Medical Policy

Enteral Nutrition

Description

Orders for Enteral Nutrition products dispensed and billed by durable medical equipment, orthotic, prosthetic and medical supply (DMEPOS) providers are referred to the Northwood Case Review department for individual coverage determination.

Enteral* nutrition products are generally prescribed for members who are at nutritional risk based upon clinical indicators, the presence of chronic disease, or increased metabolic requirements due to impaired ability to ingest or absorb food adequately.

*Enteral nutrition that is orally administered is considered not medical in nature and therefore not reasonable and necessary unless mandated by state law.

Policy

For Medicare Members

Enteral nutrition is the provision of nutritional requirements through a tube into the stomach or small intestine.

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

The member must have a permanent impairment. Permanence does not require a determination that there is no possibility that the member's condition may improve sometime in the future. If the judgment of the attending physician, substantiated in the medical record, is that the condition is of long and indefinite duration (ordinarily at least 3 months), the test of permanence is considered met. Enteral nutrition will be denied as non-covered in situations involving temporary impairments.

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

The member must require tube feedings to maintain weight and strength commensurate with the member's overall health status. Adequate nutrition must not be possible by dietary adjustment and/or oral supplements. Coverage is possible for beneficiaries with

partial impairments - e.g., a member with dysphagia who can swallow small amounts of food or a member with Crohn's disease who requires prolonged infusion of enteral nutrients to overcome a problem with absorption.

Enteral nutrition products that are administered orally and related supplies are noncovered.

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

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

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

Self-blenderized formulas are noncovered by Medicare.

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

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

The medical necessity for special enteral formulas (B4149, B4153-B4155, B4157, B4161, and B4162) must be justified in each member. 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.

Enteral nutrition may be administered by syringe, gravity, or pump. Some enteral members may experience complications associated with syringe or gravity method of administration.

If a pump (B9002) is ordered, there must be documentation in the member’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.

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The feeding supply allowance (B4034-B4036) must correspond to the method of administration. If it does not correspond, it will be denied as not reasonable and necessary.

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

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

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

For Non-Medicare Members
Enteral* nutrition (including special medical infant formulas) are considered reasonable and necessary for members at nutritional risk when:

1. The formula is the predominant source of the member's daily caloric nutritional intake (i.e., >50%)**; **and** (**This requirement is not applicable for New Hampshire Medicaid pediatric members which need to be reviewed under EPSDT guidelines.)

2. The member meets coverage criteria for enteral* nutrition for one of the covered conditions listed below.

Enteral nutrition may be administered by syringe, gravity, or pump. Some enteral patients may experience complications associated with syringe or gravity method of administration. If a pump (B9002) is ordered, the pump must be included on the Medical Necessity Review form for Enteral Nutrition (Question 19). The member's record must contain documentation to justify the need for a feeding pump. If one or more criterion below is **not** met, the pump will be denied as not reasonable and necessary.

- Gravity feeding is not satisfactory due to reflux and/or aspiration
- Severe diarrhea
- Dumping syndrome
- Administration rate less than 100ml./hr.
- Blood glucose fluctuations
- Circulatory overload
- Gastrostomy/jejunostomy tube used for feeding

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*Enteral nutrition that is orally administered is considered not medical in nature and therefore not reasonable and necessary unless mandated by state law.

Non-Medicare Member Policy Guidelines:

Special medical formulas and/or enteral nutrition are considered reasonable and necessary when **ALL** the following criteria are met:

Note: For each situation listed below, orally administered enteral nutrition is considered NOT reasonable and necessary unless mandated by state law.

1. Detailed clinical notes and supportive testing document that the member meets one of the Covered Conditions Criteria listed below**.**

2. The enteral nutrition requested is the predominant source of the member's nutritional intake (i.e. > 50% of the daily caloric intake)**.****
**This requirement is not applicable for New Hampshire Medicaid pediatric members which need to be reviewed under EPSDT guidelines.

3. There is documentation confirming that the requested enteral nutrition is reasonable and necessary to prevent clinical deterioration, and that age or the medical condition precludes the use of regular food and supplementation with commercially available nutritional supplemental foods (e.g. Carnation Instant Breakfast, food thickeners, butter or cream added to prepared foods) in sufficient caloric density to provide > 50% of the member's daily caloric needs**. (This requirement is not applicable for New Hampshire Medicaid pediatric members which need to be reviewed under EPSDT guidelines.)

