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# Nutritional Support

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## Disclaimer

**Carefully check state regulations and/or the member contract.**
Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

## Legislative Mandates

**EXCEPTION: For Illinois only:** Illinois Public Act 103-0458 [Insurance Code 215 ILCS 5/356z.61] (HB3809 Impaired Children) states all group or individual fully insured PPO, HMO, POS plans amended, delivered, issued, or renewed on or after January 1, 2025 shall provide coverage for therapy, diagnostic testing, and equipment necessary to increase quality of life for children who have been clinically or genetically diagnosed with any disease, syndrome, or disorder that includes low tone neuromuscular impairment, neurological impairment, or cognitive impairment.

**EXCEPTION:** Illinois legislation requires coverage and reimbursement for amino-acid based elemental formulas regardless of delivery method for the diagnosis and treatment of eosinophilic disorders and short bowel syndrome when the prescribing physician has issued a written order stating that the amino acid formula is a medical necessity.

**EXCEPTION:** Texas legislation requires coverage and reimbursement for amino-acid based elemental formulas regardless of delivery method, when the prescribing physician has issued a written order stating that the amino acid formulas are medical necessary for the treatment of enrollees diagnosed with:

1. Immunoglobulin E and non-immunoglobulin E mediated allergies to multiple food proteins; OR

2. Severe food protein-induced enterocolitis syndromes; OR
3. Eosinophilic disorders, as evidenced by the results of biopsy; OR
4. Disorders affecting the absorptive surface, functional length, and motility of the gastrointestinal tract.

**EXCEPTION:** Montana legislation requires coverage and reimbursement for physician- supervised treatment of inborn errors of metabolism that involve amino acid, carbohydrate and fat metabolism and for which medically standard methods of diagnosis, treatment and monitoring exist. Benefits include expenses of diagnosing, monitoring, and controlling the disorders by nutritional and medical assessment, including but not limited to clinical services, biochemical analysis, medical supplies, prescription drugs, corrective lenses for conditions related to the inborn error of metabolism, nutritional management, and medical foods used in treatment to compensate for the metabolic abnormality and to maintain adequate nutritional status.

**EXCEPTION:** Illinois legislation requires coverage of human breast milk for infants when prescribed by a physician and specific criteria are met.

**EXCEPTION:** For HCSC members residing in the state of Louisiana, R.S. 22:1059.2 requires inpatient and outpatient coverage for prescribed human donor milk for up to 2 months when prescribed by the infant's pediatrician or licensed pediatric provider, and where the infant is medically or physically unable to receive maternal human milk or participate in breastfeeding, or the infant's mother is medically or physically unable to produce maternal human milk in sufficient quantities. Coverage may be restricted to milk obtained from a member bank of the Human Milk Banking Association of North America.

EXCEPTION: For HCSC members residing in the state of Arkansas, § 23-79-703 relating to medical foods, requires coverage for medical foods and low protein modified food products including low protein modified food products, amino-acid-based elemental formulas, extensively hydrolyzed protein formulas, formulas with modified vitamin or mineral content; and modified nutrient content formulas. The coverage shall be regardless of delivery method, whether enteral or oral, or sole source or supplemental, or the age of the covered person, for the treatment of a covered person with a medical disorder requiring specialized nutrients or formulas if the product is determined to be medically necessary. To be covered by a health plan, treatment of a medical disorder requiring specialized nutrients or formulas shall be derived from evidence-based practice guidelines; and efficacious. This applies to the following: Fully Insured Group, Student, Small Group, Mid-Market, Large Group, HMO, EPO, PPO, POS. Unless indicated by the group, this mandate or coverage will not apply to ASO groups.

## Coverage

**NOTE 1: CAREFULLY REVIEW the member's benefit contract.** Except as mandated by legislation cited above, coverage of nutritional supplements, including enteral formula, is subject to the member's benefit contract. **If there is a discrepancy between this medical policy and the member's benefit contract, the contract will govern.**

**NOTE 2:** Per the U. S. Food and Drug Administration, infant formula (including human milk fortifiers with or without a prescription by a healthcare provider acting within the scope of their licensure under applicable state laws) is food and therefore inclusive in the inpatient setting as part of room and board and in an outpatient setting is a non-covered benefit.

**NOTE 3:** Banked breast milk is considered to be food and is therefore inclusive in the inpatient setting as part of room and board, and a non-covered benefit in the outpatient setting.

**NOTE 4**: The coverage criteria for Oral Nutrition are applicable to all patient settings (e.g., inpatient and outpatient/home).

**ORAL NUTRITION**

Oral nutrition (ON) formula, with a prescription from a healthcare provider acting within the scope of their licensure under applicable state law, (when used as a supplement or for dietary replacement) **may be considered medically necessary** for the treatment of inborn errors of metabolism when:

- Used to prevent illness resulting from a by-product of metabolism or amino acid accumulation; OR
- Required to restore an essential nutrient that is lacking because of an inborn error of metabolism.

**SUPPLIES FOR ENTERAL NUTRITION**

**(*For Coverage of enteral nutrition Formula Refer to The Member's Benefit Plan)**

Supplies for enteral nutrition (EN) **may be considered medically necessary** when ONE of the following criteria is met:

- Presence of nonfunctional proximal gastrointestinal tract or disease of the structures that normally allows food to reach the small bowel (e.g., head and neck cancer or tumor obstructing the esophagus or stomach, or a proximal small bowel fistula) where the tube feedings are needed to provide adequate nutrition to maintain the patient's overall health status; OR
- Presence of a central nervous system disease interfering with the neuromuscular coordination of chewing and swallowing and where a risk of aspiration exists (i.e., dysphagia secondary to cerebral vascular accident or Parkinson's disease).

If less than 12 kcal/kg/day are being administered by EN in an adult, supplies for EN are **considered not medically necessary** as the EN is considered supplemental because it is not the primary source of caloric intake for the individual.

In-line digestive enzyme cartridges (e.g., Relizorb™, Alcresta Therapeutics, Inc.) which connect to enteral feeding tubes for hydrolysis (digestion) of fats in enteral formula, **may be considered medically necessary** in individuals ages 1 year and above with cystic fibrosis.

More than two in-line digestive enzyme cartridges per day **are considered not medically necessary**.

