Clinical Policy: Oral and Enteral Formula

Reference Number: CA.CP.PMN.01
Effective Date: 11/13
Last Review Date: 04/19 Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Enteral nutrition is feeding provided through the gastrointestinal tract via a tube, catheter, or stoma that delivers nutrients distal to the oral cavity.

Enteral nutrition products may be covered if administered orally or through a feeding tube if medically necessary to prevent serious disability or death in patients with medically diagnosed conditions that preclude the full use of regular food (22 California Cod of Regulations (CCR) 51313.3(e)(2)).

Products are grouped by the following product categories:

- Elemental and semi-elemental (contain partially or fully broken down macronutrients)
- Metabolic (indicated for inborn errors of metabolism diagnosis)
- Specialized (disease-specific with intact macronutrients and modulars)
- Specialty infant (indicated for specific diagnosis or conditions)
- Standard (contain intact macronutrients)

Policy/Criteria
It is the policy of California Health & Wellness that oral and enteral formula are **medically necessary** when the following criteria are met. Refer to the appropriate product category type in the *List of Enteral Nutrition Products* in Appendix A for specific medical criteria. Determinations for standard prior authorization (PA) requests are made within five (5) business days. Decisions for urgent or expedited PA requests are issued within 72 hours of receiving the request. Refer to Plan Policy CA.UM.05 for Timeliness of UM Decisions and Notifications.

I. Initial Approval Criteria for members 21 years of age and older

A. Standard Products (must meet all):

1. A written prescription signed by a physician.
2. Documentation must be dated within three (3) months at the time of PA submission.
3. Refer to *List of Enteral Nutrition Products* for product-specific criteria that may also apply.
4. Member meets one of the following (A or B):
   A. Have a documented medical diagnosis that requires enteral nutrition products administered through a feeding tube.
   B. For enteral nutrition products administered orally, member meets one of the following:

a. Have a documented chronic medical diagnosis and unable to meet their nutritional needs with dietary adjustment of regular or altered-consistency (soft or pureed) foods. There must be clinical indicators identified and documented that support the patient is nutritionally at risk.
b. Have a medical condition and adequate nutrition is not possible with dietary adjustment of regular or altered-consistency (soft or pureed) foods. There must be documentation the member is nutritionally at risk with one of the following:
    i. Involuntary loss of 10% or more of usual body weight within six (6) months
    ii. Involuntary loss of 7.5% or more of usual body weight within three (3) months
    iii. Involuntary loss of 5% or more of usual body weight in one (1) month
    iv. Body mass index less than 18.5 kg/m2
c. Have severe swallowing or chewing difficulty due to one of the following:
    i. Cancer in the mouth, throat or esophagus
    ii. Injury, trauma, surgery or radiation therapy involving the head or neck
    iii. Chronic neurological disorders
    iv. Severe craniofacial anomalies
d. Documentation of transitioning from parenteral or enteral tube feeding to an oral diet

B. Specialized Products (must meet all):

1. A written prescription signed by a physician.
2. Documentation must be dated within three (3) months at the time of PA submission.
3. Refer to the *List of Enteral Nutrition Products* for product-specific criteria that may also apply.
4. For disease-specific products, member must have a documented medical diagnosis, specific to the product requested and meet one of the standard products medical criteria.
    a. For diabetic products, member must have a documented diagnosis of hyperglycemia or diabetes and HbA1c measured within six (6) months of the authorization request. The diagnosis name and ICD-10-CM diagnosis code and the HbA1c value must be clearly supplied on the authorization request
    b. For renal products, one of the following indicators measured within six (6) months of the request must be clearly supplied on the authorization request for patients 18 years and older.
        i. Blood serum potassium
        ii. BUN levels greater than 20 mg/dl
        iii. Urine Creatinine greater than 26 mg/kg/day for men or greater than 20 mg/kg/day for women
        iv. GFR less than 60 mL/min/1.73m2
    c. For hepatic products, LFT results measured within six (6) months of the request must be clearly supplied on the authorization request

4. For carbohydrate modular products, there must be documented clinical evidence to support the member is unable to meet caloric nutritional need with the current use of an enteral nutrition product
5. For lipid (fat) modular products, member must meet one of the following:
   a. Have documented diagnosis of inability to digest or absorb conventional fats
   b. Have documented diagnosis of uncontrolled seizure or other neurological disorder that cannot otherwise be medically managed
5. For protein modular products, there must be documented clinical evidence to support the member is unable to meet protein requirement with current use of a high protein enteral nutrition product.

