

## Medical Necessity Guidelines: Oral Formula: Rhode Island Products

Effective: October 21, 2020

<b>Prior Authorization Required</b> If <u>REQUIRED</u> , submit supporting clinical documentation pertinent to service request.	<b>Yes</b> <input type="checkbox"/> <b>No</b> <input checked="" type="checkbox"/>
<p><b>Applies to:</b></p> <p><b>COMMERCIAL Products</b></p> <p><input checked="" type="checkbox"/> Tufts Health Plan Commercial products; Fax: 617.972.9409</p> <p><input type="checkbox"/> Tufts Health Freedom Plan products; Fax: 617.972.9409</p> <ul style="list-style-type: none"> <li>CareLink<sup>SM</sup> – Refer to <a href="#">CareLink Procedures, Services and Items Requiring Prior Authorization</a></li> </ul> <p><b>TUFTS HEALTH PUBLIC PLANS Products</b></p> <p><input type="checkbox"/> Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 888.415.9055</p> <p><input type="checkbox"/> Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; Fax: 888.415.9055</p> <p><input type="checkbox"/> Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax: 857.304.6404</p> <p><input type="checkbox"/> Tufts Health Unify* – OneCare Plan (a dual-eligible product); Fax: 857.304.6304</p> <p>*The MNG applies to Tufts Health Unify members unless a less restrictive LCD or NCD exists.</p> <p><b>SENIOR Products</b></p> <ul style="list-style-type: none"> <li>Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product) – Refer to the <a href="#">Tufts Health Plan SCO Prior Authorization List</a></li> <li>Tufts Medicare Preferred HMO, (a Medicare Advantage product) – Refer to the <a href="#">Tufts Medicare Preferred HMO Prior Authorization and Inpatient Notification List</a></li> </ul>	

### 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

Tufts Health Plan coverage of oral formula for Rhode Island products is limited to the following diagnoses. Prior authorization is not required. The member will be able to order one month's supply at a time.

- Formulas prescribed for treatment of inborn errors of metabolism as mandated by Rhode Island 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 Rhode Island law.
  - Crohn's disease
  - Ulcerative colitis
  - Gastrointestinal dysmotility
  - Gastroesophageal reflux (GERD)
  - Chronic intestinal pseudo-obstruction
  - Inherited diseases of amino acids and organic acids

**Note:** For Rhode Island products, Tufts Health Plan does not cover formula for the treatment of any diagnosis not listed in bullets 1 and 2 of the above coverage guidelines. All members with a Rhode Island product must obtain the formula from a medical supply vendor.

**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**

<b>ICD-10 Codes</b>	<b>Description</b>
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

<b>ICD-10 Codes</b>	<b>Description</b>
E72.03	Lowe's syndrome
E72.04	Cystinosis
E72.09	Other disorders of amino-acid transport
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

ICD-10 Codes	Description
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
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
K51.819	Other ulcerative colitis with unspecified complications
K51.90	Ulcerative colitis, unspecified, without complications
K51.911	Ulcerative colitis, unspecified with rectal bleeding
K51.912	Ulcerative colitis, unspecified with intestinal obstruction
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

## ATTACHMENTS

Oral formulas for Rhode Island Products: [Attachment A](#)  
[Attachment B](#)

## REFERENCES

State of Rhode Island. Enteral Nutrition Products. H7441, Section 40-6-3, 12. July 5, 2008. [webserver.rilin.state.ri.us/PublicLaws/law08/law08253.htm](http://webserver.rilin.state.ri.us/PublicLaws/law08/law08253.htm). 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". These criteria are 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 Guidelines.

- 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 created and now separate from the Medical Necessity Guidelines for Massachusetts Products. Additional formulas have been listed by category in Attachment A.
- December 10, 2014: Reviewed by IMPAC, renewed without changes
- August 12, 2015: Reviewed by IMPAC, renewed without changes
- 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, 2018: Coding updated, code E72.53 added to list of ICD-10 codes, 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

#### **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](#)