

**Subject: Formulas and Enteral Nutrition**

**Background:** Nutritional formulas are prescription or over-the-counter liquid products that are used as supplements in place of normal food. Enteral nutrition, also known as tube feeding, is a method used to supply nutrition to individuals who may have difficulties in swallowing, or some type of surgery that interferes with eating. It consists of providing nutrients through the gastrointestinal tract. Selection of formulas and enteral nutrition can depend on the member's age, tolerance to intact protein, and disease-specific considerations. Common indications for enteral nutrition include impaired swallowing or intestinal dysfunction, excessive metabolic demands, and impaired absorption or digestion.

**Authorization:** Prior authorization is required for ALL formulas and enteral nutrition requested for members enrolled in commercial (HMO, POS, and PPO) products.

Prior authorization is NOT required for low protein foods ordered for individuals with inherited diseases of amino acids or organic acids.

Coverage requests must include pertinent clinical notes, and be submitted on the appropriate Harvard Pilgrim Health Care (HPHC) Request form (available in HPHC's Provider Manual).

Required documentation includes:

- For infants and pediatric patients: weight for age, weight for height growth charts, and Body Mass Index (BMI) charts (if applicable);
- For adults, documentation of BMI and/or weight measured over time.

**Policy and Coverage Criteria:**

Harvard Pilgrim Health Care (HPHC) considers low protein foods, oral special medical formulas and enteral as medically necessary when a member is at risk for developing malnutrition due to a medical condition, chronic disease or increase metabolic requirements resulting from inability to ingest or adequately absorb food and when ALL the following administration criteria and age-specific criteria are met:

**Oral Administration Criteria:**

1. The member's age and/or medical condition precludes the use of regular food, standard commercial formulas and/or or supplementation with commercially available food products (e.g., Carnation Instant Breakfast, thickeners, butter or cream added to prepared foods) in sufficient caloric density to provide more than 50% of individual's daily caloric needs, AND

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2. The medical formula or enteral nutrition is expected to provide more than 50% of the member's daily nutritional intake when a licensed physician has diagnosed and documented significant risk factors for actual or potential malnutrition, AND
3. Non-prescription formulas for home use are expected to be utilized as standard transitional formula for premature infants whose weight is above the 10<sup>th</sup> percentile, AND
4. Clinical documentation confirms need for enteral formulas to treat ANY of the following:
  - a. Medical conditions in adults and pediatric members related to malabsorption and associated with:
    - Crohn's disease
    - Ulcerative colitis
    - Gastroesophageal reflux disease (GERD)
    - Gastrointestinal motility disorder
    - Chronic intestinal pseudo-obstruction
    - Inherited diseases of amino acids and organic acids
  - b. Medical conditions in adults and pediatric members related to inborn errors of metabolism and associated with:
    - Tyrosinemia
    - Homocystinuria
    - Maple syrup urine disease
    - Propionic acidemia
    - Methylmalonic acidemia
    - Urea cycle disorders
    - Phenylketonuria (PKU)
    - Protection of fetus in pregnant individual with PKU
    - Other organic acidemias
  - c. Medical conditions in adults and pediatric related to interferences with nutrient absorption and assimilation and associated with:
    - Allergy or hypersensitivity to cow or soy milk
    - Allergy to foods (e.g. food-induced anaphylaxis)
    - Cystic fibrosis
    - Diarrhea or vomiting
    - Allergic or eosinophilic enteritis
    - Failure to thrive based

### **Tube Administration Criteria:**

Harvard Pilgrim Health Care considers tube administration of medical formulas and enteral nutrition as medically necessary when the member meets oral administration criteria, provides justification for insufficiency of oral method, confirms the necessity for a tube, and meets ALL the following criteria:

1. The medical formula or enteral nutrition is expected to provide more than 50% of the individual's daily nutritional intake, AND
2. The member experiences difficulty swallowing due to a medical condition (e.g. tumors, neurological conditions, severe chronic anorexia nervosa) and is unable to maintain weight and nutrition with oral administration, AND

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- The individual is under the supervision of a healthcare provider who is authorized to prescribe such dietary treatments.

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

**Condition-Specific Criteria**

<b>Condition</b>	<b>Criteria</b>	<b>Additional Information</b>
<b>Atopic Dermatitis (AD)</b>	<p>Special medical formula is authorized for infants up to age 1 year when:</p> <ol style="list-style-type: none"> <li>Attending allergist confirms the presence of formula induced atopic dermatitis; AND.</li> <li>Documentation confirms role of commercial formulas in causing atopic dermatitis (e.g., an immediate reaction after ingestion, or a well-defined elimination diet).</li> </ol> <p>Subsequent requests for children over age 1 year must include documentation of ALL the following:</p> <ol style="list-style-type: none"> <li>Results of nutritionist consult including calorie counts;</li> <li>Results of allergist re-evaluation to further document food allergy;</li> <li>Consideration of re-trial of commercial foods or formula.</li> </ol>	
<b>Bloody Stools with or Without Weight Loss or Other GI Symptoms</b>	<p>Special medical formulas are authorized for eligible infants up to 1-year-old when ALL the following are met:</p> <ol style="list-style-type: none"> <li>Guaiac card testing confirms the presence of bloody stools;</li> <li>Other etiologies (e.g., anorectal fissure, infectious/inflammatory colitis) have been excluded by history and physical exam, and/or further testing and serial guaiac (as appropriate);</li> <li>Bloody stools occurred while the infant was given a cow milk-based formula or breastfeeding, and a dairy-elimination diet resolved the problem.</li> </ol>	<p>Potential formula-related diagnoses include:</p> <ul style="list-style-type: none"> <li>Non-IgE mediated food protein-induced proctocolitis associated with blood streaked stools in a generally healthy member;</li> <li>Food protein-induced enteropathy associated with malabsorption, failure to thrive, diarrhea and vomiting</li> <li>Food protein-induced enterocolitis associated with</li> </ul>

