Coverage of Atypical Antipsychotics Among Medicare Drug Plans in the State of Washington for Fiscal Year 2007

Chi-Chuan Wang, B.Pharm., M.H.P.A.; Jae Kennedy, Ph.D.;
Lawrence J. Cohen, Pharm.D., B.C.P.P.; and David A. Sclar, B.Pharm., Ph.D.

Objective: To examine drug coverage and patient costs for 6 atypical antipsychotics (olanzapine, quetiapine, ziprasidone, aripiprazole, clozapine, and risperidone) in Medicare Part D formularies using health plan data from the state of Washington.

Method: Fiscal year 2007 coverage and cost-sharing characteristics for 57 prescription drug plans (PDPs) and 43 Medicare advantage prescription drug plans (MAPDs) were collected from the Centers for Medicare and Medicaid Services. Plans were compared in terms of formulary restrictions, out-of-pocket costs, and premium charges. Medicare released plan information for fiscal year 2007 in October 2006. Data were collected for this study in February 2007.

Results: Almost all plans covered the 6 atypical antipsychotics. The PDPs were more likely to restrict coverage than the MAPDs. Prior authorization requirements were enforced in 5% to 21% of plans, depending on plan type and medication. Monthly drug plan premiums were higher for PDPs than MAPDs, but the MAPDs had concurrent monthly health premiums. About 80% of MAPDs and 60% of PDPs also had no annual deductible for medications. The patient out-of-pocket cost for atypical antipsychotics varied depending on the stage of coverage—median monthly drug costs ranged from $5 to $50 during the initial period, but if costs exceeded the annual cap, patients were responsible for the full cost of the drug, which ranged from $292 to $665. Patients with low incomes and those who exceeded the annual spending limit ($3850 in fiscal year 2007) had a median monthly cost of $17 to $33.

Conclusion: There is considerable variation across health plans in terms of patients' out-of-pocket drug costs. Given the significant needs and vulnerabilities of Medicare beneficiaries with mental illness, changes for atypical antipsychotic coverage should be monitored carefully, and the complexity of Medicare drug plans should be minimized.

(Prim Care Companion J Clin Psychiatry 2008;10:313–317)

Received Oct. 26, 2007; accepted Feb. 12, 2008. *From the Department of Pharmaceutical Sciences, Division of Pharmaceutical Outcomes and Policy, School of Pharmacy, University of North Carolina, Chapel Hill (Ms. Wang); the Departments of Health Policy and Administration (Drs. Kennedy and Sclar) and Pharmacotherapy (Drs. Cohen and Sclar), College of Pharmacy, Washington State University, Spokane; and Washington Institute for Mental Illness Research and Training, Spokane (Drs. Cohen and Sclar).*

Dr. Cohen has served as a consultant to Eli Lilly; has received honoraria from Eli Lilly, AstraZeneca, and Janssen; and has served on the speakers or advisory boards of Eli Lilly, AstraZeneca, Janssen, and Wyeth. Drs. Kennedy and Sclar and Ms. Wang report no financial affiliations relevant to the subject of this article.

Corresponding author and reprints: Chi-Chuan Wang, B.Pharm., M.H.P.A., Department of Pharmaceutical Sciences, Division of Pharmaceutical Outcomes and Policy, School of Pharmacy, University of North Carolina, CB 7360, Kerr Hall, Chapel Hill, NC 27599-7360 (e-mail: chicwang@email.unc.edu).

