

# Advisory Committee on Heritable Disorders and Genetic Diseases in Newborns and Children

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Washington, DC

By Jill Levy-Fisch

# Subcommittee on Follow-up and Treatment

- Reimbursement related issues for Medical Formulas and Foods
- Public Sector Funding

# Formula Reimbursement Workgroup

- December 7th conference call- Present:
- Workgroup chair Coleen Boyle (CDC), Shawne Suggs-Anderson (FDA), Sue Ann Anderson (FDA), Paul Fernhoff (Emory), Jill Levy-Fisch (consumer), Denise Green (CDC), Ethan Hauseman (FDA), Rani Singh (Emory), Benson Silverman (FDA), Michele Puryear (HRSA), Jennifer Kraszewski (HRSA), Jill Shuger (HRSA)

# Key Points Made During Call

# Discussions Needed About Issues Faced by Parents and Providers Regarding Medical Foods and Formulas

- Great variability among the states regarding insurance reimbursement
- Difficult for patients to get coverage when adults
- Problems with Medicare/Medicaid
- Coverage issue must be addressed on the national level

# Possibility of Recategorizing Foods/Formulas as a Drug

- Drawbacks:
  - Previously regulated as drugs; taken out of this category in order to promote research and development
  - Led to increased number of available products with significant difference in pricing
  - Clinical trials and more stringent manufacturing practices would be required

# Legislation

- In states where there is food/formula legislation, it is subject to interpretation and may not be implemented
- Georgia- food/formula covered under WIC program until children turn 21
- Some states have similar coverage, but the children are not covered when they become adults

# Questions Generated from Conference Call

- Possible questions for white paper:
- 1. What are the state-level Medicaid regulations/rules for reimbursement for medical foods and formulas?
- 2. How do the statutes vary from state to state? How does this translate to actual practice?



# Questions, cont.

- 3. Does the Title V program cover medical foods and formulas? If so, is reimbursement based upon family income? How do reimbursement practices vary from state to state? Are there any State or Federal programs that cover the cost of medical foods and formulas for patients with metabolic disorders over 18 years of age? If yes, then what are they, and how can patients participate in these programs?

# Questions, cont.

- 4. What is covered under WIC? Are the statutes for WIC applicable for use under Medicaid?

# Private Sector Funding

- How does reimbursement/coverage from major private providers vary by provider and major geographic region?
- Do the major private providers have written policies about coverage?
- For those that have written policies, do these vary from state to state, or are they national policies? Does this correspond to Medicaid coverage?
- What is the difference in coverage for children vs. adults?

# FDA-Related Issues: Medical Foods vs. Drugs

- Q: What are the FDA definitions of Medical Foods and Formulas?
- A: There is no regulatory product category named medical formulas. A medical food is “a food which is formulated to be consumed or administered internally 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 principals, are established by medical evaluation” (21 U.S.C. 360ee(b)(3)).

# FDA-Related Issues: Medical Foods vs. Drugs cont.

- Q: What are the drawbacks from changing the regulation of medical foods/formulas as foods back to the regulation of these products as drugs?
- A: The FDA deregulated these products due to certain drawbacks.

# Drawbacks

- 1. Increase in time, expense and review of the products before marketing
- 2. Decrease in the number of products
- 3. Decrease in the number of manufacturers
- 4. Decrease in research, innovation, and development
- 5. Increase in the preclinical and clinical studies required before marketing

# FDA-Related Issues: Medical Foods vs. Drugs cont.

- Q: Can reclassification occur for a subset of the products that are more medically necessary (or some other criteria)?
- A: Same drawbacks as outlined earlier

# FDA-Related Issues: Medical Foods vs. Drugs cont.

- Q: Are there other protections that can be offered by the FDA? (e.g. more oversight regarding safety of the manufacturing process, particularly for products that are used by children over 1 year of age)



# FDA-Related Issues: Medical Foods vs. Drugs cont.

- A:
  - Medical foods must comply with all applicable requirements for food manufacture, including the Current Good Manufacturing Practices regulations, Registration of Food Facilities requirements, and if applicable, the Low Acid Canned Food regulations and Emergency Permit Control regulations
  - If ingredients are not Generally Recognized as Safe (GRAS), they must be an approved food additive or a food additive that is the subject of exemption for investigational use
  - The Food Allergen Labeling and Consumer Protection Act of 2004 would dictate that medical foods containing milk, eggs, fish, crustacean, shellfish, tree nuts, wheat, peanuts, and soybeans declare the food on the ingredient list

# FDA-Related Issues: Medical Foods vs. Drugs cont.

- Q: What is the possibility that the FDA could come up with a new category of medical foods that require a written prescription, but wouldn't require same level of pre-market and post-market pharmaceutical testing?