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	<p>Note: Trial of soy formula trial is not required for infants up to age 1 year due to the high cross intolerance to soy-based formula for these conditions.</p> <p>Subsequent requests for children over the age of 1 year must include results of nutritionist consultation (including calorie counts) and gastroenterologist evaluation.</p> <ul style="list-style-type: none"> <li>• Unless contraindicated, retrial of commercial formulas must be considered.</li> </ul>	<p>malabsorption and failure to thrive. (Acute reactions include recurrent vomiting, diarrhea, and dehydration.)</p>
<p><b>Eosinophilic Esophagitis (EE)</b></p> <p><b>Eosinophilic Gastroenteritis</b></p>	<p>Enteral nutrition is authorized for eligible infants and children when documentation (including endoscopy and biopsy) confirms ALL the following:</p> <ol style="list-style-type: none"> <li>1. Member is closely followed by nutritionist, gastroenterologist, and allergist (if clinically indicated); AND</li> <li>2. Either of the following: <ul style="list-style-type: none"> <li>• For formula fed infants: A high suspicion (confirmed by elimination diet or supportive IgE-specific antibody testing) that symptoms are caused by milk and soy exposure; OR</li> <li>• For children: Condition is caused by multiple food groups, and multi-food elimination diet (including elimination of milk and soy) is planned.</li> </ul> </li> </ol> <p>When criteria are met, the requested special medical formula/enteral nutrition need not constitute more than 50% of the member's daily caloric intake as treatment goal is to provide calories and nutrients that cannot be obtained through regular foods/allergy-free-vitamins in these highly allergic members.</p> <p>Subsequent requests must include documentation of intervening medical and</p>	<p>In children, these conditions are typically characterized by symptoms including intermittent vomiting, food refusal, dysphagia, abdominal pain, and/or weight loss. (These conditions rarely occur in infants.)</p>

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	nutritional reassessments (including calorie counts) and follow up endoscopy to determine if the clinical condition has improved enough to allow intake of other nutrients.	
<p><b>Failure to Thrive (FTT)</b></p> <p><b>Note: Diagnosis of FIT does not automatically apply to infants or children whose growth velocity is tracking along a weight for length growth curve, even if the curve is &lt;2<sup>nd</sup> percentile.</b></p>	<p>Special medical formula/enteral nutrition is authorized for up to 6 months when documentation confirms a member at nutritional risk meets ANY of the following:</p> <ol style="list-style-type: none"> <li>1. For infants and children age 0-24 months, ANY of the following: <ul style="list-style-type: none"> <li>• Decrease of 2 or more major weight for age percentile lines over time; or</li> <li>• Weight less than the 5<sup>th</sup> percentile for age (corrected for prematurity); or</li> <li>• Weight for length less than the 10th percentile.</li> </ul> </li> <li>2. For children and adolescents (aged 2-18 years): BMI for age less than the 5<sup>th</sup> percentile.</li> <li>3. For adults, ANY of the following: <ul style="list-style-type: none"> <li>• Involuntary loss of &gt;10% of usual body weight over 3-6 months; or</li> <li>• BMI less than the 5<sup>th</sup> percentile, or 18.5 kg/m<sup>2</sup>.</li> </ul> </li> <li>4. For members with cystic fibrosis and weight loss: Weight for length/height, or BMI &lt; 25<sup>th</sup> percentile.</li> <li>5. For members on renal dialysis, ANY of the following: <ul style="list-style-type: none"> <li>• Weight loss with BMI &lt; 22; or</li> <li>• Falling serum albumin to &lt; 4 g/dl.</li> </ul> </li> </ol> <p>Subsequent authorization requests must include documentation of intervening clinical and nutritional reassessments (including calorie counts) to evaluate if the member's clinical condition has improved enough to allow for the adequate intake of other nutrients.</p>	<p>Required documentation includes:</p> <ul style="list-style-type: none"> <li>• Clinical history, and results of physical exam and supportive testing to evaluate potential treatable causes of growth failure;</li> <li>• Evidence that the member has attempted, or is unable to tolerate, supplementation with commercially available foods and nutritional supplements (e.g., Carnation Instant Breakfast, food thickeners, butter or cream added to prepared foods, etc.), if appropriate;</li> <li>• A written plan of care for regular monitoring of signs and symptoms to detect improvement in the member's condition.</li> </ul> <p>For members over age 1 year, documentation must also include ALL the following:</p> <ul style="list-style-type: none"> <li>• Detailed dietary/feeding history including calorie counts;</li> <li>• Evidence of referral to a nutritionist, and findings (if available);</li> <li>• Results of appropriate specialist evaluation (e.g., gastroenterologist,</li> </ul>

