

Medical Policy Bulletin

Title:

Enteral Nutritional Therapy

Policy #:

MA08.003h

The Company makes decisions on coverage based on the Centers for Medicare and Medicaid Services (CMS) regulations and guidance, benefit plan documents and contracts, and the member's medical history and condition. If CMS does not have a position addressing a service, the Company makes decisions based on Company Policy Bulletins. Benefits may vary based on contract, and individual member benefits must be verified. The Company determines medical necessity only if the benefit exists and no contract exclusions are applicable. Although the Medicare Advantage Policy Bulletin is consistent with Medicare's regulations and guidance, the Company's payment methodology may differ from Medicare.

When services can be administered in various settings, the Company reserves the right to reimburse only those services that are furnished in the most appropriate and cost-effective setting that is appropriate to the member's medical needs and condition. This decision is based on the member's current medical condition and any required monitoring or additional services that may coincide with the delivery of this service.

This Policy Bulletin document describes the status of CMS coverage, medical terminology, and/or benefit plan documents and contracts at the time the document was developed. This Policy Bulletin will be reviewed regularly and be updated as Medicare changes their regulations and guidance, scientific and medical literature becomes available, and/or the benefit plan documents and/or contracts are changed.

Policy

Coverage is subject to the terms, conditions, and limitations of the member's Evidence of Coverage.

This policy uses coverage criteria developed solely based on applicable Medicare statutes, regulations, NCDs, LCDs, CMS manuals and other applicable Medicare coverage documents.

MEDICALLY NECESSARY

Enteral nutrition and administration supplies and equipment are considered medically necessary and, therefore, covered when the individual meets the following criteria:

- The individual has **one** of the following indications that requires tube feedings to provide sufficient nutrients to maintain weight and strength commensurate with their overall health status:
 - Permanent* full or partial nonfunctional or disease of the structures that normally permit food to reach the small bowel (e.g., obstruction due to head and neck cancer or reconstructive surgery, central nervous system [CNS] disease leading to interference with the neuromuscular mechanisms of ingestion of such severity that the individual cannot be maintained with oral feeding, or due to a motility disorder [e.g., severe dysphagia following a stroke]); or
 - Disease of the small bowel that impairs digestion and absorption of an oral diet (e.g., inflammatory bowel disease, surgical resection of small bowel, cystic fibrosis, chronic pancreatitis, and advanced liver disease)

Adequate nutrition must not be possible by dietary adjustment and/or oral supplements. Coverage is possible for individuals with partial impairments (e.g., an individual with dysphagia who can swallow small amounts of food or an individual with Crohn's disease who requires prolonged infusion of enteral nutrients to overcome a problem with absorption).

**A permanent impairment is defined as a permanence that does not require a determination that there is no possibility that the individual'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, the test of permanence is considered met.*

NUTRIENTS

Enteral formulas consisting of semisynthetic intact protein/protein isolates (B4150 or B4152) are appropriate for the majority of individuals requiring enteral nutrition.

The medical necessity for special enteral formulas (B4149, B4153-B4155, B4157, B4161, and B4162) must be supported for each individual. If a special enteral nutrition formula is provided and the medical necessity is not supported and documented in the medical record, it will be considered not medically necessary and, therefore, not covered.

EQUIPMENT AND SUPPLIES

Enteral nutrition may be administered by syringe, gravity, or pump. Some individuals receiving enteral nutrition may experience complications associated with the syringe or gravity method of administration. Therefore, if a pump (B9002) is ordered, there must be documentation in the individual'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 supported and documented in the medical record, the pump will be considered not medically necessary and, therefore, not covered.

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 medically necessary and, therefore, not covered.

The feeding supply allowance and associated codes for feeding supply kits (B4034-B4036 and B4148) are specific to the route of administration (syringe, pump, gravity, elastomeric control fed), and, therefore, the feeding supply kit must correspond to the method of administration. If it does not correspond, it will be considered not medically necessary and, therefore, not covered. The codes for enteral feeding supply allowances (B4034-B4036 and B4148) include all supplies, other than the feeding tube and nutrient, required for the administration of enteral nutrients to the individual for one day. Claims for more than one type of kit code delivered on the same date or provided on an ongoing basis will be considered not medically necessary and, therefore, not covered.

More than three nasogastric tubes (B4081-B4083), or one gastrostomy/jejunostomy tube (B4087-B4088) every 3 months, is considered not medically necessary and, therefore, not covered.

