
Medical Policy



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of the Blue Cross and Blue Shield Association

Joint Medical Policies are a source for BCBSM and BCN medical policy information only. These documents are not to be used to determine benefits or reimbursement. Please reference the appropriate certificate or contract for benefit information. This policy may be updated and is therefore subject to change.

***Current Policy Effective Date: 7/1/24**
(See policy history boxes for previous effective dates)

Title: Enteral Nutrition

Description/Background

Nutritional support is essential for Individuals who are unable to meet their daily caloric or fluid requirements orally. Enteral delivery (into the stomach or intestine) is the preferred delivery method as it is most similar to the normal physiologic method of nutrient delivery. Enteral delivery is less expensive than parenteral (intravenous) nutritional support and, additionally, there are fewer complications.

Enteral nutrition is provided by inserting a tube 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.

Infants who cannot tolerate cow milk formulas, soy formula, breast milk or hydrolyzed formulas may require an elemental formula (ex, Neocate®, Neocate® with DHA and ARA or EleCare)

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 foods do not have to undergo premarket review or approval by FDA and individual medical food products do not have to be registered with FDA”.

Medical Policy Statement

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

Inclusionary and Exclusionary Guidelines

The patient must have an impairment that is long-term or “permanent”. Coverage is possible for Individuals with partial impairments, eg, 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 all information relevant to: a) the patient requiring the nutrition and b) the nutritional prescription.

Inclusions:

Enteral nutrition is established for individuals who require tube feedings to provide sufficient nutrients to maintain weight and strength commensurate with the individual’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

If enteral nutrition criteria are met, all tube feeding supplies are covered for the individual.

Note: When a feeding pump is requested, it must be supported by sufficient medical documentation to establish that the pump is medically necessary (eg, 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:

- Individuals with a functioning gastrointestinal tract whose need for enteral nutrition is due to reasons such as anorexia or nausea associated with mood disorder.
- Individuals 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 even if they are given as enteral nutrition.

Note: This policy does not address infants (up to 12 months of age) who cannot tolerate cow milk formulas, soy formula, breast milk or hydrolyzed formulas who may require an elemental formula (eg, Neocate®, Neocate® with DHA and ARA or EleCare).

Note: For individuals 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 Individuals. 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 preservation of gastrointestinal function. When nutritional support is necessary, tube feedings provide nutrients sufficient 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), RETIRED Effective Date of this Version 07/11/1984, Ending Effective Date of this Version:04/10/2023

Benefit Category

Prosthetic Devices

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

180.2 - Enteral and Parenteral Nutritional Therapy (RETIRED)

(Rev. 11892; Issued: 03-09-23; Effective: 04-10-23; Implementation: 04-10-23)

Effective January 1, 2022, the Centers for Medicare & Medicaid Services determined that no national coverage determination (NCD) is appropriate at this time for Enteral and Parenteral

Nutritional Therapy. In the absence of an NCD, coverage determinations will be made by the Medicare Administrative Contractors under 1862(a)(1)(A) of the Social Security Act.

Local:

CGS Administrators, LLC

Local Coverage Determination (LCD): Enteral Nutrition (L33783)

Original Effective Date 10/01/2015, Revision Effective Date 01/01/2020

Retirement Date: 11/12/2020

CGS Administrators, LLC

Local Coverage Determination (LCD): Enteral Nutrition (L38955)

Original Effective Date 09/5/2021, Revision Effective Date 10/01/2023

Retirement Date: N/A

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.

The purpose of a Local Coverage Determination (LCD) is to provide information regarding “reasonable and necessary” criteria based on Social Security Act § 1862(a)(1)(A) provisions.

In addition to the “reasonable and necessary” criteria contained in this LCD there are other payment rules, which are discussed in the following documents, that must also be met prior to Medicare reimbursement:

- The LCD-related Standard Documentation Requirements Article, located at the bottom of this policy under the Related Local Coverage Documents section.
- The LCD-related Policy Article, located at the bottom of this policy under the Related Local Coverage Documents section.
- Refer to the Supplier Manual for additional information on documentation requirements.
- Refer to the DME MAC web sites for additional bulletin articles and other publications related to this LCD.

