Medical Necessity Guidelines: Oral Formula: Massachusetts Products

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

This guideline is for the review of formulas given or taken by mouth. It does not apply to those formulas given via a tube.

CLINICAL COVERAGE CRITERIA FOR MASSACHUSETTS PRODUCTS

FORMULA AVAILABLE WITHOUT PRIOR AUTHORIZATION

Tufts Health Plan will cover formula for the following diagnoses without prior authorization. The member will be able to order one month's supply at a time.

- law.
  - Tyrosinemia
  - Homocystinuria
  - Maple syrup urine disease
  - Propionic acidemia
  - Methylmalonic acidemia
  - Urea cycle disorders
  - Phenylketonuria (PKU)
  - Other organic acidemias
- Enteral formulas prescribed for the medical treatment of malabsorption resulting from one of the following conditions, as mandated by Massachusetts law.
  - Crohn's disease
  - Ulcerative colitis
  - Gastrointestinal dysmotility
  - Gastroesophageal reflux (GERD)
  - Chronic intestinal pseudo-obstruction
  - Inherited diseases of amino acids and organic acids

FORMULA REQUIRING PRIOR AUTHORIZATION

Tufts Health Plan may cover formula in the following circumstances with prior authorization. A letter of medical necessity from the prescribing physician is required. Documentation must include the reason (s) for failure of the cow-milk or soy-milk trial if indicated. See Attachment A for a list of formulas.

1. **Prematurity**:
   Authorized up to three months post-hospital discharge when either a or b below is met:
   a. Specialized oral formula may be authorized for six months for members born at less than or equal to 35 completed weeks of gestation.
   b. Specialized oral formula may be authorized for three months for members born at more than 35 weeks and less than or equal to 37 weeks gestation with one of the following:
      1. A hospital discharge weight below the 10th percentile for age
      2. Unable to tolerate cow milk-based formula (soy-based formula trial not required)

   Note: Authorization past 3 or 6 months post-hospital discharge will be based on meeting the criteria for one of the conditions listed below.

2. **Gastroesophageal Reflux Disease**: Associated with either weight loss, lack of weight gain, severe or bloody regurgitation based on the following:
   - Special formula may be authorized up to 9 months of age: a failed trial of cow-milk or soy-based formulas required
   - Re-authorization from 9-12 months of age: a failed trial of cow-milk or soy-based formulas required
   - Re-authorization over one year of life: A letter of medical necessity from the treating Gastroenterologist is required, which documents ongoing medical necessity of formula, any attempts to wean from formula, and the treatment plan.

3. **Infant Formula Intolerance:**
   a. **Protein hydrolysate formulas** may be authorized for members from two (2) weeks to one (1) year of age who exhibit either of the following:
      - Symptoms of IgE-associated formula intolerance including angioedema, wheezing, rhinitis, uticaria, vomiting, eczema, and anaphylaxis
      - Symptoms of non-IgE-associated formula intolerance including hemosiderosis, **malabsorption** with villous atrophy, eosinophilic proctocolitis, enterocolitis, esophagitis, and colic

   b. **Amino acid preparations** may be authorized from age two (2) weeks to one (1) year of age for those members exhibiting any of the signs/symptoms noted above **AND** experienced a failed trial of protein hydrolysate formula.

   Special Formula Authorizations for Infants Older Than One Year:
   Special formula may be authorized for members beyond the age of one when all of the following are met:
   - Consideration of a retrial of both cow-milk based foods/formulas and soy-based formula
   - A nutritionist consult including calorie counts
   - A consult with a pediatric allergist and/or gastroenterologist documenting the continued indication for special formula

   Note: Authorizations subsequent to one (1) year of age will be for no more than six (6) month intervals.

4. **Treatment of Growth Failure:**
   Tufts Health Plan may authorize supplemental formulas or caloric supplements for members with growth failure when the following criteria are met:
   - The member's weight from a submitted growth chart is less than 75% of the median weight for age (to calculate, divide the member's weight by the average weight for age, as determined by the growth chart. If this number is less than 0.75, this criterion is met.)
   - A complete evaluation has been performed to rule out medical causes of the growth failure. (e.g., GERD, malabsorption, heart disease, parasites, adenoid hypertrophy, cystic fibrosis, diabetes mellitus, immunodeficiency). This evaluation should include a detailed dietary history to ensure that the formula is properly diluted and/or the member is receiving adequate calories

- The member must have failed other more basic forms of caloric supplementation (e.g., Carnation Instant Breakfast, addition of butter or cream to prepared foods, etc.)

