



MEDICAL POLICY No. 91517-R5

PARENTERAL NUTRITIONAL THERAPY

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Date of Origin: August 9, 2006

Status: Current

Summary of Changes

Additions:

- Added section I. C. Exclusions
- Added section II. GOVERNMENTAL REGULATIONS
 - Added the following direction for Medicare members within section II. GOVERNMENTAL REGULATIONS:

Note: All Medicare coverage authorization requests for Parenteral Nutrition should be submitted to the Pharmacy department. Instructions for pharmacy coverage authorization requests can be found here.

Deletions:

- Deleted the following note from top of policy:

Note: This policy incorporates Intradialytic Parenteral Nutrition (IDPN) criteria formerly part of the End Stage Renal Disease (ESRD) & Home Hemodialysis Medical Policy #91526 now known as "End Stage Renal Disease (ESRD): Renal Dialysis".

Clarifications:

- Restructured section I. POLICY/CRITERIA for enhanced clarity.

I. POLICY/CRITERIA

A. Home parenteral nutrition

1. **Inclusions:** Home parenteral nutrition may be considered medically necessary when member meets **both a and b**:
 - a. **Malabsorptive condition:** Member has a structural or functional gastrointestinal tract disease or condition resulting in insufficient absorption of nutrients to maintain adequate strength and weight that cannot be corrected by modifying the nutrient composition of the enteral/oral diet (e.g., lactose-free) or utilizing pharmacologic means to treat the etiology (e.g., pancreatic enzymes or botulinum toxin*).

Specific malabsorptive conditions include, but are not limited to, the following:

- Crohn's disease

- Newborn infants with catastrophic gastrointestinal anomalies such as tracheoesophageal fistula, gastroschisis, omphalocele, or massive intestinal atresia
- Infants and young children who fail to thrive due to short bowel syndrome, malabsorption, or chronic idiopathic diarrhea
- Short bowel syndrome secondary to massive small bowel resection
- Prolonged paralytic ileus after major surgery or multiple injuries
- Radiation enteritis
- Chronic or severe acute pancreatitis when a feeding tube cannot be placed or tube feeding is not tolerated
- Hyperemesis Gravidarum (severe hyperemesis during pregnancy) when a feeding tube cannot be placed or tolerated.
- Obstruction secondary to stricture or neoplasm of the esophagus or stomach, where a feeding tube cannot be placed beyond the obstruction
- Small bowel obstruction that cannot be bypassed by a feeding tube
- Malabsorption due to enterocolic, enterovesical, or enterocutaneous fistulas (parenteral nutrition being temporary until the fistula is repaired)
- Motility disorder (pseudo-obstruction)

b. at least one of the following:

- i. > 10% loss of body weight over three-months or less
- ii. Serum albumin concentration < 3.4 g/dl
- iii. The clinical record demonstrates that the patient cannot be maintained on enteral feedings.

*Note: Botulinum toxin and total parenteral nutrition (TPN) will not be authorized together for the treatment of gastroparesis.

2. **Equipment:** If the criteria for parenteral nutrition are met, medically necessary nutrients, administration supplies, and equipment are considered medically necessary.
3. **Prior authorization period:** Initial authorization will not exceed three months and continuing authorization is required at least every three months.
4. **Exclusions:** Home intravenous parenteral nutrition is considered not medically necessary in circumstances including, but not limited to, the following:
 - a. To increase protein or caloric intake in addition to the patient's daily diet
 - b. For routine pre- and/or postoperative care

- c. Patients with functional GI tracts including but not limited to the following:
 - i. Disorders that induce anorexia including cancer
 - ii. Swallowing disorders
 - iii. A temporary defect in gastric emptying such as a metabolic or electrolyte disorder.
 - iv. A psychological disorder impairing food intake such as depression or anorexia nervosa.
 - v. A physical disorder impairing food intake such as dyspnea of severe pulmonary or cardiac disease.
 - vi. A side effect of a medication
 - vii. Renal failure or dialysis.

B. Intradialytic Parenteral Nutrition (IDPN), including intraperitoneal nutrition (IPN)

1. **Inclusions:** IDPN, including IPN, may be considered medically necessary when all of the following apply:
 - a. member has end stage renal disease (ESRD)
 - b. member has one of the following:
 - i. serum albumin < 3.4 g/dl
 - ii. protein < 6 g/dl and one of the following:
 - BMI < 18.5 kg/m² or
 - Unintentional weight loss > 10% within last 6 months or
 - BMI < 20 kg/m² and unintentional weight loss > 5% within last 3-6 months
2. **Prior authorization period:** Clinical re-evaluation is required after six months for consideration of continued treatment

C. Exclusions

Parenteral nutritional therapy or intravenous therapy is considered NOT medically necessary if any of the following apply:

- A prescription is not required.
- Doctor approval is not required.
- Entity providing such therapy has indicated that insurance does not cover its therapies or products.
- Entity providing such therapy has stipulated that the services it provides have not been evaluated by the Food and Drug

Administration, or that its products are not intended to diagnose, treat, cure or prevent any disease.

