

# Webinar Series Medical Foods- April 2023



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# Webinar Speakers





#### Rani Singh, PhD, RD, LD Professor, Emory University Project Director, SERN

Megan Lyon, MPH

Co-Project Director, NCC



Learning Objectives

- Describe the importance of medical foods coverage.
- Identify current policies related to medical foods
- Apply lessons in improving medical foods coverage in your work.



Webinar Outline Basics of Medical Foods Coverage

- Medical Foods Policy Information in GPH
- Efforts to Improve Medical Foods Coverage Q&A



for the Regional Genetics Networks

# Basics of Medical Foods Coverage

# FDA Definition: Medical Food



"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."

1958-1972 drugs as defined in section 5(b) of the Orphan Drug Act (21 U.S.C. 360ee (b) (3)) 1972: Foods for special dietary use FSDU

\*1988: Medical Foods (MF)Orphan Drug Amendments

1990 and 1993 Nutrition labeling and Education Act identified 5 criteria to qualify as medical Food 21CFR101.9(j)(8)

\*Eased regulatory conditions: No premarket: approval, safety & efficacy, review of label claims, mandatory adverse event reporting Still MF regulated to ensure their products are safe under the intended conditions of use Manufacturers must follow cGMPs, with registration and periodic inspection of facilities & includes post market surveillance

# Medical Food Guidance May13, 2016

Contains Nonbinding Recommendations

Definition of medical foods narrowly constrains the types of products that fit within this category

#### To gain better understanding of o compliance and regulations for manufactures

- Stated as "Non-binding Recommendations
- Easy to read Q&A form
- Provides information on

Definition of medical foods and further clarification

- Types of diseases and conditions appropriate and inappropriate to be considered for a medical food
- Label statements reserved only for drugs:
- Specially formulated and processed--as opposed to naturally occurring
- For partial or exclusive feeding orally or enteral feeding by tube

#### Link to FDA's page with direct link to download Final Guidance pdf

https://www.fda.gov/food/cfsan-constituent-updates/fda-issues-final-guidance-frequently-asked-questions-about-medical-foods

Adapted from Timothy Morck, PhD: The Current Regulatory Framework of Medical Foods: Challenges and Opportunities; 2020 presentation

Frequently Asked Questions About Medical Foods; Second Edition

Guidance for Industry

Additional copies are available from: Office of Nutrition and Food Labeling, HFS-800 Center for Food Safety and Applied Nutrition Food and Drug Administration 5001 Campus Drive College Park, MD 20740 (Tel) 240-402-2373 http://www.file.gov/Food/Suidances

You may submit written comments regarding this guidance at any time. Submit electronic comments to <u>http://www.regulations.pov</u>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the Federal Register.

> U.S. Department of Health and Human Services Food and Drug Administration Center for Food Safety and Applied Nutrition May 2016

# Food As Medicine: Let thy food be thy medicine

- They fall between food (supplies nutrients) and drugs (prevents, treats, cures, or mitigates a disease).
- Blurring the line between food and health (Adelaja, 2000)
- Therapeutic potential of medical foods is established, but has also generated valuable insights in the complex and dynamic transition from health to disease (adapted Renger F W *et al: 2018)*

# Barrier?

# PKU: Untreated and Treated , Success with Medical Foods

#### THEN



Specialized medical nutrition is standard-of-care therapy



#### NOW





## Metabolic Disease: Issues throughout life cycle



#### ACMG Recommended Panel PKU has Become an Exemplar for the Promise of Genetic Nutrition



# 20 Primary targets22 "Secondary" targets

	Amino Acid Disorders	Fatty Oxidation Disorders
P A N E L	Phenylketonuria MSUD Homocystinuria Tyrosinemia type I Argininosuccinic acidemia Citrullinemia type I	MCAD deficiency VLCAD deficiency LCHAD deficiency TFP deficiency Carnitine uptake defect
T A R G E T S	Hyperphenylalaninemia Tyrosinemia type II Biopterin defects (Bios) Tyrosinemia type III Biopterin (Reg) Argininemia Hypermethioninemia Citrullinemia type II	M/SCHAD deficiency SCAD deficiency MCKAT deficiency CPT-I deficiency Glutaric acidemia type II CACT deficiency Dienoyl red. deficiency CPT-II deficiency

