Guidelines for Medical Necessity Determination for Enteral Nutrition and Special Medical Formulas

This edition of Guidelines for Medical Necessity Determination (Guidelines) identifies the clinical information that MassHealth needs to determine medical necessity for enteral nutrition and special medical formulas. These Guidelines are based on generally accepted standards of practice, review of the medical literature, and federal and state policies and laws applicable to Medicaid programs.

Providers should consult MassHealth regulations (130 CMR 409.000: Durable Medical Equipment Services) and (130 CMR 450.000: Administrative and Billing Regulations), Subchapter 6 of the Durable Medical Equipment Manual, and the *MassHealth DME and Oxygen Payment and Coverage Guidelines Tool* for information about coverage, limitations, service conditions, and other prior-authorization (PA) requirements. The links to the regulations, subchapter 6, and the tool can be found in the reference section.

Providers serving members enrolled in a MassHealth-contracted accountable care partnership plan (ACPP), managed care organization (MCO), integrated care organization (ICO), senior care organization (SCO), or program of all-inclusive care for the elderly (PACE), should refer to the ACPP's, MCO's, ICO's, SCO's, or PACE's medical policies for covered services.

MassHealth requires PA for all enteral nutrition and special medical formulas. MassHealth reviews requests for PA on a case-by-case basis of medical necessity. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including member eligibility, other insurance, and program restrictions.

1 SECTION I. GENERAL INFORMATION

Enteral nutrition and special medical formulas are used in a home setting (a setting in which normal life activities take place) to meet or help meet the specialized nutrition needs of members with a medical condition that precludes the use of regular food, standard commercial formulas, and/or supplementation with commercially available food products to meet their nutritional needs for growth or weight maintenance. Medical conditions often requiring enteral nutrition or special medical formulas include fat malabsorption and/or malnutrition related to chronic conditions like ulcerative colitis or significant gastrointestinal dysmotility, inborn errors of metabolism such as phenylketonuria and urea cycle deficits, and IgE- and non-IgE-mediated formula intolerance. Other conditions, such as prematurity, may benefit from the use of formulas with higher content in calories and minerals, such as calcium, based on gestational age, birth weight, and post-natal age and growth.

Enteral nutrition and special medical formulas are nutrition provided via the gastrointestinal cavity by mouth (orally) or through a tube or stoma that delivers the nutrients to the gastrointestinal tract distal to the oral cavity. A member with malnutrition or the potential for developing malnutrition as evidenced by clinical indicators, the presence of chronic disease, or increased metabolic requirements due to impaired ability to ingest or absorb food adequately is considered to be at nutritional risk.

There are a variety of illnesses that result in fat malabsorption, including, but not limited to, cystic fibrosis (CF), chronic pancreatitis, lactose intolerance, celiac disease. CF is the leading cause of malabsorption and the primary illness addressed in digestive enzyme cartridge literature and studies.

A digestive enzyme cartridge contains the enzyme lipase and is designed to break down fats that patients with malabsorption syndromes and exocrine pancreatic enzyme deficiency are not able to digest. It has been approved by the FDA for adults and pediatric patients over 5 years old with fat malabsorption and is used during enteral feeds.

The digestive enzyme cartridge aids tube feeding by hydrolyzing fats from their triglyceride forms to absorbable fatty acids and monoglycerides such as omega-3-fats DHA (docosahexaenoic acid) and EPA (eicosapentaenoic acid).

Many people with CF have pancreatic insufficiency (PI) leading to poor growth and nutrition. Clinical evidence has established that good nutrition and, particularly, improved fat absorption, increase pulmonary function in patients with CF. Whether patients require enteral feeds (10-15% of patients with CF) or eat by mouth, those with PI require pancreatic enzyme replacement, or PERT. PERT is a combination of enzymes used to break down protein, carbohydrates and fats. Enzyme replacements should be given with each meal.

Patients who require overnight enteral tube feeds in addition to meals, require an alternative to PERT for the overnight tube feedings. PERT is not FDA- approved for continuous tube feeds, such as overnight feeding, in part because PERT requires multiple administrations and dosing is difficult. Digestive enzyme cartridges are the only FDA-approved alternative to PERT for tube feeding.

