NO. 91278

ENTERAL NUTRITIONAL THERAPY

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Instructions for use: This document is for informational purposes only. Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable. Eligibility and benefit coverage are determined in accordance with the terms of the member's plan in effect as of the date services are rendered. It is not an authorization, certification, explanation of benefits, or contract. Receipt of benefits is subject to satisfaction of all terms and conditions of coverage. Priority Health's medical policies are developed with the assistance of medical professionals and are based upon a review of published and unpublished information including, but not limited to, current medical literature, guidelines published by public health and health research agencies, and community medical practices in the treatment and diagnosis of disease. Because medical practice, information, and technology are constantly changing, Priority Health reserves the right to review and update its medical policies at its discretion. Priority Health's medical policies are intended to serve as a resource to the plan. They are not intended to limit the plan's ability to interpret plan language as deemed appropriate. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment they choose to provide.

Policy scope: This policy addresses enteral nutrition, nutrition provided through a tube (e.g., nasogastric, gastrostomy etc.) into the stomach or small intestine.

Related policies:

- Parenteral Nutritional Therapy No. 91517

I. MEDICAL NECESSITY CRITERIA

A. Enteral nutritional therapy via a tube (e.g. nasogastric, gastrostomy, jejunostomy) is considered medically necessary when ALL the following apply:
   1. 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
   2. The solution/formula being administered is the primary source of nutrition

Inclusions:

B. 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.

1. A pump is considered medically necessary provided member:
    a. is experiencing complications associated with bolus feedings; OR
    b. meets medical necessity criteria for and is utilizing an in-line digestive enzyme cartridge (e.g., RELiZORB)
2. Formulas: The following formulas are considered medically necessary:
    a. Commercial or prescription food thickeners, provided ALL of the following apply:
        i. A clinical feeding/swallowing evaluation of the member has been conducted by a specialist (e.g., speech-language pathologist, occupational therapist).
        ii. Ongoing complicated feeding issues (e.g., dysphagia, swallowing dysfunction)
        iii. 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.
3. 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.
4. 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.

5. 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:
    a. Criteria for enteral nutritional therapy via a tube have been met.
    b. 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:
        i. Exocrine pancreatic insufficiency
        ii. Cystic fibrosis
        iii. Pancreatic insufficiency due to Cystic Fibrosis
    c. RELiZORB is to be used in conjunction with enteral feeding
    d. RELiZORB is NOT being used with incompatible formula containing insoluble fiber or food particulates. Examples of such formulas include the following:
        i. Nutren® 1.0 with Fiber
        ii. Jevity®
        iii. Glucerna®
        iv. Compleat®/Compleat® Pediatric
        v. PediaSure Harvest™
    e. RELiZORB is NOT being used with a gravity feed system
    f. RELiZORB is being used with enteral tube feeding pump that has a low flow/no flow alarm. Examples of such pumps include the following:
        i. EnteraLite® Infinity® (Moog)
        ii. Kangaroo™ Joey (Covidien)
        iii. 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

II. CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS) COVERAGE DETERMINATION

Any applicable federal or state mandates will take precedence over this medical coverage policy.

Medicare: Refer to the CMS Online Manual System (IOMs) and Transmittals.
For the most current applicable CMS National Coverage Determination (NCD)/Local Coverage Determination (LCD)/Local Coverage Article (LCA) refer to CMS Medicare Coverage Database.

The information below is current as of the review date for this policy. However, the coverage issues and policies maintained by CMS are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. MAC jurisdiction for purposes of local coverage determinations is governed by the geographic service area where the Medicare Advantage plan is contracted to provide the service. Please refer to the Medicare Coverage Database website for the most current applicable NCD, LCD, LCA, and CMS Online Manual System/Transmittals.

National Coverage Determinations (NCDs)	
Durable Medical Equipment Reference List 280.1	
Local Coverage Determinations (LCDs)	
CGS Administrators, LLC	Enteral Nutrition L38955 External Infusion Pumps L33794
First Coast Service Options, Inc.	None identified
National Government Services, Inc.	None identified
Noridian Healthcare Solutions	Enteral Nutrition L38955 External Infusion Pumps L33794
Novitas Solutions, Inc.	None identified
Palmetto GBA	Hospice The Adult Failure To Thrive Syndrome L34558 A56679
WPS Insurance Corporation	None identified

III. BACKGROUND

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. 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 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 in pediatric (including neonates and infants) and adult patients to hydrolyze fats during enteral feeding.*

Numerous tube feeding formulas and enteral tube feeding pumps have been formally evaluated for use with RELiZORB (RELiZORB® (iMMOBILIZED LIPASE) CARTRIDGE Compatible Formulas and Pumps).

> 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.

