BOSTON MEDICAL CENTER HEALTHNet PLAN

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WELL SENSE HEALTH PLAN

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Medical Policy

# Enteral Nutrition (Tube Feeding) Products Supplied and Billed by Home Infusion Providers and Digestive Enzyme Cartridges

**Policy Number:** OCA 3.37
**Version Number:** 27
**Version Effective Date:** 12/01/21

| Product Applicability | ☒ **All Plan+ Products** |
|---|---|
| **WellSense Health Plan**<br>☒ NH Medicaid<br>☒ NH Medicare Advantage | **Boston Medical Center HealthNet Plan Δ**<br>☒ MassHealth ACO<br>☒ MassHealth MCO<br>☒ Qualified Health Plans/ConnectorCare/Employer Choice Direct<br>☒ Senior Care Options |

+ Note: Disclaimer and audit information is located at the end of this document.

## Policy Summary

The Plan considers tube fed enteral nutrition products dispensed and billed by home infusion providers to be **medically necessary** for a member who is at nutritional risk due to a specific medical condition when Plan criteria are met. Prior authorization is required. Tube fed enteral nutrition must be ordered by a treating physician or a licensed independent practitioner (e.g., advanced practitioner registered nurse or physician assistant) working within the scope of the practitioner's license. The use of RELiZORB®, an FDA-cleared digestive enzyme cartridge, is considered medically necessary to hydrolyze fats in individuals five (5) years or older with cystic fibrosis in tube-fed enteral formula when clinical review criteria are met. Prior authorization is required for enteral tube feedings, digestive enzyme cartridges used with enteral tube feedings, and oral enteral products, as specified below in items 1 through 3:



+ *Plan* refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name WellSense Health Plan.

1. **Enteral Tube Feedings:** This Plan policy applies to **home infusion providers** dispensing and billing tube fed enteral nutrition products for Plan members. Tube fed enteral products dispensed and billed by durable medical equipment (DME) providers for Plan members are managed by Northwood, Inc. Providers may contact Northwood at www.northwoodinc.com or by phone at 1-866-802-6471 to obtain prior authorization. Northwood does NOT manage requests for RELiZORB® for any provider type.

2. **Digestive Enzyme Cartridges for Enteral Tube Feedings:** This Plan policy applies to any provider type requesting Plan authorization for the use of a digestive enzyme cartridge (e.g., RELiZORB®) with enteral tube feedings for a Plan member.

3. **Oral Enteral Products:** Enteral products administered orally are managed by Northwood, Inc. when dispensed and billed by any provider type for Plan members. Providers may contact Northwood at www.northwoodinc.com or by phone at 1-866-802-6471 to obtain prior authorization.

## Clinical Criteria

For pediatric members (i.e., members age 20 or younger on the date of service), services are considered medically necessary when criteria are met for EPSDT services or the following criteria are met. The Plan requires prior authorization for certain categories of tube fed enteral nutrition formulas dispensed and billed by **home infusion providers**.

I. **Criteria for Tube Fed Enteral Nutrition Formulas** – ALL criteria must be met in items A through D:

A. Tube fed enteral nutrition formula (including a prescription or non-prescription product) is ordered for the member by a treating physician or a licensed practitioner (e.g., advanced practitioner registered nurse or physician assistant) working within the scope of the practitioner's license; AND

B. Evidence that the member's nutritional needs cannot be met by the use of regular food; standard, commercial formula and food products; and/or supplementation with commercially available products; AND

C. Use of tube fed enteral nutrition and/or special medical formulas is a therapeutic regimen for a member with a medically diagnosed condition that precludes the full use of regular food/formula; AND

D. The tube fed enteral nutrition formula will be used for at least ONE (1) of the following indications and applicable criteria are met, as specified below in items 1 through 7:

1. **Indication: Formula Intolerance for Infants and Children** - The Plan considers extensively hydrolyzed, partially hydrolyzed, or amino acid-based tube fed enteral nutrition products to

be medically necessary for **infants or children** who meet criteria in items a through c **regardless of the member's weight**:

a. A trial of commercial formulas meets ONE (1) of the criteria in item (1) or item (2):

   (1) At least 2 different commercial, tube fed infant formulas have been attempted, cow milk-based and/or soy milk-based products± with generally a 4-5 day trial for each product (or for the timeframe recommended by the treating provider), with an unfavorable outcome (e.g., documented formula intolerance, lack of weight gain, or weight loss) for each trial of the commercial, tube fed infant formula; OR

   ± Note: A soy formula trial is not required for a member with documented intolerance to cow milk-based formula due to the high cross intolerance to soy-based formula.