**PARENTERAL NUTRITION**

Parenteral nutrition (PN) **may be considered medically necessary** in the treatment or prevention of malnutrition associated with conditions resulting with impaired gastrointestinal

ingestion, digestion, absorption, or motility where EN is not possible. These conditions may include:

- Crohn's disease; OR
- Obstruction secondary to a stricture or neoplasm affecting the esophagus, stomach, small intestine, large bowel, colon or rectum; OR
- Loss of the swallowing mechanism due to a central nervous system disorder, where there is a great risk of aspiration; OR
- Short bowel syndrome-intestinal failure; OR
- Malabsorption due to intestinal fistula(s) (PN being temporary until fistula repair or resolution); OR
- Intractable motility disorders (i.e., chronic intestinal pseudo-obstruction, scleroderma, visceral organ myopathy, mitochondrial encephalopathies); OR
- Newborn infants with gastrointestinal anomalies (i.e., tracheoesophageal fistula, gastroschisis, omphalocele or intestinal atresia); OR
- Infants and young children with a diagnosis of failure to thrive, due to systemic disease or secondary to intestinal insufficiency (associated with short bowel syndrome, necrotizing enterocolitis, malabsorption, microvillus inclusion disease, or chronic idiopathic diarrhea); OR
- Patients with prolonged paralytic ileus following major surgery or multiple injuries; OR
- Severe mesenteric ischemia; OR
- Loss of mucosal surface area from radiation enteritis, chemotherapy-induced enteritis, graft versus host disease, rejection of an intestinal graft, autoimmune enteritis, refractory sprue, or other diseases that disrupt the mucosal epithelium; OR
- Radiation enteritis; OR
- Hyperemesis gravidarum when EN is not tolerated; OR
- Chyle leak; OR
- Intractable nausea, vomiting or diarrhea; OR
- Severe pancreatitis.

**ALL of the following requirements must be met for alternative site (outpatient and home setting) PN**:

1. Documentation that the patient is metabolically stable and serum potassium (K), sodium (Na), phosphate ($PO_4$) and magnesium (Mg) are all normal and serum glucose is < 160 mg/dl;
2. Prior to initiation of PN there must be documentation that sufficient EN is not feasible (e.g., EN is contraindicated, insufficient EN is tolerated or there is insufficient bowel function to maintain or restore nutritional status with EN alone) to provide necessary energy. The patient can receive no more than 50% of their energy requirements orally or from tube feeding;
3. Documentation of a comprehensive medical, clinical and psychosocial assessment of the patient before PN can be initiated;
4. If cancer is present, documentation showing patient is either notably malnourished or at risk of becoming so during cancer treatment (e.g., treatment affects ability to eat or absorb

nutrients) AND the patient has a potentially curable disease or possibility of long disease-free period after cancer treatment (e.g., months to years);
5. For patients with advanced cancer who are terminally ill and have estimated life span of 1-3 months, documentation of education/care plan conversation with patient/family/caregiver on patient's condition and risks and benefits of PN and other treatment options;
6. Absence of severe dementia;
7. Age > 18 years if initiating PN at home (vs hospital);
8. Documentation that the central venous catheter (CVC) used for PN delivery is either single lumen, or if multilumen, that one lumen has been designated for PN;
9. The CVC tip should be verified in the inferior vena cava (IVC) or superior vena cava (SVC);
10. PN must be prescribed by a clinician with expertise in managing PN;
11. Documentation that intravenous fat emulsion infusion is at least 1g/kg/week but does not exceed 1g/kg/day;
12. Documentation that a caregiver at home or alternative site must be identified (this may be the patient themselves);
13. Documentation that patient and/or designated care giver has completed a formal teaching program that includes: a) catheter care and cleaning b) intravenous pump use c) PN solution storage, preparation of the PN solution including the addition of prescribed additives and bag spiking and d) prevention, recognition, and management of PN-related complications and that written instructions have been provided;
14. Documentation that the home environment (if discharge is to home) includes a dedicated refrigerator for PN and that there is adequate clean space for PN preparation;
15. Request is limited to a maximum of 90 days at a time; the nutrition care plan should be re-evaluated every 90 days.

If less than 12 kcal/kg/day are being administered by PN in an adult, it **is considered not medically necessary** and is considered supplemental because it is not the primary source of caloric intake for the individual.

**Prior to continuation of PN after every 6 continuous months, for the initial two (2) years of PN, BOTH of the following must be documented:**
1. Evidence of response to PN for continued use at least once every 6 months;
2. Documentation of at least one attempt to taper the PN energy and volume at least once every 6 months.

PN **is considered experimental, investigational and/or unproven** for all other indications.

**<u>INTRADIALYTIC PARENTERAL NUTRITION</u>**

Intradialytic parenteral nutrition (IDPN) **may be considered medically necessary** when provided for hemodialysis individuals with severely impaired gastrointestinal function as outlined above and with malnutrition uncorrected by oral, enteral or intravenous PN. Prior to the beginning of IDPN, **<u>ALL</u> of the following criteria must be met:**
1. IDPN should not be the sole source of nutrition;
2. There must be documentation of intolerance of BOTH adequate oral and EN intake;

3. There must be documentation that the patient is malnourished.

IDPN **is considered not medically necessary** in individuals who are considered candidates for PN in which IDPN is to be used in addition to regularly scheduled infusions of PN.

IDPN **is considered not medically necessary** when provided for individuals with impaired nutrition due to a poor appetite but without significant gastrointestinal disease.

**INTRAPERITONEAL AMINO ACIDS**

Intraperitoneal amino acid (IPAA) **is considered experimental, investigational and/or unproven**.

**NUTRITIONAL SUPPLEMENTS**

Coverage for nutritional supplements or substances **is considered not medically necessary** when used:

- To increase protein or caloric intake (i.e., protein powders used to enhance muscle development) in addition to the patient's daily diet; OR
- For routine, pre-and post-operative care; OR
- In patients with stable nutritional status, where short-term parenteral nutrition might be used for 14 days or less.

Blenderized baby food and regular shelf food used with an enteral system **are considered not medically necessary.**

## Policy Guidelines

Services for nutritional support (those meeting criteria) may include:

- Cost of nutritional solutions;
- Cost of rental and/or purchase of infusion pumps;
- Cost of supplies and/or equipment required for effective delivery of nutrients;
- Home visits by a medical practitioner administering skilled care.

## Description

Oral nutrition (ON) therapy is prescribed formula or medical food taken by mouth to replace or supplement an oral diet.

