

Medical Policy Bulletin

Title:

Total Parenteral Nutrition (TPN) / Intradialytic Parenteral Nutrition (IDPN) / Intraperitoneal Nutrition (IPN)

Policy #:

MA08.008g

The Company makes decisions on coverage based on the Centers for Medicare and Medicaid Services (CMS) regulations and guidance, benefit plan documents and contracts, and the member's medical history and condition. If CMS does not have a position addressing a service, the Company makes decisions based on Company Policy Bulletins. Benefits may vary based on contract, and individual member benefits must be verified. The Company determines medical necessity only if the benefit exists and no contract exclusions are applicable. Although the Medicare Advantage Policy Bulletin is consistent with Medicare's regulations and guidance, the Company's payment methodology may differ from Medicare.

When services can be administered in various settings, the Company reserves the right to reimburse only those services that are furnished in the most appropriate and cost-effective setting that is appropriate to the member's medical needs and condition. This decision is based on the member's current medical condition and any required monitoring or additional services that may coincide with the delivery of this service.

This Policy Bulletin document describes the status of CMS coverage, medical terminology, and/or benefit plan documents and contracts at the time the document was developed. This Policy Bulletin will be reviewed regularly and be updated as Medicare changes their regulations and guidance, scientific and medical literature becomes available, and/or the benefit plan documents and/or contracts are changed.

Policy

Coverage is subject to the terms, conditions, and limitations of the member's Evidence of Coverage.

When services can be administered in various settings, the Company reserves the right to reimburse only those services that are furnished in the most appropriate and cost-effective setting that is appropriate to the member's medical needs and condition. This decision is based on the member's current medical condition and any required monitoring or additional services that may coincide with the delivery of this service.

MEDICALLY NECESSARY

TOTAL PARENTERAL NUTRITION (TPN)

Initial Therapy for malnutrition

Total parenteral nutrition (TPN), for initial therapy, is considered medically necessary and, therefore, covered when **all** of the following are met:

- The individual is not able to maintain weight and strength commensurate with the individual's general condition
- The individual has been screened for malnutrition by a professional provider with appropriate skills and training
- The individual meets **one** of the following:
 - Currently having malnutrition based on **both** of the following:
 - Individual has **one** of the following:
 1. A body mass index (BMI) of less than 20 kg/m²
 2. Unintentional weight loss >5 percent within the past six months or >10 percent beyond six months
 3. Reduced muscle mass assessed by a validated body composition measuring technique (e.g., dual-energy absorptiometry, bioelectrical impedance, ultrasound computed tomography, magnetic resonance imaging, anthropometric measurements)
 - Individual has **one** of the following:
 1. Reduced food intake or assimilation of less than or equal to 50 percent of the individual's energy requirements for >1 week or any reduction for >2 weeks

2. Individual has any chronic gastrointestinal condition (e.g., dysphagia, diarrhea, nausea/vomiting, pancreatic insufficiency, gastroparesis) that adversely impacts food assimilation or absorption
 3. Individual has inflammation caused by acute disease/injury (e.g., major infection, burns, trauma, closed head injury) or related to chronic disease (e.g., malignancy, renal disease, heart failure, obstructive lung disease)
- Adult currently at risk for malnutrition based on **one** of the following:
 - The individual is eating little or nothing for more than five days and/or is likely to eat little or nothing for five days or longer
 - The individual has a poor absorptive capacity and/or high nutrient losses and/or increased nutritional needs from causes such as catabolism
 - The individual has experienced severe trauma or is experiencing severe acute illness that will contribute to the rapid development of malnutrition if left untreated
 - Child currently at risk for malnutrition based on **one** of the following:
 - Weight for length, weight for height, or sex less than 10th percentile
 - BMI for age or sex less than 5th percentile
 - Increased metabolic requirements that are unable to be adequately met either through the oral or enteral route
 - Impaired ability to ingest or tolerate oral feeding
 - Documented inadequate provision of or tolerance to nutrients
 - Inadequate weight gain or a significant decrease in usual growth percentile
 - Neonate currently at risk for malnutrition based on **one** of the following:
 - Preterm less than 28 weeks at birth (high risk) or 28-31 weeks (moderate risk)
 - Low birth weight less than 1000 g (high risk) or 1000-1500 g (moderate risk)
 - Infant establishing feeds after episode of necrotizing enterocolitis or gastrointestinal perforation (high risk)
 - Infants with severe congenital gastrointestinal malformations (high risk)
 - Intrauterine growth restriction (weight less than 9th percentile) (moderate risk)
 - Illness or congenital anomaly that may compromise feeding (moderate risk)
 - The individual's provider documents **one** of the following:
 - Enteral nutrition (EN) has been considered and ruled out
 - Enteral nutrition (EN) has been tried and been found ineffective
 - Enteral nutrition (EN) exacerbates gastrointestinal (GI) tract dysfunction
 - The individual has **one** of the following:
 - A condition involving the small intestine and/or its exocrine glands which significantly impairs the absorption of nutrients
 - A disease of the stomach and/or intestine which is a motility disorder and impairs the ability of nutrients to be transported through and absorbed by the GI system
 - A post-operative complication or condition that would require complete bowel rest (e.g., post-operative gastrointestinal anastomotic leak, gastrointestinal fistula)
 - The GI impairment or other cause of malnutrition is permanent*

*For an impairment to be considered to be permanent does not require a determination that there is no possibility that the individual's condition may improve sometime in the future. If, in the judgement of the provider, the impairment will be of long and indefinite duration, the test of permanence is considered met.

