FORMULA & SPECIALIZED FOOD

Policy Number: HOME 005.17 T2

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INSTRUCTIONS FOR USE

The services described in Oxford policies are subject to the terms, conditions and limitations of the member's contract or certificate. Unless otherwise stated, Oxford policies do not apply to Medicare Advantage members. Oxford reserves the right, in its sole discretion, to modify policies as necessary without prior written notice unless otherwise required by Oxford's administrative procedures or applicable state law. The term Oxford includes Oxford Health Plans, LLC and all of its subsidiaries as appropriate for these policies.

Certain policies may not be applicable to Self-Funded members and certain insured products. Refer to the member specific benefit plan document or Certificate of Coverage to determine whether coverage is provided or if there are any exclusions or benefit limitations applicable to any of these policies. If there is a difference between any policy and the member specific benefit plan document or Certificate of Coverage, the member specific benefit plan document or Certificate of Coverage will govern.

CONDITIONS OF COVERAGE

Applicable Lines of Business/ Products
This policy applies to Oxford Commercial plan membership.

Benefit Type
Refer to the state specific grid in the Benefit Considerations section.²

Referral Required
(Does not apply to non-gatekeeper products)
No

Authorization Required
(Precertification always required for inpatient admission)
Yes

Precertification with Medical Director Review Required
Yes¹²

Applicable Site(s) of Service
(If site of service is not listed, Medical Director review is required)
Home

Special Considerations
¹Precertification with Medical Director review or their Designee is required.
²For Self-Funded Plans, refer to Member’s certificate of coverage/health benefits plan for specific benefit and coverage guidelines.

BENEFIT CONSIDERATIONS

Before using this policy, please check the member specific benefit plan document and any federal or state mandates, if applicable. For Self-Funded Plans, refer to member specific benefit plan document for specific benefit and coverage guidelines. In the event of a conflict, the member specific benefit plan document governs.
The intent of this policy is to outline the conditions under which Oxford will authorize the use of food/formula that is specially formulated for specific medical conditions.

**Coverage Limitations and Exclusions**

- Standard cow’s milk or soy-based baby formula, for children under one year of age
- Nutritional supplements (Note: Nutritional *products* are considered *supplements* when they are non-essential or convenience additions or substitutions to a regular formula or adult solid or blenderized (liquefied) food diet)
- Banked breast milk

The grid below provides the benefit that should apply based on the product authorized.

**Notes:**

- Refer to the member specific benefit plan document for applicable cost share information.
- All branded nutritional therapies covered under the Pharmacy benefit are Tier 3 for commercial members who have a three tier Pharmacy benefit.

<table>
<thead>
<tr>
<th>State</th>
<th>Product</th>
<th>Applicable Benefit Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Connecticut (CT)</td>
<td>Specialized food</td>
<td>Pharmacy benefit</td>
</tr>
<tr>
<td></td>
<td>Non-standard infant formula</td>
<td>CT requires coverage:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>o Of specialized infant formula to age 12 when medically necessary</td>
</tr>
<tr>
<td></td>
<td></td>
<td>o Under the general benefit package if plan does not have pharmacy coverage</td>
</tr>
<tr>
<td>New Jersey (NJ)</td>
<td>Specialized food</td>
<td>General benefit package</td>
</tr>
<tr>
<td></td>
<td>Non-standard infant formula</td>
<td>Pharmacy benefit</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Infant is to age 1 year (12 months)</td>
</tr>
<tr>
<td>New York (NY)</td>
<td>Specialized food</td>
<td>Pharmacy benefit</td>
</tr>
<tr>
<td></td>
<td>Non-standard infant formula</td>
<td></td>
</tr>
</tbody>
</table>

**Essential Health Benefits for Individual and Small Group**

For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits (“EHBs”). Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs. However, if such plans choose to provide coverage for benefits which are deemed EHBs, the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans. The determination of which benefits constitute EHBs is made on a state by state basis. As such, when using this policy, it is important to refer to the member specific benefit plan document to determine benefit coverage.

**Coverage Rationale**

Oxford will cover specialized formula and specialized foods as outlined below.

