

Corporate Medical Policy

Parenteral Nutrition/Total Parenteral Nutrition

Description of Procedure or Service

Total parenteral nutrition (TPN), also known as parenteral hyperalimentation, involves the delivery of micronutrients and macronutrients via infusion to an individual with complex nutritional needs. TPN 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. TPN bolsters and/or maintains the nutritional status of moderately to severely malnourished individuals who have medical or surgical conditions such as gastrointestinal (GI) anomalies or impaired intestinal absorption or motility.

For individuals who have moderate GI abnormalities (e.g., malabsorption disorders), TPN is typically instituted when enteral nutrition via a nasogastric, gastrostomy, or jejunostomy tube has failed. TPN may be part of the treatment plan for individuals who have severe pathology of the digestive system that does not allow for the absorption of sufficient nutrients to maintain weight and strength. Highly concentrated parenteral products are available for individuals who have fluid restrictions.

TPN is administered through a central intravenous line access or a peripherally inserted central catheter (PICC). An infusion pump regulates the flow of the solution on either a continuous (24-hour) or intermittent schedule.

The indications for intradialytic parenteral nutrition (IDPN) and intraperitoneal parenteral nutrition (IPN) are similar to those for TPN. IDPN refers to the delivery of micronutrients and macronutrients to individuals who have complex nutritional needs during hemodialysis. It is the infusion of supplemental nutrition (composed of dextrose, amino acids, and sometimes, lipids) during dialysis in individuals with protein calorie malnutrition. This process typically begins 30 minutes after dialysis is initiated, and is continued for remainder of the dialysis session. In peritoneal dialysis, also referred to as intraperitoneal parenteral nutrition (IPPN) or intraperitoneal nutrition (IPN), the infusion of nutrition is done through the peritoneal cavity.

Background

Parenteral nutrition involves the delivery of micronutrients and macronutrients through catheters in central or peripheral veins. In most instances, the central venous route is utilized, and for long-term total parenteral nutrition a central catheter (e.g., Hickman, Broviac, PICC) is burrowed through a subcutaneous tunnel on the anterior chest.

In order to initiate parenteral nutrition, appropriate access must be obtained and the prescription (i.e., composition and infusion rate) must be determined. Guidelines suggest that when tolerance to enteral nutrition is evident, parenteral nutrition should be weaned and discontinued when >60 percent of the patients' needs are met enterally, although there are no data to support this practice¹. Short-term TPN is commonly used in the inpatient setting for acutely ill patients for a period of up to 30 days and requires no pre-certification." Long-term parenteral nutrition requires a tunneled central venous catheter (e.g., Hickman catheter, Groshong catheter, or implanted infusion port) or a peripherally inserted central catheter (PICC). A tunneled catheter is preferable, since infections are more common among patients receiving parenteral nutrition at home through a PICC. Single lumen central venous catheters should be dedicated solely for the infusion of parenteral nutrition, while multiple lumen central venous catheters should have one port dedicated solely for the infusion of parenteral nutrition. In addition, catheter manipulations should be minimized. These interventions may decrease the infectious complications associated with parenteral nutrition. For patients who have an existing line, a new line is not typically required unless there has been septicemia during the life of the existing line.

INTRADIALYTIC PARENTERAL NUTRITION AND INTRAPERITONEAL NUTRITION

Protein energy wasting (PEW) is a common condition in individuals with end-stage renal disease (ESRD). While the nutritional status assessment in individuals with ESRD is multifactorial, measurement of serum albumin levels is a clinically practiced method in evaluation of protein calorie malnutrition, which is associated with increased morbidity and mortality. Although albumin concentrations can be affected by multiple other disease states, these levels are considered to be a clinically relevant measurement for assessing nutritional status by the National Kidney Foundation (NKF)/Kidney Disease Outcomes Quality Initiative (KDOQI) (2000). The KDOQI guidelines recommend dietary protein intake of no less than 1.2 g/kg in individuals undergoing hemodialysis, and no less than 1.3 g/kg in individuals undergoing peritoneal dialysis. Generally, serum albumin concentration of 3.5 g/dL to 5.5 g/dL are considered normal; although the KDOQI guidelines recommend a serum albumin concentration of 4.0 g/dL. Serum albumin concentrations below 3.5 g/dL are associated with twice the mortality rate of that of concentrations greater than or equal to 4.0 g/dL, while concentration below 2.5 g/dL are associated with a 10-fold increase in mortality.

Available published peer-reviewed medical literature on IDPN consists of poorly designed randomized controlled trials (RCTs), as well as case series which do not control for critical variables common in individuals with chronic kidney disease. In a 2010 systematic review (Sigrist, et al), the authors concluded that the three available RCTs published to date were insufficient to demonstrate net benefit or net harm associated with IDPN and that further clinical trials are warranted to demonstrate net benefits in health outcomes. To date, there are no studies addressing IPN in individuals undergoing peritoneal dialysis.

As of May 2016, there are no ongoing clinical trials addressing IDPN, and two completed clinical trials (NCT00501956, NCT00244075) on www.clinicaltrials.gov. Results of the completed trials have not been published.