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eficiency Isovaleric acidemia deficiency Glutaric acidemia type I deficiency HMG deficiency ciency 3MCC deficiency e uptake defect BKT deficiency Multiple carboxylase deficiency Methylmalonic acidemia (MUT) Methylmalonic acidemia (Cbl A,B) Propionic acidemia

> Methylmalonic acidemia (Cbl A,B) 2M3HBA deficiency IBG deficiency 2MBCAD deficiency Methylglutaconic acidemia Malonic acidemia

**Organic Acid Disorders** 

Conditions are Primarily treated with medical foods and/or single amino acids, amino acid mixtures, vitamins, or other cofactors Therrell BL, MGM 113 2014

# **Reality for Pateints**

Lunch without low-protein modified food (LPMF)\* & medical food





Low protein Modified Foods (LPMF)

\*Low-protein modified food (LPMF)): specially manufactured food that is formulated to be distinctly lower in the amount of protein compared to natural food and is intended for the medical and nutritional management of patients with limited capacity to metabolize the protein found in regular foodstuffs.

## Medical Foods are Not a Choice of Health vs Fuel

- After Positive NBS, Child needs different food to survive, as the traditional food can harm the child
- Medical food caters to people identified with Inherited Metabolic Disorders to survive and improve outcomes and are not optional.
- Must avoid specific food components or nutrients to prevent illness or death or must ingest increased amounts of certain metabolites to stimulate a specific metabolic pathway for survival (Bristrian et al., 1976, JAMA).
- Studies have found that even fairly small reductions in intakes of problematic foods can yield substantial health benefits (Browner, Westenhouse, & Tice, 1991, JAMA; Zarkin and Anderson 1992, AJAE).
- **THEY ARE THE PREVENTION & TREATMENT** but excluded by insurers because they are foods.

# Affected persons cannot survive without; What should families do if they cant afford?

## **Medical Foods**



Are the Primary recognized therapy for many Inherited metabolic disorders identified on newborn screen and clinically •Reduce morbidity and mortality and improve health outcomes •Have a half century history of use

- •Lower costs than drugs
- So, why aren't they accessible to all patients of all ages ?



for the Regional Genetics Networks

# Medical Foods Information in GPH



Funded by the Health Resources and Services Administration (HRSA), the Regional Genetics Networks (RGNs), the National Coordinating Center for the Regional Genetics Networks (NCC), and the National Genetics Education and Family Support Center (NGEFSC or Family Center) mission is to improve access to genetic services for underserved populations.



# Mission



# Core Focus Areas



### Genetics and Genomics Education



### Telegenetics



Family Engagement and Partnership



### Genetics Policy Hub



Genetics Policy Hub Background With the passage of the Affordable Care Act, the NCC and regional system began to develop specific resources to help support the genetic service delivery system through the lens of policy.

Since 2017, NCC has been tasked by HRSA to accomplish the following related to genetics policy:

- Monitor, analyze, track, and report on national policy issues related to the genetics care service delivery system with a focus on finance and insurance coverage; genetics workforce; and emerging issues in the use of genetic testing and technologies.
- Disseminate information on practices, policies, and resources related to the genetics care delivery system to states and stakeholders.



Genetics Policy Hub Background



geneticspolicy. nccrcg.org NCC has developed multiple resources over the years to meet this goal and recently compiled all resources in a new policy website, called the Genetics Policy Hub.





Medicaid Coverage of Medical Foods



geneticspolicy.nccrcg .org/medicaidcoverage/ **81%** of Medicaid programs have coverage related to medical foods. Policies range from how to determine medical necessity for medical foods to who is covered.

Coverage can be specified by:

- Genetic condition
- Age
- EPSDT eligible children



Sample Medicaid Policies



geneticspolicy.nccrcg. org/medicaidpolicy/new-hampshire/

## Example Policy from New Hampshire:

"Coverage is provided for medically necessary Medical Nutrition Therapy when provided as a part of EPSDT services for Members who are age 21 and under when furnished by a registered dietician and prescribed by a physician. Coverage for Medical Nutrition Services includes (but is not limited to):

- 1. Scientific evaluation of your diet;
- 2. Suggestions for diet modification;
- 3. Nutritional screening;
- 4. Preventive or therapeutic dietary therapy.

Services must be rendered by a registered dietician and prescribed by a physician that is participating with NH Healthy Families, unless authorized in advance.

Prior authorization is not required for Medical Nutritional Services when provided as part of EPSDT services for Members age 21 and under. Prior authorization is not required for Nutritional Services when provided as part of extended services offered to pregnant women, regardless of age."