II. GOVERNMENTAL REGULATIONS

Centers for Medicare & Medicaid Services (CMS)

National Coverage Determinations (NCDs)	
None identified	
Local Coverage Determinations (LCDs)	
CGS Administrators, LLC	Parenteral Nutrition L38953 A58836
First Coast Service Options, Inc.	None identified
National Government Services, Inc.	None identified
Noridian Healthcare Solutions, LLC	Parenteral Nutrition L38953 A58836
Novitas Solutions, Inc.	None identified
Palmetto GBA	None identified
WPS Insurance Corporation	None identified

Note: All Medicare coverage authorization requests for Parenteral Nutrition should be submitted to the Pharmacy department. Instructions for pharmacy coverage authorization requests can be found [here](#).

III. MEDICAL NECESSITY REVIEW

Prior authorization for certain drugs, services, and procedures may or may not be required. In cases where prior authorization is required, providers will submit a request demonstrating that a drug, service, or procedure is medically necessary. For more information, please refer to the [Priority Health Provider Manual](#).

IV. APPLICATION TO PRODUCTS

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

- ❖ **HMO/EPO:** *This policy applies to insured HMO/EPO plans.*
- ❖ **POS:** *This policy applies to insured POS plans.*
- ❖ **PPO:** *This policy applies to insured PPO plans. Consult individual plan documents as state mandated benefits may apply. If there is a conflict between this policy and a plan document, the provisions of the plan document will govern.*
- ❖ **ASO:** *For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern.*
- ❖ **INDIVIDUAL:** *For individual policies, consult the individual insurance policy. If there is a conflict between this medical policy and the individual insurance policy document, the provisions of the individual insurance policy will govern.*

- ❖ **MEDICARE:** *Coverage is determined by the Centers for Medicare and Medicaid Services (CMS) and/or the Evidence of Coverage (EOC); if a coverage determination has not been adopted by CMS, this policy applies.*
- ❖ **MEDICAID/HEALTHY MICHIGAN PLAN:** *For Medicaid/Healthy Michigan Plan members, this policy will apply. Coverage is based on medical necessity criteria being met and the appropriate code(s) from the coding section of this policy being included on the Michigan Medicaid Fee Schedule located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_42542_42543_42546_42551-159815--,00.html. If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_5100-87572--,00.html, the Michigan Medicaid Provider Manual will govern. If there is a discrepancy or lack of guidance in the Michigan Medicaid Provider Manual, the Priority Health contract with Michigan Medicaid will govern. For Medical Supplies/DME/Prosthetics and Orthotics, please refer to the Michigan Medicaid Fee Schedule to verify coverage.*

IV. DESCRIPTION

Parenteral Nutrition (PN)

Parenteral Nutritional Therapy (PNT) refers to the intravenous administration of nutrients, either through a central or peripheral vein, bypassing the gastrointestinal (GI) tract entirely. It is used when a patient is unable to receive adequate nutrition through oral or enteral (tube feeding) routes due to severe dysfunction or disease of the GI system. The purpose of initiating parenteral nutritional therapy is to prevent or correct specific nutrient deficiencies and to prevent the adverse effects of malnutrition when the gastrointestinal tract cannot be used effectively or safely.

Generally, the parenteral approach is considered medically necessary only if adequate nutritional intake is not possible via the oral or tube-feeding route.

A daily caloric intake for adults of 20-40 kcal/kg is generally sufficient to maintain body weight. If less than 20-30 kcal/kg per day it may be considered supplemental.

Parenteral nutritional therapy is covered as defined above for patients with 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.

Intradialytic Parenteral Nutrition (IDPN) for ESRD

Intradialytic Parenteral Nutrition (IDPN) is a specialized form of parenteral nutrition administered during dialysis sessions, primarily used to treat protein-calorie malnutrition in patients with end-stage renal disease (ESRD) undergoing hemodialysis.

