

Medical Policy

Enteral Nutrition Formulas and Supplements

Policy Number: 020

	Commercial and Qualified Health Plans	MassHealth
Authorization required	X	X
No notification or authorization		
Not covered		

Overview

The purpose of this document is to describe the guidelines Mass General Brigham Health Plan utilizes to determine medical appropriateness for the limited circumstances under which Mass General Brigham Health Plan authorizes coverage for enteral nutritional formulas and supplements. This document does not pertain to supplies related to enteral products. For supplies related to enteral products, please reference the DME Prior Authorization list. The treating provider must include information supporting the diagnosis, condition, and medical necessity in the request for prior authorization of enteral nutritional formulas and supplements.

Coverage Guidelines

Mass General Brigham Health Plan covers enteral nutrition formulas and supplements administered orally or via enteral tube as well as digestive enzyme cartridges when the member meets one of the conditions listed under the coverage criteria and when prescribed by the treating physician and in accordance with Massachusetts State Mandate.

Medical necessity for nutritional formula or supplements administered orally or via enteral tube is established for members in the following situations:

1. Enteral nutrition, orally or by tube feeding, when used as a therapeutic regimen to prevent serious disability or death in a member with a medically diagnosed condition that precludes the full use of regular food or precludes adequate ingestion of calories to achieve sufficient growth.
2. Prematurity. Formulas formulated for premature infants may be covered for those infants born at less than or equal to 36 weeks gestation. The formulas may be covered for up to 3 months of age. Documentation required includes gestational age.
3. The member presents with clinical signs and symptoms of impaired digestion, malabsorption, or nutritional risk, as indicated by one of the following:
 - a. The member cannot ingest regular food because of a medical condition; or has a medical condition which causes difficulty with swallowing and the inability to take nutrition by mouth;
 - b. Evidence of weight loss with measurements on more than one consecutive occasion that presents actual, or potential for developing, malnutrition, despite oral and/or tube feeds as defined below:
 - Adults and post-pubertal adolescents showing involuntary or acute weight loss of greater than or equal to 10 percent of usual body weight during a 3- to 6-month period, or body mass index below 18.5 kg/m²;¹ in members with chronic immobility for whom height is difficult to measure, another anthropometric method such as height associated with arm span or ratio of upper body to lower extremity length should be used.

¹ With consideration for measurement of BMI in members with chronic immobility for whom height is difficult to measure by using another anthropometric method such as height associated with arm span or ration of upper body to lower extremity length.

- Neonates, infants, and children, showing:
 - a. Very low birth weight (VLBW <1500 g) within the first three months of life corrected for prematurity even in the absence of gastrointestinal, pulmonary, or cardiac disorders;
 - b. A sustained decrease in weight or weight-for-height-for-age-and-gender across two or more major percentiles after having previously established a stable rate of growth (growth velocity);
 - c. A lack of weight gain, or weight gain less than two standard deviations below the age-appropriate mean (i.e., below the 2nd percentile), and not growing at a rate parallel to the growth curve in a three-month period for children under six months, or four-month period for children aged six to 12 months, and that does not reverse with instruction in appropriate diet for age;
 - d. No weight gain, slow rate of gain for six months, for children older than one year, and/or documented weight loss that does not reverse promptly with instruction in appropriate diet for age; or
 - e. Weight or weight-for height less than two standard deviations below the mean for age and gender (i.e., below the second percentile) and not growing at a rate parallel to the growth curve;
 - f. For individuals with genetic or other syndromes, where syndrome-specific growth charts are available, weight gain and growth are abnormally slow for the specific condition using the condition-specific growth chart;
 - g. Abnormal laboratory tests pertinent to the diagnosis.
- 4. The risk factors for actual or potential malnutrition have been identified and documented. Such risk factors include, but are not limited to, the following:
 - a. Anatomic structures of the gastrointestinal tract that prevents food from reaching the stomach (e.g., esophageal cancer), impair digestion and absorption;
 - b. Neurological disorders that impair swallowing or chewing;
 - c. Diagnosis of inborn errors of metabolism that require food products modified to be low in protein (for example, phenylketonuria (PKU), tyrosinemia, homocystinuria, maple syrup urine disease, propionic acidemia and methylmalonic acidemia);
 - d. Allergy to cow's milk protein and soy infant formulas as manifested by one or more of the conditions/symptoms listed in **Table A** that occurs while given a cow's milk formula, soymilk formula, or breast milk AND each of the following must be present:
 - i. Documented allergy to cow's milk (breast milk or formula) as evidenced by improvement with elimination of dairy from the diet;
 - ii. Documented multiple protein intolerance with a successful trial of extensively hydrolyzed protein formula (i.e., Alimentum, Nutramigen, Pregestimil) or, if such trial failed, a successful trial of elemental amino acid-based formula (Enfamil PurAmino, Neocate, Elecare);
 - iii. Hydrolyzed and elemental amino acid formulas for infants up to 12 months may initially be prescribed by a primary care provider pending a consultation with a pediatric allergist or pediatric gastroenterologist.
 - iv. Hydrolyzed and elemental amino acid-based formulas for infants older than 12 months must be prescribed by a pediatric allergist or pediatric gastroenterologist.

