Implications of Benzodiazepine Exclusion Under Medicare Part D Coverage

Alan T. Kaell, MD, and Steve A. Freedman, PhD, FAAP, NASI

A CLINICAL VIGNETTE

For 12 months, a 68-year-old, unemployed widow has been experiencing chronic palpitations, poor concentration, and excessive worrying about multiple somatic concerns. Because of these symptoms, she has progressively withdrawn from her circle of family and friends.

Prior to the onset of these symptoms, she was essentially healthy, without significant medical problems and living independently. Within the last month, she has consulted a pantheon of physicians, including an internist, a neurologist, a rheumatologist, a cardiologist, a urologist, and a pulmonologist. She complains to her three daughters that irrespective of her intractable symptoms, the doctors can find “nothing wrong.”

A week ago, while shopping at her supermarket, she entered the walk-in clinic where the nurse practitioner recognized the “unexplained” symptoms as anxiety, a condition prevalent in the ambulatory setting.1 The patient completed a simple screening questionnaire, the Kroenke Generalized Anxiety Scale (Table 1).2 She attained a maximum score of 21 out of 21 possible points.

After a referral visit, a psychiatrist concurred with the diagnosis of anxiety with panic disorder and prescribed a benzodiazepine. The patient took the prescription back to her supermarket pharmacy but was told that she is not insured for this particular medication under her Part D Medicare coverage.

BACKGROUND

In a 1987 article, Ray et al. found a positive correlation between the use of benzodiazepines and the incidence of hip fractures.3 Inferring a cause–effect relationship between injury-producing falls and the use of the drugs, policymakers at the state and federal levels apparently assumed that reducing the number of individuals taking benzodiazepines would diminish the incidence of costly hip fractures. Consequently, in 1989, the state of New York restricted benzodiazepine coverage by instituting a triplicate prescription policy (TPP). More recently, the federal 2006 Prescription Drug Improvement and Modernization Act (Medicare Part D drug benefit) specifically excluded coverage of benzodiazepines.

In a study published in 2007, Wagner et al. compared longitudinal data from New York and New Jersey on the association between the use of benzodiazepines and the incidence of hip fractures.4 New Jersey, unlike New York, had not restricted the use of benzodiazepines in 1989. The findings of that study showed that although New York’s public policy had reduced the use of benzodiazepines by 60% in the subsequent year, there was no significant reduction in hip fractures resulting from the restriction of the drug. In their article, the Wagner team also cited other literature that addresses the conflicting findings and

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Table 1  Seven-Item Scale for Generalized Anxiety Disorder (GAD 7)

<table>
<thead>
<tr>
<th>Over the last 2 weeks, how often have you been bothered by the following problems?</th>
<th>Not at all</th>
<th>Several days</th>
<th>More than half the days</th>
<th>Nearly every day</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Feeling nervous, anxious or on edge</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>2. Not being able to stop or control worrying</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>3. Worrying too much about different things</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>4. Trouble relaxing</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>5. Being so restless that it is hard to sit still</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>6. Becoming easily annoyed or irritable</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>7. Feeling afraid as if something awful might happen</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
</tbody>
</table>

*Total score ______ = Add Columns ______ + ______ + ______

If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?

**Circle one**

<table>
<thead>
<tr>
<th>Not difficult at all</th>
<th>Somewhat difficult</th>
<th>Very difficult</th>
<th>Extremely difficult</th>
</tr>
</thead>
</table>

* Score: 5–9 = mild anxiety; 10–14 = moderate anxiety; 15–21 = severe anxiety.

Adapted and reproduced with permission from Spitzer, RL, Kroenke, K, Williams, JB, Lowe, B. Arch Intern Med 2006;166:1092. Copyright © 2006, American Medical Association. All rights reserved.
stirs the debate about the alleged associations among benzodiazepine use and hip fractures.

**PUBLIC POLICY: APPLYING PROCESS STANDARDS**

Government can draw an important lesson from science and jurisprudence from experiences like these. Simply, the evidence base must meet sufficiently high standards to support an initial action or a change in course. In the courts, the standard is the “preponderance of evidence.”¹⁶ In the delivery of drug therapies, the most widely known standard is that of the Food and Drug Administration (FDA), the standard of “safe and effective.”¹⁵

Although the quality of the deliberations on which the FDA relies may be debatable, a standard and a process are, nevertheless, in place to provide physicians with reasonable confidence that a pharmaceutical product has an appropriate use. Indeed, the FDA requires publication of contraindications, side effects, and alternatives so that the decision to prescribe is a well-informed one.