MassHealth considers approval for coverage of enteral nutrition and special medical formulas on an individual, case-by-case basis, in accordance with 130 CMR 409.000 and 450.204 and current clinical evidence.

2 SECTION II. CLINICAL GUIDELINES

A. CLINICAL COVERAGE FOR ENTERAL NUTRITION AND SPECIAL MEDICAL FORMULAS

MassHealth bases its determination of medical necessity for enteral nutrition, including digestive enzyme cartridges and special medical formula, on clinical data, including but not limited to, indicators that would affect the relative risks and benefits of the products. Medical need must be manifested by the presence of both a medical condition known to cause nutritional risk and evidence of nutritional and/or growth implications that are not amenable to the use of regular food or standard formulas. Applicable medical criteria include, but are not limited to, criteria 1-6 below.

1. The member has been diagnosed with one or more of the medical conditions below and meets the condition-specific criteria set forth below:
    a. An anatomic or metabolic condition that includes one or more of the following:
        i. anatomic structures of the gastrointestinal tract that interfere with digestion and absorption;
        ii. neurological disorders that impede swallowing or chewing;

iii. diagnosis of inborn errors of metabolism that require food products to be modified to be low in protein (for example, phenylketonuria (PKU), tyrosinemia, homocystinuria, maple syrup urine disease, propionic aciduria, and methylmalonic aciduria).

b. Allergies to cow's milk protein and soy infant formulas evidenced by the presence of any symptoms of conditions listed in Table A below while receiving breast milk, cow milk formula or soy infant formulas AND

i. documentation of allergy to cow's milk (breast milk or formula) as evidenced by improvement with elimination of dairy from the diet

ii. documentation of multiple protein intolerance with a successful trial of extensively hydrolyzed protein formula (i.e., Alimentum, Nutramigen, Pregestimil) or, if such trial failed, a successful trial of elemental amino acid- based formula (Enfamil PurAmino, Neocate, Elecare).

iii. Hydrolyzed and elemental amino acid formulas for infants up to 12 months may be initially prescribed by a primary care provider pending or consultation with a Pediatric Allergist or Pediatric Gastroenterologist.

iv. Hydrolyzed and elemental amino acid formulas for infants older than 12 months must be prescribed by a Pediatric Allergist or Pediatric Gastroenterologist.

See Section III.A. for how to submit a PA request and PA documentation requirements.

TABLE A: INFANTS: ALLERGIES TO COW'S MILK PROTEIN AND SOY FORMULAS

MEDICAL CONDITION	EVIDENCE OF NUTRITIONAL AND/OR GROWTH IMPLICATIONS
Severe atopic dermatitis in a child less than a year old	Formula may be prescribed by a primary care provider pending consultation with a Pediatric Allergist or Pediatric Gastroenterologist. The role of commercial formulas in causing the atopic dermatitis should be confirmed, such as by an immediate reaction after ingestion or improvement after a well-defined elimination diet. For children older than one year, a retrial of commercial food and any reevaluation should demonstrate continued evidence of food allergy.
IgE-mediated cow's milk protein allergy	1. Characterized by one or more of the following symptoms related to the ingestion of cow's milk protein: a. severe vomiting and abdominal pain within minutes to hours of food ingestion; b. severe diarrhea within six hours of food ingestion; c. pruritis or severe itching of the skin (localized or generalized); d. angioedema and urticaria; e. stridor, wheezing, or anaphylaxis. OR

