

# MEDICAL POLICY

<b>Medical Policy Title</b>	<b>Enteral Nutrition</b>
<b>Policy Number</b>	<b>10.01.03</b>
<b>Current Effective Date</b>	<b>February 19, 2026</b>
<b>Next Review Date</b>	<b>February 2027</b>

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service.

(Link to [Product Disclaimer](#))

**Refer to the section regarding Pharmacy Benefits for Medicaid Managed Care product members at the end of this policy for coverage criteria for those members.**

## POLICY STATEMENT(S)

- I. Enteral formulas for home use, whether administered orally or via tube feeding (e.g., nasogastric [NG] tubes, naso-enteral [NE] tubes, gastrostomy [G-] tubes, jejunostomy [J-] tubes), are considered **medically appropriate** when:
  - A. A physician or other licensed health care provider has issued a written order stating that the enteral formula is medically necessary and has been proven effective as a disease-specific treatment regimen including, but not limited to, **ANY** of the following conditions:
    1. Inherited diseases of amino acid or organic acid metabolism (e.g., Phenylketonuria/PKU);
    2. Branch-chain ketonuria, galactosemia, or homocystinuria;
    3. Crohn's disease;
    4. Gastroesophageal reflux;
    5. Impaired absorption of nutrients caused by disorders affecting the absorptive surface, function, length, and motility of the gastrointestinal tract (e.g., chronic intestinal pseudo-obstruction, Ogilvie's syndrome);
    6. Ulcerative colitis;
    7. Severe food protein-induced enterocolitis syndrome;
    8. Eosinophilic disorders; **or**
    9. Multiple, severe food allergies, including, but not limited to, immunoglobulin E- and non-immunoglobulin E-mediated allergies to multiple food proteins.
- II. Modified solid food products that are low-protein, contain modified protein, or are amino acid-based are considered **medically appropriate** for the following indications:
  - A. Certain inherited diseases of amino acid (e.g., maple syrup urine disease (MUSD)) and organic acid metabolism;

## Medical Policy: Enteral Nutrition

Policy Number: 10.01.03

Page: 2 of 12

- B. Severe protein allergic conditions. (Refer to Policy Guideline I regarding reimbursement guidelines).
- III. Enteral nutrition with enteral feeding tubes (e.g., NG tubes, NE tubes, G-tubes, J-tubes) is considered **medically appropriate** for functional impairments that include, but are not limited to, the following:
- A. Muscular paralysis in which the individual is unable to swallow because a damaged brain or spinal cord can no longer communicate to the muscles of the alimentary tract to initiate function. The paralysis may be the result of a disease process such as:
    - 1. Cerebral vascular accident (CVA);
    - 2. Trauma/accident;
    - 3. Spinal cord injury;
    - 4. Birth defects/cerebral palsy;
    - 5. Parkinson's disease;
    - 6. Amyotrophic lateral sclerosis (ALS);
    - 7. Multiple sclerosis (MS);
    - 8. Myasthenia gravis; **or**
    - 9. Huntington's chorea;
  - B. Cognitive neurological disorders that may cause the individual to forget how to swallow, such as:
    - 1. Senile dementia;
    - 2. Alzheimer's disease; **or**
    - 3. Organic brain syndrome;
  - C. Mechanical dysfunction of the gastrointestinal tract in which there is a functional impairment that results in a specific inability to swallow or may prevent food from reaching the stomach (e.g., esophageal obstruction or stricture, cancer of the larynx or tongue);
  - D. Compromised ability for oral intake in individuals with a functioning gastrointestinal tract who, due to pathology, disease or non-function of the structures that normally permit food to reach the digestive tract, cannot maintain weight and strength commensurate with the individuals' general condition.
- IV. In-line digestive enzyme cartridges (e.g., RELiZORB) are considered **medically necessary** when **ALL** of the following criteria are met:
- A. Individual meets the criteria for enteral nutrition;
  - B. Has a diagnosis of Cystic Fibrosis and Exocrine Pancreatic Insufficiency (EPI);
  - C. Has documented failure to achieve feeding goals with pancreatic enzyme replacement