C. Elemental and Semi-Elemental Products (must meet all):

1. A written prescription signed by a physician.
2. Documentation must be dated within three (3) months at the time of PA submission.
3. Refer to the *List of Enteral Nutrition Products* for product-specific criteria that may also apply. In rare cases, off-age products may be authorized if medical justification for off-age use is documented and attached to the authorization request.
4. One of the following criteria must be met:
   a. Have an intestinal malabsorption diagnosis (ICD-10-CM codes K90.0 - K90.9 and K91.2); lactose intolerance alone is excluded. The diagnosis name and ICD-10-CM code must be clearly supplied on the authorization request.
   b. Have a chronic medical diagnosis and present clinical signs and symptoms of inability to absorb nutrients or to tolerate intact protein that cannot otherwise be medically managed. Member must have a history of use with a standard or specialized disease-specific enteral nutrition product that failed to provide adequate nutrition unless such products are medically contraindicated.

D. Metabolic Products (must meet all):

1. A written prescription signed by a physician.
2. Documentation must be dated within six (6) months at the time of PA submission.
3. Authorization is restricted to ICD-10-CM diagnosis codes for Inborn Errors of Metabolism (genetic, metabolic condition) in Appendix C. The ICD-10-CM code and diagnosis must be clearly supplied on the authorization request as documented in the member's medical record. Refer to *List of Enteral Nutrition Products* for product-specific criteria that may also apply.
4. For metabolic ketogenic formulas, authorization may also be considered when documentation confirms the beneficiary meets one of the criteria below:
   a. Have seizures that are refractory to standard anti-seizure medications
   b. Have a chronic medical diagnosis where a ketogenic diet is medical necessary and a history of use with a product in another enteral nutrition category that failed to provide nutrition unless such products are medically contraindicated.

Approval duration: 6 months*

*Authorization quantities must be appropriate for the product size (quantity) dispensed and product description on the *List of Enteral Nutrition Products* in Appendix A. Rounding quantities is not permitted.

II. Initial Approval Criteria for members under 21 years of age:

Instructions: Send to Health Plan CCS Team for review of CCS eligibility. If not CCS covered per CCS Team, review request for medical necessity meeting the criteria below

A. Standard Products (must meet all):

1. A written prescription signed by a physician.
2. Documentation must be dated within three (3) months at the time of PA submission.
3. Refer to *List of Enteral Nutrition Products* for product-specific criteria that may also apply.
4. Member meets one of the following (A or B):
   A. Have a documented medical diagnosis that requires enteral nutrition products administered through a feeding tube.
   B. For enteral nutrition products administered orally, member meets one of the following:
      a. Have a documented chronic medical diagnosis and unable to meet their nutritional needs with dietary adjustment of regular or altered-consistency (soft or pureed) foods. There must be clinical indicators identified and documented that support the patient is nutritionally at risk.
      b. Have documented clinical signs and symptoms including anthropometric status indicators (stunting, wasting or underweight) of nutritional risk. Standard and modified growth charts should be used to document nutritional need and patient deficiency.
      c. Have severe swallowing or chewing difficulty due to one of the following:
         i. Cancer in the mouth, throat or esophagus
         ii. Injury, trauma, surgery or radiation therapy involving the head or neck
         iii. Chronic neurological disorders
         iv. Severe craniofacial anomalies
      d. Documentation of transitioning from parenteral or enteral tube feeding to an oral diet.

B. Specialized Products (must meet all):

1. A written prescription signed by a physician.
2. Documentation must be dated within three (3) months at the time of PA submission.
3. Refer to the *List of Enteral Nutrition Products* for product-specific criteria that may also apply.

4. For disease-specific products, member must have a documented medical diagnosis, specific to the product requested and meet one of the standard products medical criteria.
    a. For diabetic products, member must have a documented diagnosis of hyperglycemia or diabetes and HbA1c measured within six (6) months of the authorization request. The diagnosis name and ICD-10-CM diagnosis code and the HbA1c value must be clearly supplied on the authorization request
    b. For renal products, one of the following indicators measured within six (6) months of the request must be clearly supplied on the authorization request for patients 18 years and older.
        i. Blood serum potassium
        ii. BUN levels greater than 20 mg/dl
        iii. Urine Creatinine greater than 26 mg/kg/day for men or greater than 20 mg/kg/day for women
        iv. GFR less than 60 mL/min/1.73m2
    c. For hepatic products, LFT results measured within six (6) months of the request must be clearly supplied on the authorization request
3. For carbohydrate modular products, there must be documented clinical evidence to support the member is unable to meet caloric nutritional need with the current use of an enteral nutrition product
4. For lipid (fat) modular products, member must meet one of the following:
    a. Have documented diagnosis of inability to digest or absorb conventional fats
    b. Have documented diagnosis of uncontrolled seizure or other neurological disorder that cannot otherwise be medically managed
5. For protein modular products, there must be documented clinical evidence to support the member is unable to meet protein requirement with current use of a high protein enteral nutrition product.

