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DATE: June 13, 2018

N.L.: 08-0618

Supersedes: N.L.: 04-0317

Index: Benefits

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

SUBJECT: ENTERAL NUTRITION PRODUCTS AS CCS PROGRAM AND GHPP
BENEFITS – REVISED - SERVICE AUTHORIZATION REQUEST (SAR)
CLARIFICATION

I. PURPOSE

The purpose of this Numbered Letter (N.L.) is to supersede CCS N.L. 04-317: Enteral Nutrition Products as CCS Program and GHPP Benefits – Revised, and to clarify that submission of a service authorization request (SAR) is required (in addition to the other requirements specified in this N.L.), as outlined in Section V. Implementation. Otherwise, the majority of the content of this N.L. is similar to N.L. 04-0317.

This N.L. disseminates policy for CCS Program and GHPP 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 N.L. also updates N.L. 05-0715, Enteral Nutrition Products as a CCS Program and GHPP 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 may either 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 eligible medical condition. Some CCS eligible medical conditions are associated with short stature, altered body composition 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. Enteral nutrition products are not a CCS benefit for clients with suboptimal nutritional status due to behavioral issues, including oral aversion, when they are unrelated to the client's CCS eligible condition.

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 percent 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. Modulators/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. Modulators 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 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:

1. Mild malnutrition is a Z-score between -1 to -1.9,
2. Moderate malnutrition is a Z-score between -2 to -2.9, and
3. 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 ISCD 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 Program 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.

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.

E. Authorization of enteral nutrition products requires that CCS Program 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. Other criteria that may be used for authorization for CCS Program clients when the client does not fall within the parameters stated in the Medi-Cal Provider Manual, include at least one of the following clinical indicators of malnutrition or inadequate growth:

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 percent 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.

(3) Significant decline in weight-for-age Z-score (decrease of more than 1) in a 3-month period when 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 (using norms for upper limb fat and muscle areas)

- (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:

Identification of two or more of the following six characteristics may be used to identify malnutrition in adults: prolonged insufficient energy intake (< 75 percent 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 to confirm clinically documented malnutrition or inadequate growth as laid out in IV E.1.a. or IV E.1.b. and CCS Program and GHPP clients' need for specific enteral nutrition product. When necessary, laboratory analyses shall be conducted to confirm malnutrition and/or nutrient deficiencies. The selection of specific tests depends on the degree of the nutritional problem and on the underlying disease.

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 may be authorized if one of the following is documented:
 - a. Infant requires concentrated formula due to a CCS Program eligible condition that requires fluid restrictions, increased calories, or need to conserve energy (e.g. congenital cardiac conditions, chronic pulmonary conditions, or renal disorders).
 - b. 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 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.

2. Specialty infant products may be authorized or continued without infant weight restrictions as stated in the Medi-Cal Provider Manual with CCS Program-paneled MD documentation for medical necessity. 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 infant birth weight is greater than 1800 grams when medically indicated.
 3. Specialty infant products may be authorized for conditions other than those listed in the Medi-Cal Provider Manual with CCS Program-paneled MD documentation for medical necessity. Example: An extensively hydrolyzed product may be authorized for infants with a heart condition such as hypoplastic left heart syndrome (HLHS).
 4. Use of specialty infant formulas beyond 12 months of age or corrected age requires documentation by the CCS Program-paneled physician and CCS Program-paneled registered dietitian (RD) stating the rationale for not advancing the infant or child to a more age appropriate formula.
- G. The local CCS program County Medical Consultant or designee may determine that an exception to the above criteria is justified with documentation in the RD nutrition report and medical record. Examples of exceptions include clinical demonstration of malnutrition/nutrient deficiency in the absence of growth failure that cannot be adequately treated by the consumption of whole foods or use of a specific formula based on individual nutrient needs or tolerance independent of the Medi-Cal age restrictions.
- 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". If the authorization start date is prior to the date the physician signs and dates the prescription and/or the "Request for Enteral Nutrition Form", documentation (e.g., a transcribed copy of the verbal order) that the physician requested the product prior to signing either of these documents must be included with the request. A transcribed copy of the verbal order must include the date and time the verbal order was placed, name and credentials of person placing the order, products prescribed, and name and credentials of pharmacy employee accessing the verbal order. Without appropriate documentation, services will be denied if products are requested prior to the signed date on either the prescription or enteral nutrition request form.
- 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) and referenced in [NL 20-0605](#) Non-Benefit Status of Regular Infant Formulas.
 4. Enteral nutrition products used orally as a convenient alternative to preparing and/or consuming regular solid, semi-solid or pureed foods unless the client has an immune compromised diagnosis and documented intolerance (inadequate weight gain for age or an increase in malabsorption).
- 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. Non-contracted enteral nutrition products used to treat a CCS Program or GHPP medically eligible condition or a complication of the medically eligible condition.
 6. Manufactured whole foods in a blenderized or pureed form are **not** a CCS Program or GHPP benefit. These products may be considered for authorization for tube fed individuals only with an immune compromised diagnosis and medically documented intolerance (inadequate weight gain for age or an increase in malabsorption) within the last twelve months to at least three enteral nutrition products listed in the Medi-Cal Manual. In addition, the client must have failed all other Medi-Cal contracted whole food products within the last three months, unless such formula is medically contraindicated. The prescription for manufactured whole foods in a blenderized or pureed form must come from a CCS Program-paneled gastroenterologist at an approved gastrointestinal Special Care Center (SCC). Documentation from the CCS Program-paneled gastroenterologist must clearly state medical necessity for use and state why other whole food formulas in the Medi-Cal Manual are

medically contraindicated. In addition, the CCS Program-paneled RD report must document dates of products tried within the last twelve months and clearly justify intolerance to those products. Prescription is limited to six months. Reauthorization requires RD report dated within the last 30 days of request documenting adequate weight gain for age, benefits of use, and medical necessity for continuation. When requested for use, the product must be nutritionally complete and age appropriate.

