

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 and 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 formulas developed for Inborn Errors of Metabolism (IEM) as infant formulas and categorizes them 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).

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*, signed and dated written documentation from WIC is required indicating ANY of the following:

1. WIC coverage unavailable OR inadequate to meet needs for growth
2. Documented medical need for alternative products not available through WIC, accompanied by a statement from WIC on the current amount and type of formula or supplements provided per month
3. Documentation that the nutritional need (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 **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
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
 - b. GI motility disorder
 - c. Severe intestinal malabsorption/disease of the small bowel
 - 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

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5. Member's life expectancy is longer than one month
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
 - b. Formulas consisting of natural intact proteins or protein isolates for individuals with an allergy or intolerance to semi-synthetic formula
 - c. Pediatric enteral formulas for children up to age 13
 - d. Special enteral formula with documented clinical justification

Continuation of Therapy

1. Member continues to meet indication for initial therapy
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 *contraindications* to enteral nutrition:

1. Absolute Contraindications

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

2. Relative Contraindications

- a. Hemodynamic instability
- b. Severe malabsorption
- c. Active diverticular abscess
- d. Fistula in the small bowel
- e. Short bowel disease in the early stages
- f. 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)
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
3. Requested product meets **ONE** of the following:

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- a. Labeled as "exempt" specialized metabolic infant formulas by the FDA*
* 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
2. Member's medical condition is considered chronic and expected to last six months or longer
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
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
 - 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
 - d. Food allergies unresponsive to dietary elimination, over the counter formulas and/or supplements curated for the specific food allergy, resulting in severe malnourishment
 - 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 ONE of the following:
 - i. Weight and height, and/or BMI below 10th percentile for age
 - ii. Growth decreased at least 2 percentile lines of weight for age on the growth chart.
 - f. Adult (\geq 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
 - ii. Documented unintentional weight loss >10% over the past 3-6 months
 - 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
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

The following are **not medically necessary** and/or **experimental, investigation, and unproven** based on insufficient evidence (regardless of whether prescribed by a physician or for a medical diagnosis):

1. Enteral nutrition for any indications other than those listed above
2. Enteral nutrition for the treatment of eating disorders
3. Enteral nutrition for routine pre- and/or post-operative care

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4. Oral liquid nutritional supplements solely based on food preference, patient convenience, or to boost caloric intake without a specific medical indication
5. 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
6. Self-blenderized formulas
7. Banked/Donor Breast Milk
8. Specialized over the counter infant formulas (e.g., Alimentum, Elecare, Neocate, and Nutramigen)
9. Oral vitamins and/or minerals
10. Nutritional or cosmetic therapy using high-dose or mega quantities of vitamins, minerals, or elements another nutrition-based therapy
11. 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
12. Non-prescribed formula for use with an enteral feeding system
13. 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.

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

Enteral nutrition is used for a wide variety of indications and disease processes and is an established part of treatment both in hospital and in the outpatient setting. There is an abundance of evidence supporting the use of enteral nutrition in the appropriate patients, as achieving optimal nutrition status leads to improved health outcomes across all populations. In addition to improved health outcomes, home enteral nutrition may also increase patients' quality of life by restoring a degree of independence and comfort for either the patient or their caregivers (Ojo et al. 2019). In the adult population, as highlighted in Folwarski et al. (2020), home enteral nutrition is used primarily in the setting of neurologic disorders, oncologic disease processes (Amano et al. 2021), gastrointestinal disease processes

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(Gonzalez-Toress et al. 2022; Sohouli et al. 2022; Narula et al. 2018), and specialized pre- or post-operative nutritional support in oncologic surgery (Liu et al. 2022; Zhang et al. 2022; Li et al. 2020).

Home enteral nutrition in adults may also be necessary in the setting of inherited diseases, in this population the use of enteral nutrition is established in infancy. These inherited diseases may be genetic disorders, such as Cystic Fibrosis, in which gastrointestinal dysfunction causes nutritional deficiencies or the inherited diseases may be inborn errors of metabolism (IEMs). 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.

National and Specialty Organizations

The **American Academy of Pediatrics (AAP)** published a guideline on *Nonoral Feeding for Children and Youth with Developmental or Acquired Disabilities* (Adams et al. 2014) that presented an overview of indications in this pediatric population that may prompt EN, tactics to support families during EN initiation, information on surgical options, and ongoing care recommendations.

