DATE: January 7, 2020

N.L.: 01-0120
Supersedes: N.L.: 04-0317
08-0718
Index: Benefits

TO: All County California Children’s Services Program and Genetically Handicapped Person’s Program Staff, Medical Consultants, Statewide Consultants and Integrated Systems of Care Division Staff

SUBJECT: Authorization of Enteral Formula, Nutrition Additives/Modulars, and Related Supplies

I. PURPOSE

The purpose of this Numbered Letter (N.L.) is to update guidance on the criteria for the authorization of enteral nutrition products and supplies by the California Children’s Services (CCS) Program and Genetically Handicapped Person’s Program (GHPP). This policy will describe 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 (Attachment 1, A-H), the “Request for Enteral Nutrition Product(s) and Equipment for CCS/GHPP Programs” form (Attachment 2), and other documentation required for authorization of enteral nutrition products.

II. BACKGROUND

Enteral nutrition products are a CCS Program and GHPP benefit when medically necessary to prevent or treat malnutrition associated with a CCS-eligible condition, or to treat or prevent malnutrition in a GHPP client.

Some CCS 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 depends on multiple factors including birth weight, intrauterine growth restriction, and residual medical complications that can be lifelong. Enteral nutrition products may provide supplemental nutrition or be the sole source of nutrition, and may be administered orally or through a feeding tube.
Some CCS-eligible 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. 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. POLICY

A. Eligibility

1. Enteral nutrition products are benefits of the CCS Program when medically necessary for the treatment of a CCS-eligible condition. The client must meet medical criteria for authorization of enteral nutrition products, as described in the Enteral Nutrition Products section of the Provider Manual\(^1\); and only those products listed on the List of Enteral Nutrition Products spreadsheet\(^2\) in the Medi-Cal Provider Manual are reimbursable by their 11 digit Medi-Cal billing number.

2. If the client does not meet criteria described in the Medi-Cal Provider Manual, a clinical indicator of malnutrition or inadequate growth may be used for authorization, including at least one of the criteria described below in III.A.2.a.- b.:

a. For CCS clients:

   (1) Documented inadequate weight gain based on expected weight gain velocity for age:

      (a) Children under 2 years of age: Weight gain velocity less than 50 percent of the norm for expected weight gain.

      (b) 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.

      (c) 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.

   (2) Malnutrition or inadequate growth as verified by one or more of the following:
(a) Growth charts percentiles:

(i) Children under 2 years of age: Weight-for-length below the 2nd percentile.

(ii) Individuals 2 years to 20 years of age: body mass index (BMI) below the 5th percentile.

(b) Z-scores (as defined in Attachment 1):

(i) Weight-for-length/height and BMI-for-age Z-score ≤ -2.

(ii) Mid-upper arm circumference (MUAC) Z-score < -2 (using norms for upper limb fat and muscle areas).

(iii) Length/height-for-age Z-score < -3 and there is medical justification that growth may be improved with increased energy and nutrient intake.

(iv) Unintentional deceleration in weight-for-length or BMI-for-age in Z-score >1, when child is at risk for malnutrition.

b. For GHPP clients:

(1) Documentation of two or more of the following:

(a) Prolonged insufficient energy intake (< 75 percent of estimated energy needs for > 1 month) leading to weight loss.

(b) Loss of muscle mass (moderate to severe depletion).

(c) Loss of subcutaneous fat (moderate to severe depletion).

(d) Fluid accumulation that masks weight loss (moderate to severe accumulation).

(e) Diminished functional status as measured by hand grip strength (reduced for age and gender).³

c. For all clients:

Laboratory analysis may be used to confirm clinically documented malnutrition or inadequate growth, but is not sufficient without documentation described in section III.A.2.a.- b. above.
3. Enteral nutrition products shall not be authorized when the client resides in a skilled nursing facility, intermediate care facility, or is a hospital inpatient.

4. 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.

5. Specialty infant enteral nutrition products administered orally or through a feeding tube are a benefit of the CCS Program when the client meets the criteria found in the Medi-Cal Provider Manual, or when the client meets conditions described in the following:

   a. Premature and low birth weight products may be authorized when both of the following are documented:

      (1) Infant requires concentrated formula due to a CCS-eligible condition that requires fluid restrictions, increased calories, or the need to conserve energy (e.g. congenital cardiac conditions, chronic pulmonary conditions, or renal disorders).

