



Clinical Review Criteria
Enteral Formula

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	Enteral Nutrition (L38955)
Local Coverage Articles	Enteral Nutrition (A58833)

For Non-Medicare Members

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, III or IV:

- I. To qualify for Nutritional Replacement Therapy, using an *elemental* formula, members must meet **ONE of the following**:
 - A. Members must have at least **ONE of the following** diagnoses:
 1. Crohn's Disease
 2. Inflammatory Bowel Disease
 3. Short Bowel Syndrome
 4. Eosinophilic gastrointestinal associated disorders
 - B. The member must also meet **ALL of the following**:
 1. Formula is intended for home use
 2. The member is managed by a Gastroenterologist
 3. The member has been evaluated and will be followed by a Registered Dietitian
 4. Elemental total nutritional replacement represents 80 - 100% of diet or 80% or greater of the daily dietary requirements
 5. Alternative approaches, other than use of an elemental formula, have not resulted in adequate nutrition and control of symptoms.
 6. Member must meet **ALL of the following**:
 - a. Able to tolerate oral supplementation
 - b. 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 or manage a surgically placed feeding 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**:
- A. Members must have at least **ONE of the following** diagnoses:
 - 1. Crohn's Disease
 - 2. Inflammatory Bowel Disease
 - 3. Short Bowel Syndrome
 - 4. Cystic Fibrosis involving the intestine
 - 5. Eosinophilic gastrointestinal associated disorders
 - B. Members must also meet **ALL of the following**:
 - 1. Intended for home use
 - 2. Growth failure/retardation or cachexia has been documented
 - 3. The member is managed by a Gastroenterologist
 - 4. The member has been evaluated and will be followed by a Registered Dietitian
 - 5. Other therapies, such as medication, have not resulted in adequate nutrition/weight gain
 - C. Member must meet **ONE of the following**:
 - 1. Able to tolerate oral supplementation
 - 2. If unable to tolerate oral supplementation, member must meet **ALL of the following**:
 - a. The member or caregiver must demonstrate the ability to place a nasogastric tube or manage a surgically placed feeding tube.
 - b. 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:
 - 1. Phenylketonuria [PKU]
 - 2. Maple syrup urine disease (MSUD)
 - 3. Homocystinuria,
 - 4. Histidinemia
 - 5. Tyrosinemia
 - 6. 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)
- IV. *Non-elemental formula* is covered for members who require tube feeding under the following conditions:
- a) Non-function or disease of the structures that normally permit food to reach the small bowel. The condition could either be anatomic (obstruction due to head and neck cancer, reconstructive surgery, etc.) or a motility disorder (e.g., severe dysphagia following a stroke, congenital defects, etc.) **AND**
 - b) Requires tube feeding to maintain weight and strength commensurate with the patient's overall health status **AND**
 - c) The patient's condition is anticipated to be long term in duration, typically at least 3 months (90 days).

*Elemental formula can be delivered by tube only if indications in I or II above are met

The following are not covered:

- Intra-peritoneal nutrition is considered experimental and investigational.

*Diagnosis Codes that are covered for Eosinophilic Gastrointestinal Associated Diseases
ICD-10

K20.0 Eosinophilic esophagitis

K52.81 Eosinophilic gastritis or gastroenteritis

K52.82 Eosinophilic colitis

If requesting these services, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist (PCP, GI specialist)
- Last 6 months of radiology notes if applicable

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations..

Background

Until 1996, the only Kaiser Permanente plans that had coverage for enteral therapy were the Medicare plans. In 1996 an appeals case caused Kaiser Permanente to reevaluate the potential inclusion of enteral therapy for all groups. The reevaluation, which included a special work group and the Benefits Committee, concluded that the use of elemental enteral therapy for ineffective GI absorption that represented a major portion of the consumer's calorie intake, should be covered up to the level of replacement of regular cost of food (80% of charges).

This coverage was to be added in 1997 to all plans under dietary formula where enteral nutrition therapy benefit is not in place. Since only subsets of specific consumers are eligible for this coverage, criteria were developed for consistent review of requests.

In 1998, Kaiser Permanente received a request to consider coverage for Glycogen Storage Type II Syndrome supplemental formula. After review of the case and literature, the decision was made to add the disease to the criteria for coverage.

In July 1998 Kaiser Permanente received an update of the Healthy Options criteria for coverage of enteral feedings. In October 2005 the MMA program updated the coverage criteria that are applicable to Healthy Options. Kaiser Permanente criteria were adjusted to reflect the new changes.

Evidence and Source Documents

03/1998

Articles: Definitions: Inflammatory Bowel Disease includes Crohn's Disease of small intestine or colon, Ulcerative Colitis, and overlap syndromes (Non-Specific IBD, Segmental Colitis) An Elemental Diet contains oligo-peptides as the major protein source. Vivonex (lower fat- 2.5%) and Vital HN (higher fat- 8%) are typical elemental diets. Non-elemental diets contain intact proteins from a defined source (such as milk protein, meat or egg)

Growth Retardation/ Failure requires: A pediatric patient (defined as age<18 years, and epiphyses not fused on radiography) and a height per age <5th percentile, or a decrease in growth velocity of ≥ 2 cm/year, or bone age > 2 SD below chronologic age Nutritional Replacement Therapy requires $>90\%$ (and preferable 100%) of the caloric intake be provided by the elemental formula Nutritional Supplementation Therapy requires that $>50\%$ of the caloric intake is provided by the elemental formula. The use of elemental enteral nutrition in inflammatory bowel disease has progressed from strictly nutritional to therapeutic. Although the mechanism is not fully understood, disease activity and intestinal permeability decrease in patients "fed" with elemental diets, as compared to regular diet or TPN. The therapeutic role is best documented in the management of Crohn's Disease [especially of the small intestine]. The role of this therapy in Ulcerative Pancolitis, Ulcerative Colitis limited to the left colon, nonspecific IBD, and Segmental Colitis is not supported by these data. Nutritional Therapy (whether Replacement or Supplement) is used only in conjunction with other drug therapy (including 5-ASA compounds, corticosteroids, immunosuppressives and antibiotics) not in lieu of these other therapies. The consideration of surgery as primary therapy must be considered in patients with significant strictures complicating nutrition.

