

**Policy: MP247**

**Section: Medical Benefit Policy**

**Subject: Nutritional Supplements**

### **I. Policy:** Nutritional Supplements

### **II. Purpose/Objective:**

To provide a policy of coverage regarding Nutritional Supplements

### **III. Responsibility:**

- A. Medical Directors
- B. Medical Management Department

### **IV. Required Definitions**

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

### **V. Additional Definitions**

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
- c. in accordance with current standards of good medical treatment practiced by the general medical community;
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

### **Medicaid Business Segment**

Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance Program and if it meets any one of the following standards:

- (i) the service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.
- (ii) the service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability.
- (iii) the service or benefit will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for members of the same age.

**Food Additives:** Commercially available products such as fiber, calorie, and/or protein supplements, thickeners, vitamins, minerals, and products to aid in lactose digestion.

**Grocery Items:** Food items available for common consumption, including baby foods and self-blendarized food mixtures.

### **LOW-PROTEIN MODIFIED FOOD PRODUCTS**

Low-protein modified food products are specially formulated to have less than 1 gram of protein per serving. Low-protein modified food products are intended for use under the direction of a physician for the dietary treatment of hereditary metabolic diseases but does not include a natural food that is naturally low in protein. Some examples of low-protein food products that are commercially available for purchase are breads, pasta, pastry shells, and rice pizza shells

### **DESCRIPTION:**

Enteral nutrition is the method of providing food into the gastrointestinal tract via a percutaneous endoscopic gastrostomy (PEG) tube, jejunostomy tube (J-tube), percutaneous endoscopic jejunostomy (PEJ) tube, Gastrostomy tube (GT), or nasogastric (NG) tube in individuals with a functioning gastrointestinal tract but have a disorder that prevents normal chewing and swallowing, a disorder of the stomach but functioning intestine, or a disorder of the intestine but a functioning colon.

### **INDICATIONS:**

### **All Business Segments:**

Oral or tube delivered nutrition products or supplements used for the treatment of members with an established diagnosis of inborn error of metabolism (eg, phenylketonuria (PKU), homocystinuria, branch chain ketonuria, galactosemia, etc) with documentation of failure of conservative dietary interventions are covered as mandated by Act 191.

Prescription medical foods (formulas) administered orally or via a tube into the alimentary canal for members diagnosed with a rare genetic (inherited) inborn errors of metabolism (IEM), such as phenylketonuria (PKU), homocystinuria, branched-chain ketonuria, and galactosemia are covered for individuals of all ages who need administration of a formula that is manufactured for the therapeutic treatment and dietary management of individuals with IEMs and is administered under the direction of a physician.

### **The Following Indications Requires Prior Authorization by a Plan Medical Director or designee**

### **Commercial Business Segments: (Coverage may vary by individual TPA)**

#### **Oral Nutritional Products:**

Oral nutritional products are not covered unless mandated by law (**see Exclusions**)

**Enteral nutrition** (including administration, supplies and formula) may be considered medically necessary in members with:

Requirement of a feeding tube; **and**

- a) Central nervous system injury or disease that results in partial or total inability to take nutrients orally and with functional gastrointestinal tract of sufficient absorptive capacity; **or**
- b) Disease or injury (permanent or temporary) that requires the use of a feeding tube in insured individuals:
  - i. Who are malnourished or are at risk of becoming malnourished; and
  - ii. Who have inadequate or anticipated inadequate oral intake for at least 7 days; and
  - iii. In whom the tube feeding provides the primary source of nutrition

**Amino acid-based Elemental formula** may be considered to be medically necessary in members age 5 years and younger when all of the following criteria are met:

- Medical record documentation of a laboratory or diagnostic test supported diagnosis of one or more of the following:
  - a. Short gut syndrome
  - b. IgE mediated allergies to food proteins
  - c. Food protein induced enterocolitis syndrome

- d. Eosinophilic esophagitis (EE)
- e. Eosinophilic gastroenteritis (EG)
- f. Eosinophilic colitis
- g. Amino acid, organic acid and fatty acid metabolic and malabsorption disorder
- h. Cystic fibrosis

**and**

- Documentation of at least two failed formula alternatives

## **Medicare Business Segment:**

### **Oral Nutritional Products:**

Oral nutritional supplementation is not covered under Medicare Part B.

