

Protocol

Intradialytic Parenteral Nutrition

(80144)

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| Medical Benefit | | Effective Date: 07/30/04 | Next Review Date: 09/20 |
| Preauthorization | No | Review Dates: 02/07, 03/08, 01/09, 01/10, 01/11, 01/12, 01/13, 09/13, 09/14, 09/15, 09/16, 09/17, 09/18, 09/19 | |

Preauthorization is not required.

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.

| Populations | Interventions | Comparators | Outcomes |
|--|---|--|--|
| Individuals: <ul style="list-style-type: none">• Who are undergoing hemodialysis | Interventions of interest are: <ul style="list-style-type: none">• Intradialytic parenteral nutrition | Comparators of interest are: <ul style="list-style-type: none">• Standard of care (e.g., oral nutritional supplementation) | Relevant outcomes include: <ul style="list-style-type: none">• Overall survival• Changes in disease status• Morbid events• Health status measures• Quality of life• Treatment-related mortality• Treatment-related morbidity |

DESCRIPTION

Intradialytic parenteral nutrition is the infusion of an intravenous hyperalimentation formula, such as amino acids, glucose, and lipids, during dialysis, to treat protein calorie malnutrition in an effort to decrease the morbidity and mortality experienced in patients with renal failure.

SUMMARY OF EVIDENCE

For individuals who are undergoing hemodialysis who receive intradialytic parenteral nutrition, the evidence includes multiple randomized controlled trials, observational studies, and systematic reviews of these studies. Relevant outcomes are overall survival, change in disease status, morbid events, health status measures, quality of life, treatment-related mortality and morbidity. Published systematic reviews, which included randomized controlled trials but could not pool data, have concluded that the current evidence does not demonstrate benefits in patient outcomes with the use of intradialytic parenteral nutrition for those who would not otherwise qualify for total parenteral nutrition. The evidence is insufficient to determine the effects of the technology on health outcomes.

POLICY

Intradialytic parenteral nutrition (IDPN) as an adjunct to hemodialysis may be considered **medically necessary**

when it is offered as an alternative to a regularly scheduled regimen of total parenteral nutrition (TPN) only in patients who would be considered candidates for TPN. (See Policy Guidelines)

IDPN is considered **not medically necessary** in patients who would be considered a candidate for TPN, but for whom IDPN is not offered as an alternative to TPN, but in addition to regularly scheduled infusions of TPN.

IDPN as an adjunct to hemodialysis is considered **investigational** in patients who would not otherwise be considered candidates for TPN.

POLICY GUIDELINES

Patients who are considered candidates for TPN are those who have a severe pathology of the alimentary tract that does not allow absorption of sufficient nutrients to maintain weight and strength commensurate with the patient's general condition.

This protocol only addresses intravenous parenteral nutrition as an adjunct to hemodialysis (not peritoneal dialysis).

BACKGROUND

PROTEIN CALORIE MALNUTRITION

Protein calorie malnutrition occurs in an estimated 25% to 40% of patients undergoing dialysis. The cause of malnutrition in patients on dialysis is often multifactorial and may include under dialysis, chronic inflammation, protein loss in the dialysate solution (particularly in peritoneal dialysis), untreated metabolic acidosis, and decreased oral intake.

Diagnosis

The clinical evaluation of malnutrition is multifactorial but typically includes measurement of serum albumin. Serum albumin levels correlate with nutritional status but are imperfect measures of nutrition because they can be affected by other disease states. Protein calorie malnutrition is associated with increased morbidity and mortality. For example, the risk of death is increased more than 10-fold in those whose serum albumin levels are less than 2.5 g/dL, and those with a serum albumin near the normal range (i.e., 3.5-3.9 g/dL) have a mortality rate twice as high as those with an albumin level greater than 4.0 g/dL.

Treatment

For patients receiving chronic dialysis, the National Kidney Foundation currently recommends a daily protein intake of 1.2 g/kg or more in patients undergoing hemodialysis and 1.3 g/kg or more in patients undergoing peritoneal dialysis.¹ When malnutrition is present, a stepwise approach to treatment is generally used, beginning with dietary counseling and diet modifications, followed by oral nutrition supplements, and then by enteral nutrition supplements or parenteral nutrition supplements if needed.

Intradialytic parenteral nutrition, which refers to the infusion of hyperalimentation fluids at the time of hemodialysis or peritoneal dialysis, has been investigated as a technique to treat protein calorie malnutrition in an effort to decrease associated morbidity and mortality. Intradialytic parenteral nutrition solutions are similar to those used for total parenteral nutrition. A typical solution contains 10% amino acids, 40% to 50% glucose, 10% to 20% lipids, or a mixture of carbohydrate or lipids, depending on patient needs. In hemodialysis, the intradialytic parenteral nutrition infusion is administered through the venous port of the dialysis tubing, typically, 30 minutes after dialysis has begun, and continued throughout the dialysis session.

REGULATORY STATUS

Total parenteral nutrition solutions are compounded by an individual pharmacy from individual ingredients (e.g., dextrose, amino acids, trace elements) into a finished medication based on a prescription and are not required to have approval from the U.S. Food and Drug Administration (FDA) through a new drug application process. Compounding pharmacies have historically been subject to regulation by state pharmacy boards, although the FDA increased its regulatory oversight under the Drug Quality and Security Act of 2013.

Peritoneal dialysis solutions are regulated as drugs as defined by the FDA. One amino acid-based peritoneal dialysate, Nutrineal™ PD4, 1.1% Amino Acid Peritoneal Dialysis Solution (Baxter), is available commercially outside of the U.S., but has not been FDA approved.

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

REFERENCES

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

1. Kopple JD. The National Kidney Foundation K/DOQI clinical practice guidelines for dietary protein intake for chronic dialysis patients. *Am J Kidney Dis.* Oct 2001;38(4 Suppl 1):S68-73. PMID 11576926.
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3. KDOQI Clinical Practice Guideline for Nutrition in Children with CKD: 2008 update. Executive summary. *Am J Kidney Dis.* Mar 2009;53(3 Suppl 2):S11-104. PMID 19231749.
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10. Brown RO, Compher C, American Society for Parenteral Enteral Nutrition Board of Directors. A.S.P.E.N. clinical guidelines: nutrition support in adult acute and chronic renal failure. *JPEN J Parenter Enteral Nutr*. Jul-Aug 2010;34(4):366-377. PMID 20631382.
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12. Department of Health and Human Services, Health Care Financing Administration. HCFA Rulings. Ruling No. 96-3. 1996; <https://www.cms.gov/Regulations-and-Guidance/Guidance/Rulings/downloads/hcfar963.pdf>. Accessed April 9, 2018.