We suggest that such a set of considerations be applied to the creation of public policy when drug therapy is regulated at the clinical level. Referring to our case study as an example, public policymakers should have initiated studies to determine whether sufficient—preponderant—evidence existed in the decision to erect functional or economic barriers to the use of benzodiazepines.

There is an implied private contract between physicians and patients. When public policymakers find it necessary to modify that private contract for the “public good,” the act of modification carries with it a special duty to prove the need for a change. Indeed, we believe that public policymakers should perform three steps before acting as they did in the case of benzodiazepines:

- They must set an evidence-based standard that is sufficiently high to overcome the implied contract between physician and patient.
- They should publish evidence meeting the established standard so that both physicians and their patients explicitly understand the need for the public policy.
- They have an obligation to identify and support evidence-based, alternative interventions that can meet the clinical need.

There might be a number of valid reasons why public policymakers would wish to modify current clinical practice. Irrespective of the reasons, they must use their power within a protocol that is grounded in science and that is pursued with an understanding of the patient-physician relationship.

David Atkins, MD, MPH, from the Center for Outcomes and Evidence, Agency for Healthcare Research and Quality (AHRQ), in a recent report to the Institute of Medicine, articulated processes to be used in evaluating evidence-based medicine (EBM). He suggested the following steps in using evidence to guide policy:⁷

- Identify the important questions.
- Decide which types of evidence are relevant.
- Evaluate the strengths and weaknesses of individual studies.
- Evaluate the quality of a body of evidence.
- Identify and weigh important outcomes (i.e., judge net benefits).
- Translate evidence into recommendations for practice or policy.

As Dr. Atkins has explained, we “need to separate assessment of evidence—defining limits of what we know—from decision-making—what we should do.”

We would emphasize that the “know” is what we currently think we “know” to be true and that it evolves over time.

For managing the patient in our clinical vignette, what clinician would not decide to “do” and would not go ahead and prescribe a benzodiazepine?

A suboptimal alternative covered benefit would be a selective serotonin reuptake inhibitor (SSRI). Recent publications suggest a possible association of hip fractures with SSRIs.⁸ Should future national policies also exclude these agents from being a covered drug benefit?

What if our patient develops peptic ulcer disease and is prescribed a proton pump inhibitor (PPI)? Some articles have also demonstrated similar associations of PPIs with an increased risk of hip fractures.⁹ Will we then have future national policies that exclude PPIs as a covered drug benefit under Medicare Part D? Will private insurers follow their lead?

Fortunately, for drugs other than benzodiazepines, Part D plans must have formularies with at least two drugs available in each category of medications, and the U.S. Pharmacopeia must be used as the information source. An “exclusions and appeals” process must provide enrollees with the opportunity to challenge the exclusion of a particular drug from a plan’s formulary or the placement of a drug on a higher cost-sharing tier.

Although the specific procedures differ from plan to plan, the basic process must comply with the following Centers for Medicare & Medicaid Services (CMS) requirements.¹⁰ An excerpt from the Medicare Part D Drug Benefit exceptions and appeals process is presented in Table 2.

Practicing clinicians are encouraged to embrace and assess EBM while they make challenging decisions daily about therapy for individual patients. Other health care stakeholders, such as public policy officials or payers, utilize and assess this EBM to help them make decisions on public policy or payment matters.

Policymakers and payers may assess or interpret the evidence in a way that differs from how clinicians interpret the same evidence for their individual patients. The decision to prescribe a particular treatment to a patient is made by consensus between clinician and patient; clinical judgment prevails.

