The Pharmacist Activist

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Editorial

Prescription Benefit Programs – A NEW MODEL IS NEEDED!

My editorials in the last two issues of *The Pharmacist Activist* have addressed problems associated with prescription benefit programs ("benefit" is emphasized so that we do not forget that individuals are receiving products and services for which much of the cost is being paid by another party). These problems are of such great importance and scope that they deserve our priority attention. However, it seems that the profession of pharmacy is often in a defensive position – we are reacting to problems in existing programs and trying to fight off changes that are planned that are even more coercive, restrictive, and inequitable than provisions in the current programs. It has been said that "the best defense is a good offense," and this is the direction we must take.

There are three basic components of a prescription benefit program: 1) a patient with a prescription; 2) the dispensing of the prescription by a pharmacist; and 3) payment for the process. The local pharmacy, and not an insurance company or pharmacy benefit manager, is strategically positioned to assume the primary responsibility for this process and should be compensated accordingly. We must devote the time, effort, and resources to develop a new model for prescription benefit programs that will 1) optimize the effectiveness and safety of medications for patients; 2) use the expertise and monitoring skills of pharmacists in attaining the best possible therapeutic outcomes for patients; 3) use drug therapy options in selected situations that reduce costs without compromising the effectiveness and safety of treatment; and 4) provide equitable compensation for pharmacists.

The recommendation of concepts (and some specifics) that should be incorporated into a model prescription benefit program is the focus of this commentary. I am optimistic that a program can be designed that is so much better than the ones that have evolved over the past 40 years that its value will be obvious to patients, payers, and pharmacists. So let's get started! We need to establish a framework that others with greater expertise regarding economic parameters than I have can build into a program that can be clinically, professionally, and economically successful.

1. Medications covered – The program will provide benefit coverage for prescription medications, as well as selected nonprescription medications (e.g., omeprazole, loratadine, pseudoephedrine) for short-term use for which the pharmacist documents consultation and initiates the claim for payment.

2. Patient access to program – The local pharmacy has the most complete record of a patient's medications, regardless of the method of payment, including prescription medications, nonprescription medications, prescription medications that cost less than the copayment, and medications that are not covered by a benefit program. In addition, the local pharmacy has personal knowledge regarding patients (e.g., previous drug-related problems) learned through consultation with patients. Therefore, in the model program, a patient brings all prescriptions to a single local pharmacy. The pharmacists at this pharmacy assume the responsibility for the provision of all medications and related services and monitoring. This arrangement does not preclude the participation of a compounding or other specialty pharmacy, or the provision of medications through the mail; however, such arrangements must be coordinated by the local pharmacy of record. The program will also include situations when it becomes necessary to obtain medications while traveling.

3. Maintenance (long-term) medications – Maintenance medications are provided in 30-day supplies.

4. Preferred drugs – With certain therapeutic classes of medications, there is no evidence of

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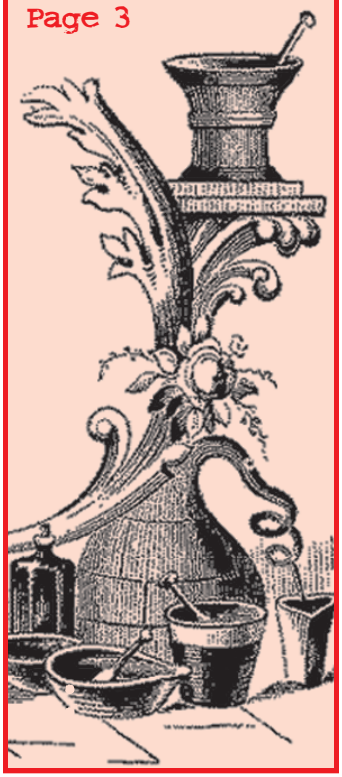


clinically significant differences in effectiveness and safety among the drugs, and there are not likely to be adverse consequences as a result of using one drug rather than another drug in the class. In these situations, a "preferred drug" may be identified and a "therapeutic class price" established. This does not preclude a physician from prescribing another drug in the class, but the patient will incur a higher cost.

5. Copayments – The copayment amounts will vary depending on the level of coverage the payer wishes to provide. The following is one example of a copayment schedule. For generic medications, the copayment is $10.00 for a 30-day supply. For brand-name medications, the copayment is $25.00 for a 30-day supply. For drugs in a therapeutic class in which a preferred drug and a therapeutic class price are designated, the copayment for a higher-priced, brand-name drug is the difference in the cost of the products plus $25.00 for a 30-day supply for the brand-name medication.