## Medical Policy: Enteral Nutrition

Policy Number: 10.01.03

Page: 3 of 12

therapy (PERT) in combination with enteral feedings;

D. Individual requires overnight enteral feedings to meet nutritional/calorie demands; **and**

E. No more than two in-line cartridges are requested per day.

V. Dietary supplements such as probiotics are considered **not medically necessary**.

### RELATED POLICIES

#### Corporate Medical Policy

1.01.00 Durable Medical Equipment (DME) and Devices, Standard and Non-Standard

11.01.04 Total Parenteral Nutrition (TPN)/Hyperalimentation

### POLICY GUIDELINE(S)

- I. To be eligible for benefits for enteral nutrition, all enteral formulas must be prescribed for the individual in a written order by a provider legally authorized to prescribe under the New York Education Law. Claims for reimbursement will be processed in accordance with the member's subscriber contract.
  - A. The written order by the provider must contain the individual's diagnosis, must state that the enteral formula is medically necessary, and has been proven effective as a disease-specific treatment regimen.
  - B. Benefits for enteral formulas administered orally (without feeding tubes) and modified solid food products, when medically appropriate, will be considered under the pharmacy benefit. If there is no pharmacy coverage with the Health Plan, benefits will not be provided.
  - C. Benefits for enteral formulas administered with feeding tubes will be considered as follows:
    1. When the individual is receiving home care, and the services are billed by a home care agency, enteral formulas and necessary supplies to administer the enteral formula (e.g., feeding tubes, pumps, etc.) will be considered under the home care benefit.
    2. When the individual is not receiving home care or has not been approved for home care benefits, charges for:
      - a. Enteral formulas will be considered under the medical contract with the individual copayment being equal to that of the third-tier pharmacy benefit. If there is no pharmacy coverage with the Health Plan, benefits will not be provided;
      - b. Necessary supplies will be considered under the prosthetic benefit of the medical contract.
- II. Individuals with cognitive/neurological disease must have documentation in the medical record that demonstrates a dysfunction of the swallowing mechanism. Swallowing assessments or evaluations are required.
- III. All individuals should be monitored in conjunction with a qualified dietitian, health care

## Medical Policy: Enteral Nutrition

Policy Number: 10.01.03

Page: 4 of 12

practitioner certified in nutritional support, gastroenterologist, or pediatric allergist when appropriate.

- IV. A comprehensive individual assessment is essential before nutritional support is provided, including consideration of the benefits and burdens of nutritional support, based on the individual's diagnosis, prognosis, goals for care, and plans for reassessment of the need for ongoing nutritional support.

### DESCRIPTION

Cederholm and colleagues (2024) summarized the three subtypes of malnutrition in adults:

- 1) Disease related malnutrition with inflammation:
  - a. Related to acute disease or injury.
  - b. Related to chronic disease (cancer cachexia or other disease-specific cachexia).
- 2) Disease-related malnutrition without inflammation.
- 3) Malnutrition or undernutrition without disease:
  - a. Related to socioeconomic or psychological factors.
  - b. Related to malnutrition.

First line treatment of insufficient oral intake consists of nutritional counseling, modified foods, or oral nutritional supplements. If this oral intake is inefficient or contraindicated, enteral nutrition is the preferred choice of treatment.

Enteral formulas are specialized mixtures designed to deliver nutrients that can be utilized by individuals who cannot maintain adequate oral intake of food or nutrients to meet their metabolic demands. Enteral nutrition is commonly used by individuals with dysphagia (difficulty swallowing), neuromuscular disorders affecting swallowing reflex, and upper gastrointestinal strictures or tumors.

