TOTAL PARENTERAL NUTRITION

This section explains the Total Parenteral Nutrition (TPN) therapy coverage, limitations, prior authorization, reimbursement methodology, and claim submission.

Provider Enrollment

Refer to Section 37.2 Provider Requirements and Participation Guidelines for enrollment instructions.

Program Coverage

The program covers the following services, equipment and supplies when medical necessity and other program criteria are met:

1. Parenteral Nutrition Therapy/TPN is covered for a patient with permanent, severe pathology of the alimentary tract which does not allow absorption of sufficient nutrients to maintain weight and strength commensurate with the beneficiary's general condition;

2. Intradialytic Parenteral Nutrition Therapy (IDPN) provided to an end stage renal disease (ESRD) patient while the patient is being dialyzed; and/or

3. Equipment and supplies, infusion pumps and accessories.

TPN Medical Necessity Criteria

1. Parenteral nutrition is covered for a beneficiary with permanent, severe pathology of the alimentary tract which does not allow absorption of sufficient nutrients to maintain weight and strength commensurate with the beneficiary's general condition;

2. Parenteral nutrition is considered to be medically necessary when any of the following conditions exist. The conditions must be deemed to be severe enough that the beneficiary would not be able to maintain their weight and strength on only

oral intake or tube enteral nutrition. The beneficiary:

a. Has undergone recent (within the past three months) massive small bowel resection leaving less than or equal to 5 feet of small bowel beyond the ligament of Treitz;

b. Has a short bowel syndrome that is severe enough that the beneficiary has net gastrointestinal fluid and electrolyte malabsorption such that on an oral intake of 2.5-3 liters/day the enteral losses exceed 50 percent of the oral/enteral intake and the urine output is less than 1 liter/day;

c. Requires bowel rest for at least three months and is receiving intravenously 20-35 cal/kg/day for treatment of symptomatic pancreatitis with/without pancreatic pseudocyst, severe exacerbation of regional enteritis, or a proximal enterocutaneous fistula where tube feeding distal to the fistula is not possible;

d. Has complete mechanical small bowel obstruction where surgery is not an option;

e. Is significantly malnourished (10 percent weight loss over three months or less and serum albumin less than or equal to 3.4 gm/dl) and has very severe fat malabsorption (fecal fat exceeds 50 percent of oral/enteral intake on a diet of at least 50 gm of fat/day as measured by a standard 72 hour fecal fat test); or

f. Is significantly malnourished (10 percent weight loss over three months or less and serum albumin less than or equal to3.4 gm/dl) and has a severe motility disturbance of the small intestine and/or stomach which is unresponsive to prokinetic medication. Prokinetic medication is defined as the presence of daily symptoms of nausea and vomiting while taking maximal doses and is demonstrated either:

    i. Scintigraphically (solid meal gastric emptying study demonstrates that the isotope fails to reach the right colon by six hours following ingestion); or

ii. Radiographically (barium or radiopaque pellets fail to reach the right colon by six hours following administration).

NOTE: These studies must be performed when the beneficiary is not acutely ill and is not on any medication which would decrease bowel motility.

3. Maintenance of weight and strength commensurate with the beneficiary's overall health status must require intravenous nutrition and must not be possible utilizing all of the following approaches:

   a. 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, etc.); and

   b. 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, etc.).

4. Beneficiaries who do not meet the criteria in B.1-6.b must meet criteria in C.1-2 (modification of diet and pharmacologic intervention) in addition to the following criteria:

   a. The beneficiary is malnourished (10 percent weight loss over three months or less and serum albumin less than or equal to 3.4 gm/dl); and

   b. A disease and clinical condition has been documented as being present and it has not responded to altering the manner of delivery of appropriate nutrients (e.g., slow infusion of nutrients through a tube with the tip located in the stomach or jejunum).

5. The following are some examples of moderate abnormalities which would require a failed trial of tube enteral nutrition before PN would be covered:

   a. Moderate fat malabsorption - fecal fat exceeds 25 percent of oral/enteral intake on a diet of at least 50 gm fat/day as measured by a standard 72 hour fecal fat test;

b. Diagnosis of malabsorption with objective confirmation by methods other than 72 hour fecal fat test (e.g., Sudan stain of stool, dxylose test, etc.);

c. Gastroparesis which has been demonstrated:

i. Radiographically or scintigraphically as described in Subsection B above with the isotope or pellets failing to reach the jejunum in three to six hours; or

ii. By manometric motility studies with results consistent with an abnormal gastric emptying, and which is unresponsive to prokinetic medication.

d. A small bowel motility disturbance which is unresponsive to prokinetic medication, demonstrated with a gastric to right colon transit time between three to six hours;

e. Small bowel resection leaving greater than 5 feet of small bowel beyond the ligament of Treitz;

f. Short bowel syndrome which is not severe (as defined in B.2);

g. Mild to moderate exacerbation of regional enteritis, or an enterocutaneous fistula; or

h. Partial mechanical small bowel obstruction where surgery is not an option.

