Medical Policy

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

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### Product Applicability

- **All Plan** Products

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**Notes:**

△ As required by state regulations and/or benefit coverage, different Plan applicable codes are specified for Boston Medical Center (BMC) HealthNet Plan products and Well Sense Health Plan products. Review the Applicable Coding section for product-specific coding.

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

◊ The guidelines included in this Plan policy are applicable to members enrolled in Senior Care Options only if there are no criteria established for the specified service in a Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) on the date of the prior authorization request. Review the member’s product-specific benefit documents at www.SeniorsGetMore.org to determine coverage guidelines for Senior Care Options.

**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. 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 a digestive enzyme cartridge (e.g., Tube Fed Enteral Nutrition Products (Supplied and Billed by Home Infusion Providers) and Digestive Enzyme Cartridges

* 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 Well Sense Health Plan.
RELiZORB™) with tube fed enteral nutrition therapy is considered experimental and investigational to assist with fat hydrolysis (breakdown), fat absorption, and/or for any other indication due to insufficient evidence to verify the clinical validity and/or clinical utility of this type of device. 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:

1. **Enteral Tube Feedings:**

   a. This Plan policy applies to home infusion providers dispensing and billing tube fed enteral nutrition products for Plan members.

   b. 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. When a DME provider is requesting an enteral feeding supply kit that does NOT include a digestive enzyme cartridge (e.g., RELiZORB™), the DME provider must also contact Northwood for prior authorization.

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. As specified in the Applicable Coding section of this policy, one (1) of the following codes should be used when billing for an enteral feeding supply kit that includes a digestive enzyme cartridge (e.g., RELiZORB™) as a component of the supply kit: HCPCS code B4034, B4035, or B4036. There is no separate billing code for the digestive enzyme cartridge.

3. **Oral Enteral Products:**

   Oral enteral products dispensed and billed by any provider type 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.

See the Plan’s policy, *Medically Necessary* (policy number OCA 3.14), for the product-specific definitions of medically necessary treatment. Review the Plan’s policy, *Experimental and Investigational Treatment* (policy number OCA 3.12), for the product-specific definitions of experimental or investigational treatment. The Plan’s medical policy, *Medical Nutrition Therapy in the Outpatient Setting or Office Setting* (policy number OCA 3.66), includes guidelines related to medical nutrition therapy. See the member’s applicable benefit document for coverage of enteral nutrition, including medical formulas and low-protein products. Benefit documents are available at www.bmchp.org for BMC HealthNet Plan members (or at www.SeniorsGetMore.org for Senior Care Options members) and www.wellsense.org for Well Sense Health Plan members.
Description of Item or Service

Tube Fed Enteral Nutrition Products: Supplemental nutritional liquids delivered to the gastrointestinal tract through a feeding tube into the stomach or small intestine (e.g. nasogastric, gastrostomy, jejunostomy). Enteral nutrition products may be classified as standard, elemental, or specialized. Standard enteral products include intact protein and contain balanced amounts of macronutrients. Elemental enteral products contain individualized amino acids which may require less digestive function and may cause less stimulation of the exocrine pancreatic secretion; types of elemental products include hydrolyzed formulas (which contain milk proteins) and amino acid-based formulas (which do not contain milk or soy). Special enteral nutrition products are designed to meet the specific nutritional requirements of patients with a variety of clinical conditions.

Digestive Enzyme Cartridge for Enteral Tube Feedings: Device designed to mimic the normal pancreatic function by breaking down fats in enteral tube feeding formula. By breaking down these fats from enteral tube feeding formulas prior to ingestion, more calories from fatty acids and monoglycerides and fat-soluble vitamins are expected to be absorbed in patients who are partially or completely unable to breakdown (hydrolysis) and absorb fats. Fat malabsorption is most common in individuals who cannot produce adequate amounts of digestive enzymes because of compromised pancreatic function, but changes in gastric, duodenal, and liver physiology can also dramatically impact malabsorption related to compromised fat absorption. In these individuals, incomplete break down of fats can result in increased gastrointestinal symptoms and malnutrition, and can adversely affect a patient’s ability to maintain or gain weight and maintain normal development and overall health.

RELiZORB™ (developed by Alcresta Therapeutics, Inc.) is a first-of-its kind digestive enzyme cartridge developed to mimic the function of the digestive enzyme lipase that is normally secreted by the pancreas. RELiZORB™, utilizing proprietary enzyme immobilization technology, is designed for use with adults on enteral tube feedings who have trouble breaking down and absorbing fats. The active ingredient in RELiZORB™ is the digestive enzyme lipase which attaches to polymeric carriers, together called iLipase®. RELiZORB™ is a single-use cartridge that connects in-line with existing enteral pump feed sets and pump extension sets. As the enteral tube feeding formula passes through RELiZORB™, it makes contact with the iLipase® and the fat in the formula is broken down to its absorbable form (fatty acids and monoglycerides) prior to ingestion. The iLipase® remains in the cartridge and does not become part of what is ingested. RELiZORB™ has been shown in some studies to break down up to 90 percent of fats in most enteral feeding tube formulas, including the most difficult to breakdown long-chain polyunsaturated fatty acids which are critical for growth and development. On November 20, 2015, Alcresta Therapeutics, Inc. (formerly Alcresta Pharmaceuticals) was granted de novo classification from the FDA for use of the RELiZORB™ device in adult patients. Currently, there is insufficient published evidence to assess the safety and/or impact on health outcomes or patient management for the use of the RELiZORB™ device. The Plan considers this type of device experimental and investigational to assist with fat hydrolysis (breakdown), fat absorption, and/or for any other indication.
Infant Formula: Pediatricians generally advise exclusively breastfeeding for all full term, healthy infants for the 12 months of life when possible, and for longer periods if desired because breast milk is nutritionally sound, and contains immunoglobulins (antibodies) that may reduce the frequency of diarrhea, gastroenteritis, otitis media, and respiratory infections in the infant. Many infants are formula-fed in addition to, or as an alternative to, breastfeeding. Common reasons for formula feeding include but are not limited to the following: Inadequate supply of maternal breast milk, inefficient sucking by the infant, inability to quantitate the precise amount of breast-milk received by the baby, concerns about transferring maternal drugs to the infant, and/or convenience. For infants to achieve normal growth and maintain normal health, infant formulas must include proper amounts of water, carbohydrate, protein, fat, vitamins, and minerals.

Formulas can be classified according to three basic criteria: caloric density, carbohydrate source, and protein composition. Most infants require a term formula with iron. Soy formulas are indicated for congenital lactase deficiency and galactosemia, but are not recommended for colic because of insufficient evidence of benefit. Hypoallergenic formulas with extensively hydrolyzed protein are effective for the treatment of milk protein allergy and the prevention of atopic disease in high-risk infants. Antireflux formulas decrease emesis and regurgitation, but have not been shown to affect growth or development. Most infants with reflux require no treatment. Types of infant formulas include:

1. Milk-based Formulas: Formulas prepared from cow milk with added vegetable oils, vitamins, minerals, and iron. These formulas are generally suitable for most healthy full-term infants.

2. Soy-based Formulas: Formulas made from soy protein with added vegetable oils (for fat calories) and corn syrup and/or sucrose (for carbohydrate). These formulas are suitable for infants who cannot tolerate the lactose in most milk-based formulas or who are allergic to the whole protein in cow milk and milk-based formulas.

