Molina Clinical Policy
Enteral Nutrition
Policy No. 406

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DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a Member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid Members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members.[1] References included were accurate at the time of policy approval and publication.

OVERVIEW

Enteral nutrition refers to any method of feeding that uses the gastrointestinal (GI) tract to deliver nutrition and calories and includes a normal oral diet, the use of liquid supplements or delivery by tube feeding (Kirby et al. 2021). Enteral tube feeding is generally defined as the provision of nutritional requirements through a tube in the stomach or small intestine such as a nasogastric tube or a percutaneous gastrostomy tube and delivered by syringe, gravity, or via an electric infusion pump. Feedings can be delivered on an intermittent or continuous basis. Individuals may require enteral nutritional therapy to provide sufficient nutrients to maintain weight and strength commensurate with overall health status if nutritional needs cannot be met through dietary adjustments and/or oral supplements. Enteral nutrition formulas differ in their protein and fat content and can be classified as elemental (based on amino acids, sugars, fats, vitamins, and minerals) or non-elemental (composed of oligopeptide or whole-protein sources) (Limketkai et al., 2019; Lochs et al., 2006) into four major types of formulas:

- **Standard/Polymeric formulas** contain whole proteins, complex carbohydrates, and long chain triglycerides (LCTs) which require full digestive function to break down the intact nutrients. Most standard formulae contain neither gluten nor lactose in clinically relevant amounts. Normal or near normal digestive and absorptive functions are necessary for the use of polymeric formulas.
- **Elemental formulas** contain individual amino acids and medium chain triglycerides (MCTs) broken down or pre-digested to their simplest form requiring minimal digestive function for those patients who have compromised digestive systems or nutrient absorption problems.
- **Semi-elemental formulas** contain amino acids of varying length, simple carbohydrates, and MCTs. These formulas are partially pre-digested or partially hydrolyzed.
- **Specialized/disease-specific** formulas are designed for a variety of clinical conditions or disease states.

Semi-elemental, as well as elemental, formulas have not been proven to be superior to polymeric formulas in some diseases or conditions. For instance, a systematic review by the Cochrane Collaboration found no significant difference in the efficacy of elemental, semi-elemental, or polymeric formulas for the induction of remission in Crohn disease (CD).

The U.S. Food and Drug Administration (FDA) defines a **'medical food'** 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.*" (FDA, May 2016). This definition distinguishes medical foods from the broader category of foods for special dietary use. Medical foods and dietary supplements are not regulated as prescription drugs; however, these products are generally not available at retail outlets and must be special ordered through a pharmacy or pharmaceutical organization (Camp et al., 2012). Medical foods do not have to undergo premarket review or approval by FDA and individual medical food products do not have to be registered with the FDA.

The FDA regulates infant formulas developed for Inborn Errors of Metabolism (IEM) and categorizes these formulas as "exempt." An **exempt infant formula** is an infant formula intended for commercial or charitable distribution that is represented and labeled for use by infants who have IEM or low birth weight, or who otherwise have unusual medical or dietary problems (21 CFR 107.3). Infant formulas have special nutritional labeling requirements (21 CFR 107.10) and must contain certain nutrients within a specified range; however, some deviations from these nutritional labeling requirements and nutrient specifications are permitted for "exempt" infant formulas. The FDA will consider, for example, whether a deviation from the nutritional requirements and regulations is necessary to provide an exempt infant formula that is appropriate for the dietary management of a specific disease, disorder, or medical condition [21 CFR 107.50(d)(4)(i)]. These formulas must meet the same regulatory requirements as standard infant formulas for the dietary management of specific diseases, disorders, or medical conditions without the offending nutrient(s). For example, products designed for phenylketonuria (PKU) do not include phenylalanine) (FDA, 2011). While infant formulas for IEM are also considered to be medical foods, they are regulated as infant formulas.

COVERAGE POLICY

Molina Healthcare determines medical necessity only if the benefit exists and no contract exclusions are applicable. Exclusions, limitations or exceptions may apply according to individual member benefits. Please check the federal, state or contractual requirements for coverage.

Coverage requires use of FDA-approved enteral nutrition feeding/infusion kits, pump, supplies, and related nutritional formulas indicated for the treatment of the patient's confirmed diagnosed medical condition. A non-professional individual or family member who has received specialized training may provide enteral nutrition safely and effectively in the home.