6. Documentation must support that a concerted effort has been made to place a tube. For gastroparesis, tube placement must be post-pylorus, preferably in the jejunum. Use of a double lumen tube should be considered. Placement of the tube in the jejunum must be objectively verified by radiographic studies or luoroscopy. Placement via endoscopy or open surgical procedure would also verify location of the tube;

7. A trial with enteral nutrition must be documented, with appropriate attention to dilution, rate, and alternative formulas to address side effects of diarrhea;

8. PN can be covered in a beneficiary with the ability to obtain partial nutrition from oral intake or a combination of oral/enteral or oral/enteral/parenteral intake as long as the following criteria are met:

    a. A permanent condition of the alimentary tract is present which has been deemed to require parenteral therapy because of its severity;

    b. A permanent condition of the alimentary tract is present which is unresponsive to standard medical management; and

    c. The person is unable to maintain weight and strength.

9. If the medical necessity criteria for parenteral nutrition are met, medically necessary nutrients, administration supplies and equipment are covered. PN solutions containing little or no amino acids and/or carbohydrates would be covered only in situations stated in B.1, 2, or 4 above.

Documentation Requirements

Beneficiaries covered under Paragraph B.4 must have documentation of the persistence of their condition. Beneficiaries covered under B.5–D.2 must have documentation that sufficient improvement of their underlying condition has not occurred which would permit discontinuation of parenteral nutrition. Coverage for these beneficiaries would be continued if the treatment has been effective as evidenced by an improvement of weight and/or serum albumin. If there has been no improvement, subsequent claims will be denied unless the physician clearly documents the medical necessity for continued parenteral nutrition and any changes to the therapeutic regimen that are planned, e.g., an increase in the quantity of parenteral nutrients provided.

A total caloric daily intake (parenteral, enteral and oral) of 20-35 cal/kg/day is considered sufficient to achieve or maintain appropriate body weight. The ordering physician must document in the medical record the medical necessity for a caloric intake outside this range in an individual beneficiary.

Parenteral nutrition would usually be non-covered for beneficiaries who do not meet criteria in H.1-3, but will be considered on an individual case basis if detailed documentation is submitted.

Beneficiaries covered under criteria in B.1 or 2 must have documentation that adequate small

bowel adaptation had not occurred which would permit tube enteral or oral feedings.

Beneficiaries covered under B.3 must have documentation of worsening of their underlying condition during attempts to resume oral feedings.

The ordering physician must document the medical necessity for protein orders outside of the range of 0.8-1.5 gm/kg/day, dextrose concentration less than 10 percent, or lipid use greater than 15 units of a 20 percent solution or 30 units of a 10 percent solution per month.

If the medical necessity for special parenteral formulas is not substantiated, authorization of payment will be denied.

For the initial request and for revised requests or reconsiderations involving a change in the order, there must be additional documentation to support the medical necessity of the following orders, if applicable:

1. The need for special nutrients;

2. The need for dextrose concentration less than 10 percent; and

3. The need for lipids more than 15 units of a 20 percent solution or 30 units of a 10 percent solution per month.

After the first six months, the PA request must include a physician's statement describing the continued need for parenteral nutrition. For situations described in B.5-D.2 under Medical Necessity Criteria, the PA request must include the results of the most recent serum albumin (within two weeks of the request date) and the beneficiary's most recent weight with the date of each. If the results indicate malnutrition, there should be a physician's statement describing the continued need for parenteral nutrition and any changes to the therapeutic regimen that are planned.

Exclusionary Criteria

Parenteral nutrition will be denied as non-covered in situations involving temporary impairments. The beneficiary must have one of the following:

1. A condition involving the small intestine and/or its exocrine glands which significantly impairs the absorption of nutrients; or

2. A disease of the stomach and/or intestine which is a motility disorder and impairs the ability of nutrients to be transported through the gastrointestinal (GI) system. There must be objective evidence supporting the clinical diagnosis.

