Clinical Review Criteria

Enteral Formulas for Nutritional Therapy

Group Health Clinical Review Criteria are developed to assist in administering plan benefits. These criteria neither offer medical advice nor guarantee coverage. Group Health reserves the exclusive right to modify, revoke, suspend or change any or all of these Review Criteria, at Group Health's sole discretion, at any time, with or without notice. Member contracts differ in their benefits. Always consult the member's Medical Coverage Agreement or call Group Health Customer Service to determine coverage for a specific medical service.

For Non-Medicare Plans:
(Excludes Microsoft plans, which have separate criteria)

The criteria are for formulas only. The pumps and associated equipment are considered durable medical equipment and are covered as part of the durable medical equipment benefit.

Elemental formulas are composed of amino acids, fats, sugars, vitamins, and minerals and lack whole or partial protein. An example of an elemental formula is Vivonex. Most formulas are not elemental as they contain complete proteins and complex carbohydrates, examples of which are Ensure or Prosobee.

To qualify for enteral nutritional formula, elemental formula (either replacement or supplemental) or non-elemental formula, the member must meet ONE of the following, either I, II or III:

I - To qualify for Nutritional Replacement Therapy, using an elemental formula, members must meet All of the following:
1) Members must have at least ALL of the following diagnoses:
   a) Crohn's Disease
   b) Inflammatory Bowel Disease
   c) Short Bowel Syndrome
   d) Eosinophilic gastrointestinal associated disorders
2) The member must also meet ALL of the following:
   a) Formula is intended for home use
   b) The member is managed by a Gastroenterologist
   c) The member has been evaluated and will be followed by a Registered Dietitian
   d) Elemental total nutritional replacement represents 80 - 100% of diet or 80% or greater of the daily dietary requirements
   e) Alternative approaches, other than use of an elemental formula, have not resulted in adequate nutrition and control of symptoms.
   f) Member must meet ALL of the following:
      i) Able to tolerate oral supplementation
      ii) If unable to tolerate oral supplementation, member must meet ALL of the following:
         • The member or caregiver must demonstrate the ability to place a nasogastric tube.
         • The member or caregiver must also be able to demonstrate the ability to regulate flow either via gravity drip or pump.

II- To qualify for Nutritional Supplementation Therapy using, an elemental formula, members must meet All of the following:
1) Members must have at least ALL of the following diagnoses:
   a) Crohn's Disease
   b) Inflammatory Bowel Disease
c) Short Bowel Syndrome  
d) Cystic Fibrosis involving the intestine  
e) Eosinophilic gastrointestinal associated disorders  

2) Members must also meet **ALL of the following:**  
   a) Intended for home use  
   b) Growth failure/retardation or cachexia has been documented  
   c) The member is managed by a Gastroenterologist  
   d) The member has been evaluated and will be followed by a Registered Dietitian  
   e) Therapy, other than use of an Elemental formula, has not resulted in clinical disease management.  

3) Member must meet **ONE of the following:**  
   a) Able to tolerate oral supplementation  
   b) If unable to tolerate oral supplementation, member must meet **ALL of the following:**  
      i) The member or caregiver must demonstrate the ability to place a nasogastric tube or manage a surgically placed feeding tube.  
      ii) The member or caregiver must also be able to demonstrate the ability to regulate flow either via gravity drip or pump.  

**III.** Oral nutrition or supplements using non-elemental formula may be considered medically necessary when used for the treatment of inborn errors of metabolism. Member must meet **ALL of the following:**  
   a) Must have **ONE of the following** diagnosis:  
      i) Phenylketonuria [PKU]  
      ii) Maple syrup urine disease (MSUD)  
      iii) Homocystinuria,  
      iv) Histidinemia  
      v) Tyrosinemia  
      vi) Glycogen Storage Type II Syndrome (GSD II or Pompe disease)  
   b) Formula is intended for home use (not for use in the hospital or nursing facility)  

**The following are not covered:**  
Member with a functional intestine and access problems (gastrostomy, jejunostomy or problems with the mechanism of oral feeding requiring tube access to the stomach) are not covered for supplemental therapy unless they meet the criteria above.