



California  
Department of  
Health Services

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N.L.: 22-0805  
Supersedes N. L.: 04-0399  
Index: Benefits

TO: ALL COUNTY CALIFORNIA CHILDREN SERVICES (CCS)  
ADMINISTRATORS, MEDICAL CONSULTANTS, AND STATE  
CHILDREN'S MEDICAL SERVICES (CMS) STAFF

SUBJECT: ENTERAL NUTRITION PRODUCTS AS A CCS BENEFIT

## **I. PURPOSE**

This Numbered Letter (N.L.) outlines the CCS criteria and process for authorization of enteral nutrition products which are:

- replacement products
- elemental products
- calorie dense enteral/oral products, and
- nutrition additives.

This letter replaces Numbered Letter 04-0399, Nutrition Products as a CCS/GHPP Benefit.

## **II. BACKGROUND**

Enteral nutrition products are a CCS program benefit when they are medically necessary for the treatment of a CCS eligible medical condition. Some CCS eligible medical conditions preclude adequate nutrition intake or increase the nutrition needs of the client, thereby requiring nutrition support in order to prevent or treat malnutrition. The duration of use of an enteral nutrition product is variable depending on birth weight, intrauterine growth restriction, and associated medical complications in the premature infant, or could be a lifelong treatment as is the standard for individuals with metabolic disorders.

Enteral nutrition products are intended to treat a nutrition deficit, imbalance, or an increased nutrition requirement. These products may be administered orally or through a tube, and may provide supplemental nutrition or be the sole source of nutrition. Prescribed products must be medically appropriate and efficacious for the CCS eligible medical condition. Some CCS eligible medical conditions are associated with short stature and depressed body mass and the inability to achieve a normal growth pattern. These conditions will not benefit from aggressive nutrition support. Moreover, enteral nutrition products are not intended to replace whole foods for a child who is able to consume whole foods. Nutrition products appropriately chosen may be crucial to the development and promotion of a child's independent feeding skills.

### III. DEFINITIONS

#### A. Replacement formulas/products:

Replacement formulas/products are complete nutritional products indicated for replacement of nutrient component(s) that, because of an underlying CCS-eligible medical condition, cannot be tolerated. These formulas/products are indicated for individuals with inborn errors of metabolism or specific organ dysfunction (e.g., renal, cardiac, or liver disease) who require a special product as an integral part of the medical management of the disorder. Replacement formulas/products do NOT include medical foods such as low protein bread and pasta products. Refer to N.L.: 05-0399 for policy regarding medical foods. Examples of conditions which generally require replacement formulas/products are:

1. Conditions requiring amino acid-restriction such as Phenylketonuria (PKU), Homocystinuria, or Maple Syrup Urine Disease (MSUD) (product examples: Phenyl-Free 1, MSUD Maxamaid, Phenex 2, UCD 1, and OS 2).
2. Conditions that require carbohydrate restriction (galactose, lactose, sucrose, and fructose) such as Glycogen Storage Disease, galactosemia or patients on the ketogenic diet (product examples: RCF and Vivonex).
3. Conditions that require mineral/electrolyte restriction such as hyperphosphatemia or hyponatremia (product examples: Similac PM 60/40 and Calcilo XD).

4. Conditions that require high nutrient, specialized formulas such as prematurity with compromising chronic lung disease (product examples: Enfamil EnfaCare LIPIL, Similac NeoSure Advance, and Similac Special Care Advance). Concentrated versions of regular infant formula that may be used to meet the nutrition needs of the premature infant are not CCS or Medi-Cal program benefits. Refer to N.L.: 20-0605 for policy on regular infant formulas.

B. Elemental formulas:

Elemental formulas are complete nutrition formulas designed for individuals who have a dysfunctional or shortened gastrointestinal tract and are unable to tolerate and absorb whole foods or formulas composed of whole proteins, fats, and/or carbohydrates. Whole foods are defined as home-prepared and significantly unaltered foods. For example, blenderized or pureed table foods are considered whole foods. Examples of conditions which result in malabsorption, intolerance or gastrointestinal dysfunction are necrotizing enterocolitis, gastroschisis, chylothorax, ulcerative colitis, HIV infection, and neoplastic conditions. Examples of elemental formulas that contain modified macronutrients that allow easier absorption are Neocate One, Peptamin Junior, Portagen, and Vivonex Pediatric.