Atypical antipsychotic drugs often provide enhanced treatment outcomes with a lower side effect burden than the older (typical) antipsychotics,[1,2] but they are also more expensive.[2–5] The therapeutic response to atypical antipsychotics may differ from patient to patient, so psychiatrists and their patients may have to test multiple drugs and dosage levels to attain the desired clinical outcome, with continuity of the medication regimen the expressed goal.[6–9] Coverage of atypical antipsychotics is often restricted by health plan formularies in an effort to contain costs.[1,2] Such restrictions may yield a false economy, as use of atypical antipsychotics is correlated with enhanced concordance and lower hospitalization rates.[4,5]

Nevertheless, controversy exists as to the overall utility of atypical antipsychotics. In the Clinical Antipsychotic Trials of Intervention Effectiveness,[10] 74% of patients discontinued pharmacotherapy within 18 months due to adverse effects such as weight gain, metabolic problems, or extrapyramidal effects. Olanzapine was shown to have the lowest discontinuation rate, yet was associated with greater weight gain and metabolic effects.[10] The Cost Utility of the Latest Antipsychotic Drugs in Schizophrenia Study (CUtLASS1) documented that within 1 year, no significant difference was discerned in terms of quality of life for patients initiating pharmacotherapy with a second-generation antipsychotic (other than clozapine) relative to a first-generation agent.[11] In a follow-up to CUtLASS1, clozapine was shown to have greater efficacy than first-generation agents.[12] However, clozapine was not shown

to have greater efficacy than other second-generation antipsychotics.[12]

Concerns regarding medication coverage restrictions for people with chronic illness such as schizophrenia figured prominently in the debate leading up to passage and implementation of the Medicare prescription drug benefit (Medicare Part D).[13] In order to ensure prescription medication accessibility, the Centers for Medicare and Medicaid Services (CMS) established special formulary guidelines requiring Medicare prescription drug plans to cover "all or substantially all" antipsychotic and antidepressant medications.[14,15]

Under Medicare Part D, beneficiaries can enroll in either a prescription drug plan (PDP) or a managed health care plan, known as a Medicare advantage prescription drug plan (MAPD).[16,17] Although the Medicare Modernization Act has established a standard prescription benefit, Part D prescription drug plans are permitted to determine their own cost-sharing characteristics and use pharmacy management tools, such as fail-first/step therapy and prior authorization, to control their costs.[16,18–20]

To contain program costs and encourage appropriate use, the majority of Medicare drug plans have formularies with 3 tiers of coverage: generic, preferred brand, and nonpreferred brand, with higher co-payments and/or coinsurance for nongeneric and nonpreferred medications.[8,16,19,21–23] In addition, plans tend to negotiate a more favorable price for 1 or more therapeutically equivalent medications in a drug group and will structure patient fees accordingly.[24] However, unlike most other therapeutic categories, it is often difficult to substitute psychiatric medications and may even be dangerous. Changing psychiatric medications (even within drug categories) may cause adverse side effects and lower concordance with prescribed regimens and thereby influence the desired treatment outcome and a patient's health status.[25–27]

The objective of this study was to assess drug coverage restrictions and patient costs among available Medicare drug plans in the state of Washington for the following 6 atypical antipsychotics: aripiprazole, clozapine, risperidone, ziprasidone, quetiapine, and olanzapine.

METHOD

The study included all approved Medicare Part D plans in the State of Washington available during fiscal year 2007. Medicare released plan information for fiscal year 2007 in October 2006. Data from all plans were collected in February 2007. Using information from the CMS Web site (http://www.cms.hhs.gov/), 57 PDPs and 43 MAPDs were identified. Because MAPDs may serve local and regional markets within the state, multiple zip codes from different rural and urban counties were entered into the "Compare Medicare Prescription Drug Plans" section of the CMS Web site.

The CMS drug plan lists show information about estimated annual cost, annual deductible, monthly drug premium, and monthly cost sharing for each drug. Under the link of each plan's title, there is information about the type of drug coverage (tier), coverage limitations (prior authorization, quantity limits, step therapy), and monthly drug costs at preferred network pharmacies (the full cost of the drug, the initial coverage level, the gap coverage, the catastrophic coverage, and the amount to be paid before the annual deductible is met).

On the basis of consultation with clinical providers and information from the Drug Facts and Comparison manual,[28] the following daily dosages were deemed typical and chosen for the plan comparisons: aripiprazole (20 mg), clozapine (600 mg), risperidone (4 mg), ziprasidone (160 mg), quetiapine (600 mg), and olanzapine (20 mg).

