Molina Clinical Policy
Enteral Nutrition: Policy No. 406

Last Approval: 10/12/2023
Next Review Due By: October 2024

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. 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 to the body and includes a normal oral diet, the use of liquid supplements, and/or delivery by tube feeding. Enteral tube feeding is the deliverance of nutrition via a prepyloric or post pyloric tube for temporary or permanent use. Enteral tube feeds may be administered by gravity or enteral infusion pump on a continuous or intermittent schedule. Enteral nutrition is indicated in individuals who are unable to meet adequate caloric and metabolic needs to maintain health via dietary adjustments and/or oral supplementation (Ley et al. 2023).

Enteral nutrition can be curated to individual needs and come in an array of different formulas. Each formula differs in its macro and micronutrient composition. There are four major types of formulas (Church et al. 2023):

- **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 formula 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.

Regulatory Status

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*." 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. Medical foods do not undergo premarket review or approval by FDA, nor do they 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. Infant formulas have special nutritional labeling requirements 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. 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). While infant formulas for IEM are also considered to be medical foods, they are regulated as infant formulas.

RELATED POLICIES

The use of Enteral Feeding In-Line Cartridge [e.g., RELiZORB™ immobilized lipase cartridge] to deliver digestive enzymes to enteral formula is ONLY considered medically necessary for **children with cystic fibrosis** who receive overnight tube feedings, usually by gastrostomy with a feeding pump to help reduce early morning satiety and bloating. Refer to the applicable Relizorb policy:

- Relizorb (immobilized lipase cartridge) MNR Policy Number: C17943-A (Medicaid)
- Relizorb (immobilized lipase cartridge) NC C12081-A (Marketplace)

COVERAGE POLICY

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

Coverage requires use of FDA-approved enteral nutrition feeding/infusion kits, pumps, supplies, and related nutritional formulas indicated for treatment of the patient's confirmed diagnosed medical condition. A non-clinical individual or family member who has received specialized training may provide enteral nutrition safely and effectively at 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. *If this is not possible*, 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 sex exceeds the allowable amount from WIC.

Enteral Tube Feedings

Enteral nutrition administered via tube and the accompanying necessary supplies are considered medically necessary when **ALL** the following criteria 1- 6 are met:

1. An order is submitted by the Member's physician in the form of a written prescription detailing Member's specific caloric/nutritional requirements, the specific enteral product requested, estimated length of need based on Member's condition/diagnosis, quantity and units of measure, and frequency and directions for use, as determined by the physician or clinical/metabolic nutritionist**.**
2. Documentation of **ONE** of the following conditions:
    a. An anatomical dysfunction or pathology of the upper GI tract that inhibits food to reach the stomach and/or small bowel; **OR**
    b. GI motility disorder; **OR**
    c. Severe intestinal malabsorption/disease of the small bowel; **OROR**
    d. Impaired cognition, developmental disability, central nervous system dysfunction, and/or neuromuscular disorder inhibiting ability to safely and effectively swallow and/or chew.
3. Adequate nutrition to sustain life is not possible via oral intake, dietary adjustment, and/or oral supplements
4. Member's medical condition is considered chronic and expected to last six months or longer; **AND**
5. Member's life expectancy is longer than one month; AND
6. Requested enteral formula meets **ONE** of the following, as applicable to member situation:
    a. Enteral formulas consisting of semi-synthetic intact protein or protein isolates for adults **OR**
    b. Formulas consisting of natural intact proteins or protein isolates for individuals with an allergy or

intolerance to semi-synthetic formula **OR**
c. Pediatric enteral formulas for children up to age 13; **OR**
d. Special enteral formula with documented clinical justification.

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 FOR ENTERAL TUBE FEEDINGS

The following are considered *contraindications* to enteral nutrition:

Absolute Contraindications
- Poor end-organ perfusion, as enteral feeding in patients with bowel ischemia can lead to bowel necrosis and/or perforation.
- Active GI bleeding
- Small or large bowel obstruction
- Paralytic ileus secondary to electrolyte abnormalities, peritonitis, or trauma
- Severe metabolic disturbances

Relative Contraindications
- Hemodynamic instability
- Severe malabsorption
- Active diverticular abscess
- Fistula in the small bowel
- Short bowel disease in the early stages
- Patient/caregiver noncompliance with enteral nutrition program

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.

Home Enteral Infusion Pumps

Durable Medical Equipment (DME) home enteral infusion is subject to terms, conditions, and limitations of the applicable Member's plan DME benefit. DME home enteral infusion is considered on a case-by-case basis when medical necessity and supporting rationale is documented for enteral tube feedings via pump, **AND** requested enteral nutrition items are FDA- approved for the use of enteral tube feedings.

