JOHNS HOPKINS HEALTH PLANS	Johns Hopkins Health Plans **Medical Policy Manual** **Medical Policy**	*Policy Number*	CMS14.04
		Effective Date	11/01/2023
		Approval Date	08/15/2023
	Subject **Nutritional Treatment - Medically Necessary Food**	*Supersedes Date*	11/01/2022
		Page	1 of 12

This document applies to the following Participating Organizations:

EHP	Johns Hopkins Advantage MD	Johns Hopkins Health Plan of Virginia Inc. (JHHPVA)	Priority Partners
US Family Health Plan			

Keywords: Medical Food, Nutrition

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I. ACTION

	New Policy	
X	Revising Policy Number	CMS14.04
	Superseding Policy Number	
	Retiring Policy Number	

II. POLICY

Cross Reference: CMS14.02 Nutritional Assessment and Management

For Advantage MD refer to: Medicare Coverage Database

- National Coverage Determination (NCD) 180.1 Medical Nutrition Therapy
- Local Coverage Determinations (LCD) L38955 Enteral Nutrition

For Employer Health Programs (EHP) refer to:

- Plan specific Summary Plan Descriptions (SPDs)

For Johns Hopkins Health Plan of Virginia Inc. (JHHPVA) refer to: Medicare Coverage Database

- National Coverage Determination (NCD) 180.1 Medical Nutrition Therapy

- Local Coverage Determinations (LCD) L38955 Enteral Nutrition

For Priority Partners refer to: Code of Maryland Regulations

- Code of Maryland Regulations (COMAR)10.67.06.04 Benefits - Pharmacy Services
- Code of Maryland Regulations (COMAR)10.67.06.20 Benefits - EPSDT Services
- Medical Assistance Program Transmittal EPSDT No. 31, Pharmacy no. 189, February 3, 2009: Oral Nutritional Supplements and Supplemental Vitamins
- Maryland Department of Health, Women, Infants and Children Program (WIC): https://health.maryland.gov/
- Maryland Department of Health, Division for Clinical Genetic Services, The Metabolic Nutrition Follow-up Program: phpa.health.maryland.gov

For US Family Health Plan refer to: Tricare Policy Manuals

- TRICARE Policy Manual 6010.63-M, April 1, 2021, Chapter 8, Section 7.1. Medically Necessary Food - For Dates of Service On Or After December 23, 2017
- Enteral and Oral Nutrition Products -Enteral Foods List: https://www.health.mil/

III. POLICY DISCLAIMER

Johns Hopkins Health Plans (JHHP) provides a full spectrum of health care products and services for Advantage MD, Employer Health Programs, Johns Hopkins Health Plan of Virginia Inc., Priority Partners, and US Family Health Plan. Each line of business possesses its own unique contract, benefits, regulations, and regulators' clinical guidelines that supersede the information outlined in this policy.

IV. POLICY CRITERIA

A. General Considerations: When benefits are provided under the member's contract, JHHP considers nutritional treatment medically necessary when ALL of the following are met:

1. The nutritional product must be prescribed, ordered, or recommended (as applicable) by a physician or other health care professional qualified to provide medical treatment for the disease or condition for which the therapy is being prescribed, ordered, or recommended.
2. The condition for which the nutritional product is being prescribed, ordered, or recommended is expected to persist for a minimum of three months.
3. Adequate nutrition cannot be achieved by adjustment of a regular diet.
4. There is clear documentation of medical diagnosis and treatment plan indicating medical necessity of the nutritional product.
5. There is ongoing medical supervision by a physician, registered dietitian, or other qualified health care professional, who has determined the need for the medical food. The supervision includes instruction on use of the medical food as part of the dietary management of the given disease or condition.
6. Treatment is for ANY of the conditions listed in Section B or C.
7. JHHP considers nutritional assessment and management by a registered dietitian medically necessary for the conditions listed in Section B or C (Refer to medical policy CMS14.02 Nutritional Assessment and Management).