RESULTS

In 2007, almost all Medicare drug plans covered all 6 atypical antipsychotics (11 plans did not cover clozapine). Three-level coverage tiers with progressively higher co-pay rates were employed by 93% of PDPs and 91% of MAPDs, with the remainder opting for 2-level (generic/nongeneric) coverage tiers. Clozapine, the 1 medication with a generic equivalent, was placed on the first tier by 53% of PDPs and 69% of MAPDs (Table 1[29]).

Coverage levels varied by type of drug and type of plan. In general, MAPDs were more likely than PDPs to label 1 or more atypical antipsychotics as nonpreferred, with higher co-payments. Among 3 types of coverage restrictions, quantity limits were the most common restriction used. The PDPs were more likely to use quantity limits than MAPDs but were less likely to use prior authorization. Step therapy requirements were rare in both types of plans.

Table 2 shows the plan fee structures among PDPs and MAPDs. The PDPs tended to have higher monthly drug premiums—only 41% of PDPs as compared with 79% of MAPDs had premiums of $30 or less. This comparison, however, is somewhat misleading, as many MAPDs have monthly health insurance premiums in addition to the drug premium. Most plans waived or discounted the annual drug deductible (set by CMS at a maximum of $265 in fiscal year 2007).

Table 3 shows that consumer drug costs vary by drug, type of plan, and, most dramatically, stage of coverage. According to CMS plan guidelines, 75% of drug costs are covered after the annual deductible is met. In fact, Table 3 documents that most plans cover greater than 75% of drug costs, presumably because of flat rates for each tiered drug (e.g., $40 per month per tier 3 nongeneric, nonpreferred medication).

Once an individual reaches the annual coverage cap, set in fiscal year 2007 at $2400, costs increase to the total

Table 1. Coverage of Atypical Antipsychotics for Prescription Drug Plans (PDPs, N = 57) and Medicare Advantage Prescription Drug Plans (MAPDs, N = 43) in the State of Washington for Fiscal Year 2007[a,b]

	Aripiprazole		Clozapine[c]		Risperidone		Ziprasidone		Quetiapine		Olanzapine	
Coverage, N (%)	PDP	MAPD	PDP	MAPD	PDP	MAPD	PDP	MAPD	PDP	MAPD	PDP	MAPD
Coverage level[d]												
Not on formulary	…	…	9 (17)	…	…	…	…	…	…	…	…	…
Tier 1 generic	…	…	28 (53)	27 (69)	…	…	…	…	…	…	…	…
Tier 2 preferred brand	30 (57)	16 (41)	16 (30)	12 (31)	51 (96)	39 (100)	33 (62)	16 (41)	51 (96)	39 (100)	44 (83)	23 (59)
Tier 3 nonpreferred brand	23 (43)	23 (59)	…	…	2 (4)	…	20 (38)	23 (59)	2 (4)	…	9 (17)	16 (41)
Coverage restrictions												
Quantity limits	32 (56)	15 (35)	4 (7)	…	27 (47)	14 (33)	28 (49)	14 (33)	28 (49)	14 (33)	31 (54)	14 (33)
Prior authorization	7 (12)	9 (21)	…	…	…	…	9 (16)	9 (21)	3 (5)	2 (5)	7 (12)	8 (19)
Step therapy	3 (5)	2 (5)	2 (4)	…	…	…	3 (5)	…	3 (5)	2 (5)	3 (5)	1 (2)

[a]Data from the Centers for Medicare and Medicaid Services.[29]
[b]Daily dosage of each drug used for comparisons was aripiprazole 20 mg, clozapine 600 mg, risperidone 4 mg, ziprasidone 160 mg, quetiapine 600 mg, and olanzapine 20 mg.
[c]Although clozapine is often classified as a tier 1 generic drug, it is typically not a first-line drug because of the need to closely monitor patients for serious side effects (i.e., agranulocytosis). Two MAPDs do not cover clozapine.
[d]Four PDPs and 4 MAPDs that have only 2 tiers (brand/generic) are not included in the coverage level comparisons (PDPs: N = 53, MAPDs: N = 39).
Symbol: … = no data.

