



Louisiana

Intradialytic Parenteral Nutrition

Policy # 00228

Original Effective Date: 02/20/2008

Current Effective Date: 02/21/2018

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: Total Parenteral Nutrition and Enteral Nutrition in the Home is addressed in medical policy 00088.

When Services Are Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider intradialytic parenteral nutrition (IDPN) as an adjunct to hemodialysis when it is offered as an alternative to a regularly scheduled regimen of total parenteral nutrition only in those patients who would be considered candidates for total parenteral nutrition (TPN) (i.e., 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) to be **eligible for coverage**.

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers IDPN as an adjunct to hemodialysis in patients who would not otherwise be considered candidates for TPN to be **investigational**.*

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers IDPN in patients who would be considered a candidate for TPN, but for whom the IDPN is not offered as an alternative to TPN, but in addition to regularly scheduled infusions to TPN to be **not medically necessary****.

Background/Overview

PROTEIN CALORIE MALNUTRITION

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

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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 multiple 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 (ie, 3.5-3.9 g/dL) have a mortality rate twice as high as those with albumin greater than 4.0 g/dL.

Treatment

In 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. When malnutrition is present, a stepwise approach to treatment is generally used, beginning with dietary counseling and diet modifications, followed by oral nutritional supplements, and then by enteral nutrition supplements or parenteral nutritional supplements if needed.

IDPN, 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. IDPN solutions are similar to those used for TPN. 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 IDPN infusion is administered through the venous port of the dialysis tubing, typically, 30 minutes after dialysis has begun, and continued throughout the dialysis session.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

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

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

Centers for Medicare and Medicaid Services (CMS)

The coverage eligibility of IDPN for Medicare beneficiaries is summarized in a Health Care Financing Administration (HCFA) ruling from December 1996, which established that intradialytic nutrition would be considered eligible for coverage only if the patient would otherwise be a candidate for TPN. This ruling reads in part:

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“Medicare coverage policies which apply to parenteral and enteral nutrition therapy items and services apply identically to intradialytic parenteral nutrition therapy items and services, because intradialytic parenteral nutrition therapy is a subset of parenteral and enteral nutrition therapy. Coverage of parenteral and enteral nutrition therapy is amplified in Medicare Coverage Issues manual section 65-10. Daily parenteral therapy is ‘considered reasonable and necessary for a patient with severe pathology of the alimentary tract which does not allow absorption of sufficient nutrients to maintain weight and strength commensurate with the patient’s general condition.’ Intradialytic parenteral nutrition therapy is administered to end stage renal disease (ESRD) patients while they are receiving dialysis. ESRD patients sometimes undergo parenteral therapy to replace fluids and nutrients lost during dialysis. ESRD patients must meet all of the parenteral nutrition therapy coverage requirements to receive intradialytic parenteral nutrition therapy. Those patients who do not meet all of the parenteral nutrition therapy coverage requirements are ineligible to receive Medicare coverage of intradialytic parenteral nutrition therapy under the prosthetic device benefit....”

The HCFA ruling goes on to clarify the benefits for patients who would be considered candidates for tTPN and when the IDPN is designed to be offered in lieu of a regularly scheduled infusion of TPN.

“However, parenteral and enteral nutrition, including intradialytic parenteral nutrition therapy, services and items which are otherwise covered under section 1861(s)(8) can be denied under section 1862(a)(1) for lack of medical necessity: ... Example, if a Medicare beneficiary with ESRD, a dialysis patient who meets all of the requirements for coverage of parenteral nutrition therapy, receives intradialytic parenteral nutrition therapy during dialysis and also receives parenteral nutrition therapy on the other days of the week when the patient is not on dialysis, it may be determined that the patient is receiving an excessive number of lipids. A claim for Medicare payment that is denied because the patient, who qualifies for parenteral nutrition therapy coverage, is receiving an excessive number of lipids would be denied as not reasonable and necessary under section 1862(a)(1)(A) of the Act... Therefore the precise statutory basis for the coverage or denial of parenteral and enteral nutrition therapy, including intradialytic parenteral nutrition therapy, services and items is crucial and determinative as to whether or not limitation on liability protections can be applied.”

Rationale/Source

For patients who qualify for TPN and are concomitantly receiving hemodialysis, it is reasonable to administer IDPN solution, which is similar to a TPN solution. IPDN is administered via the existing venous port of the dialysis tubing rather than through an alternative intravenous site.