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.

Enteral nutrition is covered for a beneficiary who requires feedings via an enteral access device to provide sufficient nutrients to maintain weight and strength commensurate with the beneficiary's overall health status and has a permanent:

- A. full or partial non-function or disease of the structures that normally permit food to reach the small bowel; OR,
- B. disease that impairs digestion and/or absorption of an oral diet, directly or indirectly, by the small bowel.

Refer to the LCD-related Policy Article for the definition of test of permanence.

Adequate nutrition must not be possible by dietary adjustment and/or oral supplements.

Typical examples of conditions associated with non-function or disease of the structures that permit food from reaching the small bowel 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 (not all inclusive).

Typical examples of conditions associated with impaired digestion and/or absorption of an oral diet by the small bowel that may qualify for coverage include inflammatory bowel disease, surgical resection of small bowel, cystic fibrosis, chronic pancreatitis, and advanced liver disease (not all inclusive).

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

For coverage of the following scenarios, see the LCD-related Policy Article:

- Enteral nutrition for temporary impairments
- Enteral nutrition for beneficiaries with a functioning gastrointestinal tract whose need for enteral nutrition is not due to reasons related to the non-function or disease of the structures that normally permit food to reach the small bowel
- Orally administered enteral nutrition products, related supplies and equipment

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, B4154, 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. (Refer to the LCD-related Policy Article for policy specific documentation requirements.)

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.

In-line digestive enzyme cartridges (B4105) are reasonable and necessary for beneficiaries who:

- A. meet the coverage criteria for enteral nutrition; AND,
- B. have a diagnosis of Exocrine Pancreatic Insufficiency (EPI) (refer to the Group 1 Codes in the LCD-related Policy Article for applicable diagnoses).

More than two in-line digestive enzyme cartridges (B4105) per day will be denied as not reasonable and necessary.

The feeding supply allowance (B4034, B4035, and 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, B4035, and 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, B4035, and B4036), are all-inclusive, with the exception of B4105 in-line digestive enzyme cartridge. 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 LCD-related Policy Article CODING GUIDELINES section for additional information about enteral feeding supply allowances.

More than three nasogastric tubes (B4081, B4082, and B4083), or one gastrostomy/jejunostomy tube (B4087 or B4088) every three months is not reasonable and necessary.

GENERAL

A Standard Written Order (SWO) must be communicated to the supplier before a claim is submitted. If the supplier bills for an item addressed in this policy without first receiving a completed SWO, the claim shall be denied as not reasonable and necessary.

For Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) base items that require a Written Order Prior to Delivery (WOPD), the supplier must have received a signed SWO before the DMEPOS item is delivered to a beneficiary. If a supplier delivers a DMEPOS item without first receiving a WOPD, the claim shall be denied as not reasonable and necessary. Refer to the LCD-related Policy Article, located at the bottom of this policy under the Related Local Coverage Documents section.

For DMEPOS base items that require a WOPD, and also require separately billed associated options, accessories, and/or supplies, the supplier must have received a WOPD which lists the base item and which may list all the associated options, accessories, and/or supplies that are separately billed prior to the delivery of the items. In this scenario, if the supplier separately bills for associated options, accessories, and/or supplies without first receiving a completed and signed WOPD of the base item prior to delivery, the claim(s) 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 treating practitioner that any changed or atypical utilization is warranted.

Regardless of utilization, a supplier must not dispense more than a 1-month quantity at a time. Supply allowance HCPCS codes (B4034, B4035, and B4036) are daily allowances which are considered all-inclusive and therefore refill requirements are not applicable to these HCPCS codes. Refer to the Coding Guidelines section in the LCD-related Policy Article for further clarification.

Summary of Evidence

N/A

Analysis of Evidence (Rationale for Determination)

N/A

CGS Administrators, LLC

Enteral Nutrition - Policy Article (A52493)

Effective 10/01/2015, Revision Effective Date 04/30/2020

Retirement Date: 11/12/2020

CGS Administrators, LLC

Enteral Nutrition-Policy Article (A58833)

Original Effective Date 09/05/2021, Revision Effective Date 10/01/2023

Retirement Date: N/A

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 for temporary impairments will be denied as non-covered, no benefit.