Inborn errors of metabolism are a group of rare genetic disorders resulting in the excessive accumulation of an amino acid or other nutrients that are not metabolized correctly. Manifestations may include:

- Central nervous system dysfunction;
- Developmental delay;
- Seizures;

- Weight loss;
- Liver dysfunction.

The clinical manifestations in many of these disorders can be prevented if diagnosis is achieved early and appropriate treatment with dietary protein/amino acid restriction is initiated immediately. These disorders are named for the accumulating amino acid and include, but are not limited to:

- Phenylketonuria (PKU);
- Maple syrup urine disease (MSUD);
- Citrullinemia;
- Cystinosis;
- Homocystinuria;
- Methylmalonic acidemia.

For some of the inborn errors of metabolism, special formulas and medical foods have been developed, which eliminate the amino acid that cannot be metabolized from the protein component of the food.

Enteral nutrition (EN) is the provision of nutrients via the gastrointestinal tract when the oral cavity is bypassed as a means of nutrient ingestion. Nutrients may be consumed orally or be infused via nasoenteric (nasogastric, nasoduodenal, or nasojejunal) feeding tubes or via gastrostomy or jejunostomy tubes. EN is preferred over parenteral nutrition (PN) because it is safer and less expensive unless there are contraindications or access cannot be obtained. Nasoenteric feeding tubes are preferred for short-term feedings (< 30 days) and gastrostomy or jejunostomy tubes are preferred for long-term feedings. Formula is typically provided using intermittent gravity or bolus feeding when delivered to the stomach and via a pump when delivered into the small bowel. The only absolute contraindication to EN is mechanical obstruction of the gastrointestinal tract. (1)

The first of its kind, Relizorb™ is a single use digestive enzyme cartridge indicated for use in adults to break down enteral formula for patients with absorptive issues. (i.e., cystic fibrosis patients requiring enteral feeds). The device fits in line with enteral feeding systems and consists of an outer casing containing an inert polymer with a covalently bound enzyme through which nutritional formula is directed. It is designed to hydrolyze fat present in the enteral formula from triglycerides into fatty acids and monoglycerides to allow for their absorption by the body. This breakdown of fats is intended to mimic the function of the enzyme lipase in patients who do not excrete sufficient levels of pancreatic lipase. (2)

PN is the provision of nutrition support intravenously. PN is used for patients with medical conditions that impair gastrointestinal absorption where oral or enteral nutrition is not possible or appropriate. PN is also used for intermittent periods of time to reinforce the nutritional status of severely malnourished patients with medical or surgical conditions. PN consists of:

- Dextrose monohydrate (carbohydrate);

- Free amino acids (protein);
- Electrolytes: (sodium, potassium, magnesium, chloride, phosphate);
- Vitamins;
- Trace elements (zinc, copper, selenium, possibly chromium);
- Lipid (fat);
- Water.

PN at home or other alternative sites typically is administered nightly over 10-16 hours (up to 20 hours in infants), depending on the patient's nutritional needs, medical status, tolerance and the components of the prescribed formula. A nutrition care plan is developed for the patient that includes the nutritional support prescription and should be reviewed every 3 months. (7) PN should not be initiated, or the patient discharged from an inpatient facility when there are electrolyte abnormalities; specifically, hypokalemia, hypomagnesemia, and/or hypophosphatemia due to the risk of refeeding syndrome. (8, 9) Patients should be metabolically stable, physically/emotionally able to cope with PN, and have an adequate home or otherwise living environment. (10, 11)

An infusion pump is always used to guarantee a safe, steady rate of administration. The pumps are programed to taper off the PN, usually over the last 60 minutes of infusion. (12) PN is infused via a central venous catheter (CVC), which should be either a PICC (percutaneously inserted central catheter) or a subcutaneously tunneled catheter (Hickman, Broviac Groshong and similar devices) or a subcutaneously inserted port (Port-a-Cath, PowerPort, SmartPort, IsoMed and similar devices). Preferably the catheter has a single lumen, but if multilumen, one lumen should be dedicated to PN in order to decrease the risk of a catheter-related bloodstream infection (CRBSI).

Common complications of PN include infection (CRBSI, exit site infections and infections of the subcutaneous tunnel), occlusion (thrombotic and non-thrombotic form lipid or protein precipitation), hepatic derangements (intestinal failure-associated liver disease [IFALD]), biliary derangements (calculous and acalculous cholecystitis), renal disease (nephrolithiasis and PN-associated nephropathy) and metabolic bone disease (osteoporosis, osteomalacia). (13) IFALD may result in the need for isolated intestine or combined intestine/liver transplant. Liver disease is more common among those patients that receive > 1g/kg/day of lipid emulsion. (14)

PN with dialysis can be grouped into categories based on the mode of dialysis and is delivered simultaneously during dialysis. The current categories are Intradialytic Parenteral Nutrition (IDPN), Intraperitoneal Amino Acid (IPAA), and Intraperitoneal PN. IDPN is the infusion of a supplemental intravenous nutritional formula, usually amino acids and dextrose, occasionally with lipids, during the dialysis treatment. IPAA is infused with dialysate fluid and allowed to dwell with the dialysate fluid for optimal fluid infusion of the amino acids. The peritoneal route is limited in the volume amount available for nutrition due to the capacity of the peritoneal cavity.

Protein calorie malnutrition occurs in an estimated 25% to 40% of patients undergoing dialysis. The cause of malnutrition in patients on dialysis is often multifactorial and may include under dialysis, chronic inflammation, protein loss in the dialysate solution (particularly in peritoneal dialysis), untreated metabolic acidosis, and decreased oral intake.

The clinical evaluation of malnutrition is multifactorial but typically includes measurement of serum albumin. Serum albumin levels correlate with nutritional status but are imperfect measures of nutrition because they can be affected by other disease states. Protein calorie malnutrition is associated with increased morbidity and mortality. For example, the risk of death is increased more than 10-fold in those whose serum albumin levels are less than 2.5 g/dL, and those with a serum albumin near the normal range (i.e., 3.5-3.9 g/dL) have a mortality rate twice as high as those with an albumin level greater than 4.0 g/dL.

For patients receiving chronic dialysis, the National Kidney Foundation currently recommends a daily protein intake of 1.2 g/kg or more in patients undergoing hemodialysis and 1.3 g/kg or more in patients undergoing peritoneal dialysis. (15) When malnutrition is present, a stepwise approach to treatment is generally used, beginning with dietary counseling and diet modifications, followed by oral nutrition supplements, and then by enteral nutrition supplements or parenteral nutrition supplements if needed.