IV. GUIDELINES / POSITION STATEMENTS

Medical/Professional Society	Guideline
American Society for Parenteral and Enteral Nutrition (ASPEN)	Guidelines for the provision of nutrition support therapy in the adult critically ill patient: The American Society for

	Parenteral and Enteral Nutrition (Compher C et al., 2022) ASPEN Consensus Recommendations for Refeeding Syndrome (da Silva JSV et al., 2020) Guidelines for the Provision and Assessment of Nutrition Support Therapy in the Pediatric Critically Ill Patient: Society of Critical Care Medicine and American Society for Parenteral and Enteral Nutrition (Mehta NM et al., 2017) ASPEN Safe Practices for Enteral Nutrition Therapy (Boullata JI et al., 2016) Guidelines for the Provision and Assessment of Nutrition Support Therapy in the Adult Critically Ill Patient: Society of Critical Care Medicine (SCCM) and American Society for Parenteral and Enteral Nutrition (A.S.P.E.N.) (McClave SA et al, 2016) Disease-Related Malnutrition and Enteral Nutrition Therapy (National Alliance for Infusion Therapy and the American Society for Parenteral and Enteral Nutrition Public Policy Committee and Board of Directors, 2010) Enteral nutrition practice recommendations (Bankhead R et al., 2009)
European Society for Parenteral and Enteral Nutrition (ESPEN)	ESPEN practical and partially revised guideline: Clinical nutrition in the intensive care unit (Singer P et al., 2023) ESPEN practical guideline: Home enteral nutrition (Bischoff SC et al., 2021) ESPEN guideline on home enteral nutrition (Bischoff SC et al., 2020)
National Institute for Health and Care Excellence (NICE)	Nutrition support for adults: oral nutrition support, enteral tube feeding and parenteral nutrition. Clinical guideline CG32 (2017)
European Society of Pediatric and Neonatal Intensive Care (ESPNIC)	Nutritional support for children during critical illness: European Society of

	Pediatric and Neonatal Intensive Care (ESPNIC) metabolism, endocrine and nutrition section position statement and clinical recommendations (Tume LN et al., 2020)
North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition and the European Society for Pediatric Gastroenterology, Hepatology, and Nutrition	Pediatric Gastroesophageal Reflux Clinical Practice Guidelines: Joint Recommendations of the North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition and the European Society for Pediatric Gastroenterology, Hepatology, and Nutrition (Rosen et al., 2018)
Cystic Fibrosis Foundation	Nutritional considerations for a new era: A CF foundation position paper (Leonard A et al., 2023)
National Institute of Allergy and Infectious Disease	Guidelines for the Diagnosis and Management of Food Allergy in the United States: Report of the NIAID-Sponsored Expert Panel (Boyce JA et al., 2010)
American Academy of Pediatrics Committee on Nutrition	Older Infant-Young Child "Formulas" (Fuchs GJ et al, 2023)
American Gastroenterological Association (AGA)	AGA Clinical Practice Update on the Epidemiology, Evaluation, and Management of Exocrine Pancreatic Insufficiency: Expert Review (Whitcomb D et al., 2023)

V. REGULATORY (US FOOD AND DRUG ADMINISTRATION)

See U.S. Food & Drug Administration (FDA) Medical Device Databases for the most current information.

Device	Premarket Approval, 513(f)(2)(De Novo), or 510(k) Number	Notice date
Pump, infusion, enteral (LZH)		
Vesco Q™ Enteral Feeding Pump (Vesco Medical, LLC)	K232205	10/23/2023
Kangaroo™ OMNI Enteral Feeding Pump (Cardinal Health)	K221603	12/20/2022
AMSure® Enteral Feeding Pump (Amsino Intl.)	K220230	11/10/2022

PUGGLE Enteral Feeding Pump and Feeding Set (Amsino International, Inc.)	K200051	09/25/2020
Kangaroo™ Connect Enteral Feeding Pump (Covidien/Medtronic)	K153074	07/06/2016
Kangaroo Connect Enteral Feeding Pump with Kangaroo Connect Feeding Sets (Covidien)	K143263	05/29/2015
Kangaroo™ ENFit Feeding Sets (500–1000 mL) (Cardinal Health)	K141479	12/23/2014
ENTERALITE INFINITY SPIKE ENTERAL DELIVERY SET; ENTERALITE INFINITY 500 ML BAG ENTERAL DELIVERY SET;	K131154	02/12/2014
MEDI-SIS SYRINGE INFUSION SYSTEM (Acacia, Inc.)	K111381	01/13/2012
COMPAT GO ENTERAL FEEDING PUMP AND ADMINISTRATION SETS (Fresenius Kabi Deutschland GmbH)	K060316	06/23/2006
NOA III ENTERAL NUTRITION PUMP (Caesarea Medical Electronics , Ltd.)	K040957	05/21/2004
Kendall EPump™ Enteral Feeding Pump (Tyco Healthcare/Kendall))	K040196	05/05/2004
EnteraLite Infinity™ Pump (ZEVEX, Inc.)	K031199	07/09/2003
ROSS EMBRACE ENTERAL PUMP (Ross Product Div. Abbott Laboratories)	K031407	05/20/2003
ENTERAL EXPRES PUMP UNIT, ENTERAL EXPRES GIVING SETS (Debio Tech SA)	K011868	09/04/2001
AMBULATORY ENTERAL NUTRITION PUMP (Ross Product Div. Abbott Laboratories)	K003047	06/12/2001
SENTINEL ENTERAL FEEDING PUMP, LH2001 ENTERAL FEEDING PUMP	K011587	06/01/2001