Enteral nutrition for beneficiaries with a functioning gastrointestinal tract whose need for enteral nutrition is not due to reasons related to the non-function or disease of the structures that normally permit food to reach the small bowel will be denied as non-covered, no benefit. Orally administered enteral nutrition products, related supplies and equipment will be denied non-covered, no benefit.

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 slenderized and used with the enteral system will be denied as non-covered.

Electrolyte-containing fluids (B4102 and B4103) are not indicated for the maintenance of weight and strength and are therefore non-covered, no benefit.

Self-slenderized formulas are non-covered 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, B4035, or B4036) is one (1) UOS per day. Claims that are submitted for more than one UOS per day for HCPCS codes B4034, B4035, or B4036 will be rejected.

TEST OF PERMANENCE:

Coverage of enteral nutrition under the prosthetic device benefit, as outlined in the Medicare *Benefit Policy Manual* (CMS Pub. 100-02), Chapter 15, Section 120, requires that a beneficiary must have a permanent impairment. However, this does not require a determination that there is no possibility that the beneficiary's condition may improve sometime in the future. If the medical record, including the judgment of the treating practitioner, indicates that the impairment will be of long and indefinite duration, the test of permanence is considered met.

REQUIREMENTS FOR SPECIFIC DMEPOS ITEMS PURSUANT TO Final Rule 1713 (84 Fed. Reg Vol 217)

Final Rule 1713 (84 Fed. Reg Vol 217) requires a face-to-face encounter and a Written Order Prior to Delivery (WOPD) for specified HCPCS codes. CMS and the DME MACs provide a list of the specified codes, which is periodically updated. The required Face-to-Face Encounter and Written Order Prior to Delivery List is available [here](#).

Claims for the specified items subject to Final Rule 1713 (84 Fed. Reg Vol 217) that do not meet the face-to-face encounter and WOPD requirements specified in the LCD-related Standard Documentation Requirements Article (A55426) will be denied as not reasonable and necessary.

If a supplier delivers an item prior to receipt of a WOPD, it will be denied as not reasonable and necessary. If the WOPD is not obtained prior to delivery, payment will not be made for that item even if a WOPD is subsequently obtained by the supplier. If a similar item is subsequently

provided by an unrelated supplier who has obtained a WOPD, it will be eligible for coverage.

POLICY SPECIFIC DOCUMENTATION REQUIREMENTS

In addition to policy specific documentation requirements, there are general documentation requirements that are applicable to all DMEPOS policies. These general requirements are located in the DOCUMENTATION REQUIREMENTS section of the LCD.

Refer to the LCD-related Standard Documentation Requirements article, located at the bottom of this Policy Article under the Related Local Coverage Documents section for additional information regarding GENERAL DOCUMENTATION REQUIREMENTS and the POLICY SPECIFIC DOCUMENTATION REQUIREMENTS discussed below.

The supplier must enter a diagnosis code corresponding to the beneficiary's diagnosis on each claim.

The beneficiary's medical record must contain sufficient documentation of the beneficiary's medical condition to substantiate the necessity for the type and quantity of items ordered and for the frequency of use or replacement (if applicable). The information should include the beneficiary's diagnosis and other pertinent information including, but not limited to, duration of the beneficiary's condition, clinical course (worsening or improvement), prognosis, nature and extent of functional limitations, other therapeutic interventions and results, past experience with related items, etc.

Information describing the medical necessity for enteral nutrition must be available upon request. In order to satisfy the test of permanence, there must be documentation to reflect that in the treating practitioner's judgement, the impairment will be of long and indefinite duration. Documentation in the medical record shall also reflect that the beneficiary has (a) full or partial non-function or disease of the structures that normally permit food to reach the small bowel; or, (b) disease that impairs digestion and/or absorption of an oral diet, directly or indirectly, by the small bowel.

