
Enteral Nutrition Products

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Note: Enteral nutrition products are pharmacy provider billing only on a pharmacy claim. All administrative services related to pharmacy claims will transition to a new Medi-Cal Rx vendor at a later date, still to be determined.

This section contains information about enteral nutrition products, program coverage and a list of products. The information provided in this section applies to the products included on the following spreadsheet:

- [List of Enteral Nutrition Products](#)
 - Products «and billing codes» no longer covered are listed on the spreadsheet Deletions Tab

The products eligible for Medi-Cal reimbursement are grouped by the following product categories:

- *Elemental and Semi-Elemental*
- *Metabolic*
- *Specialized*
- *Specialty Infant*
- *Standard*

Beneficiaries must meet the medical criteria for the product category specific to the product requested.

Program Coverage

Enteral nutrition products may be covered 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 (*California Code of Regulations [CCR], Title 22, Section 51313.3*).

Enteral nutrition products covered are subject to the Medi-Cal *List of Enteral Nutrition Products* and utilization controls (*Welfare and Institutions Code [W&I Code], Sections 14132.86, 14105.8 and 14105.395*).

Products on the Medi-Cal *List of Enteral Nutrition Products* are separately covered upon authorization for eligible Medi-Cal fee-for-service outpatients when supplied by a pharmacy provider upon the prescription of a physician within the scope of his or her practice as defined by California laws.

Eligibility Requirements

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

Medi-Cal Managed Care Plans

Beneficiaries enrolled in Medi-Cal managed care plans (MCPs) must receive Medi-Cal enteral nutrition benefit from plan providers. MCPs are required to provide or arrange for medically necessary enteral nutrition products as a covered Medi-Cal benefit. Each MCP is unique in its billing and service procedures. Providers must contact the individual MCP for billing instructions.

«**Note:** Effective April 1, 2021, beneficiaries may receive Medi-Cal enteral nutrition benefit from plan providers or through the Medi-Cal fee-for-service pharmacy delivery system. Provider must contact the individual MCP for billing instructions.»

CCS or GHPP

The *List of Enteral Nutrition Products* and coverage criteria applies to Medi-Cal claims for beneficiaries enrolled in the California Children's Services (CCS) or Genetically Handicapped Persons Program (GHPP).

Inpatient

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.

Nursing Facilities or Intermediate Care Facilities

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 an 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).

The Department of Health Care Services (DHCS) shall recover overpayments for non-covered services, which include 100 percent of the ingredient cost and professional fee pursuant to CCR, Title 22, Section 51488.1(a)(2).

Equipment-Related Supplies

For enteral feeding supplies, refer to the *Medical Supply Products* section of this manual for billing codes and additional information.

Non-Coverage

The following nutrition products are not covered by Medi-Cal:

- «Regular food, including solid, semi-solid and pureed foods»
- Common household items
- 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
- Vitamin and/or mineral supplements, except for pregnancy and birth up to 5 years of age (Refer to the appropriate contract drugs list section in this manual for more information).
- Enteral nutrition products used orally as a convenient alternative to preparing and/or consuming regular solid or pureed foods

Other Health Coverage

Refer to the *Other Health Coverage (OHC)* section in this manual for OHC billing information.

Medicare Covered Services

Medicare covered enteral nutrition products must be billed to Medicare before billing Medi-Cal for dual-eligible beneficiaries with Medicare Part B coverage. Additional information is included in the *Medicare/Medi-Cal Crossover Claims* section in this manual.

To ensure refills are delivered prior to exhaustion of existing supplies, providers may overlap the date of service up to five days on crossover claims billed for the following HCPCS codes:

«Table of Enteral Nutrition Products»

HCPCS Code	Description
B4034 thru B4036	Enteral feeding supply kits, tubing and tubes
B4081 thru B4083	Enteral feeding supply kits, tubing and tubes
B4087 thru B4088	Enteral feeding supply kits, tubing and tubes
B4102	Enteral formula, for adults
B4103	Enteral formula, for pediatrics
B4150	Enteral formulas
B4152 thru B4155	Enteral formulas
B4157 thru B4162	Enteral formulas
B9998	NOC for enteral supplies

Providers must verify that the previous month's supplies are almost exhausted prior to shipping a refill of the product

Providers should contact the Medicare carrier for coverage and billing instructions.

Prescription Requirement

A written prescription signed by a physician is required for authorization of all enteral nutrition products

The physician's full name, address and telephone number must be clearly supplied if not pre-printed on the prescription form.

