



Subject: Formulas and Other Enteral Nutrition

Revision Date: 8/5

POLICY

According to the Ohio State University Faculty and Staff Health Plans Specific Plan Details Document (SPD), the medical benefit does not provide coverage for supplements (<50% intake), food, and commercially available milk/soy nutritional powder/liquids, including infant or adult formula, even if prescribed by a physician. Oral nutrition, supplements, and regular food products are not considered medical items and are the responsibility of the patient and/or caregiver. Therefore, exceptions to this benefit exclusion are only made in severe clinical conditions when specialized formula is required to avoid hospitalization according to the guidelines set forth in this policy.

APPLICABILITY

This policy applies to all OSU Health Plan (OSUHP) benefit plans

DEFINITIONS

Enteral Nutrition also called “tube feeding,” is a way of providing nutrition directly into the gastrointestinal (GI) tract through an enteral access device

Failure to Thrive describes a lack of adequate weight gain and/or growth in pediatric-aged patients.

Malabsorption is a term used for a wide range of disorders that affect your ability to absorb nutrients from your food.

Medical Food is a food which is formulated to be consumed or administered enterally under the supervision of a physician which is intended for the specific dietary management of a disease or condition for which distinctive nutrition requirements, based on recognized scientific principles, are established by the medical evaluation.

Monomeric (Elemental) Formula contains proteins that have been fully broken down into their individual amino acids. This makes them easier to digest and absorb, ideal for individuals with severe digestive problems or malabsorption.

Oligomeric (Semi-elemental) Formula contains proteins that have been partially broken down into smaller chains of amino acids, called peptides. This partial hydrolysis makes it easier to digest and absorb, especially for individuals with some digestive issues or impaired absorption.

Polymeric Formula is the most common type of formula and is designed for individuals with normal or near-normal digestive and absorptive function. They contain proteins, complex carbohydrates, and fats, similar to a regular diet.

Specialized Formula is designed for individuals with specific disorders, diseases, or medical conditions that require unique nutritional support that cannot be met with standard polymeric formulas or food. Some require a prescription, although others may be available in the grocery store. They contain added, subtracted, or altered nutrients to address specific needs, such as:

- Partially or extensively hydrolyzed proteins for easier digestion.
- Modified amino acid profiles for metabolic disorders.
- Higher calorie and nutrient density for premature infants.

Standard (Commercially Available) Formula is intended for the general population and provides complete nutrition for individuals without complex medical conditions. They are polymeric formulations and are widely available in grocery stores. Usually, they are cow milk or soy-based formulas.

POLICY

OSU Health Plan considers specialized medical formula medically necessary for covered persons at nutritional risk when all of the following criteria are met:

- The formula is the predominant source of the covered person's nutritional intake (i.e., > 50% of the daily caloric intake) as evidenced by one of the following:
 - Covered person is under the age of one year; or
 - Covered person is over the age of one year and a nutritionist evaluation is provided that includes the following information:
 - Daily caloric needs; and
 - Daily calorie intake from specialized formula; and
 - Documentation that nutritional needs cannot be met through regular food or supplementation with commercially available nutritional supplements.
- The covered person meets criteria for one or more of the following covered conditions:
 - Atopic Dermatitis:
 - Initial Request:
 - Infant is under 12 months old; and
 - There is a well-documented role of both cow-milk-based and soy-based formula in causing the atopic dermatitis (e.g., an immediate reaction after ingestion or a well-defined elimination diet); and
 - There is an allergist evaluation confirming the formula induced atopic dermatitis.

- Subsequent request(s):
 - Nutritionist and Allergist evaluations required documenting the child continues to experience severe symptoms that cannot be resolved through use of regular food or commercially available supplements.
- Bloody Stools (non-IgE mediated):
 - Diagnoses include (not all-inclusive):
 - Food protein-induced proctocolitis
 - Food protein-induced enteropathy
 - Food protein-induced enterocolitis
 - Initial request:
 - Infant is under 12 months old; and
 - Bloody stools are documented by guaiac card testing or there is visible blood in stools; and
 - Other etiologies, such as anorectal fissure or infection/inflammatory colitis, have been excluded by history and exam, and when applicable, further testing and serial guaiacs; and
 - The bloody stools occur while using cow-milk-based formula or breast-feeding and eliminating dairy resolved the infant's symptoms.
 - Subsequent request(s):
 - Nutritionist and Gastroenterology evaluations required documenting the child continues to experience severe symptoms that cannot be resolved through use of regular food or commercially available supplements.
- Eosinophilic Esophagitis:
 - Eosinophilic esophagitis is documented by endoscopy and biopsy; and

- The covered person is closely followed by a gastroenterologist, a nutritionist, and an allergist (if indicated); and
- There is high suspicion that the diagnosis is caused by milk and soy exposure, as evidenced by one or more of the following:
 - Elimination diet; or
 - IgE antibody testing; or

If all of the above criteria are met, the requested special medical formula does not need to constitute > 50% of the daily caloric intake since the goal is to provide not only calories, but also nutrients that cannot be obtained through regular foods/allergy-free-vitamins in these highly allergic covered persons.

