



# MEDICAL POLICY

MEDICAL POLICY DETAILS	
Medical Policy Title	ENTERAL NUTRITION
Policy Number	10.01.03
Category	Government Mandate
Effective Date	10/18/01
Revised Date	10/18/01, 08/28/03, 10/28/04, 10/27/05, 10/26/06, 12/13/07, 08/28/08, 08/27/09, 08/26/10, 08/25/11, 08/23/12, 08/22/13, 08/28/14, 08/27/15, 08/25/16, 08/25/17, 02/22/18, 08/23/18, 02/28/19, 02/27/20
Product Disclaimer	<ul style="list-style-type: none"> <li>• If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.</li> <li>• If a commercial product (including an Essential Plan product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit.</li> <li>• If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.</li> </ul>

**Note:** Refer to the section regarding Pharmacy Benefits for Medicaid Managed Care product members at the end of this policy for coverage criteria for those members.

## POLICY STATEMENT

- I. Enteral formulas for home use, whether administered orally or via tube feeding (e.g., NG tubes, NE tubes, G- tubes, J-tubes), are considered **medically appropriate** when a physician or other licensed health care provider has issued a written order stating that the enteral formula is medically necessary and has been proven effective as a disease-specific treatment regimen. Health Plan contracts with prescription drug coverage will provide benefits for:
  - A. Diseases for which enteral formulas have been proven as an effective treatment, including, but not limited to, the following:
    1. Inherited diseases of amino acid or organic acid metabolism (e.g., Phenylketonuria/PKU);
    2. Branch-chain ketonuria, galactosemia, or homocystinuria;
    3. Crohn's disease;
    4. Gastroesophageal reflux;
    5. Impaired absorption of nutrients caused by disorders affecting the absorptive surface, function, length, and motility of the gastrointestinal tract (e.g., chronic intestinal pseudo-obstruction, Ogilvie's syndrome);
    6. Ulcerative colitis;
    7. Severe food protein induced enterocolitis syndrome;
    8. Eosinophilic disorders; or
    9. Multiple, severe food allergies, including, but not limited to, immunoglobulin E and non-immunoglobulin E-mediated allergies to multiple food proteins.
  - B. Modified solid food products that are low-protein, contain modified protein, or are amino acid based have been proven medically effective and, therefore, are considered **medically appropriate** in the treatment of certain inherited diseases of amino acid and organic acid metabolism or severe protein allergic conditions. *Refer to policy guideline I regarding reimbursement guidelines.*
- II. Enteral nutrition *with enteral feeding tubes* (e.g., NG tubes, NE tubes, G- tubes, J-tubes) is considered **medically appropriate** for, but not limited to, the following functional impairments:
  - A. Muscular paralysis in which the patient is unable to swallow because a damaged brain or spinal cord can no longer communicate to the muscles of the alimentary tract to function. The paralysis may be a result of, but not limited to:

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1. Cerebral vascular accident (CVA);
  2. Trauma/accident;
  3. Spinal cord injury;
  4. Birth defects/cerebral palsy;
  5. Parkinson's disease;
  6. Amyotrophic lateral sclerosis (ALS);
  7. Multiple sclerosis (MS);
  8. Myasthenia gravis; or
  9. Huntington's chorea.
- B. Cognitive neurological disorders that may cause the patient to forget how to swallow, such as:
1. Senile dementia;
  2. Alzheimer's disease; or
  3. Organic brain syndrome.
- C. Mechanical dysfunction of the gastrointestinal tract in which there is a functional impairment that results in a specific inability to swallow or may prevent food from reaching the stomach (e.g., esophageal obstruction or stricture, cancer of the larynx or tongue).
- D. Compromised ability for oral intake in patients with a functioning gastrointestinal tract who, due to pathology, disease or non-function of the structures that normally permit food to reach the digestive tract, cannot maintain weight and strength commensurate with the patient's general condition.
- III. Dietary supplements such as probiotics and digestive enzymes (e.g., RELiZORB™) do not meet the criteria for enteral nutrition, as stated in policy statement I above. Probiotics and digestive enzymes are considered **not medically necessary**.

