



Life-Sustaining Enteral Nutrition

Last Revision/Review Date: March 17, 2021

P&P # C.6.05

Policy

This Medical Policy does not constitute medical advice. When deciding coverage, the enrollee's specific plan document must be referenced. The terms of an enrollee's plan document (Certificate of Coverage (COC) or Summary Plan Description (SPD)) may differ from this Medical Policy. In the event of a conflict, the enrollee's specific benefit plan document supersedes this Medical Policy. All reviewers must first identify enrollee eligibility, any federal or state regulatory requirements, and the plan benefit coverage prior to use of this Medical Policy. Other Policies and Coverage Determination Guidelines may apply. Quartz reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary.

Procedure

A. Documentation Required:

In order to facilitate the authorization process referral requests must include the following:

1. Medical diagnosis of a qualifying condition:
 - a. Physician evaluation and order(s);
 - b. Expected duration of condition;
 - c. Ongoing evaluation and management;
2. Nutritional assessment;
3. Dietician recommendations for treatment;
4. Response to current nutritional feeding or supplementation.

B. Criteria for Medical Necessity:

General Criteria for Enteral Nutrition or Supplementation

1. Prescribed enteral nutrition or supplementation is considered to be medically necessary if it meets **ALL** of the following criteria:
 - a. The enteral nutrition or supplementation must be fed through a feeding tube; **AND**
 - b. The patient would be unable to obtain sufficient nutrients without the enteral nutrition; **AND**
 - c. Dietary adjustment and/or oral supplements alone would not provide sufficient nutrients; **AND**
 - d. The patient has **ONE** of the following conditions, that is expected to be permanent or of indefinite duration:
 - i. An anatomical or motility disorder of the gastrointestinal tract that prevents food from reaching the small bowel; **OR**
 - ii. Disease of the small bowel that impairs absorption of an oral diet; **OR**
 - iii. A central nervous system/neuromuscular condition that significantly impairs the ability to safely ingest oral nutrition.

Criteria for Specific Medical Conditions

Life sustaining nutritional feeding or supplementation for specific medical conditions is considered to be medically necessary if **ANY** of the following is met:

2. The prescribed oral nutrition or supplementation is for patients with inborn errors of metabolism or inherited metabolic disease, which include (see definitions):
 - a. Maple Syrup Urine Disease (MSUD); **OR**
 - b. Phenylketonuria (PKU); **OR**
 - c. Homocystinuria; **OR**
 - d. Tyrosinemia. **OR**

3. *Ketogenic formula* for bottle-fed infants or enterally fed children:
 - a. For **initial 3-month** ketogenic formula trial that meets **ALL** of the following:
 - 1) Patient has a drug resistant seizure disorder (i.e., unsuccessful treatment trial of at least 2 antiseizure drugs) **OR** rare metabolic genetic disorder (pyruvate dehydrogenase deficiency (PDH) or Glucose transporter-1 deficiency syndrome (GLUT1), **AND**
 - 2) The ketogenic diet is under direct supervision of a dietician and neurologist in an epilepsy center with experience in this therapy, **AND**
 - 3) **ONE** of the following:
 - a) Children ages 2-18 who meet general criteria for enteral feeding (see above), **OR**
 - b) Infant/child under age 2.

 - b. For ketogenic diet **continuation after initial 3-month trial up to 2 years** of diet therapy that meets **ALL** of the following:
 - 1) Evidence of response to initial trial with clinically relevant decrease in seizure frequency, **AND**
 - 2) Evidence of compliance with diet therapy, **AND**
 - 3) The ketogenic diet is under direct supervision of a dietician and neurologist in an epilepsy center with experience in this therapy, **AND**
 - 4) **ONE** of the following:
 - a) Children ages 2-18 who meet general criteria for enteral feeding (see above). NOTE: Persons who exceed age 18 during the continuation of diet therapy can continue for 2 years total therapy, **OR**
 - b) Infant or child under age 2 up until the age of 2.

 - c. For ketogenic diet **continuation after 2 years of diet therapy** that meet **ALL** of the following:
 - 1) Evidence of response to trial with clinically relevant decrease in seizure frequency; **AND**
 - 2) Worsening of seizure frequency with weaning or discontinuation of ketogenic diet therapy **OR** a diagnosis of Glucose transporter-1 deficiency syndrome (GLUT1); **AND**
 - 3) Evidence of compliance with diet therapy; **AND**
 - 4) The ketogenic diet is under direct supervision of a dietician and neurologist in an epilepsy center with experience in this therapy; **AND**
 - 5) Aged 2-18 who meet general criteria for enteral feeding (see above).

NOTE: Determination of the medical necessity of initial and continued ketogenic formula diet use in persons with seizure disorder who are older than age 18 and exclusively enterally fed requires Medical Director review.

