

Medical Policy



Enteral Nutrition

▼Description

Orders for Enteral Nutrition products dispensed and billed by durable medical equipment, orthotic, prosthetic and medical supply (DMEPOS) providers are referred to the Northwood Case Review department for individual coverage determination.

Enteral nutrition products are considered medically necessary for members who are at nutritional risk based upon clinical indicators, the presence of chronic disease, or increased metabolic requirements due to impaired ability to ingest or absorb food adequately.

▼Policy

Enteral Nutrition Products: Supplemental nutritional liquids are delivered to the gastrointestinal tract through the mouth, stomach or small intestine. These liquids may be administered orally or through a feeding tube, catheter or stoma. Enteral nutrition products may include the following:

- **Low Protein Food Products:** Food products which have been modified to be low in protein for individuals who have been diagnosed with phenylketonuria (PKU) and other inherited diseases of amino acids and organic acids.
- **Special Medical Formulas:** Formulas that are for use by infants and children who have inborn errors of metabolism.

Policy Guidelines:

1. Enteral nutritional therapy with specialized formulas is considered medically necessary for infants and adults who are at nutritional risk who have any one of the following conditions:
 - Gastrointestinal motility disorders
 - Gastrointestinal reflux disease
 - Failure to thrive
 - Crohn's Disease
 - Ulcerative Colitis

- Chronic intestinal pseudo-obstruction
 - Prolonged nutrient losses due to malabsorption syndromes short-bowel syndromes, diabetes, celiac disease, chronic pancreatitis, renal disease or dialysis, draining abscess or wounds, cancers, congenital or acquired heart disease
2. As a result of any one of the above conditions, the member must present with any of the following clinical signs and symptoms of impaired digestion and/or malabsorption:
- Neonates, infants and children must show weight for height or BMI for age less than 10% or crossed (downwards) 2 percentile lines weight for age on the growth chart.
 - Adults must show involuntary or acute weight loss of greater than or equal to 10 percent of usual body weight during a three to six month period, or body mass index (BMI) below 18.5 kg/m²
3. Hydrolyzed and partially hydrolyzed formulas are considered medically necessary for members who exhibit **ANY** of the following clinical conditions **regardless of weight** when at least two different commercial infant formulas (at least one of which is cow milk based and one of which is soy milk based), have been attempted and have failed for a minimum of a **two** week trial or are contraindicated:
- Atopic disease associated with allergy related formula intolerance including any of the following symptoms: anaphylaxis, angioedema, eczema, rhinitis, urticaria, vomiting, persistent blood and/or mucus in stools, and wheezing may be medically necessary for up to **three** years of age
 - Conditions associated with non-allergy related formula intolerance including any of the following conditions may be medically necessary for up to **two** years of age:
 - Enterocolitis
 - Esophagitis
 - Malabsorption syndromes
 - Colic
 - Proctocolitis
 - Allergic enteropathy and/or eosinophilic gastritis as evidenced by persistent blood and/or mucus in the stools
 - Eosinophilic esophagitis
 - For infants with uncomplicated gastrointestinal reflux symptoms enteral nutrition therapy with specialized formulas is considered medically necessary for the following clinical circumstances:
 - a. For infants with persistent “spitting”, a two to four week trial of hydrolyzed formula may be considered medically necessary. Documentation of improved symptoms must be submitted for continued requests for hydrolyzed formulas after the trial up to **9 months of age**.

- b. For infants with regurgitation and vomiting, a two to four week trial of hydrolyzed formula may be considered medically necessary. Documentation of improved symptoms must be submitted for continued requests for hydrolyzed formulas after the trial up to **2 years of age**.
 - c. For documented cow/soy milk allergy a two to four week trial of hydrolyzed formulas may be considered medically necessary. Documentation of improved symptoms must be submitted for continued requests for hydrolyzed formulas after the trial up to **2 years of age**.
- 4. Specialized enteral formulas are considered medically necessary for premature infants who are born under 34 weeks of gestational age.
- 5. Enteral nutritional formulas are considered medically necessary for the following impairments that are expected to be permanent or of indefinite duration:
 - Neuromuscular or central nervous system disorders that impair the ability to ingest oral nutrition
 - Motility or anatomical dysfunction of the gastrointestinal tract which prevents food from reaching the stomach or intestine.
 - Disease of the small bowel that impairs absorption of an oral diet
- 6. Oral infant nutritional specialized formulas and modified food products that are low in protein or contain modified protein are considered medically necessary for inborn errors of metabolism and inherited metabolic disease. These conditions include but are not limited to the following:
 - Phenylketonuria (PKU)
 - Tyrosinemia
 - Homocystinuria
 - Maple syrup urine disease
 - Methylmalonic academia
 - Histidinemia
 - Cystinosis
 - Hartnup disease
 - Glutaric academia
 - Propionic aciduria
- 7. Regular formulas will be covered that WIC covers if the member does not meet WIC eligibility criteria or does not receive adequate amounts above the monthly allotment by the WIC program for medical needs. All of the following information must be submitted:
 - Evidence that WIC is providing the maximum allowed amount; and
 - A provider statement that additional calories are required to provide adequate nutrition; and
 - A growth chart demonstrating inadequate growth on the maximum calories allowed by WIC; and or

