

ENTERAL NUTRITIONAL THERAPY

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Status: Current

I. POLICY/CRITERIA

A. Enteral nutritional therapy via a tube (e.g. nasogastric, gastrostomy, jejunostomy) is a covered benefit when **all** of the following apply:

1. The patient has a functioning gastrointestinal tract and, due to pathology or dysfunction of the structures that normally permit food to reach the digestive tract, cannot maintain weight and strength commensurate with the patient's general condition; **and**
2. The solution being administered is the primary source of nutrition; **and**
3. Enteral nutritional therapy supplies, equipment, accessories, and solutions (covered at the DME & Supplies benefit level) are preauthorized by the Health Management Department and obtained from a Priority Health contracted provider of DME products. DME copays apply. It is expected that the formula will be administered by syringe or gravity. Pumps are covered if the member is experiencing complications associated with bolus feedings.

NOTE: When the above criteria are met, enteral formulas consisting of semi-synthetic intact protein/protein isolates are covered and appropriate in most cases. Coverage is provided for formulas consisting of natural intact protein/protein isolates when the member has an allergy or intolerance to semi-synthetic formulas.

B. Oral 100% hydrolyzed amino acids infant formulas are covered up to 24 months of age when **both** of the following are met (*see F. below for specific Medicaid member coverage criteria*):

1. 100% hydrolyzed amino acids infant formulas and supplies are a covered benefit under a member's Durable Medical Equipment (DME) & Supplies benefit and must be preauthorized by the Health Management Department and obtained from a Priority Health contracted provider of DME products. DME copays apply.
2. 100% hydrolyzed amino acids infant formulas are a covered benefit when **all** of the following apply:
 - a. Documented allergy to cow's milk **and**
 - b. Documented soy formula intolerance **and**

- c. Documented multiple protein intolerance *and*
 - d. The 100% hydrolyzed amino acids nutritional formula being administered is the primary source of nutrition *and*
 - e. Must be recommended by a Pediatric Allergist, Pediatric Pulmonologist or Pediatric Gastroenterologist.
- C. Oral nutritional formula for Inborn Errors of Metabolism (IEM) is a covered benefit when *all* of following are met:
1. The formula is a medical food labeled and used for the dietary management of an IEM that interferes with the metabolism of specific nutrients (e.g. Phenylketonuria[PKU], Homocystinuria, Maple Syrup Urine Disease), AND
 2. Nutrition is ordered and managed by a team consisting of a board-certified clinical or medical biochemical geneticist and a metabolic dietician, AND
 3. The following limits and exclusions apply:
 - a. Formula that meets the criteria in 1 and 2 above is covered at the DME/Supplies benefit level as defined in coverage documents.
 - b. Formulas, food products, and supplements that do not require a physician's order are not a covered benefit (e.g. grocery products for a low-protein diet).
 - c. When criteria 1 and 2 above are met, coverage for IEM formula is not limited by age, weight or lab values.
- Note:* Medicaid/Healthy Michigan Plan members diagnosed with inborn errors of metabolism that have been authorized for and use metabolic formulas (B4157 and B4162) will receive all of their Medicaid services through the Medicaid Fee-For-Service Program and should not be enrolled in a Priority Health Medicaid/Healthy Michigan plan.
- D. Food thickeners that are medically necessary are a covered benefit.
- E. The following are **not covered** benefits:
1. Solutions not requiring a doctor's prescription (except when they are given via a tube feeding and are the primary source of nutrition), for example, Ensure and Osmolyte.
 2. Infant formula, even if administered via a tube.
 3. Nutritional supplements not requiring a physician's prescription for the sole purpose of boosting protein and caloric intake.
 4. Baby food and other regular grocery products that are blenderized for use with enteral systems.