References:

Griffiths et al "Meta-analysis of Enteral Nutrition as a Primary Treatment of Active Crohn's Disease" Gastro 108, 1995

Meta-analysis of enteral nutrition vs. steroids as primary therapy; findings were that steroids were more effective. Also compared composition of diets and found no clear data [not significant power] supporting elemental over polymeric.

Teahon et al "Alterations in Nutritional Status and Disease Activity during Treatment of Crohn's Disease with Elemental Diet" Scand J Gastro 30, 1995

Replacement of diet with Vivonex or similar for 5-week period, 1850-3700 kcal/d. Required significant malnutrition at entry into study. Improvement in inflammatory activity preceded nutritional improvement in most cases.

Fernandez-Banares et al "How Effective is Enteral Nutrition in Inducing Clinical Remission in Active Crohn's Disease? A meta-analysis of the Randomized Clinical Trials" JPEN 19, 1995

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

Elemental formula

HCPC Codes	Description
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
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

Formula for inborn errors of metabolism

HCPC Codes	Description
B4157	Enteral formula, nutritionally complete, for special metabolic needs for inherited disease of metabolism, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit
B4162	Enteral formula, for pediatrics, special metabolic needs for inherited disease of metabolism, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit

Non-elemental formula

HCPC Codes	Description
B4150	Enteral formula, nutritionally complete with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit
B4152	Enteral formula, nutritionally complete, calorically dense (equal to or greater than 1.5 kcal/ml) with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit
B4158	Enteral formula, for pediatrics, nutritionally complete with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber and/or iron, administered through an enteral feeding tube, 100 calories = 1 unit
B4159	Enteral formula, for pediatrics, nutritionally complete soy based with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber and/or iron, administered through an enteral feeding tube, 100 calories = 1 unit
B4160	Enteral formula, for pediatrics, nutritionally complete calorically dense (equal to or greater than 0.7 kcal/ml) with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit

Other specialized formulas

Not routinely covered; the medical record must document why the specific formula is medically necessary

*Not covered by Medicare

HCPC Codes	Description
B4102*	Enteral formula, for adults, used to replace fluids and electrolytes (e.g., clear liquids), 500 ml = 1 unit
B4103*	Enteral formula, for pediatrics, used to replace fluids and electrolytes (e.g., clear liquids), 500 ml = 1 unit
B4105	In-line cartridge containing digestive enzyme(s) for enteral feeding, each
B4149	Enteral formula, manufactured blenderized natural foods with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit
B4154	Enteral formula, nutritionally complete, for special metabolic needs, excludes inherited disease of metabolism, includes altered composition of proteins, fats, carbohydrates, vitamins and/or minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit <i>(i.e., diabetic, renal, post-surgical, ketogenic)</i>
B4155	Enteral formula, nutritionally incomplete/modular nutrients, includes specific nutrients, carbohydrates (e.g., glucose polymers), proteins/amino acids (e.g., glutamine, arginine), fat (e.g., medium chain triglycerides) or combination, administered through an enteral feeding tube, 100 calories = 1 unit

<i>*almost always taken with another formula unless eating orally and requiring one specific nutrient</i>

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

**To verify authorization requirements for a specific code by plan type, please use the [Pre-authorization Code Check](#).

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7/11/1984	1/5/2010 ^{MDCRPC} , 11/2/2010 ^{MDCRPC} , 9/6/2011 ^{MDCRPC} , 7/3/2012 ^{MDCRPC} , 5/07/2013 ^{MDCRPC} , 2/04/2014 ^{MPC} , 12/02/2014 ^{MPC} , 10/06/2015 ^{MPC} , 08/02/2016 ^{MPC} , 06/06/2017 ^{MPC} , 04/03/2018 ^{MPC} , 04/02/2019 ^{MPC} , 04/07/2020 ^{MPC} , 04/06/2021 ^{MPC} , 04/05/2022 ^{MPC} , 04/04/2023 ^{MPC}	11/13/2023

^{MDCRPC} Medical Director Clinical Review and Policy Committee
^{MPC} Medical Policy Committee

Revision History	Description
8/31/2016	Added LCD for Enteral Therapy
12/06/2016	Added Intraperitoneal Nutrition (IPN) to the non-covered list
05/31/2018	Removed the Microsoft link
03/02/2021	MPC approved to amend the current criteria to include indications for non-elemental formula for patients receiving nutrition via tube feeding. Requires 60-day notice, effective date 08/01/2021.
08/13/2021	Added clarifying timeframe to define long term in IV.c. as typically at least 3 months (90 days).
7/28/2023	Updated Medicare policy article link (A58833)
11/13/2023	Updated Medicare LCD link Enteral Nutrition (L38955) and policy article link (A58833).