Doctors' Orders:

What Prescribers Need to Know about Medication Access Under Part D

Claudia Schlosberg

In recent months, senior citizens and the health care community have been barraged by public service announcements, newspaper articles, and promotions extolling the benefits of enrolling in Medicare Part D, the new prescription drug benefit. The Centers for Medicare and Medicaid Services (CMS) has assured seniors that the new drug plans will save them money and that branded and generic drugs will be covered. But as details of plan formularies emerge from the thicket of public relations messaging, questions are being raised regarding whether beneficiaries will have access to needed medications.

This article examines emerging issues with respect to medication access under Medicare Part D and the important role of the physician or other prescriber. In particular, I will look at what these practitioners need to know about Medicare Part D to help ensure that patients receive pharmacotherapy in accordance with their orders.

Formulary Factors: Key Determinants of Drug Coverage Under Part D

The Medicare prescription drug benefit is premised on the belief that private plans, paid on a capitated basis in a competitive marketplace, would be better able to negotiate lower prices with drug manufacturers and offer better benefits than if the government stepped in with price controls and prescriptive regulations. Consequently, Congress ensured that new prescription drug plans (PDPs) and Medicare Advantage (MA-PDs) plans offering the Medicare drug benefit have maximum flexibility to design their benefit offerings.

Certain drugs, including benzodiazepines and barbiturates, are excluded from Medicare Part D coverage by statute. In addition, CMS requires plans, at minimum, to cover at least two drugs that are not therapeutically equivalent or bioequivalent in each distinct therapeutic category and drug class. Formularies are not required; but if one is used, it must be developed by a Pharmacy and Therapeutics Committee that has based its decisions on scientific evidence. Finally, each plan's benefit design and utilization management program must not substantially discourage enrollment of certain Medicare enrollees.

To ensure that drug plans do not discriminate against beneficiaries with high cost illnesses and to improve access in high risk categories, CMS issued guidance requiring plans to cover all or substantially all antidepressants, antipsychotics, anticonvulsants, antiretrovirals, immunosuppresants and antineoplastics. Beyond these few rules, the new prescription drug plans were largely free to decide what drugs to cover and how.

An important factor driving coverage are the financial incentives at play in the Part D program. Prescription drug plans provide *only* the drug benefit and are paid on a capitated basis based on the bid they submitted to CMS. PDPs are not responsible for the downstream medical costs. As a result, PDPs have strong financial incentives to negotiate the lowest drug prices from manufacturers. They also are motivated to lead prescribers and patients to the least expensive medications.

With these considerations in mind, it is no surprise that all approved PDPs plans have opted to structure their benefits around traditional, tiered formularies—a primary cost-containment tool used by commercial plans. The vast majority of plans utilize a three-tiered structure with generic products on the first tier, preferred brands on the second, and non-preferred brands on the third. However, some plans have added a fourth tier for "specialty" drugs. The higher the tier, the higher the beneficiary co-payment.

Actual drug coverage by plans, however, is widely divergent and also very fluid. A November 2005 analysis by Goldman Sachs of 21 products in 651 Medicare PDP plans from 15 regions (covering 74 percent of the Medicare population) found wide variation in coverage of branded products.[1] Significantly, despite CMS guidance requiring that plans cover all or substantially all antidepressants, the analysis found many are not covered. For example, Lexapro™, a drug widely prescribed for treatment of depression in the elderly, was not covered on 31% of the plans. In contrast, generic Prozac™, a drug that is appears on the Beers list and is not recommended for use in the elderly, and generic Paxil™ were the two most widely covered antidepressants. A December 2005 *Pink Sheet* analysis of the 10 PDPs approved to

provide coverage nationwide also found uneven coverage of antidepressants.[2] Specifically, eight out of nine plans covered five or fewer of the nine branded antidepressants.

Moreover, many plans are using step therapy and other formulary management tools to control access to commonly used drugs. For example, according to the *Pink Sheet* analysis, Wellcare, CMS's choice as a back-up plan for dual eligible beneficiaries, employs step therapy for all branded antidepressants except for Parnate™, a relatively rarely used MAO inhibitor. Another industry analyst is predicting greater reliance on step therapy and even the addition of two levels of step therapy in the same antidepressant class as Zoloft™ loses patent protection.[3]

Liberal use of various formulary management tools such as prior authorization, step therapy, and quantity limits is not restricted to antidepressants. An October 2005 analysis by the American Society of Consultant Pharmacists looked at four different PDPs. According to CMS' Web site, two of the plans provided 97% coverage of drugs commonly used by Medicare beneficiaries. However, a closer look at the plans' formularies revealed that one plan required prior authorization and quantity limits on approximately 43% of its covered medications. While the ASCP review was not comprehensive, the findings underscore the importance of taking time to choose a plan that not only offers broad formulary coverage but one that does not overly restrict access through use of formulary management tools.

Unfortunately, given the complexity of the benefit and the difficulty of accessing and comparing information among plans, ALF residents and other seniors may end up in plans that do not cover or that restrict access to the medications they need. The risk is especially great for 7.5 million dual eligibles. The dual eligible population includes beneficiaries with significant levels of disability including mental illness.

Although CMS has required all PDP plans to establish an appropriate transition process for all new enrollees and has recommended that all plans provide new enrollees with a one time, 30-day fill of any nonformulary drug, the adequacy of PDP transition plans remains to be seen. Generally, PDPs have not publicized their transitions plans, and calling plan customer service centers yields little useful information.