3. Hypoallergenic Formulas (Protein Hydrolysate Formulas): Formula for infants who have allergies to food protein and for those with skin rashes or wheezing caused by allergies. Hypoallergenic formulas are generally much more expensive than regular formulas, sometimes as much as three (3) more costly than standard formula. Symptoms of food protein allergy include those commonly associated with immunoglobulin E (IgE)-associated reactions, such as angioedema, urticaria, wheezing, rhinitis, vomiting, eczema, and anaphylaxis. Non–IgE-associated, immunologically mediated conditions have also been associated with the ingestion of cow’s milk, soy, and other dietary proteins in infant feedings; these disorders include pulmonary hemosiderosis, malabsorption with villous atrophy, eosinophilic proctocolitis, enterocolitis, and esophagitis. Finally, some infants may experience extreme irritability or colic as the only symptom of food protein allergy.

4. Lactose-free Formulas: These formulas are also used for galactosemia and for children who can't digest lactose. A child who has an illness with diarrhea usually will not need lactose-free formula.
5. Special Formulas: Formulas used for babies with certain health problems such as heart disease, malabsorption syndromes, problems digesting fat or processing certain amino acids, and/or reflux with inability to gain weight. Special formulas may be used with term or preterm infants, low birth weight infants, low sodium formulas for infants that need to restrict salt intake, and predigested protein formulas for infants who cannot tolerate or are allergic to the whole proteins (casein and whey) in cow milk and milk-based formulas.

Special Medical Formulas: Specialized enteral nutrition formulas used for the treatment of a Plan member with any of the following conditions: an infant or child with formula intolerance, a premature infant, or an adult or pediatric member who has an inborn error of metabolism, impaired digestion, malabsorption, or is at nutritional risk (based on the Plan criteria specified in the Medical Policy Statement section of this Plan policy).

Medical Policy Statement

For BMC HealthNet Plan pediatric members (i.e., members under age 21 on the date of service), services are considered medically necessary when criteria are met for EITHER early intervention services (according to Massachusetts law) or criteria are met in this Medical Policy Statement section, as specified below. For Well Sense HealthNet Plan pediatric members (i.e., members under age 21 on the date of service), services are considered medically necessary when criteria are met for EITHER EPSDT services (according to New Hampshire law) or criteria are met in this Medical Policy Statement section, as specified below.

The use of a digestive enzyme cartridge (e.g., RELiZORB™) with tube enteral feedings is considered experimental and investigational 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 (as specified in the Limitations section of this policy). When a home infusion provider is requesting an enteral feeding supply kit that does NOT include a digestive enzyme cartridge (e.g., RELiZORB™), the Plan will authorize the enteral feeding supply kit when the tube fed enteral nutrition therapy is authorized by the Plan according to applicable criteria, as specified below in this Medical Policy Statement section.

The Plan requires prior authorization for certain categories of tube fed enteral nutrition formulas dispensed and billed by home infusion providers. The following Plan criteria must be met and documented in the member’s medical record for medically necessary tube fed enteral nutrition services, as specified below in item A and the applicable criteria in item B based on the indication for treatment. (See the applicable HCPCS codes in the Applicable Coding section of this policy.)
Indications for Tube Fed Enteral Nutrition Formulas:

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. The tube fed enteral nutrition formula will be used for at least ONE (1) of the following eight (8) indications (and corresponding criteria are met), as specified below in items 1 through 8:

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 members who are **infants or children** and meet the following medical criteria **regardless of the member’s weight**, as specified below in items a through c (with age-specific guidelines determined by indication):

   a. A trial of commercial formulas meets ONE (1) of the following criteria, as specified below in item (1) or item (2):

      (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.)

      (1) At least TWO (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 for each trial; OR

      (2) Trial of commercial formula(s) is contraindicated, as determined by the treating provider; 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. At least ONE (1) of the following categories of criteria is met based on the member’s condition, as specified below in item (1) for allergy-related formula intolerance, item (2) for non-allergy related formula intolerance, or item (3) for uncomplicated gastrointestinal reflux:
(1) **Allergy-Related Formula Intolerance:**

Member is an infant or child that has atopic disease associated with allergy-related formula intolerance and meets BOTH of the following criteria, as specified below in item (a) and item (b):

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

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 (with Plan Medical Director review required for requests for amino-acid based tube fed enteral nutrition for a member after his/her 1st birthday until the member’s 3rd birthday, as specified in the Limitations section of this policy); AND

(b) The member has at least ONE (1) of the following symptoms for atopic disease associated with allergy-related formula intolerance, as specified below in items i through viii:

i. Anaphylaxis; OR

ii. Angioedema; OR

iii. Eczema; OR

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

v. Rhinitis; OR

vi. Urticaria; OR

vii. Vomiting; OR

viii. Wheezing; OR
(2) Non-allergy Related Formula Intolerance:

Member is an infant or child that has atopic disease associated with non-allergy related formula intolerance and meets BOTH of the following criteria, as specified below in item (a) and item (b):

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

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 (with Plan Medical Director review required for requests for amino-acid based tube fed enteral nutrition for a member after his/her 1st birthday until the member’s 3rd birthday, as specified in the Limitations section of this policy); AND

(b) The member has at least ONE (1) of the following conditions associated with non-allergy related formula intolerance, as specified below in items i through vi:

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

ii. Colic; OR

iii. Enterocolitis; OR

iv. Eosinophilic esophagitis; OR

v. Esophagitis; OR

vi. Malabsorption syndrome; OR

(3) Uncomplicated Gastrointestinal Reflux:

For a member that is an infant or child with uncomplicated gastrointestinal reflux symptoms, the Plan considers tube fed enteral nutritional therapy with extensively hydrolyzed, partially hydrolyzed, or amino acid-based formula to be medically necessary for at least ONE (1) of the following clinical circumstances, as specified below as either
item (a), item (b), or item (c) with age-specific guidelines determined by the member’s condition:

(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 two (2) to four (4) week trial of hydrolyzed formula is considered medically necessary (and is attempted with an unfavorable outcome before a two [2] to four [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, the applicable criterion for trial or continued use is met, as specified below in item i or item ii:

i. **Trial:** A two (2) to four (4) week trial of hydrolyzed formula is considered medically necessary (and is attempted with an unfavorable outcome before a two [2] to four [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

(c) For an infant or child with documented cow milk allergy and/or soy milk allergy, the applicable criterion for trial or continued use is met, as specified below in item i or item ii:

i. **Trial:** A two (2) to four (4) week trial of hydrolyzed formula is considered medically necessary (and is attempted with an unfavorable outcome before a two [2] to four [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 effective for this condition, hydrolyzed formula may be used for a member **until the member’s 2nd birthday** and an amino acid-based formula may be used for a member **until the member’s 1st birthday**.
2. **Indication: Impaired Digestion, Malabsorption, or Nutritional Risk**

The Plan considers 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) to be medically necessary for ALL members with impaired absorption‡ or nutritional risk when at least ONE (1) of the following applicable Plan criteria is met, as specified below as item a (for an acute condition) or item b (for a chronic condition):

a. The member is a nutritional risk from at least ONE (1) of the following **acute** conditions, as specified below in items (1) or (2):

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

   (Note: It is expected that the treating provider will discontinue tube fed enteral nutrition before eight [8] weeks if it is no longer medically necessary for the member. A request for administration of tube fed enteral nutrition beyond eight [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 (as specified in the Limitations section of this policy); OR

b. BOTH of the following Plan criteria are met for tube fed enteral nutrition therapy for a **chronic** condition, as specified below as item (1) and item (2):