○ Failure to Thrive:

- Initial request:
 - Weight loss meets one of the following:
 - Infants and children ages 0 – 24 months old:
 - Decrease over time of two or more major weight for age percentile lines; or
 - Weight < 5th percentile for age when corrected for prematurity; or
 - Weight for length < 10th percentile.
 - Children and adolescents ages 2 – 18 years old:
 - BMI for age < 5th percentile
 - Adults:
 - An involuntary weight loss of > 10 percent of usual body weight during a three-to-six-month period; or
 - BMI < 5th percentile or 18.5 kg/m²
 - Cystic Fibrosis (any age):

- Weight loss; and
 - Weight for length/height or BMI < 25th percentile.
- Renal Dialysis (any age):
 - Weight loss and a BMI of < 22; or
 - Serum albumin to < 4 g/dl
- Documentation includes clinical history, physical exam, and supportive testing to evaluate potential treatable causes of growth failure; and
- A written plan of care for regular monitoring of signs and symptoms to detect improvement in the covered person's condition; and
- Covered person has failed to improve with use of regular food or commercially available formulas as evidenced by the following:
 - For formula fed infants, a failure of both cow-milk-based and soy-based formula trials; or
 - For breastfed infants, lactation consultation required to evaluate other causes of weight loss; or
 - For covered persons over one year of age:
 - A detailed dietary/feeding history with calorie counts; and
 - Failed trial of supplementation with other commercially available foods and nutritional supplemental foods (e.g., Carnation Instant Breakfast, food thickeners, butter or cream added to prepared foods, etc.); and
 - Relevant specialist evaluation(s), such as gastroenterology, feeding/swallowing specialist, or other specialist evaluations; and

- Subsequent request(s):
 - Nutritionist and Gastroenterology evaluations required documenting the child continues to experience severe symptoms that cannot be resolved through use of regular food or commercially available supplements.
- Gastroesophageal Reflux Disease (GERD):
 - Initial request:
 - Infant is under 9 months old; and
 - Medical records from a Gastroenterologist or Pediatrician document diagnosis of GERD as evidenced by all of the following:
 - Regurgitation is associated with complications (e.g., blood in regurgitated foods); and
 - Nutritional compromise (e.g., weight loss, lack of weight gain) due to insufficient caloric intake or formula refusal.
 - Infant's symptoms have failed to improve after a trial of both cow- milk-based and soy-based formulas or a maternal elimination diet; and
 - Infant's symptoms have failed to improve with thickened feeds.
 - Subsequent request(s):
 - Infant is under 12 months old:
 - Medical records document significant improvement of the infant's symptoms with the requested specialized formula; and
 - If infant is over 9 months old, a failed retrial of both cow- milk-based and soy-based formula, each for 4-5 days is required.
 - Child is over one year old:
 - Nutritionist and Gastroenterology evaluations required documenting the child continues to

experience severe symptoms causing weight loss that cannot be resolved through use of regular food or commercially available supplements.

○ Gastrointestinal Irritability:

▪ Initial request:

- Infant is under 6 months old; and
- Symptoms are severe and persistent, causing weight loss or lack of weight gain; and
- Infant failed trials of cow-milk-based and soy-based formula, each lasting at least 4-5 days. If breast-fed, an appropriate maternal elimination should be performed without resolution of symptoms.

▪ Subsequent request(s):

- Infant is under 12 months old:
 - Documentation that the symptoms significantly improved with the use of the requested specialized formula; and
 - A failed retrial of cow-milk-based and soy-based formula, each lasting 4-5 days.
- Child is over 12 months old:
 - Nutritionist and Gastroenterology evaluations required documenting the child continues to experience severe symptoms that cannot be resolved through use of regular food or commercially available supplements.