4. For infant and pediatric special medical formula requests:
    a. For formula fed infants and pediatric members, both cow-milk-based and soy-based formula must have been tried for a period of time, at least 4-5 days for each trial, with the reason for failure well documented; or
    b. If the formula trial is contraindicated based on the clinical condition or clinical diagnosis (e.g., prematurity under 3 months of life, food protein-induced proctocolitis/enteropathy/enterocolitis), this rationale must be documented.
    c. For infants and pediatric members transitioning from breast milk to formula:
        i. When the symptoms/clinical condition resolved with a well documented and appropriate maternal elimination diet, a same protein formula trial is not required.
        ii. If the elimination diet did not resolve the symptoms/clinical condition, a trial of milk-based and soy-based formula is required.

5. For members over one year of age, in addition to a nutritionist evaluation and calorie counts, a gastroenterologist evaluation or allergist is required depending on the Covered Condition Criteria**.** (This requirement is not applicable for New Hampshire Medicaid pediatric members which need to be reviewed under EPSDT guidelines.)

6. Formula Request forms along with pertinent clinical notes must be submitted. For infants and pediatric patients, weight for age and weight for height growth charts must be submitted.

Non-Medicare Member Covered Conditions:

Prematurity:

Note: Enteral nutrition, when orally administered, is **NOT** considered reasonable and necessary unless mandated by state law.

1. When a premature infant's birth weight is </= 1500g and the hospital discharge weight is below the 10th percentile for age corrected for prematurity, a premature transition formula (e.g., Neosure, Enfacare) is authorized for the first 3 months of life.

2. For premature infants less than 3 months of life, who are unable to tolerate cow-milk-based formula due to any one of the medical conditions listed below, a soy-based formula trial is not required. A premature transition formula (e.g., Neosure, Enfacare) is authorized for the first 3 months of life.

After 3 months of life, subsequent requests are re-evaluated based on meeting general eligibility requirements and one of the other covered conditions below.

Gastroesophageal Reflux and Gastroesophageal Reflux Disease:

Note: Enteral nutrition, when orally administered, is **NOT** considered reasonable and necessary unless mandated by state law.

Special medical formulas are not usually reasonable and necessary for gastroesophageal reflux. The regurgitation of gastric contents is common in infants, peaks at 4-6 months of life, and generally does not need medical treatment or a change in formula. Parental reassurance, restriction of volume in overfed infants, and a trial of thickened formula generally suffice.

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Special medical formulas may be medically necessary for infants with gastroesophageal reflux disease (GERD), regurgitation associated with complications and nutritional compromise (i.e., wt. loss/lack of weight gain due to insufficient caloric intake/formula refusal, blood in regurgitated foods, or severe vomiting).

a. Clinical history and physical exam document a high probability of GERD and not simply gastroesophageal reflux; and
b. Both cow-milk-based and soy-based formula trials have failed:
    i. Thickened foods should be tried as well.
    ii. Medical therapies, such as H2-blockers or proton-pump inhibitors are at the discretion of the physician.

1. Subsequent requests for infants up to one year of life require:
    a. Evidence that the symptoms significantly improved with the use of the requested special medical formula; and
    b. A failed retrial of both cow-milk-based and soy-based formula, each for 4-5 days respectively, **or** a gastroenterologist evaluation.

2. Subsequent requests for children after one year of life require:
    a. Consideration of a retrial of both cow-milk-based foods/formula and soy-based formula; and
    b. A nutritionist consult including calorie counts; and
    c. A gastroenterologist evaluation.

The authorization period for the subsequent formula/enteral nutrition request depends on the member's clinical condition and timing of needed follow up visits.

For more information on the treatment of GERD in children:
(NIH Information Clearinghouse)
http://digestive.niddk.nih.gov/ddiseases/pubs/gerdinfant/index.htm
http://digestive.niddk.nih.gov/ddiseases/pubs/gerinchildren/index.htm
(NASHGAN Pediatric GE Reflux Clinical Practice Guidelines)
http://www.naspghan.org/user-assets/Documents/pdf/PositionPapers/GERD.pdf

Bloody Stools with or without other GI symptoms or weight loss:

Note: Enteral nutrition, when orally administered, is **NOT** considered reasonable and necessary unless mandated by state law.

Potential formula related diagnoses include the non IgE mediated; food protein-induced proctocolitis (generally healthy member with blood streaked stools), food protein-induced enteropathy (malabsorption, failure to thrive, diarrhea and vomiting), and food protein-

induced enterocolitis (chronically associated with malabsorption and failure to thrive; acute reactions associated with recurrent vomiting, diarrhea, and dehydration). Common non-food related etiologies are rectal fissures and infectious/inflammatory colitis.