LIMITATIONS

Tufts Health Plan may not authorize oral formula for any of the following:

- Standard infant milk or soy formulas
- Baby food or other regular food products including those that are blended and used in tube feedings
- Formula or food products used for dieting, or a weight-loss program
- Banked breast milk
- Food for a ketogenic diet when dietary needs can be met with regular, store-bought food;
- Dietary or food supplements
- Food thickeners, high protein powders and mixes
- Lactose free foods, or products that aid in lactose digestion
- Gluten-free products
- Baby foods
- Oral vitamins and minerals
- Medical foods (e.g., Foltx, Metanx, Cerefolin, probiotics such as VSL#3) including FDA-approved medical foods obtained via prescription
- Soy formula in children able to tolerate soy-based foods

CODES

The following ICD-10 diagnosis codes are covered without prior authorization.

ICD-10 Codes

ICD-10 Codes	Description
E70.0	Classical phenylketonuria
E70.1	Other hyperphenylalaninemias
E70.20	Disorder of tyrosine metabolism, unspecified
E70.21	Tyrosinemia
E70.29	Other disorders of tyrosine metabolism
E70.40	Disorders of histidine metabolism, unspecified
E70.41	Histidinemia
E70.49	Other disorders of histidine metabolism
E70.5	Disorders of tryptophan metabolism
E70.8	Other disorders of aromatic amino-acid metabolism
E70.81	Aromatic L-amino acid decarboxylase deficiency
E70.89	Other disorders of aromatic amino-acid metabolism
E70.9	Disorder of aromatic amino-acid metabolism, unspecified
E71.0	Maple-syrup-urine disease
E71.110	Isovaleric academia
E71.111	3-methylglutaconic aciduria
E71.118	Other branched-chain organic acidurias
E71.120	Methylmalonic academia
E71.121	Propionic academia
E71.128	Other disorders of propionate metabolism
E71.19	Other disorders of branched-chain amino-acid metabolism
E71.2	Disorder of branched-chain amino-acid metabolism, unspecified
E72.00	Disorders of amino-acid transport, unspecified
E72.01	Cystinuria
E72.02	Hartnup's disease
E72.03	Lowe's syndrome
E72.04	Cystinosis
E72.09	Other disorders of amino-acid transport

ICD-10 Codes	Description
E72.10	Disorders of sulfur-bearing amino-acid metabolism, unspecified
E72.11	Homocystinuria
E72.12	Methylenetetrahydrofolate reductase deficiency
E72.19	Other disorders of sulfur-bearing amino-acid metabolism
E72.20	Disorder of urea cycle metabolism, unspecified
E72.21	Argininemia
E72.22	Arginosuccinic aciduria
E72.23	Citrullinemia
E72.29	Other disorders of urea cycle metabolism
E72.3	Disorders of lysine and hydroxylysine metabolism
E72.4	Disorders of ornithine metabolism
E72.50	Disorder of glycine metabolism, unspecified
E72.51	Non-ketotic hyperglycinemia
E72.52	Trimethylaminuria
E72.53	Hyperoxaluria
E72.59	Other disorders of glycine metabolism
E72.8	Other specified disorders of amino-acid metabolism
E72.9	Disorder of amino-acid metabolism, unspecified
K21.9	Gastro-esophageal reflux disease without esophagitis
K31.84	Gastroparesis
K50.00	Crohn’s disease of small intestine without complications
K50.011	Crohn's disease of small intestine with rectal bleeding
K50.012	Crohn's disease of small intestine with intestinal obstruction
K50.013	Crohn's disease of small intestine with fistula
K50.014	Crohn's disease of small intestine with abscess
K50.018	Crohn's disease of small intestine with other complication
K50.111	Crohn's disease of large intestine with rectal bleeding
K50.112	Crohn's disease of large intestine with intestinal obstruction
K50.113	Crohn's disease of large intestine with fistula
K50.114	Crohn's disease of large intestine with abscess
K50.118	Crohn's disease of large intestine with other complication
K50.119	Crohn's disease of large intestine with unspecified complications
K50.80	Crohn's disease of both small and large intestine without complications
K50.811	Crohn's disease of both small and large intestine with rectal bleeding
K50.812	Crohn's disease of both small and large intestine with intestinal obstruction
K50.813	Crohn's disease of both small and large intestine with fistula
K50.814	Crohn's disease of both small and large intestine with abscess
K50.818	Crohn's disease of both small and large intestine with other complication
K51.00	Ulcerative (chronic) pancolitis without complications
K51.011	Ulcerative (chronic) pancolitis with rectal bleeding
K51.012	Ulcerative (chronic) pancolitis with intestinal obstruction
K51.013	Ulcerative (chronic) pancolitis with fistula
K51.014	Ulcerative (chronic) pancolitis with abscess
K51.018	Ulcerative (chronic) pancolitis with other complication
K51.313	Ulcerative (chronic) rectosigmoiditis with fistula
K51.314	Ulcerative (chronic) rectosigmoiditis with abscess
K51.818	Other ulcerative colitis with other complication
K51.819	Other ulcerative colitis with unspecified complications

