MEDICAL POLICY

POLICY TITLE	ENTERAL NUTRITION
POLICY NUMBER	MP 2.015

CLINICAL BENEFIT	☐ MINIMIZE SAFETY RISK OR CONCERN. ☒ MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS. ☐ ASSURE APPROPRIATE LEVEL OF CARE. ☐ ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS. ☒ ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET. ☐ ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.
Effective Date:	**10/1/2024**

I. POLICY

Non-Mandated Enteral Nutrition

When administration of an enteral feeding* requires the use of a nasogastric, jejunostomy, or gastrostomy tube, the enteral nutrition product and all related equipment and supplies are considered **medically necessary**.

Enteral feedings* when administered by mouth are considered **medically necessary** when the enteral nutrition product provides **50% or more** of total nutritional intake.

Digestive enzyme cartridges (e.g. Relizorb) which connect to enteral feeding tubes for hydrolysis (digestion) of fats in enteral formula are considered **medically necessary** for individuals who:

- Require enteral feedings due to a diagnosis of cystic fibrosis; **AND**
- Are ages 2 years or above

*The enteral nutrition product (feeding) meets the U.S. Food and Drug Administration (FDA) definition of “Medical Food”.

Definition of Medical Food

The U.S. food and Drug Administration defines “Medical Food” as the following: Defined in Section 5(b) of the Orphan Drug Act 21 U.S.C. 360ee (b) (3) is a “food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation.”

In general, to be considered a **medical food,** a product must, at a minimum, meet **ALL** of the following criteria:

- The product must be a food for oral or tube feeding.
- The product must be labeled for the dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements.
- The product must be intended to be used under medical supervision.

Mandated Enteral Nutrition

Effective June 20, 1997, enteral formulas administered by mouth or through the feeding tube are considered **medically necessary** for the therapeutic treatment of the following hereditary genetic disorders as defined in Act 191-1997 (Medical Necessary Supplemental Foods Act). Under this Act, enteral formulas are considered **medically necessary** for **ANY** one of the following conditions:

- Branched-chain ketonuria
- Galactosemia
- Homocystinuria
- Phenylketonuria (PKU)

As set forth in Act 158 of 2014, amino acid-based elemental medical formulas made of 100% free amino acids as the sole protein source may be considered **medically necessary** when ordered by a physician and administered orally or enterally for infants and children for the following conditions after both breast milk (if available) **AND** hydrolyzed formulas have not been tolerated:

- Food protein allergies, or
- Food protein-induced enterocolitis syndrome, or
- Eosinophilic disorders, or
- Short bowel syndrome

Commonly prescribed pure amino acid formulae are:

- Neocate
- Elecare
- PurAmino
- Nutramigen AA

Cross-references:

MP 2.079 Intensive Pediatric Feeding Programs
MP 3.008 Parenteral Nutrition
MP 6.026 Durable Medical Equipment (DME) and Supplies

II. PRODUCT VARIATIONS TOP

This policy is only applicable to certain programs and products administered by Capital Blue Cross and subject to benefit variations as discussed in Section VI below. Please see additional information below.

FEP PPO - Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at: https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies

III. DESCRIPTION/BACKGROUND TOP

Enteral nutrition involves the use of special formulas and medical foods that are administered by mouth or through a tube placed in the gastrointestinal tract. Enteral nutritional feedings are provided when the body cannot properly process food taken orally to maintain nutritional status, as in rare hereditary genetic disorders. In the presence of such hereditary disorders, severe intellectual disabilities, and chronic physical disabilities may occur without proper therapeutic management.

Enteral feeding is often indicated for individuals with diagnoses of cystic fibrosis (CF) or other causes of exocrine pancreatic insufficiency (EPI), as conditions such as these can cause difficulty in maintaining appropriate weight and nutritional status due to poor intake. Poor absorption of certain nutrients also occurs frequently in this population due to lack of pancreatic enzymes such as lipase, amylase, and protease. Often, these individuals will be provided with pancreatic enzyme replacement therapy (also known as PERT) in order to aid in adequate nutrition and absorption. Without these enzymes to break down and absorb fats, individuals can frequently experience symptoms such as steatorrhea, bloating, and poor appetite. Regular absorption of long-chain fatty acids has also been shown to decrease inflammatory markers which can have long term benefits in pulmonary status, cardiovascular health, memory, and vision.

