Implications Of Part D For Mentally Ill Dual Eligibles: A Challenge For Medicare

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Health Aff. 2006;25(2):491-500. ©2006 Project HOPE
Posted 03/09/2006

Medicare's greatest challenge will be to regulate and monitor private prescription drug plans to assure quality and protect beneficiaries.

Abstract and Introduction

Abstract

Through the Part D drug program, Medicare has assumed responsibility for the prescription drug needs of beneficiaries and, consequently, for an important component of mental health treatment: psychotropic drugs. Managing the prescription drug benefits of mentally ill dual eligibles could challenge this new program. Efforts to balance quality assurance and cost-effectiveness will be complicated by this population's vulnerability and high level of health care need, the uncertainties surrounding optimal psychotropic drug use, and the economic incentives of prescription-only insurers. We discuss the details and policy implications of this challenge.

Introduction

With the implementation of the Medicare prescription drug benefit (Part D), a major component of mental health care—managing mental health medication benefits for "dual eligibles" (those who qualify for both Medicare and Medicaid)—has shifted from state to federal control. Because psychotropic medications are now the predominant treatment for mental illness and the fastest-growing component of mental health spending, this responsibility is medically and economically important.[1] This development heralds the further federalization of mental health treatment in the United States.

In January 2006 the drug benefits of approximately six million dual eligibles shifted from state Medicaid programs to Medicare Part D.[2] Nearly a third of these beneficiaries have mental illnesses.[3] The needs of this population will test Medicare as it strives to maintain quality of care while delivering the cost-effectiveness expected of private prescription drug plans (PDPs).

Characteristics of Dual Eligibles

Relative to other Medicare beneficiaries, dual eligibles are disproportionately members of minority populations, are sicker, and use many more health care resources.[4] Mental illness is an important component of the excess morbidity and spending of this population (Exhibit 1). A recent study found that Medicare beneficiaries with mental illness spent, on average, 61 percent more on drugs than beneficiaries without mental illness.[5] Disproportionate prevalence of nonpsychiatric illness also contributes to this population's high levels of service and prescription use.[6]

The 1.6 million dual eligibles residing in nursing homes are the sickest subset of beneficiaries.[7] Six-to eight-tenths of these residents are mentally impaired.[8] In contrast to the community-dwelling population, whose dominant mental disorders are psychiatric, mental impairment in this generally older population is largely the result of organic brain conditions such as Alzheimer's disease and other dementias.[9] In 2000, average health spending for institutionalized dual eligibles was more than four times that of their community-dwelling counterparts ($44,600 versus $10,900).[10] In the same year, nursing home residents in general received, on average, 9.4 medications per day, almost twice the number (5.0) used by those in the community with drug coverage.[11]

Drug Coverage Prior to Part D

Before Part D was implemented, full dual eligibles received prescription drug benefits through their state Medicaid programs. Despite recent efforts to control spending, Medicaid programs generally offer broad drug coverage. Many of them exempt psychotropics from some or all of their prescription access restrictions.[12] Prescription copayments are nominal, and prescriptions cannot legally be withheld if a beneficiary cannot pay the copayment.[13]

Psychotropic Medications and the Prescription Drug Market

Psychotropic drug spending increased 15-17 percent per year from 1991 to 2001, contributing to overall growth in drug spending, which rose an average of 15.9 percent annually from 1999 to 2002.[14] By comparison, growth of total health spending peaked at 9.3 percent in 2001-02.[15] The rise in psychotropic drug spending reflects the introduction of new, costly medications as well as a long-term shift in U.S. mental health care: Medication use has increased, while psychotherapy and other outpatient treatments have decreased.[16] Nationally, eight of the twenty-five top-selling drugs in 2001 were psychotropics. Antidepressants had the highest retail sales ($12.5 billion), and antipsychotics ranked thirteenth ($4 billion).[17]

Prescription Access for the Mentally Ill: Unique Concerns

Psychiatric illnesses are heterogeneous, with variable drug responses. In treating mental illnesses, patients and physicians typically work through a trial-and-error process to identify the best medication or medication combination.[18] Consequently, mental health care beneficiaries and their physicians may be highly invested in individual drug regimens. This complicates formulary-driven medication switches. Unlike other chronic conditions such as hyperlipidemia, hypertension, and osteoporosis, disrupting psychiatric medications can have immediate health consequences resulting in symptoms, functional impairment, and accelerated use of health services.[19]

