Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines:
Oral Formula and Enteral Nutrition

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; 857-304-6304
☐ 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, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Benefits for prescription or over-the-counter formula are available when a Physician issues a prescription or written order stating the formula or product is Medically Necessary for the therapeutic treatment of a condition requiring specialized nutrients and specifying the quantity and the duration of the prescription or order. The formula or product must be administered under the direction of a Physician or registered dietitian

The Member will be able to order one month's supply at a time unless otherwise noted below

Clinical Guideline Coverage Criteria

Oral Administration

The Plan may cover oral enteral nutrition as medically necessary when member requires management of a specific condition, disease, and/or is at risk for developing malnutrition and meets **ALL** of the following:

1. The medical formula or enteral nutrition is expected to provide more than 50% of the individual's daily nutritional intake, AND
2. The individual is under the supervision of a healthcare provider who is authorized to prescribe such dietary treatments, AND
3. Medical conditions related to interferences with nutrient absorption and assimilation and associated with **one** of the following:

a. Inborn errors of metabolism
    i. Tyrosinemia
    ii. Homocystinuria
    iii. Maple syrup urine disease
    iv. Propionic acidemia
    v. Methylmalonic acidemia
    vi. Urea cycle disorders
    vii. Phenylketonuria (PKU)
    viii. Other organic acidemias
b. Malabsorption resulting from **one** of the following conditions,
    i. Crohn's disease
    ii. Ulcerative colitis
    iii. Gastrointestinal dysmotility
    iv. Gastroesophageal reflux (GERD)
    v. Chronic intestinal pseudo-obstruction
    vi. Inherited diseases of amino acids and organic acids
    vii. Cystic fibrosis
c. Allergy or hypersensitivity to cow or soy milk diagnosed through a formal food challenge
d. Allergy to specific foods including food-induced anaphylaxis
e. Diarrhea or vomiting resulting in clinically significant dehydration requiring treatment by a medical provider
f. Prematurity (authorized up to three months post-hospital discharge) when one of the following is met::
    i. Specialized oral formula may be authorized for six months for members born at less than or equal to 35 completed weeks of gestation.
    ii. Specialized oral formula may be authorized for three months for members born at more than 35 weeks and less than or equal to 37 weeks gestation with one of the following:
        - A hospital discharge weight below the 10th percentile for age
        - Unable to tolerate cow milk-based formula (soy-based formula trial not required)

Note: Authorization past 3- or 6-months post-hospital discharge will be based on meeting the criteria for one of the conditions listed below

g. **Gastroesophageal Reflux Disease** Associated with either weight loss, lack of weight gain, severe or bloody regurgitation may be authorized based on the following:
    i. Special formula may be authorized up to 9 months of age: a failed trial of cow-milk or soy- based formulas required
    ii. Re-authorization from 9-12 months of age: a failed trial of cow-milk or soy-based formulas required
    iii. Re-authorization over one year of life: A letter of medical necessity from the treating Gastroenterologist is required, which documents ongoing medical necessity of formula, any attempts to wean from formula, and the treatment plan.

h. Infant Formula Intolerance:
    i. Protein hydrolysate formulas may be authorized for members from two (2) weeks to one (1) year of age who exhibit **one** of the following:
        - Symptoms of IgE-associated formula intolerance including angioedema, wheezing, rhinitis, urticaria, vomiting, eczema, and anaphylaxis
        - Symptoms of non-IgE-associated formula intolerance including hemosiderosis, malabsorption with villous atrophy, eosinophilic proctocolitis, enterocolitis, esophagitis, and colic
    ii. Amino acid preparations may be authorized from age two (2) weeks to one (1) year of age for those members exhibiting any of the signs/symptoms noted above AND experienced a failed trial of protein hydrolysate formula.
    iii. Special Formula may be authorized for infants older than One Year when **all** of the following are

met:

- Consideration of a retrial of both cow-milk based foods/formulas and soy-based formula
- A nutritionist consult including calorie counts
- A consult with a pediatric allergist and/or gastroenterologist documenting the continued indication for special formula

Note: Authorizations subsequent to one (1) year of age will be for no more than six (6) month intervals.

i. Growth Failure:

i. The Plan may authorize supplemental formulas or caloric supplements for members with growth failure when **all** the following criteria are met:

- The member's weight from a submitted growth chart is less than 75% of the median weight for age and gender (to calculate, divide the member's weight by the average weight for age)
- A complete evaluation has been performed to rule out medical causes of the growth failure. (e.g., GERD, malabsorption, heart disease, parasites, adenoid hypertrophy, cystic fibrosis, diabetes mellitus, immunodeficiency). This evaluation should include a detailed dietary history to ensure that the formula is properly diluted and/or the member is receiving adequate calories
- The member must have failed other more basic forms of caloric supplementation (e.g., Carnation Instant Breakfast, addition of butter or cream to prepared foods, etc.)

Note: Coverage requests must include pertinent clinical notes including but not limited to growth charts

Tube Administration:

The Plan considers tube administration of medical formulas and enteral nutrition as medically necessary when the Member meets oral administration criteria, with the exception of food type, provides justification for insufficiency of oral method, confirms the necessity for a tube, and meets **ALL** the following criteria:

1. The medical formula or enteral nutrition is expected to provide more than 50% of the individual's daily nutritional intake; **and**
2. The Member experiences difficulty swallowing due to a medical condition (e.g., tumors, neurological conditions, severe chronic anorexia nervosa) OR is associated with obstruction of the GI tract proximally and is unable to maintain weight and nutrition with oral administration; **and**
3. The individual is under the supervision of a healthcare provider who is authorized to prescribe such dietary treatments.