Continuation Therapy for Malnutrition

Total parenteral nutrition (TPN) continuation is considered medically necessary and, therefore, covered if the individual's evidence for malnutrition has stabilized or improved after the initial period of therapy based on screening by a professional provider and documented in the medical record. Weaning of TPN can begin when the individual is able to meet 50-75 percent of their caloric, protein, and micronutrient needs through oral and/or enteral intake unless there is an underlying condition that will preclude the individual from ever meeting 100 percent of their nutritional needs through oral and/or enteral intake (e.g., impaired gastrointestinal function).

Therapy for Hyperemesis Gravidarum (HG)

Total parenteral nutrition (TPN) is considered medically necessary and, therefore, covered when the individual has severe Hyperemesis Gravidarum (HG) when **all** of the following are met:

- Weight loss of more than five percent
- Other causes of nausea and/or vomiting have been ruled out (e.g., cholecystitis, gastroenteritis, gastroesophageal reflux, migraines, molar pregnancy)
- Inability to adequately control nausea and/or vomiting with the administration of pharmaceutical agents, unless deemed unsafe for the individual or fetus by the professional provider or the individual (e.g., antiemetics, vitamin B6, antihistamines, promotility agents, steroids)
- Inability to maintain or gain weight with the administration of oral or enteral nutrition (unless contraindicated or deemed unsafe for the individual by the professional provider due to an underlying comorbidity)

INTRADIALYTIC PARENTERAL NUTRITION (IDPN)

Intradialytic parenteral nutrition (IDPN) is considered medically necessary and, therefore, covered when it is infused as an alternative to a regularly scheduled regimen of TPN in individuals who meet the medical necessity criteria for TPN, not in addition to a regularly scheduled infusion of TPN.

For individuals with a functional gastrointestinal tract, IDPN is not covered under the medical benefit (Part B); however, IDPN, in members with a functional gastrointestinal tract, may be considered for coverage under the Pharmacy Benefit (Part D), if such a benefit exists.

INTRAPERITONEAL NUTRITION (IPN)

Total Parenteral Nutrition (TPN) for individuals on continuous ambulatory peritoneal dialysis (CAPD) is considered medically necessary and, therefore, covered in individuals who meet the medical necessity criteria for TPN.

SPECIAL FORMULATIONS OF PARENTERAL NUTRITION

Special nutrient formulas are produced to meet the unique nutrient needs for specific disease conditions. The individual's medical record must adequately document the specific condition and the necessity for the special nutrient.

ASSOCIATED SERVICES

When an infusion therapy service is covered, all associated services (e.g., solutions, additives, equipment and/or supplies, nursing) are considered covered and eligible for reimbursement.

When an infusion therapy service is noncovered, all associated services (e.g., solutions, equipment and/or supplies, nursing) are considered noncovered and ineligible for reimbursement.

REQUIRED DOCUMENTATION

For individuals who meet the criteria for TPN, a total daily caloric intake of 20-35 kcal/kg/day is considered sufficient to achieve or maintain appropriate body weight. A total daily protein intake of 0.8-2.0 g/kg/day is considered sufficient. The ordering professional provider must document the medical necessity for orders outside of these ranges. If the individual is at a high risk of developing refeeding issues, the TPN may need to be initiated at 50 percent of the target caloric and protein intake and be titrated up over the course of the first few days to weeks. A total fluid intake of 30-40 ml fluid/kg/d (account for extra output from drains or fistulas and additional input from other sources such as IV drugs) will be needed to maintain hydration status. If appropriate, electrolytes, minerals, and micronutrients may need to be added but should be individualized based on the individual's specific needs and comorbidities.

The ordering professional provider is required to evaluate the individual within 30 days prior to initiation of TPN. If the professional provider does not see the beneficiary within this timeframe they must document the reason why and describe what other monitoring methods were used to evaluate the individual's PN needs. There must be documentation in the medical record supporting the clinical diagnosis.

The Company may conduct reviews and audits of services to our members regardless of the participation status of the provider. Medical record documentation must be maintained on file to reflect the medical necessity of the care and services provided. These medical records may include but are not limited to: records from the professional provider's office, hospital, nursing home, home health agencies, therapies, and test reports. This policy is consistent with Medicare's documentation requirements, including the following required documentation.

