Medicare Rights Center

Clearing Hurdles and Hitting Walls: Restrictions Undermine Part D Coverage of Mental Health Drugs

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Introduction

The Medicare Modernization Act gives Part D prescription drug plans broad leeway in constructing their formularies but also mandates that the Centers for Medicare & Medicaid Services (CMS) ensures access to all medically necessary drugs. To fulfill that mandate and to ensure that Part D plans provided coverage that met current industry standards, CMS issued sub-regulatory guidance requiring plans to cover "substantially all" drugs in six classes, including antipsychotics and antidepressants, two critical classes of mental health drugs. Furthermore, for patients stabilized on drugs in these classes before enrollment in a Medicare drug plan, CMS expected that "plans would not use management techniques like prior authorization or step therapy, unless a plan can demonstrate extraordinary circumstances."[1]

These laudable steps taken by CMS have undoubtedly mitigated the potential disruptions to psychotherapy drug regimens that would have occurred absent establishment of these minimum benchmarks for formularies. But, as demonstrated by the stories of people with Medicare, they have not prevented restrictive plan formularies from disrupting, and sometimes derailing, the treatment regimens of people with Medicare suffering from mental illness.

True Story

Ms. Z is 64 years old and has suffered from schizophrenia for over 30 years. She takes Abilify and Zyprexa to control her symptoms and has been stable for the last five years because Medicaid had covered her medications. Because she has both Medicare and Medicaid, Ms. Z was auto-enrolled in a Medicare private drug plan with her new drug coverage starting January 1, 2006. In January, Ms. Z attempted to fill her prescriptions for Abilify and Zyprexa but was told by her pharmacist that her Medicare private drug plan requires prior authorization for those drugs. Ms. Z left the pharmacy empty-handed and confused. The pharmacist had not explained what prior authorization was nor used her plan's transition policy to fill her prescriptions. She was told by a caseworker at the medical clinic she uses that because the doctor only comes to the clinic twice a week and sees over 50 patients each day, it would be virtually impossible for the doctor to provide prior authorization.

Some Part D plans have failed to include all the antipsychotic or antidepressant medicines required by CMS formulary guidance. More commonly, the imposition of utilization management techniques by Part D drug plans has resulted in delayed or denied access to critical drugs. Plans have failed to distinguish between maintenance prescriptions and new prescriptions, resulting in the widespread imposition of utilization management restrictions for patients already stabilized on these medicines. Finally, CMS' review of plan formularies has failed to ensure that all utilization management restrictions imposed on these mental health drugs, in particular quantity or dosage limits, are clinically sound.

The potential impact of impaired access to these drugs is vast. One in five older adults and over half of people on Medicare because of disability have a mental or cognitive impairment.[2] Older adults

[1] Centers for Medicare & Medicaid Services, "Why Is CMS Requiring 'All or Substantially All' of the Drugs in the Antidepressant, Antipsychotic, Anticonvulsant, Anticancer, Immunosuppressant and HIV/AIDS Categories?" 2005

[2] Henry J. Kaiser Family Foundation, "The Faces of Medicare: Medicare and the Under-65 Disabled," July 1999.

have the highest suicide rate in the United States.[3] People with mental illness find it more difficult than others to navigate the bureaucratic process that is required to obtain coverage for nonformulary drugs or those restricted by utilization management techniques.[4] The frustrations and stress that accompany that process can lead patients with mental illness to abandon their medication regimens and trigger episodes of decompensation (the inability to maintain defense mechanisms in response to stress, resulting in depression, anxiety or delusions).[5]

Impaired access to mental health drugs has a disproportionate impact on individuals with low incomes who have both Medicare and Medicaid (dual eligibles). Nearly 40 percent of dual eligibles—2.5 million individuals—have a cognitive or mental impairment.[6] Until Part D began in 2006, dual eligibles received prescription drug coverage through state Medicaid programs. Most of those programs, including the New York Medicaid program, provided unimpeded access to mental health drugs.[7]

In advance of the January 1, 2006, start date to the Part D benefit, nearly six million dual eligibles were randomly assigned to low-cost Part D plans without regard to whether their medicines were covered or subject to utilization management restrictions by their plan. This random assignment contributed to the chaos that accompanied the kickoff of Part D as individuals discovered at the pharmacy counter that their assigned plan did not cover their medicines.

