LOCKTON PHARMACY NEWSLETTER

2nd QTR 2020

THIS QUARTER'S ARTICLES

The Rebate Bubble

Everyone knows the recent 'bubbles' that have impacted the economy in major way: The Dot Com bubble at the turn of the century, the housing bubble that burst in 2008, and the potential impending student loan bubble. In the pharmacy benefits world, there may be another looming bubble: The Rebate Bubble.

Rebates have received a lot of attention in recent years due to the Trump Administration targeting them as one of the possibilities for lowering drug costs and driving transparency in the drug supply chain. While this policy discussion was occurring in Washington, PBM rebate percentages and dollars were reaching record highs for employers, health plans, and the like. Pharmaceutical manufacturers argue that the only way they can achieve these high rebate numbers are by increasing the AWP (average wholesale price). With rebates driving such a large portion of 'savings' that PBMs are proposing to clients to lower costs, rumblings have started in the industry. How much higher can rebates go? Are these rebate proposals sustainable?

With most PBM contracts being a three-year commitment, PBMs are entering into rebate contracts with Pharma companies years in advance so they can provide an accurate proposal to potential clients. That means that PBMs are looking at what the rebate environment will be in 2023 to provide proposals right now.

With that in mind, the pipeline for new drugs, as well as predicted drug utilization of products currently on the market is at the core of a rebate proposal. But what if the pipeline for high rebate drugs is small? And what if the existing highest rebated products are set to lose their patents?

According to industry reports, the top 10 rebated drugs have limited patent life, and 6 of the top 20 rebated products are expected to lose patent protection or have biosimilar competition entering the market between 2020-2023. This represents over 30% of current rebate dollars, with Humira accounting for over half of that amount, followed by Lantus, Januvia, Symbicort, and Victoza.

Due to the reasons above, along with some offset for new pipeline drugs reaching the market, a 15-20% decline in total rebates is projected by the end of 2023. However, a loss in rebates does not necessarily translate into increased costs for a plan. It will be important to account and plan for the dissapearing rebate dollars, but the loss of patents will lead to an increase in generics and biosimilar options that have lower list prices than their branded counterparts. Most of the PBMs and carriers have formulary options that focus more on ingredient cost and less on rebates. If your current strategy for managing pharmacy spend is substantially driven by rebates, it may be time to rethink your plan and begin to pivot towards another strategy such as a more tightly managed generics first formulary and removal of high cost/low value drugs from coverage.

Jonalan Smith, PharmD, FASCP
Senior Vice President

Jonalan has more than 15 years of pharmacy and healthcare experience. As a pharmacist and former managed care organization executive, Jonalan brings broad pharmacy, operational, and clinical experience in Health Plans and government programs.

Jonalan joined Lockton in 2019 to support leading the team focused on developing strategies for employers and health plans to efficiently manage their pharmacy benefit while improving the health of their population.

Rx Savings Programs Available for the Unemployed and Uninsured

As the COVID-19 pandemic continues to impact the global economy, over 30 million Americans have filed for unemployment benefits due to losing their jobs. There are also thousands who have been furloughed and currently retain health insurance benefits but may be exploring options if the furlough becomes a layoff. A few of the first questions many of these Americans ask are – "What will happen to my health insurance?" and "Will I be able to afford my medications?" Depending on an individual's situation there may be the ability to sign up for other health coverage. Outside of that, there are viable options during this time to help, including products and programs aimed at lessening the financial burden of paying full retail prices for prescription drugs.

Even prior to the COVID-19 outbreak, drug discount cards and coupon websites were emerging and offering alternative options to reduce the out of pocket expense for many prescription medications. A drug discount card is a program that provides a discount on drugs when filled at the pharmacy. The drug discount card may be created and marketed by a state or local government, membership organization, non-profit or for-profit businesses. There are also many companies such as GoodRx, Blink Health or RxSaver who provide an online tool and app to find the pharmacy with the lowest price for a specific medication. A coupon can be printed from the website or shown on a mobile app at the pharmacy when filling a prescription. For those consumers using multiple pharmacies to take advantage of the lowest cost option with discount cards and/or coupons, it is important to maintain an accurate list of medications and make all providers aware so they can look for any type of potential problems such as drug-drug interactions, etc. Prices typically vary by medication and by pharmacy; often there is a choice to get the medication filled at a retail pharmacy or delivered to their home through mail order.