6. Product cost reimbursement – The reimbursement for a pharmacy's cost of a medication is based on the amount designated on the invoice. This "invoice cost" is "acquisition cost" but does not include trade discounts to induce early payment. A range for the invoice cost for a medication will be established by the program administrator based on this information that is provided by the pertinent pharmaceutical companies and wholesalers. The program administrator will update the costs of medications on a daily basis.

   The implementation of a program that utilizes invoice cost as the basis for the reimbursement of the cost of a medication must be accompanied by the provision of an equitable professional fee required for optimum patient care.

7. Professional fee – The fee for the pharmacist's services should be $15.00 (in 2009 dollars) when a prescription is dispensed. The fee will be reviewed on an annual basis and adjusted by an amount that is at least equivalent to the change in the cost of living.

8. Payments to pharmacies – The program administrator will pay pharmacies the sum of the product cost and professional fee, or the pharmacy's usual and customary charge or advertised price, whichever is lower. Payments will be made to pharmacies within 10 days of receipt of the claim. The goal will be to establish systems through which payment for most prescriptions will be provided at the time of receipt of the claim.

9. Services for patients – A pharmacist or pharmacy student must personally counsel a patient or caregiver regarding the use of the medication(s) dispensed. If it is not possible to provide counseling in the pharmacy, counseling may be provided via a telephone discussion.

   A pharmacist or pharmacy student must maintain communication with patients to the extent that permits assessment of compliance and, as needed, the initiation of follow-up measures. Participating pharmacies should establish a refill program in which all refills for maintenance medications should be dispensed on the same day to coincide with a scheduled consultation with the patient.

   When necessary, medications should be delivered to patients (i.e., via a delivery service or, when appropriate, via mail).

   In the treatment of certain medical problems (e.g., diabetes, asthma), it is advantageous for pharmacists to assume expanded responsibilities. The provision of medication therapy management (MTM) by pharmacists will be of value for patients in attaining desired therapeutic outcomes, as well as being cost-effective with respect to overall health care costs. Criteria are already established for certain MTM programs and such initiatives for additional illnesses and medications will be developed. The compensation for pharmacists participating in such programs should be based on a rate of $100.00 per hour (in 2009 dollars).

   Wellness programs (e.g., immunization initiatives) should also be implemented with pharmacists being compensated at the same rate as for providing MTM.

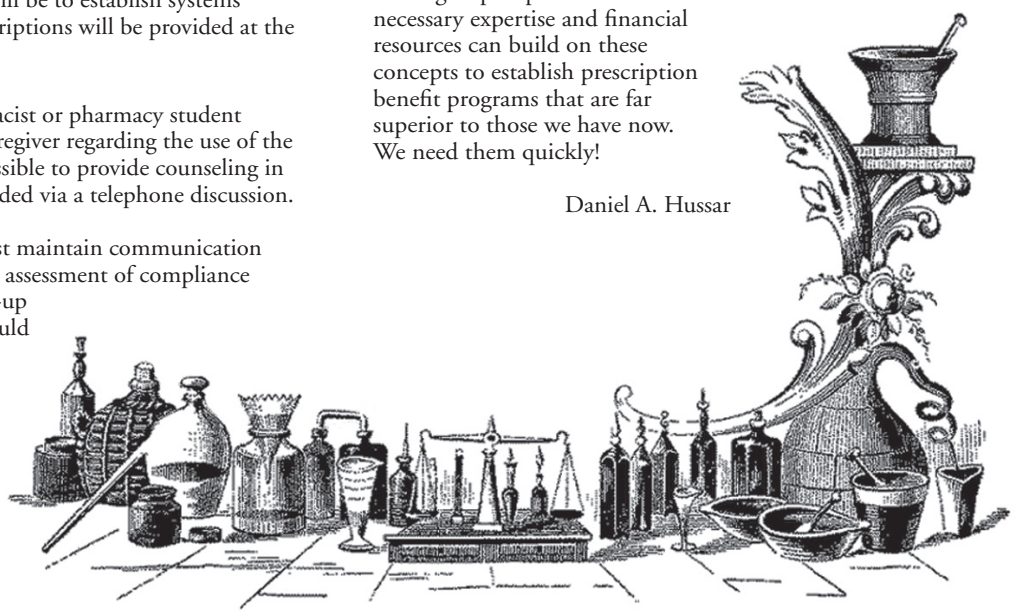
10. Transparency – The confidentiality of patient records must be protected. The financial and other terms of agreements (e.g., between the program administrator and clients, the program administrator and pharmacies, pharmacies and pharmaceutical companies and wholesalers) must be available for review at the request of participating parties.

