



POLICIES AND PROCEDURES

Policy #: 403-1136

Lead Department: Pharmacy

Title: Enteral Nutrition Products

Original Date: 05/05/2014

Policy Hub Approval Date: 10/02/2018

Approved by: Utilization Management Work Group (UMWG)

Purpose:

The purpose of this policy is to define Central California Alliance for Health's, (the Alliance's) requirements for the provision of medically necessary enteral nutrition formulas and supplements.

Policy:

The Alliance will cover enteral nutrition products for Medi-Cal members when medical necessity criteria is met.

Definitions:

BMI: Body Mass Index (BMI) is a simple index of weight-for-height that is commonly used to classify underweight, overweight and obesity in adults. It is defined as the weight in kilograms divided by the square of the height in meters (kg/m²).

Enteral Nutrition: Involving or passing through the intestine, either naturally via the mouth and esophagus, or through an artificial opening.

Gestational Age: Is the common term used during pregnancy to describe how far along the pregnancy is. It is measured in weeks, from the first day of the woman's last menstrual cycle to the current date. A normal pregnancy can range from 38 to 42 weeks.

Oral Nutrition: Nutrients of any form taken my mouth. The terms "Oral Nutrition" and "Enteral Nutrition" may be used interchangeably.

California Children's Services (CCS): CCS is a State program for children with certain diseases or health problems. Through this program, children up to 21 years of age can get the health care and services they need for CCS-eligible conditions.

Whole Child Model (WCM): The purpose of the WCM program is to incorporate services covered by the CCS Program into Medi-Cal managed care for Medi-Cal-eligible CCS Program members. Managed care plans (MCPs) operating in WCM counties will integrate Medi-Cal managed care and CCS Program administrative functions to provide comprehensive treatment of the whole child and care coordination in the areas of primary, specialty, and behavioral health for CCS-eligible and non-CCS-eligible conditions.



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Medical Food: A medical food product is defined as a food that:

1. Is specially formulated to be consumed or administered enterally and is a substitution for necessary components of the diet (e.g., ordinary proteins/amino acids) that the child/adult cannot consume because of his or her medical condition;
2. Is intended for the specific dietary management of a disease or condition, such as metabolic conditions, for which specific nutritional requirements exist.

Low-Protein Therapeutic Foods: Limited to Whole Child Model-Medi-Cal members with CCS eligibility. Foods primarily intended to manage metabolic disorders by preventing organ damage and supporting proper growth and overall health status. These foods are specially formulated and not available in grocery stores.

Therapeutic Diet (Regimen): A diet used as part of a treatment of a disease or clinical condition.

Tube Fed (Tube Feeding): Tube feeding is when a special liquid food mixture containing protein, carbohydrates (sugar), fats, vitamins and minerals, is given through a tube into the stomach or small bowel. The terms "Tube Feeding" and "Enteral Nutrition" may be used interchangeably.

Weight/Body Weight: Actual, measured body weight of an individual.

Procedures:

1. Member Eligibility

To receive authorization for reimbursement, the beneficiary must be eligible for Medi-Cal on the date of service.

2. Coverage:

- a. Enteral nutrition products may be covered upon authorization when used as a therapeutic diet regimen to prevent serious disability or death in patients with medically diagnosed conditions that preclude the full use of regular food.
(California Code of Regulations (CCR), Title 22, Section 51313.3.)



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- b. Enteral nutrition products covered are subject to the Medi-Cal list of enteral nutrition products and utilization controls. (*Welfare and Institutions Code (CWI) Sections 14132.86, 14105.8 and 14105.395*)
- c. Medical necessity will be determined using the criteria outlined in the Enteral Nutrition Products Sections of the Medi-Cal Part 2 Pharmacy Provider Manual and as defined in the Alliance’s *Procedure and Assessment for Medical Necessity Determination of Enteral Nutrition Products* (Attachment A).
- d. Enteral and Parenteral Nutrition medical supplies: enteral formula and additives, adult and pediatric, including for inherited diseases of metabolism; enteral feeding supply kits; enteral nutrition infusion pump; enteral tubing; gastrostomy/jejunostomy tube and tubing adaptor; nasogastric tubing; parenteral nutrition infusion pump; parenteral nutrition solutions; stomach tubes; If not otherwise specified, the Alliance will cover enteral nutrition products for six months duration.
- e. Enteral nutrition products provided to inpatients receiving inpatient hospital services are included in the hospital’s reimbursement made under the *CCR, Title 22, Section 51536*. These products are not separately reimbursable.
- f. Enteral nutrition products provided to inpatients receiving Nursing Facility Level A services or Nursing Facility Level B services are not separately reimbursable.


Enteral nutrition products provided to patients in the Intermediate Care Facility for the Developmentally Disabled (ICF/DD), Intermediate Care Facility for the developmentally Disabled/ Habilitative (ICF/DD-H) or Intermediate Care Facility for the Developmentally Disabled/ Nursing (ICF/DD-N) are reimbursed as part of the facility’s daily rate and are not separately reimbursable (CCR, Title 22, Sections 51510.1, 51510.2 and 51510.3) Enteral nutrition products and infusion nutrients that are provided to beneficiaries during chronic outpatient hemodialysis in renal dialysis centers and community hemodialysis units, or for use during home dialysis are not separately reimbursable. Pharmacies that furnish enteral or infusion nutrition products to hemodialysis centers, community hemodialysis units or to beneficiaries for home dialysis should bill the dialysis provider directly.



