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MEDICAL POLICY



| Medical Policy Title | Total Parenteral Nutrition (TPN) or Hyperalimentation | |
|-------------------------------|---|--|
| Policy Number | 11.01.04 | |
| Current Effective Date | February 20, 2025 | |
| Next Review Date | February 2026 | |

Our medical policies are based on the assessment of evidence based, peer-reviewed literature, and professional guidelines. Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. (Link to <u>Product Disclaimer</u>)

POLICY STATEMENT(S)

- I. Total parenteral nutrition (TPN), is considered **medically appropriate** for malnourished individuals* (Please refer to Policy Guideline VI) with indications that include, but are not limited to, the following:
 - A. Gastrointestinal (gut) failure:
 - 1. Short bowel syndrome (e.g., secondary to mesenteric infarction, surgical treatment of Crohn's disease, midgut volvulus, traumatic gastroschisis, small bowel atresia in neonates);
 - 2. Radiation enteritis;
 - 3. Intestinal pseudo-obstruction-motility disorder;
 - 4. Idiopathic diarrhea; or
 - 5. Secondary gastrointestinal failure (e.g., scleroderma).
 - B. Crohn's disease:
 - 1. Growth retardation;
 - 2. Diffuse small bowel disease refractory to medical management; or
 - 3. Enterocutaneous fistulae.
 - C. Severe mucosal injury with intractable malabsorption (e.g., selected cases of celiac disease, immunodeficiency syndromes with enterocolitis, idiopathic mucosal failure with congenital failure to develop villi).
 - D. Cystic fibrosis with malnutrition unresponsive to enteral nutrition.
 - E. Intestinal lymphangiectasia with failure of dietary management.
 - F. Short-term treatment of a condition requiring "bowel rest," where prolonged hospitalization would otherwise be required (e.g., pancreatic pseudocysts, proximal enterocutaneous fistulae in which surgical management is not indicated).
 - G. Short-term treatment for children with severe reflux and aspiration who fail to thrive, until a surgical procedure can be performed.

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- H. Adjunctive therapy for malnourished individuals with specific cancers who are receiving intense and frequent chemotherapy that causes severe gastrointestinal toxicity.
- I. Liver failure in children approved for liver transplants, who fail to grow while receiving enteral nutritional support.
- J. Liver failure in adults who have hepatic encephalopathy and cannot tolerate a protein source consisting of standard amino acids or enteral nutritional support (TPN used for the administration of a liver-specific amino acid mixture).
- K. Acute necrotizing pancreatitis in adults with an inadequate oral intake for longer than a week, where enteral feedings exacerbate abdominal pain, ascites, or fistulous output.
- II. Parenteral therapy with home TPN for the management of intractable hyperemesis gravidarum is considered **medically appropriate** when **ALL** of the following criteria have been met:
 - A. The individual has attempted and failed the step therapy approach;
 - B. Other potential causes of nausea and vomiting have been ruled out;
 - C. Information about symptoms, food intake, urinary ketones, urine specific gravity, and daily weights is supplied;
 - D. Clinical signs of hyperemesis gravidarum, including nausea and vomiting, have been persistent for three (3) or more weeks;
 - E. Within this time, there has been documented weight loss and dehydration or electrolyte abnormalities;
 - F. There has been over five (5) percent weight loss since the beginning of pregnancy, and the individual is over 14 weeks pregnant;
 - G. Has failed intravenous (IV) or subcutaneous (SQ) Zofran or Reglan therapy;
 - H. Has failed, or is not a candidate for, enteral therapy (nausea is unrelated to olfactory or gustatory cues);
 - I. Has fully consented with respect to the risks of line infection, bacteremia, sepsis, thrombosis, and fetal loss; **and**
 - J. The PICC line is started by a qualified medical professional within an appropriate clinical setting (e.g., inpatient or outpatient).
- III. Intradialytic nutrition, including intradialytic parenteral nutrition (IDPN) or intraperitoneal nutrition (IPN), for individuals with end-stage renal disease (ESRD) who are undergoing hemodialysis or peritoneal dialysis, is considered **medically appropriate** when **BOTH A and B** are met:
 - A. It is utilized as an alternative to regularly scheduled TPN in individuals who meet the criteria for TPN therapy; **and**
 - B. Intradialytic nutrition provides an incremental boost in calories and is not used as the sole source of nutrition.