B. When benefits are provided under the member's contract, JHHP considers nutritional treatment with medical foods/ medical formulas to be medically necessary when ALL the requirements in Section A are met and for ANY of the following:

1. Inborn errors of metabolism (IEM), including the following categories:
   a. Disorders of amino acid metabolism, including but not limited to:
      i. maple syrup urine disease (MSUD),
      ii. homocystinuria (HCU),
      iii. phenylketonuria (PKU),
      iv. tyrosinemia
   b. Organic acidemias, including but not limited to:
      i. methylmalonic acidemia (MMA) ,
      ii. propionic acidemia (PA),
      iii. isovaleric acidemia (IVA),
      iv. 3-methylcrotonyl-CoA carboxylase deficiency (3-MCC),
      v. 3-methylglutaconic aciduria (3-MGA),
      vi. holocarboxylase synthetase deficiency,
      vii. biotinidase deficienicy,
      viii. glutaric acidemia type 1 (GA1),
      ix. ß-Ketothiolase deficiency
   c. Urea cycle defects, including but not limited to:
      i. argininosuccinate synthetase deficiency (also known as type I citrullinemia [CTLN1]),
      ii. ornithine transcarbamylase deficiency (OTC),
      iii. carbamyl phosphate synthetase I deficiency (CPSI),
      iv. arginosuccinate lyase deficiency (also known as arginosuccinic aciduria or ASL deficiency)
      v. N-acetyl glutamate synthetase deficiency (NAGS)
      vi. arginase deficiency (also known as argininemia)
      vii. lysinuric protein intolerance (LPI)
   d. Fatty acid oxidation disorders requiring dietary treatment, including:
      i. very long chain acyl-CoA dehydrogenase deficiency (VLCADD),
      ii. long chain 3-hydroxyacyl-CoA dehydrogenase deficiency (LCHADD),
      iii. trifunctional protein deficiency (TFPD),
      iv. carnitine transporter deficiency (CTD),
      v. carnitine palmitoyltransferase 1A deficiency (CPT1D),
      vi. carnitine palmitoyltransferase 2 deficiency (CPT2D),
      vii. medium-chain acl-coA dehydrogenase deficiency (MCADD)
      viii. multiple acyl-CoA dehydrogenase deficiency (MADD)
      ix. short-chain acyl-CoA dehydrogenase deficiency (SCADD)
      x. short-chain L-3-hydroxyacyl-CoA dehydrogenase deficiency (M/SCHAD)
      xi. HMG-coA lyase deficiency
   e. Glycogen storage diseases
   f. Hereditary fructose intolerance.

C. When benefits are provided under the member's contract, JHHP considers nutritional treatment with amino acid-based formulas to be medically necessary when ALL the requirements in Section A are met and for ANY of the following:
   1. Immunoglobulin E and non-immunoglobulin E mediated allergies to multiple food proteins
   2. Food protein induced enterocolitis syndrome (FPIES)
   3. Eosinophilic gastrointestinal disorders (EGID), as evidenced by the results of a biopsy
   4. Medical disorders resulting in malabsorption of nutrients caused by disorders affecting the absorptive surface, functional length, and motility of the gastrointestinal tract, which may include, but is not limited to, cystic fibrosis and short gut syndrome

5. Failure to initiate nutritional therapy will result in malnutrition, physical or mental disability, or death.

D. When benefits are provided under the member's contract, nutrition products for oral or enteral tube feeding consumption that may be approved under this policy when ALL the requirements in Section A are met and either the requirements of Section B or C are met (as applicable) include:
   1. For conditions listed in Section B above:
      a. Formulas/products used as a main source of nutrition containing protein, without the offending amino acid, and a range of other nutrients - specially produced for the dietary treatment of the specific disease/condition (e.g. Propimex-1).
      b. Low protein modified food products (excluding natural foods that are by nature low in protein) (e.g. Loprofin rice).
      c. Modular food/Supplements:
         i. Amino acid mixtures (e.g. Nutricia Complete Amino Acid Mix)
         ii. Single amino acids to be added to the nutritional solution (e.g. L-Citrulline)
         iii. Medically necessary vitamins and minerals, or other compounds used to replace conditionally essential nutrients or enhance enzyme activity (e.g. L-Carnitine)
         iv. Caloric modulars to assure that caloric needs are met when other macronutrients are severely restricted (e.g. Duocal, PFD Toddler).
   2. For conditions listed in Section C above:
      a. Amino acid-based elemental formulas (e.g. PurAmino, Elecare, Neocate).

