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

TO: ALL LOCAL COUNTY CALIFORNIA CHILDREN SERVICES (CCS)
PROGRAMS AND GENETICALLY HANDICAPPED PERSON'S
PROGRAM (GHPP) STAFF, MEDICAL CONSULTANTS, STATEWIDE
CONSULTANTS AND STATE SYSTEMS OF CARE DIVISION STAFF

SUBJECT: ENTERAL NUTRITION PRODUCTS AS CCS PROGRAM AND GHPP
BENEFITS

I. PURPOSE

The purpose of this Numbered Letter (N.L.) is to disseminate policy for CCS and GHPP Programs regarding the criteria and process for the authorization of enteral nutrition products that are categorized in the Enteral Nutrition Products section of the Medi-Cal Provider Manual as follows:

- A. Elemental and semi-elemental products
- B. Metabolic products
- C. Specialized products
- D. Specialty infant products
- E. Standard enteral products

This letter supersedes N. L. 22-0805, Enteral Nutrition Products as a CCS Program Benefit.

II. BACKGROUND

Enteral nutrition products are a CCS Program and GHPP benefit when deemed medically necessary to prevent or treat malnutrition associated with a CCS Program eligible condition or to treat or prevent malnutrition in a GHPP client. Some CCS Program and GHPP eligible conditions preclude adequate nutrient or caloric intake or

increase the nutrition needs of the client, thereby requiring nutrition support in order to prevent or treat malnutrition. The duration of use for an enteral nutrition product is variable depending on birth weight, intrauterine growth restriction, and associated medical complications in the premature infant or can be a lifelong treatment for individuals with metabolic disorders. These products may be administered orally or through a feeding tube and may provide supplemental nutrition or be the sole source of nutrition.

Prescribed enteral nutrition products must be medically appropriate and efficacious for the CCS Program eligible medical condition. Some CCS Program eligible medical conditions are associated with short stature, depressed body mass and the inability to achieve a normal growth pattern. While aggressive nutrition support may be indicated in patients with these conditions, enteral nutrition products should not be used to try to achieve growth patterns associated with healthy children. Moreover, enteral nutrition products are not intended to replace whole foods for an individual who is able to consume whole foods. However, when whole foods are not appropriate, enteral nutrition products may be essential for optimal growth and development of the child or to improve or maintain nutrition status in the adult.

III. DEFINITIONS

A. Elemental and Semi-Elemental Enteral Nutrition Products:

Elemental formulas contain protein in the form of free amino acids. Semi-elemental formulas contain hydrolyzed proteins broken down into oligopeptides, tripeptides, dipeptides and/or free amino acids. Elemental and semi-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. Examples of conditions, which result in malabsorption or gastrointestinal dysfunction, are gastroschisis, chylothorax, ulcerative colitis, HIV infection, and neoplastic conditions.

B. Metabolic Enteral Nutrition Products:

Metabolic formulas and products are designed to meet the specialized nutrient needs of individuals with inborn errors of metabolism including but not limited to galactosemia, phenylketonuria, maple syrup urine disease, organic acidemias, fatty acid oxidation disorders, and urea cycle disorders. These formulas restrict a nutrient that cannot be adequately metabolized due to the absence or reduced activity of an enzyme or cofactor.

C. Specialized Enteral Nutrition Products:

Specialized formulas and products are designed to meet the needs of individuals with specific disease states including, but not limited to, diabetes, renal diseases, pulmonary diseases, and hepatic diseases. These formulas may limit or provide additional levels of a nutrient, may be calorically dense, and may be used as a supplement or sole-source of nutrition.

D. Specialty Infant Products:

Specialty infant formulas and products are designed to meet the needs of infants from birth through one year of age or the corrected age (CA) of one year. When these products are used beyond the age of one (including CA when applicable), medical justification must be provided. Specialty infant enteral products include premature and low birth weight products, extensively hydrolyzed products, 100% amino acid based products, fat malabsorption products, renal products, and long-chain 3-hydroxyacyl-CoA dehydrogenase (LCHAD) deficiency products.

