



Policy: GG.1407
Title: **Nutrition Products**
Department: Medical Management
Section: Pharmacy Management

CEO Approval: /s/ Michael Hunn 12/16/2024

Effective Date: 04/01/2004

Revised Date: 12/01/2024

Applicable to: ☒ Medi-Cal
☐ OneCare
☐ PACE
☐ Administrative

I. PURPOSE

This policy defines the scope of coverage for nutrition products on an outpatient basis.

II. POLICY

- A. As of January 1, 2022, CalOptima Health shall be responsible for reviewing Prior Authorizations for medical supplies and Enteral Nutritional Products billed on a medical claim. Medi-Cal Rx shall be responsible for these benefits when billed on a pharmacy claim.
- B. CalOptima Health or a Health Network shall be responsible for reviewing all Prior Authorizations for Enteral Nutrition pumps and tubing supplies.
- C. All nutrition products shall be prescribed by a licensed practitioner and meet Medical Necessity and benefit coverage criteria.
- D. CalOptima Health shall adopt the criteria for Enteral Nutrition products as published by the Department of Health Care Services (DHCS).
- E. Enteral Nutrition Products may be approved by CalOptima Health or a Health Network upon authorization when used as a therapeutic regimen to prevent serious disability or death in patients with medically diagnosed conditions that preclude the full use of regular food and are subject to the CalOptima Health Prior Authorization Criteria for Enteral Nutrition. The following nutrition products are not covered by CalOptima Health and are not within the scope of benefit for Medi-Cal:
 - 1. Regular foods, including solid, semi-solid, and puréed foods;
 - 2. Regular infant formula as defined in the Federal Food, Drug and Cosmetic Act (FD&C Act);
 - 3. Thickeners;
 - 4. Shakes, cereals, thickened products, puddings, bars, gels, and other non-liquid products; and
 - 5. Enteral Nutrition products used orally as a convenient alternative to preparing and/or consuming regular solid or puréed foods.

- F. Medical Foods prescribed for the treatment of inborn errors of metabolism (i.e. phenylketonuria (PKU), maple syrup urine disease (MSUD), homocystinuria, histidinemia, and tyrosinemia) shall be covered when mandated by state law.

III. PROCEDURE

- A. The Prior Authorization request shall include the following information:
1. The Member's diagnosis and indication for the nutrition product;
 2. Current International Statistical Classification of Diseases and Related Health Problems diagnosis code;
 3. The Member's documented Medical Record:
 - a. For standard, elemental/semi-elemental, and specialized products: Documentation must be within twelve (12) months of the time of Prior Authorization submission;
 - b. For metabolic products: Documentation must be within twelve (12) months of the time of Prior Authorization submission; and
 - c. For specialty infant products: Documentation must be within four (4) months of the time of Prior Authorization submission;
 4. The method of administration of the nutrition product;
 5. The Member's current age, weight, height (length), and body mass index (BMI);
 6. A growth chart for children (if available); and
 7. Reasons why regular solid or pureed foods cannot be used.
- B. Nutrition products may be approved in accordance with the CalOptima Health Prior Authorization Criteria for Enteral Nutrition products.
1. Authorization procedures and review for approval of Enteral Nutrition products shall be supervised by qualified healthcare professionals.
 2. Decisions and appeals regarding Enteral Nutrition products shall be performed in a timely manner based on the sensitivity of medical conditions and rendered as:
 - a. Emergency requests: CalOptima Health or a Health Network shall not require Prior Authorization in the event of an emergency requiring immediate treatment.
 - b. Expedited request: CalOptima Health or a Health Network shall render a decision within three (3) business days when a Provider, CalOptima Health or a Health Network determines that the standard timeframe could seriously jeopardize the Member's life or health or ability to attain, maintain, or regain maximum function.
 - c. Non-emergency request: CalOptima Health or a Health Network shall render a decision within five (5) business days when a proposed treatment meets Prior Authorization criteria and is not contraindicated.

