

Clinical UM Guideline

Subject: Home Parenteral Nutrition

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Description

This document addresses parenteral nutrition given in the home setting.

Clinical Indications

Medically Necessary:

Initial use of home parenteral nutrition is considered medically necessary when all of the following criteria (A, B, and C) are met:

- A. The individual is malnourished or at risk for malnutrition as evidenced by:
 - 1. Adults:
 - a. Loss of 10% or more of their ideal body weight within a 3 month period; or
 - b. Loss of 20% of their usual body weight within a 3 month period; or
 - c. Serum total protein level less than 6 g/dL; or
 - d. Serum albumin level less than 3.4 g/dL; or
 - e. None of the conditions listed above (a-d) are present but one or more are considered inevitable given the individual's expected course of illness.
 - 2. Children:
 - 1. Under the 10th percentile of expected weight for length/height, or weight for sex (–1.28 z score); or
 - 2. Under the $\mathbf{5}^{th}$ percentile of expected body mass index.

an

B. The individual has a condition that prevents adequate nutritional supplementation using the enteral route (for example, impaired gastrointestinal digestion, absorption, or motility);

and

- C. Home parenteral nutrition can be safely administered including documentation of the following:
 - Metabolic stability with normal serum sodium, potassium, phosphate, and magnesium levels and serum glucose less than 160 mg/dL; and
 - Completion of training for the individual or their designated caregiver in the safe preparation and administration of parenteral nutrition; and
 - 3. A nutrition care plan including the nutritional prescription.

Continuing use of home parenteral nutrition will be reviewed every 6 months and is considered medically necessary when all of the following criteria are met:

- A. A physician certifies that the criteria for initial treatment (A, B, and C above) continue to be metand
- C. An updated nutrition care plan is provided.

Not Medically Necessary:

Initial use of home parenteral nutrition is considered not medically necessary when the above criteria have not been met.

Continuing use of home parenteral nutrition is considered not medically necessary when the above criteria have not been met.

Coding

The following codes for treatments and procedures applicable to this guideline are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services may be Medically Necessary when criteria are met:

HCPCS	
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 grams 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
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 - 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
B9004	Parenteral nutrition infusion pump, portable
B9006	Parenteral nutrition infusion pump, stationary
B9999	NOC for parenteral supplies
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); one 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 one liter but no more than two 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 two liters but no more than three 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 three 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

ICD-10 Diagnosis

All diagnoses

When services are Not Medically Necessary:

For the procedure codes listed above when criteria are not met or for situations designated in the Clinical Indications section as not medically necessary.

Discussion/General Information

Parenteral nutrition (PN) delivers macronutrients intravenously to bypass the gastrointestinal tract. It is used for individuals who have medical conditions that impair gastrointestinal absorption when oral or enteral nutrition is not possible or is not appropriate. It can be given long-term or for intermittent periods of time to reinforce the nutritional status of those with, or at risk for, severe malnutrition. This can be done via catheter placed in the central or peripheral veins. The central venous route is used for long-term indications. Peripherally inserted central catheter (PICC) can be used for short-term or intermittent indications. PN can be given either in the hospital setting, outpatient setting, or home setting. Home parenteral nutrition (HPN) is delivered by an infusion pump, usually overnight

In a 2017 consensus statement by the American Society for Parenteral and Enteral Nutrition (ASPEN; Worthington, 2017), malnutrition in an adult is defined 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.

Consensus recommendations made in 2017 by ASPEN (Worthington, 2017) list common indications for HPN. These include short bowel syndrome, Crohn's disease, intestinal motility disorders, chronic bowel obstruction due to benign adhesions or strictures, radiation enteritis, malabsorptive disorders, intestinal and pancreatic fistula, gastrointestinal malignancy, malignant bowel obstruction (carcinomatosis), complications of bariatric surgery, gastroschisis, and long-segment Hirschsprung's disease. HPN may also be appropriate for other, less common, conditions leading to chronic intestinal failure (CIF). ASPEN recommends that the decision to provide HPN should be based on the presence of CIF rather than on the condition causing the CIF.

