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| **Subject: Oral and Tube Fed Enteral Nutrition** | **Original Effective Date:** 9/10/09 |
| **Guidance Number:** MCG-070<br>*(This MCG replaces MCG-071) | **Revision Date(s):** 6/29/12, 8/7/14 |
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## SUMMARY

The term "medical food" is defined in section 5(b) (21 U.S.C. 360ee (b) (3)) of the Orphan Drug Act as: "A food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation." [1]

*Oral Enteral Nutrition:* Nutritional liquids prescribed to be ingested by the oral route for the purpose of restoring or maintaining nutrition, weight and strength commensurate with the member's overall health status.

*Tube Fed Enteral Nutrition:* Nutritional liquids prescribed to be delivered to the gastrointestinal tract through a feeding tube into the stomach or small intestine.

***NOTE:*** *Each state plan has a specific definition provided by their respective state Medicaid benefits plan. Coverage criteria are outlined within each state Medicaid regulation. This document serves as an additional tool to provide direction for specific situations that are not defined within each state plan regulation.*

## RECOMMENDATION [4-11]

1. Tube fed enteral nutritional therapy (e.g., nasogastric, gastrostomy, jejunostomy) may be considered medically necessary when the following criteria are met: [ALL]

   - ❑ Presence of a neurological, musculoskeletal, cognitive disease or anatomical abnormality that impairs swallowing (e.g., CVA, trauma, spinal cord injury, birth defects, multiple sclerosis, myasthenia gravis, parkinson's disease, ALS, obstruction due to head and neck cancer or reconstructive surgery), and

   - ❑ The additional criteria outlined below for oral enteral therapy is met:

2. Oral enteral nutritional therapy may be considered medically necessary when the following criteria are met: [ALL]

   - ❑ Prescription must be used under the supervision of a physician or nurse practitioner, or ordered by a registered dietician upon referral by a health care provider authorized to prescribe dietary treatments; and

   - ❑ Documentation outlining risk factors for malnutrition: [ALL]

- Anatomic or mechanical dysfunction of the structures of the gastrointestinal tract that impair chewing or swallowing solid foods; and

- 50 % of caloric or nutritional requirements are not able to be met from ordinary food to maintain life-sustaining functions; and

- Presence of a medical condition that is a significant risk factor for developing malnutrition that include but are not limited to: [ONE]
  - Diagnosis of inborn errors of metabolism that require modified food products (e.g., phenylketonuria (PKU), maple syrup urine disease, citrullinemia, cystinosis, homocystinuria, methylmalonic acidemia, propionic acidemia, isovaleric acidemia [and other disorders of leucine metabolism], glutaric acidemia type I, tyrosinemia types I and II, and urea cycle disorders.)
  - Atopic disease associated with allergy-related formula intolerance
  - Malabsorption syndromes or short-bowel syndromes resulting in prolonged nutrient losses (e.g., Pediatric Crohn's disease, acute ulcerative colitis, short bowel syndromes, gastroparesis, ischemic bowel disease with massive bowel resection)
    - Must meet weight loss criteria below
  - Failure to thrive (FTT) diagnosis with the inability to meet caloric nutritional requirements:
    - Must meet weight loss criteria below
  - Severe disease (e.g., anorexia/bulimia, HIV, end stage renal disease, cancer)
    - Must meet weight loss criteria below

**OR**

- Weight loss: Documentation demonstrating clinical signs and symptoms of impaired digestion, malabsorption, or nutritional risk from failure to thrive as indicated by the following measures:

**In adults** who are ≥ 18 years of age: [ONE]

- BMI ≤ 18.5 kg/m$^2$ ***and*** albumin level of < 3.5 or a cholesterol level of 160 or below; or albumin < 4.0 in end stage renal patients; or
- Documented unintentional weight loss ≥10% over the past 3-6 months

- **In neonates, infants and children** who are <18 years of age: [ONE]

  - Weight for height or BMI for age ≤ 10 percent; or
  - Crossed (downward) at least 2 percentile lines of weight for age on the growth chart.

- ❑ A 4 week trial of standard formulas has been completed that demonstrates no benefit
  - ❖ Not required for inborn errors of metabolism

3. **WIC:** Children who are < 5 years of age are required to obtain enteral products from the WIC Program. Coverage is limited to specific approved enteral products designated on the WIC preferred list. The following signed and dated written notification from WIC is required: [ONE]

   - ❑ Not eligible for the WIC program; **or**

   - ❑ The requested product is not available through the WIC program: [ALL]
     - Documentation of similar WIC products tried and failed; and
     - Documentation of medical need for the alternative products; **or**
     - The need for the oral nutrition product or formula exceeds the allowed amount

4. Subsequent reviews are required every 3 months or when any of the following occur:

   - ❑ Change in formula type; or
   - ❑ Increase or decrease in number of calories per day or days per week of administration; or
   - ❑ Change in route of administration (oral to enteral feedings)

5. Enteral nutrition is ***excluded*** for any of the following:

   - ❑ Any of the above criteria is not met
   - ❑ Specialized diets that can be achieved through normal food consumption (e.g., gluten free foods)
   - ❑ For convenience purposes
   - ❑ Food preference of an enteral formula over other acceptable standard dietary interventions
   - ❑ Noncompliance with a special diet
   - ❑ Nutritional supplements not requiring a physician's prescription for the sole purpose of boosting protein and/or caloric intake
   - ❑ Weight reduction, bodybuilding, athletic performance, anorexia or bulimia
   - ❑ Nutritional needs can be met using regular foods, baby foods, and other regular grocery items that can be blenderized to maximally meet nutritional needs.

