Policy Number	MED201.011
Policy Effective Date	01/01/2026

Nutritional Support

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None

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 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 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.

EXCEPTION: For members residing in the state of Maine, 24-A s 2837-D and 24-A s 4238 (for HMO's) requires coverage for metabolic formula and special modified low-protein food products that have been prescribed by a licensed physician for a person with an inborn error of metabolism. This applies to Fully Insured Small Group, Mid-Market, Large Group, Student PPO, HMO, POS, EPO.

EXCEPTION: For members residing in the state of Maine, 24-A s 2847-P and 24-A s 4256 (for HMOs) requires that all group health insurance policies, contracts and certificates must provide coverage for amino acid-based elemental infant formula for children 2 years of age and under in accordance with this section. Coverage for amino acid-based elemental infant formula must be provided when a licensed physician has submitted documentation that the amino acid-based elemental infant formula is medically necessary health care that the amino acid-based elemental infant formula is the predominant source of nutritional intake at a rate of 50% or greater and that other commercial infant formulas, including cow milk-based and soy milk-based formulas have been tried and have failed or are contraindicated. A

licensed physician may be required to confirm and document ongoing medical necessity at least annually. Coverage for amino acid-based elemental infant formula must: be provided without regard to the method of delivery of the formula; be provided when a licensed physician has diagnosed and through medical evaluation has documented one of the following conditions: (1) Symptomatic allergic colitis or proctitis; (2) Laboratory- or biopsy-proven allergic or eosinophilic gastroenteritis; (3) A history of anaphylaxis; (4) Gastroesophageal reflux disease that is nonresponsive to standard medical therapies; (5) Severe vomiting or diarrhea resulting in clinically significant dehydration requiring treatment by a medical provider; (6) Cystic fibrosis; or (7) Malabsorption of cow milk-based or soy milk-based infant formula. This applies to Fully Insured Small Group, Mid-Market, Large Group, Student PPO, HMO, POS, EPO.

EXCEPTION: For members residing in the state of Maine, 24-A s 4320-V requires coverage for pasteurized donor breast milk provided to an infant eligible for coverage under the health plan if a physician or physician assistant or an advanced practice registered nurse signs an order stating that: A. The infant is medically or physically unable to receive maternal breast milk or participate in breastfeeding or the infant's parent is medically or physically unable to produce maternal breast milk in quantities sufficient for the infant; and B. The infant: a. Was born at a birth weight of less than 1,500 grams; b. Has a gastrointestinal anomaly or metabolic or digestive disorder or is recovering from intestinal surgery and the infant's digestive needs require additional support; c. Is not appropriately gaining weight or growing; d. Has formula intolerance and is experiencing weight loss or difficulty feeding; e. Has low blood sugar; f. Has congenital heart disease; g. Has received or will receive an organ transplant; or h. Has another serious medical condition for which donor breast milk is medically necessary. This applies to Fully Insured Small Group, Mid-Market, Large Group, Student PPO, HMO, POS, EPO.

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.

ENTERAL NUTRITION

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

Enteral Nutrition **may be considered medically necessary** when the following criteria are met:

- Individual requires feedings via enteral access device to provide sufficient nutrients to maintain weight and strength commensurate with beneficiary's overall health status.
- Individual with permanent impairment that meets **1 or more** of the following:
    - Full or partial nonfunction or disease of structures that normally permit food to reach small bowel; or
    - Disease impairs digestion and/or absorption of oral diet, directly or indirectly, by small bowel.
- Adequate nutrition is not possible by dietary adjustment and/or oral supplements.
- Equipment and/or supplies are reasonable and necessary, as indicated by **1 or more** of the following:
    - Enteral formula meets **1 or more** of the following:
        - Enteral formula consisting of semisynthetic intact protein/protein isolates provided; or
        - Special enteral formula provided, and medical record supports medical necessity.
    - Enteral nutrition infusion pump (e.g., gravity feeding is not satisfactory due to reflux and/or aspiration, severe diarrhea, dumping syndrome, administration rate less than 100 ml/hr, blood glucose fluctuations, circulatory overload, gastrostomy/jejunostomy tube used for feeding) and medical record supports medical necessity of pump;
    - In-line digestive enzyme cartridge for an individual with a diagnosis of exocrine pancreatic insufficiency;
    - Feeding supply allowance, as indicated by **1 or more** of the following:
        - Supplies correspond with method of enteral nutrition administration (syringe, pump, gravity, elastomeric control fed).
    - Feeding tube, and number meets **1 or more** of the following:
        - Nasogastric tubes: up to 3 every 3 months;
        - Gastrostomy/jejunostomy tube: up to 1 every 3 months.

