Clinical Guideline

Guideline Number: CG011, Ver. 4

Oral Liquid Nutritional Supplements

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Oscar may delegate utilization management decisions of certain services to third-party delegates, who may develop and adopt their own clinical criteria.

The clinical guidelines are applicable to all commercial plans. Services are subject to the terms, conditions, limitations of a member’s plan contracts, state laws, and federal laws. Please reference the member’s plan contracts (e.g., Certificate/Evidence of Coverage, Summary/Schedule of Benefits) or contact Oscar at 855-672-2755 to confirm coverage and benefit conditions.

Summary

Oscar members who have difficulty ingesting or digesting food or who are at risk for malnutrition may be eligible for coverage of oral liquid nutritional supplements. Oral liquid nutritional supplements can provide essential nutrients and calories as part of a therapeutic regimen in patients who are unable to ingest or digest adequate food and fluid to meet their nutritional requirements as a result of abnormal gastrointestinal function or other medical conditions.

Coverage of oral liquid nutritional supplementation is only applicable when prescribed by a licensed provider. If authorized, supplements can be obtained through a participating vendor, with eligibility and cost of coverage as outlined in the member’s individual Schedule of Benefits and Certificate of Coverage.

Definitions

“Oral Liquid Nutritional Supplements” must be “medical foods” as defined by the FDA. These include nutrition shakes and protein drinks that can be obtained in either a pharmacy or over-the-counter. Common trade brands include Ensure, Boost, Glucerna, Nepro, and Suplena.

“Elemental and Semi-Elemental Products” contain partially or fully broken down macronutrients.

“Food Additives” are products available over-the-counter that are ingested in addition to a regular diet. Examples include calorie supplements, digestive aids, fiber supplements, minerals, protein supplements, thickeners, and vitamins.
“Enteral Nutrition” refers to nutrition administered through the alimentary (Gastrointestinal) tract, including:
1. Through the oral cavity, as in traditional eating
2. Through a nasogastric or orogastric tube (tube placed through the nose or mouth into the stomach)
3. Through a gastric or gastro-jejunal feeding tube (placed percutaneously directly into the stomach or small intestine, bypassing the oral cavity and esophagus)

“Parenteral Nutrition” refers to nutrition administered outside of the GI tract, such as intravenous feeding. May be used in cases where traditional enteral feeding is impossible due to obstructions, malabsorption, or congenital conditions. Parenteral nutrition is not discussed in this guideline.

“Poor Weight Gain” is applicable to children aged 2-18, and defined using the 2000 CDC Growth Charts and BMI-For-Age Charts which can identify weight gain issues including:
1. Abrupt weight loss following a period of normal growth along a well-established pattern of height and weight gain defined as crossing two or more major weight percentiles; or
2. Slow, steady weight gain below the fifth percentile of the NCHS growth curves; or
3. A growth curve proportionate to, but lower than, the child’s expected height trajectory; or
4. Growth milestones that have been met but only with nutritional support consisting of high-calorie foods and/or nutritionally dense foods, where support with nutritional and calorie appropriate food is necessary.

“Failure to Thrive (FTT)” is applicable to children younger than 2 years old, and defined using WHO growth charts which can identify weight gain issues including:
1. Children weighing less than the 2nd percentile for gestation-corrected age and sex when plotted on the appropriate growth chart on more than one occasion (Note: Special charts for patients with genetic syndromes or prematurity may be applicable); and
2. Decreased growth velocity of weight gain compared to growth in length.

Clinical Indications and Coverage

Adult Patients
Enteral/oral nutritional supplements are considered medically necessary and covered in adult patients 18 and older with a prescription from a licensed provider and when ONE of the following criteria are met:
1. Patients who require tube feeding; or
2. For patients not requiring tube feeds (i.e. taking oral nutrition), any ONE of the following:
   a. Documented chronic medical disease (e.g. HIV/AIDS, Crohn’s disease, cystic fibrosis, etc) that is being appropriately treated and inability to meet nutritional needs even with a dietary adjustment of regular or altered consistency (soft/pureed) foods; or
   b. Medical condition (acute or chronic) such as a metabolic, gastrointestinal, or gastroesophageal disorder that is being appropriately treated AND associated with an
inability to meet nutritional needs with a dietary adjustment of regular or altered consistency foods and ONE of the following:

i. Involuntary weight loss of:
   1. 10% or more loss in 6 months; or
   2. 7.5% in 3 months; or
   3. 5% in 1 month.

ii. BMI <18.5.

c. Multiple, severe food allergies which if left untreated will cause malnourishment, chronic physical disability, mental retardation or death; or

d. Swallowing or mastication difficulty secondary to any one of the following:
   i. Cancer in throat, oral cavity, or neck; or
   ii. Injury, trauma, surgery, or current/prior radiation therapy to neck; or
   iii. Chronic neurological disorders (e.g. stroke); or
   iv. Severe craniofacial abnormality.

e. Currently undergoing transition from parenteral or enteral diet (with tube feeding) to oral diet.