C. Calorie dense enteral/oral products:

Calorie dense enteral/oral products are prescribed for individuals with fluid restrictions, increased nutrient requirements, and/or specific feeding impairments that preclude an adequate oral food intake. Examples of medical conditions that result in increased nutrient requirements or severe limitations of adequate oral intake are severe burns, severe head injury, cystic fibrosis, renal disease, and cardiac conditions. Examples of complete nutrition formulas that provide higher caloric density such as one to two calorie per milliliter or greater than 30 calories/ounce are Ensure, Ensure Plus, PediaSure, Isocal HN Plus, Jevity 1.5, Kindercal, TwoCal HN, and Boost.

D. Nutrition additives:

Nutrition additives or modular products are non-whole food preparations that may be added to regular foods or formulas in order to provide supplemental calories/nutrients, or alter the nutrient composition to meet the unique nutrition needs of the medical condition. Examples of medical conditions that require

specific additives are prematurity, cardiac and renal conditions, and cystic fibrosis. Examples of nutritional additives according to macronutrient content are carbohydrate supplements such as Polycose, fat supplements such as MCT Oil or Microlipid, protein supplements such as ProMod, and combination supplements such as Duocal and Benecalorie.

#### IV. POLICY

- A. Effective September 1, 2005, all enteral nutrition product categories defined in this N.L. are removed from the CCS program service code groupings and placed on the excluded drug/product list. Therefore, these enteral nutrition products require individual authorization.
- B. The following enteral nutrition products are a CCS program benefit for outpatient use (i.e., client is not a resident of a licensed care facility) when the products are medically necessary for the treatment of a CCS eligible medical condition:
- Replacement formulas/products
  - Elemental formulas
  - Nutrition additives
- C. Calorie dense enteral/oral products are a CCS program benefit for outpatient use (i.e., client is not a resident of a licensed care facility) when the products are medically necessary for the treatment of a CCS eligible medical condition (such as, HIV infection, cystic fibrosis, malignancy, and dialysis) **and** the enteral nutrition products make up greater than 20 percent of the CCS client's recommended daily nutrient intake **and** one of the following criteria are met:
1. There is a CCS eligible medical condition that renders the client to be at nutrition/health risk because of severe oral impairments; these impairments must result in:
    - Inadequate nutrition intake as a result of a risk of aspiration, or
    - severe swallowing/choking during feeding per occupational or speech therapy assessment, or
    - prolonged feeding times beyond thirty minutes per meal; or

2. There is inadequate growth or growth deficiency which cannot be corrected by using home-prepared calorie dense foods and is evidenced by one of the following:
  - a. The weight for length/height or body mass index (2-20 years) is at or below the 5<sup>th</sup> percentile on one of the CDC growth charts; or
  - b. Skinfold measurements are at or below the 5<sup>th</sup> percentile on standardized scales such as Frisancho; or
  - c. Growth velocity for weight is falling and is approaching the 10<sup>th</sup> percentile on standardized scales such as Guo; or
  - d. Weight is at or below the 5<sup>th</sup> percentile for gestational age on Low Birth Weight/Very Low Birth Weight (LBW/VLBW) charts for clients up to the adjusted age of 36 months; or
  - e. Severe unintentional weight loss has occurred such as 10 percent weight loss or falling by two major percentile lines for weight over six months on CDC growth charts (for example falling from the 25<sup>th</sup> percentile to the 5<sup>th</sup> percentile); or
  - f. Client cannot achieve adequate nutrition status such as maintaining his/her weight for length/height above the 5<sup>th</sup> percentile on CDC growth chart and is unable to advance to whole foods.
  
3. The CCS county or regional office medical consultant, after consulting with the CCS paneled physician may determine that an exception to the above criteria is medically justified. An example of an exception is a clinical demonstration of malnutrition/nutrient deficiency (growth failure is not demonstrated) which cannot be adequately treated by the consumption of whole foods.

