



# Guidelines for Medical Necessity Determination for Enteral Nutrition Products

These Guidelines for Medical Necessity Determination (Guidelines) identify the clinical information that MassHealth needs to determine medical necessity for enteral nutrition products. 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 at 130 CMR 409.000 and 450.000, 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 requirements. Providers serving members enrolled in a MassHealth-contracted managed care organization (MCO) should refer to the MCO's medical policies for covered services.

MassHealth requires prior authorization for all enteral nutrition products. MassHealth reviews requests for prior authorization 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 is defined as nutrition requirements that are provided via the gastrointestinal cavity by mouth (orally) or through a tube or stoma that delivers the nutrients distal to the oral cavity. A member is considered to be at nutritional risk if he or she has actual, or 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. MassHealth considers approval for coverage of enteral nutrition products on an individual, case-by-case basis, in accordance with 130 CMR 409.000 and 450.204.

## Section II: Clinical Guidelines

### A. Clinical Coverage

MassHealth bases its determination of medical necessity for enteral nutrition products on clinical data, including but not limited to, indicators that would affect the relative risks and benefits of the products. These criteria include, but are not limited to, the following.

1. Enteral nutrition, whether orally or by tube feeding, is used as a therapeutic regimen to prevent or treat serious disability, or to prevent death, in a member with a medically diagnosed condition that precludes the full use of regular food.
2. 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/m<sup>2</sup>;
    - ii. in *neonates, infants, and children*, showing
      - (a) very low birth weight (VLBW <1500g) even in the absence of gastrointestinal, pulmonary, or cardiac disorders;



- (b) 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 12 months;
                  - (c) 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
                  - (d) weight for height less than the 10<sup>th</sup> percentile; and
- b. abnormal laboratory tests pertinent to the diagnosis.
3. The risk factors for actual or potential malnutrition have been identified and documented. Such risk factors include, but are not limited to, the following:
  - a. anatomic structures of the gastrointestinal tract that impair digestion and absorption;
  - b. neurological disorders that impair swallowing or chewing;
  - c. diagnosis of inborn errors of metabolism that require food products modified to be low in protein (for example, phenylketonuria (PKU), tyrosinemia, homocystinuria, maple syrup urine disease, propionic aciduria, and methylmalonic aciduria);
  - d. 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;
  - e. prolonged nutrient losses due to malabsorption syndromes or short-bowel syndromes, diabetes, celiac disease, chronic pancreatitis, renal dialysis, draining abscess or wounds, etc.;
  - f. treatment with anti-nutrient or catabolic properties (for example, anti-tumor treatments, corticosteroids, immunosuppressants, etc.);
  - g. increased metabolic and/or caloric needs due to excessive burns, infection, trauma, prolonged fever, hyperthyroidism, or illnesses that impair caloric intake and/or retention; or
  - h. a failure-to-thrive diagnosis that increases caloric needs while impairing caloric intake and/or retention.
4. A recent (within the past year) comprehensive medical history and a physical examination and, if applicable, laboratory tests have been conducted to detect factors contributing to nutritional risk
5. 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.

## B. Noncoverage

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.

- 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.
- 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.

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, 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](http://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 products require prior authorization from MassHealth. Requests for prior authorization for enteral nutrition products must be accompanied by clinical documentation that supports the medical necessity for the enteral nutrition 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 prior authorization request. Providers are strongly encouraged to submit PA requests electronically, and all information pertinent to the request must be submitted using the Provider Online Service Center or by completing a MassHealth Prior Authorization Request form (PA-1) and attaching the pertinent documentation. Questions about POSC access should be directed to MassHealth Customer Service at 1-800-841-2900.
- B.** Documentation of medical necessity must include all of the following:
1. the primary diagnosis name and ICD-CM code specific to the nutritional disorder for which enteral nutrition products are requested;
  2. the secondary diagnosis name and ICD-CM code specific to the comorbid condition;
  3. documentation of clinical signs and symptoms of impaired digestion, malabsorption, or nutritional risk, as indicated in Section II.A.2. 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 as indicated in Section II.A.3 of these Guidelines;
  6. laboratory tests sufficient to establish the diagnosis of malnutrition if applicable;
  7. documentation of route of enteral nutrition treatment;
  8. documentation of past and current treatment regimens; and
  9. documentation of type and estimated duration of the need (can not be lifetime) for enteral nutrition products.
- C.** A new or updated prior authorization request for enteral nutrition products must be submitted to continue use of enteral nutrition products before the expiration of the current prior authorization.

### Select References

ASPEN. American Society for Parenteral and Enteral Nutrition Board of Directors. Standards of Practice for Home Nutrition Support., *Nutrition in Clinical Care Practice*, 1999, vol. 14:151-162.

American Gastroenterological Association Medical Position Statement: Guidelines for the Use of Enteral Nutrition, 1995. Publication for updated guidelines due fall 2004 pending approval of AGA as of June 14, 2004.



Kirby DF, Delegge MH, and Fleming CR. American Gastroenterological Association Technical Review on Tube Feeding for Enteral Nutrition, *Gastroenterology* 1995, vol. 108 (4), 1280–1301.

Guidelines for altered nutritional status. American Medical Directors Association (AMDA), Columbia, MD, 2001.


EAST Practice Management Guidelines Work Group. Practice management guidelines for nutritional support of the trauma patient. Allentown, Penn: Eastern Association for the Surgery of Trauma (EAST). 2001.

---

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, contact your health-care provider for guidance or explanation.

**Policy Effective Date:** December 1, 2004

**Approved by:**  , Medical Director  
David F. Polakoff, MD, MSc

**Reviewed:** March 1, 2011