IgE-mediated cow's milk protein allergy, cont.	2. Characterized by a non-urticarial rash or with a rash and a negative IgE to soy. 3. The child must fail trials of commercial formulas. For children older than one year, a retrial of commercial food and reevaluation should demonstrate continued evidence of food allergy.
Severe and persistent gastrointestinal irritability	1. For infants up to six months of age, characterized by: a. weight loss or lack of weight gain; b. presence of significant vomiting or gastrointestinal bleeding; c. failure of trials of commercial formula; and d. recommended use of specialized formula by a pediatric primary care provider pending consultation with a gastrointestinal specialist. 2. For infants from six to 12 months of age: a. demonstration that symptoms are significantly improved with the use of the requested medical formula; b. a retrial of commercial formula is unsuccessful; and c. continuation of special formula use is recommended by a pediatric gastrointestinal specialist. 3. For children older than one year of age, a retrial of commercial food and re-evaluation should demonstrate continued evidence of need for specialized formula.
Non-IgE mediated conditions associated with cow's milk allergy	For children older than one year of age, a retrial of commercial food and reevaluation should demonstrate continued evidence of food allergy, as evidenced by any of the following: 1. food protein-induced proctocolitis associated with blood streaked stools not caused by anal fissures, infection, or other common causes of bloody stools; 2. pulmonary hemosiderosis; 3. food protein-induced enterocolitis associated with malabsorption and failure to thrive; 4. food protein-induced enteropathy associated with malabsorption, failure to thrive, diarrhea, and vomiting; 5. esophageal eosinophilia and/or eosinophilic gastroenteritis, associated with malabsorption and dysmotility.

c. prolonged nutrient losses due to malabsorption syndromes or short-bowel syndromes such as or related to diabetes, celiac disease, cystic fibrosis, chronic pancreatitis, renal dialysis, draining abscess, or wounds;

d. evidence of weight loss during treatment with anti-nutrient or catabolic properties including, but not limited to, anti-tumor treatments, corticosteroids, and immunosuppressants;

e. evidence of increased metabolic and/or caloric needs and weight loss due to excessive burns, infection, trauma, prolonged fever, hyperthyroidism, or illnesses that impair caloric intake and/or retention; or

f. diagnosis of failure-to-thrive with increased caloric needs and impaired caloric intake and/or retention.

2. Evidence that the member's nutritional needs cannot be met by a regular food diet, standard, commercial formula or food products, or supplementation with commercially available products.

3. Therapeutic regimen of enteral nutrition and special medical formulas, whether orally or by tube feeding, in a member with a medically diagnosed condition that limits the full use of regular food.

4. The member has clinical signs and symptoms of impaired digestion, malabsorption, or nutritional risk, as indicated by one of the following:

   a. a medical condition that prohibits the ingestion of regular food

   b. a medical condition causes difficulty with swallowing and the inability to take nutrition by mouth

   c. evidence of weight loss with measurements on more than one consecutive occasion that presents actual, or potential for developing, malnutrition, despite oral and/or tube feeds as defined below:

      i. in adults and post-pubertal adolescents, showing involuntary or acute weight loss of greater than or equal to 10 percent of usual body weight during a three-to-six-month period, or body mass index (BMI) below 18.5 kg/m2; in members with chronic immobility for whom height is difficult to measure, another anthropometric method such as height associated with arm span or ratio of upper body to lower extremity length should be used;

      ii. in neonates, infants, and children, with

         (a) very low birth weight (VLBW <1500g) within the first three months of life corrected for prematurity even in the absence of gastrointestinal, pulmonary, or cardiac disorders;

         (b) a sustained decrease in weight or weight-for-height-for-age-and-gender across two or more major percentiles after having previously established a stable rate of growth (growth velocity);

         (c) a lack of weight gain, or weight gain less than two standard deviations below the age-appropriate mean (i.e., below the 2nd percentile), and not growing at a rate parallel to the growth curve in a three-month period for children under six months, or four-month period for children aged six to 12 months, and that does not reverse with instruction in appropriate diet for age;

         (d) no weight gain or slow rate of gain for six months for children older than one year, or documented weight loss that does not reverse with guidance in appropriate diet for age; or

(e) weight or weight-for-height less than two standard deviations below the mean for age and gender (i.e., below the second percentile) and not growing at a rate parallel to the growth curve;

(f) for individuals with genetic or other syndromes, where syndrome-specific growth charts are available, weight gain and growth are abnormally slow for the specific condition using the condition-specific growth chart;

OR

d. abnormal laboratory tests pertinent to the diagnosis.