   (2) Treating provider has determined that trial of commercial formula is contraindicated; AND

b. Before using an amino acid-based tube fed enteral nutrition product, the member has attempted an extensively hydrolyzed or partially hydrolyzed tube fed enteral nutrition product with an unfavorable outcome; AND

c. ANY of the following categories of criteria in items (1) through (3) is met based on the member's condition:

   (1) **Formula Allergy** - Member is an infant or child with atopic disease associated with allergy-related formula intolerance and BOTH criteria in items (a) and (b) are met:

      (a) Age-specific criteria in item i or item ii is met based on the type of tube fed enteral nutrition product prescribed by the treating provider:

         i. Extensively hydrolyzed and/or partially hydrolyzed tube fed enteral nutrition product(s) may be used for a member **until the member's 3rd birthday**; OR

         ii. Amino acid-based tube fed enteral nutrition products may be used **until the member's 1st birthday**; AND

      (b) The member has ANY of the symptoms for atopic disease associated with allergy-related formula intolerance listed in items i through xi:

         i. Allergic enteropathy and/or eosinophilic gastritis as evidenced by persistent blood and/or mucus in the stools; OR

ii. Anaphylaxis; OR

iii. Angioedema; OR

iv. Persistent blood and/or mucus in stools; OR

v. Pulmonary hemosiderosis; OR

vi. Rash, pruritus or eczema (localized or generalized); OR

vii. Rhinitis; OR

viii. Significant diarrhea, vomiting, or abdominal pain; OR

ix. Stridor or wheezing; OR

x. Urticaria; OR

xi. Weight loss or lack of weight gain; OR

(2) **Non-Allergy Related Formula Intolerance -** Member is an infant or child with atopic disease associated with non-allergy related formula intolerance and BOTH criteria in item (a) and item (b) are met:

(a) ONE (1) of the age-specific criteria in item i or ii is met based on the type of tube fed enteral nutrition product prescribed by the treating provider:

i. Extensively hydrolyzed and/or partially hydrolyzed tube fed enteral nutrition product(s) may be used for a member **until the member's 3rd birthday**; OR

ii Amino acid-based tube fed enteral nutrition products may be used **until the member's 1st birthday**; AND

(b) The member has ANY of the conditions associated with non-allergy related formula intolerance listed in items i through v:

i. Colic; OR

ii. Enterocolitis; OR

iii. Eosinophilic esophagitis; OR

iv. Esophagitis; OR

v. Malabsorption syndrome or short-bowel syndrome; OR

(3) **Uncomplicated Gastrointestinal Reflux** - The Plan considers tube fed enteral nutritional therapy with extensively hydrolyzed, partially hydrolyzed, or amino acid-based formula to be medically necessary for an infant or child with uncomplicated gastrointestinal reflux symptoms for ANY of the following clinical circumstances in item (a) or item (b):

(a) For an **infant** with persistent "spitting," the applicable criterion for trial or continued use is met, as specified below in item i or item ii:

i. **Trial**: A 2 to 4 week trial of hydrolyzed formula is considered medically necessary and is attempted with an unfavorable outcome before a 2 to 4 week trial of an amino acid-based formula; OR

ii. **Continued Use:** Documentation of improved symptoms must be submitted for continued requests for hydrolyzed formula or amino acid-based formula. If effective for this condition, the hydrolyzed formula or amino acid-based formula may be used for a member **until the member's 1st birthday**; OR

(b) For an **infant or child** with regurgitation and vomiting, ANY of criterion for trial or continued use is met in item i or item ii:

i. **Trial:** A 2 to 4 week trial of hydrolyzed formula is considered medically necessary (and is attempted with an unfavorable outcome before a 2 to 4 week trial of an amino acid-based formula); OR

ii. **Continued Use:** Documentation of improved symptoms must be submitted for continued requests for the hydrolyzed formula or amino acid-based formula. If the formula is effective for this condition, the hydrolyzed formula may be used for a member **until the member's 3rd birthday** and an amino acid-based formula may be used **until the member's 1st birthday**; OR

2. **Indication: Impaired Digestion, Malabsorption, or Nutritional Risk** - Tube fed enteral nutritional therapy with specialized formulas (i.e., prescription formulas and/or non-prescription formulas ordered by a treating physician or licensed practitioner working within the scope of the practitioner's license) are medically necessary for ALL members with impaired absorption‡ or nutritional risk when ANY of criteria in item a or b are met:

a. The member is a nutritional risk from ANY of the **acute** conditions listed items (1) or (2):

(1) Acute pancreatitis requiring tube fed enteral nutrition for up to 8 weeks; ¥ OR

¥ Note: It is expected that the treating provider will discontinue tube fed enteral nutrition before 8 weeks if it is no longer medically necessary for the member. A request for administration of tube fed enteral nutrition beyond 8 weeks requires Plan Medical Director review when the member is recovering from acute pancreatitis within the same episode of care.

