Intradialytic Parenteral Nutrition

Policy Number: 8.01.44  Last Review: 8/2017
Origination: 8/2014  Next Review: 8/2018

Policy
Blue Cross and Blue Shield of Kansas City (Blue KC) will provide coverage for Intradialytic Parenteral Nutrition when it is determined to be medically necessary because the criteria shown below are met.

When Policy Topic is covered
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 total parenteral nutrition (TPN).

When Policy Topic is not covered
Intradialytic parenteral nutrition is considered not medically necessary in patients who would be considered a candidate for TPN, but for whom the intradialytic parenteral nutrition is not offered as an alternative to TPN, but in addition to regularly scheduled infusions to TPN.

Intradialytic parenteral nutrition 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 policy is only addresses intravenous parenteral nutrition as an adjunct to hemodialysis (not peritoneal dialysis).

Description of Procedure or Service

<table>
<thead>
<tr>
<th>Populations</th>
<th>Interventions</th>
<th>Comparators</th>
<th>Outcomes</th>
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<tbody>
<tr>
<td>Individuals:</td>
<td>Interventions of interest are:</td>
<td>Comparators of interest are:</td>
<td>Relevant outcomes include:</td>
</tr>
<tr>
<td>• Who are undergoing hemodialysis</td>
<td>• Intradialytic parenteral nutrition</td>
<td>• Standard of care (eg, oral nutritional)</td>
<td>• Overall survival</td>
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<td></td>
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<td>• Change in disease status</td>
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<td>• Morbid events</td>
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Intradialytic parenteral nutrition (IDPN) is the infusion of an intravenous nutritional formula of hyperalimentation, such as amino acids, glucose, and lipids, during dialysis, to treat protein calorie malnutrition in an effort to decrease the associated morbidity and mortality experienced in patients with renal failure.

For individuals who are undergoing hemodialysis who receive IDPN, the evidence includes multiple randomized controlled trials (RCTs) and systematic reviews. Relevant outcomes are overall survival, change in disease status, morbidity 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.

For individuals who qualify to receive total parenteral nutrition (TPN) and are undergoing hemodialysis, IDPN can be used as an alternative to TPN. Avoiding the morbidity related to establishing and maintaining an additional venous access site for TPN will support improvement in health outcomes. In these cases, it is clinically reasonable to offer IDPN as an alternative to a regularly scheduled TPN regimen.

**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 underdialysis, 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.

**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 nutrition supplements, and then by enteral nutrition supplements or parenteral nutrition supplements if needed.

Intradialytic parenteral nutrition (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 total parenteral nutrition (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.

**Regulatory Status**
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 FDA increased its regulatory oversight under 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), is available commercially outside of the United States, but has not been FDA approved.

**Rationale**
This evidence review was originally created in December 2003 and has been updated regularly with searches of the MEDLINE database. The most recent literature review was performed through March 23, 2017.

For patients who qualify for total parenteral nutrition (TPN) and are concomitantly receiving hemodialysis, it is reasonable to administer intradialytic parenteral nutrition (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.

### 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. Dukkipati 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
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.

**Summary of Evidence**

For individuals who are undergoing hemodialysis who receive intradialytic parenteral nutrition (IDPN), the evidence includes multiple randomized controlled trials (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.

**Supplemental Information**

**Practice Guidelines and Position Statements**

**National Kidney Foundation**

The 2001 clinical guidelines from the National Kidney Foundation (NKF) established target daily protein requirements in patients undergoing chronic dialysis. In 2009, NKF updated its pediatric nutrition guideline 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.
**German Association for Nutritional Medicine**

The German Association for Nutritional Medicine’s guidelines indicated that “IDPN should only be carried out when modifiable causes of malnutrition are excluded and enhanced oral or enteral supply is unsuccessful or cannot be carried out.”

