Parenteral Nutrition and Enteral Nutrition Therapy

Policy # 00088
Original Effective Date: 11/22/1993
Current Effective Date: 09/09/2024

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) in the Home

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
- Malabsorption due to entercolic, 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^2 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);
- 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) in the Home

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.*

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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;
- 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:
    - 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™‡ 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.***

Intradialytic Parenteral Nutrition (IDPN)

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.*

Based on review of available data, the Company may consider intradialytic parenteral nutrition (IDPN) as an adjunct to hemodialysis when it is offered as an alternative to a regularly scheduled regimen of total parenteral nutrition only in those individuals who would be considered candidates for total parenteral nutrition (TPN) (i.e., a severe pathology of the alimentary tract that does not allow absorption of sufficient nutrients to maintain weight and strength commensurate with the patient's general condition) to be **eligible for coverage.****

Note: This policy only addresses intravenous parenteral nutrition as an adjunct to hemodialysis (not peritoneal dialysis).

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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 IDPN as an adjunct to hemodialysis in individuals who would not otherwise be considered candidates for TPN to be **investigational.***

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers IDPN in individuals who would be considered a candidate for TPN, but for whom the IDPN is not offered as an alternative to TPN, but in addition to regularly scheduled infusions to TPN to be **not medically necessary.****

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.

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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

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

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®‡ 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).

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.

Intradialytic parenteral nutrition

Protein Calorie Malnutrition
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.

Diagnosis
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 (ie, 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.

Treatment
For patients receiving chronic dialysis, the National Kidney Foundation currently recommends a daily protein of 1.2 g/kg or more in patients undergoing hemodialysis and 1.3 g/kg or more in patients undergoing peritoneal dialysis. 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.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Total parenteral nutrition solutions are compounded by an individual pharmacy from individual ingredients (eg, 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), is available commercially outside of the U. S., but has not been FDA approved.

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.

Intradialytic parenteral nutrition is the infusion of an intravenous hyperalimentation formula, such as amino acids, glucose, and lipids, during dialysis, to treat protein calorie malnutrition in an effort to decrease the morbidity and mortality experienced in patients with renal failure.

Summary of Evidence

For individuals who are undergoing hemodialysis who receive intradialytic parenteral nutrition, the evidence includes multiple randomized controlled trials, observational studies, and systematic reviews of these studies. Relevant outcomes are overall survival, change in disease

status, morbid events, health status measures, quality of life, treatment-related mortality and morbidity. 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. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Supplemental Information

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

National Kidney Foundation

In 2001, the National Kidney Foundation clinical guidelines established target daily protein requirements in patients undergoing chronic dialysis. In 2008, the National Kidney Foundation updated its pediatric nutrition guidelines to recommend a trial of intradialytic parenteral nutrition to augment inadequate nutritional intake for malnourished children (body mass index for height and age <5th percentile) receiving maintenance hemodialysis who are unable to meet their nutritional requirements through oral and tube feeding.

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." This statement was based on an evidence review of 3 studies published

from 1989 to 2007 in individuals who were malnourished. Strength of evidence ratings were not provided.

American Society for Parenteral and Enteral Nutrition
In 2010, the American Society for Parenteral and Enteral Nutrition issued guidelines on nutritional support in adults in acute and chronic renal failure. The American Society for Parenteral and Enteral Nutrition assigned a level C recommendation (supported by at least one level II investigation) that intradialytic parenteral nutrition 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 intradialytic parenteral nutrition and malnourished patients receiving oral supplements without intradialytic parenteral nutrition. An additional concern was that intradialytic parenteral nutrition "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 American Society for Parenteral and Enteral Nutrition further recommended larger randomized controlled trials "in malnourished patients are needed to ensure that a clinical benefit of IDPN does not exist."

U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage
The coverage eligibility of intradialytic parenteral nutrition for Medicare beneficiaries was summarized in a 1996 Health Care Financing Administration ruling, which established that intradialytic nutrition would be considered eligible for coverage only if the patient would otherwise be a candidate for total parenteral nutrition. This ruling reads in part:

> "Medicare coverage policies which apply to parenteral and enteral nutrition therapy items and services apply identically to intradialytic parenteral nutrition therapy items and services, because intradialytic parenteral nutrition therapy is a subset of parenteral and enteral nutrition therapy.
> ... Daily parenteral therapy is ‘considered reasonable and necessary for a patient with severe pathology of the alimentary tract which does not allow absorption of sufficient

> nutrients to maintain weight and strength commensurate with the patient's general condition.' Intradialytic parenteral nutrition therapy is administered to end stage renal disease (ESRD) patients while they are receiving dialysis. ESRD patients sometimes undergo parenteral therapy to replace fluids and nutrients lost during dialysis. ESRD patients must meet all of the parenteral nutrition therapy coverage requirements to receive intradialytic parenteral nutrition therapy. Those patients who do not meet all of the parenteral nutrition therapy coverage requirements are ineligible to receive Medicare coverage of intradialytic parenteral nutrition therapy under the prosthetic device benefit.…"

The Health Care Financing Administration ruling went on to clarify the benefits for patients who would be considered candidates for total parenteral nutrition and when the intradialytic parenteral nutrition is to be offered in lieu of a regularly scheduled infusion of total parenteral nutrition.