C. Elemental and Semi-Elemental Products (must meet all):
1. A written prescription signed by the physician.
2. Documentation must be dated within three (3) months at the time of PA submission.
3. Refer to the *List of Enteral Nutrition Products* for product-specific criteria that may also apply. In rare cases, off-age products may be authorized if medical justification for off-age use is documented and attached to the authorization request.
4. One of the following criteria must be met:
    a. Have an intestinal malabsorption diagnosis (ICD-10-CM codes K90.0 - K90.9 and K91.2); lactose intolerance alone is excluded. The diagnosis name and ICD-10-CM code must be clearly supplied on the authorization request.
    b. Have a chronic medical diagnosis and present clinical signs and symptoms of inability to absorb nutrients or to tolerate intact protein that cannot otherwise be medically managed. Member must have a history of use with a standard or

specialized disease-specific enteral nutrition product that failed to provide adequate nutrition unless such products are medically contraindicated.

D. Metabolic Products (must meet all):

1. A written prescription signed by a physician.
2. Documentation must be dated within six (6) months at the time of PA submission.
3. Authorization requires a diagnosis of inborn errors of metabolism (genetic, metabolic condition). Refer to the *List of Enteral Nutrition Products* for product-specific criteria that may also apply.
4. For metabolic ketogenic formulas, authorization may also be considered when documentation confirms the beneficiary meets one of the criteria below:
   a. Have seizures that are refractory to standard anti-seizure medications
   b. Have a chronic medical diagnosis where a ketogenic diet is medical necessary and a history of use with a product in another enteral nutrition category that failed to provide nutrition unless such products are medically contraindicated.

E. Specialty Infant Products (must meet all):

1. A written prescription signed by a physician.
2. Documentation must be dated within two (2) months at the time of PA submission.
3. Maximum age at time of authorization is nine months plus 29 days; Corrected Age applies (see approval duration), except when noted.
4. Request is for one of the following specialty infant product types:
   a. Premature and Low Birth Weight Products
   b. Human Milk Fortifier
   c. Extensively Hydrolyzed Products (EH)
   d. Amino Acid-Based Products (100%)
   e. Renal Products
   f. Chylothorax or long-chain 3-hydroxyacyl-CoA dehydrogenase deficiency (LCHAD deficiency) products
5. For infant metabolic products, refer to the products listed under the metabolic category.
6. Refer to the amino acid-based products (100 percent) for products used in fat malabsorption.
7. Regular infant formula products as defined in the Federal Food, Drug and Cosmetic Act (FD&C Act) are not covered.
8. Member must meet the criteria listed below specific to the product and/or product type requested. Please refer to the *List of Enteral Nutrition Products* for a list of specialty infant products.
   A. Premature and low birth weight products (meets one of the following):
      a. Products 20 or 22 kcal/ounce are limited to beneficiaries born prior to 37 weeks gestation or birth weight less than 3500 grams

b. Products 24 or 30 kcal/ounce are authorized for one month only per reques.t and limited to current weight (at time of dispensing) less than 3500 grams.

B. Human milk fortifier products (must meet all):
   a. Authorization is limited to one month only per request for beneficiaries with current weight less than 3600 grams.
   b. Meets one of the following:
      1. Receiving only human milk and no other infant nutrition product (formula) used at the same time
      2. Breast fed or receiving human milk in combination with infant nutrition product (formula) administered only through a feeding tube
      3. Breast fed or receiving human milk in combination with infant nutrition product (formula) administered orally when one of the following conditions is currently documented and met:
      i. Infant is at risk for necrotizing enterocolitis
      ii. Mother of infant is establishing milk supply
      iii. Human milk intake is increasing

C. Extensively hydrolyzed products without probiotics, member must meet one of the following:
   a. Current diagnosis of cow's milk protein allergy (CMPA)
   b. Severe food allergy indicating a sensitivity to intact protein product

D. Extensively hydrolyzed products with probiotics, member must have current diagnosis of cow's milk protein allergy (CMPA) or intolerance to breast milk or regular infant formulary and meet all of the following:
   a. No immune function disorder
   b. Born full term (between 37 weeks and 42 weeks)
   c. No indwelling venous catheters

