RELiZORB® SUPPORT SERVICES

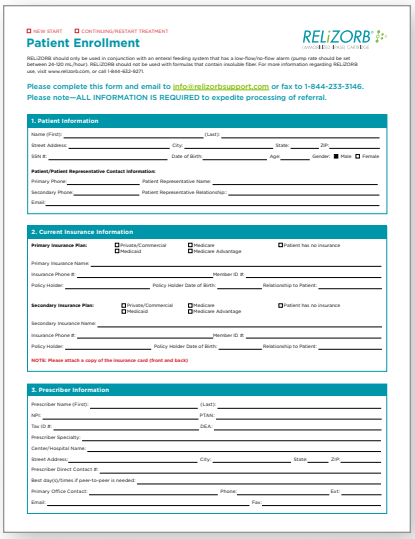
For questions, please call RELiZORB Support Services at **1-844-632-9271** or email **info@relizorbsupport.com**

Clinical Documentation Checklist

Depending on the individual patient, to help avoid delays in RELiZORB® (immobilized lipase) cartridge approval, it may be helpful to include documentation (such as the below) with the RELiZORB Enrollment Form and Letter of Medical Necessity (LOMN), available at **RELiZORB.com**.

Clinical documentation to accompany RELiZORB Enrollment Form

- ☐ Copy of front and back of insurance card
- ☐ MD office visit notes including initial evaluation/H&P, referrals
- ☐ RD office notes
- ☐ Medication list
- ☐ Weight history
- ☐ Letter of medical necessity, if needed



NEW START ☐ CONTINUING/RESTART TREATMENT

Patient Enrollment

RELIZORB

RELiZORB should only be used in conjunction with an enteral feeding system that has a low-flow/no-flow alarm (pump rate should be set between 24-120 mL/hour). RELiZORB should not be used with formulas that contain insoluble fiber. For more information regarding RELiZORB use, visit www.relizorb.com, or call 1-844-632-9271.

Please complete this form and email to info@relizorbsupport.com or fax to 1-844-233-3146.
Please note—ALL INFORMATION IS REQUIRED to expedite processing of referral.

1. Patient Information

Name (First): _____ (Last): _____
Street Address: _____ City: _____ State: _____ ZIP: _____
SSN #: _____ Date of Birth: _____ Age: _____ Gender: ■ Male ☐ Female

Patient/Patient Representative Contact Information:
Primary Phone: _____ Patient Representative Name: _____
Secondary Phone: _____ Patient Representative Relationship: _____
Email: _____

2. Current Insurance Information

Primary Insurance Plan: ☐ Private/Commercial ☐ Medicaid ☐ Medicare ☐ Medicare Advantage ☐ Patient has no insurance
Primary Insurance Name: _____
Insurance Phone #: _____ Member ID #: _____
Policy Holder: _____ Policy Holder Date of Birth: _____ Relationship to Patient: _____

Secondary Insurance Plan: ☐ Private/Commercial ☐ Medicaid ☐ Medicare ☐ Medicare Advantage ☐ Patient has no insurance
Secondary Insurance Name: _____
Insurance Phone #: _____ Member ID #: _____
Policy Holder: _____ Policy Holder Date of Birth: _____ Relationship to Patient: _____

NOTE: Please attach a copy of the insurance card (front and back)

3. Prescriber Information

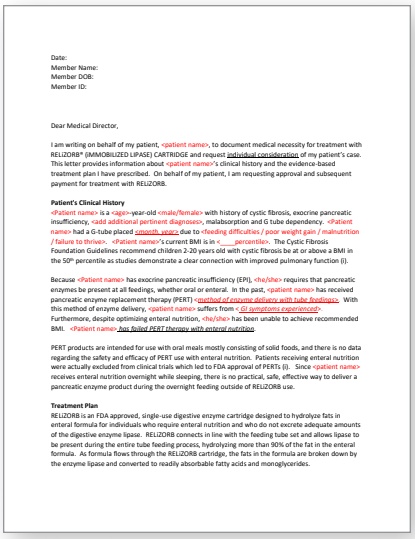
Prescriber Name (First): _____ (Last): _____
NPI: _____ PTAN: _____
Tax ID #: _____ DEA: _____
Prescriber Specialty: _____
Center/Hospital Name: _____
Street Address: _____ City: _____ State: _____ ZIP: _____
Prescriber Direct Contact #: _____
Best day(s)/times if peer-to-peer is needed: _____
Primary Office Contact: _____ Phone: _____ Ext: _____
Email: _____ Fax: _____

