

**The Patients & Providers for Medical Nutrition Equity Coalition (PPMNE) recommends the model language below to ensure that any national policy meets our four principles to adequately cover the needs of the patients with GI and metabolic disorders who rely on medically-necessary foods and formulas for treatment:**

1. First and foremost, it is critical that any coverage policy include the full range of GI and metabolic disorders for which medical nutrition is necessary. Please see the attachment, which lists the conditions that should be included.
2. There should be no age restrictions. While many patients are diagnosed as infants or children, diagnosis can occur at any age and most of the conditions persist throughout the patient's life.
3. Further, coverage should not be limited to individuals who require medically-necessary nutrition as their sole source of nutrition, and should extend to those who require it for partial nutrition. Many patients with certain GI and metabolic disorders are able to supplement medical foods and specialized formulas with other sources of nutrition on a limited basis; however, they still rely on medical food and specialized formulas as their treatment and for a majority of their nutrition.
4. Specialized formulas must also be covered for both oral consumption and administration through an enteral feeding tube. While patients may prefer oral consumption as the preferred route of administration, insurance companies often require administration through a nasogastric or jejunostomy tube. Surgical placement of a jejunostomy tube is invasive and has higher associated costs and risk of infection. The decision of the best route of administration should be left to patients in consultation with their treating physicians.
5. It is absolutely critical that any coverage policy include the full range of medically necessary foods and formulas, including specialized vitamin formulations, for the treatment and management of GI and metabolic diseases and disorders.

#### **MODEL LANGUAGE**

##### **Covered Service:**

**Medically Necessary Foods:** Certain medical formulas, low protein foods and amino acid preparation products

This health plan covers medically necessary food and medical equipment and supplies necessary to administer such food when prescribed for dietary management of a covered disease or condition. Medically necessary food includes: specialized formulas (including non-prescription formulas), a Low Protein Modified Food (LPMF) product, a modified fat preparation product, an amino acid preparation product, or an individual amino acid.

**Medically necessary food and medical equipment and supplies may be covered when it is:**

- Furnished pursuant to the prescription or written order of a physician, certified Nurse Practitioner (NP), or a certified Physician Assistant (PA) acting within the provider's

scope of license/certificate of practice for the dietary management of a covered disease or condition; and

- A specifically formulated and processed product (as opposed to a naturally occurring foodstuff used in its natural state) for the partial or exclusive feeding of an individual by means of oral intake or enteral feeding by tube; and
- Intended for the dietary management of an individual who, because of therapeutic or chronic medical needs, has limited or impaired capacity to ingest, digest, absorb, or metabolize ordinary foodstuffs or certain nutrients, or who has other special medically determined nutrient requirements, the dietary management of which cannot be achieved by the modification of the normal diet alone; and
- Intended to be used under medical supervision, which may include in a home setting; and
- Intended only for an individual receiving active and ongoing medical supervision.

**Covered disease or conditions include:**

Inherited metabolic disorders, including the following:

- Disorders classified as metabolic disorders on the Recommended Uniform Screening Panel Conditions list of the Secretary of Health and Human Services' Advisory Committee on Heritable Disorders in Newborns and Children.
- N-acetylglutamate synthase deficiency.
- Ornithine transcarbamylase deficiency.
- Carbamoyl phosphate synthetase deficiency.
- Inherited disorders of mitochondrial functioning.

Medical and surgical conditions of malabsorption, including the following:

- Impaired absorption of nutrients caused by disorders affecting the absorptive surface, functional length, and motility of the gastrointestinal tract, including short bowel syndrome and chronic intestinal pseudo-obstruction.
- Malabsorption due to liver or pancreatic disease.

Immunoglobulin E and non Immunoglobulin E-mediated allergies to food proteins, including the following:

- Immunoglobulin E and non-Immunoglobulin E-mediated allergies to food proteins.
- Food protein-induced enterocolitis syndrome.

Eosinophilic disorders, including the following:

- Eosinophilic esophagitis, eosinophilic gastritis, eosinophilic gastroenteritis, eosinophilic duodenitis, eosinophilic colitis, and post-transplant eosinophilic disorders.

Inflammatory or immune mediated conditions of the alimentary tract, including the following:

- Inflammatory bowel disease, including Crohn's disease, ulcerative colitis, and indeterminate colitis.
- Gastroesophageal reflux disease that is nonresponsive to standard medical therapies.

### **Specialized Formulas**

Specialized formulas are to include amino acid based formulas, when covered as medically necessary food. Specialized formulas are covered for enteral and oral consumption.

### **Low Protein Modified Foods (LPMFs)**

LPMFs, when covered as medically necessary foods are those food products that have been modified to be low in protein for use by individuals who have been diagnosed with an inborn error of metabolism (IEM) (e.g., phenylketonuria (PKU), or maple syrup urine disease), and are not typically readily available in grocery stores. LPMFs are primary to the management of IEM, as they help those diagnosed with the condition, avoid organ damage, grow properly, and maintain or improve health status. LPMFs may be covered pursuant to a prescription, when medically necessary and appropriate for the treatment of IEM.

### **Medically Necessary Vitamins and Minerals**

Medically necessary vitamin and mineral formulations are covered when furnished pursuant to the prescription or written order of a physician, certified Nurse Practitioner (NP), or a certified Physician Assistant (PA) acting within the provider's scope of license/certificate of practice for the dietary management of a covered disease or condition.

### **Preauthorization**

Preauthorization is required of all medically necessary foods, including prescribed specialized formulas (including non-prescription formulas), a LPMF product, a modified fat preparation product, a vitamin or mineral formulations, or an amino acid preparation product, to ensure such products are medically necessary and appropriate medical care for the treatment of covered conditions. If preauthorization is not obtained by the beneficiary and the beneficiary purchases medically necessary foods directly from a vendor, and all policy criteria are met, the appropriate out-of-network cost-share shall apply.