# Medical Necessity Guidelines:
# Enteral Nutrition Products and Digestive Enzyme Cartridges for Adults and Children

*Effective: January 20, 2021*

| **Prior Authorization Required**<br>If REQUIRED, submit supporting clinical documentation pertinent to service request. | **Yes ☒ No ☐** |
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**Applies to:**
**COMMERCIAL Products**

☐Tufts Health Plan Commercial products; Fax: 617.972.9409

☐Tufts Health Freedom Plan products; Fax: 617.972.9409

- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

**TUFTS HEALTH PUBLIC PLANS Products**

☐Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax:888.415.9055

☐Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; Fax: 888.415.9055

☒Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax: 857.304.6404

☐Tufts Health Unify* – OneCare Plan (a dual-eligible product); Fax: 857.304.6304

*The MNG applies to Tufts Health Unify members unless a less restrictive LCD or NCD exists.

**SENIOR Products**

- Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product) – Refer to the Tufts Health Plan SCO Prior Authorization List
- Tufts Medicare Preferred HMO, (a Medicare Advantage product) – Refer to the Tufts Medicare Preferred HMO Prior Authorization and Inpatient Notification List

For Tufts Health Plan Commercial Plans, refer to the Medical Necessity Guidelines: Oral Formula: Massachusetts Products.

**Note:** While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to make sure that prior authorization has been obtained.

## 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 5 years and above) receiving enteral tube feedings. By hydrolyzing (digesting) fats from enteral formulas, RELiZORB™ 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 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:
         a. Very low birth weight (VLBW< 1500g) even in the absence of gastrointestinal, pulmonary, or cardiac disorders;
         b. 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;
         c. No weight gain or abnormally slow rate of gain for three months for children older than one year; or
         d. Weight for height less than the $10^{th}$ 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**

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

1. Member meets age requirements:
   a) In adults (≥ 18 years of age) and children (≥ 5 years of age)
2. Member has a diagnosis of Cystic Fibrosis
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:

- Written prescription and letter of medical necessity signed by the prescribing provider
- The Combined MassHealth Managed Care Organization (MCO) Medical Necessity Review Form For Enteral Nutrition Products (Special Formula)
- Primary diagnosis name and diagnosis code specific to the nutritional disorder
- Secondary diagnosis name and diagnosis code specific to the co-morbid condition
- 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)
- The most recent comprehensive medical history and physical exam
- Documentation of risk factors for developing malnutrition
- Laboratory tests sufficient to establish the diagnosis of malnutrition if applicable
- Documentation of route of enteral nutrition treatment
- Documentation of past and current treatment regimens/formulae
- Documentation of estimated duration of the need (cannot be lifetime) for enteral nutrition products
- 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:

- 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.
- The member is underweight but has the ability to meet nutritional needs through the use of regular formula or food consumption
- 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
- Enteral nutrition products are used as supplements to a normal or regular diet in a member showing no clinical indicators of nutritional risk
- 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
- Enteral nutrition products used for dieting or a weight loss program
- 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.

## 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. Last accessed August 6, 2020.
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 HISTORY

March 12, 2010: Approved by Utilization Management Committee

Subsequent endorsement date(s) and changes made:

- March 11, 2011: Utilization Management Committee Review, 12 month extension of current version granted to allow reconstruction of new policy version
- December 16, 2011: Executive Policy Review and Update by Utilization Management Committee Chair and Network Health President, limited to policy scops update to include new coverage product (Medical Security Program)
- February 17, 2012: Document revised and reorganized to reflect new content for adults in addition to pediatric application; Utilization Management Committee reviewed, annual review period extended three months (May, 2012)
- March 26, 2012: Utilization Management Committee review recommended further edits to content and document structure; annual review period extended six months (October, 2012)
- February 1, 2013: Utilization Management Committee Annual Review (extended), discussion of re-challenge of formula deleted under *Required Clinical Documentation*, several grammatical changes
- February 20, 2013: Utilization Management Committee Review, "Network Health Choice" added to *Scope*
- November 8, 2013: Updated to include "Careplus" product line
- January 17, 2014: Utilization Management Committee Annual Review, "Network Health Forward (Commonwealth Care)" and "Network Health Extend (Medical Security Plan)" deleted from *Scope*; "Choice" changed to "Direct" in *Scope*
- August 12, 2015: Reviewed by IMPAC, renewed without changes
- September 2015: Branding and template change to distinguish Tufts Health Plan products in "Applies to" section. Added Tufts Health Freedom Plan products, effective January 1, 2016.
- September 14, 2016: Reviewed by IMPAC, renewed without changes
- April 2017: Added RITogether Plan product to template. For MNGs applicable to RITogether, effective date is August 1, 2017
- August 9, 2017: Reviewed by IMPAC, renewed without changes
- October 10, 2018: Reviewed by IMPAC, renewed without changes
- October 2018: Template and disclaimer updated
- October 16, 2019: Reviewed by IMPAC, renewed without changes
- January 15, 2020: Newly created separate MNG for Tufts Health Together and Tufts Health Unify is reviewed by the Integrated Medical Policy Advisory Committee (IMPAC) with an effective date of April 1, 2020. Tufts Health Together and Tufts Health Unify removed as applicable products from this MNG effective April 1, 2020
- April 1, 2020: Fax number for Unify updated
- 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

- January 20, 201: 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

## 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.

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.