- Evidence that the member is not WIC eligible.
8. Enteral nutrition may be administered by syringe, gravity, or pump. Some enteral patients may experience complications associated with syringe or gravity method of administration. If a pump (B9002) is ordered, the pump must be included on the Medical Necessity Review form for Enteral Nutrition Question 19 and justification in the member's record to justify its need. If one or more criterion below is **not** met the pump will be denied as not reasonable and necessary.
- Gravity feeding is not satisfactory due to reflux and/or aspiration
 - Severe diarrhea
 - Dumping syndrome
 - Administration rate less than 100ml./hr.
 - Blood glucose fluctuations
 - Circulatory overload
 - Gastrostomy/jejunostomy tube used for feeding

Ketogenic Formula for Uncontrolled Seizures

1. Ketogenic formulas are authorized for up to a period of 6 months when there is clinical documentation confirming that the member:
 - a. Has seizures refractory to standard anti-seizure medications OR **CANNOT TOLERATE SEIZURE MEDICINES**; and
 - b. Requires a formula/liquid diet to maintain weight for age growth because of inability to tolerate solid foods due to developmental or other issues (the formula requested does not need to meet >50% of daily caloric intake) OR, **IS UNDER 2 YEARS AND CONSUMED FORMULA OR BREAST MILK PRIOR TO INITIATING THE DIET.**
 - c. Neither milk nor a soy trial is required.
2. Subsequent requests for authorization require intervening clinical and nutritional reassessments to determine if the clinical condition has improved to allow intake of other nutrients and to document calorie counts. The authorization period for the subsequent formula/enteral nutrition request depends on the member's clinical condition and timing of needed follow up visits.

Additional Definitions:

Allergic Enteropathy: A gastrointestinal food allergy involving the small and large intestines causing symptoms that include diarrhea, abdominal pain, blood and/or mucus in the stool and malabsorption.

Atopic Disease: Clinical disease characterized by atopy; typically refers to atopic dermatitis, asthma, allergic rhinitis and food allergy.

Atopic Dermatitis: (eczema): A pruritic, chronic inflammatory skin disease that commonly presents during early childhood and is often associated with a personal or family history of other atopic diseases.

Crohn's Disease: A type of inflammatory bowel disease (IBD), resulting in swelling and dysfunction of the intestinal tract.

Eosinophilic Esophagitis (EE): an inflammatory condition of the esophagus that is characterized by having above normal amounts of eosinophils in the esophagus. Symptoms of EE vary with age and may mimic GERD. Infants often present with vomiting, irritability and poor weight gain.

Eosinophilic Gastritis: An uncommon gastritis that affects both children and adults characterized by abdominal pain, malabsorption, and often obstructive symptoms, associated with peripheral eosinophilia and areas of eosinophilic infiltration of the stomach.

Failure to Thrive: A condition in which the weight gain and growth are far below usual levels for age. In general, failure to thrive is considered if weight falls lower than the 3rd percentile (as outlined in standard growth charts) or 20% below the ideal weight for their height. Growing may have slowed or stopped after a previously established growth curve.

Gastroesophageal Reflux: Also known as esophageal reflux or gastric reflux is a backflow of the contents of the stomach into the esophagus, caused by relaxation of the lower esophageal sphincter.

Gastrointestinal pseudo-obstruction: The decreased motility of the intestines often causing dilation of various parts of the bowel. The clinical and radiological findings are often similar to true intestinal obstruction.

Malabsorption Syndromes: Conditions that result in the inadequate absorption of nutrients in the intestinal tract. Examples of malabsorption syndromes include short bowel syndrome, radiation enteritis, pancreatitis, celiac disease, post gastrectomy and intestinal resection, sprue, infections, cystic fibrosis, liver disease and Whipple's disease.

Nutritional Risk: A member who has actual or the potential for developing malnutrition as evidenced by clinical indicators, the presence of chronic disease, or increased metabolic requirements due to the inability to ingest, digest or absorb food adequately.

