Drug Therapy Guidelines

Nutritional Supplements, Enteral Formulas

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I. Medication Description

Prescription coverage of enteral formulas is not intended to provide normal food products used in the dietary management of disorders, but to provide for such coverage of formulas that are equivalent to a prescription drug administered under the direction of a physician.

II. Position Statement

Coverage is determined through a prior authorization process with supporting clinical documentation for every request.

III. Policy

Coverage of enteral formulas can be provided when:

- Patient has a valid prescription from a licensed prescriber for the requested enteral formula **AND**
- The benefits of the requested enteral formula must not be duplicable through calorie supplementation that could be obtained through alternative dietary means alone **AND**
- The enteral formula is clearly medically necessary and has been proven effective as a disease-specific treatment regimen for those individuals who are or will become malnourished or suffer from disorders, which if left untreated, cause chronic physical disability, mental retardation, or death.
  - **Specific diseases** for which enteral formulas have been proven effective shall include, but are not limited to:
    - Inherited diseases of amino acid or organic acid metabolism
    - Crohn’s disease
    - Gastroesophageal reflux with failure to thrive
      - Weight below the 5th percentile for age on the appropriate growth chart **OR**
      - Shift of two or more curves on the appropriate growth chart during a six-month period **OR**
      - Height to weight ratio below the 5th percentile for age on the appropriate growth chart.
    - Disorders of gastrointestinal motility such as chronic intestinal pseudo-obstruction
    - Multiple, severe food allergies
    - Swallowing disorders as supported by a dysphagic evaluation by a GI specialist, developmental pediatrician, neurologist, or speech pathologist
    - Cases where adult BMI is less than 19
The following documentation must be provided to support the medical necessity claim (where applicable):

- Appropriate diagnosis
- Clinical history, including any pertinent specialist consultations
- Growth charts for children
  - For premature infants, growth chart should be adjusted for gestational age during the first two years of life.
- Allergy testing results
- Other appropriate tests (e.g. prealbumin, serum albumin)
  - Serum albumin < 3.5 or prealbumin < 15 within the previous 3 months will be reviewed for coverage
- Other failed treatment modalities

IV. **Quantity Limitations**

Quantities sufficient to fulfill the written request for coverage will be reviewed.

V. **Coverage Duration**

Coverage may be provided for up to 12 months and may be renewed.

VI. **Coverage Renewal Criteria**

Coverage can be renewed based upon the following criteria:

- Same as prior authorization criteria
- For specific chronic diseases:
  - Stabilization of disease or in absence of disease progression **AND**
  - Absence of unacceptable toxicity from the drug

VII. **Billing/Coding Information**

n/a

VIII. **Summary of Policy Changes**

- 12/15/12: max duration of authorization extended to one year, renewal criteria updated to include that the original approval criteria must be met for non-chronic diseases.
- 6/2013: Included newly communicated New York State Medicaid coverage requirements
- 12/15/13: No policy changes
- 1/1/15: no policy changes
- 7/1/15: formulary distinctions made
- 3/15/16: no policy changes
- 11/1/16: Medicaid-specific criteria removed from policy
IX. References

1. New York State legislation, January 1, 1998
2. Black, M., Kirshnakumar, A. Predicting Longitudinal Growth Curves of Height and Weight for Children with
   (9): 558-567.
   Mosby
   (reaffirmed 1999); Jul-Aug; 17 (4 Suppl): 29SA-32SA.
7. Baldwin, C., Parsons, T., Logam, S. Dietary Advice and Oral Supplements for Illness-Related Malnutrition in
   Nutrition* 1993 (reaffirmed 1999); Jul-Aug; 17 (4 Suppl): 12SA-26SA.
   Nutrition* 1993 (reaffirmed 1999); Jul-Aug; 17 (4 Suppl): 39SA-49S
10. Tanis R. Fenton T. A new growth chart for preterm babies; Babson and Benda's chart updated with recent
    *American Family Physician*; May 1, 1998

*The Plan fully expects that only appropriate and medically necessary services will be rendered. The Plan reserves
the right to conduct pre-payment and post-payment reviews to assess the medical appropriateness of the above-
referenced therapies.*

*Drug therapy initiated with samples will not be considered as meeting medical necessity for coverage for non-preferred or prior authorized medications.*

*The preceding policy applies only to members for whom the above named pharmacy benefit medications are included on their covered formulary. Members with closed formulary benefits are subject to trying all appropriate formulary alternatives before a coverage exception for a non-formulary agent will be considered.*

*The preceding policy is a guideline to allow for coverage of the pertinent medication/product, and is not meant to serve as a clinical practice guideline.*