In-line digestive cartridges (i.e., Relizorb) are a relatively new approach to PERT. Relizorb delivers immobilized lipase through a cartridge that is attached directly and runs in-line with the enteral feeding. Relizorb achieved initial FDA approval in 2015 for patients age 18 and older, and has since gained additional FDA approval for children with CF ages 5-18 in July 2017. In 2023, FDA approval was expanded to children ages 2 and older.

Until the development of Relizorb, PERT therapy was only managed with oral medications such as Creon, Zenpep, or Pancreaze which provide a combination of lipase, amylase, and protease via oral route. Often, these medications are given by mouth during the day, while sometimes enteral feedings are only delivered overnight. By using the Relizorb in-line cartridge system, the patient is able to have supplemental lipase delivered simultaneously during the entire course of enteral feeding, thus improving nutrient, particularly fatty-acid, absorption. Circumstances where Relizorb may be prescribed include diagnosis of cystic fibrosis or EPI, where EPI has been

proven by testing such as fecal elastase testing, the individual requires enteral feeding by any route, and has persistent symptoms despite regular oral PERT therapy.

IV. RATIONALE

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The ASSURE (Absorption and Safety with Sustained Use of Relizorb Evaluation) study completed from 2016 to 2017 revealed that usage of in-line digestive cartridges did lead to significant improvement in absorption of fatty acids. Increased absorption of healthy fatty acids led to improved weight maintenance, decreased GI symptoms, and diminished inflammatory markers that were linked to poor pulmonary function.

However, there has been a lack of large, randomized control studies of in-line digestive cartridges to this point. Additionally, as these cartridges only deliver immobilized lipase, these may not completely eliminate the need for oral PERT. The evidence is insufficient to determine the effects of this technology on health outcomes.

A multicenter, randomized, double-blind crossover clinical trial was completed in 2017 in which plasma omega 3 fatty acid concentrations were measured and used as markers for fat absorption. Compared with placebo, cartridge use resulted in a statistically significant 2.8-fold increase in plasma omega-3 FA concentrations. There were no adverse experiences associated with cartridge use, and a decrease in the frequency and severity of most symptoms of malabsorption was observed with cartridge use. Participants reported increased preservation of appetite and breakfast consumption with cartridge use compared with their pre-study regimen.

In a single-center, retrospective case review of patients with CF using a digestive enzyme cartridge published for the American Society of Parenteral and Enteral Nutrition, the prolonged use of a digestive enzyme cartridge with EN demonstrated improved clinical outcomes and a reduction in GI symptoms in patients with CF.

The Journal of Cystic Fibrosis published “Enteral tube feeding for individuals with cystic fibrosis: Cystic Fibrosis Foundation evidence- informed guidelines” in September 2016. While the document notes that “The CF Foundation does not recommend for or against a specific method of providing pancreatic enzyme therapy during enteral tube feeding in individuals with CF”, it also later lists “use of an inline cartridge enzyme delivery system for enteral feeding” as a practical consideration for enteral feeding management after G-tube placement.

V. DEFINITIONS

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BRANCH-CHAIN KETONURIA: A hereditary disease due to deficiency of an enzyme involved in amino acid metabolism, characterized by urine that smells like maple syrup. Another name for the disease is called Maple Syrup Urine Disease.

ENTERAL FEEDING: The provision of nutrition to increase caloric intake through the use of special enteral formula either by mouth or through a tube placed into the gastrointestinal tract. The short-term methods of enteral tube feedings include nasogastric, nasoduodenal, and, less frequently, nasojejunal tubes. Long-term enteral feedings are best administered by a percutaneous gastrostomy or jejunostomy tube.

GALACTOSEMIA: An autosomal recessive disorder marked by an inability to metabolize galactose because of a congenital absence of one of two enzymes needed to convert galactose to glucose.

HOMOCYSTINURIA: An inherited disease caused by the absence of the enzyme essential to the metabolism of homocysteine (an amino acid).

ORAL FEEDINGS: The process of being able to take in nutrition by mouth.