Table 2. Premium Costs and Deductibles for Prescription Drug Plans (PDPs, N = 57) and Medicare Advantage Prescription Drug Plans (MAPDs, N = 43) in the State of Washington for Fiscal Year 2007[a,b,c,d]

Variable, N (%)	PDP	MAPD
Monthly drug premium, $		
≤ 20	2 (4)	22 (51)
21–30	21 (37)	12 (28)
31–40	13 (23)	6 (14)
41–50	14 (25)	2 (5)
> 51	7 (12)	1 (2)
Monthly health premium, $		
≤ 20	…	17 (40)
21–40	…	3 (7)
41–60	…	5 (12)
61–80	…	3 (7)
81–100	…	9 (21)
> 100	…	6 (14)
Annual drug deductible		
None	33 (58)	35 (81)
< Standard deductible	5 (9)	1 (2)
Standard deductible ($265)	19 (33)	7 (16)

[a]Data from the Centers for Medicare and Medicaid Services.[29]
[b]Only 41% of PDPs as compared with 79% of MAPDs had premiums ≤ $30.
[c]In addition to the drug premium, many MAPDs have a monthly health insurance premium.
[d]Most PDPs and MAPDs waived or discounted the annual drug deductible ($265 in fiscal year 2007).
Symbol: … = no data.

price for beneficiaries not eligible for federal low-income subsidies. For example, a patient taking olanzapine at a cost of $650 per month will reach this so-called "donut hole" in coverage some time before his or her fourth month of benefits. He or she will then be fully responsible for the next $3850 in drug costs. Once the patient exceeds $6250 in total drug costs (at the end of the seventh month of benefits), he or she will become eligible for catastrophic coverage, which in turn pays for 95% of drug costs.

DISCUSSION

This study shows that there is substantial variation in drug coverage, formulary design, and cost-sharing structures among different plans in the state of Washington. Those variations could have a significant impact on beneficiaries' access to medications and on their out-of-pocket expenditures. Due to the volume and complexity of available Medicare drug plans, it may be difficult for beneficiaries, inclusive of the elderly and disabled, to select a plan best suited to their financial and health needs.

This study has several limitations that should be noted and addressed in future research. First, it is limited to a single state, and other states may face different market conditions and population needs. Cross-state comparisons would be a useful extension of this analysis. Second, it provides a brief snapshot of a complex rapidly evolving health system. Ongoing longitudinal studies will be required to monitor the evolution and impact of Medicare Part D on patients' access to, use of, and outcomes with prescription medication.

A series of possible market and regulatory changes could have a dramatic impact on the number of drug plans and the type and amount of coverage they provide. For example, several of the atypical antipsychotics will lose patent protection in coming years, along with the entry of several new patent-protected medications. Moreover, the U.S. Congress is likely to challenge the current reimbursement system, which pays a significant differential for Medicare advantage plans. Program-wide formularies like those employed by the U.S. Department of Veterans Affairs have been touted as holding the promise of significant cost savings but could dramatically restrict or eliminate market competition.

It is important to note that relatively high out-of-pocket costs and gaps in coverage may cause patients to

Table 3. Consumer Costs of Atypical Antipsychotics For Prescription Drug Plans (PDPs, N = 57) and Medicare Advantage Prescription Drug Plans (MAPDs, N = 43) in the State of Washington for Fiscal Year 2007[a,b]