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<p><b>Gastroesophageal Reflux Disease (GERD)</b></p>	<p>Special medical formulas are authorized for eligible infants up to 9 months of life when documentation (including history and physical exam) confirms a high probability of GERD characterized by ALL:</p> <ol style="list-style-type: none"> <li>1. Regurgitation associated with complications (e.g., blood in regurgitated foods); AND</li> <li>2. Nutritional compromise (i.e., severe vomiting, weight loss, lack of weight gain) due to insufficient caloric intake or formula refusal.</li> </ol> <p>For infants transitioning from breast milk to formula, documentation must include evidence of an appropriate maternal elimination diet.</p> <p>For formula fed infants, documentation must confirm that trials of appropriate commercial formulas (e.g., cow-milk based, soy-based) and thickened feeds have not been successful in resolving symptoms.</p> <p>Subsequent requests for special medical formulas for infants up to age 1 year must include documentation confirming that symptoms were significantly improved with the use of the requested special medical formula; and EITHER:</p> <ol style="list-style-type: none"> <li>1. Retrials of commercially available foods or formula were unsuccessful; OR</li> <li>2. Gastroenterologist evaluation confirms the on-going need for the requested special medical formula.</li> </ol> <p>Subsequent requests for children over the age of 1 year must include documentation of ALL:</p> <ol style="list-style-type: none"> <li>1. Nutritionist consultation (including calorie counts); AND</li> <li>2. Gastroenterologist evaluation.</li> </ol>	<p>feeding/swallowing specialist).</p> <p>Special medical formulas are typically not authorized for treatment of gastroesophageal reflux (GER).</p> <ul style="list-style-type: none"> <li>• GER (regurgitation of gastric contents) is common in infants, and usually peaks at 4-6 months of life.</li> <li>• In most cases, parental reassurance, restriction of volume in overfed infants, and a trial of thickened formula are usually sufficient.</li> <li>• Medical therapies (e.g., H2-blockers, proton-pump inhibitors) may be ordered at the discretion of the attending physician.</li> </ul>

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	<p>Retrial of commercially available foods or formula (e.g., cow milk-based and soy-based) must be considered unless contraindication is documented.</p>	
<b>GI Irritability</b>	<p>Special medical formula is authorized when documentation confirms an infant up to age 6 months of life has severe and persistent symptoms, AND General Eligibility Criteria (above) are met.</p> <p>Special medical formula is authorized for infants age 6 months to 1 year when documentation confirms symptoms were significantly improved with the use of the requested special medical formula, and EITHER of the following:</p> <ol style="list-style-type: none"> <li>1. Trial of commercial formula was unsuccessful; OR</li> <li>2. Gastroenterologist evaluation confirms on-going use of the special medical formula is reasonable and medically necessary.</li> </ol> <p>Subsequent requests for children age 1 and older must include ALL the following:</p> <ul style="list-style-type: none"> <li>• Consideration of a retiral of commercial foods/formula;</li> <li>• Nutritionist consult including calorie counts;</li> <li>• Gastroenterologist evaluation.</li> </ul>	<p>Mild to moderate symptoms (e.g., spitting, fussiness, gassiness, loose or mucousy stools), in the absence of weight loss, lack of weight gain, significant vomiting or gastrointestinal bleeding, generally do not require a formula change.</p>
<b>IgE Mediated Food Allergy</b>	<p>Special medical formula is authorized for infants up to 1 year of age when documentation confirms the presence of ANY of the following:</p> <ul style="list-style-type: none"> <li>• Severe vomiting and abdominal pain within minutes to hours of food ingestion;</li> <li>• Severe diarrhea within 6 hours of food ingestion;</li> <li>• Pruritis (localized or generalized);</li> <li>• Angioedema and urticaria;</li> <li>• Stridor, wheezing, or anaphylaxis.</li> </ul>	<p>When cow milk-based formula is clearly implicated in the highly likely IgE mediated reaction, a soy-based formula trial is not required.</p>

