association of clinicians for the underserved

Access to Medications by Underserved Populations: Recommendations for Process Improvement

Access to adequate and timely treatment can be improved by enhancing the quality of formulary and prior authorization processes, and by facilitating access to non-formulary medications.

Prepared by
Ileana Burgos, MSW, Project Manager
Kathie Westpheling, MPH, Executive Director

Contributors
Sandra Leal, PharmD, CDE
Richard Levy, PhD
Ellis Frazier, MD

Contact
Association of Clinicians for the Underserved
1420 Spring Hill Road, Suite 600
McLean, VA 22102; 703-442-5318
acu@clinicians.org; www.clinicians.org

The operation of the Pharmacy and Therapeutics Committee (P&T) is the cornerstone of pharmaceutical management. Clinician representation in the P&T Committee process, which involves an evidence-based approach to clinical decision making, is part of the transdisciplinary team model that ACU supports. This sharing of knowledge and expertise, along with trust and respect, provides some assurance that clinicians will have the medications and processes in place to offer quality health care to their patients and communities.

Adequate and timely treatment can be made more accessible to patients by enhancing the quality of formulary and prior authorization processes, and by facilitating access to appropriate non-formulary medications.

Basic principles for formulary development and implementation

The ACU recommends the following basic principles for formulary development and implementation, and emphasizes the vital role of clinicians in the pharmaceutical management process.

Well-designed preferred drug lists (PDLs) and formularies can be a helpful tool to reduce expenses and do not necessarily compromise health care quality.

Effectiveness, not cost, is the main objective when developing formularies. A lower cost drug will not necessarily result in a lower quality of care; and a higher cost drug may not necessarily result in greater effectiveness for an individual patient. Finding the best drug for the individual patient is the overriding principle.

The involvement of clinicians in the P&T Committee process, at both the local and state levels, recognizes and respects the importance of their clinical judgment. The development and implementation of pharmaceutical management processes cannot be effective without the participation and buy-in of these key stakeholders.

Direct, on-going communication between prescribers and the P&T Committee allows for flexibility in deciding which medications are

most needed by specific patient groups, and is especially important as patient populations and conditions change.

Policy recommendations

ACU urges policymakers to adhere to the following basic principles when establishing formularies and managing the formulary process:

- Improve the prior authorization process by standardizing documents and streamlining the application process through the use of computerized methods.
- Increase communication between state Medicaid offices and local health care systems by inclusion of front-line clinicians on state Medicaid P&T Committees and through open public forums where both parties contribute regularly to the state formulary review and authorization process.
- Consider the following factors when selecting formulary medications:
    1. both long- and short-term overall treatment costs and health outcomes
    2. flexibility and breadth of coverage sufficient to allow for personalized prescribing
    3. a range of dosage forms to ensure adherence to therapy in individual patients
    4. medications for disease prevention
- Ensure that exclusion mechanisms are easily available to enable patients with complex or specialized pharmaceutical needs to receive appropriate therapy.
- Stipulate that patients are informed about alternative medications and, when possible and in cooperation with the prescriber, be able to choose among alternates based on clinical, cost, and quality of life factors.
- Assure that an adequate range of medications is available especially for persons with psychiatric illness, who are at particular risk for sub-

optimal care. It is recommended that a range of newer and older indicated medications be available to help ensure adherence and that no patient who has suffered a disabling psychiatric condition and is now doing well should be switched to a different medication.

- Incorporate P&T Committee models that have been effective in various systems into the professional development and training of health professionals who have prescribing privileges.
- Support policy initiatives that would reduce any barrier to access created by the increasing cost of medications. Such initiatives may include obtaining adequate funding of state Medicaid programs and extending insurance coverage to uninsured persons. Improved access to financial assistance programs sponsored by pharmaceutical companies (see page 7) can also help low-income individuals access needed medicines.

The role of P&T Committees in assuring access to appropriate medicines in the Part D Medicare program

The new Part D program of the Medicare Modernization Act of 2003 represents the most important expansion of the Medicare program since its inception. This benefit brings important changes in coverage for medications, especially for the dual eligible beneficiaries, e.g., those enrolled in both Medicare and Medicaid. These "duals" are the sickest, the poorest and the most disabled. Their prescription drug coverage will switch from Medicaid to Medicare, and be administered through prescription drug plans (PDP) and Medicare Advantage plans (MA-PD).