E. Amino acid-based (100%) products without probiotics, member must meet one of the following:
   a. Documented intolerance to breast milk or infant formula due to one of the following:
      i. A clinical diagnosis of cow's milk protein (CMPA), multiple food protein allergies, or eosinophilic GI disorder
      ii. Protein maldigestion or malabsorption diagnosis where extensively hydrolyzed specialty infant products have been tried and failed
      iii. A clinical diagnosis of gastrointestinal (GI) disorders such as short bowel syndrome of GI impairment
   b. Extensively hydrolyzed (semi-elemental) products are contraindicated
   c. For initial requests, documented in hospital use prior to discharge, establishing the need for the product. Must meet on of the other criteria for subsequent request.
   d. Documented clinical fat malabsorption or steatorrhea diagnosis not effectively addressed by breast milk, regular infant formula and extensively hydrolyzed

protein. Authorization may also be considered for fat malabsorption or steatorrhea as a secondary diagnosis associated with cystic fibrosis, short-bowel syndrome or other related clinical conditions.

F. For amino based (100%) products with probiotics, member must meet one of the above listed criteria (Ea-d) and all of the following:
   a. No immune function disorder
   b. Born full term (between 37 weeks and 42 weeks)
   c. No indwelling venous catheters or post-pyloric feeding type
G. Renal products (documentation of one of the following):
   a. Renal function impairment
   b. Hypercalcemia
   c. Hypocalcemia due to hyperphosphatemia
H. Chylothorax or LCHAD deficiency product (meets one of the following diagnoses):
   a. Chylothorax
   b. Long-chain-3-hydroxyacyl-CoA-dehydrogenase deficiency (LCHAD deficiency)
   c. Cystic Fibrosis
   d. Mitochondrial disorder

Approval Duration (all enteral nutrition products except specialty infant): 6 months*

Approval Duration (Specialty Infant): 2 months* authorization and is restricted for use at time of birth through age 12 months except when one of the following criteria has been met:

1. Corrected age (CA) applies only to infants born prior to 37 weeks gestation. For example, if birth date is 36 weeks gestation (four weeks early), remove four weeks from actual age (AA) since birth to get CA. CA is always younger than AA.

2. Use beyond age 12 months (including CA when applicable) requires documented medical justification clearly supplied on, or with, the authorization request, as documented in the infant's medical record.

3. Sole-source nutrition: Up to six months of age, except for infants that do not make expected progress in advancement to solid foods, usually associated with a lessening in kcals/kg of body weight need recognized by American Academy of Pediatrics. Additional medical documentation, stated clearly on or with the authorization request, as documented in the infant's medical record is required.

*****Authorization quantities must be appropriate for the product size (quantity) dispensed and product description on the *List of Enteral Nutrition Products* in Appendix A. Rounding quantities is not permitted.

III. Continued Approval (all enteral nutrition products):
Member continues to meet initial approval criteria

Approval Duration (all enteral nutrition products except specialty infant): 6 months*

Approval Duration (Specialty Infant): 2 months* authorization and is restricted for use at time of birth through age 12 months except when one of the following criteria has been met:

1. Corrected age (CA) applies only to infants born prior to 37 weeks gestation. For example, if birth date is 36 weeks gestation (four weeks early), remove four weeks from actual age (AA) since birth to get CA. CA is always younger than AA.

2. Use beyond age 12 months (including CA when applicable) requires documented medical justification clearly supplied on, or with, the authorization request, as documented in the infant's medical record.

3. Sole-source nutrition: Up to six months of age, except for infants that do not make expected progress in advancement to solid foods, usually associated with a lessening in kcals/kg of body weight need recognized by American Academy of Pediatrics. Additional medical documentation, stated clearly on or with the authorization request, as documented in the infant's medical record is required.

*****Authorization quantities must be appropriate for the product size (quantity) dispensed and product description on the *List of Enteral Nutrition Products* in Appendix A. Rounding quantities is not permitted.

Appendices

Appendix A:
List of Enteral Nutrition Products

Appendix B:
Table 1. Nutrition Products not covered by Medi-Cal

Regular food, including solid, semi-solid, blenderized and pureed foods	Common household items
Regular infant formula defined in the Federal Food, Drug and Cosmetic Act (FD&C Act)	Shakes, cereals, thickened products, puddings, bars, gels and other non-liquid products
Thickeners	Products for assistance with weight loss
Vitamin and/or mineral supplements, except for pregnancy and birth up to 5 years of age	Enteral nutrition products used orally as a convenient alternative to preparing and/or consuming regular solid or pureed foods

Appendix C:
Medi-Cal Enteral Nutrition Policy ICD-10 Diagnosis Codes for Inborn Errors of Metabolism for members 21 years of age and older.