Enteral nutrition formulas are given through the gastrointestinal tract (mouth, esophagus, stomach, or small intestine). They may be administered orally (by mouth) or enterally (with a feeding tube). Examples of feeding tubes are:

- I. Nasogastric (NG) tube: nose to stomach;
- II. Naso-enteral (NE) tube: nose to small bowel;
- III. Gastrostomy (G-tube): surgically placed into the stomach through the abdominal wall; and
- IV. Jejunostomy (J-tube): surgically placed into the small bowel through the abdominal wall.

Modified solid food products are alternatives to commercial enteral formulas. They are blenderized formulations of whole foods reduced to a consistency that can be successfully delivered through enteral access devices without becoming blocked. Modified solid food products can be home or commercially made, with commercial products containing synthetic blends of processed proteins, carbohydrates, fats, vitamins, minerals, and preservatives to extend shelf life. The American Society for Parenteral and Enteral Nutrition recognize both as forms of enteral nutrition; however, does not

## **Medical Policy: Enteral Nutrition**

**Policy Number: 10.01.03**

**Page: 5 of 12**

that these may not meet complete nutritional needs and should be evaluated individually for appropriateness. Exocrine Pancreatic Insufficiency (EPI) is a common concern (~85%) for patients with cystic fibrosis, resulting in malabsorption and increased energy requirements leading to malnutrition. It is estimated that 10% of CF patients require enteral tube feedings overnight to maintain caloric intake. Immobilized lipase cartridges were developed to support nutrient absorption for these individuals. The cartridge hydrolyzes intact triglyceride fats from within the enteral formula into more absorbable forms while the lipase stays within the cartridge. While a tube fed patient can take pancreatic enzyme replacement therapy (PERT) via opening of a capsule or crushing a tablet, this is an off-label use and requires the individual to take PERT prior to bedtime, and wait until morning to re-take PERT, or wake throughout the night to supplement the feeding to properly maximize the absorption of the fats in the formula being given.

Probiotics are dietary supplements of live microorganisms (e.g., *Lactobacillus* species, *Bifidobacterium* species, yeasts) that are intended to beneficially affect an individual upon ingestion by improving the balance of the intestinal microflora. Dietary supplements are generally excluded under most Health Plan contracts.

### **SUPPORTIVE LITERATURE**

Shivrastava and colleagues (2024) conducted a retrospective chart review on 29 patients with cystic fibrosis and exocrine pancreatic insufficiency (EPI) of patients receiving supplemental tube feedings with in-line lipase cartridges for a continuous 12-month period between 2015 and 2019. Mean anthropometric measures were taken before and after cartridge use. Results demonstrated a statistically significant change in the mean height scores, while weight and BMI trended upward, although were not statistically significant. When the authors excluded seven patients identified with severe lung disease ( $FEV1 < 40\%$ ), the mean weights moved closer to but did not reach statistical significance. Authors conclude that the findings strongly support the use of in-line lipase cartridges as the most appropriate source of PERT therapy in patients receiving nocturnal feedings.

### **PROFESSIONAL GUIDELINE(S)**

A perspective commentary was published by the Cystic Fibrosis Foundation in 2019 (Schwarzenberg et al), advocating for the use of immobilized lipase cartridges to support nutrient absorption in tube-fed patients, citing particular improvements in gastrointestinal symptoms, treatment burden, and tolerability in patients with CF. The signatories of the letter (including gastroenterologists, pulmonary providers, dieticians and PharmDs, approximate their treatment of 450 subjects with CF who have utilized the tube feedings and imply that the immobilized lipase cartridges can produce "measurable, clinically relevant benefits". The authors additionally noted that during the three years of the products availability, more than 725,000 cartridges had been distributed, representing nearly 2000 patients with no identified medical device reports or adverse events reported to the U.S. Food and Drug Administration (FDA).