   (1) The member is at nutritional risk from at least ONE (1) of the following chronic conditions, as specified below in items (a) through (h):

   (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) Ulcerative colitis; † OR

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(g) Inherited diseases of amino acids and organic acids;† ‡ OR

(h) Prolonged nutrient losses due to at least ONE (1) of the following, as specified below 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; AND

(2) As a result of at least ONE (1) of the conditions specified above in item a, the member presents with at least ONE (1) of the following clinical signs and symptoms of impaired digestion and/or malabsorption, as specified below in the member’s age-specific section of item (a) or item (b):

(a) Adult Member:

An adult member (i.e., a member age 21 or older on the date of service) has at least ONE (1) of the following conditions, as specified below as item i or item ii:

i. Member has involuntary or acute weight loss of greater than or equal to 10 percent 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; OR
(b) **Pediatric Member:**

Neonate, infant, or pediatric member (i.e., member under age 21 on the date of service) has at least ONE (1) of the following conditions, as specified below as item i or item ii:

i. Member’s weight-for-height child growth standard or BMI-for-age child growth standard is less than 10 percent; OR

ii. Deceleration of growth velocity and the member has crossed downward at least 2 percentile lines (or below two standard deviations) of weight for age on the standard growth chart.

**Notes:**

† According to Massachusetts state law, non-prescription enteral formulas are covered for specific conditions (indicated above with a †) 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 enrolled in BMC HealthNet Plan products and Well Sense Health Plan products when Plan criteria are met. See the Reference to Applicable Laws and Regulations section of this Plan policy.

‡ 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 enrolled in BMC HealthNet Plan products and Well Sense Health Plan products when Plan criteria are met. See the Reference to Applicable Laws and Regulations section of this Plan policy.

3. **Indication: Inborn Errors of Metabolism**

The Plan considers tube fed enteral nutrition products to be medically necessary for ALL members (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) when BOTH of the following criteria are met, as specified below in item a or item b:
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 at least ONE (1) of the following conditions, as specified below in items (1) through (12):

(1) Cystinosis; OR

(2) Glutaric acidemia; OR

(2) Hartnup disease; OR

(3) 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 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 which 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 enrolled in BMC HealthNet Plan products and Well Sense Health Plan products when Plan criteria are met. See the Reference to Applicable Laws and Regulations section of this Plan policy.

◊ 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 all members enrolled in BMC HealthNet Plan products and Well Sense Health Plan products when Plan criteria are met. See the Reference to Applicable Laws and Regulations section of this Plan policy.

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 and/or non-prescription formulas ordered by a treating physician or licensed practitioner working within the scope of the practitioner’s license) for ALL members with at least ONE (1) of the following conditions that is expected to be a permanent impairment or one of an indefinite duration, as specified below in items a through c:

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

**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 [CMS] guidelines for review).

5. **Indication: Treatment of Malabsorption**

   The Plan considers non-prescription and/or prescription tube fed enteral formulas to be medically necessary for the treatment of malabsorption for ALL members for home use when ordered by a physician (or a licensed practitioner, such as an advanced practitioner registered nurse or physician assistant, when working within the scope of the practitioner’s license) when malabsorption is caused by at least ONE (1) of the following conditions, as specified below in items a through g:

   a. Chronic intestinal pseudo-obstruction;† OR

   b. Crohn’s disease; †OR

   c. Gastroesophageal reflux disease; †OR

   d. Gastrointestinal motility disorder; †OR

   e. Inherited diseases of amino acids and organic acids;† OR

   f. Ulcerative colitis†; OR

   g. Inherited diseases of amino acids and organic acids;†‡
† Note: According to Massachusetts state law, non-prescription enteral formulas are covered for specific conditions (indicated above with a †) 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 enrolled in BMC HealthNet Plan products and Well Sense Health Plan products when Plan criteria are met. See the Reference to Applicable Laws and Regulations section of this Plan policy. (Also review Indication 2 for conditions related to impaired digestion and malabsorption.)

‡ Note: 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 enrolled in BMC HealthNet Plan products and Well Sense Health Plan products when Plan criteria are met. See the Reference to Applicable Laws and Regulations section of this Plan policy.

6. 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 working within the scope of the practitioner’s license).

7. 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 following information must be submitted, as specified below in items a through c:

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.
8. **Indication: Tube Fed Ketogenic Formula for Seizure Disorders in Pediatric Members**

ALL of the following criteria are met, as specified below in items a through d:

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

b. The member has recurrent, uncontrolled seizures with severe epilepsy and is refractory to antiepileptic drug (AED) treatment as determined by the treating physician; AND

c. Member does not have any disorders of fatty acid metabolism or other related pathways; AND

d. Member requires tube fed enteral nutrition as a component of a ketogenic diet treatment because of an inability to tolerate store bought food or liquid ketogenic diet due to a developmental issue or medical issue as demonstrated by at least ONE (1) of the following conditions, as specified below as item (1) or item (2):

(1) Member’s weight-for-height child growth standard or BMI-for-age child growth standard is less than 10 percent; OR

(2) Deceleration of growth velocity and the member has crossed (downward) at least 2 percentile lines of weight for age on the standard growth chart.

**Limitations**

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. See the member’s applicable benefit document available at www.bmchp.org for a BMC HealthNet Plan member (or at www.SeniorsGetMore.org for a Senior Care Options member) or www.wellsense.org for a Well Sense Health Plan member for benefit coverage guidelines and limits, including limits for low protein nutrition products.

2. The use of a digestive enzyme cartridge (e.g., RELiZORB™) with tube enteral feedings is considered experimental and investigational 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. When a home infusion provider is requesting an enteral feeding supply kit that does NOT include a digestive enzyme cartridge (e.g., RELiZORB™), the Plan will authorize the enteral feeding supply kit when the tube fed enteral nutrition therapy is authorized by the Plan according to applicable criteria, as specified in the Medical Policy Statement section of this policy.
3. 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, including findings of nutritionist evaluation, calorie counts, gastroenterologist and/or allergist evaluation (as appropriate).

4. Any request for a tube fed enteral nutrition product for a member with formula intolerance beyond the specified maximum age limits (as specified in the Medical Policy Statement section of this policy) requires Plan Medical Director review. (Review limitations 4 and 5 listed below.)

5. Plan Medical Director review is required for requests for amino-acid based tube fed enteral nutrition for a pediatric member with atopic disease associated with allergy-related formula intolerance after his/her 1st birthday until the member’s 3rd birthday. Authorizations subsequent to one (1) year of age will be for no more than six (6) month intervals. The treating provider must submit ALL of the following medical record documentation to the Plan for Medical Director review, as specified below in items a through e:
   a. Unsuccessful retrial of TWO (2) different cow milk-based and/or soy milk-based commercial, tube fed infant formulas or documentation that the retrial is contraindicated for the member; AND
   b. A nutritionist consult including calorie counts; AND
   c. A consult with a Pediatric Allergist and/or Gastroenterologist documenting the continued indication for the special formula requested; AND
   d. Documentation that supports the use of amino-acid based tube fed enteral nutritional rather than an extensively hydrolyzed and/or partially hydrolyzed tube fed enteral nutrition product with ONE (1) of the following criteria met, as specified below in item (1) or item (2):
      (1) Unsuccessful three (3) to five (5) day trial/challenge of a hydrolyzed and/or partially hydrolyzed tube fed enteral nutrition product every six (6) months rather than an amino-acid based tube fed enteral nutrition product; OR
      (2) Documentation that the trial is contraindicated for the member; AND
   e. The member has a documented history of at least ONE (1) of the following symptoms with atopic disease associated with allergy-related formula intolerance, as specified below in items (1) through (8):
(1) Anaphylaxis; OR
(2) Angioedema; OR
(3) Eczema; OR
(4) Persistent blood and/or mucus in stools; OR
(5) Rhinitis; OR
(6) Urticaria; OR
(7) Vomiting; OR
(8) Wheezing.