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	<p>NOTE: GI symptomatology generally does not occur in isolation, and most often is associated with involvement in other organ systems.</p> <p>For members with a non-urticarial rash, or a rash and a negative IgE to soy, documentation of failed commercial formula trials is required.</p> <p>Subsequent requests for children over age 1 year must include documentation of ALL the following:</p> <ul style="list-style-type: none"> <li>• Consideration of re-trial of commercial foods or formula;</li> <li>• Results of nutritionist consultation (including calorie counts);</li> <li>• Results of allergist evaluation to further document the food allergy.</li> </ul>	
<p><b>Inborn Error of Metabolism including:</b></p> <ul style="list-style-type: none"> <li>▪ <b>Phenylketonuria (PKU)</b></li> <li>▪ <b>Tyrosinemia</b></li> <li>▪ <b>Homocystinuria</b></li> <li>▪ <b>Maple Syrup Urine Disease</b></li> <li>▪ <b>Propionic Acidemia</b></li> <li>▪ <b>Methylmalonic Acidemia</b></li> <li>▪ <b>Other Organic Acidemias</b></li> <li>▪ <b>Urea Cycle Disorders</b></li> </ul>	<p>Special formula or enteral nutrition is authorized when a letter of medical necessity documenting relevant clinical history, supportive evaluation and testing is submitted.</p>	<p>Prior authorization is not required for low protein foods ordered for individuals with inherited diseases of amino acids or organic acids.</p> <p>Trial of commercial formula/foods is not required.</p>
<p><b>Ketogenic Formula for Uncontrolled Seizures</b></p>	<p>Ketogenic formulas are authorized for up to 6 months when documentation confirms a member:</p> <ol style="list-style-type: none"> <li>1. Has seizures that are refractory to standard anti-seizure medications; AND</li> <li>2. Requires a formula/liquid diet to maintain</li> </ol>	<p>Requested formula is not expected to provide more than 50% of the member's nutritional intake, and trial of commercial formula/foods is not required.</p>

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	<p>weight for age growth because of inability to tolerate solid foods due to developmental or other issues.</p> <p>Subsequent requests must include documentation of intervening clinical and nutritional reassessment (e.g., calorie counts) to evaluate if the member's clinical condition has improved sufficiently to allow adequate intake of other nutrients.</p>	
<b>Malabsorption</b>	<p>Special medical formula is authorized for eligible infants up to 1 year old when documentation confirms ALL the following:</p> <ol style="list-style-type: none"> <li>1. Diagnosis of food protein-induced enteropathy or enterocolitis, confirmed by pediatric gastroenterology evaluation; AND</li> <li>2. Symptoms (e.g., chronic diarrhea, weight loss, dehydration) occurred while the infant was being fed cow milk-based formula or breast milk, and symptoms resolved with a dairy elimination diet.</li> </ol> <p>Enteral nutrition is authorized for up to 6 months for children (over 1 year of age) and adults when documentation confirms malabsorption and nutritional compromise (i.e., weight loss, lack of weight gain, other nutritional deficiencies), and ALL the following:</p> <ol style="list-style-type: none"> <li>1. Clinical history and supportive testing confirm ANY of the following: <ul style="list-style-type: none"> <li>• Crohn's Disease</li> <li>• Ulcerative Colitis</li> <li>• Gastrointestinal Motility Disorders</li> <li>• Chronic Intestinal Pseudo-Obstruction</li> <li>• Cystic Fibrosis</li> </ul> </li> <li>2. The member is being closely followed by a gastroenterologist and a nutritionist.</li> </ol> <p>For formula fed infants and children, there must be documentation confirming that cow</p>	<p>For infants with food protein-induced enteropathy or enterocolitis, soy formula trial is not required because of the high cross intolerance to soy-based formula in children with this condition.</p>

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	<p>milk-based and soy-based formula trials have failed or are contraindicated.</p> <p>Subsequent requests for authorization must include documentation of intervening clinical and nutritional reassessments (including documented calorie counts) to determine if the member's clinical condition has improved sufficiently to allow intake of adequate calories and nutrients.</p> <p>For children age 1 and older, subsequent requests must also include evidence that a trial of cow-milk-based and soy-based foods/formula was considered or is contra-indicated, and ALL the following:</p> <ol style="list-style-type: none"> <li>1. Nutritionist consult including calorie counts;</li> <li>2. Gastroenterologist evaluation.</li> </ol>	
<b>Prematurity</b>	<p>Transition formulas (e.g., Neosure, Enfacare) are authorized for premature infants up to 3 months of life when documentation confirms EITHER of the following:</p> <ul style="list-style-type: none"> <li>• Birth weight 1500g or less, and hospital discharge weight less than the 10<sup>th</sup> percentile for age corrected for prematurity; OR Intolerance to cow milk-based formula due to ANY Covered Condition.</li> </ul> <p>All requests related to premature infants over 3 months of life (including subsequent requests) are re-evaluated against General Eligibility Criteria, and relevant Covered Condition Criteria.</p>	<p>A trial of soy-based formula is not required for premature infants younger than 3 months of life with documented intolerance of cow milk-based formula.</p>

**Exclusions:**

Harvard Pilgrim Health Care (HPHC) does not cover special medical formulas and enteral nutrition solely for food preference. There must be an underlying medical condition requiring a non-traditional food source. In addition, HPHC does not cover:

- Infant formulas for indications not listed above, or when a medical history or physical examination has not been completed, and/or there is no documentation that supports the need for enteral nutrition products.
- Special medical formulas and enteral nutrition solely for food preference
- Nutritional and/or food supplements (e.g. Boost and Ensure)