Additionally, the consensus recommendations consider an adult to be nutritionally at-risk if there is an involuntary weight loss of 10% of usual body weight within 6 months, an involuntary loss of 10 pounds within 6 months, body mass index (BMI) less than 18.5 kg/m², an increase in metabolic requirements, altered diets or diets schedule, or inadequate nutrition intake. They consider children to be at-risk nutritionally if there is weight for length, weight for height, or sex less than 10% percentile (-1.28z score), BMI for age or sex less than 5th percentile (-1.64z score), an increase in metabolic requirements, an impaired ability to digest or tolerate oral feeding, documentation of inadequate provision of or tolerance to nutrients, or inadequate weight gain or significant decrease in usual growth percentile.

Proper nutrition is essential for body maintenance and growth. Inability to achieve proper nutrition can lead to weight loss and electrolyte imbalances. Ideal body weight is the optimal weight associated with maximum life expectancy for a given height. Usual body weight is the value used to compare a person's current weight with their own baseline weight. Lack of proper nutrition affects metabolism, growth, development, and health. Metabolic changes include reduced production of protein and catabolism of existing body proteins. This includes enzymes and hormones that regulate body function. Albumin assists in the transport of bilirubin, hormones, metals, vitamins and drugs. Albumin also plays an important role in the metabolism of fat. Protein malnutrition can also

lead to lymphocytopenia and impaired immune functioning.

In 2015 the European Society for Clinical Nutrition and Metabolism (ESPEN; Pironi, 2015) published their recommendations on the definition and classification of intestinal failure (IF) in adults. They define intestinal failure as, "the reduction of gut function below the minimum necessary for the absorption of macronutrients and/or water and electrolytes, such that intravenous supplementation is required to maintain health and/or growth." IF is classified into three types; Type I is acute, short-term, and is usually self-limiting. Type II IF is a prolonged acute condition in which intravenous (IV) supplementation can be required over weeks or months. Type III IF is a chronic condition which requires IV supplementation over months or years. It may or may not be reversible. Pathophysiological conditions that can cause IF include, but are not limited to, short bowel, intestinal fistula, intestinal dysmotility, mechanical obstruction, and extensive small bowel mucosal disease.

The 2023 HPN guideline by ESPEN (Pironi, 2023) also describes individuals who are unable to meet their nutritional requirements by an oral or enteral route as having IF. IF can be characterized as acute intestinal failure (AIF) or chronic intestinal failure (CIF). IF can also be characterized as transient and reversible or permanent and irreversible. ESPEN recommends PN for individuals with IF who can be managed safely outside the hospital.

Several studies and professional society statements demonstrate that HPN can be provided safely. A 2017 retrospective review by Turkot and colleagues reported on 46 subjects with severe inflammatory bowel disease who received HPN as an alternative to abdominal surgery. There were 38 subjects with Crohn's disease and 8 with ulcerative colitis. Three of the subjects had no prior history of bowel resection, 18 subjects had history of partial resection of the small intestine, 6 subjects had history of resection of the large intestine, and 19 participants had history of resection of both the small and large intestine. As a result of surgery, 27 subjects developed short bowel syndrome. HPN treatment ranged from 2 to 212 months with a mean of 66.3 months. While receiving HPN, one participant had complications which required 12 hospital admissions. No hospitalizations were required in 18 participants. While receiving HPN, body mass index decreased in 2 participants, remained stable in 1 participant, and increased in 38 participants.

During HPN, albumin level increased by an average of 2.4 g/L and mean lymphocyte count dropped by 474 lymphocytes/mm³. Mean leukocyte count was 747.6/mm³ with the authors concluding there was no correlation between the leukocyte count and duration of HPN. Using the Subjective Global Assessment of nutritional assessment questionnaire, the authors found that 7.4% of subjects were able to work in a limited capacity, 87.5% of subjects were able to move on their own, and 7.4% of subjects were non-ambulatory while receiving HPN. 39 participants had follow-up data available regarding assessment of condition. Self-described condition was described as good by 34 participants, 2 participants reported fatigue, and 2 participants reported nausea, vomiting, diarrhea, and abdominal pain, with 1 participant reporting hunger. While this study has limitations including the small sample size and retrospective design, the authors conclude that use of HPN in this cohort improved general condition, increased body mass index and observed improvement in net health outcomes with a return to home and social life.

