



ENTERAL NUTRITION PRODUCTS REVIEW AND CONTRACTING POLICIES AND PROCEDURES

This document, by the Department of Health Care Services (DHCS), Pharmacy Benefits Division, Enteral Nutrition and Medical Supplies Benefit Branch (ENMSBB), represents the review, evaluation and contracting policies and procedures used by the ENMSBB's team to make recommendations and decisions regarding addition, retention or deletion for enteral nutrition products (enteral formula).

This document applies to the review and evaluation of products for retention on, addition to, or deletion from the Medi-Cal Rx list of *Covered Enteral Nutrition Products (List)* in accordance to California Welfare and Institutions Code (W&I Code), Section 14105.8. Enteral nutrition products subject to review and coverage are those that would be administered through the Medi-Cal Rx pharmacy delivery system. The review may result in a contract with DHCS for product placement on the List. California Board of Pharmacy law, which provides requirements for the dispensing of prescriptions, applies to enteral nutrition items dispensed by a pharmacy provider. In accordance with Pharmacy law, products must be clearly labeled. Please refer to BPC § 4076 (a-e) and 16 CCR § 1707.5 (a-e) for additional information.

The contract is a Maximum Acquisition Cost (MAC) Agreement, which is a guarantee by the contractor that any Medi-Cal Rx pharmacy provider can purchase the product at or below the contracted price for dispensing to eligible Medi-Cal Rx beneficiaries and billing Medi-Cal Rx for reimbursement. The review process may result in DHCS contracting with multiple manufacturers and distributors for product placement on the List. This is NOT a competitive bid process.

Confidentiality is required of all participants engaged in the contracting process. All anti-trust and collusion laws must be strictly adhered to by all during the review process.

Manufacturers and distributors may discuss products that have been proposed or petitioned to DHCS, but shall not reveal or actively promote products have been or will be added to the List until providers are notified by the Medi-Cal Rx bulletins or Alerts published on the Medi-Cal Rx website.

DHCS will not initiate a product review unless the proposed product's NDC-like billing code is active and updated within DHCS' primary price reference source, currently First Data Bank (FDB), and is available for purchase by any Medi-Cal Rx pharmacy provider.

DHCS reviews and evaluates individual enteral nutrition products for retention on, addition to, or deletion from the List either as an Individual Product Petition (IPP) or as part of a Product Category Review (PCR) based on the following five criteria:

1. The safety of the product
2. The effectiveness of the product
3. The essential need for the product

4. The potential for misuse of the product
5. The immediate or long-term cost effectiveness of the product.

PRODUCT CATEGORY REVIEW (PCR)

DHCS initiates the PCR process approximately every three years to determine whether products will be retained on, added to, or deleted from the List. DHCS sends a notification and invitation letter to companies that manufacture and distribute enteral nutrition products to participate in the PCR process. Interested companies are encouraged to keep DHCS updated with a contact name, email address and phone number to ensure notification of an upcoming PCR.

The notification letter will provide DHCS contact information, the PCR submission requirements and due dates to be eligible for participation. During the PCR process, companies will have an opportunity to meet with DHCS to discuss the proposed products, present the five review criteria, product studies and required documents. The PCR process may result in contract cost negotiations with DHCS for product placement on the List.

INDIVIDUAL PRODUCT PETITION (IPP)

To accommodate new products or new formulations an IPP may be submitted outside of the PCR process. DHCS reviews and evaluates individual product petitions for addition to the contracted list at least once during the State Fiscal Year (July 1 – June 30).

Manufacturers, relabelers, or distributors interested in adding products to the list must submit all the Product Review Required Documents on or before **June 30** of the current fiscal year to be eligible for review in the subsequent fiscal year.

An IPP must be submitted for any changes that may affect the performance, use, specifications, safety, appearance, or labeling to products currently on the List to meet the contractual requirement and for approval of product retention on the List. The manufacturer or distributor should submit an IPP on company letterhead providing a detailed explanation of product changes including any changes to the product name, description, formulation, nutrient content, 11-digit billing number and package UPC/UPN or size.

To request new products be added to the List, manufacturers or distributors may submit an IPP as a package containing the following information:

1. A “Letter of Intent to Contract”, on company letterhead signed by a person with legal authority, specifically requesting for the addition of proposed products be added to the List. The letter must include name and email address for two company contact persons.
2. A detailed description of the proposed product formula and recommended use (marketing materials are acceptable).
3. Brief documentation on the proposed product benefits and how the proposed product compares to products currently on the List with similar/same use and/or in the same category (Elemental/Semi-Elemental, Metabolic, Specialized, Specialty Infant and Standard).

