**National Medical Policy**

**Subject:** Intradialytic Parenteral Nutrition/Intraperitoneal Amino Acid (IPAA) Supplementation

**Policy Number:** NMP308

**Effective Date:** December 2006

**Updated:** August 2015

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This National Medical Policy is subject to the terms in the IMPORTANT NOTICE at the end of this document.

For Medicaid Plans: Please refer to the appropriate Medicaid Manuals for coverage guidelines prior to applying Health Net Medical Policies.

**The Centers for Medicare & Medicaid Services (CMS)**

For Medicare Advantage members please refer to the following for coverage guidelines first:

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Instructions
- Medicare NCDs and National Coverage Manuals apply to ALL Medicare members in ALL regions.
- Medicare LCDs and Articles apply to members in specific regions. To access your specific region, select the link provided under “Reference/Website” and follow the search instructions. Enter the topic and your specific state to find the coverage determinations for your region. *Note: Health Net must follow local coverage determinations (LCDs) of Medicare Administration Contractors (MACs) located outside their service area when those MACs have exclusive coverage of an item or service. (CMS Manual Chapter 4 Section 90.2)
- If more than one source is checked, you need to access all sources as, on occasion, an LCD or article contains additional coverage information than contained in the NCD or National Coverage Manual.
- If there is no NCD, National Coverage Manual or region specific LCD/Article, follow the Health Net Hierarchy of Medical Resources for guidance.

Current Policy Statement
Health Net, Inc. considers intradialytic parenteral nutrition (IDPN) medically necessary in individuals who would otherwise be considered candidates for total parenteral nutrition (TPN) and all of the following are met:

1. The patient has end stage renal disease (ESRD) and is on maintenance hemodialysis; and
2. The patient has severe weakness and wasting (inanition) from malnourishment because of any of the following:
   - The patient has a chronic (i.e., > 3 months) disease of the gastrointestinal tract that precludes absorption of sufficient nutrients to maintain weight and strength by the oral or tube-feeding route; or
   - The patient is unable to tolerate protein-rich foods or formula by the oral or tube-feeding route; and
3. The patient has clinical sign(s) of malnutrition as documented by any of the following:
   - A total protein of < 6 g/dL
   - Serum albumin concentrations of < 3.4 g/dL*
   - The patient has a documented loss of > 10% of ideal body weight over a three-month period; and
4. The intradialytic parenteral nutrition is offered as an alternative to a regularly scheduled regimen of total parenteral nutrition.

* Measurement of serum albumin is by using a dye binding technique using bromocresol green (BCG) or purple (BCP): this tends to overestimate albumin concentration when the serum albumin is low - especially when there is increased levels of α or β globulin. Because of this overestimation, is rare to see a serum albumin < 10 - 15g/l. BCP is more sensitive than BCG. The ability to convert between these measurements will be of use in clinical situations where the absolute value of the serum albumin is important. The conversion factor is Alb_{BCG}=5.5+Alb_{BCP}.

Note: Sign(s) of malnutrition will be assessed on an every three-month basis.
Intraperitoneal Amino Acid (IPAA) Supplementation
Health Net, Inc. considers intraperitoneal amino acid (IPAA) supplementation medically necessary for a patient on maintenance peritoneal dialysis when all of the following are met:

1. There is evidence of inadequate daily dietary protein intake (DPI) as evidenced by protein malnutrition (i.e., a daily dietary protein intake of < 1.3 g/kg); and
2. Inability to administer or tolerate adequate oral protein nutrition (including food supplements) and/or enteral tube feeding.