      (2) Infant has failed to gain adequate weight-for-length and/or age after transitioning to a standard formula and the concentrating of standard formula is contraindicated.

   b. Specialty infant products may be authorized or continued without consideration of Medi-Cal infant weight requirements or for conditions other than those listed in the Medi-Cal Provider Manual if a CCS Program-paneled physician has provided documentation of a medical necessity.

   c. Specialty infant products may be authorized beyond 12 months of corrected age when documentation of medical necessity is submitted by a CCS Program-paneled physician and CCS Program-paneled registered dietitian (RD).

6. The County CCS program Medical Consultant or designee may determine that an exception to the above criteria is justified, with documentation in the RD nutrition report and medical report.

B. Benefits

1. Enteral nutrition products are only a benefit of and authorized by the CCS program when the product is medically necessary to treat a CCS-eligible medical condition.
2. Enteral nutrition products are a benefit of the GHPP when the product is medically necessary to treat the client, whether or not the condition requiring medical nutrition therapy (MNT) is a GHPP-eligible condition.

3. The following nutrition additives/modulars and manufactured whole foods are not covered by Medi-Cal, but may be authorized for CCS Program and GHPP clients, when medically indicated and justified, and requests are submitted with the appropriate documentation:

   a. Thickeners
   
   b. Vitamins and minerals used to treat a CCS Program or GHPP medically eligible condition or a complication of the medically eligible condition.
   
   c. Amino acids used to treat a CCS Program or GHPP medically eligible condition or a complication of the medically eligible condition.
   
   d. Prebiotics and/or probiotics.
   
   e. Manufactured whole foods may be considered for authorization for tube fed individuals with a congenital or acquired immune deficiency and medically documented intolerance (inadequate weight gain for age or an increase in malabsorption) to at least one standard nutrition product, one semi-elemental product and one elemental product listed in the Medi-Cal Manual within the last 12 months. In addition, the client must have failed at least two 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 describe that the product is medically necessary and nutritionally complete. Documentation must clarify why the other whole food formulas in the Medi-Cal Manual are medically contraindicated. In addition, the CCS Program-paneled RD report must provide dates of products attempted within the last 12 months and document intolerance to those products. The prescription is limited to six months. Reauthorization requires RD report dated within the last 30 days of the request documenting adequate weight gain for age, benefits of use, and medical necessity for continuation.

4. Enzyme cartridges, including Relizorb or similar devices which attach to a feeding tube with the purpose of improving absorption of nutrients, may be authorized with code, B4105, beginning January 1, 2020. Authorizations with
B4105 (in-line cartridge containing digestive enzyme(s) for enteral feeding, each) must meet Medi-Cal Program guidelines, published in the medical supply section of the Medi-Cal Provider Manual (mc sup (9, 11, 12)). Authorization is limited to no more than two enzyme cartridges per day up to three months. Questions or deviations from the Medi-Cal Program policy must be referred to the Integrated Systems of Care Division (ISCD) Medical Director or designee.

5. The following nutrition products are not covered by the CCS Program or GHPP:

   a. Regular foods including solid, semi-solid, and pureed foods.

   b. Manufactured whole foods in a blenderized or pureed form used for convenience or preference.

   c. Regular infant formula as defined in the Federal Food Drug and Cosmetic Act, in Title 21 of the Code of Federal Regulations, section 106.3, and referenced in N.L. 20-0605.4

   d. Enteral nutrition formulas used orally as a convenient alternative to preparing and/or consuming regular solid, semi-solid or pureed foods.