E. Standard Enteral Products:

Standard enteral formulas are composed of complex proteins, fats and carbohydrates with added vitamins and minerals. Standard enteral formulas are complete nutrition products for individuals with normal digestive functions. They are designed for individuals who need additional calories and/or nutrients or require tube feedings.

F. Modulars/Additives:

Nutrition additives or modular products are non-whole food preparations that are composed of a single nutrient or multiple nutrients that can be added to regular foods or formulas in order to alter the nutrient composition of the diet and/or provide supplemental calories. Modulars are used to increase caloric density without increasing volume, manage macronutrient levels, and can be used to prevent or control constipation and/or diarrhea.

G. Whole Foods:

Whole foods are defined as foods that are significantly unaltered from their natural state, which are prepared at home, in a market, or at a restaurant. For CCS Program purposes, processed foods such as pastas, cereals, frozen entrees, etc. are considered whole foods. In addition, blenderized or pureed foods are considered whole foods even though they have been rendered to a liquid consistency. Whole foods are not a benefit of the Medi-Cal Program, CCS Program, or GHPP.

H. Low-Protein Therapeutic Food (Medical Foods):

A medical food, as defined in section 5(b) (3) of the Orphan Drug Act (21 U.S.C. 360ee (b)(3)), is “a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation.” Based on this definition, many enteral nutrition manufacturers and Medi-Cal are now referring to most enteral nutrition formulas as “Medical Foods”.

For the CCS Program and for GHPP, Medical Foods have traditionally referred to products that are specially formulated for the treatment of certain inborn errors of metabolism and are purchased from vendors who specialize in the distribution of low-protein foods. Due to the extended meaning of Medical Foods by the Food and Drug Administration (FDA) and Medi-Cal, the CCS Program and GHPP will now refer to these foods as low-protein therapeutic foods.

Low-protein therapeutic foods are primary to the management of metabolic disorders as they help patients avoid organ damage, grow properly, and maintain or improve health status. Low-protein therapeutic foods are specifically formulated food products and are not readily available in grocery stores. These foods are a benefit of the CCS Program and GHPP but are not a benefit of the California Medi-Cal Program. Low-protein therapeutic foods may be authorized according to the process described in “This Computes!” # 266.

I. Corrected Age:

Corrected age is calculated by subtracting the number of weeks born before 40 weeks of gestation from the chronological or actual age. Corrected age is typically used for the assessment of growth and development until the preterm infant turns two years old. For infants weighing less than 1000 grams at birth, corrected age is often used until the child’s third birthday.

J. Z-Scores:

A Z-score represents the number of standard deviations an observation or data point is above or below the mean. Z-scores are used to identify malnutrition (undernutrition) in children.¹ Identifying malnutrition in children is critical for determining appropriate treatment options. Z-scores for the following indicators may

¹ Mehta, N.M., Corkins, M.R., Lyman, B., et al. Defining Pediatric Malnutrition: A Paradigm Shift toward Etiology-Related Definitions. *JPEN J Parenter Enter Nutr.* 2013; 37(4):460-481.

be used to determine malnutrition: weight-for-height (WFH), length/height-for-age, BMI-for-age, and mid-upper arm circumference (MUAC). Levels of malnutrition based on Z-scores are defined as follows: mild malnutrition is a Z-score between -1 to -1.9, moderate malnutrition is a Z-score between -2 to -2.9, and severe malnutrition is a Z-score greater or equal to -3.