Not Medically Necessary
Health Net, Inc. considers intradialytic parenteral nutrition not medically necessary for any of the following:

1. A dialysis patient who would not otherwise be considered a candidate for TPN
2. The dialysis patient is considered to be an appropriate candidate for TPN, but IDPN is offered in addition to regularly scheduled infusions of TPN and not as an alternative to TPN
3. Infusions are supplemental to a deficient oral and/or enteral tube diet or deficiencies caused by dialysis and are not considered vital to the nutritional stability of the patient
4. To increase protein and caloric intake in addition to the patient’s daily diet
5. For routine pre- and/or postoperative care
6. The patient has impaired nutrition due to a poor protein or caloric intake but has a functioning gastrointestinal tract, as in the presence of any of the following medical conditions:
   - An anatomical inability to swallow (e.g., stricture of the esophagus, obstructing tumors of the head and neck)
   - Swallowing disorders leading to sufficient interference with the neuromuscular coordination of chewing and swallowing that causes a risk of aspiration (e.g., dysphagia associated with cerebral vascular accident [CVA])
   - The intravenous infusion is for weight maintenance only, and one of the following methods is used:
     → 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)
     → 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).
- A temporary defect in gastric emptying such as a metabolic or electrolyte disorder
- A psychological disorder impairing food intake (e.g., depression)
- A metabolic disorder inducing anorexia (e.g., cancer)
- A physical disorder impairing food intake (e.g., dyspnea of severe pulmonary or cardiac disease)
- A side effect of a medication

**Codes Related To This Policy**

NOTE:
The codes listed in this policy are for reference purposes only. Listing of a code in this policy does not imply that the service described by this code is a covered or non-covered health service. Coverage is determined by the benefit documents and medical necessity criteria. This list of codes may not be all inclusive.

On October 1, 2015, the ICD-9 code sets used to report medical diagnoses and inpatient procedures will be replaced by ICD-10 code sets. Health Net National Medical Policies will now include the preliminary ICD-10 codes in preparation for this transition. Please note that these may not be the final versions of the codes and that will not be accepted for billing or payment purposes until the October 1, 2015 implementation date.

**ICD-9 Codes**

585.1-585.9  Chronic kidney disease
586  Renal failure, unspecified

**ICD-10 Codes**

N18.1-N18.9  Chronic kidney disease
N19  Unspecified kidney failure

**CPT Codes**

N/A

**HCPCS Codes**

B4164-B5200  Parenteral nutrition code range
B9000-B9999  Enteral and parenteral pumps

**Scientific Rationale – Update August 2013**

Lacson et al. (2012) Insufficient clinical data exist to determine whether provision of oral nutritional supplements during dialysis can improve survival in hypoalbuminemic maintenance hemodialysis patients. The authors completed a retrospective matched-cohort study. All oral nutritional supplement program-eligible in-center maintenance hemodialysis patients with albumin level≤3.5 g/dL in quarter 4 of 2009 without oral nutritional supplements in the prior 90 days. Monitored intradialytic oral nutritional supplements were provided to eligible maintenance hemodialysis patients upon physician order, to continue for a year or until serum albumin level was≥4.0 g/dL. Mortality (including deaths and withdrawals), followed up until December 31, 2010.
Both an intention-to-treat (ITT) and an as-treated analysis was performed using a 1:1 geographic region and propensity score-matched study population (using case-mix, laboratory test, access type, 30-day prior hospitalization, and incident patient status) comparing patients treated with intradialytic oral nutritional supplements with usual-care patients. Cox models were constructed, unadjusted and adjusted for facility standardized mortality ratio and case-mix and laboratory variables. The ITT and as-treated analyses both showed lower mortality in the oral nutritional supplement group. The conservative ITT models with 5,227 matched pairs had 40% of controls subsequently receiving oral nutritional supplements after January 1, 2010 (because many physicians delayed participation), with comparative death rates of 30.1% versus 30.4%. The corresponding as-treated (excluding crossovers) death rates for 4,289 matched pairs were 30.9% versus 37.3%. The unadjusted ITT mortality HR for oral nutritional supplement use was 0.95 (95% CI, 0.88-1.01), and the adjusted HR was 0.91 (95% CI, 0.85-0.98); the corresponding as-treated HRs were 0.71 (95% CI, 0.66-0.76) and 0.66 (95% CI, 0.61-0.71) before and after adjustment, respectively. Limited capture of oral nutritional supplement intake outside the facility and potential residual confounding from unmeasured variables, such as dietary intake. Maintenance hemodialysis patients with albumin levels≤3.5 g/dl who received monitored intradialytic oral nutritional supplements showed survival significantly better than similar matched patient controls, with the as-treated analysis highlighting the potentially large effect of this strategy in clinical practice.