Special medical formula is reasonable and necessary for infants up to the first year of life when the general eligibility criteria and all of the following are met a. Bloody stools are documented by guaiac card testing; and
b. Other etiologies, such as anorectal fissure and infectious/inflammatory colitis, have been excluded by history and exam, and when applicable, by further testing and serial guaiacs; and
c. The bloody stools occurred while using cow-milk-based formula, or while breastfeeding and a dairy elimination diet resolved the problem. (No soy formula trial is required because of the high cross intolerance to soy-based formula for these conditions).

1. Subsequent requests for children after one year of life require:
   a. Consideration of a retrial of both cow-milk-based foods/formula and soy-based formula; and
   b. A nutritionist consult including calorie counts; and
   c. A gastroenterologist evaluation.

The authorization period for the subsequent formula/enteral nutrition request depends on the member's clinical condition and timing of needed follow up visits.

GI Irritability

Note: Enteral nutrition, when orally administered, is **NOT** considered reasonable and necessary unless mandated by state law.

Mild to moderate GI irritability, spitting, fussiness and gassiness or loose/mucous containing stools in the absence of weight loss, lack of weight gain, significant vomiting or gastrointestinal bleeding, generally does not require a formula change.

1. For severe and persistent symptoms, special medical formula is authorized for infants up to the first 6 months of life when the general eligibility criteria are met and both cow-milk-based and soy-based formula trials each lasting at least 4-5 days, respectively, have failed.

2. Subsequent requests for infants up to one year of life require:
   a. Evidence that the symptoms significantly improved with the use of the

requested special medical formula; and
b. A failed retrial of both cow-milk-based and soy-based formula, each lasting 4-5 days respectively, **or** a gastroenterologist evaluation.

3. Subsequent requests for children after one year of life require:
   a. Consideration of a retrial of both cow-milk-based foods/formula, and soy-based formula; and
   b. A nutritionist consult including calorie counts; and
   c. A gastroenterologist evaluation.

The authorization period for the subsequent formula/enteral nutrition request depends on the member's clinical condition and timing of needed follow up visits.

Eosinophilic Esophagitis (EE)2

Note: Enteral nutrition, when orally administered, is **NOT** considered reasonable and necessary unless mandated by state law

Eosinophilic esophagitis rarely occurs in infants. In children it is characterized by intermittent vomiting, food refusal, dysphagia, abdominal pain, and weight loss.

1. Special medical formula or other enteral nutrition is authorized when the general eligibility criteria and all of the following are met:

   a. Eosinophilic esophagitis is documented by endoscopy and biopsy; and
   b. For formula fed infants, there is high suspicion either by elimination diet or supportive IgE specific antibody testing that it is caused both by milk and soy exposure; or for children, the EE is caused by an unclear number of food groups and there is a planned multi-food elimination diet that includes the elimination of milk and soy; and
   c. The member is closely followed by a gastroenterologist, and a nutritionist who documents diet and calorie needs, and by an allergist if indicated.
   d. If all of the above criteria are met, the requested special medical formula/enteral nutrition does not need to constitute > 50% of the daily caloric intake since the goal is to provide not only calories, but also nutrients that cannot be obtained through regular foods/allergy-free-vitamins in these highly allergic members.

The period of authorization for formula/enteral nutrition depends on the member's clinical condition, timing of needed follow up visits and repeat endoscopy and biopsy documented in the clinical notes.

Subsequent requests require documentation of intervening medical and nutritional reassessments and follow up endoscopy to determine if the clinical condition has improved enough to allow intake of other nutrients and to document calorie counts.

Malabsorption:

Note: Enteral nutrition, when orally administered, is **NOT** considered reasonable and necessary unless mandated by state law.

Malabsorption in infants and children can be associated with chronic diarrhea and weight loss, and may be secondary to food protein-induced enteropathy or enterocolitis (acute enterocolitis reactions are associated with recurrent vomiting, diarrhea, and dehydration), or to non-food related etiologies as well.

1. Special medical formula is authorized for infants up to the first year of life when the general eligibility criteria and all of the following are met:

    a. Causes of the malabsorption have been evaluated and the diagnosis of food protein-induced enteropathy or enterocolitis is confirmed by a pediatric gastroenterology evaluation; and
    b. The malabsorption symptom occurred while using cow-milk-based formula, or while breast feeding a dairy elimination diet resolved the problem. (No soy formula trial is required when food protein- induced enteropathy or enterocolitis is diagnosed because of the high cross intolerance to soy- based formula for this condition).

2. Subsequent requests for members after one year of life require:
    a. A consideration for a retrial of cow-milk-based food/formula and soy-based formula; and
    b. Continued evaluation by a gastroenterologist and a nutritionist.

