

# 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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WORKGROUP

# What is a Medical Food? What is it NOT?

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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

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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

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Depends on

- Age
- Disorder
- State of residence
- Nature of insurance coverage

# Updates to document - content

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## 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

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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

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- 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

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- Acceptance of draft text?
- Endorsement of principles?
- Strategy for dissemination?
- Next steps?