	Aripiprazole, $		Clozapine, $[c]		Risperidone, $		Ziprasidone, $		Quetiapine, $		Olanzapine, $	
Coverage	PDP	MAPD	PDP	MAPD	PDP	MAPD	PDP	MAPD	PDP	MAPD	PDP	MAPD
Initial coverage[d]												
Mean (SD)	71 (62)	50 (24)	29 (39)	21 (15)	44 (41)	33 (14)	59 (47)	48 (16)	59 (72)	37 (25)	82 (103)	49 (34)
Median	50	40	10	5	30	29	50	40	30	29	32	40
Range	20–371	15–125	0–127	0–127	18–300	15–76	20–334	15–85	18–491	15–124	18–657	15–164
No coverage (full cost)[e]												
Mean (SD)	490 (11)	494 (13)	471 (30)	482 (18)	299 (3)	299 (4)	331 (10)	334 (4)	485 (17)	490 (7)	649 (19)	650 (16)
Median	494	494	485	482	299	299	334	334	490	490	657	650
Range	452–500	448–541	401–506	408–506	292–303	295–311	298–338	329–344	413–497	484–514	595–665	595–657
Catastrophic coverage[f]												
Mean (SD)	25 (1)	24 (3)	23 (4)	24 (0)	15 (1)	15 (1)	17 (1)	16 (1)	24 (2)	24 (3)	33 (2)	31 (4)
Median	25	24	24	24	15	15	17	17	25	24	33	32
Range	23–35	10–24	0–25	24–25	15–21	10–15	15–23	10–16	21–34	10–24	30–46	10–31

[a]Data from the Centers for Medicare and Medicaid Services.[29]
[b]Daily dosage of each drug used for comparisons was aripiprazole 20 mg, clozapine 600 mg, risperidone 4 mg, ziprasidone 160 mg, quetiapine 600 mg, and olanzapine 20 mg.
[c]Nine PDPs and 2 MAPDs do not cover clozapine and are therefore omitted from this column.
[d]After the annual deductible ($265) is met, 75% of drug costs are covered.
[e]When a patient reaches the annual coverage cap ($2400), there is no coverage until the patient exceeds $6250 in total drug costs.
[f]Once a patient spends over $6250, Medicare will cover 95% of drug costs.

discontinue or otherwise disrupt their medication regimens. Under the cost-sharing structure of Medicare Part D, patients often exceed the initial coverage threshold, thereby increasing the potential for nonadherence to therapy. For patients with schizophrenia or other serious mental illnesses, such nonadherence can have catastrophic clinical as well as economic consequences.

Managed care plans have a clear financial interest in efficiently managing serious mental illness and preventing unnecessary hospitalization, but from a broader public health perspective, no one is well served by a system that contains drug costs by limiting access to critical psychiatric medications. Unlike other treatment categories, antipsychotic medications often work uniquely among individuals. Therefore, having full access to a variety of antipsychotic agents is very important. With plans favoring generic use and restrictions on brand-name products, patients lose the option of being prescribed individualized therapy. Ineffective treatment may reduce patients' quality of life and increase other health care costs.

Drug names: aripiprazole (Abilify), clozapine (Clozaril, FazaClo, and others), olanzapine (Zyprexa), quetiapine (Seroquel), risperidone (Risperdal), ziprasidone (Geodon).