That situation threatens to repeat itself on a smaller scale in January 2007 as an estimated one million dual eligibles and other low-income people with Medicare face reassignment from plans that no longer qualify for a full premium subsidy (plans with premiums above regional benchmarks). Reassignment will again be done on a random basis, without regard to matching formulary coverage and individuals' drug regimens. Individuals who stay in their current plan may also be subject to formulary changes their plan makes for the 2007 benefit year. Although CMS has extended the requirement to cover "substantially all" mental health drugs into 2007, Part D plans retain extensive leeway in their ability to restrict access through utilization management techniques.

True Story

Mr. B suffers from a number of chronic conditions. He takes 16 prescription medications, including Lexapro for clinical depression. Although the recommended dose of Lexapro is 10 milligrams per day, Mr. B's depression is severe and his doctor increased his dose to 20 milligrams per day. Mr. B is a dual eligible and was auto-assigned to a Medicare private prescription drug plan. In January, he was informed by his pharmacist that while his plan covered all 16 of his prescriptions, it only covered the 10 milligram tablets of Lexapro and limited that coverage to 30 tablets per month. Mr. B's doctor has tried unsuccessfully to contact the drug plan to request an exception for Mr. B.

[3] American Psychological Association, "Facts About Suicide in Older Adults."
[4] Jensen, R. "The New Medicare Prescription Drug Law: Issues for Enrolling Dual Eligibles Into Drug Plans," Kaiser Commission on Medicaid and the Uninsured, January 2005.
[5] Park, J., Hariprasad, R., and L. Park. "Medicare Part D and Decompensation, Psychiatric Services," May 2006.
[6] MedPAC, "Report to Congress: New Approaches in Medicare," June 2004.
[7] Kaiser Commission on Medicaid and the Uninsured, "State Medicaid Outpatient Prescription Drug Policies: Findings from a National Survey, 2005 Update." Found online at http://www.kff.org/medicaid/upload/State-Medicaid-Outpatient-Prescription-Drug-Policies-Findings-from-a-National-Survey-2005-Update-report.pdf.

This brief evaluates access to antipsychotics and antidepressants in the 15 prescription drug plans in New York that received auto assignment of dual eligibles in 2006. All of these plans also received auto assignment in other states in 2006, and some will undoubtedly remain eligible for auto assignment in the next benefit year.

Scope and Methodology

This paper looks both at whether antidepressants and antipsychotics were listed on plan formularies and analyzes the prevalence of utilization management techniques. Three types of utilization management techniques were tracked: prior authorization, step therapy and quantity limits. Prior authorization is the requirement that doctors certify specific diagnoses for plan coverage of certain drugs. Step therapy is the requirement that an alternative, cheaper medicine is tried and shown to be ineffective or cause adverse side effects before a more expensive drug will be covered. Quantity limits specify the number of pills or dosage of a particular drug a plan will cover each month or restrict the duration of coverage.

True Story

Mr. H is a 40-year-old schizophrenic who has been on Medicaid and Medicare for years. Because relapse is very common in schizophrenia, Mr. H is always careful to take every dose of Risperdal, his antipsychotic. The regimen prescribed by his doctor is six 1-milligram pills of Risperdal per day (180 pills per month)—which he has been taking for the last five years. As a dual eligible, he was auto-enrolled into a Medicare private drug plan. Because the pharmacy was unable to properly bill his Medicare plan in the months of January and February, Mr. H was able to get his Risperdal through New York Medicaid's emergency coverage. In March, however, the pharmacist informed Mr. H that his Medicare drug plan would only pay for 60 pills of Risperdal per month. The pharmacist told Mr. H that he could get the remaining 120 pills only if he paid the $700 retail price.

