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Newsletter

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Medication Adherence: Is it a Waste of Money?

There is an old proverb that says, "An apple a day keeps the doctor away." Yet most of the population does not adhere to this prescription for good health. A few reasons for non-adherence could be lack of access, lack of money, or a disbelief in the power of prevention. Whichever the reason, the result is that if not taken as prescribed it cannot work. So, how do you get people to change their behaviors? When we look at medication adherence, this is a common phenomenon and a dilemma that many Plan Sponsors are facing with their population.

Improving medication adherence can be a heavy lift since there are many different factors. Members' lack of adherence could be related to beliefs, inadequate understanding, financial hardships, medication side effects, or even something as simple as forgetfulness. The struggle is that Plan Sponsors do not have control or influence on many of these factors. Yet, there is an inclination to find a solution since nonadherence to medications is linked to higher healthcare costs, in the form of increases in hospital admissions, ER utilization, morbidity and mortality from chronic diseases. While there are numerous studies that point to the cost incurred in the healthcare system from nonadherence, the question remains, How do you get people to be adherent?

Plan Sponsors have options to remove certain barriers by implementing behavioral health programs, disease management programs, $0 copay programs, expanded preventive lists, condition specific care pathways, etc. It is up to the plan sponsor to decide which program would best address the barrier that their population is facing. For example, if financial hardship is a major barrier, then a $0 copay incentive could be the best fit. However, if diabetes is a top cost driver, then an expanded diabetes preventive list to provide coverage before the deductible is met may be adopted. There is a range of interventions and different combinations that have the potential to improve medication adherence and health outcomes.

So, after the apples are provided, how do you prove they are being eaten? The methods for evaluating medication adherence vary as much as the programs. Plan Sponsors can illustrate program effectiveness by reviewing utilization increases in script counts, evaluating care gap closures, or examining longitudinal cohort studies. Medication adherence programs can be beneficial and result in improved outcomes, but they work best when customized for a target audience and when regularly analyzed for effectiveness. The type of analysis to use can be determined based on the type of program implemented and the need to show return on investment. Since these programs are often multifaceted, the measurement can be complicated. In a recent example, Lockton evaluated an employer using a two-year cohort study. The plan offered financial incentives for patients who engaged in the chronic condition management programs. While the adherence results were mixed, there were improvements in other measures, such as preventive care visits, to where the plan sponsor decided the program was worth the investment.

Lockton can help Plan Sponsors understand the impact of these scenarios, evaluate strategies to mitigate their impact on Plan Sponsors and participants, and allow for an informed decision that balances the pharmacy benefit with the Plan Sponsor's benefit philosophy and budget

Shavsha Davis
Assistant Vice President

Shavsha is an experienced Pharmacy Benefits consultant with a demonstrated history of working in the insurance industry. She works as part of a team which analyzes behaviors, Plan performance and marketplace trends, while providing strategic thinking and vision for clients.

Shifting Focus: From COVID Vaccines to Easily Accessible Treatments

Much of the emphasis over the last year of the COVID-19 pandemic has been on vaccines. Are they safe? Who is eligible? Which vaccine is "better"? When and how to boost? Recently, though, two new drugs have emerged from clinical trials that are showing substantial promise in treating COVID-19 infections with doses that could be obtained from retail pharmacies and taken at home.

Treating viral infections with oral antiviral medications isn't a new concept. Viruses as diverse as HIV, herpes, hepatitis C, and influenza each have oral prescription medication treatments that are readily and conveniently available from retail or mail service pharmacies. Since time will be of the essence in starting COVID-19 treatments (as it is with treating influenza), local retail pharmacies will likely be the predominant dispensing channel. Having such treatments for COVID-19 will add another tool to the treatment toolbox in reducing disease severity, hospitalization, and death associated with COVID-19.

Molnupiravir — Merck

On Oct. 1, 2021, Merck announced clinical trial results for molnupiravir that showed that a dose of 600mg every 12 hours for five days reduced the risk of COVID-19-associated hospitalization or death by about 50%. On Oct. 11, 2021, Merck applied for an expanded use authorization to the FDA. On Nov. 26, 2021, Merck announced an update on the observed efficacy of molnupiravir that reduced its expected efficacy to 30% from 50%. The FDA's Antimicrobial Drugs Advisory Committee (ADAC) met on Nov. 30, 2021, and voted 13-10 that molnupiravir's potential benefits to reduce hospitalizations and deaths from COVID-19 outweighs its risks, which were also discussed in depth. As of Dec. 3, 2021, the full FDA has not yet decided whether or not to grant an EUA for molnupiravir, but it typically follows the ADAC's recommendations, though it is not required to do so.

The U.S. government placed an initial order for 1.7 million courses of molnupiravir at a price of approximately $700 per five-day treatment course, and expanded that initial purchase on Nov. 9, 2021, through the exercise of two more purchase options for 1.4 million additional courses of molnupiravir, bringing the total to 3.1 million courses at a price of approximately $2.2 billion. Until these government-purchased treatment courses have been exhausted, pharmacy benefit plans will not incur any expense for molnupiravir itself, although as with vaccines, dispensing fees by pharmacies may be incurred. The U.K. granted molnupiravir its first conditional approval on Thursday, Nov. 4, 2021, although it was not immediately clear how soon it will be available to patients.

