Priority Health

MEDICAL POLICY
No. 91278-R20

ENTERAL NUTRITIONAL THERAPY

Effective Date: June 1, 2025	**Review Dates: 1/93, 10/95, 6/99, 12/00, 12/01, 5/02, 5/03, 5/04, 1/05, 12/05, 4/06, 4/07, 7/07, 4/08, 4/09, 4/10, 4/11, 4/12, 4/13, 5/14, 5/15, 5/16, 8/16, 8/17, 8/18, 5/19, 5/20, 8/20, 8/21, 8/22, 5/23, 5/24, 5/25**
Date Of Origin: March 31, 1989	**Status: Current**

Summary of Changes

Changes:

- I. C. 2.: RELiZORB is now indicated for use in pediatric (ages 1 and above) and adult patients to hydrolyze fats in enteral formula (previously ages 2 and above) to reflect new labeling effective January 15, 2025.
- Criteria for food thickeners have been changed.

Clarifications:

- Section for Medicaid/Health MI members: This section was a replication of information found in the Michigan Department of Health and Human Services (MDHHS) Medicaid Provider Manual. Sections A through D have been deleted and replaced with a link to the Medicaid Provider Manual and the titles of the relevant sections.

I. POLICY/CRITERIA

Enteral nutritional therapy via a tube (e.g. nasogastric, gastrostomy, jejunostomy) is considered medically necessary when **ALL** the following apply:

A. The member 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**
B. The solution/formula being administered is the primary source of nutrition

Inclusions:

A. **Supplies: All supplies, equipment, and accessories (durable medical equipment, DME) required for enteral nutritional therapy delivered via a tube** (e.g. nasogastric, gastrostomy, jejunostomy), including syringes and tubing (**NOT** including storage units such as refrigerators or freezers—see Exclusions/Limitations below) are considered medically necessary.

   A **pump** is considered medically necessary provided member:

   - is experiencing complications associated with bolus feedings; **OR**,
   - meets medical necessity criteria for and is utilizing an in-line digestive enzyme cartridge (e.g., RELiZORB)

B. **Formulas**: The following formulas are considered medically necessary:

1. Commercial or prescription food thickeners, provided ALL of the following apply:

   a. A clinical feeding/swallowing evaluation of the member has been conducted by a specialist (e.g., speech-language pathologist, occupational therapist).
   b. Ongoing complicated feeding issues (e.g., dysphagia, swallowing dysfunction).
   c. Non-commercial means of thickening food (e.g., cereals, fruit or vegetable purees) have proven unsuccessful, are contraindicated (e.g., allergy, intolerance, sensitivity), or are inappropriate.

2. 100% hydrolyzed amino acids infant formulas (e.g., Similac Alimentum; Enfamil Nutramigen, Gerber Good start Extensive HA), provided **ALL** the following apply:

   a. Member is 24 months of age or younger; **AND**
   b. Documented allergy to cow's milk; **AND**
   c. Documented soy formula intolerance; **AND**
   d. Documented multiple protein intolerance; **AND**
   e. The 100% hydrolyzed amino acids nutritional formula being administered is the primary source of nutrition; **AND**
   f. Formula is recommended by a Pediatric Allergist, Pediatric Pulmonologist or Pediatric Gastroenterologist.

3. Formula to treat a specific **inborn error of metabolism (IEM)**, provided **ALL** the following apply:

   a. 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**
   b. Nutrition is ordered and managed by a team consisting of a board-certified clinical or medical biochemical geneticist and a metabolic dietician; **AND**

   When criteria a and b above are met, medical necessity for IEM formula is NOT limited by age, weight or lab values.

   Formulas, food products, and supplements that do **NOT** require a physician's order are considered medically necessary **ONLY** when said

formula, food product, or supplement is designed and intended solely for the dietary management of an **inborn error of metabolism (IEM)** (e.g. Periflex®, Anamix®, Lophlex®, Maxamum®, Complex MSD®)

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 their Medicaid services through the Medicaid Fee-For-Service Program and should **NOT** be enrolled in a Priority Health Medicaid/Healthy Michigan plan.