(2) When the member is discharged from an inpatient facility to a home setting with continuation of tube fed enteral nutrition therapy initiated during the admission, Plan Medical Director review is required; OR

b. BOTH of the criteria are met in items (1) and (2) for enteral nutrition therapy for a **chronic** condition:

(1) Member at nutritional risk from ANY of chronic conditions in items (a) through (j):

(a) Chronic intestinal pseudo-obstruction; ¤ OR

(b) Crohn's disease; ¤ OR

(c) Failure to thrive (with or without feeding aversion); OR

(d) Gastroesophageal reflux disease; ¤ OR

(e) Gastrointestinal motility disorder; ¤ OR

(f) Inherited diseases of amino acids and/or organic acids; ¤ ‡ OR

(g) Ulcerative colitis; ¤ OR

(h) Prolonged nutrient losses due ANY of the conditions in items i through ix:

i. Cancer; OR

ii. Celiac disease; OR

iii. Chronic pancreatitis; OR

iv. Congenital or acquired heart disease; OR

v. Diabetes; OR

vi. Draining abscess or wound; OR

vii. Malabsorption syndrome; OR

viii. Renal disease or dialysis; OR

ix. Short-bowel syndrome; OR

(i) Anatomic structure of the gastrointestinal tract that impairs digestion and absorption; OR

(j) Neurological disorder that impairs swallowing or chewing; AND

(2) As a result of ANY of the conditions specified above in item a, the member presents with ANY of the clinical signs and symptoms of impaired digestion and/or malabsorption listed in item (a) or item (b):

(a) **Adult Member -** Member age 21 or older on the date of service has ANY of the following conditions listed item i or item ii:

i. Member has involuntary or acute weight loss of greater than or equal to 10% of his/her usual body weight during a 3 to 6-month period; OR

ii. Member's body mass index (BMI) is 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; OR

(b) **Pediatric Member** - A member age 20 or younger (until the member's 21st birthday) has ANY of the following conditions listed in items i through vi:

i. Very low birth weight (VLBW < 1500 g) within the first 3 months of life corrected for prematurity even in the absence of a gastrointestinal, pulmonary, and/or cardiac disorder; OR

ii. Member's weight-for-height child growth standard or BMI-for-age child growth standard is less than the 10th percentile; OR

iii. Deceleration of growth velocity (a sustained decrease in weight or weight-for-height-for-age-and-gender) and the member has crossed

downward at least two percentile lines (or below two standard deviations) of weight for age on the standard growth chart; OR

iv. A lack of weight gain, or weight gain less than 2 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 3-month period for children under 6 months of age, or 4-month period for children aged 6-12 months, and that does not reverse with instruction in appropriate diet for age; OR

v. No weight gain or abnormally slow rate of gain for 6 months for children older than 1 year, or documented weight loss that does not reverse with instruction in appropriate diet for age; OR

vi. Weight or weight-for-height less than 2 standard deviations below the mean for age and gender (i.e., below the 2nd percentile) and not growing at a rate parallel to the growth curve; OR

Notes:

ᴑ According to Massachusetts state law, non-prescription enteral formulas are covered for specific conditions (indicated above with ᴑ) for fully insured members when a written order has been issued by a physician; tube fed enteral nutrition is covered to treat these conditions for all members when Plan criteria are met.

‡ According to New Hampshire Medicaid coverage guidelines, non-prescription enteral formulas are covered to treat inherited diseases of amino acids, organic acids and conditions of impaired absorption of nutrients caused by disorders affecting the absorptive surface, functional length, or motility of the gastrointestinal tract when prescribed by a physician who has issued a written order; tube fed enteral nutrition is covered to treat the conditions specified in this section for all members when Plan criteria are met.

3. **Indication: Inborn Errors of Metabolism** - The Plan considers tube fed enteral nutrition products medically necessary for ALL members (i.e., prescription formulas and/or non-prescription formulas ordered by a treating physician or licensed practitioner) when BOTH of the criteria in items a and b are met:

   a. ONE (1) of the following criteria must be met, as specified below in item (1) or item (2):

      (1) Tube fed enteral nutrition is used to treat a member's condition resulting from inborn errors of metabolism; OR

      (2) Used to prevent the effects of inherited metabolic disease in the unborn fetus of a pregnant member; AND

b. The member has ANY of the conditions listed below in items (1) through (12):