The **American Society for Parenteral and Enteral Nutrition (ASPEN)** publishes a multitude of guidelines to aid clinicians in treatment decisions where nutrition is concerned. Notable guidelines are as follows:

- *When is Enteral Nutrition Indicated?* (Betchold et al. 2022) outlining comprehensive practice guidelines for the indications for EN. The guidelines highlighted that EN is a vital component of nutrition around the world and is indicated in those who cannot maintain adequate nutrition via standard oral intake alone. The guideline outlines the following:
 - Disease states, oncologic, GI diseases, and specific non-GI diseases, in which enteral nutrition should be a part of the treatment plan.
 - Time frames for initiation of EN in high-risk patients/malnourished patients/stable patients, as well as hemodynamically unstable patients.
 - EN's role in the setting of other medical interventions such as paralytic therapy and respiratory support.
- *Safe Practices for Enteral Nutrition Therapy* (Boullata et al. 2017) comprehensively addresses topics such as:
 - Assessment and recommendations
 - Prescribing and communicating enteral nutrition orders
 - Enteral access
 - Procuring, preparing, labeling, and dispensing enteral nutrition
 - Administration, including concurrent medication administration
 - Complication avoidance and error reporting
 - Monitoring and reassessment
 - Transitioning care

The **European Society for Parenteral and Enteral Nutrition (ESPEN)** also publish a plethora of guidelines to aid clinicians. Notable guidelines are as follows:

- *Guideline on Home Enteral Nutrition* (Bischoff et al. 2020) that provides evidence-based indications and practice guidance on the home EN, its indications and contraindications, and its implementation and

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monitoring. The guideline also addressed indications for various access sites, appropriate use of different EN formulas, the structural requirements needed to perform home EN, and how to safely terminate home EN.

- *Guidelines on Clinical Nutrition in Inflammatory Bowel Disease* (Bischoff et al. 2023) indicates that patients with IBD are at a significantly higher risk for malnutrition and need to be repeatedly screened for proper nutrition and treated appropriately because malnutrition increases poor outcomes. Recommendations regarding EN were as follows:
 - Recommendation 18: In patients with CD with intestinal strictures or stenosis in combination with obstructive symptoms, a diet with adapted texture, or exclusive EN via a tube ending distal to the obstruction (post-stenosis) can be recommended (Strong Consensus).
 - Recommendation 23: If oral feeding is not sufficient then EN can be considered as supportive therapy. EN using formulas or liquids usually take preference over PN unless it is completely contraindicated (Strong Consensus).
 - Recommendation 24: Exclusive EN is effective and can be recommended as the first line of treatment to induce remission in children and adolescents with mild active CD (Strong Consensus).
 - Recommendation 27: Tube feeding in IBD should be preferentially administered via an enteral feeding pump, in particular, if EN is administered via a jejunal and not a gastric tube (Strong Consensus).
 - Recommendation 28: Standard EN (polymeric diet with moderate fat content) should be employed for primary and supportive nutritional therapy in active IBD (Strong Consensus).
 - Recommendation 29: Specific formulations or substrates (e.g. glutamine, n-3-fatty acids) should not be recommended in the use of EN or PN in patients with IBD (Strong Consensus).
 - Recommendation 37: EN appears safe and can be recommended as supportive therapy according to standard nutritional practice in patients with severe UC (Strong Consensus).

The **National Institute for Health and Clinical Excellence (NICE)** (2017) published guidelines titled *Nutrition Support for Adults: Oral Nutrition Support, Enteral Tube Feeding and Parenteral Nutrition [CG32]*. 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/m²
 - Unintentional weight loss greater than 10% within the last 3–6 months
 - BMI of less than 20 kg/m² 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 Cystic Fibrosis* (Wilschanski et al. 2024) 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.

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HCPCS (Healthcare Common Procedure Coding System)

Code	Description
B4034	Enteral feeding supply kit; syringe fed, per day, includes but not limited to feeding/flushing syringe, administration set tubing, dressings, tape
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
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
B4148	Enteral feeding supply kit; elastomeric control 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

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which

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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 not 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

10/09/2024	Policy reviewed. No changes to coverage criteria.
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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Enteral Nutrition: Policy No. 406

Last Approval: 10/09/2024

Next Review Due By: October 2025



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APPENDIX

Reserved for State specific information. Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.

Washington

<https://www.hca.wa.gov/assets/billers-and-providers/Enteral-Nutrition-bg-20240701.pdf>Page 35: “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.”