Sample Medicaid Policies



geneticspolicy.nccrcg. org/medicaidpolicy/tennessee/

### Example Policy from Tennessee:

*"Food supplements and substitutes including formulas are not covered except for Parenteral Nutrition formulas Enteral Nutrition formulas for tube feedings and phenylalanine-free formulas (not foods) used to treat PKU."* 



Proposed Legislation and Regulation Related to Medical Foods in 2023



geneticspolicy.nccrcg. org/legislative-policies/

# 6 states have proposed legislation related to medical foods.





Sample Proposed Legislation Related to Medical Foods



bit.ly/ILMedicalFoods

## Proposed Bill from Illinois

#### Introduced

#### IL HB 3229

#### An Act concerning regulation

- "An insurance policy amended, delivered, issued, or renewed in Illinois on or after the effective date of this Act shall provide coverage for medically necessary treatments for genetic conditions."
- "For an insurance policy that provides coverage for prescription drugs, the coverage shall include medical food."
- "An insurance policy that limits the quantity of a medication in accordance with applicable State and Federal law shall not require pre-approval for the treatment of patients with rare metabolism conditions that may need a higher dose of medication than what is otherwise allowed within a time frame or prescription schedule."

@geneticspolicy | geneticspolicy.nccrcg.org



### Medical Foods Policy Area



geneticspolicy.nccrcg.org/ policy-area/medicalfoods/



Policy Areas Proposed Legislation/Regulation Medicaid Coverage General Resources ~ O

#### **Medical Foods**

T VIEW AS PDF

POLICY AREA UPDATED ON MAR 27, 2023

This information is meant to be used for educational purposes to inform providers, patients, and genetic service delivery stakeholders about genetics policy topics. Sharing of information, resources, or policy statements is no way an endorsement

#### Introduction

of stated positions by NCC.

Medical nutrition refers to medical food products that are used for the nutritional management of a condition or disease. For example, if a baby is born prematurely and cannot eat, that baby will receive tube feeding. The food that is put through the tube is medical nutrition.

One well-known example of medical nutrition can be seen in the case of children with phenylketonuria (PKU) who are unable to properly process foods with phenylalanine. If they eat food with phenylalanine, their body cannot convert it to tyrosine. The phenylalanine will cause intellectual disability. To avoid this, they need to eat a PKU diet that includes medical nutrition. The medical nutrition has essential amino acids, such as tyrosine, but no phenylalanine. It is impossible to find these types of foods in the grocery store.



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### Download the Medical Foods Policy Brief



bit.ly/MedicalFoodsPolicy



#### Policy Overview March 2023

#### **Medical Foods**

The Genetics Policy Hub (CPH), a program of the National Coordinating Center for the Regional Genetics Networks, is a policy education website where you can explore state-based policies, ranging from Medicaid to policies being proposed by state governments to federa policies, ranging from proposed ligibilition to policy statements written by professional againations. This policy overview highlights the data writhin GPH related to genetics privacy. This document is for informational purposes only, and specific questions about to information provide should be directed to the government agencies or againations discussed. If you have questions about to arrest should be directed to the government agencies or againations discussed. If you have questions about our methodology or feedback on what should be added to GPH, please get in touch with geneticsgoil/overnex.cs.org.

Medical nutrition refers to medical food products that are used for the nutritional management of a condition or disease. One well-known example of medical nutrition can be seen in the case of children with phenylketonuria (PKU) who are unable to process foods with phenylalanine properly. If they eat food with phenylalanine, their body cannot convert it to tyrosine. The phenylalanine will cause intellectual disability. To avoid this, they need to eat a PKU diet that includes medical nutrition.

#### **Proposed Legislation and Regulation**

8 Pieces of legislation and regulation are currently proposed related to genetics privacy.

The proposed legislative efforts are mainly related to coverage of medical foods. Some of the proposed bills provide general criteria of what medical foods would be covered; other legislation specifies which conditions should be covered.



https://geneticspolicy.nccrcg.org/legislative-policies/

#### Medicaid Policies

Updated annually each fall

**81%** Medicaid programs have policies related to medical foods

Most policies relate to when and how medical foods are covered in a Medicaid program. Some programs provide general coverage guidance while others specify which genetic conditions are covered.



