The Pharmacist Activist

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Editorial

The Chaos of Prescription Drug Benefit Programs

I do not think of another issue that causes more frustration and financial concerns for pharmacists than prescription drug benefit programs. We are well aware of the many inequities and other problems associated with these programs; however, the complexities of these programs are sufficiently confusing to patients, employers who fund the programs, and legislators that we often fail in having them understand our concerns and support us in resolving them. We must do a better job in educating those whose support we need in addressing these challenges.

We must not assume that others even have a basic understanding of the inequities that are of such great concern to us. Accordingly, we must communicate our concerns in the clearest manner possible and I recommend that the following issues be included in our message:

1. The terms and other conditions of the program, including the compensation for drug product costs and professional fees, are established unilaterally by insurance companies and/or pharmacy benefit managers (PBMs) without consultation with the pharmacists they expect to participate in their programs.

2. Contracts for participation in a program are provided to pharmacists by insurance companies and/or PBMs on a "take it or leave it" basis. Individual pharmacists have no opportunity or influence to negotiate different terms of a contract, and groups of pharmacists and professional associations of pharmacists are prevented from negotiating by federal antitrust laws.

3. Some prescription drug benefit programs require certain patients being treated with medications for chronic conditions to obtain these medications from a mail-order pharmacy. This requirement fragments the provision of medications and pharmacy services to these patients and increases the risk of drug-related problems because the different pharmacies do not have a complete record of the medications prescribed for these individuals.

4. Some prescription drug benefit programs provide financial incentives to patients to obtain certain medications in a 90-day supply from a mail-order pharmacy. However, local pharmacies are prevented from dispensing more than a 30-day supply. The mail-order pharmacy is permitted to provide a 90-day supply of medication for two copayments or one copayment, whereas a patient would have to pay three copayments to obtain a 90-day supply (as three 30-day supplies) of the

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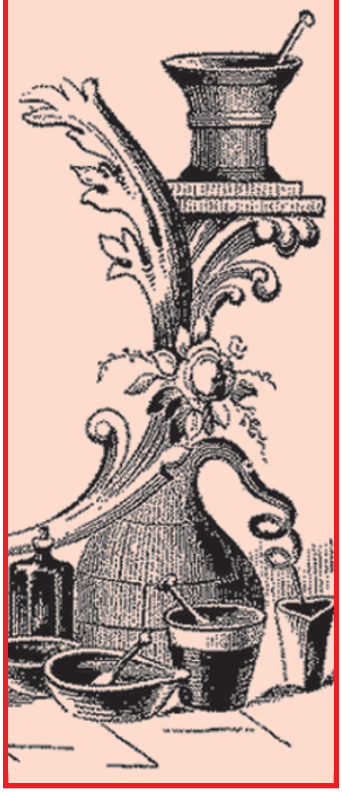

medication from a local pharmacy. When local pharmacies have sought the right to dispense a 90-day supply of medication as a mail-order pharmacy is permitted to do, they are usually denied that opportunity.

5. Formularies and other program restrictions often excessively limit the therapeutic options available to prescribers in treating their patients. When pharmacists or other pharmacy personnel seek clarification or prior authorization in endeavoring to assist a patient, they often spend long periods of time "on hold" on the telephone or encounter other delays in attempting to resolve questions and other issues.

6. There is little understanding of who receives how much money when a prescription is dispensed. For example, if a prescription for a "brand-name" medication has a value of $100.00, what amount would typically be received by each of the following?

Pharmaceutical company	$
Pharmaceutical wholesaler	$
Insurance company	$
Pharmacy benefit manager	$
Pharmacy	$

We know that the pharmacy dispensing the medication receives only a very small fraction of the total cost of the prescription. However, our patients, their employers, and legislators do not know that because we have not done a good enough job in calling this to their attention. Because the dispensing of a prescription occurs in the pharmacy, there may even be reason for some to think that the pharmacy receives a large fraction of the cost of a prescription. This type of information is essential in our efforts to achieve understanding of the financial concerns of pharmacists, and one of the national pharmacy associations should develop the best estimates of these revenues for at least the ten most frequently prescribed brand-name drugs.

7. Copayments are a source of great misunderstanding for patients that pharmacists have done far too little to clarify. For example, if a patient provides a copayment of $25 at the time he obtains a prescription, he has reason to assume that this is the pharmacy's compensation and may even think that the pharmacy has additional sources of income from that prescription. I believe that patients and others will be supportive in helping to address the financial concerns of pharmacists when they have a good understanding of how small a fraction of the cost of a prescription is actually received by the pharmacy.

8. Some insurance companies and pharmacy benefit managers utilize audit procedures that are intrusive and unfair. Inappropriate allegations of fraud are sometimes made based on errors in recording numbers or other minor mistakes. Data gleaned from reviewing a sampling of prescriptions is sometimes extrapolated to larger numbers of prescriptions and extended periods of time. Financial arrangements with some auditors provide compensation that is based, at least in part, on the amount of the financial penalties recovered from those audited, thereby providing an incentive for extrapolation of findings based on limited data and other questionable procedures.