(1) Cystinosis; OR

(2) Glutaric acidemia; OR

(3) Hartnup disease; OR

(4) Histidinemia; OR

(5) Homocystinuria; ⌂ OR

(6) Maple syrup urine disease; ⌂ OR

(7) Methylamalonic acidemia; ⌂ OR

(8) Phenylketonuria (PKU); ⌂ OR

(9) Propionic aciduria; OR

(10) Tyrosinemia; OR

(11) Urea cycle disorder; OR

(12) Other organic and/or amino acidemias ⌂ ◊

Notes:

⌂ The General Laws of Massachusetts mandate coverage for non-prescription enteral formulas for home use for which a physician has issued a written order and are medically necessary for the treatment of malabsorption/malnutrition caused by Crohn's disease, ulcerative colitis, gastroesophageal reflux, gastrointestinal motility, chronic intestinal pseudo-obstruction, and inherited diseases of amino acids and organic acids. Coverage for inherited diseases of amino acids and organic acid shall include food products modified to be low protein (low protein food products). Coverage is also mandated for those special medical formulas which are approved by the Commissioner of the Department of Public Health, prescribed by a physician, and are medically necessary for treatment of phenylketonuria (PKU), tyrosinemia, homocystinuria, maple syrup disease, propionic acidemia, or methylmalonic acidemia in infants and children or medically necessary to protect the unborn fetuses of pregnant individuals with phenylketonuria. Tube fed enteral nutrition is covered to treat these conditions for members when Plan criteria are met.

◊ According to New Hampshire Medicaid coverage guidelines, enteral formulas are covered to treat inherited diseases of amino acids organic acids and conditions of impaired absorption

of nutrients caused by disorders affecting the absorptive surface, functional length, or motility of the gastrointestinal tract when prescribed by a physician who has issued a written order; tube fed enteral nutrition is covered to treat the conditions specified in this section for members when Plan criteria are met.

4. **Indication: Disorders that Require Permanent or Long-Term Use of Tube Fed Enteral Nutrition**

   The Plan considers tube fed enteral nutrition products medically necessary (i.e., prescription formulas or non-prescription formulas ordered by a treating physician or licensed practitioner working within the scope of the practitioner's license) for members with ANY of the conditions listed in items a though c if expected to be a permanent impairment:¤

   a. Disease of the small bowel that impairs absorption of an oral diet; OR

   b. Dysmotility or anatomical obstruction of the gastrointestinal tract which prevents food from reaching the stomach or intestine; OR

   c. Neuromuscular or central nervous system disorders that impair the ability to ingest oral nutrition; OR

¤ Note: Permanent impairment is defined as an impairment expected to exceed 90 days, as determined by the treating physician or a licensed practitioner (e.g., advanced practitioner registered nurse or physician assistant) working within the scope of the practitioner's license and substantiated in the member's medical record (which is consistent with Center for Medicare & Medicaid Services guidelines for review).

5. **Indication: Treatment for Premature Infants -** The Plan considers specialized tube fed enteral nutrition products medically necessary for premature infants who are born under 34 weeks of gestational age (i.e., prescription products and/or non-prescription products ordered by a treating physician or licensed practitioner).

6. **Indication: Plan Coverage of Formulas Covered by WIC When Used for Tube Feedings** - The Plan will cover the regular formulas that the Women, Infants and Children (WIC) Nutrition Program covers, when intended for tube feeding, if the member does not meet WIC eligibility criteria or does not receive adequate amounts above the monthly allotment by the WIC program for medical needs. ALL of the information listed in items a through c must be submitted:

   a. Evidence that WIC is providing the maximum allowed amount or evidence that the member is not WIC eligible; AND

b. A provider statement that additional calories are required to provide adequate nutrition; AND

c. A growth chart demonstrating inadequate growth on the maximum calories allowed by WIC.

7. **Indication: Tube Fed Ketogenic Formula for Seizure Disorders in Pediatric Members -** ALL of the following criteria in items a through c must be met:

a. The member is between the ages of 6 months and 20 years of age (until the member's 21st birthday) on the date of service; AND

b. The member has a seizure disorder that is refractory to antiepileptic drugs; AND

c. Member requires tube fed enteral nutrition to maintain ketogenic diet that cannot be maintained otherwise.

II. **Criteria for the Use of RELiZORB® -** The following medical necessity criteria in items A through E must be met for the use of a digestive enzyme cartridge to hydrolyze fats and enhance the absorption of nutrients of enteral formula:

A. Member is diagnosed with cystic fibrosis and is $\geq$ 5 years of age on the date of service; AND

B. RELiZORB® is prescribed for the member by a treating physician or a licensed practitioner (e.g., advanced practitioner registered nurse or physician assistant) working within the scope of the practitioner's license; AND

C. Member has a confirmed history of exocrine pancreatic insufficiency and documented failure of pancreatic enzyme replacement therapy (PERT); AND

D. Member requires tube fed enteral nutrition for continuous durations of 6 hours or more; AND

E. RELiZORB® will be used according to FDA-cleared guidelines and manufacturer's instructions, including but not limited to the following: single-use cartridge, no greater than 2 cartridges will be used in a 24-hour period per member, and utilized only with compatible enteral formulas, pump systems, and tubing sets within established thresholds for maximum feeding volumes.