Women, Infants and Children (WIC) Program. Children who are under age 5 are required to obtain enteral products from the WIC Program. Coverage is limited to specific approved enteral products designated on the WIC preferred list. The following signed and dated written notification from WIC is required:

1. WIC coverage unavailable OR inadequate to meet needs for growth; **AND**
2. The requested product is not available through the WIC program **AND** the following documentation:
    - A statement from WIC on the amount and type of formula or supplements provided per month; **OR** Documentation of medical need for alternative products (not available from WIC); **AND**
    - Nutritional need is the amount of formula to establish or maintain an appropriate weight for age and gender exceeds the allowable amount from WIC.

Enteral Tube Feedings

Enteral Nutrition administered by tube is considered medically necessary when **ALL** of the following criteria are met:

1. Prescribed in a written order by the member's physician with specific caloric/nutritional requirements determined by the physician or clinical/metabolic nutritionist**; AND**

2. Member has a functioning GI tract but due to pathology to, or non-function of, the structures that normally permit food to reach the digestive tract, cannot maintain weight and strength adequate with their general condition; **AND**

3. Documentation of **ONE** of the following conditions:
    a. A non-function (full or partial) or disease of the structures that normally permit food to reach the small bowel (*i.e., obstruction or abnormality of structures due to head and neck cancer or reconstructive surgery*) or a GI motility disorder (e.g., severe dysphagia following a stroke, neuromuscular or disease of the central nervous system that interferes with the ability to chew or swallow, etc.); **OR**
    b. Disease that impairs digestion and/or absorption of an oral diet, directly or indirectly, by the small bowel;
    c. Comatose patients on mechanical ventilation or with severe head injury; **OR**
    d. Cognitive neurological disorders that impair (or cause to forget) swallowing or chewing (e.g., Dementia,

Alzheimer's disease, or Organic brain syndrome); **OR**
a neuromuscular disorder affecting swallowing reflex (e.g., Parkinson disease, multiple sclerosis, cerebrovascular accident); **OR**

e. Mechanical dysfunction of the GI tract in which there is a functional impairment that results in a specific inability to swallow or may prevent food from reaching the stomach (e.g., esophageal obstruction or stricture, cancer of the larynx or tongue); **OR**
f. Severe disorders such as physical disability, intellectual disability, or psychiatric conditions or mental illness causing severe malnutrition and possibly death if enteral nutrition is not instituted.

4. Adequate nutrition must not be possible by dietary adjustment and/or oral supplements according physician and/or clinical nutritionist; **AND**

5. Requested enteral formula meets **ONE** of the following as applicable:
   a. Requests for enteral formulas consisting of semi-synthetic intact protein or protein isolates (B4150 or B4152) for adults (e.g., Enrich, Ensure, Ensure HN, Ensure Powder, Isocal, Lonalac Powder, Meritene, Meritene Powder, Osmolite, Osmolite HN, Portagen Powder, Renu, Sustacal, Sustagen Powder, Travasorb); **OR**
   b. Requests for formulas consisting of natural intact proteins or protein isolates (e.g., Compleat B, Compleat B Modified, Vitaneed) for individuals with an allergy or intolerance to semi-synthetic formulae; **OR**
   c. Requests for pediatric enteral formulas (B4160) may be appropriate for children up to age 13; **OR**
   d. Special enteral formula (B4149, B4153–B4155, B4157, B4161 and B4162) must be documented with clinical justification.

   NOTE: Enteral nutrition HCPCS coding (B4149-B4162) is covered only if given through a feeding tube.
   Reference: CMS NCD and CMS NCD

AND

6. Submit order/prescription for the specific enteral product requested, estimated length of need based on member's condition/diagnosis, quantity and units of measure, frequency and directions for use.

LIMITATIONS AND EXCLUSIONS

The following are **considered contraindications** to enteral nutrition:

Absolute Contraindications

- Hemodynamic instability with poor end-organ perfusion. Enteral feeding in patients with bowel ischemia or necrosis can make a bad situation worse
- Active GI bleeding
- Small or large bowel obstruction
- Paralytic ileus secondary to electrolyte abnormalities, peritonitis

Relative Contraindications

- Moderate to severe malabsorption
- Active diverticulitis
- Fistula in the small bowel
- Short bowel disease in the early stages.

QUANTITY LIMITATIONS Up to a 6-month supply may be authorized. Quantity sufficient to meet the member's nutritional need in accordance with confirmed diagnosis and caloric requirement as ordered by the prescribing physician or clinical nutritionist for a one-month (30-day) supply of the product size or as indicated by applicable State laws.

