



# Parenteral Nutrition and Enteral Nutrition Therapy in the Home

**Policy #** 00088

**Original Effective Date:** 11/22/1993

**Current Effective Date:** 08/14/2023

*Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.*

## **Parenteral Nutrition (PN)**

### **When Services May Be Eligible for Coverage**

*Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:*

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider parenteral nutrition (PN) in individuals whose gastrointestinal (alimentary) tract does not adequately function to permit enteral feeding (oral or tube feeding), resulting in malnutrition, including such conditions, but not limited to, any of the following to be **eligible for coverage**.\*\*

#### **Patient Selection Criteria for Parenteral Nutrition (PN)**

- Loss of the swallowing mechanism due to a central nervous system disorder, where the risk of aspiration is great; or
- Crohn's disease with growth retardation, diffuse small bowel disease refractory to medical treatment, or fistulae; or
- Obstruction secondary to stricture, neoplasm, or carcinomatosis; or
- Short bowel syndrome (e.g., secondary to mesenteric infarction, massive bowel resection, trauma sustained to intra-abdominal organs, small bowel atresia in neonates); or
- Radiation enteritis; or
- Secondary gastrointestinal failure (e.g., scleroderma, cystic fibrosis with malnutrition unresponsive to enteral nutrition); or
- Severe mucosal injury with intractable malabsorption (e.g., immunodeficiency syndromes with enterocolitis, idiopathic mucosal failure with congenital failure to develop villi); or

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- Malabsorption due to enterocolic, enterovesical or enterocutaneous fistulas (PN being temporary until the fistula is repaired); or
- Motility disorder (pseudo-obstruction); or
- Newborn infants with catastrophic gastrointestinal anomalies such as tracheoesophageal fistula, gastroschisis, omphalocele, or
- 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
- Individuals with prolonged paralytic ileus following major surgery or multiple injuries; or
- Adjunctive therapy for malnourished individuals with specific cancers that are responding to treatment, who are receiving intense and frequent chemotherapy that causes severe gastrointestinal toxicity; or
- Liver failure in children approved for liver transplant who fail to grow while receiving enteral nutritional support; or
- Short-term treatment of a condition requiring “bowel rest”, where prolonged hospitalization would otherwise be required, such as
  - pancreatic pseudocysts
  - pancreatitis in adults with an inadequate oral intake where enteral feedings exacerbate pain, ascites or fistulous output
  - children with severe reflux and aspiration who fail to thrive, until a surgical procedure can be performed.

Documentation is required before the initial implementation of parenteral nutrition (PN), supporting nutritional insufficiency and failure of enteral nutrition as shown by ALL of the following (in some circumstances, i.e., anticipation of prolonged course of illness when the patient has eaten little or nothing for 5 days or longer, all of these criteria need not be applied):

- Serum albumin is less than or equal to 3.4 g/dL along with unintentional weight loss of 10% or greater in the last 3 to 6 months; OR
  - Body mass index (BMI) less than 20 kg/m<sup>2</sup> along with unintentional weight loss of 5% or greater in the last 3 to 6 months;
- Blood urea nitrogen (BUN) is below 10 mg/dL (not an accurate marker in renal failure individuals);

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- The patient is unable to receive more than 30% of his/her caloric needs orally or the patient cannot benefit from tube feedings as a result of a malabsorptive disorder.

Continuation request will require documentation supporting presence of condition resulting in nutritional insufficiency and failure of enteral nutrition, physician evaluation at least every three months, proper use and monitoring, and evidence of continued benefit and medical necessity. Guidelines suggest that when tolerance to enteral nutrition is evident, parenteral nutrition should be weaned and discontinued when >60 percent of the individuals' needs are met enterally.

### When Services Are Considered Not Medically Necessary

If parenteral nutrition (PN) is eligible for coverage under the member contract but patient selection criteria are not met, the use of nutritional supplementation is considered **not medically necessary**.\*\*

### When Services Are Not Covered

Parenteral nutrition is used for individuals who require supplementation of their daily protein and caloric intake. Nutritional supplements are often given between meals to boost protein/caloric intake and are **not eligible for coverage** under most member contracts.

### Enteral Nutrition (EN)

### When Services May Be Eligible for Coverage

*Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:*

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider enteral nutrition (EN) to be **eligible for coverage**\*\* under the following conditions:

#### Patient Selection Criteria for Enteral Nutrition (EN)

- An anatomical inability to swallow exists, due to, for example, head and neck cancer or an obstructing tumor or stricture of the esophagus or stomach;

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- Central nervous system disease leading to sufficient interference with the neuromuscular coordination of chewing and swallowing so that a risk of aspiration exists.

Enteral nutrition will be considered when accepted medical standards for the use of EN are supported in clinical records, including documentation of the underlying medical condition(s) that necessitate the use of EN. However, some member contracts do not cover food or medical foods, including those used for EN.