Malnutrition is common in patients with ESRD due to factors such as poor eating habits and loss of nutrients during dialysis. Maintaining adequate nutrition in patients undergoing hemodialysis is vital, as a number of nutritional parameters are associated with increased mortality, including low body fat, fat loss over time, low body mass index (BMI) ($< 20 \text{ kg/m}^2$), reduced serum albumin levels, and reduced creatinine levels. In the 1980s, a trend began in which decisions regarding the use of IDPN in the United States were empirically based, and, although this was controversial, IDPN gained approval through the Centers for Medicaid & Medicare Services as a Medicare-covered benefit. As IDPN use expanded, the increasing use and associated costs attracted scrutiny, due to the limited evidence base that supported IDPN use. Accordingly, in 1994, Medicare coverage of IDPN was tightened and then further restricted in 1996, which resulted in a decline in its use. Several manufacturers produce premixed bags for IDPN, or components of a formulation can be made up on site from previously prepared ingredients. IDPN formulas generally contain a mix of amino acids, carbohydrate (usually dextrose), and lipids. Trace elements and multivitamins may also be included. IDPN may be considered for hemodialysis patients who show physical wasting and significant weight loss; have serum hypoalbuminemia (low albumin) and/or other markers of malnutrition; have failed to respond to oral nutrition supplements; have failed, or are contraindicated, for enteral feeding; and whose caloric and/or protein intake is insufficient to meet recommended daily requirements. IDPN is given at the same time as hemodialysis by a dialysis nurse or other licensed healthcare practitioner, at an outpatient center. IDPN is infused through an existing dialysis access catheter or site, via an infusion pump; no additional needle stick or line is necessary.

The results of three comparative retrospective studies suggest that IDPN for up to 1 year in duration may reduce mortality in malnourished patients undergoing hemodialysis. In contrast, the results of the single prospective randomized study conducted in France, provide strong evidence that there is no reduction in mortality for 1 year of IDPN plus oral nutritional supplementation compared with oral nutritional supplementation alone. Despite the lack of strong evidence, IDPN is an established therapy and it is possible that it offers potential advantages to a subset of malnourished patients in ESRD; however, prospective studies are needed to define these subpopulations.

Companies that market intravenous wellness treatments and therapies directly to consumers have emerged. An example of such a company is [Drip Hydration](#). Such companies provide numerous products that may be shipped directly to the consumer, administered by staff at the consumer's home, or administered by staff at a company facility. The following typically apply for such treatments:

- A prescription is not required.
- Doctor approval is not required.

- Entity providing such therapy has indicated that insurance does not cover its therapies or products.
- Entity providing such therapy has stipulated that the services it provides have not been evaluated by the Food and Drug Administration, or that its products are not intended to diagnose, treat, cure or prevent any disease.

Because of the above conditions, such therapies and services are considered not medically necessary and therefore excluded from coverage.

V. CODING

ICD-10 Codes that may apply

E08.43	Diabetes mellitus due to underlying condition with diabetic autonomic (poly) neuropathy
E09.43	Drug or chemical induced diabetes mellitus with neurological complications with diabetic autonomic (poly) neuropathy
E10.43	Type 1 diabetes mellitus with diabetic autonomic (poly) neuropathy
E11.43	Type 2 diabetes mellitus with diabetic autonomic (poly) neuropathy
E13.43	Other specified diabetes mellitus with diabetic autonomic (poly) neuropathy
E46	Unspecified protein-calorie malnutrition
E64.0	Sequelae of protein-calorie malnutrition
K31.6	Fistula of stomach and duodenum
K31.84	Gastroparesis
K31.89	Other diseases of stomach and duodenum
K50.00 - K50.919	Crohn's disease
K51.012 - K51.919	Ulcerative colitis
K56.0	Paralytic ileus
K56.2	Volvulus
K56.50	Intestinal adhesions [bands] with obstruction (post procedural) (post infection)
K56.600	Unspecified intestinal obstruction
K56.690	Other intestinal obstruction
K56.7	Ileus, unspecified
K60.3	Anal fistula
K60.4	Rectal fistula
K60.5	Anorectal fistula
K63.1	Perforation of intestine (nontraumatic)
K63.2	Fistula of intestine
K63.9	Disease of intestine, unspecified
K90.49	Malabsorption due to intolerance, not elsewhere classified
K90.89	Other intestinal malabsorption
K90.9	Intestinal malabsorption, unspecified
K91.2	Postsurgical malabsorption, not elsewhere classified
K91.850	Pouchitis
K91.858	Other complications of intestinal pouch
K92.9	Disease of digestive system, unspecified

K94.01	Colostomy hemorrhage
K94.09	Other complications of colostomy
K94.11	Enterostomy hemorrhage
K94.19	Other complications of enterostomy
O21.1	Hyperemesis gravidarum with metabolic disturbance
P77.1 – P77.9	Necrotizing enterocolitis in newborn
Q43.0 – Q43.9	Other congenital malformations of intestine
Q79.2	Exomphalos
Q79.3	Gastrochisis
T81.83xA - T81.83xS	Persistent post procedural fistula

CPT/HCPCS Codes:

Presence of codes on this list does not guarantee coverage.

