

| | | |
|---|--|---|
|  | Nutritional Supplements Guideline | |
| Guideline # 6190 | Categories Clinical → Care Management CM, TCHP Guidelines, Utilization Management UM | This Guideline Applies To: Texas Children's Health Plan |
| | | Document Owner Bhavana Babber |

GUIDELINE STATEMENT:

Texas Children's Health Plan (TCHP) performs authorization of most nutritional products.

DEFINITIONS:

Enteral Nutrition: The provision of nutritional requirements through a tube into the stomach; it may be administered by syringe, gravity, or pump.

Exocrine Pancreatic Insufficiency: a condition characterized by deficiency of the secreted pancreatic digestive enzymes resulting in the inability to digest food properly and poor absorption of nutrients. Most commonly seen in individuals with cystic fibrosis.

Food allergy or hypersensitivity: A clinically abnormal response believed to be caused by an immunologic reaction resulting from the ingestion of a food or food additive.

Food anaphylaxis: A classic allergic hypersensitivity reaction to food or food additives involving IgE antibody that occurs rapidly and may be life threatening.

Food challenge: This is an evaluation technique that may be used to assist in the diagnosis of food or eating-related disorders. After an adequate time with the exclusion of suspected foods (usually a week or two), the suspected food or foods are administered under close supervision in a dose escalation manner with proper observation periods between doses. Food challenges may be done in an open manner with the subject aware of what they are being given, with the subject unaware, or with both the subject and physician unaware.

Oral Nutrition: The intake of food through the mouth and esophagus to provide necessary nutrients for health and growth.

Proximal gastrointestinal tract: The section of the GI tract from the mouth to the small bowel

PRIOR AUTHORIZATION GUIDELINES

1. TCHP will not cover the following (excluded from Comprehensive Children's Program):
 - 1.1. Nutritional products that are traditionally used for infant feeding
 - 1.2. Nutritional products for the primary diagnosis of failure to thrive, failure to gain weight, or lack of growth. The underlying cause of failure to thrive, gain weight, and lack of growth is required.
 - 1.3. Nutritional bars
 - 1.4. Nutritional products for members who could be sustained on an age-appropriate diet

2. Nutritional products may be reimbursed with the following procedure codes:

| CPT Code | Description |
|----------|---|
| B4100 | Food Thickener, Administered Orally, Per Ounce |
| B4103 | Enteral Formula, For Pediatrics, Used To Replace Fluids And Electrolytes (E.G. Clear Liquids), 500 MI = 1 Unit |
| B4104 | Additive For Enteral Formula (E.G. Fiber) |
| B4149 | Enteral formula, manufactured blenderized natural foods with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit |
| B4150 | Enteral formula, nutritionally complete with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, May include fiber, administered through an enteral feeding tube, 100 calories = 1 unit |
| B4152 | Enteral formula, nutritionally complete, calorically dense (equal to or greater than 1.5 kcal/ml) with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, May include fiber, administered through an enteral feeding tube, 100 calories = 1 unit |
| B4153 | Enteral formula, nutritionally complete, hydrolyzed proteins (amino acids and peptide chain), includes fats, carbohydrates, vitamins and minerals, May include fiber, administered through an enteral feeding tube, 100 calories = 1 unit |
| B4154 | Enteral formula, nutritionally complete, for special metabolic needs, excludes inherited Disease of metabolism, includes altered composition of proteins, fats, carbohydrates, vitamins and/or minerals, May include fiber, administered through an enteral feeding tube, 100 calories = 1 unit |
| 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 |
| B4105 | Immobilized Lipase Cartridges (Relisorb), one cartridge per 500 ml of formula, max 2 per day, for the aided digestion and absorption of fats in members with exocrine pancreatic insufficiency. |
| B4157 | Enteral formula, nutritionally complete, for 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 |
| B4158 | Enteral formula, for pediatrics, nutritionally complete with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, May include fiber and/or iron, administered through an enteral feeding tube, 100 calories = 1 unit |
| B4159 | Enteral formula, for pediatrics, nutritionally complete soy based with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, May include fiber and/or iron, administered through an enteral feeding tube, 100 calories = 1 unit |
| B4160 | Enteral formula, for pediatrics, nutritionally complete calorically dense (equal to or greater than 0.7 kcal/ml) with intact nutrients, 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 an 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 |

