MEDICAL POLICY

SUBJECT: ENTERAL NUTRITION
POLICY NUMBER: 10.01.03
CATEGORY: Government Mandate

EFFECTIVE DATE: 10/18/01
REVISED DATE: 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, 10/20/15, 9/21/17

PAGE: 1 OF: 7

• If the member's subscriber contract excludes coverage for a specific service it is not covered under that contract. In such cases, medical policy criteria are not applied.
• Medical policies apply to commercial and Medicaid products only when a contract benefit for the specific service exists.
• Medical policies only apply to Medicare products when a contract benefit exists and where there are no National or Local Medicare coverage decisions for the specific service.

Note: Refer to the section regarding Medicaid Managed Care and Family Health Plus product members at the end of this policy for coverage criteria for those members.

POLICY STATEMENT:

I. Based upon our criteria and review of the peer-reviewed literature, enteral nutrition is considered medically necessary for certain conditions in which, without these products, the patient’s condition would deteriorate to the point where severe malnutrition could cause physical disability, mental disorders or death.

II. Health Plan contracts that cover prescription drugs will provide benefits for:

A. Enteral formulas that have been proven medically effective and are medically appropriate in the treatment of, but not limited to, the following conditions:
   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 with failure to thrive;
   5. Disorders of gastrointestinal motility (e.g., chronic intestinal pseudo-obstruction, Ogilvie’s syndrome);
   6. Ulcerative colitis; or
   7. Multiple severe, food allergies which if left untreated will cause malnourishment, chronic physical disability, mental retardation or death, or
   8. Adults with a diagnosis of HIV infection, AIDS, or HIV-related illness, or other disease or condition,

B. Modified solid food products that are low protein or which contain modified protein have been proven medically effective and are medically appropriate in the treatment of certain inherited diseases of amino acid and organic acid metabolism. Refer to policy guideline I regarding reimbursement guidelines.

III. Enteral nutrition with enteral feeding tubes (e.g., NG tubes, NE tubes, G-tubes, J-tubes) is considered medically necessary for, but not limited to, the following functional impairments:

1. Tube-fed individuals who cannot chew or swallow food and must obtain nutrition through formula via tube;
2. Individuals with rare inborn metabolic disorders requiring specific medical formulas to provide essential nutrients not available through any other means; [and for]
3. Children under age 21 when caloric and dietary nutrients from food cannot be absorbed or metabolized[,] ; and
4. Persons with a diagnosis of HIV infection, AIDS, or HIV-related illness, or other disease or condition, who are oral-fed and who:
(a) require supplemental nutrition, demonstrate documented compliance with an appropriate medical and nutritional plan of care, and have a body mass index under 18.5 as defined by the Centers for Disease Control, up to 1,000 calories per day; or
(b) require supplemental nutrition, demonstrate documented compliance with an appropriate medical and nutritional plan of care, and have a body mass index under 22 as defined by the Centers for Disease Control and a documented, unintentional weight loss of 5 percent or more within the previous 6 month period, up to 1,000 calories per day; or
(c) require total nutritional support, have a permanent structural limitation that prevents the chewing of food, and the placement of a feeding tube is medically contraindicated

IV. Probiotics are dietary supplements and do not meet the criteria for enteral nutrition, as stated in policy statement # 1 above. Probiotics are not medically necessary.

Refer to Corporate Medical Policy #1.01.00 regarding Durable Medical Equipment (DME).

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

POLICY GUIDELINES:

I. All enteral nutrition benefits must be prescribed in a written order by the patient’s physician and will be processed in accordance with the member’s subscriber contract.
A. 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.
B. 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 co-payment 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. Documentation of medical necessity should include:
A. The patient’s diagnosis;
B. The functional impairment that prevents adequate nutrition by conventional means;
C. The patient’s weight history before initiating enteral feeding that demonstrates oral intake without enteral nutrition is inadequate;
D. The percentage of the patient’s average daily nutrition taken by mouth and by tube; and
E. The anticipated consequences of not initiating or withdrawing enteral nutrition.

III. 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.

IV. Coverage is not intended for inpatient or skilled nursing facility acute care.

V. All patients must be monitored in conjunction with a qualified dietitian, health care practitioner certified in nutritional support, gastroenterologist, or pediatric allergist.

