**Nutritional Therapy, Oral and Enteral**

**Policy Number:** NMP254  
**Effective Date:** February 2006  
**Updated:** December 2015

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**This National Medical Policy is subject to the terms in the**  
**IMPORTANT NOTICE**  
**at the end of this document**

**For Medicaid Plans:** Please refer to the appropriate State’s Medicaid manual(s), publication(s), citation(s), and documented guidance for coverage criteria and benefit guidelines prior to applying Health Net Medical Policies

**The Centers for Medicare & Medicaid Services (CMS)**  
For Medicare Advantage members please refer to the following for coverage guidelines first:

<table>
<thead>
<tr>
<th>Use</th>
<th>Source</th>
<th>Reference/Website Link</th>
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<tbody>
<tr>
<td></td>
<td>National Coverage Manual Citation</td>
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<tr>
<td></td>
<td>Local Coverage Determination (LCD)*</td>
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<tr>
<td></td>
<td>Article (Local)*</td>
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</tbody>
</table>
Instructions
- Medicare NCDs and National Coverage Manuals apply to ALL Medicare members in ALL regions.
- Medicare LCDs and Articles apply to members in specific regions. To access your specific region, select the link provided under "Reference/Website“ and follow the search instructions. Enter the topic and your specific state to find the coverage determinations for your region. *Note: Health Net must follow local coverage determinations (LCDs) of Medicare Administration Contractors (MACs) located outside their service area when those MACs have exclusive coverage of an item or service. (CMS Manual Chapter 4 Section 90.2)
- If more than one source is checked, you need to access all sources as, on occasion, an LCD or article contains additional coverage information than contained in the NCD or National Coverage Manual.
- If there is no NCD, National Coverage Manual or region specific LCD/Article, follow the Health Net Hierarchy of Medical Resources for guidance.

Current Policy Statement
Health Net, Inc. considers nutritional therapy medically necessary as follows:

**VERY IMPORTANT**

When taken orally, Health Net plans do not specifically include coverage of infant formulas in the Explanation of Coverage (EOC). We consider special medical foods medically necessary only when mandated by state law. Most states now have mandates requiring coverage of these dietary formulas. In the absence of a specific inclusion in the EOC or state mandate, specialized infant formulas are not a covered benefit.

- To access state laws, go to: [http://www.findlaw.com/11stategov/](http://www.findlaw.com/11stategov/)
- Click on State; then Primary Materials - Cases, Codes and Regulations, General Statutes
- Then search the Statutes by Keyword

Infant Formulas, Oral
Health Net, Inc. considers oral infant formulas not medical in nature, unless mandated by state law. They may be medically necessary if administered via the tube-feeding route when criteria in the Enteral Nutrition section below are met.

Specialized Infant Formulas (Oral)
‘Specialized formula’ means a nutritional formula for children up to age eight 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.
Specialized infant formulas given orally are not medical in nature unless they are given for the treatment of all inherited metabolic diseases for which newborn screening is required, including any of the following metabolic diseases:

<table>
<thead>
<tr>
<th>Biotinidase Deficiency</th>
<th>Isovaleric acidemia (and other disorders of leucine metabolism)</th>
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</thead>
<tbody>
<tr>
<td>Citrullinemia</td>
<td>Maple syrup urine disease (MSUD)</td>
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<tr>
<td>Cystinosis</td>
<td>Methylmalonic acidemia</td>
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<td>Galactosemia</td>
<td>Phenylketonuria (PKU)*</td>
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<td>Glutaric acidemia type I</td>
<td>Propionic acidemia</td>
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<tr>
<td>Histidinemia</td>
<td>Tyrosinemia types I and II</td>
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<td>Homocystinuria</td>
<td>Urea cycle disorders</td>
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<tr>
<td>Cystic Fibrosis</td>
<td>Other organic acidemias</td>
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**PKU Guidelines**

In accordance with state mandates and/or member benefits, medically necessary treatment may be provided for infants, children and adults as well as for the protection of unborn babies of women who have PKU. Please refer to specific state mandates and/or member EOC for coverage information as it may vary.

