Parenteral, Enteral and Oral Nutrition in The Home

**DISCLAIMER**

Our medical policies are designed for informational purposes only and are not an authorization, explanation of benefits or a contract. Receipt of benefits is subject to satisfaction of all terms and conditions of the coverage. Medical technology is constantly changing, and we reserve the right to review and update our policies periodically.

**POLICY**

Parenteral Nutrition (PN) *(prescribed by an MD, DO, NP, or PA)* may be considered medically necessary for patients who are unable to maintain adequate nutrition intake via oral or tube feedings due to: 1) severe pathology of the alimentary tract that does not allow absorption of sufficient nutrients; and 2) the inability to receive no more than 30% of their caloric needs orally; or 3) the patient cannot benefit from tube feedings as a result of a malabsorptive disorder, which may include but is not limited to the following conditions:

1. inflammatory bowel disease (Crohn’s disease or ulcerative colitis); or
2. obstruction secondary to stricture or neoplasm of the esophagus or stomach; or
3. loss of the swallowing mechanism due to a central nervous system disorder, where the risk of aspiration is great; or
4. short bowel syndrome secondary to massive small bowel resection; or
5. malabsorption due to enterocolic, enterovesical, or enterocutaneous fistulas (PN being temporary until the fistula is repaired); or
6. intractable motility disorder (i.e., intestinal pseudo-obstruction and gastroparesis); or
7. newborn infants with severe gastrointestinal anomalies (i.e., tracheoesophageal fistula, gastoschisis, omphalocele, or intestinal atresia); or
8. infants and young children who fail to thrive due to systemic disease or secondarily to intestinal insufficiency (associated with short bowel syndrome, malabsorption, or chronic idiopathic diarrhea); or
9. patients with prolonged paralytic ileus following major surgery or multiple injuries; or
10. hyperemesis gravidarum after medical management has been tried and been unsuccessful in maintaining adequate nutritional intake.

Enteral nutrition (EN) formula *(prescribed by an MD, DO, NP, or PA)* may be considered medically necessary when administered via a surgically placed feeding tube when one of the following criteria is met:

1. the presence of a non-functional proximal gastrointestinal tract or disease of the of the structures that normally allows food to reach the small bowel (e.g., head and neck cancer a tumor that obstructs the esophagus or stomach) where the tube feedings are needed to provide
adequate nutrition to maintain the patient's overall health status; or

2. central nervous system disease leading to sufficient interference with the neuromuscular coordination of chewing and swallowing that a risk of aspiration exists (i.e., dysphagia secondary to Cerebral Vascular Accident [CVA]).

Enteral Nutrition (EN) formula (prescribed by an MD, DO, NP, or PA) may be considered medically necessary when administered via a nasogastric feeding tube when the following criterion is met:

1. 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).

Digestive enzyme cartridges (e.g. Relizorb™, Alcresta Pharmaceuticals) are considered investigational for all indications, including but not limited to, patients receiving enteral tube feedings.

Oral Nutrition (ON) formula (prescribed by an MD, DO, NP, or PA) when used as a supplement or for dietary replacement may be considered medically necessary for the treatment of inborn errors of metabolism when:

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

Generally, a daily caloric intake of 2000-2200 calories is sufficient to maintain body weight. If 750 calories per day or less are being administered by EN or PN, it is considered not medically necessary and is considered supplemental because it is not the primary source of caloric intake for the patient.

POLICY GUIDELINES

Nutrients and their manner of administration for both PN and EN must be specifically ordered by a physician and be preapproved on an individual consideration basis.

Approved PN, EN, and ON services (those meeting criteria) may include, but are not limited to, the following:

- cost of nutritional solutions
- cost of rental or purchase of an infusion pump
- cost of supplies and/or equipment required for effective delivery of PN or EN
- home visits by a medical practitioner administering skilled care

BENEFIT APPLICATION

BLUECARD / NATIONAL ACCOUNT ISSUES

State or federal mandates (e.g., FEP) may dictate that certain U.S. Food and Drug Administration–approved devices, drugs, or biologics may not be considered investigational, and thus these devices may be assessed only on the basis of their medical necessity.

