Medical Foods for Inborn Errors of Metabolism: Issues in Patient Access and Recommendations for Improvement

Presentation of Draft and Discussion of Possible Actions

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What is a Medical Food?  
What is it NOT?

Orphan Drug Amendments of 1988 definition of medical foods:  
“... 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.”

Medical foods are NOT drugs:

not for "diagnosis, cure, mitigation, treatment, or prevention of disease"

However, like drugs, medical foods, are intended to be used under medical supervision as a primary intervention for specific diseases
Charge to the Follow Up and Treatment Workgroup

Provide a policy analysis/brief that summarizes:

• The current state of coverage for medical foods
• Previous work by the ACHDNC
• A synthesis of previous external efforts to improve coverage for medical foods
• Provide recommendations re potential actions
Reminder: Access to medical food is highly variable

Depends on

• Age
• Disorder
• State of residence
• Nature of insurance coverage
Updates to document - content

Added sections describing
- The use of medical foods in conditions on the RUSP
- Inborn errors of metabolism and why they are treated with medical foods
- How medical foods differ from regular foods and why medical supervision is required in their use
- Review of the consequences of failure to use medical foods
- The numbers of persons impacted by a need for medical foods

Added details of the variations of coverage from state to state

Added information about costs to families
- Financial
- Other costs
Change in approach

Our intended audience is a broad stakeholder group.

In recognition of the complex issues and limited responses to date, a more general target is suggested.

Broader direction allows a wider spectrum of responses
The Principles to be affirmed

• Medical foods must be covered as required medical benefits.
• Affected persons should have access to these essential interventions irrespective of the source of their health coverage.
• All federally supported programs should cover medical foods.
• Regulations regarding medical foods should not be subject to state exclusions.

  Health and Human Services regulations and guidance should ensure that individuals of all ages who are diagnosed with an IEM should be able to access comprehensive coverage for medical foods.
Discussion

• Acceptance of draft text?

• Endorsement of principles?

• Strategy for dissemination?

• Next steps?