According to Bischoff et al (2022), enteral nutrition a medical treatment and decisions on route, content, and management of nutritional support are best made by multidisciplinary nutrition teams. See The European Society of Parenteral and Enteral Nutrition (ESPEN) Practical Guidelines for Home

## **Medical Policy: Enteral Nutrition**

**Policy Number: 10.01.03**

**Page: 6 of 12**

Enteral Nutrition (HEN). [accessed 2026 Jan 09]. Available from:

[https://www.clinicalnutritionjournal.com/article/S0261-5614\(21\)00497-0/fulltext](https://www.clinicalnutritionjournal.com/article/S0261-5614(21)00497-0/fulltext)

The American Society for Parenteral and Enteral Nutrition (ASPEN) Clinical Guidelines and Clinical Resources. [accessed 2026 Jan 09]. Available from: <https://nutritioncare.org/clinical-resources/guidelines-standards/>

The National Kidney Foundation (NKF) updated its clinical practice guidelines for nutrition in chronic kidney disease (CKD) (Ikizler et al 2020). The guideline was expanded to include individuals with end-stage kidney disease or advanced CKD, and for individuals with stages 1- 5 CKD who are not receiving dialysis, and patients with a functional kidney transplant. The updated guideline statements focus on 6 primary areas: nutritional assessment, medical nutrition therapy (MNT), dietary protein and energy intake, nutritional supplementation, micronutrients, and electrolytes. The guidelines primarily cover dietary management rather than all possible nutritional interventions (see the reference section for guidance).

National Institute for Health and Care Excellence (NICE). Nutrition support for adults: oral nutrition support, enteral tube feeding and parenteral nutrition. Clinical guidelines. 2006 Feb 22. [updated 2017 Aug 04; accessed 2026 Jan 20]. Available from: <https://www.nice.org.uk/guidance/cg32>

The American College of Obstetricians and Gynecologists (ACOG) published a 2018 practice bulletin on the clinical management of nausea and vomiting of pregnancy. The ACOG does address enteral tube feeding (nasogastric or nasoduodenal) initiation as the first line treatment to provide nutritional support to women with HG who are not responsive to medical therapy and cannot maintain their weight.

### **REGULATORY STATUS**

The New York Insurance Law mandates coverage of enteral formulas under contracts that cover prescription drugs. The required coverage is for home use of enteral formulas, whether administered orally or via tube feeding, pursuant to a written order by the individual's physician stating that the enteral formula is medically necessary and has been proven effective as a disease-specific treatment regimen.

The mandate also requires coverage of modified solid food products to treat inherited diseases of amino acid and organic acid metabolism up to \$2,500 per individual per calendar year or a continuous benefit period of 12 months. However, the federal Patient Protection and Affordable Care Act (PPACA) prohibit dollar limits on essential health benefits, including these conditions, and supersedes the New York State mandate; therefore, the Health Plan does not apply the \$2,500 limit.

The U.S. Food and Drug Administration (FDA) is responsible for ensuring the safety, efficacy, and quality of drugs sold in the United States. This includes both prescription and over-the-counter medications. Refer to the FDA Drug website. Available from: <https://www.fda.gov/drugs> [accessed 2025 Jan 09]

The FDA maintains information for consumers and health professionals on new drug warnings and other safety information, drug label changes, and shortages of medically necessary drug products. Available from: [Drug Safety and Availability | FDA](#) [accessed 2025 Jan 09]

## Medical Policy: Enteral Nutrition

Policy Number: 10.01.03

Page: 7 of 12

The United States Food and Drug Administration has approved a device known as RELiZORB, which is an in-line cartridge intended to aid in the delivery of fat absorption with cystic fibrosis individuals who have confirmed exocrine pancreatic insufficiency.

### CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

### CPT Codes

Code	Description
No specific code(s)	

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### HCPCS Codes

Refer to the HCPCS manual for codes appropriate to specific formulas.

HCPCS codes listed below from B4034 - S9343 refer to enteral TUBE feedings.