In-line digestive enzyme cartridges (B4105) are considered medically necessary and, therefore, covered when the individual meets the coverage criteria for enteral nutrition AND has a diagnosis of exocrine pancreatic insufficiency (EPI). More than two in-line digestive enzyme cartridges (B4105) per day are considered not medically necessary and, therefore, not covered. In-line digestive enzyme cartridges (B4105) are eligible for separate reimbursement from the enteral feeding supply kits (B4034-B4036 and B4148).

NOT SEPARATELY REIMBURSABLE

Reimbursement for enteral formula additives (B4104) is considered included in the allowance for the enteral formula. Therefore, enteral formula additives are not separately reimbursable when billed with the enteral formula.

Reimbursement for a catheter/tube anchoring device (A5200) is considered included in the allowance for enteral feeding supply kits (B4034-B4036 and B4148). Therefore, catheter/tube anchoring devices are not separately reimbursable when billed with the enteral feeding supply kits.

Enteral feeding supply kits (B4034-B4036 and B4148) are all-inclusive. Separate billing for any component of these kits are not appropriate. Therefore, a specific HCPCS code, if one exists, or using B9998 (ENTERAL SUPPLIES, NOT OTHERWISE CLASSIFIED) as separate components of these kits are not eligible for separate reimbursement.

NOT COVERED

Enteral nutrition is not covered by the Company for any of the following indications, because these indications are not covered by Medicare. Therefore, they are not eligible for reimbursement consideration:

- For individuals 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.
- For individuals with temporary impairments.
- Enteral nutrition products and supplies, when the nutrition is administered orally.

Nutritional supplements (used as the mainstay of a daily nutritional plan, or in between meals to boost protein-caloric intake) are not covered by the Company because these items are not covered by Medicare. Therefore, they are not eligible for reimbursement consideration.

Food thickeners (B4100), baby food, and other regular grocery products that can be blenderized and used with the enteral system are not covered by the Company because these items are not covered by Medicare. Therefore, they are not eligible for reimbursement consideration.

Electrolyte-containing fluids (B4102 and B4103) are not covered by the Company because these items are not covered by Medicare. Therefore, they are not eligible for reimbursement consideration.

Self-blenderized formulas are not covered by the Company because these items are not covered by Medicare. Therefore, they are not eligible for reimbursement consideration.

EXPERIMENTAL/INVESTIGATIONAL

All other uses for enteral nutrition, administration supplies, and equipment are considered experimental/investigational and, therefore, not covered unless the indication is supported as an accepted off-label use, as defined in the Company medical policy on off-label coverage for prescription drugs and biologics.

REQUIRED DOCUMENTATION

The Company may conduct reviews and audits of services to our members regardless of the participation status of the provider. Medical record documentation must be maintained on file to reflect the medical necessity of the care and services provided. These medical records may include but are not limited to: records from the professional provider's office, hospital, nursing home, home health agencies, therapies, and test reports.

STANDARD ORDER REQUIREMENTS

Before submitting a claim to the Company, the supplier must have on file a timely, appropriate, and complete order for each item billed that is signed and dated by the professional provider who is treating the member. Requesting a provider to sign a retrospective order at the time of an audit or after an audit for submission as an original order, reorder, or updated order will not satisfy the requirement to maintain a timely professional provider order on file.

PROOF OF DELIVERY

Medical record documentation must include a contemporaneously prepared delivery confirmation or member's receipt of supplies and equipment. The medical record documentation must include a copy of delivery confirmation if delivered by a commercial carrier and a signed copy of delivery confirmation by member/caregiver if delivered by the durable medical equipment (DME) supplier/provider. All documentation is to be prepared contemporaneous with delivery and be available to the Company upon request.

CONSUMABLE SUPPLIES (WHEN APPLICABLE)

The DME supplier must monitor the quantity of accessories and supplies an individual is actually using. Contacting the individual regarding replenishment of supplies should not be done earlier than approximately **30** days prior to the delivery/shipping date. Dated documentation of this contact with the individual is required in the individual's medical record. Delivery of the supplies should not be done earlier than approximately **10** days before the individual would exhaust their on-hand supply.

If required documentation is not available on file to support a claim at the time of an audit or record request, the DME supplier may be required to reimburse the Company for overpayments.