1. Treatment of neonates born with PKU should begin 7-10 days after birth.
2. All infants with blood phenylalanine levels over 10 mg/dL measured while eating a normal protein diet (2-3 grams protein/kg/day), and in whom other amino acids levels, such as tyrosine, are low or normal.
3. The PKU enteral formula should be enriched with tyrosine, and provide 2-3 grams protein/kg/day. It should be taken as evenly as possible throughout the day.
4. Blood phenylalanine levels should be monitored weekly during periods of rapid growth, fluctuating blood levels, or when food intake is unpredictable. In older children and adults, this monitoring can occur 1-2 times per month. The ideal time for this blood test is 2 hours after eating.
5. Diet, including special formula intake, is modified to achieve optimal blood levels.
6. Optimal blood phenylalanine levels:

<table>
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<tr>
<th>Age/Circumstance</th>
<th>Optimal Levels</th>
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<tbody>
<tr>
<td>under age 10</td>
<td>2-6 mg/dL</td>
</tr>
<tr>
<td>over age 10</td>
<td>2-10 mg/dL</td>
</tr>
<tr>
<td>women trying to conceive</td>
<td>2-6 m/dL</td>
</tr>
<tr>
<td>pregnant women</td>
<td>2-6 m/dL</td>
</tr>
</tbody>
</table>

7. Women who wish to have children should optimize their levels 2-3 months before conception, and continue close nutritional monitoring during pregnancy.

In California:

Senate bill 148 on Health Care Coverage: Phenylketonuria

http://www.leginfo.ca.gov/pub/99-00/bill/sen/sb_0101-0150/sb_148_bill_19990910_enrolled.html
Elimination Diets (Hypoallergenic Diets)
Health Net, Inc. considers elimination diets medically necessary for any of the following:

- Acute, severe (sometime multisystem) gastrointestinal reaction immediately after ingestion (“gastrointestinal anaphylaxis”)
- Unrelenting bloody diarrhea
- Severe gastroesophageal reflux in infants

Health Net, Inc. does not consider any of the following medical in nature, even if they are required to maintain weight or strength:

- “Specialized” infant formulas (e.g., Nutramigen, Alimentum, etc.) unless otherwise specified in this policy
- Food supplements
- Banked breast milk
- Vitamins and/or minerals taken orally
- Lactose-free foods for lactose intolerance
- Food to supplement a deficient diet
- Foods as alternative nutrition in the presence of such conditions as hypoglycemia, allergies, obesity, and gastrointestinal disorders.
- Oral allergy syndrome (oral/perioral pruritus associated with food-specific IgE)
- Dietary protein proctitis/proctocolitis of infancy
- Dietary protein–induced enteropathy of infancy
- Celiac disease
- Dietary protein–induced enterocolitis of infancy
- Occult blood loss from the gastrointestinal tract of milk-fed infants
- Subset with food allergy
- Eosinophilic esophagitis, any age group
- Eosinophilic gastroenteritis
- Enteropathy/malabsorption, any age group
- Constipation in early childhood
**Infantile colic**

**Ketogenic Diet**

As most benefit plan descriptions exclude coverage of over-the-counter dietary supplements or regularly purchased foods items typically used in the ketogenic diet, Health Net, Inc. does not consider any food supplements for the ketogenic diet. Check benefit plan descriptions for details.

Health Net, Inc. considers hospitalization for initiation of a ketogenic medically necessary when for children (older than 12 months and younger than 8 years old) with seizures, refractory to or intolerant of multiple conventional anti-epileptic drugs. The inpatient setting is needed not only to monitor the patient during the initial fasting period to induce marked ketosis and weight loss, but also to provide the intense education required to maintain a ketogenic diet once discharged. The length of hospital stay will depend on the proposed initial starvation period, and generally should not exceed 3 days.

**Enteral Nutrition for Infants, Children and Adults**

Enteral nutrition is defined as the provision of liquid food feedings through a tube into the stomach or small intestine (e.g., nasogastric, nasojejunal, gastrostomy or jejunostomy tubes). Formulas consisting of semi-synthetic intact proteins or protein isolates (e.g., Enrich, Ensure, Ensure HN, Ensure Powder, Isocal, Lonalac Powder, Meritene, Meritene Powder, Osmolite, Osmolite HN, Portagen Powder, Renu, Sustacal, Sustagen Powder, Travasorb) can be used for enteral feeding in the majority of patients who meet criteria for enteral feeding.