7. Enzyme cartridges, including Relizorb or like devices, that attach to a feeding tube with the purpose of improving absorption of nutrients. Requests must be referred to the ISCD Medical Consultant for case-by-case review until numbered letter is released.
- K. Durable Medical Equipment (DME) and Medical Supplies related to enteral feedings are a benefit of the CCS Program and GHPP with medical justification by SCC. Information regarding authorization of DME and medical supplies can be found in the [Durable Medical Equipment and Medical Supplies \(DME\)](#) sections of the Medi-Cal Provider Manual. This Computes # 267 - [Provider Billing For Medical Supplies And Low Cost Durable Medical Equipment \(DME\)](#) and This Computes # 328 - [New Guidance for Medical Supplies and Low Cost DME](#) provide additional clarification for the SAR authorization of DME/MS items.
- L. Documentation Requirements
1. Documentation requirements for authorization of enteral nutrition products are listed in the [Enteral Nutrition Products \(enteral\)](#) section of the Medi-Cal Provider Manual.
 2. Additional required documentation includes:
 - a. Medical justification for product clearly stated on "Enteral Nutrition Product Request Form" and in RD Medical Nutrition Therapy (MNT) report.
 - b. SCC/CCS Program-paneled registered dietitian's current nutrition assessment and care plan clearly stated in MNT report dated within six months of the enteral nutrition products request.
 - c. 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 2 to 20 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.
- (5) Z-scores when used to define malnutrition or faltering growth in children.

V. Implementation

A. Authorization for CCS Program 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 has been completed by the CCS approved SCC and signed by a CCS Program-paneled physician.
 - b. The "Request for Enteral Nutrition Product(s)" form has been completed. If request form is not signed and dated by the CCS Program-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 SAR has been completed by the pharmacy vendor. Once completed, both the SAR and the "Request for Enteral Nutrition Product Form" are forwarded by the pharmacy vendor to the appropriate CCS program for action. Please note guidance is being released on CCS electronic SARs or eSARs. Please refer to the appropriate CCS This Computes! and Medi-Cal provider bulletins on eSARs.
 - e. All pertinent medical reports/records, signed by the CCS Program-paneled physician and dated within six months of the enteral nutrition request, have been received by the local county CCS program authorizing agent.

- f. CCS Program paneled RD's MNT reports including justification for use of the product(s) 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 have been received by the local county CCS program authorizing agent. Appropriate growth chart(s) and Z-scores (when used to define malnutrition or faltering growth) must accompany or be incorporated into RD MNT reports. The MNT report must be signed by the CCS Program-paneled RD and dated within six months of the enteral nutrition request.
 - g. 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(s) and Z-scores (when used to define malnutrition or faltering growth) must accompany or be incorporated into RD MNT report.
2. The authorization period will be determined according to the following criteria:
- a. Authorizations will be for up to six months for all clients that do not meet the criteria above,
 - b. Authorization will be for up to 12 months when:
 - i. The client is over 14 years of age.
 - ii. The family has demonstrated motivation and adherence to child's treatment plan, and
 - iii. Has one of the following conditions:
 - (a) Metabolic disorder requiring specialized formula;
 - (b) Renal failure on dialysis needing low phosphorus formula;
 - (c) Inflammatory bowel disease on elemental diet;
 - (d) Short bowel syndrome on elemental formula;
 - (e) Client is NPO and completely gastrostomy tube dependent except for tiny amount by mouth for oral gratification;
 - (f) Intractable seizures on ketogenic formula.

- iv. There has been no change in enteral nutrition treatment plan for at least 12 months
 - v. There has been no history of intolerance to formula.
 - c. The county CCS Program authorizing agent will evaluate the request then authorize, deny, or request additional information necessary to complete the review.
3. For CCS Program clients enrolled in Medi-Cal managed care plans (MCMCP) with CCS Program benefits carved into the plan, the MCMCP is required to provide or arrange for **all** medically necessary enteral nutrition products, including products not listed in the Medi-Cal Manual.

B. Authorization for GHPP Clients

- 1. For GHPP Medi-Cal clients enrolled in a MCMCP.
 - a. MCMCPs are required to provide or arrange for **all** enteral nutrition products for GHPP clients, including products not listed in the Medi-Cal Manual, as enteral nutrition products are a benefit carved into all MCMCPs for GHPP clients.
 - b. Providers must contact the individual MCMCP for billing instructions, as each MCMCP is unique in its billing process.
- 2. For GHPP clients not enrolled in a MCMCP, the requests for enteral nutrition products will be authorized per the process for CCS Program 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 are signed by a physician from an Integrated System of Care Division approved SCC.
 - 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 the physician.
 - (2) Completed SAR from the pharmacy.
 - (3) Pertinent medical reports/records signed and dated within last six months by GHPP authorizing physician.

(4) RD's MNT report including justification for the use of the product(s) 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 MNT report. The nutrition care plan MNT 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 MCMCP 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 MCMCP's appeal process. If the plan's appeals process has been expended, the client or legal guardian may contact the Department of Managed Health Care [Office of the Ombudsman](#) for additional assistance.

The Integrated 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 Jill Abramson, M.D. M.P.H, ISCD Medical Consultant at 916-327-2108 or by email at Jill.Abramson@dhcs.ca.gov

Sincerely,

ORIGINAL SIGNED BY

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