INSTRUCTIONS FOR USE

This Coverage Determination Guideline provides assistance in interpreting UnitedHealthcare benefit plans. When deciding coverage, the federal, state or contractual requirements for benefit plan coverage must be referenced. The terms of the federal, state or contractual requirements for benefit plan coverage may differ greatly from the standard benefit plan upon which this Coverage Determination Guideline is based. In the event of a conflict, the federal, state or contractual requirements for benefit plan coverage supersedes this Coverage Determination Guideline. All reviewers must first identify member eligibility, any federal or state regulatory requirements, and the contractual requirements for benefit plan coverage prior to use of this Coverage Determination Guideline. Other Policies and Coverage Determination Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary. This Coverage Determination Guideline is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

BENEFIT CONSIDERATIONS

Before using this guideline, please check the federal, state or contractual requirements for benefit coverage.

COVERAGE RATIONALE

Enteral Nutrition administered by tube is proven and/or medically necessary when all of the following criteria are met:

- Ordered by a physician; and
- The item(s) meets the plan’s medically necessary definition (refer to state specific documents); and
- Service is not otherwise excluded from coverage.
  - Adults: Enteral formulas consisting of semi-synthetic intact protein/protein isolates (B4150 or B4152) are appropriate for the majority of adults requiring Enteral Nutrition.
  - Children: Pediatric enteral formulas (B4160) may be appropriate for children ages 0–13 years.
  - The medical necessity for special nutrient formulas (B4149, B4153–B4155, B4157, B4161 and B4162) must be justified for each member. Special enteral formula is produced to meet unique nutrient needs for specific conditions and requires documentation to establish medical necessity.
  - If a pump is requested (B9002), justification as to why gravity administration is not satisfactory and the rate of infusion must be included.

Formula for Metabolic Diseases or Inborn Errors of Metabolism

The American Academy of Pediatric Consensus Statement 2002, reaffirmed 2006: "Metabolic diseases include inborn errors of amino acid metabolism such as phenylketonuria, maternal phenylketonuria, maple syrup urine disease,
homocystinuria, methylmalonicacidemia, propionicacidemia, isovalericacidemia, and other disorders of leucine metabolism; glutaric aciduria type I and tyrosinemia types I and II; and urea cycle disorders.”

“These are all disorders treatable by dietary modifications, which can prevent complications like severe mental retardation and death.”

Examples (not all-inclusive list):
- Glutaric aciduria
- Glycogen storage disease
- Homocystinuria
- Maple syrup urine disease
- Methylmalonic aciduria
- Organic acid metabolism disorders
- Phenylketonuria (PKU)
- Tyrosinemas
- Urea cycle disorders

**Oral Nutritional Supplements for Other Medical Conditions**

Specialized oral formula will be covered when all of the following criteria, one of the conditions, and all of the documentation requirements are met:

- **Criteria:**
  - A physician prescribes the therapy; and
  - The condition is chronic and is expected to last for an undetermined or prolonged period of time; and
  - Adequate nutrition is not possible by dietary adjustment; and
  - Nutritional therapy is provided as replacement therapy; and
  - The material used is specially formulated as a nutrition replacement; and

- **Conditions (must meet one of the following):**
  - Crohn's disease; or
  - Disorders of gastrointestinal motility such as chronic intestinal pseudo-obstruction; or
  - Severe malabsorption syndrome; or
  - Individuals who will become malnourished or suffer from severe disorders such as physical disability, mental retardation or death if the nutritional therapy is not instituted; or
  - Severe food allergies, those which if left untreated will cause malnourishment, chronic physical disability, mental retardation or death (mild and moderate food allergies or food intolerance can usually be treated with formula that is readily available in food stores and pharmacies, or by careful food selection. Formulas for the treatment of such conditions are not covered); or
  - GE reflux with failure to thrive; or
  - In members 21 years of age and older: Weight loss greater than 10% of body weight over a three to six month period.