STANDARD WRITTEN ORDER REQUIREMENTS

Before submitting a claim to the Company, the supplier must have on file a timely, appropriate, and complete order for each item billed that is signed and dated by the professional provider who is treating the member. Requesting a

provider to sign a retrospective order at the time of an audit or after an audit for submission as an original order, reorder, or updated order will not satisfy the requirement to maintain a timely professional provider order on file.

PROOF OF DELIVERY REQUIREMENTS

Medical record documentation must include a contemporaneously prepared delivery confirmation or member's receipt of supplies and equipment. The medical record documentation must include a copy of delivery confirmation if delivered by a commercial carrier and a signed copy of delivery confirmation by member/caregiver if delivered by the supplier/provider. All documentation is to be prepared contemporaneous with delivery and be available to the Company upon request.

CONSUMABLE SUPPLIES (WHEN APPLICABLE)

For items and supplies provided on a recurring basis, billing must be based on prospective, not retrospective use. For products that are supplied as refills to the original order, suppliers must contact the beneficiary, and document an affirmative response, prior to dispensing the refill and not automatically ship on a pre-determined basis, even if authorized by the beneficiary. This shall be done to ensure that the refilled item remains reasonable and necessary, existing supplies are expected to end, and to confirm any changes or modifications to the order. Contact with the beneficiary or designee regarding refills must take place no sooner than 30 calendar days prior to the expected end of the current supply. For delivery of refills, the supplier must deliver the product no sooner than 10 calendar days prior to the expected end of the current supply. This is regardless of which delivery method is utilized. Regardless of utilization, a supplier must not dispense more than a 1-month quantity at a time.

If required documentation is not available on file to support a claim at the time of an audit or record request, the durable medical equipment (DME) supplier may be required to reimburse the Company for overpayments.

Guidelines

MEDICARE DETERMINATION

This policy is consistent with Medicare's coverage determination. The Company's payment methodology may differ from Medicare.

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable Evidence of Coverage, total parenteral nutrition (TPN), intradialytic parenteral nutrition (IDPN), and intraperitoneal nutrition (IPN) are covered under the medical benefits of the Company's products when the medical necessity criteria listed in this medical policy are met.

For individuals with a functional gastrointestinal tract, IDPN is not covered under the medical benefit (Part B); however, IDPN, in members with a functional gastrointestinal tract, may be considered for coverage under the Pharmacy Benefit (Part D), if such a benefit exists.

MACRONUTRIENTS

The following tables are examples of ranges for macronutrients for adult and pediatric individuals. The macronutrients for an individual should be determined based upon their clinical situation.

Macronutrients for Adult Individuals

Clinical State	Daily Protein Intake (g/kg)	Daily Energy Intake (kcal/kg)	Dextrose Intake (mg/kg/min)	Daily Fat Emulsions (g/kg)	Daily Fluid Intake (ml/kg)
Stable	0.8-1.5	20-35	4-5	1	30-40
Critically ill	1.2-2.5	12-25 in the early ICU stay	<3-4	<1	Minimal to provide adequate macronutrients
Burns	1.5-2.0	20-30	4-5	1	30-40
Open abdomen	Additional 15-30 g/L exudate	20-30	4-5	1	30-40
Acute kidney injury	0.8-2.0	20-30	4-5	1	30-40

Continuous renal replacement therapy	Additional 0.2 g/kg/d not to exceed 2.5 g/kg/d	25-35	4-5	1	30-40
Chronic Kidney Disease (CKD) stages 3-5 without diabetes	0.55-0.60	25-35	4-5	1	30-40
CKD stages 3-5 with diabetes	0.6-0.8	25-35	4-5	1	30-40
CKD 5D on maintenance hemodialysis or peritoneal dialysis	1.2-1.5	25-35	4-5	1	30-40
Hepatic failure	1.2-2.0 based on "dry" weight and tolerance	20-30	4-5	1	30-40
Obese	2.0-2.5 based on ideal body weight (IBW)	22-25 based on IBW	4-5	1	30-40

