

Clinical Policy: Oral and Enteral Formula

Reference Number: CA.CP.PMN.01

Effective Date: 11/13

Last Review Date: 02/25

Line of Business: Medicaid

[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:

- Standard: Contain intact macronutrients and be nutritionally complete and a sole source of nutrition where no additional elements, vitamins, minerals, nor macronutrients are additionally required.
- Specialized: Disease-specific with intact macronutrients and modulars
- Elemental and semi-elemental: Nutritionally complete formula which contain extensively hydrolyzed products (EH) (peptide) or fully broken-down (amino acid) protein macronutrients.
- Metabolic: Indicated for inborn errors of metabolism diagnoses for infant, pediatric, and adult members.
- Specialty infant: Indicated for specific diagnosis or conditions for individuals 1 year of age and younger.

Policy/Criteria

It is the policy of Health Net of California 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. Refer to [Appendix B](#) for Noncovered Nutrition Products. 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.58 Provision of Nutritional Supplements/Replacements for regulatory requirements specific to the Medi-Cal Managed Care Division's (MMCD) Policy Letter 14-003.

This policy shall be used for enteral nutrition requests billed under the medical benefit. For pharmacy requests, please submit the authorization to Medi-Cal Rx. For members under 21, send to Health Plan CCS Team for review of CCS eligibility.

CLINICAL POLICY

Oral and Enteral Formula

Documentation Requirements (applies to all requests)

All of the following clinical and product information, as documented in the member's medical record, must be clearly supplied on the PA request or as an attachment within the PA request. Required information includes the following:

1. Medical diagnosis name related to the product requested.
 - a. ICD-10-CM codes are required for certain product category types and/or diagnosis. Refer to the product category medical criteria specific for the product requested.
Note: If the ICD-10 Code diagnosis is not listed in product-specific sections, but the prescriber has determined the member meets the product-specific requirements, documentation should be included supporting the request of the non-listed ICD-10.
2. Daily caloric requirements of the requested enteral nutrition product. This information (along with other medical measurements and labs) must be dated within 365 days (12 months) of the request, with the exception of specialty infant products which must be dated within 120 days (4 months) of the request.
3. Indication if member is tube fed or orally fed.
4. 11-digit product NDC

I. Initial Approval Criteria

A. Standard Products (must meet all):

1. A written or electronic prescription signed by the provider.
2. Documentation must be dated within 12 months of the request.
3. Product must be on the [List of Enteral Nutrition Products](#).
4. Product meets the product category and product specific requirements.
5. Request does not exceed one of the following maximum daily caloric limits:
 - a. Tube Fed: up to 2,000 calories/day
 - b. Orally Fed and 22 years of age and older: up to 1,200 calories/day
 - c. Orally Fed and 21 years of age and younger: up to 1,000 calories/day
6. Member must meet **one** of the diagnoses as listed below:
 - a. Have severe swallowing or chewing difficulty due to one of the following:
 - Cancer in the mouth, throat or esophagus
 - Injury, trauma, surgery or radiation therapy involving the head or neck
 - Chronic neurological disorders
 - Severe craniofacial anomalies
 - Transitioning from parenteral or enteral tube feeding to an oral diet
 - b. Diagnosis listed in the following Standard Product Type Diagnosis Table in [Appendix C](#).

B. Specialized Products (must meet all):

1. A written or electronic prescription signed by the provider.

CLINICAL POLICY

Oral and Enteral Formula

2. Documentation must be dated within 12 months of the request.
3. Product must be on the [List of Enteral Nutrition Products](#).
4. Product meets the product category and product specific requirements.
5. Request does not exceed one of the following maximum daily caloric limits:
 - a. Tube Fed: up to 2,000 calories/day
 - b. Orally Fed and 22 years of age and older: up to 1,200 calories/day
 - c. Orally Fed and 21 years of age and younger: up to 1,000 calories/day
6. For diabetic, hepatic, or renal specialized products, the member must meet one diagnosis from the Standard Product Type criteria **AND** one diagnosis from the following Specialized Products Diagnosis Table ([Appendix D](#)).
7. For modular products, the member must meet one diagnosis from the Standard Product Type criteria **AND** provide clinical justification for why additional supplementation is required if the member is taking other enteral nutrition supplementation. Weight management diagnosis is excluded.
Member must also meet one of the following:
 - a. For modular lipid (fat) products:
 - Clinical documentation that supports a fat malabsorption diagnosis from the Specialized Products Diagnosis Table ([Appendix D](#)); OR
 - Indication for why the member requires a ketogenic diet for the control of a chronic condition, where other enteral nutrition formulas do not meet the member's needs.
 - b. For modular carbohydrate or protein products:
 - Clinical documentation that supports a pulmonary diagnosis from the Specialized Products Diagnosis Table ([Appendix D](#)); OR
 - Diagnosis and clinical justification that indicates the need for modified macronutrients with additional caloric intake or macronutrient intake.