Scientific Rationale – Update November 2010
Bossola et al (2010) performed a review of the current literature regarding oral nutritional supplements (ONSs) and intradialytic parenteral nutrition (IDPN) in the treatment of malnutrition in patients undergoing hemodialysis (HD). Thirty-four studies (3223 patients) were identified and included randomized clinical trials, comparative nonrandomized clinical trials, studies with patients who were controls for themselves, and single-arm studies. Seventeen studies were on ONS (778 patients) and 17 were on IDPN (2475 patients.) The authors reported that ONS may improve serum albumin levels and/or other nutritional parameters, whereas there are insufficient data on clinical outcome. IDPN improves serum albumin and body weight. The authors concluded data on survival are conflicting but the only study with an adequate population sample shows that IDPN does not influence survival. They recommend randomized, controlled studies to clarify the role of ONS and IDPN in the treatment of malnutrition in HD.

Cano et al (2007) performed a prospective, randomized trial in which 186 malnourished hemodialysis patients received oral nutritional supplements with or without 1 year of IDPN. IDPN did not improve 2-year mortality (primary end point), hospitalization rate, Karnofsky score, body mass index, or laboratory markers of nutritional status. Instead, both groups demonstrated improvement in body mass index and the nutritional parameters serum albumin and prealbumin (P < 0.05). Multivariate analysis showed that an increase in prealbumin of >30 mg/L within 3 months, a marker of nutritional improvement, independently predicted a 54% decrease in 2-year mortality, as well as reduced hospitalizations and improved general well-being as measured by the Karnofsky score. The investigators concluded that although they found no definite advantage of adding IDPN to oral nutritional supplementation, this prospective study demonstrated that an improvement in prealbumin during nutritional therapy is associated with a decrease in morbidity and mortality in malnourished hemodialysis patients.
According to some local Medicare carriers, IDPN is covered when documentation verifies that the patient suffers from a permanently impaired gastrointestinal tract and that there is insufficient absorption of nutrients to maintain adequate strength and weight. Records should document that the patient cannot be maintained on oral or enteral feedings and that due to severe pathology of the alimentary tract, the patient must be intravenously infused with nutrients. Infusions must be vital to the nutritional stability of the patient and not supplemental to a deficient diet or deficiencies caused by dialysis. Physical signs, symptoms and test results indicating severe pathology of the alimentary tract must be clearly evident in any documentation submitted. Patients receiving IDPN must meet the parenteral nutrition coverage criteria.

**Scientific Rationale Initial Intradialytic Parenteral Nutrition**

Malnutrition is a common problem in most patients with end-stage renal disease (ESRD) undergoing chronic hemodialysis (CHD) even though they have intact and fully functional gastrointestinal systems. An estimated 10% of patients with ESRD are severely malnourished, and another 33% are moderately malnourished. Studies have shown that malnutrition in these patients is associated with increased morbidity and mortality. Decreased dietary protein and caloric intake due to loss of appetite (anorexia) and increased energy expenditure result in net negative protein and energy balance and are among several factors that predispose CHD patients to malnutrition. Other factors may include inadequate dialysis, loss of substantial amounts of amino acids in the dialysate, frequent acute intercurrent illness, dietary restrictions, and catabolic factors such as metabolic acidosis, accelerated rates of whole-body and skeletal muscle proteolysis, hyperparathyroidism, and insulin resistance. Comorbid conditions such as diabetes, cardiovascular disease, and peripheral vascular disease may also contribute to malnutrition in these patients. Since attempts to increase protein intake by dietary counseling are usually ineffective, intradialytic parenteral nutrition (IDPN) has been proposed as a potential therapeutic approach in malnourished CHD patients in both the acute and chronic settings.