*Refer to Corporate Medical Policy #1.01.00 Durable Medical Equipment-Standard and Non-Standard (DME).*

*Refer to Corporate Medical Policy #11.01.04 Total Parenteral Nutrition (TPN) /Hyperalimentation.*

**POLICY GUIDELINES**

- I. All enteral nutrition benefits must be prescribed for the patient in a written order by a provider legally authorized to prescribe under the Education Law and will be processed in accordance with the member's subscriber contract.
  - A. The written order by the patient's provider must contain the patient's diagnosis and must state that the enteral formula is medically necessary and has been proven effective as a disease-specific treatment regimen.
  - B. Benefits for enteral formulas administered orally (without feeding tubes) and modified solid food products, when medically appropriate, will be considered under the pharmacy benefit. If there is no pharmacy coverage with the Health Plan, benefits will not be provided.
  - C. Benefits for enteral formulas administered with feeding tubes:
    1. When the patient is receiving home care and the services are billed by a home care agency, enteral formulas and necessary supplies to administer the enteral formula (e.g., feeding tubes, pumps, etc.) will be considered under the home care benefit.
    2. When the patient is not receiving home care or has not been approved for home care benefits, charges for:
      - a) enteral formulas will be considered under the medical contract with the patient copayment being equal to that of the third-tier pharmacy benefit. If there is no pharmacy coverage with the Health Plan, benefits will not be provided; and
      - b) necessary supplies will be considered under the prosthetic benefit of the medical contract.
- II. Patients with cognitive/neurological disease must have documentation in the medical record that demonstrates a dysfunction of the swallowing mechanism. Swallowing assessments or evaluations are required.
- III. Coverage is not intended for inpatient or skilled nursing facility acute care.

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- IV. All patients should be monitored in conjunction with a qualified dietitian, health care practitioner certified in nutritional support, gastroenterologist, or pediatric allergist when appropriate.
- V. Coverage is not intended for patients requiring foods for specialized diets (e.g., gluten free foods), other than as mandated by New York State law. *Refer to policy statement I above.*
- VI. A comprehensive patient assessment is essential before nutritional support is provided, including consideration of the benefits and burdens of nutritional support, based on the patient's diagnosis, prognosis, and goals for care, and plans for reassessment of the need for ongoing nutritional support.

### **DESCRIPTION**

For patients whose bodies lack the ability to properly digest essential nutrients contained in everyday foods, enteral feeding provides nutritional support. Enteral nutrition formulas are specialized mixtures designed to deliver nutrients that can be utilized by these patients' bodies. Modified solid food products are everyday solid foods with essential nutrients removed in order to avoid allergic or other adverse reactions that the foods might otherwise cause.

Enteral nutrition formulas are given through the gastrointestinal tract (mouth, esophagus, stomach or small intestine). They may be administered orally (by mouth) or enterally (with a feeding tube). Examples of feeding tubes are:

- I. Nasogastric (NG): nose to stomach,
- II. Naso-enteral (NE): nose to small bowel,
- III. Gastrostomy (G-tube): surgically placed into the stomach through the abdominal wall, or
- IV. Jejunostomy (J-tube): surgically placed into the small bowel through the abdominal wall.

Hyperemesis gravidarum is a term reserved to describe the most severe cases of nausea and vomiting in pregnancy (NVP). It results from severe nausea and vomiting, and the resultant inability to rehydrate and replenish nutritional reserves. A diagnosis of hyperemesis gravidarum is made based on objective findings such as moderate to large ketonuria and weight loss. Weight loss of 5% or greater is often described as diagnostic of hyperemesis gravidarum. Hyperemesis gravidarum tends to begin earlier in pregnancy and last longer than those patients with less severe NVP.

Probiotics are dietary supplements of live microorganisms (e.g., *Lactobacillus* species, *Bifidobacterium* species, yeasts) that are intended to beneficially affect a patient upon ingestion by improving the balance of the intestinal microflora. Dietary supplements are generally excluded under most Health Plan contracts.

New York State laws (ISC § 3216, § 3221, and § 4303) mandate coverage for enteral formulas for all contracts that cover prescription drugs. The mandate requires coverage for home use of enteral formulas, whether administered orally or via tube feeding, pursuant to a written order by the patient's physician stating that the enteral formula is medically necessary and proven effective as a disease-specific treatment regimen.

The mandate also requires coverage of modified solid food products to treat inherited diseases of amino acid and organic acid metabolism up to \$2,500 per individual per calendar year or continuous benefit period of 12 months. However, the Patient Protection and Affordable Care Act (PPACA) prohibits dollar limitations on essential health benefits, including these conditions, and supersedes the state mandate; therefore, the Health Plan does not apply the \$2,500 limit.

For information regarding the Medical Orders for Life Sustaining Treatments (MOLST) program refer to the following website: <http://www.compassionandsupport.org>.

