PRO PHARMA
PHARMACEUTICAL CONSULTANTS, INC.

Pharmacy Benefit News

Issue #328 | May 31st, 2018

01 | Commentary: What Is the FDA Approval Process?

Several people have asked what the Food and Drug Administration (FDA) approval process is? What does it mean to be in Phase I-III? As a service let us offer a quick summary.

Before a new drug can reach consumers, it must first be approved by the FDA Center for Drug Evaluation and Research.

> Preclinical
--Identify a new medication/compound or therapy
--Preclinical testing
--Investigational new drug application

> Clinical Trials in patients
--Phase I: Clinical Trial – determine safe dosage
--Phase II: Clinical Trial – determine safety and effectiveness
--Phase III: Clinical Trial – comparison to standard treatment(s)

> New Drug Application (NDA) and FDA Analysis
--Submit clinical trial evidence as well as a New Drug Application (NDA) to the FDA
--FDA analyzes the target condition and available treatments
--FDA assesses safety and effectiveness, benefits, and risks
--FDA reviews appropriate labeling and quality control
--Consideration for accelerated approval – applies to promising therapies for life-threatening conditions

> Post Market Surveillance

Other countries have similar processes, but not identical. The key features are the clinical trials and NDA process that drive the fundamental questions of safety and efficacy, i.e., effectiveness. Post marketing surveillance is designed to identify any safety issues when the drug is exposed to a large US population.

Analytics At Work | Retrospective Audit

Problem: A common request these days is -- Can an audit help me to understand why costs are high, when my PBM is not helpful? At the same time other PBMs say they can help, but I am not sure if this is just marketing. A client contacted us for an expedited Retrospective Audit to determine the drivers of cost and the options available for change.

Methodology: Pro Pharma performed a Retrospective Audit including tests for eligibility, benefit compliance, brand and generic pricing, specialty pricing/utilization, benchmarking to national and local standards, and transparency in bases of cost. The Audit was expedited through the use of 100% electronic/digital analyses to facilitate quick turn-around time to significantly reduced Audit Costs, and available for desk and mobile devices.

Findings included potential problems with formulary claims that were coded as Brand when the Plan Expected Generics; problems with transparency such that AWP was inflated from national reference databases; specialty approved for total Rx without tests for FDA approvals, quantity, dosage and companion diagnostic tests; pricing above benchmarks, discount generic programs, Medicare/Medicaid when applicable, and patients paying more than cost of drug.

Outcome: The client used the findings to redirect coding options to include only Generic formulary options for multisource (especially timed-release products), OTC, store brands and private labels. They worked with the PBM to correct inflated AWP issues, and variances from Medicare and Medicaid. They moved specialty to Prior Authorization (PA) and improved criteria. They expanded the benefit to include payments for discount generic programs and removed zero-balance options. The result was normative pricing that was measurable and validated, low single digit point-of-sale trends, and a solution for analyzing future spend.

The client felt that they now had control, as they were equipped with a plan, an understanding of the drivers of cost, a solution for matching actual spend to expectations, and improved satisfaction.

Learn More >

02 | Commentary: Access, Coverage, & Affordability. What the Patient Wants!

One argument in the continuing debate about the Affordable Care Act (ACA), i.e., Obamacare, is the lack of subsidies to pay for the care of low income peoples.

The subsides were included in the ACA based on the Medicaid populations of each state. States that fully expanded Medicaid received greater subsidies to treat their Medicaid population. However, since subsidies have not been paid, there is less money to pay for the State's low-income population. A further result is that patients will use emergency rooms as sites for preventive and primary care. This impacts all patients who use the emergency room and urgent care centers for crises, as access is impacted for everyone. This situation is like pre-ACA times, but it is not an efficient or affordable method for receiving care.

What to do? Patients need coverage for their medical conditions and access to quality care. Unfortunately, the health care debate has revolved around affordability which is only one aspect of the problem. The real issue is to manage access, coverage and affordability at the same time. Managing people as populations, not as targets for payment, can lead to better options for global reform. The emphasis needs to be placed on the patient and not the method of payment.

It is necessary to anchor the coverage and access problems, in order to accomplish the population model. For example, people who are afraid of losing coverage, or have pre-existing conditions, or have behavioral health or substance abuse problems, need some assurance that coverage and access will be guaranteed. The patient population then needs to be grouped by health care need and severity so that appropriate quality care is provided to each group to accomplish this. When done efficiently, costs can be reduced.

Pro Pharma has had extensive personal client-related experiences over decades with this approach, but so have hospital systems like Aurora Health Care and Dignity Health, integrated care networks like Mayo and Cleveland Clinics, integrated managed care plans like United Healthcare and Kaiser Permanente, some individual provider groups, etc. The problem is to expand the process across the entire health care system.

Where do we focus our efforts? First, focus on the patient. That focus drives the need. Second, focus on the data so that all providers (physicians, nurses, pharmacists, etc.) have the requisite information to manage their services. Third, focus on the long term. This is not a light versus darkness. It is an evolving process!

Learn More About Pro Pharma >

Professor Speaks | Watch the Latest Episode

Weekly Discussion on Issues that Matter.

New Episodes available Fridays on YouTube.

Watch the Latest Episode >

03 | Commentary: Do Generics Bend the Cost Curve?

Historically, generics provided a lower cost option to branded medications. More specifically, generics represented approximately one-fifth the cost of a standard brand prescription for 30 days.

However, because the cost of drugs continues to rise, manufacturers continue to consolidate, and the generic dispensing rate is more than 82-84%; there isn't much room to be able to decrease overall cost.

Based on 2017 data, prescription drugs represent 10% of the US Healthcare spend. Brands represent about 18% of utilization, but about 78% of the cost. Generics prices, on the other hand, decreased about 59%. Alternatively, over 103 generic drugs experienced price increases over 100% in Medicare Part D from 2014-2015. The result is that drug cost is still driven by brands, and

brands are increasing in cost led by specialty medications that cost on average $1500 per dose, as compared to approximately $150 per brand prescription per month.

While emphasis has always been on cost, affordability is just as important. Aligned with cost and affordability are the dual requirements for therapeutic benefit and minimizing risk. Utilization is a cost multiplier and impacts both benefit and risk.

What to do? We need to keep our focus on cost but learn to manage multiple components at the same time, i.e., cost/affordability, benefit, risk and utilization. This sounds like a math problem, and it is. With analytics – including data, math, benefit, and risk – we have a better chance of helping to manage the health care spend as a whole.

About | Pro Pharma

Pro Pharma is a woman owned pharmaceutical consulting firm. Established in 1986, Pro Pharma's services are built on a foundation of data analytics, which are then communicated to the client which provide results and recommendations.

Pro Pharma provides customized support to Health Plans, Self-Insured Employers, Physician Groups, and Workers' Compensation Companies, among others, both in the private and public sectors.

Learn More About Us >