Harvard Pilgrim Health Care | TUFTS Health Plan

Point32Health companies

Medical Necessity Guidelines:

Enteral Nutrition Products and Digestive Enzyme Cartridges for Tufts Health RITogether, Adults and Children

Effective: August 1, 2026

Prior Authorization Required If REQUIRED, submit supporting clinical documentation (electronically recommended or by fax)	Yes ☒ No ☐
Notification Required	Yes ☐ No ☒

Applies to:

- Tufts Health RITogether

We recommend submitting prior authorization electronically. If you opt to submit prior authorization requests via fax, please refer to this reference chart for the appropriate fax number (varies by product).
For details on all our products, please visit the Our Plans page on our provider website. For additional Prior Authorization and Notification details on other lines of business not listed on our Medical Necessity Guidelines page, please also reference our Prior Authorization Resources page.

Note: While you may not be the provider responsible for obtaining prior authorization or notifying Point32Health, as a condition of payment you will need to ensure that any necessary prior authorization has been obtained and/or Point32Health has received proper notification. If notification is required, providers may additionally be required to provide updated clinical information to qualify for continued service.

Overview

Enteral nutrition is defined as nutrition requirements that are provided via the gastrointestinal cavity, by mouth (orally), or through a tube or stoma that delivers the nutrients distal to the oral cavity.

Pediatric Nutritional Supplementation specifically refers to specialized formulas and supplements for infants and children.

Adult Nutritional Supplementation specifically refers to specialized formulas and supplements for adults.

Digestive Enzyme Cartridge (RELiZORB ™) is a digestive enzyme cartridge that contains the enzyme lipase. It is considered a first of its kind enzyme cartridge designed to mimic the action of pancreatic lipase for use in adults and children (ages 1 years and above) receiving enteral tube feedings. By hydrolyzing (digesting) fats from enteral formulas, RELiZORBTM allows for the delivery of absorbable fatty acids and monoglycerides to patients. This treatment can aid in normalization of fat absorption, improve symptoms commonly associated with fat malabsorption and enhance nutritional status in patients with cystic fibrosis receiving enteral feedings.[2-3]

Clinical Guideline Coverage Criteria

Specialized nutritional formulae and supplements, whether oral or by feeding tube, are considered medically necessary in the following circumstances:

1. As a therapeutic regimen to prevent or treat serious disability or to prevent death in a member with a medical diagnosed condition that precludes the age-appropriate use of standard milk-based formula.
2. The member presents clinical signs and symptoms of impaired digestion, malabsorption, or nutritional risk, as indicated by the following anthropometric measures:
    a. Weight loss that presents actual or potential for developing, malnutrition as defined below
        i. In adults (≥ 18 years of age), showing 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
        ii. In neonates, infants, and children (< 18 years of age) with one of the following:
            - Very low birth weight (VLBW< 1500g) even in the absence of gastrointestinal, pulmonary,

or cardiac disorders;

- A lack of weight gain, or weight gain less than two standard deviations below the age-appropriate mean in a one-month period for children under six months, or two-month period for children aged six to 12 months;
- No weight gain or abnormally slow rate of gain for three months for children older than one year; or
- Weight for height less than the 10th percentile, abnormal laboratory tests pertinent to the diagnosis and risk factors for actual or potential malnutrition have been identified and documented.

3. 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 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 (e.g., phenylketonuria (PKU), tyrosinemia, homocystinuria, maple syrup urine disease, propionic aciduria, and methylmalonic aciduria);
    d. Intolerance or allergy to standard milk-based or soy formulas (e.g., diarrhea, bloody stool, excessive gas, abdominal pain, severe GERD, severe eczema) that have improved with a trial of specialized formula and where such formula is needed for adequate nutrition;
    e. Prolonged nutrient losses due to malabsorption syndromes or short-bowel syndromes, diabetes, celiac disease, chronic pancreatitis, renal dialysis, draining abscess or wounds;
    f. Treatment with anti-nutrient or catabolic properties (e.g., anti-tumor treatments, corticosteroids, immunosuppressant, stimulant medications);
    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
4. A recent (within the past year) comprehensive medical history and a physical examination,
5. A written plan of care has been developed for regular monitoring of signs and symptoms to detect improvement in the person's condition. Nutritional status should be monitored regularly
6. 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.

Digestive Enzyme Cartridge

The Plan may authorize coverage for RELiZORB™, when enteral nutrition is considered medically necessary, as evidenced by the above criteria and **ALL** of the following criteria are met:

1. Member meets age requirements:
    a. In adults (≥ 18 years of age) and children (≥ 1 year of age); **and**
2. Member has a diagnosis of Cystic Fibrosis; **and**
3. Body Mass Index (BMI) less than 50 percentile for the past 6 months on prescribed enteral nutrition via tube feeding

Note: Initial authorization will be approved for 6 months

Reauthorization requests may be approved in up to 12-month intervals when the following criteria are met:

1. Member is continuing on enteral tube feedings
2. Documentation of no decrease in BMI, while maintained on enteral feedings and RELiZORB™ digestive enzyme cartridge therapy

Documentation Requirements:

The following documentation is required in order to request coverage of enteral nutrition products and RELiZORB™ digestive enzyme cartridge therapy:

1. Written prescription and letter of medical necessity signed by the prescribing provider
2. The Combined MassHealth Managed Care Organization (MCO) Medical Necessity Review Form For Enteral Nutrition Products (Special Formula)
3. Primary diagnosis name and diagnosis code specific to the nutritional disorder
4. Secondary diagnosis name and diagnosis code specific to the co-morbid condition
5. Documentation of the clinical signs and symptoms of impaired digestion, malabsorption, or nutritional risk

including anthropometric measures (e.g., height, weight, BMI, BMR, growth charts, and prognosis for children)
6. The most recent comprehensive medical history and physical exam
7. Documentation of risk factors for developing malnutrition
8. Laboratory tests sufficient to establish the diagnosis of malnutrition if applicable
9. Documentation of route of enteral nutrition treatment
10. Documentation of past and current treatment regimens/formulae
11. Documentation of estimated duration of the need (cannot be lifetime) for enteral nutrition products
12. Documentation of nutritional evaluation, disorder and treatment by a gastroenterologist or nutritionist

A new or updated prior authorization request for enteral nutrition products and RELiZORB™ digestive enzyme cartridge therapy must be submitted to continue use of enteral nutrition products before the expiration of the current prior authorization.