CONTINUATION OF THERAPY

1. Member continues to meet indication for initial therapy; **AND**
2. Documentation of regular interval monitoring and nutritional reassessments, including current nutritional status, evidence of response to the prescribed enteral nutrition, and the continued requirement of enteral nutrition to maintain appropriate current body weight and health must be submitted with subsequent requests.

Formula for Metabolic Diseases or Inborn Errors of Metabolism (IEM) is considered medically necessary when **ALL** the following are met:

1. Confirmed diagnosis of an IEM, including but not limited to: tyrosinemia, homocystinuria, maple syrup urine disease, propionic acidemia, methylmalonic acidemia, urea cycle disorders, PKU, protection of fetus in pregnant individual with PKU, and other organic acidemias (NOTE: Food allergies are not considered an IEM); **AND**

2. Requested product meets **ONE** of the following:
   a. Labeled as "exempt" specialized metabolic infant formulas by the FDA: Exempt Infant Formulas Marketed in the United States By Manufacturer and Category (list may not be all inclusive as the agency becomes aware of newer information, the list will be periodically updated); **OR**
   b. Labeled as a "medical food" by the FDA in accordance with the Orphan Drug Act [Code of Federal Regulations Title 21] **AND** will be used under medical supervision.

AND

3. Member will receive ongoing medical supervision by the prescribing physician; **AND**

4. A new order/prescription for the specific item or service requested, the member's continued need based on clinical condition/diagnosis, estimated length of need, quantity and units of measure, frequency and directions for use.

NOTE: Formula that is not specifically made for IEM, even when the formula is the sole source of nutrition, may not be authorized.

Oral Enteral Nutrition Therapy may be considered medically necessary when **ALL** the following criteria are met:

A. Prescribed in a written order by the member's physician with specific caloric/nutritional requirements determined by the physician or clinical/metabolic nutritionist; **AND**
B. Member meets the following additional criteria
   1. 50% of caloric or nutritional requirements are not able to be met from ordinary food to maintain life-sustaining functions; **AND**
   2. Presence of a medical condition that is a significant risk factor for developing malnutrition including, but not limited to, **ONE** or more of the following:
      a. Malabsorption syndromes or short-bowel syndromes resulting in prolonged requirement for nutritional support (e.g., Pediatric Crohn's disease, ulcerative colitis, short bowel syndromes, gastroparesis, massive bowel resection); **OR**
      b. Exocrine Pancreatic Insufficiency (EPI): pancreatic (*e.g., chronic pancreatitis, pancreatic amylase deficiency, pancreatic cancer, pancreatic resection, Shwachman-Diamond Syndrome*) and nonpancreatic causes (*e.g., celiac disease, inflammatory bowel disease, diabetes, gastrointestinal surgery*).[Capurso et al. 2019]
      c. Disorders of GI motility such as chronic intestinal pseudo-obstruction; **OR**
      d. Failure To Thrive/Weight loss: Unresponsive to standard age-appropriate interventions over four weeks with clinical signs and symptoms of nutritional risk from failure to thrive as indicated by the following:
         Adults ≥ 18 years of age:
         - BMI ≤ 18.5 kg/m^2 *and* albumin level of < 3.5 or a cholesterol level of 160 or below; or albumin < 4.0 in end stage renal patients; **OR**
         - Documented unintentional weight loss ≥10% over the past 3-6 months.

         Neonates, Infants and Children <18 years of age:
         - Weight for height or BMI for age ≤ 10 percent; **OR**
         - Crossed (downward) at least 2 percentile lines of weight for age on the growth chart.

         OR
      e. Physiologic anorexia (such as cancer, sepsis, liver disease, HIV/AIDS); **OR**
      f. Severe food allergies, which if left untreated will cause malnourishment, chronic physical disability, intellectual disability or death. This does not include mild to moderate food allergies which can usually be treated with formula that is readily available in food stores and pharmacies, or by careful food selection. Formulas for the treatment of such conditions are not covered.

Informational Note: There is no consensus on the definition of childhood failure to thrive; however, the term is often used for infants and children with weight below the 5th percentile for sex and corrected age. Supporting definitions include weight for length or body mass index below the 5th percentile; or a sustained decrease in growth velocity, in which weight for age or weight for length/height falls by two major percentiles over time (Homan 2016 Yoo et al., 2013).

