Title: Enteral Nutrition

Description/Background

Nutritional support is essential for patients who are unable to meet their daily caloric or fluid requirements orally. Enteral delivery (directly into the stomach or intestine) is the preferred delivery method as it is more similar to the normal physiologic method of nutrient delivery. Cost is less with enteral delivery than with parenteral (intravenous) nutritional support and there are fewer side effects.

Enteral nutrition is provided by inserting a tube directly into the stomach or small intestine for delivery of the required dietary supplements. The nutritional formula can be delivered by gravity or by pump. Feeding may be either intermittent or continuous throughout the day and/or night. Enteral nutrition may range from supplementing a patient’s oral intake to supplying all of the patient’s daily nutrition. Special formulas are available to meet different nutritional needs. Enteral nutrition may be provided safely and effectively in the home by a nonprofessional person or family member who has received specialized training.

Enteral nutrition is an option when a patient is unable to maintain a caloric intake sufficient to maintain weight and overall health.

Regulatory Status:

According to the U.S. Food and Drug Administration, “the term medical food, as defined in section 5(b) of the Orphan Drug Act (21 U.S.C. 360ee (b) (3)) is ‘a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation.’"
Medical Policy Statement

The safety and effectiveness of enteral nutrition for patients who meet the patient selection criteria have been established. It is a useful therapeutic option when indicated.

Inclusionary and Exclusionary Guidelines (Clinically based guidelines that may support individual consideration and pre-authorization decisions)

The patient must have an impairment that is long term or “permanent”. Coverage is possible for patients with partial impairments, e.g., a patient with dysphagia who can swallow small amounts of food or a patient with Crohn’s disease who requires prolonged infusion of enteral nutrients to overcome problems with absorption.

Note: Permanence does not require a determination that there is no possibility that the patient’s condition may improve sometime in the future. If the physician substantiates that a condition is of long and indefinite duration (ordinarily at least three months) the test of permanence may be met.

The medical record must document:
• The patient’s general condition, including age, height and weight, estimated duration of therapy, ambulatory status and mental status
• The patient’s condition must be either anatomic or due to a motility disorder
• A clinical assessment of the patient with an evaluation of nutrition, albumin, transferrin, hematocrit, clinical findings, etc. within 30 days prior to certifying or re-certifying the need for the enteral nutrition
• The patient’s nutritional prescription, (including but not limited to):
  - Name of the nutrient
  - Number of calories per day (100 calories = 1 unit)
  - Frequency/day
  - Method (syringe, gravity or pump)
  - Route (nasogastric tube, gastrostomy tube)
  - Rationale for pump, if necessary
  - Attending physician’s signature

Inclusions:
Enteral nutrition is established for patients who require tube feedings to provide sufficient nutrients to maintain weight and strength commensurate with the patient’s overall health status due to the following conditions:
• A dysfunction of indefinite duration or disease of the structures that normally permit food to reach the small bowel, or
• A disease of the small bowel that impairs digestion and absorption of an oral diet

Note: When/if a feeding pump is requested, it must be supported by sufficient medical documentation to establish that the pump is medically necessary (e.g., gravity feeding is not satisfactory due to aspiration, diarrhea, dumping syndrome, etc.). Allowance is made for the
simplest model that meets the medical needs of the patient as established by medical documentation.

**Exclusions:**
- Patients with a functioning gastrointestinal tract whose need for enteral nutrition is due to reasons such as anorexia or nausea associated with mood disorder, end-stage disease, etc.
- Patients in whom adequate nutrition is possible by dietary adjustment and/or oral supplements
- Enteral nutrition products that are administered orally and related supplies
- Food thickeners, baby food, infant formulas and other regular grocery products are not covered in conjunction with oral or enteral feedings and related supplies

*For patients with inborn errors of metabolism who require specialized medical formula, please refer to the policy “Medical Formula for Inborn Errors of Metabolism”.