Macronutrients for Pediatric Individuals

Macronutrients for Pediatric Individuals						
Infants (<1yr)	Initiation		Advance by		Goals	
	Preterm	Term	Preterm	Term	Preterm	Term
Daily Protein Intake (g/kg) (use higher end of range for critically ill)	1.5	1.5	N/A	N/A	2.5-3.5	3.0
Dextrose Intake (mg/kg/min)	4-8	2.5-5.0	Increase gradually over 2-3 days	Increase gradually over 2-3 days	8-10 (max 12)	5-10 (max 12)
Daily Fat Emulsions (g/kg)	0.5-1.0	0.5-1.0	0.5-1.0	0.5-1.0	3-4	2.5-4.0
Children (1 to 10 yrs) Stable (Critically ill-when different)						
Daily Protein Intake (g/kg)	1		N/A		1-2 (use higher end of range for critically ill)	
Dextrose Intake (mg/kg/min)	3-6		1-2		8-10	
Daily Fat Emulsions (g/kg)	1-2		0.5-1.0		2-3 (2-4 with monitoring of triglycerides)	
Adolescents (11 to <18 yrs) Stable (Critically ill-when different)						
Daily Protein Intake (g/kg)	1		N/A		1-2 (use higher end of range for critically ill)	
Dextrose Intake (mg/kg/min)	2.5-3.0		1-2		5-6	
Daily Fat Emulsions (g/kg)	1		1		1-2 (2-4 with monitoring of triglycerides)	

Description

Malnutrition is defined in American Society for Parenteral and Enteral Nutrition (ASPEN) guidelines as: “an acute, subacute, or chronic state of nutrition in which a combination of varying degrees of overnutrition or undernutrition, with or without inflammatory activity, has led to a change in body composition and diminished function”. The malnutrition can have any number of causes including, but not limited to, anorexia, intestinal disease/failure, acute/chronic pancreatitis, burns, trauma, and sepsis. The malnutrition can be the result of inadequate intake of nutrients, increased requirements for nutrients, altered/impaired absorption of nutrients, altered/impaired transportation of the nutrients through the gastrointestinal tract, or altered/impaired utilization of the nutrients by the body.

TOTAL PARENTERAL NUTRITION (TPN)

Malnutrition exists when there is a deficiency of nutrients such as protein, energy, and micronutrients that cause adverse effects on an individual's body function, body composition, or on the individual's clinical outcome or vulnerability to additional adverse effects or events. Strategies to improve or maintain adequate nutrition include the administration of oral nutritional supplements (ONS), enteral nutrition (EN) where the nutrition is infused directly into the gastrointestinal (GI) tract through a tube or catheter, or parenteral nutrition (PN). Parenteral nutrition (PN) is the provision of nutritional requirements intravenously. PN is administered through a central intravenous line access or a peripherally inserted central catheter (PICC), often in the home. An infusion pump regulates the flow of the solution on either a continuous (24-hour) or intermittent schedule. PN consists of the optimal levels of glucose, amino acids, electrolytes, vitamins, minerals, and fats; the concentration of each component is calculated for the individual's specific metabolic need. The benefit of PN is that it is a life-sustaining source of nutrition for individuals who are unable to meet their nutritional needs through an oral or enteral route, usually due to impaired gastrointestinal tract function. The use of PN may be temporary, such as an individual who experiences hyperemesis gravidarum (HG), or it may be permanent, such as an individual with intestinal failure. PN can be infused during hemodialysis or peritoneal dialysis, in certain circumstances. When nutritional support, other than the oral route is necessary, enteral nutrition (EN) is usually initially preferable to parenteral nutrition (PN) for the following reasons:

- In a fluid-restricted individual, EN permits delivery of all necessary nutrients in a more concentrated volume than PN
- Enteral nutrition allows for safer home delivery of nutrients
- Enteral nutrition lowers the risk of central line-associated bloodstream infections (CLABSI)
- Even small amounts of EN can help support and maintain intestinal function

INTRADIALYTIC PARENTERAL NUTRITION (IDPN)

Protein-energy wasting (PEW) is the term used for the loss of body protein mass and fuel reserves seen in chronic kidney disease (CKD). PEW is associated with increased morbidity and mortality among individuals with CKD. PEW can be diagnosed if certain characteristics are present in an individual. These include, but are not limited to, low serum albumin, reduced body mass (low/reduced body/fat mass or weight loss associated with the reduced intake of protein and/or energy), and reduced muscle mass (muscle wasting). According to the literature, the prevalence of PEW in individuals on chronic hemodialysis (HD) ranges from 20-70 percent. The prevalence increases with the individual's age and number of years on HD. It is estimated that the annual mortality rate is between 20-30 percent for individuals undergoing HD who are malnourished. The life expectancy for these individuals is 3-11 years shorter than individuals not on chronic HD.

Many factors associated with renal failure can contribute to PEW in individuals receiving chronic HD. These can include decreased oral intake/anorexia, dietary restrictions, loss of nutrients (including amino acids) during HD, loss of water-soluble vitamins during HD, loss of blood during HD, loss of electrolytes during HD, uremic toxicity, physical inactivity, metabolic acidosis, impaired lipolysis, gastrointestinal issues (impaired absorption of nutrients, gastroparesis), endocrine issues (increased leptin levels, peripheral insulin resistance, hyperparathyroidism), protein catabolism, and chronic microinflammation. Feeding through the gastrointestinal tract is the preferred route for nutritional intake, but if that is not possible, then parenteral nutrition is an alternative.