3. For malabsorption with nutritional compromise in children and adults associated with such conditions as Crohn's disease, ulcerative colitis, gastrointestinal motility disorders, chronic intestinal pseudo-obstruction or cystic fibrosis, enteral nutrition is authorized for up to a period of 6 months when the general eligibility criteria and all of the following are met:

    a. The diagnosis is confirmed by testing; and
    b. Nutritional compromise is documented by weight loss/lack of weight gain or other nutritional deficiencies; and
    c. For formula fed infants and children, both cow-milk-based and soy-based

formula trials have failed; and
d. If applicable, the member must have first attempted supplementation with other commercially available foods and nutritional supplemental foods (e.g. Carnation Instant Breakfast, food thickeners, butter or cream added to prepared foods, etc.); and
e. The member is being closely followed by gastroenterology and a nutritionist.

Subsequent requests for authorization require documentation of intervening clinical and nutritional reassessments to determine if the clinical condition has improved enough to allow intake of other nutrients and to document calorie counts. The authorization period for the subsequent formula/enteral nutrition request depends on the member's clinical condition and timing of needed follow up visits.

Failure to Thrive

Note: Enteral nutrition, when orally administered, is **NOT** considered reasonable and necessary unless mandated by state law.

The diagnosis includes growth failure due to inadequate nutrient intake or absorption, increased nutritional losses, or ineffective nutrient utilization. The failure to thrive diagnosis does not automatically include infants and children with intrauterine growth restriction, prematurity, and genetic short stature when the member otherwise has appropriate growth velocity and is tracking along a weight for length growth curve even if it is less than 2nd percentile.
Special medical formula/enteral nutrition is authorized for up to a period of 6 months when the general eligibility criteria and all of the following are met:

1. The member is at nutritional risk with one of the following weight loss parameters:

   a. For infants and children, a decrease over time of two or more major weight for age percentile lines or weight <5th percentile for age when corrected for prematurity, or weight for length <10th percentile; or
   b. For children older than 24 months including adolescents, a BMI for age <5th percentile; or
   c. For adults, an involuntary weight loss of > 10 percent of usual body weight during a three-to-six-month period, or BMI <5th percentile or 18.5 kg/m.

2. There must be documentation of:

a. Clinical history, physical exam and supportive testing to evaluate potential treatable causes of growth failure; and
b. For formula fed infants and children, a failure of both cow-milk-based and soy-based formula trials; and
c. For members over one year of age, a detailed dietary/feeding history with calorie counts and referral to a nutritionist; and
d. If applicable, the member must have first attempted supplementation with other commercially available foods and nutritional supplemental foods (e.g. Carnation Instant Breakfast, food thickeners, butter or cream added to prepared foods, etc.); and
e. For member's over one year of age, documentation/results of relevant specialist evaluation(s), such as gastroenterologist, feeding/swallowing specialist, or other specialist evaluations; and
f. A written plan of care for regular monitoring of signs and symptoms to detect improvement in the member's condition.

Subsequent requests for authorization require intervening clinical and nutritional reassessments to determine if the clinical condition has improved enough to allow intake of other nutrients and to document calorie counts.

The authorization period for the formula/enteral nutrition request depends on the member's clinical condition and timing of needed follow up visits.

IgE Mediated Food Allergy:

Note: Enteral nutrition, when orally administered, is **NOT** considered reasonable and necessary unless mandated by state law

Symptoms include the following: severe vomiting and abdominal pain within minutes to hours of the ingestion; severe diarrhea within six hours of the ingestion; localized or general pruritis, angioedema and urticaria; stridor, wheezing; anaphylaxis. GI symptomatology generally does not occur in isolation, and most often is associated with involvement in other organ systems.

1. Special medical formula is authorized for infants up to the first year of life when the general eligibility criteria and one of the following are met:

    a. When a cow-milk-based formula is clearly implicated in the highly likely IgE mediated reaction, a soy- based formula trial is not required (Although soy cross reactivity for an IgE mediated response is low at 10-15%, and the cross occurrence of anaphylaxis less than 1%); or

b. For members with a non-urticarial rash or with a rash and a negative IgE to soy, a failure of a both cow-milk-based and soy-based formula trials is required.

2. Subsequent requests for children after one year of life require:
   a. Consideration of a retrial of both cow-milk-based foods/formula and soy-based formula; and
   b. A nutritionist consult including calorie counts; and
   c. An allergist evaluation to further document the food allergy.

The authorization period for the subsequent formula/enteral nutrition request depends on the member's clinical condition and timing of needed follow up visits.

