The Pharmacist Activist

Volume 2, No. 3 • March 2007

Editorial

Pharmacy MUST DEMAND

Fair and Immediate Payment for Medications and Services!

The "system" through which pharmacies are paid by a third party for dispensing prescriptions is so badly broken that it can't be repaired and it must be abandoned. We need a new system, but we also must learn from the problems and mistakes associated with the current system so that we don't repeat them. To start, there must be a clear distinction between the reimbursement to the pharmacy for the cost of the medication and the professional fee that includes compensation for the pharmacist's services and overhead costs.

Cost of medications

For many years the average wholesale price (AWP) provided a close approximation of the cost of a medication to a pharmacy. However, in recent years this indicator has been extensively abused by many pharmaceutical companies who have charged widely varying prices for the same formulation of the same medication to different pharmacy purchasers. These companies have destroyed the previous credibility of AWP, placed many pharmacies at a serious financial disadvantage, and created chaos for those who are administering prescription drug benefit programs and the pharmacies that must accept the terms they dictate without any opportunity to negotiate. As one individual has noted, "AWP stands for 'ain't what's paid'."

With the recognition that AWP is often a fictitious number, the Centers for Medicare and Medicaid Services (CMS) plans to use the average manufacturer price (AMP) as the cost of a medication to a pharmacy. However, there is no fair basis for establishing an AMP and trying to do so does no more than substitute another fictitious number for the previous one. The process for determining AMPs has been secretive and, to add insult to injury for pharmacists, it is the pharmaceutical companies who have a primary role in providing the information that will be used in determining AMPs. This involvement of the same companies who destroyed the credibility of AWP through their pricing policies, or lack thereof, is a blatant conflict of interest! In many prescription benefit programs, pharmaceutical companies pay rebates for their medications that are dispensed in the programs. Therefore, it is in the interest of these companies to have the AMPs be as low as possible so that their rebate payments will be lower. To the extent that plans and information regarding the development of AMPs has become known, it is clear that this system will have a devastating financial impact on many community pharmacies. The use of AMPs must be rejected!

We have reached the point at which actual acquisition cost (AAC) must be used in reimbursing the cost of drug products to pharmacies. However, the provision of fair professional fees for the services of pharmacists and overhead costs must be implemented simultaneously with the use of AAC. In the context of the chaos that currently exists with respect to drug pricing practices, some may consider the use of AAC to be prohibitively complex. However, it does not have to be and, indeed, offers the opportunity to develop a system for reimbursement that is much more transparent and understandable than those used now. I propose the following:

Contents

1. There should be four classes of purchasers of medications from pharmaceutical companies that include:
    a. Pharmacy wholesalers
    b. For-profit pharmacies
    (e.g., independent, chain, and mail-order pharmacies)
    c. Non-profit organizations
    (e.g., hospitals, charitable organizations)
    d. Government agencies
    (e.g., Veterans Administration)

2. For each medication, a company should identify the cost of a unit (e.g., for one tablet), derived from the cost of the smallest commercially available container of the medication, that is charged to each of the four classes of purchasers. The only changes in this cost per unit should be discounts for quantity purchases (e.g., that could be based on quantities of multiples of 10). For example, for a medication for which the smallest container contains 100 tablets, quantity discounts can be provided for purchases of 1,000, 10,000, 100,000, 1,000,000 tablets, etc. The cost of a medication to each class of purchaser and the specific quantity discounts must be public information to avoid the secrecy and deception that characterizes many current pricing practices.

3. To encourage efficiency in the operation of a pharmacy, the first-level quantity discount should be retained by the pharmacy. The incremental savings represented by the second-level and beyond quantity discounts should be shared by the pharmacy and the sponsor or administrator of the prescription benefit program.

Professional fee

Until fairly recently, the difference between AWP and the pharmacy's actual acquisition cost provided enough of a "cushion" that the profession has been passive in tolerating low professional fees that do not reflect the value of a pharmacist's services and time. However, with AWP under attack and professional fees being reduced and even eliminated in some programs, many pharmacies are facing a financial crisis. The use of AAC (as proposed above) to determine drug product cost mandates the provision of an equitable professional fee for the pharmacist's services and overhead costs. Some studies of the costs to dispense a prescription suggest that these costs amount to approximately $10.00 a prescription.

I propose a fee structure that would provide most pharmacies with a $10.00 professional fee for a prescription for a brand-name drug and a fee of $15.00 for a prescription for a generic drug. To receive fees in these amounts, pharmacists must provide services such as drug utilization review and patient counseling. Lower fees (e.g., $5.00/$7.50) should be provided to mail-order pharmacies because they do not incur the cost of the time devoted to patient counseling, and the community pharmacies that do not provide these services on a regular basis. It will not be sufficient to have patients sign a form that they think is necessary for their insurance coverage when, in fact, they are waiving their right to counseling.

Some pharmacies should receive higher fees if they provide additional "value-added" professional services (e.g., drug monitoring programs) or incur higher-than-usual operating costs as a result of factors such as their location.

