



# DIET FOR LIFE WORK GROUP: FOCUS ON ADULTS

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# Objectives for today

- Clarify medical food definitions
- Understand what coverage is like in Michigan today
- Become familiar with other state models
- Identify opportunities and barriers presented by those models

# Proposed Definitions

- Nutritional products specially formulated and processed for patients who require them as a major treatment modality
- Labeled for use under medical supervision; available only by prescription?
- General terms: Dietary Treatment for Inborn Errors of Metabolism; or Nutritional Treatment
- Three Treatment Sub-types
  - Medical Food
  - Low-protein modified special food
  - Medically necessary supplements

# Medical Food

- Main alternative to natural protein
- **Infant formula:** substitute milk formula based on the composition of regular milk but lacking the toxic ingredients
- **Alternate protein products:** Solid and powder forms of critical nutrients, amino acids and protein free beverages that are more acceptable to older children, adolescents, and adults

# Low-protein modified special food

(or Low-protein special food)

- Energy source important for a balanced diet; used in conjunction with medical foods to prevent metabolic decompensation
- Low protein substitute products designed to be as similar as possible to the “normal” counterparts but with minimal protein
  - Products in the form of baking mixes, pastas, rice, sauces, etc.
- Important dietary component to increase patient acceptance and compliance
- Does not include foods naturally low in protein

# Medically necessary supplements

- Used to replace conditionally essential nutrients or enhance enzyme activity
  - Not utilized or produced by the affected person's body
- Single amino acids and amino acid mixtures, vitamins, and other compounds
  - Examples: tyrosine, arginine, citrulline, carnitine, biotin
- Concerns about safety due to lack of regulation?

# Mandated coverage of medical treatment for adults with PKU

- 48.1% of states mandate coverage for medical foods and low protein special foods for adults
  - Another 15.4% mandate coverage medical foods only
  - 1.9% (Louisiana) mandates coverage of low protein special foods
  - 34.6% have NO MANDATED COVERAGE for adults (n=18)
    - Alabama, Alaska, Colorado, Florida, Georgia, Guam, Idaho, Iowa, Kansas, MICHIGAN, Mississippi, North Carolina, Ohio, Oklahoma, South Carolina, Virginia, West Virginia, Wyoming
      - 6 have mandates for pediatric coverage, not Michigan
- Source: Berry et al., Genetics in Medicine 15(8) –Table 3

## Funding Sources Available to Michigan Adults for Dietary Treatment

Population	CSHCS	Medicaid/Medicaid Health Plan	Medicare	WIC	Commercial insurance	Newborn Screening Contract	No Coverage
<i>Young Adults, 18-20 years</i>	 <b>Eligibility:</b> Medical with annual fee to join based on income  <b>Covers:</b> Formula & supplements based on medical need	 <b>Eligibility:</b> Based on income and under age 21  <b>Covers:</b> Formula & supplements based on medical need			 <b>Covers:</b> varies by plan; may have co-pays	 <b>Eligibility:</b> IEM detectable by NBS & seen at CHM clinic at least 1x/year <b>Covers:</b> Formula, occasional food & supplements	 Ability to purchase depends on income
<i>Adults, 21-64 years</i>		 <b>Eligibility:</b> Based on Social Security determination of medical disability OR based on income through Medicaid expansion <b>Covers:</b> Formula & supplements based on medical need	 <b>Eligibility:</b> Based on Social Security determination of medical disability <b>Covers:</b> Formula only in hospital or by tube feeding		 <b>Covers:</b> varies by plan; may have co-pays	 <b>Eligibility:</b> IEM detectable by NBS & seen at CHM clinic at least 1x/ year; under 48 yrs <b>Covers:</b> Formula, occasional food & supplements	 Ability to purchase depends on income
<i>Pregnant females</i>		 <b>Eligibility:</b> Based on income; only while pregnant <b>Covers:</b> Formula & supplements based on medical need		 <b>Eligibility:</b> Based on income & other factors; only while pregnant or postpartum <b>Covers:</b> Limited authorization of special formulas for IEM			
<i>Adults, over 65</i>		 <b>Eligibility:</b> medically disabled based on Social Security determination <b>Covers:</b> Formula & supplements based on medical need	 <b>Eligibility:</b> Over age 65 <b>Covers:</b> Formula only in hospital or by tube feeding		 <b>Covers:</b> varies by plan; may have co-pays		

 = Program eligibility with some level of coverage for low protein medical food products such as formula

 = Program eligibility but currently limited coverage for low protein medical food products such as formula

IEM= Inborn Errors of Metabolism

Supplements= medically necessary supplements, eg tyrosine

# Other State Models

- **Gaps? Barriers?**
- **What about it would fit well for Michigan's needs?**
- **What would be needed to implement this package or element of package in Michigan?**

# State Models

- Variety
  - Mandate for insurers to cover medical foods and/or low protein modified foods and/or other medical costs
    - May cover NBS conditions only or wider list of inborn errors of metabolism
    - Age limits
    - May have cap in coverage or dollar amount of coverage
  - Tax credit for costs
  - State program to provide Metabolic Foods and Formula
    - Differing by eligibility: age, age/gender
    - Last resort (i.e., insurers and other state resources must be used first)
    - Sliding scales
    - What provided varies
    - Process differs

# Ohio

- No mandates
- Health Department provides metabolic formula to individuals with IEM
- Family will receive all required metabolic formula if:
  - Resident of Ohio
  - Receive care for specified IEM at an approved Ohio Center
  - Apply annually to Bureau of Children with Medical Handicaps Treatment Program if under 21
  - Apply to Medicaid if financially eligible
  - Apply to WIC if <5 years and attend WIC appointments, if eligible
  - Consume formula as directed by metabolic dietician
- Formula shipped directly to patient's home.
- Funds: portion of NBS fee, Bureau for Children with Medical Handicap program, WIC