Atopic Dermatitis (AD)

Note: Enteral Nutrition, when orally administered, is **NOT** considered reasonable and necessary unless mandated by state law

Mild to moderate AD is generally not related to formula allergy even in the presence of food specific IgE antibodies. Food allergy may cause 1-3% of mild AD and 5-10% of moderate AD. For severe AD, defined as widespread skin involvement which impairs quality of life that persists despite first line medical therapy (moisturizers, wraps, topical steroids, and antihistamines), and occurring in very young infants, causal food allergy may be present in 20-30%.

1. Special medical formula is authorized for infants up to the first year of life when the general eligibility criteria are met and all of the following are met:
   a. There is a well documented role of both cow-milk-based and soy-based formula in causing the atopic dermatitis (e.g. an immediate reaction after ingestion or a well defined elimination diet); and
   b. There is an allergist evaluation confirming the formula induced atopic dermatitis.

2. Subsequent requests for children after one year of life require:
   a. Consideration of a retrial of both cow-milk-based food/formula and soy-based formula; and
   b. A nutritionist consult including calorie counts; and
   c. An allergist evaluation to further document to food allergy.

The authorization period for the subsequent formula/enteral nutrition request depends on the member's clinical condition and timing of needed follow up visits.

Inborn Errors of Metabolism

Note: Enteral nutrition, when orally administered, is **NOT** considered reasonable and necessary unless mandated by state law.

These include the following diagnoses:

Phenylketonuria (PKU)
Tyrosinemia
Homocystinuria
Maple Syrup Urine Disease
Propionic Acidemia
Methylmalonic Acidemia
Other Organic Acidemias
Urea Cycle Disorders

Special formulas/enteral nutrition are authorized when a letter of medical necessity from a Metabolic Clinic documenting the clinical history, supportive evaluation and testing is submitted. Neither milk nor a soy trial is required.

Ketogenic Formula for Uncontrolled Seizures

Enteral nutrition, when orally administered, is NOT considered reasonable and necessary unless mandated by state law.

1. Ketogenic formulas are authorized for up to a period of 6 months when there is clinical documentation confirming that the member:

    a. Has seizures refractory to standard anti-seizure medications OR CANNOT TOLERATE SEIZURE MEDICINES; and
    b. Requires a formula/liquid diet to maintain weight for age growth because of inability to tolerate solid foods due to developmental or other issues (the formula requested does not need to meet >50% of daily caloric intake) OR, IS UNDER 2 YEARS AND CONSUMED FORMULA OR BREAST MILK PRIOR TO INITIATING THE DIET.
    c. Neither milk nor a soy trial is required.

2. Subsequent requests for authorization require intervening clinical and nutritional reassessments to determine if the clinical condition has improved to allow intake of other nutrients and to document calorie counts. The authorization period for the

subsequent formula/enteral nutrition request depends on the member's clinical condition and timing of needed follow up visits.

Limitations – Medicare and Non-Medicare Members

1. Payment for a catheter/tube anchoring device is considered included in the allowance for enteral feeding supply kits (B4034-B4036). Code A5200 should not be billed separately and is not paid in addition to the supplies for enteral nutrition.
2. The codes for enteral feeding supplies (B4034-B4036) include all supplies, other than the feeding tube itself, required for the administration of enteral nutrients to the member for one day. Codes B4034-B4036 describe a daily supply fee rather than a specifically defined "kit". Some items are changed daily; others may be used for multiple days. Items included in these codes are not limited to pre-packaged "kits" bundled by manufacturers or distributors. These supplies include, but are not limited to, 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, declogging device, etc. These items must not be separately billed using the miscellaneous code (B9998) or using specific codes for dressings or tape. The use of individual items may differ from member to member and from day to day. Only one unit of service may be billed for any one day. Units of service in excess of one per day will be rejected as incorrect coding.
3. More than three nasogastric tubes (B4081-B4083), or one gastrostomy/jejunostomy tube (B4087-B4088) every three months is not reasonable and necessary.