REFERENCES

1. Cohen LJ. Looking beyond the formulary budget in cost-benefit analysis. Am J Manag Care 1997 Feb;3(suppl):S11–S17
2. Anderson PO, Knoben JE, Troutman WG. Handbook of Clinical Drug Data. New York, NY: McGraw-Hill; 2002
3. Stahl SM. Essential Psychopharmacology of Antipsychotics and Mood Stabilizers. New York, NY: Cambridge University Press; 2002
4. Tunis SL, Faries DE, Nyhuis AW, et al. Cost-effectiveness of olanzapine as first-line treatment for schizophrenia: results from a randomized, open-label, 1-year trial. Value Health 2006 Mar-Apr;9(2):77–89
5. Glazer WM. Formulary decisions and health economics. J Clin Psychiatry 1998;59(suppl 19):23–29
6. Taylor DM, Young C, Paton C. Prior antipsychotic prescribing in patients currently receiving clozapine: a case note review. J Clin Psychiatry 2003 Jan;64(1):30–34
7. Advokat CD, Bertman LJ, Comaty JE Jr. Clinical outcome to clozapine treatment in chronic psychiatric inpatients. Prog Neuropsychopharmacol Biol Psychiatry 1999 Jan;23(1):1–14
8. Mauri MC, Volonteri LS, Dell'Osso B, et al. Predictors of clinical outcome in schizophrenic patients responding to clozapine. J Clin Psychopharmacol 2003 Dec;23(6):660–664
9. Bach PB, McClellan MB. A prescription for a modern Medicare program. N Engl J Med 2005 Dec;353(26):2733–2735
10. Lieberman JA, Stroup TS, McEvoy JP, et al. Effectiveness of antipsychotic drugs in patients with chronic schizophrenia. N Engl J Med 2005 Sep;353(12):1209–1223
11. Jones PB, Barnes TR, Davies L, et al. Randomized controlled trial of the effect on Quality of Life of second- vs first-generation antipsychotic drugs in schizophrenia: Cost Utility of the Latest Antipsychotic Drugs in Schizophrenia Study (CUtLASS 1). Arch Gen Psychiatry 2006 Oct;63(10):1079–1087
12. Lewis SW, Barnes TR, Davies L, et al. Randomized controlled trial of effect of prescription of clozapine versus other second-generation antipsychotic drugs in resistant schizophrenia. Schizophr Bull 2006 Oct;32(4):715–723
13. Moffic HS. Ethical principles for psychiatric administrators: the challenge of formularies. Psychiatr Q 2006;77(4):319–327
14. Rosack J. CMS acknowledges need for inclusive part D formulary. Psychiatr News 2006 Mar;41(6):1–8
15. Huskamp HA, Stevenson DG, Donohue JM, et al. Coverage and prior authorization of psychotropic drugs under Medicare Part D. Psychiatr Serv 2007 Mar;58(3):308–310
16. Usdin S. Medicare Part D: an overview of its practical and clinical impact. Am J Geriatr Cardiol 2005 Nov-Dec;14(6):284–288
17. Gold M. Premiums and Cost-Sharing Features in Medicare's New Prescription Drug Program, 2006. The Henry J. Kaiser Family Foundation. Available at: http://www.kff.org/medicare/upload/7517.pdf. Accessed 6-25-08
18. Andersen LS. Prescription drug benefits under Part D of the Medicare Modernization Act: the genie's out of the bottle. Issue brief 2005;5(10):1–10
19. Huskamp HA, Keating NL. The new Medicare drug benefit: formularies and their potential effects on access to medications. J Gen Intern Med 2005 Jul;20(7):662–665
20. Donohue JM. Economic grand rounds: the economics of the new

Medicare drug benefit: implications for people with mental illnesses. Psychiatr Serv 2005 Jun;56(6):645–647
21. Huskamp HA, Deverka PA, Epstein AM, et al. The effect of incentive-based formularies on prescription-drug utilization and spending. N Engl J Med 2003 Dec;349(23):2224–2232
22. Maio V, Pizzi L, Roumm AR, et al. Pharmacy utilization and the Medicare Modernization Act. Milbank Q 2005;83(1):101–130
23. Sethi RC. Prescription drugs: recent trends in utilization, expenditures, and coverage. EBRI Issue Brief 2004 Jan;(265):1–35
24. Goodwin FK. Impact of formularies on clinical innovation. J Clin Psychiatry 2003;64(suppl 17):11–14
25. Heisler M, Langa KM, Eby EL, et al. The health effects of restricting prescription medication use because of cost. Med Care 2004 Jul;42(7): 626–634
26. Leslie DL, Rosenheck RA. From conventional to atypical antipsychotics and back: dynamic processes in the diffusion of new medications. Am J Psychiatry 2002 Sep;159(9):1534–1540
27. Lazarus A. Impact of formulary restrictions on patient safety. Physician Exec 2005 Jul-Aug;31(4):42–44
28. Wickersham RM, Novak KK, eds. Drug Facts and Comparisons. St. Louis, Mo: Wolters Kluwer Health, Inc; 2005
29. Prescription Drug Coverage. Medicare Prescription Drug Plan Finder. Available at: http://www.medicare.gov/pdphome.asp. Accessed 6-25-08