We examined the coverage details of 24 antidepressants and 17 antipsychotics identified by the United States Pharmacopeia (USP)[8] (Table 1). Our assessment evaluated 16 generic antidepressants and eight single-source brand-name antidepressants. The coverage details of nine generic and eight single-source brand-name antipsychotics were studied. Generic drugs are chemically and therapeutically equivalent to the corresponding brand-name drug but are available at a lower price. Single-source brand-name drugs are available from only one manufacturer and are patent protected. No generic equivalent is available.

Formulary inclusion of drugs was evaluated based on a plan's coverage of generics and single-source brand-name drugs:[9] if a plan formulary included the generic, but not the multisource brand, the drug was counted as covered.[10] Similarly, plans that opted to cover citalopram but not Lexapro (escitalopram), as allowed under CMS guidance, were considered to meet the "substantially all"

[8] The USP's Model Guidelines were developed in 2004 as an outline of the drug categories, classes and key drug types that should be included in formularies of all private drug plans participating in Part D.
[9] CMS does not require drug plans to cover multisource brand-name drugs.
[10] Multisource brand-name drugs are drugs that were formerly patent-protected drugs but now have at least one generic alternative

benchmark.[11] Plans were considered to include drugs if they listed the drug as covered in any form (capsule, tablet, solution) and any dosage.[12]

Plans were considered to impose utilization management techniques if they used quantity limits, prior authorization and/or step therapy, or if they listed a drug as covered under Medicare Part B. Some plans imposed age limit restrictions, requiring prior authorization if a patient's age is above limits established by manufacturers, Food and Drug Administration or clinical recommendations. For the purpose of this report, age limit restrictions were considered forms of prior authorization.

Research was conducted using formularies posted on plan web sites and double-checked with calls to plan customer service representatives (see sidebar).

[11] CMS required plans to cover either citalopram hydrobromide or Lexapro.

[12] CMS does not require drugs plans to cover all dosages of drugs.

The Medicare web site and the web sites of plan sponsors and plan representatives provide incorrect, misleading or conflicting information about plan coverage and utilization management restrictions.

While the government encourages people to compare drug plans by using the Medicare web site, the information found there often does not match the information found on the web sites of plan sponsors or the information provided by plan customer service representatives. In fact, although plans are required to cover "substantially all" drugs in six categories, including antidepressants and antipsychotics, federal officials found some of these drugs missing from the lists submitted by insurers for posting on the Medicare web site.[13]

Similarly, in our formulary review we discovered a number of inconsistencies between Medicare's web site and the web sites of plan sponsors. Inconsistencies were noted in more than two-thirds of plans examined. For example, when evaluating whether plans covered Wellbutrin, several plans listed the extended-release tablets but did not list regular Wellbutrin tablets on their formularies. However, the Medicare web site listed regular Wellbutrin tablets as covered by these plans. To further complicate matters, plan representatives were similarly perplexed by the conflicting information and stated within the same conversation that regular Wellbutrin tablets were and were not covered by the plan.

Similar confusion surrounded drugs subject to utilization management techniques. Information was not always consistent between Medicare's web site and plan web sites. Sometimes Medicare's web site showed utilization management techniques that were not reflected in a plan's formulary and vice versa. Furthermore, neither Medicare's web site nor plan web sites offered a sufficient explanation of utilization management techniques. Plan representatives also were usually not able to explain these coverage restrictions.

Inaccurate or insufficient information about a plan's coverage restrictions could discourage enrollment of people with higher drug costs. Furthermore, some people might enroll in a plan unaware of how difficult it will be to get the drugs they need.

[12] Pear, R. "Deadline Near, Jams Are Seen for Drug Plan," *New York Times*, April 24, 2006.

