



Clinical Policy: Nutritional Supplementation Therapy

Reference Number: HNCA. CP.MP.254

Effective Date: 02/06

Last Review Date: 03/20

[Coding Implications](#)

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Please note that this policy is benefit related and must be administered in accordance with state mandates and/or member benefits and Evidence of Coverage which take precedence over this policy.

Description

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.

Policy/Criteria

- I. It is the policy of Health Net of California that enteral nutrition (formulas usually consisting of semi-synthetic intact protein/protein isolates) are medically necessary when:
 - A. Prescribed by a physician for use in the home through enteral feeding tubes (N-G tube, N-E feeding tubes, G-tubes, J-tube, and
 - B. The feedings exceed 750 kilocalories a day (Note: there are no kilocalorie minimum in pediatric patients in order to maintain weight and strength commensurate with the patient's overall health status), and
 - C. Three-month history of any of the following:
 1. Increased nutritional needs that cannot be met thru oral intake (e.g. burns, trauma)
 2. Increased oral intake resulting in deterioration of nutritional status or
 3. Disease of the intestine which impairs digestion and/or absorption of an oral diet in the small bowel, such as:
 - a. Crohn's disease when the patient requires prolonged infusion of enteral nutrients to overcome a problem with absorption
 - b. Acute ulcerative colitis
 - c. Granulomatous colitis
 - d. Gastroesophageal reflux with failure to thrive



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- e. High output fistula
 - f. Certain severe short bowel syndromes
 - g. Severe intestinal malabsorption syndrome and the formula comprises the sole source or an essential source of nutrition
 - h. Severe acute or chronic pancreatitis
 - i. Ischemic bowel disease with massive bowel resection
 - j. Irradiated bowel
 - k. Gastrointestinal dysmotility such as chronic intestinal pseudo-obstruction (Ogilvie’s syndrome)
 - l. Allergic enteropathy, including allergic colitis
 - m. Multiple, severe food allergies which if left untreated will cause malnourishment, chronic physical disability, mental retardation or death
 - n. Hyperemesis gravidarum
- D. A permanent anatomic or structural problem that prevents food from reaching the small intestine, for example:
- 1. An obstructing tumor or stricture of the esophagus or stomach
 - 2. Obstruction due to head and neck cancer and reconstructive surgery
 - 3. Jaw fracture
 - 4. Gastrointestinal cancer
 - 5. Obstruction of gastric outlet due to ulcer diathesis
 - 6. Intestinal atresia (infants)
- E. A neurological problem that significantly interferes with the ability to chew or swallow such that a risk of aspiration exists, for example:
- 1. Severe dysphagia following a stroke
 - 2. Patients with partial impairments, e.g., a patient with dysphagia who can swallow small amounts of food
 - 3. Neuromuscular or CNS disease

II. It is the policy Health Net of California that standard oral infant formula is not medical in nature unless mandated by state law.

III. It is the policy of Health Net of California that specialized infant formula may be considered medically necessary for treatment of inherited metabolic diseases for which newborn screening is required including any of the following:

Biotinidase Deficiency	Isovaleric acidemia (and other disorders of leucine metabolism)
Citrullinemia	Maple syrup urine disease (MSUD)
Cystinosis	Methylmalonic acidemia
Galactosemia	Phenylketonuria (PKU)*
Glutaric acidemia type I	Propionic acidemia
Histidinemia	Tyrosinemia types I and II



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Homocystinuria	Urea cycle disorders
Cystic Fibrosis	Other organic acidemias

IV. It is the policy of Health Net of California that medically necessary treatment for phenylketonuria (PKU) may be provided for infants, children and adults as well as for the protection of unborn babies of women according to specific state mandates and/or member evidence of coverage.