PHENYLKETONURIA (PKU): A congenital, autosomal recessive disease marked by failure to metabolize the amino acid phenylalamine to tyrosine. It results in severe neurological deficits in infancy if it is unrecognized or left untreated.

SOLE SOURCE OF NUTRITION: Liquid enteral formulas either by mouth or through a tube used as the only nutritional intake for patients in hospital and community settings.

TOTAL PARENTERAL NUTRITION (TPN): The provision of feeding a person receives intravenously (IV), bypassing the usual process of eating and digestion. The person receives nutritional formulas containing salts, glucose, amino acids, lipids, and added vitamins, also known as parenteral hyperalimentation, and is used for patients with either a temporary or permanent medical or surgical condition in which the ability of the gastrointestinal system to absorb nutrients from food is severely impaired.

VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits, and which require preauthorization. There are different benefit plan designs in each product administered by Capital Blue Cross. Members and providers should consult the member's health benefit plan for information or contact Capital Blue Cross for benefit information.

VII. DISCLAIMER

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Capital Blue Cross' medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital Blue Cross' Provider Services or Member Services. Capital Blue Cross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

TOP

Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Covered when Medically Necessary:
The following codes represent enteral supplies and home therapy services:

Procedure Codes							
B4034	B4035	B4036	B4081	B4082	B4083	B4087	B4088
B4105	B4148	B9002	B9998	S9340	S9341	S9342	S9343

The following codes represent non-mandated Enteral Nutrition:

Procedure Codes							
B4149	B4150	B4152	B4154	B4155	B4158	B4159	B4160

Non-mandated Enteral Nutrition Coverage Indications:
There are no specific diagnoses

The following codes represent mandated Enteral Nutrition (Act 191):

Procedure Codes							
B4157	B4162	S9433	S9434	S9435			

Mandated Enteral Nutrition (Act 191) coverage indications:

ICD-10-CM Diagnosis Codes	Description
E70.0	Classical phenylketonuria
E71.0	Maple-syrup-urine disease
E71.110	Isovaleric acidemia
E71.111	3-methylglutaconic aciduria
E71.118	Other branched-chain organic acidurias
E71.120	Methylmalonic acidemia
E71.121	Propionic acidemia
E71.128	Other disorders of propionate metabolism
E71.19	Other disorders of branched-chain amino-acid metabolism
E72.11	Homocystinuria
E74.05	Lysosome-associated membrane protein 2 [LAMP2] deficiency
E74.21	Galactosemia
E74.29	Other disorders of galactose metabolism

The following codes are used to report amino acid-based elemental medical formulas (mandated by Act 158), but can be used to report hydrolyzed formulas (not mandated by act 158):

Procedure Codes							
B4153	B4161						

Amino acid-based elemental medical formula (Act 158) coverage indications:

ICD-10-CM Diagnosis Codes	Description
K20.0	Eosinophilic esophagitis
K52.21	Food protein-induced enterocolitis syndrome
K52.81	Eosinophilic gastritis or gastroenteritis
K52.82	Eosinophilic colitis
K91.2	Postsurgical malabsorption, not elsewhere classified
Z91.010	Allergy to peanuts
Z91.012	Allergy to eggs
Z91.013	Allergy to seafood
Z91.014	Allergy to mammalian meats
Z91.018	Allergy to other foods
Z91.02	Food additives allergy status

VIII. REFERENCES

TOP

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IX. POLICY HISTORY

TOP

MP 2.015	**02/24/2020 Consensus Review.** Policy statement unchanged. References updated. Coding reviewed.
	02/09/2021 Consensus Review. Policy statement unchanged. References updated. FEP section updated.
	02/11/2022 Minor Review. Policy statement changed to include in-line digestive enzyme cartridges as not medically necessary. Updated FEP, cross-references, background, and references. Added HCPCS code B4105 to non-covered coding table. Added ICD-10 code Z91.014.
	04/24/2023 Consensus Review. No change to policy statement. Product variation language updated. References added.
	09/11/2023 Administrative Update. New code B4148 added. Effective 10/1/2023
	03/28/2024 Minor Review. Changed Relizorb from NMN to MN with criteria. Updated rationale, references. Updated B4105 from not covered to MN. No other coding changes.

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Top