- d. Continuing therapy request: CalOptima Health or a Health Network shall render a decision within five (5) business days as consistent with the urgency of the Member's medical condition.
 - e. Any decision on Enteral Nutrition products that is delayed beyond these timeframes is considered approved and will be immediately processed as such.
 - f. CalOptima Health, or a Health Network, shall provide written or verbal notification to the prescribing Practitioner requesting Prior Authorization of Enteral Nutrition products that are approved, modified in any amount, denied, or approved for a duration that is less than that requested.
 - g. CalOptima Health, or a Health Network, shall notify Members in writing of denied, deferred, and modified requests for Enteral Nutrition products.
 - h. Both Members and Providers have the right to appeal CalOptima Health pharmacy decisions, as outlined in CalOptima Health Policy GG.1510 Appeals Process.
- E. The maximum duration of authorization approval before reauthorization is required shall be up to twelve (12) months depending on the nutrition product being requested.
- F. For a Health Network Member, the Provider shall follow the Health Network's authorization procedures.
- G. Regular infant formula as defined in the FD&C Act is not covered under the scope of the Medi-Cal benefit and therefore is not covered by CalOptima Health. These products may be covered under the Women, Infants, and Children (WIC) Program. CalOptima Health shall identify Members who are eligible for WIC services and shall refer Members twelve (12) months of age and younger to the WIC Program for standard enteral formulas. CalOptima Health shall notify prescribing practitioners that as part of the referral process to WIC, prescribing practitioners shall provide the WIC program a current, and periodically as needed, hemoglobin or hematocrit laboratory value and shall also document the laboratory values and the referral in the Member's Medical Record.
- H. CalOptima Health, a Health Network, a Provider, or a Perinatal Support Services (PSS) Provider shall refer a Member to the local WIC program and document that referral in accordance with CalOptima Health Policy GG.1701: CalOptima Health Perinatal Support Services (PSS) Program.

IV. ATTACHMENT(S)

Not Applicable

V. REFERENCE(S)

- A. CalOptima Health Contract with the Department of Health Care Services (DHCS) for Medi-Cal
- B. CalOptima Health Policy GG.1401: Physician Administered Drug (PAD) Prior Authorization Process
- C. CalOptima Health Policy GG.1639: Post-Hospital Discharge Medication Supply
- D. CalOptima Health Policy GG.1701: CalOptima Health Perinatal Support Services (PSS) Program
- E. CalOptima Health Prior Authorization Criteria for Enteral Nutrition Products
- F. DHCS Medi-Cal Managed Care Division Policy Letter 14-003: Enteral Nutrition Products (Supersedes Policy Letter 12-005)
- G. DHCS Provider Manual, Version 23.0, Section 12.0: Enteral Nutrition Products
- H. Title 22, California Code of Regulations (C.C.R), § 51313.3(e)(2)

- I. Welfare & Institutions Code, §§ 14094.13(d), 14103.6, and 14132.86
- J. Department of Health Care Services (DHCS) All Plan Letter (APL) 22-012: Governor's Executive Order N-01-19, Regarding Transitioning Medi-Cal Pharmacy Benefits from Managed Care to Medi-Cal RX (Supersedes APL 20-020)
- K. California Health and Safety Code (HSC) § 1374.56

VI. REGULATORY AGENCY APPROVAL(S)

None to Date

VII. BOARD ACTION(S)

None to Date

VIII. REVISION HISTORY

| Action | Date | Policy | Policy Title | Program(s) |
|-----------|------------|---------|--------------------|------------|
| Effective | 04/01/2004 | GG.1407 | Nutrition Products | Medi-Cal |
| Revised | 09/01/2008 | GG.1407 | Nutrition Products | Medi-Cal |
| Revised | 04/01/2014 | GG.1407 | Nutrition Products | Medi-Cal |
| Revised | 11/01/2015 | GG.1407 | Nutrition Products | Medi-Cal |
| Revised | 10/01/2016 | GG.1407 | Nutrition Products | Medi-Cal |
| Revised | 05/01/2017 | GG.1407 | Nutrition Products | Medi-Cal |
| Revised | 10/01/2018 | GG.1407 | Nutrition Products | Medi-Cal |
| Revised | 10/01/2019 | GG.1407 | Nutrition Products | Medi-Cal |
| Revised | 02/01/2020 | GG.1407 | Nutrition Products | Medi-Cal |
| Revised | 12/01/2020 | GG.1407 | Nutrition Products | Medi-Cal |
| Revised | 09/01/2021 | GG.1407 | Nutrition Products | Medi-Cal |
| Revised | 01/01/2023 | GG.1407 | Nutrition Products | Medi-Cal |
| Revised | 10/01/2023 | GG.1407 | Nutrition Products | Medi-Cal |
| Revised | 12/01/2024 | GG.1407 | Nutrition Products | Medi-Cal |