E. Unless specific benefits are provided under the members contract, JHHP considers the following to be NOT MEDICALLY NECESSARY/NOT COVERED, (*not an all-inclusive list*):
   1. Food products consumed as part of a diet or treatment plan designed to reduce the risk of a disease or medical condition or as weight-loss products, even if recommended by a physician or other health care professional.
   2. Nutritional supplements administered for the sole purpose of boosting protein or caloric intake in the absence of a medical condition for which the accepted treatment consists of or includes administration of nutritional supplements.
   3. Vitamin or mineral preparations, except as provided in section III.D (also refer to Pharmacy benefit).
   4. Nutritional products as follows:
      a. regular grocery items
      b. baby food
      c. banked breast milk (unless specifically covered by a benefit plan)
      d. food thickeners, fiber additives (unless specifically covered by a benefit plan)
      e. gluten-free food products for the management of celiac disease or non-celiac gluten sensitivity
      f. lactose-free products
      g. food marketed for the management of diabetes
      h. products marketed to aid weight loss
      i. products used to replace fluids and electrolytes.
   5. Formulas, foods, or additives designed and marketed for the treatment of food intolerances (e.g. formulas for fussiness or gas).
   6. Nutrition product(s) covered for a member through a state agency (e.g. Women, Infants and Children (WIC) Nutrition Program).
   7. Products determined to be investigational or experimental in the treatment of a specific disease or condition.

V. DEFINITIONS

Amino Acid-Based Elemental Formula: A class of nutritional formulas designed for use in the treatment of patients with conditions of the bowel which cause maldigestion or malabsorption. These formulas contain 100% free amino acids as the only protein source and are highly osmotic. They can be administered orally or enterally (through nasogastric, gastrostomy or jejunostomy tubes). The nutritional requirements for patients requiring these formulas are established by medical evaluation and medical supervision is required for their usage (Maryland General Assembly, 2009) .

Eosinophilic Gastrointestinal Disorders (EGID): A group of immune-mediated chronic inflammatory disorders characterized by pathologic eosinophilic (WBC) infiltration of the esophagus, stomach, small intestine, or colon leading to organ dysfunction and clinical symptoms. Symptoms include abdominal pain, nausea, vomiting, early satiety, diarrhea, and weight loss (Gonsalves, 2019).

Food Protein–Induced Enterocolitis (FPIES): A non–IgE-mediated food allergy typically presents in infancy, with repetitive protracted vomiting beginning approximately 1 to 4 hours after food ingestion with the absence of classic IgE-mediated allergic skin or respiratory symptoms. Associated symptoms include: lethargy, pallor, diarrhea, hypotension, hypothermia, increased neutrophil count. Milk and soy FPIES resolve in a majority of patients by three to five years of age(Nowak-Wegrzyn, 2022).

Inborn Errors of Metabolism (IEM): These include inherited biochemical disorders in which a specific enzyme defect interferes with the normal metabolism of protein, fat, or carbohydrate. The diminished or absent enzyme activity in these disorders causes certain compounds to accumulate in the body at toxic levels. Other endogenously made nutrients may become deficient, making them conditionally essential. Left untreated, these metabolic disturbances can result in intellectual disability, severe cognitive impairment or death (Camp, 2012).

Low Protein Modified Food: A food product that is specially formulated to have less than 1 gram of protein per serving and is intended to be used under the direction of a physician for the dietary treatment of an inherited metabolic disease, excluding natural foods that are naturally low in protein (Maryland Code, Insurance § 15-807).

Medical Food: Food intended for the dietary treatment of a disease or condition for which nutritional requirements are established by medical evaluation and formulated to be consumed or administered enterally under the direction of a physician (Maryland Code, Insurance § 15-807). A medical food must be intended for a patient who has a 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 (21 CFR 101.9(j)(8)(ii)).

Medical Nutrition Therapy: Nutritional diagnostic, therapy, and counseling services for the purpose of disease management which are furnished by a registered dietitian or nutrition professional. MNT is a specific application of the Nutrition Care Process in clinical settings that is focused on the management of diseases. MNT involves in-depth individualized nutrition assessment and the duration and frequency of care using the Nutrition Care Process to manage disease (Academy of Nutrition and Dietetics, 2023). It includes recommendations for foods or nutrients to treat conditions and may involve simple changes in a person's diet, or intravenous or tube feeding (also called nutrition therapy) (NIH, 2020).

VI. BACKGROUND

Medical Nutrition Therapy (MNT) is a practice which consists of administering personalized diet plans, nutritional therapy and counseling services to patients for the treatment and management of diseases and other medical conditions. MNT is a therapeutic approach often used for patients with diabetes, hypertension, and renal disease.

Dietary management of diseases or conditions also includes the treatment of severe allergies, disorders of the gastrointestinal tract and inborn errors of metabolism (IEM) for which the provision of medical foods may be required to allow for growth and development or to prevent neurological devastation and death. Many inborn errors of metabolism for which nutritional treatments serve as the primary medical treatment are identified through newborn screening programs (NBS). Individual states determine what disorders are included in their NBS program. However, most states include the disorders included on the Recommended Uniform Screening Panel supported by the Advisory Committee on Heritable Disorders in Newborns and Children (HRSA.gov, 2023).

