

Medication access through patient assistance programs

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Am J Health-Syst Pharm. 2006; 63:1254-9

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The retail cost of prescription medications increased an average of 7.4% annually from 1993 to 2003.¹ This has significant implications for the millions of Americans who lack health insurance or prescription drug coverage. Among individuals with health insurance plans, 1 in 10 individuals age 65 years or younger and 1 in 3 persons over age 65 years lack prescription drug coverage.² While not all individuals who lack prescription drug coverage face financial hardship, it is well documented that medication costs often impede access and adherence to

medication regimens.³⁻⁵ Individuals without prescription drug coverage are more likely to skip doses or not fill prescriptions in order to lower medication costs.^{5,6} While physicians are aware of the high cost of prescription medications, they often are unaware of patients' out-of-pocket costs.⁷ Evidence indicates that conversations between the provider and patient regarding the burden of out-of-pocket expenses are infrequent.⁸⁻¹⁰

Patient assistance programs (PAPs) are offered by pharmaceutical companies to help provide brand-name medications for low-income

individuals who lack prescription drug coverage.^{11,12} While these programs have the potential to increase patients' access to needed medications, many patients who qualify for these programs may not be aware that they exist. Many PAPs can only be found on the Internet, limiting the programs' use to individuals with computer access. Therefore, difficulty in obtaining information and applications may hinder PAP use.¹³

Manufacturer-sponsored PAPs have been used in various health care settings, such as hospitals and ambulatory care and specialty clinics, to improve patient access to needed medications at little or no cost.¹³⁻¹⁵ While the main objective of PAPs has been to increase patients' access to medication, limited evidence indicates that PAPs may also improve health outcomes in patients who qualify for PAPs, including increased adherence to medication regimens resulting in improved control of surrogate measures, such as blood pressure and hemoglobin A_{1c}.¹⁶

MEDBANK of Maryland, Inc. is a statewide 501(c)(3) nonprofit organization that helps the uninsured and underinsured who are eligible for PAPs gain access to brand-name prescription medications. MEDBANK funds operations through state and foundation grants, as well as monetary donations from individual sponsors. Since its conception, MEDBANK has helped patients access \$64.9 million worth of free medications.¹⁷ MEDBANK acts as a conduit among patients, providers, and pharmaceutical manufacturers to obtain the information necessary to

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DOI 10.2146/ajhp050457

submit new applications, refills, and renewal applications.

RxBridge, a Web-accessible database developed by MEDBANK, allows for required patient and physician data to be entered into a standardized format. The program allows the pharmaceutical company's PAP application to be selected and merged with the appropriate applicant and physician information. The completed application is then printed out for the physician's and applicant's signatures. Over 100 company programs are represented in the database, comprising over 800 brand-name medications.

In addition to helping patients complete PAP applications, MEDBANK has partnered with pharmaceutical companies to establish an inhouse pharmacy to increase the speed at which patients can receive select medications. Since 2001, MEDBANK has processed approximately 250,000 prescription requests for over 30,000 patients. In 2004 alone, MEDBANK had 10,000 active patients receiving prescription medications.¹⁷

The purpose of this article is to describe pharmaceutical manufacturer-sponsored PAPs and their enrollment process and to demonstrate the complexity of accessing PAPs using a convenience sample of MEDBANK enrollees. While disease-specific foundations and patient advocacy organizations exist that may assist patients with medication access, this article focuses solely on manufacturer-sponsored programs.

Methods. Pharmaceutical manufacturers that provide PAPs were identified using the Internet search engines Google, Yahoo, and MSN. The keywords patient assistance program, medication assistance, and pharmaceutical company assistance were used to identify PAPs. Companies were contacted to verify acceptance of new patient applications for the programs. The data collection process included documentation

that the drugs were available through PAPs, identification of eligibility criteria (i.e., qualifying income levels, age requirements, and insurance restrictions), and verification of the enrollment process to include program contact information, other required documentation, and any program renewal processes.

The data analysis phase of this project examined the number of drugs that a typical individual would request through PAPs and the related number of applications required to apply for those drugs. This involved generating a convenience sample of MEDBANK enrollees using RxBridge, a relational database built in SQL Server 2000 (Microsoft Corporation, Redmond, WA). RxBridge is compliant with the Health Insurance Portability and Accountability Act and able to facilitate application processing across thousands of patients. The database was used to provide descriptive analyses and to determine the most commonly requested and received medications. The number of unique programs from which applicants requested medications were calculated to determine the mean number of different applications completed and processed by MEDBANK enrollees.

Eligible individuals who requested medications through MEDBANK from January 2001 to April 2004 with complete application information in the database were included in the convenience sample for this analysis. Demographic information included age, gender, and race for descriptive purposes. In addition, total annual income was calculated based on financial information provided by applicants. Our analysis was exempted by the university's investigational review board.

