Medical Policy

Enteral and Parenteral Nutrition

Policy Number: PG0114
Last Review: 12/01/2024

PARAMOUNT
HMO AND PPO
ELITE (MEDICARE ADVANTAGE)
MARKETPLACE

GUIDELINES:

- This policy does not certify benefits or authorization of benefits, which is designated by each individual policyholder terms, conditions, exclusions, and limitations contract. It does not constitute a contract or guarantee regarding coverage or reimbursement/payment. Self-Insured group specific policy will supersede this general policy when group supplementary plan document or individual plan decision directs otherwise.
- Paramount applies coding edits to all medical claims through coding logic software to evaluate the accuracy and adherence to accepted national standards.
- This medical policy is solely for guiding medical necessity and explaining correct procedure reporting used to assist in making coverage decisions and administering benefits.

SCOPE:

X Professional
_ Facility

DESCRIPTION:

Enteral Nutrition is commonly defined as the provision of nutritional requirements through a tube in the stomach or small intestine such as a nasogastric (NG) tube or a percutaneous gastrostomy (PEG) tube. Enteral feedings are 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 their overall health status if their nutritional needs cannot be met through dietary adjustments and/or oral supplements.

Relizorb is a single-use, point-of-care digestive enzyme cartridge that connects in-line with existing enteral pump feed sets and pump extension sets. Relizorb is designed to hydrolyze fats contained in the enteral formulas, mimicking the function of the digestive enzyme lipase that is normally secreted by the pancreas. There is insufficient published evidence to assess the safety and/or impact on health outcomes or patient management for the use of the Relizorb device.

Parenteral Nutrition refers to the intravenous provision of micro- or macro-nutrients to prevent or correct nutritional deficiency. Total parenteral nutrition (TPN), also known as hyperalimentation, is administered to patients with medical conditions that impair gastrointestinal absorption to a degree that is incompatible with life. TPN is also used for variable periods of time to bolster the nutritional status of severely malnourished patients with medical or surgical conditions. Peripheral parenteral nutrition (PPN) is typically used for a short time (up to two weeks) because of limited patient tolerance and few suitable peripheral veins. In patients whose disease produces temporary or permanent loss of the absorptive surface of the small intestine, longer-term parenteral nutrition may be required. Long-term TPN is necessary when parenteral feedings are indicated for longer than two weeks, peripheral access is limited, nutrient needs are large or fluid restriction is required. This method of nutrition contains nutrients such as glucose, amino acids, lipids and added vitamins and dietary minerals delivered intravenously through a peripheral or central vein.

POLICY:

Paramount Commercial Insurance Plans and Elite (Medicare Advantage) Plans
Paramount considers enteral nutrition medically necessary when a member is at risk for developing malnutrition due to a medical condition, chronic disease or increase metabolic requirements resulting from inability to ingest or adequately absorb food when the criteria below is met.

Enteral nutrition requires prior authorization for items B4102-B4104, B4149-B4155, B4158-B4161 for all product lines. Exception: Items B4157 & B4162 do not require a prior authorization for members diagnosed with inborn errors of metabolism for all product lines.

Food thickener (B4100) is non-covered

Effective 01/01/2022: In-line digestive enzyme cartridges (B4105) are reasonable and necessary only for members who:

- **meet the coverage criteria for enteral nutrition; AND,**
- **have a diagnosis of Exocrine Pancreatic Insufficiency (EPI) - K86.81**

Parenteral Nutrition does not require a prior authorization for all product lines, when the coverage criteria indicated below is met.

See Medical Policy PG0501 for Intradialytic Parenteral Nutrition (IDPN) coverage.

COVERAGE CRITERIA:

Paramount Commercial Insurance Plans and Elite (Medicare Advantage) Plans

Enteral Nutrition

Enteral Nutrition administered by whether administered orally or via tube feeding (e.g., nasogastric [NG] tubes, nasoenteral [NE] tubes, gastrostomy [G-] tubes, jejunostomy [J-] tubes) is considered medically necessary when the following criteria are met:

- Enteral nutrition with enteral feeding tubes is considered medically appropriate for functional impairments that include, but are not limited to, the following:
    - Muscular paralysis in which the patient is unable to swallow because a damaged brain or spinal cord can no longer communicate to the muscles of the alimentary tract to initiate function.
    - Cognitive neurological disorders that may cause the patient to forget how to swallow.
    - Mechanical dysfunction of the gastrointestinal 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).
    - Compromised ability for oral intake in patients with a functioning gastrointestinal tract who, due to pathology, disease or non-function of the structures that normally permit food to reach the digestive tract, cannot maintain weight and strength commensurate with the patient's general condition.
    - Cognitive neurological disorders that may cause the patient to forget how to swallow, such as: senile dementia, Alzheimer's disease, organic brain syndrome;
- Home use enteral nutrition when used as a therapeutic regimen to prevent serious disability or death in members with a medically diagnosed condition that precludes the full use of regular food or precludes adequate ingestion of calories to achieve sufficient growth, has been medically proven to be an effective treatment, including, but not limited to, the following:
        - Inherited diseases of amino acid or organic acid metabolism (e.g., Phenylketonuria/PKU);
        - Branch–chain ketonuria, galactosemia, or homocystinuria;
        - Crohn's disease;
        - Gastroesophageal reflux;
        - Impaired absorption of nutrients caused by disorders affecting the absorptive surface, function, length, and motility of the gastrointestinal tract (e.g., chronic intestinal pseudo-obstruction, Ogilvie's syndrome);
        - Ulcerative colitis;
        - Severe food protein-induced enterocolitis syndrome;
        - Eosinophilic disorders;
        - Multiple, severe food allergies, including, but not limited to, immunoglobulin E- and non-immunoglobulin E-mediated allergies to multiple food proteins;

- Enteral feeding must be the members sole source of nutrition (defined as obtaining > 70% of the members total caloric intake daily, and
- For enteral tube feeding the member experiences difficulty swallowing due to a medical condition (e.g., tumors, neurological conditions, severe chronic anorexia nervosa) and is unable to maintain weight and nutrition with oral administration, and
- The member is under the supervision of a healthcare provider who is authorized to prescribe such dietary treatments and has issued a written order stating that the enteral formula is medically necessary, and
- The service is not otherwise excluded from coverage.

All patients should be monitored in conjunction with a qualified dietitian, health care practitioner certified in nutritional support, gastroenterologist, or pediatric allergist when appropriate.

Prior Authorization, the treating provider must include the following supporting medical necessity:

1. The treating provider must include information supporting the diagnosis, condition, signs/symptoms and medical necessity in the request for prior authorization of enteral nutritional formulas and supplements.
2. Prior authorization requests for members who cannot maintain weight must include a current weight history, documentation of BMI and/or weight measured over time.
3. Patients with cognitive/neurological disease must have documentation in the medical record that demonstrates a dysfunction of the swallowing mechanism. Swallowing assessments or evaluations are required.
4. Initial prior authorization requests for enteral nutrition products may be approved for a maximum of twelve months. Subsequent PAs for the same member for the same disease state may be approved for a maximum of twelve months.
5. Members having a change in their treatment plan that requires the use of an enteral product that is different from a previously authorized enteral product will require a new certificate of medical necessity before a new enteral product will be authorized.
6. Enteral nutrition requires prior authorization for items B4102-B4155, B4158-B4161. Items B4157 & B4162 do not require a prior authorization for members diagnosed with inborn errors of metabolism. Metabolic diseases include inborn errors of amino acid metabolism such as phenylketonuria, maternal phenylketonuria, maple syrup urine disease, homocystinuria, methylmalonicacidemia, propionicacidemia, isovalericacidemia, and other disorders of leucine metabolism; glutaric aciduria type I and tyrosinemia types I and II; and urea cycle disorders.

Prescription medical foods administered orally or via a tube into the alimentary canal for individuals diagnosed with genetic (inherited) inborn errors of metabolism (IEM), are considered medically appropriate in the treatment for individuals of all ages who need administration of a formula that is manufactured for individuals with IEMs, such as:

- phenylketonuria (PKU) (PKU benefit coverage is provided for infants and children as well as for the protection of unborn babies of women who have PKU),
- homocystinuria,
- propionic academia,
- methylmalonic academia,
- urea cycle disorders,
- branched-chain ketonuria,
- tyrosinemia,
- galactosemia,
- maple syrup urine disease,

Medical foods for individuals diagnosed with genetic (inherited) IEM, are not required to meet the coverage definition of sole source of nutrition (i.e., the formula provides more than 70 percent of estimated basal caloric requirements); therefore, an estimated basal caloric requirement is not required for IEMs.
Examples of medical foods for individuals diagnosed with IEM include, but are not limited to, BCAD 1 or 2, OA 1 or 2, PFD 2 or Toddler, PhenylAde, Phenyl-Free 1 or 2 or 2HP, Ketonex 1 or 2.

Dispensing

- A physician’s order or prescription (updated at least annually).
- Enteral nutrition products shall be dispensed in no greater quantity than one month's supply.
- Providers may dispense enteral nutrition products' generic equivalents (e.g., vendor branded or private label equivalent) if available, as long as the substituted product is correctly formulated to meet the needs of the member and the member's prescriber is notified in advance of dispensing.
- Providers may not provide a re-supply of enteral nutrition products sooner than one week before a member's next scheduled supply dispense date.
- No dispensing, mailing, or delivery fees are separately reimbursable.
- The member will be supplied with the ordered enteral product that is in the most cost-effective formulation that the member can tolerate.