Limitations

Enteral nutrition may be considered not medically necessary under the following circumstances:

1. A medical history and physical examination have been performed and other alternatives comparable in effect and available to the member that are more conservative or less costly to MassHealth 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 formula or food consumption
3. The member has constipation, mild gastroesophageal reflux disease (GERD) which does not require pharmacologic treatment, mild eczema which only requires topical corticosteroids, fussiness, colic, and gassiness without the indications of malabsorption or nutritional risk indicated above
4. Enteral nutrition products are used as supplements to a normal or regular diet in a member showing no clinical indicators of nutritional risk
5. 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 comparable in effect and available to the member that is more conservative or less costly
6. Enteral nutrition products used for dieting or a weight loss program
7. The Enteral nutrition is available elsewhere at no cost to the enrollee through any agency of the state. With respect to formula, Tufts Health Plan-Network Health is the payer of last resort for certain formula because the Women, Infants and Children (WIC) Nutrition Program administered by the Massachusetts Department of Public Health has primary responsibilities for the provision of “standard infant formula” to WIC eligible enrollees.

Codes

The following code(s) are associated with this service:

Table 1: CPT/HCPCS Codes

Code	Description
B4105	In-line cartridge containing digestive enzyme(s) for enteral feeding, each
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

Code	Description
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

References:

1. Executive Office of Human Health and Services, State of Rhode Island. Coverage Guidelines For Durable Medical Equipment and Clinical Guidelines for Enteral Nutrition. Available at eohhs.ri.gov/ProvidersPartners/ProviderManualsGuidelines/MedicaidProviderManual/DME/CoverageGuidelinesforDurableMedicalEquipment.aspx..
2. Vandenplas Y. Prevention and Management of Cow's Milk Allergy in Non-Exclusively Breastfed Infants. Nutrients. 2017;9(7):731. Published 2017 Jul 10. doi:10.3390/nu9070731.
3. Greer FR, Sicherer SH, Burks AW; Committee on Nutrition; Section on Allergy and Immunology. The Effects of Early Nutritional Interventions on the Development of Atopic Disease in Infants and Children: The Role of Maternal Dietary Restriction, Breastfeeding, Hydrolyzed Formulas, and Timing of Introduction of Allergenic Complementary Foods. Pediatrics. 2019;143(4):e20190281. doi:10.1542/peds.2019-0281.
4. Meyer R, Groetch M, Venter C. When Should Infants with Cow's Milk Protein Allergy Use an Amino Acid Formula? A Practical Guide. J Allergy Clin Immunol Pract. 2018;6(2):383-399. doi:10.1016/j.jaip.2017.09.003
5. Kemp AS, Hill DJ, Allen KJ, et al. Guidelines for the use of infant formulas to treat cows milk protein allergy: an Australian consensus panel opinion. Med J Aust. 2008, updated 2013;188(2):109-112.
6. Stevens J, Wyatt C, Brown P, Patel D, Grujic D, Freedman SD. 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. doi:10.1097/MPG.0000000000002110.
7. Freedman S, Orenstein D, Black P, et al. Increased Fat Absorption From Enteral Formula Through an In-line Digestive Cartridge in Patients With Cystic Fibrosis. J Pediatr Gastroenterol Nutr. 2017;65(1):97-101. doi:10.1097/MPG.0000000000001617.

Approval And Revision History

October 21, 2020: Reviewed by IMPAC. Language clarified in risk factors section; added a written plan of care has been developed and nutritional status should be monitored regularly; added age parameters for adults ≥ 18 years and children < 18 years of age

Subsequent endorsement date(s) and changes made:

- January 20, 2021: Reviewed by IMPAC, Medical Necessity Guideline name change to include “Digestive Enzyme Cartridges” and RELiZORB ™ criteria added for adults ≥ 18 years of age and children ≥ 5 years of age
- May 19, 2021: Reviewed by IMPAC. Applicable HCPCS codes added: B4105, B4149- B4162
- December 21, 2021: Reviewed by Medical Policy Approval Committee (MPAC), renewed without changes

- April 5, 2022: Template updated
- May 18, 2022: Reviewed by MPAC for removal of PA with an effective date of May 25, 2022
- December 1, 2022: Reviewed by MPAC, renewed without changes
- September 20, 2023: Reviewed by MPAC, renewed without changes
- November 2023: Rebranded Unify to One Care effective January 1, 2024
- November 21, 2024: Reviewed by MPAC, renewed without changes, effective January 1, 2025
- February 19, 2025: Reviewed by MPAC, criteria for Relizorb updated to reflect FDA label allowing coverage for members age 1 year and older effective April 1, 2025
- August 20, 2025: Reviewed by MPAC for annual review, renewed without changes effective October 1, 2025
- June 17, 2026: Reviewed by MPAC for annual review, renewed without changes effective August 1, 2026

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member's benefit document, and in coordination with the Member's physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.