



PROVIDER POLICIES & PROCEDURES

DIGESTIVE ENZYME CARTRIDGES (e.g. RELiZORB®- IMMOBILIZED LIPASE CARTRIDGE)

The primary purpose of this document is to assist providers enrolled in the Connecticut Medical Assistance Program (CMAP) with the information needed to support a medical necessity determination for digestive enzyme cartridges. By clarifying the information needed for prior authorization of services, HUSKY Health hopes to facilitate timely review of requests so that individuals obtain the medically necessary care they need as quickly as possible.

Digestive enzyme cartridges connect in-line with an existing enteral pump feed set and pump extension set. They are designed to mimic the action of pancreatic lipase for use in adults and pediatric patients receiving enteral tube feedings. One type of digestive enzyme cartridge is RELiZORB®, which has been approved by the FDA for this indication. RELiZORB® is designed for use by individuals on enteral tube feeding who have difficulty breaking down and absorbing fats despite optimal therapy with pancreatic enzyme replacement therapy (PERT), which remains the recommended first line treatment.

CLINICAL GUIDELINE

Coverage guidelines for digestive enzyme cartridges are made in accordance with the DSS definition of Medical Necessity. The following criteria are guidelines *only*. Coverage determinations are based on an assessment of the individual and their unique clinical needs. If the guidelines conflict with the definition of Medical Necessity, the definition of Medical Necessity shall prevail. The guidelines are as follows:

Digestive enzyme cartridges are considered medically necessary when:

- A. The individual has an established diagnosis of a condition leading to exocrine pancreatic insufficiency (e.g., cystic fibrosis);
- B. The individual requires enteral tube feeding to meet nutritional/caloric needs; and
- C. The individual has documented failure to achieve feeding goals with PERT or is unable to tolerate PERT.

Ongoing use of digestive enzyme cartridges is considered medically necessary when:

- A. The individual continues to require enteral tube feeding to meet nutritional/caloric needs; and
- B. The individual continues to be unable to achieve feeding goals with PERT or is unable to tolerate PERT.

Authorization Duration and Maximum Units

- If the above criteria are met, requests for digestive enzyme cartridges will be approved at 12 month intervals.
- Maximum Units:
 - For infants less than or equal to ($\leq$) 6 months of age, a maximum supply of 2 cartridges per day will be authorized.

Please note that authorization is based on medical necessity at the time the authorization is issued and is not a guarantee of payment. Payment is based on the individual having active coverage, benefits and policies in effect at the time of service.

To determine if a service or procedure requires prior authorization, CMAP Providers may refer to the *Benefit and Authorization Grids* summaries on www.ct.gov/husky by clicking on "For Providers" followed by "Benefit Grids". For a definitive list of benefits and service limitations, CMAP Providers may access the CMAP provider fee schedules and regulations at www.ctdssmap.com.

- For infants greater than (>) 6 months of age, children, and adults, a maximum supply of 6 cartridges per day will be authorized.

NOTE: EPSDT Special Provision

Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) is a federal Medicaid requirement that requires the Connecticut Medical Assistance Program (CMAP) to cover services, products, or procedures for Medicaid enrollees under 21 years of age where the service or good is medically necessary health care to correct or ameliorate a defect, physical or mental illness, or a condition identified through a screening examination. The applicable definition of medical necessity is set forth in Conn. Gen. Stat. Section 17b-259b (2011) [ref. CMAP Provider Bulletin PB 2011-36].

PROCEDURE

Prior authorization of digestive enzyme cartridges is required. Requests for coverage are reviewed in accordance with procedures in place for reviewing requests for medical supplies. Coverage determinations are based upon a review of requested and/or submitted case-specific information.

The following information is needed to review authorization requests for digestive enzyme cartridges:

1. Fully completed Outpatient Prior Authorization Request Form via fax or fully completed authorization request via on-line web portal;
2. Prescription, signed and dated within the past 6 months, from the treating physician, advanced practice registered nurse (APRN), or physician assistant (PA);
3. Documentation from the treating provider, written within the past 6 months for initial authorization requests and within the past 12 months for reauthorization requests, supporting the medical need for digestive enzyme cartridges as outlined in the *Clinical Guideline* section of this policy; and
4. Pricing information as outlined in the [DSS Pricing Policy for MEDS Items](#).