Health Net, Inc. considers enteral nutrition (enteral formulas usually consisting of semi-synthetic intact protein/protein isolates) medically necessary when:

1) Prescribed by a physician for use in the home through enteral feeding tubes (N-G tube, N-E feeding tubes, G-tubes, J-tubes), and

2) The feedings exceed 750 kilocalories a day (Note: there are no kilocalories minimums in pediatric patients in order to maintain weight and strength commensurate with the patient's overall health status and

3) Three month history of any of the following:
   a) Increased nutritional needs that cannot be met through oral intake (e.g., burns, trauma)
   b) Inadequate oral intake resulting in deterioration of nutritional status or delayed recovery from illness
   c) Disease of the intestine which impairs digestion and/or absorption of an oral diet in the small bowel, such as:
      i) Crohn’s disease when the patient requires prolonged infusion of enteral nutrients to overcome a problem with absorption
      ii) Acute ulcerative colitis
      iii) Granulomatous colitis
      iv) Gastroesophageal reflux with failure to thrive
v) High output fistula
vi) Certain severe short bowel syndromes
vii) Severe intestinal malabsorption syndrome and the formula comprises the sole source or an essential source of nutrition
viii) Severe acute or chronic pancreatitis
ix) Ischemic bowel disease with massive bowel resection
x) Irradiated bowel
xi) Gastrointestinal dysmotility such as chronic intestinal pseudo-obstruction (Ogilvie’s syndrome)
xii) Allergic enteropathy, including allergic colitis.
xiii) Multiple, severe food allergies which if left untreated will cause malnourishment, chronic physical disability, mental retardation or death
xiv) Hyperemesis gravidarum

4) A permanent anatomic or structural problem that prevents food from reaching the small intestine, for example:
   a) An obstructing tumor or stricture of the esophagus or stomach
   b) Obstruction due to head and neck cancer and reconstructive surgery
   c) Jaw fracture
   d) Gastrointestinal cancer
   e) Obstruction of gastric outlet due to ulcer diathesis
   f) Intestinal atresia (infants)

5) A neurological problem that significantly interferes with the ability to chew or swallow such that a risk of aspiration exists, for example:
   a) Severe dysphagia following a stroke
   b) Patients with partial impairments, e.g., a patient with dysphagia who can swallow small amounts of food
   c) Neuromuscular or CNS disease

Note: If the patient has an allergy or intolerance to semi-synthetic formulas, natural intact proteins or protein isolates (e.g., Compleat B, Compleat B Modified, Vitaneed) may be used for enteral feeding.

**Not Medical in Nature**
Health Net, Inc. does not consider any of the following medical in nature:

1. Over-the-counter nutritional items, food and food substitutes
2. Food thickeners, baby food, and other regular grocery products that can be blenderized by the patient or caregiver for administration through a tube
3. Oral vitamins or mineral preparations
4. Self-blenderized formulas and enteral formula additives, including vitamins, minerals, and fiber
5. Formulas containing natural foods that are blenderized and packaged by a manufacturer (e.g., Ensure).
6. Usual and customary infant formulas for children less than one-year of age who require enteral nutritional therapy
7. Enteral nutrition in situations involving temporary impairments
8. Enteral nutrition for patients with a functioning gastrointestinal tract whose need for enteral nutrition is due to reasons such as anorexia or nausea associated with mood disorder, end-stage disease, etc.
9. When adequate nutrition is possible by dietary adjustment, counseling and/or oral supplements.
10. Oral rehydration therapy (ORT) (e.g., Pedialyte, Infalyte, Naturalyte, and Rehydralyte) which is intended for very short-term use primarily with infants or children to replace water and electrolytes lost during severe bouts of vomiting and diarrhea. An ORT fluid does not serve the same purpose as a food; therefore, it is not an eligible formula.