5. Plan Medical Director review is required for requests for amino-acid based tube fed enteral nutrition for a pediatric member with atopic disease associated with non-allergy-related formula intolerance after his/her 1st birthday until the member’s 3rd birthday. Authorizations subsequent to one (1) year of age will be for no more than six (6) month intervals. The treating provider must submit ALL of the following medical record documentation to the Plan for Medical Director review, as specified below in items a through e:

a. Unsuccessful retrial of TWO (2) different cow milk-based and/or soy milk-based commercial, tube fed infant formulas or documentation that the retrial is contraindicated for the member; AND

b. A nutritionist consult including calorie counts; AND

c. A consult with a Pediatric Allergist and/or Gastroenterologist documenting the continued indication for the special formula requested; AND

d. Documentation that supports the use of amino-acid based tube fed enteral nutritional rather than an extensively hydrolyzed and/or partially hydrolyzed tube fed enteral nutrition product with ONE (1) of the following criteria met, as specified below in item (1) or item (2):

(1) Unsuccessful three (3) to five (5) day trial/challenge of a hydrolyzed and/or partially hydrolyzed tube fed enteral nutrition product every six (6) months rather than an amino-acid based tube fed enteral nutrition product; OR

(2) Documentation that the trial is contraindicated for the member; AND
e. The member has a documented history of at least ONE (1) of the following conditions with atopic disease associated with non-allergy-related formula intolerance, as specified below in items (1) through (6):

(1) Allergic enteropathy and/or eosinophilic gastritis as evidenced by persistent blood and/or mucus in the stools; OR

(2) Colic; OR

(3) Enterocolitis; OR

(4) Eosinophilic esophagitis; OR

(5) Esophagitis; OR

(6) Malabsorption syndrome.

6. A request for continued tube fed enteral nutrition beyond eight [8] weeks requires Plan Medical Director review when the member is recovering from acute pancreatitis within the same episode of care; clinical documentation must be submitted to the Plan by the treating provider to support the medical necessity of continued tube fed enteral nutrition.

7. 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; is required (as specified in the Limitations section of this policy); clinical documentation must be submitted to the Plan by the treating provider to support the medical necessity of continued tube fed enteral nutrition.

Definitions

**Allergic Enteropathy:** A gastrointestinal food allergy involving the small and large intestines causing symptoms that include diarrhea, abdominal pain, blood and/or mucus in the stool and malabsorption.

**Atopic Dermatitis (Eczema):** A pruritic, chronic inflammatory skin disease that commonly presents during early childhood and is often associated with a personal or family history of other atopic diseases.

**Atopic Disease:** Clinical disease characterized by atopy, the genetic tendency to develop the classic allergic diseases; typically refers to atopic dermatitis, asthma, allergic rhinitis, and food allergy.

**Atopy:** A personal or familial tendency to produce immunoglobulin E (IgE) antibodies in response to low dose allergens may be confirmed by a positive skin-prick test result.
**Crohn’s Disease:** A type of inflammatory bowel disease (IBD), resulting in swelling and dysfunction of the intestinal tract.

**Cystinosis:** A genetic disease characterized by the widespread deposition of the amino acid cystine in cells due to a defect in cystine transport. (Cystine normally forms after protein degradation and is transported from structures called lysosomes into the cytoplasm. In cystinosis, cystine accumulates in the lysosomes and eventually forms crystals throughout the body. Cystinosis is therefore a lysosomal storage disease.)

**Early Intervention Services for BMC HealthNet Plan Members:** (Source: Massachusetts Department of Public Health. Early Intervention Operational Standards. July 2013.) Early Intervention services are:

1. Developmental services designed to meet the needs of each eligible infant or toddler and the needs of the family related to enhancing the infant or toddler’s development in the following areas: physical development, cognitive development, communication development, social or emotional development, or adaptive development;

2. Determined in collaboration with the family in accordance with the Individualized Family Service Plan (IFSP);

3. Provided by qualified personnel as defined by these standards;

4. Subject to the Early Intervention Operational Standards, DPH contracting, and Part C requirements (of the Massachusetts Department of Public Health Early Intervention Operational Standards, July 2013); AND

5. Available to all eligible infants and toddlers including Indian infants and toddlers, homeless infants and toddlers, and infants and toddlers who are wards of the state.

**Early and Periodic Screening, Diagnosis and Treatment (EPSDT) Services for Well Sense Health Plan Members:** (Source: General Court of New Hampshire Chapter He-W 500 Medical Assistance Section 546 Early and Periodic Screening, Diagnosis and Treatment Services.) EPSDT means a program, pursuant to 42 CFR 440.40, designed to provide preventative health care, diagnostic services, and early detection and treatment of disease or abnormalities to Title XIX eligible individuals under age 21.

1. EPSDT screening services:

   Comprehensive and age-appropriate medical assessments and screenings of the child’s physical and mental status provided according to the March 2000 periodicity schedule entitled “Recommendations for Preventive Pediatric Health Care” of the American Academy of Pediatrics including the following, as specified below in items a through l:
a. Comprehensive health and developmental history; AND

b. Comprehensive unclothed physical examination; AND

c. Developmental and behavioral assessment; AND

d. Measurements of the child’s height and weight, head circumference, and blood pressure; AND

e. Appropriate immunizations; AND

f. Appropriate laboratory tests will include the following, as specified below in item (1) and item (2):

(1) Testing for lead toxicity for EPSDT eligible children at 12 and 24 months of age; AND

(2) Testing for lead toxicity for EPSDT eligible children between 36 and 72 months of age, if not previously screened for lead poisoning; AND

g. Appropriate vision testing; AND

h. Appropriate hearing testing; AND

i. Assessment of nutritional status; AND


k. Health education about the benefits of healthy lifestyles and practices; AND

l. Anticipatory guidance about child safety and injury prevention.

2. EPSDT diagnostic and treatment services, if medically necessary as a result of assessment and screening, include the following specified below in items 1 through f:

a. Urinalysis; AND

b. Sickle cell screening; AND
c. Tuberculosis screening/testing; AND

d. Blood testing for hematocrit and/or hemoglobin levels; AND

e. Immunizations provided according to the 2006 issue of the “Recommended Childhood and Adolescent Immunization Schedule, United States 2006” jointly approved by the Advisory Committee on Immunization Practices, the American Academy of Pediatrics, and the American Academy of Family Physicians; AND

f. Any other Title XIX services as specified in He-W 522 through He-W 589, to treat conditions discovered during a screen.

3. Any services not listed in He-W 522 through He-W 589 as covered services shall be given independent review by the department for coverage based on medical necessity in accordance with He-W 546.06.

4. Transportation services, pursuant to He-W 574, 42 CFR 43.153, and 42 CFR 441.62, shall be covered for EPSDT-eligible children.

5. Services in excess of the service limits in He-W 530 shall be covered for EPSDT-eligible children, if medically necessary, in accordance with the requirements in He-W 546.