Table 1: List of Drugs in the Study Sample

Antidepressants	
Drug Name	**Drug Type**
Amitriptyline	Generic
Amoxapine	Generic
Bupropion	Generic
Citalopram	Generic
Clomipramine	Generic
Cymbalta	Single-source brand-name
Desipramine	Generic
Doxepin	Generic
Effexor	Single-source brand-name
Fluoxetine	Generic
Fluvoxamine	Generic
Impramine	Generic
Lexapro	Single-source brand-name
Maprotiline	Generic
Mirtazapine	Generic
Nardil	Single-source brand-name
Nefazodone	Generic
Nortriptyline	Generic
Parnate	Single-source brand-name
Paroxetine	Generic
Surmontil	Single-source brand-name
Trazodone	Generic
Vivactil	Single-source brand-name
Zoloft[14]	Single-source brand-name

Antipsychotics	
Drug Name	**Drug Type**
Abilify	Single-source brand-name
Chlorpromazine	Generic
Clozapine	Generic
FazaClo	Single-source brand-name
Fluphenazine	Generic
Geodon	Single-source brand-name
Haloperidol	Generic
Loxapine	Generic
Moban	Single-source brand-name
Orap	Single-source brand-name
Perphenazine	Generic
Prochlorperazine	Generic
Risperdal	Single-source brand-name
Seroquel	Single-source brand-name
Thioridazine	Generic
Trifluoperazine	Generic
Zyprexa	Single-source brand-name

Findings

1. Not all plans meet the "all or substantially all" coverage benchmark. Use of utilization management restrictions varies widely and is often without clinical rationale.

Not all the Part D plans surveyed cover all single source antidepressants and antipsychotics as required by CMS formulary guidance. For example, in March, two plans listed the antidepressant Cymbalta as off-formulary and one plan did not cover the antipsychotic Geodon. Plan representatives confirmed the drugs were not covered by the plans. However, a review of plan formularies in September found all these formulary omissions had been corrected, although many of these drugs are now subject to prior authorization or quantity limits.

More commonly, however, plans listed drugs as on-formulary but subjected them to one or more utilization management restriction. Plans utilized the full complement of utilization management

[14] Formulary research was conducted in March 2006 before Zoloft became subject to generic competition.

techniques, requiring prior authorization (including for drugs covered by Part B when administered by a doctor), imposing step therapy requirements and setting quantity and age limits on drugs.[15]

The prevalence of utilization management restrictions varied widely across plans. An analysis of plan formularies shows some plans imposed restrictions or listed drugs as noncovered[16] at nearly twice the average rate, despite CMS pledge to subject "outlier" formularies to greater scrutiny.

Table 2: Percentage of Drugs Not Covered or Restricted By Utilization Management

Plan	Percent of Antidepressants	Percent of Antipsychotics
AARP Medicare Rx	21%	17%
First Health Premier	42%	44%
GHI Medicare PDP	29%	33%
Health Net Orange 003	33%	44%
Health Net Orange 009	33%	44%
Humana PDP Standard	29%	28%
PacifiCare Saver	21%	22%
PacifiCare Select	17%	22%
Rx Pathway Bronze	4%	11%
SilverScript	0%	6%
Simply Rx	29%	17%
Unicare Rx Rewards	21%	11%
United Health Rx	21%	17%
United Medicare MedAdvance	21%	17%
WellCare Signature	21%	33%
Average:	**23%**	**24%**

Among antidepressants, the average rate of noncoverage or coverage subject to utilization management restriction was 23 percent. The most restrictive plan, First Health Premier, restricted access to 42 percent of the drugs in this class and both Health Net Orange plans restricted access to one-third of the antidepressant class. Only one plan, SilverScript, allowed unrestricted access to all drugs in the class.

Among antipsychotics, on average plans denied or restricted coverage to 24 percent of the drugs. Once again, First Health Premier and Health Net Orange had the most restrictive formularies, restricting or denying coverage to 44 percent of drugs in the class. At the other extreme,

[15] When formularies were rechecked in September, almost all utilization management restrictions remained in place. There were, however, two exceptions. The three plans offered by UnitedHealth Group lifted quantity limits on mirtazapine, Zoloft, Cymbalta and Lexapro, and the Health Net Orange plans no longer imposed step therapy on Seroquel. The chart reflects the formulary restrictions in place on March 2006.