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- g. The Alliance will inform members about the process and procedures for obtaining medically necessary enteral nutrition products.
 - h. Food thickener may be considered for members with impaired swallowing function.
 - i. The Alliance will review requests for the provisions of human milk for newborns in the following situation: Mother is unable to breastfeed due to medical reasons, and the infant cannot tolerate or has medical contraindications to the use of any formula, including elemental formulas.
 - j. The Alliance will review requests for special food products which are used in place of normal food products such as grocery store foods used by the general population that are prescribed by a physician or nurse practitioner. These products are 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.
 - k. The same formulary is used for all Alliance members including Whole child members with CCS eligibility with the exception of Low-Protein Therapeutic Foods which are limited to Whole child members with CCS eligibility.
 - l. Members that are part of the Whole Child Model will have their authorization requests reviewed based on the more lenient criteria of CCS Numbered Letters and Alliance PA Criteria.
3. Non-Coverage: The following nutrition products are not covered by the Alliance under this policy:
- a. Regular food including solid, semi-solid, blenderized, and pureed foods
 - b. Common household items
 - c. Regular infant formula as defined in the Federal Food, Drug and Cosmetic Act (FDC Act) to meet the normal needs of healthy infants, regardless of the route of administration, or reduced iron content, or thickened form;
 - d. Shakes, cereals, thickened products, puddings, bars, gels, and other non-liquid products;

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- e. Any products for assistance with weight loss;
 - f. Vitamin and/or mineral supplements, except for pregnancy and birth up to 5 years of age;
 - g. Nutrition products used orally as a convenient alternative to preparing and/or consuming regular solid or pureed foods (such as picky eaters).
4. Requirements for Authorization:
- a. A written prescription signed by a licensed practitioner within the scope of his or her practice as established in California law is required for authorization of all enteral nutrition products.
 - 1. The Alliance does not accept a WIC referral in place of a signed prescription.
 - b. Authorization of all enteral nutrition products requires the dispensing or prescribing provider to submit an Authorization Request (AR) Form via the Alliance web-based electronic provider portal or to the Pharmacy Department via fax.
 - 1. The product number requested on the Prior Authorization request (via electronic or fax submission) must be the same as the product number dispensed and billed.
 - c. Review for medical necessity of authorization requests and approval determinations of enteral nutrition products shall be supervised by the Alliance’s Registered Dietitian (RD).
 - d. A qualified Physician (Medical Director) may modify or deny prior authorizations for enteral nutrition products.
5. Documentation
- a. To demonstrate the member meets medical necessity criteria for Enteral Nutrition Products, the following clinical information, as documented in the beneficiary’s medical record, must be submitted with the AR via the Alliance




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web-based electronic portal or to the Alliance Pharmacy department via fax.

NOTE: The documentation must be dated within 3 months at the time of AR or submission.

- b. Member's full name;
- c. Member's Alliance ID Number;
- d. Member's date of birth (with gestational age at birth if applicable to request); and
- e. Medical diagnosis related to the request for enteral or oral nutrition product coverage.
 - i. For disease-specific products, documentation must also include the product's disease-specific indication (diagnosis name) and ICD-9/ICD-10 code as documented in the beneficiary's medical record.
- f. Secondary Medical diagnosis and code if applicable to disease-specific or specialized formula being requested and statement why standard formula not appropriate.
- g. Current Anthropometric measurements: Weight, Height (length), body mass index (BMI), amount of recent weight change, and time frame of recent weight change.
 - i. Growth charts for height/ length, weight, weight-for-height or weight-for-length and BMI for age with current anthropometric measurement values plotted accurately are required for all members 0-20 years of age.
- h. Daily Nutritional Needs: Calories, protein and fluid requirement; as determined by whom, and on what date.
- i. Biochemical, clinical and/or dietary indicators related to the request for a product.
- j. Prior Treatments (failed or successful; duration and outcome).

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- k. Estimated duration of need for the formula or supplement product. Complete nutrition care plan will also be accepted.
 - l. For Diabetes products: Hemoglobin A1c (HgbA1c) value measured within 6 months of the authorization request submission.
 - i. If HgbA1c not available, please provide results from multiple blood glucose tests indicating consistent presence of hyperglycemia.
 - m. For renal products: One of the following measured within 6 months of the authorization request submission:
 - i. Blood serum potassium, BUN levels (> than 20 mg/dL for approval), or Urine Creatinine (> 26 mg/kg/day for men, or >20 mg/kg/day for women), or Estimated Glomerular Filtration Rate (GFR) (< 60 mL/min/1.73m² for approval).
 - n. For Hepatic products: Results of Liver Function Tests measured within 6 months of the authorization request submission.
 - o. An objective summary of medical justification detailing member's inability to meet his/ her nutritional needs with dietary adjustments of regular or altered-consistency (soft or pureed) foods.
 - p. For Low-Protein Therapeutic Foods: Limited to Whole Child Model-Medical members with CCS eligibility. Documentation must demonstrate need for low-protein therapeutic foods to treat diagnosis. The Medical Foods Request & Order Form must be filled out by the Special Care Center Dietitian detailing food product requested and submitted with a current physician and nutrition report. These two reports may be combined in a single team report. The form can be accessed here:
<http://www.dhcs.ca.gov/services/ccs/cmsnet/Documents/thiscomputes266.pdf>
6. Authorization Request Review Process
- a. Authorization Request Review Time Frames