Intradialytic parenteral nutrition is the administration of parenteral nutrition while the individual is undergoing HD. The parenteral nutrition is infused three times a week through the venous line. Some benefits of IDPN include reduced protein catabolism, improved nutritional parameters (e.g., albumin, prealbumin), some parameters that improve quality of life for the individual, decreased PEW-related complications including mortality, and IDPN may reduce hospitalization rates. Some drawbacks to infusing IDPN during HD include that clinical studies have been unable to demonstrate an improvement in the individuals' overall nutritional status, an improvement in most quality-of-life

parameters, or an overall increase in the two-year survival of individuals receiving IDPN along with oral nutritional supplements (ONS) as well as the possibility of adverse effects occurring due to the rapid infusion of glucose and lipids during a HD session. It is therefore recommended that individuals on HD with severe PEW receive daily PN if their nutritional needs cannot be supplied by the oral or enteral route.

INTRAPERITONEAL NUTRITION (IPN)

Many of the same factors contributing to PEW in individuals on chronic HD can also affect individuals receiving continuous abdominal peritoneal dialysis (CAPD). Usually, however, individuals on CAPD have better residual renal function, metabolic abnormalities are not as severe, and uremic toxicity is less pronounced. There are some unique issues associated with CAPD that can contribute to PEW including significant losses of proteins and protein-bound nutrients during CAPD, the presence of dialysate in the abdomen may cause the individual to feel full and lead to a decreased oral intake, there can be slow gastric emptying which can decrease the appetite, and the absorption of glucose from the CAPD exchange solution can not only decrease the individual's appetite but it can also increase the percentage of body fat while masking the loss of lean body mass. The increased glucose levels can also induce or aggravate diabetes and hypertriglyceridemia, as well as increase low-density lipoprotein (LDL) and very low-density lipoprotein (VLDL) cholesterol levels. Intraperitoneal nutrition (IPN) is the substitution of a regular exchange with an exchange containing increased amino acids. This is usually done during one dialysate exchange daily into the peritoneal cavity. Studies have found that IPN does improve nutritional parameters in malnourished individuals. There are currently no commercially available amino acid-based solutions for intraperitoneal nutrition in the US.

HYPEREMESIS GRAVIDARUM (HG)

Hyperemesis gravidarum (HG) is defined as vomiting during pregnancy that is so protracted and severe that the individual experiences some, or all, of the following: weight loss, dehydration, starvation acidosis, alkalosis from vomiting, and electrolyte derangement. The incidence in the US is estimated to be about 0.5 percent of live births. Some of the risk factors for HG include a personal history of HG, fetal anomalies, a female fetus, a diet high in saturated fat prior to pregnancy, gestational trophoblastic disease, and multiple pregnancies. Some factors associated with HG include slow gastric emptying due to abnormal thyroid hormones during pregnancy, the size of the placental mass, a *Helicobacter pylori* infection, and high levels of human chorionic gonadotropin (hCG). Severe complications due to HG can include esophageal tears/rupture, retinal hemorrhage, intrauterine growth retardation/low fetal birth weight, pneumothorax/pneumomediastinum, Wernicke's encephalopathy, and maternal/fetal death.

References

American Gastroenterological Association. American Gastroenterological Association medical position statement: guidelines for the use of enteral nutrition. *Gastroenterology*. 1995;108:1280-1301.

American Gastroenterological Association. American Gastroenterological Association medical position statement: parenteral nutrition. *Gastroenterology*. 2001;121(4):966-969.

American Society for Parenteral and Enteral Nutrition (ASPEN). Appropriate dosing for parenteral nutrition: ASPEN recommendations. [ASPEN web site]. 11/17/2020. Available at: https://www.nutritioncare.org/uploadedFiles/Documents/Guidelines_and_Clinical_Resources/PN Dosing 1-Sheet-Nov 2020-FINAL.pdf. Accessed October 28, 2024.

Burkart JM. Nutritional status and protein intake in peritoneal dialysis patients. [Up To Date web site]. 08/08/2024. Available at: https://www.uptodate.com/contents/nutritional-status-and-protein-intake-in-patients-on-peritoneal-dialysis?search=Nutritional status and protein intake in peritoneal dialysis patients&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1 [via subscription only]. Accessed October 28, 2024.

Brown RO, Compher C, 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):366-377.

Cano NJM, Aparicio M, Brunori G, et al. ESPEN guidelines on parenteral nutrition: adult renal failure. *Clin Nutr*. 2009;28:401-414.

Cano NJM, Fouque D, Roth H, et al. Intradialytic parenteral nutrition does not improve survival in malnourished hemodialysis patients: a 2-year multicenter, prospective, randomized study. *J Am Soc Nephrol*. 2007;18(9):2583-

2591.

Cederholm T, Jensen GL, Correia MITD, et al. GLIM criteria for the diagnosis of malnutrition - a consensus report from the global clinical nutrition community. *J Cachexia Sarcopenia Muscle*. 2019;10:201-217.

