

Rx Pulse: Year in Review - 2023

When we look back at 2023, we see five major events. While our latest edition of the Rx Pulse newsletter covers most of these events, below you will find summaries of each topic:

Obesity Drugs and Support Programs

Obesity remains a pressing global health concern, affecting millions and contributing to various chronic diseases while significantly compromising quality of life. In recent years, there has been a growing emphasis on innovative approaches to combat obesity, and the year 2023 marked a significant milestone in this ongoing battle. In addition to Wegovy and Saxenda, the U.S. Food and Drug Administration recently approved Zepbound for chronic weight management. With the introduction of new weight loss medications and support programs, the landscape of obesity management is undergoing a transformation, offering hope to those dealing with this complex condition.

Biosimilars

It's been a busy year for the drug pipeline and new medication launches thus far. Many medications and companies made the news, most recently the release of Humira biosimilars. In January, the US saw its first Humira biosimilar come to market, Amjevita by Amgen. In July, seven more were released. Pharmacy benefit managers (PBMs) are still developing how they are going to incorporate these biosimilars into their formularies, which is something to watch out for in 2024.

Gene Therapy

It is easy to see why gene therapy continues to be a topic of conversation in the industry. Not only are these medications significant from a research and development perspective, but they also have a significant cost associated with treatment, leaving many plans questioning how best to offer these potentially life-altering medications to members without breaking the bank. This question has led PBMs and medical carriers to develop strategies to help plans mitigate the costs surrounding these

Who?

The Rx Pulse newsletter is created to inform clients and VPS partners of everything in the pharmacy industry that may impact employee benefit plans.

What?

In the Rx Pulse, VPS' team of clinical pharmacists write about new and noteworthy topics in the pharmacy world. You can expect to read about pharmacy legislation updates, new drugs to the market, trends we are noticing and more.

Where?

VPS consultants distribute via email with attachments and links to the newest editions. You can also always find our newsletter posted on the VPS Website at valuedpharmacyservices.com.

When?

New editions of the Rx Pulse go live quarterly, typically in the second month of each quarter.

Why?

The goal with Rx Pulse is not only to keep clients and our VPS partners informed, but to help better prepare all parties for the future.

medications. Cigna (Express Scripts), Optum and CVS/Caremark have all developed their own programs to allow plans to purchase gene therapy-related insurance at a per member per month cost to the plan. These programs will likely evolve as more gene therapies are introduced into the market. Gene therapy, and how to cover it, will continue to be a topic of interest in the coming years — if the current drug pipeline is any indication.

Drug Shortages

There were several impactful drug shortages during 2023. Many of them have even continued despite manufacturers' hopes to have them resolved by now. Drug shortages can be caused by several things, including manufacturing quality issues, production delays, increased demand, and delays in receiving raw materials from suppliers. These shortages can lead to negative effects on members' health and in turn increase plan spend on that member. The longer the shortage continues, the more likely it will negatively impact members. The shortages have fluctuated and varied by region and pharmacy (including international impacts), making it hard to predict what members will be impacted and difficult to put a proactive solution in place for members.

Legislation

Insulin Pricing Changes Coming – The American Rescue Plan Act, signed by President Biden in March of 2021, included a provision that eliminated the cap on prescription drug rebates paid by pharmaceutical manufacturers to state Medicaid programs, effective January 1, 2024. This is referred to as average manufacturer's price (AMP) cap removal. As a result, manufacturers could potentially be required to pay rebates to Medicaid that exceed the cost paid by Medicaid. This legislation has led to many insulin manufacturers to lower their list prices for next year.

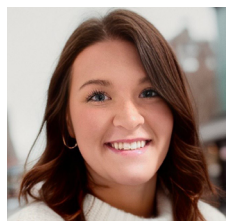
The reduction of the overall cost of the insulin products means that for members with a high deductible health plan (HDHP) or who pay coinsurance for their prescriptions, the out-of-pocket expenses will be lowered. For members who pay flat copay amounts for their prescriptions, the amount may not be different unless the copay was greater than the new product specific cost being offered by the drug manufacturers. .

Court Ruling on Copay Accumulator Programs – Under the Affordable Care Act (ACA), certain insurance plans must limit a member's total annual cost-sharing payments for in-network essential health benefits (EHB) to a specified amount. These essential benefits are determined by the IRS. A 2021 federal regulation permitted plans and insurers to excluded

from the EHB limits the value of drug manufacturer assistance (e.g., coupons) that a member uses to satisfy a cost-share obligation. Essentially this means that any assistance provided through a manufacturer program would not need to be applied toward the member's total annual cost share limit.

In September of 2023, a federal district court called this regulation into question and directed federal regulators to issue a definitive interpretation of the regulation. The court believed that the regulation offered contradictory interpretations of what "cost-sharing" means under the ACA guidelines. In October of 2023, the New York State Department of Financial Services (DFS), who originally brought forth the proposal, announced that they have withdrawn the proposed PBM regulations and have instead adopted a replacement final regulation focused entirely on PBM licensing requirements which are expected to have minimal impact.

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