## SUMMARY OF MEDICAL EVIDENCE

Enteral formulas are classified as standard, elemental or specialized. There is lack of prospective, randomized, controlled trials supporting the reported indications for the majority of specialized formulas on the market. Standard formulas have been shown to be effective in meeting the nutritional requirements for the majority of patients.

**CODING INFORMATION:** THE CODES LISTED IN THIS POLICY ARE FOR REFERENCE PURPOSES ONLY. LISTING OF A SERVICE OR DEVICE CODE IN THIS POLICY DOES NOT IMPLY THAT THE SERVICE DESCRIBED BY THIS CODE IS A COVERED OR NON-COVERED. COVERAGE IS DETERMINED BY THE BENEFIT DOCUMENT. THIS LIST OF CODES MAY NOT BE ALL INCLUSIVE.

| CPT | Description |
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| | N/A |

| HCPCS | Description: The following website is useful to determine which products are assigned to a |
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| | specific HCPCS code: https://www.dmepdac.com/ |
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| B4149 | Enteral formula, manufactured blenderized natural foods with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 |
| B4150 | Enteral formula, nutritionally complete with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit |
| B4152 | Enteral formula, nutritionally complete, calorically dense (equal to or greater than 1.5 kcal/ml) with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit |
| B4153 | Enteral formula, nutritionally complete, hydrolyzed proteins (amino acids and peptide chain), includes fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit |
| B4154 | Enteral formula, nutritionally complete, for special metabolic needs, excludes inherited disease of metabolism, includes altered composition of proteins, fats, carbohydrates, vitamins and/or minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit |
| B4155 | Enteral formula, nutritionally incomplete/modular nutrients, includes specific nutrients, carbohydrates (e.g., glucose polymers), proteins/amino acids (e.g., glutamine, arginine), fat (e.g., medium chain triglycerides) or combination, administered through an enteral feeding tube, 100 calories = 1 unit |
| B4157 | Enteral formula, nutritionally complete, for special metabolic needs for inherited disease of metabolism, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit |
| B4158 | Enteral formula, for pediatrics, nutritionally complete with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber and/or iron, administered through an enteral feeding tube, 100 calories = 1 unit |
| B4159 | Enteral formula, for pediatrics, nutritionally complete soy based with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber and/or iron, administered through an enteral feeding tube, 100 calories = 1 unit |
| B4160 | Enteral formula, for pediatrics, nutritionally complete calorically dense (equal to or greater than 0.7 kcal/ml) with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit |
| B4161 | Enteral formula, for pediatrics, hydrolyzed/amino acids and peptide chain proteins, includes fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit |
| B4162 | Enteral formula, for pediatrics, special metabolic needs for inherited disease of metabolism, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit |

| ICD-9 | Description |
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| | All Diagnoses |

| ICD-10 | Description |
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| | All Diagnoses |

## RESOURCE REFERENCES


1. Orphan Drug Amendments of 1988 (amending the Federal Food, Drug, Cosmetic Act respect to Orphan Drugs for Other Purposes). Pub L. No. 100-290.
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5. American Society for Parenteral and Enteral Nutrition (A.S.P.E.N.). Clinical Guidelines. Accessed at: http://www.nutritioncare.org/Clinical_Practice_Library/
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8. American Academy of Pediatrics. Effects of Early Nutritional Interventions on the Development of Atopic Disease in Infants and Children: The Role of Maternal Dietary Restriction, Breastfeeding, Timing of Introduction of Complementary Foods, and Hydrolyzed Formulas. Pediatrics. Jan 2008;121(1):183-191. Accessed at: http://pediatrics.aappublications.org/content/121/1/183.full.html
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11. UpToDate. Collier S. Duggan C. Enteral Nutrition in Infants and Children. July 2014.


## DISCLAIMER

***This Medical Guidance is intended to facilitate the Utilization Management process. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (i.e., will be paid for by Molina) for a particular member. The member's benefit plan determines coverage. Each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their providers will need to consult the member's benefit plan to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid members. CMS's Coverage Database can be found on the following website: http://www.cms.hhs.gov/center/coverage.asp.***

## CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

*The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this Molina medical coverage guidance (MCG) document and provide the directive for all Medicare members.* There is a NCD and several LCD's on this topic. [1-2]