Special nutrient formulas, HCPCS codes B4149, B4153, B4154, B4155, B4157, B4161, and B4162, are produced to meet unique nutrient needs for specific disease conditions. If a special nutrient formula is ordered, the beneficiary's medical records must specify why a standard formula cannot be used to meet the beneficiary's metabolic needs. This documentation may include other formulas tried and failed or considered and ruled out. A diagnosis alone is not sufficient to support the medical need for a specialty formula. For example, an order for a diabetes-specific formula may be supported by documentation in the medical record that the beneficiary has a diagnosis of diabetes mellitus and has experienced severe fluctuations of glucose levels on standard formula.

DME INFORMATION FORM (DIF)

A DME Information Form (DIF) which has been completed, signed, and dated by the supplier, must be kept on file by the supplier and made available upon request.

The DIF for enteral nutrition is CMS Form 10126. The initial claim must include an electronic copy of the DIF.

A new Initial DIF for enteral nutrients is required when:

- A formula billed with a different code, which has not been previously certified, is ordered, or
- Enteral nutrition services are resumed after they have not been required for two consecutive months.

A new Initial DIF for a pump (B9002) is required when:

- Enteral nutrition services involving use of a pump are resumed after they have not been required for two consecutive months, or
- A beneficiary receiving enteral nutrition by the syringe or gravity method is changed to administration using a pump.

A revised DIF is required when:

- The number of calories per day is changed, or
- The number of days per week administered is changed, or
- The method of administration (syringe, gravity, pump) changes, or
- The route of administration is changed from tube feedings to oral feedings (if billing for denial), or
- The HCPCS code for the current nutrient changes (revised DIF for the pump)

A revised DIF must be submitted when the length of need previously entered on the DIF has expired and the treating practitioner is extending the length of need for the item(s).

If two enteral nutrition products, which are described by the same HCPCS code, are being provided at the same time, they should be billed on a single claim line with the units of service reflecting the total calories of both nutrients.

CODING GUIDELINES

Enteral feeding supply allowances (B4034, B4035, and B4036) include all supplies, other than the feeding tube and nutrients, required for the administration of enteral nutrients to the beneficiary for one day. Only one unit of service may be billed for any one day. Codes B4034, B4035, and B4036 describe a daily supply fee rather than a specifically defined “kit.” The use of individual items may differ from beneficiary to beneficiary, and from day to day. Items included in these codes are not limited to pre-packaged “kits” bundled by manufacturers or distributors. These supply allowances include, but are not limited to, a catheter/tube anchoring device, feeding bag/container, flushing solution bag/container, administration set tubing, extension tubing, feeding/flushing syringes, gastrostomy tube holder, dressings (any type) used for gastrostomy tube site, tape (to secure tube or dressings), Y connector, adapter, gastric pressure relief valve, deluging device. These items must not be separately billed using the miscellaneous code (B9998) or using a specific code for any individual item, should a unique HCPCS code for item exist (for examples dressing, tape).

B4105 (IN-LINE CARTRIDGE CONTAINING DIGESTIVE ENZYME(S) FOR ENTERAL FEEDING, EACH) is eligible for separate payment.

Products that are only administered orally should be coded as A9270.

Code B4149 describes formulas containing natural foods that are blenderized and packaged by a manufacturer. B4149 formulas are classified based upon this manufacturer requirement, not on the composition of the enteral formula. Code B4149 must not be used for foods that have been blenderized by the beneficiary or caregiver for administration through a tube.

The only products which may be billed using codes B4149, B4153, B4154, B4155, B4157, B4161, or B4162 are those for which a written Coding Verification Review has been made by the Pricing, Data Analysis and Coding (PDAC) Contractor and subsequently published on the Product Classification List (PCL). If a product is billed to Medicare using a HCPCS code that

requires written coding verification review, but the product is not on the PCL for that particular HCPCS code, then the claim line will be denied as incorrect coding.

Suppliers should refer to the enteral nutrition PCL on the PDAC Contractor web site or contact the PDAC for guidance on the correct coding for these items.