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- Standard over-the-counter commercial formulas (cow and soy milk based) for members without GI disorders including, but not limited to: Similac, Similac Advance, Enfamil, Lipil, Enfamil Gentlease Lipil, Lacto Free, Parent's Choice and Carnation Good Start, Isomil, Prosobee, Similac Soy or Carnation Soy
- Formula or food products used for dieting, or a weight-loss program
- Banked breast milk
- Food for a ketogenic diet when dietary needs can be met with regular, store-bought food
- Dietary or food supplements, including fortifiers (e.g., Duocal, Benecalorie®)
- Food thickeners
- Supplemental high protein powders and mixes
- Lactose free foods, or products that aid in lactose digestion
- Gluten-free products
- Baby foods
- Oral vitamins and minerals
- Medical foods (e.g., Foltx, Metanx, Cerefolin, probiotics such as VSL#3) including FDA-approved medical foods obtained via prescription
- Relizorb
- Enteral electrolyte hydration fluids

### **Supporting Information:**

VSL#3-DS: VSL#3®DS is a medical food probiotic for the dietary management of ulcerative colitis (UC) or an ileal pouch and is available only at your local pharmacy. VSL#3-DS consists of 8 strains of live, freeze-dried lactic acid bacteria.

Each sachet contains at least 900 billion lyophilized lactic acid bacteria and is supplied in a box containing 20 sachets. VSL#3-DS can be mixed with any cold, non-carbonated beverage or any cold food such as yogurt, ice cream or applesauce, and then consumed. Primary Ingredients: VSL#3-DS contains 1 strain of *Streptococcus*, 3 strains of *bifidobacterium*, and 4 strains of *lactobacillus*. Inactive Ingredients: Maltose, silicon dioxide.

There are limited clinical trials, many of which are small pilot studies, using the prescription level dose of VSL #3 which contains at least 900 billion lyophilized bacteria. Most trials used the dose of VSL #3 that is available over-the-counter, a dose of 450 billion lyophilized bacteria. The evidence for efficacy in the studies using the prescription level dose is conflicting. Additionally, the prescription level dose may be attained by doubling the over-the-counter dose.

McClave et al. (2016) reviewed guidelines from the Society of Critical Care Medicine (SCCM) and American Society for Parenteral and Enteral Nutrition (A.S.P.E.N.) to assess the potential benefits of probiotics and nutrition support therapy. The guidelines were derived from data obtained from 727 literature reviews. They concluded that although probiotic species and strains appear to be safe, they should be used for only select populations. A recommendation for the routine use of probiotics across the general population could not be made.

Fedorak et al. (2014) investigated the ability of VSL #3 to prevent Crohn's disease recurrence after ileocolonic resection and re-anastomosis. Patients either received VSL #3 with 900 billion viable bacteria (n = 59) or a

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placebo (n = 60). The authors concluded that there were no statistical differences in endoscopic recurrence rates at day 90 between patients who received VSL#3 and patients who received placebo. Lower mucosal levels of inflammatory cytokines and a lower rate of recurrence among patients who received early VSL#3 (for the entire 365 days) indicate that this probiotic should be further investigated for prevention of Crohn's disease recurrence.

Dhiman et al. (2014) analyzed the recurrence of hepatic encephalopathy, the number of hospitalizations, and the severity of liver disease in 130 patients with cirrhosis who received a probiotic preparation of VSL #3 with 900 billion bacteria or a placebo. There was no significant reduction in the development of breakthrough hepatic encephalopathy among patients receiving the probiotic. Significantly less patients who received the probiotic were hospitalized for hepatic encephalopathy or for complications of cirrhosis compared to the placebo group. End-stage liver disease scores improved significantly from baseline to 6 months in the probiotic group, but not the placebo group.

Pellino et al. (2013) conducted a small study comparing VSL #3 at 900 billion bacteria daily with a placebo in 18 patients over the age of 70 who were undergoing laparoscopic colorectal surgery. All patients received a perioperative antibiotic treatment and received either VSL #3 or placebo postoperatively. There were no significant differences between groups.

Ebrahimi-Mameghani et al. (2013) analyzed the effect of VSL #3 on inflammation, antioxidant capacity and lipid peroxidation in 40 critically ill patients. Patients who were admitted to the ICU were randomly assigned to VSL #3 or placebo for 7 days. There was a significant improvement in CRP levels and APACHE II score in the VSL #3 group compared to the placebo group. There was no difference in TAC and MDA levels between groups. The authors concluded that administration of VSL #3 to critically ill patients caused a reduction in inflammation and improvement in clinical outcome, however, did not have an effect on oxidative stress.

Jayakumar et al. (2013) evaluated the effect of VSL #3 on the hepatic venous pressure gradient in 15 patients with decompensated cirrhosis. Patients were randomized to receive VSL #3 with 900 billion bacteria or a placebo. The authors concluded that VSL #3 therapy does not appear to have an impact on portal pressure reduction in patients with decompensated cirrhosis.