6. Durable Medical Equipment (DME) and medical supplies related to enteral feedings are a benefit of the CCS Program and GHPP with documentation of medical necessity by a SCC. Information regarding authorization of DME and medical supplies can be found in the Durable Medical Equipment and Medical Supplies sections of the Medi-Cal Provider Manual.5

   a. Providers billing for medical supplies and low cost DME are able to bill for medical supplies and/or low cost DME without using a product specific SAR, if:

      (1) The medical supplies requested are within the billing limits set by Medi-Cal as referenced in the Medi-Cal Provider Manual, Allied Health, Part 2, Durable Medical Equipment and Medical Supplies, pertaining to each medical supply category (e.g., incontinence, ostomy, urological, wound); and/or

      (2) The DME requested is within the frequency limits for authorization as referenced in the Medi-Cal Provider Manual, Allied Health, Part 2, Durable Medical Equipment and Medical Supplies, Durable Medical Equipment: An Overview; and
(3) The provider prescribing the medical supplies and/or DME has a Service Code Grouping (SCG) SAR for either SCG 01, 02, 03, 07, 10, or 12 authorized with dates of service that include the dates of service on which the medical supplies and/or DME are dispensed.

b. Otherwise, a separate, product specific SAR\(^6\) is required when billing medical supplies and/or low cost DME\(^7\) when the quantity of medical supplies/DME exceeds the Medi-Cal limit, or a miscellaneous code is used.

IV. POLICY IMPLEMENTATION

A. Authorization for CCS Program Clients:

1. Effective the date of this letter, the request for enteral nutrition products may be authorized once the following process is completed:

a. Vendor submits to CCS Program:

   (1) Prescription, signed by a CCS Program-paneled physician, A faxed prescription cannot be used in lieu of the request form.

   (2) All pertinent medical reports/records, signed by the CCS Program-paneled physician or designated nurse practitioner (NP) and dated within six months of the enteral nutrition request.

   (3) CCS Program-paneled RD’s MNT reports including justification for use of the product(s) requested, documentation regarding attempts to increase calories with whole or modified textured 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 County CCS Program authorizing agent. The MNT report must be signed by the CCS Program-paneled RD and dated within six months of the enteral nutrition request.

   (4) Appropriate growth charts (weight/age, length/age, and BMI/age or weight/length) and Z-scores (when used to define malnutrition or faltering growth) must accompany or be incorporated into the RD’s MNT reports.

b. The SCC, specifically the CCS Program-paneled MD, NP, or RD, sends all of the above paperwork to the pharmacy vendor.

c. If submitting a paper SAR, the pharmacy vendor completes the SAR and submits items above (1-4), along with Attachment 2, to the County CCS
Program Office for independent counties or to the ISCD Special Populations Authorization Unit for dependent counties at CCS_Operations@dhcs.ca.gov or via secure RightFax number (916) 440-5768. For counties in the Whole Child Model, the pharmacy vendor will submit the required documents to the client’s managed care plan (MCP).

d. If submitting an electronic SAR⁸, the pharmacy vendor submits the request via the Children’s Medical Services Network System (CMS Net), along with the necessary attachments listed above.⁹

e. If the request is for reauthorization, physician/NP and RD reports (signed and dated within six months of the request) must document medical necessity 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 for enteral nutrition products and feeding supplies shall be for up to six months, except when criteria described below are met. Authorization for enteral nutrition products for greater than six months (up to 12 months) requires:

a. The client is at least 14 years of age.

b. The client’s nutritional treatment plan has not changed over the previous 12 months.

c. The client has one of the following conditions:
   
   (1) Metabolic disorder requiring specialized formula.

   (2) Renal failure on dialysis.

   (3) Inflammatory bowel disease on elemental diet.

   (4) Short bowel syndrome on elemental formula.

   (5) Complete gastrostomy tube dependence.

   (6) Intractable seizures on ketogenic formula.

   (7) Cerebral palsy.

d. The family has demonstrated motivation to adhere to the client’s treatment plan.
e. Documentation of the rationale for extending the request beyond six months is described in the RD MNT report dated within six months of the enteral nutrition products request, and on Attachment 2. The MNT report must include RD assessment at least every six months.

B. Authorization for GHPP Medi-Cal clients enrolled in a managed care plan (MCP):

1. For GHPP clients who are also enrolled in a MCP, GHPP shall cover only enteral nutrition products that are not covered under the client’s MCP. If the enteral nutrition product is not covered under the MCP, providers should submit a SAR to the GHPP program along with all necessary medical documentation, a copy of the client’s explanation of benefits, and a copy of the claim denial from the MCP.