(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 (retired)
Relizorb
Total Parenteral Nutrition (Hyperalimentation)
Elemental Formulas

References

1. Blue Cross Blue Shield Association. Total Parenteral Nutrition and Enteral Nutrition in the Home. # 1.02.01, Issue 1:2003, original policy date 7/31/96, last review date 12/14/05, Archived June 2009.
2. Centers for Medicare & Medicaid Services (CMS). NCD for Enteral and Parenteral Nutritional Therapy. Medicare Coverage Database, Manual Section Number 180.2, original effective date 7/11/1984.
3. CGS Administrators, LLC. LCD for Enteral Nutrition (L33783). Effective date 10/01/2015, Revision Effective Date 01/01/2020, Retirement Date 11/12/2020.
4. CGS Administrators, LLC. Article for Enteral Nutrition (A52493). Original Effective Date 10/1/15, Revision Effective Date 04/30/2020, Retirement Date 11/12/2020.
5. Shepherd A et al. Nutrition support: Risk factors, causes and physiology of malnutrition. *Nursing Practice*. 2009, Vol. 105, No. 4, pp. 18-20.
6. Shepherd A et al. Nutrition support 2: Exploring different methods of administration. *Nursing Practice*. 2009, Vol. 105, No. 5, pp. 14-16.
7. U.S. Food and Drug Administration. Medical Foods Guidance Documents & Regulatory Information. <https://www.fda.gov/food/guidance-documents-regulatory-information-topic-food-and-dietary-supplements/medical-foods-guidance-documents-regulatory-information> Accessed 2/26/24.
8. Weissman B et al. Enteral feeding. *American Academy of Pediatrics*. 2008, Vol. 28, pp. 105-106.

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through 2/26/24, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
5/20/02	5/20/02	5/20/02	Joint policy established
6/24/04	6/24/04	7/26/04	Routine maintenance
5/19/05	5/19/05	5/19/05	Routine maintenance
11/1/06	8/30/06	10/29/06	Routine maintenance
11/1/07	8/21/07	10/27/07	Routine maintenance
5/1/08	2/19/08	3/14/08	Routine maintenance
5/1/09	2/10/09	2/10/09	Routine maintenance
5/1/11	2/15/11	3/3/11	Routine maintenance; policy criteria clarified
7/1/13	4/16/13	4/22/13	Routine maintenance
7/1/15	4/24/15	5/8/15	Routine maintenance
7/1/16	4/19/16	4/19/16	Routine maintenance
5/1/17	2/21/17	2/21/17	Routine maintenance Updated Government Regulations section Deleted procedure code B9000
5/1/18	2/20/18	2/20/18	Routine maintenance Updated Government Regulations section
5/1/19	2/19/19		Routine maintenance
5/1/20	2/18/20		Routine maintenance. Added asterisk to exclusions section, referencing Medical Formula for Inborn Errors of Metabolism policy
5/1/21	2/16/21		Routine maintenance.
5/1/22	2/15/22		Routine maintenance
5/1/23	2/21/23		Routine maintenance (jf) Vendor Managed: NA
7/1/23	4/26/23		Routine maintenance (jf) Vendor Managed: NA Added to inclusions: If tube feeding criteria are met, tube feeding supplies are covered for the individual Removed from exclusions:

			<p>in conjunction with oral or enteral feedings and related supplies.</p> <p>Add under inclusions section if enteral nutrition criteria are met, add "all" tube feeding supplies are covered for the individual.</p> <p>Added 5th bullet under exclusions as a note:</p> <ul style="list-style-type: none"> • This policy does not address infants (up to 12 months of age) who cannot tolerate cow milk formulas, soy formula, breast milk or hydrolyzed formulas who may require an elemental formula (eg, Neocate®, Neocate® with DHA and ARA or EleCare).
7/1/24	4/16/24		<p>Routine Maintenance (jf)</p> <p>Vendor Managed: NA</p> <p>Elemental Formulas added in the related policy section</p>

Next Review Date: 1st Qtr, 2025

Pre-Consolidation Medical Policy History

Original Policy Date	Comments
BCN: 10/26/99	Revised: N/A
BCBSM: N/A	Revised: N/A

**BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: ENTERAL NUTRITION**

I. Coverage Determination:

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

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.