Intradialytic parenteral nutrition, which refers to the infusion of hyperalimentation fluids at the time of hemodialysis or peritoneal dialysis, has been investigated as a technique to treat protein calorie malnutrition in an effort to decrease associated morbidity and mortality. Intradialytic parenteral nutrition solutions are similar to those used for total parenteral nutrition. A typical solution contains 10% amino acids, 40% to 50% glucose, 10% to 20% lipids, or a mixture of carbohydrate or lipids, depending on patient needs. In hemodialysis, the intradialytic parenteral nutrition infusion is administered through the venous port of the dialysis tubing, typically, 30 minutes after dialysis has begun, and continued throughout the dialysis session.

**Regulatory Status**

Total parenteral nutrition solutions are compounded by an individual pharmacy from individual ingredients (e.g., dextrose, amino acids, trace elements) into a finished medication based on a prescription and are not required to have approval from the U.S. Food and Drug Administration (FDA) through a new drug application process. Compounding pharmacies have historically been subject to regulation by state pharmacy boards, although the FDA increased its regulatory oversight under the Drug Quality and Security Act of 2013.

Peritoneal dialysis solutions are regulated as drugs as defined by the FDA. One amino acid-based peritoneal dialysate, Nutrineal™ PD4, 1.1% Amino Acid Peritoneal Dialysis Solution (Baxter Healthcare), is available commercially outside of the U.S., but has not been FDA approved.

In 2015, the U.S. FDA approved Relizorb™ (Alcresta Pharmaceuticals) under the De Novo product classification. In 2016, Relizorb™ was approved by the FDA through the premarket approval process (K161247). There were no changes to device design, technology, or functionality. (3) In 2017, Relizorb™ received FDA premarket approval for device K163057 to hydrolyze fats in enteral formula in adults and pediatric patients (ages 5 years and above). (4) In 2019, Relizorb™ obtained FDA premarket approval for device K191379 for changes in technology and design but the indications for use and target population was identical to the predicate. The differences did not raise new questions of safety and effectiveness. (5) In August 2023, Relizorb™ (K232784) was cleared by the FDA for expanded use in pediatric patients ages 2 years and above. (6)

## Rationale

**Oral Nutrition (ON)**
Due to legislative mandates and contract limitations, inborn errors of metabolism are included in coverage.

Practice Guidelines and Position Statements: ON
*American Academy of Pediatrics (AAP)*
The AAP Policy Statement published in 2003, reaffirmed 2006 states the following: "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." (16)

"These are all disorders treatable by dietary modifications, which can prevent complications like severe mental retardation and death." (16)

**Enteral Nutrition (EN) and Parenteral Nutrition (PN)**
EN and PN therapies are valuable adjunctive treatments in the management of select patients requiring nutritional support to prevent or treat the adverse effects of malnutrition. To determine the type of nutritional support and accurately calculate the patient's nutritional needs, review of the following data is necessary (17, 18, 19):

- Patient age and gender;
- Review of pre-existing medical conditions and history;
- Know the source and amount of exogenous nutrient losses;
- Body mass index determination.

Generally, a daily caloric intake of 110-120 kcal/kg/day for pre-term infants, 90-100 kcal/kg/day for full term infants, 75-90 kcal/kg/day for children aged 1-7 years, 60-75 kcal/kg/day for children aged 7-12 years, 30-60 kcal/kg/day for children aged 12-18 years, and 25-30 kcal/kg/day for adults is sufficient to maintain body weight. (17, 18) Protein requirements generally range from 3-3.5 g/kg/day in pre-term infants (19) to 0.8-2.0 g/kg/day in adults. In

2023, the European Society for Clinical Nutrition and Metabolism (ESPEN) updated the guidelines for home parenteral nutrition and note “This guideline does not include recommendations for the patient's nutrient requirements in specific conditions, for which the reader can refer to previous ESPEN guidelines.” (21)

PN may lengthen survival and improve quality of life in some palliative care patients. If the patient’s life expectancy is months to years, nutritional support, including enteral and parenteral feeding as appropriate should be considered when the disease or treatment affects the ability to eat and/or absorb nutrients. (21) There is no conclusive evidence supporting the use of nutrition support (EN or PN) in patients with severe dementia. (22) The majority of patients that require long-term PN are those with short bowel syndrome (SBS) - intestinal failure. It is noted that not all patients with SBS will require PN and others that require it initially, may be successfully weaned from it. SBS-intestinal failure is characterized by surgical resection, congenital defect, or disease-associated loss of absorption and is characterized by the inability to maintain protein-energy, fluid, electrolyte, or micronutrient balances when on a conventionally accepted, normal diet. (23) Fifty percent (50%) of adult patients (73% of children) with SBS-intestinal failure and 25-50% of adult patients (25-38% of children) with chronic intestinal pseudo-obstruction may be weaned from home parenteral nutrition (HPN) within 2 years of the start of HPN. (10)

The use of PN is not without risk, catheter-related infection is the most common and serious complication for adult patients receiving HPN. The central venous catheter (CVC) connection/ hub must be meticulously cleaned prior to connection of PN as well as disconnection in order to avoid development of a catheter-related bloodstream infection (CRBSI), and patients/caregivers must be educated in proper technique to disinfect the hub. (10, 12, 24, 25) In addition, there is an increased risk of infection when there is more than one CVC lumen and thus it is preferred that one lumen be designated for PN if a multilumen catheter is clinically indicated. (10, 26) The risk of infection is decreased with lower hospital pre-discharge blood glucose. (27) The risk of infection is also decreased through a rigorous aseptic cleaning of the junction (hub) between the catheter connector and attached tubing or syringe prior to connection and disconnection. (28) A formal teaching program should be completed for the patient and/or caregiver that includes a) catheter care and cleaning, b) intravenous pump use, and c) prevention, recognition, and management of PN-related complications. (21) Patients that receive both oral and written instructions on catheter care have a lower risk of PN-related infection. (29) There is an increased risk of venous thrombosis if the tip of the PN CVC is not located within the distal superior vena cava (SVC) at the junction of the right atrium (7, 10, 12, 30).