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

1. A written or electronic prescription signed by the provider.
2. Documentation must be dated within 12 months of the request.
3. Product must be on the [List of Enteral Nutrition Products](#).
4. Product meets the product category and product specific requirements.
5. Request does not exceed one of the following maximum daily caloric limits:
 - a. Tube Fed: up to 2,000 calories/day
 - b. Orally Fed and 22 years of age and older: up to 1,200 calories/day
 - c. Orally Fed and 21 years of age and younger: up to 1,000 calories/day
6. Member must meet the following requirements:
 - a. Have an intestinal malabsorption diagnosis (ICD-10-CM codes K90.0 - K90.9 and K91.2). The diagnosis name and ICD-10 code must be documented on the authorization request.
 - Note: Lactose intolerance alone is excluded unless documentation is included that supports a cow's milk protein allergy (CMPA).
 - b. Documentation that a standard or specialized enteral nutrition product on the [List of Enteral Nutrition Products](#) has been tried and considered but did not provide adequate nutrition, unless such products are medically contraindicated.

CLINICAL POLICY

Oral and Enteral Formula

D. Metabolic Products (must meet all):

1. A written or electronic prescription signed by a physician.
2. Documentation must be dated within 12 months of the request.
3. Product must be on the [List of Enteral Nutrition Products](#).
4. Product meets the product category and product specific requirements.
5. Request does not exceed one of the following maximum daily caloric limits:
 - a. Tube Fed: up to 2,000 calories/day
 - b. Orally Fed and 22 years of age and older: Up to 1,200 calories/day
 - c. Orally Fed and 21 years of age and younger: Up to 1,000 calories/day
6. For ketogenic metabolic products (must meet all):
 - a. One of the following diagnoses:
 - Diagnosis from the Metabolic Products Diagnosis Table (See [Appendix E](#));
 - Epilepsy and recurrent seizures (ICD-10-CM Code G40);
 - Disorders of plasma protein metabolism (ICD-10-CM Code E88)
 - b. Documentation that a standard or specialized enteral nutrition product on the [List of Enteral Nutrition Products](#) has been tried or considered and the listed alternatives are otherwise considered to be clinically inappropriate/inadequate to meet the medical needs of the member.
7. For all other metabolic products (must meet all):
 - a. Diagnosis from the Metabolic Products Diagnosis Table (See [Appendix E](#))
 - b. Documentation that a standard or specialized enteral nutrition product on the [List of Enteral Nutrition Products](#) has been tried or considered and the listed alternatives are otherwise considered to be clinically inappropriate/inadequate to meet the medical needs of the member.

E. Specialty Infant Products (must meet all):

1. A written or electronic prescription signed by the provider.
2. Documentation must be dated within 4 months of the request.
3. Request does not exceed up to 800 calories/day regardless of feeding status.
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. Chylolthorax 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. For products used in fat malabsorption, refer to the amino acid-based products (100 percent).
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.