**Enteral Nutrition** (including administration, supplies and formula) when ordered by a registered dietician, gastroenterologist or bariatrician may be considered medically necessary in members with:

Requirement of a feeding tube; **and**

- a. Central nervous system injury or disease that results in partial or total inability to take nutrients orally and with functional gastrointestinal tract of sufficient absorptive capacity; **or**
- b. Disease or injury (permanent or temporary) that requires the use of a feeding tube in insured individuals:
  - i. Who are malnourished or are at risk of becoming malnourished; and
  - ii. Who have inadequate or anticipated inadequate oral intake for at least 7 days; and
  - iii. In whom the tube feeding provides the primary source of nutrition

## **Medicaid Business Segment:**

Oral or enteral nutrition products or supplements used for the treatment of members with an established diagnosis of inborn error of metabolism (eg, phenylketonuria (PKU) homocystinuria, branch chain ketonuria, galactosemia, etc) with documentation of failure of conservative dietary interventions are covered as mandated by Act 191

### **Oral Nutritional Products:**

#### **For members under age 21 years:**

Each case will be determined based on medical necessity. Physician documentation must provide all of the following:

- a description of the member's clinical condition that clearly outlines why the nutritional needs cannot be met through dietary modification to increase caloric intake (snacks, higher calorie/protein foods)
- A description of the member's current nutritional status (eg, height, weight, percentiles for pediatric members)
- A prescription or order including the product, administration route and rate of intake
- An estimated duration of therapy
- For oral nutritional supplementation expected to be required long term (months), documentation of a nutritional assessment needs to be provided that includes an assessment of current caloric intake, caloric needs, and why dietary modification cannot meet those needs.

### **Pasteurized Human Donor Breast Milk**

Requests for pasteurized human donor breast milk will be reviewed using the American Academy of Pediatrics guidelines: <http://pediatrics.aappublications.org/content/pediatrics/139/1/e20163440.full.pdf>

- Donor human milk may be used for high-risk infants when the mother's milk is not available or the mother cannot provide milk. Priority will be given to providing donor human milk to infants <1500 g birth weight.
- The donor must be identified and screened using methods such as those currently used by HMBANA milk banks or other established commercial milk banks.
- The donor milk is pasteurized according to accepted standards.

### **For members age 21 years and older:**

Commercial oral nutrition products are covered if such products constitute 50% or more of total patient caloric intake and are found to be medically necessary. The following criteria must be met:

- Member must have a documented medical condition that limits his or her ability to ingest, digest, or absorb regular food; and
- reversible causes have been ruled out; and
- nutritional assessment has been completed to document current caloric intake, caloric needs, and why dietary modification cannot meet those needs

### **Enteral Nutrition:**

Enteral Nutrition (including administration, supplies and formula) when ordered by a registered dietician, gastroenterologist or bariatrician may be considered medically necessary in members with:

Requirement of a feeding tube; and

- a. Central nervous system injury or disease that results in partial or total inability to take nutrients orally and with functional gastrointestinal tract of sufficient absorptive capacity; **or**
- b. Disease or injury (permanent or temporary) that requires the use of a feeding tube in members:
  - i. Who are malnourished or are at risk of becoming malnourished; and
  - ii. Who have inadequate or anticipated inadequate oral intake for at least 7 days; and
  - iii. In whom the tube feeding provides the primary source of nutrition
- c. Human Immunodeficiency Virus (HIV) /Acquired Immunodeficiency Syndrome (AIDS)

A limit of 960 units per month equating to 96,000 calories per month, or 3,000 calories per day, for 32 days, which will meet the daily caloric needs of the vast majority of members will be considered medically necessary. However, if needed, an exception of the limits may be requested. A one-month supply will be provided each 32 days.

