The Pros and Cons of Formularies

by John Jones and John M. Cronin

The use of the formulary, a tool managed care has adopted from the armamentarium of hospitals, has generated considerable debate. The debate centers on whether the formulary process can apply in managed care, and whether it can adequately address the clinical, humanistic, and economic concerns of all parties.

Generally, health plans, payors, and pharmacy benefit managers are the greatest proponents of formularies. The growing ranks of adversaries include physicians, patients, and consumer groups, both inside and outside managed care practice, who consider formularies a stumbling block on the road to quality care. John Jones presents the advocate's opinion. John Cronin advances the opposing view.

Pro

National policymakers in private industry and in government are slowly accepting that formularies are a necessity if every health plan member is to receive an *affordable and sustainable* pharmacy benefit. Drug costs rising at 20%–60% annually have changed their views. Formularies are only superfluous if you have an unlimited budget and little concern with overall cost. With current limited financial resources to pay for a potentially unlimited demand for service, we must rely on tools that assure proper utilization and

maximize the pharmacy benefit. Good formulary design and management can encourage desirable outcomes while saving considerable costs.

The word *formulary* is subject to broad semantic challenge. It means different things to different people. *Closed* formularies strictly limit drug selection to specific agents selected by a group that conducts therapeutic evaluation. Electronic edits encourage or direct compliance with closed formularies. *Open* formularies are less restrictive; they can range from simple guidelines to preferred drug lists.

The *managed* formulary is becoming the norm in managed care: A specific list of drugs is carefully chosen, but nonformulary drugs are allowed if prior authorization is obtained. A managed formulary addresses product evaluation, formulation of policy and procedure, and distribution of guidelines and clinical information to all health care providers, not just prescribers. Our organization boasts 80%–90% compliance with our managed formulary, and there is always a route to obtain a nonformulary drug if there is adequate justification from the physician. The low rate of nonformulary drug use indicates that formularies can work.

The best formularies are based on a therapeutically sound approach to choosing drugs with proven track records. Considerations include improvements in quality of life, decreases in hospitaliza-

tion, replacements for surgery, or cures that were previously unknown. A formulary is a flexible management tool.

Too often, the word formulary conjures up visions of cheap drugs. Managed care formularies often include products that are new or more expensive and lead to better outcomes for members. Pharmacy and therapeutics (P&T) committees must address changes in the health care environment energetically but cautiously to ensure the best care for their plan members. Formulary committees must include pharmacists, for their drug expertise, and physicians from all levels of the organization for their clinical proficiency and assessment of the applicability of each decision in the direct care setting.

More and more, formulary committees include representatives from other areas of the organization as well. Nurses, administrators, dietitians, and legal experts help committees address nondrug adjunctive therapy, among other considerations. Together, the members of the committee work toward an evidence-based formulary.

Accordingly, cost is only one factor under consideration. Safety, efficacy, side-effect profile, and alternatives must also be considered. Drugs that have high value to members must be reviewed carefully, and the overall cost of therapy with the drug or its alternatives must be considered. Only when drug products are

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TABLE 1 Four Factors Have Changed the Underpinnings of Formulary Management

1. The pharmacy benefit has attracted growing attention as drugs account for an increasing proportion of the health care dollar. This attention may not be warranted if the expanding availability and increasing utility of drugs is considered.
2. There are more drugs available to treat many conditions.
3. Managed care organizations have become larger and more diverse.
4. Information about drugs, disease states, and alternatives is readily available to all Americans, and there is increased patient advocacy and more government oversight directed at formularies.

deemed therapeutically equivalent should cost become the deciding factor. Therapeutic equivalency must be determined by the weight of scientific evidence, not by marketing hyperbole.

Formularies have an educational value as well. Treatment guidelines can help prescribers sort through the proliferation of guidelines promulgated by various organizations. Many prescribers in our organization have been pleased; our guidelines are often the first they have seen on certain disease states, or had presented clearly and concisely.

All health care providers employed by an organization can benefit when formulary selections are linked to guidelines. Guidelines acquaint providers with the basic disease state, and dispel lore or misperception by citing recent findings or ongoing studies. Both drug and nondrug interventions should be reviewed. Prudent

use of step-care therapies becomes the organization norm, and the level of care for members improves. Treatment—not just prescribing—becomes better and more cost-effective. Ultimately, overall health care improves.

Formularies also provide oversight beyond that provided by the Food and Drug Administration's approval process. As unprecedented numbers of drugs are approved, many side effects will be identified only after the drugs have been used in the general population. Some, albeit a very small number, will be serious.

For patients who have not responded to previous therapies or who have non-responsive and life-threatening conditions, new drugs offer hope and should be given expedited review. Treatments for cancer and human immunodeficiency virus (HIV) infection usually fall into this category. As more or better treatments

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become available, a broader array of drugs will be subject to formulary review. Some will be therapeutic equivalents. Although various types of cancers and HIV infection currently have carte blanche standing with respect to formulary review of new drugs, as new drugs that possess similar characteristics are developed, the review process will certainly become more deliberative. Except for very serious conditions, opening the formulary to every available drug can be irresponsible in a clinical as well as a financial sense.