Non-Covered

- A medical history and physical examination have been performed and other possible alternatives have been identified to minimize nutritional risk.
- The member is underweight but has the ability to meet nutritional needs through regular food consumption and/or commercially available caloric supplements.
- Enteral nutrition products that are designed to provide meal replacements, or snack alternatives to be eaten within the context of a member's individualized meal plan, are not covered. These products include, but are not limited to:
    - Shakes
    - Meal bars
    - Snack bars
    - Supplement thickeners
    - Cereals
    - Baby foods
    - Puddings
    - Vitamins/ minerals
    - Blenderized or pureed foods
- Nutritional and/or fold supplements (e.g., Boost, Enfamil Enfacare, Ensure, NeoSure, PediaSure, Scandishake) for infants and children
- Nutritional and/or food supplements (e.g., Boost, Ensure, NeoSure, PediaSure, Scandishake) for adults with a diagnosis of malnutrition due to anorexia or failure to thrive
- Oral polymeric or oligomeric (hydrolyzed) formulas to support a low ketogenic diet (e.g., Ketovie 4:1)
- Oral organic formulas (e.g., Kate Farms Organic formula, Similac Organic formula)
- Medical foods (e.g., Foltx, Metanx, Cerefolin, probiotics such as VSL#3) including FDA-approved medical foods obtained via prescription
- Enteral products used for dieting or a weight-loss program.
- Enteral nutrition products that are designed as meal replacements, or to be eaten within the context of a member's prescribed reduced calorie diet for members with diabetes, obesity issues, pre- or post-gastric bypass, or bariatric surgery, are not covered.
- Enteral nutrition and special medical formulas and foods are requested solely because of food preference in the absence of a medical condition
- Nutritional or cosmetic therapy using high dose or mega quantities of vitamins, minerals or elements and other nutrition-based therapy. Examples include supplements and electrolytes.
- Ketogenic diet for the treatment of seizure disorders
- The following items are considered not medically necessary for any indication, not all inclusive:
    - banded breast milk provided to a non-hospitalized infant,
    - dietary additives and food supplements,
    - grocery items that can be blenderized and used with an external feeding system,
    - high protein powders and mixes,
    - low carbohydrate diets,

    - normal grocery items and
    - weight-loss foods and formula (products to aid weight loss).
- Dietary supplements such as probiotics and digestive enzymes do not meet the criteria for enteral nutrition.
    - Exception: Digestive enzyme cartridges (e.g., Relizorb, Alcresta Therapeutics, Inc.) are used in conjunction with enteral tube feeding. They contain a lipase enzyme that helps to break down fats in enteral formulas to allow for their absorption and utilization by the body. This allows the delivery of more absorbable calories to the patient and helps maintain or increase weight gain, leading to increased patient growth and development.
      Digestive enzyme cartridges (e.g., Relizorb) (B4105)) with tube feed enteral nutrition therapy is medically necessary and eligible for reimbursement for exocrine pancreatic insufficiency.

digestive enzyme cartridges medically necessary and eligible for reimbursement providing that all of the following medical criteria are met:
• Ages 5 years and older
• Enteral feedings are necessary
• Diagnosis of cystic fibrosis.
Use of digestive enzyme cartridges for any other indication may be considered experimental/investigational.

Elite (Medicare Advantage) Plans
According to the Centers for Medicare & Medicaid Services, CGS Administrators Local Coverage Determination (LCD/LCA): Enteral Nutrition (L38955) (A58833)

Enteral nutrition is covered for a beneficiary who requires feedings via an enteral access device to provide sufficient nutrients to maintain weight and strength commensurate with the beneficiary's overall health status and has a permanent:

A. full or partial non-function or disease of the structures that normally permit food to reach the small bowel; OR,

B. disease that impairs digestion and/or absorption of an oral diet, directly or indirectly, by the small bowel.

Adequate nutrition must not be possible by dietary adjustment and/or oral supplements.

Typical examples of conditions associated with non-function or disease of the structures that permit food from reaching the small bowel that qualify for coverage are: head and neck cancer with reconstructive surgery and central nervous system disease leading to interference with the neuromuscular mechanisms of ingestion of such severity that the beneficiary cannot be maintained with oral feeding (not all inclusive).

Typical examples of conditions associated with impaired digestion and/or absorption of an oral diet by the small bowel that may qualify for coverage include inflammatory bowel disease, surgical resection of small bowel, cystic fibrosis, chronic pancreatitis, and advanced liver disease (not all inclusive).

If the coverage requirements for enteral nutrition are met, medically necessary nutrients, administration supplies, and equipment are covered.

Enteral formulas consisting of semi-synthetic intact protein/protein isolates (B4150 or B4152) are appropriate for the majority of beneficiaries requiring enteral nutrition.