EFFECTIVE DATE

This policy for the prior authorization of digestive enzyme cartridges for individuals covered under the HUSKY Health Program is effective November 01, 2026.

LIMITATIONS

N/A

CODES:

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

DEFINITIONS

1. **HUSKY A:** Connecticut children and their parents or a relative caregiver; and pregnant women may qualify for HUSKY A (also known as Medicaid). Income limits apply.

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2. **HUSKY B:** Uninsured children under the age of 19 in higher income households may be eligible for HUSKY B (also known as the Children's Health Insurance Program) depending on their family income level. Family cost-sharing may apply.
3. **HUSKY C:** Connecticut residents who are age 65 or older or residents who are ages 18-64 and who are blind, or have another disability, may qualify for Medicaid coverage under HUSKY C (this includes Medicaid for Employees with Disabilities (MED-Connect), if working). Income and asset limits apply.
4. **HUSKY D:** Connecticut residents who are ages 19-64 without dependent children and who: (1) do not qualify for HUSKY A; (2) do not receive Medicare; and (3) are not pregnant, may qualify for HUSKY D (also known as Medicaid for the Lowest-Income populations).
5. **HUSKY Health Program:** The HUSKY A, HUSKY B, HUSKY C, HUSKY D and HUSKY Limited Benefit programs, collectively.
6. **HUSKY Limited Benefit Program or HUSKY, LBP:** Connecticut's implementation of limited health insurance coverage under Medicaid for individuals with tuberculosis or for family planning purposes and such coverage is substantially less than the full Medicaid coverage.
7. **Medically Necessary or Medical Necessity:** (as defined in Connecticut General Statutes § 17b-259b) Those health services required to prevent, identify, diagnose, treat, rehabilitate or ameliorate an individual's medical condition, including mental illness, or its effects, in order to attain or maintain the individual's achievable health and independent functioning provided such services are: (1) Consistent with generally-accepted standards of medical practice that are defined as standards that are based on (A) credible scientific evidence published in peer-reviewed medical literature that is generally recognized by the relevant medical community, (B) recommendations of a physician-specialty society, (C) the views of physicians practicing in relevant clinical areas, and (D) any other relevant factors; (2) clinically appropriate in terms of type, frequency, timing, site, extent and duration and considered effective for the individual's illness, injury or disease; (3) not primarily for the convenience of the individual, the individual's health care provider or other health care providers; (4) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the individual's illness, injury or disease; and (5) based on an assessment of the individual and his or her medical condition.
8. **Prior Authorization:** A process for approving covered services prior to the delivery of the service or initiation of the plan of care based on a determination by CHNCT as to whether the requested service is medically necessary.

REFERENCES

- Freedman S, Orenstein D, Black P, et al. Increased Fat Absorption from Enteral Formula Through an In-line Digestive Cartridge in Patients with Cystic Fibrosis. *J Pediatr Gastroenterol Nutr*. 2017;65(1):97-101. doi:10.1097/MPG.0000000000001617
- Freeman AJ, Reid E, Schindler T, et al. Real-World Evidence of Growth Improvement in Children 1 to 5 Years of Age Receiving Enteral Formula Administered Through an Immobilized Lipase Cartridge. *Nutrients*. 2026;18(2):287. Published 2026 Jan 16. doi:10.3390/nu18020287
- Hendrix SJ, Flume PA, First ER, Stone AA, Van Buskirk M. Improvements in anthropometric measures and gastrointestinal tolerance in patients with cystic fibrosis by using a digestive enzyme cartridge with overnight enteral nutrition. *Nutr Clin Pract*. 2022;37(2):344-350. doi:10.1002/ncp.10831

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- Shrivastava S, Shaw K, Lee M, et al. Association of in-line digestive enzyme cartridge with enteral feeds on improvement in anthropometrics among pediatric patients with cystic fibrosis. *Nutr Clin Pract.* 2024;39(4):903-910. doi:10.1002/ncp.11142
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- U.S. Food & Drug Administration. 510(k) Premarket Notification (K250499). Enzyme Packed Cartridge, RELiZORB®. April 17, 2025. Expanded Use. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf25/K250499.pdf.

PUBLICATION HISTORY

Status	Date	Action Taken
Original Publication	August 2026	Approved at the August 26, 2026, CHNCT Medical Reviewer meeting. Approved by the CHNCT Clinical Quality Subcommittee on September 21, 2026. Approved by DSS on October 9, 2026.

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