**Amino acid-based Elemental formula** may be considered to be medically necessary in members age 21 years and younger when all of the following criteria are met:

- Medical record documentation of a laboratory or diagnostic test supported diagnosis of one or more of the following:
  - a. Short gut syndrome
  - b. IgE mediated allergies to food proteins
  - c. Food protein induced enterocolitis syndrome
  - d. Eosinophilic esophagitis (EE)
  - e. Eosinophilic gastroenteritis (EG)
  - f. Eosinophilic colitis
  - g. Amino acid, organic acid and fatty acid metabolic and malabsorption disorder
  - h. Cystic fibrosis

**and**

- Documentation of at least two failed formula alternatives

### **LIMITATION:**

Standard formula for newborns or infants is not considered to be medically necessary and is therefore not covered. Standard infant formula for normal infants or for infants with medical illness or disability is considered to be non-medical in nature, as nutrition is a normal need for all infants.

### **EXCLUSIONS:**

### **Commercial Business Segment:**

Oral nutrition products and/or supplements **NOT** used to treat inborn errors of metabolism are **NOT COVERED** including, but not limited to:

- Formula or Supplements to treat a deficient diet or to provide an alternative source of nutrition in conditions such as, but not limited to, allergies, obesity, hypo- or hyper-glycemia **and** gastrointestinal disorders; **or**

- Lactose-free foods; **or**
- Banked breast milk; **or**
- Standardized or specialized infant formulas (including over-the-counter infant formulas (such as Similac, Enfamil, etc.)

Grocery items and food additives as defined under section V. Additional Definitions or medical food products are **NOT COVERED**.

Enteral products for the diagnosis of “failure to thrive” are **NOT COVERED**.

Enteral products for the purpose of augmenting normal dietary sources of nutrition are **NOT COVERED**.

Digestive enzyme cartridges (e.g. Relizorb) used in conjunction with enteral nutrition therapy is considered to be of unproven benefit and therefore not medically necessary and **NOT COVERED**.

**NOTE:** May be considered on a per-case basis through the Program Exception process for Medicaid Business segment members ages 5 years and older with exocrine pancreatic insufficiency who are partially or completely unable to hydrolyze fats in enteral formula.

Low-protein modified food products are **NOT COVERED** for inherited errors of metabolism because they do not meet the policy definition of medical foods or nutritional formulas. This information is in accordance with the state mandate. Pennsylvania Mandate does not require coverage for low-protein modified food products such as breads, pasta, pastry shells, and rice pizza shells that can be purchased commercially without a prescription and are used in the dietary management of rare hereditary genetic metabolic disorders such as PKU, branched chain-ketoneuria, galactosemia, and homocystinuria.

### **Medicaid Business Segment:**

Any requests for services, that do not meet criteria set in the PARP, may be evaluated on a case by case basis.

**CODING ASSOCIATED WITH:** Enteral nutrition

*The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at [www.cms.gov](http://www.cms.gov) or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements*

### **CPT/HCPCS Coding:**

B4034 – B4162

B9000

B9002

B9998

T2101 – human breast milk processing, storage and distribution only

S9342 home therapy; enteral nutrition via pump; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (enteral formula and nursing visits coded separately), per diem

S9343 home therapy; enteral nutrition via bolus; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (enteral formula and nursing visits coded separately), per diem

S9432 Medical foods for non-inborn errors of metabolism

S9433 medical food nutritionally complete, administered orally, providing 100% of nutritional intake

S9435 Medical foods for inborn errors of metabolism

S9434 Modified solid food supplements for inborn errors of metabolism

For amino acid elemental formula:

B4161 Enteral formula, for pediatrics, hydrolyzed/amino acids and peptide chain proteins, includes fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit

B4105- in-line cartridge containing digestive enzyme(s) for enteral feeding,

Current Procedural Terminology (CPT®) © American Medical Association: Chicago, IL

**LINE OF BUSINESS:**

**Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD's and NCD's will supercede this policy. For PA Medicaid Business segment, this policy applies as written.**

**REFERENCES:**

Centers for Medicare and Medicaid Services (CMS). National Coverage Determination (NCD). 180.2: Enteral and parenteral nutrition therapy.