5. Evidence of nutritional risk documented by a recent (within the past year) comprehensive medical history and physical examination and, if applicable, laboratory tests.
6. Evidence that enteral nutrition is essential in conditions that impair digestion or malabsorption, and for the management of surgical preparation or postoperative care.

B. CLINICAL COVERAGE: DIGESTIVE ENZYME CARTRIDGES

MassHealth bases its determination of medical necessity for digestive enzyme cartridge on clinical data, including, but not limited to, indicators that would affect the relative risks and benefits of the product. Medical need must be manifested by the presence of both a medical condition known to cause nutritional risk and evidence of nutritional and/or growth implications due to malabsorption syndromes. Applicable medical criteria include, but are not limited to, criteria 1- 3 below.

The member must:

1. be receiving overnight enteral feeds
2. have laboratory-proven pancreatic insufficiency and
3. have a proven response to digestive enzyme cartridge including, but not limited to, increased weight/BMI; significant improvement in gastrointestinal symptoms such as bloating or flatulence; or decreased diarrhea, dehydration, or hospitalizations due to gastrointestinal symptoms.

C. NONCOVERAGE

1. ENTERAL NUTRITION PRODUCTS

MassHealth pays providers only for medically necessary services (see 130 CMR 450.204). MassHealth does not consider enteral nutrition products to be medically necessary under certain circumstances. Examples of such circumstances include, but are not limited to, the following.

a. A medical history and physical examination have been performed and other alternatives comparable in effect and available to the member that are more conservative or less costly to MassHealth have been identified to minimize nutritional risk.

b. The member is underweight but is able to meet nutritional needs through the use of regular food consumption and/or commercially available caloric supplements.

c. Enteral nutrition products used as supplements to a normal or regular diet in a member showing no clinical indicators of nutritional risk.

d. The member has food allergies, lactose intolerance, or dental problems, but is able to meet his or her nutritional requirements through an alternative food source comparable in effect and available to the member that is more conservative or less costly to MassHealth.

e. Enteral nutrition products are to be used for diets or a weight-loss programs.

f. Enteral nutrition and special medical formulas and foods are requested solely because of food preference in the absence of a medical condition.

g. Enteral nutrition products for premature infants older than three months (age corrected for prematurity). Standard infant formulas for home use (in a setting in which normal life activities take place) are expected to be used for premature infants older than three months corrected age and whose weight growth is parallel to or growing faster than the appropriate growth curve for age.

h. Growth parameters are consistent with specialized condition-specific growth charts for members with genetic conditions.

i. Children who exhibit a normal growth rate parallel to the growth curve despite being small in weight and stature.

2. DIGESTIVE ENZYME CARTRIDGES

MassHealth does not consider digestive enzyme cartridges to be medically necessary under certain circumstances. Examples of such circumstances include, but are not limited to, the following.

Patients who do NOT:

a. have a diagnosis of Pancreatic Insufficiency (PI); and

b. require overnight enteral feedings.

3. SERVICES AVAILABLE AT NO COST TO MEMBERS

MassHealth does not pay for any health care or related services that are available at no cost to a member, including through any agency of the state (see 130 CMR 450.204, 503.007(B)(2), 517.008(B)(2)). MassHealth is the payor of last resort for certain formulas. This is because the Women, Infants and Children (WIC) Nutrition Program administered by the Massachusetts Department of Public Health has primary responsibility for the provision of "standard infant formula" to WIC-eligible MassHealth members. Accordingly, MassHealth does not cover medically necessary formula if there is an available alternative less costly to MassHealth, such as under the following circumstances:

1. the member is WIC-eligible;

2. the enteral nutrition product being requested is listed as a "standard infant formula" on the current list of formula covered by WIC; and

3. the formula is available in adequate amounts to the member through the WIC program.

Providers may visit www.mass.gov/WIC (reference "What can I buy with WIC checks?" WIC Formula List) to obtain the current WIC formula list.