Paxlovid (PF-07321332; ritonavir) — Pfizer

On Nov. 5, 2021, Pfizer reported clinical trial results that showed that its investigational oral COVID-19 treatment, Paxlovid (PF-07321332; ritonavir) was 89% effective in reducing the risk of COVID-19-related hospitalization and death in patients with mild to moderate COVID-19. Patients took the drug either within three days or within five days of a confirmed COVID-19 diagnosis. Part of Pfizer's superior results vs. Merck's molnupiravir may be attributable to the arm of the study that started treatment within three days of diagnosis since earlier antiviral treatment typically leads to better results, and molnupiravir was administered within five days of a confirmed COVID-19 diagnosis only. Of note, Paxlovid is a combination of an as yet unnamed Pfizer proprietary compound currently referred to as "PF-07321332," and ritonavir. Co-administration of PF-07321332 with a low dose of ritonavir slows the breakdown of PF-07321332 by the body allowing it to remain in the body longer and facilitate the twice daily dosing, five-day long treatment regimen. On Thursday, Nov. 18, 2021, Pfizer reported that the U.S. government

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will pay around $5.3 billion for 10 million treatment courses of Paxlovid (~$530 per treatment course), pending FDA approval. Earlier that same week, the company filed for emergency use authorization to treat mild to moderate COVID-19 in patients at higher risk of hospitalizations or death.

As with molnupiravir, until all of any government-purchased treatment courses of Paxlovid have been exhausted, pharmacy benefit plans will not incur any expense for Paxlovid itself until those supplies have been depleted, although pharmacies may charge dispensing fees for dispensing the government-purchased medications.

While it is impossible to say at this time how closely U.S. government pricing will compare with both products' eventual retail pricing, we assume both products will be available from retail pharmacies. The exact distribution channel and availability are unknown at this time.

Both of these oral treatments are potential game-changers in the fight against COVID-19 as we move from the vaccine/prevention phase to active treatment. Both products will impact your pharmacy benefit in the long run, after government purchased supplies have been exhausted.

Robert Kordella, RPh, 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.

Value Based Contracting Is Starting to Evolve with Pfizer's New Warranty Program for Oral Cancer Therapy Xalkori

With high-cost specialty drugs being approved at a record pace, value based contracting in pharmacy benefits has become more relevant as a means of controlling costs for Plan Sponsors. Drug manufacturers are looking to maximize the use and market share of their products and as a result, are often willing to tie the overall clinical performance and effectiveness of the drug to the cost. We have seen these types of programs in Cigna/Express Scripts' SafeGuardRx programs and many other health plans across the industry leveraging these arrangements in their rebate negotiations with drug manufacturers. As the drug manufacturers look to continue to innovate, Pfizer quietly launched a pilot warranty program in early October for one of their oral lung cancer therapies that will provide a refund to both members and plan sponsors (including Medicare Part D) if the drug is discontinued in the first three months of therapy for clinical reasons.

The oral cancer drug, Xalkori, was initially approved by the FDA and originally brought to market by Pfizer in 2011 for the treatment of advanced non-small cell lung cancer (NSCLC). In January 2021, Pfizer received approval for an expanded indication of Xalkori for the treatment of pediatric patients and young adults with relapsed or refractory systemic anaplastic large cell lymphoma (ALCL). Pfizer's new pilot program, called Pfizer Pledge, will refund both the member and the plan sponsor up to a maximum of $19,144 for each bottle (30-day supply) or an aggregate maximum of up to $57,432. There are, of course, eligibility requirements that must be met to qualify for the refund:

- The member must be prescribed Xalkori for the treatment of an approved indication.
- There must be a documented clinical reason for the discontinuation of the use of the drug. This must be submitted by the prescribing physician as part of the process.
- The pilot program includes claims processed from June 1, 2021 through Dec. 31, 2021, so there is a limited timeframe of potential claims that may qualify. The request for refund must be submitted within 120 days of the claim for the last bottle of Xalkori.
- The discontinuation of the drug must have happened within the first three months (before the fourth fill of the drug).
- There are both member forms and prescriber forms that must be completed and submitted (along with receipts) to Pfizer to qualify for the refund.

The Pfizer warranty program differs from other current value based programs in many aspects. The member and plan receive full refunds for their respective cost of the drug. The warranty program closely resembles that of a typical warranty a consumer receives with a purchase of a new appliance and puts the onus on the prescriber and patient. Pfizer is leveraging an insurance company to be the intermediary to handle the claims for the refund which allows for the manufacturer to steer clear of any violation of federal anti-kickback statutes or best price concerns (for government sponsored plans). While this program has not garnered a lot of attention due to the quiet roll out, we anticipate other manufacturers may follow with launching similar programs for drugs that have been successful in their indications. While we support the concept of value based contracting, this process may limit any real effectiveness or recoupment for plan sponsors.

For more information on the program, please contact the Lockton Pharmacy team and we can help evaluate if there are any potential opportunities for refund within your plan.

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Pharmacy Practice Leader

Ryan is director of pharmacy solutions for Employee Benefits in Lockton's Northeast Series Boston office. In this role he provides Lockton Northeast Series clients with comprehensive pharmacy consulting services, including prescription benefit contract negotiation, claims and financial auditing, and ongoing vendor/contract management. These services help reduce plan prescription costs by identifying clinical and ingredient cost savings opportunities across the entire pharmacy benefit.