Authorization

All enteral nutrition products require the beneficiary's pharmacy provider to submit either a *Treatment Authorization Request* (TAR) or a *Service Authorization Request* (SAR) for authorization. The required information to demonstrate that both medical criteria and product criteria are met, must be supplied on or attached to the authorization request as documented in the beneficiary's medical record.

The product number approved on a TAR or SAR must be the same product number dispensed and billed. Authorization for all enteral nutrition products is limited to billing up to a 31-day supply per claim, based on documented caloric and nutrient requirements per day, converted to a 31-day supply.

Note: Billing quantities must be appropriate for the product size (quantity) dispensed and product description on the *List of Enteral Nutrition Products*. Rounding quantities on claims for enteral nutrition products is not permitted (for example: billing a quantity of 240 ml for a package size of 237 ml is not allowed).

Refer to the *TAR Completion* section of this manual for additional TAR information. TARs for Medi-Cal beneficiaries must be submitted to the TAR Processing Center.

Refer to the *California Children's Services (CCS) Program Service Authorization Request (SAR)* section of this manual for instructions for submitting a SAR or contact a California Children's Services (CCS)/Genetically Handicapped Persons Program (GHPP) Program representative.

Product Criteria

The enteral nutrition product requested on an authorization must be on the *List of Enteral Nutrition Products* and the beneficiary must meet the medical criteria for the specific product category and, if applicable, product-specific criteria.

Products are listed in one or more of the following enteral nutrition 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 and be nutritionally complete)
- Refer to the *List of Enteral Nutrition Products* for product-specific criteria.

Medical Criteria

Refer to the appropriate product category type for the specific medical criteria that must be met.

Standard Products

To be considered for authorization of standard products (contain intact macronutrients) that are on the *List of Enteral Nutrition Products*, the beneficiary must meet one of the criteria below.

Note: Refer to the *List of Enteral Nutrition Products* for product-specific criteria that may also apply.

1. A documented medical diagnosis that requires enteral nutrition products administered through a feeding tube
2. For enteral nutrition products administered orally, beneficiary must meet 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 beneficiary is nutritionally at risk.
 - b. Beneficiaries (21 years of age and older) with 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 beneficiary is nutritionally at risk with one of the following anthropometric measures:
 - i. Involuntary loss of 10 percent or more of usual body weight within six months
 - ii. Involuntary loss of 7.5 percent or more of usual body weight within three months
 - iii. Involuntary loss of 5 percent or more of usual body weight in one month
 - iv. Body mass index less than 18.5 kg/m²
 - c. Beneficiaries under 21 years of age with 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.

- d. 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
- e. Transitioning from parenteral or enteral tube feeding to an oral diet

Specialized Products

To be considered for authorization of specialized nutrition products that are on the *List of Enteral Nutrition Products*, documentation must include evidence to support the beneficiary meets one of the 'standard products' medical criteria and the criteria specific to the product requested.

The beneficiary must also meet the criteria below specific to the product type requested. Refer to the *List of Enteral Nutrition Products* for product-specific criteria that may also apply.

1. For disease-specific products administered orally or through a feeding tube, the beneficiary must have a documented medical diagnosis, specific to the product requested and meet one of the standard products medical criteria.
 - a. For diabetic products, the beneficiary must have a documented diagnosis of hyperglycemia or diabetes and HbA1c (A1c) value measured within six 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 months of the request must be clearly supplied on the authorization request for individuals 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. Glomerular Filtration Rate (GFR) less than 60mL/min/1.73m²

- c. For hepatic products, results of liver function test measured within six months of the request must be clearly supplied on the authorization request.
2. For carbohydrate modular products administered orally or through a feeding tube, there must be documented clinical evidence to support the beneficiary is unable to meet caloric nutritional need with the current use of an enteral nutrition product
3. For lipid (fat) modular products administered orally or through a feeding tube, the beneficiary must meet one of the following:
 - a. Have a documented diagnosis of inability to digest or absorb conventional fats
 - b. Have a documented diagnosis of uncontrolled seizure or other neurological disorder that cannot otherwise be medically managed
4. For protein modular products administered orally or through a feeding tube, there must be documented clinical evidence to support the beneficiary is unable to meet protein requirement with current use of a high protein enteral nutrition product.

Elemental and Semi-Elemental Products

To be considered for authorization of elemental or semi-elemental products that are on the *List of Enteral Nutrition Products* and administered orally or through a feeding tube, the beneficiary must meet one of the criteria below.

Note: 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.