IV. POLICY

- A. Effective the date of this policy, only those enteral nutrition products included on the [List of Enteral Nutrition Products](#) spreadsheet in the [Enteral Nutrition Products \(enteral\)](#) section of the Medi-Cal Provider Manual are reimbursable by their 11 digit Medi-Cal billing number. Individuals involved with the ordering, procurement, and authorization of enteral nutrition products should access the current spreadsheet for all enteral nutrition product requests.
- B. Products not listed on the enteral nutrition products spreadsheet are not reimbursable by Fee-For-Service Medi-Cal. If deemed medically necessary, these non-listed products may be authorized using the Systems of Care Division's (SCD) approved workaround procedure. Information regarding the workaround can be found in "This Computes" # 421. Updates to the workaround process will be communicated through a "CCS Information Notice".
- C. Enteral nutrition products are not separately billable when the client resides in a skilled nursing facility, intermediate care facility, or is a hospital inpatient. Separately billed enteral nutrition products are for outpatients only.
- D. For CCS Program clients, authorization of an enteral nutrition product requires the product be medically necessary for the treatment of a CCS medically eligible condition. For GHPP clients, authorization of an enteral nutrition product requires the product be medically necessary to prevent or treat malnutrition independent of the GHPP medically eligible condition.
- E. Authorization of enteral nutrition products requires CCS and GHPP clients meet specified criteria. General criteria and medical criteria for authorization of enteral nutrition products are described in the [Enteral Nutrition Products \(enteral\)](#) section of the Medi-Cal Provider Manual.
 1. Additional criteria for authorization for CCS Program clients, includes clinical indicators of nutrition risk including malnutrition or inadequate growth as verified by one of the following:
 - a. Documented inadequate weight gain based on expected weight gain velocity for age.

- (1) Children under 2 years of age: Weight gain velocity less than 50% of the norm for expected weight gain.
- (2) Individuals 2 to 20 years of age: Current weight is 7.5 percent below usual body weight and weight loss or inadequate weight gain is unintentional.

b. Malnutrition or inadequate growth as verified by:

(1) Growth charts.

- (a) Children under 2 years of age: Weight-for-length below the 2nd percentile.
- (b) Individuals 2 years to 20 years of age: Body-Mass-Index (BMI) below the 5th percentile.

(2) Z-scores – For weight-for-length/height, BMI-for-age, mid-upper arm circumference (MUAC), or length/height-for-age:

- (a) Weight-for-length/height and BMI-for-age Z-score ≤ -2
- (b) MUAC Z-score < -2
- (c) Length/height-for-age Z-score < -3 and there is medical justification that growth may be improved with increased energy and nutrient intake.
- (d) Unintentional deceleration in weight-for-length/height or BMI-for-age in Z-score > 1 when child is at risk for malnutrition.

2. Authorization specific to GHPP clients:

Adult malnutrition is currently being redefined. Identification of two or more of the following six characteristics may be used to identify malnutrition: prolonged insufficient energy intake ($< 75\%$ of estimated energy needs for >1 month), weight loss (see Medi-Cal Manual - [Enteral Nutrition Products](#) - Medical Criteria), loss of muscle mass (moderate to severe depletion), loss of subcutaneous fat (moderate to severe depletion), fluid accumulation that masks weight loss (moderate to severe accumulation), and diminished

functional status as measured by hand grip strength (reduced for age and gender).²

3. Laboratory analysis for determining malnutrition status of CCS Program and GHPP Clients:

Laboratory analyses are frequently used to identify malnutrition and/or nutrient deficiencies. The selection of specific tests depends on the degree of the nutritional problem and on the underlying disease. Pertinent laboratory values may be used to confirm malnutrition and the need for enteral nutrition products.

F. Authorization of a specialty infant enteral nutrition product administered orally or through a feeding tube must meet the criteria found in the Medi-Cal Provider Manual except as noted below:

1. Premature and low birth weight products.

- a. Infant requires concentrated formulas due to a CCS Program eligible condition that requires fluid restrictions, increased calories, or need to conserve energy.
- b. Products may be authorized or continued without infant weight restrictions as stated in the Medi-Cal Provider Manual with CCS-paneled MD documentation for medical need. Example: For liquid extensively hydrolyzed products, per Medi-Cal Provider Manual, birth weight may not be greater than 1800 grams. Formula may be authorized when medically necessary, if infant birth weight is greater than 1800 grams.
- c. Infant has failed to gain adequate weight-for-length and/or age after transitioning to a standard formula and concentrating standard formula is contraindicated.

2. Use of specialty infant formulas beyond 12 months of age or corrected age requires documentation by the CCS-paneled physician and CCS-paneled registered dietitian (RD) stating the rationale for not advancing the infant or child to a more age appropriate formula.

² White, J.V., Guenter, P., Jensen, G. Consensus Statement of the Academy of Nutrition and Dietetics/American Society for Parenteral and Enteral Nutrition: Characteristics recommended for the identification and documentation of adult malnutrition (undernutrition). JPEN J Parenter Enter Nutr. 2012; 36(3):275-283.