QUANTITY LIMITATIONS Up to a 6-month supply may be authorized. Quantity sufficient to meet the member's nutritional need in accordance with confirmed diagnosis and caloric requirement as ordered by the prescribing physician or clinical nutritionist for a one-month (30-day) supply of the product size or as indicated by applicable State laws.

CONTINUATION OF THERAPY

1. Member continues to meet indication for initial therapy; **AND**
2. Documentation of regular interval monitoring and nutritional reassessments, including current nutritional status, evidence of response to the prescribed enteral nutrition, and the continued requirement of enteral nutrition to maintain appropriate current body weight and health must be submitted with subsequent requests.

LIMITATIONS AND EXCLUSIONS

The following are **considered exclusions** based on insufficient evidence (regardless of whether prescribed by a physician or for a medical diagnosis):

1. Oral liquid nutritional supplements solely based on food preference, patient convenience, or to boost caloric intake without a specific medical indication.
2. Food products or food supplements, including but not limited to:
    a. Food thickeners
    Note: Commercial food thickeners (B4100) have demonstrated no significant nutritional value
    b. Baby food
    c. Gluten-free or lactose-free foods
    d. High protein powders and mixes
    e. Low carbohydrate diet foods, grocery items
    f. Nutritional supplement puddings
    g. Weight loss or weight gain products
    h. Grocery items that are used in specialized diets or have been modified for a special nutritional need
    i. Regular grocery products that can be mixed in blenders and used with an enteral system regardless of whether these regular food products are taken orally or parenterally.

    NOTE: Food products are not considered medical food items, regardless of their intended use.
3. Self-blenderized formulas
4. Over-the-counter foods
5. Modified grocery item foods, even if categorized as medical foods by the manufacturer.
6. Banked/Donor Breast Milk
7. Specialized infant formulas (e.g., Alimentum, Elecare, Neocate, and Nutramigen)
8. Vitamins and/or minerals taken orally
9. Nutritional or cosmetic therapy using high-dose or mega quantities of vitamins, minerals or elements another nutrition-based therapy
10. Any supplements used to replace intolerable foods, for lactose intolerance, to supplement a deficient diet, or to provide alternative nutrition in the presence of such conditions as allergies, gastrointestinal disorders, hypoglycemia, and obesity.
11. Non-standard formulas when given orally, including regular store-bought formula, for use with an enteral feeding system (e.g., Elecare; Nutramigen; Progestimil; Neocate; Portagen; Alimentum; NeoSure; Monogen)
12. Oral rehydration therapy (e.g., Pedialyte, Infalyte, Naturalyte, and Rehydralyte) intended for very short-term use primarily with infants or children to replace water and electrolytes lost during severe bouts of vomiting and diarrhea.

The following are considered **experimental, investigational and unproven** based on insufficient evidence:

1. Any indications other than those listed above
2. For the treatment of eating disorders, except in life-threatening cases of severe cases of anorexia nervosa (Hale and Logomarsino 2019)
4. For routine pre- and/or post-operative care
5. Malnutrition secondary to nonorganic causes (e.g., anorexia nervosa, bulimia nervosa); exception: severe anorexia from chemotherapy, HIV, sepsis
6. Pediatric medical conditions that require certain medications and/or a change in infant formula or nutrition for treatment but are usually *not considered life-threatening conditions* and may improve with time (e.g., colic, gastroesophageal reflux disease (GERD), cow's milk protein allergy, soy protein allergy, lactose intolerance, viral gastroenteritis, eczema, asthma/wheezing and eosinophilic gastroenteritis).

Home Enteral Infusion Pumps

Durable Medical Equipment (DME) home enteral infusion, is subject to the terms, conditions and limitations of the applicable benefit plan's DME benefit, may be considered on a case-by-case basis when medical necessity is documented for ALL of the criteria below.

1. Requested enteral nutrition item(s) must be FDA-approved enteral nutrition feeding/infusion kits, pump, *supplies, and related nutritional formulas indicated for the treatment of the patient's confirmed medical condition.
   **Enteral feeding supplies typically include the feeding container, flushing solution, tubing for administration, extension tubing, syringes, gastrostomy tube holder, dressings, tape, connectors, adapters, a gastric pressure relief valve, and a declogging device.*

   NOTE: Enteral nutrition products that are administered *orally* and related supplies do not meet criteria.