IDPN therapy consists of administering a mixture of amino acids, dextrose, and lipid emulsion into the vascular shunt as it emerges from the dialyzer during each HD session. This improves the nutritional status by providing 1000-1200 kcal per treatment and normalizing the amounts of albumin, glucose, and other nutrients in the blood stream. IDPN is recommended for patients have not responded to or are intolerant of oral and/or enteral supplements and who have clinical signs of malnutrition, such as a serum albumin concentration of < 3.4 g/dL, a dietary protein intake of < 0.8 g/kg, a daily dietary intake of < 25 kcal/kg, or a > 10% loss of ideal body weight over a three-month period. Goals of IDPN include an increase in appetite, weight, and serum albumin in an effort to decrease the associated morbidity and mortality. Beneficial effects of IDPN are expected to occur three to six months after the start of therapy, after which IDPN should be discontinued and nutrition maintained through oral supplementation.

While many markers are used to evaluate the nutritional status of ESRD patients, serum albumin is of particular importance to clinicians, as it has been directly correlated with an increased risk of morbidity and mortality. Measuring serum albumin levels assesses the threat of a condition called protein calorie malnutrition. When the serum albumin concentrations decrease to < 3.5 g/dL, mortality rate increases to twice that of serum albumin concentrations of >/= 4.0 g/dL; severely
depressed albumin levels (< 2.5 g/dL) are linked to a more than 10-fold increase in mortality. Most labs consider an albumin level of 3.5 to 5.5 g/dL to be normal.

Advantages of IDPN as compared to tube feeding or TPN include the following: (1) provides calories and protein during HD without the need for a dedicated enteral feeding tube or vascular access; (2) ultrafiltration during dialysis (which reduces the risks of fluid overload); (3) no demands on the time or effort of the patient since there is no significant increase in the time needed to complete a dialysis session; and (4) multivitamins, electrolytes, trace elements, and drugs such as insulin can be added whenever necessary. Disadvantages to IDPN include provision of insufficient calories and protein to support long-term daily needs (i.e., IDPN is given during dialysis for only 3 days out of 7), it does not change the patient’s food behavior or encourage them to eat more healthy meals, and it is expensive.

While IDPN has been available for many years, there has never been a consensus regarding both its efficacy and patient selection criteria. In 1993, the Office of Health Technology Assessment (OHTA) published a review concluding that studies of IDPN reported equivocal results and the data did not validate its efficacy. Foulks (1999) reported on an evidence-based systematic review of the literature to evaluate the quality of evidence regarding the use of IDPN in dialysis patients. He described the same limitations as identified in the OHTA report. Three randomized studies were identified with only one randomized, double-blinded, controlled trial identified. One was a feasibility study only and the latter trial (n=7) examined the effects of oral versus intravenous amino acids given during the last 90 minutes of dialysis. None of the patients were malnourished and no clinical effect was observed. Limitations noted in the three “randomized” studies included lack of described randomization, use of an IDPN product not routinely used or available in the United States, and an unclear definition of malnutrition. The remaining literature consists of case series, which cannot control for the many variables in the renal dialysis population that may contribute to increased morbidity and mortality. According to Foulks' analysis, the majority of case series had methodological flaws including heterogeneity in study design, patient selection criteria, types of IDPN used, adequacy of dialysis and outcome criteria. The investigator reported that the data in actuality represented observational studies and no well designed, randomized, controlled trial comparing IDPN with standard care that used a well-defined malnourished population of hemodialysis patients and clinically valid or meaningful outcome criteria was found. The investigator concluded that the data supporting the use of IDPN were weak and a clear recommendation could not be made.