Access Restrictions

The Centers for Medicare and Medicaid Services (CMS) responded to concerns about interruption and changes in psychotropics that could result from access restrictions under Part D. For most medication classes, original Part D legislation requires PDPs to provide a minimum of only two drugs.[20] Regulation amendments, however, stipulate that all antidepressants and antipsychotics be included in PDP formularies and that patients stabilized on these medications before switching to Part D should not be subject to utilization management (UM) strategies, such as prior authorization or requirements to first fail a preferred product (fail first), to continue therapy.[21]

These broad access requirements aimed to ease the transition of mentally ill beneficiaries to Part D. Those requiring treatment modification and those diagnosed with mental illnesses after switching to Part D might still experience access restrictions. Although all antidepressants and antipsychotics are on PDP formularies, PDPs could apply fail-first policies, prior authorization requirements, and differential copayments. If used intensively for psychotropics, these measures will direct prescribers to less costly options and reduce drug spending as intended. The administrative obstacles they would create, however, could increase the burden of the treatment selection process and limit options effectively available to unstable or new mental health patients.

UM tools will likely be used aggressively for psychotropics. Under capitation, PDPs have strong financial incentives to limit the use of costly drugs. As plans negotiate prices with manufacturers, broad formulary requirements limit their ability to obtain price concessions in exchange for formulary inclusion. Differential application of UM might be the only negotiating leverage available to PDPs.

Nondiscrimination and Adverse Selection

Beneficiaries with mental illnesses are intensive users of psychiatric and nonpsychiatric services and medications.[22] Although risk adjustment limits financial risk, PDPs still have an incentive to manage the composition of their enrollee panels.[23] They are likely to maintain formularies and UM strategies designed to avert adverse selection (disproportionate enrollment of the highest users). To prevent such tactics, the CMS seeks to prohibit formularies that would "discourage enrollment of certain beneficiaries."[24]

Formularies and formulary changes are reviewed prospectively. Discriminatory application of UM, however, might be apparent only once PDPs have a record to review, which could delay recognition of the problem.[25]

Plan Selection and Advocacy

Under Medicaid, except for a minority in managed care, dual eligibles did not choose their prescription plans: They received the one plan offered by their state. Under Part D they may select a PDP. To ensure that there is no temporal gap in prescription coverage, the CMS automatically and randomly enrolled dual eligibles in a PDP in September 2005.[26] The transition of benefits occurred 1 January 2006. Dual eligibles may change plans at any time under the special enrollment period (SEP) provision.[27] Although random enrollment initially minimized the opportunity for favorable selection by PDPs, negative effects could result from the complexity of ongoing plan selection and the fact that initial plan assignment was random, with no consideration of current or future medication needs.

Beneficiaries with limited mental abilities will likely need ongoing assistance evaluating and selecting plans. If the process of selecting and changing plans proves prohibitively complex, dual eligibles may remain with the plan to which they were initially assigned, leaving their coverage match to chance. Alternatively, if plan enrollment and disenrollment are easy, the SEP provision could result in frequent plan changes by dual eligibles in response to confusion, prescription needs, or access hurdles designed to encourage disenrollment and achieve favorable deselection.

The Nursing Home Population

For the institutionalized, transition and access concerns are magnified. The prevalence of mental limitations and high rates of polypharmacy complicate the plan selection process and augment PDPs' incentive to avoid this population.

Under Part D, nursing homes continue to manage drug purchase and procurement from pharmacies on behalf of beneficiaries. Beneficiaries or their guardians, however, must manage plan selection. Debilitated nursing home residents will be challenged by choosing a plan and may consequently keep their random plan assignment, however appropriate the match. For this frail population, medication changes and interruptions are especially disruptive. The elderly are more susceptible to and less tolerant of medication side effects than other populations are.[28] They are more likely than others to be adversely affected by access restrictions that limit their options or require a trial of drugs with greater potential for side effects or interactions with other drugs.

