to their terms and conditions.

A few of the drugs that will be impacted by this update are Humira, Skyrizi, Rinvoq, and Xeljanz. As of February 1st, the big 3 have started to phase out AbbVie and J&J medications from their maximizer programs.

What's next for the Copay Coupon?

While we believe that these programs still provide must need relief for plan sponsors, we have warned multiple times that these programs are not sustainable in the long term. They are a double-edged sword. The more patients maxing out the assistance, the more the manufacturer loses in their revenue, so they combat it by increasing the cost of the medication. But plans without the program don't get a discount in the cost of the medication if they don't enroll in the programs.

We believe that if AbbVie and J&J are successful at fighting these programs without impact to their sales, it is likely that other manufacturers will follow quickly, which would likely end these programs as we know them today, at least for specialty medications.

Sources:

1. *"SaveOnSP Program and Other Co-pay Maximizers" FrierLevitt, accessed February 02, 2023, SaveOnSP Program and Other Co-pay Maximizers Costing Manufacturers, Patients, and Plan Sponsors More (frierlevitt.com)*
2. *AbbVie News, accessed February 02, 2023, https://news.abbvie.com/*

Disease Spotlight

Long COVID and it's connection to ME/CFS

What is Long COVID

At this point many people have either come down with or know someone that has experienced COVID-19. While some may have gotten past the initial glaring symptoms, others still feel as though they have little to no energy and find basic day to day responsibilities taxing. You, along with many others, are not sure what is happening since you no longer are COVID-19 positive. Your doctor may tell you that you are depressed and are experiencing some form of post-traumatic stress disorder.

You try the psychiatric treatment, but it does not seem to help and are now lumped into the 50% to 80% of individuals that experience symptoms three months after contracting COVID-19.[1] The virus is no longer detectable in the body, but you still experience disruptive symptoms and cannot get back to feeling like your pre-virus self.

How is ME/CFS connected to Long COVID?

You may not have heard about Myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS), but it can be a life altering and incapacitating affliction. ME/CFS shares characteristics to autoimmune illnesses (when the immune system attacks healthy tissues in the body) such as Rheumatoid Arthritis, but tissue damage is not found in ME/CFS patients. Prior to a diagnosis of ME/CFS, patients have reported to have experienced physical and emotional stress before becoming ill. ME/CFS is a diagnosis through exclusion for patients who experience ongoing symptoms for six months. Dr. Anthony Fauci, director of the National Institute of Allergy and Infectious Diseases, has speculated that long COVID is possibly the same or very close to ME/CFS.[1]

While the cause has not yet been pinpointed, researchers are led to believe that an infection, such as Epstein-Barr virus, mononucleosis, Lyme disease, or severe acute respiratory syndrome (SARS), another coronavirus disease, may trigger a change to an individual's auto-immune system.[1]

According to Harvard Health Publishing, consistent symptoms of Long COVID or ME/CFS are:

- Ongoing low-level inflammation in the brain and spinal cord;[1]
- An autoimmune condition in which the body makes antibodies to attack the brain;[1]
- Abnormalities of the autonomic nervous system with decreased blood flow to the brain;[1]
- Difficulty making enough energy molecules to satisfy the needs of the brain and body.[1]

What can be done to help manage Long COVID or ME/CFS

There is currently no way to prevent or cure Long COVID or ME/CFS. Do not overexert yourself post COVID-19 recovery and if you are feeling body aches and extreme weakness, contact your doctor. If diagnosed, a patient needs to manage symptoms and work with their doctor to determine what symptoms are most problematic. If your symptoms are severe, antidepressants and sleep aids may be prescribed along with counseling to manage symptoms.[2] Patients need to pace themselves and not overextend their daily mental, physical, and emotional activity so that it does not take more than 24 hours to recover.

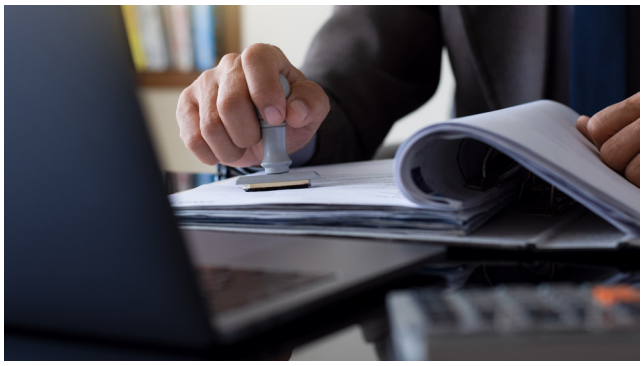
With treatment, some symptoms may improve. However, many people do not return to their pre-illness level or functional state.[2] It is important to listen to your body and minimize stress levels when trying to recover from any infection or virus.

Sources:

1. *"The tragedy of long COVID" Harvard Health Publishing, accessed January 25, 2023, https://www.health.harvard.edu/blog/the-tragedy-of-the-post-covid-long-haulers-202010152479*
1. *"Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS)" Cleveland Clinic, accessed January 25, 2023, https://my.clevelandclinic.org/health/diseases/17720-myalgic-encephalomyelitischronic-fatigue-syndrome-mecfs*

Clinical Spotlight

Patent Thickets & Their Impact on Plan Spend



Big name drugs are facing generic and biosimilar entry after years of exclusivity.