Parenteral nutrition is not covered for the beneficiary with a functioning gastrointestinal tract whose need for parenteral nutrition is only due to:

1. A swallowing disorder;

2. A temporary defect in gastric emptying such as a metabolic or electrolyte disorder;

3. A psychological disorder impairing food intake such as depression;

4. A metabolic disorder inducing anorexia such as cancer;

5. A physical disorder impairing food intake such as the dyspnea of severe pulmonary or cardiac disease;

6. A side effect of a medication; or

7. Renal failure and/or dialysis.

Intradialytic Parenteral Nutrition Therapy

Intradialytic Parenteral Nutrition Therapy (IDPN) is parenteral nutrition therapy provided to a beneficiary with end stage renal disease (ESRD) while the beneficiary is being dialyzed.

In order to cover IDPN, documentation must be clear and precise to verify that the beneficiary suffers from a permanently impaired gastrointestinal tract and that there is insufficient absorption of nutrients to maintain adequate strength and weight. The supporting documentation must substantiate that the beneficiary cannot be maintained on oral or enteral feedings and that due to severe pathology of the alimentary tract, the beneficiary must be intravenously infused with nutrients.

Infusions must be vital to the nutritional stability of the beneficiary 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. Beneficiaries receiving IDPN must also meet the criteria for parenteral nutrition.

If the medical necessity criteria for parenteral nutrition are met, one supply kit and one administration kit will be covered for each day that parenteral nutrition is necessary and used.

Equipment and Supplies

An infusion pump is used to deliver nutritional requirements intravenously. Infusion pumps are covered for the delivery of parenteral nutrition for those beneficiaries who cannot absorb nutrients by the gastrointestinal tract. Only one pump (ambulatory or stationary) will be covered at any one time. Additional pumps will be denied as not medically necessary.

1. An external ambulatory infusion pump is a small portable electrical device that is used to deliver parenteral nutrition. It is designed to be carried or worn by the beneficiary; or

2. A stationary infusion pump is an electrical device, which serves the same purpose as an ambulatory pump, but is larger and typically mounted on a pole.

An intravenous (IV) pole is a device to suspend fluid to be administered by gravity or pump. An IV pole will be covered when a beneficiary is receiving parenteral fluids and the beneficiary is not using an ambulatory infusion pump.

Infusion pumps, ambulatory and stationary, are indicated for the administration of parenteral medication in the home when parenteral administration of the medication in the home is reasonable and medically necessary, and an infusion pump is necessary to safely administer the medication.

An external ambulatory infusion pump is a small portable electrical device that is used to deliver parenteral medication. It is designed to be carried or worn by the beneficiary.

Prior Authorization

Prior Authorization Requirements

Parenteral nutrition therapy may be approved by the Prior Authorization Unit (PAU) at periodic intervals not to exceed six months. However, Medicaid will pay for no more than one month's supply of nutrients at any one time. All requests to the PAU shall include the following:

1. The prognosis as well as the diagnosis;

2. The date the beneficiary was first infused;

3. Whether the beneficiary has been trained to use parenteral equipment;

4. A statement that the beneficiary is capable of operating the parenteral equipment;

5. Either the Medicaid certificate of medical necessity form for TPN, or the Medicare certificate of medical necessity form, Form DMERC 10.02A, completed and signed by the treating physician; and

6. Documentation showing that the beneficiary has a permanent impairment. Permanence does not require a determination that there is no possibility that the beneficiary's condition may improve sometime in the future. Medical documentation must substantiate that the condition is expected to last a long and indefinite duration (at least three months).

Additional documentation must be included with the initial request for parenteral nutrition.

In the situations addressed in B.1-4 under Medical Necessity Criteria, the documentation must include copies of the operative report and/or hospital discharge summary and/or x-ray reports and/or a physician letter which document the condition and the necessity for PN therapy.

For the situations addressed in B.5 and D.2 under Medical Necessity Criteria (when appropriate), include the results of the fecal fat test and dates of the test.

For the situations addressed in B.6 and D.2 under Medical Necessity Criteria, include a copy of the report of the small bowel motility study and a list of medications that the beneficiary was on at the time of the test.

For the situations addressed in B.5 – D.2 under Medical Necessity Criteria, include the results of serum albumin and the date of the test (within one week prior to initiation of PN) and a copy of a nutritional assessment by a physician, dietitian or other qualified professional within one week prior to initiation of PN, to include the following information:

1. Current weight with date and weight one – three months prior to initiation of PN;

2. Estimated daily calorie intake during the prior month and by what route (e.g., oral, tube);

3. Statement of whether there were caloric losses from vomiting or diarrhea and whether these estimated losses are reflected in the calorie count; and

4. Description of any dietary modifications made or supplements tried during the prior month (e.g., low fat, extra medium chain triglycerides, etc.).