The professional fees should be reviewed on an annual basis and adjusted by an amount that represents, at the least, the cost of living adjustment.

Immediate payment

Pharmacies often experience long delays in being compensated for prescriptions that are dispensed. When I make a purchase over the telephone for which I use a credit card, the amount of the purchase is very quickly billed to my credit card account. The technology is available (e.g., electronic transfer of funds) to provide immediate payment to pharmacies when prescriptions are dispensed. Pharmacies have had to make large investments in inventories of very expensive drugs and are entitled to immediate payment when prescriptions are dispensed. The administrators of third-party programs have incurred no drug inventory costs and must no longer be permitted to avoid paying pharmacists immediately. They must not be allowed to accrue interest on funds that are owed pharmacists and which pharmacists had to expend much earlier to maintain adequate inventories of medications.

Expensive inventory

The high cost of many medications significantly contributes to the financial challenges experienced by pharmacies. To have these medications available on a timely basis results in a need to incur high inventory costs. The pharmaceutical companies that have established the high drug prices must be required to assume the burdensome costs of making the drugs available on a timely basis from pharmacies. This can be done by having the companies make expensive medications available to pharmacies on consignment (dictionary definition—"sent to a retailer who is expected to pay following sale").

I propose that each medication that has a cost of $100 or more for a one-month or less supply be provided by the pharmaceutical companies to pharmacies on consignment. When a pharmacist dispenses the medication and receives payment from the patient or third-party program, the pharmacist will then submit the appropriate payment to the company.

A model program

The pharmaceutical companies are responsible for many of the problems in the current drug distribution and utilization system, but they also have an opportunity to develop model programs that will resolve or avoid many existing problems. Some of these companies have thousands of employees for whom they provide health care benefits including a prescription drug benefit. Pharmaceutical companies are in a position to insist to insurance companies and administrators of third-party prescription programs that they will only accept for their employees prescription drug benefit programs that provide reimbursement for the actual cost of the medications and equitable professional fees. Because research-oriented pharmaceutical companies would not be expected to be enthusiastic about a fee structure that provides an incentive for dispensing generic medications, a single professional fee of $12.50 could be provided for both brand and generic medications in these programs.

I am confident that such programs can be successfully implemented and will serve as positive examples that will be adopted by others.

Urgency

The profession of pharmacy has been pushed around for far too long, to the point that our role and services are often being severely compromised. We need to communicate and take action on our concerns, and demand that appropriate changes be made to resolve the current inequities for pharmacists and the disservices to our patients. It is urgent that we do so without delay.

Daniel A. Hussar

New Drug Review

Aliskiren hemifumarate (Tekturna – Novartis)

Antihypertensive 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:

Treatment of hypertension, alone or in combination with other antihypertensive agents.

Most important risks/adverse events:

Fetal and neonatal morbidity and death if used during the second or third trimester of pregnancy (boxed warning); angioedema of the face, extremities, lips, tongue, glottis and/or larynx; hyperkalemia, particularly if used in combination with an angiotensin-converting enzyme inhibitor in patients with diabetes.

Most common adverse events:

Diarrhea (2%), cough (1%), hyperkalemia (1%), rash (1%).

Usual dosage:

150 mg once a day; if blood pressure is not adequately controlled, may be increased to 300 mg once a day; bioavailability may be reduced if taken with a high-fat meal and should be administered in a consistent relationship with a meal.

Products:

Tablets – 150 mg, 300 mg

Comparable drugs:

Angiotensin-converting enzyme inhibitors (ACEIs) such as lisinopril (e.g., Prinivil, Zestril), angiotensin II receptor blockers (ARBs) such as losartan (Cozaar) – Additional information regarding the ACEIs and ARBs is provided on page 4.

Advantages:

- Unique mechanism of action (direct renin inhibitor);
- Less likely than the ACEIs to cause cough as an adverse event.

Disadvantages:

- Labeled indications are more limited (compared with ACEIs and ARBs that have been approved for other indications in addition to hypertension);
- Not available in a combination product with hydrochlorothiazide;
- More expensive (compared with some of the ACEIs that are available in lower cost generic formulations).

Comments:

The renin-angiotensin system (RAS) has an important role in the regulation of blood pressure. Renin is secreted by the kidney and acts on angiotensinogen to form angiotensin I. Although angiotensin I is inactive, it is converted to angiotensin II that is a potent vasoconstrictor that can increase blood pressure. The ACEIs inhibit the conversion of angiotensin I to angiotensin II, and the ARBs act at the angiotensin II receptors to reduce its action. Aliskiren is a direct renin inhibitor and is the first antihypertensive agent with this mechanism of action. Like the ACEIs and ARBs, aliskiren suppresses the negative feedback loop, resulting in a compensatory rise in plasma renin concentration. With the ACEIs and ARBs, this response results in increased plasma renin activity (PRA) whereas, with aliskiren, the effect of increased renin concentrations is blocked and PRA is reduced. The aliskiren-induced reductions of PRA do not correlate with blood pressure reductions and it is not known whether this difference in the effect on PRA provides any clinical advantage for the new drug.