3. B9998 is a miscellaneous nutritional product code and must include an appropriate modifier in order to be considered.
 - 3.1. Exception: B9998 may be used for requesting donor breast milk or a carrying case for a portable breast pump and will not have an associated modifier
 - 3.2. U1: Disposable G-tube adapter set (4 per month)
 - 3.3. U2: Nonobturated gastrostomy or jejunostomy tube with insertion supplies and extensions (2 per rolling year)
 - 3.4. U3: Low profile enteral extension set (4 per month)
 - 3.5. U4: Standard gastrostomy tube (2 per rolling year)
 - 3.6. U5: Standard enteral extension set (4 per month)

4. Immobilized Lipase Cartridges (B4105) are a benefit when provided by a durable medical equipment supplier in the home setting and requires prior authorization. The following criteria must be met:
 - 4.1. The member has exocrine pancreatic insufficiency
 - 4.2. The member utilizes an enteral feeding pump
 - 4.3. The member utilizes a compatible formula and the amount of formula (mL) the client is receiving daily is documented in the request.
 - 4.4. The request does not exceed the maximum benefit of 2 cartridges per day/62 per month. Normal usage is one cartridge per 500 mL of formula.

5. Prior authorization for nutritional products is not required for a member who is 20 years of age and younger and who meets at least one of the following criteria:
 - 5.1. Member receives all or part of their nutritional intake through a tube.
 - 5.2. Member has a metabolic disorder that has been documented with one of the diagnosis codes listed in the TMHP manual for Nutritional Products:

6. All requests for prior authorization for nutritional products are received via online submission, fax, phone or mail by the Utilization Management Department and processed during normal business hours.

7. The Utilization Management professional receiving the request evaluates the submitted information to determine if the documentation supports the nutritional supplement request as a covered benefit.

8. Prior authorization may be given for up to 12 months. Prior authorization may be recertified with documentation that supports the ongoing medical necessity of the requested nutritional products.

9. To request prior authorization for nutritional formula, supplies, or equipment, the following documentation must be provided:
 - 9.1. A completed Prior Authorization Request Form that prescribes the nutritional supplement:
 - 9.1.1. Must be signed and dated by a prescribing physician who was familiar with the member before making the authorization request.
 - 9.1.2. Must include the procedure codes and numerical quantities for the services requested.
 - 9.2. Accurate diagnostic information pertaining to the underlying diagnosis or condition as well as any other medical diagnoses or conditions, to include:
 - 9.2.1. The member's overall health status
 - 9.2.2. Height and weight.
 - 9.2.3. Growth history and growth charts for members under the age of 20.

- 9.2.4. Why the member cannot be maintained on an age-appropriate diet OR noting that enteral nutritional products for tube feedings are the member's sole or primary source of nutrition
 - 9.2.5. Other formulas tried and why they did not meet the member's needs
 - 9.3. Diagnosis or conditions (including the appropriate International Classification of Diseases, Tenth Revision, Clinical Modification [ICD-10-CM] code)
 - 9.4. The goals and timelines on the medical plan of care
 - 9.5. Total caloric intake prescribed by the physician
 - 9.6. Acknowledgement that the member has a feeding tube in place when applicable
- 10.** Nutritional products that are provided to WIC members are carved-out of the Medicaid Managed Care Program and must be billed to TMHP for payment consideration. Carved-out services are those that are rendered to Medicaid Managed Care members but are administered by TMHP and not the member's managed care organization (MCO).
- 11.** Medical necessity for nutritional products is generally established for members 21 years of age or older when all or part of the member's nutritional intake is received through a feeding tube, and the enteral formula is:
- 11.1. The member's sole source of nutrition
 - 11.2. The member's primary source of nutrition (more than 70 percent of the caloric intake needed to maintain the member's weight)
- 12.** Medical necessity for nutritional products is generally established for members 20 and younger in any of the following situations:
- 12.1. Member receives all or part of their nutritional intake through a tube
 - 12.2. Oral Nutrition is considered medically necessary, when:
 - 12.2.1. The condition is chronic and is expected to last for an undetermined or prolonged period of time such as:
 - 12.2.1.1. Anatomic structures of the proximal gastrointestinal tract that prevents food from reaching the stomach (e.g. esophageal cancer), impairing digestion and absorption;
 - 12.2.1.2. Neurological disorders that impair swallowing or chewing;
 - 12.2.1.3. Diagnosis of inborn errors of metabolism that require modified food products (for example, phenylketonuria (PKU), tyrosinemia, homocystinuria, maple syrup urine disease, propionic acidemia and methylmalonic acidemia);