5. Storage unit (e.g. refrigerator).
 6. Formulas (e.g. KetoCal, RCF) or supplements (e.g. MCT oil, vitamins) for a ketogenic diet. This exclusion applies to formula used for complete or supplemental nutrition. Exceptions to allow coverage for ketogenic formulas or supplements if the criteria for tube feeding are met as defined in section IA of this policy.
 7. Enteral nutritional therapy by mouth (po, orally) is not a covered benefit, except as defined in B above. See F4 for Medicaid member coverage of oral nutrition.
 8. Enzyme packed cartridges (e.g. Relizorb (Alcresta Pharmaceuticals)) for enzyme replacement in patients receiving enteral tube feedings.
- F. The following applies to Medicaid and Healthy Michigan members only:
1. Enteral nutritional therapy supplies, equipment, accessories and solution are a covered benefit and must be preauthorized by the Health Management Department and obtained from a Priority Health participating pharmacy, contracted DME provider or enteral provider. Most of the criteria in Section I of this policy are applicable. Exceptions are listed below.
 2. 100% hydrolyzed amino acids formulas (including Neocate®) are available through the Women, Infants & Children (WIC) program for children under 5. Priority Health will only prior authorize elemental 100% hydrolyzed amino acids infant formula with written documentation from the member's local health department that it is not available through WIC and medical criteria in Section I above are met.
 3. Enteral nutrition administered through a tube follows the commercial guidelines above.
 4. Enteral nutrition administered orally (not by tube) may be covered for members. Prior authorization is required and it must be ordered by a Gastroenterologist and/or Developmental Pediatrician (for members under the age of 21). The following guidelines must all be met:
 - a. For members under the age of 21:
 - A chronic medical condition exists that prohibits eating or absorbing of food, resulting in nutritional deficiencies. Written documentation from the ordering specialist that a three-month trial is required to prevent gastric tube placement; or
 - A chronic medical condition exists that the member's weight to height ratio has fallen below the fifth percentile on the standard growth grids, and supplementation to regular diet or meal replacement is required; or

- Specialist documentation details low percentage increase in growth pattern or trend directly related to the nutritional intake and associated diagnosis/medical condition.
 - For Healthcare Common Procedure Coding System (HCPCS) code B4157, the beneficiary must have a specified inherited disease of metabolism identified by the International Classification of Diseases (ICD).
- b. For members age 21 and over:
- The member must have a medical condition that requires the unique composition of the formulae nutrients that the member is unable to obtain from food; or
 - The nutritional composition of the formulae represents an integral part of treatment of the specified diagnosis/medical condition; or
 - The member has experienced significant weight loss of 10% or greater of their body weight.
 - Mechanical or physiological conditions precluding normal dietary intake are taken into consideration for coverage as well as temporary medical complications necessitating a short-term (less than two months) use of the formula. However, coverage to accommodate psychological or behavioral conditions, food preferences, allergies, loss of appetite, or non-compliance with a specialized diet would not be a consideration.
 - For Healthcare Common Procedure Coding System (HCPCS) code B4157, the beneficiary must have a specified inherited disease of metabolism identified by the International Classification of Diseases (ICD).
- c. For all members meeting guidelines outlined in 4.a and 4.b (above), a Gastroenterologist and/or Developmental Pediatrician (for members under the age of 21) must submit documentation that includes the following:
- Specific diagnosis/medical condition related to member's inability to take or eat food.
 - Duration of that need.
 - Amount of calories needed per day.
 - Current height and weight, as well as change over time. (For members under 21, weight to height ratio).
 - Specific prescription identifying levels of individual nutrients that are required in increased or restricted amounts.
 - List of economic alternatives that have been tried.

- Current laboratory values for albumin or total protein for members over age 21 only.

G. Non-covered items for Medicaid and Healthy Michigan members:

1. Any supplemental formula or drinks that are for convenience or are an additive to a regular diet.
2. Any supplements or formula intended for weight loss or treatment of anorexia or other eating disorders.
3. Coverage to accommodate psychological or behavioral conditions, food preferences, loss of appetite, or non-compliance with a specialized diet would not be a consideration.
4. *Enteral formula for Medicaid members under age 5. Enteral formula should be obtained through the USDA Women, Infants and Children (WIC) program.

**Note: Priority Health will only prior authorize enteral formula with written documentation from the member's local health department that it is not available through WIC and criteria above are met.*

SPECIAL NOTES:

This policy was previously titled "Parenteral/Enteral Nutritional Therapy"

II. MEDICAL NECESSITY REVIEW

Required Not Required Not Applicable

III. APPLICATION TO PRODUCTS

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

- ❖ **HMO/EPO:** *This policy applies to insured HMO/EPO plans.*
- ❖ **POS:** *This policy applies to insured POS plans.*
- ❖ **PPO:** *This policy applies to insured PPO plans. Consult individual plan documents as state mandated benefits may apply. If there is a conflict between this policy and a plan document, the provisions of the plan document will govern.*
- ❖ **ASO:** *For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern.*
- ❖ **INDIVIDUAL:** *For individual policies, consult the individual insurance policy. If there is a conflict between this medical policy and the individual insurance policy document, the provisions of the individual insurance policy will govern.*

- ❖ **MEDICARE:** Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, this policy applies.
- ❖ **MEDICAID/HEALTHY MICHIGAN PLAN:** For Medicaid/Healthy Michigan Plan members, this policy will apply. Coverage is based on medical necessity criteria being met and the appropriate code(s) from the coding section of this policy being included on the Michigan Medicaid Fee Schedule located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_42542_42543_42546_42551-159815--,00.html. If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_5100-87572--,00.html, the Michigan Medicaid Provider Manual will govern. If there is a discrepancy or lack of guidance in the Michigan Medicaid Provider Manual, the Priority Health contract with Michigan Medicaid will govern. For Medical Supplies/DME/Prosthetics and Orthotics, please refer to the Michigan Medicaid Fee Schedule to verify coverage.