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- i. The Alliance will perform decisions and appeals regarding enteral nutrition products in a timely manner based in the sensitivity of the medical conditions as follows:
 - 1) **Routine (Non-Emergency) Requests:** The Alliance will process non-emergency requests for service within five (5) working days when the proposed treatment meets objective medical necessity criteria and is not contraindicated.
 - 2) **A Regimen Already in Place:** The Alliance will process a regimen of services already in place within five (5) working days as consistent with the urgency of the member’s medical condition, as required by Health and Safety Code (CCHS) Section 1367.01.
 - 3) **Expedited (Urgent) Requests:** The Alliance will provide for expedited requests on services and process within three (3) working days when a provider or the Alliance determines that the standard timeframes above could seriously jeopardize the member’s life or health or ability to attain, maintain or regain maximum function.
 - 4) **Emergency Requests:** The Alliance will not require prior authorization of service when there is a bona fide emergency requiring immediate treatment as required by CWI, Section 14103.6.
- ii. If the Alliance determines there is insufficient information to render a medically appropriate decision, (only applicable to Medi-Cal members) the Alliance may defer the request process for up to fourteen (14) calendar days from the date of receipt.

b. Notification of Determination

- i. Approval of an authorization request is communicated to the member through their provider. Providers are notified of approval via fax.
- ii. The Alliance will provide written notification to any provider and member when an Enteral Nutrition Product authorization has been

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deferred, denied or modified in an amount, duration, or scope that is less than what is submitted in the original requested.

- iii. Written notification of determination will contain procedures for appeals for both providers and members.

7. Quantity Restrictions

Claims billed for each dispensing of authorized enteral or oral nutrition products benefit are limited to no more than a 31-day supply. A 31-day supply is defined as the patient’s daily caloric requirement for product (specified by licensed prescriber on the prescription), multiplied by 31 days, divided by caloric density of product (kcal/milliliter of liquid product, or kcal/gram of powdered product), and rounded up to the smallest available package size (can, bottle, bag, or brikpak). Rounding up does not include rounding up to six packs or full cases of product.

8. Informing Providers and Members:

- a. The Alliance shall inform providers about prescription and authorization procedures for the provision of enteral nutrition products, including timeliness standards, requirements for periodic physical assessment and follow-up evaluation, local referral resources, and the formulary list of covered enteral nutrition products (formulas) annually via the Provider Manual.
- b. The Alliance shall inform members about the processes and procedures for obtaining medically necessary enteral nutrition products annually via the Member Handbook Evidence of Coverage.

References:

Alliance Policies:

Impacted Departments:

Care Management

Member Services

Provider Services

Utilization Management

Regulatory:

22 CCR, Section 51313.3

44 CFR, Section 431.63(c)



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CCHS, Section 1367.01
 CCS Numbered Letter 08-0718 enteral Nutrition Products As CCS Program And
 GHPP Benefits - Revised
 CWI, Section 141.32.86 paragraph (ab) (1-4)
 CWI, Section 14103.6
 CWI, Section 14105.395
 CWI, Section 14105.8
 CWI, Section 14132.86
 FDC Act, Chapter IV; Section 412
 HSC § 1300.67.005 9(B)(i)
 HSC § 1367.56
 OIL131-14

Legislative:

Contractual:

DHCS Medi-Cal contract, Exhibit A, Attachment 5, Provision 3.G

MMCD Policy Letter:

Policy Letter 07-016

Policy Letter 14-003

NCQA:

Supersedes:

Other References:

Attachments:

Attachment A: Procedure and Assessment for Medical Necessity Determination of Enteral Nutrition Products

Lines of Business This Policy Applies To

- Medi-Cal
- Alliance Care IHSS

LOB Effective Dates

- (01/01/1996 – present)
- (07/01/2005 – present)

Revision History:

Reviewed Date	Revised Date	Changes Made By	Approved By
04/15/2015	04/15/2015	Logan Vanderpool, R.D., Registered Dietitian	UMWG
08/04/2015	08/04/2015	Logan Vanderpool, RD, Registered Dietitian	UMWG
05/23/2016	05/23/2016	Tony Nannini, RD Registered Dietitian	UMWG
04/14/2017	04/14/2017	Jacqueline Van Voerkens, Admin	UMWG



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Reviewed Date	Revised Date	Changes Made By	Approved By
		Specialist – CMO	
05/01/2018	05/01/2018	Michelle Williams, Pharmacy Operations Manager	UMWG
08/24/2018	08/24/2018	Christine Lally, RD, Registered Dietician	UMWG