### **RATIONALE**

The FDA-approved device RELiZORB™ is an in-line cartridge intended to aid in the delivery of fat absorption with cystic fibrosis (CF) patients who have confirmed exocrine pancreatic insufficiency. The current peer-reviewed literature is insufficient to support the efficacy of the services. The evidence is insufficient to determine the effects of the technology on health outcomes. Additional studies with a larger number of subjects are needed, to evaluate the effect of the RELiZORB™ device with increased levels of plasma omega-3 FA as related to increased fat absorption and weight gain versus the current standard of care.

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- Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.
- **CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.**
- Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.
- Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).

**CPT Codes**

Code	Description
No specific code(s)	

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**HCPCS Codes**

Refer to the HCPCS manual for codes appropriate to specific formulas.

HCPCS codes listed below from B4034 - S9343 refer to enteral TUBE feedings.

Code	Description
B4034-B4036	Enteral feeding supply kit (code range)
B4102	Enteral formula, for adults, used to replace fluids and electrolytes (e.g. clear liquids), 500 ml = 1 unit
B4103	Enteral formula, for pediatrics, used to replace fluids and electrolytes (e.g. clear liquids), 500 ml = 1 unit
B4104	Additive for enteral formula (e.g. fiber)
B4105 (NMN)	In-line cartridge containing digestive enzyme(s) for enteral feeding, each
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

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<b>Code</b>	<b>Description</b>
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
B9000	Enteral nutrition infusion pump – without alarm
B9002	Enteral nutrition infusion pump –any type
B9998	NOC for enteral supplies
S9340	Home therapy; enteral nutrition; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (enteral formula and nursing visits coded separately), per diem
S9341	Home therapy; enteral nutrition via gravity; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (enteral formula and nursing visits coded separately), per diem
S9342	Home therapy; enteral nutrition via pump; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (enteral formula and nursing visits coded separately), per diem
S9343	Home therapy; enteral nutrition via bolus; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (enteral formula and nursing visits coded separately), per diem
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

**ICD10 Codes**

<b>Code</b>	<b>Description</b>
Numerous	

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\*Key Article

### **KEY WORDS**

Enteral nutrition, Enteral therapy, Probiotics, Tube feeding.

### **CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS**

There is currently a National Coverage Determination for Enteral and Parenteral Nutritional Therapy. Please refer to the following website for Medicare Members: <http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=242&ncdver=1&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=New+York+-+Entire+State&Keyword=enteral&KeywordLookUp=Title&KeywordSearchType=And&bc=gAAAABAAAAAAAA%3d%3d&>

There is currently a Local Coverage Determination (LCD): Enteral Nutrition (L33783) Please refer to the following website for Medicare Members: <https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33783&ver=14&DocType=All&bc=AgIAAABAAAA&>

### **NY STATE COVERAGE OF PHARMACY BENEFITS FOR MEDICAID MANAGED CARE PRODUCT MEMBERS**

There are currently guidelines for Pharmacy benefits of Enteral Nutrition Formula for New York State (NYS) Medicaid Managed Care members. For those members, enteral nutritional formula benefit coverage is limited to:

1. Beneficiaries who are fed via nasogastric, gastrostomy or jejunostomy tube.
2. Beneficiaries with inborn metabolic disorders.
3. Children up to 21 years of age, who require liquid oral enteral nutritional formula when there is a documented diagnostic condition where caloric and dietary nutrients from food cannot be absorbed or metabolized.

For complete coverage guidelines please refer to the following website:

[https://www.emedny.org/providermanuals/communications/enteral\\_nutritional\\_formula\\_benefit\\_update\\_20110418.pdf](https://www.emedny.org/providermanuals/communications/enteral_nutritional_formula_benefit_update_20110418.pdf).

In addition, the Medicaid Managed Care benefit for enteral nutritional formula includes coverage of *orally* administered formula for adults with a diagnosis of HIV infection, AIDS, HIV-related illness, or other disease or condition, who are oral-fed, and who:

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1. require supplemental nutrition, demonstrate documented compliance with an appropriate medical and nutritional plan of care, and have a body mass index (BMI) under 18.5 as defined by the Centers for Disease Control, up to 1,000 calories per day; or
2. require supplemental nutrition, demonstrate documented compliance with an appropriate medical and nutritional plan of care, have a body mass index (BMI) under 22 as defined by the Centers for Disease Control, and have a documented, unintentional weight loss of five percent or more within the previous six-month period, up to 1,000 calories per day; or
3. require total oral nutritional support, have a permanent structural limitation that prevents the chewing of food, and placement of a feeding tube is medically contraindicated.