

May 18, 2012

Insurance coverage of medical foods for treatment of inherited metabolic disorders

**Secretary's Advisory Committee on Heritable Disorders in Newborns and
Children (SACHDNC)**

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For the Follow-up and Treatment Subcommittee**

Why did we do this?

Don't know

Section E. This section is for any comments you may have about this survey. We welcome any comments you might wish to share You may use the back of this page.

I do not think it is fair for children with medical problems and you do not get help to provide for your child. I have a child with LCHAD & I am very short for money and unable to work do to my child's needs. I am getting help on medical bills but not for her MCT oil that she needs for the rest of her life or she may not survive. I currently have that medical in collection cuz I am unable to pay for. What I am suppose to do to pay for it and keep getting her meds. Also it is very expensive to buy the foods she requires. I do not get help for her fat free - low fat foods. Please help pass this on thru states and put yourself in our position.
(What do u do?)

What is the problem?

- Medical foods, often referred to by families as “special formulas” or “protein substitutes” are NOT drugs, they are substances of nutritional value
- Medical foods are not optional, they ARE the treatment
- Treatment is LIFE-LONG
- Everyone needs food, yet traditional foods can be harmful to persons with inborn errors of metabolism
- Medical foods are substantially more expensive than traditional foods
- Because they are foods, they are EXCLUDED from coverage by many insurers
- Costs may be prohibitive; coverage is at best variable
- *Affected persons cannot survive without medical foods but they cannot afford to buy them*

FDA Definition: Medical Food

“a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation.”

as defined in section 5(b) of the Orphan Drug Act (21 U.S.C. 360ee (b) (3))

This legal definition of a medical food was added to the Orphan Drug Amendments of 1988

What are the nutritional treatments?

- Medical foods
 - ▣ Specially compounded formulas that supply a substantial portion of nutrition for the treatment of inborn errors of metabolism
- Supplements
 - ▣ Pharmacologic doses of cofactors or vitamins, e.g. biotin for biotinidase deficiency
 - ▣ Amino acids provided to give substrate or prevent specific amino acid deficiency
 - ▣ Other vitamin-like drugs that may provide benefit, e.g. carnitine
 - ▣ MCT oil
- Specially manufactured modified low-protein foods (MLPF)

Medical foods require physician supervision

All are essential elements of therapies for treatment of inborn errors of metabolism

Medical equipment and supplies may be needed for feeding

Follow-up and Treatment Subcommittee Addresses Challenges

- Medical Foods Workgroup meeting, June 2008: Insurance coverage of medical foods, modified low protein foods, nutritional supplements and related feeding supplies – private and public insurance perspectives, and employment-based health plan issues
- Medical Foods Survey: Parent Survey of Insurance Coverage of Medical Foods for Children with Metabolic Conditions

What are (some of) the barriers?

- Each insurer has its own practices
 - ▣ Private insurers (public using private vendor, self-insured, employers)
 - ▣ Public practices vary state to state
- Each policy, even with the same company, may have differing coverage; contracts may result in differences for the SAME insurer
- Each state has different rules / laws covering provision of medical foods
 - (see <http://www.ncsl.org/programs/health/lawsfoodsformula.htm> for list of laws)
- Even when laws exist they may not cover all insurance carriers (ERISA)
- Even when laws/guidelines exist they are subject to interpretation by insurers and the states

Objectives of Medical Foods Survey

- Purpose: to survey parents of children (birth to 18 years of age) with metabolic disorders to assess current health insurance coverage and actual coverage for medical foods (and related materials).
- Rationale: to inform federal and state public health policy decisions aimed at reducing financial barriers and improving coverage of medical foods for the treatment of children with inborn errors of metabolism.
- Information sought:
 - ▣ 1) What are the needs of children for metabolic foods and formulas, modified low protein foods, prescribed dietary supplements, and medical feeding supplies and equipment?
 - ▣ 2) What are the out-of-pocket expenses for foods and formulas?
 - ▣ 3) What proportion of expenses for medical foods is paid for?