# FDA-Related Issues: Medical Foods vs. Drugs cont.

- A:
  - Medical foods need to be associated with drugs in order to invoke prescription requirement
  - Prescriptions do not guarantee coverage

# Burden and Cost

- Q: How many more children will require formula and foods due to the expansion of newborn screening over the past few years?
  - Possible cost benefit analysis: If foods/formulas are medically necessary, the harmful effects that the children suffer if not supplied with the necessary foods/formulas

# Limited Sources of Assistance for Medical Foods Reimbursement\*\*

- 1. Federal agencies/organizations
  - A. The Special Supplemental Food program for Women, Infants and Children (WIC); varies from state to state
  - B. Health Resources and Services Administration, Title V program Office of Maternal Child and Health
  - C. Medicaid/Medicare

# Limited Sources of Assistance for Medical Foods Reimbursement cont.\*\*

- 2. State Agencies
  - A. Public Health Departments
  - B. Crippled Childrens' Programs
  - C. Childrens' Medical Service programs

# Limited Sources of Assistance for Medical Foods Reimbursement cont.\*\*

- 3. Third Party Carriers
  - A. Coverage provided by some private carriers on a case-by-case basis
  - B. Some states require insurance carriers to provide coverage under certain conditions
  - C. HMO's

# Limited Sources of Assistance for Medical Foods Reimbursement cont.\*\*

- 4. Manufacturers/Distributors
  - A. Some assist clients in requesting insurance coverage for products
  - B. Donations
  - \*\*This information is a partial listing of sources that may assist consumers in receiving reimbursement for medical foods. This list is provided as a service to consumers. The FDA does not endorse a particular source, nor does the agency have information on the internal policies of these sources.



# Informal Formula Survey-FOD and OAA groups

- New York state mandates coverage for formulas. Section 3216 of the insurance law in New York was amended by the addition of a new paragraph 21, which states:

# Informal Formula Survey-FOD and OAA groups cont.

- “Every policy which provides coverage for prescription drugs shall include coverage for the cost of enteral formulas for home use, for which a physician or other licensed healthcare provider legally authorized to prescribe under Title Eight of the Education Law has issued a written order. Such order shall state that the enteral formula is clearly medically necessary and has been proven effective as a disease-specific treatment regimen for those individuals who are or will become malnourished or suffer from disorders, which if left untreated cause chronic physical disability, mental retardation or death. Specific diseases for which enteral formulas have been proven effective shall include, but are not limited to, inherited diseases of amino acid or organic acid metabolism.”

# Informal Formula Survey-FOD and OAA groups cont.

- Case 1:
  - Female, 24 years of age
    - States-CA, UT, CT
    - Disorder-IVA
    - Formula-I-Valex-2
    - Manufacturer-Ross
    - Price per unit: \$7000 for 6 months; \$580 per case
    - Mode of usage-oral

# Informal Formula Survey-FOD and OAA groups

- Case 2
  - 2 females; aged 3 & 5 years
    - State-Missouri
    - Disorder-IVA
    - Formula-I-Valex-2
    - Manufacturer-Ross
    - Price per unit-\$395 per case of 6 cans, family uses 4 cases per month
    - Mode of usage-oral

# Informal Formula Survey-FOD and OAA groups

- Case 3
  - Male, 8 years old
    - State-Missouri
    - Disorder-Propionic Acidemia
    - Formula-Propimex-2
    - Manufacturer-Ross
    - Price per unit-\$395 per case; Uses 1 case per month
    - Mode of usage- g-tube
    - Formula 2-Polycose powder
    - Manufacturer-Ross
    - Price per unit: \$41 per case of 6 cans; uses 4 cases per month
    - The state of Missouri only requires insurance companies to pay for thee formulas up until the age 6
    - Family has paid about \$13,000 out of pocket in 2 years

# Next Steps

- Completion of white paper
- Committee recommendations
- Address issues on national level