Exclusions – Medicare (as applicable) and Non-Medicare Members

1. Enteral nutrition including infant formulas for indications not listed above and when administered orally unless mandated by state law.
2. Enteral nutrition including infant formulas when a medical history or physical examination has not been completed, and/or there is no documentation that supports the need for enteral nutrition products.
3. Enteral nutrition including infant formulas when a medical history and physical examination have been performed and other possible alternatives have been identified to minimize the member's nutritional risk.
4. Enteral nutrition including infant formulas when the member is underweight but has the ability to meet nutritional needs through the use of regular food consumption.
5. Enteral nutrition including infant formulas when the member has food allergies or dental problems but has the ability to meet his or her nutritional requirements

through an alternative store-bought food source.
6. Standard infant milk or soy formulas;
7. Formula or food products used for dieting, or a weight-loss program;
8. Banked breast milk;
9. Food for a ketogenic diet when dietary needs can be met with regular, store-bought food;
10. Dietary or food supplements;
11. Food thickeners, high protein powders and mixes;
12. Lactose free foods, or products that aid in lactose digestion;
13. Gluten-free products;
14. Baby foods;
15. Oral vitamins and minerals;
16. Medical foods (e.g., Foltx, Metanx, Cerefolin, probiotics such as VSL#3) including FDA-approved medical foods obtained via prescription.

Documentation Requirements

Submitting Clinical Documentation:

Requests for prior authorization for enteral nutrition products must be accompanied by clinical documentation that supports the medical necessity for this product.

A. Documentation of medical necessity must include all of the following:
    1. The primary diagnosis name and ICD-10-CM code specific to the nutritional disorder for which enteral nutrition products are requested;
    2. The secondary diagnosis name and ICD-10-CM code specific to the comorbid condition;
    3. Clinical signs and symptoms, including anthropometric measures (for example, height, weight, BMI, BMR, growth charts, and prognosis for children);
    4. Comprehensive medical history and physical exam;
    5. Risk factors for developing malnutrition;
    6. Laboratory tests sufficient to establish the diagnosis of malnutrition;
    7. Route of enteral nutrition treatment;
    8. Documentation of past and current treatment regimens; and
    9. Type and estimated duration of the need for enteral nutrition products.

B. Clinical information may be submitted on the required Medical Necessity Review Form for Enteral Nutrition Products. Required documentation must be completed by the prescribing physician or clinical staff involved in the member's care. A written

prescription signed by the physician or nurse practitioner must also accompany the forms.

C. A new or updated prior authorization request for enteral nutrition products must be submitted to continue use of enteral nutrition products before the expiration of the current prior authorization.

Additional Definitions:

Allergic Enteropathy: A gastrointestinal food allergy involving the small and large intestines causing symptoms that include diarrhea, abdominal pain, blood and/or mucus in the stool and malabsorption.

Atopic Disease: Clinical disease characterized by atopy: typically refers to atopic dermatitis, asthma, allergic rhinitis and food allergy.

Atopic Dermatitis: (eczema): Aprutic, chronic inflammatory skin disease that commonly presents during early childhood and is often associated with a personal or family history of other atopic diseases.

Crohn's Disease: A type of inflammatory bowel disease (IBD), resulting in swelling and dysfunction of the intestinal tract.

Eosinophilic Esophagitis (EE): an inflammatory condition of the esophagus that is characterized by having above normal amounts of eosinophils in the esophagus. Symptoms of EE vary with age and may mimic GERD. Infants often present with vomiting, irritability and poor weight gain.

Eosinophilic Gastritis: An uncommon gastritis that affects both children and adults characterized by abdominal pain, malabsorption, and often obstructive symptoms, associated with peripheral eosinophilia and areas of eosinophilic infiltration of the stomach.

Failure to Thrive: A condition in which the weight gain and growth are far below usual levels for age. In general, failure to thrive is considered if weight falls lower than the 3rd percentile (as outlined in standard growth charts) or 20% below the ideal weight for their height. Growing may have slowed or stopped after a previously established growth curve.

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Gastroesophageal Reflux: Also known as esophageal reflux or gastric reflux is a backflow of the contents of the stomach into the esophagus, caused by relaxation of the lower esophageal sphincter.

Gastrointestinal pseudo-obstruction: The decreased motility of the intestines often causing dilation of various parts of the bowel. The clinical and radiological findings are often similar to true intestinal obstruction.

Malabsorption Syndromes: Conditions that result in the inadequate absorption of nutrients in the intestinal tract. Examples of malabsorption syndromes include short bowel syndrome, radiation enteritis, pancreatitis, celiac disease, post gastrectomy and intestinal resection, sprue, infections, cystic fibrosis, liver disease and Whipple's disease.

Nutritional Risk: A member who has actual or the potential for developing malnutrition as evidenced by clinical indicators, the presence of chronic disease, or increased metabolic requirements due to the inability to ingest, digest or absorb food adequately.

Ulcerative Colitis: A chronic disease of unknown cause characterized by ulceration of the colon and rectum, with rectal bleeding, mucosal crypt abscesses, inflammatory pseudopolyps, abdominal pain, and diarrhea; frequently causes anemia, hypoproteinemia, and electrolyte imbalance, and is less frequently complicated by peritonitis, toxic megacolon, or carcinoma of the colon.