Although screening programs may vary, major categories tested include fatty acid oxidation disorders, amino acids disorders, urea cycle defects, and organic acidurias (Camp, 2012). Fatty acid oxidation disorders (FAODs) are inborn errors of metabolism that result in failure of mitochondrial beta-oxidation or the carnitine-based transport of fatty acids into mitochondria (Vockley, 2022a). The recommended diet for FAODs is fat restricted with carbohydrate supplementation. Treatment of long-chain FAODs includes supplementation with medical foods containing medium-chain triglyceride's (MCT) to provide a substrate for beta-oxidation. Carnitine supplementation is given when secondary carnitine deficiency is identified. Essential to treatment of FAODs is avoidance of prolonged fasting and maintenance of a constant energy supply during times of catabolism (Vockley, 2022b). Inborn errors of metabolism involving amino acid metabolism include phenylketonuria (PKU), the first newborn screening disorder. It is the most common IEM requiring nutritional treatment and is caused by insufficient or absent phenylalanine hydroxylase, the enzyme that converts the amino acid phenylalanine to tyrosine (Camp, 2012). Medical nutrition therapy for inborn errors of metabolism involving amino acid disorders include two different forms of medical foods - one containing protein without the amino acid(s) specific to the IEM and the other consisting of foods that have been modified to be low in protein (Camp, 2012). These patients typically require caloric modulars, particularly as infants, in order to meet caloric requirements on a severely protein restricted diet. Urea cycle defects result from a defect in one of the five enzymes in the urea cycle, which is an essential metabolic pathway to dispose of excess nitrogen. Treatment is geared toward minimizing the nitrogen load on the urea cycle and preventing hyperammonemia, which includes maintaining a diet that is high in calories but low in protein (Matsumoto, 2019). Patients often require caloric modulars, low protein modified foods, and essential amino acid supplements to promote growth and development while also minimizing nitrogen load. Organic acidurias, also referred to as organic acidemias, are a class of inborn errors of metabolism characterized by accumulation of abnormal and often toxic organic acid metabolites with increased excretion of organic acids in urine. They mainly occur from deficiencies of specific enzymes in the breakdown pathways of amino acids (Bodamer, 2022c). Successful treatment of organic acidurias involves synthetic amino acid-based formulas which should provide about 50% of daily protein needs, as well as supplementation with L-carnitine to treat the secondary carnitine deficiency that develops as a result of accumulation of toxic organic acid metabolites. Simultaneously, the dietary precursor amino acid has to be restricted and fasting must be avoided (Vaidyanathan, 2011).

Nutritional products classified as medical foods used to treat inborn errors of metabolism include three main categories. Products with a full complement of nutrients, excluding the offending nutrients which come in powders to be reconstituted, ready to drink products, and bars. This category includes specialty infant formulas. Secondly, are modular products which include amino acid mixtures, ready to drink products, low volume, low calorie foods, and tablets. Lastly, foods modified to be low in protein include specialty baked goods, pasta, rice, meat and cheese substitutes, and snack foods (Camp, 2016). Medical foods are distinct from the broader category of foods for special dietary use, as medical foods must be intended to meet the distinctive nutritional requirements of a disease or condition, be intended for the specific dietary management of a disease or condition, and require medical supervision. Medical foods do not include all foods recommended by a physician as part of an overall diet to manage the symptoms or reduce disease risk, and not all foods administered to patients with a disease, including diseases that require dietary management, like diabetes, are medical foods. Instead, medical foods are foods that are specially formulated and processed for a patient who requires use of the product as a major component of a disease or condition's specific dietary management (U.S.Dept of HHS, 2023).

VII. CODING DISCLAIMER

Note: The following CPT/HCPCS codes are included below for informational purposes and may not be all inclusive. Inclusion or exclusion of a CPT/HCPCS code(s) below does not signify or imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member's specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee of payment. Other policies and coverage determination guidelines may apply.

Note: All inpatient admissions require preauthorization.