CLINICAL POLICY

Oral and Enteral Formula

- a. **Premature and low birth weight products (meets the following):**
 - i. One of the diagnoses from the Premature and Low Birth Weight Diagnosis Table ([Appendix F](#)); AND
 - ii. For products 20 or 22 kcal/ounce:
 - Members born prior to 37 weeks gestation; OR
 - Birth weight less than 3500 grams
 - iii. For products 24 or 30 kcal/ounce:
 - Current weight (at time of dispensing) is less than 3,500 grams; AND
 - Approvals are limited to a length of authorization of 1 month only.
- b. **Human milk fortifier products (meets the following):**
 - i. Current weight must be less than 3,600 grams; AND
 - ii. Meets one of the following:
 - Receiving only human milk and no other infant nutrition product (formula) used at the same time;
 - Human fed or receiving human milk in combination with infant nutrition product (formula) administered only through a feeding tube;
 - Human 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:
 - o Infant is at risk for necrotizing enterocolitis.
 - o Mother of infant is establishing milk supply.
 - o Human milk intake is increasing.
 - iii. Approvals are limited to a length of authorization of 1 month only.
- c. **Extensively hydrolyzed (EH) products:**
Meets one of the diagnoses from the Extensively Hydrolyzed Products (EH) Diagnosis Table below.

ICD-10 Code	Diagnosis
Z91.011	Allergy to milk products (CMPA)
Z91.018	Allergy to other foods (prescriber must indicate soy)
K52.29	Other allergic and dietetic gastroenteritis and colitis
K52.21	Food protein-induced enterocolitis syndrome (FPIES)

- d. **Amino acid-based (100%) products (meets the following):**
 - i. Meets one of the diagnoses from the Amino Acid-Based (100%) Products Diagnosis Table ([Appendix G](#)); AND
 - ii. Documentation that a specialty infant Extensively Hydrolyzed Products (EH) on the [List of Enteral Nutrition Products](#) have been tried or considered and the listed alternatives are determined to be clinically inappropriate/inadequate to meet the medical needs of the member or are contraindicated.
- e. **Renal products:**
Meets one of the diagnoses from the Renal Specialty Infant Products Diagnosis Table below.

ICD-10 Code	Diagnosis
N17	Acute kidney failure
N18	Chronic kidney disease

CLINICAL POLICY

Oral and Enteral Formula

P96.0	Congenital renal failure
N00	Acute nephritic syndrome
I12	Hypertensive chronic kidney disease
I13	Hypertensive heart and chronic kidney disease
E83.52	Hypercalcemia
E83.39	Other disorders of phosphorus metabolism

f. For Chyllothorax or LCHAD deficiency products:

Meets one of the diagnoses from the Chyllothorax or LCHAD Deficiency Specialty Infant Products Diagnosis Table below.

ICD-10 Code	Diagnosis
J94.0	Chylous effusion
I89.8	Other specified noninfective disorders of lymphatic vessels and lymph nodes
E71.310	Long chain/very long chain acyl CoA dehydrogenase deficiency
E84.0-E84.9	Cystic fibrosis
E88.4	Mitochondrial cystic fibrosis disorder

Approval Duration:

Specialty infant products: Up to 1 year of age, unless noted.

All other products: 12 months

Note: Enteral nutrition products are restricted to a maximum quantity limit based on the maximum daily caloric limit for each product for a maximum of a 30-day supply. For all products, except infant products, the maximum daily caloric limit of 2,000 calories/day is used to determine the maximum quantity limit. For infant products regardless of feeding status, the maximum daily caloric limit of 800 calories/day is used. Claims submitted for quantities that exceed the limitation will require a PA request submission establishing medical necessity for the requested quantity versus the member's daily caloric need.

Enteral nutrition products are limited to a maximum day supply of 30 days per claim. The day supply is based on documented caloric and nutrient requirements per day, converted to a 30-day supply. A "30-day supply" is defined as the member's daily caloric requirement for product (specified by the physician on the prescription), multiplied by 30 days, divided by caloric density of product, and rounded up to the smallest available package size. Rounding up does not include rounding up to six packs or full cases of product.

$(\text{Member's Daily Caloric Requirement} \times 30) \div \text{Product Caloric Density} = \text{Total (Rounded Up)}$

II. Continued Approval (all enteral nutrition products):

Member continues to meet initial approval criteria.

Appendices

Appendix A:

CLINICAL POLICY

Oral and Enteral Formula

[List of Enteral Nutrition Products](#)

Appendix B:

Nutrition Products not covered by Medi-Cal

- Regular food, including solid, semi-solid, blenderized, and pureed foods.
- Common household items and remedies such as medical foods, enteral nutritional supplements, or replacements except for items included in the [List of Enteral Nutrition Products](#).
- Regular infant formula as 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.
- Enteral nutrition products used orally as a convenient alternative to preparing and/or consuming regular, solid, or pureed foods.
- Combination vitamin and mineral products for members 22 years of age and older (except for prenatal vitamin-mineral combination products for use during pregnancy). Vitamins or mineral products used for dietary supplementation are not a benefit.