Covered conditions may include but are not limited to the following:

1. Atopic Dermatitis
2. Presence of Bloody stool with or without weight loss or other GI symptoms
3. Eosinophilic Esophagitis
4. Eosinophilic Gastroenteritis
5. Failure to Thrive
6. Gastroesophageal Reflux Disease (GERD)
7. GI Irritability
8. IgE Mediated Food Allergy
9. Inborn Error of Metabolism:
    a. Phenylketonuria (PKU)
    b. Tyrosinemia
    c. Homocystinuria
    d. Maple Syrup Urine Disease
    e. Propionic Acidemia
    f. Other Organic Acidemia
    g. Urea Cycle Disorders
10. Uncontrolled Seizures using Ketogenic Formula
11. Malabsorption
    a. Crohn's Disease

b. Ulcerative Colitis
c. Gastrointestinal Motility Disorders
d. Chronic Intestinal Pseudo Obstruction
e. Cystic Fibrosis
f. Prematurity

Note: Medical Formula or enteral nutrition (for diets requiring less than 50% for individuals daily nutritional intake) may be considered medically necessary in patients with the inability to maintain body weight and nutritional status prior to initiating or after discontinuing use of enteral supplements

Note: Covered formulas include hypoallergenic (protein hydrolysate) formulas, transitional formulas for premature infants, extensively hydrolyzed formulas, amino acid-based formulas, ketogenic formulas, specific metabolic formulas and special medical formulas that are medically necessary to treat specific medical conditions.

Note: Food or nutritional supplements, including, but not limited to, FDA-approved medical foods obtained by prescription, as required by law and prescribed for members who meet HPHC policies for enteral tube feedings for certain conditions are considered medically necessary (Exclusions list applies). Conditions for which this may apply includes (but not limited to):

- Phenylketonuria (PKU)
- Tyrosinemia
- Homocystinuria
- Maple Syrup Urine Disease
- Propionic Acidemia
- Other Organic Acidemia
- Urea Cycle Disorders

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 year 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- 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 is ≥ 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 RELiZORB™ digestive enzyme cartridge therapy

Limitations

1. Infant formulas for indications not listed above, or when a medical history or physical examination has not been completed, and/or there is no documentation that supports the need for enteral nutrition products.
2. Special medical formulas and enteral nutrition solely for food preference
3. Nutritional and/or food supplements (e.g., Boost and Ensure)
4. Standard over-the-counter commercial formulas (cow and soy milk based) for members without GI disorders including, but not limited to: Similac, Similac Advance, Enfamil, Lipil, Enfamil Gentlease Lipil, Lacto Free, Parent's Choice and Carnation Good Start, Isomil, Prosobee, Similac Soy or Carnation Soy

5. Formula or food products used for dieting, or a weight-loss program
6. Banked breast milk
7. Food for a ketogenic diet when dietary needs can be met with regular, store -bought food
8. Dietary or food supplements, including fortifiers (e.g., Duocal, Benecalorie®)
9. Food thickeners
10. Supplemental high protein powders and mixes
11. Lactose free foods, or products that aid in lactose digestion
12. Gluten-free products
13. Baby foods
14. Oral vitamins and minerals
15. Medical foods (e.g., Foltx, Metanx, Cerefolin, probiotics such as VSL#3) including FDA-approved medical foods obtained with or without prescription
16. Enteral electrolyte hydration fluids

Codes

The following code(s) require prior authorization for all plans with the exception noted below:

*For Tufts Health Plan Products, Prior Authorization is not required for codes with an asterisk

Table 1: HCPCS Codes

HCPCS Codes	Description
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
B4104*	Additive for enteral formula (e.g., fiber)
B4105	In-line cartridge containing digestive enzyme(s) for enteral feeding, each
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
B4148*	Enteral feeding supply kit; elastomeric control fed, per day, includes but not limited to feeding/flushing syringe, administration set tubing, dressings, tape
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, fasts, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100-calories=1unit
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,

HCPCS Codes	Description
	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:

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Approval And Revision History

December 21, 2022: Reviewed by the Medical Policy Approval Committee (MPAC), criteria and coding updated for Integration between Tufts Health Plan and Harvard Pilgrim Health Care. Criteria added for Relizorb Digestive Enzyme Cartridge for April 1, 2023 effective date.

Subsequent endorsement date(s) and changes made:

- October 1, 2023: HCPCS code B4148 added to require prior authorization for Harvard Pilgrim Commercial
- September 20, 2023: Reviewed at MPAC, renewed without changes
- November 2023: Rebranded Unify to One Care effective January 1, 2024
- November 21, 2024: Reviewed by MPAC, language added to require providers to submit a growth chart for members with growth failure; clarification regarding coverage for nutritional supplements; criteria updated for Relizorb due to FDA labeling to now allow coverage for members age 2 and older, effective January 1, 2025
- February 19, 2025: Reviewed by MPAC, criteria for Relizrob updated to reflect current FDA guidelines to allow 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.