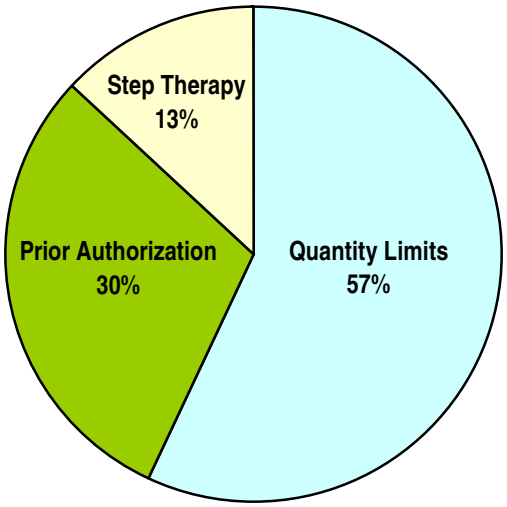
[16] From the perspective of a plan member, there is no difference between a drug that requires prior authorization in order for the drug to be covered or one that is off-formulary and can only be covered after the plan grants an exception. In theory at least, the granting of both prior authorization and an exception is done on the basis of medical necessity.

two plans offered less restrictive formularies, subjecting 11 percent of these drugs to formulary restrictions, while one plan, SilverScript, restricted access to only one drug (6 percent of the class).

Such significant deviations by certain plans from the overall averages clearly demonstrate the flaws inherent to the random assignment of dual eligibles to drug plans. Under random assignment, a dual eligible has an equal chance of ending up in any of these plans, but not every plan provides the same access to these critical medicines. Such variance in coverage also means that although people with Medicare may have multiple plan options, they have fewer legitimate choices that provide appropriate access to the drugs they need.

The utilization management technique imposed most frequently was quantity limits (Figure 1). Many plans indicate that quantity limits are based on Food and Drug Administration (FDA) recommended doses. Other plans do not specify the quantity limit in their formularies, but experience with the exceptions and appeals process shows that most quantity limits are set at the maximum dose recommended by the FDA.

Figure 1: Comparative Frequency of Utilization Management Techniques



However, utilization management techniques are not applied consistently to the same drugs by different plans. For instance, no single antipsychotic has quantity limits imposed on it by more than five drug plans. Similarly, while 9 of the 15 plans impose a quantity limit on Paroxetine, all others offer it with no restrictions. Such an inconsistent application of utilization management techniques undermines claims that they function as safety checks.

But even maximum thresholds established on the basis of FDA recommendations may limit coverage for individual patients at below dosage levels that are medically necessary. CMS acknowledged this in recent policy clarification explaining that plans "may have dose limitations based on FDA labeling, but an enrollee may request (and be granted) an exception to a dose

limitation through the formulary exception process **based on medical necessity criteria**" (emphasis added).[17]

In fact, practice guidelines for treatment of both schizophrenia and major depressive disorder specifically recommend adjusting dosages (titration) based on the response of individual patients.

The treatment guidelines for major depressive disorder developed by the American Psychiatric Association (APA) say "use of higher antidepressant doses may be helpful for patients who have received only modest doses or for those who for pharmacodynamic reasons have low serum drug levels despite usual doses and adherence."[18] The guidelines also note the lack of studies clearly establishing dose-response relationships and clarifies that the recommended doses "are intended to serve as general guidelines, and actual doses may vary from individual to individual."[19] Finally, for patients who have shown a partial response to initial antidepressant treatment, the guidelines note that "use of higher antidepressant doses is another strategy to maximize an initial treatment regimen."[20]

For treatment in the stable phase of schizophrenia, the APA notes that "second generation antipsychotics can generally be administered at doses that are therapeutic but that will not induce" side effects."[21] Furthermore, APA's 2004 treatment guidelines note that for Zyprexa and Seroquel, two of the second-generation antipsychotics most subject to quantity limits, treatment at higher-than-usual dosing has been used effectively in the acute phase of schizophrenia, with few side effects.[22] By contrast, for first-generation antipsychotics, which are much less likely to be subject to quantity limits, the guidelines note that "higher doses are no more effective for acute treatment than normal doses, but higher doses are associated with a greater incidence of side effects."[23]