4. Prescribed enteral nutrition or oral supplementation with medium chain triglycerides formula (e.g. Enfaport™) for children and adults who meet ALL of the following:
 - a. Diagnosis of refractory chylothorax or chylous ascites; **AND**
 - b. Patient is not currently receiving parenteral nutrition beyond free fatty acid supplementation.

NOTE: The initial approval is for a two-month time period. After the initial two-month period, medical director approval must be obtained for continuing therapy.

C. Indications Considered Experimental and Investigational: (*Not an all-inclusive list*):

1. Digestive enzyme cartridge (e.g., Relizorb™, code B4105) for use with enteral tube feedings

D. Indications Considered Not Medically Necessary: (*Not an all-inclusive list*):

1. Grocery products, products available for purchase without a prescription, or over-the-counter infant formulas (e.g., Similac, Nutramigen, Enfamil);
2. Medical food products that are prescribed without a diagnosis requiring such foods;
3. Pre-packaged blenderized products created from pureed or liquified whole foods, or organic pre-packaged blenderized foods (e.g., Nourish, Liquid Hope, Compleat® Organic Blends or Compleat® Pediatric Organic Blends)
4. Organic medical food products (e.g., Nourish, Liquid Hope);
5. Medical food products that have no proven therapeutic benefit without an underlying disease, condition or disorder; used as a substitute for acceptable standard dietary interventions; or used exclusively for nutritional supplementation (i.e. Ensure®, BOOST®);
6. Foodstuffs which may be commercially promoted as a “nutritional supplement” or “formula” to include **ANY** of the following items for any condition or indication:
 - a. Standardized or specialized infant formula for conditions other than inborn errors in metabolism or inherited metabolic diseases; including, but not limited to: (*Not all inclusive*)
 - i. Food allergies; multiple protein intolerances;
 - ii. Lactose intolerances;
 - iii. Gluten-free formula for gluten-sensitive enteropathy/celiac disease;
 - iv. Milk allergies;
 - v. Sensitivities to intact protein;
 - vi. Protein or fat maldigestion;
 - vii. Intolerances to soy formulas or protein hydrolysates
 - b. Food thickeners;
 - c. Dietary and food supplements;
 - d. Lactose-free products; products to aid in lactose digestion;
 - e. Gluten-free food products;
 - f. Weight-loss foods and formula or products to aid weight loss;
 - g. Normal grocery items;
 - h. Low carbohydrate diets;
 - i. Baby food;
 - j. Grocery items that can be blenderized and used with an enteral feeding system;
 - k. Nutritional supplement puddings;
 - l. High protein powders and mixes;
 - m. Oral vitamins and minerals;
 - o. Ketogenic diet formula for adults for the treatment of obesity or Alzheimer’s disease.

CPT/HCPCS Codes:

B4149-B4162	Enteral formula (administered through an enteral feeding tube) NOTE: For code B4149, only Compleat® Pediatric tube feeding product is covered.
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

References:

American Society for Parenteral and Enteral Nutrition (A.S.P.E.N.). Enteral Nutrition Practice Recommendations. J Parenter Enteral Nutr. 2009;33(3):122-167.

CMS Pub 100-03 Part 3; Centers for Medicare and Medicaid Services. Section 180.2 National Coverage Determination for Enteral and Parenteral Nutritional Therapy.

Hayes, Inc. Search & Summary. Hospitalization for Initiation of Ketogenic Diet for Treatment of Refractory Seizures in Children. Publication Date March 14, 2019. Archived April 13, 2020. Accessed June 2, 2020.

Jackson CF, Makin SM, Marson AG, Kerr M. Non-pharmacological interventions for people with epilepsy and intellectual disabilities. Cochrane Database of Systematic Reviews 2015, Issue 9. Art. No.: CD005502. DOI: 10.1002/14651858.CD005502.pub3.

Kossoff, EHW. Ketogenic dietary therapies for the treatment of epilepsy. UpToDate. Last updated April 28, 2020. Accessed Jan 4, 2021.

Kossoff EH, Henry BJ, Cervenka MC. Transitioning pediatric patients receiving ketogenic diets for epilepsy into adulthood. Seizure. 2013;22(6):487-489.

Kossoff, Eric H et al. "Optimal clinical management of children receiving dietary therapies for epilepsy: Updated recommendations of the International Ketogenic Diet Study Group." *Epilepsia open* vol. 3,2 175-192. 21 May. 2018, doi:10.1002/epi4.12225

Wisconsin Newborn Screening Test Panel

<http://www.slh.wisc.edu/clinical/newborn/health-care-professionals-guide/nbs-test-panel-of-diseases/>

Accessed June 2, 2020.

UpToDate. Management of Chronic Pleural Effusion in the Neonate. [Church JT, Antunez AG, Dean A, et al. Evidence-based management of chylothorax in infants. J Pediatr Surg 2017; 52:907.](#) Accessed June 5, 2020.