The largest study was conducted by Chertow et al (1994), a multicenter retrospective case series comparing the morbidity of IDPN patients (n=1679) with untreated controls (n=22,517). This study found that dialysis patients with a serum albumin of <3.4 g/dL who were treated with IDPN experienced significant increases in albumin over time. Additionally, these patients experienced a significant decrease in the odds ratio for death at one year compared to those who were not treated with IDPN. The authors concluded that while the data demonstrated an association in survival between IDPN treatment and malnourished chronic hemodialysis patients, the study had significant methodological flaws, including retrospective design. Two other uncontrolled studies also suggest an improved outcome associated with IDPN, however, due to the numerous biases inherent in any uncontrolled trial, these studies cannot validate whether IDPN is associated with decreased mortality. The observed treatment effect could be related to a selection bias in which very ill patients, i.e., those expected to die, were not offered IDPN. In addition, IDPN
administration may be associated with an increased attentiveness to dialysis parameters, counseling nutritional advice, etc. These studies do suggest that being selected for IDPN may be associated with decreased mortality rate, but analysis of the direct contribution of IDPN will require controlled trials.

Capelli et al (1994) conducted a nonrandomized trial (n=81) comparing use of IDPN in patients receiving maintenance hemodialysis (MHD). Treated patients (n=50) had depressed serum albumins and at least one of the following: body weight at least 10% below calculated ideal body weight or over 10% total weight loss over two consecutive months. Untreated patients served as controls and had a depressed serum albumin, but their body weight or weight loss was not consistently below the 10% limits. The study period was conducted over 24 months and treated patients received IDPN during their hemodialysis treatments (average period of treatment = nine months). The patients treated with IDPN had improved serum albumin levels and a better survival rate than those who were untreated (64% versus 52%, respectively). The authors concluded that IDPN has beneficial effects on the protein malnutrition in chronic MHD patients and improves survival. Study design flaws such as patient selection protocol, retrospective design and lack of randomization limit the conclusions from this study.

Pupim et al (2002) conducted a randomized crossover trial (n=7) to compare the use of IDPN to control. All patients were crossed over and participated in both protocols with at least four weeks between each protocol. The study evaluated protein and energy homeostasis during two sessions of dialysis. The results showed that IDPN promoted a large increase in whole-body protein synthesis and a significant decrease in whole-body proteolysis, along with a significant increase in forearm muscle protein synthesis. The net result was a change from an essentially catabolic state to a highly positive protein balance, both in whole-body and forearm muscle compartments. The authors concluded that the administration of IDPN had a significant positive effect on protein and energy metabolism in stable chronic hemodialysis patients.

Cherry et al. (2002) studied the efficacy of IDPN in malnourished hemodialysis patients in a nonrandomized uncontrolled study (n=24). A total of 26 courses of IDPN was given (mean duration of treatment = 4.3 months). Follow-up was done at three, six, nine and 12 months after therapy began. Outcomes were measured using the percent change from baseline in dry body weight and serum albumin concentration. The authors reported that IDPN significantly increased body weight and serum albumin in malnourished hemodialysis patients.

Bossola et al (2005) conducted a review on malnutrition in hemodialysis patients. They reported that protein-energy malnutrition (PEM) is common in patients with end stage renal disease (ESRD) who are on maintenance hemodialysis (MHD) and is thought to be a predictor of morbidity and mortality. In predialysis patients, the prevalence of PEM is 20%-80%, in patients on HD the prevalence is still 23%-73%. They found that before starting dialysis, many ESRD patients are started on low protein and low phosphate diets. These diets are often hypocaloric, thus many of these patients who start HD are already in a poor nutritional condition.

The Dialysis Outcomes Quality Initiative guidelines (2000) for nutrition state that daily energy intake should be > 35 kcal/kg of body weight in adults younger than 60 years and 30-35 kcal/kg body weight for individuals 65 years or older per day. Protein intake should be 1.2 g/kg body weight per day. The recommended daily protein intake for patients on maintenance hemodialysis (MHD) is 1.2 g/kg body
weight/day; at least 50% should be of high biological value. Protein of high biological value has an amino acid composition that is similar to human protein, is likely to be an animal protein, and tends to be utilized more efficiently by humans to conserve body proteins. It is difficult for some patients to maintain this level of protein intake, however, and nutritional support may be needed. The serum albumin level is considered to be a key measure for assessing nutritional status. Energy and protein intake is most often insufficient and can be caused by taste abnormalities, gastropathy and enteropathy, accumulation of anorectic factors, inflammation and/or infection, medications, psychosocial factors (depression, poverty, alcohol or drug abuse), and HD–related (postdialysis fatigue and cardiovascular instability).