The widespread use of quantity limits in effect overrides the titration process and substitutes a cost-based quantity limit for a psychiatric practice according to clinical guidelines (see finding number 5). Initial experience with the exceptions and appeals process, moreover, shows that, even with evidence that dosages above quantity limits are based on a clinical history, plans do not make appropriate exceptions for individual patients. Instead, plans rely almost exclusively on requirements for citations in approved compendiums for evidence of **general** effectiveness of doses above FDA labeling, ignoring evidence of effectiveness for the individual patient. Furthermore, plans have taken a restrictive view of the evidence from compendiums, using it to set new maximum levels in individual cases rather than as evidence for the potential effectiveness of dosages at above FDA-recommended levels for individuals.

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[17] Centers for Medicare and Medicaid Services, Q&A #6987, April 2006
[18] American Psychiatric Association, *Practice Guideline for the Treatment of Patients with Major Depressive Disorder*, 2nd Edition, 2000.
[19] Ibid.
[20] Ibid.
[21] American Psychiatric Association, *Practice Guideline for the Treatment of Patients with Schizophrenia*, 2nd Edition, 2004.
[22] Ibid.
[23] Ibid.

2. Plans do not consistently impose utilization management restrictions on drugs contraindicated for use in older adults.

The Beers Criteria[24] identify drugs generally considered inappropriate when given to older adults because they are either ineffective or pose an unnecessarily high risk and a safer alternative is available. Amitriptyline, for example, has been identified as the medication most often inappropriately prescribed to older adults.[25] The most common adverse reactions involve anticholinergic effects such as dry mouth, disturbances of visual accommodation, constipation and urinary retention. Also commonly seen are light-headedness, drowsiness, increased perspiration and mild tremors, as well as insomnia. Adverse reactions of the cardiovascular system may be much more serious; however, these occur less frequently.

In addition to amitriptyline, the Beers list includes three other drugs examined in our study: the antidepressants doxepin and fuoxetine, and the antipsychotic thioridazine.

Since the Beers list has identified these drugs as unsafe for older adults, it is reasonable to expect a higher rate of utilization management be imposed on them. To the contrary, however, the rate of utilization management imposed on these drugs was lower than or the same as the average overall rate of utilization management. All but two of the plans offered amitriptyline, doxepin and thioridazine with no restrictions, and 75 percent of the plans offered Fluoxetine with no restrictions (Table 4).

Table 2: Coverage Details for Drugs Identified as Unsafe for Older Adults

Drug Name	Percent of Plans that Restricted Coverage of the Drug
Amitriptyline	13%
Doxepin	13%
Fluoxetine	25%
Thioridazine	13%

The lack of utilization management techniques raises doubts about the validity of these techniques as safety checks.

3. Individual plans impose utilization management techniques differently on multisource brand names and corresponding generic alternatives and on different dosages of the same drug.

In some instances when both a multisource brand name and the corresponding generic were covered by a plan, the utilization management techniques imposed varied. For instance, a number of plans that cover both brand-name Prozac and its generic Fluoxetine impose utilization management techniques only on the brand-name version. Despite already placing the drugs on different tiers, one such plan imposed quantity limits on Prozac but covered Fluoxetine with no restrictions. While

[24] The Beers Criteria were adopted by CMS in July 1999 for nursing home regulation.
[25] Traynor, K. "Many Elderly Receive Unsuitable Psychotropics." American Society of Health-System Pharmacists. October 27, 2000.

there is no specific clinical rationale for placing these restrictions only on the brand name, there is a financial incentive. Prozac's retail price is approximately six times higher than that of Fluoxetine.

Even for the same drug, plans' coverage details varied by dosage. For instance, one plan imposed quantity limits on Paroxetine, the generic of Paxil, for 10, 20 and 40mg tablets but covered the 30mg tablet with no restrictions.

Again, such a varied imposition of utilization management techniques indicates that their use is not uniquely motivated by a clinical rationale.