Gupta et al. (2013) investigated the effect of probiotics on portal pressure in 94 cirrhotic patients having large oesophageal varices without history of variceal bleeding. Patients were given a 2-month treatment of propranolol plus placebo, propranolol plus antibiotics, or propranolol plus VSL #3 at 900 billion bacteria per day. Adjunctive probiotics increased the response rate compared with propranolol alone. No other significant differences were observed. The authors concluded that adjunctive probiotic therapy merits further research for portal pressure reduction.

The Food and Drug Administration approach is to regulate probiotics using the regulatory structure pertinent for the intended use of the probiotic. Possible regulatory categories would include food, food ingredient, dietary supplement or drug. Each category has specific standards regarding efficacy, allowable claims, safety and good manufacturing practices.

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### **Formulas and Enteral Nutrition**

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**Coding:**

**Codes are listed below for informational purposes only, and do not guarantee member coverage or provider reimbursement. The list may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible.**

<b>HCPCS Codes</b>	<b>Description</b>
<b>B4102</b>	Enteral formula, for adults, used to replace fluids and electrolytes (e.g., clear liquids), 500 ml = 1 unit
<b>B4103</b>	Enteral formula, for pediatrics, used to replace fluids and electrolytes (e.g., clear liquids), 500 ml = 1 unit
<b>B4104</b>	Additive for enteral formula (e.g., fiber)
<b>B4149</b>	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 (effective 10/28/16)
<b>B4150</b>	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=1unit
<b>B4152</b>	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
<b>B4153</b>	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
<b>B4154</b>	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
<b>B4155</b>	- 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
<b>B4157</b>	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
<b>B4158</b>	Enteral formula, for pediatrics, nutritionally complete with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber and/or iron, administered through an enteral feeding tube, 100 calories = 1 unit
<b>B4159</b>	Enteral formula, for pediatrics, nutritionally complete soy based with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber and/or iron, administered through an enteral feeding tube, 100 calories = 1 unit
<b>B4160</b>	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

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	minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit
<b>B4161</b>	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
<b>B4162</b>	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

### Billing Guidelines:

Member's medical records must document that services are medically necessary for the care provided. Harvard Pilgrim Health Care maintains the right to audit the services provided to our members, regardless of the participation status of the provider. All documentation must be available to HPHC upon request. Failure to produce the requested information may result in denial or retraction of payment.

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**Summary of Changes**

Date	Changes
12/18	Coding updated

**Approved by Clinical Medical Advisory Committee: 12/11/18**

**Approved by Clinical Policy Operational Committee: N/A**

**Policy Effective Date: 3/1/18**

**Initiated: 4/01**

**Attachment A**

**Summary of State Mandated Benefit Requirements**

State	Benefit Requirements
Connecticut  <b>Conn. Gen. Stat. § 38a-518c</b>	<b>Coverage for low protein modified food products, amino acid modified preparations and specialized formulas.</b> For purposes of this section: "Inherited metabolic disease" includes (A) a disease for which newborn screening is required under section 19a-55; and (B) cystic fibrosis.

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<b>State</b>	<b>Benefit Requirements</b>
	<p>“Low protein modified food product” means a product formulated to have less than one gram of protein per serving and intended for the dietary treatment of an inherited metabolic disease under the direction of a physician.</p> <p>“Amino acid modified preparation” means a product intended for the dietary treatment of an inherited metabolic disease under the direction of a physician.</p> <p>“Specialized formula” means a nutritional formula for children up to age twelve that is exempt from the general requirements for nutritional labeling under the statutory and regulatory guidelines of the federal Food and Drug Administration and is intended for use solely under medical supervision in the dietary management of specific diseases.</p> <p>Each group health insurance policy providing coverage of the type specified in subdivisions (1), (2), (4), (11) and (12) of section 38a-469 delivered, issued for delivery, renewed, amended or continued in this state shall provide coverage for amino acid modified preparations and low protein modified food products for the treatment of inherited metabolic diseases if the amino acid modified preparations or low protein modified food products are prescribed for the therapeutic treatment of inherited metabolic diseases and are administered under the direction of a physician.</p> <p>Each group health insurance policy providing coverage of the type specified in subdivisions (1), (2), (4), (11) and (12) of section 38a-469 delivered, issued for delivery, renewed, amended or continued in this state shall provide coverage for specialized formulas when such specialized formulas are medically necessary for the treatment of a disease or condition and are administered under the direction of a physician.</p> <p>Such policy shall provide coverage for such preparations, food products and formulas on the same basis as outpatient prescription drugs.</p>
<p><b>Maine</b> <b>c. 369, §4</b></p>	<p><b>24 §2320-D. MEDICAL FOOD COVERAGE FOR INBORN ERROR OF METABOLISM</b></p> <p>All individual and group nonprofit medical services plan policies and contracts and all nonprofit health care plan policies and contracts must provide coverage for metabolic formula and special modified low-protein food products that have been prescribed by a licensed physician for a person with an inborn error of metabolism. The policies and contracts must reimburse:</p> <p>A. For metabolic formula; and [1995, c. 369, §1 (NEW).]</p> <p>B. Up to \$3,000 per year for special modified low-protein food products. [1995, c. 369, §1 (NEW).] [ 1995, c. 369, §1 (NEW).]</p>