These guidelines noted:

“The following international criteria for malnutrition have been suggested, even though they are not based on firm evidence:

- Middle predialysis serum albumin <3.4 g/L for >3 months
- Middle predialysis serum creatinine <8.0 mg/L for >3 months
- Weight loss >10% of ideal body weight or >20% of normal body weight (no time limit)
- Clinical examination indicates moderate to severe malnutrition
- Dietary history indicating protein intake <0.8 g/kg, reduced calorie intake <25 kcal/kg
- Subjective Global Assessment (SGA) “C”= severe malnutrition

IDPN should be considered when three of the above-mentioned criteria are associated with the following conditions:

- Aborted attempts to increase oral/enteral food intake
- Refusal of enteral gavage

**American Society for Parenteral and Enteral Nutrition**

In 2010, the American Society for Parenteral and Enteral Nutrition (ASPEN) issued guidelines on nutritional support in adults in acute and chronic renal failure. ASPEN assigned a level C recommendation (supported by at least 1 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 (RCT) that found mortality rates did not differ between malnourished patients receiving IDPN and malnourished patients who received 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 effects because of the rapid infusion of glucose and lipids. ASPEN further recommended larger RCTs “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 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 total parenteral nutrition (TPN). This ruling reads in part:
“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 TPN 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.”

**Ongoing and Unpublished Clinical Trials**
A search of ClinicalTrials.gov in March 2017 did not identify any ongoing or unpublished trials that would likely influence this review.
References


### Billing Coding/Physician Documentation Information

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>90935</td>
<td>Hemodialysis procedure with single evaluation by a physician or other qualified health care professional</td>
</tr>
<tr>
<td>90937</td>
<td>Hemodialysis procedure requiring repeated evaluation(s) with or without substantial revision of dialysis prescription</td>
</tr>
<tr>
<td>90940</td>
<td>Hemodialysis access flow study to determine blood flow in grafts and arteriovenous fistulae by an indicator method</td>
</tr>
<tr>
<td>90945</td>
<td>Dialysis procedure other than hemodialysis (eg, peritoneal dialysis, hemofiltration, or other continuous renal replacement therapies), with single evaluation by a physician or other qualified health care professional</td>
</tr>
<tr>
<td>90947</td>
<td>Dialysis procedure other than hemodialysis (eg, peritoneal dialysis, hemofiltration, or other continuous renal replacement therapies) requiring repeated evaluations by a physician or other qualified health care professional, with or without substantial revision of dialysis prescription</td>
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<tr>
<td>90951</td>
<td>End-stage renal disease (ESRD) related services monthly, for patients younger than 2 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 4 or more face-to-face visits by a physician or other qualified health care professional per month</td>
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<tr>
<td>90952</td>
<td>End-stage renal disease (ESRD) related services monthly, for patients younger than 2 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 2-3 face-to-face visits by a physician or other qualified health care professional per month</td>
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<tr>
<td>90953</td>
<td>End-stage renal disease (ESRD) related services monthly, for patients younger than 2 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 1 face-to-face visit by a physician or other qualified health care professional per month</td>
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<tr>
<td>90954</td>
<td>End-stage renal disease (ESRD) related services monthly, for patients 2-11 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 4 or more face-to-face visits by a physician or other qualified health care professional per month</td>
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<tr>
<td>90955</td>
<td>End-stage renal disease (ESRD) related services monthly, for patients 2-11 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 2-3 face-to-face visits by a physician or other qualified health care professional per month</td>
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</table>
| 90956 | End-stage renal disease (ESRD) related services monthly, for patients 2-11 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with
1 face-to-face visit by a physician or other qualified health care professional per month

90957 End-stage renal disease (ESRD) related services monthly, for patients 12-19 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 4 or more face-to-face visits by a physician or other qualified health care professional per month

90958 End-stage renal disease (ESRD) related services monthly, for patients 12-19 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 2-3 face-to-face visits by a physician or other qualified health care professional per month

90959 End-stage renal disease (ESRD) related services monthly, for patients 12-19 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 1 face-to-face visit by a physician or other qualified health care professional per month

90960 End-stage renal disease (ESRD) related services monthly, for patients 20 years of age and older; with 4 or more face-to-face visits by a physician or other qualified health care professional per month