4. Commonly prescribed drugs had higher rates of utilization management.

In a comprehensive review of Part D formularies, the Office of the Inspector General (OIG) identified 200 of the most commonly used drugs by dual eligibles.[26] Our assessment included 15 antidepressants and 9 antipsychotics on the OIG's list. Overall, this subset of 24 drugs had an average utilization management rate of 38 percent (Table 4), which was greater than the overall average utilization management rate of 23 percent.

Table 4: Coverage of Drugs Most Commonly Used by Dual Eligibles

Drug Name	Percent of Plans That Restricted Coverage of the Drug
Abilify	40%
Bupropion	0%
Citalopram	60%
Clozapine	33%
Cymbalta	73%
Fluoxetine	27%
Geodon	53%
Haloperidol	0%
Mirtazapine	27%
Paroxetine	60%
Risperdal	40%
Seroquel	40%
Trazodone	0%
Zoloft	87%
Average:	**39%**

Furthermore, Zoloft, Cymbalta and Paroxetine were among the antidepressants with the highest overall rates of utilization management (Table 6), with Zoloft being the most commonly prescribed antidepressant and the antidepressant with the highest rate of utilization management. The antipsychotics Geodon, Zyprexa, Abilify, Seroquel and Risperdal had the highest overall rates of utilization management (Table 6) with an average rate of 43 percent, with Zyprexa being the most

[26] "Duals Eligibles Transition: Part D Formularies' Inclusions of Commonly Used Drugs" Office of Inspector General, January 2006.

commonly prescribed antipsychotic and the antipsychotic with the second highest rate of utilization management.

5. More expensive drugs had higher rates of utilization management.

The antidepressants Zoloft, Cymbalta, Effexor, Citalopram (generic Celexa) and Paroxetine had the highest overall rates of utilization management (Table 6) with an average rate of 67 percent. Cymbalta, Zoloft and Effexor are among the most expensive antidepressants examined in this study and all are single-source brand name drugs.. Zoloft, Cymbalta and Paroxetine were identified by the Office of the Inspector General as among the most commonly prescribed drugs to dual eligibles.

Geodon, Zyprexa, Abilify, Seroquel and Risperdal were all among the most expensive antipsychotics examined, and all had the highest overall rates of utilization management (Table 6) with an average rate of 43 percent. All of these drugs are single-source brand-name atypical antipsychotics, and all were among the 200 most commonly prescribed drugs to dual eligibles.

Table 5: Drugs With Highest Rate of Utilization Management

Antidepressants	Rate of Utilization Management	Average Monthly Retail Price[27]
Zoloft * **$**	87%	$82.49-$164.98
Cymbalta * **$**	69%	$114.68-$207.62
Citalopram	60%	$44.99-$134.97
Effexor **$**	60%	$67.74-$203.23
Paroxetine *	60%	$45.49-$113.98
Average:	**67%**	**$71.08-$164.96**

Antipsychotics	Rate of Utilization Management	Average Monthly Retail Price
Geodon * **$**	50%	$289.99
Zyprexa * **$**	47%	$306.49
Seroquel * **$**	40%	$275.00-$1585.00
Risperdal * **$**	40%	$112.56-$582.50
Abilify * **$**	40%	$324.49
Average:	**43%**	**$496.57**

NOTE: * indicates drug commonly used by dual eligibles. $ indicates drug with high retail price.

A higher rate of utilization management techniques imposed on these drugs clearly indicates an overall steering of people to drugs that are less expensive and also sometimes less effective.

In addition, the higher incidence of quantity limits imposed on second-generation antipsychotics compared to first-generation drugs indicates that cost, not safety, is the underlying rationale. First

[27] Average retail price information was gathered from www.walgreens.com and www.riteaid.com. Prices reflect the recommended dosage or dosage range.

Health Premier, along with the GHI, WellCare and Humana plans, imposed some type of utilization management to all five of the most expensive antipsychotics.

Conclusions and Recommendations

True Story

Ms. L has Medicare and Medicaid and was auto-enrolled in a Part D plan. In January, she attempted to fill prescriptions for three antidepressants, Mirtazapine, Wellbutrin and Cymbalta, but her plan would not pay for the prescribed doses. It set a quantity limit for each drug at 30 pills per month.