AND

2. For enteral nutrition involving pump requests: Medical documentation and supporting rationale that the pump is medically necessary.

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

SUMMARY OF MEDICAL EVIDENCE

Formula for Metabolic Diseases or Inborn Errors of Metabolism

Inherited metabolic disorders, also referred to as inborn errors of metabolism (IEMs), are genetic disorders characterized by deficiencies or defects in vital enzymes that are needed to facilitate normal metabolism resulting in malnourishment or toxic accrual of substances in the body, and consequently, organ damage. These metabolic disturbances can lead to a range of medical and developmental consequences including developmental delay, irreversible cognitive dysfunction, life-threatening metabolic crises, and death. Early identification and medical intervention may mitigate or prevent many of the adverse outcomes. Prompt nutritional treatment including replacement of essential nutrients via special enteral formula is necessary for infants diagnosed with an IEM disorder. Treatment for many of these disorders consists of a diet low in protein, fat, or carbohydrate and daily supplementation of essential nutrients via enteral formula. Nutritional products include two different forms of medical foods: one containing protein without the offending amino acid(s) and the other consisting of foods that have been modified to be low in protein (Camp et al., 2012). Treatment goals for patients with an IEM are prevention of further accumulation of harmful substances, correction of metabolic abnormalities, and elimination of toxic metabolites. Special formulas and medical foods have been developed for certain IEM disorders which eliminate the amino acid that cannot be metabolized from the protein context of the food which leads to clinical manifestations and long-term complications. Medical foods for IEM are administered orally or by enteral tube. The medical requirement of enteral formula never diminishes with age for most IEM patients. There is no evidence in the

current literature base suggesting that enteral formula may be discontinued after the age of two, or at any point during childhood. Patients with IEM maintain their prescribed diet, including enteral formula, in order to maintain safe levels of otherwise toxic compounds in the blood into adolescence and adulthood.

Enteral Nutrition in the Treatment of Eating Disorders

Hale and Logomarsino (2019) examined the efficacy of EN in the treatment of eating disorders through a literature search of 7 databases using a search strategy of combined key terms anorexia nervosa (AN), bulimia nervosa (BN), and eating disorders with terms associated with EN. The authors noted that while there are standardized guidelines for treatment at this time; however, EN is often used in the treatment of AN, and less frequently, bulimia nervosa (BN). Studies that assessed the effect of EN on weight restoration, refeeding syndrome, and binge/purge behaviors in the treatment of AN and BN were included. The search yielded 73 full-text articles reviewed with 22 met inclusion criteria. 19 studies reported that significant short-term weight gain was achieved when EN was used for re-feeding malnourished AN patients; however, results varied for the 6 studies reporting on long-term weight gain, maintenance, and recovery. In studies with a comparator, no significant differences were found between the EN and oral re-feeding cohorts regarding GI disturbance, re-feeding syndrome, or electrolyte abnormalities. Five studies examined the effect of EN on binge/purge behaviors, suggesting the frequency and severity of binge/purge episodes temporarily decreased with exclusive EN. The results of this systematic review highlighted the need for prospective controlled trials with adequate sample sizes to make comparisons between specific feeding methods, formulations, and defined short- and long-term outcomes. The authors concluded that although EN is an essential life-saving treatment in severe cases of AN, it does not guarantee long-term success or recovery and concluded that evidence-based standards for clinical practice are needed with specific guidelines for best results for AN and BN treatment.

Exclusive Enteral Nutrition (EEN) in the Treatment of Crohn Disease

EEN involves the use of EN as the predominant source of nutrition, while concurrently abstaining from other food sources. A peer review published by UpToDate on the management of Crohn disease (CD) in children and adolescents defines EEN as therapy that involves the cessation of eating and intake of all dietary energy from formula (taken by mouth, nasogastric tube, or gastrostomy) for 8 to 12 weeks.

