



## Medicare Drug Plans Should Lift Restrictions on Mental Health Drugs

*I am a person with Medicare and Medicaid because of a disability. I was automatically enrolled in a Part D drug plan that did not cover all of my prescriptions. I then re-enrolled in another plan that did cover all my prescriptions. After I received a notice from my new plan that I was enrolled, I went to the pharmacy to pick up my prescriptions. I was denied prescriptions three times because the pharmacist said I did not have the necessary “pre-approval.” I was given the choice of paying out-of-pocket or leaving without medicine.*

*Prior Authorization Means No Medicine  
Minneapolis, MN*

*My son is an adult with a disability. He takes seven prescriptions every month and is on both Medicare and Medicaid. As of the first of the year he has been enrolled in a Medicare prescription drug plan. When his prescriptions were filled in early January he only received a half month's supply of his most important medication—his atypical antipsychotic. This is the medication that keeps him from having hallucinations. Unfortunately, because the other six prescriptions had been completely filled, my son did not detect the shortage until shortly before he was about to run out of pills. When I contacted the pharmacist and told him that we needed another 15 days worth of pills (30 more pills because he takes the pills twice a day), he said he didn't know if the drug plan would approve the request for a refill. I replied that if the plan did not allow the refill it would be just a short matter of time until my son would start hallucinating!*

*Quantity Limits Risk My Son's Stability  
Lincoln, NE*

Restrictions imposed by Medicare Part D drug plans on mental health drugs are preventing people with Medicare from complying with established drug regimens that keep them stabilized.

Although drug plans are required by the Centers for Medicare and Medicaid Services (CMS) to cover “substantially all” antipsychotics and antidepressants, there is no strict prohibition against the imposition of utilization management restrictions.

Rather than allowing doctors to determine their patients' treatment—a core principle of the Medicare program—Congress created a drug benefit that allows insurance companies administering the drug benefit to limit treatment options. These limitations can have devastating consequences for people stabilized on mental health medications. Recognizing this potential, CMS has tried to impose minimum coverage standards but has failed to bar utilization management techniques that can effectively deny coverage to essential medicines.

Utilization management techniques restrict access to medications included on a formulary in three ways. First, plans may require **prior authorization** before they will cover a certain drug, demanding that physicians certify specific diagnoses that are necessary for coverage. Second, they may impose **step therapy**—the requirement that an alternative, cheaper, medicine is first tried and shown to be ineffective or cause adverse side effects before a more expensive drug will be covered. Finally, plans can impose **quantity limits** on certain drugs. Quantity limits can specify the number of pills a particular drug a plan will cover each month or they can cap the total number of drugs it will cover at a set amount.

A review of plan formularies finds that some plans require prior authorization or step therapy for the atypical antipsychotics Risperdal and Zyprexa used to treat schizophrenia. Other plans impose quantity limits that limit the monthly dosage on these drugs and others in the same class. Among antidepressants, some plans place quantity limits, prior authorization or step therapy on Cymbalta, Zoloft and even generic Prozac.

There are widespread reports of people with Medicare and those who advocate on their behalf finding it extremely difficult, if not impossible, to obtain prior authorization or an exemption to quantity limits from Part D plans. Among the most common problems is the inability to get through to the customer service lines to start the process to obtain coverage. The lack of standard prior authorization or formulary exceptions forms among plans also impedes the ability of plan enrollees, their physicians or counselors, to obtain approval for restricted drugs. These obstacles in turn have led to the refusal of some physicians to process the required paperwork and obtain the necessary documentation required by the plans.

As a result, the utilization management restrictions imposed by plans act as a **de facto** exclusion of certain drugs, undermining the mandate that plans cover “substantially all” mental health drugs. It also subverts the goals of CMS guidance that deals specifically with the impact of utilization management techniques. For drugs that are covered, but subject to step-therapy or prior authorization restrictions, plans “should ensure that procedures limiting access are appropriate in situations in which a new enrollee is already stabilized on a drug or has already tried lower step agents.”<sup>i</sup> For patients stabilized before enrollment on drugs in six classes—antidepressants, antipsychotics, anticonvulsants, antineoplastics (cancer medications), immunosuppressants and antiretrovirals, CMS expects that “plans would not use management techniques like prior authorization or step therapy, unless a plan can demonstrate extraordinary circumstances.”<sup>ii</sup>

The access problems reported during the first month of the drug benefit prompted CMS to tell plans they should also provide temporary supplies of drugs that are restricted by prior authorization or step therapy, as well as for drugs that are excluded from formularies. The

continued concern that people with Medicare would again be turned away at the pharmacy counter without their drugs then prompted an extension of the transition period through March. Neither of these measures, even if universally applied by Part D plans and systematically enforced by CMS, will permanently solve the access problems that utilization management restrictions, including quantity limits, present for people with mental illness.