4. Pertinent medical literature or other product information.
5. Provide evidence that the 11-digit (NDC-like) billing number is currently available in the appropriate database for pharmacy claims processing.
6. Provide the product UPN/UPC numbers for the each and case packages as it appears on the package.

An IPP package may be submitted electronically to medicalsupplies@dhcs.ca.gov or by mail to:

California Department of Health Care Services
Pharmacy Benefits Division
Chief of Enteral Nutrition and Medical Supplies Benefits Branch
P.O. Box 997413, MS 4604
Sacramento, CA 95899-7413

DHCS will notify the manufacturer or distributor by email that the product review has been initiated. IPPs may be deferred until the next PCR process if such a review is currently scheduled or planned and the proposed products do not offer any significant clinical benefit over products currently on the List.

PRODUCT REVIEW CRITERIA

Enteral nutrition products reviewed and evaluated are those that can be 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 (22 CCR Section 51313.3(e)(2)). When evaluating enteral nutrition products for retention on, addition to, or deletion from the List, DHCS considers the following five review criteria pursuant to W&I Code 14105.8 (b) (1):

1. *The safety of the product.* The relative freedom from side effects that is determined by reviewing the contraindications, precautions, warnings and adverse effects of the enteral nutrition product. Evaluation of safety may involve a single enteral nutrition product or comparisons between two or more enteral nutrition products, and may take into account such factors as safety of alternative methods of treatment or the relationship of safety of an enteral nutrition product to the severity of prognosis of the medical conditions for which the enteral nutrition product is indicated. Product manufacturing, handling and packaging requirements are also considered when evaluating safety.
2. *The effectiveness of the product.* The extent to which an enteral nutrition product will provide needed nutrients, in a form compatible with a medical condition. Evaluation of efficacy may involve a single enteral nutrition product or comparisons between two or more enteral nutrition products, and may take into account such factors as efficacy of alternative methods of treatment.
3. *The essential need for the product.* Evaluation of essential need may involve a single enteral nutrition product or comparisons between two or more enteral nutrition products, and may take into account such factors as the availability of alternative methods of treatment, the incidence, severity and prognosis of the medical conditions for which an

enteral nutrition product is indicated; or whether an enteral nutrition product may provide nutrition support for a medical condition not adequately offered by any other product.

4. *The potential for misuse of the product.* The likelihood for unjustified, inappropriate, irresponsible or improper use of an enteral nutrition product. Evaluation of misuse potential may take into account such factors as; utilization of an enteral nutrition product where there is insufficient medical necessity for its use; continued use of an enteral nutrition product despite loss of effectiveness; and/or utilization of an enteral nutrition product where a less costly, but equally safe and efficacious alternative may be used.
5. *The cost of the product.* The immediate or long-term cost effectiveness of an enteral nutrition product. Evaluation of cost will take into account the NET COST of the product to DHCS and may involve a single enteral nutrition product or comparisons between two or more enteral nutrition products. The net cost would include any statutory mark-up or dispensing fee minus any rebate (if applicable).

As part of the cost evaluation, DHCS considers data presented by the manufacturer or distributor related to; the comparison of two or more treatment alternatives having identical outcomes (Cost-Minimization Analysis); the comparison of treatment alternatives which have different cost and treatment outcomes associated with them (Cost-Benefit Analysis); or the comparison of total health care system cost of treatment alternatives having similar treatment outcomes (Cost-Effectiveness Analysis).

The deficiency of a product when measured by one of the five review criteria may be sufficient to support a decision that the product should be deleted from, should not be added to, or should not be retained on the Medi-Cal Rx list of *Covered Enteral Nutrition Products*. However, the superiority of a product under one criterion may be sufficient to warrant the addition or retention of the product, notwithstanding a deficiency in another criterion.

PRODUCT EVALUATION

All of the documents and information listed below are required when a product review is initiated. Upon receipt and review by the project lead, DHCS will conduct an internal meeting to evaluate the product.

List of Required Documents

1. Company Information
 - a. Company's legal name (as it will appear on the contract)
 - b. Contract signature – name, title and address of person with legal authority to sign agreement (contract)
 - c. Specify preferred method to receive and sign contract documents:

FedEx Shipment – provide name, title and address of person to receive by FedEx shipment the contract documents.

Or

Electronically via *DocuSign* – provide email address of person with legal authority to sign contract electronically. Include name, title and email address of other individuals within the company to receive and review the contract via *DocuSign*.

- d. Ownership – List of name and address of each person or corporation or in any subcontractor in which the proposed contractor has direct or indirect ownership of 5% or more. (Subpart B (commencing with Section 455.100) of Part 455 of Subchapter C of Chapter IV of Title 42 of the Code of Federal Regulations.)