○ IgE Mediated Food Allergy:

▪ Initial request:

- Infant is under 12 months old; and
- There is high suspicion that the diagnosis is caused by milk and soy exposure, as evidenced by one or more of the following:

- IgE antibody testing; or
 - Rash with cow-milk based formula; or
- Subsequent request(s):
 - Nutritionist and Allergist evaluations required documenting the child continues to experience severe symptoms that cannot be resolved through use of regular food or commercially available supplements.
- Inborn Errors of Metabolism:
 - Diagnoses include:
 - Homocystinuria
 - Maple Syrup Urine Disease
 - Methylmalonic Acidemia
 - Other Organic Acidemias
 - Phenylketonuria (PKU)
 - Propionic Acidemia
 - Tyrosinemia
 - Urea Cycle Disorders
 - Documentation from specialist supporting diagnosis is provided.
- Ketogenic Formula for Uncontrolled Seizures:
 - Initial Request:
 - Documentation of uncontrolled seizures refractory to standard anti-seizure medications; and
 - Covered person requires a formula/liquid diet to maintain weight for age because of inability to tolerate solid foods due to developmental or other issues.
 - Subsequent Request(s):

- Specialist evaluations required documenting the covered person continues to experience severe symptoms that cannot be resolved through use of regular food or commercially available supplements.
- Malabsorption:
 - Initial request:
 - Food protein-induced enteropathy or enterocolitis:
 - Infant is under 12 months old; and
 - Diagnosis is confirmed by a gastroenterologist; and
 - Symptoms occurred while using cow-milk-based formula or breast-feeding and eliminating dairy resolved them.
 - Other malabsorption disorders:
 - Diagnoses include:
 - Crohn's Disease
 - Ulcerative Colitis
 - Gastrointestinal motility disorders
 - Chronic intestinal pseudo-obstruction
 - Cystic fibrosis
 - Diagnosis is confirmed by appropriate specialist (e.g., gastroenterology) and applicable testing; and
 - Nutritional compromise is documented by weight loss, lack of weight gain, or other nutritional deficiency; and
 - Symptoms cannot be resolved using regular food or commercially available formula, as evidenced by one of the following:
 - For formula-fed infants and children, both cow- milk-based and soy-based formula trials have failed; or

- For older children and adults, supplementation with commercially available foods and nutritional supplements (e.g., Carnation Instant Breakfast, food thickeners, butter or cream added to prepared foods, etc.) has failed.
 - Subsequent request(s):
 - Food protein-induced enteropathy or enterocolitis and other malabsorption disorders:
 - Nutritionist and Gastroenterology evaluations required documenting the child continues to experience severe symptoms that cannot be resolved through use of regular food or commercially available supplements.
 - Prematurity:
 - Infant is under 3 months old; and
 - One of the following criteria are met:
 - Birth weight was 1500 grams or less and hospital discharge weight was less than the 10th percentile for age when corrected for prematurity; or
 - Intolerance to cow-milk-based formula due to another covered condition (trial of soy-based formula is not required)
- The specialized formula will be given via the least invasive route appropriate for the covered person's clinical condition:
 - Oral; or
 - Enteral: Medical records document a permanent (90 days or more) non-function or disease of the structures that normally permit food to reach the digestive tract; or
 - Parenteral: Severe pathology of the alimentary tract which does not allow absorption of sufficient nutrients to maintain weight and strength commensurate with the patient's general condition.
- The following documentation is provided for review:

- Medical records documenting the covered condition (including applicable specialist consultations and related testing); and
- Growth charts or BMI depending on age; and
- Cow-milk-based and soy-based formula trial when applicable (including date span of each trial and reason for failure); and
- Nutrition consultation for covered persons over 12 months old; and
- Completed OSU Health Plan Formula Request Form

Digestive Enzyme Cartridge

An in-line digestive enzyme cartridge (e.g., Relizorb™) for use with enteral tube feeding is considered medically necessary for the treatment of exocrine pancreatic insufficiency (such as due to complications of diabetes, cystic fibrosis, pancreatitis, pancreatectomy, celiac disease, Crohn's disease, ulcerative colitis, or congenital malformations of the pancreas) when the covered person meets criteria for enteral nutrition. A digestive enzyme cartridge (e.g., Relizorb™) for ANY other indication is considered experimental, investigational, or unproven.

