Coverage and Prior Authorization of Psychotropic Drugs Under Medicare Part D

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This study examined formulary coverage and use of utilization management tools for three classes of psychotropic medications (antidepressants, antipsychotics, and anticonvulsants) among Medicare Part D prescription drug plans serving individuals dually eligible for the Medicare and Medicaid programs. Plans must cover "all or substantially all" molecules (distinct drugs) in these classes. Plans serving "dual eligibles" generally covered at least one formulation of all molecules in the three classes. However, certain product formulations were not covered by a number of plans, and use of prior authorization was common for a minority of plans. The effect of Part D will depend on the restrictiveness of the prior authorization and appeals processes, which is currently unknown. (*Psychiatric Services* 58: 308–310, 2007)

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The Medicare Modernization, Improvement, and Prescription Drug Act (MMA) of 2003 created Medicare Part D, a voluntary prescription drug benefit available to all Medicare beneficiaries. The MMA also shifted drug coverage from the Medicaid program to Part D for the more than six million individuals dually eligible for both Medicare and Medicaid, requiring that "dual eligibles" enroll in a private prescription drug plan (PDP). Dual eligibles were randomly assigned to PDPs with monthly premiums at or below regional premium benchmarks (below benchmark). Part D relies on private plans to administer the benefit and offers beneficiaries a variety of plan options with different formulary coverage, cost sharing, and use of utilization management tools, such as prior authorization.

Although the MMA requires plans to cover a minimum of two drugs in each therapeutic class, the Centers for Medicare and Medicaid Services (CMS) extended special protections to three common psychotropic drug classes: antidepressants, antipsychotics, and anticonvulsants. For these three "protected" classes, plans must cover "all or substantially all" molecules (distinct drugs), but they are not required to cover both the generic and brand versions of the same molecule (for example, they must cover fluoxetine or Prozac but not necessarily both) or all formulations of a molecule (for example, they must cover Effexor or Effexor XR but not necessarily both). However, Part D enrollees can appeal for coverage of a particular medication that is not covered by their plan. In addition, plans can use a variety of utilization management tools, such as prior authorization, for all psychotropic drugs.

There was some concern that PDP formulary coverage and prior authorization would restrict use of psychotropic medications despite the special protections granted and that such restrictions could negatively impact patients with mental illness, particularly dual eligibles, who are disproportionately more likely to have a mental illness. Prior authorization, used widely in state Medicaid programs to contain prescription drug costs, has been shown to shift the market share away from drugs requiring prior authorization and to reduce the overall use of medications in affected drug classes (1–3). However, because psychotropic medications were excluded from most Medicaid prior authorization programs until recently, the effect of prior authorization on psychotropic medication use is poorly understood. Because psychotherapeutic drugs may be less therapeutically interchangeable for some patients than drugs in certain other categories, the effects of coverage restrictions and prior authorization may be particularly problematic for psychotropic medications (4).

We investigated these concerns by examining coverage and use of prior authorization among covered drugs for commonly used medications in the three protected classes among the below-benchmark stand-alone PDPs to which dual eligibles may be au-

toenrolled (an individual is automatically assigned to a PDP, so coverage will not lapse). Dual eligibles pay a fixed copayment for all generic drugs (either $1 or $2, depending on their income) and a higher fixed copayment for all brand drugs (either $3 or $5, depending on their income). Because these copayment levels are similar to what dual eligibles faced under Medicaid and because dual eligibles pay a single rate for all brand drugs, regardless of whether the brands are preferred by the plan or not, we focused our analysis on coverage and prior authorization rather than on tiering and cost-sharing levels.

We obtained data from CMS for all PDPs as of December 2005, reflecting coverage at the inception of Part D. Our unit of observation was the PDP at the regional level, so PDPs offering a plan across multiple regions were counted once for each region. By using this definition, there were 1,429 PDPs serving the United States as of December 2005, and 519 of these were below-benchmark plans to which dual eligibles could be autoenrolled. We focused on coverage and prior authorization among below-benchmark plans only. If any dosage of a given drug was covered, we considered that drug to be covered. Similarly, if prior authorization was required for any dosage form of a covered drug, we considered that drug to require prior authorization. Some plans also used stepped therapy or quantity limits to control drug utilization, but we were unable to study use of these tools with our data source.

Findings

Formulary coverage

As shown in Table 1, below-benchmark plans generally covered at least one formulation of all molecules in the three classes. The exception is that a number of plans covered either Celexa or Lexapro but not both; because these drugs are isomers of the same molecule, CMS requires that only one be covered. Coverage can be more limited for certain product formulations or for the brand version of a drug with a generic equivalent available. For example, 100% of plans covered the generic paroxetine, whereas only 19% covered the brand Paxil and

Table 1

Coverage and prior authorization under Medicare Part D across selected reviewed classes of drugs in 519 prescription drug plans[a]