The medical necessity for special enteral formulas (B4149, B4153, B4154, B4155, B4157, B4161, and B4162) must be justified in each beneficiary. If a special enteral nutrition formula is provided and if the medical record does not document why that item is medically necessary, it will be denied as not reasonable and necessary.

In-line digestive enzyme cartridges (B4105) are reasonable and necessary for beneficiaries who:

A. meet the coverage criteria for enteral nutrition; AND,

B. have a diagnosis of Exocrine Pancreatic Insufficiency (EPI) - K86.81

More than two in-line digestive enzyme cartridges (B4105) per day will be denied as not reasonable and necessary.

Parenteral Nutrition

Parenteral Nutrition is proven and/or medically necessary when all the following criteria are met:

- Weight and strength maintenance commensurate with the patient's overall health status cannot be achieved by modifying the nutrient composition of the enteral diet or by utilizing pharmacologic means to treat the etiology of the malabsorption.
- The adult patient is malnourished, as indicated by any of the following:
    - Weight is significantly less than normal body weight for height and age, in comparison with pre-illness weight, weight loss > 10% of ideal body weight in 3 months, or > 20% of usual body weight;
    - Total protein < 6 g/dL in the past 4 weeks;
    - Serum albumin < 3.4 g/dL in the past 4 weeks;
    - Blood urea nitrogen (BUN) is below 10 mg (not a good marker in patients receiving dialysis, due to protein catabolism);
    - Phosphorous level is less than 2.5 mg (normal is 3 - 4.5 mg); and
    - The patient can receive no more than 30 percent of caloric needs enterally (oral or tube feeding).
- Children:
    - Under the 10th percentile of expected weight for length/height, or weight for sex (–1.28 z score); or
    - Under the 5th percentile of expected body mass index
- The patient has a disease or clinical condition that has not responded to altering the manner of delivery of appropriate nutrients. Evidence of structural or functional bowel disease that makes oral or tube feedings inappropriate, or a condition in which the gastrointestinal tract is non-functioning for a period of time.
- TPN must be specifically ordered by a physician and pre-approved on an individual consideration basis.

For parenteral nutrition to be considered reasonable and necessary, the treating practitioner must document that enteral nutrition has been considered and/or ruled out tried and been found ineffective, or that enteral nutrition exacerbates gastrointestinal tract dysfunction.

Continuing use of home parenteral nutrition will be reviewed every 6 months.

TPN has been medically proven to be effective and, therefore, is considered medically appropriate for malnourished patients with indications that include, but are not limited to, the following:

- Gastrointestinal (gut) failure:
    - Short bowel syndrome (e.g., secondary to mesenteric infarction, surgical treatment of Crohn’s disease, midgut volvulus, traumatic gastroschisis, small bowel atresia in neonates);
    - Radiation enteritis;
    - Intestinal pseudo-obstruction-motility disorder;
    - Idiopathic diarrhea; or
    - Secondary gastrointestinal failure (e.g., scleroderma).
- Inflammatory bowel disease
    - Ulcerative colitis
    - Crohn’s disease:
        - Growth retardation;
        - Diffuse small bowel disease refractory to medical management; or
        - Enterocutaneous fistulae.
- Severe mucosal injury with intractable malabsorption (e.g., selected cases of celiac disease, immunodeficiency syndromes with enterocolitis, idiopathic mucosal failure with congenital failure to develop villi)

- Cystic fibrosis with malnutrition unresponsive to enteral nutrition;
- Intestinal lymphangiectasia with failure of dietary management;
- Obstruction secondary to stricture or neoplasm or the esophagus or stomach;
- Intractable motility disorder (i.e., intestinal pseudo-obstruction and gastroparesis);
- The patient has undergone (within the past three months) massive small bowel resection leaving less than or equal to five feet of small bowel beyond the ligament of Treitz;
- Short-term treatment of a condition requiring “bowel rest,” where prolonged hospitalization would otherwise be required (e.g., pancreatic pseudocysts, proximal enterocutaneous fistulae in which surgical management is not indicated);
- Short-term treatment for children with severe reflux and aspiration who fail to thrive, until a surgical procedure can be performed;
- Newborn infants with catastrophic gastrointestinal anomalies such as tracheoesophageal fistula, gastroschisis, omphalocele, or massive intestinal atresia;
- Adjunctive therapy for malnourished patients with specific cancers who are receiving intense and frequent chemotherapy that causes severe gastrointestinal toxicity;
- Liver failure in children approved for liver transplants, who fail to grow while receiving enteral nutritional support;
- Liver failure in adults who have hepatic encephalopathy and cannot tolerate a protein source consisting of standard amino acids or enteral nutritional support (TPN used for the administration of a liver-specific amino acid mixture);
- Acute necrotizing pancreatitis in adults with an inadequate oral intake for longer than a week, where enteral feedings exacerbate abdominal pain, ascites, or fistulous output ;
- The patient has complete mechanical small bowel obstruction where surgery is not an option.