HCPCS Level II Codes and Description

A5200	PERCUTANEOUS CATHETER/TUBE ANCHORING DEVICE, ADHESIVE SKIN ATTACHMENT
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
B4087	GASTROSTOMY / JEJUNOSTOMY TUBE, STANDARD, ANY MATERIAL, ANY TYPE EA.

B4088	GASTROSTOMY/JEJUNOSTOMY TUBE, LOW PROFILE, ANY MATERIAL, ANY TYPE, EA.
B4100	FOOD THICKENER, ADMINISTERED ORALLY, PER OUNCE
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
B9998	NOC FOR ENTERAL SUPPLIES. (TO INCLUDE EXTENSION SET FOR MIC-KEY BUTTON. QTY. 5 PER MONTH).
B4104	ADDITIVE FOR ENTERAL FORMULA (E.G. FIBER)
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
B9002	ENTERAL NUTRITION INFUSION PUMP, ANY TYPE
E0776	IV POLE

Important Note:

Northwood's Medical Policies are developed to assist Northwood in administering plan benefits and determining whether a particular DMEPOS product or service is reasonable and necessary. Equipment that is used primarily and customarily for a non-medical purpose is not considered durable medical equipment.

Coverage determinations are made on a case-by-case basis and are subject to all of the terms, conditions, limitations, and exclusions of the member's contract including medical necessity requirements.

The conclusion that a DMEPOS product or service is reasonable and necessary does not constitute coverage. The member's contract defines which DMEPOS product or service is covered, excluded or limited. The policies provide for clearly written, reasonable and current criteria that have been approved by Northwood's Medical Director.

The clinical criteria and medical policies provide guidelines for determining the medical necessity for specific DMEPOS products or services. In all cases, final benefit determinations are based on the applicable contract language. To the extent there are any conflicts between medical policy guidelines and applicable contract language, the contract language prevails. Medical policy is not intended to override the policy that defines the member's benefits, nor is it intended to dictate to providers how to direct care. Northwood Medical policies shall not be interpreted to limit the benefits afforded to Medicare or Medicaid members by law and regulation and Northwood will use the applicable state requirements to determine required quantity limit guidelines.

Enteral Nutrition

Northwood's policies do not constitute medical advice. Northwood does not provide or recommend treatment to members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

References

1. Centers for Medicare and Medicaid Services, Medicare Coverage Database, National Coverage Documents. Accessed December 15, 2017.

2. National Government Services, Inc. Automatic External Defibrillators. Local Coverage Determination No. L33783. Durable Medical Equipment Medicare Administrative Carrier Jurisdiction B; revised October 1, 2015.

3. http://digestive.niddk.nih.gov/ddiseases/pubs/gerd/#4 (NIH Information Clearinghouse)

4. http://digestive.niddk.nih.gov/ddiseases/pubs/gerdinfant/index.htm

5. http://digestive.niddk.nih.gov/ddiseases/pubs/gerinchildren/index.htm

6. http://www.naspghan.org/user-assets/Documents/pdf/PositionPapers/GERD.pdf (NASHGAN Pediatric GE Reflux Clinical Practice Guidelines)

7. Harvard Pilgrim Health Care: Medical Review Criteria. Formula and Other Enteral Nutrition https://www.harvardpilgrim.org/pls/portal/docs/PAGE/PROVIDERS/MEDMGMT/MEDICAL_REVIEW_CRITERIA/FORMULA_ENTERAL_NUTRITION_FINAL-EFF021512.PDF

8. Health Net: National Medical Policy. Nutritional Therapy, Oral and Enteral https://www.healthnet.com/static/general/unprotected/pdfs/national/policies/Nutritional_Therapy_Oral_and_Enteral_Mar_11.pdf