Eosinophilic Esophagitis (EE): An inflammatory condition of the esophagus that is characterized by having above normal amounts of eosinophils in the esophagus. Symptoms of EE vary with age and may mimic GERD. Infants often present with vomiting, irritability and poor weight gain.

Eosinophilic Gastritis: An uncommon gastritis that affects both children and adults characterized by abdominal pain, malabsorption, and often obstructive symptoms, associated with peripheral eosinophilia and areas of eosinophilic infiltration of the stomach.

Failure to Thrive: A condition in which the weight gain and growth are far below usual levels for a specified age. In general, failure to thrive is considered if weight falls lower than third percentile (as outlined in standard growth charts) or 20 percent below the ideal weight for the height. Growing may have slowed or stopped after a previously established growth curve.

Gastroesophageal Reflux: Also known as esophageal reflux or gastric reflux, condition is a backflow of the contents of the stomach into the esophagus, caused by relaxation of the lower esophageal sphincter.

Gastrointestinal Pseudo-Obstruction: The decreased motility of the intestines often causing dilation of various parts of the bowel. The clinical and radiological findings are often similar to true intestinal obstruction.
**Glutaric Acidemia:** A rare organic aciduria or inborn error of metabolism, the disease is caused by a heterogeneous group of genetic mutations that impair either mitochondrial (types I and II) or peroxisomal (type III) metabolism.

**Hartnup Disease:** An autosomal recessive disorder caused by impaired neutral amino acid transport in the apical brush border membrane of the small intestine and the proximal tubule of the kidney. Patients present with pellagra-like skin eruptions, cerebellar ataxia, and gross aminoaciduria.

**Histidinemia:** An inherited metabolic disorder caused by an enzyme defect marked by excessive histidine in the blood and urine due to deficient histidase activity. The condition may lead to nervous system disorders and may be controlled by diet that limits the intake of histidine.

**Hydrolyzed Formulas:** Formulas created by using enzymatic processes to break native proteins into smaller fragments. These nutrition products may prevent the development of allergic diseases by reducing exposure to intact allergens. Hydrolyzed formulas are created by using enzymatic processes to break native proteins into smaller fragments, and the enzymatic digestion may be partial or extensive resulting in larger (partially hydrolyzed) or smaller (extensively hydrolyzed) peptide fragments. An infant with formula intolerance may require extensively hydrolyzed formulas (e.g., cow's milk formulas or rice protein formulas), partially hydrolyzed formulas, modified soy formulas, or amino acid-based formulas (which are milk-free and made up of non-allergenic amino acids).

**Ketogenic Diet:** A high-fat, low-protein, and low-carbohydrate diet intended to control the occurrence of seizures by inducing a state of ketosis. It is generally used for patients with epilepsy who have not responded to conventional drug therapy. There is evidence from a number of studies that ketogenic diets can significantly reduce seizure frequency in a sizable percentage of pediatric patients with epilepsy who have failed or cannot tolerate anti-epileptic drug treatment. There is less evidence regarding the efficacy of ketogenic diets in adult patients. While ketogenic diets can have a number of adverse effects, they need to be balanced against the dangers posed by uncontrolled seizures and the side effects of alternative treatment options.

**Malabsorption Syndromes:** Conditions that result in the inadequate absorption of nutrients in the intestinal tract. Examples of malabsorption syndromes include short bowel syndrome, radiation enteritis, pancreatitis, celiac disease, post gastrectomy and intestinal resection, sprue, infections, cystic fibrosis, liver disease, and Whipple’s disease.

**Medical Food:** According to the U. S. Food and Drug Administration (FDA) and section 5(b) of the Orphan Drug Act 21 [U.S.C. 360ee (b)(3)], medical food is defined as "a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation." The FDA lists the following criteria that define a medical food: (1) Specially formulated and processed for the partial or exclusive feeding of a patient by means of oral intake or enteral feeding tube; (2) intended for the dietary management of a patient who has limited or impaired capacity to ingest, digest, absorb, or
metabolize ordinary foodstuffs or certain nutrients, or who has other special medically determined nutrient requirements, the management of which cannot be achieved by the modification of the normal diet alone; (3) provides nutritional support specifically modified for the management of the unique nutrient needs that result from the specific disease or condition, as determined by medical evaluation; (4) intended to be used under medical supervision; and (5) intended only for a patient receiving active and ongoing medical supervision. Medical foods do not undergo premarket review or approval by FDA. Individual medical food products do not have to be registered with FDA; however, food facilities must be registered.

**Methylmalonic Acidemia:** An inherited metabolic disease caused by inability to convert methylmalonic acid to succinic acid; the body cannot break down certain proteins and fats and the result is a buildup of a methylmalonic acid in the blood. Clinically, signs are failure to grow, mental retardation, severe metabolic acidosis, seizures, and stroke. Babies may appear normal at birth, but develop symptoms once they start eating more protein, which can cause the condition to get worse. About 1 in 48,000 babies are born with this condition and the disease is usually diagnosed in the first year of life.

**Nutritional Risk:** A member who has actual or the potential for developing malnutrition as evidenced by clinical indicators, the presence of chronic disease, or increased metabolic requirements due to the inability to ingest, digest, or absorb food adequately.

**Organic Acidemias:** A group of inheritable genetic metabolic disorders in which there is a defect in protein metabolism where an essential enzyme is absent or malfunctioning. This defect results in a buildup of chemicals, in this case usually acids, on one side of the metabolic blockage and a deficiency of vital chemicals on the other. This causes an over dosage of one chemical (often toxic) and the shortage of another which is essential to normal body functioning. Characteristics of the conditions include general malaise, reluctance to feed, breathing problems, vomiting, hypotonia (floppiness) and/or spasticity (stiffness).

**Phenylketonuria (PKU):** A congenital, autosomal recessive disease marked by failure to metabolize the amino acid phenylalanine (Phe) to tyrosine. Phe is in almost all foods. The best treatment for PKU is a diet of low-protein foods. The disease results in severe neurological deficits in infancy if it is unrecognized or left untreated. It is recommended that individuals who wish to become pregnant should optimize their levels two (2) to three (3) months before conception and continue close monitoring during pregnancy.

**Ulcerative Colitis:** A chronic disease of unknown cause characterized by ulceration of the colon and rectum, with rectal bleeding, mucosal crypt abscesses, inflammatory pseudopolyps, abdominal pain, and diarrhea; frequently causes anemia, hypoproteinemia, and electrolyte imbalance, and is less frequently complicated by peritonitis, toxic megacolon, or carcinoma of the colon.

**Urea Cycle Disorder:** A genetic disorder caused by a mutation that results in a deficiency of one of the six enzymes in the urea cycle. These enzymes are responsible for removing ammonia from the blood. 

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stream. The urea cycle involves a series of biochemical steps in which nitrogen, a waste product of protein metabolism, is removed from the blood and converted to urea in the blood. Urea is normally transferred into the urine and removed from the body. In urea cycle disorders, the nitrogen accumulates in the form of ammonia, a highly toxic substance, resulting in hyperammonemia (elevated blood ammonia). Ammonia then reaches the brain through the blood, where it can cause irreversible brain damage, coma and/or death.

**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). Because 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 Medical Policy Statement section and Limitation section 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 the Applicable Coding section of this Plan policy. Coverage for services is subject to benefit eligibility under the member’s benefit plan. Please refer to the member’s benefits document in effect at the time of the service to determine coverage or non-coverage as it applies to an individual member. See Plan reimbursement policies for Plan billing guidelines. Review Plan policy, Reimbursement Guidelines – *Infusion/Parenteral/Tube Fed Enteral Nutrition Therapy* (policy number 4.121) for reimbursement guidelines for services rendered to BMC HealthNet Plan members.