It is important that the duals receive the maximum value of this new drug benefit. There will be transition issues when the plan is implemented on January 1, 2006: not everyone will be reached; others may be confused by their plan assignment; and those wishing to switch plans may not understand the process. *It is vital that these individuals receive assistance in understanding and using the new benefit.*

The new program requires that drug formularies must contain at least two agents from each pharmacological class. The expectation of CMS is

that the best practice formularies will contain the majority of drugs within the following classes: antidepressants, antipsychotics, anticonvulsants, antiretrovirals, immunosuppressants, and antineoplastics. But since CMS states that plans may deviate from best practices if they provide clinical justification, it is currently unclear if patients will have full access to these medications in all cases.

Some drug classes are excluded from coverage under the new Medicare plan, and if the states do not step in and pay for these products they will be unavailable to most dual eligibles. Consider a dual eligible in a skilled nursing facility who for many years was receiving a benzodiazepine drug to control seizures. Since benzodiazepines are excluded from Part D coverage, the patient must be switched to a medication covered on the formulary. Although these substitutions can often be made without incident, complications may arise consequent to the sudden discontinuation of a medication, an inappropriate choice of medicine, or selection of an inappropriate dose of the new medicine. These problems can be minimized by education, preparation, and collaboration on the part of practitioners, pharmacists, and nursing staff, as well as residents and family members.

Special attention must be given to Medicare patients who are stabilized on a drug that are not on a Part D formulary and then switched to a similar agent that is on the formulary. Clinicians should be alert to this possibility, especially if the patient has not been seen since the inception of the Part D program on January 1, 2006. Such patients should be followed to assure continuity of care: Is the new therapy adequate? Are there adverse effects? Is the patient adhering to the new medication regimen? If there are substantial problems with the new drug, the patient may need assistance in obtaining re-authorization of the original drug. Alternatively, the clinician can prescribe another formulary drug that is better suited to that patient's needs.

Part D Guidelines make clear that a primary goal in reviewing formularies of participating drug plans will be to ensure access to "medically necessary" medications by using treatment guidelines and "best practices" found in commercial plans and state Medicaid programs.

P&T Committees will play a critical role in ensuring best practices are implemented. This will involve frequent review and modification of the practices when new therapies become available, additional information is gathered about current therapies, and when medical practice changes. P&T committees should perform the following additional functions to further assure access to appropriate medicines under Part D:

P&T Committees can provide important checks on the financial incentives governing individual drug plans by bringing research findings and clinical experience to bear on decisions that will restrict access to certain medications.

P&T Committees must be charged with a strong mission to promote and protect the health of beneficiaries, taking into account the unique needs and co-morbidities commonly associated with aging populations and people with disabilities. Their responsibilities must include permission to modify prior authorization review processes and other restrictive policies, including cost-sharing schemes, as necessary to ensure appropriate coverage.

P&T Committees should be charged with ensuring that each therapeutic drug class included in the formulary contains enough variety and number of agents. Although the Act requires coverage for two drugs in each class, additional agents may in some cases be necessary to reflect current utilization patterns and meet the needs of the Medicare beneficiaries that are older, have complex disease, or have many co-morbid conditions.

P&T Committees must seek the meaningful input of beneficiaries as they consider medications to treat different conditions and disorders. This may include using advisory committees representing those living with disabilities and chronic illnesses. The processes used by P&T committees to develop formularies for the Medicare Part D benefit should be open to enrollees and the public. Public hearings should be held when formularies are adopted or revised to allow input from enrollee populations such as seniors and persons with disabilities.

Accessing Pharmaceutical Assistance Programs (PAPs)

A variety of public and private pharmaceutical assistance programs are available that provide eligible low-income, uninsured patients with free or nearly free medicines. However, finding a program for which a patient is eligible and that will cover his/her specific medicines can be frustrating and time consuming. Several ACU member organizations and other non-profits have been working over the past few years to offer services to improve access to affordable medications and to reduce the dependence on samples for management of chronic diseases.

- The ACU website, *www.clinicians.org*, provides links to many national, state and regional resources to assist clinicians.
- The most recent program sponsored by the Pharmaceutical Research and Manufacturers Association (PhRMA) is the *Partnership for Prescription Assistance (PPARx)*. PPARx is a clearinghouse for consumers and prescribers, offering a single point of access to more than 275 PAPs sponsored by pharmaceutical firms, state and federal government, local organizations, and private charities. The program is accessed directly at *www.pparx.org* or a toll-free number (1-888-4PPA-NOW).
- *RxOutreach.org* offers reduced prices on generic drugs.
- *TogetherRxAccess.com* may be of value to those who are not Medicare eligible but above the income eligibility of PAP programs offered by individual pharmaceutical firms.