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SECTION III: SUBMITTING CLINICAL DOCUMENTATION

A. HOW TO SUBMIT A PRIOR AUTHORIZATION REQUEST

All enteral nutrition, special medical formula and digestive enzyme cartridges require PA from MassHealth. Requests for PA for these products must be accompanied by clinical documentation that supports the medical necessity for the product(s) being requested and must be submitted to MassHealth in accordance with 130 CMR 409.418. As part of the PA request, the provider of durable medical equipment (DME) must obtain a written prescription and letter of medical necessity signed by the member's prescribing provider. The prescription and letter of medical necessity must meet the requirements at 130 CMR 409.416. The MassHealth Prescription and Medical Necessity Review Form for Enteral Nutrition Products should be used for this purpose. Any additional clinical documentation supporting medical necessity must be submitted with the PA request.

Providers are strongly encouraged to submit PA requests electronically, and all information pertinent to the request must be submitted through the LTSS Provider Portal at www.MassHealthLTSS.com or by completing a MassHealth Prior Authorization Request form and attaching the pertinent documentation. If submitting a non-electronic request, the PA-1 form and the MassHealth Prescription and Medical Necessity Review for Enteral Nutrition Products form are required; these forms and any supporting documentation should be mailed to the address on the back of the PA-1 form. Questions regarding portal access should be directed to the LTSS Provider Service Center by calling toll-free at (844) 368-5184.

When submitting PA requests for Community Case Management (CCM) members, all information related to the request should be submitted using the Provider Online Service Center (POSC) or by mail by completing a MassHealth Prior Authorization Request form (PA-1) and attaching the supporting documentation. If submitting a non-electronic request, the provider should mail the PA-1 form, and any supporting documentation, to the address on the back of the PA-1 form. Providers with any questions about POSC access may direct them to the MassHealth Customer Service Center, at 1-800-841-2900.

B. PRESCRIBERS

1. ENTERAL NUTRITION AND SPECIAL MEDICAL FORMULAS FOR INFANTS UP TO 12 MONTHS OLD

MassHealth requires that enteral nutrition and special medical formulas be prescribed by a pediatric primary care provider or pediatric subspecialist.

The initial prescription for hydrolyzed and elemental amino acid formulas may be prescribed by a pediatric primary care provider. Subsequent prescriptions may be submitted by a pediatric primary care provider with supporting documentation of consultation with a Pediatric Allergist or Pediatric Gastroenterologist.

2. ENTERAL NUTRITION AND SPECIAL MEDICAL FORMULAS FOR INFANTS OLDER THAN 12 MONTHS

Prescriptions for infants older than 12 months must be submitted by a Pediatric Allergist or Pediatric Gastroenterologist.

3. **DIGESTIVE ENZYME CARTRIDGES**

   For members with CF, PA requests must be supported by **a prescription or a letter of medical necessity** from a Pediatric Pulmonologist or Pediatric Gastroenterologist.

   For members with pancreatic insufficiency (PI) unrelated to CF, PA requests must be supported by **a prescription by a letter of medical necessity** from a Gastroenterologist.

C. **DOCUMENTATION OF MEDICAL NECESSITY FOR FORMULA**

Documentation of medical necessity for enteral formulas must include all of the following:

1. the primary diagnosis name and ICD-CM code specific to the medical condition causing the nutritional risk or disorder for which enteral nutrition products are requested;
2. if applicable, the secondary diagnosis name(s) and ICD-CM code(s) specific to the nutritional risk/disorder and comorbid condition(s) including the impact on nutrition and growth;
3. documentation of clinical signs and symptoms of impaired digestion, malabsorption, or nutritional risk, as indicated in Section II. A. Clinical Coverage of these Guidelines, including anthropometric measures (for example, height, weight, BMI, BMR, growth charts, and prognosis for children);
4. the most recent comprehensive medical history and physical exam;
5. documentation of risk factors for developing malnutrition;
6. laboratory tests sufficient to establish the diagnosis of malnutrition, inborn error of metabolism, or other testing related to the causal medical condition if applicable;
7. documentation of route of enteral nutrition and special medical formula treatment;
8. documentation of past and current treatment regimens; and
9. documentation of type and estimated duration of the need for enteral nutrition and special medical formula.