90961 End-stage renal disease (ESRD) related services monthly, for patients 20 years of age and older; with 2-3 face-to-face visits by a physician or other qualified health care professional per month

90962 End-stage renal disease (ESRD) related services monthly, for patients 20 years of age and older; with 1 face-to-face visit by a physician or other qualified health care professional per month

90963 End-stage renal disease (ESRD) related services for home dialysis per full month, for patients younger than 2 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents

90964 End-stage renal disease (ESRD) related services for home dialysis per full month, for patients 2-11 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents

90965 End-stage renal disease (ESRD) related services for home dialysis per full month, for patients 12-19 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents

90966 End-stage renal disease (ESRD) related services for home dialysis per full month, for patients 20 years of age and older

90967 End-stage renal disease (ESRD) related services for dialysis less than a full month of service, per day; for patients younger than 2 years of age

90968 End-stage renal disease (ESRD) related services for dialysis less than a full month of service, per day; for patients 2-11 years of age

90969 End-stage renal disease (ESRD) related services for dialysis less than a full month of service, per day; for patients 12-19 years of age

90970 End-stage renal disease (ESRD) related services for dialysis less than a full month of service, per day; for patients 20 years of age and older
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B4164 Parenteral nutrition solution: carbohydrates (dextrose), 50% or less (500 ml = 1 unit), home mix
B4168 Parenteral nutrition solution; amino acid, 3.5%, (500 ml = 1 unit) - home mix
B4172 Parenteral nutrition solution; amino acid, 5.5% through 7%, (500 ml = 1 unit) - home mix
B4176 Parenteral nutrition solution; amino acid, 7% through 8.5%, (500 ml = 1 unit) - home mix
B4178 Parenteral nutrition solution: amino acid, greater than 8.5% (500 ml = 1 unit), home mix
B4180 Parenteral nutrition solution: carbohydrates (dextrose), greater than 50% (500 ml = 1 unit), home mix
B4185 Parenteral nutrition solution, per 10 grams lipids
B4189 Parenteral nutrition solution: compounded amino acid and carbohydrates with electrolytes, trace elements, and vitamins, including preparation, any strength, 10 to 51 g of protein, premix
B4193 Parenteral nutrition solution: compounded amino acid and carbohydrates with electrolytes, trace elements, and vitamins, including preparation, any strength, 52 to 73 g of protein, premix
B4197 Parenteral nutrition solution: compounded amino acid and carbohydrates with electrolytes, trace elements and vitamins, including preparation, any strength, 74 to 100 grams of protein - premix
B4199 Parenteral nutrition solution; compounded amino acid and carbohydrates with electrolytes, trace elements and vitamins, including preparation, any strength, over 100 grams of protein - premix
B4216 Parenteral nutrition; additives (vitamins, trace elements, Heparin, electrolytes), home mix, per day
B4220 Parenteral nutrition supply kit; premix, per day
B4222 Parenteral nutrition supply kit; home mix, per day
B4224 Parenteral nutrition administration kit, per day
B5000 Parenteral nutrition solution: compounded amino acid and carbohydrates with electrolytes, trace elements, and vitamins, including preparation, any strength, renal - Amirosyn RF, NephrAmine, RenAmine - premix
B5100 Parenteral nutrition solution: compounded amino acid and carbohydrates with electrolytes, trace elements, and vitamins, including preparation, any strength, hepatic - FreAmine HBC, HepatAmine - premix
B5200 Parenteral nutrition solution: compounded amino acid and carbohydrates with electrolytes, trace elements, and vitamins, including preparation, any strength, stress - branch chain amino acids – premix

ICD-10 Codes
N18.1- Chronic kidney disease, code range
N18.9
N19 Unspecified kidney failure

Additional Policy Key Words
N/A
**Policy Implementation/Update Information**

8/1/14  New policy. Check for medical necessity.
8/1/15  Policy statements edited to clarify that they are intended to apply to parenteral nutrition administered during hemodialysis; policy statements otherwise unchanged.
8/1/16  No policy statement changes.
8/1/17  No policy statement changes.

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