Documentation

- The medical record must reflect that the member has (a) a condition involving the small intestine and/or its exocrine glands that significantly impairs the absorption of nutrients or (b) disease of the stomach and/or intestine, which is a motility disorder and impairs the ability of nutrients to be transported through and absorbed by the gastrointestinal (GI) system.
- The medical record must include the member’s diagnosis and other pertinent information including, but not limited to, duration of the member’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.
- Information describing the medical necessity for parenteral nutrition must be available upon request.

Non-Covered

- To increase protein or caloric intake in addition to the patient’s daily diet
- In patients with a stable nutritional status, in whom only short-term parenteral nutrition might be required (for example, less than two weeks)
- For routine pre- and/or postoperative care
- If 750 calories per day or less are being administered by TPN
- Children who were previously well-nourished or mildly malnourished, who are undergoing oncologic treatment associated with a low nutrition risk (e.g., less-advanced disease, less-intense cancer treatments, advanced disease in remission during maintenance treatment).
- Patients (either adult or pediatric) with advanced cancer whose malignancy is documented as unresponsive to chemotherapy or radiation therapy.
- Patients for whom liver transplantation is not feasible and whose prognosis will not change in spite of TPN therapy.

Elite (Medicare Advantage) Plans

According to the Centers for Medicare & Medicaid Services, CGS Administrators Local Coverage Determination (LCD/LCA): Enteral Nutrition (L38953) (A58836)

When nutritional support other than the oral route is necessary, enteral nutrition (EN) is usually initially preferable to parenteral nutrition for the following reasons: (1) In a fluid restricted beneficiary, EN permits delivery of all necessary nutrients in a more concentrated volume than parenteral nutrition; (2) EN allows for safer home delivery of nutrients; and (3) EN lowers the risk of Central Line- Associated Bloodstream Infections (CLABSI).

For parenteral nutrition to be considered reasonable and necessary, the treating practitioner must document:

- enteral nutrition has been considered and ruled out,
- tried and been found ineffective, or
- EN exacerbates gastrointestinal tract dysfunction.

The beneficiary must have:

- a condition involving the small intestine and/or its exocrine glands, which significantly impairs the absorption of nutrients or
- disease of the stomach and/or intestine, which is a motility disorder and impairs the ability of nutrients to be transported through and absorbed by the gastrointestinal (GI) system.
- The beneficiary must have a permanent impairment.

The treating practitioner is required to evaluate the beneficiary within 30 days prior to initiation of parenteral nutrition.

If not seen by the treating practitioner within the specified timeframe,

- There must be documentation for the reason why, and
- Describe what other monitoring methods were used to evaluate the beneficiary's parenteral nutrition needs

Documentation in the medical record must support the clinical diagnosis

A total caloric daily intake of 20-35 cal/kg/day is considered reasonable and necessary to achieve or maintain appropriate body weight. The treating practitioner must document the medical necessity for a caloric intake outside this range in an individual beneficiary.

The treating practitioner must document the medical necessity for nutrients orders outside of the ranges:

- Protein 0.8-2.0 gm/kg/day (B4168, B4172, B4176, B4178),
- Dextrose concentration less than 10% (B4164, B4180), or
- Lipid use per month in excess of the product-specific, FDA-approved dosing recommendations (B4185, B4187), or
- Special nutrient formulas, HCPCS codes B5000, B5100, and B5200 are produced to meet the unique nutrient needs for specific disease conditions. The beneficiary's medical record must adequately document the specific condition and the necessity for the special nutrient.

Unlisted Procedures B9998 and B9999

Unlisted Procedures B9998 and B9999 requires NDC and/or invoice review to determine the products reported for these codes.

B9998 is denied when used to report feeding supplies such as extension tubing and gravity sets because these are considered included in the supply of the standard feeding sets.

Exceptions, may not be all-inclusive:

- The MIC-KEY® Gastrostomy Tube Extension Set for this is a specific attachment and the basic feeding set will not attach to the MIC-KEY® Gastrostomy button without this specific extension.
- The Farrell valve is a vented, closed, disposable system used for gastric pressure relief with some enterally fed beneficiaries. It is used to eliminate the buildup of gastric reflux and gas in the stomach and around the outside of a feeding tube. The Farrell valve is not indicated or required for all enterally fed beneficiaries.
    - The beneficiary is receiving continuous enteral feedings via gravity or pump;

- There is documented evidence of disorders or complications with enteral feedings, including gastric dysmotility, abdominal distention, aspiration pneumonia, anti-reflux surgery, gastric pseudo-obstruction, tracheoesophageal fistula, or atresia repair; and
- Other attempted gastric decompression measures have failed.
- The Farrell valve is not covered when clinical documentation demonstrates that the beneficiary is tolerating continuous enteral feedings without difficulty or complications.
- Coverage maximum of one valve per day per beneficiary for a maximum period of six months. For additional approvals, medical necessity must be re-established for each successive six months.
- The health record must contain documentation by the physician, physician assistant, or nurse practitioner substantiating the medical necessity requirement. A starting date and expected duration for the use of the Farrell valve must also be included. The medical necessity must specifically address the beneficiary's complicating factors, such as gastric dysmotility, distention, reflux, aspiration risk, excessive gastric residuals, pain, neurological impairments, and dates of any anti-reflux procedures. The inability of the beneficiary to tolerate enteral feedings without the Farrell valve must be documented. Note: Only one Farrell valve per day is allowed. The valve is not provided and billed under routine enteral feeding supply kits.