IV. DESCRIPTION

Enteral nutrition is nutrition provided through a tube (e.g., nasogastric, gastrostomy etc.) into the stomach or small intestine.

It is generally accepted that, whenever possible, enteral rather than parenteral feeding should be used in patients who need nutritional support. Enteral nutrition has many advantages compared with parenteral nutrition. They are:

- Enteral nutritional therapy is probably associated with fewer serious complications
- Enteral nutrition can supply gut-preferred fuels—glutamine, glutamate, and short-chain fatty acids that are absent from commercially available parenteral formulations
- Enteral feeding prevents atrophy of intestinal mucosa and the pancreas, maintains mucosal protein and deoxyribonucleic acid concentrations, preserves mucosal and pancreatic digestive enzyme function, and maintains gastrointestinal IgA secretion
- Enteral feeding prevents cholelithiasis by stimulating gallbladder motility

The American Academy of Pediatrics recommends that cow milk formula not be introduced to an infant's diet during the first year of life. In addition to food allergies, infants fed cow milk based formulas are at risk for iron deficiency anemia. Cow milk, which is a poor source of iron, causes gastrointestinal blood loss, and use of other dietary sources or supplements fail to prevent iron deficiency. Smaller newborns are at especially high risk for adverse outcome due to the higher solute content present in supplemental formulas.

Formula intolerance encompasses a wide variety of pathogenic mechanisms, including allergy. Formula intolerance may be caused by congenital or acquired enzyme deficiency (eg, disaccharidase or lactase deficiency, etc.), toxin ingestion (eg, *Staphylococcus aureus* toxin) pharmacologic agents (eg, caffeine), or true

hypersensitivity that has immunologic mechanism. Food intolerance may occur in both breastfed and bottle fed infants; in the case of breastfed infants, it is believed immunogenic peptides come from the maternal diet and pass into mother's milk. Trial maternal dietary restriction is often a recommended first step to remedy symptoms of intolerance in newborns. Infants and children who have specific food allergy are often incorrectly placed on restrictive diets that avoid multiple foods resultant in diet lacking nutrient. Without careful clinical evaluation, food avoidance diets are not recommended.

Cow milk protein allergy is an immunoglobulin (Ig) mediated food reaction that affects 2-3% of infants within the first postnatal year. Typical symptoms include immediate (eg, onset <30 minutes after ingestion) flushing, urticaria, angioedema, atopic dermatitis, and anaphylaxis. With IgE-mediated reactions, the quantity of milk required to result in a reaction is often minimal (eg, milk touching the skin, taste on tongue). Taking a detailed history about the specific food (s) involved, timing of the onset of symptoms, and type of symptoms are important to distinguish IgE-mediated reactions from other adverse reactions. Once IgE-mediated allergy is suspected, IgE skin prick testing or specific serum IgE testing should be performed. Interpretation of the results by an allergist is recommended because the predictive value for each test differs for each antigen.

Fortunately, although cow milk allergy is one of the most common IgE-mediated food allergies in children, more than 90% of infants can safely be switched to soy formula.

Soy protein formula contains sucrose or corn syrup solids, which are comparable to tapioca starch and sucrose present in hydrolyzed formulas. The corn, MCT, safflower oils, that comprise fat content of the hydrolyzed formulas are similar to the fat composition of the soy formulas. The protein content of soy based formulas is approximately 2.0g/100ml, that of the hydrolysate formula is 1.8 to 2.2g/100ml.

Non-IgE-mediated cow milk reactions (food protein induced enterocolitis syndrome) typically affects infants in the first 3 postnatal months characterized by loose stool that contains small amount of mucous and flecks of blood. If performed, endoscopic exam demonstrates erythematous colonic mucosa with lymphoid nodules, biopsy shows an inflammatory infiltrate comprised primarily of eosinophils. Unlike IgE-mediated cow milk allergy, many infants who have food protein colitis continue to have symptoms on soy formula and may require hypoallergenic or amino-acid based formulas.