Results. *PAP application process.* Approximately 80 pharmaceutical manufacturers provided PAPs for brand-name medications to eligible individuals. Pharmaceutical companies manufacturing only generic

medications did not sponsor PAPs. Approximately 75% of the top 200 prescribed medications in 2003 had a PAP available (Table 1).¹⁸

Applications for PAPs were accessed in a variety of ways. The most convenient method for accessing an application was downloading it from the sponsor company's Web site or through Web sites sponsored by organizations such as the Pharmaceutical Research and Manufacturers of America, the Robert Wood Johnson Foundation, and patient advocacy groups, allowing individuals to search by medication or company for available programs.¹⁹⁻²¹ Health care professionals, patients, and caregivers typically were eligible to request applications. Exceptions existed for medications requiring additional medical documentation or expedited delivery, as was the case with specialty medications. Programs for specialty medications and high-cost medications required the prescribing health care worker to contact the company's program directly to obtain applications and approval.

Specific information on both the patient and prescribing physician was required for all applications. The patient needed to provide complete demographic information, including date of birth and address. In addition, information on the applicant's financial status was required. Some programs requested that financial documentation, such as copies of recent federal income tax forms or social security benefit letters, be submitted with the application. The patient (or guardian) signed the application before submission.

The prescribing physician was required to complete and sign the designated portion of the application, providing name, office address, phone number, and fax number. Applications required the prescribing physician to provide his or her Drug Enforcement Administration number or state license number. All information pertaining to the requested

■ **NOTE Medication access**

Table 1.
Medications for Which a Patient Assistance Program Is Available

Company Sponsor	Product
AAI Pharma Inc. (888) 224-0099	Darvocet
Abbott Laboratories (800) 222-6885	Biaxin, Biaxin XL, ^a Depakote, Depakote ER, Flomax, Mobic, Omnicef, ^a Synthroid, TriCor
Alcon (800) 222-8103	Ciloxan, Tobradex
AstraZeneca (800) 424-3727	Nexium, Plendil, Pulmicort, Rhinocort AQ, Seroquel, Toprol XL
Aventis (800) 221-4025	Allegra, Allegra-D, Amaryl, Diabeta, ^{a,b} Lantus, Nasocort AQ
Bayer (800) 998-9180	Adalat CC, ^b Avelox, Cipro
Bertek (888) 823-7835	Maxide ^b
BMS (800) 736-0003	Avalide, Avapro, Cefzil, Coumadin, Desryl, ^b Glucophage, ^b Glucophage XR, Glucovance, Monopril, Plavix, Pravachol, Tequin
Braintree (781) 843-2202	Miralax
Celltech (866) 523-3994	Tussionex
Collaagenex (888) 339-5678	Periostat ^b
Eisai Inc. (800) 226-2072	Aricept
Eli Lilly (800) 545-6962	Evista, Humalog, Humulin N, Keflex, ^b Strattera, Zyprexa ^c
First Horizon (800) 869-4514 Ext. 321	Nitrolingual ^b
Forest Pharmaceutical (800) 851-0758	Armour Thyroid, Celexa, Levothroid, Lexapro, Tiazac
GlaxoSmithKline (866) 728-4368	Advair Diskus, Amoxil, Augmentin, ^b Augmentin XR, Avandia, Bactroban, Coreg, Flonase, Flovent, Imitrex, Lamictal, Lanoxin, Paxil, Valtrex, Wellbutrin SR, Zantac ^b Aciphex, ^c Duragesic, Risperidal ^c
Janssen (800) 652-6227	Niaspan
KOS Pharm (866) 363-1024 Ext. 2	
Merck (800) 994-2111	Cosopt, Cozaar, Fosamax, Hyzaar, Prinivil, ^b Prinizide, ^b Proscar, Singulair, Zetia, ^c Zocor
Novartis (800) 277-2254 Ext. 2	Diovan, Diovan HCT, Elidel, Lamisil, Lescol, Lescol XL, Lotensin, Lotrel, Miacalcin, Remeron, ^c Trileptal
Ortho-McNeil (800) 577-3788	Ditropan XL, Flexeril, ^b Levaquin, Topamax, Tylenol with codeine, ^{a,b} Ultracet, Ultram
Proctor & Gamble (800) 830-9049	Actonel, Macrobid, Prilosec ^c
Pfizer (800) 707-8990	Accupril, Antivert, ^b Atarax, ^{a,b} Celebrex, Covera HS, ^b Detrol LA, Diflucan, ^a Dilantin, Glucotrol XL, Lipitor, Lopid, ^b Neurontin, Norvasc, Procardia XL, Prozac, ^b Viagra, Xalatan, Zithromax, ^c Zolof, Zyrtec
Roche (877) 757-6243	Anaprox, ^b Klonopin, ^b Valium ^b
Schering-Plough (800) 656-9485	Imdur, ^b K-Dur, ^b Lotrisone, ^b Nasonex, Proventil ^b
Takeda (800) 830-9159	Actos
TAP (800) 830-1015	Prevacid
Upsher-Smith (800) 654-2299	Klor-Con
Wyeth (800) 568-9938	Effexor XR, Inderal, ^b Inderal LA, Phenergan, ^b Premarin, Protonix

^aEligibility only for persons age 65 years or older.