- 12.2.1.4. Prolonged nutrient losses due to malabsorption syndromes or short-bowel syndrome, diabetes, celiac disease, chronic pancreatitis, renal dialysis, draining abscess or wounds
- 12.2.1.5. Increased metabolic and/or caloric needs due to excessive burns, infection, trauma, prolonged fever, hyperthyroidism, or illnesses that impair caloric intake and/or retention
- 12.2.1.6. Allergic or eosinophilic enteritis (colitis/proctitis, esophagitis, gastroenteritis);
- 12.2.1.7. Cystic fibrosis with malabsorption;
- 12.2.1.8. Crohn's disease;
- 12.2.1.9. Disorders of gastrointestinal motility such as chronic intestinal pseudo-obstruction;
- 12.2.1.10. Individuals who will become malnourished or suffer from severe disorders such as physical disability, mental retardation or death if the nutritional therapy is not instituted; or
- 12.2.1.11. GE reflux with failure to thrive
- 12.2.1.12. Severe food allergies, those which if left untreated will cause malnourishment, chronic physical disability, mental retardation or death
- 12.2.2. Adequate nutrition is not possible by dietary adjustment using age appropriate foods

13. The following are considered NOT Medically necessary:

- 13.1. Oral Nutrition for lack of appetite or cognitive conditions is not covered (e.g., lack of appetite secondary to stimulant medications, or “picky eaters”).
- 13.2. Formulas for the treatment of mild and moderate food allergies or food intolerance are not covered (severe food allergies, those which if left untreated will cause malnourishment, chronic physical disability, mental retardation or death, may be medically necessary).

14. Medical Necessity criteria by product type:

- 14.1. Food thickener may be considered for members under the age of 20 with a swallowing disorder.
 - 14.1.1. Units of food thickener is determined by the number of ounces of thickener required to thicken 4 oz of liquid. One ounce of thickener product is one unit of thickener.
 - 14.1.2. The standard amount of thickener used is presumed to be 0.2 ounces (0.2 units) of thickener per 4 oz of liquid to be thickened. Additional amounts of thickener

to make thicker fluids will require documentation of medical necessity for the level of thickness desired.

14.1.3. The monthly amount of thickener required is based upon the monthly amount of liquid to be thickened and consumed.

14.2. Nutritional pudding products may be considered for members under the age of 20 who have a documented oropharyngeal motor dysfunction and receive greater than 50 percent of their daily caloric intake from a nutritional pudding product.

14.3. Requests for electrolyte replacement products, such as Pedialyte or Oralyte, require documentation of medical necessity, including:

14.3.1. The underlying acute or chronic medical diagnoses or conditions that indicate the need to replace fluid and electrolyte losses.

14.3.2. The presence of mild to moderate dehydration due to the persistent mild to moderate diarrhea or vomiting.

14.3.3. They are not intended for members with:

14.3.3.1. Intractable vomiting

14.3.3.2. Adynamic ileus

14.3.3.3. Intestinal obstruction or perforated bowel

14.3.3.4. Anuria, oliguria, or impaired homeostatic mechanism

14.3.3.5. Severe, continuing diarrhea, when intended for use as the sole therapy

15. Requests that do not meet the criteria established by this procedure will be referred to a TCHP Medical Director/Physician Reviewer for review and the Denial Policy will be followed.

