Resolving The Paradox
Optional Medical Food Reimbursement vs Mandatory Newborn Screening
FAQ & OAA Conference – Portland, OR July 20-21, 2012

Newborn Screening Saves Babies
One Foot At A Time

Kathleen Huntington, MS, RD, LD
Metabolic Clinic/Child Development & Rehabilitation Center
Oregon Health & Science University
Portland, Oregon

Medical Food Reimbursement Paradox
In the United States We Screen Babies For Rare Conditions That Are Treatable

BUT Insurance Coverage for Treatment Is Typically Denied

PARADOX
one exhibiting inexplicable or contradictory aspects

All 50 States Mandate Expanded Newborn Screening

~ 15 Inherited Metabolic Disorders Require Medical Nutritional Therapy

Only 16 States Mandate Treatment Coverage For All Screened Inherited Metabolic Disorders out of 38 States That Have Passed Medical Food Legislative Mandates
38 States Have Passed Treatment Mandates for Either State or Private Payor Plan Coverage

- 1983 (1) Wisconsin
- 1985 – (1) Minnesota
- 1991 – (1) Alaska
- 1992 – (1) S. Dakota
- 1993 – (1) Massachusetts
- 1996 – (2) Tennessee, Pennsylvania
- 1998 (3) Vermont, Utah, Nebraska
- 1999 (5) Arkansas, California Hawaii, Montana, Texas
- 2000 – (1) Arizona
- 2001 (4) N. Dakota, Louisiana, Colorado, Virginia
- 2002 – (2) Missouri, Kentucky
- 2003 – (2) New Mexico, Indiana
- 2007 – (1) Delaware
- 2008 – (1) Rhode Island


Examples of State Mandate Differences

Mandate Passed: 1996
Disorder Covered: PKU only
Medical Food: Formula only

Mandate Passed: 1997
Disorder Covered: All IEM
Medical Food: Medical Protein, Low Protein Med Foods & Other Modules

Case Example

9 Yrs old
Diagnosis: PKU

• Age based DRI: 34 Grams Protein
• Estimated Energy: 1950 Calories

• Tolerates 300 mg of Phenylalanine Per Day
  (= 6 grams protein)

Provides ~ 450 calories
38 State Medical Food Mandates & What They Mandate

Since 2000, 11/38 mandates have been passed, 9 include coverage of low protein foods.

Mandate Distribution State by State
Medical Food Reimbursement
What’s Not Working

- Lack of a State Mandate or Dissimilar State Laws
- ERISA
- HCPC Codes

Make Healthcare Coverage
An Uphill Battle
& Inconsistently Available

Denials, Delays & Underinsurance Undermines Preventive Healthcare

“In the absence of a specific inclusion or state mandate, ...Aetna does not cover specialized formula.

It is determined that there is no applicable state mandate in this case because of the Washington State self-insured origin of this plan.”

Medical Food Reimbursement
What’s not working

- Lack of a State Mandate or Dissimilar State Laws
- ERISA
- HCPC Codes

Make Healthcare Coverage
An Uphill Battle
**ERISA**
Employee Retirement Income Security Act 1974

- Original intent—regulate pension plans & address problem of conflicting regulations across the nation.

- Its scope came to include health care provided as part of an employee’s benefit package.

**ERISA**
Employee Retirement Income Security Act 1974

- Section 514 – allows ERISA to preempt any state regulation of employment benefits to facilitate uniformity to help keep national administration costs down and variation out. Eliminated the state role in regulating employee benefit plans provided by self-insured employers.

Nearly **six in ten** American private and public sector workers covered by employer-provided health care in 2010 were covered under a self-insured plan, up from about **four in ten** in 1999.

[Employer Health Benefits: 2010 Annual Survey sponsored by the Kaiser Family Foundation and Health Research and Educational Trust (KFF survey)](http://ehbs.kff.org)
Medical Food Reimbursement

What’s not working

- Lack of a State Mandate or Dissimilar State Laws
- ERISA
- HCPC Codes

Make Healthcare Coverage An Uphill Battle

---

HCPCS – B Codes

Enteral Nutrition

**Purpose:** Products listed under the B codes primarily revolve around malnutrition & malabsorption

**Fee Schedule:**

100 calories/unit

**Product System:**

Formulas, solutions, pumps, disposables

---

Enteral Nutrition -

A form of nutrition that is delivered into the digestive system as a liquid
Current Medical Food: Reimbursement Codes

- **B4155** Incomplete/Modular Nutrients
  - Includes carbohydrates (e.g. glucose polymers), proteins/amino acids (e.g. glutamine, arginine), fats (e.g. medium chain triglycerides) or combination

- **B4157** Enteral formula nutritionally complete, for special metabolic needs for inherited disease of metabolism
  - Both include Proteins, Fats, Carbohydrates, Vitamins and Minerals, may include Fiber
  - Administered through an enteral feeding tube
  - 100 calories = 1 unit
  - Add the BO modifier to the HCPC if the product is being administered orally and not by a feeding tube.