VI. Coverage is intended for patients who cannot eat and provision of nutritional support meets their goals for care. Coverage is not intended for patients who will not eat.

VII. 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 guideline III above.
VIII. 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, goals for care, and plans for reassessment of the need for ongoing nutritional support.

DESCRIPTION:

For patients who lack the ability for the body 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 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.

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 Law mandates 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 the enteral formula is medically necessary and proven effective as a disease-specific treatment regimen for those individuals who are, or will become, malnourished or suffer from disorders which, if left untreated, will lead to chronic physical disability, mental retardation or death.

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; so that the Health Plan will 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](http://www.compassionandsupport.org).

**CODES:**

<table>
<thead>
<tr>
<th>Number</th>
<th>Description</th>
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<tbody>
<tr>
<td>Eligibility for reimbursement is based upon the benefits set forth in the member’s subscriber contract.</td>
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<tr>
<td>CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.</td>
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Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

**CPT:**

No specific code(s)

**HCPCS:**

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

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

B4034-B4036 Enenteral 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

<table>
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<tr>
<th>Code</th>
<th>Description</th>
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<tr>
<td>B4104</td>
<td>Additive for enteral formula (e.g. fiber)</td>
</tr>
<tr>
<td>B4149</td>
<td>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</td>
</tr>
<tr>
<td>B4150</td>
<td>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</td>
</tr>
<tr>
<td>B4152</td>
<td>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</td>
</tr>
<tr>
<td>B4153</td>
<td>Enteral formulae; 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</td>
</tr>
<tr>
<td>B4154</td>
<td>Enteral formulae; 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</td>
</tr>
<tr>
<td>B4155</td>
<td>Enteral formulae, 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</td>
</tr>
<tr>
<td>B4157</td>
<td>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</td>
</tr>
<tr>
<td>B4158</td>
<td>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</td>
</tr>
<tr>
<td>B4159</td>
<td>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</td>
</tr>
<tr>
<td>B4160</td>
<td>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</td>
</tr>
<tr>
<td>B4161</td>
<td>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</td>
</tr>
<tr>
<td>B4162</td>
<td>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</td>
</tr>
<tr>
<td>B9000</td>
<td>Enteral nutrition infusion pump – without alarm</td>
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B9002  Enteral nutrition infusion pump – with alarm
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

NDC:  Numerous  Refer to Pharmacy Management
ICD9:  Numerous
ICD10:  Numerous

REFERENCES:


Itkin M; Society of Interventional Radiology; American Gastroenterological Association Institute; Canadian Interventional Radiological Association; Cardiovascular and Interventional Radiological Society of Europe. Multidisciplinary practical guidelines for gastrointestinal access for enteral nutrition and decompression from the Society of Interventional Radiology and American Gastroenterological Association (AGA) Institute, with endorsement by Canadian Interventional Radiological Association (CIRA) and Cardiovascular and Interventional Radiological Society of Europe (CIRSE). Gastroenterology 2011 Aug;141(2):742-65.


Motoori M, et al. Relationship between immunological parameters and the severity of neutropenia and effect of enteral nutrition on immune status during neoadjuvant chemotherapy on patients with advanced esophageal cancer. Oncology 2012;83(2):91-100.


New York State Insurance Law, Section 4303 (y) (1).

New York State Consolidated Laws § 3216 (21).


KEY WORDS:
Eneral 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=gAAAABAAAAAAA%3d%3d&](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=gAAAABAAAAAAA%3d%3d&).

**NY STATE COVERAGE FOR MEDICAID MANAGED CARE AND FAMILY HEALTH PLUS PRODUCT MEMBERS**

There are currently guidelines for Enteral Nutrition Formula Benefits for New York State (NYS) Medicaid Managed Care and Family Health Plus members. See above for changes incorporated into policy. 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).

As of June 7, 2013, the Medicaid Managed Care and Family Health Plus benefit for enteral nutritional formula has been changed to include coverage of orally administered formula for adults with a diagnosis of HIV infection, AIDS, or HIV-related illness, or other disease or condition, who are oral-fed, and who:

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 a documented, unintentional weight loss of 5 percent or more within the previous 6 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.