Centers for Medicare & Medicaid Services (CMS). Medicare Benefit Policy Manual. Chapter 15 Covered medical and other health services. 120 - Prosthetic devices (Rev. 1, 10-01-03). Available at: <https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/bp102c15.pdf>. Accessed October 28, 2024.

Centers for Medicare & Medicaid Services (CMS). Medicare Claims Processing Manual. Chapter 8. Outpatient ESRD hospital, independent facility, and physician/supplier claims. 02/22/2024. Available at: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS018912>. Accessed October 28, 2024.

Centers for Medicare & Medicaid Services (CMS). Medicare Claims Processing Manual. Chapter 20. Durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). 03/28/2024. Available at: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS018912>. Accessed October 28, 2024.

Centers for Medicare & Medicaid Services (CMS). Medicare Prescription Drug Benefit Manual. Chapter 6. Part D drugs and formulary requirements. 01/15/2016. Available at: https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/pub100_18.pdf. Accessed October 28, 2024.

Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD) 180.2: Enteral and parenteral nutritional therapy – RETIRED. 04/10/2023. Available at: <https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=242&ncdver=3&bc=0>. Accessed October 28, 2024.

Compher C, Bingham AL, McCall M, et al. Guidelines for the provision of nutrition support therapy in the adult critically ill patient: the American Society for Parenteral and Enteral Nutrition. *JPEN J Parenter Enteral Nutr*. 2022;46(1):12-41.

Durfee SM, Adams SC, Arthur E, et al. A.S.P.E.N. standards for nutrition support: home and alternate site care. *Nutr Clin Pract*. 2014;29(4):542-555.

Elsevier clinical overview. Nausea and vomiting of pregnancy and hyperemesis gravidarum. [Elsevier web site]. 11/08/2022. Available at: https://www.clinicalkey.com/#!/content/clinical_overview/67-s2.0-693def4b-3a08-4947-bac5-7687fb04d12b. Accessed October 28, 2024.

Evidence of Coverage.

Fejzo MS, Poursharif B, Korst, et al. Symptoms and pregnancy outcomes associated with extreme weight loss among women with hyperemesis gravidarum. *J Women's Health (Larchmt)*. 2009;18(12):1981-1987.

Herrell HE. Nausea and vomiting of pregnancy. *Am Fam Physician*. 2014;89(12):965-970.

Ikizler TA, Burrowes JD, Byham-Gray LD, et al. KDOQI clinical practice guideline for nutrition in CKD: 2020 update. *Am J Kidney Dis*. 2020;76(3)(suppl 1):S1-S107.

Korzets A, Azoulay O, Ori Y, et al. The use of intradialytic parenteral nutrition in acutely ill haemodialysed patients. *J Ren Care*. 2008;34(1):14-8.

Kuscu NK, Koyuncu F. Hyperemesis gravidarum: current concepts and management. *Postgrad Med J*. 2002;78:76-79.

Lapillonne A, Fidler Mis N, Goulet O, et al.; ESPGHAN/ESPEN/ESPR/CSPEN working group on pediatric parenteral nutrition. ESPGHAN/ESPEN/ESPR/CSPEN guidelines on pediatric parenteral nutrition: lipids. *Clin Nutr*. 2018;37(6 Pt B):2324-2336.

Marsen TA, Beer J, Mann H, et al. Intradialytic parenteral nutrition in maintenance hemodialysis patients suffering from protein-energy wasting. Results of a multicenter, open, prospective, randomized trial. *Clin Nutr*. 2017;36(1):107-117.

Mehta NM, Compher C; ASPEN Board of Directors. A.S.P.E.N. Clinical Guidelines: nutrition support of the critically ill child. *JPEN J Parenter Enteral Nutr.* 2009;33(3):260-276.

Mesotten D, Joosten K, van Kempen A, et al.; ESPGHAN/ESPEN/ESPR/CSPEN working group on pediatric parenteral nutrition. ESPGHAN/ESPEN/ESPR/CSPEN guidelines on pediatric parenteral nutrition: carbohydrates. *Clin Nutr.* 2018;37(6 Pt B):2337-2343.

Mirtallo J, Canada T, Johnson D, et al; Task Force for the Revision of Safe Practices for Parenteral Nutrition. Safe practices for parenteral nutrition. *JPEN J Parenter Enteral Nutr.* 2004;28(6):S39-S70.

National Institute for Health and Care Excellence (NICE). Nutritional support for adults: oral nutrition support, enteral tube feeding and parenteral nutrition. [NICE web site]. 08/04/2017. Available at: <https://www.nice.org.uk/guidance/cg32>. Accessed October 28, 2024.

National Kidney Foundation. KDOQI Clinical Practice Guideline for Nutrition in Children with CKD: 2008 update. *Am J Kidney Dis.* 2009;53(3)(Suppl 2):S1-124.