<u>Practice Guidelines and Position Statements: Enteral Nutrition (EN) and Parenteral Nutrition (PN)</u>

*National Comprehensive Cancer Network (NCCN)*

The NCCN guidelines (v.1.2025) state the following: “The goals and intensity of nutritional support change as life expectancy is reduced to weeks to days. Education and emotional support should be provided regarding the natural history of the disease, as nutritional support

may not reverse weight loss in patients with advanced cancer. Overly aggressive enteral or parenteral nutrition therapies can actually increase the suffering of dying patients." (20)

**Digestive Enzyme Cartridges**

The U.S. Food and Drug Administration (FDA) approval for Relizorb™, a digestive enzyme cartridge, was based on well-established pre-clinical porcine models that mimics the inability to digest and absorb fat.

A search of ClinicalTrials.gov, identified 1 randomized, double-blind, crossover trial with an open-label safety evaluation period (31), a multicenter, open label study, and an ongoing 90-day, phase 4 open labeled exploratory study. This multicenter, randomized, double-blind, crossover clinical trial enrolled 34 subjects (pediatric and adult) and 33 completed the study. Subjects with confirmed exocrine pancreatic insufficiency used an enteral feeding digestive enzyme cartridge (Relizorb™) connected to enteral pump set. The objective of this study was to evaluate the safety, tolerability, and fat absorption of a new in-line digestive cartridge (Relizorb™) that hydrolyzes fat in enteral formula provided to patients with cystic fibrosis (CF). The authors concluded that the use of this in-line digestive cartridge was safe and well tolerated and resulted in significantly increased levels of plasma omega-3 fatty acid (FA) used with enteral formula, suggesting an overall increased fat absorption. This study was supported by the product manufacturer, Alcresta Therapeutics, Inc. (NCT02598128).

Stevens et al. (2018) conducted a multicenter, 90-day open label study; Relizorb was used with overnight EN in patients with CF. (32) This single-arm, multicenter trial (ASSURE) was conducted between July 20, 2016 and March 30, 2017 and included a total of 36 subjects that completed the study. The objective was to evaluate safety, tolerability, and efficacy of sustained use of Relizorb over a 90-day period in patients with CF and exocrine pancreatic insufficiency (EPI) as part of their regular nutrition regimen. Safety and tolerability outcomes included the frequency and severity of adverse events (AEs) and unanticipated adverse device effects (UADEs), incidence of gastrointestinal (GI) symptoms, clinical and laboratory findings, vital signs, and use of concomitant medications. The authors concluded that the use of Relizorb with overnight EN feedings is safe, well-tolerated, and associated with increased levels of FA in red blood cell (RBC) membranes and plasma. ASSURE is the first prospective study to demonstrate EN can improve FA abnormalities in CF. Because improvement in omega-3 levels has been shown to help pulmonary and inflammatory status as well as anthropometric parameters in CF, Relizorb may have important long-term therapeutic benefits in patients with CF. (NCT02750501)

Sathe et al. (2021) evaluated the effectiveness of in-line immobilized lipase cartridges (ILC) in enterally fed patients with cystic fibrosis. (33) Baseline anthropometric data were obtained, and subsequent measurements of height, weight, and body mass index were collected at 6 and 12 months (n=100; age 0-45). Over 12 months of use in patients >2 years of age (n=93), there were significant improvements seen in height and weight z-scores with an improvement trend seen in BMI. The frequency of achieving the 50th percentile increased steadily for weight and BMI from baseline to 12 months but not for height. Authors concluded that better growth is possible over standard of care. The association of ILC use with significant improvements in

anthropometric parameters over a 12- month period in people with cystic fibrosis demonstrates the effectiveness of ILC as a rational enzyme therapy during enteral feedings.

In a 2024 UpToDate article, Katkin and colleagues (2024) addressed pancreatic insufficiency as the most common gastrointestinal complication of cystic fibrosis. (34) The limited available data regarding Relizorb efficacy includes small studies which suggest that Relizorb can help reduce early morning satiety and bloating for some individuals, as well as improve fat absorption when compared with the patient's baseline pancreatic enzyme replacement therapy regimen.

Practice Guidelines and Position Statements: Digestive Enzyme Cartridges

In 2019, Schwarzenberg et al. published a consensus statement with the support of the Cystic Fibrosis Foundation that states that this product, Relizorb, "has proven successful in a real-world setting….", "Use of immobilized lipase cartridge to support enteral feedings is making a positive difference for many patients with CF and is a rational alternative to the historical but illogical current standard of care. (35)

Abu-El-Haija et al. (2018) reported on a consensus statement regarding nutrition in pediatric pancreatic diseases through a joint European Society for Pediatric Gastroenterology, Hepatology and Nutrition and North American Society for Pediatric Gastroenterology, Hepatology and Nutrition working group that performed an evidence-based search of the literature on nutrition in acute pancreatitis, acute recurrent pancreatitis, and chronic pancreatitis with a focus in pediatrics. (36) The literature was summarized, quality of evidence reviewed, and expert recommendations developed. A consensus of at least 75% was required to approve a recommendation. Authors reported that literature on pediatric pancreatitis is limited. Gaps were noted in the knowledge relating to: optimal nutrition for acute pancreatitis in children; the role of diet or dietary supplements on recurrent attacks of pancreatitis and pain episodes; monitoring practices to detect early growth and nutritional deficiencies in chronic pancreatitis; and identifying risk factors that predispose children to these deficiencies. The authors indicated there was insufficient literature reporting on the benefit of pancreatic enzyme replacement therapy in acute recurrent pancreatitis, whether in pediatrics or adults. A recommendation was made against routine pancreatic enzyme replacement therapy in children diagnosed with acute recurrent pancreatitis who do not have exocrine pancreatic insufficiency. The lack of information in the literature indicated that most recommendations were expert lead rather than having a strong evidence base. Further research was recommended to address the aforementioned gaps. The authors concluded that early enteral nutrition with a return to a normal-fat diet appears most optimal for children along the spectrum of acute pancreatitis, acute recurrent pancreatitis, and cerebral palsy. Well-designed clinical trials supporting the efficacy of in-line digestive enzyme cartridges for the treatment of pancreatic insufficiency caused by multiple conditions including, but not limited to celiac disease, chronic pancreatitis, Crohn's disease, diabetes mellitus, gastrectomy, pancreatic cancer, pancreatic duct obstruction, small bowel resection, and short bowel syndrome are lacking.

Unpublished Clinical Trials

A currently ongoing and unpublished trial that might influence this policy is listed in Table 1.

**Table 1. Summary of Key Trials**

| NCT Number | Trial Name | Planned Enrollment | Completion Date |
|---|---|---|---|
| ***Ongoing*** | | | |
| NCT03530852 | A 90-Day, Phase 3, Open Labeled Exploratory Study of Relizorb | 32 | Sept 2028 |

NCT: national clinical trial.