@geneticspolicy

#### Policy Statements

6 Policy statements related to genetics privacy from professional organizations

Professional organizations write policy statements to communicate what they believe is best for their community. Healthcare provider organizations (such as Genetic Metabolic Dietitians International) and patient organizations (such as the National Organization for Rare Disease) have statements supporting medical foods' coverage.

> https://geneticspolicy.nccrcg.org/policyarea/medical-foods/



for the Regional Genetics Networks

Efforts to Improve Medical Foods Coverage

# Access to medical foods: Sources

- Out of Pocket Purchase: pharmacies, hospitals, health departments, medical supply and medical food companies
- Reimbursement by private insurance or not?
- Programs administered by States
  - Medicaid/CHIP/WIC
- Military Health benefits
- Newborn Screening programs or metabolic clinics
- Multiple sources

#### Genetics inMedicine ORIGINAL RESEARCH ARTICLE 2013



#### Insurance coverage of medical foods for treatment of inherited metabolic disorders

Susan A. Berry, MD<sup>1</sup>, Mary Kay Kenney, PhD<sup>2</sup>, Katharine B. Harris, MBA<sup>3</sup>, Rani H. Singh, PhD, RD<sup>4</sup>, Cynthia A. Cameron, PhD<sup>5</sup>, Jennifer N. Kraszewski, MPH<sup>6</sup>, Jill Levy-Fisch, BA<sup>7</sup>, Jill F. Shuger, ScM<sup>8</sup>, Carol L. Greene, MD<sup>9</sup>, Michele A. Lloyd-Puryear, MD, PhD<sup>10</sup> and Coleen A. Boyle, PhD, MS<sup>11</sup>





# Nature of the Reimbursement Debate



### Support Of professional organizations (AAP, GMDI,SIMD, ACMG) **YES**

Adapted Soji Adelaja, Ph.D.John A. Hannah Distinguished Professor in Land Policy

## Medical Nutrition Therapy for Prevention (MNT4P) CORE VALUES

Education	Research	Health Care Services
<b>Training:</b> Doctoral students in nutrition and health sciences	<b>Clinical Research Trials:</b> with a focus on nutrition and relationship with genetics and metabolomics	Clinical support: • Outpatient • Inpatient
Fellowships: MNT4P post-masters and post-doctoral fellowship in clinical research	Industry-sponsored registries	Community Outreach  Muc contract  Medical Food Access and Trained RDIv
<b>Clinical Rotations:</b> dietetic interns, medical fellows	research support for industry-sponsored protocols	<ul> <li>support</li> <li>Iviewing Camp</li> </ul>
Lectures: Medical students SOM, dietetic interns, graduate nutrition programs at RSPH, Center for the Study of Human Health, Genetic Counseling students Thesis and Capstone Projects: MPH students, Nutrition students, Genetic Counseling students Online Global Education: Electronic	<ul> <li>Health Services Research: investigating relationships between interventions and outcomes</li> <li>Bio nutrition Core lab in partnership with NIH funded GCRC</li> <li>MNT4P interventions for IMD patients that result in optimal outcomes</li> <li>Telemedicine interventions</li> <li>Met Camp: annual research-based metabolic camp for women/girls with UAD</li> </ul>	<ul> <li>Southeast Regional Network (HRSA funded Grant)</li> <li>Building regional infrastructure to identify, develop, and disseminate critical genetics resources</li> <li>Training workforce and consumer education</li> <li>Support genetics and newborn screen capacity</li> <li>Understanding genetic gaps in services</li> </ul>

Goals: Prevent poor health outcomes; Improve health-related quality of life; Evaluate MNT4P for continuous quality improvement; Generate new knowledge in the field of IMD: *Paving the way for Precision Nutrition* 

### **MNT4P COMMUNITY OUTREACH SERVICES**

To create a national model for medical nutrition therapy for inherited metabolic disorders identified through newborn screening.