Formula for Metabolic Diseases or Inborn Errors of Metabolism (IEM)

Formula for Metabolic Diseases or Inborn Errors of Metabolism is considered medically necessary when **ALL** the following are met:
1. Confirmed diagnosis of an IEM is documented (Note: Food allergies are not considered an IEM); **AND**
2. An order is submitted by the Member's physician in the form of a written prescription detailing Member's specific caloric/nutritional requirements, the specific formula requested, estimated length of need based on Member's condition/diagnosis, quantity and units of measure, and frequency and directions for use, as determined by the physician or clinical/metabolic nutritionist; **AND**
3. Requested product meets **ONE** of the following:
   a. Labeled as "exempt" specialized metabolic infant formulas by the FDA*; **OR**
      * Formula that is not specifically made for IEM, even when the formula is the sole source of nutrition, may not be authorized*
   b. Labeled as a "medical food" by the FDA in accordance with the Orphan Drug Act
4. Member will receive ongoing medical supervision by the prescribing physician.

Oral Enteral Nutrition Therapy

Oral enteral nutrition therapy may be considered medically necessary when **ALL** the following criteria are met:
1. An order is submitted by the Member's physician in the form of a written prescription detailing Member's specific caloric/nutritional requirements, the specific enteral product requested, estimated length of need

based on Member's condition/diagnosis, quantity and units of measure, and frequency and directions for use, as determined by the physician or clinical/metabolic nutritionist; **AND**

2. Member's medical condition is considered chronic and expected to last six months or longer; **AND**
3. Fifty percent of caloric and/or nutritional requirements to maintain life sustaining functions are unable to be met from Member's ordinary oral intake; **AND**
4. 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; **OR**
    b. Exocrine Pancreatic Insufficiency (EPI) from pancreatic (*e.g., chronic pancreatitis, pancreatic amylase deficiency, pancreatic cancer, pancreatic resection, Shwachman-Diamond Syndrome*) and/or nonpancreatic causes (*e.g., celiac disease, inflammatory bowel disease, diabetes, gastrointestinal surgery*).
    c. GI motility disorder; **OR**
    d. Food allergies unresponsive to dietary elimination, over the counter formulas and/or supplements curated for the specific food allergy, resulting in severe malnourishment; **OR**
    e. Pediatric Failure to Thrive: Pediatric (Neonates, Infants and Children <18 years of age) weight loss unresponsive to standard age-appropriate interventions for four weeks with clinical signs and symptoms of malnutrition as indicated by the following:
        i. Weight and height, and/or BMI below 10th percentile for age; **OR**
        ii. Growth decreased at least 2 percentile lines of weight for age on the growth chart.
    f. Adult (≥ 18 years of age) severe weight loss unresponsive to standard interventions for four weeks with clinical signs and symptoms of nutritional risk from weight loss as indicated by the following:
        i. BMI < 18.5 kg/m2 and albumin level of < 3.5 or a cholesterol level of 160 or below; or albumin < 4.0 in end stage renal patients; **OR**
        ii. Documented unintentional weight loss >10% over the past 3-6 months; **OR**
        iii. Physiologic anorexia and/or cachexia due to a disease process such as cancer, chronic kidney disease, sepsis, liver disease etc.

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 body weight and health must be submitted with subsequent requests.

LIMITATIONS AND EXCLUSIONS OF ORAL ENTERAL NUTRITION THERAPY

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* and/or food supplements, including but not limited to: *Food products are not considered medical food items, regardless of their intended use*
    a. Food thickeners
    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, even if categorized as medical food by the manufacturer.
    i. Regular grocery products that can be mixed in blenders and used with an enteral system.
3. Self-blenderized formulas
4. Banked/Donor Breast Milk
5. Specialized over the counter infant formulas (e.g., Alimentum, Elecare, Neocate, and Nutramigen)
6. Oral vitamins and/or minerals
7. Nutritional or cosmetic therapy using high-dose or mega quantities of vitamins, minerals, or elements another nutrition-based therapy.

8. 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.
9. Non-prescribed formula for use with an enteral feeding system
10. Acute short term oral rehydration therapy intended to replace water and electrolytes lost during severe bouts of dehydration, vomiting, and/or diarrhea.

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.

The following indications for enteral feedings of any kind 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
3. For routine pre- and/or post-operative care

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, to maintain safe levels of otherwise toxic compounds in the blood into adolescence and adulthood.

Home Enteral Nutrition for Adults
Amano et al (2021) conducted a secondary analysis of a multicenter cohort study comparing survival rates in cancer patients with cachexia when treated with enteral nutrition, parenteral nutrition, and a control group. Differences in survival rates among the three groups were significant (Log-rank P < 0.001). Median survival times were 43.0 (95% CI 40-46), 33.0 (95% CI 29-37), and 15.0 (95% CI 14-16) days, respectively (P < 0.001). A significantly lower risk of mortality was observed in Cox's proportional hazard model in the EN group and parenteral nutrition groups (HR 0.43 [95% CI 0.37-0.49], P < 0.001; and HR 0.52 [95% CI 0.44-0.62], P < 0.001, respectively) than in the control group. Concluding nutrition is an integral part of treatment, with enteral nutrition being the superior route.