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State	Benefit Requirements
	<p><b>24-A §2764. COVERAGE FOR MEDICALLY NECESSARY INFANT FORMULA (REALLOCATED FROM TITLE 24-A, SECTION 2763)</b>  All individual health insurance policies, contracts and certificates must provide coverage for amino acid-based elemental infant formula for children 2 years of age and under in accordance with this section. [2007, c. 2, §11 (RAL).]</p> <p><b>Determination of medical necessity.</b> Coverage for amino acid-based elemental infant formula must be provided when a licensed physician has submitted documentation that the amino acid-based elemental infant formula is medically necessary health care as defined in section 4301-A, subsection 10-A, that the amino acid-based elemental infant formula is the predominant source of nutritional intake at a rate of 50% or greater and that other commercial infant formulas, including cow milk-based and soy milk-based formulas have been tried and have failed or are contraindicated. A licensed physician may be required to confirm and document ongoing medical necessity at least annually. [2007, c. 2, §11 (RAL).]</p> <p><b>Method of delivery.</b> Coverage for amino acid-based elemental infant formula must be provided without regard to the method of delivery of the formula. [2007, c. 2, §11 (RAL).]</p> <p><b>Required diagnosis.</b> Coverage for amino acid-based elemental infant formula must be provided when a licensed physician has diagnosed and through medical evaluation has documented one of the following conditions:  Symptomatic allergic colitis or proctitis; [2007, c. 2, §11 (RAL).]  Laboratory- or biopsy-proven allergic or eosinophilic gastroenteritis; [2007, c. 2, §11 (RAL).]  A history of anaphylaxis; [2007, c. 2, §11 (RAL).]  Gastroesophageal reflux disease that is nonresponsive to standard medical therapies; [2007, c. 2, §11 (RAL).]  Severe vomiting or diarrhea resulting in clinically significant dehydration requiring treatment by a medical provider; [2007, c. 2, §11 (RAL).]  Cystic fibrosis; or [2007, c. 2, §11 (RAL).]  Malabsorption of cow milk-based or soy milk-based infant formula. [2007, c. 2, §11 (RAL).] [2007, c. 2, §11 (RAL).]</p> <p><b>24-A §2847-P. COVERAGE FOR MEDICALLY NECESSARY INFANT FORMULA (REALLOCATED FROM TITLE 24-A, SECTION 2847-N)</b>  All group health insurance policies, contracts and certificates must provide coverage for amino acid based elemental infant formula for children 2 years of age and under in accordance with this section. [2007, c. 695, Pt. C, §15 (RAL).]</p>

State	Benefit Requirements
	<p><b>Determination of medical necessity.</b> Coverage for amino acid-based elemental infant formula must be provided when a licensed physician has submitted documentation that the amino acid-based elemental infant formula is medically necessary health care as defined in section 4301-A, subsection 10-A, that the amino acid-based elemental infant formula is the predominant source of nutritional intake at a rate of 50% or greater and that other commercial infant formulas, including cow milk-based and soy milk-based formulas have been tried and have failed or are contraindicated. A licensed physician may be required to confirm and document ongoing medical necessity at least annually. [ 2007, c. 695, Pt. C, §15 (RAL).]</p> <p><b>Method of delivery.</b> Coverage for amino acid-based elemental infant formula must be provided without regard to the method of delivery of the formula. [ 2007, c. 695, Pt. C, §15 (RAL).]</p> <p><b>Required diagnosis.</b> Coverage for amino acid-based elemental infant formula must be provided when a licensed physician has diagnosed and through medical evaluation has documented one of the following conditions:  Symptomatic allergic colitis or proctitis; [2007, c. 695, Pt. C, §15 (RAL).]  Laboratory- or biopsy-proven allergic or eosinophilic gastroenteritis; [2007, c. 695, Pt. C, §15 (RAL).]  A history of anaphylaxis; [2007, c. 695, Pt. C, §15 (RAL).]  Gastroesophageal reflux disease that is nonresponsive to standard medical therapies; [2007, c. 695, Pt. C, §15 (RAL).]  Severe vomiting or diarrhea resulting in clinically significant dehydration requiring treatment by a medical provider; [2007, c. 695, Pt. C, §15 (RAL).]  Cystic fibrosis; or [2007, c. 695, Pt. C, §15 (RAL).]  Malabsorption of cow milk-based or soy milk-based infant formula. [2007, c. 695, Pt. C, §15 (RAL).] [2007, c. 695, Pt. C, §15 (RAL).]</p> <p>SECTION HISTORY  2007, c. 695, Pt. C, §15 (RAL).</p> <p><b>24-A §4256. COVERAGE FOR MEDICALLY NECESSARY INFANT FORMULA (REALLOCATED FROM TITLE 24-A, SECTION 4254)</b>  All individual and group health maintenance organization policies, contracts and certificates must provide coverage for amino acid-based elemental infant formula for children 2 years of age and under in accordance with this section. [2007, c. 695, Pt. C, §16 (RAL).]</p> <p><b>Determination of medical necessity.</b> Coverage for amino acid-based elemental infant formula must be provided when a licensed physician has submitted documentation that the amino acid-based elemental infant formula is medically necessary health care as defined in section 4301-A, subsection 10-A,</p>