Noridian. Enteral and parenteral nutrition refill requirements. 06/20/2024. Available at: <https://med.noridianmedicare.com/web/jadme/article-detail/-/view/6547796/enteral-and-parenteral-nutrition-refill-requirements>. Accessed October 28, 2024.

Noridian. Local Coverage Article (LCA). A55426: Standard documentation requirements for all claims submitted to DME MACs. Effective date 01/01/2017. Revision date 01/01/2024. Available at: <https://med.noridianmedicare.com/web/jadme/policies/lcd/active>. Accessed October 28, 2024.

Noridian. Local Coverage Article (LCA). A58836: Parenteral Nutrition. Effective date 09/05/2021. Revision date 07/02/2024. Available at: <https://med.noridianmedicare.com/web/jadme/policies/lcd/active>. Accessed October 28, 2024.

Noridian. Local Coverage Determination (LCD). L38953: Parenteral Nutrition. Effective date 09/05/2021. Revision date 01/01/2024. Available at: <https://med.noridianmedicare.com/web/jadme/policies/lcd/active>. Accessed October 28, 2024.

Sigrist MK, Levin A, Tejani AM. Systematic review of evidence for the use of intradialytic parenteral nutrition in malnourished hemodialysis patients. *J Ren Nutr.* 2010;20(1):1-7. Epub 2009 Sep 27.

Singer P, Blaser AR, Berger MM, et al. ESPEN guideline on clinical nutrition in the intensive care unit. *Clin Nutr.* 2019;38(1):48-79.

Smith JA, Fox KA, Clark SM. Nausea and vomiting of pregnancy: treatment and outcome. [Up To Date web site]. 10/16/24. Available at: [https://www.uptodate.com/contents/nausea-and-vomiting-of-pregnancy-treatment-and-outcome?search=Nausea and vomiting of pregnancy: treatment and outcome&source=search_result&selectedTitle=1~101&usage_type=default&display_rank=1](https://www.uptodate.com/contents/nausea-and-vomiting-of-pregnancy-treatment-and-outcome?search=Nausea+and+vomiting+of+pregnancy:treatment+and+outcome&source=search_result&selectedTitle=1~101&usage_type=default&display_rank=1) [via subscription only]. Accessed October 28, 2024.

van Goudoever JB, Carnielli V, Darmaun D; ESPGHAN/ESPEN/ESPR/CSPEN working group on pediatric parenteral nutrition. ESPGHAN/ESPEN/ESPR/CSPEN guidelines on pediatric parenteral nutrition: amino acids. *Clin Nutr.* 2018;37(6 Pt B):2315-2323.

White JV, Guenter P, Jensen G, et al. Consensus statement: Academy of Nutrition and Dietetics and American Society for Parenteral and Enteral Nutrition: characteristics recommended for the identification and documentation of adult malnutrition (undernutrition). *JPEN J Parenter Enteral Nutr.* 2012;36(3):275-283.

Worthington P, Balint J, Bechtold M, et al. When is parenteral nutrition appropriate? *JPEN J Parenter Enteral Nutr.* 2017;41(3):324-377.

Inclusion of a code in this table does not imply reimbursement. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

The codes listed below are updated on a regular basis, in accordance with nationally accepted coding guidelines. Therefore, this policy applies to any and all future applicable coding changes, revisions, or updates.

In order to ensure optimal reimbursement, all health care services, devices, and pharmaceuticals should be reported using the billing codes and modifiers that most accurately represent the services rendered, unless otherwise directed by the Company.

The Coding Table lists any CPT, ICD-10, and HCPCS billing codes related only to the specific policy in which they appear.

CPT Procedure Code Number(s)

N/A

ICD - 10 Procedure Code Number(s)

N/A

ICD - 10 Diagnosis Code Number(s)

N/A

HCPCS Level II Code Number(s)

THE FOLLOWING CODES ARE USED TO REPRESENT HOME INFUSION THERAPY:

- | | |
|-------|--|
| 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 (do not use with home infusion codes S9365-S9368 using daily volume scales) |
| 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 |

THE FOLLOWING CODES ARE USED TO REPRESENT PARENTERAL NUTRITION SOLUTIONS:

- | | |
|-------|---|
| 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, not otherwise specified, 10 grams lipids |
| B4187 | Omegaven, 10 g lipids |

- B4189 Parenteral nutrition solution; compounded amino acid and carbohydrates with electrolytes, trace elements, and vitamins, including preparation, any strength, 10 to 51 grams 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 grams 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

THE FOLLOWING CODES ARE USED TO REPRESENT SPECIALIZED NUTRITION SOLUTIONS:

- B5000 Parenteral nutrition solution compounded amino acid and carbohydrates with electrolytes, trace elements, and vitamins, including preparation, any strength, renal-aminosyn-rf, nephramine, renamine-premix
- B5100 Parenteral nutrition solution compounded amino acid and carbohydrates with electrolytes, trace elements, and vitamins, including preparation, any strength, hepatic, 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