Narula et al. (2018), in a systematic review by the Cochrane Collaboration, evaluated the safety and effectiveness of exclusive EN as primary therapy to induce remission in CD and examined the importance of formula composition on effectiveness. This Cochrane review suggests that EEN is superior to corticosteroids in pediatric CD, but slightly inferior in adult CD for the induction of remission. It is noted that corticosteroids are often preferred over EN as induction therapy for CD. The authors conducted a large meta-analysis of 27 randomized trials (1,011 participants). The systematic review concluded a very low-quality evidence suggesting that corticosteroids therapy may be more effective than EN for induction of clinical remission in adults with active CD. A very low-quality evidence also suggests that EN may be more effective than steroids for induction of remission in children with active CD. Furthermore, protein composition does not appear to influence the effectiveness of EN for the treatment of active CD. The review found no significant difference in the efficacy of elemental, semi-elemental, or polymeric formulas for the induction of remission in CD, therefore the need for specialty formulas is unclear. The authors recommended that EN should be considered in pediatric CD patients or in adult patients who can comply with nasogastric tube feeding or perceive the formulations to be palatable, or when steroid side effects are not tolerated or better avoided. The authors noted that additional research is required to confirm the superiority of corticosteroids over EN in adults and further research is also needed to confirm the benefit of EN in children.

National and Specialty Organizations

The **European Society for Parenteral and Enteral Nutrition (ESPEN)** guidelines on clinical nutrition in inflammatory bowel disease (IBD) indicates that "there is no 'IBD diet' that can be generally recommended to promote remission in IBD patients with active disease." However, due to serious concerns over corticosteroid use and aiming for optimal growth in children, EN is often first-line therapy for pediatric patients with active Crohn's disease. In adults with Crohn's disease, the guidelines noted that while EN as primary therapy in adults has been considered to be effective "the data are not robust" and the "meta-analyses do not support the use of EN as primary treatment for acute exacerbations of CD in adults. Patchy clinical conviction and the data, which appear better than might be expected with placebo, ensure continuing controversy over its role in adults." (Forbes, et al., 2017)

National Institute for Health and Clinical Excellence (NICE)
Clinical Guidelines [CG32]: Nutrition Support for Adults: Oral Nutrition Support, Enteral Tube Feeding and Parenteral Nutrition

Summary of the clinical guidelines include the following recommendations (in relevant part) regarding nutrition support and enteral tube feeding:

1.3.1 Nutrition support should be considered in people who are malnourished, as defined by any of the following:
- a BMI of less than 18.5 kg/m^2
- unintentional weight loss greater than 10% within the last 3–6 months
- a BMI of less than 20 kg/m^2 and unintentional weight loss greater than 5% within the last 3–6 months.

1.3.2 Nutrition support should be considered in people at risk of malnutrition who, as defined by any of the following:
- have eaten little or nothing for more than 5 days and/or are likely to eat little or nothing for the next 5 days or longer
- have a poor absorptive capacity, and/or have high nutrient losses and/or have increased nutritional needs from causes such as catabolism.

1.3.3 Healthcare professionals should consider using oral, enteral or parenteral nutrition support, alone or in combination, for people who are either malnourished or at risk of malnutrition, as defined in 1.3.1 and 1.3.2. Potential swallowing problems should be taken into account.
1.7.1 Healthcare professionals should consider enteral tube feeding in people who are malnourished or at risk of malnutrition as defined in 1.3.1 and 1.3.2, respectively, and have:
- inadequate or unsafe oral intake, and
- a functional, accessible gastrointestinal tract.

1.7.2 Enteral tube feeding should not be given to people unless they meet the criteria in 1.7.1, or they are taking part in a clinical trial.
1.7.3 Enteral tube feeding should be stopped when the patient is established on adequate oral intake.

ESPEN-ESPGHAN-ECFS Guidelines on Nutrition Care for Infants, Children, and Adults with Cystic Fibrosis
The guidelines addressed nutritional management of patients with CF. A summary of recommendations on enteral tube feeding for CF patients include the following:
- Recommendation of a progressive approach to intensification of nutrition interventions as needs increase: preventive nutritional counseling, dietary modification and/or oral nutrition supplements, and enteral tube feeding (Grade of evidence: low)
- Recommendation for clinicians to consider the use of polymeric enteral tube feeding when oral interventions have failed to achieve acceptable rates of growth and nutritional status. (Grade of evidence: high)
- Recommendation for the use of parenteral nutrition be reserved for exceptional cases when enteral feeding is not possible. (Grade of evidence: low)

SUPPLEMENTAL INFORMATION

Enteral feeding supplies typically include the feeding container, flushing solution, tubing for administration, extension tubing, syringes, gastrostomy tube holder, dressings, tape, connectors, adapters, a gastric pressure relief valve, and a declogging device.

