

CASE STUDIES IN PART D

Volume 3 Number 9



Cornell University
College of Human Ecology
Cornell Cooperative Extension

CUR_xED

Cornell University Resource Education for Medicare Part D

MEDICAL FOOD

THE CASE

Because her husband is fortunate enough to have an excellent job, Donna does not need to work and stays at home to look after her elderly father. Her father, BD, has Alzheimer's disease and requires continual monitoring and oversight. If Donna was unable to care for her father, BD would have needed to go to a Nursing Care facility several months ago.

At the onset of his illness, BD would need to write notes for himself to remember things. He then started to forget to look at the notes. Eventually, he began to lose items in the house, missed some appointments, and forgot to pay some important bills. At one point he lost track of what he was doing in the grocery store and an employee needed to call his home for help.

BD's current medication regimen includes Aricept and Namenda, both of which are used to slow the progression of the disease. Recently, however, BD has experienced a rapid deterioration of his illness. He is no longer sleeping at night, wanders throughout the house, and on several occasions has been found out in the yard in the early morning hours. The family is giving consideration to hiring an overnight sitter to stay with him.

The only family member who BD now recognizes and properly calls by name is Donna. He is rarely able to effectively communicate his needs and frequently shows expressions of anxiety on his face when asked to sit quietly. On one occasion, the low battery warning signal in the smoke alarm made him quite agitated.

His physician has provided trials of various medications, including Haldol and several different sedatives. There has been little improvement in his symptoms. In fact, he is even starting to get suspicious of the medications he is being given, calling them "the devil's venom."

Now, BD's physician would like to give him a trial of Axona. The physician tells Donna that Axona is not a medication, but instead is classified as a medical food. It is intended for the clinical dietary management of the metabolic processes associated with mild to moderate Alzheimer's disease.

When Donna goes to the Pharmacy to have her father's prescription for Axona filled, she is told that it is not covered by his Medicare Part D plan and a one month supply costs just over \$100. Upon her return home, Donna checks the plan finder to see if there is another Part D plan that will cover this medication but finds that it is not even listed on the web site.

WHAT WOULD YOU DO?

Part D Trivia Question

How many beneficiaries, is it estimated, are eligible for but are not receiving the Medicare drug benefit low income subsidy?

- A. 0.5 million
- B. 2.3 million
- C. 9.6 million
- D. 12.5 million

THE STUDY

Medical foods are not new, but because medical food products have been predominantly used in hospitals and other institutional care settings, general awareness of these products is lacking. Traditional medical foods on the market are typically in the form of liquids or powdered drink mixes and include formulations for newborns and patients with AIDS, kidney disease, and other disorders. Recently, several medical foods have become available in pill form and include therapies for osteoarthritis and pancreatitis, as well as Alzheimer's disease.

A medical food is defined as a food which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements are established by medical criterion, based on recognized scientific principles. Medical foods, medications, and nutritional supplements are not interchangeable and each has very discrete Food and Drug Administration (FDA) regulatory classifications.

The ingredients in medical foods are generally recognized as safe by the FDA, but only their clinical claims are supported by laboratory and clinical trials. Both the safety and therapeutic claims must be supported by testing and data for drug products. Curiously, unlike medications, there are virtually no labeling requirements for medical foods while labeling requirements for drugs are very strict.

Generally, medical food claims reference the "dietary management" or "distinctive nutritional requirements" of a particular disease. Drug claims reference "curing, treating, preventing or mitigating" a disease or the effects or symptoms of a particular disease. While medications are used to treat an illness or control the symptoms or the process of a disease, medical foods help to manage a metabolic process and promote normal physiologic function.

Although both medical foods and nutritional supplements have nutritional ingredients, they, too, should not be confused. Dietary supplements are intended for a healthy population, are sold over-the-counter, and cannot make specific disease claims. Medical foods are intended for persons with a specific illness and make medical claims regarding the management of a disease.

Medical foods are not meant to be used by the general public, or by normal healthy adults, and may not be available in all stores or supermarkets. A medical food is prescribed by a physician for a patient with specific medical nutritional needs and as with a medication, patients should receive ongoing medical supervision and care.

Axona, as described in this report, is not intended to be a recommendation of therapy, but rather, is used to highlight a type of therapy known as medical foods. Unfortunately for Donna and her father, medical foods, including Axona, are considered by the FDA to be distinct entities from medications. Since Medicare Part D covers only prescription medications, these products will not be found in the plan finder, and will not be covered under Part D.

Part D Trivia Answer

As of February, 2009, it is estimated that there are about 12.5 million beneficiaries who are eligible for the Low Income Subsidy. Of these, about **2.3 million** beneficiaries (or about 19% of those that are eligible) are not receiving the subsidy. There are about 9.6 million people currently receiving the subsidy and 6.3 million of them are dual eligibles. Another 0.5 million are thought to be eligible but have other coverage.

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CURxED Cornell University Resource Education for Medicare Part D

www.CURxED.human.Cornell.edu/

email: CURxED@Cornell.edu

This material is based upon work supported by a grant from the Dean of the College of Human Ecology and Smith Lever funds from the Cooperative State Research, Education, and Extension Service, U.S. Department of Agriculture. Any opinions, findings, conclusions, or recommendations expressed in this publication are those of the author(s) and do not necessarily reflect the view of the U.S. Department of Agriculture. Cornell University offers equal program and employment opportunity.