Plans may wish to establish global allowances for PN services to include nursing services, cost of supplies, clinical pharmacy service, supply delivery, and administrative overhead. Prior authorization is recommended.

Benefits may be provided for placement of central venous catheters and gastrostomy or jejunostomy feeding tubes when policy guidelines have been met for PN or EN.
The total cost of renting equipment should not exceed the purchase cost of the equipment.

Benefits are usually not provided for nutritional substances when used:

- 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, (i.e., for less than 2 weeks);
- for routine pre- and/or postoperative care;
- for over-the-counter enteral nutrition.
- Blenderized baby food and regular shelf food used with an enteral system are not eligible for benefits.

**BACKGROUND**

Parenteral nutrition (PN), also known as parenteral hyper-alimentation, provides nutritional requirements through an intravenous route. PN is used for patients with medical conditions that impair gastrointestinal absorption to a level incompatible with life. A nutritionally adequate hypertonic solution consisting of glucose (sugar), amino acids (protein), electrolytes (sodium, potassium), vitamins, minerals, and lipids (fats) is administered daily. An infusion pump is generally used to assure a steady flow of the solution either on a continuous (24-hour), intermittent, or cyclic schedule. If intermittent, a heparin lock device and diluted heparin are used to prevent clotting inside the catheter.7

Enteral nutrition (EN) is used for treating patients with severe malabsorption or patients with a functioning intestinal tract, but with disorders of the pharynx, esophagus, or stomach that prevent nutrients from reaching the absorbing surfaces in the small intestine. EN involves administering special nutritional liquids directly into the gastrointestinal tract through nasogastric, gastrostomy, or jejunostomy tubes. An infusion pump may be used to assist the flow of liquids. Feedings may be either intermittent or continuous (infused 24 hours a day).7

Relizorb™ (Alcresta Pharmaceuticals) enzyme cartridge was approved by U.S. Food and Drug Administration (FDA) in 2015 under the De Novo product classification. Relizorb is a single use digestive enzyme cartridge indicated for use in adults to break down enteral formula. 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.

Oral nutrition therapy is formula or medical food taken orally to replace or supplement a diet.

Inborn errors of metabolism are a group of disorders resulting in the excessive accumulation of an amino acid or other product along the metabolic pathway. Manifestations may include: central nervous system dysfunction; developmental delay; seizures; and liver dysfunction.

If diagnosis is achieved early and appropriate treatment with dietary protein or amino acid restriction is initiated immediately, clinical manifestations in many of these disorders can be prevented. These disorders are named for the accumulating amino acid and include but are not limited to: phenylketonuria (PKU); citrullinemia; cystinosis; homocystinuria; and methylmalonic acidemia.

**RATIONALE**

**PARENTERAL NUTRITION (PN)**
A search of peer reviewed literature on parenteral nutrition identified the following medical position and guideline:

The American Gastroenterological Association (AGA) published a medical position on parenteral nutrition in 2001 that states:

In general, parenteral nutrition is indicated to prevent the adverse effects of malnutrition in patients who are unable to obtain adequate nutrients by oral or enteral routes. The decision to use parenteral nutrition requires an understanding of the patient’s clinical condition and anticipated outcome, judgment as to the patient’s ability to tolerate undernutrition, knowledge of the clinical efficacy of parenteral nutrition and an appreciation of the patient’s desires and needs.¹

The American Society for Parenteral and Enteral Nutrition (ASPEN) (2002) published clinical guidelines as an update to the first published guidelines in 1993 as a result of new evidence. The ASPEN update included the following recommendations:

When specialized nutrition support (SNS) is indicated, PN should be used when gastrointestinal tract is not functional or cannot be accessed and in patients who cannot be adequately nourished by oral diets or EN”. This was a grade B recommendation which provides fair research-based evidence to support the guideline (well-designed studies without randomization).

