

## OHCA Guideline

<b>Medical Procedure Class:</b>	Digestive enzyme cartridge used with enteral tube feedings.
<b>Initial Implementation Date:</b>	March 5, 2024
<b>Last Review Date:</b>	February 13, 2025
<b>Effective Date:</b>	March 25, 2025
<b>Next Review/Revision Date:</b>	March 2028
* This document is not a contract, and these guidelines do not reflect or represent every conceivable situation. Although all items contained in these guidelines may be met, this does not reflect or imply any responsibility of this agency or department to change the plan provision to include the stated service as an eligible benefit.	
<input type="checkbox"/> New Criteria <input checked="" type="checkbox"/> Revision of Existing Criteria	
<b>Summary</b>	
<b>Purpose:</b>	To provide guidelines to assure medical necessity and consistency in the prior authorization process.
<b>Definitions</b>	
<p><b>Body Mass Index (BMI)</b> - A value derived from the mass and height of a person. The BMI is defined as the body mass divided by the square of the body height and is expressed in units of kg/m<sup>2</sup>.</p> <p><b>Cystic fibrosis</b> - An inherited life-threatening disorder that affects the cells which produce mucus, sweat, and digestive juices. It causes these fluids to become thick and sticky. Symptoms vary and can include cough, repeated lung infections, inability to gain weight, and fatty stools.</p> <p><b>Digestive enzyme cartridge</b> – In-line cartridge designed to break down fats in enteral tube formula prior to patient ingestion, allowing them to absorb more calories despite their own inability to break down and absorb fats. This malabsorption is common among those with impaired pancreatic function.</p> <p><b>Exocrine Pancreatic Insufficiency (EPI)</b> – The body is missing the enzymes it needs to digest food, which causes important nutrients to pass through the body unabsorbed. Those with EPI cannot properly digest or absorb the fats, proteins, and carbohydrates found in food, which can result in weight loss.</p> <p><b>Enteral Nutrition</b> – The intake of food via the gastrointestinal (GI) tract. The GI tract is composed of the mouth, esophagus, stomach, and intestines. Enteral feeding may mean nutrition taken through the mouth or through a tube that goes directly to the stomach or small intestine. In the medical setting, the term enteral feeding is most often used to mean tube feeding.</p> <p><b>Enteral Pump</b> - A pump used to deliver liquid nutrients and medications to a patient's digestive tract.</p> <p><b>Pancreatic Enzyme Replacement Therapy (PERT)</b> - Capsules that replace the enzymes the pancreas would normally make. These help you to digest your food by breaking down carbohydrates, fats and proteins in your food. Pancreatic enzymes can help manage the symptoms of problems with digestion, such as weight loss or diarrhea.</p>	

**Weigh-for-age percentile (WAP)** - A percentile that shows the relative position of the child's BMI, Weight, or Height among children of the same sex and age. A lower WAP has reduced height velocity (i.e., growth spurt) compared to those at or above the 50th percentile. In children with a WAP >50% there was a higher survival rate into adulthood and fewer acute pulmonary exacerbations at age 18. BMI is adjusted for height and can underestimate nutritional stunting. Clinical WAP growth charts are available from the WHO and the CDC.

### Description

Digestive enzyme cartridge aids pancreatic enzyme replacement via an inline cartridge for enteral feedings and is used by patients with pancreatic insufficiency who rely on tube feedings for most of their nutritional intake. The enzyme cartridge mimics the action of pancreatic lipase, improves fat absorption, and increases the number of absorbable calories from enteral formulas. The system is a single-use, point-of-care digestive enzyme cartridge that connects in-line with existing enteral pump feed sets and extension sets.

### CPT Codes Covered Requiring Prior Authorization (PA)

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

### Approval Criteria

#### I. GENERAL

- A. Digestive enzyme cartridge aids pancreatic enzyme replacement via an inline cartridge for enteral feedings and is used by patients with pancreatic insufficiency who rely on tube feedings for most of their nutritional intake.
- B. Authorization for up to 2 units per day, with a limit of 60 per month. The manufacturer expanded utilization to include compatibility with continuous and bolus feedings. In addition, formula compatibility expanded to allow for use with some formulas with insoluble fibers. (see link under references for allowed formulas)

#### II. INDICATIONS

PA request for an in-line digestive enzyme cartridge should include the following documentation:

- A. Diagnosis of Cystic Fibrosis OR Exocrine Pancreatic Insufficiency, Diagnosis codes K86.81 OR E84 (includes E84.0, E84.1, E84.11, E84.19, E 84.8, E84.9)
- B. Age 1 year or older; age compliant with FDA approval for device,
- C. Current authorization for enteral tube feedings,
- D. Current Age and Weight. A WAP below the 50th percentile for the initial PA in children 2-20 years old.
- E. All documentation and the PA request form must be submitted through the OHCA provider portal.

#### III. CONTINUED MEDICAL NECESSITY

- A. Authorization is for a limited duration of 6 months. Subsequent PA requests should include the above items listed in II. INDICATIONS A-E.

- B. For renewal of the PA each 6 months, medical records should reflect a consistent weight gain with the use of the PERT product.
- C. In pediatric members, medical documentation should demonstrate the administration of a PERT during overnight enteral tube feedings is necessary to maintain a WAP > the 50th percentile.
- D. All documentation supporting continued use and the PA request form must be submitted through the OHCA provider portal.

### **Discontinuation Criteria**

- I. Medical records show continued WAP < the 50<sup>th</sup> percentile in pediatric patients after 6 months of use.
- II. No improvement in weight despite 6 months of continued nutritional support with the enzyme cartridge.
- III. Member no longer receives enteral tube feedings.

### **Additional Information**

Requests outside of this guideline will require medical director review.

### **References**

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11. RELiZORB (iMMOBILIZED LIPASE) Cartridge Compatible Formulas and Pumps.  
<https://www.relizorb.com/pdf/RELiZORB-Compatible-Formulas-and-Pumps.pdf>
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