C. **Digestive enzyme (lipase) cartridge (e.g., RELiZORB Immobilized Lipase Cartridge, Alcresta Therapeutics)** that connects directly to an enteral feeding tube in order to hydrolyze the fat in enteral formula to fatty acids and monoglycerides.

These cartridges are considered medically necessary when ***ALL*** of the following are met:

1. Criteria for enteral nutritional therapy via a tube have been met.
2. Member is 1 year of age or older.
3. Member has received a **clinical diagnosis characterized by inability to absorb and/or properly digest/metabolize/hydrolyze fats**. Examples of such diagnoses include the following:

    a. **Exocrine pancreatic insufficiency**
    b. **Cystic fibrosis**
    c. **Pancreatic insufficiency due to cystic fibrosis**

4. RELiZORB is to be used in conjunction with enteral feeding,
5. RELiZORB is **NOT** being used with incompatible formula containing insoluble fiber or food particulates. Examples of such formulas include the following:

    - Nutren® 1.0 with Fiber
    - Jevity®
    - Glucerna®
    - Compleat®/Compleat® Pediatric
    - PediaSure Harvest™

6. RELiZORB is **NOT** being used with a gravity feed system
7. RELiZORB is being used with enteral tube feeding pump that has a low flow/no flow alarm. Examples of such pumps include the following:

    - EnteraLite® Infinity® (Moog)
    - Kangaroo™ Joey (Covidien)
    - Kangaroo™ ePump (Covidien)

Exclusions/Limitations:

A. **Storage units** (e.g., refrigerator, freezer)
B. **Formulas**: The following formulas are considered **NOT** medically necessary, whether administered orally without a tube, or via an enteral feeding tube, as they are considered food:

1. **Routine formulas that are typically fed to healthy, full-term infants.** These formulas typically contain cow's milk, goat's milk, or soy (e.g., Similac Advance, Enfamil Infant, Enfamil ProSobee, Similac Soy Isomil).
2. **Partially hydrolyzed infant formula** containing cow's milk proteins that have already been partially hydrolyzed, or broken down, rendering them easier to digest (e.g., Enfamil Gentlease, Gerber Good Start SoothePro, Gerber Good Start GentlePro, Similac Pro-Total Comfort, Enfamil Reguline, Gerber Good Start Soy).
3. **Lactose-free formula** containing no lactose (a sugar found in milk) for infants that have difficulty digesting lactose.
4. 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 for ketogenic formulas or supplements only if the criteria for enteral nutritional therapy via a tube are met (as defined above)
5. **Nutritional supplements** NOT requiring a physician's prescription for the sole purpose of boosting protein and caloric intake (e.g., Ensure)
6. **Baby food** and other regular grocery products that are blenderized for use with enteral systems.

THE FOLLOWING APPLIES TO MEDICAID AND HEALTHY MICHIGAN MEMBERS ONLY:

For medical necessity requirements and related guidance around enteral nutrition and feeding for Michigan Medicaid and Health Michigan members only, please refer to the following sections of the Michigan Department of Health and Human Services (MDHHS) Medicaid Provider Manual:

- *Billing & Reimbursement for Professionals – Modifiers – DMEPOS – Enteral Nutrition*
- *Medical Supplier – Coverage Conditions and Requirements – Enteral Nutrition*
- *Nursing Facility Coverages – Medicaid Service Descriptions – Dietary Services and Food*
- *Forms Appendix – Medical Justification for Enteral Therapy (form BPHASA-2401)*

Non-covered items for Medicaid and Healthy Michigan members:

- Any supplemental formula or drinks that are for convenience or are an additive to a regular diet.
- Any supplements or formula intended for weight loss or treatment of anorexia or other eating disorders.
- Coverage to accommodate psychological or behavioral conditions, food preferences, loss of appetite, or non-compliance with a specialized diet would not be a consideration.

SPECIAL NOTES:

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

SEE ALSO: ENTERAL NUTRITION. BILLING POLICY NO. 073.