# Indiana

- **Mandate:** Department's NBS program will ensure all Indiana residents with IEM diagnosed by NBS will have access to appropriate metabolic formula as follows:
  - Single brand of metabolic formula for each metabolic condition on NBS will be designated by state contracted metabolic geneticist
  - Appropriate metabolic formula will be made available regardless of Individual's ability to pay or SES as follows:
    - Payment for formula will be on sliding scale as designated by department
    - All efforts will be made to collect payment for metabolic formula from private insurance companies or other third party payers
    - NBS program will serve as payer of last resort for patients without private insurance coverage or for whom reimbursement cannot be obtained by another third-party payer.

# Iowa Metabolic Food and Formula Program

- No insurance mandate
- Mandate: (641-4.3)(9) and (10) “Department shall include as part of this fee an amount determined by the committee and department to fund the provision of special **medical formula and foods** for eligible individuals with inherited diseases of amino acids and organic acids who are identified through the [NBS] program...”
- Provided through the University of Iowa.
  - Payments received from clients based on third-party payment, sliding fee scales and donations.
  - Individuals with incomes at or above 185 percent of FPL charged a fee.
- “Provision through this funding allocation shall be available only after individual has shown that all benefits from third-party payers including, but not limited to, health insurers, health maintenance organizations, Medicare, Medicaid, WIC and other government assistance programs have been exhausted.”

# Virginia

- No insurance mandate
- Mandate: Health department shall assist eligible persons in obtaining metabolic formula, low protein modified foods and metabolic supplements.
- Expenditures shall be limited to available funding.
- Applicants must demonstrate they are not eligible for other state/fed med assist program and that they do not have insurance coverage for products listed below:
  - **Formula Distribution and Purchase Plan**
    - Resident children <21 years with condition and meet financial eligibility for CSHCSN Program pool of funds may qualify to receive metabolic formula at no cost.
    - Resident adults ages 21+ with condition and who have a gross family income at or below 300% FPL may qualify to receive metabolic formula at no cost.
    - Resident adults age 21+ with condition who DO NOT meet financial criteria may qualify to purchase metabolic formula through the Virginia DH.
  - **Food/Supplement Reimbursement Plan**
    - Residents with condition who have a gross family income at or below 300% FPL may be eligible to receive reimbursement from the department of up to \$1,500 per year to purchase low protein modified foods and medical supplement.

# Oregon

- **Mandate:** insurance coverage shall include expenses of diagnosing, monitoring and controlling the [inborn errors of metabolism] by nutritional and medical assessment, including but not limited to clinical visits, biochemical analysis and medical foods used in treatments of such disorders.
- **Oregon Medical Foods Program**
  - Provides:
    - Medical protein options
    - Low protein medical foods labeled to be used under medical supervision
    - Conditional essential amino acids
    - Specific types of energy modules required by patients diagnosed with carbohydrate or fatty acid oxidation disorders
  - Orders placed with Medical Food Inventory Administrator with updated insurance information
    - MFIA requests authorizations
    - Obtains food from medical food inventory
    - Packages order for shipment through UPS or family picks it up
  - Billing department issues claims to health plan providers (HCPC S9435)
    - Patients billed if they are responsible for co-pay by their health plan
    - Oregon Medicaid patients are covered but not non-disabled adults with PKU

# Kentucky

- **Insurance Mandate:** “Health plan that provides prescription drug coverage shall include in that coverage therapeutic food, formulas, supplements, and low-protein modified food products for the treatment of inborn errors of metabolism.....”
  - Annual cap of \$25,000 for therapeutic food, formulas, and supplements.
  - Separate annual cap of \$4,000 for low protein modified foods
- **Women, Infants and Children:** Cost of formula for eligible WIC client, without other source of coverage, shall be covered by WIC
- **Mandate: Kentucky Metabolic Food and Formula Program:**
  - Verified Kentucky residents who do not qualify for another insurance program or whose insurance coverage is exhausted or denied
  - Medically necessary therapeutic foods, formulas, supplements and low-protein modified food products
  - Products must be billed and denied before a person can seek coverage (including WIC, Medicaid, K-CHIP and private insurance).
  - Program works with DME providers, pharmacies and university metabolic centers
  - Provider shall submit prescription, authorization form, and invoice from supplier to receive actual cost plus 20%.
  - Source of funds is Vital Records fee \$1 for certified copies of birth certificates.

# New Jersey

- Mandate: Individual, group or health service corporation medical health insurer, small employer health benefits, and HMO plans must cover therapeutic treatment of any inherited metabolic disease that is screened for in the state's NBS program.
- Medical food and low protein modified food products covered
- Coverage mandated to be on *same basis as other conditions that are covered under the same plan.*
- Includes Medicare/Medicaid
- State Health Benefits Program also covers IEMs
  - State employees and their families
  - 90% in-network; 70% out-of-network

# Wisconsin

- Mandate: Department shall provide the special diet required upon recommendation of any physician who diagnoses a patient as having a medical disorder that requires a special dietary treatment. .... Shall impose a fee for tests performed... and shall include... an amount the department determines is sufficient to fund the provision of special dietary treatment under this subsection. “
- State NBS covers food and formula, no age limit
- Clinicians in contracted clinics order food and formula off formulary - invoice department
- \$50.50 fee on NBS - \$1.6 million/year in metabolic foods alone
- Program in the red