**CPT/HCPCS Level II Codes** *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure)*

**Established codes:**

- B4034
- B4035
- B4036
- B4081
- B4082
- B4083
- B4087
- B4088
- B4102
- B4103
- B4104
- B4149
- B4150
- B4152
- B4153
- B4154
- B4155
- B4157
- B4158
- B4159
- B4160
- B4161
- B4162
- B9002
- B9998

**Other codes (investigational, not medically necessary, etc.):**

- B4100

**Rationale**

The development of techniques to secure a patient’s nutrition has increased the survival of severely ill patients. Feeding by the enteral route is more physiologic than the intravenous route, and therefore has fewer short and long-term complications. The use of the gastrointestinal tract results in superior fluid homeostasis and the function of the intestine are better preserved. In these conditions, tube feedings provide sufficient nutrients to maintain weight and strength commensurate with the patient’s overall health status.
Government Regulations

National:

National Coverage Determination (NCD) for Enteral and Parenteral Nutritional Therapy (180.2), Effective Date of this Version 7/11/1984

Benefit Category
Prosthetic Devices
Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.

Item/Service Description
There are patients who, because of chronic illness or trauma, cannot be sustained through oral feeding. These people must rely on either enteral or parenteral nutritional therapy, depending upon the particular nature of their medical condition.

Indications and Limitations of Coverage
Coverage of nutritional therapy as a Part B benefit is provided under the prosthetic device benefit provision which requires that the patient must have a permanently inoperative internal body organ or function thereof. Therefore, enteral and parenteral nutritional therapy are not covered under Part B in situations involving temporary impairments. Coverage of such therapy, however, does not require a medical judgment that the impairment giving rise to the therapy will persist throughout the patient's remaining years. If the medical record, including the judgment of the attending physician, indicates that the impairment will be of long and indefinite duration, the test of permanence is considered met.

If the coverage requirements for enteral or parenteral nutritional therapy are met under the prosthetic device benefit provision, related supplies, equipment and nutrients are also covered under the conditions in the following paragraphs and the Medicare Benefit Policy Manual, Chapter 15, "Covered Medical and Other Health Services," §120.

Enteral Nutrition Therapy
Enteral nutrition is considered reasonable and necessary for a patient with a functioning gastrointestinal tract who, due to pathology to, or nonfunction of, the structures that normally permit food to reach the digestive tract, cannot maintain weight and strength commensurate with his or her general condition. Enteral therapy may be given by nasogastric, jejunostomy, or gastrostomy tubes and can be provided safely and effectively in the home by nonprofessional persons who have undergone special training. However, such persons cannot be paid for their services, nor is payment available for any services furnished by nonphysician professionals except as services furnished incident to a physician's service.

Typical examples of conditions that qualify for coverage are head and neck cancer with reconstructive surgery and central nervous system disease leading to interference with the neuromuscular mechanisms of ingestion of such severity that the beneficiary cannot be maintained with oral feeding. However, claims for Part B coverage of enteral nutrition therapy for these and any other conditions must be approved on an individual, case-by-case basis. Each claim must contain a physician's written order or prescription and sufficient medical documentation (e.g., hospital records, clinical findings from the attending physician) to permit an independent conclusion that the patient's condition meets the requirements of the prosthetic device benefit and that enteral nutrition therapy is medically necessary. Allowed claims are to
be reviewed at periodic intervals of no more than 3 months by the contractor's medical consultant or specially trained staff, and additional medical documentation considered necessary is to be obtained as part of this review.

Medicare pays for no more than one month's supply of enteral nutrients at any one time. If the claim involves a pump, it must be supported by sufficient medical documentation to establish that the pump is medically necessary, i.e., gravity feeding is not satisfactory due to aspiration, diarrhea, dumping syndrome. Program payment for the pump is based on the reasonable charge for the simplest model that meets the medical needs of the patient as established by medical documentation.

**Local:**

**CGS Administrators, LLC - Local Coverage Determination (LCD):**
**Enteral Nutrition (L33783), Original Effective Date 10/01/2015, Revision Effective Date 01/01/2019**

Coverage Indications, Limitations, and/or Medical Necessity

For the items addressed in this LCD, the "reasonable and necessary" criteria, based on Social Security Act § 1862(a)(1)(A) provisions, are defined by the following coverage indications, limitations and/or medical necessity.