11. Program integrity – The integrity of the pharmacists and the program administrator is essential. Fraud perpetrated by pharmacists will be prosecuted, and noncompliance with terms of the agreement with respect to the services to be provided to patients will be the basis for being withdrawn from the program. Audit abuses perpetrated by the program administrator will be addressed using the mechanism identified in #12.

12. Resolution of issues/questions – A mechanism will be established through which disagreements can be considered and resolved. An individual (e.g., an arbitrator) or a panel of three individuals who do not have any affiliation or bias with respect to the parties involved will have the authority to review the issue and provide a binding decision.

   Many of the concepts addressed in this commentary are each deserving of a separate editorial. Many more specifics are needed and there are other pertinent issues that have not been considered. However, as I conclude these comments, I am highly optimistic that a group of pharmacists with the necessary expertise and financial resources can build on these concepts to establish prescription benefit programs that are far superior to those we have now. We need them quickly!

   Daniel A. Hussar



New Drug Review

Besifloxacin hydrochloride
(Besivance – Bausch & Lomb)

Antibacterial Agent

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:
For ophthalmic administration for the treatment of bacterial conjunctivitis caused by susceptible isolates of the following bacteria: CDC Corynebacterium group G, *Corynebacterium pseudodiphtheriticum*, Corynebacterium striatum*, Haemophilus influenzae, Moraxella lacunata*, Staphylococcus aureus, Staphylococcus epidermidis, Staphylococcus hominis*, Staphylococcus lugdunensis*, Streptococcus mitis group, Streptococcus oralis, Streptococcus pneumoniae, Streptococcus salivarius** (efficacy against bacteria designated with an asterisk was demonstrated in fewer than 10 infections).

Comparable drugs:
Ophthalmic fluoroquinolones: Ciprofloxacin (e.g., Ciloxan), ofloxacin (e.g., Ocuflox), levofloxacin (e.g., Quixin), gatifloxacin (Zymar), and moxifloxacin (Vigamox).

Advantages:
- Effectiveness in the treatment of bacterial conjunctivitis has been demonstrated against a larger number of bacteria;
- Is administered less frequently (three times a day, compared with ciprofloxacin, gatifloxacin, levofloxacin, and ofloxacin).

Disadvantages:
- Has not been directly compared with other ophthalmic fluoroquinolones in clinical studies;
- Labeled indications are more limited (compared with ciprofloxacin, levofloxacin, and ofloxacin that are also indicated for the treatment of corneal ulcers);
- Is available in fewer formulation options (compared with ciprofloxacin that is also available in an ophthalmic ointment).

Most important risks/adverse events:
Prolonged use may result in superinfection; patients should not wear contact lenses if they have signs or symptoms of bacterial conjunctivitis, or during the course of treatment with besifloxacin.

Most common adverse events:
Conjunctival redness (2%).

(Continued on Page 4)

New Drug Review (cont.)

Usual dosage:

One drop in the affected eye(s) three times a day, four to 12 hours apart, for seven days.

Product:

Ophthalmic suspension – 0.6%; bottle should be inverted and shaken once prior to each dose.

Comments:

Bacterial conjunctivitis, often referred to as "pink eye," is one of the most common eye infections that usually continues for seven to 14 days. Besifloxacin is the sixth fluoroquinolone to be marketed for ophthalmic use in the treatment of bacterial conjunctivitis but, unlike its predecessors, it is not also marketed in other formulations for the treatment of systemic infections. The new drug has been demonstrated to be effective against a larger number of specific bacteria than the other fluoroquinolones, but certain of the older drugs have been demonstrated to be effective in the treatment of bacterial conjunctivitis caused by bacteria for which the efficacy of besifloxacin has not been established (e.g., ofloxacin for infection caused by *Pseudomonas aeruginosa*, moxifloxacin for infection caused by *Chlamydia trachomatis*).

The effectiveness of besifloxacin was demonstrated in clinical studies in which the drug was compared with its vehicle. Patients treated with the drug experienced a faster rate of resolution of the infection. Clinical resolution of the infection was achieved in 45% of those receiving the drug compared with 33% of those treated with the vehicle. Microbiological outcomes demonstrated eradication rates for the causative pathogens of 91% and 60%, respectively, in the drug and vehicle treated groups, although microbiologic eradication does not always correlate with clinical outcomes. Besifloxacin has not been directly compared with other fluoroquinolones in clinical studies.

The effectiveness and safety of besifloxacin have been demonstrated in children as young as one year of age.

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