

	<h2>Nutritional Supplements Guideline</h2>	
<p>Guideline # 6190</p>	<p>Categories Clinical → Care Coordination, Care Coordination – Utilization management , TCHP Guidelines</p>	<p>This Guideline Applies To: Texas Children's Health Plan</p>
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GUIDELINE STATEMENT:

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

DEFINITIONS:

Allowed Practitioner – means an individual that maintains a valid and registered prescriptive authority agreement in accordance with Texas Occupations Code, Chapter 157, Subchapter B; and is a physician assistant (PA) licensed in Texas under Texas Occupations Code Chapter 204 or an advanced practice registered nurse licensed by the Texas Board of Nursing as a certified nurse practitioner or a clinical nurse specialist.

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.

Medical Supplies - means health care related items that are consumable or disposable or cannot withstand repeated use by more than one individual, that are required to address an individual medical disability, illness or injury.

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

Plan of Care – means a written regimen established and periodically reviewed by a physician or an allowed practitioner in consultation with home health agency staff, which meets the POC standards at 42 CFR §484.60 and 1 TAC §354.1037.

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 ML = 1 Unit
B4104	Additive For Enteral Formula (E.G. Fiber)
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.
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
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 may be reimbursed as needed without a modifier or with the following modifiers and limitations:

Procedure Codes	Descriptions	Limitations
B9998		As Needed
B9998 with modifier U1	Disposable G-tube adapter set	4 per month
B9998 with modifier U2	Nonobtured gastrostomy or jejunostomy tube with insertion supplies and extensions	2 per rolling year

B9998 with modifier U3	Low profile enteral extension set	4 per month
B9998 with modifier U4	Standard gastrostomy tub	2 per rolling year
B9998 with modifier U5	Standard enteral extension set	4 per month

3.1.1. A backpack or carrying case for a portable enteral nutrition infusion pump may be a benefit of Home Health Services, when medically necessary and prior authorized, using procedure code B9998. The following criteria must be met:

3.1.1.1. The client requires enteral feedings lasting greater than eight hours continuously, or feeding interval exceed the time that the client must be away from home to:

- 3.1.1.1.1. Attend school or work
- 3.1.1.1.2. participate in extensive outpatient therapies ordered by the physician or allowed practitioner
- 3.1.1.1.3. attend frequent, multiple medical appointments

3.1.1.2. the client is ambulatory, or uses a wheelchair which will not support the use of a portable pump by other means, such as an IV pole

3.1.1.3. the portable enteral feeding pump is client owned

4. Immobilized Lipase Cartridges (B4105) are a benefit when provided by a durable medical equipment supplier in the home setting and require 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 member is receiving daily is documented in the request.

4.1.1.1. One cartridge can be used with up to 500 mL of formula with a maximum of two cartridges used per day. Procedure code B4105 will be limited to 62 per month.

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 current Texas Medicaid Provider Procedures Manual, Durable Medical Equipment, Medical Supplies, and Nutritional Products Handbook.

6. All requests for prior authorization for nutritional products are received via fax, mail and electronically 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. Initial prior authorization may be given for up to 6 months. Prior authorization may be recertified with documentation from the ordering physician or allowed practitioner that supports the ongoing medical necessity of the requested nutritional products for a period of up to 12 months.
9. If there is a change in the Member's status before expiration of the authorization period, the MCO must ensure that the DME provider work with the requesting physician or Allowed Practitioner to modify the plan of care and seek a new authorization or change in authorization
10. To request prior authorization for nutritional formula, supplies, or equipment, the following documentation must be provided:
 - 10.1. A completed CCP Prior Authorization Form that prescribes the nutritional supplement:
 - Must be signed and dated by a prescribing physician who was familiar with the member before making the authorization request.
 - Must include the procedure codes and numerical quantities for the services requested.
 - 10.2. Accurate diagnostic information pertaining to the underlying diagnosis or condition as well as any other medical diagnoses or conditions, to include:
 - The member's overall health status.
 - Height and weight.
 - Growth history and growth charts for members under the age of 20.
 - 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
 - Other formulas tried and why they did not meet the member's needs
 - 10.3. Diagnosis or conditions (including the appropriate International Classification of Diseases, Tenth Revision, Clinical Modification [ICD-10-CM] code)
 - 10.4. The goals and timelines on the medical plan of care
 - 10.5. Total caloric intake prescribed by the physician
 - 10.6. Acknowledgement that the member has a feeding tube in place when applicable
11. 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).