Phenylketonuria (PKU), an inborn error of metabolism, is a rare genetic disease that results an inability to break down phenylalanine (Phe), an amino acid. Amino acids are the chemical building blocks of proteins and are essential for proper growth and development. PKU is characterized by absence or deficiency of an enzyme called phenylalanine hydroxylase (PAH), responsible for processing the amino acid Phe, which is present in protein-containing foods and high-intensity sweeteners used in a variety of foods and beverages. With normal PAH activity, Phe is converted to another amino acid, tyrosine. However, when PAH is absent or deficient, Phe accumulates and is toxic to the brain. Without treatment, most people with PKU would develop severe intellectual disability. To prevent intellectual disability, treatment consists of a carefully controlled, Phe-restricted diet beginning during the first days or weeks of life. (NORD, 2021)

CODING & BILLING INFORMATION

Codes may vary. Please refer to State contract language, Medicaid criteria and other mandated criteria. Exclusions, limitations or exceptions may apply according to individual member benefits. Please check the federal, state or contractual requirements for coverage.

CPT	Description

HCPCS	Description
B4150	Enteral formula, nutritionally complete with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit
B4152	Enteral formula, nutritionally complete, calorically dense (equal to or greater than 1.5 kcal/ml) with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit
B4153	Enteral formula, nutritionally complete, hydrolyzed proteins (amino acids and peptide chain), includes fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit
B4154	Enteral formula, nutritionally complete, for special metabolic needs, excludes inherited disease of metabolism, includes altered composition of proteins, fats, carbohydrates, vitamins and/or minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit
B4155	Enteral formula, nutritionally incomplete/modular nutrients, includes specific nutrients, carbohydrates (e.g., glucose polymers), proteins/amino acids (e.g., glutamine, arginine), fat (e.g., medium chain triglycerides) or combination, administered through an enteral feeding tube, 100 calories = 1 unit
B4157	Enteral formula, nutritionally complete, for special metabolic needs for inherited disease of metabolism, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit.
B4158	Enteral formula, for pediatrics, nutritionally complete with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, 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 proteins, fats, carbohydrates, vitamins and minerals, may include fiber and/or iron, administered through an enteral feeding tube, 100 calories = 1 unit
B4160	Enteral formula, for pediatrics, nutritionally complete calorically dense (equal to or greater than 0.7 kcal/ml) with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories =1 unit
B4161	Enteral formula, for pediatrics, hydrolyzed/amino acids and peptide chain proteins, includes fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit
B4162	Enteral formula, for pediatrics, special metabolic needs for inherited disease of metabolism, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit.
B9002	Enteral nutrition infusion pump, any type
S9433	Medical food nutritionally complete, administered orally, providing 100% of nutritional intake
S9434	Modified solid food supplements for inborn errors of metabolism
S9435	Medical foods for inborn errors of metabolism

Enteral nutrition HCPCS coding (B4149-B4162) is covered only if given through a feeding tube.

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered

trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

10/13/2021 New policy. IRO Peer Review. 9/28/2021. Practicing physician board certified in Gastroenterology.

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APPENDIX

Reserved for State specific information *(to be provided by the individual States, not Corporate). Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*

Centers for Medicare & Medicaid Services (CMS)

Coverage of enteral nutrition for patients with non-function of the structures that normally permit food to reach the digestive tract has been established in the Medicare National Coverage Determinations (NCD) Manual (CMS Pub. 100-03), Chapter 1, Part 4, Section 180.2.

NCD 180.1 for medical nutrition therapy (MNT), CMS covers MNT for a beneficiary with a diagnosis of renal disease and/or diabetes according to CMS established criteria based on duration of treatment, episode of care, date of service,

and number of units administered per day. As stated in NCD 180.1, additional treatment may be considered medically necessary and covered if the treating physician determines that there is a change in the beneficiary's medical condition, diagnosis, and/or treatment regimen that requires a change in MNT and the physician orders additional MNT during that episode of care.