THE FOLLOWING CODE IS USED TO REPRESENT PARENTERAL NUTRITION SOLUTIONS CONTAINING LESS THAN 10 GRAMS OF PROTEIN PER DAY:

- B9999 NOC for parenteral supplies

THE FOLLOWING CODES ARE USED TO REPRESENT PARENTERAL NUTRITION EQUIPMENT AND SUPPLIES:

- B4220 Parenteral nutrition supply kit; premix, per day
- B4222 Parenteral nutrition supply kit; home mix, per day
- B4224 Parenteral nutrition administration kit, per day
- B9004 Parenteral nutrition infusion pump, portable
- B9006 Parenteral nutrition infusion pump, stationary
- E0776 IV Pole

Revenue Code Number(s)

N/A

Policy History

Revisions From MA08.008g:

03/28/2025	This version of the policy will become effective 03/28/2025.
	Documentation requirements have been revised in alignment with Noridian Local Coverage Determination [LCD] 38953 Parenteral Nutrition [effective 01/01/2024]).

Revisions From MA08.008f:

05/07/2024	This policy has been reissued in accordance with the Company's annual review process.
07/03/2023	This version of the policy will become effective 07/03/2023.
	Policy criteria have been revised in alignment with Noridian Local Coverage Determination [LCD] 38953 Parenteral Nutrition [effective 01/01/2022]), professional medical society guidelines, and peer-reviewed literature.

	The following has been added to the Guidelines section of the policy: Tables containing examples of macronutrient ranges for adult and pediatric individuals in alignment with Noridian Local Coverage Determination [LCD] 38953 Parenteral Nutrition [effective 01/01/2022]), professional medical society guidelines, and peer-reviewed literature.
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Revisions From MA08.008e:

11/22/2021	This version of the policy will become effective 11/22/2021. Criteria have been revised in alignment with Centers for Medicare & Medicaid Services (CMS) guidance (National Coverage Determination [NCD] 180.2 Enteral and Parenteral Nutrition Therapy [effective 07/11/1984] and Noridian Local Coverage Determination [LCD] 38953 Parenteral Nutrition [effective 09/05/2021]) and professional medical society guidelines. The following HCPCS codes were added to this policy: • B4187 omegaven, 10 grams lipids • E0776 IV Pole
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Revisions From MA08.008d:

01/01/2020	This version of the policy will become effective 01/01/2020. The following HCPCS code B4185 has a revised narrative.
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Revisions From MA08.008c:

07/17/2019	The policy has been reviewed and reissued to communicate the Company's continuing position on Total Parenteral Nutrition (TPN) / Intradialytic Parenteral Nutrition (IDPN) / Intraperitoneal Nutrition (IPN).
11/21/2018	This policy became effective 9/21/2016. It has been reviewed and reissued to communicate the Company's continuing position on Total Parenteral Nutrition (TPN) / Intradialytic Parenteral Nutrition (IDPN) / Intraperitoneal Parenteral Nutrition (IPN).
06/21/2017	This policy has been reissued in accordance with the Company's annual review process.
09/21/2016	The policy criteria was expanded regarding Specialized Formulations, to include coverage of solutions such as Proplete. Updates were made to the Coding Table to allow for billing by eligible participating home infusion companies.

Revisions From MA08.008b:

01/29/2016	The intent of this policy remains unchanged, but the policy has been updated to further clarify current benefits.
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Revisions From MA08.008a:

01/01/2016	The following HCPCS narratives have been revised in this policy effective 1/1/2016. B5000 FROM: Parenteral nutrition solution; compounded amino acid and carbohydrates with electrolytes, trace elements, and vitamins, including preparation, any strength, renal - Amirosyn RF, nephramine, renamine - premix TO: Parenteral nutrition solution compounded amino acid and carbohydrates with electrolytes, trace elements, and vitamins, including preparation, any strength, renal-aminosyn-rf, nephramine, renamine-premix B5100 FROM: Parenteral nutrition solution; compounded amino acid and carbohydrates with electrolytes, trace elements, and vitamins, including preparation, any strength, hepatic - Freamine HBC, HepatAmine - premix TO: Parenteral nutrition solution compounded amino acid and carbohydrates with electrolytes, trace elements, and vitamins, including preparation, any strength, hepatic, hepatamine-premix
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	B5200 FROM: Parenteral nutrition solution; compounded amino acid and carbohydrates with electrolytes, trace elements, and vitamins, including preparation, any strength, stress - branch chain amino acids – premix TO: 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
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Revisions From MA08.008:

01/01/2015	This is a new policy.
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Version Effective Date:

03/28/2025

Version Issued Date:

03/28/2025

Version Reissued Date:

N/A