1. Have an intestinal malabsorption diagnosis (ICD-10-CM codes K90.0 thru 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.
2. 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. The beneficiary 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.

Metabolic Products

Authorization of metabolic products on the *List of Enteral Nutrition Products* administered orally or through a feeding tube is restricted to beneficiaries with 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.

Exception: For metabolic ketogenic formulas, authorization may also be considered when documentation confirms the beneficiary meets one of the criteria below:

1. Have seizures that are refractory to standard anti-seizure medications
2. 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 adequate nutrition unless such products are medically contraindicated.

Note: For adult beneficiaries 21 years of age and older, authorization is restricted to the ICD-10-CM diagnosis codes on the tables below. The ICD-10-CM code and diagnosis name must be clearly supplied on the authorization request as documented in the beneficiary's medical record.

«Table of ICD-10-CM Diagnosis Codes Authorized for Metabolic Products»

ICD-10-CM Code	Diagnosis: Inborn Errors of Metabolism (IEM)
E70.0	Classical phenylketonuria
E70.1	Other hyperphenylalaninemias
E70.20 thru E70.29	Disorders of tyrosine metabolism
E70.30 thru E70.39	Albinism
E70.40 thru 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 thru 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 thru 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

**«Table of ICD-10-CM Diagnosis Codes Authorized for Metabolic Products
(continued)»**

ICD-10-CM Code	Diagnosis: Inborn Errors of Metabolism (IEM)
E71.50 thru E71.548	Peroxisomal disorders
E72.00 thru E72.09	Disorders of amino-acid transport
E72.10 thru E72.19	Disorders of sulphur-bearing amino-acid metabolism
E72.20 thru E72.29	Disorders of urea cycle metabolism
E72.3	Disorders of lysine and hydroxylysine metabolism
E72.4	Disorders of ornithine metabolism
E72.50 thru 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 thru E74.9	Other disorders of carbohydrate metabolism
E75.00 thru E75.6	Disorders of sphingolipid metabolism and other lipid storage disorders
E76.01 thru E76.9	Disorders of glycosaminoglycan metabolism
E77.0 thru E77.9	Disorders of glycoprotein metabolism
E84.0 thru E84.9	Cystic fibrosis
E88.40 thru E88.49	Mitochondrial metabolism disorders

Specialty Infant Products

The specialty infant products are grouped in the following product types:

- Premature and Low Birth Weight Products
- Human Milk Fortifier
- Extensively Hydrolyzed Products (EH)
- Amino Acid-Based Products (100 percent)
- Renal Products (Renal)
- Chylolothorax or long-chain 3-hydroxyacyl-CoA dehydrogenase deficiency (LCHAD deficiency) Products

For infant metabolic products, refer to the products listed under the metabolic category.

Refer to the amino acid-based products (100 percent) for products used in fat malabsorption.

Note: Regular infant formula products as defined in the Federal Food, Drug and Cosmetic Act (FD&C Act) are not covered.

Specialty infant products are 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.

Maximum age at time of authorization is nine months plus 29 days; CA applies, except when noted.

Note: Quantities for specialty infant enteral nutrition products based on sole source nutrition are approved up to six months of age except 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 for specialty infant products are limited to a maximum two-month term, except when noted.

To be considered for authorization of specialty infant products that are on the *List of Enteral Nutrition Products* and administered orally or through a feeding tube, the beneficiary must meet the criteria listed below specific to the product and/or product type requested:

1. For premature and low birth weight products:
 - 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 request and limited to current weight (at time of dispensing) less than 3500 grams
2. For human milk fortifier products:
 - a. Authorization is limited to one month only per request for beneficiaries with current weight less than 3600 grams and meet one of the following:
 - i. Receiving only human milk and no other infant nutrition product (formula) used at the same time.

- ii. Breast fed or receiving human milk in combination with infant nutrition product (formula) administered only through a feeding tube
- iii. 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:
 - A. Infant is at risk for necrotizing enterocolitis
 - B. Mother of infant is establishing milk supply
 - C. Human milk intake is increasing

Note: Calculate 31-day supply limit based on expected infant weight gain of 33-34 grams/day during an authorization term.