Ulcerative Colitis: A chronic disease of unknown cause characterized by ulceration of the colon and rectum, with rectal bleeding, mucosal crypt abscesses, inflammatory pseudopolyps, abdominal pain, and diarrhea; frequently causes anemia, hypoproteinemia, and electrolyte imbalance, and is less frequently complicated by peritonitis, toxic megacolon, or carcinoma of the colon.

▼ HCPCS Level II Codes and Description

A5200	PERCUTANEOUS CATHETER/TUBE ANCHORING DEVICE, ADHESIVE SKIN ATTACHMENT
B4034	ENTERAL FEEDING SUPPLY KIT; SYRINGE FED, PER DAY, INCLUDES BUT NOT LIMITED TO FEEDING/FLUSHING SYRINGE, ADMINISTRATION SET TUBING, DRESSINGS, TAPE
B4035	ENTERAL FEEDING SUPPLY KIT; PUMP FED, PER DAY, INCLUDES BUT NOT LIMITED TO FEEDING/FLUSHING SYRINGE, ADMINISTRATION SET TUBING, DRESSINGS, TAPE
B4036	ENTERAL FEEDING SUPPLY KIT; GRAVITY FED, PER DAY, INCLUDES BUT NOT LIMITED TO FEEDING/FLUSHING SYRINGE, ADMINISTRATION SET TUBING, DRESSINGS, TAPE
B4087	GASTROSTOMY / JEJUNOSTOMY TUBE, STANDARD, ANY MATERIAL, ANY TYPE EA.
B4088	GASTROSTOMY/JEJUNOSTOMY TUBE, LOW PROFILE, ANY MATERIAL, ANY TYPE, EA.
B4100	FOOD THICKENER, ADMINISTERED ORALLY, PER OUNCE
B4102	ENTERAL FORMULA, FOR ADULTS, USED TO REPLACE FLUIDS AND ELECTROLYTES (E.G. CLEAR LIQUIDS), 500 ML = 1 UNIT
B4103	ENTERAL FORMULA, FOR PEDIATRICS, USED TO REPLACE FLUIDS AND ELECTROLYTES (E.G. CLEAR LIQUIDS), 500 ML = 1 UNIT
B9998	NOC FOR ENTERAL SUPPLIES. (TO INCLUDE EXTENSION SET FOR MIC-KEY BUTTON. QTY. 5 PER MONTH).
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

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

B9002 ENTERAL NUTRITION INFUSION PUMP, ANY TYPE

E0776 IV POLE

▼ Documentation Requirements

Non-coverage

Under certain circumstances enteral products are **not** considered medically necessary.

1. A medical history and physical examination have been performed and other possible alternatives have been identified to minimize nutritional risk.
2. The member is underweight but has the ability to meet nutritional needs through the use of regular food consumption.
3. Enteral products are used as supplements to a normal or regular diet in a member showing no clinical indicators of nutritional risk.
4. The member has food allergies, lactose intolerance, or dental problems. But has the ability to meet his or her nutritional requirements through an alternative food source.
5. Enteral products are to be used for dieting or a weight-loss program.
6. No medical history or physical examination has been taken and there is no documentation that supports the need for enteral nutrition products.

7. Baby food and other regular grocery products that can be blenderized and used with the enteral system will be denied as non-covered.

Submitting Clinical Documentation:

Requests for prior authorization for enteral nutrition products must be accompanied by clinical documentation that supports the medical necessity for this product.

- A. Documentation of medical necessity must include all of the following:
 1. The primary diagnosis name and ICD-10-CM code specific to the nutritional disorder for which enteral nutrition products are requested;
 2. The secondary diagnosis name and ICD-10-CM code specific to the comorbid condition;
 3. Clinical signs and symptoms, including anthropometric measures (for example, height, weight, BMI, BMR, growth charts, and prognosis for children);
 4. Comprehensive medical history and physical exam;
 5. Risk factors for developing malnutrition;
 6. Laboratory tests sufficient to establish the diagnosis of malnutrition;
 7. Route of enteral nutrition treatment;
 8. Documentation of past and current treatment regimens; and
 9. Type and estimated duration of the need for enteral nutrition products.
- B. Clinical information may be submitted on the required Medical Necessity Review Form for Enteral Nutrition Products. Required documentation must be completed by the prescribing physician or clinical staff involved in the member's care. A written prescription signed by the physician or nurse practitioner must also accompany the forms.
- C. A new or updated prior authorization request for enteral nutrition products must be submitted to continue use of enteral nutrition products before the expiration of the current prior authorization.

▼ Important Note:

Northwood's Medical Policies are developed to assist Northwood in administering plan benefits and determining whether a particular DMEPOS product or service is reasonable and necessary. Equipment that is used primarily and customarily for a non-medical purpose is not considered durable medical equipment.

