



23 August 2004

Benzodiazepines, a group of medications commonly prescribed to America's older adults for the treatment of insomnia and anxiety will not be covered by the new Medicare prescription drug benefit.

Benzodiazepines include such branded drugs as Xanax, Ativan, Restoril and Valium and their generic equivalents. Researchers estimate that benzodiazepines are prescribed to 1 in 5 Medicare recipients.

Despite their efficacy — and low cost — at treating short-term anxiety and insomnia, benzodiazepines were specifically excluded by Congress when it created Medicare's new prescription drug benefit program, called Medicare Part D.

The benzodiazepine exclusion was reaffirmed in proposed rules recently published by the US Department of Health and Human Services and its Centers for Medicare & Medicaid Services. See "Medicare Program; Medicare Prescription Drug Benefit (CMS-4068-P)" at : <http://www.cms.hhs.gov/medicarerreform/> or as a downloadable pdf file at : <http://a257.g.akamaitech.net/7/257/2422/06jun20041800/edocket.access.gpo.gov/2004/pdf/04-17234.pdf>

The consequences of this exclusion — which affects 41.2 million Medicare recipients, including 6.4 million dual-eligibles currently covered under Medicaid — clearly were inadequately assessed by Congress and the Administration.

Come January 1, 2006, when the Medicare drug benefit begins, physicians expect that many older adults will ask that they be switched from their benzodiazepine prescription to a covered drug. Health care advocates fear the switches may come abruptly — leading to harmful drug interactions or drug withdrawal. And they're worried that some users will be switched to costly branded alternatives — when no medication may be best.

You can help let the Administration and Congress know that the Medicare benzodiazepine exclusion is an ill-considered and harmful approach to health care for America's older adults and that it must be remedied.

The Centers for Medicare & Medicaid Services is accepting written comments about its proposed rules to govern the Medicare prescription drug benefit. Your comments must be received no later than 5 p.m. Eastern Time on October 4, 2004.

Please submit your written objections to the benzodiazepine exclusion electronically at :
http://www.accessdata.fda.gov/scripts/oc/dockets/comments/COMMENTSMain.CFM?EC_DOCUMENT_ID=15&SUBTYP=CONTINUE&CID=&AGENCY=CMS.

After completing the "Docket Management Comment Form," which seeks your name, affiliation and zip code, please click on the "continue" button. Your browser will be directed to an issues page. Please click on "Issues 1-10." In the section headlined "Benefits and Beneficiary Protections," please type your comments or paste them from a Word or text document. Click the "continue" button at the bottom of the page. Your browser will be directed to a summary page that allows you to review and modify your comments. You also may attach a Word file, if you wish. After reviewing your comments, click the "save comments" button and proceed to view and print.

Alternatively, you may submit your written comments by mail (one original and two copies) to the following address only: Centers for Medicare & Medicaid Services, US Department of Health and Human Services, Attention: CMS-4068-P, P.O. Box 8014, Baltimore, MD 21244-8014. When commenting by mail, it is important that you include "Re: File Code CMS-4068-P" on your documents.

Attached are some facts and observations you may wish to restate in your own words and include in your written comments.

Finally, please forward a copy of your comments to: mbsg@noemaine.org .

This exclusion as anticipated will not permit the needed use, address inappropriate use, and may increase abuse and diversion.

Thank you for adding your voice in opposition to the Medicare benzodiazepine exclusion.

Stevan Gressitt, MD

Co-Founder

Maine Benzodiazepine Study Group

www.noemaine.org/benzo/benzo.htm

The Maine Benzodiazepine Study Group was formed to study the use, misuse, and abuse of benzodiazepines.

Consequences of Medicare's Benzodiazepine Exclusion

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Deadline: October 4, 2004

Comments to be restated in your own words

- The exclusion of benzodiazepines by Medicare Part D will be harmful to the older adults that my organization serves.
- The consequences of the benzodiazepine exclusion may be life threatening for Medicare recipients and dual-eligibles who are long-term benzodiazepine users.
- Many of my Medicare-recipient clients are unlikely to pay out-of-pocket for continued benzodiazepine therapy. Dual-eligibles we work with do not have the resources to pay out-of-pocket for on-going benzodiazepine therapy.
- The benzodiazepine exclusion will prompt many of my Medicare-recipient clients with benzodiazepine prescriptions to ask their physician to switch them to a covered drug.
- Upon a Medicare recipient's request for a covered benzodiazepine alternative, benzodiazepine therapy is likely to be suddenly stopped. Since many of my Medicare-recipient clients have been taking benzodiazepines for more than 2 months, abrupt cessation may cause severe withdrawal symptoms such as seizures that require Medicare-funded emergency room treatment and hospitalization.
- The sudden switch to a covered anti-insomnia or anti-anxiety medication may cause severe drug interactions, as it takes several days for benzodiazepines to leave the system of a long-term patient.

- My Medicare-recipient clients and their physicians are not prepared to initiate a smooth transition off of benzodiazepines.

- Benzodiazepine alternatives are likely to be much more costly to Medicare than benzodiazepines, which typically are generic medications.

- In the best interests of health care, CMS must find a way to include benzodiazepines as a covered drug under Medicare Part D.

Other Information To Include

Describe your organization, including the services provided to older adults, number of older adults and geographic area served.

If possible, provide an estimated number of Medicare-eligible clients with which your organization works that may be currently on benzodiazepines.