Formularies also help clinicians (and program beneficiaries) sort out the marketing claims of pharmaceutical manufacturers. Today's abundance of advertising, both to prescribers and consumers, can be confusing. Manufacturers understandably present their drugs in the best possible light; comparative data is sometimes absent or skewed. Such advertising may

present concerns for safety or side effects only in the often-overlooked small print. Formulary selection committees look at the validity of marketing claims or studies, the scientific risk and benefit, and the unique population they serve. Despite claims that managed care processes in general and formulary use specifically limit fair competition in the marketplace, the fact remains that because managed care has increased the availability of drugs to members, pharmaceutical manufacturers are more successful than ever.

With some frequency, formularies are assailed by the public, the press, government representatives, and health plan members. Critics often expect unrestricted access to all drugs for every member. This expectation is unreasonable. Public policy and government mandate continuously address formulary use, generally concluding that open access is not possi-

ble under current financial constraints. Any intervention by government restrictions and mandates impacts formulary viability. When governmental agencies require that certain products be covered (e.g., certain forms of birth control), determination of medical necessity at the plan level is complicated.

A well-run formulary can encourage the best care at a reasonable cost. Mechanisms to address the 10%–20% of prescriptions that fall outside the formulary must be streamlined. Constant review of new drugs, or new uses for older agents, helps build a comprehensive selection of medications.

The ideal of sound, cost-effective pharmaceutical care rests on the building block of the formulary. Our only alternatives are a return to fee-for-service or the use of drug price controls. Fee-for-service has already failed in our society, and

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physicians who rely on us to administer high tech infusion therapies at home, and pharmaceutical and biopharmaceutical companies that come to us for clinical testing and distribution of therapeutic advances. And we are proud to say that we also have one of the highest patient satisfaction ratings in the industry. So when you want care you can count on, now and in the future, you know you can count on Gentiva.

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price controls are never popular.

All parties must remember that as the cost of health care increases, the availability of affordable health coverage for all Americans decreases.

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Formularies and formulary management tools have historically been successful in managed care organizations (MCOs). Until recently, formularies accomplished much of their intent. MCOs were able to control costs and eliminate marginally effective drugs, and the pharmacy benefit became more widely available. But over the past five years, major changes have decreased formulary efficacy and chipped away at the incentives for formularies.

Consequently, formulary management has become an administrative burden at all levels. Physicians face potentially adversarial communication with members

when they prescribe within the formulary. Members often come to physicians with preconceived ideas about which drug therapy is needed. Prior-authorization procedures may compromise care if a physician is deterred by the perceived (as well as the real) process, or spends time applying for prior authorization instead of talking to the patient. The perception prevails that cost is more important than outcome.

The drug approval process used in the U.S. is one of the most stringent in the world. While the FDA can ensure safety and efficacy for indications included in the labeling, the true economic value of a drug product is very difficult to assess, especially if the drug is new. Quality-of-life indicators, clinical outcomes, and pharmacoeconomic data take years to accumulate. Rarely do all parties in the process agree on the economic

value of a product; if that was the case, most formularies would be remarkably similar. They are not.

Unlike other nations, the U.S. has no national formulary or cost controls. We also have no national health coverage. Consequently, each MCO assesses its own needs and develops its own formulary.

Organizational changes within managed care have also complicated formulary management. Mergers and acquisitions have led to larger organizations covering more diverse populations. Geographic magnitude has increased, leading to communication challenges. MCOs define customers more broadly to include employers, plans, physicians, and members. Meeting everyone's needs—even just hearing their concerns—is much more complicated.

Government intervention has increased significantly, especially in the

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aftermath of organizational changes. Member dissatisfaction when medication change is mandated by a merged MCO's formulary restrictions often leads to complaints that act on public policymakers.

To deal with these issues, MCOs appoint a P&T committee to establish a formulary. Committee members are expected to make informed, unbiased decisions about drugs proposed for inclusion. But committees vary widely in composition, the process used to appoint members, the aspects of care they examine, and the clarity of their role. Consequently, their decision-making processes vary widely—as does the validity of their decisions. There are few studies that examine or suggest best practices for P&T committees, suggesting that the formulary process remains an unproven tool.

With all factors considered, the economic and emotional cost of formularies

becomes more apparent. The MCO must identify new tools to manage the pharmacy benefit. These tools could be directed at educating critics about the real economic value of drugs and deflecting concerns about cost as a percentage of the health care budget. Educating members about health in general and drugs in particular, and improving the physician-patient relationship, would also help. Tiered copayments would make the patient an economic partner in decision making.

Conclusion

Like many other aspects of managed care, the pharmacy benefit is changing as circumstances change for employers, plans, clinicians, and members. As Internet technology and the electronic medical edit advance, formulary administration becomes simpler. As plans merge and members move from one MCO to another,

member or clinician concern about perceived or real restrictions change. If the MCO does not act on these concerns, they may migrate to members elected representatives. This will eventually result in increased oversight.

Pharmacists who practice in MCOs must understand the importance of responsible formulary development and implementation. Whenever possible, legitimate concerns must be addressed quickly. When misperception emerges, we have a responsibility to communicate factual information effectively. Our unique role as the drug expert and health educator is essential in the entire formulary process.

Clearly, the debate about managed care formularies will continue. The intensity of the debate will only be tempered by our ability to find reasonable middle ground. ■

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