PRO PHARMA
PHARMACEUTICAL CONSULTANTS, INC.

Pharmacy Benefit News

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COMMENTARY |

Recall of ARBs Is Bad News, Maybe

Generic versions of Angiotensin II Receptor Blockers (ARBs) have been recalled by the FDA (starting in summer of 2018). These medications treat high blood pressure and heart failure. The story is now well-known. Some generic versions were identified to contain nitrosoamines, i.e., N-Nitrosodimethylamine) impurities that could cause cancer. Essentially, the impurities did not meet the FDA's safety standards. Nitrosoamines are also environmental contaminants found in water and foods including meats, dairy products and vegetables. No one seems to be talking about the level of impurities as de minimis.

On the positive side, not all ARBs were recalled. The FDA did approve Valsartan (Diovan®) from Alkem Laboratories (March 12). The FDA also identified 40 ARB medications that don't contain nitrosoamines. Finally, the FDA did not object to temporary distribution of specific lots of Losartan that contain impurities above the "interim acceptable intake limit" for short-duration therapy.

It is also interesting that no one is bring up the alternative to ARBs, i.e. Angiotensin Converting Enzyme Inhibitor (ACEI). The marketing argument for ARBs was that they did the same thing as ACEI but did not produce "ACE coughs". The occurrence of ACEI induced cough is about 10%, and half of those patients may require the ACEI to be discontinued. The ACEI cough is a dry cough that usually persists with continued coughing usually for 2 weeks

offered as an alternative. However, impurities may be the rationale to revisit the marketing argument in favor of ACEI.

ANALYTICS AT WORK |

Medical Specialty Rebates

Pro Pharma Provides Complete Transparency to Medical Specialty Rebate Collections to Lower the Cost-of-Goods Sold

This program provides fully transparent identification, analysis, submission and collection of Medical Specialty utilization for payers and manufacturers.

Contracts are between Plans/Employers/Coalitions and Manufacturers to ensure complete knowledge of submissions and payments. All results are documented for accounting purposes.

Summary Analysis Outputs:

- Provide an output Rebatable Drug File with filters for potential 340b Providers and supporting NDC codes for Rebate review
- Manage the preparation and submission for rebate collections and overall management of manufacturers for recovery of fees for every rebate receipt
- All data submitted to manufacturers is sterilized to remove individual identifiers of patients and physicians

Implementation and Process:

1. Analyze 12 months of medical data to help you decide which manufacturers to contact and which drugs to select
2. Arrange for manufacturer contracts for selected drugs
3. Submit usage data to the manufacturers for applicable rebates
4. Validate rebate receipts, including valid deductions for accounting

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COMMENTARY |

Common. Is this wise use of drugs?

There is a 21% chance (that is 1 in every 5 prescriptions) that prescriptions written by office-based doctors for common prescribed drugs is for off-label uses. “Off-label” means that the doctor is prescribing a medication that is not FDA approved for a patient’s diagnosis. Off-label also refers to prescriptions for age groups, dosages, and durations that are beyond the package insert labeling approved by the FDA. This is entirely legal, and the physician does not have to inform the patient. Both the American Medical Association and the American Psychiatric Association support this practice.

However, there are few studies to support the use of off-label prescriptions, and little evidence if they are effective or safe. This is clearly not evidence-based medicine.

Why does this happen? Doctors learn of these uses from medical conferences, case studies in journals and posters, and from each other. For example, Gabapentin is an anticonvulsant frequently used for neuropathic pain. Propranolol that is approved for high blood pressure and rapid heart rates is often used off-label for anxiety.

Drug manufacturers have profited handsomely from this practice, but they are not the only "bogeyman". The drug cost does not change for label versus off-label uses of drugs. So, the market expands when drugs are used off-label. Patients frequently ask prescribers for medicines taken by family or friends without knowledge of labeling. Physicians have read case studies of particular uses without regard to labeling. On-line chat rooms for HIV/AIDS, women’s health and other hot topics, frequently talk about off-label uses of drugs.

What to do? In a world driven by evidence-based reviews of doctor prescribing, lowering prescription cost and transparency in pricing, value-based contracts for therapy based on whether the drug works or not, the needle is moving to effectiveness and safety. People are asking why a drug costs so much? Ask your doctor and pharmacist if the drugs you are taking are for approved indications. In the current environment, either a drug works or not. Either it is safe or not. Off-label may be legal, but it is an experiment. Make sure that everyone knows enough, prescriber pharmacist and patient, to ensure

expensive!

(This commentary was suggested by an article in the AARP Bulletin)

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COMMENTARY |

Drug Cost Inflation vs. Improved Effectiveness

The Institute for Clinical and Economic Review (ICER) published a study in October 2019 indicating that 7 drugs increased drug spending in the United States by $5.1 billion between 2017 and 2018. Three of the drugs were Humira at 15.9% increase, Rituxan a 23.6% increase and Lyrica a 22.2% increase. Yet certain information is not commonly published. What is the percentage improvement in effectiveness for each of these drugs over current therapies? Are the improvements in effectiveness equal to, or more than, the cost inflation?

Differences of one standard deviation between the drug and placebo group are uncommon. Examples of medications that are one standard deviation, or more, are Proton Pump Inhibitors (e.g., Prilosec, Omeprazole) and Oxycodone plus Acetaminophen for post-operative pain. Yet, compared to placebo antihypertensives lower blood pressure by 5mmHg diastolic on average. Antidepressants lower depression about 17% lower than placebo, and aspirin lowers primary cardiovascular events by 0.07% per year vs. placebo. Data on expensive specialty medications relating to effectiveness is not well studied. Benefits are usually in compliance. New medications to treat previously untreatable conditions is an example of significant effectiveness.

The critical point here is that initial drug price and continuing annual cost inflation must demonstrate a benefit that is equal to or greater than the comparative benefit of the drug to placebo or current therapies. Simply, if the benefit is 10% above the current therapy, then the cost inflation should not be more than 10%.

New life-saving treatments are exceptions to this concept, but later annual cost inflation is not. Humira, Rituxan and Lyrica have proven their benefit, so one can question why do they require double-digit price inflation.

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ABOUT | Pro Pharma

Pro Pharma is a woman owned healthcare analytics and 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.

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