**CONCLUSION**

Medicare’s policy explicitly excludes coverage of the benzodiazepines even if a patient has an indicated, medically necessary diagnosis. The ultimate medicolegal responsibility for the decision to appropriately diagnose and prescribe, however, rests upon the clinician whose fiduciary responsibility is to the patient. When public policy intervenes in the patient-physician relationship, there is an extraordinary duty on the part of policymakers to explain the underpinnings of the policy and to suggest alternative evidence-based interventions.
Table 2  Exceptions and Appeals Process for Non-benzodiazepines under the Medicare Part D Drug Benefit

The Exceptions Process

An exception can be requested by the Part D Plan enrollee, the prescribing physician, or the enrollee’s appointed or authorized representative (e.g., a State Pharmaceutical Assistance Program). Exceptions may be requested under the following circumstances:

- The enrollee is using a drug covered on a plan’s formulary that has been removed during the plan year for reasons other than safety.1
- The enrollee is using a drug that has been moved during the plan year from the preferred to the non-preferred cost sharing tier.1
- The enrollee’s physician prescribed a non-formulary drug for the enrollee that the physician believes is medically necessary.
- The enrollee’s physician prescribed a drug for the enrollee that is included in a plan’s more expensive cost sharing tier because the prescribing physician believes the drug included in the less expensive cost sharing tier is medically inappropriate for the enrollee.

Generally, plans must grant exceptions when they determine that it is medically appropriate to do so. If the exceptions request involves a plan’s tiered cost-sharing issue, the Part D drug being prescribed may be covered at a lower tier cost if the prescribing physician supports [the notion] that the preferred drug for treatment of the same condition would not be as effective as the non-preferred drug or would have an adverse effect for the enrollee, or both.

If the enrollee is requesting coverage of a non-formulary drug, the drug may be covered if the prescribing physician supports [the notion] that all of the drugs on the formulary would not be as effective as the non-formulary drug or would have adverse effects for the enrollee, or both. In both cases, the plan would only approve the exception if it agreed with the physician’s determination.

Plans must make their determinations as expeditiously as an enrollee’s health condition requires, but no later than 24 hours for expedited decisions involving enrollees who suffer from serious health conditions, and 72 hours for standard decisions. The exceptions process with determination time frames is summarized in the following chart:

<table>
<thead>
<tr>
<th>Standard Exceptions Request</th>
<th>Expedited Exceptions Request*</th>
</tr>
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<tbody>
<tr>
<td>Determination by Part D Plan</td>
<td>A Part D plan can be requested to conduct a determination regarding a request for an exception to an exclusion of a particular drug from a plan’s formulary or the placement of a drug on a higher cost-sharing tier. The plan has up to 72 hours to make its decision</td>
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</table>

* An expedited decision is requested based on the urgency of an enrollee’s health condition. Exceptions and appeal considerations are required to be placed on the expedited time frame, where applicable, if the prescribing physician indicates that applying the standard time frame would seriously jeopardize the life or health of the enrollee or the enrollee’s ability to regain maximum function.

From the American College of Physicians. Available at: www.acponline.org/pmc/exceptions.pdf.

The Appeals Process

Once a plan makes an unfavorable coverage determination such as denying an exceptions request, the enrollee, the enrollee’s appointed or authorized representative, or the prescribing physician may appeal the plan’s decision. Plans must inform the enrollee of the procedure to make an appeal request to the Part D plan at the time of notification of an unfavorable determination.

This first level of appeal, called a redetermination, is made directly to the Part D plan and must be responded to no later than within 72 hours for expedited decisions and seven days for standard decisions.

If the Part D’s plan redetermination is unfavorable, the enrollee or his or her appointed or authorized representative can request a second level appeal, called a reconsideration. These are conducted by an Independent Review Entity (IRE), which is independent of the Part D plans and are contracted by CMS specifically to review plan determinations.

The Part D plan must inform the enrollee of the procedure to make this reconsideration request to the IRE at the time of notification of the unfavorable reconsideration. The timeline for these IRE reconsiderations are the same as the first level appeal redeterminations.

The enrollee can pursue increasingly higher levels of appeals if the decision of the IRE is unfavorable. An appeal can be made to an Administrative Law Judge (Level 3 appeal), the Medicare Appeals Council (Level 4 appeal) and the Federal District Court (Level 5 appeal). Appeals at these levels are not timely and may have to meet additional requirements.

1 The new drug benefit requires plans to provide notice to affected enrollees 60 days in advance of a change in its formulary or tiering structure, or provide notice regarding the change along with a 60-day supply after an enrollee’s request for a refill affected by the change.

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REFERENCES