<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description: Codes Covered When Medically Necessary</th>
</tr>
</thead>
<tbody>
<tr>
<td>B4102</td>
<td>Enteral formula, for adults, used to replace fluids and electrolytes (e.g., clear liquids), 500 ml = 1 unit</td>
</tr>
</tbody>
</table>

Δ Plan note: HCPCS code B4102 is an applicable code for BMC HealthNet Plan products only (including MassHealth, Qualified Health Plans/ConnectorCare/Employer Choice Direct, and Senior Care Options products); this code does not apply to members enrolled in a Well Sense Health Plan product.
<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>B4103</td>
<td>Enteral formula, for pediatrics, used to replace fluids and electrolytes (e.g., clear liquids), 500 ml = 1 unit</td>
</tr>
<tr>
<td></td>
<td>Δ Plan note: HCPCS code B4103 is an applicable code for MassHealth and Qualified Health Plans/ConnectorCare/Employer Choice Direct products only; this code does not apply to members enrolled in a Well Sense Health Plan product or Senior Care Options product.</td>
</tr>
<tr>
<td>B4104</td>
<td>Additive for enteral formula (e.g., fiber)</td>
</tr>
<tr>
<td>B4149</td>
<td>Enteral formula, manufactured blended/modified 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</td>
</tr>
<tr>
<td>B4150</td>
<td>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</td>
</tr>
<tr>
<td>B4152</td>
<td>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</td>
</tr>
<tr>
<td>B4153</td>
<td>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</td>
</tr>
<tr>
<td>B4154</td>
<td>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</td>
</tr>
<tr>
<td>B4155</td>
<td>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</td>
</tr>
<tr>
<td>B4157</td>
<td>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</td>
</tr>
<tr>
<td>B4158</td>
<td>Enteral formula, for pediatrics, nutritionally complete 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</td>
</tr>
<tr>
<td>B4159</td>
<td>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</td>
</tr>
</tbody>
</table>
### Tube Fed Enteral Nutrition Products (Supplied and Billed by Home Infusion Providers) and Digestive Enzyme Cartridges

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Description: Code Considered Either Medically Necessary or Experimental and Investigation Based on Code-Specific Guidelines</th>
</tr>
</thead>
<tbody>
<tr>
<td>B4160</td>
<td>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</td>
</tr>
<tr>
<td>B4161</td>
<td>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</td>
</tr>
<tr>
<td>B4162</td>
<td>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</td>
</tr>
</tbody>
</table>

Plan notes:
1. One (1) of the following codes should be used when billing for an enteral feeding supply kit that includes a digestive enzyme cartridge (e.g., RELiZORB™) as a component of the supply kit: HCPCS code B4034, B4035, or B4036. There is no separate billing code for the digestive enzyme cartridge.
2. Plan prior authorization is required for the use of a digestive enzyme cartridge. The Plan considers a digestive enzyme cartridge (e.g., RELiZORB™) experimental and investigational, as specified in the Limitations section of this policy.
3. When this code is used by a durable medical equipment (DME) provider for an enteral feeding supply kit that does NOT include a digestive enzyme cartridge (e.g., RELiZORB™), the DME provider must contact Northwood, Inc. at [www.northwoodinc.com](http://www.northwoodinc.com) or by phone at 1-866-802-6471 to obtain prior authorization from Northwood.
4. When this code is used by a home infusion provider for an enteral feeding supply kit that does NOT include a digestive enzyme cartridge (e.g., RELiZORB™), the Plan will authorize the enteral feeding supply kit when the tube fed enteral nutrition therapy is authorized by the Plan (according to guidelines in the Medical Policy Statement section of this policy).

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Description: Code Considered Either Medically Necessary or Experimental and Investigation Based on Code-Specific Guidelines</th>
</tr>
</thead>
<tbody>
<tr>
<td>B4034</td>
<td>Enteral feeding supply kit; syringe fed, per day, includes but not limited to feeding/flushing syringe, administration of set tubing, dressings, tape</td>
</tr>
</tbody>
</table>

Plan notes:
1. One (1) of the following codes should be used when billing for an enteral feeding supply kit that includes a digestive enzyme cartridge (e.g., RELiZORB™) as a component of the supply kit: HCPCS code B4034, B4035, or B4036. There is no separate billing code for the digestive enzyme cartridge.

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</thead>
<tbody>
<tr>
<td>B4035</td>
<td>Enteral feeding supply kit; pump fed, per day, includes but not limited to feeding/flushing syringe, administration of set tubing, dressings, tape</td>
</tr>
</tbody>
</table>

Plan notes:
1. One (1) of the following codes should be used when billing for an enteral feeding supply kit that includes a digestive enzyme cartridge (e.g., RELiZORB™) as a component of the supply kit: HCPCS code B4034, B4035, or B4036. There is no separate billing code for the digestive enzyme cartridge.

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2. Plan prior authorization is required for the use of a digestive enzyme cartridge. The Plan considers a digestive enzyme cartridge (e.g., RELiZORB™) experimental and investigational, as specified in the Limitations section of this policy.

3. When this code is used by a durable medical equipment (DME) provider for an enteral feeding supply kit that does NOT include a digestive enzyme cartridge (e.g., RELiZORB™), the DME provider must contact Northwood, Inc. at www.northwoodinc.com or by phone at 1-866-802-6471 to obtain prior authorization from Northwood.

4. When this code is used by a home infusion provider for an enteral feeding supply kit that does NOT include a digestive enzyme cartridge (e.g., RELiZORB™), the Plan will authorize the enteral feeding supply kit when the tube fed enteral nutrition therapy is authorized by the Plan (according to guidelines in the Medical Policy Statement section of this policy).

| B4036 | Enteral feeding supply kit; gravity fed, per day, includes but not limited to feeding/flushing syringe, administration of set tubing, dressings, tape |

Plan notes:

1. One (1) of the following codes should be used when billing for an enteral feeding supply kit that includes a digestive enzyme cartridge (e.g., RELiZORB™) as a component of the supply kit: HCPCS code B4034, B4035, or B4036. There is no separate billing code for the digestive enzyme cartridge.

2. Plan prior authorization is required for the use of a digestive enzyme cartridge. The Plan considers a digestive enzyme cartridge (e.g., RELiZORB™) experimental and investigational, as specified in the Limitations section of this policy.

3. When this code is used by a durable medical equipment (DME) provider for an enteral feeding supply kit that does NOT include a digestive enzyme cartridge (e.g., RELiZORB™), the DME provider must contact Northwood, Inc. at www.northwoodinc.com or by phone at 1-866-802-6471 to obtain prior authorization from Northwood.

4. When this code is used by a home infusion provider for an enteral feeding supply kit that does NOT include a digestive enzyme cartridge (e.g., RELiZORB™), the Plan will authorize the enteral feeding supply kit when the tube fed enteral nutrition therapy is authorized by the Plan (according to guidelines in the Medical Policy Statement section of this policy).