Code	Description
B4034-B4036	Enteral feeding supply kit (code range)
B4102	Enteral formula, for adults, used to replace fluids and electrolytes (e.g., clear liquids), 500 ml = 1 unit
B4103	Enteral formula, for pediatrics, used to replace fluids and electrolytes (e.g., clear liquids), 500 ml = 1 unit
B4104	Additive for enteral formula (e.g., fiber)
B4105	In-line cartridge containing digestive enzyme(s) for enteral feeding, each
B4148	Enteral feeding supply kit; elastomeric control fed, per day, includes but not limited to feeding/flushing syringe, administration set tubing, dressings, tape
B4149	Enteral formula, manufactured blenderized natural foods with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit
B4150	Enteral formula, nutritionally complete with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit
B4152	Enteral formula, nutritionally complete, calorically dense (equal to or greater than 1.5 kcal/ml) with intact nutrients, includes proteins, fats, carbohydrates, vitamins

**Medical Policy: Enteral Nutrition****Policy Number: 10.01.03****Page: 8 of 12**

<b>Code</b>	<b>Description</b>
	and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit
B4153	Enteral formula, nutritionally complete, hydrolyzed proteins (amino acids and peptide chain), includes fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit
B4154	Enteral formula, nutritionally complete, for special metabolic needs, excludes inherited disease of metabolism, includes altered composition of proteins, fats, carbohydrates, vitamins and/or minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit
B4155	Enteral formula, nutritionally incomplete/modular nutrients, includes specific nutrients, carbohydrates (e.g., glucose polymers), proteins/amino acids (e.g., glutamine, arginine), fat (e.g., medium chain triglycerides) or combination, administered through an enteral feeding tube, 100 calories = 1 unit
B4157	Enteral formula, nutritionally complete, for special metabolic needs for inherited disease of metabolism, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit
B4158	Enteral formula, for pediatrics, nutritionally complete with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber and/or iron, administered through an enteral feeding tube, 100 calories = 1 unit
B4159	Enteral formula, for pediatrics, nutritionally complete soy based with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber and/or iron, administered through an enteral feeding tube, 100 calories = 1 unit
B4160	Enteral formula, for pediatrics, nutritionally complete calorically dense (equal to or greater than 0.7 kcal/ml) with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit
B4161	Enteral formula, for pediatrics, hydrolyzed/amino acids and peptide chain proteins, includes fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit
B4162	Enteral formula, for pediatrics, special metabolic needs for inherited disease of metabolism, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit
B9002	Enteral nutrition infusion pump, any type
B9998	NOC for enteral supplies
S9340	Home therapy; enteral nutrition; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (enteral formula and nursing visits coded separately), per diem

## Medical Policy: Enteral Nutrition

Policy Number: 10.01.03

Page: 9 of 12

Code	Description
S9341	Home therapy; enteral nutrition via gravity; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (enteral formula and nursing visits coded separately), per diem
S9342	Home therapy; enteral nutrition via pump; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (enteral formula and nursing visits coded separately), per diem
S9343	Home therapy; enteral nutrition via bolus; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (enteral formula and nursing visits coded separately), per diem
S9432	Medical foods for non-inborn errors of metabolism
S9433	Medical food nutritionally complete, administered orally, providing 100% of nutritional intake
S9434	Modified solid food supplements for inborn errors of metabolism
S9435	Medical foods for inborn errors of metabolism

### ICD10 Codes

Code	Description
Multiple Codes	

### REFERENCES

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Berry SA, et al. Follow-up and Treatment (FUTR) Workgroup for the Advisory Committee on Heritable Disorders in Newborns and Children. Medical Foods for Inborn Errors of Metabolism: History, Current

## **Medical Policy: Enteral Nutrition**

**Policy Number: 10.01.03**

**Page: 10 of 12**

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Morton A and Wolfe S. Enteral tube feeding for cystic fibrosis. *Cochrane Database Syst Rev*. 2015 Apr 9;(4):CD001198.

