



Approved Revised: Do Not Implement Until 7/1/25

Home Nutritional Support (Total Parenteral / Enteral Nutrition)

DESCRIPTION

Total parenteral nutrition (TPN), also known as parenteral hyperalimentation, is used for individuals with medical conditions that impair gastrointestinal absorption to a degree incompatible with life. It is also used for variable periods of time to bolster the nutritional status of severely malnourished individuals with medical or surgical conditions. TPN involves percutaneous transvenous implantation of a central venous catheter into the vena cava or right atrium. A nutritionally adequate hypertonic solution consisting of glucose, amino acids, electrolytes, vitamins, and minerals and sometimes fats, is administered daily. An infusion pump is generally used to assure a steady flow of the solution either on a continuous (24-hour) or intermittent schedule. The catheter is kept patent between infusions.

Enteral nutrition (EN) is used for individuals with a functional gastrointestinal tract who are unable to meet nutritional requirements by the oral route. EN can be defined as a life-sustaining therapy and should be considered if an individual's nutritional intake is likely to be qualitatively or quantitatively insufficient for a week or more due to a complex health condition. EN involves administering non-sterile liquids directly into the gastrointestinal tract through a nasogastric, gastrostomy or jejunostomy tubes. An infusion pump may be used to assist the flow of liquids. Feedings may be intermittent or continuous (infused 24 hours a day).

Relizorb® is a single-use, point-of-care digestive enzyme cartridge that connects in-line with existing enteral feeding circuits. Relizorb® is designed to hydrolyze (break down) fats contained in enteral formulas from triglycerides into fatty acids and monoglycerides to allow for their absorption and utilization by the body. This hydrolysis of fats is intended to mimic the function of the digestive enzyme lipase in individuals who do not excrete sufficient levels of the lipase enzyme. Relizorb® is comprised of a clear cylindrical, plastic cartridge with a single inlet connection port and a single outlet connection port. Lipase is covalently bound to small white beads contained within the cartridge. The fat in enteral formulas is hydrolyzed when it contacts the lipase.

POLICY

- Home nutritional support is considered *medically necessary* if the medical appropriateness criteria are met. (See Medical Appropriateness below.)
- The use of in-line cartridges containing digestive enzymes (i.e., Relizorb®) is considered *medically necessary* if the medical appropriateness criteria are met. (See Medical Appropriateness below.)
- Home nutritional support (total parenteral nutrition/enteral nutrition) for the treatment of dementia is considered *investigational.*

MEDICAL APPROPRIATENESS

- Home nutritional support is considered **medically appropriate** if **ANY ONE** of the following criteria are met:
 - Enteral nutrition (EN) for individuals with **ALL** of the following:
 - Functioning GI tract of sufficient length and conditions to allow adequate nutritional absorption
 - Documentation of malnourishment or risk of malnutrition due to complex medical condition including, but not limited to ANY ONE of the following:
 - Increased nutritional requirements (such as burns, cystic fibrosis)

This document has been classified as public information.





Approved Revised: Do Not Implement Until 7/1/25

- Swallowing disorder due to neurological disorder
- Obstruction due to malignancy
- Cachexia due to cancer
- Chronic obstructive pulmonary disease
- Heart disease
- Chronic infection
- Mild to moderate malabsorption/maldigestion due to liver, pancreas, or intestinal diseases
- Use of in-line cartridges containing digestive enzymes (i.e., Relizorb®) with ALL of the following:
 - Diagnosis of pancreatic insufficiency due to cystic fibrosis
 - Documented failure of pancreatic enzyme replacement therapy (PERT)
 - Individual is 1 year of age or older
 - Individual requires enteral nutrition
- Total parenteral nutrition (TPN) for individuals with **ALL** of the following:
 - Unable to benefit from tube feedings due to severe pathology of the alimentary tract that does not allow absorption of sufficient nutrients including, but not limited to ANY ONE of the following:
 - Prolonged gastrointestinal failure
 - Chronic small bowel disease with malabsorption and dysmotility syndrome (e.g., short bowel, fistula)
 - Inflammatory bowel disease
 - Surgical complications
 - Mesenteric vascular disease
 - Radiation enteritis
 - Infants and young children who fail to thrive due to systemic disease or secondary to intestinal
 insufficiency associated with short bowel syndrome, malabsorption, or chronic idiopathic diarrhea