## Limitations and Exclusions

Limitations related to tube fed enteral nutrition therapy are specified below in items 1 through 10:

1. The Plan only considers non-prescription tube fed enteral formula medically necessary when Plan criteria are met, when store-bought food does NOT meet the member's nutritional needs (including food for a ketogenic diet), and as mandated by applicable state law.

2. The Plan considers the use of tube fed enteral nutrition therapy to NOT be medically necessary for members with stable nutritional status, in whom only short-term parenteral nutrition might be required for less than 2 weeks.

3. The Plan considers the use of tube fed enteral nutrition therapy to NOT be medically necessary for routine pre-operative care and/or routine post-operative care for Plan members.

4. Plan Medical Director review is required for a prior authorization request for tube fed enteral nutritional therapy with specialized formulas (i.e., prescription formulas and/or non-prescription formulas ordered by a treating physician or licensed practitioner working within the scope of the practitioner's license) for a member with a medical condition that may result in impaired digestion, malabsorption, or nutritional risk BUT applicable Plan criteria (either for an acute condition or chronic condition) are NOT met.

5. The use of digestive enzyme cartridges other than RELiZORB® is considered experimental and investigational or NOT medically necessary with tube enteral feedings to assist with fat hydrolysis (breakdown), fat absorption, and/or for any other indication due to insufficient evidence in the peer-reviewed literature documenting the clinical utility and clinical validity of this type of device; these requests will be evaluated by a Plan Medical Director for individual consideration.

6. When medically necessary, the initial Plan authorization for RELiZORB® will NOT exceed **90 calendar days**. Reauthorizations for the use of RELiZORB® are required every **3 months** with medical record documentation of weight gain and/or reduction of gastrointestinal symptoms for the member.

7. Plan prior authorization for tube fed enteral nutrition products will be for no more than a **12-month supply**, unless otherwise specified by the Plan. Plan authorization for a supply of tube fed enteral nutrition requires relevant clinical documentation (e.g., findings of nutritionist evaluation, calorie counts, gastroenterologist and/or allergist evaluation).

8. Any request for a tube fed enteral nutrition product for a member with formula intolerance beyond the specified maximum age limits specified in the Clinical Criteria section requires Plan Medical Director review.

9. A request for continued tube fed enteral nutrition beyond 8 weeks requires Plan Medical Director review when the member is recovering from acute pancreatitis within the same episode of care.

10. A request for continued tube fed enteral nutrition when the member is discharged from an inpatient facility to a home setting with continuation of tube fed enteral nutrition therapy initiated during the admission requires Plan Medical Director review.

## Variations

The Plan uses guidance from the Centers for Medicare & Medicaid Services (CMS) for medical necessity and coverage determinations for Senior Care Options (SCO) members and WellSense Medicare Advantage HMO members, including but not limited to national coverage determinations (NCDs), local coverage determinations (LCDs), local coverage articles (LCAs), and documentation included in Medicare manuals. At the time of the Plan's most recent policy review, NCD 180.2 includes guidelines for enteral and parenteral nutritional therapy. Verify CMS guidelines in effect on the date of the prior authorization request. When there is no guidance from CMS for the requested service, Plan-adopted clinical review criteria will be used to determine the medical necessity of the service.

## Applicable Coding for BMC HealthNet Plan Products

The Plan uses and adopts up-to-date Current Procedural Terminology (CPT) codes from the American Medical Association (AMA), International Statistical Classification of Diseases and Related Health Problems, 10th revision (ICD-10) diagnosis codes developed by the World Health Organization and adapted in the United Stated by the National Center for Health Statistics (NCHS) of the Centers for Disease Control under the U.S. Department of Health and Human Services, and the Health Care Common Procedure Coding System (HCPCS) established and maintained by the Centers for Medicare & Medicaid Services (CMS). Since the AMA, NCHS, and CMS may update codes more frequently or at different intervals than Plan policy updates, the list of applicable codes included in this Plan policy is for informational purposes only, may not be all inclusive, and is subject to change without prior notification. Whether a code is listed in the Applicable Coding section of this Plan policy does not constitute or imply member coverage or provider reimbursement. Providers are responsible for reporting all services using the most up-to-date industry-standard procedure and diagnosis codes as published by the AMA, NCHS, and CMS at the time of the service.