**Coverage Limitations and Exclusions (Unless Otherwise Mandated)**

- Self-blenderized formulas are not covered.
- Commercial food thickeners (B4100) have no significant nutritional value, are a convenience item and are not medically necessary. Baby food, gravy, other grocery products and other food preparation techniques are preferred alternatives.
- Code B4104 is an enteral formula additive. The enteral formula codes include all nutrient components, including vitamins, mineral, and fiber. Therefore, code B4104 will be denied as not separately payable.
- Codes B4102 and B4103 describe electrolyte-containing fluids that are not covered.
- Nutritional or cosmetic therapy using high-dose or mega quantities of vitamins, minerals or elements and other nutrition based therapy are excluded from coverage. Examples include supplements, electrolytes, and foods of any kind. This includes, but is not limited to: high protein foods, low protein foods, and low carbohydrate foods.
- Formula that is not specifically made for inborn errors of metabolism. Even when a formula is the sole source of nutrition, formula that is not specifically made for persons with inborn errors of metabolism is not covered.
- Formulas for the treatment of mild and moderate food allergies or food intolerance are not covered (severe food allergies, those which if left untreated will cause malnourishment, chronic physical disability, mental retardation or death, may be medically necessary).
- Oral Nutrition for lack of appetite or cognitive conditions is not covered (e.g., lack of appetite secondary to stimulant medications).
DEFINITIONS

Please check the definitions within the member benefit plan document that supersede the definitions below.

Enteral Nutrition: The provision of nutritional requirements through a tube into the stomach; it may be administered by syringe, gravity, or pump.

Food Additives: Commercially available products such as thickeners, vitamins, minerals, fiber supplements, calorie supplements, protein supplements, and products to aid in lactose digestion.

Oral Nutrition: The intake of food through the mouth and esophagus to provide necessary nutrients for health and growth.

Specialized Nutrient Formula: Formula that is produced to meet unique nutrient needs for specific disease conditions.

APPLICABLE CODES

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by federal, state or contractual requirements and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Coverage Determination Guidelines may apply.

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>B4100</td>
<td>Food thickener, administered orally, per oz.</td>
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<tr>
<td>B4102</td>
<td>Enteral formula, for adults, used to replace fluids and electrolytes (e.g., clear liquids), 500 ml = 1 unit</td>
</tr>
<tr>
<td>B4103</td>
<td>Enteral formula, for pediatrics, used to replace fluids and electrolytes (e.g., clear liquids), 500 ml = 1 unit</td>
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<tr>
<td>B4104</td>
<td>Additive for enteral formula (e.g., fiber)</td>
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<tr>
<td>B4149</td>
<td>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 unit</td>
</tr>
<tr>
<td>B4150</td>
<td>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</td>
</tr>
<tr>
<td>B4152</td>
<td>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</td>
</tr>
<tr>
<td>B4153</td>
<td>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</td>
</tr>
<tr>
<td>B4154</td>
<td>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</td>
</tr>
<tr>
<td>B4155</td>
<td>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</td>
</tr>
<tr>
<td>B4157</td>
<td>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</td>
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<tr>
<td>HCPCS Code</td>
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<tr>
<td>B4158</td>
<td>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</td>
</tr>
<tr>
<td>B4159</td>
<td>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</td>
</tr>
<tr>
<td>B4160</td>
<td>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</td>
</tr>
<tr>
<td>B4161</td>
<td>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</td>
</tr>
<tr>
<td>B4162</td>
<td>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</td>
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<tr>
<td>B9002</td>
<td>Enteral nutrition infusion pump, any type</td>
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**Metabolic and Specialized Foods**

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<th>HCPCS Code</th>
<th>Description</th>
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<tr>
<td>S9433</td>
<td>Medical food nutritionally complete, administered orally, providing 100% of nutritional intake</td>
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<tr>
<td>S9434</td>
<td>Modified solid food supplements for inborn errors of metabolism</td>
</tr>
<tr>
<td>S9435</td>
<td>Medical foods for inborn errors of metabolism</td>
</tr>
</tbody>
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**CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)**

Medicare covers oral and enteral nutrition when criteria are met. Refer to the National Coverage Determination (NCD) for Enteral and Parenteral Nutritional Therapy (180.2). Also see the DME MAC Local Coverage Determinations (LCDs) for Enteral Nutrition and the DME MAC LCDs for Parenteral Nutrition. (Accessed February 2, 2018)

**REFERENCES**


**GUIDELINE HISTORY/REVISION INFORMATION**

<table>
<thead>
<tr>
<th>Date</th>
<th>Action/Description</th>
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| 05/01/2018 | • Updated list of related policies; added reference link to policy titled *Nutritional Therapy: Enteral and Parenteral Nutritional Therapy*  
• Updated coverage rationale; replaced language indicating “[the listed service] is proven and medically necessary” with “[the listed service] is proven and/or medically necessary”  
• Updated definitions; added instruction to check the definitions within the member benefit plan document that supersede the definitions [listed in the policy]  
• Updated supporting information to reflect the most current CMS information and references  
• Archived previous policy version CS136.F |