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 patient's Medical Coverage Agreement or call Group Health Customer Service to determine coverage for a specific medical service.

Criteria

For Medicare Members
See NCD for Enteral and Parenteral Nutritional Therapy (180.2) and the LCD for Enteral Nutrition (L11568).

For Non-Medicare Members
See separate criteria pages for:
Non-Medicare Plans
Microsoft Plans

The following information was used in the development of this document and is provided as background only. It is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Until 1996, the only Group Health plans that had coverage for enteral therapy were the Medicare plans. In 1996 an appeals case caused Group Health to reevaluate the potential inclusion of enteral therapy for all groups. The reevaluation, which included a special work group and the Cooperative 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, Group Health 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 Group Health 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. Group Health criteria were adjusted to reflect the new changes.

Evidence/ Source Documents

<table>
<thead>
<tr>
<th>Date of Literature Search</th>
<th>Articles</th>
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<tbody>
<tr>
<td>3/1998</td>
<td>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</td>
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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 >= 2cm/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.


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