Section Summary: Digestive Enzyme Cartridges

For individuals ages 2 years and above with cystic fibrosis, the U.S. Food and Drug Administration approved Relizorb to address fat malabsorption in enteral tube fed patients. The evidence includes a randomized, double-blind, crossover trial with an open-label safety evaluation period, a multicenter, open label study that demonstrated the absorption normalization of key fatty acids, decrease gastrointestinal adverse events and increased weight, and a study evaluating a program initiated to provide access to relizorb. In addition, a published consensus statement supported by the Cystic Fibrosis Foundation, consider Relizorb a valuable therapeutic option for use in cystic fibrosis patients. There is insufficient evidence to support the effectiveness of digestive enzyme cartridges for the treatment of pancreatic insufficiency caused by other conditions.

**Intradialytic Parenteral Nutrition (IDPN)**

For patients who qualify for total parenteral nutrition and are concomitantly receiving hemodialysis, it is reasonable to administer intradialytic parenteral nutrition (IDPN) solution, which is similar to a total parenteral nutrition solution. IDPN is administered via the existing venous port of the dialysis tubing rather than through an alternative intravenous site. This medical policy focuses on studies evaluating whether IDPN as an adjunct to hemodialysis improves outcomes for individuals who may be at risk for malnutrition but who would not otherwise receive parenteral nutrition (PN).

A systematic review conducted for the U.S. Department of Veterans Affairs Evidence Synthesis Program was published in 2018 (Table 2). (37) The review addressed the effectiveness and adverse effects of IDPN for the treatment of malnutrition in hemodialysis patients (Table 2). The reviewers included five RCTs and six comparative observational studies (four prospective and two retrospective). The reviewers also identified three systematic reviews but because they did not include a formal quality assessment of individual studies or did not include any relevant primary studies, these were used only to identify additional primary studies. Outcomes included clinically relevant improvements in individual indicators of nutrition status, global nutrition status, mortality, morbidity, hospitalization, and quality of life (QOL). Included primary studies compared IDPN to oral supplements, dietary counseling, or usual care. Usual care was not well-defined in the studies and could include dietary counseling or oral supplements based on patient condition and physician recommendation. The study sample sizes were small (range 12 to 196), with the exception of one large retrospective cohort study (n=24,196). The criteria for malnutrition varied across the studies, with most using serum albumin of <3.5 g/dL or <4.0

g/dL along with at least one other predictor of malnutrition (weight loss, BMI, nutritional score or assessment). No studies compared IDPN to enteral nutrition.

**Table 2. Systematic Review Characteristics**

| Study | Dates | Studies | Participants | N (Range) | Design | Duration |
|---|---|---|---|---|---|---|
| Anderson et al. (2018) (37) | 2009-2017 | 5 RCTs, 4 prospective cohort, 2 retrospective cohort | • Mean age 65 years (37 to 80)<br>• Mean 50% male<br>• At least 6 months on dialysis prior to inclusion in study<br>• Mean serum albumin 3.77 g/dL (range 3.02 to 3.8 g/dL)<br>• BMI range 19.2 to 23.4 kg/m$^2$<br>• Race/ethnicity not reported | 602 (12 to 196), excluding one large retrospective cohort study (N= 24,196) | RCTs and observational studies | 12 weeks to 2 years |

RCT: randomized controlled trial; BMI: body mass index

Compared to oral supplements and dietary counseling, IDPN did not improve the patient health outcomes mortality, hospitalization, or QOL (See Tables 3 and 4). Observational studies found mixed results for IDPN compared to usual care for mortality, with results differing based on baseline serum albumin levels. The effect of IDPN on nutritional indicators also varied across comparisons and studies.

**Table 3. Systematic Review Results**

| Study | IDPN vs Oral Supplements: Mortality | IDPN vs Oral Supplements: Hospitalization | IDPN vs Oral Supplements: Quality of life | IDPN vs Oral Supplements: Nutritional Indicators | IDPN vs Dietary Counseling: Mortality |
|---|---|---|---|---|---|
| **Anderson et al. (2018) (37)** | | | | | |
| Evidence | 1 RCT (38) | 1 RCT (38) | 1 RCT (38) | 2 RCTs, (38, 39) 1 cohort study (40) | 1 RCT (41) |
| Total N (range) | 186 (NA) | 186 (NA) | 186 (NA) | 238 (20 to 186) | 107 (NA) |
| Effect | 43% vs 39%; P=NS | # days hospitalized/days follow up: 0.008 vs 0.06 (P=NS) | No difference in Karnofsky score (data NR) | Mean change: SA (g/dl): 0.18 (P=.048) vs 0.28 (P=.17) | 26.4% (14/53) vs 12.9% (7/54) (P-value NR) |

| | | | | | |
|---|---|---|---|---|---|
| | | | | Mean change: BMI: -0.10 (P=0.87) vs -0.10 (P=.69)<br><br>MAC: -1 (P=.09) vs 0.47 (P=.35) TSF: -0.43 (P=0.5) vs 0.42 (P=.66) | |
| Summary | No improvement | No improvement | No improvement | Variable effect with no Improvement except serum albumin in a single study | No improvement |

IDPN: intradialytic parenteral nutrition; RCT: randomized controlled trial; N: sample size; NA: not applicable; NS: nonsignificant; NR: not reported; SA: serum albumin; BMI: body mass index; OR: odds ratio; PA: serum prealbumin; SGA: subjective global assessment; RR: relative risk; vs: versus; CI: confidence interval; SF-12: 12-Item Short-Form Health Survey; TSF: tricep skin fold; MAC: mid-arm circumference.