^bBrand name available for generic medications.

^cSeparate application for medication.

medication, including the name, strength, dosage, and quantity, was required. While the quantity of medication supplied varied by company, the allowed quantity ranged from one to six months per fill; most companies dispensed a three-month supply. For specialty medications and medications for temporary use, the days supplied were tailored to the medication and the dosage or quantity requested by the physician. Some applications required a hard copy of the prescription signed by the physician to be included with the application.

Specific eligibility criteria varied by company. Medication assistance programs were available only for individuals who did not have prescription drug coverage from either public or private insurance. PAPs were primarily based on financial need. The specific level of financial eligibility varied by company. The primary determinant of financial eligibility was the annual household income adjusted to the current federal poverty level. Income eligibility also included the number of individuals living in the household, number of dependents, total assets, and total living expenses.

Applications were mailed to the designated program address unless it was specified that faxed applications were permissible. The sponsor company only reviewed applications that included all pertinent information and signatures of both the patient and prescribing physician. Applications took four to six weeks to process. If the patient was approved for the program, medications were sent to the physician's office or clinic to be picked up by the patient. Medications were sent directly to the patient in a few exceptions.

The process for obtaining medication refills varied by company. In some cases, a new application had to be submitted for every medication request. For programs enrolling patients for one year at a time, a refill

was requested by mail or fax. Applications for refills had to be submitted two to four weeks before the supply ran out in order to maintain continuity of care. Reapplication was necessary for each medication request, every month, biannually, or annually, depending on the assistance program. Finally, program eligibility criteria could change without notice and no guarantees were made for the continuation of a program.

MEDBANK experience. Data for 24,541 patients were entered into the RxBridge database between January 2001 and April 2004. Of those, 15,925 patients with complete application information requesting branded medications from PAPs were included in the convenience sample. The mean \pm S.D. age of patients was 64.5 ± 15.9 years, and the average annual income was \$15,500. The majority of the sample was Caucasian (65.5%) and female (69%) (Table 2).

Overall, medications for controlling chronic conditions such as dyslipidemia, hypertension, and diabetes were among the most commonly requested and received by MEDBANK enrollees. Requests for cardiovascu-

lar agents, antidiabetic agents, gastrointestinal agents, antidepressants, and analgesics were 40%, 13%, 6%, 6%, and 5% of the total number of requests, respectively. Thirty percent of the total requests were for medications in other therapeutic classes. The receipt rate for the top 25 medications requested, reflecting the number of medication requests received from those requested, ranged from 5.2% to 65.5% (mean, 52.9%) (Table 3). The number of individuals requesting a drug was calculated by counting initial requests made for a medication. The count requested did not reflect medication refills or application renewals.

On average, patients filed applications for medication requests from approximately 5 distinct programs (mean = 4.7, range = 1–23). These requests may have included situations in which two medications from the same therapeutic class were requested from separate companies. This was possible if the first attempt was unsuccessful or if a change in the prescribed medication occurred.

Discussion. Our analysis suggests that accessing PAPs is a complex process. Many patients using these

programs require multiple medications. The cost of monthly pharmacy bills can be substantial and may affect patients' compliance to medication regimens. Manufacturer-sponsored medication assistance programs have the potential to allow those patients who lack prescription drug coverage and face financial hardship to access needed medications. However, the complexity of the application process may act as a barrier to those who qualify. Understanding program availability and eligibility criteria will help identify patients who may benefit from these programs. Familiarity with the nuances of these programs will increase the ability to help guide patients through the application process.

The MEDBANK experience described in this article demonstrates that patients who qualify for PAPs are likely to access multiple programs to fulfill their medication needs. In addition, medications for chronic medical conditions such as diabetes, dyslipidemia, and hypertension were the most commonly requested. This is consistent with limited reported findings from other experiences with helping patients access PAPs.¹⁴ The rate of receiving requested medications reflects the variation in individual experiences and programs. Applications submitted may be rejected for reasons including income ineligibility, patient enrollment into an entitlement program during the application process, and the existence of unreported insurance. In addition, some companies approve a large percentage of applications, while others approve very few. Programs change over time, resulting in fewer applications being accepted, or may be discontinued altogether.