Coverage determinations are made on a case-by-case basis and are subject to all of the terms, conditions, limitations, and exclusions of the member's contract including medical necessity requirements.

The conclusion that a DMEPOS product or service is reasonable and necessary does not constitute coverage. The member's contract defines which DMEPOS product or service is covered, excluded or limited. The policies provide for clearly written, reasonable and current criteria that have been approved by Northwood's Medical Director.

The clinical criteria and medical policies provide guidelines for determining the medical necessity for specific DMEPOS products or services. In all cases, final benefit determinations are based on the applicable contract language. To the extent there are any conflicts between medical policy guidelines and applicable contract language, the contract language prevails. Medical policy is not intended to override the policy that defines the member's benefits, nor is it intended to dictate to providers how to direct care. Northwood Medical policies shall not be interpreted to limit the benefits afforded to Medicare or Medicaid members by law and regulation and Northwood will use the applicable state requirements to determine required quantity limit guidelines.

Northwood's policies do not constitute medical advice. Northwood does not provide or recommend treatment to members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

▼ **Cross Reference to Related Policies and Procedures**

1. AdminaStar Federal, Inc, National Health Insurance Co., Local Coverage Determination (LCD) for Enteral Nutrition (L5041), CMS Pub. 100-3 (National Coverage Determinations Manual), Chapter 1, Section 180.2, DME Region LCD Covers: Jurisdiction A/B, Original determination effective date: For services performed on or after 10/01/1993, revision effective date: For services performed on or after 01/01/2007.
2. <http://digestive.niddk.nih.gov/ddiseases/pubs/gerd/#4> (NIH Information Clearinghouse)
3. <http://digestive.niddk.nih.gov/ddiseases/pubs/gerdinfant/index.htm>
4. <http://digestive.niddk.nih.gov/ddiseases/pubs/gerinchildren/index.htm>
5. <http://www.naspghan.org/user-assets/Documents/pdf/PositionPapers/GERD.pdf> (NASHGAN Pediatric GE Reflux Clinical Practice Guidelines)

6. Centers for Medicare and Medicaid Services, Medicare Coverage Database, National Coverage Documents. Accessed December 15, 2017.

Applicable URAC Standard

Core 8	Staff operational tools and support
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Change/Authorization History

Revision Number	Date	Description of Change	Prepared/Reviewed by	Approved by	Review Date:
A	11-06	Initial Release	Rosanne Brugnani	Ken Fasse	n/a
01	01- 08	Revisions: Added HCPCS codes B4087 & B4088	Susan Glomb	Ken Fasse	
02		Annual Review	Susan Glomb	Ken Fasse	Dec.2008
03		Annual Review with “supply kit” information update.	Susan Glomb	Ken Fasse	Dec.4, 2009
04	12-22-09	Annual Review- No further changes.	Susan Glomb	Ken Fasse	Dec.2009
05	11-19-10	Annual Review – No Changes	Susan Glomb	Ken Fasse	Nov.2010
06	02-18-11	Policy updated to reflect current practice	Susan Glomb	Dr. Almasri	
07	03-02-11	Policy updated to reflect current practice/ BMCHP inclusions	Susan Glomb	Dr. Almasri	
08	03-25-11	Added statement #8 about enteral pumps	Susan Glomb	Dr. Almasri	
09	05-13-11	Policy updated to reflect current practice	Susan Glomb	Dr. Almasri	
10	07-20-11	Added Important Note to all Medical Policies	Susan Glomb	Dr. Almasri	
11	11-08-11	Annual Review. Added References to Policy	Susan Glomb	Dr. Almasri	Nov. 2011
12	11-28-12	Annual review – no changes.	Susan Glomb	Dr. Almasri	Nov. 2012

13	12-30-13	Annual review. No changes	Susan Glomb	Dr. Almasri	
14	11-25-14	Annual Review. No changes	Susan Glomb	Dr. B. Almasri	
15	11-30-15	Annual Review. No Changes.	Lisa Wojno	Dr. B. Almasri	November 2015
16	12-02-16	Annual Review. No Changes.	Lisa Wojno	Dr. B. Almasri	December 2016
17	12-15-17	Annual review. Per Medicare database, deleted code B9000; added narrative to B9002.	Carol Dimech	Dr. C. Lerchin	December 2017
18	7-31-18	Added information regarding ketogenic formula criteria.	Carol Dimech	Dr. C. Lerchin	July 2018
19	12-3-18	Annual review. No additional changes – see last entry.	Carol Dimech	Dr. C. Lerchin	December 2018
20	12-14-18	Added additional criteria (in caps) regarding ketogenic formula for uncontrolled seizures.	Carol Dimech	Dr. C. Lerchin	December 2018