A general consensus among professional societies regarding treatment options, net health outcomes, and patient selection to address malnutrition in individuals with chronic kidney disease is varied.

The National Institute of Health and Clinical Excellence (NICE) published guidelines in 2006 to address nutritional support in adults and states nutritional support should be considered in the following populations:

Malnourished individuals as defined by any of the following:

A BMI of less than 18.5 kg/m²

Unintentional weight loss greater than 10% within the last 3-6 months

A BMI of less than 20 kg/m² and unintentional weight loss greater than 5% within the last 3-6 months

Individuals at risk of malnutrition as defined by any of the following:

Have poor absorptive capacity and/or have high nutrient losses and/or have increased nutritional needs from causes such as catabolism

Have eaten little or nothing for more than five days and/or are likely to eat little or nothing for the next five days or longer

The NICE guidelines also state parenteral nutrition should only be considered in malnourished individuals or individuals at risk of malnutrition if they meet either of the following criteria:

Inadequate or unsafe oral and/or enteral nutritional intake

A non-functional, inaccessible, or perforated (leaking) gastrointestinal tract

The National Kidney Foundation/Kidney Disease Outcomes Quality Initiative (KDOQI), published clinical practice guidelines for nutrition in children with chronic kidney disease (2008). They state that a trial of IDPN should be considered in malnourished children, as defined by BMI-for-height-age <5th percentile, on hemodialysis, who do not meet adequate nutritional intake through oral and tube feeding.

Guidelines by the German Association of Nutritional Medicine on Parenteral Nutrition recommend use of IDPN only when modifiable causes of malnutrition are excluded, and enhanced oral or enteral supply is unsuccessful or cannot be carried out.

A position statement published by the American Gastroenterological Association in 1995 states enteral nutrition should be considered for individuals who cannot or will not eat, and who have a functional gastrointestinal tract and a safe method of access. Furthermore, if there are no contraindications, and access can be obtained safely (and oral intake is not possible), preference should be given to enteral feeding over parenteral therapy. An additional statement published in 2001 on parenteral nutrition states, in general, that parenteral nutrition is indicated to avoid malnutrition in individuals who cannot obtain adequate nutrients by oral or enteral routes.

Overall, the evidence of efficacy of intradialytic parenteral nutrition in individuals with chronic kidney disease is limited. Although the available published peer-reviewed scientific literature is not robust, it suggests that IDPN therapy may be beneficial in a subset of the population in whom both oral and

enteral nutrition have continually failed to provide patients' nutritional needs. Additional well-designed prospective studies, with outcomes in long-term data, survival, and quality of life are warranted.

Regulatory Status

Total parenteral nutrition is subject to FDA approval. Numerous FDA approved solutions are available.

Policy Statement

GEHA will provide coverage for parenteral nutrition when it is determined to be medically necessary because the medical criteria and guidelines as documented below have been demonstrated.

Benefit Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits.

Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Parenteral Nutrition is covered

Total parenteral nutrition (TPN) is considered medically necessary when either of the following indications are met:

- The individual has a permanently impaired* (non-functioning) gastrointestinal tract resulting in insufficient absorption of nutrients to maintain adequate strength and weight.
- The individual failed a tube trial of enteral nutrition through an enteral feeding tube by meeting at least one of the following:
 1. A concerted effort was made to place an enteral feeding tube or is contraindicated.
 2. A trial with enteral nutrition was made, with appropriate attention to dilution, rate, and alternative formulas, to address side effects of diarrhea.

AND EITHER:

- The individual meets one of the following conditions, which are considered to be severe enough that the individual would not be able to maintain weight and strength on only oral intake or through an enteral feeding tube:
 1. The individual has undergone a recent (within the past 3 months) massive small bowel resection leaving less than or equal to 5 feet of small bowel beyond the ligament of Treitz, or
 2. The individual has a short bowel syndrome that is severe enough that the individual has net gastrointestinal fluid and electrolyte malabsorption such that on an oral intake of 2.5-3 liters/day the enteral losses exceed 50% of the oral/enteral intake and the urine output is less than 1 liter/day, or

3. The individual requires bowel rest for at least 3 months and is receiving intravenously 20-35 cal/kg/day for treatment of symptomatic pancreatitis with/without pancreatic pseudocyst, severe exacerbation of regional enteritis, or a proximal enterocutaneous fistula where tube feeding distal to the fistula isn't possible, or
4. The individual has complete mechanical small bowel obstruction where surgery is not an option, or
5. The individual is significantly malnourished (10% weight loss over 3 months or less and serum albumin less than or equal to 3.4 gm/dl) and has very severe fat malabsorption (fecal fat exceeds 50% of oral/enteral intake on a diet of at least 50 gm of fat/day as measured by a standard 72 hour fecal fat test), or
6. The individual is significantly malnourished (10% weight loss over 3 months or less and serum albumin less than or equal to 3.4 gm/dl) and has a severe motility disturbance of the small intestine and/or stomach which is **unresponsive to prokinetic medication and is demonstrated by either:
 - (a) Scintigraphically (solid meal gastric emptying study demonstrates that the isotope fails to reach the right colon by 6 hours following ingestion), or
 - (b) Radiographically (barium or radiopaque pellets fail to reach the right colon by 6 hours following administration). These studies must be performed when the individual is not acutely ill and is not on any medication which would decrease bowel motility.
7. The individual has severe Hyperemesis Gravidarum.

