

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
Center for Beneficiary Choices
7500 Security Boulevard
Baltimore, Maryland 21244-1850



CENTER FOR BENEFICIARY CHOICES

Date: April 11, 2006

To: All Part D Sponsors

From: Abby Block, Director

Subject: CMS Clarification of Coverage of Prescription Niacin Under Part D

On February 3, 2006, we sent a letter to Part D plans explaining our view that prescription Niacin products (Niaspan®, Niacor®) are prescription vitamins and therefore excluded from the definition of a Part D drug under the statute. We have reviewed this issue more closely. The prescription niacin products Niaspan® and Niacor® are approved by the Food and Drug Administration as safe and effective drugs, are used therapeutically for the treatment of dyslipidemia, and do not serve as nutritional supplements or address a vitamin deficiency. These products are used at dosages much higher than appropriate for nutritional supplementation. For these reasons, we have concluded that these products should not be considered prescription vitamins for purposes of Part D coverage, and therefore, are not universally excluded from coverage under the Medicare prescription drug program.

Application of Policy Clarification to Contract Year 2006

This policy clarification supersedes our February 3, 2006 letter. However, because we had initially identified prescription niacin products as excluded, and plans may have relied on this communication, we do not believe that plans should now be required to add these drugs to their formularies. Thus, plans will have the option to begin covering these drugs immediately and, if so, should submit the additions to the HPMS and Medicare Prescription Drug Plan Finder formulary files with the next available upload periods. Plans that previously notified enrollees that prescription niacin products would be removed from their formularies, but that now intend to cover these products, should update their enrollees through the “upcoming Formulary change section” of the Explanation of Benefits (EOB) document.

Application of Policy Clarification to Contract Year 2007

For contract year 2007 formularies, prescription niacin products used at dosages much higher than appropriate for nutritional supplementation should be considered for formulary inclusion similar to all other Part D drugs. As outlined in the Final Formulary Guidance for 2007, we will review formularies for appropriate access to drugs and drug classes addressed in widely accepted treatment guidelines, including the guidelines for lipid disorders.