Enteral Nutrition **is considered not medically necessary** for **ANY** of the following:

- Enteral nutrition for temporary impairment;
- Enteral nutrition for individual with functioning gastrointestinal tract that normally permits food to reach the small bowel;
- Orally administered enteral nutrition product, related supplies and equipment;
- In-line digestive enzyme cartridges in excess of 2 per day;

- Feeding supply allowance that does not correspond to method of enteral nutrition administration (syringe, pump, gravity, elastomeric control fed);
- Pump supply allowance provided without documentation of medical necessity of pump;
- More than one type of feeding supply allowance kit code delivered on same date or provided on ongoing basis;
- Nasogastric tubes in excess of 3 every 3 months;
- Gastrostomy/jejunostomy tubes in excess of 1 every 3 months.

PARENTERAL NUTRITION

Parenteral Nutrition **may be considered medically necessary** when meeting A, B, C and D:

A. Individual is not appropriate for enteral nutrition, as indicated by **1 or more** of the following:
   - Enteral nutrition has been considered and ruled out.
   - Enteral nutrition has been tried and been found ineffective.
   - Enteral nutrition exacerbates GI tract dysfunction.

B. Individual with permanent impairment that meets **1 or more** of the following:
   - Condition involving small intestine and/or its exocrine glands that significantly impairs absorption of nutrients;
   - Disease of stomach and/or intestine that is motility disorder and impairs ability of nutrients to be transported through and absorbed by GI system.

C. Treating practitioner has evaluated the individual within 30 days prior to initiation of parenteral nutrition or has documented reason why beneficiary not evaluated and describes what other monitoring methods were used to evaluate the individual's parenteral nutrition needs.

D. Nutrients are appropriate, as indicated by **ALL** of the following:
   - Total caloric daily intake meets **1 or more** of the following:
     - 20 to 35 cal/kg/day;
     - Outside range of 20 to 35 cal/kg/day and treating practitioner documents medical necessity.
   - Protein order meets **1 or more** of the following:
     - 0.8 to 2.0 gm/kg/day;
     - Outside of range of 0.8 to 2.0 gm/kg/day and treating practitioner documents medical necessity.
   - Dextrose concentration meets **1 or more** of the following:
     - Greater than or equal to 10%;
     - Less than 10% and treating practitioner documents medical necessity.
   - Lipid use per month meets **1 or more** of the following:
     - Product-specific FDA-approved dosing recommendation;
     - Amount greater than product-specific U.S. Food and Drug Administration-approved dosing recommendation and treating practitioner documents medical necessity.
   - Formula meets **1 or more** of the following:
     - Standard formula;

- Special parenteral formula produced for unique nutrient needs of specific disease condition and treating practitioner documents specific condition and medical necessity of formula.

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

1. For a safe HPN program, the patient has to be sufficiently metabolically stable outside the acute hospital setting. The HPN program shall provide an individualized, safe, effective and appropriate nutrition support plan which should be supervised and evaluated on a regular basis.
2. For a safe HPN program, the patient and/or the patient's legal representative have to give fully informed consent to the treatment proposed.
3. HPN should be administered to those patients unable to meet their nutritional requirements via the oral and/or enteral route and who can be safely managed outside of the hospital.
4. Documentation of a comprehensive medical, clinical and psychosocial assessment of the patient before PN can be initiated;
5. HPN should be prescribed to prevent an earlier death from malnutrition in advanced cancer patients with CIF, if their life expectancy related to the cancer is expected to be longer than one to three months, even in those not undergoing active oncological treatment.
6. Absence of severe dementia;
7. 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;
8. The tip of the CVAD should be placed at the level of the right atrial-superior vena cava junction.
9. All HPN patients should be cared for by a NST with experience in HPN management, independent from the underlying disease leading to intestinal failure. The NST consists of experts in HPN provision. This can include a physician, specialist nurses (including in catheter, wound and stoma care), dietitians, pharmacists, social worker, psychologist, as well as an appropriate practitioner with expertise in CVC placement. Surgeons with expertise in intestinal failure should also be available for structured consultation.
10. Documentation that intravenous fat emulsion infusion is at least 1g/kg/week but does not exceed 1g/kg/day;
11. A formal individualized HPN training program for the patient and/or caregiver and/or home care nurses shall be performed, including catheter care, pump use and preventing, recognizing and managing complications. Incidence of catheter-related infection, incidence of hospital readmission and QoL should be used as criteria to assess the quality of care of HPN program.
12. The home care environment should be assessed and approved by the HPN team before the education program starts. For a safe HPN program, the patient's home environment has to be adequate to safely deliver the therapy proposed.
13. Request is limited to a maximum of 90 days at a time; the nutrition care plan should be re-evaluated every 90 days. See Rationale for specific monitoring requirements.

INTRADIALYTIC PARENTERAL NUTRITION

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, **ALL 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.