The hydrolysate formulas contain enzymatically degraded proteins that have low molecular weight. Both Casein and whey hydrolysate formulas are nutritionally complete, but may be unpalatable. Studies comparing casein and whey hydrolysate formulas have confirmed their efficacy in feeding infants who have

milk protein allergy. The available formulas both contain tapioca starch and sucrose. The source of fat is either safflower oil and medium chain triglyceride or corn oil. Although some infants may respond quickly to introduction of these formulas, a lag period is often encountered for certain clinical findings (eg, resolution of rectal bleeding). In extremely sensitive patients the small peptides in the hydrolysate formula may still trigger an allergic type response. These neonates may be switched to an elemental formula, in which the protein source is individual amino acids. Whether an infant requires a hydrolyzed formula or amino acid based formula, intolerance typically resolves by 12-18 months of age.

Lactose intolerance (lactose maldigestion) is a common condition that results from decreased lactase activity. Lactase is a digestive enzyme located in the intestinal villi that converts the disaccharide lactose (milk sugar) to the monosaccharides glucose and galactose. The monosaccharides can be readily absorbed across the intestinal villi. In an individual with low intestinal lactase, the lactose passes undigested into the lower intestine and colon. The malabsorbed lactose results in an osmotic diarrhea or is fermented by gut bacteria, resulting in the delayed onset of gastroenteral symptoms (eg, onset >30 minutes after ingestion). Lactose intolerance can be either primary (lactase activity that declines with aging), or secondary (enteropathy damage to intestinal villi). Primary lactose intolerance (adult-type hypolactasia) is extremely common, affecting as many as 20% of Caucasian adults, 80% of African American, and 90% of Asian adults. It is uncommon in children before the age of 6. Secondary lactase deficiency is not uncommon in younger children and infants, often developing after infectious gastroenteritis suggested by recurrent loose stool after reintroduction of lactose into diet. Those with lactase maldigestion often have tolerance of smaller milk servings or may be remedied by an elimination diet.

Congenital disaccharidase deficiency is reflected in an osmotic malabsorptive diarrhea accompanied by bacterial fermentation of unabsorbed carbohydrate. The most common congenital disaccharidase deficiency is sucrase-isomaltase (SI) deficiency. Sucrose is composed of glucose and fructose present in table sugar, rice cereal, fruits and juices. Infants usually present with symptoms when sucrose starches are introduced to the diet. Infants who have SI deficiency also may not tolerate soy or protein hydrolysate formulas because both sucrose and glucose polymers are maldigested.

Intestinal carbohydrate malabsorption is usually suspect on the basis of clinical findings however specific screening tests can be used to document the malabsorptive state. Initial screening should include exam of the stool. Acidic fecal pH indicates bacterial fermentation, and stool reducing substances test identifies unfermented reducing sugars. Lactose breath hydrogen testing may also be used in confirmation of the diagnosis. Intestinal biopsy or direct assay for disaccharidase activity may be confirmatory.

RELIZORB is a single-use, point-of-care digestive enzyme cartridge that connects in-line with existing enteral pump feed sets and pump extension sets. RELIZORB is designed to hydrolyze fats contained in the enteral formulas, mimicking the function of the digestive enzyme lipase that is normally secreted by the pancreas. There is insufficient published evidence to assess the safety and/or impact on health outcomes or patient management for the use of the Relizorb device.

V. CODING INFORMATION

ICD-10 Diagnosis Codes:

Not specified – see criteria

HCPCS Codes:

** Not covered for Priority Health Medicaid*

Not Covered for Priority Medicare

- B4034 Enteral feeding supply kit; syringe, per day
- B4035 Enteral feeding supply kit; pump fed, per day
- B4036 Enteral feeding supply kit; gravity fed, per day
- B4082 Nasogastric tubing without stent
- B4087 Gastrostomy/jejunostomy tube, standard, any material, any type, each
- B4088 Gastrostomy/jejunostomy tube, low profile, any material, any type, each
- B9998 NOC for enteral supplies

- B9002 Enteral nutrition infusion pump - with alarm
(Pumps are reimbursed as capped rental items)

- 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)
- 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

- B4100# Food thickener, administered orally, per oz
(Not covered for Priority Health Medicare; no authorization required)

Not Covered - Relizorb Cartridge:

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|---|---|--|
| <ul style="list-style-type: none"> B4034 Enteral feeding supply kit; syringe, per day B4035 Enteral feeding supply kit; pump fed, per day B4036 Enteral feeding supply kit; gravity fed, per day B9998 NOC for enteral supplies | } | <i>bundled in these codes per Medicare</i> |
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VI. REFERENCES

AdminaStar Federal, Inc, National Health Insurance Co., Local Coverage Determination (LCD) for Enteral Nutrition (L5041), CMS Pub. 100-3 (National Coverage Determinations Manual), Chapter 1, Section 180.2, DME Region LCD Covers: Jurisdiction A/B, Original determination

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Hayes, Inc. Relizorb (Alcresta Pharmaceuticals), February 4, 2016

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