Providers are responsible for obtaining prior authorization for the services specified in the Clinical Criteria and Limitations and Exclusions sections of this Plan policy, even if an applicable code appropriately describing the service that is the subject of this Plan policy is not included in this Applicable Coding section of this Plan policy. Review the Plan's reimbursement policies for Plan billing guidelines. Coverage for services is subject to benefit eligibility under the member's benefit plan. Member benefit documents are available at www.bmchp.org for BMC HealthNet Plan members and at www.SeniorsGetMore.org for Senior Care Options members.

| HCPCS Codes | Description: Codes Covered When Medically Necessary |
|---|---|
| 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<br><br>Plan note: Code is NOT payable for Senior Care Options product. |
| B4104 | Additive for enteral formula (e.g., fiber) |
| B4105 | In-line cartridge containing digestive enzyme(s) for enteral feeding, each |

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| | Plan note: Code used for a digestive enzyme cartridge (e.g., RELiZORB®). |
| 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 |
| 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 protein, fats, carbohydrates, vitamins and mineral, 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 protein, 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 |

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| | include fiber, administered through an enteral feeding tube, 100 calories = 1 unit |

## Applicable Coding for WellSense Health Plan Products

The Plan uses and adopts up-to-date Current Procedural Terminology (CPT) codes from the American Medical Association (AMA), International Statistical Classification of Diseases and Related Health Problems, 10th revision (ICD-10) diagnosis codes developed by the World Health Organization and adapted in the United Stated by the National Center for Health Statistics (NCHS) of the Centers for Disease Control under the U.S. Department of Health and Human Services, and the Health Care Common Procedure Coding System (HCPCS) established and maintained by the Centers for Medicare & Medicaid Services (CMS). Since the AMA, NCHS, and CMS may update codes more frequently or at different intervals than Plan policy updates, the list of applicable codes included in this Plan policy is for informational purposes only, may not be all inclusive, and is subject to change without prior notification. Whether a code is listed in the Applicable Coding section of this Plan policy does not constitute or imply member coverage or provider reimbursement. Providers are responsible for reporting all services using the most up-to-date industry-standard procedure and diagnosis codes as published by the AMA, NCHS, and CMS at the time of the service.

Providers are responsible for obtaining Plan prior authorization for the home health care services, as specified in the Clinical Criteria, and Limitations and Exclusions sections of this policy, even if an applicable code appropriately describing the service is not included in this Applicable Coding section. Review the Plan's reimbursement policies for Plan billing guidelines. Coverage for services is subject to benefit eligibility under the member's benefit plan in effect at the time of the service. Benefit documents for WellSense New Hampshire Medicaid members are available at www.wellsense.org and posted at www.WellSense.org/Medicare for WellSense Medicare Advantage HMO members.

| HCPCS Codes | Description: Codes Covered When Medically Necessary |
|---|---|
| B4104 | Additive for enteral formula (e.g., fiber) |
| B4105 | In-line cartridge containing digestive enzyme(s) for enteral feeding, each<br><br>Plan note: Code used for a digestive enzyme cartridge (e.g., RELiZORB®). |
| 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 |

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|---|---|
| | 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 protein, fats, carbohydrates, vitamins and mineral, 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 protein, 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 |

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## Policy History

| Original Approval Date | Original Effective Date* and Version Number | Policy Owner | Original Policy Approved by |
|---|---|---|---|
| Regulatory Approval: N/A<br><br>Internal Approval: 03/25/03 | 05/25/03<br>Version 1 | Medical Policy Manager as Chair of Medical Policy, Criteria, and Technology Assessment Committee (MPCTAC) | Quality and Clinical Management Committee (Q&CMC) |

*Effective Date for the BMC HealthNet Plan Commercial Product: 01/01/12
*Effective Date for the WellSense New Hampshire Medicaid Product: 01/01/13
*Effective Date for Senior Care Options Product: 01/01/16
*Effective Date for WellSense Medicare Advantage HMO Product: 01/01/22

Policy title from 05/25/03 to 03/31/17 was *Tube Fed Enteral Nutrition (Supplied and Billed by Home Infusion Providers)*.
Policy title from 04/01/17 to 07/31/20 was changed to *Tube Fed Enteral Nutrition (Supplied and Billed by Home Infusion Providers) and Digestive Enzyme Cartridges*.
Policy title as of 08/01/20 is *Enteral Nutrition (Tube Feeding) Products Supplied and Billed by Home Infusion Providers and Digestive Enzyme Cartridges*.