IV. TPN is considered **not medically necessary** for **ANY** of the following indications:

- A. Children who were previously well-nourished or mildly malnourished, who are undergoing oncologic treatment associated with a low nutrition risk (e.g., less-advanced disease, less intense cancer treatments, advanced disease in remission during maintenance treatment);
- B. Individuals (either adult or pediatric) with advanced cancer whose malignancy is documented as unresponsive to chemotherapy or radiation therapy; **or**
- C. Individuals for whom liver transplantation is not feasible and whose prognosis will not change in spite of TPN therapy.
- V. Intradialytic parenteral nutrition (IDPN) or intraperitoneal nutrition (IPN), for individuals with end-stage renal disease (ESRD) who are undergoing hemodialysis or peritoneal dialysis, is considered **not medically necessary** when:
 - A. It is used as an adjunct to regularly scheduled TPN infusions; or
 - B. TPN is considered not medically necessary for the individual.

RELATED POLICIES

Corporate Medical Policy

10.01.03 Enteral Nutrition

POLICY GUIDELINE(S)

- I. Home TPN should be employed as therapy only in individuals in whom enteral feeding (employing the individuals own gastrointestinal tract) is considered contraindicated or in whom such feeding has been unsuccessful.
- II. Because of the potential risks of home TPN, this therapy should generally not be employed when simpler, more routine therapies may be the first choice of treatment (e.g., pharmacological therapy for an acute exacerbation of short segment illness due to Crohn's disease).
- III. The individual must be medically stable for TPN to be safely administered in the home setting.
- IV. The individual and/or caregiver must be adequately trained in the techniques of home TPN, to ensure that it is administered according to policy and that complications requiring appropriate treatment are recognized.
- V. The need for continuing TPN therapy must be periodically reassessed because, in many disease processes causing gut failure, intestinal adaption may take place.
- VI. *Malnourished individuals are those in a stage of wasting, as indicated by the following:
 - A. Weight is significantly less than normal body weight for height and age, in comparison with pre-illness weight;
 - B. Serum albumin is less than 2.5 grams;

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- C. Blood urea nitrogen (BUN) is below 10 mg (not a good marker in individuals receiving dialysis, due to protein catabolism);
- D. Phosphorous level is less than 2.5 mg (normal is 3 4.5 mg); and
- E. The individual can receive no more than 30 percent of caloric needs enterally (oral or tube feeding).

DESCRIPTION

Total parenteral nutrition (TPN), also known as hyperalimentation, is administered to individuals with medical conditions that impair gastrointestinal absorption to a degree that is incompatible with life. TPN is also used for variable periods of time to bolster the nutritional status of severely malnourished individuals with medical or surgical conditions.

TPN involves the percutaneous transvenous implantation of a central venous catheter into the vena cava or right atrium. A nutritionally adequate hypertonic solution consisting of glucose, amino acids, electrolytes, vitamins, minerals, and sometimes fats is administered daily. An infusion pump is generally used to assure a steady flow of the solution, either on a continuous or intermittent schedule.

For individuals with severe dysfunction of the gastrointestinal tract, in whom survival was previously precluded, the individual can often be restored to a near-normal nutritional state. The goals of TPN are:

- I. Nutritional repletion;
- II. Avoidance of repeated and prolonged hospitalization;
- III. Return to gainful employment, where appropriate; and
- IV. Improvement of the quality of life.