Pharmacy Benefit Managers (PBMs) are also developing and launching temporary programs to help those who are unemployed and uninsured which provide deep discounts on many prescriptions. Cigna/Express Scripts' ParachuteRx caps the cost for many generic drugs (30-day supply) at $25 and certain brand name drugs (30-day supply) at $75. Other discount card programs offered through PBMs and pharmacies, such as OptumRx's Perks program, CVS Drug Discount Card and Costco's Member Prescription Program, are available as an additional option for those without insurance.

The drug discount cards and programs provide an avenue to reduce the out of pocket expense for many medications and may assist consumers with remaining on their medications until they return to work.

Ryan Czado, PharmD, MBA
Vice President | Director of Pharmacy

Ryan has 10 years of pharmacy benefit management experience spanning across PBM, health plan and consulting. In his role, Ryan provides clients comprehensive pharmacy consulting services including pharmacy benefit contract procurement and negotiation, claims and financial analysis, clinical consulting and ongoing vendor management.

Ryan earned his Doctor of Pharmacy (PharmD) from Albany College of Pharmacy and Health Sciences and his master's degree of business administration (MBA) from University of Missouri-St. Louis.

More Acronyms: Implications of the NDA to BLA Conversion

What does this mean?

As if we weren't already drowning in a sea of acronyms in the pharmacy benefit business, we now have a couple of more to assimilate. Back in 2009, the Biologics Price Competition and Innovation (BPCI) Act was signed into law. One of its provisions called for biologic products previously approved under the New Drug Application (NDA) process to be handled as if they had instead been approved under the Biologic License Application (BLA) process. As of March 23, 2020, a small, select list of products, which for complex historical reasons had previously been regulated as drugs by the FDA, were deemed to be subject to the provisions of the BLA process instead.

How is the new classification system different from the old classification system?

The NDA system was designed to facilitate the replication of what are sometimes referred to as "small molecule drugs," meaning drugs that are essentially chemicals by nature. Such drugs are created by using what is effectively a "recipe" that starts with a list of chemical ingredients that are combined under specified conditions, and when completed, results in an identical product. We call those identical products "generic drugs".

Insulin and growth hormones aren't small molecule compounds. They are large, complex hormones produced by living organisms. Thus, they are sometimes referred to as "biologics". Because biologics do not have the milestone checkpoints that exist in the manufacturing of small molecule drugs, the NDA system wasn't equipped to evaluate how similar alternative versions of insulin, growth hormone, etc. were to the original, innovator products. The BLA system solves that deficit because it was designed to accomplish precisely that task.

What is the practical difference between the two approval methods?

Generally speaking, both methods assure the safety and efficacy of the products under review. One of the main differences is that drugs approved under NDAs are subject to generic competition at the end of their respective patent lives, while products approved under BLAs are subject to biosimilar competition at the end of their respective patent lives.

Which products are primarily impacted by this transition?

The number of products impacted by this transition is relatively small (88 in total), with two broad categories – insulin & growth hormones – constituting the most impactful categories in terms of pharmacy benefit spend. Certain infertility medications and pancreatic enzymes are also included in the transition.

What are potential cost benefits to clients?

Now that the regulatory pathway to biosimilar competition has been cleared, the historic impediments to lower cost competitive products in the impacted categories will result in greater incentives for lower cost insulin, growth hormone, and other impacted products to be developed and marketed. In the long run, as biosimilar manufacturing capacity increases, allowing biosimilar product prices to decline, the NDA-to-BLA conversion creates the opportunity for savings that the NDA system couldn't produce.

CONTINUED>>

More Acronyms: Implications of the NDA to BLA Conversion

What does the future hold?

It is difficult to predict how many new biosimilar insulin and/or growth hormone products may become available under the BLA system. Manufacturers will have to balance the high costs associated with building and expanding their biologic manufacturing capacity against pricing biosimilar products aggressively vs. their innovator competitors to be able to capture market share.

Bob Kordella, R.Ph., MBA
Chief Clinical Officer

Bob has more than 35 years of diverse experience in the pharmacy industry. Over the course of his career, Bob has led clinical and PBM operations teams in successfully managing more than $4 billion in annual drug spend. This was also while limiting per-member-per-year spending growth to levels that have simultaneously drawn industry acclaim and consistently high levels of member and payer satisfaction.