Ms. L has severe refractory depression and has been prescribed numerous combinations of various drugs over the past eight years. Lower doses of all three drugs had been tried but failed to provide relief. According to both her treating doctor and a consulting psychiatrist, this is the only combination that gives her any relief.

Despite this evidence of medical necessity, Ms. L's plan twice denied coverage of these medicines at the prescribed dosages. Maximus, the independent review entity contracted by CMS, also rejected Ms. L's appeal. The case was appealed to an administrative law judge, which decided in favor of Ms. L and told her plan to cover the full dosage of all three medicines.

In requiring Part D plans to cover "all or substantially all" antipsychotics and antidepressants, CMS has recognized the special vulnerability of those suffering from mental illness, particularly those stabilized on these medicines, if these medicines were not covered through Part D. But the protection provided by this minimum coverage requirement is undermined when plans are allowed to exclude drugs in these classes from their formularies despite CMS' review of plan formularies. However, the major threat to this crucial protection comes through the excessive use of utilization management techniques—prior authorization, step therapy and quantity limits—that also effectively deny coverage for vital medicines. Masquerading as safety edits, these restrictions substitute crude cost controls for the clinical judgment of the treating doctor and drug regimens proven effective for individual patients. To ensure people with Medicare are not denied access to medicines that are crucial to their mental health, we recommend that CMS take the following steps:

1. **Subject all formularies to a rigorous review to ensure compliance with the "all or substantially all" standard.** Review published plan formularies and data provided through medicare.gov to ensure all drugs in these classes are listed as on-formulary as required by CMS.

2. **Review all utilization management restrictions to ensure they are clinically sound and are not designed simply to steer patients to low-cost alternatives that are medically inappropriate.** Ensure drugs that do pose safety concerns, such as those on the Beers list, are subject to appropriate utilization management and do not become the default option because access is restricted to more expensive, but more appropriate, medications. Require that all quantity limits have a clinical justification. Similarly, criteria for approval of prior authorization requests and algorithms under step therapy protocols must be based on recognized practice guidelines.

3. **Require that all Part D plans have the means to distinguish at the point of sale, both for current and new members, between prescriptions for newly initiated therapies and prescriptions for patients already stabilized on a medication regimen.** Plans that do not have that capability should be barred from imposing utilization management restrictions. In addition, as with prior authorization and step therapy requirements, quantity limits on mental health drugs, when not necessary for reasons of safety, should not be imposed on patients already stabilized on antidepressants or antipsychotics.

4. **Because of the risk that impediments to access will trigger lapses in compliance with drug regimens and the risk of decompensation that accompanies interruptions in drug regimens, all utilization management techniques should be enforced not through denied access at the pharmacy counter but through dialogue with prescribing doctors**. Prescribing patterns that reveal deviation from practice guidelines and dosing recommendations and cost-effective prescribing should prompt plans to enter into a dialogue with doctors on a retrospective basis. With the exception of bona fide safety concerns (such as a drug on the Beers list), restrictions imposed at the pharmacy counter should be barred for these two classes of drugs.

5. **Reassignment of dual eligibles and other recipients of the Part D low-income subsidy program (Extra Help) to below-benchmark[28] plans should ensure that drug regimens will not be interrupted under the plan assigned for 2007.** CMS is using its demonstration authority to minimize the number of individuals subject to reassignment; it should use that same authority to ensure reassignment does not interrupt drug regimens, particularly for the mentally ill. Plans that accept reassignment should be required to waive formulary restrictions that restrict the drug regimens of the auto-enrolled new members.

[28] The low-income benchmark for each region is set at the average premium for basic coverage charged by all stand-alone prescription drug plans and prescription drug plans offered by Medicare Advantage plans. Recipients of the full low-income subsidy, other than individuals who had affirmatively selected their plan, will be randomly reassigned to a below-benchmark plan if their current plan will charge more than $2 above the 2007 regional benchmark. CMS has estimated that about one million people with Medicare will be subject to reassignment.