**Contraindications to Enteral Feedings**
- Bowel obstruction
- Inadequate bowel surface area
- Feeding intolerance
- Diarrhea
- High gastric residual volumes
- Enteral access unattainable

**Infusion Pumps**
Health Net, Inc. considers the use of an FDA-approved infusion pump medically necessary durable medical equipment (DME) to administer the enteral feedings in any of the following circumstances:

1. For patients with dumping syndrome who cannot tolerate bolus feedings; or
2. For use in gastrostomy/jejunostomy tube feedings; or
3. For patients with inflammatory bowel disease who require small amounts of slow, continuous feedings; or
4. For patients who, through surgery or congenital abnormality, do not have a stomach and who require slow, continuous feedings.
5. Documentation in the patient’s medical record to justify its use because gravity or syringe feedings have caused complications, such as any of the following:
   - Reflux and/or aspiration
   - Severe diarrhea
   - Dumping syndrome
   - Administration rate less than 100 ml/hr
- Blood glucose fluctuations
- Circulatory overload

**Codes Related To This Policy**

NOTE:
The codes listed in this policy are for reference purposes only. Listing of a code in this policy does not imply that the service described by this code is a covered or non-covered health service. Coverage is determined by the benefit documents and medical necessity criteria. This list of codes may not be all inclusive.

On October 1, 2015, the ICD-9 code sets used to report medical diagnoses and inpatient procedures have been replaced by ICD-10 code sets.

**ICD-9 Codes** (May not be an all-inclusive list)
- 261 Nutritional marasmus
- 263.0–263.9 Malnutrition
- 307.1 Anorexia nervosa
- 307.50–307.59 Eating Disorders
- 307.59 Effects of hunger
- 783.0–783.43 Symptoms concerning nutrition, metabolism, and development

**ICD-10 Codes**
- E40–E46 Malnutrition
- F50.00–F50.9 Eating disorders
- F98.21–F98.29 Other feeding disorders of infancy and early childhood
- F98.3 Pica of infancy and childhood
- R63.0–R63.8 Symptoms and signs concerning food and fluid intake

**CPT Codes**
- 43246 Upper gastrointestinal endoscopy with directed placement of percutaneous gastrostomy tube
- 44015 Tube or needle jejunostomy for enteral alimentation, intraoperative, any method

**HCPCS Codes**
- A5200 Percutaneous catheter/tube anchoring device, adhesive skin attachment
- B4034–B4083 Enteral supplies code range
- B4102 Enteral formula for adults, used to replace fluids and electrolytes (e.g., clear liquids), 500 ml=1 unit
- B4103 Enteral formula, for pediatrics, used to replace fluids and electrolytes (e.g., clear liquids), 500 ml=1 unit
- B4104 Additive for enteral formula (e.g., fiber)
- B4149 Enteral formula, blenderized natural foods with intact nutrients, includes proteins, fat, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories=1 unit
- B4150–B4155 Enteral formula code range
- B4157 Enteral formula, nutritionally complete, for special metabolic needs for inherited disease of metabolism, includes protein, fats, carbohydrates, vitamins and minerals, may include fiber, administered through
enteral feeding tube, 100 calories=1 unit

B4158 Enteral formula, for pediatrics, nutritionally complete with intact nutrients, includes protein, fats, carbohydrates, vitamins and mineral, may include fiber and/or iron, administered through an enteral feeding tube, 100 calories=1 unit

B4159 Enteral formula, for pediatrics, nutritionally complete soy based with intact nutrients, includes protein, fats, carbohydrates, vitamins and mineral, may include fiber and/or iron, administered through an enteral feeding tube, 100 calories=1 unit

B4160 Enteral formula, for pediatrics, nutritionally complete calorically dense (equal to or greater than 0.7 kcal/ml) with intact nutrients, includes protein, fats, carbohydrates, vitamins and mineral, may include fiber, administered through an enteral feeding tube, 100 calories=1 unit

B4161 Enteral formula, for pediatrics, hydrolyzed/amino acids and peptide chain proteins, includes fats, carbohydrates, vitamins and mineral, may include fiber and/or iron, administered through an enteral feeding tube, 100 calories=1 unit

B4162 Enteral formula, for pediatrics, special metabolic needs for inherited disease of metabolism, includes protein, fat, carbohydrates, vitamins and mineral, may include fiber and/or iron, administered through an enteral feeding tube, 100 calories=1 unit

B9000-B9002 Enteral nutrition infusion pump code range

B9998 NOC for enteral supplies

E0776 IV pole

S9342 Home therapy; enteral nutrition via pump; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (enteral formula and nursing visits coded separately), per diem