2. Product Specifications and Cost Proposals

Submit product specifications and cost proposals on an Excel spreadsheet, (if petition is mailed submit both as hard copy and electronically by email), using the column headings outlined below.

- a. Product Label Name (exact product description)
- b. Product Category/Type (e.g. elemental/semi-elemental, metabolic, specialized, specialty infant or standard)
- c. Specific Indications for Use – include benefits and leading authorities (e.g. ASPEN, NIH) recommendations for use and dosage
- d. Pharmacy Billing Number (11-digit number as it is listed in First Data Bank)
- e. Universal Product Code (UPC) (for item each and case packages)
- f. Cost Proposals (per gram or milliliter)
- g. Ingredients and Nutritional Composition (per gram or milliliter)
 - i. Protein, carbohydrate and fat sources
 - ii. Vitamins and minerals
 - iii. Other ingredients
 - iv. Caloric and protein densities
- h. Nutritionally Complete - Yes/No

If yes, provide evidence the product would provide the Recommended Dietary Allowance considered necessary to meet the nutrient requirements for most people by the Food and Nutrition Board of the Institute of Medicine, National Academy of Sciences.

3. Manufacturing of proposed products

- a. A current GMP certificate documenting the manufacturing facility location for each product proposed

- b. Evidence of compliance with Good Manufacturing Practices (GMP consistent with Title 21 of the Code of Federal Regulations Chapter 1, Subchapter B, Part 110)
- c. Evidence of compliance with the FDA Bioterrorism Act regulations
- d. Written verification on company letterhead signed by a person with legal authority that, upon request from DHCS, Contractor would make available copies of most recent inspection reports (FDA Form 483 or the Department "Report of Observations") and related documents resulting from FDA or the California Department of Public Health's Food, Drug and Radiation Safety Office inspections.

The project lead may request additional product information for considerations from the manufacturer or distributor, such as:

- A written presentation for each proposed product or product types using the five criteria; safety, efficacy, essential need, potential for misuse and cost
- Product marketing materials, catalog page or package inserts describing each proposed product ingredients and indications
- Copies of all relevant published clinical studies of efficacy or other information for each of the proposed products
- Provide a compare/contrast analysis with products currently on the List
- List other state Medicaid or federal programs, managed care plans or other health coverages that list the proposed product as preferred and/or contracted
- Recommendations by other entities contacted for input and unsolicited input if appropriate

NEGOTIATIONS

DHCS may present a price counter offer following the product evaluation meeting. The manufacturer or distributor may accept, reject, or present an alternative to the counter offer within the timeframe requested by the project lead.

Confidentiality is required of all participants engaged in the negotiations and contracting process. All anti-trust and collusion laws must be strictly adhered to by all.

Prices proposed to DHCS, counter offers from DHCS, and final contracted prices shall not be shared or announced until the provider bulletins are published. Failure to comply with confidentiality requirements may result in delay of the addition of products to the List or cancellation of a signed contract.

At the conclusion of a PCR contract negotiations, but prior to the provider bulletin publishing dates, statute requires DHCS to meet with representatives from the California Association of Medical Product Suppliers (CAMPS) and the California Pharmacists Association (CPhA). During this meeting, DHCS will share proposed or petitioned products and broad-spectrum product pricing with stakeholders.

DECISION NOTIFICATION

Upon successful review and cost negotiations to add or retain an enteral nutrition product on the List, DHCS will send a contract to the manufacturer or distributor. Once DHCS receives the contract signed by the authorized representative, DHCS will instruct Magellan to inform providers of changes to the Medi-Cal Rx List and to take action for processing provider claims for these enteral nutrition products.

The project lead will notify the manufacturer or distributor of the proposed effective date the product will be added to the List. The effective date to add an enteral nutrition product is not official until published in the Medi-Cal provider bulletins. **Manufacturers or distributors must not announce an effective date prior to the Medi-Cal Rx provider bulletin publications.**

If DHCS decides not to contract for a product, a notification letter regarding such a decision will be sent to the manufacturer or distributor.

APPEALS

If a petition of a product has been denied, the manufacturer, relabeler, or distributor must wait until the next product category review (PCR), until they may re-petition the same product. An appeal may be made before the PCR if significant changes have been made to the product to justify a secondary review. An appeal must include specific documentation in a letter or email to the project lead requesting a new review. The project lead will determine whether the product will be considered or deferred and respond within 30 days of receipt of the appeal.

ADDITIONAL INFORMATION

To learn more about the Medi-Cal Program and to view the Medi-Cal Rx list of *Covered Enteral Nutrition Products* published on the Medi-Cal Rx website, please visit <https://medi-calrx.dhcs.ca.gov/home/>

To contact DHCS enteral nutrition team, please email medicalsupplies@dhcs.ca.gov.