CODING/BILLING INFORMATION:

The appearance of a code in this section does not necessarily indicate coverage. Codes that are covered may have selection criteria that must be met. Payment for supplies may be included in payment for other services rendered.

HCPCS CODES	
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
B4081	Nasogastric tubing with stylet
B4082	Nasogastric tubing without stylet
B4083	Stomach tube - levine type
B4087	Gastrostomy/jejunostomy tube, standard, any material, any type, each
B4088	Gastrostomy/jejunostomy tube, low-profile, any material, any type, each
B4100	Food thickener, administered orally, per ounce
B4102	Enteral formula, for adults, used to replace fluids and electrolytes (e.g. clear liquids), 500 ml = 1 unit
B4103	Enteral formula, for pediatrics, used to replace fluids and electrolytes (e.g. clear liquids), 500 ml = 1 unit
B4104	Additive for enteral formula (e.g. fiber)
B4105	In-line cartridge containing digestive enzyme(s) for enteral feeding, each
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
B4164	Parenteral nutrition solution: carbohydrates (dextrose), 50% or less (500 ml = 1 unit) - homemix
B4168	Parenteral nutrition solution; amino acid, 3.5%, (500 ml = 1 unit) - homemix
B4172	Parenteral nutrition solution; amino acid, 5.5% through 7%, (500 ml = 1 unit) - homemix
B4176	Parenteral nutrition solution; amino acid, 7% through 8.5%, (500 ml = 1 unit) - homemix
B4178	Parenteral nutrition solution: amino acid, greater than 8.5% (500 ml = 1 unit) - homemix
B4180	Parenteral nutrition solution; carbohydrates (dextrose), greater than 50% (500 ml=1 unit) - homemix
B4185	Parenteral nutrition solution, per 10 grams lipids
B4189	Parenteral nutrition solution; compounded amino acid and carbohydrates with electrolytes, trace elements, and vitamins, including preparation, any strength, 10 to 51 grams of protein - premix
B4193	Parenteral nutrition solution; compounded amino acid and carbohydrates with electrolytes, trace elements, and vitamins, including preparation, any strength, 52 to 73 grams of protein - premix
B4197	Parenteral nutrition solution; compounded amino acid and carbohydrates with electrolytes, trace elements and vitamins, including preparation, any strength, 74 to 100 grams of protein - premix
B4199	Parenteral nutrition solution; compounded amino acid and carbohydrates with electrolytes, trace elements and vitamins, including preparation, any strength, over 100 grams of protein - premix
B4216	Parenteral nutrition; additives (vitamins, trace elements, heparin, electrolytes) homemix per day
B4220	Parenteral nutrition supply kit; premix, per day
B4222	Parent Nutrition Supply Kit, Home Mix, Complete
B4224	Parenteral nutrition administration kit, per day
B5000	Parenteral nutrition solution: compounded amino acid and carbohydrates with electrolytes, trace elements, and vitamins, including preparation, any strength, renal - amirosyn rf, nephramine, renamine - premix
B5100	Parenteral nutrition solution: compounded amino acid and carbohydrates with electrolytes, trace elements, and vitamins, including preparation, any strength, hepatic - freamine hbc, hepatamine - premix
B5200	Parenteral nutrition solution: compounded amino acid and carbohydrates with electrolytes, trace elements, and vitamins, including preparation, any strength, stress - branch chain amino acids - premix