Appendix C: Standard Product Type Diagnosis Table

ICD-10 Code	Diagnosis
E45	Retarded development following protein-calorie malnutrition
M62	Other disorders of muscle
M62.5	Muscle wasting and atrophy, not elsewhere classified
R63.6	Underweight
R13.1	Dysphagia
R13.19	Other dysphagia
R13.0	Aphagia
K22.0	Achalasia of cardia
E46	Unspecified protein-calorie malnutrition
E43	Unspecified severe protein-calorie malnutrition
E64.0	Sequelae of protein-calorie malnutrition
R64	Cachexia
C15.3	Malignant neoplasm of upper third of esophagus
C15.4	Malignant neoplasm of middle third of esophagus
C15.5	Malignant neoplasm of lower third of esophagus
C15.8	Malignant neoplasm of overlapping sites of esophagus
C15.9	Malignant neoplasm of esophagus, unspecified
K91.30	Postprocedural intestinal obstruction, unspecified as to partial versus complete
K91.89	Other postprocedural complications and disorders of digestive system
K31.8	Other specified diseases of stomach and duodenum
K31.84	Gastroparesis
K14.4	Atrophy of tongue papillae

CLINICAL POLICY

Oral and Enteral Formula

Appendix D: Specialized Products Diagnosis Table

Product Type	ICD-10 Code	Diagnosis
Specialized, Diabetic	E08	Diabetes mellitus due to underlying condition
	E09	Drug or chemical induced DM
	E10	Type 1 diabetes mellitus
	E11	Type 2 diabetes mellitus
	E13	Other specified diabetes mellitus
	E89.1	Postprocedural hypoinsulinemia
	O24	Diabetes mellitus in pregnancy, childbirth, and puerperium
	R73.9	Hyperglycemia, unspecified
Specialized, Hepatic	B15	Acute hepatitis A
	B17	Other acute viral hepatitis
	E80	Disorders of porphyrin and bilirubin metabolism
	K70	Alcoholic liver disease
	K71	Toxic liver disease
	K72	Hepatic failure, not elsewhere classified
	K74	Fibrosis and cirrhosis of liver
	K76	Other diseases of liver
	K83	Other diseases of biliary tract
	K91	Intraoperative and postprocedural complications and disorders of digestive system, not elsewhere classified
	P78	Other perinatal digestive system disorders
	Q26	Congenital malformations of great veins
Specialized, Renal	I12	Hypertensive chronic kidney disease
	I13	Hypertensive heart and chronic kidney disease
	N00	Acute nephritic syndrome
	N17	Acute kidney failure
	N18	Chronic Kidney Disease
	Z99.2	Dependence on renal dialysis
Specialized, Modular Lipid	E74.00	Glycogen storage disorder
	E74.810	Glucose transporter 1 deficiency disorder
	E84.0	Cystic fibrosis, with pulmonary manifestations
	E84.1	Cystic fibrosis, with intestinal manifestations
	E84.8	Cystic fibrosis, with other manifestations
	E84.9	Cystic fibrosis, unspecified
	E88.40	Mitochondrial metabolism disorder, unspecified
	E88.41	MELAS syndrome
	E88.42	MERRF syndrome
	G40.909	Seizure Disorder

CLINICAL POLICY

Oral and Enteral Formula

	G40.919	Epilepsy, unspecified, intractable, without status epilepticus
Specialized, Modular Carbohydrate or Protein	E84	Cystic fibrosis
	J41	Simple and mucopurulent chronic bronchitis
	J42	Unspecified chronic bronchitis
	J43	Emphysema
	J44	Other chronic obstructive pulmonary disease
	J95	Intraoperative and postprocedural complications and disorders of respiratory system, not elsewhere classified
	J96	Respiratory failure, not elsewhere classified