The maximum number of supplies that can be dispensed at one time is no more than a 1-month supply (maximum 31-day supply). Supply allowance HCPCS codes (B4034, B4035, B4036, and B4148) are daily allowances which are considered all-inclusive and therefore refill requirements are not applicable to these HCPCS codes.

Guidelines

This policy is consistent with Medicare's coverage determination. The Company's payment methodology may differ from Medicare.

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable Evidence of Coverage, certain enteral nutrition products and supplies are covered under the medical benefits of the Company's Medicare Advantage products when the medical necessity criteria listed in this medical policy are met. Additionally, certain enteral nutrition products and supplies are not separately reimbursable or not covered and, therefore, are not eligible for payment under the medical benefits of the Company's Medicare Advantage products because the enteral nutrition products or supplies are considered not separately reimbursable or not covered.

For Medicare Advantage members, certain drugs are available through either the member's medical benefit (Part B benefit) or pharmacy benefit (Part D benefit), depending on how the drug is prescribed, dispensed, or administered. This medical policy only addresses instances when enteral nutrition is covered under a member's medical benefit (Part B benefit). It does not address instances when enteral nutrition is covered under a member's pharmacy benefit (Part D benefit).

Description

Enteral nutrition is the provision of nutritional requirements through a tube into the stomach or small intestine. Enteral therapy may be given by nasogastric, jejunostomy, or gastrostomy tubes and can be provided safely and effectively in the home by nonprofessional individuals who have undergone special training.

Enteral nutrition is appropriate for individuals who, because of chronic illness or trauma, cannot be sustained through oral feeding and must rely on enteral nutritional therapy to provide sufficient nutrients to maintain weight and strength.

RELIZORB is a US Food and Drug Administration (FDA)-approved, single-use device that hydrolyzes (digests) fats in enteral formulas for adults and pediatric individuals ages 2 years of age and older. There have been a small number of clinical trials that reviewed its use in individuals with cystic fibrosis.

References

American Society for Parenteral and Enteral Nutrition (ASPEN). Enteral Nutrition Practice Recommendations. *JPEN J Parenter Enteral Nutr.* 2009; 33(3):122-167.

Centers for Medicare & Medicaid Services (CMS). *Medicare Benefit Policy Manual*. Chapter 15: Covered medical and other health services. 120 - Prosthetic Devices (Rev. 1, 10-01-03). [CMS Web site]. Available at: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-loms-Items/Cms012673.html>. Accessed November 29, 2023.

Noridian Medicare Local Coverage Determination (LCD): Enteral Nutrition (L38955). Original Effective Date 09/05/2021. Revision Effective date 01/01/2024. Available at: <https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=38955>. Accessed March 27, 2024.

Noridian Medicare Local Coverage Article (LCA): Enteral Nutrition (A58833). Original Effective Date 09/05/2021. Revision Effective date 10/01/2023. Available at: <https://med.noridianmedicare.com/web/jadme/article-detail/-/view/6547796/enteral-and-parenteral-nutrition-refill-requirements>. Accessed March 27, 2024.

RELIZORB®. Prescribing information. Alcresta Therapeutics, Inc. 9/2023. Available at: <https://www.relizorb.com/hcp#>. Accessed November 29, 2023.

US Food and Drug Administration (FDA). 510(k) Premarket Notification for Relizorb. Available at: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm>. Accessed November 29, 2023.

Coding

Inclusion of a code in this table does not imply reimbursement. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

The codes listed below are updated on a regular basis, in accordance with nationally accepted coding guidelines. Therefore, this policy applies to any and all future applicable coding changes, revisions, or

updates.

In order to ensure optimal reimbursement, all health care services, devices, and pharmaceuticals should be reported using the billing codes and modifiers that most accurately represent the services rendered, unless otherwise directed by the Company.

The Coding Table lists any CPT, ICD-10, and HCPCS billing codes related only to the specific policy in which they appear.

CPT Procedure Code Number(s)

N/A

ICD - 10 Procedure Code Number(s)

N/A

ICD - 10 Diagnosis Code Number(s)

Report the most appropriate diagnosis code in support of medical necessity as listed in the policy.