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

and

AB-30 Health care coverage: phenylketonuria: inborn errors of metabolism

http://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=200720080AB30

V. It is the policy of Health Net of California that elimination diets are considered medically necessary for any of the following:

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

VI. It is the policy of Health Net of California that over the counter dietary supplements or regularly purchased food items typically used in ketogenic diets are not covered under most benefit plans. Hospitalization (usually 3 days or less) for the initiation of a ketogenic diet may be considered medically necessary when the following are met:

- A. Children older than 12 months and younger than 8 year old with seizures refractory to or intolerant of multiple conventional anti-epileptic drugs, and
- B. Hospitalization is needed for monitoring during the initial fast, intended to induce marked ketosis and weight loss, and
- C. To provide intense education needed to maintain a ketogenic diet once discharged

VII. It is the policy of Health Net of California that FDA- approved infusion pumps are considered medically necessary durable medical equipment (DME) to administer enteral feedings for any of the following indications:

- A. For patients with dumping syndrome who cannot tolerate bolus feedings; or
- B. For use in gastrostomy/jejunostomy tube feedings; or
- C. For patients with inflammatory bowel disease who require small amounts of slow, continuous feedings; or
- D. For patients who, through surgery or congenital abnormality, do not have a stomach and who require slow, continuous feedings.



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- E. 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:
 - 1.Reflux and/or aspiration
 - 2.Severe diarrhea
 - 3.Dumping syndrome
 - 4.Blood glucose fluctuations
 - 5.Circulatory overload

- VIII.** It is the policy of Health Net of California that the following are not considered medical in nature, unless otherwise specified in other coverage documents:
- A. Over-the-counter nutritional items, food and food substitutes
 - B. Food thickeners, baby food, and other regular grocery products that can be blenderized by the patient or caregiver for administration through a tube
 - C. Oral vitamins or mineral preparations
 - D. Self-blenderized formulas and enteral formula additives, including vitamins, minerals, and fiber
 - E. Formulas containing natural foods that are blenderized and packaged by a manufacturer.
 - F. Usual and customary infant formulas for children less than one-year of age who require enteral nutritional therapy
 - G. When adequate nutrition is possible by dietary adjustment, counseling and/or oral supplements.
 - H. 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
 - I. "Specialized" infant formulas (e.g., Nutramigen, Alimentum, etc.) unless otherwise specified in this policy
 - J. Food supplements
 - K. Banked breast milk
 - L. Vitamins and/or minerals taken orally
 - M. Lactose-free foods for lactose intolerance
 - N. Food to supplement a deficient diet
 - O. Foods as alternative nutrition in the presence of such conditions as hypoglycemia, allergies, obesity, and gastrointestinal disorders, including:
 - 1. Oral allergy syndrome (oral/perioral pruritus associated with food-specific IgE)
 - 2. Dietary protein proctitis/proctocolitis of infancy
 - 3. Dietary protein-induced enteropathy of infancy
 - 4. Celiac disease
 - 5. Dietary protein-induced enterocolitis of infancy
 - 6. Occult blood loss from the gastrointestinal tract of milk-fed infants
 - 7. Eosinophilic esophagitis, any age group



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8. Eosinophilic gastroenteritis
9. Enteropathy/malabsorption, any age group
10. Constipation in early childhood
11. Infantile colic

Background

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 principles, are established by medical evaluation.

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.

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. 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.

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



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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 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.

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. 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 should be limited to infants with well-defined clinical indications.

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 fail to respond to antireflux medications like omeprazole or cisapride. 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.

Coding Implications



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This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2015, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

These lists may not be all inclusive

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

HCPCS Codes	Description
B4032- 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



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HCPCS Codes	Description
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
S9342 - S9343	Home therapy:enteral nutrition
S9433	Medical food nutritionally complete, administered orally, providing 100% of nutritional intake
S9435	Medical foods for inborn errors of metabolism

ICD-10-CM Diagnosis Codes that Support Coverage Criteria

ICD-10-CM Code	Description
E40-E46	Malnutrition
F50.00-F50.9	Eating disorders
F98.21-F98.3	Other feeding disorders of infancy and early childhood
R63.0-R63.8	Symptoms and signs concerning food and fluid intake

Reviews, Revisions, and Approvals	Date	Approval Date
Converted to new template	3/17	3/17
Update, no changes	3/18	3/18
Update, no change	3/19	3/19
Update, added this phrase to VIII: “unless otherwise specified in other coverage documents”	03/20	03/20



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Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy,



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contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare members, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at <http://www.cms.gov> for additional information.

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