S9343 Home therapy; enteral nutrition via bolus; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (enteral formula and nursing visits coded separately), per diem

S9433 Medical food nutritionally complete, administered orally, providing 100% of nutritional intake

S9435 Medical foods for inborn errors of metabolism

**Scientific Rationale**

Medical nutrition therapy involves the assessment of the nutritional status of patients with a condition, illness, or injury that puts them at risk. Based on the assessment, those nutrition modalities most necessary to manage the condition or treat the illness or injury are chosen and include the following: (1) diet modification and counseling leading to the development of a personal dietary plan to achieve nutritional goals and desired health outcomes; (2) specialized nutrition therapies including supplementation with foods specifically modified to meet the needs of patients for those unable to obtain adequate nutrients through usual food intake only; (3) enteral nutrition delivered via tube feeding into the gastrointestinal tract for individuals with conditions for the digestive system that prevent them from absorbing sufficient nutrients to meet their bodily needs; (4) parenteral nutrition delivered via intravenous infusion for those unable to absorb nutrients; and (5) entry through the peritoneal cavity.
Specialized infant formulas given by mouth are reserved for, but are not limited to, inborn errors of metabolism, such as phenylketonuria, medical conditions of malabsorption, such as, short bowel syndrome and acute ulcerative colitis, and other pathologies of the alimentary or gastrointestinal tract, such as, allergic eosinophilic gastroenteritis and neurological or physiological conditions. Patients with renal disease, including those on dialysis, are prone to develop deficiency of protein and impairment of storage vitamins. Inadequacy of energy and protein can result in conditions such as hypoalbuminemia and hyperlipidemia. Methods of delivery include oral, enteral, parenteral, and entry through the peritoneal cavity. Parental and enteral nutrition therapies are a means of providing nutrition for patients who have pathology of the alimentary or gastrointestinal tract which does not allow absorption of sufficient nutrients to maintain weight and strength commensurate with the patients general condition. These therapies may be provided on either an inpatient or outpatient basis or in the home setting.

Enteral nutrition (EN) is used for the treatment of patients with severe intestinal malabsorption or for patients with a functioning intestinal tract, but with disorders of the pharynx, esophagus, or stomach that prevent nutrients from reaching the absorbing surfaces in the small intestine. The patient is at risk of severe starvation. Medical foods are 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 principals, are established by medical evaluation. Enteral formulas consisting of semi-synthetic intact protein/protein isolates are necessary for the majority of patients requiring enteral nutrition. EN involves administering these specialized nutritional liquids directly into the gastrointestinal tract through nasogastric, gastrostomy, or jejunostomy tubes. An infusion pump may be used to assist the flow of liquids. Tube feedings may be given several times a day, one "bolus" of liquid at a time, or continuous over 24 hours a day. Generally, a daily caloric intake of 2000-2200 calories is sufficient to maintain body weight. If fewer than 750 calories are taken daily by enteral nutrition, they are considered supplemental, and are not medically necessary.

Enteral nutrition may be administered by syringe, gravity, or pump. Some enteral patients may experience complications associated with syringe or gravity method of administration. A pump may be necessary when gravity feeding is not satisfactory due to reflux and/or aspiration, severe diarrhea, dumping syndrome, administration rate less than 100 ml/hr, blood glucose fluctuations, circulatory overload, gastrostomy/ jejunostomy tube used for feeding.

In 1994, the American Academy of Pediatrics Committee on Nutrition issued its recommendations on reimbursement for medical foods for inborn errors of metabolism. In-born errors of metabolism are a group of rare disorders resulting in the excessive accumulation of an amino acid or other product along the metabolic pathway for lack of a natural enzyme required to digest certain foods. Manifestations of these disorders generally include central nervous system dysfunction, developmental delay, seizures and liver dysfunction. The clinical manifestations in many of these disorders can be prevented if diagnosis is achieved early and necessary treatment with dietary protein or amino acid restriction is instituted immediately. These disorders are named for the accumulating amino acid and include, but are not limited to, phenylketonuria (PKU), maple syrup urine disease, citrullinemia, cystinosis, homocystinuria, methylmalonic acidemia, propionic acidemia, isovaleric acidemia (and other disorders of leucine metabolism), glutaric
acidemia type I, tyrosinemia types I and II, and urea cycle disorders. Treatment might include restriction of specific amino acids, restriction of total nitrogen intake, or supplementation of certain substances. For some of the inborn errors of metabolism, special formulas and medical foods have been developed which eliminate the amino acid that cannot be metabolized from the protein context of the food. As adults, they must avoid certain foods as well. Women with classic PKU desiring pregnancy need to alter their diet by using a special maternal dietary supplement low in phenylalanine. The use of this supplement reduces the risk of severe retardation in the infant of a mother with PKU.