In January 2002, the American Association for Parenteral and Enteral Nutrition published evidence-based guidelines for the use of parenteral and enteral nutrition in which it is stated that:

"IDPN should be reserved for patients who cannot meet their nutrient needs orally and who are not candidates for enteral nutrition because of gastrointestinal intolerance or parenteral nutrition due to venous access problems."

The American Gastroenterological Association published a medical position on enteral nutrition (1995) that states:

"Enteral nutrition is considered for patients who cannot or will not eat, who have a functioning gastrointestinal tract and a safe method of access. Enteral feeding is preferable over parenteral therapy provided there are no contraindications, access can be obtained safely, and oral intake is not possible. Mechanical obstruction is the only contraindication to enteral feeding. For short term, a nasogastric or nasoenteric tube is used whereas a gastrostomy or jejunostomy tube is used for long term needs."

The American Gastroenterological Association published medical position on parenteral nutrition (2001) states:

"In general, parenteral nutrition is indicated to prevent the adverse effects of malnutrition in patients who are unable to obtain adequate nutrients by oral or enteral routes. The decision to use parenteral nutrition requires an understanding of the patient’s clinical condition and anticipated outcome, judgment as to the patient’s ability to tolerate undernutrition, knowledge of the clinical efficacy of parenteral nutrition and an appreciation of the patient’s desires and needs."

Along with such conventional interventions as nutritional counseling, oral nutritional supplements, appetite stimulants, growth hormone, androgenic anabolic steroids, and anti-inflammatory drugs, with contradictory and nonconclusive results, malnutrition still remains a great challenge for nephrologists. Much progress has been made in recent years in identifying the causes and pathogenesis of malnutrition in HD patients, as well as recognizing the link between malnutrition and morbidity, hospitalization events and mortality. There is no question that nutritional status is an important predictor of clinical outcome in ESRD patients on HD and that severe malnutrition is a powerful predictor of morbidity and mortality. Studies have shown that the provision of nutrients in the form of IDPN during hemodialysis has been
shown to adequately compensate for the catabolic effects of the hemodialysis procedure. However, a lack of adequate prospective randomized studies have hampered definitive conclusions as to the management and clinical benefits of IDPN.

Published guidelines and available recommendations suggest that counseling to increase dietary protein and energy intake, nutritional supplements, and tube feeding should be considered before attempting forms of parenteral nutrition in HD patients. If the intestinal tract is functional, enteral tube feeding is traditionally considered the first line of nutritional therapy in the hospitalized patient who is unable to eat adequately. Advantages to enteral feeding include its ability to provide a patient's total nutritional needs chronically and on a daily basis, to provide balanced nutrients, to administer specialized formulas, to provide a smaller water load than intravenous feedings, to constitute a lower risk of infection than total parenteral nutrition (TPN), and to be less expensive than TPN or IDPN. Risks of enteral feeding include pulmonary aspiration, fluid overload, reflux esophagitis, and other complications of enteral feeding devices.

Due to the numerous biases inherent in any uncontrolled trials, these studies cannot validate whether intradialytic nutrition is associated with an improved mortality. The observed treatment effect could be related to a selection bias in which very ill patients were not offered intradialytic parenteral nutrition. In addition, this therapy may be associated with an increased attentiveness to dialysis parameters, counseling nutritional advice, etc. These studies do suggest that being selected for intradialytic nutrition may be associated with an improved mortality rate, but analysis of the direct contribution of therapy will require controlled trials. Additionally, these patients experienced a significant decrease in the odds ratio for death at one year compared to those who were not treated with intradialytic parenteral nutrition. The strongest evidence-based conclusion that can be derived from this literature is that being selected for IDPN may be associated with improved survival. Without randomized studies, it is not known whether or not the IDPN itself is the causative factor.