IMPORTANT REMINDERS

- Any specific products referenced in this policy are just examples and are intended for illustrative purposes only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available. These examples are contained in the parenthetical e.g. statement.
- We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

SOURCES

CMS.gov: Centers for Medicare & Medicaid Services. CGS Administrators, LLC. (2021, September; last update 2024, January). *Enteral Nutrition.* (LCD ID L38955). Retrieved January 29, 2025 from <u>https://www.cms.gov</u>.

CMS.gov: Centers for Medicare & Medicaid Services. CGS Administrators, LLC. (2021, September/ last update 2024, January). *Parenteral Nutrition*. (LCD ID L38953). Retrieved January 29, 2025 from <u>https://www.cms.gov</u>.





Approved Revised: Do Not Implement Until 7/1/25

Cystic Fibrosis Foundation. (1995, November; last reviewed July 2021). *Pancreatic enzymes clinical care guidelines*. Retrieved January 29, 2025 from <u>www.cff.org</u>.

Cystic Fibrosis Foundation. (2016; last reviewed July 2021). *Enteral tube feeding for individuals with cystic fibrosis.* Retrieved January 29, 2025 from www.cff.org.

European Society for Clinical Nutrition and Metabolism. (2013). *ESPEN endorsed recommendations: Nutritional therapy in major burns.* Retrieved October 8, 2021 from <u>https://www.espen.org/guidelines-home/espen-guidelines.</u>

European Society for Clinical Nutrition and Metabolism. (2018). *ESPGHAN-ESPEN-ECPR-CSPEN guidelines on pediatric nutrition: Home parenteral nutrition.* Retrieved October 13, 2021 from <u>https://www.espen.org/guidelines-home/espen-guidelines.</u>

European Society for Clinical Nutrition and Metabolism. (2020). *ESPEN guideline on home enteral nutrition.* Retrieved October 8, 2021 from <u>https://www.espen.org/guidelines-home/espen-guidelines</u>.

European Society for Clinical Nutrition and Metabolism. (2020). *ESPEN guideline on home parenteral nutrition*. Retrieved October 8, 2021 from <u>https://www.espen.org/guidelines-home/espen-guidelines</u>.

European Society for Clinical Nutrition and Metabolism. (2024). *ESPEN guideline on nutrition and hydration in dementia*. Retrieved January 30, 2025 from <u>https://www.espen.org/guidelines-home/espen-guidelines</u>.

European Society for Clinical Nutrition and Metabolism. (2024). *ESPEN-ESPGHAN-ECFS guideline on nutrition care for cystic fibrosis*. Retrieved January 30, 2025 from <u>https://www.espen.org/guidelines-home/espen-guidelines</u>.

Freedman, S., Orenstein, D., Black, P, Brown, P., McCoy, K., Stevens, J., et al. (2017). Increased fat absorption from enteral formula through an in-line digestive cartridge in patients with cystic fibrosis. *JPGN*, 65 (1), 97 -101. (Level 2 evidence)

National Institute of Health and Clinical Excellence. (2006). *Nutrition support for adults: oral nutrition support, enteral tube feeding and parenteral nutrition*. Retrieved June 26, 2019 from <u>www.nice.org.uk</u>.

U. S. Food and Drug Administration. (2014, December). Center for Devices and Radiological Health. Evaluation of Automatic Class III Designation (De Novo) Summaries. *DEN150001*. Retrieved October 8, 2021 from http://www.fda.gov/cdrh/pdf4/k040126.pdf.

U. S. Food and Drug Administration. (2025, January). Center for Devices and Radiological Health. *510(k) Premarket Notification Database. K243284.* Retrieved March 17, 2025 from <u>http://www.accessdata.fda.gov</u>.

EFFECTIVE DATE 7/1/2025

ID_BT

This document has been classified as public information.





Approved Revised: Do Not Implement Until 7/1/25

This document has been classified as public information.