- **B4162** Enteral formula, for pediatrics, special metabolic needs for inherited disease of metabolism
  - Both include Proteins, Fats, Carbohydrates, Vitamins and Minerals, may include Fiber

HCPCS For Unique Applications -- but Not Used Universally

- **S9435** -- Medical Foods for Inborn Errors of Metabolism
- **S9434** -- Modified Solid Food Supplements for Inborn Errors of Metabolism

- < 1 gram of protein/serving
- Does not include natural food naturally low in protein
- And/or prescribed by a physician

HCPCS For Unique Applications -- but Not Used Universally

- **S9435** -- Medical Foods for Inborn Errors of Metabolism
- **S9434** -- Modified Solid Food Supplements for Inborn Errors of Metabolism

The S Codes for reporting
- Drugs
- Services
- Supplies

For which there are no national codes & for meeting the particular needs of the private sector

These codes: --
- Used by the Medicaid program
- Not payable by Medicare.
HCPCS For Unique Applications -- but Not Used Universally

- **S9435** — Medical Foods for Inborn Errors of Metabolism
- **S9434** — Modified Solid Food Supplements for Inborn Errors of Metabolism

CURRENT HCPCS DON’T WORK for Inherited Disorders of Amino Acid Metabolism

100 Calories = 1 Unit

Malabsorption and Malnutrition Are **NOT** The Issue

A New HCPCS Should Reference the Clinical Purpose of the Enteral Product for Inherited Disorders of Amino Acid Metabolism

1 Gram of Protein = 1 Unit

Medical Protein Product is Allocated Based on Protein Content **NOT** Calories
In turn requires time consuming appeals

**HCPCS That Don’t Apply**

Create Opportunities for Insurance to say NO

HCPCS That Don’t Apply

Create Opportunities for Insurance to say NO

In turn requires time consuming appeals

Generally, to be considered a medical food, a product must meet the following criteria:

1. The product is a food for oral or tube feeding;
2. The product is labeled for the dietary management of a medical disorder, disease, or condition; and
3. Medical foods are distinguished from the broader category of foods for special dietary use and from foods that make health claims by the requirement that medical foods are to be used under medical supervision.
4. The term "medical foods" does not pertain to all foods fed to sick patients. Medical foods are foods that are specially formulated and processed (as opposed to a naturally occurring foodstuff used in its natural state) for the patient who is seriously ill or who requires the product as a major treatment modality.


The Centers for Medicare and Medicaid Services (CMS) Healthcare Common Procedure Coding System (HCPCS) coding identifies that administration of enteral therapy must be given by feeding tube – nasogastric, jejunostomy or gastrostomy tubes.

We Need HCPC Reimbursement Codes That Bridge the Gap

Council for Affordable Health Insurance

(Active advocate for market-oriented solutions to the problems in America’s health care system)

2010: Medical food mandates increase the cost of a health insurance policy by less than 1%.

PKU/Metabolic Disorders

Inherited metabolic diseases such as PKU, which is a genetically determined abnormality caused by a missing enzyme called phenylalanine hydroxylase. Mandate provides for evaluation, education, treatment and supplies like formula or special foods.


Infant Formulas

Typically Used for VLCAD, LCHAD & TFP

Medical Food Options for those 1 year – Adulthood

Estimated costs for treating a one year cohort of infants with a Fatty Acid Oxidation Disorder based on incidence of disease by NBS.

<table>
<thead>
<tr>
<th>Disorder</th>
<th>Incidence (Yr⁻¹)</th>
<th>Average Cost Per Year for 180 Infants</th>
<th>Average Cost Per Person 10 yr old</th>
<th>Cost of Tx for 1-10 yr old/yr</th>
</tr>
</thead>
<tbody>
<tr>
<td>Long-Chain 3 Hydroxyacyl-CoA Dehydrogenase (LCHAD)</td>
<td>20</td>
<td>$3,650</td>
<td>$1,800</td>
<td>$3.6 million</td>
</tr>
<tr>
<td>Tri Functional Protein Deficiency (TFP)</td>
<td>20</td>
<td>$660 Thousand</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Very long-chain acyl-coenzyme A dehydrogenase (VLCAD)</td>
<td>140</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>180</td>
<td></td>
<td>1800</td>
<td></td>
</tr>
</tbody>
</table>