B9000	Enteral nutrition infusion pump - without alarm
B9002	Enteral nutrition infusion pump - with alarm
B9004	Parenteral nutrition infusion pump, portable
B9006	Parenteral Nutrition Infusion Pump-Stationary
B9998	Enteral Supplies, Not Otherwise Specified
B9999	Parenteral Supplies, Not Otherwise Specified
ICD-10 DIAGNOSIS CODES THAT SUPPORT ENTERAL NUTRITION, not an all-inclusive listing	
D81.3	Adenosine deaminase [ADA] deficiency
D81.30	Adenosine deaminase deficiency, unspecified
D81.32	Adenosine deaminase 2 deficiency
D81.39	Other adenosine deaminase deficiency
D81.5	Purine nucleoside phosphorylase [PNP] deficiency
D81.810	Biotinidase deficiency
E70.0	Classic phenylketonuria
E70.1	Other hyperphenylalaninemias
E70.20 – E70.29	Disorders of tyrosine metabolism
E70.30	Albinism, unspecified
E70.40 – E70.49	Disorders of histidine metabolism
E70.5	Disorders of tryptophan metabolism
E70.81	Aromatic L-amino acid decarboxylase deficiency
E70.89	Other disorders of aromatic amino-acid metabolism
E70.9	Disorder of aromatic amino-acid metabolism, unspecified
E71.0	Maple-syrup-urine disease
E70.1	Other hyperphenylalaninemias
E70.20 – E70.29	Disorders of tyrosine metabolism
E70.30	Albinism, unspecified
E70.40 – E70.49	Disorders of histidine metabolism
E70.5	Disorders of tryptophan metabolism
E70.81	Aromatic L-amino acid decarboxylase deficiency
E70.89	Other disorders of aromatic amino-acid metabolism
E70.9	Disorder of aromatic amino-acid metabolism, unspecified
E71.0	Maple-syrup-urine disease
E71.110	Isovaleric acidemia
E71.111	3-methylglutaconic aciduria
E71.118	Other branched-chain organic acidurias
E71.120	Methylmalonic acidemia
E71.121	Propionic acidemia
E71.128	Other disorders of propionate metabolism
E71.19	Other disorders of branched-chain amino-acid metabolism
E71.2	Disorder of branched-chain amino-acid metabolism, unspecified
E71.310	Long chain/very long chain acyl CoA dehydrogenase deficiency (LCHAD)
E71.311	Medium chain acyl CoA dehydrogenase deficiency
E71.312	Short chain acyl CoA dehydrogenase deficiency
E71.313	Glutaric aciduria type II
E71.314	Muscle carnitine palmitoyltransferase deficiency
E71.318	Other disorders of fatty-acid oxidation
E71.40	Disorder of carnitine metabolism, unspecified

E71.41	Primary carnitine deficiency
E71.42	Carnitine deficiency due to inborn errors of metabolism
E71.43	Iatrogenic carnitine deficiency
E71.448	Other secondary carnitine deficiency
E72.00 – E72.19	Other disorders of amino-acid metabolism
E72.21	Argininemia
E72.22	Arginosuccinic aciduria
E72.23	Citrullinemia
E72.3	Disorders of lysine and hydroxylysine metabolism
E72.4	Disorders of ornithine metabolism
E72.50	Disorder of glycine metabolism, unspecified
E72.51	Non-ketotic hyperglycinemia
E72.52	Trimethylaminuria
E72.59	Other disorders of glycine metabolism
E72.9	Other specified and unspecified disorders of amino-acid metabolism
E74.00 – E74.39	Other disorders of carbohydrate metabolism
E74.4	Disorders of pyruvate metabolism and gluconeogenesis
E74.81	Disorders of glucose transport, not elsewhere classified
E74.810	Glucose transporter protein type 1 deficiency
E74.818	Other disorders of glucose transport
E74.819	Disorders of glucose transport, unspecified
E74.89	Other specified disorders of carbohydrate metabolism
E74.9	Disorder of carbohydrate metabolism, unspecified
E78.6	Lipoprotein deficiency
E78.9	Disorder of lipoprotein metabolism, unspecified
E79.1	Lesch-Nyhan syndrome
E79.2	Myoadenylate deaminase deficiency
E79.8	Other disorders of purine and pyrimidine metabolism
E79.9	Disorder of purine and pyrimidine metabolism, unspecified
E80.3	Defects of catalase and peroxidase
E84.0	Cystic fibrosis with intestinal manifestations
E84.19	Cystic fibrosis with other intestinal manifestations
P70.0 – P70.9	Transitory disorders of carbohydrate metabolism specific to newborn
P71.0 – P71.9	Transitory neonatal disorders of calcium and magnesium metabolism
P72.1	Transitory neonatal hyperthyroidism
P72.8, P72.9	Other specified and unspecified transitory neonatal endocrine disorders
P74.0	Late metabolic acidosis of newborn
P74.1	Dehydration of newborn
P74.4	Other transitory electrolyte disturbances of newborn
P74.8, P74.9	Other specified and unspecified transitory metabolic disturbances of newborn
P94.0	Transient neonatal myasthenia gravis