- G. The local program's CCS County 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 or by advancing to a different formula based on age.
- H. For enteral nutrition products, the first date of service may begin the date the physician signs and dates the prescription and/or the "Request for Enteral Nutrition Form". Services will be denied if products are requested before the signed date on these documents.
- I. The following nutrition products are not covered by Medi-Cal, the CCS Program or GHPP:
1. Regular food including solid, semi-solid, and pureed foods.
 2. Manufactured whole foods in a blenderized or pureed form used for convenience or preference.
 3. Regular infant formula as defined in the Federal Food Drug and Cosmetic Act (FD&C Act).
 4. Enteral nutrition products used orally as a convenient alternative to preparing and/or consuming regular solid, semi-solid or pureed foods.
- J. Items not covered by Medi-Cal, but obtainable for CCS Program and GHPP clients by using the appropriate workaround when medically indicated and justified with appropriate documentation include:
1. Thickeners.
 2. Vitamins and minerals used to treat a CCS Program or GHPP medically eligible condition or a complication of the medically eligible condition.
 3. Amino acids used to treat a CCS Program or GHPP medically eligible condition or a complication of the medically eligible condition.
 4. Prebiotics and/or probiotics.
 5. Manufactured whole foods in a blenderized or pureed form with documented intolerance to at least two standard enteral nutrition products listed in the Medi-Cal manual and other formulas in the Medi-Cal Manual are inappropriate for the

client. When requested for use as a sole source of nutrition, the product must be nutritionally complete. Authorization of product requires approval from the SCD Statewide Nutrition Consultant.

K. Documentation Requirements

1. Documentation requirements for authorization of enteral nutrition products are described in the [Enteral Nutrition Products \(enteral\)](#) section of the Medi-Cal Provider Manual.
2. Additional required documentation:
 - a. Medical justification clearly stated on “Enteral Nutrition Product Request Form” and in RD reports.
 - b. Appropriate Growth Chart.
 - (1) World Health Organization (WHO) growth charts must be included for infants and toddlers from birth to two years old.
 - (2) Center for Disease Control and Prevention (CDC) growth charts must be included for children and adolescents two to twenty years old.
 - (3) Premature infant charts when applicable.
 - (4) Specialty growth charts for specific conditions such as quadriplegic cerebral palsy, achondroplasia, Down syndrome, etc. may be included in addition to standard growth charts. Due to the limitations of these charts, they are not to be used without the accompanying age appropriate growth chart.
 - c. Z-scores when used to define malnutrition or faltering growth in children.

V. Implementation

A. Authorization for CCS Clients

1. Effective the date of this letter, the requests for enteral nutrition products may be authorized once the following process is completed:
 - a. The prescription or “Request for Enteral Nutrition Product(s)” form is signed by a CCS-paneled physician.

- b. The "Request for Enteral Nutrition Product(s)" form has been completed. If the request form is not signed and dated by the CCS-paneled physician, a signed and dated physician's prescription must accompany the request form. A faxed prescription cannot be used in lieu of the request form.
 - c. The CCS Program paneled-RD or designated person has forwarded a "Request for Enteral Nutrition Product(s)" form to the pharmacy vendor.
 - d. The service authorization request (SAR) has been completed by the pharmacy vendor. Once completed, both the SAR and the "Request for Enteral Nutrition Product(s) Form" are forwarded by the pharmacy vendor to the County CCS program for action.
 - e. All pertinent medical reports/records, signed by the CCS-paneled physician and dated within six months of the enteral nutrition request, have been received by CCS County authorizing agent.
 - f. CCS Program paneled RD nutrition assessment and nutrition care plan including justification for use of the product requested, documentation regarding attempts to increase calories with whole foods when an oral product is requested and plans to transition to whole foods or less
 - g. Specialized products when appropriate have been received by the CCS County authorizing agent. Appropriate growth chart and Z-scores (when used to define malnutrition or faltering growth) must accompany RD nutrition care plan. The nutrition care plan must be signed by the CCS-paneled RD and dated within six months of the enteral nutrition request.
 - h. If the request is for reauthorization, physician and RD reports (signed and dated within six months of the request) must document need and effectiveness of the nutrition product in use and explain why the client cannot be advanced to whole food products. Appropriate growth chart and Z-scores must accompany report or be incorporated into RD nutrition care plan.
2. The CCS County authorizing agent will evaluate the request then authorize, deny, or request additional information necessary to complete the review.
 3. For CCS clients enrolled in Medi-Cal managed care plans (MCPs) with CCS benefits carved into the plan, the MCP is required to provide or arrange for medically necessary enteral nutrition products as a covered Medi-Cal benefit.

