



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Secretary's Advisory Committee on Heritable
Disorders in Newborns and Children
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June 14, 2010

The Honorable Kathleen Sebelius
Secretary of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Secretary Sebelius:

On October 2, 2009 you responded to the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children (the Committee) May 19, 2009 and April 7, 2009 letters (enclosed) pertaining to the Committee's recommendations on insurance coverage of medical foods and other foods modified to be low in protein for the treatment of a number of disorders identified through newborn screening. The letters detailed the Committee's recommendations that the Secretary initiate appropriate action to address the gaps in coverage and lack of uniformity in reimbursement for medical foods and foods that are critical treatments for children and adults with inborn errors of metabolism. The Committee expressed the desire for: 1) a more uniform approach toward coverage by both private insurers and public payers of medical foods and foods essential to the treatment of conditions recommended by the Committee and 2) specific amendments to the Medicaid statute to ensure uniform coverage by State Medicaid programs.

The Committee appreciates your recognition that medical foods and other foods modified to be low in protein are important treatments for inborn errors of metabolism, as well as the Department's plans to further explore these proposals. Although the Committee understands that the original Committee recommendations to enact legislation were beyond the Department's authority, now that the Department is in the process of developing specific regulations to implement the recently enacted health reform legislation the Committee urges the Department to consider the inclusion of medical foods and other foods modified to be low in protein as essential benefits for treating children and adults with inborn errors of metabolism.

The Committee continues to examine the issue of insurance coverage of medical foods, foods modified to be low in protein, and pharmacological doses of vitamins and amino acids that are prescribed for the treatment of a number of childhood disorders identified through newborn screening. Of particular concern is the cost of the medical foods and foods

modified to be low in protein that are designed exclusively for treatment of these disorders. A recent survey of families conducted through the Health Resources and Services Administration-funded Regional Genetic and Newborn Screening Service Collaboratives found that the cost to families of these prescribed medical foods is significant. The survey revealed that:

- Coverage for medical foods and modified low protein foods is provided by both public programs and private insurance, but coverage for these essential treatments is typically capped at a level far below its true cost, imposing substantial cost-sharing on families;
- At least 25% of medical foods and more than 50% of modified low protein foods are not reimbursed by private health insurance.

While our survey data is preliminary, these observations and another recent study support our concern that families face a substantial out of pocket financial burden in providing treatment for their children. For example, the cost of medical food for a 15 year-old with Phenylketonuria is estimated at \$12,483, annually and the cost of foods modified to be low in protein ranges from \$1,200 to \$3,500 per year (Top Clin Nutr 24 (4):289-306, 2009).

As the Department develops the specific regulations for implementation of health reform, the Committee recommends that the Department ensure that families with individuals diagnosed with these disorders have access to health coverage that includes these essential components of treatment:

- Medical foods (as defined by the Food and Drug Administration and, in addition, for those conditions recommended by the Committee) delivered either orally or by tube (both are enteral) and foods modified to be low in protein that are prescribed by a physician should be considered medical benefits (and be included as essential health care services, and should not be restricted to pharmacy benefits);
- Individuals of all ages who are diagnosed with one or more of the conditions recommended by the Committee should be considered high risk and HHS regulations should ensure that they can access comprehensive coverage. This can best be accomplished through private health plans or publically supported programs such as Medicaid and high risk pools that cover medically necessary treatments – including medical foods and modified low protein foods; and
- Families should have access to these essential benefits irrespective of the source of their health coverage, including private plans, federally supported programs such as Medicaid, the Children’s Health Insurance Program, Tricare, and the Indian Health Service, as well as plans participating in, the Federal Employees Health Benefits program, and should not be subject to state exclusions.

The Committee believes that our nation has a special responsibility to assure evidence-based treatments for individuals identified with these disorders. This responsibility does not end with identification of these disorders, rather it extends to ensuring medically necessary coverage for these life saving treatments. Your appropriate policy decisions will have an immediate and substantial impact for thousands of affected individuals and their families.

Sincerely yours,

/S/

R. Rodney Howell, M.D.
Chairperson

Enclosures:

Tab A – Response from the Secretary to the SACHDNC: October 2, 2009

Tab B – Letter from SACHDNC to the Secretary: May 19, 2009

Tab C – Letter from SACHDNC to the Secretary: April 7, 2009