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State	Benefit Requirements
	<p>that the amino acid-based elemental infant formula is the predominant source of nutritional intake at a rate of 50% or greater and that other commercial infant formulas, including cow milk-based and soy milk-based formulas have been tried and have failed or are contraindicated. A licensed physician may be required to confirm and document ongoing medical necessity at least annually. [ 2007, c. 695, Pt. C, §16 (RAL).]</p> <p><b>Method of delivery.</b> Coverage for amino acid-based elemental infant formula must be provided without regard to the method of delivery of the formula. [ 2007, c. 695, Pt. C, §16 (RAL).]</p> <p><b>Required diagnosis.</b> Coverage for amino acid-based elemental infant formula must be provided when a licensed physician has diagnosed and through medical evaluation has documented one of the following conditions:  Symptomatic allergic colitis or proctitis; [2007, c. 695, Pt. C, §16 (RAL).]  Laboratory- or biopsy-proven allergic or eosinophilic gastroenteritis; [2007, c. 695, Pt. C, §16 (RAL).]  A history of anaphylaxis; [2007, c. 695, Pt. C, §16 (RAL).]  Gastroesophageal reflux disease that is nonresponsive to standard medical therapies; [2007, c. 695, Pt. C, §16 (RAL).]  Severe vomiting or diarrhea resulting in clinically significant dehydration requiring treatment by a medical provider; [2007, c. 695, Pt. C, §16 (RAL).]  Cystic fibrosis; or [2007, c. 695, Pt. C, §16 (RAL).]  Malabsorption of cow milk-based or soy milk-based infant formula. [2007, c. 695, Pt. C, §16 (RAL).] [ 2007, c. 695, Pt. C, §16 (RAL) .]</p>
<p><b>Massachusetts</b></p> <p><b>M.G.L. 175 §47C and 47I, M.G.L. 176G §4D</b></p>	<p><b>Special infant formulas</b></p> <p>Members enrolled through non-group or employer groups must be covered for special medical formulas prescribed by a physician, and medically necessary to treat infants or children with phenylketonuria (PKU), tyrosinemia, homocystinuria, maple syrup urine disease, propionic acidemia, or methylmalonic acidemia, or to protect the fetuses of pregnant women with PKU. (M.G.L. 175 §47C)</p> <p>Non-prescription enteral formulas and low protein foods:  Members enrolled through employer groups or with individual coverage must be covered for non-prescription enteral formulas ordered by a physician for home use to treat malabsorption caused by Crohn's disease, ulcerative colitis, gastroesophageal reflux, gastrointestinal motility disorders, chronic intestinal pseudo-obstruction, and inherited diseases of amino acids and organic acids when medically necessary and a written order has been issued by a physician. Coverage required for group policies.</p> <p>Low protein foods are covered up to \$5,000 per member per year for inherited diseases of amino acids and organic acids. (M.G.L. 176G §4D)</p>

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State	Benefit Requirements
	<p><b>Non-prescription Enteral Formulas for Home Use</b>  Section 4K. Any subscription certificate under an individual or group medical service agreement that shall be delivered, issued or renewed in the commonwealth shall provide, as benefits to all individual subscribers and members within the commonwealth, all group members having a principal place of employment within the commonwealth and all persons included in section four C, coverage for nonprescription enteral formulas for home use for which a physician has issued a written order and which are medically necessary for the treatment of malabsorption caused by Crohn's disease, ulcerative colitis, gastroesophageal reflux, gastrointestinal motility, chronic intestinal pseudoobstruction, and inherited diseases of amino acids and organic acids. Coverage for inherited diseases of amino acids and organic acids shall include food products modified to be low protein in an amount not to exceed \$5,000 annually for any insured individual.</p>
<p><b>New Hampshire</b>   <b>NH R.S.A. 420-A:17</b></p>	<p><b>Special infant formulas:</b> Not Applicable</p> <p>Non-prescription enteral formulas and low protein foods:  Members enrolled through employer groups must be covered for non-prescription enteral formulas to treat impaired absorption of nutrients caused by disorders affecting the absorptive surface, functional length, gastrointestinal tract motility, and inherited diseases of amino acids and organic acids. A written order must be issued by a physician stating that the enteral formula is medically necessary, needed to sustain life, and is the least restrictive and most cost-effective treatment.</p> <p>Additionally, members must be covered for non-prescription enteral formulas and food products required for persons with inherited diseases of amino and organic acids. Physician must provide a written order, stating that enteral formula or food product is medically necessary and is the least restrictive and most cost-effective approach to meet patient needs. There is no dollar limit on enteral formulas.</p> <p>Low protein foods are limited to \$1,800 per member per year. (NH R.S.A. 420-A:17)</p>

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