Clinical Review Criteria Related to Formula and Enteral Nutrition:

1. **Criteria for Approval**

A. Minuteman Health (MHI) considers Formulas and Enteral Nutrition medically necessary when the following criteria are met:

I. The member presents clinical signs and symptoms of impaired digestion, malabsorption, or nutritional risk, as indicated by the following anthropometric measures:

a. Weight loss that presents actual, or potential for developing, malnutrition as defined below:

i. In *adults*, 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

ii. In *neonates, infants,* and *children*, showing:

- Very low birth weight (LBW <1500g) even in the absence of gastrointestinal, pulmonary, or cardiac disorders
- A lack of weight gain, or weight gain less than two standard deviations below the age appropriate mean in a one-month period for children under six months, or two- month period for children aged six to twelve months
- No weight gain or abnormally slow rate of gain for three months for children older than one year, or documented weight loss that does not reverse promptly with instruction in appropriate diet for age;

OR

- Weight for height less than the 10th percentile

b. **and** abnormal laboratory tests pertinent to the diagnosis.

II. **and** the risk factors for actual or potential malnutrition have been identified and documented. Such risk factors include, but are not limited to, the following:

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a. Anatomic structures of the gastrointestinal tract that permanently impair digestion and absorption (Permanence is defined as expected to exceed three months or ninety days.)

OR

b. Neurological disorders that impair swallowing or chewing,

OR

c. The member has an inborn error of metabolism and inherited metabolic disease when prescribed by a licensed health care provider for the following diagnosis:

i. phenylketonuria (PKU)

ii. tyrosinemia

iii. homocystinuria

iv. maple syrup urine disease

v. propionic aciduria

vi. methylmalonic aciduria in a Dependent child

vii. protection of an unborn fetus of a pregnant member with PKU

viii. histidinemia

ix. cystinosis

x. Hartnup disease

xi. glutaric academia

OR

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d. The member has increased metabolic and/or caloric needs due to excessive burns, infection, trauma, prolonged fever, hyperthyroidism, or illnesses that impair caloric intake and/or retention; failure-to-thrive diagnosis that increases caloric needs while impairing caloric intake and/or retention;

OR

e. Treatment with anti-nutrient or catabolic properties (for example, anti-tumor treatments, corticosteroids, immunosuppressants, etc.);

OR

f. A failure-to-thrive diagnosis that increases caloric needs while impairing caloric intake and/or retention

g. The member has prolonged nutrient losses due to malabsorption or caused by any of the following:
   i. Crohn's disease
   ii. tropical sprue
   iii. celiac disease
   iv. pancreatic insufficiency
   v. pancreatitis
   vi. cystic fibrosis
   vii. post-gastrectomy or post-intestinal resection malabsorption
   viii. ulcerative colitis
   ix. short-bowel syndrome
   x. radiation enteritis
   xi. parenchymal liver disease
   xii. cholestatic liver disease
   xiii. Whipple's disease
   xiv. giardiasis
   xv. lymphangiectasia
   xvi. renal dialysis
   xvii. draining abscess or wounds
   xviii. diabetes

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h. Specialized infant formula
   i. Intolerance or allergy to standard milk-based or soy infant formulas (for example, diarrhea, bloody stool, excessive gas, abdominal pain, severe GERD, severe eczema) that have improved with a trial of specialized formula;
   ii. At least two different commercial infant formulas - one cow based and one soy based - must be trialed and have failed. (Infants transitioning from breast milk with evidence of allergy symptoms resolving after maternal elimination diet need to trial one product.)
   iii. If the above criteria are met, a 4-week trial of hydrolyzed formula will be approved.
   iv. After the trial, formula will be approved up to 12 months of age with documentation that trial was successful in reducing the episodes of vomiting.
   v. If symptoms continue beyond 12 months of age, the member must have a GI consult prior to approving further formula.

III. **and** enteral nutrition is indicated as the primary source of nutritional support essential for the management of risk factors that impair digestion or malabsorption, and for the management of surgical preparation or postoperative care.

a. New Hampshire only:

   i. **Impaired absorption of nutrients caused by disorders affecting the absorptive surface, functional length, or motility of the gastrointestinal tract:** physician must issue a written order stating that the enteral formula is needed to sustain life, is medically necessary, and is the least restrictive and most cost effective means for meeting the needs of the patient.

   ii. **Inherited diseases of amino acids and organic acids**: MHI covers nonprescription enteral formulas and food products; physician must issue a written order stating that the enteral formula is needed to sustain life, is medically necessary, and is the least restrictive and most cost effective means for meeting the needs of the patient.

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2. What is Not Covered

A. A medical history and physical examination have been performed and other possible alternatives have been identified to minimize nutritional risk.

B. The member is underweight but has the ability to meet nutritional needs through the use of regular food consumption.

C. Enteral products are 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 has the ability to meet his or her nutritional requirements through an alternative food source.

E. Enteral products are to be used for dieting or a weight-loss program.

F. No medical history or physical examination has been taken and there is no documentation that supports the need for enteral nutrition products.

G. New Hampshire only

I. Dietary supplements

II. Special infant formulas (such as Nutramigen®, Elecare®, and Neocate®)

III. Vitamins and/or minerals taken orally to replace intolerable foods, supplement a deficient diet, or provide alternative nutrition for conditions such as:

a. Hypoglycemia

b. Allergies

c. Excessive weight

d. Gastrointestinal disorders

The items above are not covered even if they are required to maintain weight or strength.

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3. Required Documentation

A. Primary diagnosis specific to the nutritional disorder for which formula or enteral nutrition products are requested

I. clinical signs and symptoms, including anthropometric measures (for example, height, weight, BMI, BMR, growth charts, and prognosis for children);

II. comprehensive medical history and physical exam

III. risk factors for developing malnutrition

IV. laboratory tests sufficient to establish the diagnosis of malnutrition

V. route of enteral nutrition treatment

VI. documentation of past and current treatment regimens **and;**

VII. type and estimated duration of the need for enteral nutrition products

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REFERENCES:

The Pediatric Gastroesophageal Reflux Clinical Practice Guidelines: Joint Recommendations of the North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition (NASPCHAN) and the European Society for Pediatric Gastroenterology, Hepatology, and Nutrition (ESPGHAN) Pediatric Gastroesophageal Reflux Clinical Practice Guidelines, 2009. (Last Accessed 2/25/14)

American Academy of Pediatrics, policy statement, hypoallergic infant formulas. Article from Pediatrics, Official Journal of American Academy of Pediatrics, Vol. 106, pp 346-349. (Last Accessed 2/25/14)

MassHealth Guidelines for Medical Necessity Determination for Enteral Nutrition Products, @ Mass.Gov. Updated 2011. (Last Accessed 2/25/14)

New Hampshire RSA 415:18-e

Massachusetts General Law M.G.L. 176G Section 4D

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