Folwarski et al (2020) conducted a nationwide Polish survey of adult patients on home enteral nutrition. Of the 4586 home enteral nutrition patients the primary disease breakdown consisted of 54.5% neurological (17.4%-neurovascular, 13.7%-neurodegenerative), 33.9% cancer (20.2%-head and neck, 11.7%-gastrointestinal cancer), 2.5%-gastroenterology, 1.5%-inherited diseases. The median age was 64 years old with 53.3% of the participants being male. Sixty-five percent of participants had PEG tubes and mostly used isocaloric (28.1%), protein-enriched isocaloric (20%), and protein-enriched hypercaloric (12%) diets. The median overall duration of HEN was 354 days, 615 days for neurological and 209 days for cancer patients.

Exclusive Enteral Nutrition (EEN) in the Treatment of Crohn's Disease
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 Crohn's Disease (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 very low-quality evidence suggesting that corticosteroids therapy may be more effective than EN for induction of clinical remission in adults with active CD. 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)** published practice guidelines in 2022 that states there are a multitude of disease processes that necessitate home enteral nutrition including, but not limited to, swallowing disorders due to neurologic disease, obstructions due to malignancies, cachexia due to cancer, chronic obstructive pulmonary disease, heart disease, chronic infections, and malabsorption due to diseases of the liver/pancreas/small intestine. ESPEN's guideline states home enteral nutrition should be offered to malnourished patients or those at nutritional risk who cannot meet their nutrient requirement by normal dietary intake and have a functional GI tract.

The **American Society for Parenteral and Enteral Nutrition (ASPEN)** published a consensus statement in 2022 outlining comprehensive practice guidelines for the indications for enteral nutrition. In congruence with ESPEN's guidelines ASPEN indicated enteral nutrition is a vital component of nutrition around the world and is indicated in those who cannot maintain adequate nutrition via standard oral intake alone. Among the disease states addressed were oncologic in nature, GI diseases, and specific non-GI diseases.

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 effective "the data is 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)

The **National Institute for Health and Clinical Excellence (NICE)** published guidelines titled *Nutrition Support for Adults: Oral Nutrition Support, Enteral Tube Feeding and Parenteral Nutrition.* A summary of the guidelines is below and includes the following recommendations (in relevant part) regarding nutrition support and enteral tube feeding:

- Nutrition support should be considered in people who are malnourished, as defined by any of the following:
  - BMI of less than 18.5 kg/m^2
  - Unintentional weight loss greater than 10% within the last 3–6 months
  - BMI of less than 20 kg/m^2 and unintentional weight loss greater than 5% within the last 3–6 months.
- Nutrition support should be considered in people at risk of malnutrition as defined by 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, and/or have a poor absorptive capacity, and/or have high nutrient losses, and/or have increased nutritional needs from causes such as catabolism.

- Healthcare professionals should consider enteral tube feeding in people who are malnourished or at risk of malnutrition and have inadequate or unsafe oral intake, and a functional, accessible gastrointestinal tract. This intervention should be stopped when patient is established on adequate oral intake.

The **ESPEN-ESPGHAN-ECFS** published *Guidelines on Nutrition Care for Infants, Children, and Adults with Cystic Fibrosis* which address 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)

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.

HCPCS (Healthcare Common Procedure Coding System) Codes

HCPCS	Description
B4035	Enteral feeding supply kit: pump fed, per day, includes but not limited to feeding/flushing syringe, administration set tubing, dressings, tape
B4036	Enteral feeding supply kit: gravity fed, per day, includes but not limited to feeding/flushing syringe, administration set tubing, dressings, tape
B4149	Enteral formula, manufactured blenderized natural foods with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit
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

APPROVAL HISTORY

10/12/2023	Coverage criteria updated to include chronic indication. Removed criteria surrounding eating disorders. Updated physician order criteria. Updated Summary of Medical Evidence and References. IRO Peer Review 8/2023.
02/08/2023	Added 'Related Policies' section with Relizorb (immobilized lipase cartridge) MNR Policy Number: C17943-A (Medicaid) and Relizorb (immobilized lipase cartridge) NC C12081-A (Marketplace). Annual Review expected in October 2023.
10/12/2022	Policy reviewed. Updated references. No changes in coverage criteria.
10/13/2021	New policy. IRO Peer Review 9/28/2021 by practicing physician board certified in Gastroenterology.

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