Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines:

Enteral Nutrition, Digestive Enzyme Cartridges and Special Medical Formulas for Tufts Health Together and Tufts Health One Care

Effective: April 1, 2025

Prior Authorization Required If REQUIRED, submit supporting clinical documentation pertinent to service request to the FAX numbers below	Yes ☐ No ☒
Notification Required IF REQUIRED, concurrent review may apply	Yes ☐ No ☒

Applies to:

Commercial Products

☐ Harvard Pilgrim Health Care Commercial products; 800-232-0816
☐ Tufts Health Plan Commercial products; 617-972-9409
CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Public Plans Products

☐ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); 888-415-9055
☒ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; 888-415-9055
☐ Tufts Health RITogether – A Rhode Island Medicaid Plan; 857-304-6404
☒ Tufts Health One Care -- A dual-eligible product; 857-304-6304

Senior Products

☐ Harvard Pilgrim Health Care Stride Medicare Advantage; 866-874-0857
☐ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); 617-673-0965
☐ Tufts Medicare Preferred HMO, (a Medicare Advantage product); 617-673-0965
☐ Tufts Medicare Preferred PPO, (a Medicare Advantage product); 617-673-0965

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. Members with malnutrition or the potential for developing malnutrition as evidenced by clinical indicators, the presence of chronic disease, or increased metabolic requirements due to an impaired ability to absorb or ingest food adequately is considered to be at nutritional risk.

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, 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 Guideline Coverage Criteria

Medical need must be manifested by the presence of both a medical condition known to cause nutritional risk and evidence of nutritional and/or growth implications that are not amenable to the use of regular food or standard formulas. Applicable medical criteria include, but are not limited to, criteria 1- 6 below.

1. The member has been diagnosed with one or more of the medical conditions below in 1.a through 1.f and meets the condition-specific criteria set forth below:
    a. An anatomic or metabolic condition that includes
        i. anatomic structures of the gastrointestinal tract that impair digestion and absorption;
        ii. neurological disorders that impair swallowing or chewing; and
        iii. diagnosis of inborn errors of metabolism that require food products to be modified to be low in protein (for example, phenylketonuria (PKU), tyrosinemia, homocystinuria, maple syrup urine disease, propionic aciduria, and methylmalonic aciduria).
    b. allergy to cow's milk protein and soy infant formulas as manifested by one or more of the conditions listed in Table A that occurs while given a cow's milk formula or breast milk with documented improvement from elimination of dairy from the diet and a successful trial of extensively hydrolyzed protein formula or, if such a trial failed, then a successful trial of amino-acid based formula. Each of the following must be present:
        i. one or more of the conditions listed in Table A (pages 3-4);
        ii. documented allergy to cow's milk;
        iii. the primary source of nutrition being extensively hydrolyzed protein formula or amino-acid based formula; and
        iv. for children age 12 months or older, the amino-acid based formula being recommended by a Pediatric Allergist, Pediatric Pulmonologist, or Pediatric Gastroenterologist.
    c. prolonged nutrient losses due to malabsorption syndromes or short-bowel syndromes such as or related to diabetes, celiac disease, chronic pancreatitis, renal dialysis, draining abscess, or wounds;
    d. evidence of weight loss during treatment with anti-nutrient or catabolic properties including, but not limited to, anti-tumor treatments, corticosteroids, and immunosuppress
    e. evidence of increased metabolic and/or caloric and weight loss due to excessive burns, infection, trauma, prolonged fever, hyperthyroidism, or illnesses that impair caloric intake and/or retention; or
    f. diagnosis of failure-to-thrive with increased caloric needs and impaired caloric intake and/or retention.
2. Evidence that the member's nutritional needs cannot be met by the use of regular food; standard, commercial formula and food products; or supplementation with commercially available products.
3. Use of enteral nutrition and special medical formulas, whether orally or by tube feeding, as a therapeutic regimen in a member with a medically diagnosed condition that precludes the full use of regular food.
4. The member presenting clinical signs and symptoms of impaired digestion, malabsorption, or nutritional risk, as indicated by the following:
    a. The member cannot ingest regular food because of a medical condition; **or**
    b. The member receives all nutrition via tube feeds because of a medical condition resulting in difficulty swallowing and the inability to take nutrition by mouth; **or**
    c. The member receives nutrition either orally or both through oral and tube feedings and has evidence of weight loss with measurements on more than one consecutive occasion that presents actual, or potential for developing, malnutrition as defined below:
        i. in 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 three-to-six- month period, or body mass index (BMI) below 18.5 kg/m2, 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;
        ii. in neonates, infants, and children, with one of the following:
            - very low birth weight (VLBW <1500g) within the first three months of life corrected for prematurity even in the absence of gastrointestinal, pulmonary, or cardiac disorders;
            - 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);
            - 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;
- no weight gain or abnormally slow rate of gain for six months for children older than one year, or documented weight loss that does not reverse with instruction in appropriate diet for age;
- 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;
- 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;

iii. abnormal laboratory tests pertinent to the diagnosis.

