Medical Necessity Guidelines: Enteral Nutrition and Special Medical Formulas for Tufts Health Together and Tufts Health Unify

Effective: October 21, 2020

Prior Authorization Required If REQUIRED, submit supporting clinical documentation pertinent to service request.	**Yes ☒ No ☐**

Applies to:

COMMERCIAL Products

☐Tufts Health Plan Commercial products; Fax: 617.972.9409

☐Tufts Health Freedom Plan products; Fax: 617.972.9409

- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

TUFTS HEALTH PUBLIC PLANS Products

☐Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax:888.415.9055

☒Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; Fax: 888.415.9055

☐ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax: 857.304.6404

☒Tufts Health Unify* – OneCare Plan (a dual-eligible product); Fax: 857.304.6304

*The MNG applies to Tufts Health Unify members unless a less restrictive LCD or NCD exists.

SENIOR Products

- Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product) – Refer to the Tufts Health Plan SCO Prior Authorization List
- Tufts Medicare Preferred HMO, (a Medicare Advantage product) – Refer to the Tufts Medicare Preferred HMO Prior Authorization and Inpatient Notification List

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to make sure that prior authorization has been obtained.

OVERVIEW

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. Members with malnutrition or the potential for developing malnutrition as evidenced by clinical indicators, the presence of chronic disease, or increased metabolic requirements due to an impaired ability to absorb or ingest food adequately is considered to be at nutritional risk.

CLINICAL COVERAGE CRITERIA

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 (pages 3-4);
ii. documented allergy to cow's milk;
iii. the primary source of nutrition being extensively hydrolyzed protein formula or amino-acid based formula; and
iv. for children age 12 months or older, the amino-acid based 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 immunosuppress
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 ration of upper body to lower extremity length;
      ii. in neonates, infants, and children, with one of the following:
         (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;

(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. 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.

TABLE A

Diagnosis Or Symptoms	Description
Severe atopic dermatitis in a child less than a year old	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.
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.

Diagnosis Or Symptoms	Description
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 gastrointestinal specialist. 2. For infants from six to 12 months: a. demonstration that symptoms are significantly improved with the use of the requested special medical formula; b. a retrial of commercial formula is unsuccessful; and c. continuation of special formula use is recommended by a 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 one of the following diagnoses: 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; and 5. esophageal eosinophilia and/or eosinophilic gastroenteritis associated with malabsorption and dysmotility. For children older than one year of age, a retrial of commercial food and re-evaluation should demonstrate continued evidence of food allergy.

LIMITATIONS

Tufts Health 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 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
- 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
- Enteral nutrition products are used as supplements to a normal or regular diet in a member showing no clinical indicators of nutritional risk
- 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
- Enteral nutrition products are to be used for dieting or a weight-loss program
- Enteral nutrition and special medical formulas and foods are requested solely because of food preference in the absence of a medical condition
- 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
- Growth parameters are consistent with specialized condition-specific growth charts for members with genetic conditions
- Children who are small, but exhibit a normal growth rate parallel to the growth curve

In addition, Tufts Health Plan does not consider formula to be medically necessary if there is an available, less costly alternative, 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 mass.gov/service-details/wic-information-for-providers to obtain the current WIC formula list.

REFERENCES

1. Commonwealth of Massachusetts, Executive Office of Health and Human Services. MassHealth Guidelines for Medical Necessity Determination for Enteral Nutrition and Special Medical Formulas. mass.gov/doc/enteral-nutrition-and-special-medical-formulas-0/download. Accessed October 21, 2020.

APPROVAL HISTORY

January 15, 2020: Reviewed by the Integrated Medical Policy Advisory Committee (IMPAC) for an effective date of April 1, 2020.

Subsequent endorsement date(s) and changes made:
- April 1, 2020: Fax number for Unify updated
- April 15, 2020: Reviewed by IMPAC. Clarified language regarding Hydrolyzed and amino-acid based formulas in section 1.b.iii and 1.c.iv, effective 4.15.2020.
- July 15, 2020: Reviewed by IMPAC. Clarified language regarding evidence of weight loss in neonates, infants, and children in section 4.c.ii and 4.c.ii.d, effective July 15, 2020.
- October 21, 2020: Review by IMPAC. Clarified language for Non-IgE mediated conditions associated with cow's milk allergy.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member's benefit document, and in coordination with the Member's physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.