### Applicable Coding for Well Sense 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 &

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Medicaid Services (CMS). Because 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 Medical Policy Statement section and Limitation section 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 the Applicable Coding section of this Plan policy. Coverage for services is subject to benefit eligibility under the member’s benefit plan. Please refer to the member’s benefits document in effect at the time of the service to determine coverage or non-coverage as it applies to an individual member. See Plan reimbursement policies for Plan billing guidelines. See Plan policy, Reimbursement Guidelines – *Home Infusion Including Parenteral/Tube Fed Enteral Nutrition* (policy number WS 4.22) for reimbursement guidelines for services provided to Well Sense Health Plan members.

<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description: Codes Covered When Medically Necessary</th>
</tr>
</thead>
<tbody>
<tr>
<td>B4104</td>
<td>Additive for enteral formula (e.g., fiber)</td>
</tr>
<tr>
<td>B4149</td>
<td>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</td>
</tr>
<tr>
<td>B4150</td>
<td>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</td>
</tr>
<tr>
<td>B4152</td>
<td>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</td>
</tr>
<tr>
<td>B4153</td>
<td>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</td>
</tr>
<tr>
<td>B4154</td>
<td>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</td>
</tr>
<tr>
<td>B4155</td>
<td>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</td>
</tr>
<tr>
<td>HCPCS Code</td>
<td>Description: Code Considered Either Medically Necessary or Experimental and Investigation Based on Code-Specific Guidelines</td>
</tr>
<tr>
<td>------------</td>
<td>---------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>B4034</td>
<td>Enteral feeding supply kit; syringe fed, per day, includes but not limited to feeding/flushing syringe, administration of set tubing, dressings, tape</td>
</tr>
</tbody>
</table>

Plan notes:
1. One (1) of the following codes should be used when billing for an enteral feeding supply kit that includes a digestive enzyme cartridge (e.g., RELiZORB™) as a component of the supply kit: HCPCS code B4034, B4035, or B4036. There is no separate billing code for the digestive enzyme cartridge.
2. Plan prior authorization is required for the use of a digestive enzyme cartridge. The Plan considers a digestive enzyme cartridge (e.g., RELiZORB™) experimental and investigational, as specified in the Limitations section of this policy.
3. When this code is used by a durable medical equipment (DME) provider for an enteral feeding supply kit that does NOT include a digestive enzyme cartridge (e.g., RELiZORB™), the DME provider must contact Northwood, Inc. at www.northwoodinc.com or by phone at 1-866-802-6471 to obtain prior authorization from Northwood.
4. When this code is used by a home infusion provider for an enteral feeding supply kit that does NOT include a digestive enzyme cartridge (e.g., RELiZORB™), the Plan will authorize the enteral feeding supply kit when the tube fed enteral nutrition is medically necessary.

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<table>
<thead>
<tr>
<th>B4035</th>
<th>Enteral feeding supply kit; pump fed, per day, includes but not limited to feeding/flushing syringe, administration of set tubing, dressings, tape</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plan notes:</td>
<td>1. One (1) of the following codes should be used when billing for an enteral feeding supply kit that includes a digestive enzyme cartridge (e.g., RELiZORB™) as a component of the supply kit: HCPCS code B4034, B4035, or B4036. There is no separate billing code for the digestive enzyme cartridge. 2. Plan prior authorization is required for the use of a digestive enzyme cartridge. The Plan considers a digestive enzyme cartridge (e.g., RELiZORB™) experimental and investigational, as specified in the Limitations section of this policy. 3. When this code is used by a durable medical equipment (DME) provider for an enteral feeding supply kit that does NOT include a digestive enzyme cartridge (e.g., RELiZORB™), the DME provider must contact Northwood, Inc. at <a href="http://www.northwoodinc.com">www.northwoodinc.com</a> or by phone at 1-866-802-6471 to obtain prior authorization from Northwood. 4. When this code is used by a home infusion provider for an enteral feeding supply kit that does NOT include a digestive enzyme cartridge (e.g., RELiZORB™), the Plan will authorize the enteral feeding supply kit when the tube fed enteral nutrition therapy is authorized by the Plan (according to guidelines in the Medical Policy Statement section of this policy).</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>B4036</th>
<th>Enteral feeding supply kit; gravity fed, per day, includes but not limited to feeding/flushing syringe, administration of set tubing, dressings, tape</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plan notes:</td>
<td>1. One (1) of the following codes should be used when billing for an enteral feeding supply kit that includes a digestive enzyme cartridge (e.g., RELiZORB™) as a component of the supply kit: HCPCS code B4034, B4035, or B4036. There is no separate billing code for the digestive enzyme cartridge. 2. Plan prior authorization is required for the use of a digestive enzyme cartridge. The Plan considers a digestive enzyme cartridge (e.g., RELiZORB™) experimental and investigational, as specified in the Limitations section of this policy. 3. When this code is used by a durable medical equipment (DME) provider for an enteral feeding supply kit that does NOT include a digestive enzyme cartridge (e.g., RELiZORB™), the DME provider must contact Northwood, Inc. at <a href="http://www.northwoodinc.com">www.northwoodinc.com</a> or by phone at 1-866-802-6471 to obtain prior authorization from Northwood. 4. When this code is used by a home infusion provider for an enteral feeding supply kit that does NOT include a digestive enzyme cartridge (e.g., RELiZORB™), the Plan will authorize the enteral feeding supply kit when the tube fed enteral nutrition therapy is authorized by the Plan (according to guidelines in the Medical Policy Statement section of this policy).</td>
</tr>
</tbody>
</table>
therapy is authorized by the Plan (according to guidelines in the Medical Policy Statement section of this policy).

Clinical Background Information

At the time of the Plan’s most recent policy review, the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) 180.2 includes medically necessary indications for enteral and parenteral nutritional therapy when applicable CMS clinical criteria and administrative guidelines (e.g., Medicare Claims Processing Manual Chapter 20 Durable Medical Equipment, Prosthetics, Orthotics, and Supplies and the Stage 2 Critical Elements for Tube Feeding Status form CMS–20093) are met for beneficiaries. NCD 180.2 states the following: “Enteral nutrition is considered reasonable and necessary for a patient with a functioning gastrointestinal tract who, due to pathology to, or non-function of, the structures that normally permit food to reach the digestive tract, cannot maintain weight and strength commensurate with his or her general condition. Enteral therapy may be given by nasogastric, jejunostomy, or gastrostomy tubes and can be provided safely and effectively in the home by nonprofessional persons who have undergone special training…Each claim must contain a physician’s written order or prescription and sufficient medical documentation (e.g., hospital records, clinical findings from the attending physician) to permit an independent conclusion that the patient’s condition meets the requirements of the prosthetic device benefit and that enteral nutrition therapy is medically necessary… If the claim involves a pump, it must be supported by sufficient medical documentation to establish that the pump is medically necessary, i.e., gravity feeding is not satisfactory due to aspiration, diarrhea, dumping syndrome…Some patients require supplementation of their daily protein and caloric intake. Nutritional supplements are often given as a medicine between meals to boost protein-caloric intake or the mainstay of a daily nutritional plan. Nutritional supplementation is not covered under Medicare Part B.” Medicare does provide reimbursement under the part-B prosthetic-device benefit for enteral nutrition. No NCD or local coverage determination (LCD) was found for ketogenic diets or RELiZORB™ was identified on the CMS website. Verify CMS criteria in the applicable NCD or local coverage determination (LCD) and coverage guidelines in effect on the date of the prior authorization request for a Senior Care Options member for the requested service (and indication for treatment).