Hyperemesis gravidarum is a term reserved to describe the most severe cases of nausea and vomiting in pregnancy (NVP). It is characterized by the inability to rehydrate and replenish nutritional reserves, after severe nausea and vomiting. A diagnosis of hyperemesis gravidarum is made based on objective findings such as moderate to large ketonuria and weight loss. Weight loss of five percent or greater is often described as diagnostic of hyperemesis gravidarum. Hyperemesis gravidarum tends to begin earlier in pregnancy and lasts longer than those individuals with less severe NVP.

Intradialytic nutrition is a specific form of TPN utilized in malnourished individuals with end-stage renal disease (ESRD) who are undergoing dialysis. It includes:

- I. Intradialytic parenteral nutrition (IDPN): a form of parenteral nutritional therapy administered to malnourished individuals undergoing hemodialysis.
- II. Intraperitoneal nutrition (IPN): a form of parenteral nutritional therapy administered to malnourished individuals undergoing peritoneal dialysis.

SUPPORTIVE LITERATURE

Clinical trials have been conducted to determine the efficacy and safety of TPN for numerous conditions, including cancer, HIV, renal failure, liver failure, and Crohn's disease. Studies have proven that nutrition support and effective oncologic treatment lessen morbidity and improve tumor response for those individuals undergoing intense chemotherapy (Mercier et al. 2022). Studies suggest that TPN is effective in repleting lean tissues of malnourished HIV individuals and minimizes nutrient loss during catabolic illness (Melchior, 1998).

Inflammatory bowel disease (IBD) comprises of Crohn's disease and ulcerative colitis. Malnutrition is prevalent among individuals with these diseases. Traditionally treatment focus on immunosuppressant to modulate the deregulated gastrointestinal and systemic immune response. Diet and nutrition are a key component of a comprehensive IBD management. TPN is not recommended as first-line therapy in IBD but does, it allows for bowel rest while supplying adequate caloric intake and essential nutrients. TPN can help correct malnutrition and maintain homeostasis, promote wound healing in the perioperative period, prevent dehydration, and correct electrolyte imbalances (Boutte 2022).

Intestinal failure (IF) in newborn infants can result from the loss of absorptive surface, mucosal dysfunction, or dysmotility. Parenteral nutrition is the standard treatment option to deliver nutrition from the time of diagnosis of short bowel syndrome (SBS) until enteral autonomy is achieved (Premkumar et al., 2022). Recommended treatment goals to restore energy and proteins can be achieved with a combination of glucose, proteins, carbohydrates, electrolytes, vitamins, minerals, and lipids.

According to the American Gastroenterological Association Clinical Practice Update (2020) on Management of Pancreatic Necrosis best practice advice four states that individuals with pancreatic necrosis, should initiate enteral feeding early to decrease the risk of infected necrosis. It is suggested that a trial of oral nutrition is recommended immediately in patients in whom there is absence of nausea and vomiting and no signs of severe ileus or gastrointestinal luminal obstruction. When oral nutrition is not feasible, enteral nutrition by either nasogastric/duodenal or nasojejunal tube should be initiated as soon as possible. Total parenteral nutrition should be considered only in cases where oral or enteral feeds are not feasible or tolerated (Baron et al., 2020).

Most individuals with end-stage renal disease (ESRD) who are undergoing hemodialysis or peritoneal dialysis have intact and fully functional gastrointestinal systems. Many of these individuals become malnourished due to inadequate intake of nutrients as the result of anorexia, frequent acute intercurrent illness, dietary restrictions, and/or nutrient losses into the dialysate. Evidence suggests that poor nutrition may contribute to increasing the morbidity and mortality of dialysis individuals. In view of these indications, nutritional supplements, referred to as intradialytic nutrition, which include intradialytic parenteral nutrition (IDPN) and intraperitoneal nutrition (IPN), have been administered during dialysis treatment in an attempt to improve the nutritional status of these individuals. The amount and composition of solutions administered during dialysis are adjusted according to the individuals' estimated needs.

