Enteral Feeding In-Line Cartridge (EFICTM)

Policy ID:	HHO-DE-MP-1010
Approved By:	Highmark Health Options – Market Leadership
Provider Notice Date:	
Original Effective Date:	09/20/2021
Annual Approval Date:	01/24/2022
Last Revision Date:	01/24/2022
Products:	Medicaid
Application:	All participating hospitals and providers
Page Number(s):	1 of 4

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 lll 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

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

2. 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.

3. 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.

4. Place of Service: Outpatient

GOVERNING BODIES APPROVAL

On July 20, 2017, Alcresta Therapeutics, Inc. received 510(k) clearance from the U.S. Food & Drug Administration (FDA) for Relizorb to be used in pediatric patients suffering from fat malabsorption.

On November 20, 2015, Alcresta Therapeutics, Inc. received de novo approval from the FDA to market Relizorb and to use Relizorb in adult patients. Relizorb is the first digestive enzyme cartridge that was created and designed to mimic the normal pancreatic function by breaking down fats in the enteral tube feeding formula.

CODING REQUIREMENTS

CPT code	Description
B4105	In-line cartridge containing digestive enzyme(s) for enteral feeding, each.

REIMBURSEMENT

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

SUMMARY OF LITERATURE

Fat malabsorption is a common condition in patients who cannot produce adequate digestive enzymes due to compromised pancreatic function. The condition causes a patient's gastrointestinal (GI) system to function incorrectly (NIH, 2017). Many diseases can cause malabsorption such as cystic fibrosis (CF), trauma to the pancreas, surgery to remove part of the pancreas, pancreatitis, and pancreatic cancer (BioSpace, 2016). Fat malabsorption affects many aspects of improving the health of critically ill patients, including a patient's ability to maintain or gain weight, immune system, wound healing, muscle strength, and psychological factors (Stroud, 2003). Patients with conditions that compromise pancreatic function do not produce enough pancreatic lipase necessary for fat hydrolysis (BioSpace, 2016). Individuals who have these conditions and receive enteral tube feeding may be receiving an incomplete breakdown of fats which can lead to decreased calorie intake, reduced fat digestion (e.g., omega-3 fatty acids), deficiencies of fat-soluble vitamins, and increased GI symptoms (Alcresta Therapeutics, 2017).

Due to the problems posed by fat malabsorption, there is clinical management in place which consists of enteral tube feeding. The enteral tube feeding consists of supplemental nutritional liquids that are delivered to the gastrointestinal tract through a feeding tube into the stomach or small intestine (Stroud, 2003). An enteral feeding in-line cartridge (EFIC) was designed to mimic the normal pancreatic function by breaking down fats in the enteral tube feeding formula. Breaking down the fats prior to ingestion will allow the patient who suffers from fat malabsorption to absorb more calories from omega-3 fatty acids, monoglycerides, and fat-soluble vitamins (Maki, 1993).

In 2017, the FDA approved the pediatric use (ages 5 years and above) of Relizorb after a study conducted by Alcresta Therapeutics. In conclusion, despite long-term use of EN in conjunction with PERT products, patients with CF exhibit low baseline levels of omega-3 FAs DHA and EPA, as well as BMI or BMI percentiles that are below target. This study demonstrated that digestive cartridge use was safe, well tolerated, and resulted in an almost 3-fold increase in absorption of omega-3 FAs DHA and EPA, a marker of fat absorption, in adults and children with CF and EPI requiring EN. Furthermore, a decrease in the occurrence and severity of reported GI symptoms and an increase in reported preservation of appetite and ability to consume breakfast was observed with digestive cartridge use.

References

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POLICY UPDATE HISTORY

09/20/2021	Approved in Medical Policy Committee
01/24/2022	Annual review