The overwhelming majority of the new enrollees in Part D who take mental health drugs are on established drug regimens. They are not new patients. Their physicians have already prescribed specific medicines and specific dosages of those medicines often after having tried alternatives that were ineffective or had adverse side effects. Patient compliance with drug regimens is crucial for the medicines to be effective; restrictions that interrupt treatment or force a switch to a medicine that is less effective or has adverse side effects can prompt patients to abandon their drug therapy.

The potential impact of impaired access to these drugs is great. One in five older adults and over half of people on Medicare because of disability have a mental or cognitive impairment.<sup>iii</sup> Older adults have the highest suicide rate in the United States.<sup>iv</sup> Furthermore, nearly forty percent of “dual eligibles”—2.5 million individuals—have a cognitive or mental impairment.<sup>v</sup>

Plans that impose blanket restrictions on mental health drugs, whether they require prior authorization, step therapy or impose quantity limits, clearly have not heeded CMS’ call to impose such restrictions only in “extraordinary circumstances.” Rather these restrictions will affect the majority of people with Medicare who are stabilized on these medicines. Moreover, the lack of consistent procedures among plans and the chronic understaffing of customer service departments have turned these restrictions into insurmountable barriers.

In its draft formulary guidance for 2007, CMS recognized the likelihood that these utilization management restrictions would impact patients already stabilized on drugs in the six protected classes, including antipsychotics and antidepressants. CMS cautioned plans against imposing them if it could not distinguish at the pharmacy counter between initial prescriptions and prescriptions for ongoing therapy.

“Part D plan sponsors may not implement prior authorization or step therapy requirements that are intended to steer beneficiaries to preferred alternatives within these classes who are currently taking a drug. If a plan cannot determine at the point of sale that an enrollee is not currently taking a drug (e.g. new enrollee filling a prescription for the first time), plans shall treat such enrollees as currently taking the drug.”

For its new enrollees this year, plans have no records of prior drug use. Pharmacies may or may not have such records. However, the experience during the first weeks of the new drug benefit, make clear that the lines of communications between pharmacies and drug plans are unable to efficiently and consistently override restrictions in the plans’ claims processing systems. Consequently, people with Medicare are being denied temporary fills of drugs subject to such restrictions, in effect proving that plans cannot distinguish between initial prescriptions and maintenance prescriptions that should trigger temporary fills.

Once those temporary fills run out, the same problems will surface when pharmacists seek to exempt patients stabilized on mental health drugs from step therapy or prior authorization requirements. Given this history and given that the vast majority of Part D enrollees should not, in CMS' own view, be subject to these restrictions, CMS should immediately require plans to remove all utilization management restrictions on mental health drugs and the other drugs in the six protected classes.

**Recommendation:**

**CMS should require Part D plans to lift all utilization management restrictions—quantity limits, prior authorization and step therapy—on antipsychotics and antidepressants, anticonvulsants, antineoplastics (cancer medications), immunosuppressants and antiretrovirals. These requirements should be enforced and backed up by meaningful sanctions.**

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<sup>i</sup> Centers for Medicare & Medicaid Services. *Information for Part D Sponsors on Requirements for a Transition Process*. March 16, 2005. Found at: [http://www.cms.hhs.gov/pdps/transition\\_process.pdf](http://www.cms.hhs.gov/pdps/transition_process.pdf).

<sup>ii</sup> Centers for Medicare and Medicaid Services, “Why is CMS requiring “all or substantially all” of the drugs in the antidepressant, antipsychotic, anticonvulsant, anticancer, immunosuppressant and HIV/AIDS categories?” (Part D plans are barred from imposing step therapy or prior authorization, but not quantity limits, on antiretrovirals used to treat HIV/AIDS with the exception of one drug, Fuzeon.)

<sup>iii</sup> The Henry J. Kaiser Family Foundation, “The Faces of Medicare: Medicare and the Under-65 Disabled,” July 1999. Found at: <http://www.kff.org/medicare/1481-index.cfm>.

<sup>iv</sup> American Psychological Association, “Facts about Suicide in Older Adults.” Found at: <http://www.apa.org/ppo/issues/oldersuicidefact.html>.

<sup>v</sup> MedPAC, *Report to Congress: New Approaches in Medicare*, June 2004, p. 72. Found at: [http://www.medpac.gov/publications/congressional\\_reports/June04\\_Entire\\_Report.pdf](http://www.medpac.gov/publications/congressional_reports/June04_Entire_Report.pdf).