According to the CMS NCD 180.1 for medical nutrition therapy (MNT), CMS covers MNT for a beneficiary with a diagnosis of renal disease and/or diabetes according to CMS established criteria based on duration of treatment, episode of care, date of service, and number of units administered per day. As stated in NCD 180.1, additional treatment may be considered medically necessary and covered if the treating physician determines that there is a change in the beneficiary’s medical condition, diagnosis, and/or treatment regimen that requires a change in MNT and the physician orders additional MNT during that episode of care.
References


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

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Welch T. Dietary management of mothers with PKU during pregnancy. J Pediatr. Feb 2004; 144(2); 1A.


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<table>
<thead>
<tr>
<th>Original Approval Date</th>
<th>Original Effective Date* and Version Number</th>
<th>Policy Owner</th>
<th>Approved by</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulatory Approval: N/A Internal Approval: 03/25/03</td>
<td>05/25/03 Version 1</td>
<td>Medical Policy Manager as Chair of Medical Policy, Criteria, and Technology Assessment Committee (MPCTAC) and member of Quality Improvement Committee (QIC)</td>
<td>Quality and Clinical Management Committee (Q&amp;CMC)</td>
</tr>
</tbody>
</table>

*Effective Date for the BMC HealthNet Plan Commercial Product(s): 01/01/12
*Effective Date for the Well Sense Health Plan New Hampshire Medicaid Product(s): 01/01/13
*Effective Date for the Senior Care Options Product(s): 01/01/16

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**Policy Revisions History**

<table>
<thead>
<tr>
<th>Review Date</th>
<th>Summary of Revisions</th>
<th>Revision Effective Date and Version Number</th>
<th>Approved by</th>
</tr>
</thead>
<tbody>
<tr>
<td>09/06/05</td>
<td>Updated clinical coverage criteria.</td>
<td>Version 2</td>
<td>09/06/05: Q&amp;CMC</td>
</tr>
<tr>
<td>11/07/06</td>
<td>Removed procedure section as preauthorization requirement does not apply.</td>
<td>Version 3</td>
<td>11/07/06: Q&amp;CMC</td>
</tr>
<tr>
<td>11/13/07</td>
<td>No changes.</td>
<td>Version 4</td>
<td>11/13/07: MPCTAC</td>
</tr>
<tr>
<td>05/13/08</td>
<td>Review for effective date 09/01/08. Updated clinical criteria and added preauthorization requirements for certain categories of formulas.</td>
<td>09/01/08 Version 5</td>
<td>05/13/08: MPCTAC, 06/24/08: Utilization Management Committee (UMC), 06/26/08: QIC</td>
</tr>
<tr>
<td>06/23/09</td>
<td>Review for effective date 10/01/09. Added 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.)</td>
<td>10/01/09 Version 6</td>
<td>06/23/09: MPCTAC, 06/23/09: UMC, 07/22/09: QIC</td>
</tr>
<tr>
<td>10/27/09</td>
<td>Revised WIC information.</td>
<td>Version 7</td>
<td>10/27/09: MPCTAC, 11/19/09: QIC</td>
</tr>
<tr>
<td>10/01/10</td>
<td>Revised the criteria for hydrolyzed formulas, updated references and definitions.</td>
<td>Version 8</td>
<td>10/20/10: MPCTAC, 11/22/10: QIC</td>
</tr>
<tr>
<td>04/01/11</td>
<td>Revised this policy to be applicable for enteral nutritional tube fed products dispensed and billed</td>
<td>Version 9</td>
<td>10/19/11: MPCTAC, 11/29/11: QIC</td>
</tr>
</tbody>
</table>

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

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**Policy Revisions History**

<table>
<thead>
<tr>
<th>Date</th>
<th>Description</th>
<th>Version</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>10/01/11</td>
<td>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.</td>
<td>Version 10</td>
<td>10/19/11: MPCTAC 11/29/11: QIC</td>
</tr>
<tr>
<td>08/20/12</td>
<td>Off cycle review for Well Sense Health Plan, reformatted Medical Policy Statement, revised code list to include all enteral products, updated references. Review of entire policy conducted.</td>
<td>Version 11</td>
<td>08/30/12: MPCTAC 09/06/12: QIC</td>
</tr>
<tr>
<td>10/01/12 and 11/01/12</td>
<td>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.</td>
<td>03/01/13 Version 12</td>
<td>10/17/12: MPCTAC 11/24/12: MPCTAC 12/20/12: QIC</td>
</tr>
<tr>
<td>08/14/13 and 08/15/13</td>
<td>Off cycle review for Well Sense Health Plan and merged policy format. Incorporate policy revisions dated 10/01/12 and 11/01/12 (as specified above) for the Well Sense Health Plan 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.</td>
<td>Version 13</td>
<td>08/14/13: MPCTAC (via electronic vote) 08/15/13: QIC</td>
</tr>
<tr>
<td>08/21/13</td>
<td>Review for effective date 10/01/13. Revised Medical Policy Statement section without changing criteria. Updated references.</td>
<td>10/01/13 Version 14</td>
<td>08/21/13: MPCTAC 09/19/13: QIC</td>
</tr>
<tr>
<td>09/01/14</td>
<td>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</td>
<td>01/01/15 Version 15</td>
<td>09/24/14: MPCTAC (electronic vote) 10/08/14: QIC</td>
</tr>
</tbody>
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<th>Version</th>
<th>Reviewer</th>
</tr>
</thead>
<tbody>
<tr>
<td>09/01/15</td>
<td>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.</td>
<td>01/01/16 Version 16</td>
<td>09/16/15: MPCTAC 10/14/15: QIC</td>
<td></td>
</tr>
<tr>
<td>11/25/15</td>
<td>Review for effective date 01/14/16. Revised language in the Applicable Coding sections.</td>
<td>01/14/16 Version 17</td>
<td>11/25/15: MPCTAC (electronic vote) 12/09/15: QIC</td>
<td></td>
</tr>
<tr>
<td>09/01/16 and 09/28/16</td>
<td>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 code list. Administrative changes made to clarify language related to gender.</td>
<td>11/01/16 Version 18</td>
<td>09/21/16: MPCTAC 09/30/16: MPCTAC (electronic vote) 10/12/16: QIC</td>
<td></td>
</tr>
<tr>
<td>12/01/16</td>
<td>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.</td>
<td>04/01/17 Version 19</td>
<td>12/21/16: MPCTAC 01/11/17: QIC</td>
<td></td>
</tr>
</tbody>
</table>

**Last Review Date**

12/01/16
Next Review Date
09/01/17

Authorizing Entity
QIC

Other Applicable Policies
Medical Policy - *Experimental and Investigational Treatment*, policy number OCA 3.12
Medical Policy - *Medically Necessary*, policy number OCA 3.14
Medical Policy - *Medical Nutrition Therapy in the Outpatient Setting or Office Setting*, policy number OCA 3.66
Reimbursement Policy - *Home Infusion Including Parenteral/Tube Fed Enteral Nutrition*, policy number WS 4.22
Reimbursement Policy - *Infusion/Parenteral/Tube Fed Enteral Nutrition Therapy*, policy number 4.121

Reference to Applicable Laws and Regulations


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The Commonwealth of Massachusetts. General Laws. Part 1. Title XXII. Chapter 175. Section 47C. Dependent Coverage for Newborn Infants or Adoptive Children; Inclusion in Policies of Accident and Sickness Insurance. (Special Infant Formulas.) Accessed at: https://malegislature.gov/Laws/GeneralLaws/PartI/TitleXXII/Chapter175/Section47c


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 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.

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