Appendix E: Metabolic Products Diagnosis Table

CLINICAL POLICY

Oral and Enteral Formula

ICD-10 Code	Diagnosis
E70.0	Classical phenylketonuria
E70.1	Other hyperphenylalaninemias
E70.20 – E70.29	Disorders of tyrosine metabolism
E70.30 – E70.39	Albinism
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

CLINICAL POLICY

Oral and Enteral Formula

ICD-10 Code	Diagnosis
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

Appendix F: Premature and Low Birth Weight Diagnosis Table

Product Type	ICD-10 Code	Diagnosis
Prematurity	P07.21	Extreme immaturity of newborn, gestational age less than 23 completed weeks
	P07.22	Extreme immaturity of newborn, gestational age 23 completed week
	P07.23	Extreme immaturity of newborn, gestational age 24 completed weeks
	P07.24	Extreme immaturity of newborn, gestational age 25 completed weeks
	P07.25	Extreme immaturity of newborn, gestational age 26 completed weeks
	P07.26	Extreme immaturity of newborn, gestational age 27 completed weeks
	P07.30	Preterm newborn, unspecified
	P07.31	Preterm newborn, 28 weeks gestation
	P07.32	Preterm newborn, 29 weeks gestation
	P07.33	Preterm newborn, 30 weeks gestation
	P07.34	Preterm newborn, 31 weeks gestation
	P07.35	Preterm newborn, 32 weeks gestation
	P07.36	Preterm newborn, 33 weeks gestation
	P07.37	Preterm newborn, 34 weeks gestation
	P07.38	Preterm newborn, 35 weeks gestation
	P07.39	Preterm newborn, 36 weeks gestation
	P07.0	Extremely low birth weight newborn, < 999 grams
	P07.00	Extremely low birth weight newborn, unspecified
	P07.01	Extremely low birth weight newborn, < 500 grams
Low Birth Weight	P07.02	Extremely low birth weight newborn, 500-749 grams
	P07.03	Extremely low birth weight newborn, 750-999 grams
	P07.1	Other low birth weight newborn, 1,000-2,499 grams
	P07.10	Other low birth weight newborn, unspecified weight
	P07.14	Other low birth weight of newborn, 1,000-1,249 grams
	P07.15	Other low birth weight of newborn, 1,250-1,499 grams

CLINICAL POLICY

Oral and Enteral Formula

	P07.16	Other low birth weight of newborn, 1,500-1,749 grams
	P07.17	Other low birth weight of newborn, 1,750-1,999 grams
	P07.18	Other low birth weight of newborn, 2,000-2,499 grams
	P05.00	Newborn light for gestational age, unspecified
	P05.10	Newborn small for gestational age, unspecified weight
	P05.11	Newborn small for gestational age, less than 500 grams
	P05.12	Newborn small for gestational age, 500-749 grams
	P05.13	Newborn small for gestational age, 750-999 grams
	P05.14	Newborn small for gestational age, 1,000-1,249 grams
	P05.15	Newborn small for gestational age, 1,250-1,499 grams
	P05.16	Newborn small for gestational age, 1,500-1,749 grams
	P05.17	Newborn small for gestational age, 1,750-1,999 grams
	P05.18	Newborn small for gestational age, 2,000-2,499 grams
	P05.19	Newborn small for gestational age, other

Appendix G: Amino Acid-Based (100 Percent) Products Diagnosis Table

ICD-10 Code	Diagnosis
E43	Unspecified severe protein-calorie malnutrition
E44	Moderate protein-calorie malnutrition
E45	Retarded development following protein calorie malnutrition
E46	Unspecified protein-calorie malnutrition
K90.49	Malabsorption due to intolerance, not elsewhere classified
K90.4	Other malabsorption due to intolerance
K90	Intestinal malabsorption
K90.821	Short bowel syndrome, with colon in continuity
K90.822	Short bowel syndrome, without colon in continuity
K90.829	Short bowel syndrome, unspecified
Z91.011	Allergy to milk products (CMPA)
Z91.018	Allergy to other foods (prescriber must indicate soy)
K52.29	Other allergic and dietetic gastroenteritis and colitis
K52.21	Food protein-induced enterocolitis syndrome
K52.81	Eosinophilic gastritis or gastroenteritis
K52.82	Eosinophilic colitis
K20.0	Eosinophilic esophagitis