#### Insurance Benefit Investigation

- In-network 100%, no deductible, no prior-authorization required; Out-of-network 70/30%
- Deductible: \$250/\$900
- DME charged high amounts on the medical foods



#### MNT4P Actions

#### Outcome

- Benefit investigation conducted on the insurance offered by his work
- Could not overturn the medical food exclusion in his employer-based insurance
- MNT4P bridged coverage of medical foods and low protein modified foods

- Patient opted to keep the employer –based insurance despite the medical food exclusion
- Not interested in switching insurance during open enrollment
- Finds paying out-of-pocket expense for medical foods feasible

### Age Limited coverage



#### Insurance Benefits Investigation

- 70/30 % coverage in network
- Deductible \$500
- No out-of-network benefits
- No prior authorization required
- Pre-determination recommended

39-year-old female

Diagnosis: HCU Insurance Plan: Cigna Main Issue: medical exclusion exists - enteral feed only; age cap of 22 years



#### MNT4P Actions

- Predetermination submitted and denied for B-codes (enteral feed exclusion)
- S-code covered under pharmacy benefits - prior authorization submitted for pharmacy benefits; denied due to age cap of 22 years



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#### MNT4P provided all documents – clinical note and letter of medical necessity -to overturn the medical food exclusion

• MNT4P continues to bridge medical foods, and dietary supplements

Age Cap and drug access as dietary supplement (Betaine Powder)





#### Insurance Benefit Investigation

- UMR/UHC covered 100% In-network
- Deductible \$5000 before 100% coverage
- Out-of-network: 80/20% after a \$10,000 deductible
- Coverage diagnosis driven
- Requires a prior authorization



- Benefit Investigation
- Pharmacy coverage
- Unable to locate a pharmacy supplier
- DME not contracted with plan

#### Outcome

- MNT4P provided Medical Food bridge
- Clinic RD referred to Nutricia Insurance Navigator
- Nutricia provided Medical Food
- Nutricia sent DME referral

Provider Time for Navigation but still no solution





#### Insurance Benefit Investigation

- 100% in-network after satisfying a \$1,000 deductible
- Prior-authorization required for products over \$750
- Out-of-network: 70/30% after a \$3,000 deductible
- Covered under pharmacy benefits



#### MNT4P Actions

- Both parents had insurance
  - options; chose the one with both medical and pharmacy benefits
- DME did not carry the product
- Switched to pharmacy benefits local pharmacy did not carry the product

### Outcome

 MNT4P continues to bridge the medical foods until a medical supplier is confirmed

New Parent : No knowledge of Insurance navigation, Disorder, MNT4P provided supplies, education, Medical Food Access & Insurance navigation and still no solution



Diagnosis: PKU Insurance Plan: Uninsured Main Issue: cannot afford to pay clinic visit due to high co-pay/high deductible



#### Social Determinants of Health

- Living by herself
- Paycheck to paycheck
- Works long hours
- Lives 30 miles away from the clinic
- Multiple comorbidities

#### MNT4P Actions

- Scheduled an appointment with MNT4P's insurance navigator after multiple attempts
- Offered insurance through marketplace
- Bridged coverage of medical foods and low protein modified foods

- •
- Revisit Open Enrollment in 2023

Outcome

- Encourage to take time to engage in insurance obtainment
- Prioritize health insurance expenditure

MNT4P access to MF, LPMF and nutrition education/support with the goal to link her to clinic

## MNT4P and Lessons Learnt...examples

- Families often did not know if they had "caps" on insurance and what the dollar amount of the cap was
- Families had a hard time telling us their out-of-pocket costs
- Most Insurance companies do not cover (Low Protein Modified Foods)
- WIC is a very important source of support for many families on a state-by-state basis.
- Patterns of coverage vary even with same insurance company depending upon the contract with employer
- Lack of knowledge about insurance navigation patients due to complex terminology
- Lower premiums usually equate to high deductible plan (selected by young people)
- Insurance navigation fatigue by providers and patients
- International visitors, immigrants and foreign students.
- Lack of clarity in understanding the term Medical Foods & different state policies
- Patients discouraged and leading to Poor outcomes in next generation despite NBS

# Action by SERN/MNT4P Partnership: Abbotts Nutrition Facility closure March 9<sup>th</sup> 2022

•Aim: to address the disruption in metabolic formula supplies caused by Abbott Nutrition's temporary facility closure

Patients and Families	Health care Providers (RD/MD/RN)	Advocacy
Created a clear messaging to the patients and families affected by the Abbott Formula Disruptions	Formulated a transition plan to other products based on the diagnosis	Reached out to patient advocacy groups, such as NPKUA, to submit a letter to the local legislatures or FDA to expedite the clearance