HCPCS Level II Code Number(s)

MEDICALLY NECESSARY

THE FOLLOWING CODES ARE USED TO REPRESENT ENTERAL SUPPLIES

B4034 Enteral Feeding Supply Kit; Syringe fed, per day, includes, but not limited to feeding/flushing syringe, administration set tubing, dressings, tape.
B4035 Enteral Feeding Supply Kit; Pump fed, per day, includes, but not limited to feeding/flushing syringe, administration set tubing, dressings, tape
B4036 Enteral Feeding Supply Kit; gravity fed, per day, includes, but not limited to feeding/flushing syringe, administration set tubing, dressings, tape
B4081 Nasogastric tubing with stylet
B4082 Nasogastric tubing without stylet
B4083 Stomach tube Levine type
B4087 Gastrostomy/jejunostomy tube, standard, any material, any type, each
B4088 Gastrostomy/jejunostomy tube, low-profile, any material, any type, each
B4105 In-line cartridge containing digestive enzyme(s) for enteral feeding, each
B4148 Enteral feeding supply kit; elastomeric control fed, per day, includes but not limited to feeding/flushing syringe, administration set tubing, dressings, tape
B9002 Enteral nutrition infusion pump, any type
B9998 NOC for enteral supplies
E0776 IV pole

THE FOLLOWING CODES ARE USED TO REPRESENT FORMULA

B4149 Enteral formula, manufactured blenderized natural foods with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit
B4150 Enteral formula, nutritionally complete with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit
B4152 Enteral formula, nutritionally complete, calorically dense (equal to or greater than 1.5 kcal/ml) with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit
B4153 Enteral formula, nutritionally complete, hydrolyzed proteins (amino acids and peptide chain), includes fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit
B4154 Enteral formula, nutritionally complete, for special metabolic needs, excludes inherited disease of metabolism, includes altered composition of proteins, fats, carbohydrates, vitamins and/or minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit
B4155 Enteral formula, nutritionally incomplete/modular nutrients, includes specific nutrients, carbohydrates (e.g., glucose polymers), proteins/amino acids (e.g., glutamine, arginine), fat (e.g., medium chain triglycerides) or

combination, administered through an enteral feeding tube, 100 calories = 1 unit

B4157 Enteral formula, nutritionally complete, for special metabolic needs for inherited disease of metabolism, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit

B4158 Enteral formula, for pediatrics, nutritionally complete with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber and/or iron, administered through an enteral feeding tube, 100 calories = 1 unit.

B4159 Enteral formula, for pediatrics, nutritionally complete soy based with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber and/or iron, administered through an enteral feeding tube, 100 calories = 1 unit.

B4160 Enteral formula, for pediatrics, nutritionally complete calorically dense (equal to or greater than 0.7 kcal/ml) with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit.

B4161 Enteral formula, for pediatrics, hydrolyzed amino acids and peptide chain proteins, includes, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories= 1 unit.

B4162 Enteral formula, for pediatrics, special metabolic needs for inherited disease of metabolism, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit.

NOT COVERED

B4100 Food thickener, administered orally, per ounce

B4102 Enteral formula, for adults, used to replace fluids and electrolytes (eg, clear liquids), 500 ml= 1 unit

B4103 Enteral formula for pediatrics, used to replace fluids and electrolytes (eg, clear liquids), 500 ml= 1 unit

S9432 Medical foods for non-inborn errors of metabolism

S9433 Medical food nutritionally complete, administered orally, providing 100% of nutritional intake

S9434 Modified solid food supplements for inborn errors of metabolism

S9435 Medical foods for inborn errors of metabolism

NOT SEPARATELY REIMBURSABLE

B4104 Additive for enteral formula (eg, fiber)

THE FOLLOWING CODE IS NOT SEPARATELY **REIMBURSABLE** WHEN REPORTED WITH B4034, B4035, B4036 and B4148:

A5200 Percutaneous catheter/tube anchoring device, adhesive skin attachment

Revenue Code Number(s)

N/A

Coding And Billing Requirements

Inclusion of a code in this policy does not imply reimbursement. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

Reimbursement for enteral formula additives (B4104) is considered included in the allowance for the enteral formula. Therefore, enteral formula additives are not separately reimbursable when billed with the enteral formula.

Reimbursement for a catheter/tube anchoring device is considered included in the reimbursement for the enteral feeding supply kits (B4034-B4036). Therefore, code A5200 is not separately reimbursable when billed with enteral feeding supply kits (B4034-B4036).