This evidence review focuses on studies evaluating whether IDPN as an adjunct to hemodialysis improves outcomes for individuals who may be at risk for malnutrition but who would not otherwise receive parenteral nutrition.

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INTRADIALYTIC PARENTERAL NUTRITION

Systematic Reviews

In 1993, the Office of Health Technology Assessment published a review that concluded existing studies of IDPN had reported equivocal results and the data did not validate its efficacy. Subsequently, in 1999, Foulks conducted an evidenced-based evaluation of IDPN. The analysis concluded that the overall quality of the literature was poor; although 3 randomized controlled trials (RCTs) were identified, 1 was excluded because it was a crossover study and assessed the feasibility of using the IDPN technique while the other 2 had methodologic flaws or used types of IDPN not routinely used or unavailable in the United States. The remaining literature consisted of case series, which cannot control for known and unknown prognostic factors that can affect study outcomes. According to Foulks's analysis, most case series had methodologic flaws, including heterogeneity in study designs, patient selection criteria, types of IDPN used, and adequacy of dialysis. Dukkupati et al conducted a systematic review of IDPN for the treatment of malnutrition in hemodialysis patients in 2010. Reviewers identified 3 RCTs and found the data insufficient to conduct a meta-analysis or to demonstrate a net benefit in health outcomes with the use of IDPN. They concluded that further clinical trials on IDPN were needed and should measure survival, quality of life, and nutritional status. In 2010, Sigrist et al reported results from a systematic review of IDPN for patients with chronic kidney disease. Reviewers evaluated RCTs and systematic reviews of RCTs that specifically enrolled malnourished patients on hemodialysis who had been randomized to IDPN (including full IDPN or amino acids plus carbohydrates only) or to any form of enteral or oral nutrition. Three studies met reviewers' inclusion criteria, only 1 of which reported mortality as an outcome. The data were insufficient to conduct a meta-analysis, and reviewers concluded that the evidence from clinical studies was insufficient to demonstrate either a net benefit or a net harm associated with the providing IDPN to malnourished hemodialysis patients.

Randomized Controlled Trials

Marsen et al (2017) reported on the results of an RCT of 107 patients on maintenance hemodialysis suffering from protein-energy wasting syndrome. Patients were randomized to IDPN 3 times weekly plus standardized nutrition counseling or standardized nutrition counseling only. Patients were included if they were moderately or severely malnourished (Subjective Global Assessment score B or C) and had 2 or more of the following markers: albumin levels less than 35 g/L, prealbumin levels less than 250 mg/L, and phase angle alpha levels less than 4.5. The trial assessed intermediate outcomes (change in serum prealbumin from baseline to week 16). The proportion of patients that showed at least 15% or more increase in prealbumin levels compared to baseline was higher in the IDPN group (41.0%) than in the control group at 16 weeks (20.5%; $p < 0.05$), with sustained response thereafter. Quality of life scores, as measured by 12-Item Short-Form Health Survey, did not differ statistically between the 2 treatment arms.

Cano et al (2007) reported on the results of an RCT of 186 malnourished hemodialysis patients from 38 treatment centers in France. Patients were randomized to IDPN plus oral supplementation or to oral supplementation alone (1 year of treatment with 2 years of follow-up). Malnutrition was defined as the presence of 2 or more of the following markers: body mass index less than 20 kg/m², body weight loss within 6 months greater than 10%, serum albumin levels less than 35 g/L, and serum prealbumin levels less

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than 300 mg/L. Based on intention-to-treat analysis, no differences were found in 2-year survival, hospitalizations, Karnofsky Performance Status score, body mass index, and serum albumin and prealbumin levels between treatment groups. The trial was powered to detect a 10% reduction in mortality with 78% power (5% α error). Meeting the stated nutritional goals (orally or parenterally) may have improved outcomes; an editorialist suggested that both groups achieved about a 15% improvement in survival compared with historical controls.