#### U.S. DEPARTMENT OF AGRICULTURE

#### Official USDA Food Plans: Cost of Food at Home at Three Levels, U.S. Average, January 2023<sup>1</sup>

	Weekly cost <sup>2</sup>		Monthly cost <sup>2</sup>			
	Low-cost	Moderate-	Liberal	Low-cost	Moderate-	Liberal
Age-sex groups	plan	cost plan	plan	plan	cost plan	plan
Individuals <sup>3</sup>						
Child:						
1 year	\$35.90	\$40.70	\$49.20	\$155.50	\$176.30	\$213.30
2-3 years	\$37.70	\$45.40	\$55.20	\$163.40	\$196.80	\$239.30
4-5 years	\$38.90	\$48.20	\$58.20	\$168.80	\$208.70	\$252.10
6-8 years	\$54.70	\$66.10	\$77.30	\$237.20	\$286.30	\$334.70
9-11 years	\$58.70	\$76.10	\$88.50	\$254.30	\$329.70	\$383.40
Male:						
12-13 years	\$68.30	\$84.90	\$99.70	\$295.80	\$367.90	\$431.90
14-18 years	\$69.50	\$87.30	\$100.60	\$300.90	\$378.20	\$436.00
19-50 years	\$68.70	\$86.20	\$104.90	\$297.50	\$373.40	\$454.70
51-70 years	\$64.70	\$81.00	\$97.10	\$280.30	\$350.90	\$420.60
71+ years	\$63.90	\$79.00	\$97.00	\$277.00	\$342.40	\$420.50
Female:						
12-13 years	\$58.40	\$70.00	\$86.30	\$253.20	\$303.50	\$373.80
14-18 years	\$58.50	\$69.80	\$86.40	\$253.70	\$302.30	\$374.40
19-50 years	\$59.60	\$72.80	\$93.00	\$258.10	\$315.30	\$403.10
51-70 years	\$58.10	\$72.00	\$86.40	\$251.90	\$311.90	\$374.30
71+ years	\$57.70	\$71.20	\$85.40	\$250.10	\$308.50	\$370.00

Official USDA Thrifty Food Plan: U.S. Average, January 2023<sup>1</sup>

Age-sex group	Weekly cost <sup>2</sup>	Monthly cost <sup>2</sup>	
Individuals <sup>3</sup>			
Child:			
1 year	\$25.30	\$109.80	
2-3 years	\$38.10	\$165.30	
4-5 years	\$41.40	\$179.40	
6-8 years	\$46.20	\$200.00	
9-11 years	\$53.30	\$230.90	
Male:			
12-13 years	\$57.00	\$246.80	
14-19 years	\$71.70	\$310.90	
20-50 years	\$70.10	\$303.70	
51-70 years	\$62.00	\$268.60	
71+ years	\$59.20	\$250.40	
Female:			
12-13 years	\$49.30	\$213.70	
14-19 years	\$56.90	\$246.50	
20-50 years	\$56.10	\$243.10	
51-70 years	\$52.20	\$226.00	
71+ years	\$57.40	\$248.80	
Reference Family: <sup>4</sup>			
Male and Female, 20-50 years			
and Two Children, 6-8 and 9-11 years	\$225.60	\$977.70	

Source: USDA Food Plans: Cost of Food Reports (monthly reports)

# **Cost Comparison** Low Protein Products and their Counterparts

Food Description	Regular Food (RF)*	Low Protein Modified Food (LPMF)**	Percent Difference (%)
Spaghetti Pasta	\$ 0.98 (16 oz)	\$ 11.99 (17.5 oz)	170
All Purpose Flour	\$ 1.16 (2 lbs)	\$ 15.99 (2 lbs)	173
Crackers	\$ 2.98 (12.7 oz)	\$ 6.99 (4.4 oz)	80
Cheddar Cheese Shreds	\$ 7.48 (2 lbs)	\$ 12.99 (2 lbs)	54
Frozen Pizza	\$ 3.98 (17.75 oz)	\$ 24.49 (16 oz)	144
Bagel	\$ 1.98 (20 oz)	\$ 13.99 (15 oz)	150
Eggs	\$ 2.48 (24 oz)	\$ 17.49 (16 oz)	200
Rice	\$ 2.94 (32 oz)	\$ 22.49 (35 oz)	154
Sausage Patty	\$ 4.78 (1.7 lbs)	\$ 30.49 (1.5 lbs)	146

\*Prices Sourced from Walmart Great Value Brand 2023

## • LPMFs on average are 141% more expensive than Real Foods

Affected families with metabolic disorders are financially stressed

Access to Low Protein-Modified Food Associated with Clinical Biomarkers in Patients with Phenylketonuria; Ellen Jordan, Saran Gurung, Kristen Narlow, Rani H. Singh July 15, 2022 SERN/SERGG meeting