B. Authorization for GHPP Clients

1. For GHPP Medi-Cal clients enrolled in an MCP
 - a. MCPs are required to provide or arrange for medically necessary enteral nutrition products as a covered Medi-Cal benefit as GHPP benefits are carved into all MCPs.
 - b. Providers must contact the individual MCP for billing instructions, as each MCP is unique in its billing process.
2. For GHPP clients not enrolled in an MCP, the requests for enteral nutrition products will be authorized per the process for CCS as stated in section V-A of this numbered letter with the following exceptions:
 - a. The "Request for Enteral Nutrition Product(s)" form and/or prescription is signed by a GHPP authorized physician.
 - b. The authorizing GHPP agent has received the following:
 - (1) Completed "Request for Enteral Nutrition Product(s)" form and copy of physician's prescription if form is not signed by physician.
 - (2) Completed SAR from pharmacy.
 - (3) Pertinent medical reports/records signed and dated within last six months by GHPP authorizing physician.
 - (4) RD's nutrition assessment and nutrition care plan including justification for the use of the product requested, documentation regarding attempts to increase calories with whole foods when an oral product is requested, and plans to transition to whole foods or less specialized products when appropriate. Record of height, weight and BMI scores must accompany RD nutrition care plan. The nutrition care plan must be signed by the RD and dated within six months of the enteral nutrition request.
 - c. The GHPP authorizing agent will evaluate the request then authorize, deny or request additional information.

- C. In the event that a MCP denies an enteral nutrition product for a CCS Program or GHPP client with enteral nutrition carved into the plan, the client or legal guardian must use the MCP's appeal process. If the plan's appeals process has been

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expended, the client or legal guardian may contact the Department of Managed Health Care [Office of the Ombudsman](#) for additional assistance.

The Systems of Care Division will continue to monitor changes with the authorization and distribution of enteral nutrition products. If you have any questions regarding this Numbered Letter, please contact Donna Vaughan at (916) 323-8064 or by email at donna.vaughan@dhcs.ca.gov.

Sincerely,

ORIGINAL SIGNED BY LOUIS R. RICO

Louis R. Rico, Chief
Systems of Care Division

REQUEST FOR ENTERAL NUTRITION PRODUCT(S) for CCS/GHPP PROGRAMS

Health Care Provider: Please complete this form for all initial and subsequent requests for enteral nutrition products. FAX this form with required documents to the pharmacy vendor. The following 4 documents (dated within 6 months of the request date) must accompany this form:

- SCC/CCS-paneled physician's signed prescription or signature on this form
- SCC/CCS-paneled physician's medical reports/records for patient
- SCC/CCS-paneled registered dietitian's MNT plan with required documentation per N.L. ____
- Appropriate growth chart for age plotted with dates of heights/lengths and weights listed

Pharmacy Vendor: _____ **Phone:** _____ **FAX:** _____

Note: Authorization for enteral nutrition products will be limited to six months. The first date of service may commence the date the physician signs this form. Enteral nutrition requests may not be backdated.