The American Academy of Pediatrics Committee on Nutrition recommendations on Reimbursement for Medical Foods for Inborn Errors of Metabolism, published in Pediatrics vol. 93 No. 5 May 1994. Inborn errors of metabolism include phenylketonuria, homocystinuria, methylmalonic acidemia, Treatment might include restriction of specific amino acids, restriction of total nitrogen intake, or supplementation of certain substances. If left untreated, these diseases cause severe mental retardation or death. US Public Law 100-290 defines medical foods 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 principals, are established by medical evaluation." (1988 Orphan Drug Amendments Act to amend the FDA provisions regarding orphan drugs). Since passage of this act, many states provided funding for such products through Medicaid, and most states offered assistance through the Crippled Children's and Women, Infants, and Children's (WIC) programs.

Some patients, such as those with "dumping syndrome", cannot tolerate a large amount of food at one time. They require slow, small amounts of feedings in a continuous flow. To achieve this, an infusion pump can regulate a small continuous flow of food. In malabsorption syndrome, the patient has a problem of properly absorbing nutrition from food, leading to malnutrition. Crohn's disease and ulcerative colitis are forms of inflammatory bowel disease, where the inner lining of the bowels is irritated, swollen, and may bleed. In severe cases, the inflammation and irritation of the bowels can cause malabsorption. In gastroesophageal reflux, gastrointestinal motility disorders, and chronic intestinal pseudo-obstruction, there are problems with the normal movements of the stomach and bowels. If severe, these disorders could result in malnutrition. Some neurological disease cause problems with chewing and swallowing, which may lead to aspiration. Such patients may have trouble eating, and will need a tube in the nose, stomach, or bowel for feedings.

Epilepsy, or seizures, can cause uncontrolled shaking movements and other signs. Most patients with epilepsy are treated with medications to control the seizures. In a few patients, medications either do not work or the patient is unable to keep taking them because of severe side effects. For some of these patients, their type of seizure might be treatable by brain surgery. However, for most patients with seizures who are refractory to medicines, surgery is not a good option because it will not solve their seizure problem. The ketogenic diet is a special high-fat, low-carbohydrate, low-protein diet. The ketogenic diet is quite restrictive, requiring the cooperation of the patient, family, and an appropriately trained dietitian. Although patients can eat regular food, the ratio of fat to carbohydrates must be strictly maintained, meaning that the precise contents of each food item must be known, and exactly measured. The composition of the diet induces ketosis, a physiologic state in which circulating ketone bodies are used as the primary fuel source in the absence of simple sugars.
If the child can follow the diet, some studies have shown that for some children ketosis may inhibit seizures through an unknown mechanism. As currently practiced, patients usually need to spend a few days in the hospital. Children are admitted to the hospital and fasted for 1 to 2 days. The diet is then instituted gradually over a number of days. A full ketogenic diet is attained by day 3 to 5 in most children, at which time the patient is discharged home and followed as an outpatient. The main reason for hospitalization is the period of fasting. Fasting potentially exposes children to dehydration and metabolic derangements that could become life threatening if not properly monitored and treated. Given the restrictions, compliance with the diet can be problematic, especially in children over 10 years of age who have well-established dietary habits and preferences.