2. For GHPP clients not enrolled in a MCP, the requests for enteral nutrition products will be authorized per the process of the CCS Program as stated in section IV.A. of this numbered letter with the following exceptions:

a. Attachment 2 and/or prescription are signed by a physician from an ISCD approved SCC.

b. The authorizing GHPP agent has received the following:

(1) Completed Attachment 2.

(2) Completed SAR from the pharmacy.

(3) Pertinent medical reports/records signed and dated within last six months by GHPP authorizing physician or NP.

(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 the 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 every 6 or 12 months, as described in Section IV.A.2.
C. For enteral nutrition products, the first date of service may begin the date the physician signs and dates the prescription and/or Attachment 2. 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.

D. Documentation Requirements:

1. Documentation requirements for authorization of enteral nutrition products are listed in the Enteral Nutrition Products section of the Medi-Cal Provider Manual.

2. Additional required documentation includes:
   
a. Medical justification for product stated on Attachment 2 and in RD MNT report.

b. SCC/CCS Program-paneled RD’s current nutrition assessment and care plan stated in MNT report dated within six months of the enteral nutrition products request.

c. Growth Charts:

   (1) World Health Organization growth charts must be included for infants and toddlers from birth to two years old.

   (2) Center for Disease Control and Prevention growth charts must be included for children and adolescents 2 to 20 years old.

   (3) Premature infant charts must be included when applicable.

   (4) Specialty growth charts for specific conditions such as quadriplegic cerebral palsy, achondroplasia, Down syndrome, etc. must be included in addition to standard growth charts.

   (5) Z-scores must be included when used to define malnutrition or faltering growth in children as described in section III.A.2.a.(2)(b).
If you have any questions regarding this N.L. please email the ISCD Medical Director or designee at ISCD-MedicalPolicy@ca.gov.

Sincerely,

ORIGINAL SIGNED BY

Roy Schutzengel
Medical Director
Integrated Systems of Care Division

Attachment(s):
Attachment 1: Definitions
Attachment 2: Request for Enteral Nutrition Product(s) and Equipment for CCS/GHPP Programs

1 Enteral Nutrition Products section of the Provider Manual
http://files.medi-cal.ca.gov/pubsdoco/publications/masters-mtp/part2/enteral_a04p00.doc

2 List of Enteral Nutrition Products Spreadsheet


4 CCS Program N.L 20-0605 Non-Benefit Status of Regular Infant Formulas is available at:

5 Durable Medical Equipment and Medical Supplies sections of the Medi-Cal Provider Manual

6 Medical Supply Codes requiring a product specific SAR can be found at:
http://www.dhcs.ca.gov/services/ccs/cmsnet/Pages/SARTools.aspx#msg

7 DME requiring a product specific SAR can be found at:
http://files.medi-cal.ca.gov/pubsdoco/publications/masters-mtp/part2/duracd_a04a06a08p00.doc

8 Guidelines for eSAR submission can be found here:

9 Guidelines for eSAR attachments can be found here:
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, acute and chronic kidney disease, 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 Nutrition 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. Nutrition Additives/Modulars:

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, blended 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 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.

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, Body Mass Index (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.

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 signed prescription or signature on page 2 of this form
- SCC/CCS-paneled physician medical reports/records for patient
- SCC/CCS-paneled registered dietitian MNT plan with required documentation per N.L. 01-0120
- 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 unless meets criteria for exception. The first date of service may commence the date the physician signs this form. Enteral nutrition requests may not be backdated.

- Authorization requested for one year because client meets criteria outlined in N.L. 01-0120

Patient Name: ____________________________________________ CCS/GHPP #: ____________

DOB: ____________________________ Age: ____________

CCS/GHPP-eligible medical condition: ____________________________________________ ICD Code: ______

Authorized CCS Special Care Center: ____________________________________________

Authorized CCS/GHPP Physician: ____________________________________________

Nutrition Products:

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<th>Delivery Route** (Circle)</th>
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* 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.):

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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: _________________
- Supplies required for tube fed individual
- 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 and all required documentation to the CCS authorizing office listed above.