## When Services Are Considered Not Medically Necessary

If enteral nutrition (EN) is eligible for coverage under the member contract but patient selection criteria are not met, the use of nutritional supplementation is considered **not medically necessary**.\*\*

## When Services Are Not Covered

Enteral nutrition is used for individuals who require supplementation of their daily protein and caloric intake. Nutritional supplements are often given between meals to boost protein/caloric intake and are **not eligible for coverage** under most member contracts.

## Specialized Nutritional Products

## When Services Are Eligible for Coverage

*Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:*

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Specialized Nutritional Products will be considered medically necessary and will be **eligible for coverage**\*\* as provided by state legislative mandate if it:

- Is a low protein food product that is especially formulated to have less than one gram of protein per serving, and
- Is intended to be used under the direction of a physician for dietary treatment of an inherited metabolic disease (shall not include a natural food that is naturally low in protein), and
- Is used to treat an inherited abnormality of body chemistry. Such disease shall be limited to:

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- Phenylketonuria (PKU)
- Maple Syrup Urine Disease (MSUD)
- Methylmalonic Acidemia (MMA)
- Isovaleric Acidemia (IVA)
- Propionic Acidemia
- Glutaric Acidemia
- Urea Cycle Defects
- Tyrosinemia

### **Relizorb cartridge**

Based on review of available data, the Company may consider initial request for Relizorb<sup>TM†</sup> cartridge to hydrolyze fats in enteral formula to be **eligible for coverage\*\*** if the following criteria are met:

- Individual has a diagnosis of cystic fibrosis and fat malabsorption, AND
- Requires enteral tube feedings; AND
- Individual has failed to achieve enteral feeding goals (e.g., insufficient weight gain or weight loss) with pancreatic enzyme replacement therapy (PERT) used in conjunction with enteral feedings.

### **Continuation**

Based on review of available data, the Company may consider continuation requests for Relizorb cartridge to be **eligible for coverage\*\*** if the following criteria are met:

- Individual continues to require enteral tube nutrition and has clinical benefit with use of Relizorb (e.g., stable or increased weight, improved symptoms associated with fat malabsorption).

## **When Services Are Considered Investigational**

*Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.*

Based on review of available data, the Company considers use of Relizorb when criteria above are not met to be **investigational.\***

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### **Policy Guidelines**

Home PN should be employed as therapy only in individuals in whom enteral feeding (employing the patient's own gastrointestinal tract) is considered contraindicated or in whom such feeding has been unsuccessful.

Because of the potential risks of home PN, this therapy should generally not be employed when simpler, more routine therapies may be the first choice of treatment (e.g., pharmacological therapy for an acute exacerbation of short segment illness due to Crohn's disease).

The patient must be medically stable in order for PN to be safely administered in the home setting. The patient and/or caregiver must be adequately trained in the techniques of home PN, to ensure that it is administered according to policy and that complications requiring appropriate treatment are recognized.

The need for continuing PN therapy must be periodically reassessed because, in many disease processes causing gut failure, intestinal adaption may take place.

Initiating nutritional support in children should be considered when oral intake does not meet 60% to 80% of requirements for more than 10 days (for children older than age 1 within 5 days, and children less than age 1 within 3 days) or if daily feeding time is not possible for more than 4 to 6 hours per day.

Nutritional support in children may be appropriate if there is evidence of wasting or stunted growth as evidenced by (Braegger et al., J Pediatr Gastroenterol Nutr 2010, 51: 110-22):

- Younger than 2 years of age and growth or weight gain inadequate for longer than a month
- Age greater than 2 years and weight loss or no gain for longer than 3 months
- Change in weight for age over 2 growth periods
- Consistent triceps skin fold values less than 5th percentile for age
- Height is more than 3 standard deviations below the median for their age
- During early to middle stage of puberty, slowing of height greater than 2 cm from prior year

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### **Background/Overview**

Parenteral nutrition, also known as parenteral hyperalimentation, is used for individuals with medical conditions that impair gastrointestinal absorption to a degree incompatible with life. It is also used for variable periods of time to bolster the nutritional status of severely malnourished individuals with medical or surgical conditions. PN involves percutaneous transvenous implantation of a central venous catheter into the vena cava or right atrium. A nutritionally adequate hypertonic solution consisting of glucose (sugar), amino acids (protein), electrolytes (sodium, potassium), vitamins and minerals, and sometimes fats is administered daily. An infusion pump is generally used to assure a steady flow of the solution either on a continuous (24-hour) or intermittent schedule. If intermittent, a heparin lock device and diluted heparin are used to prevent clotting inside the catheter.

Enteral nutrition is used for individuals 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. The patient is at risk of severe malnutrition. EN involves administering non-sterile 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).

Relizorb is indicated for use in pediatric individuals (ages 5 years and above) and adults to hydrolyze fats in enteral formula (it is for enteral feeding only). It is a single-use, point-of-care digestive enzyme cartridge that contains iLipase<sup>®†</sup> and connects in-line with enteral feeding systems. Lipase is covalently bound to small white beads inside the cartridge and is retained in the cartridge during use by two filters. Enteral formula flows through, allowing for fat breakdown. Relizorb is designed to hydrolyze (digest) fats contained in enteral formulas from triglycerides into fatty acids and monoglycerides to allow for their absorption and utilization by the gastrointestinal track and the body.