**Table 4. Systematic Review Results Continued**

| Study | IDPN vs Dietary Counseling: Hospitalization | IDPN vs Dietary Counseling: Quality of life | IDPN vs Dietary Counseling: Nutritional Indicators | IDPN vs Usual Care: Mortality | IDPN vs Usual Care: Quality of life | IDPN vs Usual Care: Nutritional Indicators |
|---|---|---|---|---|---|---|
| **Anderson et al. (2018) (37)** | | | | | | |
| Evidence | 1 RCT (41) | 1 RCT (41) | 1 RCT (41) | 3 cohort studies (40, 42) | 1 RCT (43) | 2 RCTs, (38, 43) 3 cohort studies (40, 42, 44) |
| Total N (range) | 107 (NA) | 107 (NA) | 107 (NA) | 24,305 (28 to 24,196) | 40 (NA) | 347 (12 to 186) |
| Effect | 59.0% vs 43.2%, P =.1509 | (SF-12) score change from baseline at 16 wks. -2.74 vs 0.34, | Positive response to IDPN (≥ 30 mg/L increase in PA) 48.7% vs 31.8% at | Survival: RR = 1.34, P <.01 (Cox)<br><br>Time to death (mo) | No improvement in functional capacity (data NR) | No difference in change in SA or PA (data NR) |

| | | | | | | |
|---|---|---|---|---|---|---|
| | | P=.1175 | week 16 (P =.1164)<br><br>Patients achieving > 15% increase from baseline at week 4, PA (mg/L): 41% vs 20.5%, P=.0415<br><br>Improved SGA score by one grade: 20.5% vs 13.6%, P =.4037 | for non-survivors: 16.9 vs 7.5, P <.01<br><br>OR death: (SA ≥ 4.0 g/dL & CRE >8.0mg/dL) = 2.6 (95% CI 1.34 - 5.04)<br><br>SA ≤ 3.3 =0.72 (P <.01)<br><br>SA ≤ 3.0 g/dL = 0.57 (95% CI 0.44 - 0.77)<br><br>Mortality: 0% vs 27.8% (P <.02) | | No difference in change in BMI (data NR)<br><br>Mean change: SA (g/dL) 0.93 (P =.001) vs -0.14 (P = 0.316)<br><br>Mean change: BMI 2.8 (P =.001) vs 0.03 (P =.981)<br><br>Mean change: MIS -8.75 (P=.001) vs 0.25 (P=.716) |
| Summary | No improvement | No Improve-ment | Variable effects on serum prealbumin No Improve-ment in serum albumin or subjective global assessment | Variable effect on mortality; effect differs by baseline serum albumin level | No improvement | Variable effect, with improve-ment in at least one nutritional indicator |

IDPN: intradialytic parenteral nutrition; RCT: randomized controlled trial; N: sample size; NA: not applicable; NS: nonsignificant; NR: not reported; SA: serum albumin; BMI: body mass index; OR: odds ratio; PA: serum prealbumin; SGA: subjective global assessment; RR: relative risk; vs: versus; mo: month; CI: confidence interval; SF-12: 12-Item Short-Form Health Survey; TSF: tricep skin fold; MAC: mid-arm circumference.

The reviewers concluded that "IDPN does not appear to improve patient health or clinically important nutritional outcomes compared to the standard and recommended treatments of oral supplementation or dietary counseling." They further concluded, "Although IDPN has not been explicitly studied in hemodialysis patients who have failed adequate trials of or are unable to receive dietary counseling, oral, and/or enteral tube feeding due to malfunctioning GI tract or other issues, since evidence – albeit limited – has not raised concerns about IDPN safety, we agree with existing guidelines that it appears reasonable to consider use of IDPN in this population." (37)

Five RCTs on IDPN were included in the systematic review conducted by Anderson et al. (2018) (37) and are discussed above.

Practice Guidelines and Position Statements: IDPN

*National Kidney Foundation*

In 2020, in a joint effort with the Academy of Nutrition and Dietetics (Academy), the National Kidney Foundation updated its Kidney Disease Outcomes Quality Initiative (KDOQI) Clinical Practice Guideline for Nutrition in Chronic Kidney Disease (CKD). The Guideline 4 on Nutritional Supplementation (4.1.3) states that "In adults with CKD with protein-energy wasting, we suggest a trial of Total Parenteral Nutrition (TPN) for CKD 1-5 patients (2C) and intradialytic parenteral nutrition (IDPN) for CKD 5D on maintenance hemodialysis (MHD) patients (2C), to improve and maintain nutritional status if nutritional requirements cannot be met with existing oral and enteral intake." (15) This statement was based on an evidence review of 3 studies published from 1989 to 2007 in individuals who were malnourished. (41, 44, 45) Strength of evidence ratings were not provided.

*American Society for Parenteral and Enteral Nutrition (ASPEN)*

In 2010, the ASPEN issued guidelines on nutritional support in adults in acute and chronic renal failure. The ASPEN assigned a level C recommendation (supported by at least one level II investigation) that IDPN should not be used as a nutritional supplement in malnourished chronic kidney disease-V hemodialysis patients. The basis for the recommendation was a large randomized controlled trial that found mortality rates did not differ between malnourished patients receiving IDPN and malnourished patients receiving oral supplements without IDPN. An additional concern was that IDPN "is limited by the need to complete the entire nutrient infusion during the hemodialysis" treatment, which may cause adverse events because of the rapid infusion of glucose and lipids. The ASPEN further recommended that larger RCTs "in malnourished patients are needed to ensure that a clinical benefit of IDPN does not exist." (46)

Ongoing and Unpublished Clinical Trials

One currently ongoing trial that might influence this policy is listed in Table 5.

**Table 5. Summary of Key Trials**

| NCT Number | Trial Name | Planned Enrollment | Completion Date |
|---|---|---|---|
| ***Ongoing*** | | | |

| | | | |
|---|---|---|---|
| NCT04094038 | The Effect of Intradialytic Parenteral Nutrition on Nutritional Status and Quality of Life in Hemodialysis Patients | 166 | Sep 2025 |

NCT: national clinical trial.

Section Summary: Intradialytic Parenteral Nutrition (IDPN)

Published systematic reviews, which included randomized controlled trials but could not pool data, have concluded that the current evidence does not demonstrate benefits in patient outcomes with the use of intradialytic parenteral nutrition for those who would not otherwise qualify for total parenteral nutrition.

## Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

| | |
|---|---|
| **CPT Codes** | None |
| **HCPCS Codes** | B4034, B4035, B4036, B4102, B4103, B4104, B4105, B4148, B4149, B4150, B4152, B4153, B4154, B4155, B4157, B4158, B4159, B4160, B4161, B4162, B4164, B4168, B4172, B4176, B4178, B4180, B4185, B4189, B4193, B4197, B4199, B4216, B4220, B4222, B4224, B5000, B5100, B5200, B9002, B9004, B9006, B9998, B9999, E0781, E0791, S9340, S9341, S9342, S9343, S9364, S9365, S9366, S9367, S9368, S9432, S9433, S9434, S9435, S9810, T2101 |

*Current Procedural Terminology (CPT®) ©2024 American Medical Association: Chicago, IL.