The nutritional requirements for adults who need SNS should be based on the results of the formal individualized nutrition assessment. The requirements for each nutrient may vary with nutrition status, disease, organ function, metabolic condition, medication use, and duration of nutrition support.⁴

Per the ASPEN guidelines, common indications for home PN include: inflammatory bowel disease, nonterminal cancer, ischemic bowel, and radiation enteritis, motility disorders of the bowel, bowel obstruction, high-output intestinal or pancreatic fistulae, celiac disease, hyperemesis gravidarum, and protein-losing enteropathy.

**ENTERAL NUTRITION (EN)**

Enteral nutrition, oral nutrition, and parenteral nutrition therapies are seen as valuable treatment in the management of select patients requiring nutritional support to prevent 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: patient age and gender; review of pre-existing medical conditions and history; and body mass index determination.

The National Institutes of Health (NIH) and the American Society for Parenteral and Enteral Nutrition (ASPEN) published a joint conference report that reviewed current literature concerning the importance of nutritional support. ⁵ The review included prospective, randomized, controlled trials where nutritional therapy was administered for a minimum of five days and provided satisfactory nutrients to meet daily requirements. In total, more than 2500 patients were included in the studies reviewed. With one final statement, the report concluded that:

- The usage of nutritional therapy requires careful integration of data from pertinent clinical trials;
- Clinical expertise is required in the illness or injury being treated;
- Clinical input from nutritional therapy clinicians;
- Input from the patient and family. No human studies were identified with the use of Relizorb. The FDA approval is based on well-established pre-clinical porcine models that mimic the inability to digest and absorb fat. ³ A search of ClinicalTrials.gov identified one multicenter safety, tolerability, and fat absorption study. This clinical trial anticipated enrolling 35 subjects (pediatric and adult) with cystic fibrosis. Subjects with confirmed exocrine pancreatic insufficiency used an enteral
feeding digestive enzyme cartridge (Relizorb) connected to enteral pump set. This study is ongoing, not actively recruiting participants, and is supported by the product manufacturer, Alcresta Pharmaceuticals (NCT02598128). The estimated completion date was June 2016. There is insufficient published literature for the use of digestive enzyme cartridges. Larger randomized controlled trials are needed to support the safety, efficacy, and the health impact on humans.

SECTION SUMMARY
There is insufficient published literature for the use of digestive enzyme cartridges. Larger randomized controlled trials are needed to support the safety, efficacy, and the health impact on humans.

SUPPLEMENTAL INFORMATION

PRACTICE GUIDELINES AND POSITION STATEMENTS
American Society for Parenteral and Enteral Nutrition
The 2002 ASPEN Practice Guidelines: Indications for Specialized Nutrition Support (SNS) state the following for home specialized nutritional support:

1. Home SNS (HSNS) should be used in patients who cannot meet their nutrient requirements by oral intake and who are able to receive therapy outside of an acute care setting. (B)
2. When HSNS is required, HEN is the preferred route of administration when feasible. (B)
3. When HSNS is indicated, HPN should be used when the gastrointestinal tract is not functional and in patients who cannot be adequately supported with HEN. (B)

Please refer to the full article for disease specific practice guidelines.

U.S. PREVENTIVE SERVICES TASK FORCE RECOMMENDATIONS
Not applicable.

MEDICARE NATIONAL COVERAGE
On July 11, 1984, Centers for Medicare and Medicaid Services published a National Coverage Determination: #180.2- Enteral and Parenteral Nutritional Therapy. 2

Please refer to the National Coverage Determination (NCD) for Enteral and Parenteral Nutritional Therapy (180.2). Also, see the DME MAC Local Coverage Determinations (LCDs) for Enteral Nutrition and the DME MAC LCDs for Parenteral Nutrition at http://www.cms.hhs.gov.

REFERENCES


**CODES**

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**MP 1.02.501**  
Parenteral, Enteral and Oral Nutrition in the home

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**ICD-10-CM**  
**ICD-10-PCS**  
Type of service: DME and Supplies  
Place of service: Home

**POLICY HISTORY**

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