

FORMULA & SPECIALIZED FOOD

Policy Number: HOME 005.19 T2

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Related Policies
None

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	Yes ^{1,2}
Applicable Site(s) of Service (If site of service is not listed, Medical Director review is required)	Home
Special Considerations	¹ Precertification with Medical Director review or their Designee is required. ² For 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.

State	Product	Applicable Benefit Type
Connecticut (CT)	Specialized food	Pharmacy benefit
	Non-standard infant formula	<ul style="list-style-type: none"> • CT requires coverage: <ul style="list-style-type: none"> ○ Of specialized infant formula to age 12 when medically necessary ○ Under the general benefit package if plan does not have pharmacy coverage
New Jersey (NJ)	Specialized food	General benefit package
	Non-standard infant formula	Pharmacy benefit <ul style="list-style-type: none"> • Infant is to age 1 year (12 months)
New York (NY)	Specialized food	Pharmacy benefit
	Non-standard infant formula	

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, **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**
- **The specialized formula is medically necessary for the treatment of a disease or condition, including but not limited to ONE of the following:**
 - 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. A 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), Tyrosinemias, 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 (prescription or non-prescription) which are deemed medically necessary and written under 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

Nutritional Formulas

Nutritional formulas will be authorized for the treatment of phenylketonuria, branched-chain ketonuria, galactosemia, and homocystinuria.

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.

HCPCS Code	Description
B4100	Food thickener, administered orally, per oz
B4102	Enteral formula, for adults, used to replace fluids and electrolytes (e.g., clear liquids), 500 ml = 1 unit
B4103	Enteral formula, for pediatrics, used to replace fluids and electrolytes (e.g., clear liquids), 500 ml = 1 unit
B4104	Additive for enteral formula (e.g., fiber)
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 unit
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

HCPCS Code	Description
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
S9433	Medical food nutritionally complete, administered orally, providing 100% of nutritional intake
S9434	Modified solid food supplements for inborn errors of metabolism
S9435	Medical foods for inborn errors of metabolism
T2101	Human breast milk processing, storage and distribution only

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):

Formula Name	Suggested Use
Alimentum	Infants with food allergies, protein or fat malabsorption
CaminoPro	Children with Phenylketonuria (PKU)
Elecare	Children with malabsorption, severe protein allergy
MJ3232A	Infants with severe carbohydrate (CHO) intolerance (CHO must be added)
Neocate	Children with malabsorption, severe protein allergy
Neocate One	Children with malabsorption, severe protein allergy
Nutramigen	Infants with food allergies
Peptamen	Children with malabsorption
Phenalcate, MSU D. powder	Children with Phenylketonuria (PKU)
Phenyl-free	Children with Phenylketonuria (PKU)
Portagen	Infants with fat malabsorption
Pregestimil	Infants with food allergies, protein or fat malabsorption
ProPeptide for Kids	Children with malabsorption
Puramino	Children with severe protein allergy
RCF	Infants with severe CHO intolerance (CHO must be added) Modified for ketogenic diet
Vivonex	Children with malabsorption, severe protein allergy

REFERENCES

- American Medical Association. Healthcare Common Procedure Coding System, Medicare's National Level II Codes: HCPCS.
- Bankhead R, Boullata J, Brantley S., et al.; A.S.P.E.N. Board of Directors. Enteral nutrition practice recommendations. JPEN J Parenter Enteral Nutr. 2009. Mar-Apr;33(2):122-67.
- CGSA § 38a-492c and § 38a-518c. State of Connecticut, Insurance Department, Bulletin HC-60. September 24, 2004.
CT Insurance Code: 38a-492c.
CT Insurance Code: 38a-518c.
- Homan GJ. Failure to Thrive: A Practical Guide. Am Fam Physician. 2016 Aug 15;94(4):295-9.
- Malabsorption Formulas for Infants.
http://www.ct.gov/dph/lib/dph/wic_2017/malabsorption_formulas_for_infants.pdf
- N.Y. ISC. LAW § 3221(k)(11) Group or blanket accident and health insurance policies; standard provisions.
NJ; Group Health and Blanket Insurance: 17B:27-46.1r, 17B: 27-46.1z.
NJ; Individual Health Insurance Reform: 17B:27A-19.6; 17B:27A-7; 17B:27A-7.4.
NY Insurance Laws: 4303 (y); 3216 (c)(21); 3221 (k)(11).
NY OGC Opinion no. 2001-94.
Oxford Certificate of Coverage and Member Handbook.
- State of Connecticut-Special Supplemental Nutrition Program for Women, Infants, and Children. Approved Contract and Specialized Formulas/Medical Food Listing
http://www.ct.gov/dph/lib/dph/wic_2016/approved_contract_and_specialized_formulas-medical_food_listing_09.02.2016.pdf
- UNICEF. <http://www.unicef.org/progressforchildren/2006n4/malnutritiondefinition.html>. Accessed December 19, 2017.
- Vandenplas Y, Rudolph CD, Di Lorenzo C, et al. Pediatric gastroesophageal reflux clinical practice guidelines: joint recommendations of the North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition (NASPGHAN) and the European Society for Pediatric Gastroenterology, Hepatology, and Nutrition (ESPGHAN). J Pediatr Gastroenterol Nutr. 2009 Oct;49(4):498-547.
- World Health Organization (WHO). Available at: <http://www.who.int/nutrition/topics/malnutrition/en/index.html>
Accessed December 19, 2017.

POLICY HISTORY/REVISION INFORMATION

Date	Action/Description
08/01/2018	<ul style="list-style-type: none">Updated benefit considerations/coverage limitations and exclusions; modified notation to clarify all branded nutritional therapies covered under the pharmacy benefit are Tier 3Archived previous policy version HOME 005.18 T2