DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
JFK Federal Building, Government Center
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CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Division of Medicare Operations / Region I

NOV 22 2006

Juan M. Cofield
President, NAACP New England Area Conference
Post Office Box 128
West Roxbury, MA 02132

Dear Mr. Cofield:

This is in response to your letter to Dr. Charlotte Yeh, and your ensuing telephone conversation with Marva Nathan, regarding Medicare Prescription Drug Plan Coverage of BiDil® .

As part of CMS's formulary review process, we ensure Part D drug lists are consistent with best practice formularies currently in widespread use today. Accordingly, CMS has determined that all Part D formularies contain either Bidil® or isosorbide dinitrate and hydralazine, in line with the following evidence.

CMS received feedback from the American College of Cardiology (ACC) and the American Heart Association (AHA), who both did not support BiDil® use over use of the individual components. For instance the ACC stated in a letter to CMS July 31, 2006, that "either BiDil® or generic hydralazine prescribed with generic isosorbide dinitrate in combination with a standard medical regimen is reasonable for the management of HF in African Americans." Further, they state that "either regimen would comply with the ACC/AHA Guideline Update for the Diagnosis and Management of Chronic Heart Failure in the Adult."

CMS also found that some widely used formularies, such as the Veterans Affairs National Formulary, do not contain BiDil® , but instead contain the individual generic components, isosorbide dinitrate and hydralazine, the active ingredients found in BiDil® .

CMS was also presented with expert opinions on BiDil® that did not demonstrate any clinical advantage over the use of the individual generic products. For instance, the 2007 USP Expert Committee was specifically asked to evaluate BiDil® and amend the USP Model Guidelines to classify BiDil® as a Key Drug Type. The USP Expert Committee denied the proposal and stated, "Combination drugs are included when an exclusive clinical benefit has been established."

Please note that we will continue to evaluate the information on BiDil® and other drug products and update our evaluation processes as new information becomes available.

In regard to affordability, the law and the final rule require that drug plans have exceptions processes when people wish to request a change from a higher cost sharing tier to a lower cost sharing tier; or for coverage of a drug that is not on the plan's formulary. Plans have flexibility to design their exceptions criteria, and exceptions must be granted for a non-formulary medication or to lower the cost sharing tier, when medically necessity is appropriately demonstrated.

We at CMS share your concern that the reduction of health disparities and the affordability of prescription drugs are significant public health issues. We look forward to continuing our working relationship in addressing these issues.

Sincerely,

Tom Devins

Thomas Devins
Associate Regional Administrator