ICD-10 Codes	Description
K51.90	Ulcerative colitis, unspecified, without complications
K51.911	Ulcerative colitis, unspecified with rectal bleeding
K51.912	Ulcerative colitis, unspecified with intestinal obstruction
K51.913	Ulcerative colitis, unspecified with fistula
K51.914	Ulcerative colitis, unspecified with abscess
K51.918	Ulcerative colitis, unspecified with other complication
K51.919	Ulcerative colitis, unspecified with unspecified complications
K59.8	Other specified functional intestinal disorders
K59.81	Ogilvie syndrome
K59.89	Other specified functional intestinal disorders
K90.41	Non-celiac gluten sensitivity
K90.49	Malabsorption due to intolerance, not elsewhere classified
K90.89	Other intestinal malabsorption

ATTACHMENT

Oral formula for Massachusetts products: Attachment A
Attachment B

REFERENCES

1. Commonwealth of Massachusetts General Law. 176B, Section 4K. Nonprescription enteral formulas for home use. malegislature.gov/Laws/GeneralLaws/PartI/TitleXXII/Chapter176B/Section4K. Accessed August 27, 2020.

APPROVAL HISTORY

July, 2002: Reviewed by the Clinical Coverage Criteria Committee

Subsequent endorsement date(s) and changes made:

- January 23, 2004: Reviewed and renewed, format changes made to clarify coverage criteria, examples of formulas added. Name of guideline changed from Pediatric Enteral and Oral Nutrition Therapy.
- January 7, 2005: Coverage criteria rewritten to reflect changes in method of supplying formula to Tufts Health Plan Members. A letter of medical necessity or a prescription, from the prescribing physician, will be necessary for all formulas.
- January 13, 2006: The title of this criterion was changed from "Enteral Formulas." This criteria is to be used for formulas given by mouth only.
- February 15, 2007: Additional coverage of phenylketonuria (PKU) specified
- February 11, 2008: Reviewed without changes
- October 8, 2008: Special Information box added to format. Rhode Island coverage, as per mandate, added to existing MNG. ICD-9 codes added. Limitations related to: dollar amounts updated/added; Provider/Vendor information added; BO modifier information added
- July 1, 2009: Attachment A: Types of Formulas added to the Medical Necessity Guideline
- October 1, 2009: Length of authorization for hydrolysate formulas changed from "six to twelve months" to six months
- May 2010: Reviewed my Medical Affairs, Medical Policy. No changes.
- January 2011: Dollar amount limit for low protein food removed as per Health Care Reform requirements (essential benefit).
- April 10, 2013: Reviewed at IMPAC. Prematurity age clarified. Tufts Health Plan will require Prior Authorization for formulas prescribed for milk intolerance and premature infants effective July 1, 2013. ICD-10 CM coding will be added prior to the next IMPAC review.
- December 11, 2013: Guidelines for the coverage of oral formula for Rhode Island Products has been removed from this Medical Necessity Guideline. It has been moved to Oral Formula: Rhode Island Products. Additional formulas have been listed by category in Attachment A.
- December 10, 2014: Reviewed by IMPAC, renewed without changes
- January 15, 2015: Adopted by Tufts Health Plan – Network Health Commercial Plans

- August 12, 2015: Reviewed by IMPAC, clarification of requirements for letter of medical necessity for gastroesophageal reflux beyond one year of life (No. 2)
- September 2015: Branding and template change to distinguish Tufts Health Plan products in "Applies to" section. Added Tufts Health Freedom Plan products, effective January 1, 2016.
- March 25, 2016: Coding updated; ICD-9-CM codes removed
- September 14, 2016: Reviewed by IMPAC, renewed without changes
- July 2017: Coding updated
- July 2017: Added RITogether Plan product to template. For MNGs applicable to RITogether, effective date is August 1, 2017
- August 9, 2017: Reviewed by IMPAC, renewed without changes
- October, 2017: Coding updated; Removed administrative requirement that members with a prescription drug benefit obtain the formula at a retail pharmacy, effective 1/1/2018
- October, 2018: Coding updated, code E72.53 added to list of ICD-10 codes covered without prior authorization, effective October 1, 2018
- October 10, 2018: Reviewed by IMPAC, renewed without changes
- October, 2018: Template and disclaimer updated
- October 16, 2019: Reviewed by IMPAC, renewed without changes
- October 1, 2020: Coding updated, codes E70.81, E70.89, K59.81, and K59.89 added to list of ICD-10 CM codes covered without prior authorization, effective October 1, 2020
- October 21, 2020: Reviewed by IMPAC, renewed without changes
- October 26, 2020: Fax number for Unify updated

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.

Provider Services