See PA request and documentation requirements below.

- e. Prolonged nutrient losses due to malabsorption syndromes or short-bowel syndrome, diabetes, celiac disease, cystic fibrosis, chronic pancreatitis, renal dialysis, draining abscess or wounds;



- f. Evidence of weight loss during treatment with anti-nutrient or catabolic properties (for example, anti-tumor treatments, corticosteroids, immunosuppressants, etc.);
 - g. Increased metabolic and/or caloric needs due to excessive burns, infection, trauma, prolonged fever, hyperthyroidism, or illnesses that impair caloric intake and/or retention; or
 - h. A failure-to-thrive diagnosis that increases caloric needs while impairing caloric intake and/or retention.
5. Enteral nutrition is indicated as the primary source of nutritional support essential for the management of risk factors that impair digestion or malabsorption and for the management of surgical preparation or postoperative care.
 6. For children older than one year of age, a retrial of commercial food and re-evaluation should demonstrate continued evidence of need for specialized formula.
 7. The use of digestive enzyme cartridges such as RELiZORB[®], an FDA-cleared digestive enzyme cartridge, is considered medically necessary to hydrolyze fats in individuals five (5) years or older with laboratory proven pancreatic insufficiency including cystic fibrosis (CF) in tube-fed enteral formula when **all** of the following criteria are met:
 - i. The member is diagnosed with cystic fibrosis or other pancreatic insufficiency;
 - ii. The member requires tube fed enteral nutrition for continuous durations of 6 hours or more and requires overnight enteral feeds;
 - iii. The member has a documented history of exocrine pancreatic insufficiency and documented failure of pancreatic enzyme replacement therapy (PERT);
 - iv. The member must have a proven response to digestive enzyme cartridge including, but not limited to, increased weight/BMI; significant improvement in gastrointestinal symptoms such as bloating or flatulence; or decreased diarrhea, dehydration, or hospitalizations due to gastrointestinal symptoms;
 - v. The digestive enzyme cartridge is prescribed for the member by a licensed treating pulmonologist or gastroenterologist, advanced practitioner registered nurse, or physician assistant working within the scope of the above practitioner's license;
 - vi. The digestive enzyme cartridge will be used according to FDA-cleared guidelines and manufacturer's instructions.

Note: Initial authorization for digestive enzyme cartridges will be approved for 6 months.