Examples of Specialized Medical Formula:

- Alfamino: Infants with multiple food allergies
- Alimentum: Infants with food allergies, protein, or fat malabsorption
- CaminoPro: Children with Phenylketonuria (PKU)
- Compleat Peptide: Adults and children with malabsorption
- Elecare: Children with malabsorption, severe protein allergy
- Enfacare: Premature infants with low birth weight
- Fortini: Infants with failure to thrive (FTT)
- Impact Peptide 1.5: Critically ill adults and children (e.g., ventilator)
- Kate Farms Peptide: Adults and children with malabsorption

- KetoCal: Adults and children with epilepsy
- Neocate: Children with malabsorption, severe protein allergy
- Neocate One: Children with malabsorption, severe protein allergy
- NeoSure: Premature infants
- Nepro: Adults and children on dialysis
- Novasource Renal: Adults and children on dialysis or with fluid restrictions due to chronic kidney disease
- Nutramigen: Infants with food allergies
- Peptamen: Children with malabsorption
- Periflex: Children with phenylketonuria (PKU)
- PhenylAde: Children and adults with phenylketonuria (PKU)
- Phenyl-free: Children with phenylketonuria (PKU)
- PKU start: Infants with phenylketonuria (PKU)
- Portagen: Infants with fat malabsorption
- Pregestimil: Infants with food allergies, protein, or fat malabsorption
- ProPeptide for Kids: Children with malabsorption
- Puramino: Children with severe protein allergy
- Suplena: Nondialyzed people with chronic kidney disease and on a protein-restricted diet
- Tolerex: Adults and children with severely impaired gastrointestinal function
- Vivonex: Children with malabsorption, severe protein allergy

PROCEDURES

When the above criteria are met, and documentation is submitted on the appropriate request

form, specialized medical formula will be approved.

PRIOR AUTHORIZATION

Prior authorization is required for all oral and enteral nutrition including special medical formulas (i.e., premature transitional formulas, extensively hydrolyzed formulas, amino acid-based formulas, ketogenic formulas, and metabolic specific formulas).

Coverage requests must include pertinent clinical notes and be submitted on the appropriate request form (available at <https://osuhealthplan.com/health-plan-tools/forms-policies>).

EXCLUSIONS

The OSU Health Plan does not cover:

1. Enteral nutrition including infant formula for indications not listed above.
2. Enteral nutrition including infant formulas when a medical history or physical examination has not been completed, and/or there is no documentation that supports the need for enteral nutrition products.
3. Enteral nutrition, including infant formulas when a medical history and physical examination have been performed, and other possible alternatives have been identified to minimize the covered persons' nutritional risk.
4. Enteral nutrition including infant formulas when the covered person is underweight but has the ability to meet nutritional requirements with regular food consumption.
5. Enteral nutrition including infant formulas when the covered person has food allergies or dental problems but has the ability to meet his or her nutritional requirements through an alternative store-bought food source.
6. Nutritional and/or food supplements (e.g., Boost and Ensure)
7. Commercially available infant or soy formulas (Similac, Similac Advance, Compleat,

Enfamil, Lipil, Enfamil, Kate Farms, Gentlease, Lipil, Lacto Free, Parent's Choice and Carnation Good Start, Isomil, Pediasure, Prosobee, Similac Soy or Carnation Soy)

8. Formula or food products used for dieting or a weight-loss program
9. Banked breast milk
10. Food for a ketogenic diet when dietary needs can be met with regular, store-bought food
11. Dietary or food supplements, including fortifiers (e.g., Duocal, Benecalorie)
12. Food thickeners
13. Supplemental high protein powders and mixes
14. Lactose free foods, or products that aid in lactose digestion
15. Gluten-free products
16. Baby food
17. Oral vitamins and minerals
18. Medical foods (e.g., Foltx, Metanx, Cerefolin, probiotics such as VSL#3) including FDA- approved medical foods obtained via prescription.
19. Solutions not requiring a doctor's prescription (e.g., Ensure and Osmolyte)
20. Regular grocery products (including formulas made from regular grocery products, such as Real Food Blends)
21. Any supplements or formula intended for weight loss or treatment of anorexia or other eating disorders
22. Requests due to food preferences, loss of appetite, or non-compliance with specialized diet
23. Storage unit (e.g., refrigerator)
24. Relizorb™ (digestive enzyme cartridge) for the treatment of malabsorption related to graft-versus-host disease
25. More than two in-line digestive enzyme cartridges per day (Relizorb™)

Unless mandated by state or federal law, OSU Health Plan does not cover standard commercial formulas (e.g., Boost, Carnation Good Start, Carnation Soy, Compleat, Enfamil, Ensure, Isomil,

Pediasure, Prosobee Similac, Similac Soy), food supplements, food fortifiers, or food thickeners.

CODES

Codes that support medical necessity include, but are not limited to the following:

CODE	DESCRIPTION
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, including proteins, fats, carbohydrates, vitamins 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

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