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 the 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.

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 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.
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: Durable Medical Equipment Services and 450.204: Medical Necessity and current clinical evidence.

SECTION II: CLINICAL GUIDELINES

A. CLINICAL COVERAGE

MassHealth bases its determination of medical necessity for enteral nutrition 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 in 1.a through 1.f and meets the condition-specific criteria set forth below:
   a) An anatomic or metabolic condition that includes
      i. anatomic structures of the gastrointestinal tract that impair digestion and absorption;
      ii. neurological disorders that impair swallowing or chewing; and
      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) allergy to cow’s milk protein and soy infant formulas as manifested by one or more of the conditions listed in Table A that occurs while given a cow’s milk formula or breast milk with documented improvement from elimination of dairy from the diet and a successful trial of extensively hydrolyzed protein formula or, if such a trial failed, then a successful trial of amino-acid based formula. Each of the following must be present:
      i. one or more of the conditions listed in Table A (page 6);
      ii. documented allergy to cow’s milk;
      iii. documented soy formula intolerance;
      iv. documented multiple protein intolerance;
      v. the primary source of nutrition being 100% hydrolyzed amino acids nutritional formula; and
      vi. the 100% hydrolyzed amino acids nutritional formula being recommended by a Pediatric Allergist, Pediatric Pulmonologist, or Pediatric Gastroenterologist.
   c) prolonged nutrient losses due to malabsorption syndromes or short-bowel syndromes such as or related to diabetes, celiac disease, 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 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 the use of regular food; standard, commercial formula and food products; or supplementation with commercially available products.

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

4. The member presenting clinical signs and symptoms of impaired digestion, malabsorption, or nutritional risk, as indicated by the following:
   a) The member cannot ingest regular food because of a medical condition; or
   b) The member receives all nutrition via tube feeds because of a medical condition resulting in difficulty swallowing and the inability to take nutrition by mouth; or
   c) The member receives nutrition either orally or both through oral and tube feedings and has evidence of weight loss with measurements on more than one consecutive occasion that presents actual, or potential for developing, malnutrition 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, with consideration for measurement of BMI in members with chronic immobility for whom height is difficult to measure by using another anthropometric method such as height associated with arm span or ratio of upper body to lower extremity length;
      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 abnormally slow rate of gain for six months for children older than one year, or documented weight loss that does not reverse with instruction 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;
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. A recent (within the past year) comprehensive medical history and a physical examination and, if applicable, laboratory tests having been conducted to detect factors contributing to nutritional risk.

6. Enteral nutrition 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.

B. NONCOVERAGE

MassHealth pays providers only for medically necessary services (see 130 CMR 450.204: Medical Necessity). 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.

1. 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.

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

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

4. 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 comparable in effect and available to the member that is more conservative or less costly to MassHealth.

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

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

7. Enteral nutrition products for premature infants older than three months of age. 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 of age (corrected for prematurity) and whose weight growth is parallel to or growing faster than the appropriate growth curve for age.

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

9. Children who are small, but exhibit a normal growth rate parallel to the growth curve.

In addition, 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: Medical Necessity, 503.007(B)(2), 517.008(B)(2)). With respect to formula, MassHealth is the payor of last resort for
certain formulae. 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 consider formula to be medically necessary 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 formulas 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.

SECTION III: SUBMITTING CLINICAL DOCUMENTATION

A. All enteral nutrition and special medical formula 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 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.

B. Documentation of medical necessity must include all of the following:

1. the primary diagnosis name and ICD 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 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.

C. 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.

**Table A**

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<tr>
<th>Diagnosis Or Symptoms</th>
<th>Description</th>
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<tr>
<td>Severe atopic dermatitis in a child less than a year old</td>
<td>Must be diagnosed by an allergist or other appropriate specialist, and role of commercial formulas in causing the atopic dermatitis 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.</td>
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| 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
   2. Characterized by a non-urticarial rash or with a rash and a negative IgE to soy. The child must fail trials of commercial formulas. For children older than a year, a retrial of commercial food and reevaluation should demonstrate continued evidence of food allergy. |
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<th>Diagnosis Or Symptoms</th>
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<td>Severe and persistent gastrointestinal irritability</td>
<td>1. For infants up to six months of age, characterized by:</td>
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<td>a. weight loss or lack of weight gain;</td>
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<td>b. presence of significant vomiting or gastrointestinal bleeding;</td>
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<td>c. failure of trials of commercial formula; and</td>
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<td>d. recommended use of specialized formula by a gastrointestinal specialist.</td>
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<td>2. For infants from six to 12 months:</td>
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<td></td>
<td>a. demonstration that symptoms are significantly improved with the use of the requested special medical formula;</td>
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<td>b. a retrial of commercial formula is unsuccessful; and</td>
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<td></td>
<td>c. continuation of special formula use is recommended by a gastrointestinal specialist.</td>
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<td></td>
<td>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.</td>
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<tr>
<td>Non-IgE mediated conditions</td>
<td>For children older than one year of age, a retrial of commercial food and reevaluation should demonstrate continued evidence of food allergy:</td>
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<td>associated with cow's milk allergy</td>
<td>1. food protein-induced proctocolitis associated with blood streaked stools not caused by anal fissures, infection, or other common causes of bloody stools;</td>
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<td>2. pulmonary hemosiderosis;</td>
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<td>3. food protein-induced enterocolitis associated with malabsorption and failure to thrive;</td>
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<td>4. food protein-induced enteropathy associated with malabsorption, failure to thrive, diarrhea, and vomiting; and</td>
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<td>5. esophageal eosinophilia and/or eosinophilic gastroenteritis, associated with malabsorption and dysmotility.</td>
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Select References


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. 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 the proposed treatment, products, or services. Some language used in this communication may be unfamiliar to other readers; in this case, contact your healthcare provider for guidance or explanation.

Revised policy effective: 07/17/2019

Approved by: ________________________________
Jill D. Morrow-Gorton, MD, MBA
Acting Chief Medical Officer, MassHealth

Supersedes policy dated: March 1, 2011