Statutory coverage criteria for enteral nutrition are specified in the related Policy Article.

**NUTRIENTS:**
Enteral formulas consisting of semi-synthetic intact protein/protein isolates (B4150 or B4152) are appropriate for the majority of beneficiaries requiring enteral nutrition.

The medical necessity for special enteral formulas (B4149, B4153-B4155, B4157, B4161, and B4162) must be justified in each beneficiary. If a special enteral nutrition formula is provided and if the medical record does not document why that item is medically necessary, it will be denied as not reasonable and necessary.

**EQUIPMENT AND SUPPLIES:**
Enteral nutrition may be administered by syringe, gravity, or pump. Some enteral beneficiaries may experience complications associated with syringe or gravity method of administration.

If a pump (B9002) is ordered, there must be documentation in the beneficiary's medical record to justify its use (e.g., gravity feeding is not satisfactory due to reflux and/or aspiration, severe diarrhea, dumping syndrome, administration rate less than 100 ml/hr, blood glucose fluctuations, circulatory overload, gastrostomy/jejunostomy tube used for feeding). If the medical necessity of the pump is not documented, the pump will be denied as not reasonable and necessary.

The feeding supply allowance (B4034-B4036) must correspond to the method of administration indicated in question 5 of the DME Information Form (DIF). If it does not correspond, it will be denied as not reasonable and necessary.

If a pump supply allowance (B4035) is provided and if the medical necessity of the pump is not
documented, it will be denied as not reasonable and necessary.

The codes for feeding supply allowances (B4034-B4036) are specific to the route of administration. Claims for more than one type of kit code delivered on the same date or provided on an ongoing basis will be denied as not reasonable and necessary.

Enteral feeding supply kit allowances (B4034-B4036), are all-inclusive. Separate billing for any item including an item using a specific HCPCS code, if one exists, or B9998 (ENTERAL SUPPLIES, NOT OTHERWISE CLASSIFIED) will be denied as unbundling.

Refer to the Enteral Nutrition Related Policy Article CODING GUIDELINES section for additional information about enteral feeding supply allowances.

More than three nasogastric tubes (B4081-B4083), or one gastrostomy/jejunostomy tube (B4087-B4088) every three months is not reasonable and necessary.

GENERAL
A Detailed Written Order (DWO) (if applicable) must be received by the supplier before a claim is submitted. If the supplier bills for an item addressed in this policy without first receiving a completed DWO, the claim shall be denied as not reasonable and necessary.

An item/service is correctly coded when it meets all the coding guidelines listed in CMS HCPCS guidelines, LCDs, LCD-related Policy Articles, or DME MAC articles. Claims that do not meet coding guidelines shall be denied as not reasonable and necessary/incorrectly coded.

Proof of delivery (POD) is a Supplier Standard and DMEPOS suppliers are required to maintain POD documentation in their files. Proof of delivery documentation must be made available to the Medicare contractor upon request. All services that do not have appropriate proof of delivery from the supplier shall be denied as not reasonable and necessary.

REFILL REQUIREMENTS
For DMEPOS items and supplies provided on a recurring basis, billing must be based on prospective, not retrospective use. For DMEPOS products that are supplied as refills to the original order, suppliers must contact the beneficiary prior to dispensing the refill and not automatically ship on a pre-determined basis, even if authorized by the beneficiary. This shall be done to ensure that the refilled item remains reasonable and necessary, existing supplies are approaching exhaustion, and to confirm any changes or modifications to the order. Contact with the beneficiary or designee regarding refills must take place no sooner than 14 calendar days prior to the delivery/shipping date. For delivery of refills, the supplier must deliver the DMEPOS product no sooner than 10 calendar days prior to the end of usage for the current product. This is regardless of which delivery method is utilized.

For all DMEPOS items that are provided on a recurring basis, suppliers are required to have contact with the beneficiary or caregiver/designee prior to dispensing a new supply of items. Suppliers must not deliver refills without a refill request from a beneficiary. Items delivered without a valid, documented refill request will be denied as not reasonable and necessary.