Hemodialysis is associated with high morbidity and mortality rates as well as low quality of life. Altered nutritional status and protein-energy wasting are important indicators of these risks. In a clinical review Carrero and colleagues (2022) surveyed existing literature and summarize views on when to use IDPN, which patients may be best suited for IDPN, and how to effectively deliver and monitor this strategy for nutritional support. Clinical outcomes from a randomized study of hemodialysis (HD) individuals who receive oral nutritional supplements (ONS) with or without IDPN over the course of 1 year showed that adding IDPN to ONS resulted in similar nutritional parameters compared with ONS alone. Regardless of the strategy, an improvement in nutritional status, defined by increases in prealbumin after the intervention, was associated with a higher 2-year survival and lower hospitalization rates which improved long term outcomes. Researchers concluded that IDPN should always be considered an intermittent supplemental nutrition strategy. Other clinically important factors for consideration include total volume to be delivered and infusion rate during the IDPN session. These will be dictated by the anticipated duration of the HD session and individual patient body weight, among other factors.

PROFESSIONAL GUIDELINE(S)

The National Kidney Foundation (NKF) updated its clinical practice guidelines for nutrition in chronic kidney (CKD) Ikizler et al., 2020)). The guideline was expanded to include individuals with end-stage kidney disease or advanced CKD, and for individuals with stages 1- 5 CKD who are not receiving dialysis, and patients with a functional kidney transplant. The updated guideline statements focus on 6 primary areas: nutritional assessment, medical nutrition therapy (MNT), dietary protein and energy intake, nutritional supplementation, micronutrients, and electrolytes. The guidelines primarily cover dietary management rather than all possible nutritional interventions (see the reference section for guidance).

American Society for Parenteral and Enteral Nutrition (ASPEN) practice guidelines (2009) addressing parenteral nutrition indicate that IDPN should be reserved for individuals who cannot meet their nutritional needs orally and who are not candidates for enteral or parenteral nutrition because of gastrointestinal intolerance or venous access problems and should only be used in situations of gut failure or other unusual circumstances where enteral or parenteral nutrition are not feasible.

REGULATORY STATUS

Not Applicable

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

| Code | Description |
|------------------|---|
| 36568 - 36573 | Insertion of peripherally inserted central venous catheter (PICC) or access device (code range) |

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HCPCS Codes

| Code | Description |
|------------------|---|
| B4164 - B4216 | Parenteral nutrition solutions and additives (code ranges) |
| B5000 - B5200 | |
| B4220 - B4224 | Parenteral nutrition supply/administration kit (code range) |
| B9004 | Parenteral nutrition infusion pump, portable |
| B9006 | Parenteral nutrition infusion pump, stationary |
| B9999 | NOC for parenteral supplies |
| S9364 - S9368 | Home infusion therapy, total parenteral nutrition (TPN); administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment including standard TPN formula, per diem (code range) |

ICD10 Codes

| Code | Description |
|-------------------|-------------|
| Numerous codes | |

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SEARCH TERMS

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Hyperalimentation, Intradialytic parenteral nutrition (IDPN), Intraperitoneal nutrition (IPN), Total parenteral nutrition (TPN), Parenteral nutrition (PN)

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Based on our review, Total Parenteral Nutrition is not addressed in National or Regional Medicare coverage determinations or policies.

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.
- If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.

POLICY HISTORY/REVISION

Committee Approval Dates

10/18/01, 07/18/02, 07/17/03, 07/15/04, 07/21/05, 06/22/06, 06/28/07, 06/26/08, 08/27/09, 08/26/10, 08/25/11, 08/23/12, 08/22/13, 08/28/14, 08/27/15, 08/25/16, 08/25/17, 02/22/18, 08/23/18, 02/28/19, 02/27/20, 02/25/21, 02/17/22, 02/16/23, 02/22/24, 02/20/25

| Date | Summary of Changes |
|----------|--|
| 02/20/25 | Policy intent unchanged; Changed the word "patient" to "individual" throughout the document. |
| 01/01/25 | Summary of changes tracking implemented. |
| 10/18/01 | Original effective date |