



Status

Active

Medical and Behavioral Health Policy

Section: Medicine

Policy Number: II-69

Effective Date: 08/27/2014

Blue Cross and Blue Shield of Minnesota medical policies do not imply that members should not receive specific services based on the recommendation of their provider. These policies govern coverage and not clinical practice. Providers are responsible for medical advice and treatment of patients. Members with specific health care needs should consult an appropriate health care professional.

AMINO ACID-BASED ELEMENTAL FORMULA

Description: An amino acid-based elemental formula is a type of exempt formula which is regulated by the U.S. Food and Drug Administration (FDA) and is prescribed for infants or children with specific medical or dietary problems. An amino acid-based formula contains proteins which are broken down into their simplest and purest form making it easier for the body to process and digest. An infant or child may be placed on an amino acid-based formula if he/she is unable to digest or tolerate whole proteins found in other formulas, due to certain allergies or gastrointestinal conditions. Examples of amino acid-based elemental formulas are Neocate[®], EleCare[®], PurAmino[™] (formerly Nutramigen[®] AA[™] LIPIL) and Vivonex[®].

Definitions: **Amino acid-based elemental formula:** A formula made of 100% free (i.e., individual) amino acids as the protein source.

Cystic fibrosis: An inherited, life-threatening disease that causes thick, sticky mucus to form in the lungs, pancreas, and other organs. In the lungs, this mucus blocks the airways, causing lung damage and making it difficult to breathe. In the pancreas, the mucus clogs the pathways leading to the digestive system and interferes with proper digestion.

IgE mediated allergy to food proteins: An immune reaction resulting from the interaction between a food protein and a type of antibody known as IgE. Symptoms are generally rapid in onset, primarily involve the skin (e.g., itching, hives) and, in severe cases, may lead to anaphylaxis.

Food protein-induced enterocolitis syndrome: A non-IgE-mediated immune reaction to one or more specific foods, commonly characterized by profuse vomiting and diarrhea. Poor growth may occur with continual ingestion of the specific food(s).

Eosinophilic esophagitis, eosinophilic gastroenteritis, and eosinophilic colitis: Conditions in which accumulation of a type of white blood cell, the eosinophil, causes injury and inflammation to the esophagus, stomach, or small or large intestine. Symptoms include vomiting, diarrhea, and poor growth.

Policy:

I. Initial Review

- A. The use of oral amino acid-based elemental formula may be considered **MEDICALLY NECESSARY** in patients five years of age and under when **BOTH** of the following criteria are met:
1. Patient has a definitive diagnosis, as supported by laboratory and/or diagnostic test results, of **ONE** of the following conditions:
 - a. Cystic fibrosis;
 - b. Amino acid, organic acid, and fatty acid metabolic and malabsorption disorders;
 - c. IgE-mediated allergies to food proteins;
 - d. Food protein-induced enterocolitis syndrome;
 - e. Eosinophilic esophagitis;
 - f. Eosinophilic gastroenteritis;
 - g. Eosinophilic colitis
 - h. Short gut syndrome
- AND**
2. Condition was diagnosed by an allergist, gastroenterologist, or pediatrician.
- B. The use of oral amino-acid based elemental formula may be considered **MEDICALLY NECESSARY** in children five years and under for up to 90 days when requested by a physician while actively seeking a confirmatory diagnosis and when **ALL** of the following documentation is submitted:
1. Presumptive diagnosis of one of the conditions defined in I.A.1; **AND**
 2. Patient's symptoms; **AND**
 3. Minimum of three to four prior failed formula alternatives.

II. Renewal Review

- A. The use of oral amino-acid based formula may be considered **MEDICALLY NECESSARY** in children five years and under when the following documentation is submitted by a physician:
1. Improvement of the patient's symptoms while on the amino acid based formula; **AND**
 2. Definitive diagnosis of one of the conditions defined in I. A.1, accompanied with supporting lab and / or diagnostic test results.

Coverage:

Blue Cross and Blue Shield of Minnesota medical policies apply generally to all Blue Cross and Blue Plus plans and products. Benefit plans vary in coverage and some plans may not provide coverage for certain services addressed in the medical policies.

Medicaid products and some self-insured plans may have additional

policies and prior authorization requirements. Receipt of benefits is subject to all terms and conditions of the member's summary plan description (SPD). As applicable, review the provisions relating to a specific coverage determination, including exclusions and limitations. Blue Cross reserves the right to revise, update and/or add to its medical policies at any time without notice.

For Medicare NCD and/or Medicare LCD, please consult CMS or National Government Services websites.

Refer to the Pre-Certification/Pre-Authorization section of the Medical Behavioral Health Policy Manual for the full list of services, procedures, prescription drugs, and medical devices that require Pre-certification/Pre-Authorization. Note that services with specific coverage criteria may be reviewed retrospectively to determine if criteria are being met. Retrospective denial of claims may result if criteria are not met.

Coding:

The following codes are included below for informational purposes only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.

HCPCS:

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

S9433 Medical food nutritionally complete, administered orally, providing 100% of nutritional intake

Policy History:

Developed April 11, 2007

Most recent history:

Reviewed September 14, 2011

Revised August 8, 2012

Reviewed August 14, 2013

Reviewed/Updated, no policy statement changes August 13, 2014

Cross Reference:

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