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Pironi L, et al. ESPEN guideline on home parenteral nutrition. *Clin Nutr*. 2020 Jun;39(6):1645-1666.

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## **Medical Policy: Enteral Nutrition**

**Policy Number: 10.01.03**

**Page: 11 of 12**

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### **SEARCH TERMS**

Not Applicable

### **CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)**

Enteral Nutrition is not addressed in National or Regional Medicare coverage determinations or policies.

### **NY STATE COVERAGE OF PHARMACY BENEFITS FOR MEDICAID MANAGED CARE PRODUCT MEMBERS**

There are currently guidelines for Pharmacy benefits of Enteral Nutrition Formula for New York State (NYS) Medicaid Managed Care Members. For those members, enteral nutritional formula benefit coverage is limited to:

1. Beneficiaries who are fed via nasogastric, gastrostomy or jejunostomy tube.
2. Beneficiaries with inborn metabolic disorders.
3. Children up to 21 years of age, who require liquid oral enteral nutritional formula when there is a documented diagnostic condition where caloric and dietary nutrients from food cannot be absorbed or metabolized.

For complete coverage guidelines please refer to the following website: [accessed 2026 Jan 09]. Available from:

[https://www.emedny.org/providermanuals/communications/enteral\\_nutritional\\_formula\\_benefit\\_update\\_20110418.pdf](https://www.emedny.org/providermanuals/communications/enteral_nutritional_formula_benefit_update_20110418.pdf)

In addition, the Medicaid Managed Care benefit for enteral nutritional formula includes coverage of orally administered formula for adults with a diagnosis of HIV infection, AIDS, HIV-related illness, or other disease or condition, who are oral-fed, and who:

1. Require supplemental nutrition, demonstrate documented compliance with an appropriate medical and nutritional plan of care, and have a body mass index (BMI) under 18.5 as defined by the Centers for Disease Control, up to 1,000 calories per day; or
2. Require supplemental nutrition, demonstrate documented compliance with an appropriate medical and nutritional plan of care, have a body mass index (BMI) under 22 as defined by the

## Medical Policy: Enteral Nutrition

Policy Number: 10.01.03

Page: 12 of 12

Centers for Disease Control, and have a documented, unintentional weight loss of five percent or more within the previous six-month period, up to 1,000 calories per day; or

- Require total oral nutritional support, have a permanent structural limitation that prevents the chewing of food, and placement of a feeding tube is medically contraindicated.

NYRx, Medical Supply Codes Billable by a Pharmacy [Internet]. [accessed 2026Jan 09]. Available from: [https://www.emedny.org/ProviderManuals/Pharmacy/PDFS/Pharmacy\\_Procedure\\_Codes.pdf](https://www.emedny.org/ProviderManuals/Pharmacy/PDFS/Pharmacy_Procedure_Codes.pdf)

### PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.
- If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.

### POLICY HISTORY/REVISION

#### Committee Approval Dates

09/16/99, 02/28/01, 08/28/03, 10/28/04, 10/27/05, 10/26/06, 12/13/07, 08/28/08, 08/27/09, 08/26/10, 08/25/11, 08/23/12, 08/22/13, 08/28/14, 08/27/15, 08/25/16, 08/25/17, 02/22/18, 08/23/18, 02/28/19, 02/27/20, 02/25/21, 02/17/22, 02/16/23, 02/22/24, 02/20/25, 02/19/26

Date	Summary of Changes
02/19/26	<ul style="list-style-type: none"><li>Annual Review. In-line digestive enzyme cartridges statement updated to medically necessary when specific criteria are met.</li></ul>
02/20/25	<ul style="list-style-type: none"><li>Annual Review. Policy intent unchanged.</li></ul>
01/01/25	<ul style="list-style-type: none"><li>Summary of changes tracking implemented.</li></ul>
09/16/99	<ul style="list-style-type: none"><li>Original effective date</li></ul>