## Lot Less than drugs: Drug Approximate Costs Before Insurance

Pegvaliase (Palynziq)	Sapropterin (Kuvan)	Sapropterin (generic)
\$561 per syringe regardless of dose <sup>1</sup>	\$42 per 100 mg <sup>1</sup>	\$37-39 per 100 mg <sup>2</sup>
For 20 mg per day, price per year is about <mark>\$204,765</mark>	For 1200 mg per day, price per year is about \$183,960 (1200 mg would provide ~20 mg/kg for a 140 lb patient)	For 1200 mg per day, price per year is about \$166,440 (1200 mg would provide ~20 mg/kg for a 140 lb patient)

#### MNT4P cost: 21,482 per year/Adult

- 1. <u>https://pages.bmrn.com/rs/424-CBN-</u> <u>212/images/2020\_US\_Product\_Price\_List.PDF?mkt\_tok=NDI0LUNCTi0yMTIAAAF7k\_IYkVm1ctYI0WYv5XFNkGI</u> <u>UqgrHxbuuf24R3ZXICSvy6h8jewarPAbqDkomH\_FD-RTnKAI0Lnd0vwmpFA</u>
- 2. <u>https://www.drugs.com/price-guide/sapropterin</u>

# Medical Foods Policy Dilemma: How are we doing?

- □ Food is responsibility of consumer and no state reimbursement policy.
- Drugs are typically covered by insurance companies via state legislative mandates.
- Some states have chosen to do something by passing reimbursement laws that force insurance companies or state agencies to reimburse afflicted individuals.
- Newborn screening was started so that everyone could be treated early. Is this happening for everyone: NO
- This has impact on the outcome of our Pateints? Does this negate the effect of Newborn screening for some despite proven benefits with intervention?
- Policy makers at the Federal and State level recognize the changes that need to be made.
- How do we work together to navigate through this barrier so 100% of the families have access to the care they need?

## Past Efforts

Legislative	Advocacy & Professional Organizations	ACHDNC Letters
Medical food equity ACT (MFEA) of 2011 (S.311;John Kerry) MFEA of 2013 (H.R. #665; John Delany	NPKUA has advocated for coverage and reimbursement in number of ways Industry-sponsored registries NORD hosted a conference on medical foods in Eeb 2011	<ul> <li>May19,2009</li> <li>Committee reiterated 2007 recommendation to address gaps in coverage and reimbursement</li> <li>Besponse on October 2, 2009</li> </ul>
American Health Security Act of 2011,2013,2015(H>R>1200 McDermott)	<ul> <li>ACMG-Management Guidelines (Vockley GIM 2014</li> <li>GMDI-Management Guidelines (Singh GIM 2014)</li> <li>SIMD &amp; GMDI - Policy statements</li> </ul>	<ul> <li>Enacting legislation is beyond the Department's authority</li> <li>June 14, 2010</li> <li>Committee recommended that health reform ensure access to medical foods</li> </ul>
		and foods modified to be low in protein
S. Res December 3, 2015 as National Phenylketonuria Awareness Day Multiple mentions of medical Foods	<ul> <li>NIH:</li> <li>Consensus Statement on Phenylketonuria, 2000</li> <li>PKU Scientific Review Conference, 2012</li> </ul>	<ul> <li>as essential health care services</li> <li>irrespective of the source of health</li> <li>coverage</li> <li>Response on December 14, 2010</li> <li>"I cannot adopt the Committee's</li> <li>recommendations at this time"; awaiting</li> <li>a DOL survey and IOM public workshop</li> </ul>

NOW: As of 2023, Federal Employee Health Benefit Program now covers medical food for IMD regardless of age

Adapted from Camp presentation ACHDNC 2016

## Medical Foods Equity Act of 2023: Potential for Closing the Gap

- Federal legislation requiring coverage of medically necessary nutrition for patients with specific inherited metabolic and gastrointestinal conditions by federal health programs and private insurance
- There is precedent TRICARE (NDAA 2017), Federal Employee Health Program IMD medical foods coverage – all ages (2023)
- Bipartisan, endorsed by 45 patient & provider organizations
- 129 House and Senate co-sponsors in 2021-2022 (HR.3783/S.2013)
- Critical to newborn screening and rare disease patients!





for the Regional Genetics Networks





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