OR:

- The individual meets **All** of the following criteria:
 1. Maintenance of weight and strength commensurate with the individual's overall health status requires intravenous nutrition and is not possible by utilizing both of the following approaches:
 - (a) Modifying the nutrient composition of the enteral diet (e.g., lactose free, gluten free, low in long chain triglycerides, substitution with medium chain triglycerides, provision of protein as peptides or amino acids, etc.) and
 - (b) Utilizing pharmacologic means to treat the etiology of the malabsorption (e.g., pancreatic enzymes or bile salts, broad spectrum antibiotics for bacterial overgrowth, prokinetic medication for reduced motility, etc.)
 2. The individual is malnourished (10% weight loss over 3 months or less and serum albumin less than or equal to 3.4 gm/dl).
 3. A disease and clinical condition has been documented as being present and it has not responded to altering the manner of delivery of appropriate nutrients (e.g., slow infusion of nutrients through an enteral feeding tube with the tip located in the stomach or jejunum).

TPN that is used in the inpatient setting for acutely ill patients on a short term basis does not require precertification.

When Parenteral Nutrition is not covered

TPN is considered not medically necessary and, therefore, not covered for individuals with a functioning gastrointestinal tract whose need for parenteral nutrition is only required because of any of the following conditions, such as, but not limited to:

- Swallowing disorder
- Temporary defect in gastric emptying, such as a metabolic or electrolyte disorder
- Psychological disorder impairing food intake, such as depression
- Metabolic disorder inducing anorexia, such as cancer
- Physical disorder impairing food intake, such as the dyspnea of severe pulmonary or cardiac disease
- Side effect of a medication
- Renal failure and/or dialysis

When Intradialytic nutrition is covered

Intradialytic parenteral nutrition (IDPN) is considered medically necessary for either of the following:

- When it is infused as an alternative to a regularly scheduled regimen of TPN in individuals who meet the medical necessity criteria for TPN, or
- In individuals with a functional gastrointestinal tract when all of the following criteria are met:
 1. The individual has a documented comprehensive nutritional assessment and dietary counseling
 2. In spite of enteral nutrition via tube feeding, or adequate oral nutrition, the individual has evidence of protein or energy malnutrition as defined by any of the following:
 - Evidence of protein intake $<1.2\text{g/Kg}$ or calories $<25\text{ Kcal/Kg}$
 - Evidence of weight loss 10-20% of usual body weight within 3-6 months
 - Serum Albumin Levels $<3.4\text{ g/l}$ (3 months average)
 3. The individual has evidence of adequate dialysis therapy

When Intraperitoneal nutrition is covered

Intraperitoneal nutrition (IPN) is considered medically necessary and, therefore, covered when all of the following criteria are met:

- The individual has a documented comprehensive nutritional assessment and dietary counseling
- In spite of enteral nutrition via tube feeding, or adequate oral nutrition, the individual has evidence of protein or energy malnutrition as defined by any of the following:
 - 1) Evidence of protein intake $<1.2\text{g/Kg}$ or calories $<25\text{ Kcal/Kg}$
 - 2) Evidence of weight loss 10-20% of usual body weight within 3-6 months
 - 3) Serum albumin Levels $<3.4\text{ g/l}$ (3 months average)
- The individual has evidence of adequate dialysis therapy

Policy Guidelines

When an infusion therapy service is covered, many of the associated services (e.g., solutions, additives, equipment and/or supplies, nursing) may be eligible for reimbursement.

When an infusion therapy service is not covered, all associated services (e.g., solutions, equipment and/or supplies, nursing) are considered not covered, and, therefore, not eligible for reimbursement.

Required documentation

NON-FUNCTIONING GASTROINTESTINAL TRACT

A total caloric daily intake (parenteral, enteral and oral) of 20-35 cal/kg/day is considered sufficient to achieve or maintain appropriate body weight. The ordering professional provider must document in the medical record the medical necessity for a caloric intake outside this range for the individual.

- The ordering professional provider must document the medical necessity for protein orders outside of the range of 0.8-1.5 gm/kg/day, dextrose concentration less than 10%, or lipid use greater than 1500 grams per month.

GEHA 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:

PRESCRIPTION (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

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 DME supplier/provider. All documentation is to be prepared contemporaneous with delivery and be available to the Company upon request.

CONSUMABLE SUPPLIES

The durable medical equipment (DME) supplier must monitor the quantity of accessories and supplies an individual is actually using. Contacting the individual regarding replenishment of supplies should not be done earlier than approximately seven days prior to the delivery/shipping date. Dated documentation of this contact with the individual is required in the individual's medical record. Delivery

of the supplies should not be done earlier than approximately five days before the individual would exhaust their on-hand supply.

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.

Scientific references

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Policy implementation and updates

10/2018 Policy reformatted and updated