RATIONALE FOR INCLUSION IN PA PROGRAM

Background
Medical foods are defined by the FDA in section 5(b) of the Orphan Drug Act (21 U.S.C. 360ee (b) (3)) 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." These foods provide enteral nutritional for patients who find them medically necessary. Medically necessary products are those that are deemed effective as a specific treatment or are required to avoid chronic disability, mental retardation or death. The plan covers special medical formulas and enteral nutrition that are ordered by a licensed health care provider, and medically necessary to prevent clinical deterioration in members at nutritional risk:

1. An inability to meet their nutritional needs orally
2. Food allergy, GI irritability, seizure disorder, malabsorption disorder, failure to thrive, or prematurity
3. An inborn error of amino acid metabolism

Per the Service Benefit Plan Brochure, benefits are available for medical foods, when administered under the supervision of a physician:

1. For children through age 21 which are administered orally and provide the sole source (100%) of nutrition;
   a. This benefit is limited to one year following the date of the initial prescription or physician order for the medical food (e.g. Neocate, in formula form only); OR
2. For children through age 21 which are specialized nutritional formulas intended for use solely under medical supervision in the dietary management of an inborn errors of amino acid metabolism; OR
3. For any age member when medically necessary to be administered by a catheter or nasogastric tube

Coverage requirements:

a. Nutritional formula must meet the definition of Medical Food;
b. The Medical Food must be medically necessary;
c. The Medical Food is not an excluded product (i.e., non-formula);
d. Member must be receiving active, regular and ongoing medical supervision; and
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e. Member must be unable to manage their condition by modification of diet alone

Benefits are not available for Medical Foods in the following situations and are therefore not addressed in this policy:

1. Products and foods other than liquid formulas or powders mixed to become formulas such as:
   a. Foods and formulas readily available in a retail environment and marketed for persons without medical conditions;
   b. Low protein modified foods (i.e., pastas, breads, rice, sauces, baking mixes, etc.);
   c. Nutritional supplements;
   d. Energy products;

2. Special medical formulas and enteral nutrition used solely for food preference

3. Products administered orally for any condition not described in this policy

4. Medical foods administered orally for individuals age 22 and older

Summary

Medical foods may be considered medically necessary if the nutritional product is being used 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. A patient is considered at nutritional risk when documentation confirms he/she is malnourished, or at risk for developing malnutrition, due to a medical condition, chronic disease, or increased metabolic requirements resulting from the inability to ingest or adequately absorb food.

Prior approval is required to ensure the safe, clinically appropriate and cost effective use of medical food products while maintaining optimal therapeutic outcomes.