To date, greater than 20 studies have investigated the effects of intradialytic nutritional support in patients with ESRD. Overall, the findings have been difficult to interpret usually because of the lack of randomized controlled trials demonstrating improved morbidity and mortality with all nutrition support interventions in maintenance HD patients. While there is compelling evidence demonstrating the role that malnutrition plays on morbidity and mortality in the chronic dialysis patient, the evidence is less clear on treatment options and the impact specific treatments, including IDPN, have on health outcomes. Evidence demonstrating improvement in patient nutritional status has been variable. While the evidence supporting the use of IDPN is not robust, it appears from the scientific literature that a small but important percentage of malnourished chronic HD patients may benefit from its use. Well-designed, large-scale, prospective studies are required to confirm these beneficial effects.

**Intraperitoneal Amino Acid (IPAA) Supplementation**

IPAA administration may increase protein balance in clinically stable, malnourished continuous peritoneal dialysis (CPD) patients who have low protein intakes. The net infusion of 2 L of peritoneal dialysate containing 1.1% amino acids with a peritoneal dwell time of 5 to 6 hours is associated with a retention of about 80% of the amino acids. The amount retained varies directly with peritoneal transport characteristics as determined by peritoneal equilibrium testing. Hence, the administration of a single
2-L exchange of 1.1% amino acid dialysate for 5 to 6 hours provides a net uptake of about 17 to 18 g of amino acids, which is greater than the quantity of both protein (about 9 g) and amino acids (about 3 g) removed each day by peritoneal dialysis.

IPAA may also reduce the infused daily carbohydrate load by about 20%, thereby reducing the risk of hyperglycemia and the tendency to hypertriglyceridemia. Most studies of IPAA were not randomized or controlled and used an open (before-after) or crossover design. Intermediate nutrition-related outcome variables (e.g., nitrogen-protein balance, serum proteins, and anthropometry) were used in all studies. No study of IPAA has evaluated patient survival, hospitalization, or other clinical outcomes (e.g., health-related quality of life). Even though the long-term effects of IPAA on nutritional status and clinical outcomes are unknown, IPAA should be considered if an oral diet fortified with energy and protein supplements or tube feedings are inadequate or not possible.

Review History
December 2006 Medical Advisory Council initial approval
November 2010 Update – no revisions
September 2011 Update – no revisions
August 2012 Update – no revisions
August 2014 Update – no revisions
August 2015 Update – no revisions. Codes updated.

This policy is based on the following evidence-based guidelines:


References – Update August 2015

References – Update August 2014

References – Update August 2013

References – Update August 2012

References – Update September 2011

References – Update November 2010

References

**Important Notice**

**General Purpose.**
Health Net's National Medical Policies (the "Policies") are developed to assist Health Net in administering plan benefits and determining whether a particular procedure, drug, service or supply is medically necessary. The Policies are based upon a review of the available clinical information including clinical outcome studies in the peer-reviewed published medical literature, regulatory status of the drug or device, evidence-based guidelines of governmental bodies, and evidence-based guidelines and positions of select national health professional organizations. Coverage determinations are made on a case-by-case basis and are subject to all of the terms, conditions, limitations, and exclusions of the member's contract, including medical necessity requirements. Health Net may use the Policies to determine whether under the facts and circumstances of a particular case, the proposed procedure, drug, service or supply is medically necessary. The conclusion that a procedure, drug, service or supply is medically necessary does not constitute coverage. The member's contract defines which procedure, drug, service or supply is covered, excluded, limited, or subject to dollar caps. The policy provides for clearly written, reasonable and current criteria that have been approved by Health Net's National Medical Advisory Council (MAC). The clinical criteria and medical policies provide guidelines for determining the medical necessity criteria for specific procedures, equipment, and services. In order to be eligible, all services must be medically necessary and otherwise defined in the member's benefits contract as described this "Important Notice" disclaimer. In all cases, final benefit determinations are based on the applicable contract language. To the extent there are any conflicts between medical policy guidelines and applicable contract language, the contract language prevails. Medical policy is not intended to override the policy that defines the member's benefits, nor is it intended to dictate to providers how to practice medicine.