| Policy Revisions History | | | |
|---|---|---|---|
| **Review Date** | **Summary of Revisions** | **Revision Effective Date and Version Number** | **Approved by** |
| 09/06/05 | Updated clinical coverage criteria. | Version 2 | 09/06/05: Q&CMC |
| 11/07/06 | Removed procedure section as preauthorization requirement does not apply. | Version 3 | 11/07/06: Q&CMC |
| 11/13/07 | No changes. | Version 4 | 11/13/07: MPCTAC |
| 05/13/08 | Review for effective date 09/01/08. Updated clinical criteria and added preauthorization requirements for certain categories of formulas. | 09/01/08<br>Version 5 | 05/13/08: MPCTAC<br>06/24/08: Utilization Management Committee (UMC)<br>06/26/08: Quality Improvement Committee (QIC) |
| 06/23/09 | Review for effective date 10/01/09. Added | 10/01/09 | 06/23/09: MPCTAC |

| Policy Revisions History | | | |
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| | additional criteria for hydrolyzed and specialized formulas, updated the names of the standard regular formulas that WIC covers. (Good Start Supreme DHA/ARA, Good Start Supreme Soy DHA/ARA, Good Start Supreme, Enfamil Lipil with Iron, Enfamil Lipil Low Iron, ProSobee Lipil were all removed and replaced with Good Start Gentle, Good Start Soy Plus and Good Start Nourish Plus Powder.) | Version 6 | 06/23/09: UMC<br>07/22/09: QIC |
| 10/27/09 | Revised WIC information. | Version 7 | 10/27/09: MPCTAC<br>11/19/09: QIC |
| 10/01/10 | Revised the criteria for hydrolyzed formulas, updated references and definitions. | Version 8 | 10/20/10: MPCTAC<br>11/22/10: QIC |
| 04/01/11 | Revised this policy to be applicable for enteral nutritional tube fed products dispensed and billed by home infusion providers only. | Version 9 | 10/19/11: MPCTAC<br>11/29/11: QIC |
| 10/01/11 | Added Commercial mandated language that tube fed prescription enteral nutrition products are medically necessary in infants and children or to protect the unborn fetuses of pregnant individuals for inborn errors of metabolism and inherited metabolic disease. Added language that non-prescription tube fed enteral formulas ordered by a physician for home use are medically necessary for the treatment of: malabsorption caused by Crohn's disease, ulcerative colitis, gastroesophageal reflux, gastrointestinal motility, chronic intestinal pseudo-obstruction and inherited diseases of amino acids and organic acids. | Version 10 | 10/19/11: MPCTAC<br>11/29/11: QIC |
| 08/20/12 | Off cycle review for WellSense New Hampshire Medicaid product, reformatted Medical Policy Statement, revised code list to include all enteral products, updated references. Review of entire policy conducted. | Version 11 | 08/30/12: MPCTAC<br>09/06/12: QIC |
| 10/01/12<br>and<br>11/01/12 | Review for effective date 03/01/13. Revised Summary section, moved text from Note section to Summary section, revised and reformatted clinical criteria for enteral nutrition, added limitations, updated language in Applicable Coding section and revised applicable code list, and updated references. | 03/01/13<br>Version 12 | 10/17/12: MPCTAC<br>11/24/12: MPCTAC<br>12/20/12: QIC |
| 08/14/13<br>and | Off cycle review for WellSense New Hampshire Medicaid product and merged policy format. | Version 13 | 08/14/13: MPCTAC<br>(via electronic vote) |

| Policy Revisions History | | | |
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| 08/15/13 | Incorporate policy revisions dated 10/01/12 and 11/01/12 (as specified above) for the WellSense New Hampshire Medicaid product; these policy revisions were approved by MPCTAC (on 10/17/12 and 11/24/12) and QIC on 12/20/13 for applicable Plan products. Review of entire policy conducted. | | 08/15/13: QIC |
| 08/21/13 | Review for effective date 10/01/13. Revised Medical Policy Statement section without changing criteria. Updated references. | 10/01/13<br>Version 14 | 08/21/13: MPCTAC<br>09/19/13: QIC |
| 09/01/14 | Review for effective date 01/01/15. Updated Summary, Description of Item or Service, Definitions, and References sections. Updated criteria in the Medical Policy Statement section and Limitations section. Added indication for tube fed enteral nutrition products (i.e., ketogenic diet for recurrent, uncontrolled seizures with severe epilepsy for pediatric members). Increased the maximum timeframe for authorizations from 6 months to 12 months. Listed applicable coding for BMC HealthNet Plan products and WellSense New Hampshire Medicaid product into two separate sections and updated the introductory paragraph in both of the Applicable Coding sections. No change made to the applicable code list for BMC HealthNet Plan products. Removed HCPCS codes B4102 and B4103 from the applicable code list for WellSense Health Plan products. | 01/01/15<br>Version 15 | 09/24/14: MPCTAC (electronic vote)<br>10/08/14: QIC |
| 09/01/15 | Review for effective date 01/01/16. Updated list of applicable products, including removing Commonwealth Care, Commonwealth Choice, and Employer Choice from the list of applicable products because the products are no longer available. Updated criteria in the Medical Policy Statement section. Revised Definitions and References sections. | 01/01/16<br>Version 16 | 09/16/15: MPCTAC<br>10/14/15: QIC |
| 11/25/15 | Review for effective date 01/14/16. Revised language in the Applicable Coding sections. | 01/14/16<br>Version 17 | 11/25/15: MPCTAC (electronic vote)<br>12/09/15: QIC |
| 09/01/16 and 09/28/16 | Review for effective date 11/01/16. Updated Definitions, Clinical Background Information, References, and References to Applicable Laws and Regulations sections. Revised Plan notes in the Applicable Coding section for BMC HealthNet Plan products without changing the applicable | 11/01/16<br>Version 18 | 09/21/16: MPCTAC<br>09/30/16: MPCTAC (electronic vote)<br>10/12/16: QIC |