Cross Reference



Total Parenteral
Nutrition (TPN), Intrad
Policy:

Policy History

Revisions From MA08.003h:

09/18/2026	This policy has been reissued in accordance with the Company's annual review process.
12/15/2025	This policy has been reissued in accordance with the Company's annual review process.
09/16/2024	This version of the policy will be effective on 09/16/2024. This policy was revised to communicate the revised requirements by Noridian Medicare Local Coverage Determination (LCD) & Local Coverage Article (LCA): Enteral Nutrition. Language regarding refills requirements for supplies was added to the Required Documentation Section of the Policy.

Revisions From MA08.003g:

05/07/2024	This policy has been reissued in accordance with the Company's annual review process.
10/01/2023	This version of the policy will be issued on 02/12/2024 with a retro-effective date of 10/01/2023. This policy was revised to communicate the revised requirements by Noridian Medicare Local Coverage Determination (LCD): Enteral Nutrition (L38955) & Local Coverage Article (LCA): Enteral Nutrition (A58833), effective 10/01/2023. The list and examples of equipment and supplies have been expanded to include the feeding supply allowance (B4148) and corresponding method of administration (elastomeric control fed). Additionally, the following language was added to the Required documentation of the Policy: REFILL REQUIREMENTS The maximum number of supplies that can be dispensed at one time is a 31-day supply. Supply allowance HCPCS codes (B4034, B4035, B4036, and B4148) are daily allowances that are considered all-inclusive and therefore refill requirements are not applicable to these HCPCS codes. The Company's coverage position of the following HCPCS codes have been added as medically necessary: B4148 ENTERAL FEEDING SUPPLY KIT; ELASTOMERIC CONTROL FED, PER DAY, INCLUDES BUT NOT LIMITED TO FEEDING/FLUSHING SYRINGE, ADMINISTRATION SET TUBING, DRESSINGS, TAPE

Revisions From MA08.003f:

09/06/2023	The policy has been reviewed and reissued to communicate the Company's continuing position on Enteral Nutritional Therapy.
10/19/2022	The policy has been reviewed and reissued to communicate the Company's continuing position on Enteral Nutritional Therapy.
12/06/2021	This version of the policy will become effective 12/06/2021.

	This policy was revised to communicate the revised requirements by Noridian Medicare Local Coverage Determination (LCD): Enteral Nutrition (L38955) & Local Coverage Article (LCA): Enteral Nutrition (A58833), effective 09/05/2021. The Company's coverage position of the following HCPCS codes have been revised: B4105 In-line cartridge containing digestive enzyme(s) for enteral feeding, each • FROM: Experimental/Investigational • TO: Medically Necessary S9435 Medical foods for inborn errors of metabolism • FROM: Medically Necessary • TO: Not Covered
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Revisions From MA08.003e:

10/01/2021	This policy has been identified for the HCPCS code update, effective 10/01/2021. The following HCPCS code has been added to this policy as not covered: S9432 Medical foods for non-inborn errors of metabolism
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Revisions From MA08.003d:

10/23/2019	This policy has been reissued in accordance with the Company's annual review process.
01/01/2019	This policy has been updated to communicate the experimental/investigational coverage of Relizorb®.

Revisions From MA08.003c:

11/22/2017	This policy has been reissued in accordance with the Company's annual review process.
01/01/2017	This policy has been identified for the HCPCS code update, effective 01/01/2017. The following HCPCS code has been deleted from this policy: B9000 Enteral nutrition infusion pump - without alarm The following HCPCS narrative has been revised in this policy: FROM: B9002 Enteral nutrition infusion pump - with alarm TO: B9002 Enteral nutrition infusion pump, any type

Revisions From MA08.003b:

09/28/2016	This policy has been updated to reflect the coverage position of newly-added HCPCS codes: Medically Necessary if criteria are met: S9435 Medical foods for inborn errors of metabolism. Non-covered, per Medicare rules: • S9433 - Medical food nutritionally complete, administered orally, providing 100% of nutritional intake • S9434 - Modified solid food supplements for inborn errors of metabolism
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Revisions From MA08.003a:

03/11/2015	The Company has clarified its position of Non-Coverage regarding nutritional supplements, as described in the Medicare <i>National Coverage Determination (NCD)</i>:180.2: Enteral and parenteral nutrition therapy. An error was identified and corrected in "Coding and Billing Requirements" Section: HCPCS code B5034 was changed to B4034.
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Revisions From MA08.003:

01/01/2015	This is a new policy.
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Version Effective Date:

09/16/2024

Version Issued Date:

09/16/2024

Version Reissued Date:

09/18/2026