Suppliers must not dispense a quantity of supplies exceeding a beneficiary's expected utilization. Suppliers must stay attuned to changed or atypical utilization patterns on the part of
their clients. Suppliers must verify with the ordering physicians that any changed or atypical utilization is warranted.

CGS Administrators, LLC - Enteral Nutrition - Policy Article (A52493)
Effective 10/01/2015, Revision Effective Date 01/01/2019

NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES
For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements. Information provided in this policy article relates to determinations other than those based on Social Security Act §1862(a)(1)(A) provisions (i.e. “reasonable and necessary”).

ENTERAL NUTRITION is covered under the Prosthetic Device benefit (Social Security Act § 1861(s)(8)). In order for a beneficiary’s nutrition to be eligible for reimbursement the reasonable and necessary (R&N) requirements set out in the related Local Coverage Determination must be met. In addition, there are specific statutory payment policy requirements, discussed below, that also must be met.

GENERAL:
ENTERAL NUTRITION is the provision of nutritional requirements through a tube into the stomach or small intestine.

ENTERAL NUTRITION is covered for a beneficiary who has (a) permanent non-function or disease of the structures that normally permit food to reach the small bowel or (b) disease of the small bowel which impairs digestion and absorption of an oral diet, either of which requires tube feedings to provide sufficient nutrients to maintain weight and strength commensurate with the beneficiary's overall health status.

The beneficiary must have 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. If the judgment of the attending physician, substantiated in the medical record, is that the condition is of long and indefinite duration (ordinarily at least 3 months), the test of permanence is considered met. ENTERAL NUTRITION will be denied as non-covered in situations involving temporary impairments.

The beneficiary's condition could be either anatomic (e.g., obstruction due to head and neck cancer or reconstructive surgery, etc.) or due to a motility disorder (e.g., severe dysphagia following a stroke, etc.). ENTERAL NUTRITION is non-covered for beneficiaries with a functioning gastrointestinal tract whose need for ENTERAL NUTRITION is due to reasons such as anorexia or nausea associated with mood disorder, end-stage disease, etc.

The beneficiary must require tube feedings to maintain weight and strength commensurate with the beneficiary's overall health status. Adequate nutrition must not be possible by dietary adjustment and/or oral supplements. Coverage is possible for beneficiaries with partial impairments - e.g., a beneficiary with dysphagia who can swallow small amounts of food or a beneficiary with Crohn's disease who requires prolonged infusion of ENTERAL nutrients to overcome a problem with absorption.
ENTERAL NUTRITION products that are administered orally and related supplies are noncovered, no benefit.

If the coverage requirements for ENTERAL NUTRITION are met, medically necessary nutrients, administration supplies, and equipment are covered.

ENTERAL NUTRITION provided to a beneficiary in a Part A covered stay must be billed by the SNF to the fiscal intermediary. No payment from Part B is available when ENTERAL NUTRITION services are furnished to a beneficiary in a stay covered by Part A. However, if a beneficiary is in a stay not covered by Part A, ENTERAL NUTRITION is eligible for coverage under Part B and may be billed to the DME MAC by either the SNF or an outside supplier.

NUTRIENTS:
Food thickeners (B4100), baby food, and other regular grocery products that can be blenderized and used with the enteral system will be denied as noncovered.

Codes B4102 and B4103 describe electrolyte-containing fluids that are noncovered by Medicare.

Self-blenderized formulas are noncovered by Medicare.

Code B4104 is an enteral formula additive. The ENTERAL formula codes include all nutrient components, including vitamins, mineral, and fiber. Therefore, code B4104 will be denied as not separately payable.

SUPPLIES:
The unit of service (UOS) for the supply allowance (B4034-B4036) is one (1) UOS per day. Claims that are submitted for more than one UOS per day for HCPCS codes B4034-B4036 will be rejected.