**Policy Effective Date and Defined Terms.**
The date of posting is not the effective date of the Policy. The Policy is effective as of the date determined by Health Net. All policies are subject to applicable legal and regulatory mandates and requirements for prior notification. If there is a discrepancy between the policy effective date and legal mandates and regulatory requirements, the requirements of law and regulation shall govern. * In some states, prior notice or posting on the website is required before a policy is deemed effective. For information regarding the effective dates of Policies, contact your provider representative. The Policies do not include definitions. All terms are defined by Health Net. For information regarding the definitions of terms used in the Policies, contact your provider representative.

**Policy Amendment without Notice.**
Health Net reserves the right to amend the Policies without notice to providers or Members. In some states, prior notice or website posting is required before an amendment is deemed effective.

**No Medical Advice.**
The Policies do not constitute medical advice. Health Net does not provide or recommend treatment to members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

**No Authorization or Guarantee of Coverage.**
The Policies do not constitute authorization or guarantee of coverage of particular procedure, drug, service or supply. Members and providers should refer to the Member contract to determine if exclusions, limitations, and dollar caps apply to a particular procedure, drug, service or supply.

**Policy Limitation: Member’s Contract Controls Coverage Determinations.**
Statutory Notice to Members: The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illnesses or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under your contract. The determination of coverage for a particular procedure, drug, service or supply is not based upon the Policies, but rather is subject to the facts of the individual clinical case, terms and conditions of the member’s contract, and requirements of applicable laws and regulations. The contract language contains specific terms and conditions, including pre-existing conditions, limitations, exclusions, benefit maximums, eligibility, and other relevant terms and conditions of coverage. In the event the Member’s contract (also known as the benefit contract, coverage document, or evidence of coverage) conflicts with the Policies, the Member’s contract shall govern. The Policies do not replace or amend the Member’s contract.

Policy Limitation: Legal and Regulatory Mandates and Requirements
The determinations of coverage for a particular procedure, drug, service or supply is subject to applicable legal and regulatory mandates and requirements. If there is a discrepancy between the Policies and legal mandates and regulatory requirements, the requirements of law and regulation shall govern.

Reconstructive Surgery
CA Health and Safety Code 1367.63 requires health care service plans to cover reconstructive surgery. "Reconstructive surgery" means surgery performed to correct or repair abnormal structures of the body caused by congenital defects, developmental abnormalities, trauma, infection, tumors, or disease to do either of the following:

1. To improve function or
2. To create a normal appearance, to the extent possible.

Reconstructive surgery does not mean "cosmetic surgery," which is surgery performed to alter or reshape normal structures of the body in order to improve appearance.

Requests for reconstructive surgery may be denied, if the proposed procedure offers only a minimal improvement in the appearance of the enrollee, in accordance with the standard of care as practiced by physicians specializing in reconstructive surgery.

Reconstructive Surgery after Mastectomy
California Health and Safety Code 1367.6 requires treatment for breast cancer to cover prosthetic devices or reconstructive surgery to restore and achieve symmetry for the patient incident to a mastectomy. Coverage for prosthetic devices and reconstructive surgery shall be subject to the co-payment, or deductible and coinsurance conditions, that are applicable to the mastectomy and all other terms and conditions applicable to other benefits. "Mastectomy" means the removal of all or part of the breast for medically necessary reasons, as determined by a licensed physician and surgeon.

Policy Limitations: Medicare and Medicaid
Policies specifically developed to assist Health Net in administering Medicare or Medicaid plan benefits and determining coverage for a particular procedure, drug, service or supply for Medicare or Medicaid members shall not be construed to apply to any other Health Net plans and members. The Policies shall not be interpreted to limit the benefits afforded Medicare and Medicaid members by law and regulation.