For situations described in D.2 under Medical Necessity Criteria, include:

1. A statement from the physician;

2. Copies of objective studies; and

3. Excerpts of the medical record giving the following information:

    a. Specific etiology for the gastroparesis, small bowel dysmotility, malabsorption;

    b. A detailed description of the trial of tube enteral nutrition including the beginning and ending dates of the trial, duration of time that the tube was in place, the type and size of tube, the location of tip of the tube, the name of the enteral nutrient, the quantity, concentration and rate of administration, and the results;

    c. A copy of the x-ray report or procedure report documenting placement of the tube in the jejunum;

    d. Prokinetic medications used, dosage, and dates of use;

    e. Nondietary treatment given during prior month directed at etiology of malabsorption (e.g., antibiotic for bacterial overgrowth); and

    f. Any medications used that might impair GI tolerance to enteral feedings

(e.g., anticholinergics, opiates, tricyclics, phenothiazines, etc.) or that might interfere with test results (e.g., mineral oil, etc.) and a statement explaining the need for these medications.

Any other information which supports the medical necessity for parenteral nutrition may also be included.

Prior Authorization Requests

The Prior Authorization (PA) request shall be submitted to the fiscal intermediary Prior Authorization Unit (PAU) where it will be considered for payment. Provider may contact the PAU (See Appendix 37.5.4 for contact information).

Providers may complete and submit electronic PA forms. These forms may be accessed at www.lamedicaid.com. For more information contact the PAU.

NOTE: Refer to Appendix 37.5.1 for Form PA01 and instructions or providers may access this form at www.lamedicaid.com.

Once a PA request is approved, the provider and beneficiary are notified of the approval, as well as what services have been approved. A prior authorization number is attached to the approved request. This number is to be used in the billing process.

Emergency Requests

A request is considered an emergency if a delay in obtaining the parenteral nutrition therapy would be life-threatening to the beneficiary. Providers should call the PAU's toll-free number. Providers should then fax a completed PA 01 form, documentation of the parenteral therapy and life-threatening situation (i.e. pending discharge). Once an approval or denial is determined within 48 hours, the procedure codes, authorized reimbursement rate and prior authorization number is phoned to the provider. A determination letter is later mailed to the provider and beneficiary.

Medicare Crossover Claims

Claims for Total Parenteral Nutrition and equipment reimbursed by Medicare do not require prior authorization from Medicaid when these claims cross over from Medicare to Medicaid for payment.

Claims denied by Medicare due to lack of medical necessity will not be considered for coverage

by Medicaid.

Medicare non-covered services may be considered for coverage by Medicaid Claims, when that service is a Medicaid covered service; however, prior authorization is necessary.

Third Party Liability

When a Medicaid beneficiary has private insurance and Medicaid, prior authorization is required from all payors, including Medicaid.

Reimbursement Methodology

The following is the Medicaid reimbursement schedule:

1. Reimbursement for Total Parenteral Nutrition Therapy (TPN) formula is 80 percent of the Medicare Fee Schedule amount or billed charges, whichever is the lesser amount;

2. Reimbursement for TPN supplies is 70 percent of the Medicare Fee Schedule or billed charges, whichever is the lesser amount; and

3. Reimbursement for TPN infusion pumps is 70 percent of the Medicare Fee Schedule or billed charges, whichever is the lesser amount.

Claim Submission

Medicaid Claims

Claims for TPN should be submitted on the CMS-1500. (See Appendix 37.5.1 for information on how to access this form).

Medicare Crossover Claims

Medicare claims will automatically cross over to Medicaid when the provider is enrolled as a Medicare provider.

NOTE: See Medicare Part B Crossover Claims in Appendix G: Medicare Prescription Drug Coverage for additional detailed information.

Third Party Liability

When a beneficiary has both Medicaid and private insurance, the provider is required to submit the claim to the private insurance first. The provider's remittance advice from the private insurance company should be submitted with the claim to Medicaid.

Adjustments/Voids

Providers should complete Form 213 Adjustment/Void form for TPN services submitted that require adjustments or voids.

NOTE: Refer to Appendix 37.5.1 of this manual chapter for a copy of this form.