Nine of the pharmaceutical industry's best-selling drugs are losing patent exclusivity in the coming years. Notably, Humira, Keytruda, Revlimid, and Eliquis, the top four of the pharmaceutical industry's best-selling drugs in 2020, are set to face generic and biosimilar entry.

Brand vs Generic Drugs

Generic drugs work in the same way as brand name drugs. Though the names may be different, generic drugs are just as effective as brand name drugs. When a new drug is developed, it is patented and sold under a brand name. When a drug is patented, only the pharmaceutical company that holds the patent is allowed to manufacture the drug. This exclusivity period protects the brand name drug from generic competition. Once the patent or patents on the brand name drug expire, generic versions of that drug may be developed and sold by other companies. Generic drugs are typically about 80-85% less expensive than brand name drugs.[1]

What is a patent thicket?

A patent thicket occurs when multiple additional patents are filed on the same drug. This extends the exclusivity of the drug beyond the end of the initial patent. Five of the top best-selling drugs in the United States have a total of 584 patent applications filed after their initial FDA approval.[2] Patents can be filed on not just the drug composition itself, but on the devices used to deliver the drug as well. For example, Humira has patents on the autoinjector device used to deliver the drug as well as a separate patent for just the "firing button" on the device.[2] Each additional patent can add years of exclusivity to the drug, keeping it protected from generic entry.

How do patent thickets affect cost?

Patent thickets do not allow for competition and can keep a drug from going generic for years or even decades. Without competition in the marketplace, pharmacy benefit managers are unable to negotiate rebates with manufacturers. Rebates reduce the overall costs for prescription drugs. Patent thickets obscuring the ability to negotiate for savings leads to patients paying higher costs for prescription drugs.

Patent Extensions Increase Additional Sales

Humira, Keytruda, Revlimid, and Eliquis pulled in $55.5 billion in sales in 2020 alone. Humira generates around 43% of AbbVie's total revenue while Keytruda generates around 30% of Merck's revenue.[3] Through patent extensions, manufacturers were able to make billions more in additional sales without the threat of competition. Humira, the world's top drug by sales, has over 257 patents attached to the drug which has caused AbbVie to face scrutiny over the years.[3] AbbVie has settled multiple lawsuits since 2017 surrounding its so-called patent thickets and has been subject to a congressional probe. Now, Humira is facing biosimilar competition in 2023, with Amgen launching Amjevita. With Humira facing biosimilar competition, Keytruda is expected to become the world's best-selling drug in 2023. Keytruda will lose market exclusivity sometime in 2028.

Sources:

1. *"Generic Drug Facts", U.S. Food & Drug Administration, accessed January 19, 2023, https://www.fda.gov/drugs/generic-drugs/generic-drug-facts*
2. *"A "Patent Thickets" are Anti-Competitive and Lead to Higher Drug Costs", PCMA, accessed January 19, 2023, https://www.pcmanet.org/patent-thickets-are-anti-competitive-and-lead-to-higher-drug-costs/*
3. *"The top 15 blockbuster patent expirations coming this decade", Fierce Pharma, accessed January 19, 2023, https://www.fiercepharma.com/special-report/top-15-blockbuster-patent-expirations-coming-decade*

Pipeline

Pending drug approvals

Drug name	Manufacturer	Indication/use	Expected FDA decision date
Filgastim (biosimilar to Amgen's Neupogen)	Tanvex	Neutropenia/leukopenia	February 2023
elacestrant	Menarini	Breast cancer	2/17/2023
fezolinetant	Astellas	VMS	2/22/2023
efanesoctocog alfa	Sanofi	Hemophilia A	2/28/2023
trofinetide	Acadia	Rett syndrome	3/12/2023
rezafungin	Cidara/Melinta	Candidemia and invasive candidiasis	3/22/2023
valoctocogene roxaparvovec	Biomarin	Hemophilia A	3/31/2023
tofersen	Biogen	ALS	4/25/2023
mirikizumab	Eli Lilly	UC	4/28/2023
natalizumab (biosimilar to Biogen's Tysabri)	Polypharma Biologics/Novartis	CD; MS	May – Jun 2023
foscarbidopa/ foslevodopa	Abbvie	Parkinson's disease	5/20/2023
nogapendekin alfa inbakicept	Immunitybio	Bladder cancer	5/23/2023
momelotinib	Sierra Oncology/ Gilead	Myelofibrosis	6/16/2023

Brands Losing Patent

Drug name	Manufacturer	Indication/use	Expected FDA decision date
Humira	adalimumab	RA; AS; PSO; PsA; JIA; CD; UC	January 2023
Numbrino	cocaine hydrochloride	Local anesthesia	January 2023
Vyvanse	Lisdexamfetamine Dimesylate	attention deficit problems and binge eating disorder	February 2023
Aubagio	Teriflunomide	MS	March 2023
Gilenya	fingolimod	MS	2023

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

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