Please refer to the full article for information on the DME Information Form (DIF) requirements and Coding Guidelines

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

Medical Formula for Inborn Errors of Metabolism
Nutritional Counseling - BCN only
Total Parenteral Nutrition (Hyperalimentation)

References


3. CGS Administrators, LLC, “LCD for Enteral Nutrition,” L33783, Effective date 10/1/15, Revision Effective Date 1/1/19.

4. CGS Administrators, LLC, “Article for Enteral Nutrition,” (A52493), Policy Article, Original Effective Date 10/1/15, Revision Effective Date 1/1/19.


The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through 1/22/20, the date the research was completed.
Joint BCBSM/BCN Medical Policy History

<table>
<thead>
<tr>
<th>Policy Effective Date</th>
<th>BCBSM Signature Date</th>
<th>BCN Signature Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>5/20/02</td>
<td>5/20/02</td>
<td>5/20/02</td>
<td>Joint policy established</td>
</tr>
<tr>
<td>6/24/04</td>
<td>6/24/04</td>
<td>7/26/04</td>
<td>Routine maintenance</td>
</tr>
<tr>
<td>5/19/05</td>
<td>5/19/05</td>
<td>5/19/05</td>
<td>Routine maintenance</td>
</tr>
<tr>
<td>11/1/06</td>
<td>8/30/06</td>
<td>10/29/06</td>
<td>Routine maintenance</td>
</tr>
<tr>
<td>11/1/07</td>
<td>8/21/07</td>
<td>10/27/07</td>
<td>Routine maintenance</td>
</tr>
<tr>
<td>5/1/08</td>
<td>2/19/08</td>
<td>3/14/08</td>
<td>Routine maintenance</td>
</tr>
<tr>
<td>5/1/09</td>
<td>2/10/09</td>
<td>2/10/09</td>
<td>Routine maintenance</td>
</tr>
<tr>
<td>5/1/11</td>
<td>2/15/11</td>
<td>3/3/11</td>
<td>Routine maintenance; policy criteria clarified</td>
</tr>
<tr>
<td>7/1/13</td>
<td>4/16/13</td>
<td>4/22/13</td>
<td>Routine maintenance</td>
</tr>
<tr>
<td>7/1/15</td>
<td>4/24/15</td>
<td>5/8/15</td>
<td>Routine maintenance</td>
</tr>
<tr>
<td>7/1/16</td>
<td>4/19/16</td>
<td>4/19/16</td>
<td>Routine maintenance</td>
</tr>
<tr>
<td>5/1/17</td>
<td>2/21/17</td>
<td>2/21/17</td>
<td>Routine maintenance Updated Government Regulations section Deleted procedure code B9000</td>
</tr>
<tr>
<td>5/1/18</td>
<td>2/20/18</td>
<td>2/20/18</td>
<td>Routine maintenance Updated Government Regulations section</td>
</tr>
<tr>
<td>5/1/19</td>
<td>2/19/19</td>
<td></td>
<td>Routine maintenance</td>
</tr>
<tr>
<td>5/1/20</td>
<td>2/18/20</td>
<td></td>
<td>Routine maintenance. Added asterisk to exclusions section, referencing Medical Formula for Inborn Errors of Metabolism policy</td>
</tr>
</tbody>
</table>

Next Review Date: 1st Qtr, 2021

Pre-Consolidation Medical Policy History

<table>
<thead>
<tr>
<th>Original Policy Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>BCN: 10/26/99</td>
<td>Revised: N/A</td>
</tr>
<tr>
<td>BCBSM: N/A</td>
<td>Revised: N/A</td>
</tr>
</tbody>
</table>
I. Coverage Determination:

<table>
<thead>
<tr>
<th>Coverage Description</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Commercial HMO (includes Self-Funded groups unless otherwise specified)</td>
<td>Covered, policy guidelines apply</td>
</tr>
<tr>
<td></td>
<td>*BCN does not cover regular or special infant formulas for infants to one year of age.</td>
</tr>
<tr>
<td>BCNA (Medicare Advantage)</td>
<td>See Government Regulations section of policy.</td>
</tr>
<tr>
<td>BCN65 (Medicare Complementary)</td>
<td>Coinsurance covered if primary Medicare covers the service.</td>
</tr>
</tbody>
</table>

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.
- Duplicate (back-up) equipment is not a covered benefit.