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Retaining Part D's Comprehensive Coverage of Antidepressants:

Not a Silver Bullet

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Clinicians prescribing antidepressant medication to elderly and disabled Medicare patients have a wide array of choices because antidepressants are among the 6 protected classes of medications in Medicare Part D. The Centers for Medicare and Medicaid Services (CMS) requires Part D plans to cover “all or substantially all” drugs in these classes to ensure vulnerable populations’ access to needed medications and to reduce the ability of Part D plans to restrict coverage of drugs used by beneficiaries with high expected costs. However, this requirement has also reduced Part D plans’ abilities to negotiate lower prices with drug companies marketing those drugs.¹

In a draft rule in January 2014, the CMS proposed to lift the protected status of antidepressants, together with antipsychotics and immunosuppressant drugs, to give plans greater negotiating power.² The proposal met with strong opposition from patient advocates, drug manufacturers, and lawmakers. Opposition was so strong that, 2 months later, the CMS

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Acquisition, analysis, or interpretation of data: All authors.

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rescinded the proposal. Absent from the debate over Part D formulary coverage of antidepressants, however, was an analysis of current prescribing practices for Medicare patients. To inform the policy debate, we briefly review evidence on the range of antidepressant choices needed for depression treatment, examine current antidepressant use patterns in Part D, and assess how the proposed change would affect the quality of antidepressant treatment in Medicare.

In its proposed rule, the CMS cited comparative effectiveness research showing little evidence for choosing one antidepressant over another when initiating antidepressant treatment. Within subclasses (eg, selective serotonin reuptake inhibitors), antidepressants have similar average efficacy and adverse-event profiles.³ Despite substantial variability in treatment response and risk of adverse events among individuals, there are no reliable predictors of which drug will be most effective for a particular patient.⁴ However, evidence also suggests that a wide range of choices may be needed over the course of treatment. For example, a major clinical trial found that only 37% of patients achieved remission of depression after the first trial of antidepressants, suggesting that 63% of patients would need a minimum of 2 trials and that patients with treatment-resistant depression would need more.⁵ Such evidence on the benefits of multiple medication trials was cited by groups opposing the proposed rule.

What are the current prescribing practices in Medicare, and how many would be affected by the removal of antidepressants from the protected classes? We analyzed 2009–2010 data from a random sample of 1.6 million fee-for-service Medicare enrollees in stand-alone Part D plans, from which we identified 47 214 patients who received a diagnosis of depression and initiated antidepressant treatment. We sought to answer 3 questions. First, what proportion of Medicare patients try multiple antidepressants over the course of a treatment episode? Second, are some Part D plans imposing restrictions on antidepressants even if they are covered on the formulary? Third, does the number of unique antidepressants used per episode vary across plans that are more vs less restrictive?

We found that 76% of patients initiating antidepressant treatment for depression used only 1 antidepressant agent (based on ingredients), 20% used 2 agents, and 4% used more than 2 agents. Should the CMS proposal go into effect, the most restrictive Part D plans would still cover at least 2 agents within each subclass of antidepressants (eg, selective serotonin reuptake inhibitors), the minimum standard for pharmacologic classes without the protected status.² Thus, if the current pattern of antidepressant treatment persisted, only 4% of Medicare patients might have their medication choices limited in the most restrictive plans.

Although plans are currently required to cover all drugs in the protected classes, they may discourage prescribing of certain drugs by imposing utilization management tools such as prior authorization, which requires prescribers to attest to patients meeting certain criteria before the prescription can be filled, and step therapy or “fail first” limits that require a trial of the most cost-effective drug before prescribing others. More than half (52%) of Medicare patients were in plans that applied these tools to at least 1 antidepressant, almost always a branded drug.

Our data indicate that these utilization management strategies have had little impact on the number of antidepressant trials a patient receives. The number of unique antidepressant agents used in the first 6 months of treatment was almost identical between plans with such strategies and those without (Figure). To the extent that the effects of these tools mimic the effects of more restricted coverage, lifting the protected status of antidepressants per se is unlikely to affect the management of antidepressants for the overwhelming majority of patients.

Lifting the protected status for antidepressants would give plans the ability to limit formulary coverage of branded drugs and would likely increase prescribing of generic antidepressants and, in turn, improve medication adherence.⁶ On the other hand, restricting coverage to generic drugs may reduce Medicare beneficiaries' access to new (and possibly more effective) antidepressants that may be developed in the future. For drug coverage policies to be sufficiently responsive to technological change, Part D plans must have adequate access to evidence on comparative effectiveness, and the CMS will need to closely monitor coverage policies to ensure that they permit access to superior treatments.

The recent debate over lifting the protected status of antidepressants highlights the tension in formulary policy between the pursuit of lower costs/greater efficiency and the need to ensure patient access to a range of treatment options. The currently very low number of antidepressant trials among Medicare patients, however, suggests that comprehensive coverage alone does not ensure high quality. Rather, the CMS, Part D plans, health care professional organizations, and patient groups should focus attention on closing the substantial gap between the currently low level of antidepressant management and what evidence suggests is needed to achieve good outcomes for the majority of patients. This will entail the systematic follow-up of patients to assess treatment response and adverse events and the use of medication management protocols that involve antidepressant switching or augmentation for patients not responding to initial treatment. Step therapy, a tool used by many but not all Part D plans, facilitates multiple antidepressant trials while helping reap the economic benefits of restricting first-line treatments to the least expensive alternative.⁷ The implementation of these tools, however, needs to be carefully designed to minimize administrative burden and maximize prescriber and patient awareness to guard against unintended consequences (such as a reduction in the number of patients starting treatment and an increased number of patients discontinuing treatment).

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Figure.
Number of Unique Agents Used in the 6 Months Following Initiation of Antidepressant Treatment