NCD 180.2 includes medically necessary indications for enteral and parenteral nutritional therapy when applicable CMS clinical criteria and administrative guidelines (e.g., Medicare Claims Processing Manual Chapter 20 Durable Medical Equipment, Prosthetics, Orthotics, and Supplies and the Stage 2 Critical Elements for Tube Feeding Status form CMS–20093) are met for beneficiaries. NCD 180.2 states the following:

> "Enteral nutrition is considered reasonable and necessary for a patient with a functioning gastrointestinal tract who, due to pathology to, or non-function of, the structures that normally permit food to reach the digestive tract, cannot maintain weight and strength commensurate with his or her general condition. Enteral therapy may be given by nasogastric, jejunostomy, or gastrostomy tubes and can be provided safely and effectively in the home by nonprofessional persons who have undergone special training…Each claim must contain a physician's written order or prescription and sufficient medical documentation (e.g., hospital records, clinical findings from the attending physician) to permit an independent conclusion that the patient's condition meets the requirements of the prosthetic device benefit and that enteral nutrition therapy is medically necessary… If the claim involves a pump, it must be supported by sufficient medical documentation to establish that the pump is medically necessary, i.e., gravity feeding is not satisfactory due to aspiration, diarrhea, dumping syndrome…Some patients require supplementation of their daily protein and caloric intake. Nutritional supplements are often given as a medicine between meals to boost protein-caloric intake or the mainstay of a daily nutritional plan. Nutritional supplementation is not covered under Medicare Part B."

Benefit category and billing guidance for enteral nutrition are outlined in the Medicare Benefit Policy Manual (CMS Pub. 100-02), Chapter 15, Section 120 and the Medicare Claims Processing Manual (CMS Pub. 100-4), Chapter 20, Section 30.7.

Medicare does provide reimbursement under the part-B prosthetic-device benefit for enteral nutrition. No NCD or local coverage determination (LCD) was found for ketogenic diets or RELiZORB® on the CMS website.

CMS

"*Enteral nutrition is considered reasonable and necessary for a patient with a functioning gastrointestinal tract who, due to pathology to, or non-function of, the structures that normally permit food to reach the digestive tract, cannot maintain weight and strength commensurate with his or her general condition. Documentation will be reviewed to determine if claims for enteral nutrition, with dates of service prior to November 12, 2020, meet coverage criteria and/or are medically reasonable and necessary."* *https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Recovery-Audit-Program/Approved-RAC-Topics-Items/0015-Enteral-Nutrition-TherapyMedical-Necessity-and-Documentation-Requirements*

Section 5.9: "For any DMEPOS item to be covered by Medicare, the patient's medical record must contain sufficient documentation of the patient's medical condition to substantiate the necessity for the type and quantity of items ordered and for the frequency of use or replacement (if applicable). The information should include the patient's diagnosis and other pertinent information including, but not limited to, duration of the patient's condition, clinical course (worsening or improvement), prognosis, nature and extent of functional limitations, other therapeutic interventions and results, past experience with related items, etc." https://www.cms.gov/regulations-and-Guidance/guidance/manuals/downloads/pim83c05.pdf

FDA

Page 4: "It is a specially formulated and processed product (as opposed to a naturally occurring foodstuff used in its natural state) for the partial or exclusive feeding of a patient by means of oral intake or enteral feeding by tube, meaning a tube or catheter that delivers nutrients beyond the oral cavity directly into the stomach or small intestine; It is intended for the dietary management of a patient who, because of therapeutic or chronic medical needs, has limited or impaired capacity to ingest, digest, absorb, or metabolize ordinary foodstuffs or certain nutrients, or who has other special medically determined nutrient requirements, the dietary management of which cannot be achieved by the modification of the normal diet alone" https://www.fda.gov/media/97726/download

Page 10: "Some examples of specific IEMs that medical foods could be used to manage involve amino acid/protein, organic acid, or fatty acid metabolism. These IEMs primarily require significant restriction of particular amino acids and/or total protein such as in phenylketonuria (phenylalanine restriction), ornithine transcarbamylase deficiency (nonessential amino acid restriction), methylmalonic acidemia (isoleucine, methionine, threonine, and valine restriction), or significant modification of fatty acids/total fat such as in very long-chain acyl-CoA dehydrogenase deficiency (long chain fatty acid restriction with an increase in medium chain fatty acid levels)" https://www.fda.gov/media/97726/download

State Medicaid:

Washington https://www.hca.wa.gov/assets/billers-and-providers/Enteral-Nutrition-bi-20200101.pdf
Page 37: "Oral enteral nutrition is a medical benefit for treating medical conditions when no equally effective, less costly alternative is available to treat the client's condition. It is not a food benefit, such as the Basic Food in Washington and WIC. When commercially available products are prescribed to correct documented nutritional or growth deficiencies, they should be used for the shortest amount of time possible before transitioning to a diet of traditional food or food products with ingredients that can be purchased for the client as grocery products."