Lefevre and Aronson (2000) published a review article that systematically reviewed and synthesized the available evidence on the efficacy of the ketogenic diet in reducing seizure activity in children with refractory epilepsy. The evidence consisted entirely of uncontrolled studies. Of the 11 studies identified for the review, 9 were retrospective series from a single institution, two were prospective studies, one of which was a multicenter trial. The results of these studies were consistent in showing that some children benefit from the ketogenic diet, demonstrated by a significant reduction in seizure frequency. Estimates of the rates of improvement by combined analysis were as follows: complete cessation of all seizures in 16% of children; >90% reduction in seizures in 32%; and >50% reduction in seizures in 56%. The authors doubted that this degree of benefit could be attributed to a placebo effect and concluded that the evidence was sufficient to determine that the ketogenic diet is efficacious in reducing seizure frequency in children with refractory epilepsy. While the published data regarding ketogenic diets consists of uncontrolled case series, the data are consistent in showing that some children benefit from the ketogenic diet, as demonstrated by a significant reduction in seizure frequency; e.g., complete cessation of seizures in 16% of children, a greater than 90% reduction in 32%, and a greater than 50% reduction in 56%. These results exceed any expected placebo effect or spontaneous remission of seizures.

Food allergy is not one particular disorder, but rather immunopathophysiologic mechanisms underlying a number of defined or poorly defined gastrointestinal disorders/symptom complexes. Identification and elimination of the causal allergenic food protein from the diet can lead to resolution of symptoms. Children whose symptoms mimic those of gastroesophageal reflux but who have normal pH values may have a distinct new disease termed eosinophilic esophagitis. Children with eosinophilic esophagitis present with abdominal pain, dysphagia, and vomiting, the classic signs of gastroesophageal reflux. But they fail to respond to antireflux medications like omeprazole or cisapride. Intraesophageal pH probe monitoring reveals normal or near-normal pH levels. On biopsy, profound eosinophilia in the esophagus is found to the order of 50-100 eosinophils per high-powered field. Physicians have used elimination diets (for example, diets without wheat, soy, milk, peanuts, and/or seafood) and elemental diets (for example, liquid diets that contain only amino acids but no proteins to act as allergens) in treating children with eosinophilic esophagitis with some success.

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. The prevalence in infancy of milk protein allergy is low 2% to 3%. Thus, the use of hypoallergenic-labeled infant formulas, which cost as much as 3 times more than standard formulas, should be limited to infants with well-defined clinical indications. Adverse reactions to cow’s milk associated with other conditions such as phenylketonuria and lactose intolerance may also be alleviated by the use of alternative formulas, although not necessarily those intended to treat infants with protein allergy.

**Review History**

- **February 2006** Medical Advisory Council initial approval
- **February 2007** Medical Advisory Council - updated
- **March 2007** Coding Updates
- **February 2009** Code updates
- **March 2011** Update. Added Medicare Table with link to LCD. No revisions.
- **December 2011** Update. No revisions.
- **December 2012** Update – no revisions
- **April 2015** Clarified coverage of PKU treatment follows state mandates and member specific benefits

This policy is based on the following evidence-based guidelines:


**References – Update December 2015**

2. U.S. Food and Drug Administration (FDA). Use of Donor Human Milk. Last Updated Aug 2015. Available at: [http://www.fda.gov/ScienceResearch/SpecialTopics/PediatricTherapeuticsResearch/ucm235203.htm](http://www.fda.gov/ScienceResearch/SpecialTopics/PediatricTherapeuticsResearch/ucm235203.htm)

**References – Update December 2014**

References – Update December 2013

References – Update December 2012

References Update – December 2011

References Update – March 2011

References Initial

Important Notice

General Purpose.
Health Net's National Medical Policies (the "Policies") are developed to assist Health Net in administering plan benefits and determining whether a particular procedure, drug, service or supply is medically necessary. The Policies are based upon a review of the available clinical information including clinical outcome studies in the peer-reviewed published medical literature, regulatory status of the drug or device, evidence-based guidelines of governmental bodies, and evidence-based guidelines and positions of select national health professional organizations. Coverage determinations are made on a case-by-case basis and are subject to all of the terms, conditions, limitations, and exclusions of the member's contract, including medical necessity requirements. Health Net may use the Policies to determine whether under the facts and circumstances of a particular case, the proposed procedure, drug, service or supply is medically necessary. The conclusion that a procedure, drug, service or supply is medically necessary does not constitute coverage. The member's contract defines which procedure, drug, service or supply is covered, excluded, limited, or subject to dollar caps. The policy provides for clearly written, reasonable and current criteria that have been approved by Health Net's National Medical Advisory Council (MAC). The clinical criteria and medical policies provide guidelines for determining the medical necessity criteria for specific procedures, equipment, and services. In order to be eligible, all services must be medically necessary and otherwise defined in the member's benefits contract as described this "Important Notice" disclaimer. In all cases, final benefit determinations are based on the applicable contract language. To the extent there are any conflicts between medical policy guidelines and applicable contract language, the contract language prevails. Medical policy is not intended to override the policy that defines the member's benefits, nor is it intended to dictate to providers how to practice medicine.

