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

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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

Letters to the Secretary

May 19, 2009

- Recommendation to address gaps in coverage and reimbursement
  - More uniform approach and to amend Medicaid for uniform coverage by State programs
- Response on October 2, 2009
  - Enacting legislation is beyond the Department's authority

June 14, 2010

- Committee recommended that health reform ensure access to medical foods and foods modified to be low in protein as essential health care services irrespective of the source of health coverage
- Response on December 14, 2010
  - "I cannot adopt the Committee's recommendations at this time"; awaiting a DOL survey and IOM public workshop

Information/data shared with ACHDNC in recent meetings

- Presentations by Kathy Camp and Christine Brown
- Presentation of the Catalyst Report summarizing state-by-state access to medical foods

Actions of FT Workgroup

Two full Workgroup meetings

Monthly meetings for subgroup

- Preparation of detailed document regarding issues in access to medical foods.
  - Draft in process (see briefing book)
- Preparation of a “2-pager” summary
  - Draft submitted for full committee discussion
- Discussion of recommendations

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

Access to medical food is highly variable

Depends on

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

Supporting external organizations

AMA

ACMG

SIMD

AAFP

AAP

GMDI

Overview

IEM are included on the RUSP because effective interventions are available, but medical foods for management of conditions for which screening is mandated are not available for many.

- Legislation has been introduced,
- advocates have spoken,
- professional organizations have provided expert opinion and recommendations,

but the division of responsibilities between federal and state regulation and ambiguities about the status of medical foods in regulation have resulted in costly inaction.

Draft policy recommendation for Committee consideration

Medical foods, which require ongoing medical supervision whereby dietary intervention cannot be achieved by modification of a normal diet alone, and that are authorized by a medical provider for management of an IEM, **should be considered medical benefits and be included in coverage as essential health care services.** Affected persons should have access to these essential interventions irrespective of the source of their health coverage. Health and Human Services regulations should ensure that **individuals of all ages who are diagnosed with an IEM**, either specified on the RUSP or identified clinically, **should be able to access comprehensive coverage for care of their disorder**.

Action option for recommendation by Committee

We respectfully request that the Secretary of Health and Human Services lead the way in the coverage of medical foods by all federally supported health programs including Medicaid, Medicare, the Children's Health Insurance Program, and the Indian Health Service and shall encourage that coverage of medical foods not be subject to state exclusions.

Possible next step for accomplishment

Recognizing the complexity of the actions required to accomplish comprehensive coverage for medical foods, we recommend a meeting of stakeholders to reach an agreement on how best to accomplish this goal expeditiously.

For discussion:

- Who should convene the meeting?
- Anticipate planning who to include?