RELiZORB Patient Enrollment Form

available at **RELiZORB.com**

Clinical documentation to accompany Letter of Medical Necessity (LOMN)

- ☐ Clinic visits in the last 6 months
- ☐ RD Nutrition notes from the last 6 months
- ☐ Growth charts, including height, weight, BMI, and weight for length (if applicable)



Date:
Member Name:
Member DOB:
Member ID:

Dear Medical Director,

I am writing on behalf of my patient, <patient name>, to document medical necessity for treatment with RELIZORB® (IMMOBILIZED LIPASE) CARTRIDGE and request individual consideration of my patient's case. This letter provides information about <patient name>'s clinical history and the evidence-based treatment plan I have prescribed. On behalf of my patient, I am requesting approval and subsequent payment for treatment with RELIZORB.

Patient's Clinical History
<Patient name> is a <age>-year-old <male/female> with history of cystic fibrosis, exocrine pancreatic insufficiency, <add additional pertinent diagnoses>, malabsorption and G tube dependency. <Patient name> had a G-tube placed <month, year> due to <feeding difficulties / poor weight gain / malnutrition / failure to thrive>. <Patient name>'s current BMI is in a <___percentile>. The Cystic Fibrosis Foundation Guidelines recommend children 2-20 years old with cystic fibrosis be at or above a BMI in the 50th percentile as studies demonstrate a clear connection with improved pulmonary function (i).

Because <Patient name> has exocrine pancreatic insufficiency (EPI), <he/she> requires that pancreatic enzymes be present at all feedings, whether oral or enteral. In the past, <patient name> has received pancreatic enzyme replacement therapy (PERT) <method of enzyme delivery with tube feedings>. With this method of enzyme delivery, <patient name> suffers from < GI symptoms experienced>. Furthermore, despite optimizing enteral nutrition, <he/she> has been unable to achieve recommended BMI. <Patient name> has failed PERT therapy with enteral nutrition.

PERT products are intended for use with oral meals mostly consisting of solid foods, and there is no data regarding the safety and efficacy of PERT use with enteral nutrition. Patients receiving enteral nutrition were actually excluded from clinical trials which led to FDA approval of PERTs (i). Since <patient name> receives enteral nutrition overnight while sleeping, there is no practical, safe, effective way to deliver a pancreatic enzyme product during the overnight feeding outside of RELIZORB use.

Treatment Plan
RELIZORB is an FDA approved, single-use digestive enzyme cartridge designed to hydrolyze fats in enteral formula for individuals who require enteral nutrition and who do not excrete adequate amounts of the digestive enzyme lipase. RELIZORB connects in line with the feeding tube set and allows lipase to be present during the entire tube feeding process, hydrolyzing more than 90% of the fat in the enteral formula. As formula flows through the RELIZORB cartridge, the fats in the formula are broken down by the enzyme lipase and converted to readily absorbable fatty acids and monoglycerides.

Letter of Medical Necessity (LOMN) Template

available at **RELiZORB.com**

RELiZORB® (iMMOBILIZED LIPASE) CARTRIDGE is indicated for use in pediatric patients (ages 5 years and above) and adult patients to hydrolyze fats in enteral formula. RELiZORB is for use with enteral feeding only; do not connect to intravenous or other medical tubing. Medications should not be administered through RELiZORB. Please see Instructions for Use for full safety information at **www.relizorb.com**.

ALCRESTA® THERAPEUTICS