



Medica Central Coverage Policy

Policy Name: Amino Acid-Based Elemental Formulas MP9355

Effective Date: January 1, 2025

Important Information – Please Read Before Using This Policy:

These services may or may not be covered by all Medica Central plans. Coverage is subject to requirements in applicable federal or state laws. Please refer to the member's plan document for other specific coverage information. If there is a difference between this general information and the member's plan document, the member's plan document will be used to determine coverage. With respect to Medicare, Medicaid, and other government programs, this policy will apply unless these programs require different coverage.

Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions may call the Provider Service Center. Please use the Quick Reference Guide on the Provider Communications page for the appropriate phone number. <https://mo-central.medica.com/Providers/SSM-employee-health-plan-for-IL-MO-OK-providers>

Medica Central coverage policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care, and treatment.

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Amino acid-based elemental oral formulas (AABFs) are **COVERED** for the following diagnoses:

1. cystic fibrosis;
2. amino acid, organic acid, and fatty acid metabolic and malabsorption disorders such as phenylketonuria (PKU), hyperlysinemia, or maple syrup urine disease (MSUD);
3. IgE mediated allergies to food proteins;
4. food protein-induced enterocolitis syndrome;
5. eosinophilic esophagitis;
6. eosinophilic gastroenteritis; and
7. eosinophilic colitis;
8. mast cell activation syndrome.

AABFs are **NOT COVERED** for all other diagnoses.

Notes:

- The AABF must contain 100% free amino acids as the protein source and **must be** dispensed in accordance with U.S. Food & Drug Administration (FDA) approved exempt formulas labelling. Refer to the FDA's AABF list in the following website:

<https://www.fda.gov/food/infant-formula-guidance-documents-regulatory-information/exempt-infant-formulas-marketed-united-states-manufacturer-and-category>

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- Enteral feedings are addressed specifically in the Utilization Management Policy *Outpatient Enteral Nutrition Therapy*.

Note: This policy does not apply to Individual Family Business (IFB) members whose plans are covered in Missouri, Illinois, or Wisconsin.

Note: This policy is no longer scheduled for routine review of the scientific literature

Description

Amino acid-based elemental formulas (AABFs) are one of four main classes of oral formula and are made from individual (single) non-allergenic amino acids unlike regular dairy (milk or soy based) formulas and foods that contain many complete proteins. Amino acid-based elemental formulas are made of proteins broken down to their "elemental level" so that they can be easily absorbed and digested. In many cases, amino acid-based elemental formulas are the only thing an infant or child can properly digest and tolerate due to various allergies or gastrointestinal conditions.

Amino acids are important for the synthesis of numerous compounds, including structural proteins, peptide hormones, and enzymes needed for gluconeogenesis or in the generation of energy. Of the 20 amino acids, 11 amino acids can be synthesized by the body and nine cannot. The nine that cannot be synthesized *in vivo* are called "essential amino acids." Their bioavailability relies completely upon dietary intake. The essential amino acids include histidine, isoleucine, leucine, lysine, methionine, phenylalanine, threonine, tryptophan, and valine.

Amino acid disorders (also called amino acidopathies) are caused by a defect in the metabolic pathways of amino acids. They are called amino acidemias when there is abnormal accumulation of amino acids in the plasma and amino acidurias when there is abnormal excretion of amino acids in the urine. Symptoms typically result from accumulation of the substance that cannot be metabolized. Examples of amino acid disorders include maple syrup urine disease and phenylketonuria.

Inborn errors of metabolism are genetic disorders in which the body cannot properly turn food into energy. The disorders are usually caused by defects in specific proteins (enzymes) that help break down (metabolize) parts of food

Oral formula refers to a commercially formulated substance, ingested through the mouth, which provides nourishment, and affects the nutritive and metabolic processes of the body; nourishment that is required to provide sufficient nutrients to maintain weight and strength related to the persons overall health status.

Prior Authorization

Prior authorization is not required. However, services with specific coverage criteria may be reviewed retrospectively to determine if criteria are being met. Retrospective denial may result if criteria are not met.

Coding Considerations

Use the current applicable CPT/HCPCS code(s). 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.

HCPC Codes:

- **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

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- **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.

	Committee/Source	Date(s)
Document		
Created:	Medical Policy Committee/Health Services Division	June 19, 2019
Revised:	Medical Policy Committee/Health Services Division	June 17, 2020
	Medical Policy Committee/Health Services Division	June 16, 2021
	Medical Policy Committee/Health Services Division	April 20, 2022
	Medical Policy Committee/Health Services Division	May 17, 2023
	Medical Policy Committee/Health Services Division	March 20, 2024
	Medical Policy Committee/Health Services Division	July 17, 2024
Reviewed:	Medical Policy Committee/Health Services Division	June 17, 2020
	Medical Policy Committee/Health Services Division	June 16, 2021
	Medical Policy Committee/Health Services Division	April 20, 2022
	Medical Policy Committee/Health Services Division	May 17, 2023
	Medical Policy Committee/Health Services Division	March 20, 2024
	Medical Policy Committee/Health Services Division	July 17, 2024

Document History:

Original Effective Date:

Re-Review Date(s): 09/18/2024

Administrative Update:

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