CLINICAL POLICY

Oral and Enteral Formula

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 E: 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 Added List of Nutrition Products not covered by Medi-Cal in Appendix B 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 E: 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
Added to Standard Product description “and be nutritionally complete” per current Medi-Cal Enteral Nutrition Policy.	03/20	04/20
Added Documentation Requirements per Medi-Cal Enteral Nutrition Products Policy. References updated.	10/20	10/20
Added updated List of Enteral Nutrition Products.	1/21	1/21
Added redirection for pharmacy requests to Medi-Cal Rx. References updated.	11/21	01/22
P&T Annual Review: Policy updated to align with Medi-Cal Enteral Nutrition Products criteria. References reviewed and updated.	09/22	10/22

CLINICAL POLICY

Oral and Enteral Formula

Reviews, Revisions, and Approvals	Date	Approval Date
<p>Annual Review: Policy updated to align with Medi-Cal Enteral Nutrition Products criteria. Significant changes include:</p> <ul style="list-style-type: none"> - Added option to submit copy of electronic Rx - Medical info provided must be dated within 12 months of the request with the exception of specialty infant requests, which is 4 months. - ICD-10 diagnosis tables added to Appendix for Standard and Specialized products. <p>References reviewed and updated.</p>	9/23	10/23
<p>Policy updated to align with Medi-Cal Enteral Nutrition Products criteria. Significant changes include:</p> <ul style="list-style-type: none"> - Updated approval duration to 6 months for all products, including specialty infant. - Tables updated to align with current ICD-10 diagnoses included in Medi-Cal Rx Provider Manual. - Specialty infant criteria updated to align with Medi-Cal Rx. - Added DHCS Numbered Letter (N.L.) 01-0120 with CCS criteria for enteral nutrition. <p>References reviewed.</p>	03/24	04/24
<ul style="list-style-type: none"> - Updated CA UM policy to CA.UM.58 Provision of Nutritional Supplements/Replacements that describes regulatory requirements specific to the Medi-Cal Managed Care Division's (MMCD) Policy Letter 14-003. - Added product must meet the product category and product specific requirements to initial criteria for all product types. - Added specialty infant approval duration can be approved up to 12 months of age or until the member's age of 11 months and 29 days to align with Medi-Cal Rx enteral nutrition criteria. - References reviewed. 	08/24	08/24
<ul style="list-style-type: none"> - Updated criteria to align with current 2.1.25 Medi-Cal Rx Provider Manual Enteral Nutrition PA Criteria. - Added Appendix F Premature and Low Birth Weight Diagnosis Table. - Added Appendix G Amino Acid-Based (100 Percent) Products Diagnosis Table. - Changed approval duration to up to 1 year of age for specialty infant and up to 12 months for all other enteral nutrition products. - References reviewed. 	02/25	02/25

References

1. State of California-Health and Human Services Agency, Department of Health Care Services. Policy Letter 14-003. April 11, 2014. Enteral Nutrition Products. Available at: <https://www.dhcs.ca.gov/formsandpubs/Documents/MMCDAPLsandPolicyLetters/PL2014/PL14-003.pdf>. Accessed Feb 2025.

CLINICAL POLICY

Oral and Enteral Formula

2. State of California-Health and Human Services Agency, Department of Health Care Services. Numbered Letter 01-0120. January 7, 2020. Authorization of Enteral Formula, Nutrition Additives/Modulars, and Related Supplies – Revised (November 17, 2020). Available at: <https://www.dhcs.ca.gov/services/ccs/Documents/CCS-NL-01-0120-Enteral-Nutrition-REVISED.pdf>. Accessed Feb 2025.
3. Medi-Cal Rx Provider Manual. Available at https://medi-calrx.dhcs.ca.gov/cms/medicalrx/static-assets/documents/provider/forms-and-information/manuals/Medi-Cal_Rx_Provider_Manual.pdf. Accessed Feb 2025.
4. Updates to the List of Enteral Nutrition Products. Available at: https://medi-calrx.dhcs.ca.gov/cms/medicalrx/static-assets/documents/provider/forms-and-information/List_of_Covered_Enteral_Nutrition_Products_v0.1_.xlsx. Accessed Feb 2025.

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.

CLINICAL POLICY

Oral and Enteral Formula

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

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.

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