REVISION HISTORY EXPLANATION: ORIGINAL EFFECTIVE DATE: 01/01/2011

Date	Explanation & Changes
02/01/08	• No Change

01/15/09	• Added exceptions
01/14/14	• Added HCPCS Codes B4222 & B9006 • Policy reviewed and updated to reflect most current clinical evidence • Policy approved per Medical Policy Steering Committee as revised
07/08/14	• Items B4157 & B4162 do not require a prior authorization for members diagnosed with inborn errors of metabolism as mandated by The Ohio Department of Medicaid • B4100 is covered for Advantage only per The Ohio Department of Medicaid • Policy approved by Medical Policy Steering Committee as revised
05/26/17	• Digestive enzyme cartridges (e.g., Relizorb) with tube fed enteral nutrition therapy are non-covered • Policy reviewed and updated to reflect most current clinical evidence per the Technology Assessment Working Group (TAWG)
07/10/18	• Added effective 7/1/18 new code Q9994 • Added modifier U1 for codes B4034, B4035, B4036, & B4100 per ODM guidelines • Food thickener (B4100, B4100-U1) is covered without prior authorization for Advantage • Food thickener (B4100, B4100-U1) is non-covered for HMO, PPO, Individual Marketplace, & Elite • Item B5200 is now covered for HMO, PPO, Individual Marketplace, Elite per CMS guidelines • Item B5200 remains non-covered for Advantage per ODM guidelines • Policy reviewed and updated to reflect most current clinical evidence per the Medical Policy Steering Committee
08/14/18	• Added CMS criteria from L33783 & A52493 for the HMO, PPO, Individual Marketplace, Elite product lines • Policy reviewed and updated to reflect most current clinical evidence per the Medical Policy Steering Committee
01/08/19	• Effective 12/31/18 code Q9994 is deleted • Added effective 01/01/19 new code B4105 • Policy reviewed and updated to reflect most current clinical evidence per the Medical Policy Steering Committee
09/23/19	• Added unlisted exception coverage and criteria for the Farrell valve
01/01/2021	• Medical policy placed on the new Paramount Medical Policy Format
12/01/2021	• Policy reviewed and updated to reflect most current clinical evidence • Removed deleted code Q9994-In-line cartridge containing digestive enzyme(s) for enteral feeding, each (Deleted code effective 12/31/18) • Added ICD-10 DIAGNOSIS CODES THAT SUPPORT ENTERAL NUTRITION for reference only • Procedure B4105 changed from noncovered to coverage with a diagnosis of Exocrine Pancreatic Insufficiency (EPI), per CMS and ODM-appendix DD, coverage indicated.
02/04/2022	• Per ODM procedure S9432 covered as of 10/1/2021, by report • Added procedure S9432 to the medical policy • Procedure S9432 requires a prior authorization, for all product lines, effective 4/1/2022
02/07/2023	• Medical Policy updated to reflect Medicaid coverage to Anthem as of 02/01/2023
03/30/2023	• Medical Policy updated to reflect DME limits calculated by CMS criteria/guidelines.
02/01/2024	• Medical Policy placed on the new Paramount Medical Policy format
12/01/2024	• Medical Policy reviewed and updated to reflect most current clinical evidence • Codes B4034-U1, B4035-U1, B4036-U1, B4100-U1 removed/deleted, they are related to Ohio Medicaid assigned • S9432 removed; Paramount does not recognize/reimburse for S-codes

Paramount reserves the right to review and revise our policies periodically when necessary. When there is an update, we will publish the most current policy to https://www.paramounthealthcare.com/providers/medical-policies/policy-library

REFERENCES/RESOURCES

Centers for Medicare and Medicaid Services, CMS Manual System and other CMS publications and services https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs

National Physician Fee Schedule Relative Value File Calendar Year XXXX, Centers for Medicare & Medicaid Services (CMS) https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Relative-Value-Files

NCCI Policy Manual for Medicare Services, current version, Chapter 1, General Correct Coding Policies https://www.cms.gov/files/document/medicare-ncci-policy-manual-2023-chapter-1.pdf

American Medical Association, *Current Procedural Terminology (CPT®)* and associated publications and services https://www.ama-assn.org/amaone/cpt-current-procedural-terminology

Centers for Medicare and Medicaid Services, Healthcare Common Procedure Coding System, HCPCS Release and Code Sets https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update

Centers for Medicare & Medicaid Services (CMS), ICD-10-CM Official Guidelines for Coding and Reporting https://www.cms.gov/medicare/coding/icd10

Centers of Medicare & Medicaid Services (CMS), Medicare Claims Processing Manual, Chapter 23-Fee Schedule administration and coding Requirements https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c23.pdf

Centers for Medicare & Medicaid Services (CMS), National Correct Coding Initiative (NCCI) Policy Manual for Medicare Services https://www.cms.gov/medicare-medicaid-coordination/national-correct-coding-initiative-ncci/ncci-medicare

Center for Medicare and Medicaid Services, Medicare NCCI Medically Unlikely Edits (MUEs) https://www.cms.gov/medicare/coding-billing/national-correct-coding-initiative-ncci-edits/medically-unlikely-edits

U.S. Preventive Services Task Force, https://www.uspreventiveservicestaskforce.org/uspstf/

Hayes, Inc., https://www.hayesinc.com/

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