**Not Covered for Medicaid*

B4164*	Parenteral nutrition solution: carbohydrates (dextrose), 50% or less (500 ml = 1 unit), home mix
B4168*	Parenteral nutrition solution; amino acid, 3.5%, (500 ml = 1 unit) - home mix
B4172*	Parenteral nutrition solution; amino acid, 5.5% through 7%, (500 ml = 1 unit) - home mix
B4176*	Parenteral nutrition solution; amino acid, 7% through 8.5%, (500 ml = 1 unit) - home mix
B4178*	Parenteral nutrition solution: amino acid, greater than 8.5% (500 ml = 1 unit), home mix
B4180*	Parenteral nutrition solution: carbohydrates (dextrose), greater than 50% (500 ml = 1 unit), home mix
B4185	Parenteral nutrition solution, per 10 grams lipids
B4189	Parenteral nutrition solution: compounded amino acid and carbohydrates with electrolytes, trace elements, and vitamins, including preparation, any strength, 10 to 51 g of protein, premix
B4193	Parenteral nutrition solution: compounded amino acid and carbohydrates with electrolytes, trace elements, and vitamins, including preparation, any strength, 52 to 73 g of protein, premix
B4197	Parenteral nutrition solution; compounded amino acid and carbohydrates with electrolytes, trace elements and vitamins, including preparation, any strength, 74 to 100 grams of protein - premix
B4199	Parenteral nutrition solution; compounded amino acid and carbohydrates with electrolytes, trace elements and vitamins, including preparation, any strength, over 100 grams of protein - premix
B4216*	Parenteral nutrition; additives (vitamins, trace elements, Heparin, electrolytes), home mix, per day
B4220	Parenteral nutrition supply kit; premix, per day
B4222*	Parenteral nutrition supply kit; home mix, per day
B4224	Parenteral nutrition administration kit, per day
B5000*	Parenteral nutrition solution: compounded amino acid and carbohydrates with electrolytes, trace elements, and vitamins, including preparation, any strength, renal - Amirosyn RF, NephroAmine, RenAmine - premix
B5100*	Parenteral nutrition solution: compounded amino acid and carbohydrates with electrolytes, trace elements, and vitamins, including preparation, any strength, hepatic - FreAmine HBC, HepatAmine - premix

- B5200* Parenteral nutrition solution: compounded amino acid and carbohydrates with electrolytes, trace elements, and vitamins, including preparation, any strength, stress - branch chain amino acids- FreAmine-HBC - premix
- B9004 Parenteral Nutrition Infusion Pump, Portable
- B9006 Parenteral Nutrition Infusion Pump, Stationary
- E0791* Parenteral infusion pump, stationary, single or multichannel

- A4211* Supplies for self-administered injections

(Per diem "S" codes include payment for TPN solution, standard additives, supplies and equipment, coverage subject to contracted service)

- S9364 Home infusion therapy, total parenteral nutrition (TPN); administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment including standard TPN formula (lipids, specialty amino acid formulas, drugs other than in standard formula and nursing visits coded separately), per diem
- S9365 Home infusion therapy, total parenteral nutrition (TPN); 1 liter per day, administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment including standard TPN formula (lipids, specialty amino acid formulas, drugs other than in standard formula and nursing visits coded separately), per diem
- S9366 Home infusion therapy, total parenteral nutrition (TPN); more than 1 liter but no more than 2 liters per day, administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment including standard TPN formula (lipids, specialty amino acid formulas, drugs other than in standard formula and nursing visits coded separately), per diem
- S9367 Home infusion therapy, total parenteral nutrition (TPN); more than 2 liters but no more than 3 liters per day, administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment including standard TPN formula (lipids, specialty amino acid formulas, drugs other than in standard formula and nursing visits coded separately), per diem
- S9368 Home infusion therapy, total parenteral nutrition (TPN); more than 3 liters per day, administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment including standard TPN formula (lipids, specialty amino acid formulas, drugs other than in standard formula and nursing visits coded separately), per diem

VI. REFERENCES

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