NUTRITIONAL SUPPLEMENTS

Blenderized baby food, nutritional supplements, 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)

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. (9) 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. (10, 11) Patients should be

metabolically stable, physically/emotionally able to cope with PN, and have an adequate home or otherwise living environment. (12, 13)

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. (14) 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).

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.

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.

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.

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)

Relizorb FDA clearance milestones:

- 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)
- In January 2025, FDA expanded clearance to include children as young as 1 year old (K243284). (7)
- In April 2025, Relizorb was cleared for expanded use to include patients of all ages, including neonates and infants (K250499). (8)

Rationale

This medical policy is based on a review of relevant Centers for Medicare and Medicaid policies and specialty society guidelines.

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

The products used to treat inborn errors of metabolism can be broadly categorized by purpose as follows: 1) those that provide the bulk of nutritional intake for individuals with an IEM, specialized for a specific disorder, and include protein and a range of other nutrients but not the offending amino acid(s); 2) those that are modified to be low in protein; and 3) those that are single amino acids, amino acid mixtures, vitamins, or other compounds used to replace conditionally essential nutrients or to enhance enzyme activity. (16)

<u>Practice Guidelines and Position Statements: ON</u>
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." (17)

"These are all disorders treatable by dietary modifications, which can prevent complications like severe mental retardation and death." (17)

Enteral Nutrition (EN) and Parenteral Nutrition (PN)

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. (18) There is no conclusive evidence supporting the use of nutrition support (EN or PN) in patients with severe dementia. (19)

Content of a teaching program for patients/caregivers discharged on home parenteral nutrition (HPN) should include: (18)

- Indication for HPN: short and/or long-term goals and HPN-regimen.
- Issues around informed consent.
- Role of the home care provider to provide parenteral formulations, equipment, supplies, and eventually nursing care.
- Determine learning abilities and readiness to self-management and self-monitoring.
    - If applicable: make a checklist for competencies achieved
- Reviewing evidence-based written policies and procedures complemented with oral instructions.
- Home care environment
    - General cleanliness (for example: Is there a clean area for aseptic/sterile procedures?)
    - Presence of animals
    - Basic home safety (telephone access, clean storage for supplies, dedicated refrigerator, toilet-bathroom, sanitary water supply, …)
- Catheter care
    - Principles of infection control and prevention (including aseptic techniques)
    - Preventing, recognizing and managing catheter related complications
    - Site care
- Storage, handling, inspection of admixtures (e.g., leaks, labels, precipitates, color), ancillaries and (medication) supplies.
- If applicable:
    - Safe addition of vitamins, trace elements or other additives
    - Safe administration of HPN
    - Connecting and disconnecting IV tubing to the vascular access device
    - Pre/post infusion flushing
    - Periodically assessment of performance/compliance with aseptic techniques
- Pump use, programming, pump care and troubleshooting.

- Preventing, recognizing and managing non-infectious related complications or problems most common mistakes.
- Available contact resources and post discharge support from the HPN center as well as the home care provider.
- Self HPN monitoring.
- Concomitant drug therapy and administration mode (total regimen management).

Parameters to be monitored and frequency of monitoring for HPN: (18)
- Monitoring should comprise of nutritional efficacy, tolerance of PN, patient/caregiver management of infusion catheter, quality of life (QoL), and quality of care (e.g., catheter-related bloodstream infection rate, readmission rate, etc.).
- In clinically stable patients on long-term HPN, body weight, body composition and hydration status, energy and fluid balance and biochemistry (hemoglobin, ferritin, albumin, C-reactive protein, electrolytes, venous blood gas analysis, kidney function, liver function and glucose) should be measured at all the scheduled (e.g., every three to six months).
- In patients on long-term HPN, clinical signs and symptoms as well as biochemical indexes of vitamin and trace metal deficiency or toxicity should be evaluated at least once per year.
- In patients on long-term HPN, bone metabolism and bone mineral density should be evaluated annually or in accordance with accepted standards (e.g., DXA at max. every 18 months).

Contraindications for HPN support in cancer patients include: (18)
- Patients not adequately informed about the aims of HPN, of its limited benefits and potential complications.
- Patients not informed of their predicted prognosis, or of the possibility of changing/ withdrawing the treatment when it becomes futile.
- Patients not sufficiently metabolically stable to be discharged home on PN.

<u>Practice Guidelines and Position Statements: Enteral Nutrition and Parenteral Nutrition</u>
National Comprehensive Cancer Network (NCCN)
The NCCN guidelines (v.1.2026) 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)

<u>National Institute for Health and Care Excellence (NICE)</u>
In 2017, the NICE updated their clinical guidelines on EN and PN. This states:
- 1.5.5 “People having PN in the community need regular assessment and monitoring. This should be carried out by home care specialists and by experienced hospital teams…they should be reviewed at a specialist hospital clinic every 3 to 6 months. Monitoring should be more frequent during the early months of home parenteral nutrition, or if there is a change in clinical condition.