Cost Sharing

In the Medicaid population, cost sharing has been shown to decrease adherence to essential medications and increase use of costly medical services. This is especially important for enrollees with severe mental illnesses, whose conditions could worsen rapidly because of lapses in medication adherence.[29]

Under Part D, dual eligibles pay no premiums or deductibles. Beneficiaries with incomes below 100 percent of the federal poverty level pay a copayment of one dollar for each generic prescription and three dollars for each brand-name prescription. Those with incomes above 100 percent of poverty pay two and five dollars, respectively.[30] For many dual eligibles, these copayments have raised cost sharing. In contrast to Medicaid, pharmacists are not required to waive Part D copayments if the beneficiary is unable to pay. Pharmacies may waive the copayments of dual eligibles if they wish, and states may pay copayments on behalf of dual eligibles.[31] How much these provisions protect beneficiaries will depend on the extent to which they are implemented.

Health Disparities

Medicare was recently lauded for its reduction of health disparities along racial and ethnic lines.[32] This reduction was attributed to the uniformity of Medicare benefits for all recipients. With the implementation of Part D, Medicare risks introducing a new source of disparities in the health care it finances. Medicaid has a disproportionately high representation of minorities who have poorer health, lower levels of education, and lower incomes than their white counterparts.[33] Consequently, minorities will be disproportionately affected by higher Part D cost sharing. This group could also be disproportionately affected by complex enrollment systems, because illness, language barriers, or education might limit optimal enrollment. Studies reveal that minorities already experience major disparities in mental health care.[34] To ensure that Part D does not worsen these disparities, Medicare must consider advocacy and quality-assurance monitoring for minority, poor, and mentally ill populations.

Implications for Psychotropic Purchasing and Pricing

In 2001, Medicaid programs paid for 75 percent of antipsychotic prescriptions and 18 percent of antidepressant medications.[35] Historically, pricing, research, and development of these agents therefore have been influenced by Medicaid policies.[36] Medicaid drug purchases are subject to a manufacturer's rebate and price-increase caps based on the Consumer Price Index (CPI).[37] Medicaid's role as the predominant purchaser has made these pricing policies especially important for the antipsychotic drug market.

In January 2006, approximately half of the state prescription market share shifted to PDPs.[38] For the psychotropic drug industry, this might increase revenue, because a proportion of drug purchases are no longer subject to Medicaid price and rebate regulations. The overall impact on revenue will depend on the proportion of psychotropic drug purchases that are shifted to Part D and the value of price concessions negotiated by PDPs relative to the federally mandated Medicaid discounts. For antipsychotics, purchase volume shifted from Medicaid to Part D could be substantial, because users of these agents are more likely to be dual eligibles as a result of their severity of illness and consequent disability and poverty. Part D could therefore disproportionately influence antipsychotic pricing, as a large percentage of sales moves from government purchase to the private market.

Nationally, consumption of medications will likely increase with continuation of Part D, as Medicare beneficiaries without prescription drug coverage gain and use this new benefit. Decentralized purchasing on behalf of the CMS (by PDPs) might mean that few or none have sufficient market power to obtain major price concessions. The financial incentive for the industry to develop new psychotropics will be maintained.[39]

Optimal Medication Access and Use

The relative efficacy and cost-effectiveness of some newer psychotropic medications compared with older, cheaper drugs is a subject of debate. Controversy surrounding the drugs most strongly affecting Medicaid budgets—atypical anti-psychotics and newer antidepressants—is especially ardent.[40] This debate was recently rekindled by a head-to-head comparison of new and old antipsychotics. The study showed that two newer agents were only slightly superior to the old and that these benefits were tempered by troublesome side effects.[41] If expensive medications are not better than the older, cheaper options, restricted access could improve cost-effectiveness without compromising quality. If, however, the use of newer agents represents a cost-effective improvement over the use of older products, curtailing access could result in increased morbidity and accelerated use of medical care services.

The balance between effectiveness and cost likely depends on the recipient. For some, old drugs will prove as effective and tolerable as new ones. For others, new medications will represent a cost-effective improvement. To achieve more-cost-effective care without compromising quality, PDPs must accurately distinguish between these two types of users and implement access controls that minimize "marginal" use of expensive products (that which is not cost-effective) while maximizing "essential" (cost-effective) use.

PDPs do not, however, have the incentive to promote essential use of costly medications. Discouraging such use could save them money, because it might encourage intensive users to disenroll. The challenge for Medicare will be careful regulation and monitoring of PDPs, tight enough to protect beneficiaries and maintain quality but flexible enough to permit the innovation and access control that might improve cost-effectiveness.