**Approved authorizations will be issued for one year.**

**CT and NJ Plans**

**Specialized Formula**

Specialized formula will be authorized when all of the following criteria and 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**
  - Individuals who will become malnourished or suffer from severe disorders such as physical disability, mental retardation or death if the medical nutritional therapy is not instituted; **and**

- **One of the following conditions:**
  - Inborn error of metabolism; or
Inherited diseases of amino-acid or organic acid metabolism; or
- Crohn's disease; or
- Disorders of gastrointestinal motility such as chronic intestinal pseudo-obstruction; or
- Severe malabsorptive syndrome; or
- Severe food allergies which if left untreated will cause malnourishment, chronic physical disability, mental retardation or death; or
  Note: See documentation required for severe food allergy.
- GE reflux with failure to thrive
  Note: See documentation required for GE reflux with failure to thrive.

and
- **Required documentation:**
  - For multiple food allergy:
    - Consultation with relevant specialist (Neonatologist, Gastroenterologist or Allergist); and
      Note: A consultation by a specialist is not required for NJ plans. Requests from the covered infant's physician is sufficient.
    - Diagnosis of multiple food protein allergy; and
      Note: Multiple food protein intolerance is also acceptable for NJ plans.
    - Office notes indicating failure to tolerate due to severe allergic reaction, or contraindication to available standard:
      - Standard cow milk based formula; and
      - Non-cow milk based formula, (including soybean)
  - For GE reflux with failure to thrive:
    - Consultation with relevant specialist (gastroenterologist or neonatologist); and
      Note: A consultation by a specialist is not required, for NJ plans. Requests from the covered infant's physician is sufficient.
    - Diagnosis of GE reflux WITH failure to thrive. Failure to thrive is defined as a child:
      - Growing below 3rd or 5th percentile; or
      - Whose decreased growth has crossed 2 major growth percentiles; and
    - Office notes indicating failure to tolerate due to severe allergic reaction or contraindication to available standard:
      - Cow milk based formula; and
      - Non-cow milk based formula, (including soybean)

**Specialized Foods**

Specialized foods (including low protein and amino acid modified food or formula) are covered for inborn errors of metabolism, which includes, but is not limited to, Homocystinuria, Maple syrup urine disease, methylmalonic aciduria, phenylketonuria (PKU), Tyrosinemas, certain inherited diseases of amino acid and organic acid metabolism, and Cystic Fibrosis.

Note: Specialized food for members with a diagnosis of Cystic Fibrosis is covered for CT Commercial plans only.

**NY Plans**

**Enteral Formulas**

Enteral formulas which are medically necessary and taken under written order from a physician for the treatment of specific diseases shall be distinguished from nutritional supplements taken electively.

Enteral formula or modified solid food products will be authorized based on all of the following criteria:
- Being used as part of disease specific treatment; and
- Treatment is for one of the following:
  - Inherited diseases of amino acid and/or organic acid metabolism
  - Crohn’s Disease
  - Gastroesophageal reflux disease with failure to thrive
  - Disorders of gastrointestinal motility such as chronic intestinal pseudo-obstruction
  - Multiple, severe food allergies
  and
- One of the following:
  - Patient is malnourished
  - Patient will become malnourished without treatment
  - If patient’s condition is left untreated it will cause one of the following:
    - Chronic physical disability
    - Mental retardation
    - Death
DEFINITIONS

**Failure to Thrive**: An abnormal pattern of weight gain defined by the lack of sufficient usable nutrition and documented by inadequate weight gain over time. Also known as weight faltering.

**Malnutrition**: Malnutrition is a broad term commonly used as an alternative to undernutrition but technically it also refers to overnutrition. People are malnourished if their diet does not provide adequate calories and protein for growth and maintenance or they are unable to fully utilize the food they eat due to illness (undernutrition).

**Severe Malnutrition**: Defined by a very low weight for height (below -3z scores of the median WHO growth standards), by visible severe wasting, or by the presence of nutritional edema.

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 the member specific benefit plan document 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 may apply.

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>B4100</td>
<td>Food thickener, administered orally, per oz</td>
</tr>
<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>
</tr>
<tr>
<td>B4104</td>
<td>Additive for enteral formula (e.g., fiber)</td>
</tr>
<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>
</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>
</tbody>
</table>
**DESCRIPTION OF SERVICES**

Nutrition is a term describing all the processes involved in the taking in and utilization of essential food substances necessary to sustain bodily functions. These processes include ingestion, digestion, absorption, and metabolism. There are conditions that inhibit any one or combination of these processes. In these cases medical nutritional therapy intervention **may** be required; a specific formula may be necessary to sustain life, or to prevent, delay, or reduce medical complications or sequelae when an inborn error of metabolism or a severe food allergy exists.