Alcresta completed a multicenter, randomized, double-blind, placebo-controlled crossover clinical study in adult and pediatric individuals with cystic fibrosis receiving enteral feeding. Thirty-five individuals were enrolled for duration of 27 days. Study demonstrated absorption of (change in plasma concentration) of physiologically relevant long-chain polyunsaturated fatty acids such as DHA and EPA (biomarkers of fat absorption).

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Recent published literature with both short and long-term data demonstrate statistically significant increases in height and weight growth scores, increases in BMI scores, and improved plasma concentrations of fatty acids in individuals with cystic fibrosis. The 2019 Journal of Cystic Fibrosis published support of Relizorb, concluding that use of the immobilized lipase cartridge (ILC) “can produce measurable clinically relevant benefits” The evidence is sufficient to determine the benefits of Relizorb as an adjunct therapy in individuals who require both enteral nutrition and pancreatic enzyme supplementation.

## **FDA or Other Governmental Regulatory Approval**

### **U.S. Food and Drug Administration (FDA)**

Parenteral nutrition and EN solutions are subject to FDA approval. Numerous FDA approved solutions are available.

## **Rationale/Source**

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. FDA approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

## **References**

1. Centers for Medicare and Medicaid Services. National Coverage Determination for Enteral and Parenteral Nutritional Therapy (180.2). <http://www.cms.hhs.gov/>.
2. American Gastroenterological Association Medical Position Statement: Guidelines for the Use of Enteral Nutrition. <http://www.gastro.org>.
3. Legislative Mandate, State of Louisiana, 2001.

## **Policy History**

Original Effective Date: 11/22/1993

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10/18/2001 Medical Policy Committee review

11/12/2001 Managed Care Advisory Council approval

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10/21/2003	Medical Policy Committee review. Format revision, no substance change in policy.
01/24/2004	Managed Care Advisory Council approval
01/04/2005	Medical Director review
01/18/2005	Medical Policy Committee review
01/31/2005	Managed Care Advisory Council approval
02/01/2006	Medical Director review
02/15/2006	Medical Policy Committee review. Format revision, Rationale updated based on literature review.
02/23/2006	Quality Care Advisory Council approval
07/07/2006	Format revision, including addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged.
02/07/2007	Medical Director review
02/21/2007	Medical Policy Committee approval.
02/13/2008	Medical Director review
02/20/2008	Medical Policy Committee approval. Title changed from nutritional support to total parenteral nutrition and enteral nutrition in the home. Deleted information on intradialytic parenteral nutrition from this policy, and made it a policy in itself.
02/04/2009	Medical Director review
02/19/2009	Medical Policy Committee approval. No change to coverage.
02/04/2010	Medical Policy Committee approval
02/17/2010	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
02/03/2011	Medical Policy Committee review
02/16/2011	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
02/02/2012	Medical Policy Committee review
02/15/2012	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/03/2013	Medical Policy Committee review
01/09/2013	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/09/2014	Medical Policy Committee review
01/15/2014	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

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01/08/2015	Medical Policy Committee review
01/21/2015	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/07/2016	Medical Policy Committee review
01/22/2016	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/01/2017	Coding update: Removing of ICD-9 Diagnosis Codes
01/05/2017	Medical Policy Committee review
01/18/2017	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/04/2018	Medical Policy Committee review
01/17/2018	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/10/2019	Medical Policy Committee review
01/23/2019	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/03/2020	Medical Policy Committee review
01/08/2020	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/07/2021	Medical Policy Committee review
01/13/2021	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
02/03/2022	Medical Policy Committee review
02/09/2022	Medical Policy Implementation Committee approval. Patient selection criteria for TPN revised. Policy Guidelines updated.
04/07/2022	Medical Policy Committee review
04/13/2022	Medical Policy Implementation Committee approval. Removed the word total from total parenteral nutrition.
07/07/2022	Medical Policy Committee review
07/13/2022	Medical Policy Implementation Committee approval. Relizorb cartridge was added as eligible for coverage with criteria.
07/06/2023	Medical Policy Committee review
07/12/2023	Medical Policy Implementation Committee approval. No change to coverage.

Next Scheduled Review Date: 07/2024

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### **Coding**

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	No codes
HCPCS	B4105, B4157, B4162, B4164, B4168, B4172, B4176, B4178, B4180, B4185, B4189, B4193, B4197, B4199, B4216, B4220, B4222, B4224, B5000, B5100, B5200, S9340, S9341, S9342, S9343, S9364, S9365, S9366, S9367, S9368, S9430, S9433, S9434, S9435
ICD-10 Diagnosis	All related diagnoses

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**\*Investigational** – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
  - 1. Consultation with technology evaluation center(s);
  - 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
  - 3. Reference to federal regulations.

**\*\*Medically Necessary (or “Medical Necessity”)** - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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**NOTICE:** If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

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