Preparation of Medical Foods Survey

- Expert panel established: metabolic genetic physicians, metabolic nutritionist, epidemiologist, statistician, parent, public health professionals.
- Parent Group cognitive interviews
 - ▣ Westchester Medical Center, NY: October 2007
 - ▣ Mount Sinai Medical Center, NY: March 2008
- Pre-testing Survey validity/reliability, Fall 2008
 - ▣ Emory University
 - ▣ University of Minnesota
 - ▣ University of Pittsburgh

Content

The survey asked families about:

- Their child's diagnosis
- The health plan(s) covering the child's care
- The medical foods/formulas, modified low protein foods, prescribed dietary supplements, and medical feeding supplies/equipment used by their child
- The extent to which those items were covered by their health plan, including dollar amounts per month
- Their monthly out-of-pocket expenses for those items, if not fully covered
- If their health plan had caps on the coverage that was provided

Conducting the Survey

- Implementation by HRSA Regional Genetics and NBS Services Collaboratives 2 (NYMAC), 3 (SERC) and Region 4 with support from the National Newborn Screening and Genetics Resource Center (NNSGRC): Summer 2009
- Targeted at families with children (0-18 years) with metabolic disorders treated with medical foods, supplements, modified low-protein foods; also asked about feeding supplies
- 305 families responded across all three regions.

Survey Implementation: Genetic Centers

- IRB Process – approval received for implementation
- Paper survey administered by genetic centers
- Parent Responders completed survey anonymously
- Limited demographics collected –
 - ▣ State of residence
 - ▣ Age of child
 - ▣ Diagnosis
- Genetic Centers submitted data to their Regional Collaborative (RC)
- Each RC used data to inform their own planning
- RCs submitted data to HRSA MCHB for integration

Acknowledgment: Genetics Centers

Region 4:

University of Minnesota Amplatz
Children's Hospital
Cincinnati Children's Hospital
Medical Center

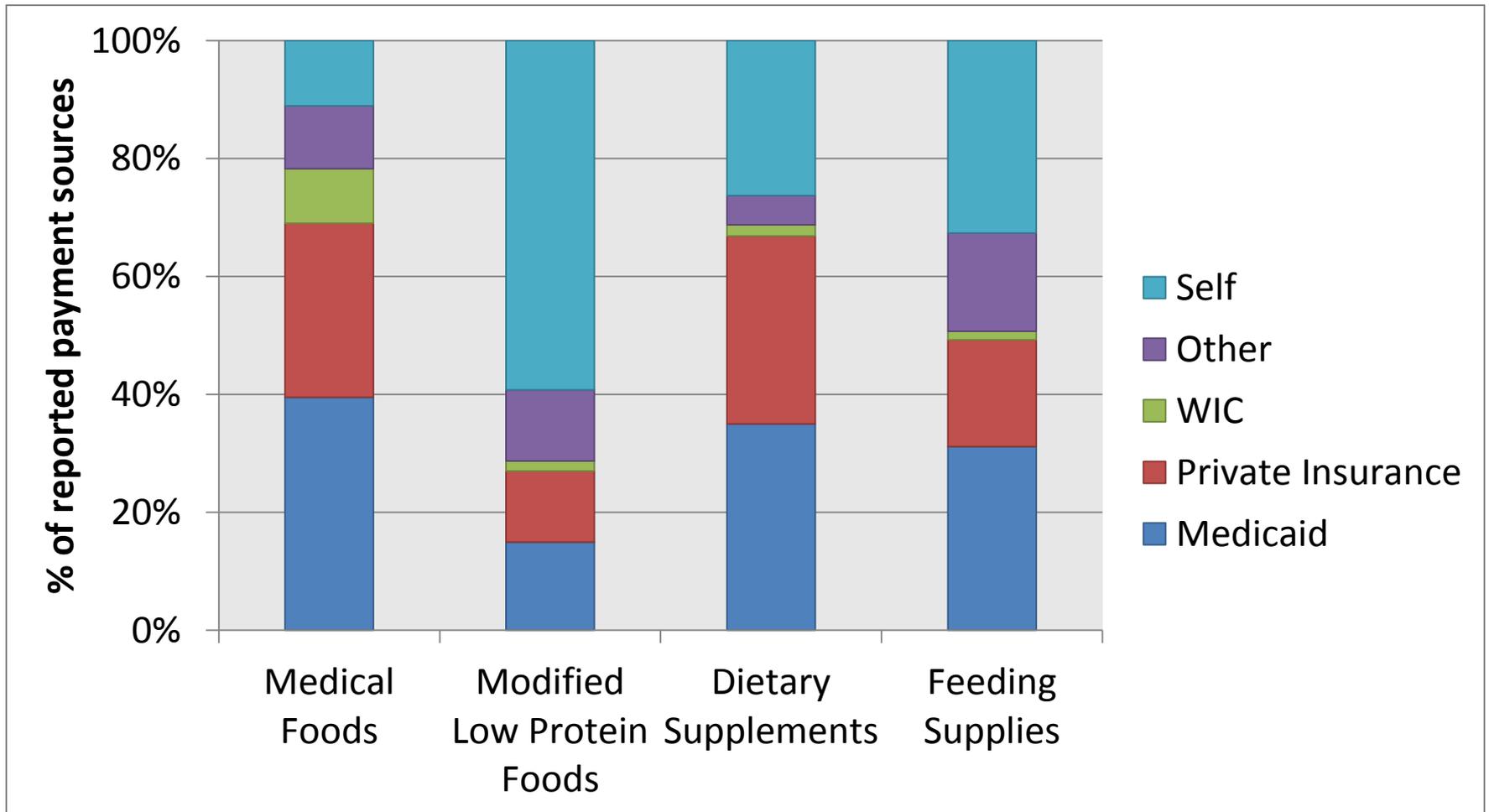
SERC:

Emory University
Greenwood Genetics Center
University of Florida
University of North Carolina -
Chapel Hill
University of Tennessee
Vanderbilt University Medical
Center

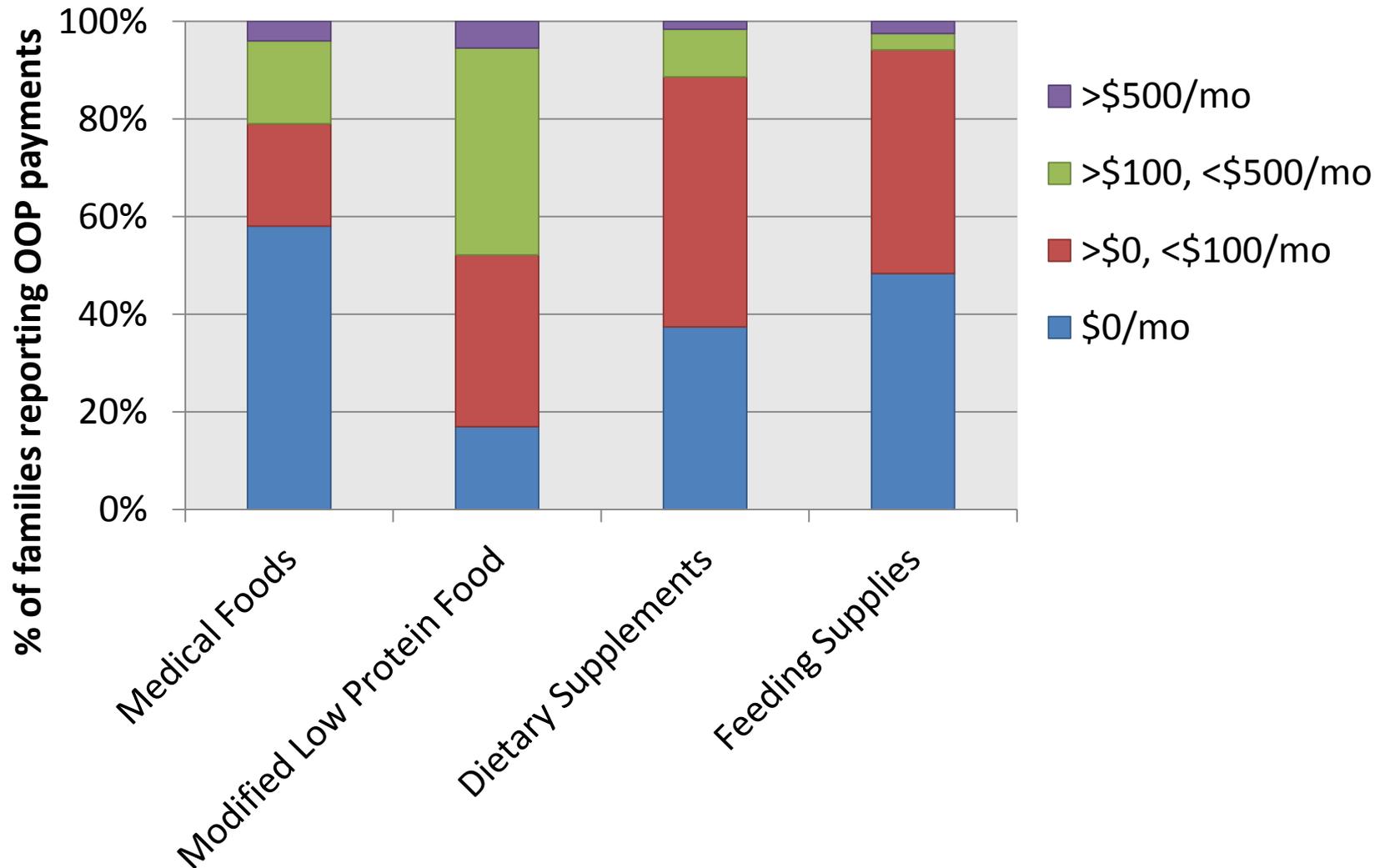
NYMAC:

Mount Sinai Medical Center
Children's Hospital at Albany
Medical Center
Children's Hospital of Pittsburgh
Golisano Children's Hospital at
Strong
Maria Fareri Children's Hospital
at Westchester Medical Center
University of Maryland Hospital
for Children

Percentage of reported payment sources used for medical foods and related products



Cost per month paid out-of-pocket for medical foods and related products



What did we learn?

- Nearly all children in this group had some type of health care coverage (even if it did not pay for these products)
- Most children needed more than one category of food/supplies
- Coverage was variable but there were at least some out-of-pocket expenses
 - ▣ For about 20% of families using Medical Foods
 - ▣ For about 30% of families using supplements
 - ▣ For about 35% of families using feeding supplies
 - ▣ For about 60% of families using MLPF

What we do and don't know...

- Families often did not know if they had “caps” on insurance and what the dollar amount of the cap was
- Families had a hard time telling us their out-of-pocket costs
- Need-based supports are currently significant resources
 - ▣ Depending on the state, WIC is an important source of support for families
 - ▣ Medicaid is a very important source of support for many families
- MLPF are particularly poorly supported
- Though patterns of coverage varied from Region to Region, *all Regions observed significant challenges to families in paying for these essential products*

What has happened?

- SACHDNC has communicated previously with the Secretary of HHS regarding Medical Foods
 - SACHDNC Letter of April 6/May 19, 2009: Gaps in Coverage and Lack of Uniformity in Reimbursement of Medical Foods and foods that are Critical Treatments for Children and Adults Identified with Inborn Errors of Metabolism through Newborn Screening
 - Response: “.. recommendations to enact legislation are beyond the Department’s authority...I am neither adopting nor rejecting the Committee’s recommendations”
 - SACHDNC Letter of June 14, 2010: Insurance Coverage of Medical Foods, Foods Modified to be Low in Protein, and Pharmacological Doses of Vitamins and Amino Acids
 - Response --- “While I appreciate your thoughtful recommendations, I cannot adopt the Committee’s recommendations at this time... until I have the results of the Department of Labor survey and the Institute of Medicine recommendations, I am not in a position to make determinations about particular benefits.”

Motion for Committee Action

- Title of report:
“Insurance coverage of medical foods for treatment of inherited metabolic disorders”
- Nature of support requested:
Committee Acknowledgement
- Committee lists report on SACHDNC website. Committee has already sent letters to Secretary regarding medical foods. No further action requested of Secretary.