Coverage for State-Mandated Conditions

- a. Formulas for the treatment of inborn diseases of metabolism of amino acids and organic acids such as:
 - Phenylketonuria (PKU);
 - Tyrosinemia;
 - Homocystinuria;
 - Maple syrup urine disease;
 - Propionic acidemia or methylmalonic **acidemia**; or
 - **Methylmalonic** acidemia.
- b. Nonprescription enteral formulas for home use for which a physician has written an order and which are medically necessary to help in the treatment of malabsorption caused by disorders affecting the absorptive surface, functional length, gastrointestinal tract motility, such as:
 - Crohn's disease;
 - Ulcerative colitis;
 - Gastroesophageal reflux;
 - Gastrointestinal dysmotility; or
 - Chronic intestinal pseudo-obstruction.



- c. Coverage for inborn diseases of amino acids and organic acids shall include food products modified to be low protein in an amount not to exceed \$5,000 annually for any insured individual. **The \$5,000 annual limitation only applies to low protein food products for Commercial Accounts.**
- d. Under the State Mandate, formulas for the above conditions may be authorized for one year and require annual review for renewal.

Exclusions

Mass General Brigham Health Plan does not consider enteral products and nutrition supplements to be medically necessary under certain circumstances. Examples of such circumstances include, but are not limited to the following:

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 regular food consumption and/or commercially available caloric supplements.
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 alternative food sources.
5. Enteral products are 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. **(Commercial members)** Mass General Brigham Health Plan does not provide coverage for standard or commercial, non-hydrolyzed, non-elemental milk, or soy-based infant formulas as these are considered food and not to treat a medical condition.
8. Mass General Brigham Health Plan does not as a rule provide coverage for “standard infant formulas” or any formula offered by the Massachusetts WIC Nutrition Program in WIC eligible members. However, Mass General Brigham Health Plan may allow coverage if the request is for medically necessary quantities to sustain a healthy weight more than the quantity allowed by the WIC Program. Refer to the WIC Information for Providers page on Mass.gov (<https://www.mass.gov/service-details/wic-information-for-providers>) to find the standard infant formulas, as the standard infant formulas offered by the WIC Program may change brands.
9. Enteral nutrition and special medical formulas and foods are requested solely because of food preference in the absence of a medical condition.
10. Enteral nutrition products for premature infants older than three months of age. Standard infant formulas for home use (in a setting in which normal life activities take place) are expected to be used for premature infants older than three months of age (corrected for prematurity) and whose weight growth is parallel to or growing faster than the appropriate growth curve for age.
11. Growth parameters are consistent with specialized condition-specific growth charts for members with genetic conditions.
12. Children who are small but exhibit a normal growth rate parallel to the growth curve.
13. The use of digestive enzyme cartridges other than RELiZORB® as they are considered experimental and investigational.
14. Authorization for enteral formulas and supplements that are not requested through a certified DME provider.

Non-Covered Products

1. Regular store-bought food for use with an enteral feeding system;
2. Food for the ketogenic diet;



3. Liquid nourishments and food products used for cleansing, detoxing, dieting or recommended by weight loss centers;
4. Nonprescription formulas, supplements, or prescription foods when store-bought food meets nutritional needs;
5. For MassHealth members, any formula that can be obtained through the WIC program (see MassHealth website for WIC formulas).
6. Human breast milk.

Documentation

The Provider is responsible for the following documentation:

1. The **MCO Combined Form for Enteral Products Authorization Requests**. A new or updated PA request for enteral nutrition and special medical formula must be submitted to continue use of enteral nutrition products before the expiration of the current PA.
2. A recent (within the past year) comprehensive medical history and physical examination and, if applicable, laboratory tests which have been conducted to detect factors contributing to nutrition risk.
3. Other evidence to support clinical criteria that may not be included in the MCO Combined Form for Enteral Products Authorization Request.
4. Requests for standard formulas in excess of what is provided by WIC requires documentation listing:
 - a. Current formula intake;
 - b. Growth parameters on the formula intake;
 - c. The anticipated increase in formula needed to provide age appropriate growth.
5. For Digestive Enzyme Cartridges, documentation of medical necessity must include all of the following:
 - a. Documentation of pancreatic insufficiency, malabsorption, and/or failure to thrive, including relevant laboratory results;
 - b. Documentation of heights, weights and BMI for the previous year;
 - c. Growth charts for pediatric patients;
 - d. If the member has received digestive enzyme cartridges previously:
 - i. documentation of weight/BMI and/or GI symptoms 6 months prior to beginning use of digestive enzyme cartridges;
 - ii. for members currently using digestive enzyme cartridges, provide documentation of increase in weight/BMI and/or improvement in GI symptoms while using digestive enzyme cartridges;
 - iii. for members that have discontinued use of digestive enzyme cartridges, weights/BMIs and/ or GI symptoms must be provided for the period of use.
 - e. Latest complete history and physical by prescribing physician;
 - f. Relevant nutrition labs;
 - g. For members with CF, the prescribing provider must be a pulmonologist, gastroenterologist, or an endocrinologist specializing in the care of CF patients.
 - h. Members with non-CF malabsorption syndromes must provide items b. through f. above and the prescribing provider must be a gastroenterologist.

Definitions

Enteral Formula: Liquid nourishment, which may be given through a feeding tube.

Supplements: Liquid nourishment which is taken by mouth and usually not associated with regular store or health store-bought food, such as instant breakfast drinks or protein powder drinks.

Malabsorption: A problem properly absorbing nutrition from food, potentially or actually leading to malnutrition.



Malnutrition: “A pathologic state of varying severity: its clinical features are caused by a deficiency, excess or imbalance of essential nutrients. The cause may be primary (involving the quantity or quality of food consumed) or secondary (involving alterations in nutrient requirements, utilization or excretion).”

Combined Managed Care Organization (MCO) Medical Necessity Review Form for Enteral Nutrition Products (Special Formula): A standardized form completed by the prescriber for the purpose of establishing medical necessity for prior authorization.

RELIZORB™: A digestive enzyme cartridge that contains the enzyme lipase. It is created to imitate the action of the pancreatic lipase in order to increase the absorption of nutrients from enteral nutrition. It digests fats from enteral formulas to allow delivery of absorbable fatty acids and monoglycerides.

Codes

Authorized HCPCS Codes	Code Description
B4100	Food Thickener Administered Orally Per Ounce (No PA required)
B4102	Enteral Formula Adlt Repl Fls&Lytes 500 MI = 1 U
B4103	Enteral Formula Ped Repl Fls&Lytes 500 MI = 1 U
B4104	Additive For Enteral Formula
B4105	In-line cartridge containing digestive enzyme(s) for enteral feeding, each
B4149	Enteral F Manf Blndrizd Nat Foods W/Nutrients
B4150	Enteral F Nutritionally Cmpl W/Intact Nutrients
B4152	Enteral F Nutrition Cmpl Cal Dense Intact Nutrnts
B4153	Enteral Formula Nutionally Cmpl Hydrolyzed Prots
B4154	Enteral F Nutrition Cmpl No Inherited Dz Metab
B4155	Enteral F Nutritionally Incmpl/Modular Nutrients
B4157	Enteral F Nutrition Cmpl Inherited Dz Metab
B4158	Enteral F Ped Nutrition Cmpl W/Intact Nutrnts
B4159	Enteral F Ped Nutritn Cmpl Soy Basd Intct Nutrnts
B4160	Enteral F Ped Nutrition Cmpl Cal Dense Nutrnts
B4161	Enteral F Ped Hydrolyzed/Aa&Peptide Chain Prots
B4162	Enteral F Ped Spcl Metab Needs Inherited Dz Metab
B4164	Parntal Nutrition Sol; Carbs 50%/Less - Hom Mix
B4168	Parntal Nutrition Sol; Amino Acid 3.5% -Hom Mix
B4172	Parntal Nut Sol; Amino Acid 5.5 Thru 7%-Hom Mix
B4176	Parntal Nut Sol; Amino Acid 7 Thru 8.5%-Hom Mix
B4178	Parntal Nutrit Sol; Amino Acid > 85% - Hom Mix
B4180	Parntal Nutrition Sol; Carbs > 50% - Home Mix
B4185	Parenteral Nutrition solution, not otherwise specified, 10 g lipids
B4187	Omegaven, 10 g Lipids
B4189	Parntal Nut Sol; Amino Acid&Carb 10-51 Gms Prot
B4193	Parntal Nut Sol; Amino Acid&Carb 52-73 Gms Prot
B4197	Parntal Nut Sol; Amino Acid&Carb 74-100 Gm Prot
B4199	Parntal Nut Sol; Amino Acid&Carb > 100 Gms Ppar
B4216	Parntal Nutrition; Additives - Home Mix Per Day
B4220	Parenteral Nutrition Supply Kit; Premix Per Day
B4222	Parntal Nutrition Supply Kit; Home Mix Per Day