The American College of Obstetrics and Gynecologist practice bulletin for nausea and vomiting of pregnancy (2018) notes that, despite potential complications from parenteral nutrition, it has been prescribed for pregnant individuals with hyperemesis gravidarum who cannot tolerate enteral feedings.

A 2019 observational study by Burden and colleagues reported on quality of life in subjects receiving HPN. The study objective was to establish mean values for the Parenteral Nutrition Impact Questionnaire (PNIQ) and determine the effect of disease state, frequency of infusions and characteristics that influence quality of life for those receiving HPN. There were 906 questionnaires sent out with 451 returned and included in the analysis. Score range on the PNIQ ranged from good quality of life (score of 0) to poor quality of life (score of 20). The mean PNIQ score for the participants in this study was 11.04. The most frequent self-reported diagnoses were short bowel syndrome (35.9%) and Crohn's disease (20.3%). The participants who reported surgical complications as their underlying disease had the highest mean PNIQ scores (14.15) indicating worse quality of life. Conversely, those who reported severe gastrointestinal dysmotility as their underlying disease had the lowest reported mean PNIQ scores (9.04) indicating a better quality of life. Frequency of HPN affected quality of life. PNIQ mean score was 9.20 for those receiving HPN 1-3 times per week compared to a mean score of 11.78 for those receiving parenteral nutrition 6-7 nights per week. There was no influence on the PNIQ scores based on gender, time since starting HPN, education and marital status. While this study has limitations including self-reported diagnoses and the assessment of one moment in time for a chronic condition, this study shows that HPN has an impact on quality of life.

In 2019 ASPEN published a guideline (Kovacevich, 2019) regarding the selection and care of central venous access devices for adult HPN administration. This document provides guidance on the choice of infusion device, functionality of the device, and choice of catheter types. The guideline notes that its recommendations are based on limited number of studies and on expert opinions. They note the most common complications for HPN therapy include mechanical complications of central venous access devices and blood stream infections related to central lines. There are recommendations for which flush solution should be used to maintain lumen patency. The authors note the goals of HPN care are to teach individuals and/or caregivers to become independent in their care, keep individuals in their home and maintain quality of life by preventing complications and hospitalizations.

PN may prolong life and improve quality of life but carries substantial risks. Potential complications include catheter-associated infection, hyperglycemia, blood electrolyte abnormalities, sepsis, and thromboembolic events. PN must be supervised by experienced clinicians and administered by properly trained caregivers. Individuals receiving HPN and their caregivers must be educated on ways to decrease potential complications. These include proper hand hygiene, proper storage and handling of supplies, operation of infusion pump, dressing changes if applicable, use of sterile technique, flushing the catheter and aseptic care of the hub.

Central venous catheter size and proper placement are important to aid in receiving parenteral nutrition appropriately and decrease risk of complications. The 2017 ASPEN consensus recommendations (Worthington, 2017) include choosing the smallest device with the least number of lumens necessary. Multi-lumen catheters receive more frequent manipulation than single-lumen catheters. This can lead to higher risk for central line-associated bloodstream infections and deep vein thrombosis. ASPEN recommends that the tip of the central venous catheter should be positioned in the lower third of the superior vena cava and that this position should be confirmed radiographically before initiating parenteral nutrition.

Whether the PN is short- or long-term, safe treatment requires development of a nutrition care plan that may need to be modified over time to meet changing needs. The 2017 ASPEN consensus recommendations suggest an interdisciplinary team with expertise in managing PN monitor each individual's care. The ASPEN guideline provides recommendations for periodic evaluation of gastrointestinal function and nutrition status. A 2017 ESPEN Guideline on Definitions and Terminology of Clinical Nutrition (Cederholm, 2017) defines the nutritional care plan as a way for nutrition therapy to be based on the results of the assessment. The care plan defines the rationale, it explains the nutrition therapy, and it provides suggestions on how to monitor the efficacy of the plan and reassessment.