5. A recent (within the past year) comprehensive medical history and a physical examination and, if applicable, laboratory tests having been conducted to detect factors contributing to nutritional risk.
6. Enteral nutrition 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.

Table A

Diagnosis Or Symptoms	Description
Severe atopic dermatitis in a child less than a year old	Must be diagnosed by an allergist or other appropriate specialist, and role of commercial formulas in causing the atopic dermatitis 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: 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. 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 continued evidence of food allergy.
Severe and persistent gastrointestinal irritability	1. For infants up to six months of age, characterized by: 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 gastrointestinal specialist. 2. For infants from six to 12 months: 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 associated with cow's milk allergy	For one of the following diagnoses: 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

Diagnosis Or Symptoms	Description
	5. esophageal eosinophilia and/or eosinophilic gastroenteritis associated with malabsorption and dysmotility. For children older than one year of age, a retrial of commercial food and re-evaluation should demonstrate continued evidence of food allergy.

Digestive Enzyme Cartridge

The 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 (≥ 1 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 RELiZORBTM digestive enzyme cartridge therapy

Limitations

Tufts Health does not consider enteral nutrition products 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 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 food consumption and/or commercially available caloric supplements
3. Enteral nutrition 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 comparable in effect and available to the member that is more conservative or less costly to MassHealth
5. Enteral nutrition products are to be used for dieting or a weight-loss program
6. Enteral nutrition and special medical formulas and foods are requested solely because of food preference in the absence of a medical condition
7. 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
8. Growth parameters are consistent with specialized condition-specific growth charts for members with genetic conditions
9. Children who are small, but exhibit a normal growth rate parallel to the growth curve

In addition, The Plan does not consider formula to be medically necessary if there is an available, less costly alternative, such as under the following circumstances:

1. the member is WIC-eligible;
2. the enteral nutrition product being requested is listed as a “standard infant formula” on the current list of formulas covered by WIC; and
3. the formula is available in adequate amounts to the member through the WIC program.

Providers may visit mass.gov/service-details/wic-information-for-providers to obtain the current WIC formula list.

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 (use for Enrich, Ensure, Ensure HN, Ensure Powder, Isocal, Lonalac Powder, Meritene, Meritene Powder, Osmolite, Osmolite HN, Portagen Powder, Sustacal, Renu, Sustagen Powder, Travasorb)
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 (use for Magnacal, Isocal HCN, Sustacal HC, Ensure Plus, Ensure Plus HN)
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 (Criticare HN, Vivonex t.e.n. (use for Total Enteral Nutrition), Vivonex HN, Vital (Vital HN), Travasorb HN, Isotein HN, Precision HN, Precision Isotonic)
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 (use for Hepatic-aid, Travasorb Hepatic, Travasorb MCT, Travasorb Renal, Traum-aid, Tramacal, Aminaid)
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 (use for Propac, Gerval Protein, Promix, Casec, Moducal, Controlyte, Polycose Liquid or Powder, Sumacal, Microlipids, MCT Oil, Nutri-source)
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. Commonwealth of Massachusetts, Executive Office of Health and Human Services. MassHealth Guidelines for Medical Necessity Determination for Enteral Nutrition and Special Medical Formulas. mass.gov/doc/enteral-nutrition-and-special-medical-formulas-0/download. Accessed December 1, 2024.
2. 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.

3. 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

January 15, 2020: Reviewed by the Integrated Medical Policy Advisory Committee (IMPAC) for an effective date of April 1, 2020.

Subsequent endorsement date(s) and changes made:

- April 1, 2020: Fax number for Unify updated
- April 15, 2020: Reviewed by IMPAC. Clarified language regarding Hydrolyzed and amino-acid based formulas in section 1.b.iii and 1.c.iv, effective 4.15.2020
- July 15, 2020: Reviewed by IMPAC. Clarified language regarding evidence of weight loss in neonates, infants, and children in section 4.c.ii and 4.c.ii.d, effective July 15, 2020
- October 21, 2020: Reviewed by IMPAC. Clarified language for Non-IgE mediated conditions associated with cow's milk allergy
- January 20, 2021: Reviewed by IMPAC. MNG 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; 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, 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

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.