B4224	Parenteral Nutrition Administration Kit Per Day
B5000	Parntal Nut Sol; Amino Acid&Carbs Renl-Amirosyn
B5100	Parenteral nutrition solution compounded amino acid and carbohydrates with electrolytes, trace elements, and vitamins, including preparation, any strength, hepatic-HepatAmine-premix
B5200	Parenteral nutrition solution compounded amino acid and carbohydrates with electrolytes, trace elements, and vitamins, including preparation, any strength, stress-branch chain amino acids-FreAmine-HBC-premix
B9004	Parenteral nutrition infusion pump, portable
B9006	Parenteral nutrition infusion pump, stationary
B9998	NOC for enteral supplies
S9341	Home therapy; enteral nutrition via gravity; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (enteral formula and nursing visits coded separately), per diem
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
S9379	Home infusion therapy, infusion therapy, not otherwise classified; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem
S9542	Home injectable therapy, not otherwise classified, including administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem

Related Policies

- [MCO Combined Form for Enteral Products Authorization Requests](#)
- [DME Prior Authorization list](#)
- [Enteral Formulae and Parenteral Nutritional Solutions, DME Provider Payment Guidelines](#)

Effective

October 2022: Annual review. Exclusion added regarding noncertified DME providers. Codes updated.

July 2022: Ad-hoc review. Coverage criteria updated to align with revised MassHealth guidelines.

December 2021: Ad-hoc review. Added coverage criteria language for RELIZORB. Definitions updated. Code updated.

October 2021: Annual review.

December 2020: Annual review. Revised risk factor criteria on page 2 to include reference to Table A. Removed “documented soy formula intolerance”. Changes to exclusions 7 and 8 for clarity. Added Table A. References updated.



March 2020: Ad-hoc review reflecting new MassHealth guidelines. Removed requirement that child be seen by a pediatric gastroenterologist, pediatric allergist or pediatric pulmonologist under criteria 4 d.

October 2019: Annual review. Page 1; Added Prematurity to list of conditions when Mass General Brigham Health Plan would cover nutritional formulas and supplements.

October 2018: Added \$5,000 annual limit under subheading Coverage for State-Mandated Conditions. Clarified exclusion #7 and added exclusion #8

September 2017: Annual review. Added HCPCS codes.

September 2016: Annual review.

December 2015: Revised sentence under subheading Coverage for State-Mandated Conditions to remove language indicating \$5,000 annual limitation.

September 2015: Annual review without substantial changes in medically necessary indicators.

September 2014: Annual review without substantial changes in medically necessary indicators.

May 2013: Added human breast milk to non-covered product list.

September 2012: Annual review.

October 2011: Annual review.

October 2010: Annual review.

October 2009: Policy modified.

January 2009: Annual review.

January 2008: Annual review.

January 2007: Annual review.

January 2006: Annual review.

January 2005: Annual review.

May 2003: Annual review.

May 2002: Effective date.