Organic Acidemias, Incidence, Average Medical Food Tx Cost

<table>
<thead>
<tr>
<th>Newborn Screening Diagnosis</th>
<th>Incidence/Yr⁻¹</th>
</tr>
</thead>
<tbody>
<tr>
<td>PKU</td>
<td>300</td>
</tr>
<tr>
<td>Propionic Acidemia</td>
<td>20</td>
</tr>
<tr>
<td>MMA MUT</td>
<td>20</td>
</tr>
<tr>
<td>Isovaleric Acidemia</td>
<td>20</td>
</tr>
<tr>
<td>Glutaric Acidemia (GA1)</td>
<td>40</td>
</tr>
<tr>
<td>OAA Total</td>
<td>100</td>
</tr>
</tbody>
</table>

## Inborn Errors of Metabolism Incidence

<table>
<thead>
<tr>
<th>Disorder</th>
<th>Incidence/Yr 1,2</th>
</tr>
</thead>
<tbody>
<tr>
<td>PKU</td>
<td>300</td>
</tr>
<tr>
<td>Organic Acidemias</td>
<td>100</td>
</tr>
<tr>
<td>FAOs</td>
<td>180</td>
</tr>
<tr>
<td>Homocystinuria</td>
<td>25</td>
</tr>
<tr>
<td>Maple Syrup Disorder</td>
<td>25</td>
</tr>
<tr>
<td>Tyrosinemia Type 1</td>
<td>15</td>
</tr>
<tr>
<td>Urea Cycle</td>
<td>140</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>~800</strong></td>
</tr>
</tbody>
</table>


## Organic Acidemias, Incidence, Average Medical Food Tx Cost

<table>
<thead>
<tr>
<th>Newborn Screening Diagnosis</th>
<th>Range of Wholesale Medical Protein Costs (per age based protein requirements)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Infant</td>
</tr>
<tr>
<td>PKU</td>
<td>$1,125</td>
</tr>
<tr>
<td>Propionic Acidemia</td>
<td>$1,900</td>
</tr>
<tr>
<td>MMA MUT</td>
<td>$1,900</td>
</tr>
<tr>
<td>Isovaleric Acidemia</td>
<td>$2,000</td>
</tr>
<tr>
<td>Glutaric Acidemia (GA1)</td>
<td>$1,950</td>
</tr>
<tr>
<td>OAA AVERAGE</td>
<td>$6,400</td>
</tr>
</tbody>
</table>


## Estimated Costs for Patients Infants + Previous 9 years

<table>
<thead>
<tr>
<th>Inborn Errors of Metabolism</th>
<th>Wholesale Costs for Medical Formulas or Medical Protein</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Total Costs/yr For Infants</td>
</tr>
<tr>
<td>Amino Acids Disorder, Organic Acidemias (500/yr)</td>
<td>$900,000</td>
</tr>
<tr>
<td>FAOs (180/yr)</td>
<td>$657,000</td>
</tr>
<tr>
<td>Urea Cycle (140/yr)</td>
<td>$168,000</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>$1,725,000</td>
</tr>
</tbody>
</table>
Medical Food Tx Costs vs Total Healthcare $ Per Year in US

$30,984 million is a little more than 1000th of 1% of $2.3 Trillion

Total = $2.3 Trillion

Options for Fixing the Problem

- Legislative
- Policy
- Advocacy

Medical Foods Equity Act
Co-Sponsors

- 6 Senators
  incl: 6-NJ, 2-NY, 1-DE, 1-CT, 1-IA

- 17 Representatives

Section 3: Coverage in federal health programs of medically necessary food and food modified to be low protein
- Coverage under the Medicare Program
- Coverage under the Medicaid Program
- Coverage under CHIP
- Coverage under TRICARE

Section 4: Coverage in the private insurance market of medically necessary food and food modified to be low protein
- Coverage under group health plans (including ERISA)
- Coverage for plans sold in the individual market
- Included in the definition of essential health benefits for qualified health plan

Affordable Care Act

December, 2011, the Department of Health and Human Services (HHS) issued a “pre-rule bulletin” announcing its decision to offer “flexibility” to the states in the selection of essential health benefits. There will be no national set of essential health benefits. Each state can choose its essential health benefits from the following four choices:

1. The largest plan by enrollment in any of the three largest small group insurance products in the State’s small group market
2. Any of the largest three State employee health benefit plans by enrollment
3. Any of the largest three national FEHBP plan options by enrollment
4. The largest insured commercial non-Medicaid Health Maintenance Organization (HMO) operating in the State.

Each State Must Rally to Include Medical Foods and Modified Low Protein Foods as EHBs

Option 2: Maximize the Preventative Potential of the Newborn Screening System

- Pass the Medical Foods Equity Act
- Include Medical Foods as Essential Benefits
- Update the HCPCS To Reflect Clinical Purpose
- ERISA

Act as if what you do makes a difference. It does. — Will James
Newborn screening is just the first step......

It’s a long road of many coordinated events and many years of challenges for the individual family – but coverage for treatment shouldn’t be so difficult to access. Let’s get rid of the obstacles!