

## Formula, oral - Amino Acid Based Elemental - DME

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### Administrative Process

Requires prior approval

### Definitions

**Oral Formula** refers to a commercially formulated substance, ingested through the mouth, that 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.

**Amino-acid based elemental formulas (AABFs)** are one of four main classes of oral formula. AABFs are not derived from a food source, but instead contain 100% free amino acids (the building blocks of protein) as the protein source. AABFs are indicated for certain adverse reactions and food allergy conditions, as the nutrients contained in AABFs are in their most broken down form.

'Vivonex' and 'Tolerex' manufactured by Novartis Nutrition, 'Neocate' manufactured by Nutricia North America, 'Elecare' by Abbott, 'Nutramigen AA' and 'Nutramigen AA LIPIL' manufactured by Mead Johnson are examples of 100% amino acid based elemental formulas.

### Coverage

Oral amino-acid based elemental formulas are generally covered subject to the indications listed below and the following limits from your member contract:

- AABF Formula is limited by the following:
  - a. All covered AABF should be the acceptable standard AABF formula, considering the member's medical condition. If a member requests formula which contains an additional ingredient that is safe and effective, HealthPartners may cover the cost up to the cost of the acceptable standard AABF formula.
  - b. Payment will not exceed the cost of an alternate AABF formula that is effective and medically necessary. Please see your member contract or specific medical coverage criteria for details.
- AABF Formula will not be approved when used for non-medically necessary reasons.
- AABF Formula must be obtained from an approved vendor.

### Indications that are covered

1. Coverage of oral amino-acid based elemental formula is limited to children age five years and younger.
2. Oral amino-acid based elemental formula is covered when ordered by a physician for a member diagnosed with any of the following conditions:
  - a. IgE mediated allergies to food proteins
  - b. Food protein induced enterocolitis syndrome
  - c. Eosinophilic esophagitis (EE)
  - d. Eosinophilic gastroenteritis (EG)
  - e. Eosinophilic colitis
  - f. Amino acid, organic acid and fatty acid metabolic and malabsorption disorders
  - g. Cystic fibrosis
3. When requesting coverage, the ordering physician is required to submit documentation of symptoms and diagnosis, expected course of treatment and duration of treatment with AABF. Interim coverage may be provided for up to 90 days when requested by a physician while actively seeking diagnosis.
4. Condition must be diagnosed by an allergist, gastroenterologist, or pediatrician.

### Indications that are not covered

1. All other conditions not listed above remain not covered for treatment with oral amino-acid based elemental formula.
2. For the treatment of conditions listed above, other formulas which do not provide 100% free amino acids as the protein source, including, but not limited to: Casein Hydrolysate formulas with added Amino Acids, (examples include Nutramigen LIPIL, Enfamil Pregestimil, Similac Alimentum Advance, and Similac Alimentum) and Hydrolyzed Whey-based formulas (examples include Carnation Good Start and Nestle Peptamen).

### Products

Consult your plan documents (Membership Contract, Summary Plan Description [SPD], Evidence of coverage [EOC] or similar plan document) to determine governing contractual provisions, including exclusions and limitations relating to your specific plan. These guidelines apply to most, but not all, plans offered by HealthPartners. We strive to ensure that the contents of this site are correct and complete, but to verify your benefits, please check your contract or SPD, or contact Member Services. In the event of a conflict between your specific plan documents and this general information, the plan documents will govern. These coverage criteria may not apply to Medicare Products if Medicare requires different coverage. For more information regarding Medicare coverage criteria or for a copy of a Medicare coverage policy contact Member Services at 952-883-7979 or 800-233-9645.

### Vendor

Must be provided by a contracted DME vendor or pharmacy for in network benefits to apply.

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Related Policies: Formula/Enteral Nutrition-DME, PKU Food Products and Formula-DME