9. The professional fees provided in most prescription drug benefit programs are insufficient for pharmacists to provide the comprehensive services and consultation that are needed to assure drug therapy for their patients that is as effective and as safe as possible. If a prescription drug benefit program is to be provided at all, it should be structured and funded in a manner that optimum benefits can be derived and drug-related problems avoided. Providing inadequate fees to pharmacists that will support only a minimum level of services is a grossly misguided strategy (involving one of the smallest components of the total cost of a prescription) that will subsequently result in even greater expenses to manage the drug-related problems that could have been avoided. However, most insurance companies and PBMs will not even conduct studies to determine the amount of equitable professional fees for pharmacists as long as they can get away with dictating "take it or leave it" terms of their programs.

10. Transparency has been lacking in many of the prescription drug benefit programs developed by insurance companies and PBMs. Federal and state agencies have alleged inappropriate practices in some of these programs that are typically settled for millions of dollars with no acknowledgement of wrongdoing.

There are so many important problems with most of the current prescription drug benefit programs that it would be easy to conclude that these programs are so broken that it is impossible to fix them. New models and strategies for these programs must be developed and this will be the subject of a future editorial. However, these will take time to be developed and accepted and we must increase our commitment to improve the programs we have now before they have even more devastating consequences for our profession and our patients.

Daniel A. Hussar

New Drug Review

Ciclesonide
(Omnaris – Nycomed)
Corticosteroid

New Drug Comparison Rating (NDCR) = 3

(no or minor advantages/ disadvantages)

in a scale of 1 to 5, with 5 being the highest rating

Indication:

Administered intranasally for the treatment of nasal symptoms associated with seasonal allergic rhinitis in adults and children 6 years of age and older, and for the treatment of nasal symptoms associated with perennial allergic rhinitis in adults and adolescents 12 years of age and older.

Comparable drugs:

Corticosteroids in nasal spray formulations: Beclomethasone dipropionate (Beconase AQ), budesonide (Rhinocort Aqua), flunisolide (e.g., Nasarel), fluticasone furoate (Veramyst), fluticasone propionate (e.g., Flonase), mometasone furoate (Nasonex), triamcinolone acetonide (Nasacort AQ).

Advantages:

- Administered once a day (compared with beclomethasone dipropionate that is administered twice a day and flunisolide that is administered two or three times a day).

Disadvantages:

- Has not been directly compared with other intranasal corticosteroids in clinical studies;
- Labeled indications are more limited (compared with beclomethasone dipropionate that is also indicated for nonallergic rhinitis and for the prevention of recurrence of nasal polyps following surgical removal, fluticasone propionate that is also indicated for nonallergic rhinitis, and mometasone furoate that is also indicated for prophylaxis of nasal symptoms of seasonal allergic rhinitis and the treatment of nasal polyps);
- Use in pediatric patients is more limited (compared with fluticasone furoate and mometasone furoate that are indicated for the treatment of seasonal and perennial allergic rhinitis in children as young as 2 years of age and fluticasone propionate that is indicated in children as young as 4 years of age);
- More expensive than intranasal corticosteroids that are available in generic formulations (flunisolide, fluticasone propionate).

Most important risks/adverse events:

Risk of acute adrenal insufficiency if a systemic corticosteroid is discontinued and replaced with a topical (e.g., nasal) corticosteroid such as ciclesonide; suppression of the immune system increases susceptibility to infection; immediate hypersensitivity reactions have been rarely reported; may delay wound healing in patients who have had recent nasal surgery or nasal septal ulcers (should not be used until healing has occurred); patients who are treated for several months or longer should be examined periodically for evidence of Candida infection; may cause a reduction in growth velocity when administered to pediatric patients.

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New Drug Review (cont.)

Most common adverse events (in patients aged 12 years and older):

Headache (6%), epistaxis (5%), nasopharyngitis (4%), ear pain (2%).

Usual dosage:

200 mcg per day administered as two sprays (50 mcg/spray) in each nostril once a day.

Product:

Nasal spray – 50 mcg/spray; is a metered dose, pump spray containing 120 metered doses; following removal from the foil pouch in which it is supplied, the bottle should be discarded either after 120 sprays following initial priming or after four months; bottle should be shaken gently prior to administration; before the first use, the pump should be primed by pressing on the applicator eight times.

Comments:

Ciclesonide is a prodrug that is enzymatically hydrolyzed by esterases in the nasal mucosa to a pharmacologically active metabolite, des-ciclesonide. Its effectiveness in the treatment of seasonal and perennial allergic rhinitis has been established in placebo-controlled studies, but it has not been directly compared with other intranasal corticosteroids in clinical studies. The onset of effect was seen within 24 to 48 hours with further symptomatic improvement observed over one to two weeks in seasonal allergic rhinitis and five weeks in perennial allergic rhinitis.

Ciclesonide was initially approved in October 2006 but was not marketed until 2008. Its initial approval for use in patients 12 years of age and older was expanded in 2007 to include children 6 to 11 years with seasonal allergic rhinitis. In early 2008 a formulation for oral inhalation (Alvesco) was approved for the treatment of asthma but has not yet been marketed.

Daniel A. Hussar and Kristen M. Albright*

**Kristen M. Albright, Pharm.D. was a candidate for her Doctor of Pharmacy degree at the time she participated in the preparation of this review. She is now a Senior Therapeutic Specialist at Centocor Ortho Biotech Services, LLC.*