Medical Policy

RELiZORB™ (immobilized lipase)	
MEDICAL POLICY NUMBER	MED_Clin_Ops_090
CURRENT VERSION EFFECTIVE DATE	1/01/2024
APPLICABLE PRODUCT AND MARKET	Individual Family Plan: ALL Small Group: ALL Medicare Advantage: ALL

Brand New Day/Central Health Medicare Plan develops policies and makes coverage determinations using credible scientific evidence including but not limited to MCG™ Health Guidelines, the ASAM Criteria™, and other third party sources, such as peer-reviewed medical literature generally recognized by the relevant medical community, physician specialty society recommendations, and expert opinion as relevant to supplement those sources. Brand New Day/Central Health Medicare Plan Medical Policies, MCG™ Guidelines, and the ASAM Criteria™ are not intended to be used without the independent clinical judgment of a qualified health care provider considering the individual circumstances of each member's case. The treating health care providers are solely responsible for diagnosis, treatment, and medical advice. Members may contact Brand New Day/Central Health Medicare Plan Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Brand New Day/Central Health Medicare Plan Medical Policy may contact the Health Plan. Brand New Day/Central Health Medicare Plan policies and practices are compliant with federal and state requirements, including mental health parity laws.

If there is a difference between this policy and the member specific plan document, the member benefit plan document will govern. For Medicare Advantage members, Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), govern. Refer to the CMS website at http://www.cms.gov for additional information.

Brand New Day/Central Health Medicare Plan medical policies address technology assessment of new and emerging treatments, devices, drugs, etc. They are developed to assist in administering plan benefits and do not constitute an offer of coverage nor medical advice. Brand New Day/Central Health Medicare Plan medical policies contain only a partial, general description of plan or program benefits and do not constitute a contract. Brand New Day/Central Health Medicare Plan does not provide health care services and, therefore, cannot guarantee any results or outcomes. Treating providers are solely responsible for medical advice and treatment of members. Our medical policies are updated based on changes in the evidence and healthcare coding and therefore are subject to change without notice. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). MCG™ and Care Guidelines® are trademarks of MCG Health, LLC (MCG).

PURPOSE

The purpose of this policy is to establish the clinical review criteria that support the determination of medical necessity for RELiZORB™ (immobilized lipase) therapy.

POLICY

RELiZORB is not considered medically necessary due to insufficient evidence of therapeutic value.

LIMITATIONS/EXCLUSIONS

1. RELiZORB is considered experimental and investigational for all indications and is therefore not covered.

BACKGROUND

RELiZORB (immobilized lipase) cartridge is a first-of-its-kind cartridge designed to hydrolyze fats prior to ingestion of enteral formula. The cartridge contains immobilized digestive enzyme lipase covalently bound to small polymer beads. When enteral formula flows through the cartridge, the lipase hydrolyzes fats from triglyceride form, which in turn allows delivery of fatty acids and monoglycerides to patient for absorption.

Despite RELiZORB's de novo FDA approval in 2015, the number of large scale studies in human subjects is inadequate to support the device's safety, effectiveness, and impact on health outcomes. At this time, RELiZORB lacks sufficient evidence in published peer-reviewed literature to support the use of this device. Therefore, the use of RELiZORB is considered experimental and investigational.

CODING

Applicable NDC Codes	
62205-0000-20	Relizorb (lipase) beads, 30 count

Applicable Procedure Code	
B4105	In-line cartridge containing digestive enzyme(s) for enteral feeding

Applicable ICD-10 Codes	
E16.4	Increased secretion of gastrin
E84.1	Cystic fibrosis with intestinal manifestations
K86.1	Other chronic pancreatitis
K86.81	Exocrine pancreatic insufficiency
K50.00	Crohn's disease of small intestine without complications
K90.0	Celiac disease
Q45.3	Other congenital malformations of pancreas and pancreatic duct

EVIDENCE BASED REFERENCES

1. Alcresta Therapeutics. RELiZORB: (Immobilized Lipase) Cartridge, 2017. Accessed on December 6, 2019 and available at: http://relizorb.com/.
2. Alcresta Therapeutics. Absorption and Safety With Sustained Use of RELiZORB Evaluation (ASSURE) Study in Patients With Cystic Fibrosis Receiving Enteral Feeding. Accessed on July 10, 2018
3. 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 July 10, 2018 and available at: https://clinicaltrials.gov/ct2/show/NCT02598128.

4. FDA Clears RELiZORB for Use With Enteral Tube Feeding, December 03, 2015. Accessed on July 10, 2018
5. Freedman S., Orenstein D et al. Increased fat absorption from enteral formula through an in-line digestive cartridge in patients with Cystic Fibrosis. Accessed on July 10, 2018 and available at: https://www.ncbi.nlm.nih.gov/pubmed/?term=relizorb

POLICY HISTORY

Original Effective Date	November 1, 2021
Revised Date	V2 –November 8, 2022 – Annual Review and approval (no policy revisions made) V3 – March 01, 2023 – Adopted by MA UMC (no policy revisions made) January 1, 2024 - Updated to Brand New Day/Central Health Medicare Plan (no policy revisions made)

Approved by Pharmacy and Therapeutics Committee on 11/8/2022