CLINICAL MEDICAL POLICY	
Policy Name:	Enteral Feeding In-Line Cartridge (EFIC™)
Policy Number:	MP-054-MD-PA
Approved By:	Medical Management
Provider Notice Date:	06/19/2017
Original Effective Date:	07/19/2017
Annual Approval Date:	04/19/2017
Revision Date:	N/A
Products:	Pennsylvania Medicaid
Application:	All participating hospitals and providers
Page Number(s):	1 of 4

Disclaimer

Gateway Health℠ (Gateway) medical payment and prior-authorization policy is intended to serve only as a general reference resource regarding payment and 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

Gateway Health℠ does not provide coverage under the 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.

(Current applicable Pennsylvania HealthChoices Agreement Section V. Program Requirements, B. Prior Authorization of Services, 1. General Prior Authorization Requirements.)

DEFINITIONS

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 Pharmaceuticals) – 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 use 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. Medical Necessity Guidelines
   The use of Enteral Feeding In-Line Cartridge (EFIC) (e.g., Relizorb) with tube enteral feedings is considered experimental and investigational due to insufficient evidence in the peer-reviewed literature documenting the clinical utility and clinical validity of this type of device.

2. Post-payment Audit Statement
   The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Gateway Health℠ at any time pursuant to the terms of your provider agreement.

Governing Bodies Approval
On November 20, 2015, Alcresta Pharmaceuticals received de novo approval from the FDA to market Relizorb. 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.

SUMMARY OF LITERATURE

Fat malabsorption is a common condition in patients who cannot produce adequate digestive enzymes due to compromised pancreatic function (NIH, 2017). 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 intestines (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 (Maki, 1993). 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).

Currently, Relizorb is the first and only EFIC that has received de novo FDA approval for adult patients who have fat malabsorption (BioSpace, 2016). Relizorb is a novel in-line digestive enzyme cartridge, utilizing proprietary enzyme immobilization technology, designed for use in adult patients who receive enteral tube feeding (BioSpace, 2016). The active ingredient in Relizorb is a type of lipase enzyme (iLipase™) that breaks down (hydrolysis) triglycerides into absorbable forms during enteral tube feeding (Alcresta Therapeutics, 2017).

Rationale

All EFICs are considered to be experimental and investigational to assist with fat hydrolysis (breakdown), fat absorption, and any other indications. Even with Relizorb's de novo FDA approval, there is insufficient evidence to support the safety, effectiveness, and impact on health outcomes resulting from the use of an EFIC (BioSpace, 2016). There is a small number of clinical trials and evidence-based health technology assessments that have evaluated Relizorb. Hayes (2016) determined that there is insufficient evidence that assesses the patient's safety, impact on health outcomes, and patient management for the use of the Relizorb device.

Although a 33-patient clinical trial was conducted across several locations in the United States, there is a lack of human subjects on a large scale (ClinicalTrials.gov, 2016). According to Hayes (2016), the current published clinical data for Relizorb is very small and consists of only six conference abstracts containing all pig models.

REIMBURSEMENT

Participating facilities will be reimbursed per their Gateway Health℠ contract.

POLICY SOURCE(S)

Alcresta Therapeutics. Relizorb: (Immobilized Lipase) Cartridge, 2017. Accessed on April 5, 2017 and available at: http://relizorb.com/.

BioSpace, October 28, 2016. PRNewswire: Alcresta' Relizorb Increases Fat Absorption in Adult and Pediatric Patients with Cystic Fibrosis Receiving Enteral Nutrition. Newton, Massachusetts. Accessed on April 14, 2017 and available at: http://www.biospace.com/news_story.aspx?StoryID=437369.

Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD) for Medical Nutrition Therapy (180.1), October 1, 2002. Accessed at: https://www.cms.gov/medicare-coverage-database/details/ncddetails.aspx?NCDId=252&ncdver=1&DocID=180.1&SearchType=Advanced&bc=IAAAAAgAAAAAAA%3d%3d&.

ClinicalTrials.gov. Safety, Tolerability and Fat Absorption Using Enteral Feeding In-line Enzyme Cartridge (Relizorb), ClinicalTrials.gov Identifier: NCT02598128. Last updated: June 2016. Accessed on April 7, 2017 and available at: https://clinicaltrials.gov/ct2/show/NCT02598128.

Hayes, Inc. Relizorb (Alcresta Pharmaceuticals), February 4, 2016. Accessed on April 14, 2016 and available at: https://www.hayesinc.com/subscribers/displaySubscriberArticle.do?articleId=37626&searchStore=%24search_type%3Dall%24icd%3D%24keywords%3DRELIZORB%24status%3Dall%24page%3D1%24from_date%3D%24to_date%3D%24report_type_options%3D%24technology_type_options%3D%24organ_system_options%3D%24specialty_options%3D%24order%3DasearchRelevance.

Maki, J., Neelagiri, M., Olshaw, B., Devarakonda, S., Loring, G. ePS05.2 Novel point of care immobilized lipase device (EFIC™) is compatible with a range of nutritional formulas and can simplify delivery of hydrolyzed fat during tube feeding, 1993. Journal of Cystic Fibrosis. Accessed on April 10, 2017 and available at: http://www.cysticfibrosisjournal.com/article/S1569-1993(15)30161-2/pdf.

National Institutes of Health (NIH): U.S. National Library of Medicine, 2017. MedlinePlus: Malabsorption. Bethesda, Maryland. Accessed on April 14, 2017 and available at: https://medlineplus.gov/ency/article/000299.htm.

Stroud, M., Duncan, H., Nightingale, J. Guidelines for enteral feeding in adult hospital patients: Institute of Human Nutrition, 2003. Accessed on April 7, 2017 and available at: http://www.bsg.org.uk/pdf_word_docs/enteral.pdf.

Policy History

Date	Activity
04/14/2017	Initial policy developed
04/19/2017	QI/UM Committee approval
05/11/2017	PARP approval
07/19/2017	Provider effective date