Policy Effective Date and Defined Terms.
The date of posting is not the effective date of the Policy. The Policy is effective as of the date determined by Health Net. All policies are subject to applicable legal and regulatory mandates and requirements for prior notification. If there is a discrepancy between the policy effective date and legal mandates and regulatory requirements, the requirements of law and regulation shall govern. * In some states, prior notice or posting on the website is required before a policy is deemed effective. For information regarding the effective dates of Policies, contact your provider representative. The Policies do not include definitions. All terms are defined by Health Net. For information regarding the definitions of terms used in the Policies, contact your provider representative.

Policy Amendment without Notice.
Health Net reserves the right to amend the Policies without notice to providers or Members. In some states, prior notice or website posting is required before an amendment is deemed effective.

No Medical Advice.
The Policies do not constitute medical advice. Health Net does not provide or recommend treatment to members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Nutritional Therapy, Oral and Enteral Dec 15

17
No Authorization or Guarantee of Coverage.
The Policies do not constitute authorization or guarantee of coverage of particular procedure, drug, service or supply. Members and providers should refer to the Member contract to determine if exclusions, limitations, and dollar caps apply to a particular procedure, drug, service or supply.

Policy Limitation: Member’s Contract Controls Coverage Determinations.
Statutory Notice to Members: The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illnesses or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under your contract. The determination of coverage for a particular procedure, drug, service or supply is subject to the facts of the individual clinical case, terms and conditions of the member’s contract, and requirements of applicable laws and regulations. The contract language contains specific terms and conditions, including pre-existing conditions, limitations, exclusions, benefit maximums, eligibility, and other relevant terms and conditions of coverage. In the event the Member’s contract (also known as the benefit contract, coverage document, or evidence of coverage) conflicts with the Policies, the Member’s contract shall govern. The Policies do not replace or amend the Member’s contract.

Policy Limitation: Legal and Regulatory Mandates and Requirements
The determinations of coverage for a particular procedure, drug, service or supply is subject to applicable legal and regulatory mandates and requirements. If there is a discrepancy between the Policies and legal mandates and regulatory requirements, the requirements of law and regulation shall govern.

Reconstructive Surgery
CA Health and Safety Code 1367.63 requires health care service plans to cover reconstructive surgery. “Reconstructive surgery” means surgery performed to correct or repair abnormal structures of the body caused by congenital defects, developmental abnormalities, trauma, infection, tumors, or disease to do either of the following:

(1) To improve function or

(2) To create a normal appearance, to the extent possible.

Reconstructive surgery does not mean “cosmetic surgery,” which is surgery performed to alter or reshape normal structures of the body in order to improve appearance.

Requests for reconstructive surgery may be denied, if the proposed procedure offers only a minimal improvement in the appearance of the enrollee, in accordance with the standard of care as practiced by physicians specializing in reconstructive surgery.

Reconstructive Surgery after Mastectomy
California Health and Safety Code 1367.6 requires treatment for breast cancer to cover prosthetic devices or reconstructive surgery to restore and achieve symmetry for the patient incident to a mastectomy. Coverage for prosthetic devices and reconstructive surgery shall be subject to the co-payment, or deductible and coinsurance conditions, that are applicable to the mastectomy and all other terms and conditions applicable to other benefits. “Mastectomy” means the removal of all or part of the breast for medically necessary reasons, as determined by a licensed physician and surgeon.

Policy Limitations: Medicare and Medicaid
Policies specifically developed to assist Health Net in administering Medicare or Medicaid plan benefits and determining coverage for a particular procedure, drug, service or supply for Medicare or Medicaid members shall not be construed to apply to any other Health Net plans and members. The Policies shall not be interpreted to limit the benefits afforded Medicare and Medicaid members by law and regulation.