11.1 Nutrition products that are provided to other Medicaid Managed Care Program clients (other than WIC clients) are not carved out and must be submitted to the managed care organization that administers the client's Medicaid managed care benefits.

12. Prior authorization **is** required for **ALL** nutritional products for members over age 21.

12.1 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:

- The member's sole source of nutrition
- The enteral tube feeding is considered the primary source of nutrition when it comprises more than 70 percent of the caloric intake needed to maintain the member's weight.

12.2 Prior authorization for members over age 21 may be given for up to 6 months.

Recertification may be given with documentation that supports ongoing medical necessity.

13 Medical necessity for nutritional products is generally established for members 20 and younger in any of the following situations:

13.1 Member receives all or part of their nutritional intake through a tube

13.2 Oral Nutrition is considered medically necessary, when:

- Anatomic structures of the proximal gastrointestinal tract that prevents food from reaching the stomach (e.g. esophageal cancer), impairing digestion and absorption;
- Neurological disorders that impair swallowing or chewing;
- 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);
- Prolonged nutrient losses due to malabsorption syndromes or short-bowel syndrome, diabetes, celiac disease, chronic pancreatitis, renal dialysis, draining abscess or wounds
- Increased metabolic and/or caloric needs due to excessive burns, infection, trauma, prolonged fever, hyperthyroidism, or illnesses that impair caloric intake and/or retention
- Allergic or eosinophilic enteritis (colitis/proctitis, esophagitis, gastroenteritis);
- Cystic fibrosis with malabsorption;
- Crohn's disease;
- Disorders of gastrointestinal motility such as chronic intestinal pseudo-obstruction;

- 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;
- GE reflux causing failure to thrive
- Severe food allergies, those which if left untreated will cause malnourishment, chronic physical disability, mental retardation or death

13.3 Adequate nutrition is not possible by dietary adjustment using age appropriate foods

14. The following are considered **NOT** Medically necessary:

14.1 Oral Nutrition for lack of appetite or cognitive conditions is not covered (e.g., lack of appetite secondary to stimulant medications, or “picky eaters”).

14.2 Formulas for the treatment of **mild and moderate food allergies or food intolerance** are not covered unless the request meets criteria listed in section 12.2.

15. Medical Necessity criteria by product type:

15.1 Food thickener may be considered for members under the age of 20 with a swallowing disorder.

- Units of food thickener are 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.
- 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. For example, a member drinking 24 oz of liquid per day would need 1.2 units of thickener per day.
- The monthly amount of thickener required is based upon the monthly amount of liquid to be thickened and consumed.

15.2 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.

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

- The underlying acute or chronic medical diagnoses or conditions that indicate the need to replace fluid and electrolyte losses.
- The presence of mild to moderate dehydration due to the persistent mild to moderate diarrhea or vomiting.
- They are not intended for members with:
 - Intractable vomiting

- Adynamic ileus
- Intestinal obstruction or perforated bowel
- Anuria, oliguria, or impaired homeostatic mechanism
- Severe, continuing diarrhea, when intended for use as the sole therapy

16. 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.
17. 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.
18. For members over age 21, providers must submit requests for medically necessary DME for members and supplies not listed as a covered benefit under Texas Medicaid through TCHP's exceptional circumstances process. DME and supplies allowed under the exceptional circumstances provision must be prior authorized by TCHP according to the TCHP Case by Case Procedure Guideline.
19. The Home Health DME and Supplies exceptional circumstances provision is not an available process to pursue for members who receive prior authorization denials for medical necessity or technical reasons (e.g., missing essential fields, incomplete documentation)

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