[http://www.cms.hhs.gov/mcd/viewnacd.asp?ncd\\_id=180.2&ncd\\_version=1&basket=ncd%3A180%2E2%3A1%3AEnteral+and+Parenteral+Nutritional+Therapy](http://www.cms.hhs.gov/mcd/viewnacd.asp?ncd_id=180.2&ncd_version=1&basket=ncd%3A180%2E2%3A1%3AEnteral+and+Parenteral+Nutritional+Therapy).

NHIC. Enteral nutrition. L5041

[http://www.cms.hhs.gov/mcd/viewarticle.asp?article\\_id=25229&article\\_version=7&basket=article%3A25229%3A7%3AEnteral+Nutrition+%E2%80%93+Policy+Article+%E2%80%93+Effective+April+2005%3ADME+MAC%3ANHIC+%2816003%29](http://www.cms.hhs.gov/mcd/viewarticle.asp?article_id=25229&article_version=7&basket=article%3A25229%3A7%3AEnteral+Nutrition+%E2%80%93+Policy+Article+%E2%80%93+Effective+April+2005%3ADME+MAC%3ANHIC+%2816003%29)

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Dellon E., Gonsalves N., et al. ACG Clinical Guideline: Evidenced based approach to the diagnosis and management of esophageal eosinophilia and eosinophilic esophagitis. *Am J Gastro.* 2013; 108:679-692.

The General Assembly of Pennsylvania, House Bill 1436, Act 158.

<http://www.legis.state.pa.us/cfdocs/legis/PN/Public/btCheck.cfm?txtType=PDF&sessYr=2013&sessInd=0&billBody=H&billTyp=B&billNbr=1436&pn=4244>

Pennsylvania Department of Human Services. Medical Assistance Bulletin 01-17-31 Pasteurized Donor Human Milk

Freedman S, Orenstein D, Black P, et al. Increased fat absorption from enteral formula through an in-line digestive cartridge in patients with cystic fibrosis. *J Pediatr Gastroenterol Nutr.* 2017;65(1):97-101

Nguyen DL. Guidance for supplemental enteral nutrition across patient populations. *Am J Manag Care.* 2017;23(12 Suppl):S210-S219.

Freedman SD. Options for addressing exocrine pancreatic insufficiency in patients receiving enteral nutrition supplementation. *Am J Manag Care.* 2017;23(12 Suppl):S220-S228.

Alkaade S, Vareedayah AA. Primer on exocrine pancreatic insufficiency, fat malabsorption, and fatty acid abnormalities. *Am J Manag Care.* 2017;23(12 Suppl):S203-S209.

Personal communication from PA Dept. of Human Services re: Coverage position for solid low-protein food. 080218

Pennsylvania Department of Human Services. MCOPS Memo #08/2019-011

This policy will be revised as necessary and reviewed no less than annually.

**Devised:** 12/10

**Revised:** 7/13, 9/15 (added Act 158 provisions); 7/16; 8/17 (added human donor breast milk); 6/18 (add exclusion); 7/19 (add indication and exclusion) 5/21 (add coverage and exclusion language)

**Reviewed:** 12/11, 12/12, 8/14, 7/20, 5/22

Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Coverage for experimental or investigational treatments, services and procedures is specifically excluded under the member's certificate with Geisinger Health Plan. Unproven services outside of an approved clinical trial are also specifically excluded under the member's certificate with Geisinger Health Plan. This policy does not expand coverage to services or items specifically excluded from coverage in the member's certificate with Geisinger Health Plan. Additional information can be found in MP015 Experimental, Investigational or Unproven Services.

Prior authorization and/or pre-certification requirements for services or items may apply. Pre-certification lists may be found in the member's contract specific benefit document. Prior authorization requirements can be found at <https://www.geisinger.org/health-plan/providers/ghp-clinical-policies>

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