- 1.5.6 People having oral nutrition support and/or enteral tube feeding in the community should be monitored by healthcare professionals with the relevant skills and training in nutritional monitoring. This group of people should be monitored every 3 to 6 months or more frequently if there is any change in their clinical condition." (21)

Expert consensus statements from the International Safety and Quality of Parenteral Nutrition Summit- 2024

The consensus statements are the collective opinion of the panel members and form best-practice guidance. (22) The authors intend that this guidance may help to improve the safety and quality of PN in a variety of settings by bridging the gap between published guideline recommendations and common practical issues. Below are statements regarding safety and quality related PN:

- 1. PN is used to provide nutrition therapy for patients when enteral feeding is not possible or sufficient. PN is always life saving or life sustaining. For optimal outcome, the PN formulation should meet the specific nutritional needs of a patient.
- 8. When more than one IV line is required, a dedicated PN IV infusion line is recommended. Medication should ideally be delivered on a separate IV line/lumen line owing to incompatibility risks and risks of infections. Aseptic handling of PN administration is required.

Additional Consensus Statements Related to Parenteral Nutrition in the Home Infusion Setting/Long-Term Parenteral Nutrition:

- 3. Engage the patient/caregiver to become an active participant in their care.
    - PN consumers should receive clear information about their PN regimen and safety (e.g., catheter hygiene). Ensure that information provided is understandable by laypeople. Multiple tools and channels of communication may be helpful.
    - Quality of life should be regularly assessed in patients with HPN and integrated into the care plan. When assessing quality of life consider outcomes meaningful for patients and regularly follow-up on the patient's perspective.
    - To foster adherence, the clinical and therapeutic PN regimen needs to be balanced with patients' lifestyle, personal needs, and goals. (22)

European Society for Clinical Nutrition and Metabolism (ESPEN)

ESPEN Guidelines on Chronic Intestinal Failure in Adults. 2023 (12)

#	Statement	SOR
2	We recommend regular audit of therapy and outcomes against standards to ensure safety and efficacy of an HPN programme.	Strong
4	We recommend that prior to discharge, patients are metabolically stable, able to physically and emotionally cope with the HPN therapy and have an adequate home environment.	Strong

6	We recommend that patient/caregiver training for HPN management be patient-centred with a multidisciplinary approach, together with written guidelines. HPN training may take place in hospital or at home.	Strong
9	We recommend that quality of life for HPN patients be regularly measured using validated tools as part of standard clinical care. Quality of care should be assessed regularly according to recognized criteria.	Strong
12	We recommend that the protein and energy requirements for CIF patients be based on individual patient characteristics (e.g., intestinal absorptive capacity as estimated by gastrointestinal anatomy and/or underlying disease) and specific needs (e.g., acute illness, protein malnutrition), and that the adequacy of the regimen is regularly evaluated through clinical, anthropometric, and biochemical parameters.	Strong
79	We recommend that access to the upper vena cava is the first choice for CVC placement, via internal jugular vein or subclavian vein.	Strong
81	We recommend that the tip of the catheter be placed at the level of the right atrial-superior vena cava junction.	Strong

HPN: home parenteral nutrition; CIF: chronic intestinal failure; CVC: central venous catheter.

Intradialytic Parenteral Nutrition (IDPN)

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)

The guideline also states “If IDPN therapy in conjunction with oral intake does not achieve the nutritional requirements of the patient or the gastrointestinal tract is impaired, TPN given on a daily basis should be considered.”

ESPEN

The 2024 ESPEN guideline on clinical nutrition in patients with acute or chronic kidney disease states, “Although the gastrointestinal route is the preferred choice for nutritional supplementation, parenteral provision of nutrients during hemodialysis is a safe and convenient approach for individuals who cannot tolerate oral or enteral administration of nutrients… Because of its non-superiority to ONS, and its time limitation (hemodialysis is usually 4 h three times a week), IDPN may be a reasonable treatment option for patients who fail to respond or

cannot receive recommended treatments, but the widespread use of IDPN before trying counseling and ONS does not appear warranted." (23)

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." (24)

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, B4081, B4082, B4083, B4087, B4088, B4102, B4103, B4104, B4105, B4148, B4149, B4150, B4152, B4153, B4154, B4155, B4157, B4158, B4159, B4160, B4161, B4162, B4164, B4168, B4172, B4176, B4178, B4180, B4185, B4187, 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
01/01/2026	Document updated. The following changes were made to Coverage: 1) Removed age limit on use of Relizorb; 2) Revised coverage criteria for enteral nutrition; 3) Revised coverage criteria for parenteral nutrition; 4) Removed section on INTRAPERITONEAL AMINO ACIDS. Added references 1, 7, 8, 16, 21-23, 25, and 26; others removed.

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 years 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 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