Patient Name: _____ **CCS/GHPP #:** _____
DOB: _____ **Age:** _____
CCS/GHPP eligible medical condition: _____ **ICD Code:** _____
Authorized CCS SCC Center: _____
Authorized CCS/GHPP Physician: _____

Nutrition Products:

Full Product Name <i>Including caloric concentration and fiber (when applicable)</i>	11 Digit Product Code*	Delivery Route** (Circle)	Amount		Duration (Max = 6 mo.)
			Liquid (ml)	Powder (g)	
		OR TF	24 hr:	24 hr:	
		OR TF	1 mo:	1 mo:	
		OR TF	24 hr:	24 hr:	
		OR TF	1 mo:	1 mo:	
		OR TF	24 hr:	24 hr:	
		OR TF	1 mo:	1 mo:	

* 11 Digit Product Code: use current Medi-Cal Provider Manual **Delivery Route: OR = Oral, TF = Tube Feeding

Justification (must be completed):

- Malabsorption or intolerance to standard formulas requiring elemental or semi-elemental product
- Metabolic condition requiring metabolic product
- Specialized enteral nutrition product required for disease state or _____
- Specialty infant product required for: _____
- Modular product or nutrition additive required for: _____
- Severe swallowing or chewing disorder and/or risk of aspiration
- Inadequate growth/malnutrition as evidenced by: _____
- Other: _____

RD name (print): _____ **Phone:** _____ **Email:** _____
Physician name (print): _____ **License #:** _____
Phone: _____ **FAX:** _____
Physician Signature: _____ **Date:** _____
CCS/GHPP County/Regional Office: _____ **FAX:** _____

Pharmacy vendor: Please forward this form, TAR/SAR, and all required documentation to the CCS authorizing office listed above.

REQUEST FOR ENTERAL NUTRITION PRODUCT(S) and EQUIPMENT for CCS/GHPP PROGRAMS

Health Care Provider: Please complete this form for all initial and subsequent requests for enteral nutrition products and supplies. FAX this form with required documents to the pharmacy vendor. The following 4 documents (dated within 6 months of the request date) must accompany this form:

- SCC/CCS-paneled physician's signed prescription or signature on page 2 of this form
- SCC/CCS-paneled physician's medical reports/records for patient
- SCC/CCS-paneled registered dietitian's MNT plan with required documentation per N.L. ____
- Appropriate growth chart for age plotted with dates of heights/lengths and weights listed

Pharmacy Vendor: _____ **Phone:** _____ **FAX:** _____

Note: Authorization for enteral nutrition products will be limited to six months. The first date of service may commence the date the physician signs this form. Enteral nutrition requests may not be backdated.

Patient Name: _____ **CCS/GHPP #:** _____

DOB: _____ Age: _____

CCS/GHPP eligible medical condition: _____ ICD Code: _____

Authorized CCS SCC Center: _____

Authorized CCS/GHPP Physician: _____

Nutrition Products:

Full Product Name <i>Including caloric concentration and fiber (when applicable)</i>	11 Digit Product Code*	Delivery Route** (Circle)	Amount		Duration (Max = 6 mo.)
			Liquid (ml)	Powder (g)	
		OR TF	24 hr:	24 hr:	
			1 mo:	1 mo:	
		OR TF	24 hr:	24 hr:	
			1 mo:	1 mo:	
		OR TF	24 hr:	24 hr:	
			1 mo:	1 mo:	

* 11 Digit Product Code: use current Medi-Cal Provider Manual

**Delivery Route: OR = Oral, TF = Tube Feeding

Equipment and Supplies: (Pumps, IV Pole, Feeding Kits, etc.)

Full Product Name	Code	Quantity

REQUEST FOR ENTERAL NUTRITION PRODUCT(S) and EQUIPMENT for CCS/GHPP PROGRAMS

Justification (must be completed):

- Malabsorption or intolerance to standard formulas requiring elemental or semi-elemental product
- Metabolic condition requiring metabolic product
- Specialized enteral nutrition product required for disease state or _____
- Specialty infant product required for: _____
- Modular product or nutrition additive required for: _____
- Severe swallowing or chewing disorder and/or risk of aspiration
- Inadequate growth/malnutrition as evidenced by: _____

- Other: _____

RD name (print): _____ **Phone:** _____ **Email:** _____

Physician name (print): _____ **License #:** _____

Phone: _____ **FAX:** _____

Physician Signature: _____ **Date:** _____

CCS/GHPP County/Regional Office: _____ **FAX:** _____

Pharmacy vendor: Please forward this form, TAR/SAR, and all required documentation to the CCS authorizing office listed above.