ACU members' experiences with current pharmaceutical management processes

Formularies and the processes required to obtain reimbursement for pharmaceuticals have the potential to channel appropriate and cost effective prescribing. However, if the principles outlined above for the operation of an effective P&T committee are not followed, process failures can occur that frustrate prescribers, pharmacists and patients alike. Communication among patient, prescriber, pharmacist, and insurer can be fragmented and patient care may be compromised.

ACU members are concerned about the extent to which current processes used to manage prescriptions may be impeding access to appropriate treatment. Accordingly, ACU recently interviewed some of its members to elicit their experiences and views regarding problems they have encountered in obtaining medications for their patients. The objective was to better understand the extent of current problems associated with pharmaceutical management processes.

Interviews were conducted during two regional conferences of ACU member organizations: *The 2004 Medicine for People in Need Conference* in Sacramento CA and *Clinicians Connect for the Underserved*, in Cincinnati OH, sponsored by the Midwest Clinicians Network and ACU. These interviews sought to determine ACU members' views on general issues related to the development, use, and importance of P&T Committees. Their comments provide a broad picture of the pharmaceutical access issues that trouble clinicians and administrators working in community-based primary health care systems.

Additional interviews by telephone were conducted between September and November, 2004. Key questions focused on issues related to formularies, the pre-authorization process, and P&T Committees. Sixteen participants were interviewed, including pharmacists, family nurse practitioners, and physicians, some of whom were medical directors for health centers. The sample included members practicing in AZ, CA, CN, DC, IL, ME, MI, MN, NY, OH, and VA. Participants shared their experiences regarding the impact of formularies and prior authorization

processes in their own practice and the systemic issues they saw as barriers to comprehensive pharmaceutical services.

Since these interviews collected experiences and opinions from a small sample of volunteer participants, the responses may not be representative of the entire ACU membership. However, several common themes emerged:

- ACU members, who are typically clinicians and clinic administrators serving Medicaid and uninsured patients, experience a variety of barriers associated with the process of obtaining appropriate medications for their patients. These clinicians, who usually work with limited funding and resources, reported that they must often seek other means to offer quality health care for their patients.
- Exclusion of a needed drug from one formulary required resourcefulness in finding other means to obtain the drug. These included company-sponsored pharmaceutical access programs (for eligible patients), in-house formularies, and the use of samples. However, while samples may provide some temporary relief, it was felt that samples are not a sustainable solution for long-term management of chronic disease.

The case summaries below, collected from the telephone interviews, illustrate some important barriers to appropriate pharmaceutical therapy, and signal a high level of frustration among ACU members. In particular, these respondents report that pre-authorization processes are often inefficient and time consuming for providers and patients alike. These processes can disrupt continuity of care and create situations where patients must wait weeks or months for needed medications.

A report from a family physician from a rural health center in Ohio

"A 40 year old HIV-positive male with advanced disease (AIDS) who has had chronic insomnia which has impacted his level of functioning. Medicaid covered his prescription for a high dose Restoril for over 3 years, but even this eventually became ineffective. I obtained an evaluation by a sleep specialist, who

recommended Ambien at 30 to 40 mg nightly and to stop the Restoril. Although the Ambien would have been less expensive in the long run, Medicaid would not cover more than 10 mg nightly despite multiple appeals over a 4- week period of time and being sent copies of consultant reports. After multiple failed prior authorization attempts, I called them and was given a flat NO answer; I was informed that the patient could appeal the process himself by writing to state Medicaid and asking for an appeal by the appeals board. If he was granted this, he would have to travel to Columbus (1 hour drive at least) to sit before the board and plead the case himself. The patient did this, and I provided a letter from my perspective as the primary care physician and a copy of the sleep specialist's report summary. It took another 2 weeks for him to get a call back to schedule his interview/interrogation, which consisted of him driving to Columbus, giving his health history, reading my letter, reading the consultant's report. He was told they would make a decision within 2 to 6 weeks and would notify him by mail.

"Over one month later he was notified that he was approved to get the Ambien at the desired and effective dose. Meanwhile, we had to have vouchers to obtain extra Ambien from the company and the Ryan White program paid for medications. The process took at least 2 months, if not more, and there was no part of this that dealt with quality of care or had any compassion. It was purely financial and bureaucratic and impersonal.

"What "process" would make an AIDS patient plead for approval from a group of physicians to obtain medication that would allow him to sleep restfully and enable him to be more functional and to care for himself?"

A report from a family physician and Medical Director of an urban community health center in So. California

"I have begun to document frustrations with the prior authorization system, including delays in reaching the staff assigned to authorize prescriptions (which usually takes about 20

minutes to finally get to the right person), and denials from staff who cite research documents to me explaining why I am wrong. In my opinion this system has been established to be a disincentive to providers and a barrier to care."