16. Preauthorization is based on medical necessity and not a guarantee of benefits or eligibility. Even if preauthorization is approved for treatment or a particular service, that authorization applies only to the medical necessity of treatment or service. All services are subject to benefit limitations and exclusions. Providers are subject to State and Federal Regulatory compliance and failure to comply may result in retrospective audit and potential financial recoupment.

REFERENCES:

Peer reviewed literature:

- Haddad RY, Thomas DR. Enteral nutrition and enteral tube feeding. Review of the evidence. Clin Geriatr Med. 2002; 18(4):867-881.
- Høst A, Koletzko B, Dreborg S, et al. Dietary products used in infants for treatment & prevention of food allergy. Joint Statement of the European Society for Paediatric Allergology and Clinical Immunology (ESPACI) Committee on Hypoallergenic Formulas and the European Society for

Paediatric Gastroenterology, Hepatology and Nutrition (ESPGHAN) Committee on Nutrition. Arch Dis Child. 1999; 81(1):80-84.

- Joly F, Dray X, Corcos O, et al. Tube feeding improves intestinal absorption in short bowel syndrome patients. Gastroenterology. 2009; 136(3):824-831.
- Klek S, Hermanowicz A, Dziwiszek G, et al. Home enteral nutrition reduces complications, length of stay, and health care costs: results from a multicenter study. Am J Clin Nutr. 2014; 100(2):609-615.
- Nakajoh K, Nakagawa T, Sekizawa K, et al. Relation between incidence of pneumonia and protective reflexes in post-stroke patients with oral or tube feeding. J Intern Med. 2000; 247(1):39-42.
- Riva E, Fiocchi A, Fiori L, Giovannini M. Prevention and treatment of cow's milk allergy. Arch Dis Child. 2001; 84(1):91.
- Schwenk WF 2nd. Specialized nutrition support: the pediatric perspective. JPEN J Parenter Enteral Nutr. 2003; 27(3):160-167, viii.

Stevens J, Wyatt C, Brown P, et al. Absorption and safety with sustained use of Relizorb Evaluation (ASSURE) Study in patients with cystic fibrosis receiving enteral feeding. J Pediatr Gastroenterol Nutr. 2018; 67(4):527-532.

Government Agency, Medical Society, and Other Publications:

Texas Medicaid Provider Procedures Manual Available at:

http://www.tmhp.com/Pages/Medicaid/Medicaid_Publications_Provider_manual.aspx Accessed February 10, 2021.

- American Academy of Family Physicians (AAFP). Failure to Thrive: An Update. S. Cole, J. Lanham. Am Fam Physician. 2011 Apr 1;83(7):829-834. Available at: <http://www.aafp.org/afp/2011/0401/p829.html>. Accessed February 10, 2021.
- American Academy of Family Physicians (AAFP). Failure to Thrive: A Practical Guide. GRETCHEN J. HOMAN, MD, University of Kansas School of Medicine, Wichita, Kansas Am Fam Physician. 2016 Aug 15;94(4):295-299. Available at: <http://www.aafp.org/afp/2016/0815/p295.html>. Accessed. February 10, 2021
- American Academy of Pediatric Consensus Statement 2002 Reaffirmed 2006. Reimbursement for Foods for Special Dietary Use @ <http://pediatrics.aappublications.org/content/111/5/1117>. Accessed February 10, 2021.
- UNICEF. <http://www.unicef.org/progressforchildren/2006n4/malnutritiondefinition.html>. Accessed July 24, 2018.
- World Health Organization (WHO). Available at: <http://www.who.int/nutrition/topics/malnutrition/en/index.html>. Accessed February 10, 2021.

| Status | Date | Action |
|---------------|-------------|---|
| Approved | 3/11/21 | Clinical & Administrative Advisory Committee Reviewed and Approved for Implementation |

Original Creation Date: 10/21/2016

Version Creation Date: 02/28/2021

Effective Date: 03/23/2021