IX. GLOSSARY

| Term | Definition |
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| California Children's Services (CCS) Program | A State and county program providing Medically Necessary services to treat CCS-Eligible Conditions. |
| CalOptima Health | For purposes of this policy, CalOptima Health means CalOptima Health Direct- Administrative and CalOptima Health Community Network (CHCN). |
| CalOptima Health Community Network (CHCN) | A managed care network operated by CalOptima Health that contracts directly with physicians and hospitals and requires a Primary Care Provider (PCP) to manage the care of the Members. |
| CalOptima Health Direct Administrative (COHD-A) | The managed Fee-For-Service health care program operated by CalOptima Health that provides services to Members who meet certain eligibility criteria as described in CalOptima Health Policy DD.2006: Enrollment in/Eligibility with CalOptima Health Direct. |
| Enteral Nutrition | Enteral nutrition generally refers to any method of feeding that uses the gastrointestinal (GI) tract to deliver part or all of a person's caloric requirements. It can include a normal oral diet, the use of liquid supplements or delivery of part or all of the daily requirements by use of a tube (tube feeding). |
| Health Network | A Physician Hospital Consortium (PHC), physician group under a shared risk contract, or health care service plan, such as a Health Maintenance Organization (HMO) that contracts with CalOptima Health to provide Covered Services to Members assigned to that Health Network. |
| International Statistical Classification of Diseases and Related Health Problems, 10 th Revision (ICD-10) | The set of diagnosis codes used in the healthcare industry to define a patient's disease state or health status. |
| Medical Food | Medical Food 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." |
| Medically Necessary or Medical Necessity | <p>Reasonable and necessary Covered Services to protect life, to prevent significant illness or significant disability, or alleviate severe pain through the diagnosis or treatment of disease, illness, or injury, as required under W&I Code 14059.5(a) and Title 22 CCR Section 51303(a). Medically Necessary services shall include Covered Services necessary to achieve age-appropriate growth and development, and attain, maintain, or regain functional capacity.</p> <p>For Members under 21 years of age, a service is Medically Necessary if it meets the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) standard of Medical Necessity set forth in Section 1396dI(5) of Title 42 of the United States Code, as required by W&I Code 14059.5(b) and W&I Code Section 14132(v). Without limitation, Medically Necessary services for Members under 21 years of age include Covered Services necessary to achieve or maintain age-appropriate growth and development, attain, regain or maintain functional capacity, or improve, support or maintain the Member's current health condition. CalOptima Health shall determine</p> |

| Term | Definition |
|------------------------------------|--|
| | Medical Necessity on a case-by-case basis, taking into account the individual needs of the child. |
| Medical Record | The record of a Member's medical information including but not limited to, medical history, care or treatments received, test results, diagnoses, and prescribed medications. |
| Member | A Medi-Cal eligible beneficiary as determined by the County of Orange Social Services Agency, the California Department of Health Care Services (DHCS) Medi-Cal Program, or the United States Social Security Administration, who is enrolled in the CalOptima Health program. |
| Perinatal Support Services (PSS) | Perinatal services as defined in the Contract for PSS. |
| Prior Authorization | A formal process requiring a Provider to obtain advance approval for the amount, duration, and scope of non-emergent Covered Services. |
| Provider | Any individual or entity that is engaged in the delivery of services, or ordering or referring for those services, and is licensed or certified to do so. |
| Women, Infants, and Children (WIC) | The special supplemental nutrition program for women, infants and children authorized by section 17 of the Child Nutrition Act of 1966, 42 U.S.C. 1786. |