Drug	Molecule	Plans covering the drug		Plans covering the drug that use prior authorization	
		N	%	N	%
Anticonvulsants					
Carbamazepine	Carbamazepine	517	100	0	—
Tegretol	Carbamazepine	507	98	0	—
Tegretol XR	Carbamazepine	486	94	37	8
Gabapentin	Gabapentin	519	100	41	8
Neurontin	Gabapentin	111	21	32	29
Lamictal	Lamotrigine	519	100	101	19
Lamotrigine ODT	Lamotrigine	331	64	68	21
Keppra	Levetiracetam	519	100	40	8
Trileptal	Oxcarbazepine	519	100	98	19
Dilantin or Phenytek	Phenytoin	478	92	0	—
Phenytoin	Phenytoin	519	100	0	—
Topamax	Topiramate	519	100	141	27
Depakote	Valproic acid	486	94	0	—
Depakote ER	Valproic acid	510	98	0	—
Valproic acid	Valproic acid	519	100	0	—
Antidepressants					
Bupropion	Bupropion	519	100	0	—
Bupropion ER or SR	Bupropion	519	100	42	8
Wellbutrin	Bupropion	98	19	0	—
Wellbutrin SR	Bupropion	98	19	0	—
Celexa	Citalopram	98	19	0	—
Citalopram	Citalopram	519	100	0	—
Cymbalta	Duloxetine	519	100	48	9
Lexapro	Escitalopram	366	71	0	—
Fluoxetine	Fluoxetine	519	100	0	—
Prozac	Fluoxetine	164	32	0	—
Mirtazapine	Mirtazapine	519	100	0	—
Remeron	Mirtazapine	165	32	0	—
Remeron SolTab	Mirtazapine	98	19	0	—
Paroxetine	Paroxetine	519	100	0	—
Paxil	Paroxetine	98	19	0	—
Paxil CR	Paroxetine	283	55	33	12
Zoloft	Sertraline	519	100	12	2
Effexor	Venlafaxine	486	94	0	—
Effexor XR	Venlafaxine	508	98	0	—
Second-generation antipsychotics					
Abilify	Aripiprazole	519	100	110	21
Clozapine	Clozapine	519	100	46	9
Clozaril	Clozapine	157	30	12	8
Zyprexa	Olanzapine	519	100	101	19
Zyprexa IM	Olanzapine	387	75	186	48
Zyprexa Zydis	Olanzapine	453	87	77	17
Seroquel	Quetiapine	519	100	46	9
Risperdal	Risperidone	519	100	43	8
Risperdal Consta	Risperidone	518	100	148	29
Risperdal M-TAB	Risperidone	489	94	43	9
Geodon	Ziprasidone	519	100	146	28
Geodon IM	Ziprasidone	507	98	240	47

[a] Source: Centers for Medicare and Medicaid Services Part D Plan data, December 2005. Findings are based on 519 private prescription drug plans with monthly premiums at or below a regional premium benchmark. XR, extended release; CR, controlled release; SR, sustained release; ER, extended release; IM, intramuscular; OTC, over the counter; ODT, oral dispersible tablet

55% covered the controlled-release form, Paxil CR.

Use of prior authorization

Although a majority of plans did not require prior authorization for covered drugs in the three classes, a sizeable minority of plans required it for specific medications. Use of prior authorization varied considerably across drugs within a class. For example, among second-generation antipsychotics, use of prior authorization for plans that covered the drug ranged from 8% (Clozaril) to 48% (Zyprexa IM). Use of prior authorization was more common for covered second-generation antipsychotics and anticonvulsants than for antidepressants.

Conclusions

The special protections afforded to antidepressant, antipsychotic, and anticonvulsant medications under the Part D benefit will help to ensure that Medicare beneficiaries with a mental illness have access to needed medications. However, despite these protections, certain product formulations may not be covered and prior authorization may be used by a minority of plans. Although dually eligible beneficiaries are permitted to change plans at any time (unlike beneficiaries without dual eligibility, who may switch plans only once a year), dual eligibles with a mental illness may have greater difficulty assessing plan options and switching plans than beneficiaries without a mental illness. The effect on beneficiaries will depend on the restrictiveness of both the prior authorization and appeals processes, which is unknown at this point. Importantly, plans' formulary coverage and use of management tools, such as prior authorization, are likely to change over time as experience with the program increases. Ongoing monitoring of these issues is important to ensure that beneficiaries have access to needed medications.

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References

1. Delate T, Mager DE, Sheth J, et al: Clinical and financial outcomes associated with a proton pump inhibitor prior-authorization program in a Medicaid population. American Journal of Managed Care 11:29–36, 2005
2. Fischer MA, Schneeweiss S, Avorn J, et al: Medicaid prior-authorization programs and the use of cyclooxygenase-2 inhibitors. New England Journal of Medicine 351:2187–2194, 2004
3. Smalley WE, Griffin MR, Fought RL, et al: Effect of a prior-authorization requirement on the use of nonsteroidal anti-inflammatory drugs by Medicaid patients. New England Journal of Medicine 332:1612–1617, 1995
4. Huskamp HA: Managing psychotropic drug costs: will formularies work? Health Affairs 22(5):84–96, 2003

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Datapoints columns are typically 350 to 400 words of text with one or two figures. Maximum text length is 500 words, including title, author names, affiliations, references, and acknowledgments. Submissions over the word limit will be returned. Submissions will be reviewed promptly; additional peer review may be warranted.

Inquiries or submissions should be directed to Harold Alan Pincus, M.D., Terri L. Tanielian, M.S., or Amy M. Kilbourne, Ph.D., M.P.H., who are editors of the column. Contact Ms. Tanielian at RAND, 1200 South Hayes St., Arlington, VA 22202 (e-mail: territ@rand.org).