- 3. For extensively hydrolyzed products without probiotics, the beneficiary must meet one of the criteria listed below. Product specific criteria may also apply.
 - a. Current diagnosis of cow's milk protein allergy (CMPA)
 - b. Severe food allergy indicating a sensitivity to intact protein
- 4. For extensively hydrolyzed products with probiotics, the beneficiary must have a current diagnosis of cow's milk protein allergy (CMPA) or intolerance to breast milk or regular infant formula 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
- 5. For amino acid-based (100 percent) products without probiotics, beneficiaries 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 severe cow's milk protein allergy (CMPA), multiple food protein allergies, or eosinophilic GI disorder
 - ii. Protein maldigestion or malabsorption diagnosis where extensively hydrolyzed specialty infant products have tried and failed
 - iii. A clinical diagnosis of gastrointestinal (GI) disorders such as short bowel syndrome or GI impairment

- b. Extensively hydrolyzed (semi-elemental) products are contraindicated
 - c. For initial request, documented in hospital use prior to discharge, establishing the need for the product. Must meet one 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.
6. For amino-based (100 percent) products with probiotics, beneficiaries must meet one of the above listed criteria (5a thru 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
7. For renal products, beneficiaries must meet one of the following:
- a. Renal function impairment
 - b. Hypercalcemia
 - c. Hypocalcemia due to hyperphosphatemia
8. For Chylothorax or LCHAD deficiency product type beneficiaries must have one of the following documented diagnoses:
- a. Chylothorax
 - b. Long-chain-3-hydroxyacyl-CoA-dehydrogenase deficiency (LCHAD deficiency)
 - c. Cystic Fibrosis
 - d. Mitochondrial disorder

Documentation Requirements

All of the clinical and product information listed below, as documented in the beneficiary's medical record, must be clearly supplied on the authorization request, or as an attachment to the request signed and dated by the physician. The physician's name, address and telephone number must also be clearly supplied on the request.

1. Medical diagnosis name related to the product requested

Note: 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.

2. Age, height (length), weight, body mass index (BMI)
3. Biochemical, clinical and/or dietary indicators related to the request for product
4. Daily caloric requirements
5. Estimated duration of need for the enteral nutrition product and/or nutrition care plan
6. Route of administration
7. Product label name being prescribed
8. Product package size (ml or gm)
9. Product caloric density (kcal/ml or kcal/gm)
10. Product 11-digit Medi-Cal billing number

Special Documentation Instructions

The documentation must be dated as follows:

- For standard, elemental, semi-elemental and specialized products, documentation must be dated within three months at the time of TAR or SAR submission.
- For metabolic products, documentation must be dated within six months at the time of TAR or SAR submission.
- For specialty infant products, documentation must be dated within two months at the time of TAR or SAR submission.

Some products require additional documentation. Refer to the product category medical criteria specific for the product requested in this section and/or the product-specific criteria on the *List of Enteral Nutrition Products*.

Billing Requirements

Enteral nutrition products are pharmacy-only dispensed and billed using the 11-digit Medi-Cal billing number on the National Council for Prescription Drug Program (NCPDP) electronic transaction or *Pharmacy 30-1* claim form.

Claims for enteral nutrition products must include the Medi-Cal billing number as published on the *List of Enteral Nutrition Products* spreadsheet. The product number approved on a TAR or SAR must be the same product number dispensed and billed.

Enteral nutrition products may not be billed on a *Compound Pharmacy Claim Form* (NCPDP or 30-4).

Billing Limitations

Claims billed for enteral nutrition products are limited to no more than a 31-day supply.

A 31-day supply is defined as the beneficiary's daily caloric requirement for product (specified by the physician 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. See documentation requirements in the previous section to establish 31-day supply.

Reimbursement

The amount reimbursed to providers for enteral nutrition products shall not exceed the published estimated acquisition cost (EAC) plus a 23 percent markup (W&I Code, Section 14105.85).

Refer to the *List of Enteral Nutrition Products* spreadsheet for the published EAC.

Contracted Products

The Department of Health Care Services (DHCS), pursuant to the W&I Code, Section 14105.8, has negotiated non-exclusive contracts for a maximum acquisition cost (MAC) for specified enteral nutrition products, with interested manufacturers. The contractors guarantee to Medi-Cal pharmacy providers the purchase of the contracted products at or below the MAC, upon request, for dispensing to eligible Medi-Cal fee-for-service outpatients. «Contracted products are listed with a MAC price. Suppliers may be contacted for identification of routes for obtaining MAC prices. Refer to the spreadsheet for suppliers contact phone numbers.»

Legend

Symbols used in the document above are explained in the following table.

Symbol	Description
«	This is a change mark symbol. It is used to indicate where on the page the most recent change begins.
»	This is a change mark symbol. It is used to indicate where on the page the most recent change ends.