Routes of medical nutritional therapy include enteral (enteral therapy may be given orally or by tube feeding and may be liquefied food preparations or medically formulated foods) and parenteral (intravenous).

Specialized foods include Low Protein Modified Food Products, Amino Acid Food Preparations, and Specialized Formula for infants.

Examples of specialized formulas for medical conditions are listed in the table below (not all inclusive):

<table>
<thead>
<tr>
<th>Formula Name</th>
<th>Suggested Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alimentum</td>
<td>Infants with food allergies, protein or fat malabsorption</td>
</tr>
<tr>
<td>CaminoPro</td>
<td>Children with Phenylketonuria (PKU)</td>
</tr>
<tr>
<td>Elecare</td>
<td>Children with malabsorption, severe protein allergy</td>
</tr>
<tr>
<td>MJ3232A</td>
<td>Infants with severe carbohydrate (CHO) intolerance (CHO must be added)</td>
</tr>
<tr>
<td>Neocate</td>
<td>Children with malabsorption, severe protein allergy</td>
</tr>
<tr>
<td>Neocate One</td>
<td>Children with malabsorption, severe protein allergy</td>
</tr>
<tr>
<td>Nutramigen</td>
<td>Infants with food allergies</td>
</tr>
<tr>
<td>Peptamen</td>
<td>Children with malabsorption</td>
</tr>
<tr>
<td>Phenalcate, MSU D. powder</td>
<td>Children with Phenylketonuria (PKU)</td>
</tr>
<tr>
<td>Portagen</td>
<td>Infants with fat malabsorption</td>
</tr>
<tr>
<td>Pregestimil</td>
<td>Infants with food allergies, protein or fat malabsorption</td>
</tr>
<tr>
<td>ProPeptide for Kids</td>
<td>Children with malabsorption</td>
</tr>
<tr>
<td>RCF</td>
<td>Infants with severe CHO intolerance (CHO must be added) Modified for ketogenic diet</td>
</tr>
<tr>
<td>Vivonex</td>
<td>Children with malabsorption, severe protein allergy</td>
</tr>
</tbody>
</table>

**REFERENCES**


POLICY HISTORY/REVISION INFORMATION

<table>
<thead>
<tr>
<th>Date</th>
<th>Action/Description</th>
</tr>
</thead>
</table>
| 03/01/2017 | Reformatted and reorganized policy; transferred content to new template  
Updated benefit considerations:  
- Added instruction to check the member specific benefit plan document and any federal or state mandates, if applicable, before using this policy; in the event of a conflict, the member specific benefit plan document governs  
- Reformatted/reorganized language pertaining to coverage limitations and exclusions  
- Reformatted/reorganized state specific benefit guidelines  
- Added language for Essential Health Benefits for Individual and Small Group plans to indicate:  
  - For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits ("EHBs")  
  - Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs; however, if such plans choose to provide coverage for benefits which are deemed EHBs (such as maternity benefits), the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans  
  - The determination of which benefits constitute EHBs is made on a state by state basis; as such, when using this guideline, it is important to refer to the member specific benefit plan document to determine benefit coverage  
- Revised coverage rationale:  
  - Updated purpose statement to indicate the intent of this policy is to outline the conditions under which Oxford will authorize the use of food/formula that is specially formulated for specific medical conditions  
  - Updated coverage criteria for Connecticut (CT) and New Jersey (NJ) plans:  
    - Replaced references to "New Jersey Commercial plans" with "NJ plans"  
    - Replaced language indicating "specialized formula will be covered when criteria are met" with "specialized formula will be authorized when criteria are met"  
    - Added language to indicate coverage for specialized foods is not limited to listed examples of inborn errors of metabolism  
  - Updated coverage criteria for New York (NY) plans; replaced language |
indicating “enteral formula or modified solid food products will be *approved* based on all of the [listed] criteria” with “enteral formula or modified solid food products will be **authorized** based on all of the [listed] criteria”

- Updated definitions:
  - Removed definition of:
    - Amino acid food preparations
    - Low protein modified foods
    - Specialized formula
  - Revised definition of:
    - Failure to thrive
    - Malnutrition
    - Severe malnutrition
- Updated list of applicable HCPCS codes; added B4100, B4102, B4103, S9434, and T2101
- Updated supporting information to reflect the most current references
- Archived previous policy version HOME 005.16 T2