ICD-10-CM CODE	DIAGNOSIS: Inborn Errors of Metabolism (IEM)
E70.0	Classical phenylketonuria
E70.1	Other hyperphenylalaninemias
E70.20 – E70.29	Disorders of tyrosine metabolism
E70.30 – E70.39	Albininsm
E70.40 – E70.49	Disorders of histidine metabolism
E70.5	Disorders of tryptophan metabolism
E70.8	Other disorders of aromatic amino-acid metabolism
E70.9	Disorder of aromatic amino-acid metabolism, unspecified
E71.0	Maple-syrup urine disease
E71.110 – E71.19	Other disorders of branched-chain amino-acid metabolism
E71.2	Disorder of branched-chain amino-acid metabolism, unspecified
E71.30	Disorder of fatty-acid metabolism, unspecified
E71.310 – E71.318	Disorders of fatty-acid oxidation
E71.32	Disorders of ketone metabolism
E71.39	Other disorders of fatty-acid metabolism
E71.40	Disorder of carnitine metabolism, unspecified
E71.42	Carnitine deficiency due to inborn errors of metabolism
E71.50 – E71.548	Peroxisomal disorders
E72.00 – E72.09	Disorders of amino-acid transport
E72.10 – E72.19	Disorders of sulphur-bearing amino-acid metabolism
E72.20 – E72.29	Disorders of urea cycle metabolism
E72.3	Disorders of lysine and hydroxylysine metabolism
E72.4	Disorders of ornithine metabolism
E72.50 – E72.59	Disorders of glycine metabolism
E72.8	Other specified disorders of amino-acid metabolism
E72.9	Disorder of amino-acid metabolism, unspecified
E74.00 – E74.9	Other disorders of carbohydrate metabolism
E75.00 – E75.6	Disorders of sphingolipid metabolism and other lipid storage disorders
E76.01 – E76.9	Disorders of glycosaminoglycan metabolism
E77.0 – E77.9	Disorders of glycoprotein metabolism

E84.0 – E84.9	Cystic fibrosis
E88.40 – E88.49	Mitochondrial metabolism disorders

Reviews, Revisions, and Approvals	Date	Approval Date
Updated medical necessity criteria to reflect latest Medi-Cal Enteral Nutrition Policy, March 2015 Added additional program coverage details in Description section Added Appendix A: List of Enteral Nutrition Products Added Appendix B: ICD-9 Diagnosis Codes for Inborn Errors of Metabolism Added Documentation Requirements per Medi-Cal Enteral Nutrition Policy Updated Approval section to include Specialty Infant products authorization instructions, including Corrected Age (CA) Updated non-covered nutrition products list in Special Instructions Updated References	06/15	06/15
Updated ICD-10-CM diagnosis codes according to Medi-Cal Enteral Nutrition Policy update	09/15	09/15
Converted to new policy template with reformatting changes Added current Medi-Cal Enteral Policy in Appendix B Added Table 1. Nutrition Products not covered by Medi-Cal in Appendix C Removed Special Instructions on turnaround times (TAT) Updated References	12/16	12/16
For specialty infant, extensively hydrolyzed product criteria, added that the additional criteria requirements is only applicable to liquid products per the Medi-Cal Enteral Nutrition Policy	12/16	01/17
Revised criteria to reflect current 2017 Medi-Cal Enteral Nutrition Policy Revised approval durations for specialty infant products based on the Medi-Cal Enteral Nutrition Policy Added Appendix C: ICD-10 Diagnosis Codes for IEM for members 21 years of age and older Added turnaround times per Plan Policy CA.UM.05 Timeliness of UM Decisions and Notifications For continued approval, added member continues to meet initial criteria	03/18	04/18
Renamed Policy from CA.PPA.01 to CA.CP.PMN.01	02/19	02/19
P&T Annual Review Updated references	04/19	04/19

References

1. Enteral Nutrition Products, MMCD Policy Letter 14-003 (Supersedes Policy Letters 12-005), April 11, 2014
2. Medi-Cal Part 2 Pharmacy Provider Manual: Enteral Nutrition Products Policy. Accessed February 2019. Medi-Cal Enteral Nutrition Product Policy

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare members, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs and LCDs should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.