Nonrandomized Comparative Studies

Multiple nonrandomized studies published before the 2017 Marsen RCT have reported on predictors of outcomes for patients treated with IDPN. The largest study (1994) is a retrospective case series that compared morbidity rates in 1679 IDPN-treated patients with those of 22,517 untreated patients. In this series, Chertow et al reported that patients with a serum albumin level of less than 3.4 g/dL experienced a significant decrease in the odds ratio (OR) for death at 1 year compared with those who were not treated with IDPN. The odds ratio for death increased for IDPN-treated patients who had an albumin level of greater than 3.4 mg/dL. Predictors of IDPN response were examined in a 2009 study of 196 hypoalbuminemic patients receiving maintenance hemodialysis who underwent IDPN. The study suggested that IDPN treatment could improve hypoalbuminemia in patients receiving maintenance hemodialysis and that the likelihood and magnitude of response to IDPN in these patients was associated with the baseline severity of hypoalbuminemia. Two other uncontrolled studies have also suggested improved outcomes associated with IDPN. Because of the numerous biases inherent in any uncontrolled trial, these studies cannot validate whether IDPN is associated with lowered mortality rates. The observed treatment effect could be related to a selection bias in which very ill patients (ie, those expected to die) were not offered IDPN. In addition, IDPN administration might be associated with an increased attentiveness to factors such as dialysis parameters, counseling, and nutritional advice. These studies suggest that being selected for IDPN may be associated with reduced mortality rate, but analysis of the direct contribution of IDPN requires controlled trials.

Section Summary: Intradialytic Parenteral Nutrition

A well-conducted, adequately powered RCT designed to evaluate the effects of 1 year of IDPN plus oral supplements failed to show any incremental benefit in mortality or hospitalization rates at 2 years compared with oral supplements alone. Other RCTs have used nutritional or inflammation outcomes to assess the impact of IDPN indicators, rather than the more important outcomes of morbidity, mortality, and quality of life. Further, there were multiple limitations related to trial designs and interpretation of results from RCTs published between 1989 and 2006. These limitations include lack of power to demonstrate benefits, heterogeneity in trial patient populations resulting from variation in diagnostic criteria for protein-energy wasting, comorbid conditions, dialysis practices, and composition and doses of IDPN solutions. Published systematic reviews, which included RCTs but could not pool data, also concluded that the available studies are inadequate to demonstrate a benefit from IDPN for patients who would not qualify for parenteral nutrition.

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SUMMARY OF EVIDENCE

For individuals who are undergoing hemodialysis who receive IDPN, the evidence includes multiple RCTs and systematic reviews. Relevant outcomes are overall survival, change in disease status, morbid events, health status measures, quality of life, treatment-related mortality and treatment-related morbidity. Findings from a well-conducted, adequately powered RCT designed to evaluate the effects of 1 year of IDPN plus oral supplements failed to show any incremental benefit in mortality or hospitalization rates at 2 years compared to oral supplements alone. Other smaller RCTs have assessed the impact of IDPN on nutritional or inflammation outcomes, rather than the more important outcomes like morbidity, mortality, and quality of life. Limitations of these smaller RCTs include inadequate power to demonstrate benefits and heterogeneity in the trial patient populations resulting from variation in diagnostic criteria for protein-energy wasting, comorbid conditions, dialysis practices, and composition and doses of IDPN solutions. Published systematic reviews, which included RCTs but could not pool data, have also concluded that the current evidence does not demonstrate benefits in the net health outcome with the use of IDPN for patients who would not otherwise qualify for IDPN. The evidence is insufficient to determine the effects of the technology on health outcomes.

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Policy History

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02/13/2008	Medical Director review
02/20/2008	Medical Policy Committee approval.
02/04/2009	Medical Director review
02/19/2009	Medical Policy Committee approval. No change to coverage eligibility.
02/04/2010	Medical Policy Committee approval
02/17/2010	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
02/03/2011	Medical Policy Committee review
02/16/2011	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
02/02/2012	Medical Policy Committee review
02/15/2012	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
02/07/2013	Medical Policy Committee review
02/20/2013	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
02/06/2014	Medical Policy Committee review
02/19/2014	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
02/05/2015	Medical Policy Committee review
02/18/2015	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
02/04/2016	Medical Policy Committee review
02/17/2016	Medical Policy Implementation Committee approval. Policy statements edited to clarify that they are intended to apply to parenteral nutrition administered during hemodialysis.
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes
02/02/2017	Medical Policy Committee review
02/15/2017	Medical Policy Implementation Committee approval. No change to coverage.
02/01/2018	Medical Policy Committee review
02/21/2018	Medical Policy Implementation Committee approval. No change to coverage.
Next Scheduled Review Date:	02/2019

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	No codes
HCPCS	B4164, B4168, B4172, B4176, B4178, B4180, B4185, B4189, B4193, B4197, B4199, B4216, B4220, B4222, B4224, B5000, B5100, B5200
ICD-10 Diagnosis	N181-N18.9, N19

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the FDA and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;

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- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

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