Patients Under the Age of 18

Enteral/oral nutritional supplements are covered in patients under the age of 18 with a prescription from a licensed provider and ONE of the following criteria is met:

1. Patients aged 2-18 with poor weight gain, as defined above in “Definitions”, that is unresponsive to standard age appropriate interventions; or

2. Patients aged <2 years old with failure to thrive, as defined above in “Definitions”, that is unresponsive to standard age appropriate interventions; or

3. Pediatric patients with malnutrition or risk of malnutrition, as demonstrated by any ONE of the following:
   a. Poor oral intake related to anatomic or motility related disorders of the GI tract; or
   b. Symptoms of malabsorption related to inflammatory disorders of the GI tract; or
   c. Allergy or hypersensitivity to cow or soy milk diagnosed through a formal food challenge; or
   d. Allergy to specific foods including food-induced anaphylaxis; or
   e. Allergic or eosinophilic enteritis (colitis/proctitis, esophagitis, gastroenteritis); or
   f. Cystic fibrosis with malabsorption; or
   g. Malabsorption unresponsive to standard age appropriate interventions when associated with failure to gain weight or meet established growth expectations.

4. Patients residing in Texas with nutritional deficiencies related to documented autism spectrum disorder; or

5. Patients with inborn errors in metabolism, including but not limited to:
   a. Phenylketonuria
   b. Maternal phenylketonuria
c. Maple syrup urine disease  
d. Homocystinuria  
e. Methylmalonic acidemia  
f. Propionic acidemia  
g. Isovaleric acidemia  
h. Other disorders of leucine metabolism  
i. Glutaric aciduria type I  
j. Tyrosinemia types I and II  
k. Urea cycle disorders.

Pregnant Women with Hyperemesis Gravidarum:
1. Oral nutrition supplements may considered medically necessary for pregnant women with hyperemesis gravidarum who meet ALL of the following criteria:
   a. Condition refractory to pharmacologic and nonpharmacologic intervention; and  
   b. Cannot maintain weight despite appropriate interventions; and  
   c. When prescribed by a licensed provider; and  
   d. The treatment plan includes assessment and consultation with a nutritionist or nutrition service.

Specific Products, when Prescribed by a Licensed Provider:
1. For diabetic products, the beneficiary must have a documented diagnosis of hyperglycemia or diabetes and HbA1c (A1c) value measured within six months of the authorization request.
2. For renal products, ONE of the following indicators measured within six months of the request must be clearly documented for individuals 18 years and older:
   a. Blood serum potassium; or  
   b. BUN levels (>20mg/dl); or  
   c. GFR < 60.
3. For hepatic products, results of liver function test measured within six months of the request must be clearly documented.
4. For carbohydrate modular products administered orally or through a feeding tube, there must be documented clinical evidence that the patient is unable to meet caloric nutritional need with the current use of an enteral nutrition product.
5. For lipid (fat) modular products administered orally or through a feeding tube, the beneficiary must meet ONE of the following:
   a. Documented diagnosis of inability to digest/absorb conventional fats; or  
   b. Documented diagnosis of uncontrolled seizure disorder that cannot be other managed (in cases of ketogenic diet).
6. For protein modular products administered orally or through a feeding tube, there must be documented clinical evidence to support the beneficiary is unable to meet protein requirement with current use of a high protein enteral nutrition product.

7. For elemental nutrition products, patients must:
   a. Have a documented, chronic intestinal malabsorption disease (lactose intolerance is excluded); and
   b. Be unable to absorb nutrients or tolerate intact protein in a way that cannot otherwise be medically managed or managed with alternative dietary options; and
   c. Have history of use of disease-specific or specialized nutrition products that have not been successful (unless medically contraindicated).

Authorization Period & Extension Requests
When approved, authorizations are provided for a thirty (30) day supply. Extension of services require re-authorization.

Coverage Exclusions
Oscar does not cover oral liquid nutritional supplements solely based on food preference, patient convenience, or to boost caloric intake without a specific medical indication. Other non-covered services include:

- Any items not categorized as medical foods
- Food thickeners
- Baby food or standard infant formula
- Gluten-free foods
- Breast milk
- Vitamins or minerals
- High-protein powders or nutritional drinks
- Low carbohydrate diet supplements
- Non-prescription weight loss or weight gain products

Oscar does not cover oral liquid nutritional supplements that are considered experimental or investigational. These may include, but are not limited to the following:

- Relizorb (enzyme cartridge)

Applicable Billing Codes
Codes covered if clinical criteria are met:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<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>
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<tr>
<td>Code</td>
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<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>
</tr>
<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>
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<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>
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<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>S9433</td>
<td>Medical food nutritionally complete, administered orally, providing 100% of nutritional intake</td>
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Modified solid food supplements for inborn errors of metabolism

Medical foods for inborn errors of metabolism

Codes not covered for indications listed in this Guideline (unless state mandated):

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<tr>
<td>A9152</td>
<td>Single vitamin/mineral/trace element, oral, per dose, not otherwise specified</td>
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<tr>
<td>A9153</td>
<td>Multiple vitamins, with or without minerals and trace elements, oral, per dose, not otherwise specified</td>
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<td>B4100</td>
<td>Food thickener, administered orally, per oz</td>
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<td>B4102</td>
<td>Enteral formula, for adults, used to replace fluids and electrolytes (e.g., clear liquids), 500 ml = 1 unit</td>
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<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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References
28. New Jersey Permanent Statutes Title 17B.  


Clinical Guideline Revision / History Information

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<td>Reviewed/Revised:</td>
<td>1/18/2018, 4/13/2018</td>
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<tr>
<td>Signed:</td>
<td>Sean Martin, MD, Medical Director</td>
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