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## Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

| Policy History/Revision | |
|---|---|
| **Date** | **Description of Change** |
| 05/15/2025 | Document updated with literature review. The following changes were made to coverage: 1) Changed age from 5 years and above to 1 year and above for use of in-line digestive enzyme cartridges; and 2) Added "More than two in-line digestive enzyme cartridges per day are considered not medically necessary". Added references 6, 19, 33, 34, and 36; others updated. |
| 08/15/2024 | Reviewed. No changes. |
| 11/01/2023 | Document updated with literature review. The following changes were made to the Coverage Section: 1) From Note 1 “that can be sold or dispensed without a prescription by a healthcare provider acting within the scope of their licensure under applicable state law” was removed and “CAREFULLY REVIEW the member’s benefit contract and is subject to the member’s benefit contract. If there is a discrepancy between this medical policy and the member’s benefit contract, the contract will govern” was added. 2) The oral nutrition formula medically necessary coverage statement changed “available only” to “with a prescription”. 3) Removed enteral nutrition formula from the enteral nutrition section in its entirety and revised to include only supplies. 4) Removed “For dietary supplements or replacements (over the counter enteral nutrition not meeting criteria)” from the nutritional supplements or substances not medically necessary coverage criteria. Removed NOTE 4 and “Enteral Nutrition” from NOTE 5. 5) Added references 10, 17 and 44-46; others updated. |
| 01/01/2023 | Reviewed. No changes. |
| 11/01/2021 | Document updated with literature review. Coverage unchanged. References 5, 8, and 28 were added and others updated. |
| 12/15/2020 | Reviewed. No changes. |
| 02/01/2020 | Document updated with literature review. The following changes were made to Coverage Section: 1) Note 3 was added to state: Banked breast milk is considered to be food and is therefore inclusive in the inpatient setting as part of room and board, and a non-covered benefit in the outpatient setting. 2) Digestive enzyme cartridges (e.g. RelizorbTM, Alcresta Pharmaceuticals) which connect to enteral feeding tubes for hydrolysis (digestion) of fats in enteral formula now includes medically necessary coverage in patients ages 5 years and above with cystic fibrosis. 3) ALL requirements for alternative site (outpatient and home setting) PN replaced numbers 4-6 with numbers 4 and 5 (4. If cancer is present, documentation showing patient is either notably malnourished or at risk of becoming so during cancer treatment [e.g., treatment affects ability to eat or absorb nutrients] AND the patient has a potentially curable disease or possibility of long disease-free period |

| | |
|---|---|
| | after cancer treatment [e.g., months to years]; 5. For patients with advanced cancer who are terminally ill and have estimated life span of 1-3 months, documentation of education/care plan conversation with patient/family/caregiver on patient's condition and risks and benefits of PN and other treatment options). References 4, 15, 29-32, 34-35, and 37-39 were added and some references removed. |
| 12/15/2017 | Document updated with literature review. The following changes were made to coverage: 1) Added "enteral formula" to Note 1. 2) Added Note 2 to address human milk fortifiers. 3) Added Note 4 to clarify coverage for oral and enteral nutrition is applicable to all patient settings. 4) Enteral nutrition section: a) Added "proximal small bowel fistula" to list of examples of diseases of the structures that normally allows food to reach the small bowel; b) Added "Parkinson's disease" as cause of dysphagia; c) added or "orogastric" to statement on nasogastric tubes; d) Added statement considering enteral nutrition NMN if not the primary source of caloric intake; e) Added an EIU statement for all other indications. 5) Parenteral nutrition section was completely revised. 6) Revised all criteria from the MN statement in the intradialytic parenteral nutrition section. 7) Replaced wording by physician's prescription in the coverage section to available only by prescription from a healthcare provider acting within the scope of their licensure under applicable state law. |
| 03/15/2017 | Document updated with literature review. The following change(s) were made to Coverage: 1) Removed Total Parenteral Nutrition initiation criteria specific to serum albumin, body weight, blood urea nitrogen, and phosphorus; 2) Modified Parenteral Nutrition statement of medical necessity; and 3) Changed "Total Parenteral Nutrition" to "Parenteral Nutrition". |
| 10/15/2016 | Document updated with a literature review specific to digestive enzyme cartridges. The following statement was added to Coverage: Digestive enzyme cartridges (e.g. Relizorb™, Alcresta Pharmaceuticals) is considered experimental, investigational, and/or unproven for all indications, including but not limited to, patients receiving enteral tube feedings. |
| 06/01/2015 | Document updated with literature review. The following was added to the coverage section: Enteral Nutrition (EN) formula (available only by physician's prescription) may be considered medically necessary when administered via a nasogastric feeding tube when the following criterion is met: Presence of inadequate nutritional oral intake, related to medical condition (less than 50% of the caloric needs are being met by oral intake) requiring supplementation for a limited time period (e.g. 4-6-weeks). |
| 01/01/2013 | CPT/HCPCS code(s) updated |
| 08/15/2011 | CPT/HCPCS code(s) updated |
| 09/01/2009 | Adding Legislation for Texas to reflect legislative mandates for payment of (1) immunoglobulin E and non-immunoglobulin E mediated allergies to |

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| | multiple food proteins; (2) severe food protein-induced enterocolitis syndrome; (3) eosinophilic disorders, as evidenced by the results of a biopsy; and (4) impaired absorption of nutrients caused by disorders affecting the absorptive surface, functional length, and motility of the gastrointestinal tract. The coverage required under Subsection (a) [1-4] is required if the treating physician has issued a written order stating that the amino acid-based elemental formula is medically necessary for the treatment of an enrollee who is diagnosed with a disease or disorder listed in Subsection (a) [1-4]. |
| 01/01/2009 | New CPT/HCPCS code(s) added |
| 05/15/2008 | Policy reviewed without literature review; new review date only. This policy is no longer scheduled for routine literature review and update. |
| 01/01/2008 | Revised/updated entire document |
| 02/01/2007 | Revised/updated entire document |
| 01/01/2006 | CPT/HCPCS code(s) updated |
| 01/01/2005 | CPT/HCPCS code(s) updated |
| 09/01/2004 | Revised/updated entire document |
| 02/01/2002 | New CPT/HCPCS code(s) added |
| 05/01/1996 | Revised/updated entire document |
| 07/01/1993 | Revised/updated entire document |
| 05/01/1990 | New medical document |