State Mandated Benefit Requirements

State	Benefit Requirements

Massachusetts	**Special infant formulas** Members enrolled through non-group or employer groups must be covered for special medical formulas to treat infants or children with phenylketonuria (PKU), tyrosinemia, homocystinuria, maple syrup urine disease, propionic acidemia, or methylmalonic acidemia, or when medically necessary to protect the fetuses of pregnant women with PKU. (M.G.L. 175 §47C) **Non-prescription enteral formulas and low protein foods:** Members enrolled through employer groups or with individual coverage must be covered for non-prescription enteral formulas for home use to treat malabsorption caused by Crohn's disease, ulcerative colitis, gastroesophageal reflux, gastrointestinal motility disorders, chronic intestinal pseudo-obstruction, and inherited diseases of amino acids and organic acids when medically necessary and a written order has been issued by a physician. Coverage required for group policies. Low protein foods are covered up to $5,000 per member per year for inherited diseases of amino acids and organic acids. (M.G.L. 176G §4D)
New Hampshire	**Special infant formulas**: Not Applicable **Non-prescription enteral formulas and low protein foods**: Members enrolled through employer groups must be covered for non-prescription enteral formulas to treat impaired absorption of nutrients caused by disorders affecting the absorptive surface, functional length, gastrointestinal tract motility, and inherited diseases of amino acids and organic acids. A written order must be issued by a physician stating that the enteral formula is medically necessary, needed to sustain life, and is the least restrictive and most cost effective and treatment.

	Additionally, members must be covered for non-prescription enteral formulas and food products required for persons with inherited diseases o amino and organic acids. Physician must provide a written order, stating that enteral formula or food product is medically necessary and is the least restrictive and most cost effective approach to meet patient needs. There is no dollar limit on enteral formulas. Low protein foods are limited to $1800 per member per year. (NH R.S.A 420-A:17)

Applicable URAC Standard

Core 8	Staff operational tools and support

Change/Authorization History

Revision Number	Date	Description of Change	Prepared/Reviewed by	Approved by	Review Date:	Effective Date:
A	11-06	Initial Release	Rosanne Brugnoni	Ken Fasse	n/a	
01	01- 08	Revisions: Added HCPCS codes B4087 &B4088	Susan Glomb	Ken Fasse		
02		Annual Review	Susan Glomb	Ken Fasse	Dec.2008	
03		Annual Review with "supply kit" information update.	Susan Glomb	Ken Fasse	Dec.4, 2009	
04	12-22-09	Annual Review- No further changes.	Susan Glomb	Ken Fasse	Dec.2009	
05	11-19-10	Annual Review – No Changes	Susan Glomb	Ken Fasse	Nov.2010	
06	02-18-11	Policy updated to reflect current practice	Susan Glomb	Dr. Almasri		

07	03-02-11	Policy updated to reflect current practice/ BMCHP inclusions	Susan Glomb	Dr. Almasri		
08	03-25-11	Added statement #8 about enteral pumps	Susan Glomb	Dr. Almasri		
09	05-13-11	Policy updated to reflect current practice	Susan Glomb	Dr. Almasri		
10	07-20-11	Added Important Note to all Medical Policies	Susan Glomb	Dr. Almasri		
11	11-08-11	Annual Review. Added References to Policy	Susan Glomb	Dr. Almasri	Nov. 2011	
12	1-4-12	Added additional references to policy and state mandate information.	Susan Glomb	Dr. Almasri	Jan. 2012	
13	04-03-12	Added reference to NH Medicaid	Susan Glomb	Dr. Almasri		
14	11-28-12	Annual Review – No changes	Susan Glomb	Dr. Almasri	Nov 12	
15	10-30-13	Added NH State guidelines to policy.	Susan Glomb	Dr. Almasri		
16	12-30-13	Annual review. No changes	Susan Glomb	Dr. Almasri		
17	11-24-14	Annual Review. No changes	Susan Glomb	Dr. Almasri		
18	6-4-15	Policy updated to reflect the change for New Hampshire Medicaid Pediatric members. **The statements #2, #3 and #5 under Policy Guidelines**	Susan Glomb	Dr. Almasri		

		include statements that these requirements are not applicable for New Hampshire Medicaid pediatric members which need to be reviewed under EPSDT guidelines.				
19	11-30-2015	Annual Review. Policy updated to reflect Medicare and Non-Medicare member criteria. Current Medicare Reference listed.	Lisa Wojno	Dr. B. Almasri	November 2015	
20	12-02-16	Annual Review. No Changes	Lisa Wojno	Dr. B. Almasri	December 2016	
21	12-15-17	Annual review. Per Medicare database, deleted HCPCS Code B9000; revised HCPCS Code B9002 narrative.	Carol Dimech	Dr. C. Lerchin	December 2017	
22	12-3-18	Annual review. No changes.	Carol Dimech	Dr. C. Lerchin	December 2018	
23	12-14-18	Added additional criteria (in caps) regarding ketogenic formula for uncontrolled seizures.	Carol Dimech	Dr. C. Lerchin	December 2018	

24	11-5-19	Added feeding tube quantity limits to non-Medicare portion of policy.	Carol Dimech	Dr. C. Lerchin	11-05-19	11-05-19
25	12-06-19	Annual review. No additional changes.	Carol Dimech	Dr. C. Lerchin	12-06-19	12-06-19