II. MEDICAL NECESSITY REVIEW

Prior authorization for certain drug, services, and procedures may or may not be required. In cases where prior authorization is required, providers will submit a request demonstrating that a drug, service, or procedure is medically necessary. For more information, please refer to the Priority Health Provider Manual.

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) and/or the Evidence of Coverage (EOC); 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, disaccahridase 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, safflour oils, that comprise fat content of the hydrolyzed formulas are like 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. Weather 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 remedied by an elimination diet.

Congenital disaccahridase deficiency is reflected in an osmotic malabsorptive diarrhea accompanied by bacterial fermentation of unabsorbed carbohydrate. The most common congenital disaccahridase 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 disaccahridase activity may be confirmatory.

Thickening feeds appears to modestly improve some of the symptoms and objective measures of reflux frequency. In a meta-analysis of eight studies, thickened feeds significantly reduced the frequency of emesis. There is no direct evidence to suggest that this symptomatic improvement corresponds to a decreased incidence of reflux-related pathology, such as esophagitis (Rosen et al., 2018).

RELiZORB Immobilized Lipase Cartridge (Alcresta Therapeutics)

RELiZORB is a single-use, point-of-care digestive enzyme cartridge that connects in-line with existing enteral feeding pump tubing sets and patient extension sets or enteral feeding tubes. RELiZORB is designed to hydrolyze (digest) fats contained in enteral formulas, mimicking the function of the digestive enzyme lipase that is normally secreted by the pancreas, the body's digestive organ. By hydrolyzing (digesting) fats from enteral formulas, RELiZORB allows for the delivery of absorbable fatty acids and monoglycerides to patients.

Current Food and Drug Administration (FDA) Indications for use:

> *RELiZORB is indicated for use with pediatric (ages 2 years and above) and adult patients to hydrolyze fats in enteral formula.*

Numerous tube feeding formulas and enteral tube feeding pumps have been formally evaluated for use with RELiZORB. The following formulas have been evaluated for use with RELiZORB and are shown to be incompatible because they contain insoluble fiber or food particulates: Nutren® 1.0 with Fiber, Jevity®. Glucerna®, Compleat®/Compleat® Pediatric, PediaSure Harvest™. RELiZORB is NOT intended for use with gravity feed systems. RELiZORB must be used with enteral tube feeding pumps that have low flow/no flow alarms.

A single RELiZORB may be used for up to 500 mL of enteral formula. If less than 500 mL of enteral formula is used per feeding, the RELiZORB is discarded after use. For volumes greater than 500 mL and up to 1000 mL, two RELiZORB cartridges can be connected together in a tandem configuration. Up to two RELiZORBs can be used in a day (24-hour period) and there are no requirements on the amount of time between using them.

Inborn Errors of Metabolism (IEM)

There are now over-the-counter (OTC) products that are formulated to address specific inborn errors of metabolism (IEM), such phenylketonuria (PKU), homocystinuria (HCU), and maple syrup urine disease (MSUD). Such products can be utilized when prescription products are unavailable, provided such products are designed solely to address the unique nutritional needs of individuals with such IEMs.

V. CODING INFORMATION

(SEE ALSO: ENTERAL NUTRITION. BILLING POLICY NO. 073.)

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
B4081 Nasogastric tubing with stylet *(No PA required)*
B4082 Nasogastric tubing without stylet *(No PA required)*
B4087 Gastrostomy/jejunostomy tube, standard, any material, any type, each *(No PA required)*
B4088 Gastrostomy/jejunostomy tube, low profile, any material, any type, each *(No PA required)*
B9998 NOC for enteral supplies

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

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

B4102 Enteral formula, for adults, used to replace fluids and electrolytes (e.g., clear liquids), 500 ml = 1 unit
B4103* Enteral formula, for pediatrics, used to replace fluids and electrolytes (e.g., clear liquids), 500 ml = 1 unit
B4104#* Additive for enteral formula (e.g., fiber)
B4105 In-line cartridge containing digestive enzyme(s) for enteral feeding, each
B4148* Enteral feeding supply kit; elastomeric control fed, per day, includes but not limited to feeding/flushing syringe, administration set tubing, dressings, tape
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
B9998	NOC for enteral supplies

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