The nutritional care plan includes information on:

- Energy, nutrient and fluid requirements
- Measureable nutrition goals (immediate and long-term)
- · Instructions for implementing the specified form of nutrition therapy

- The most appropriate route of administration and method of nutrition access
- Anticipated duration of therapy
- Monitoring and assessment parameters
- Discharge planning and training at home (if appropriate)

PN is a complex formula which consists of nutrient-based components. Modification of the nutrition prescription requires an understanding of fluid balance and the metabolism of macronutrients and micronutrients. For those on long-term HPN, the 2023 ESPEN HPN guideline (Pironi, 2023) recommends monitoring of body weight, body composition, hydration status, energy and fluid balance and laboratory values which may include hemoglobin, ferritin, albumin, C-reactive protein, electrolytes, glucose, blood gasses, kidney function, and liver function.

Management of HPN is complex. This complexity is often increased by the need to manage the underlying condition causing the CIF. Management may include clinicians from multiple disciplines with knowledge of dietary requirements and gastrointestinal disorders. Constant care must be taken to prevent complications whenever possible and to effectively treat them as soon as possible if they occur.

Definitions

Chronic intestinal failure: Intestinal failure persisting over months or years.

Enteral nutrition: Provision of nutrients through the gastrointestinal tract. This may be done by oral ingestion or by instillation through a feeding tube.

Intradialytic parenteral nutrition: Provision of intravenous nutrients during a hemodialysis session.

Intestinal failure: The inability of an individual's gastrointestinal system to absorb sufficient nutrients, water, and electrolytes to maintain health.

Nutrition care plan: A detailed plan of interventions or actions to achieve nutrition goals.

Parenteral nutrition: Provision of nutrients intravenously.

Short bowel syndrome: A condition in which there is a physical or functional loss of a part of the small and/or large intestine which leads to a reduced ability to absorb nutrients with a total small bowel length of less than 200 cm.

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Peer Reviewed Publications:

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- 2. 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.
- 3. Nagelkerke SCJ, van Oers HA, Haverman L, et al. Longitudinal development of health-related quality of life and fatigue in children on home parenteral nutrition. J Pediatr Gastroenterol Nutr. 2022; 74(1):116-122.
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Government Agency, Medical Society, and Other Authoritative Publications:

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- 3. Bischoff SC, Barazzoni R, Busetto L, Campmans-Kuijpers M, et al. European guideline on obesity care in patients with gastrointestinal and liver diseases Joint ESPEN/UEG guideline. Clin Nutr. 2022; 41(10):2364-2405.
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- 8. Green PHR, Paski S, Ko CW, Rubio-Tapia A. AGA Clinical practice update on management of refractory celiac disease: expert review. Gastroenterology. 2022; 163(5):1461-1469.
- 9. Iyer K, DiBaise JK, Rubio-Tapia A. AGA Clinical practice update on management of short bowel syndrome: expert review. Clin Gastroenterol Hepatol. 2022; 20(10):2185-2194.e2.
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- 12. Pironi L, Boeykens K, Bozzetti F, et al. ESPEN practical guideline: Home parenteral nutrition. Clin Nutr. 2023; 42(3):411-430.
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Federal and State law, as well as contract language, and Medical Policy take precedence over Clinical UM Guidelines. We reserve the right to review and update Clinical UM Guidelines periodically. Clinical guidelines approved by the Medical Policy & Technology Assessment Committee are available for general adoption by plans or lines of business for consistent review of the medical necessity of services related to the clinical guideline when the plan performs utilization review for the subject. Due to variances in utilization patterns, each plan may choose whether to adopt a particular Clinical UM Guideline. To determine if review is required for this Clinical UM Guideline, please contact the customer service number on the member's card.

Alternatively, commercial or FEP plans or lines of business which determine there is not a need to adopt the guideline to review services generally across all providers delivering services to Plan's or line of business's members may instead use the clinical guideline for provider education and/or to review the medical necessity of services for any provider who has been notified that his/her/its claims will be reviewed for medical necessity due to billing practices or claims that are not consistent with other providers, in terms of frequency or in some other manner.

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