Adherence to the provision in this policy may be monitored and addressed through post-payment data analysis and/or medical review audits
Advantage MD: Regulatory guidance supersedes JHHP Medical Policies. If there are no statutes, regulations, NCDs, LCDs, or LCAs, or other CMS guidelines, apply the Medical Policy criteria.
Employer Health Programs (EHP): Specific Summary Plan Descriptions (SPDs) supersedes JHHP Medical Policy. If there are no criteria in the SPD, apply the Medical Policy criteria.
Johns Hopkins Health Plan of Virginia Inc. (JHHPVA): Regulatory guidance supersedes JHHP Medical Policies. If there are no statutes, regulations, NCDs, LCDs, or LCAs, or other CMS guidelines, apply the Medical Policy criteria.
Priority Partners (PPMCO): Regulatory guidance supersedes JHHP Medical Policy. If there are no criteria in COMAR regulations, or other State guidelines, apply the Medical Policy criteria.
US Family Health Plan (USFHP): Regulatory guidance supersedes JHHP Medical Policy. If there are no TRICARE policies, or other regulatory guidelines, apply the Medical Policy criteria.

VIII. CODING INFORMATION

	CPT® CODES ARE FOR INFORMATIONAL PURPOSES
CPT® CODES	**DESCRIPTION**
97802	Medical nutrition therapy; initial assessment and intervention, individual, face-to-face with the patient, each 15 minutes
97803	Medical nutrition therapy; re-assessment and intervention, individual, face-to-face with the patient, each 15 minutes
97804	Medical nutrition therapy; group (2 or more individual(s)), each 30 minutes

	HCPCS CODES ARE FOR INFORMATIONAL PURPOSES
HCPCS CODES	**DESCRIPTION**
A9152	Single vitamin/mineral/trace element, oral, per dose, not otherwise specified
A9153	Multiple vitamins, with or without minerals and trace elements, oral, per dose, not otherwise specified

B4100	Food thickener, administered orally, per oz
B4104	Additive for enteral formula (e.g., fiber)
B4105	In-line cartridge containing digestive enzyme(s) for enteral feeding, each
B4155	Enteral formula, nutritionally incomplete/modular nutrients, includes specific nutrients, carbohydrates (e.g., glucose polymers), proteins/amino acids (e.g., glutamine, arginine), fat (e.g., medium chain triglycerides) or combination, administered through an enteral feeding tube, 100 calories = 1 unit
B4157	Enteral formula, nutritionally complete, for specific metabolic needs for inherited disease of metabolism, includes proteins, fats carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit
B4161	Enteral formula, for pediatrics, hydrolyzed/amino acids and peptide chain proteins, includes fats, carbohydrates, vitamins and minerals, may include fiber, administered through and enteral feeding tube, 100 calories = 1 unit
B4162	Enteral formula, for pediatrics, special metabolic needs for inherited disease of metabolism, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit
G0270	Medical nutrition therapy; reassessment and subsequent intervention(s) following second referral in same year for change in diagnosis, medical condition or treatment regimen (including additional hours needed for renal disease), individual, face-to-face with the patient, each 15 minutes
G0271	Medical nutrition therapy, reassessment and subsequent intervention(s) following second referral in same year for change in diagnosis, medical condition, or treatment regimen (including additional hours needed for renal disease), group (2 or more individuals), each 30 minutes
S9433	Medical food nutritionally complete, administered orally, providing 100% of nutritional intake
S9434	Modified solid food supplements for inborn errors of metabolism
S9435	Medical foods for inborn errors of metabolism
S9470	Nutritional counseling, dietitian visit

	ICD10 CODES ARE FOR INFORMATIONAL PURPOSES
ICD-10 CODES	**DESCRIPTION**
E70.0 - E70.9	Disorders of aromatic amino-acid metabolism
E71.0 - E71.548	Disorders of branched-chain amino-acid metabolism and fatty-acid metabolism
E72.00 - E72.9	Other disorders of amino-acid metabolism
E74.00 - E74.09	Glycogen storage disease
E84	Cystic fibrosis
K52.21	Food protein-induced enterocolitis syndrome

K52.81	Eosinophilic gastritis or gastroenteritis
K91.2	Postsurgical malabsorption, not elsewhere classified

IX. REFERENCE STATEMENT

Analyses of the scientific and clinical references cited below were conducted and utilized by the Johns Hopkins Health Plans (JHHP) Medical Policy Team during the development and implementation of this medical policy. The Medical Policy Team will continue to monitor and review any newly published clinical evidence and revise the policy and adjust the references below accordingly if deemed necessary.

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XI. APPROVALS

Historical Approval Dates: 03/03/2017, 07/01/2019, 11/01/2021, 11/01/2022, 11/01/2023