



# BlueCross BlueShield of Louisiana

An independent licensee of the Blue Cross and Blue Shield Association.

## Total Parenteral Nutrition and Enteral Nutrition in the Home

Policy # 00088

Original Effective Date: 11/22/1993

Current Effective Date: 01/15/2014

*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.*

### Total Parenteral Nutrition (TPN)

#### **When Services May Be 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 total parenteral nutrition (TPN) in the treatment of inanition associated with conditions resulting in impaired intestinal absorption, including such conditions, but not limited to, any of the following to be **eligible for coverage**:

#### Patient Selection Criteria for Total Parenteral Nutrition (TPN)

- Crohn's disease; or
- Obstruction secondary to stricture or neoplasm of the esophagus or stomach; or
- Loss of the swallowing mechanism due to a central nervous system disorder, where the risk of aspiration is great; or
- Short bowel syndrome secondary to massive small bowel resection; or
- Malabsorption due to enterocolic, enterovesical or enterocutaneous fistulas (total parenteral nutrition [TPN] being temporary until the fistula is repaired); or
- Motility disorder (pseudo-obstruction); or
- Newborn infants with catastrophic gastrointestinal anomalies such as tracheoesophageal fistula, gastroschisis, omphalocele, or
- Massive intestinal atresia; or
- Infants and young children who fail to thrive due to systemic disease or secondarily to intestinal insufficiency associated with short bowel syndrome, malabsorption or chronic idiopathic diarrhea; or
- Patients with prolonged paralytic ileus following major surgery or multiple injuries.

All of the following criteria must be met prior to the initial implementation of total parenteral nutrition (TPN):

- The patient must be in a stage of wasting as indicative of the following:
  - o Weight is significantly less than normal body weight for a patient's height and age in comparison with pre-illness weight
  - o Serum albumin is less than 2.5 gm;
  - o Blood urea nitrogen (BUN) is below 10 mg (but this is not a good marker in patients receiving dialysis due to protein catabolism);
  - o Phosphorus level is less than 2.5 mg (normal phosphorus is 3–4.5 mg);
  - o The patient can receive no more than 30% of his/her caloric needs orally or the patient cannot benefit from tube feedings as a result of a malabsorptive disorder.

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## **When Services Are Not Medically Necessary**

If total parenteral nutrition (TPN) is eligible for coverage under the member contract but patient selection criteria are not met, the use of nutritional supplementation is considered **not medically necessary**.\*\*

## **When Services Are Not Covered**

Total parenteral nutrition is used for patients who require supplementation of their daily protein and caloric intake. Nutritional supplements are often given between meals to boost protein/caloric intake and are **not eligible for coverage** under most member contracts.

## **Enteral Nutrition (EN)**

### **When Services May Be 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 enteral nutrition (EN) to be **eligible for coverage** under the following conditions:

### **Patient Selection Criteria for Enteral Nutrition (EN)**

- An anatomical inability to swallow exists, due to, for example, head and neck cancer or an obstructing tumor or stricture of the esophagus or stomach;
- Central nervous system disease leading to sufficient interference with the neuromuscular coordination of chewing and swallowing so that a risk of aspiration exists.

Enteral nutrition will be considered when accepted medical standards for the use of enteral nutrition (EN) are supported in clinical records, including documentation of the underlying medical condition(s) that necessitate the use of enteral nutrition (EN). However, some member contracts do not cover food or medical foods, including those used for enteral nutrition (EN).

## **When Services Are Not Medically Necessary**

If enteral nutrition (EN) is eligible for coverage under the member contract but patient selection criteria are not met, the use of nutritional supplementation is considered **not medically necessary**.\*\*

## **When Services Are Not Covered**

Enteral nutrition is used for patients who require supplementation of their daily protein and caloric intake. Nutritional supplements are often given between meals to boost protein/caloric intake and are **not eligible for coverage** under most member contracts.