## **V. IMPLEMENTATION**

- A. Determination of medical necessity for an enteral nutrition product is the responsibility of the CCS medical consultant or designee.
- B. The requesting Special Care Center (SCC), CCS paneled physician, or pharmacy vendor submits the request for authorization to the County CCS program or CMS Regional Office.
- C. The CCS Program shall fax a "Request for Enteral Nutrition Product(s)" (Enclosure) form to the requesting SCC, physician, and/or pharmacy vendor for completion.
- D. The CCS Program must receive all of the following documents dated within six months of the request in order to authorize or reauthorize the product(s):
  - 1. Completed "Request for Enteral Nutrition Products" form and a physician's prescription if the form is not signed. Note that the form can either be signed by the physician or a prescription can be faxed instead of signing the form.
  - 2. Client's CDC growth chart, LBW/VLBW growth chart, BMI chart, skinfold measurement/percentile or growth velocity percentile (usually part of the nutrition assessment report).
  - 3. Medical report(s) by the CCS SCC physician or CCS approved physician who is authorized to care for the CCS eligible medical condition.
  - 4. CCS paneled registered dietitian's (RD) nutrition assessment and treatment plan which explains the justification for use of the product requested and discusses the plan for improving nutrition status and advancement of feedings to whole foods or less specialized products.
  - 5. If the request is for reauthorization, physician and nutritionist's reports must document the need and effectiveness of the nutrition product in use and, in addition, explain why the client cannot be advanced to more normalized food products.

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Specific instructions on issuing authorizations for enteral nutrition products will follow in a "This Computes!"

If you have questions regarding this policy letter, please contact your CCS Regional Office Medical Consultant or the CCS Branch Nutrition Consultant.

**Original signed by Marian Dalsey, M.D., M.P.H.**

Marian Dalsey, M.D., M.P.H.  
Acting Chief  
Children's Medical Services Branch

Enclosure: "Request for Enteral Nutrition Products" form

**REQUEST FOR ENTERAL NUTRITION PRODUCT(S)**  
**California Children's Services (CCS)**

**CCS County/Regional Office:** \_\_\_\_\_ **Fax:** \_\_\_\_\_

**Instructions:** Initial and subsequent requests for enteral nutrition products require completion of this form. The following **4** documents (*dated within six months of the request date*) must accompany this form:

- CCS paneled physician prescription or signature on the bottom of this form (*preferred*)
- CDC growth chart with dates of heights and weights
- CCS paneled physician medical reports
- CCS paneled dietitian (RD) assessment/plan (documenting and plotting height, weight, recommended calories and treatment plan)

**Note: Authorizations for enteral nutrition products will be limited to six months.**

**Patient name:** \_\_\_\_\_ **CCS #:** \_\_\_\_\_

(Resident of a licensed care facility?) Yes \_\_\_ No \_\_\_

DOB: \_\_\_\_\_ Age: \_\_\_\_\_

CCS eligible medical condition: \_\_\_\_\_

Authorized CCS SCC Center: \_\_\_\_\_

Authorized CCS Physician: \_\_\_\_\_

**Pharmacy vendor name:** \_\_\_\_\_ **Telephone #:** \_\_\_\_\_

**Address:** \_\_\_\_\_ **Fax #:** \_\_\_\_\_

**Enteral nutrition product(s) requested:** \_\_\_\_\_

Include: Complete product name: \_\_\_\_\_ NDC product code: \_\_\_\_\_

Requested amount: Liquid: \_\_\_\_\_ mL per 24 hours \_\_\_\_\_ mL per month  
Powder: \_\_\_\_\_ g per 24 hours \_\_\_\_\_ g per month

Duration: \_\_\_\_\_ number of months (not to exceed six months)

This is a:  Replacement Formula  Elemental Formula  
 Calorie Dense Product  Nutrition Additive

Route of delivery:  enteral (bolus / continuous)  oral

**For calorie dense products only, (check applicable boxes):**

In addition to the CCS eligible medical condition, nutrition needs must be greater than 20 % of recommended daily nutrient intake and identify **one** of the following:

- Severe oral motor impairment and/or risk of aspiration **OR**
- Inadequate growth (attach CDC growth chart):
  - Weight/length or height is at or below the 5<sup>th</sup> percentile
  - Skinfold measurement is at or below the 5<sup>th</sup> percentile
  - Growth velocity is falling or at or below the 10<sup>th</sup> percentile
  - Weight for gestational age for LBW/VLBW infants is at or below 5<sup>th</sup> percentile
  - Severe unintentional weight loss of 10 percent or falling by 2 growth channels
  - Unable to maintain weight/length or height above the 5<sup>th</sup> percentile

(If there is a signed prescription, fax it with this completed form. The information below can be left blank.)

**Physician name (print):** \_\_\_\_\_ **License #:** \_\_\_\_\_

**Date/signature:** \_\_\_\_\_ **Telephone #:** \_\_\_\_\_ **Fax #:** \_\_\_\_\_