(Entracon Corp.)		
Gastrointestinal tubes with enteral specific connectors (PIF)		
Percutaneous Endoscopic Gastrostomy (PEG) Kit (Degania Silicone , Ltd.)	K254170	03/20/2026
Enteral Drainage System, Enteral Medicine straw (HMC Premedical S.P.A.)	K242917	06/18/2025
Extension Feeding Set with ENFit™ Connectors (SKY Medical, A.S.)	K250481	04/18/2025
Disposable Enteral Feeding Sets (Beijing L&Z Medical Technology Development Co., Ltd.)	K240052	07/03/2024
Mobility+™ Enteral Feeding System (Rockfield Medical)	K233034	04/12/2024
ENFit to ENFit Extension Sets (Vesco Medical)	K230326	11/02/2023
Kangaroo™ Skin-Level Balloon Gastrostomy Kit (Cardinal Health)	K232046	10/06/2023
Feeding Tube (Anhui Tiankang Medical Technology Co., Ltd.)	K222773	08/17/2023
EnteraLoc™ Flow Direct-Connect System (Vonco Products)	K223683	07/10/2023
Mobility+ Enteral Feeding System (Rockfield Medical)	K222678	10/27/2022
Nasogastric Feeding Tubes - ENFit Port – PVC (Cair Lgl)	K213258	06/09/2022
Salem Sump™ NG Tube (ENFit) (Cardinal Health)	K213174	06/15/2022
Entuit® PEG / PEG-J (Wilson-Cook)	K213356	01/20/2022
Enteral Feeding Set (ENFit) (KB Medical Group)	K210854	11/16/2021
Pediatric Nasogastric Feeding Tubes - Single ENFit Port (Cair Lgl)	K210598	11/02/2021
Enteral Extension Sets (GBUK Group, Ltd.)	K203633	08/19/2021
EnteraLoc Flow (Vonco Products)	K210971	08/18/2021

Moss Gastrostomy Tube (Mark IV) (Moss Tubes, Inc.)	K190414	06/14/2019

VI. CODING

Related Billing Policy: Enteral Nutrition No. 073

See also *Priority Health Medical Policy No. 91636 - Category III Current Procedural Terminology (CPT®) Codes ("T" codes)*

ICD-10 Codes that may support medical necessity
Not specified – see criteria

CPT/HCPCS Codes

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

VII. MEDICAL NECESSITY REVIEW

Prior authorization for certain drugs, devices, 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, refer to the Priority Health Provider Manual.

Individual case review may allow coverage for care or treatment that is investigational yet promising for the conditions described. Requests for individual consideration require

prior plan approval. All determinations of coverage for experimental, investigational, or unproven treatment will be made by a Priority Health medical director or clinical pharmacist. The exclusion of coverage for experimental, investigational, or unproven treatment may be reviewed for exception if the condition is either a terminal illness, or a chronic, life threatening, severely disabling disease that is causing serious clinical deterioration.

VIII. APPLICATION TO PRODUCTS

Coverage is subject to the 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. If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual, 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.

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SUMMARY OF CHANGES

Changes:

- Digestive enzyme (lipase) cartridge (e.g., RELiZORB Immobilized Lipase Cartridge, Alcresta Therapeutics): Labeling has expanded to include neonates and infants. Accordingly, 1 year age limitation has been removed.

Past committee review dates: 01/93, 10/95, 06/99, 12/2000, 12/2001, 05/2002, 05/2003, 05/2004, 01/2005, 12/2005, 04/2006, 04/2007, 07/2007, 04/2008, 04/2009, 04/2010, 04/2011, 04/2012, 04/2013, 05/2014, 05/2015, 05/2016, 08/2016, 08/2017, 08/2018, 05/2019, 05/2020, 08/2020, 08/2021, 08/2022, 05/2023, 05/2024, 05/2025