D. **DOCUMENTATION OF MEDICAL NECESSITY FOR DIGESTIVE ENZYME CARTRIDGES**

Documentation of medical necessity for digestive enzyme cartridges must include all of the following:

1. Documentation of pancreatic insufficiency, malabsorption, and/or failure to thrive, including relevant laboratory results.
2. Documentation of overnight enteral feeds. Provide the name of formula and rate and duration of feeds. The member must be prescribed a formula compatible with digestive enzyme cartridges. Formulas containing insoluble fibers can clog the cartridge, thus wasting the product and not providing the intended benefit.
3. Documentation of heights, weights and BMI for the previous year.
4. Growth charts for pediatric patients.
5. If the member has received digestive enzyme cartridges previously:
   a. documentation of weight/BMI and/or GI symptoms 6 months prior to beginning use of digestive enzyme cartridges,

b. for members currently using digestive enzyme cartridges, provide documentation of increase in weight/BMI and/or improvement in GI symptoms while using digestive enzyme cartridges

c. for members that have discontinued use of digestive enzyme cartridges, weights/BMIs and/or GI symptoms must be provided for the period of use.

6. Latest complete history and physical by prescribing physician
7. Relevant nutrition labs
8. For members with CF, the prescribing provider must be a Pulmonologist, Gastroenterologist, or an Endocrinologist specializing in the care of CF patients.
9. Members with non-CF malabsorption syndromes must provide items 2 through 7 above and the prescribing provider must be a gastroenterologist.

E. **DOCUMENTATION FOR NEW OR CONTINUED PRIOR AUTHORIZATION REQUEST**

A new or updated PA request for enteral nutrition and special medical formula must be submitted to continue use of enteral nutrition products before the expiration of the current PA.

Select References

1. Becker P, Carney LN, Corkins MR, Monczka J, Smith E, Smith SE, Spear BA, White JV; Academy of Nutrition and Dietetics; American Society for Parenteral and Enteral Nutrition. Consensus statement of the Academy of Nutrition and Dietetics/American Society for Parenteral and Enteral Nutrition: indicators recommended for the identification and documentation of pediatric malnutrition (undernutrition). Nutr Clin Pract. 2015 Feb; 30(1):147-61. doi: 10.1177/0884533614557642. Epub 2014 Nov 24. Accessed September 12, 2018.

2. Haymond M, Kappelgaard AM, Czernichow P, Biller BM, Takano K, Kiess W; Global Advisory Panel Meeting on the Effects of Growth Hormone. Early recognition of growth abnormalities permitting early intervention. Acta Paediatr. 2013 Aug; 102(8):787-96. doi: 10.1111/apa.12266. Accessed September 12, 2018.

3. Homen GJ. Failure to thrive: A practical guide. Am Fam Phy. 2016 Aug; 94(4):295-9. https://www.ncbi.nlm.nih.gov/pubmed/27548594. Accessed September 12, 2018.

4. Jaffe AC. Failure to Thrive: Current Clinical Concepts. Pediatr Rev. 2011 Mar 32(3):100. http://pedsinreview.aappublications.org/content/32/3/100 Accessed September 12, 2018.

5. Koletzko S, Niggemann B, Arato A, Dias JA, Heuschkel R, Husby S, Mearin ML, Papadopoulou A, Ruemmele FM, Staiano A, Schäppi MG, Vandenplas Y. Diagnostic approach and management of cow's-milk protein allergy in infants and children: ESPGHAN GI Committee practical guidelines. J Pediatr Gastroenterol Nutr. 2012 Aug; 55(2):221-9. doi: 10.1097/MPG.0b013e31825c9482.

6. Lodge CJ, Lowe AJ, Dharmage SC. Do hydrolyzed formulas reduce the risk of allergies? Br Med J.2016 Mar; 352:i1143 http://www.bmj.com/content/352/bmj.i1143. Accessed September 12, 2018.

7. Martinez JA, Ballew, MP. Infant Formulas. Pediatr Rev. 2011 May; 32(5):179. http://pedsinreview.aappublications.org/content/32/5/179. Accessed September 12, 2018.