Prescriber's Choice Versus Payor Prerogative

Under Medicare Part D, a written prescription, alone, may not be enough to ensure choice of medication reaches the patient. Rather, as noted above, plan formularies and formulary management tools can eliminate or restrict access to specific drugs.

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Consider one possible scenario. Dr. X has written an order for Mrs. Jones for medication A. Mrs. Jones has been doing well on this drug without adverse affects for several months. During the transition to Medicare Part D, Mrs. Jones enrolls in a PDP that does not cover medication A or has a step therapy protocol that requires that she fail on medication B before she can receive medication A. When Mrs. Jones seeks to refill her medication at the pharmacy, she is informed that her Medicare PDP will not cover the drug at all or will only cover it after she has tried and failed on medication B.

At this point, several things could happen:

- *Scenario 1.* Mrs. Jones could decide to pay for medication A out of her own pocket as a nonformulary drug if she can afford it. However, if she does this, the cost of the medication is not acountable as a "true out-of-pocket" (TrOOP) expense and, therefore, will not help her reach the level of out-of-pocket expenditures that eventually will enable her to qualify for catastrophic prescription drug coverage.
- *Scenario 2.* If Mrs. Jones is unable to afford to pay for medication A, she can request that the prescription drug plan grant *an exception* and effectively waive the step therapy requirement or cover the drug as if it is a formulary-listed medication. Legally, a PDP must respond to an exception's request as expeditiously as the patient's health condition requires, but no later than 72 hours after receipt of the request. In situations involving a serious risk to life or health or the patient's ability to regain maximum function, the patient or the patient's physician can request an expedited determination. If granted, the PDP must respond within 24 hours.

Scenario 1 is fine if ALF residents or other seniors or their families can afford to pay for these medications. However, this will not be a feasible options for many individuals, particularly dual eligibles and other low income seniors. At the same time, there is a critical limitation to Mrs. Jones' ability to successfully seek an exception in that she must enlist the support and

cooperation of Dr. X. This is because, under Medicare Part D, a physician's supporting statement establishing that the requested drug is medically necessary must accompany every exception's request.

- *Scenario 3:* The PDP could switch Mrs. Jones to a preferred medication. Drug substitution generally takes two forms: generic substitution and therapeutic substitution. Generic substitution is the act of dispensing the generic equivalent of the prescribed branded product. Therapeutic substitution is the act of dispensing a different chemical entity from the same therapeutic class as a therapeutic alternative to the prescribed drug.

Although state laws governing generic and therapeutic substitution vary, generic substitution generally is permissible when the substituted products contain the same chemical entity and are bioequivalent to one another and the treating physician has authorized generic substitution or has not affirmatively disapproved generic substitution.

Therapeutic substitution is more controversial. Because a therapeutic alternative generally is not a generic equivalent, a pharmacist legally will not be able to dispense a therapeutic alternative without prescriber authorization and patient consent. However, some health plans have policies that allow therapeutic substitution without contacting the prescriber when the medications have been deemed therapeutically equivalent and approved for substitution by the plan's Pharmacy and Therapeutics (P&T) Committee. Although the American Medical Association and most other medical societies oppose therapeutic substation without prescriber authorization, CMS has been supportive of PDPs' efforts to promote therapeutic substitution of non-equivalent drugs as an appropriate cost-saving strategy in Medicare Part D.

Recommendations for Prescribers

There is little question that Medicare Part D embraces a model of care delivery that emphasizes cost containment. Whether and to what extent this new model will constrain medication access will depend on a variety of factors. Prescribers can help ensure a smooth and safe transition to Part D. Here are a few recommendations:

- First, patients who are eligible to enroll in Medicare Part D need to be counseled to make wise choices. While it is tempting to choose a plan based on price alone, a critical consideration is the plan's formulary. Beneficiaries need to understand that drug lists, tier placement, and formulary controls must be evaluated.
- Second, beyond writing a prescription, prescribers play a critical roll in ensuring that patients receive medically necessary therapy from their drug plans. Physicians need to reacquaint themselves with the laws and regulations governing prescribing and drug substitutions in their state. When a patient needs to consider a switch to a preferred drug, either because the prescribed drug is not covered or because of a step therapy protocol or therapeutic substitution program, the prescriber needs to engage in the same deliberative process that culminated in the initial prescribing decision. If the prescriber's judgment is that the patient should only receive the medication as prescribed, that practitioner should be sure to include "dispense as written" on the prescription form. If a change in medication is not medically appropriate or places the patient at risk, the prescriber should oppose the change and support the exception process.
- Third, prescribers should monitor outcomes. If a patient's medication regimen is changed because of formulary compliance and the patient experiences serious adverse outcomes or fails on the new drug, findings should be documented and reported to appropriate drug regulatory authorities and to CMS.

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Finally, PDPs are required by law to provide medically necessary medications and are subject to civil fines and penalties if they do not comply with the law. Whether a specific medication is medically necessary, however, depends on the prescriber's judgment. With pressures growing to contain rising prescription drug costs, prescribers may need to become advocates in defense of their own choices. ALC

Claudia Schlosberg is a Partner at Blank Rome, LLP, in Washington, DC. She will be a regular contributor to *Assisted Living Consult* during the coming year.

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