This member also shared with ACU the following letter he wrote to document one of his experiences with the pre-authorization process.

"This letter is written to document what I consider to be an unacceptable delay in the authorization of a medication for a patient who complained of abdominal pain and dysuria. His entire assessment, including a call to an urologist, took less than 15 minutes. I concluded that the most likely diagnosis was prostatitis and decided that a fluoroquinolone would be the best choice of therapy for this poorly controlled diabetic patient. I called the Member Services line and after a 5-minute delay was informed that I needed to transfer to an 800 number for more assistance. After a delay of 10 minutes the operator transferred me to Med Impact where I waited another 10 minutes before I could speak with the representative. It took about 7 minutes to determine that the medication I wanted to prescribe would need authorization, but another similar medication would not. I was then offered the option of moving forward with the authorization process or accepting the alternate medication. It was over 30 minutes before I could return to the patient's room to inform him of the treatment plan and discharge him. This extended a 15-minute appointment into a 45-minute drama.

"If your intent is to restrict access to care then I must say that you have succeeded in doing so quite well. The process of restricting access to certain medications, or developing formularies that require authorization for certain therapeutic agents as a means of cutting costs, is truly a shortsighted perspective. While your organization may save money by having such policies in place, it was certainly a cost to my organization to have a physician on the phone for a half an hour. You must not

consider the prior authorization system a cost saving measure-it is merely a saving to you."

A report from a general practitioner from Ohio

"A 41 year old African American male with advanced HIV disease was recently discharged from the hospital where he was treated for exacerbation of his pulmonary histoplasmosis. He presented with fatigue and stated he had not filled his prescription for Procrit (used for anemia) because Medicaid would not pay for it. He had the diagnosis of anemia which was multifactoral in cause. While in the hospital he was seen by the hematology specialist and was started on Procrit there. He was to continue on Procrit until his hemoglobin began to approach normal range. But Medicaid refused to authorize/approve the drug. After multiple phone calls for prior authorization by my staff, I was finally given the direct phone number of the medical director of state Medicaid. He was annoyed that I had his phone number and lectured me about the use of expensive drugs. He finally authorized the Procrit after I continued to plead that this medication was indicated for this situation. This process required considerable time by my staff and me and disrupted the continuity of the care initiated while the patient was in the hospital."

A report from a family physician and Medical Director of a rural community health center in Arizona

"The Arizona Medicaid program only pays for medications dispensed through its contracted pharmacies. However, because there are few pharmacies in the region of the state where the clinic is located, the state made an exception and allowed medications to be obtained from a specific, for-profit company. However, this company does not provide all the medications the clinic needs. For example, Aricept, an important medication for Alzheimer's, is not covered under this company's formulary and therefore patients cannot obtain it through this arrangement. To obtain this medicine, patients must travel to the nearest contract pharmacy, about 30 miles away. As a result, they are often untreated."

A report from a family nurse practitioner in a community health center in Connecticut

> "A fairly young woman with long-standing daily pain from chronic arthritis was prescribed several NSAIDs and Tylenol without any relief over many months. She was then given samples of Celebrex, which provided the only pain relief she experienced in years. A prescription for Celebrex was then written but her insurance company required pre-authorization. Forms were submitted and one week later the response came: 'denied – try several other NSAIDs that have not yet been tried.' The patient then endured a month-long trial with each of the 3 NSAIDs they listed, none of which worked. Finally, the pre-authorization form was re-submitted and Celebrex was approved for one year. The patient is doing better now, but renewal of the pre-authorization is approaching soon, so we will see what happens."

These adverse experiences document the need to reduce the "friction" within pharmaceutical management processes. Movement toward this goal can start with adoption of the recommendations above for a greater involvement of clinicians in the design and implementation of formularies and other cost management tactics. Smooth functioning of these processes will be especially important to the many elderly patients soon to be served by the new Medicare Part D program.

The Association of Clinicians for the Underserved (ACU) is a nonprofit, transdisciplinary organization of clinicians, advocates, and health care organizations united in a common mission to improve the health of America's underserved populations and to enhance the development and support of the health care clinicians serving these populations.

Established in 1996 by participants and alumni of the National Health Service Corps, ACU's membership represents individuals in 18 professional disciplines, community clinics, state and national health care organizations, and professional societies. ACU's scope encompasses a unique group of health professionals, geographic regions, practice models, and patient populations. ACU defines access to comprehensive health care to include medical, oral, behavioral, and pharmaceutical services and supports the transdisciplinary team approach to health care.