8. MassHealth DME payment and coverage tool, https://www.mass.gov/service-details/masshealth-payment-and-coverage-guideline-tools

9. MassHealth DME regulations, https://www.mass.gov/regulations/130-CMR-409000-durable-medical-equipment-services

10. MassHealth Administrative and Billing regulations, https://www.mass.gov/regulations/130-CMR-450000-administrative-and-billing-regulations

11. MassHealth DME subchapter 6, https://www.mass.gov/guides/durable-medical-equipment-dme-manual

12. O'Connor N. Infant Formulas. Am Fam Physician. 2009 Apr 1; 79(7):565-570 https://www.aafp.org/afp/2009/0401/p565.html. Accessed September 12, 2018.

13. Olsen EM, Peterson J, Skovgaard AM, Weile B, Jorgenson T, Wright CM. Failure to Thrive: The prevalence and concurrence of anthropometric criteria in a general infant population. Arch Dis Child. 2007 Feb; 92(2):109-14. Epub 2006 Mar 10. https://www.ncbi.nlm.nih.gov/pubmed/16531456 Accessed September 12, 2018.

14. Vanderhoof J, Moore N, de Boissieu D. Evaluation of an amino acid–based formula in infants not responding to extensively hydrolyzed protein formula. J Ped Gastroenterol Nutr. 2016 Nov; 63(5):531–533. https://www.ncbi.nlm.nih.gov/pubmed/27526059. Accessed September 12, 2018.

15. Venter C, Brown T, Meyer R, Walsh J, Shah N, Nowak-Węgrzyn A, Chen TX, Fleischer DM, Heine RG, Levin M, Vieira MC, Fox AT. Better recognition, diagnosis and management of non-IgE-mediated cow's milk allergy in infancy: iMAP—an international interpretation of the MAP (Milk Allergy in Primary Care) guideline. Clin Transl Allergy. 2017; 7: 26. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5567723/. Accessed September 12, 2018.

16. Venter C, Brown T, Shah N, Walsh J, Fox AT. Diagnosis and management of non-IgE-mediated cow's milk allergy in infancy - a UK primary care practical guide. Clin Transl Allergy. 2013; 098773: 23. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3716921/. Accessed September 12, 2018.

17. Medical Necessity Guidelines: Enteral Nutrition, Digestive Enzyme Cartridges and Special Medical Formulas for Tufts Health Together and Tufts Health Unify Effective: January 20, 2021

ENZYME CARTRIDGE REFERENCES:

1. Freedman S; Orenstein ;, Black P; Brown P; McCoy K; Stevens J,; Grujic D and Clayton R. Increased Fat Absorption From Enteral Formula Through an In-line Digestive Cartridge in Patients With Cystic Fibrosis. JPGN Volume 65, Number 1, July 2017.

2. Stevens J; Wyatt, C; Brown P; Patel D; Grujic D; Freedman S. Absorption and Safety with Sustained Use of Relizorb Evaluation (ASSURE) Study in Patients with Cystic Fibrosis Receiving Enteral Feeds. J Pediatric Gastroent and Nutrition 2018. Oct:67(4) 527-532.

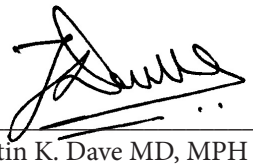
3. Iwanicki C; Bourma S; Nasr S. Use of immobilized lipase cartridge with overnight enteral feeds improves symptoms and result in weight gain in children with cystic fibrosis. Pediatr Pulmonol 2017; 52 (suppl 47); Abstract 612: 452-3.

4. Hendrix S; Flume P; Michel S; Jump C. Use of an in line digestive enzyme cartridge in pediatric patients. Pediatr Pulmonol 2017: 52 (suppl 47): Abstract 634: 461.

These Guidelines are based on review of the medical literature and current practice in the use of enteral nutrition products. MassHealth reserves the right to review and update the contents of these Guidelines and cited references as new clinical evidence and medical technology emerge.

This document was prepared for medical professionals to assist them in submitting documentation supporting the medical necessity of proposed treatment. Some language used in this communication may be unfamiliar to other readers; in this case, they should contact their health care provider for guidance or explanation.

Revised policy effective: June 15, 2022

Approved by: 

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Supersedes policy dated: March 1, 2011