A gateway program titled Partnership for Prescription Assistance was recently developed.²¹ The program is the result of a collaboration of pharmaceutical companies, health care providers, patient advocacy groups, and community organizations to

Table 2.
Characteristics of MEDBANK of Maryland Enrollees ($n = 15,925$)

Characteristic	No. (%) Enrollees
Sex	
Female	11,406 (69.0)
Male	4,879 (31.0)
Age (yr)	
18–44	2,014 (12.6)
45–64	5,355 (33.6)
65–74	3,722 (23.4)
75–85	3,289 (20.7)
>85	1,545 (9.7)
Race and ethnicity	
African American	3,984 (25.0)
Caucasian	10,425 (65.5)
Hispanic	830 (5.2)
Asian	158 (1.0)
Other ^a	528 (3.3)
Total annual income (\$)	
<10,000	2,468 (15.5)
10,000–12,500	3,857 (24.2)
12,501–15,000	3,190 (20.0)
15,001–20,000	3,563 (22.8)
>20,000	2,847 (17.5)

^aNative American, Middle Eastern, Pacific Islander, and unreported.

Table 3.
Top 25 Brand-Name Medications Requested by MEDBANK Enrollees^a

Requested Medication	Company	No. Medication Requests	No. Requests Received	Receipt Rate (%) ^b
Atorvastatin	Pfizer	3993	2304	57.7
Metoprolol ER	AstraZeneca	2795	1831	65.5
Amlodipine	Pfizer	2521	1262	50.1
Lansoprazole	TAP	2105	1162	55.2
Furosemide ^c	Aventis	1942	100	5.2
Lisinopril ^{c,d}	AstraZeneca	1923	1055	54.9
Levothyroxine	Abbott	1878	1071	57.0
Metformin	BMS	1604	794	49.5
Simvastatin	Merck	1558	897	57.6
Celecoxib	Pfizer	1505	713	47.4
Sertraline	Pfizer	1484	748	50.4
Glipizide ER	Pfizer	1338	723	54.0
Clopidigrel	BMS	1314	678	51.6
Esomeprazole	AstraZeneca	1248	882	70.7
Warfarin	BMS	1225	620	50.6
Pravastatin	BMS	1180	610	51.7
Quinipril	Pfizer	1127	676	60.0
Gabapentin	Pfizer	1109	616	55.6
Paroxetine	GlaxoSmithKline	1098	611	55.7
Atenolol ^c	AstraZeneca	1098	582	53.0
Refocoxib ^c	Merck	1074	604	56.2
Rosiglitazone	GlaxoSmithKline	1031	553	53.6
Lisinopril ^e	Merck	1029	490	47.6
Digoxin	GlaxoSmithKline	965	475	49.2
Metformin ER	BMS	955	593	62.1

^aCounts do not include multiple requests or refills.

^bThe receipt rate reflects the percentage of cases where the medication requested by the individual was received.

^cMedication applications no longer available from manufacturer.

^dRequested as Zestril.

^eRequested as Prinivil.

help patients without prescription drug coverage gain access to PAPs in both the public and private domains.²¹ This program has generated increased awareness of PAPs in the medical and lay communities. MEDBANK provides additional support to the PAP application process beyond what Internet portals provide, by offering personal assistance in understanding and completing applications. MEDBANK also employs one part-time employee to monitor companies for program changes and programs that have closed. When such changes occur, patients and physicians may be contacted to make the necessary adjustments to maintain continuity of care. The inhouse pharmacy also provides two major benefits. First, it reduces the application processing time, and as a result eligible patients are able to access medications faster. Second, MEDBANK

will send the medications directly to the patient's home relabeled with the patient's name and directions for use. This has significant implications for reducing improper medication use.

The Medicare Prescription Drug Benefit that commenced January 1, 2006, has affected access to PAPs for Medicare Part D enrollees. The Office of Inspector General released a special advisory bulletin in November 2005 discussing PAPs for Medicare Part D enrollees.²² The bulletin stated that Medicare Part D enrollees cannot be offered free medications by manufacturers through formal PAPs because it is considered an inducement to the use of more expensive medications, leading to a "heightened risk of fraud and abuse under the Federal anti-kickback statute."²² The bulletin stated that alternatives to traditional PAPs may exist,

including situations where pharmaceutical manufacturers donate medications to bona fide independent charities. MEDBANK is actively pursuing this possible avenue to support Medicare Part D enrollees who cannot afford the out-of-pocket costs.

Conclusion. The application process for PAPs was complex, especially when patients applied to multiple programs with different requirements and enrollment procedures. Understanding these programs and the application procedures will increase pharmacists' ability to counsel patients on access to prescription drugs and appropriate drug utilization.

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