Table A

Diagnosis Or Symptoms	Description
Severe atopic dermatitis in a child less than a year old	Formula may be prescribed by a primary care provider pending consultation with a Pediatric Allergist or Pediatric Gastroenterologist. The role of commercial formulas in causing the atopic dermatitis should be confirmed, such as by an immediate reaction after ingestion or improvement after a well-defined elimination diet. For children older than one year, a retrial of commercial food and any reevaluation should demonstrate continued evidence of food allergy.
IgE-mediated cow’s milk protein allergy	1. Characterized by one or more of the following symptoms related to the ingestion of cow’s milk protein: <ol style="list-style-type: none"> a. severe vomiting and abdominal pain within minutes to hours of food ingestion; b. severe diarrhea within six hours of food ingestion; c. pruritis or severe itching of the skin (localized or generalized); d. angioedema and urticaria; e. stridor, wheezing, or anaphylaxis. OR



	2. Characterized by a non-urticarial rash or with a rash and a negative IgE to soy. The child must fail trials of commercial formulas. For children older than a year, a retrial of commercial food and reevaluation should demonstrate evidence of food allergy.
Severe and persistent gastrointestinal irritability	<ol style="list-style-type: none"> 1. For infants up to six months of age, characterized by: <ol style="list-style-type: none"> a. weight loss or lack of weight gain; b. presence of significant vomiting or gastrointestinal bleeding; c. failure of trials of commercial formula; and d. recommended use of specialized formula by a pediatric primary care provider pending consultation with a gastrointestinal specialist. 2. For infants from six to 12 months: <ol style="list-style-type: none"> a. demonstration that symptoms are significantly improved with the use of the requested special medical formula; b. a retrial of commercial formula is unsuccessful; and c. continuation of special formula use is recommended by a gastrointestinal specialist. 3. For children older than one year of age, a retrial of commercial food and re-evaluation should demonstrate continued evidence of need for specialized formula.
Non-IgE mediated conditions	For children older than one year of age, a retrial of commercial food and reevaluation should demonstrate continued evidence of food allergy
Associated with cow's milk allergy	<ol style="list-style-type: none"> 1. food protein-induced proctocolitis associated with blood streaked stools not caused by anal fissures, infection, or other common causes of bloody stools; 2. pulmonary hemosiderosis; 3. food protein-induced enterocolitis associated with malabsorption and failure to thrive; 4. food protein-induced enteropathy associated with malabsorption, failure to thrive, diarrhea, and vomiting; and 5. esophageal eosinophilia and/or eosinophilic gastroenteritis, associated with malabsorption and dysmotility.

References:

Davis, M.A. Failure to thrive. Journal of Pediatrics and Adolescent Medicine, [Electronic version], 9395(76) 3193-3448.

American Society for Parenteral and Enteral Nutrition [ASPEN]. Guidelines for the use of parenteral and enteral nutrition in adult and pediatric patients. From <http://www.nutritioncare.org/>.

CMS National Coverage Determination (NCD) for Enteral and Parenteral Nutritional Therapy (180.2), effective 7/11/1984 V.1 found at <http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=242&ncdver=1&bc=AgAAGAAAAA&> .



General Laws of Massachusetts, Part I, Title XXII, Chapter 176G, § 4 Required coverage for certain conditions and groups, Chapter 175 § 47C Dependent coverage for newborn infants or adoptive children; inclusion in policies of accident and sickness insurance.

General Laws of Massachusetts, Part 1, Title XXII, Chapter 176 G, § 4D Nonprescription enteral formulas for home use.

MassHealth regulations at 130 CMR 409.000 and 450.000 and MassHealth Guidelines for Medical Necessity Determination for Enteral Nutrition and Special Medical Formulas. Accessed at <https://www.mass.gov/guides/masshealth-guidelines-for-medical-necessity-determination-for-enteral-nutrition-and-special>

MassHealth MVACO Contract, Section 2.6D