> "However, parenteral and enteral nutrition, including intradialytic parenteral nutrition therapy, services and items which are otherwise covered under section 1861(s)(8) can be denied under section 1862(a)(1) for lack of medical necessity.… Example: If a Medicare beneficiary with ESRD, a dialysis patient who meets all of the requirements for coverage of parenteral nutrition therapy, receives intradialytic parenteral nutrition therapy during dialysis and also receives parenteral nutrition therapy on the other days of the week when the patient is not on dialysis, it may be determined that the patient is receiving an excessive number of lipids. A claim for Medicare payment that is denied because the patient, who qualifies for parenteral nutrition therapy coverage, is receiving an excessive number of lipids would be denied as not reasonable and necessary under section 1862(a)(1)(A) of the Act…
>
> Therefore, the precise statutory basis for the coverage or denial of parenteral and enteral nutrition therapy, including intradialytic parenteral nutrition therapy, services and items is crucial and determinative as to whether or not limitation on liability protections can be applied."

Ongoing and Unpublished Clinical Trials

One currently unpublished trial that might influence this review is listed in Table 1.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT04094038	The Effect of lntradialytic Parenteral Nutrition on Nutritional Status and Quality of Life in Hemodialysis Patients	166	Sep 2023 (last verified 7/22)

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.
4. Kopple JD. The National Kidney Foundation K/DOQI clinical practice guidelines for dietary protein intake for chronic dialysis patients. Am J Kidney Dis. Oct 2001; 38(4 Suppl 1): S68-73. PMID 11576926
5. Anderson J, Peterson K, Bourne D, Boundy E. Evidence Brief: Use of lntradialytic Parenteral Nutrition (IDPN) to Treat Malnutrition in Hemodialysis Patients. VA ESP Project #09-199; 2018; https://www.hsrd.research.va.gov/publications/esp/idpn-supplemental.pdf.
6. KDOQI Work Group. KDOQI Clinical Practice Guideline for Nutrition in Children with CKD: 2008 update. Executive summary. Am J Kidney Dis. Mar 2009; 53(3 Suppl 2): S11-104. PMID 19231749

7. Liu Y, Xiao X, Qin DP, et al. Comparison of lntradialytic Parenteral Nutrition with Glucose or Amino Acid Mixtures in Maintenance Hemodialysis Patients. Nutrients. Jun 02 2016; 8(6). PMID 27271658
8. Oguz Y, Bulucu F, Vural A. Oral and parenteral essential amino acid therapy in malnourished hemodialysis patients. Nephron. Oct 2001; 89(2): 224-7. PMID 11549907
9. Capelli JP, Kushner H, Camiscioli TC, et al. Effect of intradialytic parenteral nutrition on mortality rates in end-stage renal disease care. Am J Kidney Dis. Jun 1994; 23(6): 808-16. PMID 8203363
10. Hiroshige K, Iwamoto M, Kabashima N, et al. Prolonged use of intradialysis parenteral nutrition in elderly malnourished chronic haemodialysis patients. Nephrol Dial Transplant. Aug 1998; 13(8): 2081-7. PMID 9719170
11. Thabet AF, Moeen SM, Labiqe MO, et al. Could intradialytic nutrition improve refractory anaemia in patients undergoing haemodialysis?. J Ren Care. Sep 2017; 43(3): 183-191. PMID 28636166
12. Joannidis M, Rauchenzauner M, Leiner B, et al. Effect of intradialytic parenteral nutrition in patients with malnutrition-inflammation complex syndrome on body weight, inflammation, serum lipids and adipocytokines: results from a pilot study. Eur J Clin Nutr. Jun 2008; 62(6): 789-95. PMID 17522619
13. lkizler TA, Burrowes JD, Byham-Gray LO, et al; KDOQI Nutrition in CKD Guideline Work Group. KDOQI clinical practice guideline for nutrition in CKD: 2020 update. Am J Kidney Dis. 2020;76(3)(suppl 1):S1-S107
14. Cano NJ, Fouque D, Roth H, et al. lntradialytic parenteral nutrition does not improve survival in malnourished hemodialysis patients: a 2-year multicenter, prospective, randomized study. J Am Soc Nephrol. Sep 2007; 18(9): 2583-91. PMID 17656473
15. Toigo G, Situlin R, Tamaro G, et al. Effect of intravenous supplementation of a new essential amino acid formulation in hemodialysis patients. Kidney Int Suppl. Nov 1989; 27: S278-81. PMID 2636671
16. Brown RO, Compher C, McClave S, et al. A.S.P.E.N. clinical guidelines: nutrition support in adult acute and chronic renal failure. JPEN J Parenter Enteral Nutr. 2010; 34(4): 366-77. PMID 20631382

17. Kopple JD, Foulks CJ, Piraino B, et al. Proposed Health Care Financing Administration guidelines for reimbursement of enteral and parenteral nutrition. Am J Kidney Dis. Dec 1995; 26(6): 995-7. PMID 7503076
18. Department of Health and Human Services, Health Care Financing Administration. HCFA Rulings. Ruling No. 96-3. 1996; https://www.cms.gov/Regulations-and-Guidance/Guidance/Rulings/downloads//hcfar963.pdf.

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10/18/2001	Medical Policy Committee review
11/12/2001	Managed Care Advisory Council approval
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.
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

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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.
07/02/2024	Medical Policy Committee review
08/01/2024	Medical Policy Committee review
08/14/2024	Medical Policy Implementation Committee approval. Content from policy 00228 merged into this policy. Title changed from "Parenteral Nutrition and Enteral Nutrition Therapy in the Home" to "Parenteral Nutrition and Enteral Nutrition Therapy."

Next Scheduled Review Date: 08/2025

Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2023 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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The responsibility for the content of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines is with Blue Cross and Blue Shield of Louisiana and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

CPT is a registered trademark of the American Medical Association.

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

*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.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.