| Policy Revisions History | | | |
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| | code list. Administrative changes made to clarify language related to gender. | | |
| 12/01/16 | Review for effective date 04/01/17. Revised policy title to include digestive enzyme cartridges. Updated Summary, Description of Item or Service, Clinical Background Information, and References sections. Revised criteria in the Medical Policy Statement and Limitations sections. Added experimental and investigational code in the Applicable Coding section. | 04/01/17<br>Version 19 | 12/21/16: MPCTAC<br>01/11/17: QIC |
| 09/01/17 | Review for effective date 10/01/17. Administrative changes made to the Policy Summary, Medical Policy Statement, Limitations, and References sections. | 10/01/17<br>Version 20 | 09/20/17: MPCTAC |
| 06/01/18 | Review for effective date 07/01/18. Updated the Policy Summary, References, and Other Applicable Policies sections. Added new HCPCS code Q9994 for a digestive enzyme cartridge (e.g., RELiZORB), an industry-wide code addition, and revised Plan notes in the Applicable Coding for BMC HealthNet Plan Products and Applicable Coding for WellSense Health Plan Products sections. | 07/01/18<br>Version 21 | 06/20/18: MPCTAC |
| 09/01/18 | Review for effective date 12/01/18. Administrative changes made to the Applicable Coding for BMC HealthNet Plan Products, Applicable Coding for WellSense Health Plan Products, References, and Other Applicable Polices sections. Updated criteria in the Limitations section. | 12/0/18<br>Version 22 | 09/19/18: MPCTAC |
| 12/01/18 | Review for effective date 01/01/19. Administrative changes made to the Policy Summary, Medical Policy Statement, Limitations, and References sections. Industry-wide code updates, revisions to applicable coding, and revisions to Plan notes made to the Applicable Coding for BMC HealthNet Plan Products section and the Applicable Coding for WellSense Health Plan Products section. | 01/01/19<br>Version 23 | 12/19/18: MPCTAC |
| 07/01/19 | Review for effective date 08/01/19. Administrative changes made to the References and Reference to Applicable Laws and Regulations sections. | 08/01/19<br>Version 24 | 07/17/19: MPCTAC |
| 07/01/20 | Review for effective date 10/01/20. Revised policy title. Updated the References section. Revised | 10/01/20<br>Version 24 | 07/15/20: MPCTAC |

| Policy Revisions History | | | |
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| | criteria in the Medical Policy Statement and Limitations sections. | | |
| 08/01/21 | Review for effective date 11/01/21. Administrative changes made to the Policy Summary, Description of Item or Service, References, Other Applicable Policies, and Reference to Applicable Laws and Regulations sections. Revised criteria in the Medical Policy Statement and Limitations sections. Added medically necessary indications for RELiZORB® and updated Applicable Coding for BMC HealthNet Plan Products and Applicable Coding for WellSense Health Plan Products sections. | 11/01/21<br>Version 24 | 08/27/21: MPCTAC (electronic vote) |
| 11/01/21 | Review for effective date 12/01/21. Adopted new medical policy template; removed administrative sections, Medical Policy Statement section renamed Clinical Criteria, the Limitations section renamed Limitations and Exclusions section. Added WellSense Medicare Advantage HMO as an applicable product effective 01/01/22. Administrative changes made to the Policy Summary, Clinical Criteria, Limitations and Exclusions, Applicable Coding for BMC HealthNet Plan Products, Applicable Coding for WellSense Health Plan Products, and References sections. | 12/01/21<br>Version 25 | 11/17/21: MPCTAC |

## Next Review Date

07/01/22

## Authorizing Entity

MPCTAC

**Disclaimer Information: [+]**

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these



[+] *Plan* refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name WellSense Health Plan.

guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.