Hypertension is the single labeled indication for aliskiren and there are no data to demonstrate that it is either more or less effective than the ACEIs and ARBs in reducing blood pressure. In addition to hypertension, most of the ACEIs are indicated for use in patients with heart failure and/or left ventricular dysfunction, and captopril (e.g., Capoten) and ramipril (Altace) also have other labeled indications. Of the ARBs, candesartan (Atacand), irbesartan (Avapro), losartan, and valsartan (Diovan) have other labeled indications in addition to hypertension.

Aliskiren is well tolerated by most patients and its risks are generally similar to those of the ACEIs and ARBs. As with the ARBs, it is less likely than the ACEIs to cause cough as an adverse event.

Like almost all of the ACEIs and ARBs, aliskiren is administered once a day. In many patients with hypertension, the use of a single antihypertensive agent is insufficient to attain the desired reduction in blood pressure and a combination antihypertensive regimen is employed. All of the ARBs and most of the ACEIs are also available in combination formulations with hydrochlorothiazide, but such a combination formulation with aliskiren is not yet available. Some of the ACEIs are now available generically at a lower cost.

Daniel A. Hussar

The Angiotensin-Converting Enzyme Inhibitors (ACEIs)

Benazepril hydrochloride (Lotensin)
Captopril (e.g., Capoten)
Enalapril maleate (e.g., Vasotec)
Fosinopril sodium (e.g., Monopril)
Lisinopril (e.g., Prinivil, Zestril)
Moexipril hydrochloride (e.g., Univasc)
Perindopril erbumine (Aceon)
Quinapril hydrochloride (e.g., Accupril)
Ramipril (Altace)
Trandolapril (Mavik)

Notable differences among the ACEIs:

Captopril is the only ACEI to have a labeled indication for the treatment of diabetic nephropathy. It is more likely to cause dysgeusia and pruritus which may be attributable to the sulfhydryl component in its chemical structure. There have been rare reports of neutropenia and agranulocytosis with its use. It is administered two or three times a day one hour before a meal.

Enalapril is the only ACEI for which effectiveness and safety have been demonstrated in children. Its active metabolite, enalaprilat, is the only ACEI available in a parenteral dosage form.

Fosinopril is excreted, in part, via hepatobiliary elimination and a reduction in dosage should not be necessary in patients with impaired renal function.

Moexipril should be administered one hour before a meal.

Quinapril tablets have a high magnesium content that may bind with and reduce the absorption of fluoroquinolones and tetracyclines if an appropriate interval of time does not separate their administration.

Ramipril has a labeled indication for the reduction of the risk of myocardial infarction, stroke, and death from cardiovascular causes in patients 55 years of age or older at high risk of developing a major cardiovascular event because of a history of coronary artery disease, stroke, peripheral vascular disease, or because of diabetes accompanied by at least one other cardiovascular risk factor.

Most ACEIs are available in a combination product with hydrochlorothiazide. Benazepril, enalapril, and trandolapril are available in combination products with a calcium channel blocker.

Most ACEIs are available in less expensive, generic formulations.

The Angiotensin II Receptor Blockers (ARBs)

Candesartan cilexetil (Atacand)
Eprosartan mesylate (Teveten)
Irbesartan (Avapro)
Losartan potassium (Cozaar)
Olmesartan medoxomil (Benicar)
Telmisartan (Micardis)
Valsartan (Diovan)

Notable differences among the ARBs:

Candesartan has, in addition to hypertension, a labeled indication for the treatment of heart failure in patients with left ventricular systolic dysfunction to reduce cardiovascular death and to reduce heart failure hospitalizations.

Irbesartan has, in addition to hypertension, a labeled indication for the treatment of diabetic nephropathy in patients with Type II diabetes and hypertension.

Losartan has, in addition to hypertension, labeled indications to reduce the risk of stroke in patients with hypertension and left ventricular hypertrophy, and for the treatment of diabetic nephropathy in patients with type 2 diabetes and a history of hypertension.

Valsartan has, in addition to hypertension, labeled indications for the treatment of heart failure, and to reduce cardiovascular mortality in clinically stable patients with left ventricular failure or left ventricular dysfunction following myocardial infarction.

Author/Editor
Daniel A. Hussar, Ph.D.
Philadelphia College of Pharmacy
University of the Sciences in Philadelphia

Publishers
Christopher J. Polli • G. Patrick Polli II

Assistant Editor
John Buck

Publications Director
Jeff Zajac

Graphic Artist/Designer
Joe Monte

The opinions and recommendations are those of the author and do not necessarily represent those of his full-time employer or the publisher.

The Pharmacist Activist
215 W. Church Rd., Suite 102
King of Prussia, PA 19406
610-337-1050 • Fax: 610-337-1049
E-mail: pharmacistactivist@news-line.com

News, Information and Career Opportunities
NEWS - Line PUBLISHING