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## **Specialized Nutritional Products**

### **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.*

Specialized Nutritional Products will be considered medically necessary and will be **eligible for coverage** as provided by state legislative mandate if it:

- Is a low protein food product that is especially formulated to have less than one gram of protein per serving, and
- Is intended to be used under the direction of a physician for dietary treatment of an inherited metabolic disease (shall not include a natural food that is naturally low in protein), and
- Is used to treat an inherited abnormality of body chemistry. Such disease shall be limited to:
  - o Phenylketonuria (PKU)
  - o Maple Syrup Urine Disease (MSUD)
  - o Methylmalonic Acidemia (MMA)
  - o Isovaleric Acidemia (IVA)
  - o Propionic Acidemia
  - o Glutaric Acidemia
  - o Urea Cycle Defects
  - o Tyrosinemia

## **Background/Overview**

Total parenteral nutrition, also known as parenteral hyperalimentation, is used for patients with medical conditions that impair gastrointestinal absorption to a degree incompatible with life. It is also used for variable periods of time to bolster the nutritional status of severely malnourished patients with medical or surgical conditions. Total parenteral nutrition involves percutaneous transvenous implantation of a central venous catheter into the vena cava or right atrium. A nutritionally adequate hypertonic solution consisting of glucose (sugar), amino acids (protein), electrolytes (sodium, potassium), vitamins and minerals, and sometimes fats is administered daily. An infusion pump is generally used to assure a steady flow of the solution either on a continuous (24-hour) or intermittent schedule. If intermittent, a heparin lock device and diluted heparin are used to prevent clotting inside the catheter.

Enteral nutrition is used for patients with a functioning intestinal tract, but with disorders of the pharynx, esophagus or stomach that prevent nutrients from reaching the absorbing surfaces in the small intestine. The patient is at risk of severe malnutrition. Enteral nutrition involves administering non-sterile liquids directly into the gastrointestinal tract through nasogastric, gastrostomy or jejunostomy tubes. An infusion pump may be used to assist the flow of liquids. Feedings may be either intermittent or continuous (infused 24 hours a day).



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## **FDA or Other Governmental Regulatory Approval**

U.S. Food and Drug Administration (FDA)

Total parenteral nutrition and EN solutions are subject to FDA approval. Numerous FDA approved solutions are available.

## **Rationale/Source**

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. FDA approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, Blue Cross and Blue Shield Association technology assessment program (TEC) and other non-affiliated technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

## **References**

1. Blue Cross Blue and Shield Association, Medical Policy Reference Manual, "Total Parental Nutrition and Enteral Nutrition in the Home" 1.02.01, 1:2003.
2. Centers for Medicare and Medicaid Services. National Coverage Determination for Enteral and Parenteral Nutritional Therapy (180.2). <http://www.cms.hhs.gov/>.
3. American Gastroenterological Association Medical Position Statement: Guidelines for the Use of Enteral Nutrition. <http://www.gastro.org>.
4. Legislative Mandate, State of Louisiana, 2001.

## **Coding**

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT)<sup>®</sup>†, copyright 2013 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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

Code Type	Code
CPT	No codes
HCPCS	S9340, S9341, S9342, S9343, S9364, S9365, S9366, S9367, S9368, S9430, S9433, S9434, S9435

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ICD-9 Diagnosis	All related diagnoses
ICD-9 Procedure	96.6, 99.15

### **Policy History**

Original Effective Date: 11/22/1993  
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10/18/2001 Medical Policy Committee review  
11/12/2001 Managed Care Advisory Council approval  
10/21/2003 Medical Policy Committee review. Format revision, no substance change in policy.  
01/24/2004 Managed Care Advisory Council approval  
01/04/2005 Medical Director review  
01/18/2005 Medical Policy Committee review  
01/31/2005 Managed Care Advisory Council approval  
02/01/2006 Medical Director review  
02/15/2006 Medical Policy Committee review. Format revision, Rationale updated based on literature review.  
02/23/2006 Quality Care Advisory Council approval  
07/07/2006 Format revision, including addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged.  
02/07/2007 Medical Director review  
02/21/2007 Medical Policy Committee approval.  
02/13/2008 Medical Director review  
02/20/2008 Medical Policy Committee approval. Title changed from nutritional support to total parenteral nutrition and enteral nutrition in the home. Deleted information on intradialytic parenteral nutrition from this policy, and made it a policy in itself.  
02/04/2009 Medical Director review  
02/19/2009 Medical Policy Committee approval. No change to coverage.  
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.  
01/03/2013 Medical Policy Committee review  
01/09/2013 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.  
01/09/2014 Medical Policy Committee review  
01/15/2014 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.  
Next Scheduled Review Date: 01/2015

\*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:

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1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
2. credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
3. reference to federal regulations.

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

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