

Enteral Feeding In-Line Cartridge (EFICT)

Policy ID:	HHO-DE-MP-1010
Approved By:	Highmark Health Options – Market Leadership
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Products:	Medicaid
Application:	All participating hospitals and providers
Page Number(s):	1 of 5

Disclaimer

Highmark Health Options medical policy is intended to serve only as a general reference resource regarding coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

POLICY STATEMENT

Highmark Health Options may provide coverage under medical surgical benefits of the Company's Medicaid products for medically necessary enteral feeding in-line cartridge.

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

The qualifications of the policy will meet the standards of the National Committee for Quality Assurance (NCQA) and the Delaware Department of Health and Social Services (DHSS) and all applicable state and federal regulations.

DEFINITIONS

Highmark Health Options (HHO) – Managed care organization serving vulnerable populations that have complex needs and qualify for Medicaid. Highmark Health Options members include individuals and families with low income, expecting mothers, children, and people with disabilities. Members pay nothing to very little for their health coverage. Highmark Health Options currently services Delaware Medicaid: Delaware Healthy Children Program (DHCP) and Diamond State Health Plan Plus members.

Enteral Feeding (EN) – Refers to intake of food via the gastrointestinal (GI) tract. Enteral feeding may mean nutrition taken through the mouth or through a tube that goes directly to the stomach or small intestine.

Fat Malabsorption – Inadequate assimilation of dietary substances due to defects in digestion, absorption, or transport.

Lipase – A digestive enzyme that breaks down fats (triglycerides) into absorbable fatty acids and monoglycerides.

RELIZORB™ (Alcresta Therapeutics) – A single-use, point-of-care digestive enzyme cartridge device that contains an enzyme called lipase. Relizorb increases the delivery of absorbable calories from an enteral tube feeding formula by connecting the cartridge in-line with an enteral pump feed set and pump extension set. The Relizorb device is connected to the enteral tube feeding pump. The device is only for enteral feeding uses and is only intended for the connection to enteral feeding lines.

De Novo FDA Classification – The Food and Drug Administration Modernization Act of 1997 (FDAMA) added the de novo classification option, which is also known as Evaluation of Automatic Class III Designation. This option provides an alternate pathway to classify novel devices of low-to-moderate risk. Devices that are classified through the de novo process may be marketed and used for future 510(k) submissions.

PROCEDURES

A prior authorization is required if billed charges are greater than \$500.00.

MEDICAL NECESSITY GUIDELINES

The use of Enteral Feeding In-Line Cartridge (EFIC) (e.g., Relizorb) with tube enteral feedings was approved by the Food and Drug Administration in July 2017, is indicated for use in pediatric patients (ages 5 years and above) and adult patients to hydrolyze fats in enteral formula.

POST-PAYMENT AUDIT STATEMENT

The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Highmark Health Options at any time pursuant to the terms of your provider agreement.

PLACE OF SERVICE: OUTPATIENT

CODING REQUIREMENTS

CPT code	Description
B4105	In-line cartridge containing digestive enzyme(s) for enteral feeding, each.
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
B4162	Enteral formula, for pediatrics, 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.
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 proteins, 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 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.
B4158	Enteral formula, for pediatrics, 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.
B4159	Enteral formula, for pediatrics, nutritionally complete soy based with intact nutrients, includes proteins, fats, carbohydrates, vitamins, and minerals, may include fiber 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 proteins, fats, carbohydrates, vitamins and minerals, may include fiber administered through an enteral feeding tube, 100 calories=1 unit.
B4034	Enteral feeding supply kit; syringe fed, per day, includes but not limited to feeding/flushing syringe, administration set tubing, dressings, tape.
B4035	Enteral feeding supply kit; pump fed, per day, includes but not limited to feeding/flushing syringe, administration set tubing, dressings, tape.
B4036	Enteral feeding supply kit; gravity fed, per day, includes but not limited to feeding/flushing syringe, administration set tubing, dressings, tape.
B4081	Nasogastric tubing with stylet.
B4082	Nasogastric tubing without stylet.
B4083	Stomach tube-levine type.
B4087	Gastrostomy/jejunostomy tube, standard, any material, any type, each.
B4088	Gastrostomy/jejunostomy tube, low-profile, any material, any type, each.
B9002	Enteral nutrition infusion pump-with alarm.
B4100	Food thickener, administered orally, per ounce.
B4102	Enteral formula, for adults, used to replace fluids and electrolytes (e.g., clear liquids), 500MI=1 unit.
B4103	Enteral formula, for pediatrics, used to replace fluids and electrolytes (e.g., clear liquids), 500MI=1 unit.
B4104	Additive for enteral formula (e.g., fiber).

DIAGNOSIS CODES
COVERED DIAGNOSIS CODES FOR B4157 AND B4162

Codes						
E70.0	E71.0	E72.11	E72.12	E72.19	E74.21	

REIMBURSEMENT

Participating facilities will be reimbursed per their Highmark Health Options contract.

References

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Hayes, Inc. Health Search and Summary. Relizorb (Alcresta Therapeutics Inc.) Lansdale, Pa: Hayes, Inc. Published October 15, 2018. Amended September 13, 2019. Accessed September 18, 2019.

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Iwanicki C, Bouma S, Nasr, S. Use of immobilized lipase cartridge with overnight enteral feeds improves symptoms and results in weight gain in children with cystic fibrosis. *Pediatr Pulmonol.* 2017;52:S452-S453.

Minor M, Nemastil CJ, Gemma S, et al Digestive enzyme cartridge (RELIZORB™) during continuous feeds among individuals with cystic fibrosis. *Pediatr Pulmonol.* 2017;52:S459-S459

POLICY UPDATE HISTORY

09/20/2021	Approved in Medical Policy Committee
01/24/2022	Annual review; approved in Medical Policy Committee
02/2022	Approved in QI/UM
03/22/2023	Annual review; approved in Medical Policy Committee
03/28/2023	Approved in QI/UM