



Louisiana

Intradialytic Parenteral Nutrition

Policy # 00228

Original Effective Date: 02/20/2008

Current Effective Date: 03/09/2020

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.****

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

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.***

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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 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 (ie, 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.

[add ESPEN consensus statement [Cederholm T, Bosaeus I, Barazzoni R, et al. Diagnostic criteria for malnutrition—an ESPEN consensus statement. Clin Nutr. 2015;34 (3):335-340.]

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. 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.

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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.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Total parenteral nutrition 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. 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.

Rationale/Source

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.

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. The 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

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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.

Supplemental Information

Practice Guidelines and Position Statements

National Kidney Foundation

National Kidney Foundation (2001) clinical guidelines established target daily protein requirements in patients undergoing chronic dialysis. The Foundation (2008) updated its pediatric nutrition guidelines to recommend a trial of intradialytic parenteral nutrition (IDPN) to augment inadequate nutritional intake for malnourished children (body mass index for height and age <5th percentile) receiving maintenance hemodialysis who are unable to meet their nutritional requirements through oral and tube feeding.

American Society for Parenteral and Enteral Nutrition

The ASPEN (2010) issued guidelines on nutritional support in adults in acute and chronic renal failure. The ASPEN assigned a level C recommendation (supported by at least one level II investigation) that IDPN should not be used as a nutritional supplement in malnourished chronic kidney disease-V hemodialysis patients. The basis for the recommendation was a large randomized controlled trial that found mortality rates did not differ between malnourished patients receiving IDPN and malnourished patients receiving oral supplements without IDPN. An additional concern was that IDPN "is limited by the need to complete the entire nutrient infusion during the hemodialysis" treatment, which may cause adverse events because of the rapid infusion of glucose and lipids. ASPEN further recommended larger randomized controlled trials "in malnourished patients are needed to ensure that a clinical benefit of IDPN does not exist."

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

The coverage eligibility of IDPN for Medicare beneficiaries was summarized in a 1996 Health Care Financing Administration ruling, which established that intradialytic nutrition would be considered eligible for coverage only if the patient would otherwise be a candidate for total parenteral nutrition. 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.

... 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 Health Care Financing Administration ruling went on to clarify the benefits for patients who would be considered candidates for total parenteral nutrition and when the IDPN is to be offered in lieu of a regularly scheduled infusion of total parenteral nutrition.

"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."

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Ongoing and Unpublished Clinical Trials

A search of [ClinicalTrials.gov](https://clinicaltrials.gov) in April 2019 did not identify any ongoing or unpublished trials that would likely influence this review.

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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 |

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- 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.
 - 02/07/2019 Medical Policy Committee review
 - 02/20/2019 Medical Policy Implementation Committee approval. No change to coverage.
 - 02/06/2020 Medical Policy Committee review
 - 02/12/2020 Medical Policy Implementation Committee approval. No change to coverage.
- Next Scheduled Review Date: 02/2021

Coding

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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	N18.1-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 U.S. Food and Drug Administration (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);

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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;
- 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.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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