Optimizing psychotropic drug use in nursing homes will be a challenge for PDPs. In this setting, marginal and essential use will be difficult to distinguish from one another. A recent study found that 28 percent of beneficiaries in nursing homes receive antipsychotics; 24 percent of these receive expensive atypical anti-psychotics, and 23 percent lack a diagnosis appropriate for such treatment.[42] Antipsychotics are used to control behavioral and psychological symptoms of dementia, although their efficacy for these indications remains uncertain.[43] When used to treat dementia symptoms, antipsychotics appear to slightly increase the risk of death.[44] In this setting of unproven benefit and risk of harm, restricting antipsychotic use could improve the safety and cost-effectiveness of care. For this frail and vulnerable population, independent research and guidelines will be necessary to ensure that restrictions are applied appropriately.

Impact on Psychotropic Spending and Disease Burden

Under Part D, if less costly therapies of equal or nearly equal effectiveness are used, true savings could be achieved and the burden of mental illness diminished. If, instead, less costly and less cost-effective therapies were used, the burden would simply shift. Some burden would shift from the insurance pool to individuals in the form of higher morbidity. Some burden would shift within the insurance pool from the prescription budget to the service budget, because greater morbidity would likely increase use of nonprescription care.

This distributional, or silo, effect is particularly important, because PDPs have budgets separate from those of Medicare Parts A and B. PDPs are at risk for a portion of prescription costs.[45] They are not, except in the setting of managed Medicare programs, at risk for any shift in service use that results from their drug benefit management. They have limited incentive to design drug benefits that promote overall cost-effectiveness by reducing spending in Parts A and B.

With the implementation of Part D, Medicare expanded its role in care for mental illness and assumed further responsibility for the needs of a fragile and vulnerable population. In the management of Part D, the greatest challenge will be assuring quality while promoting cost-effectiveness.

Prescription-only insurers have financial incentives to limit access, which could compromise quality of care and undermine Medicare's overall cost-effectiveness. Policymakers must ensure that quality monitoring is timely, sufficient, and particularly attentive to vulnerable populations. To help resolve uncertainties about safety and the relative value of drugs and to further inform prescription benefits design, more drug comparison studies should be funded. The claims data created by Part D should be used for post marketing drug surveillance and the long term outcomes research that is now egregiously scarce.[46]

Exhibit 1. Summary Statistics: Dual Eligibles Compared With Other Medicare Beneficiaries, 2000

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	Dual eligibles	Other Medicare beneficiaries
Total (millions)	7.2	40.4
Percent female	64%	55%
Percent African American[a]	20%	7%
Percent Hispanic[a]	15%	6%
Percent with annual income under $10,000	77%	18%
Percent residing in nursing home	25%	2%
Percent under age 65[b]	36%	9%
Percent under age 65 with mental illness	59%	37%
Percent over age 65 with mental illness	25%	2%
Total annual health care costs	$18,100	$8,400
Percent self-reporting health status fair or poor[b]	55%	26%

SOURCE: J. Kasper, R. Elias, and B. Lyons. *Dual Eligibles: Medicaid's Role in Filling Medicare's Gaps.* March 2004. http://www.kff.org/medicaid/7058.cfm (accessed 21 May 2005); and see below.

[a] J. Ryan and N. Super. "Dually Eligible for Medicare and Medicaid: Two for One or Double Jeopardy?" September 2003. http://www.nhpf.org/index.cfm?fuseaction=Details&key=480 (accessed 6 December 2005).

[b] Centers for Medicare and Medicaid Services, data from the Medicare Current Beneficiary Survey (MCBS) 2000 Access to Care File, June 2002.

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Acknowledgements

An earlier version of this paper was presented at the Third NIMH Pharmacoeconomics Workshop: MMA03 and Psychotropic Medication, held 23 May 2005 in Bethesda, Maryland. The authors are indebted to workshop chairs Agnes Rupp and Richard Scheffler, discussants Jon Christianson and Penny Mohr, and all workshop attendees who provided insightful discussion about and critical assessment of the original manuscript. They also thank Sean Sullivan and Tom Hazlet for comments on earlier drafts.

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