ENTERAL NUTRITION PRODUCTS
REVIEW AND CONTRACTING POLICIES AND PROCEDURES

This document represents the review, evaluation, and contracting procedures for the Medi-Cal Rx enteral formula outpatient pharmacy benefit. These procedures apply to the review and evaluation of products for retention on, addition to, or deletion from the Medi-Cal Rx *List of Contracted Enteral Nutrition Products* (List) in accordance with the California State Plan and California Welfare and Institutions Code (W&I Code), Section 14105.8.

Petitions may be submitted by enteral nutrition formula manufacturers, re-labelers, or distributors (Petitioners). Enteral nutrition products subject to review and coverage are those that would be administered through the Medi-Cal Rx pharmacy outpatient delivery system. The review may result in a contract with DHCS for product placement on the Medi-Cal Rx List. California Board of Pharmacy law, which provides requirements for the dispensing of prescriptions, applies to enteral nutrition formula 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 members and billing Medi-Cal Rx for reimbursement from one source. The review process may result in DHCS contracting with multiple manufacturers or 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. Petitioners 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 Alert published on the Medi-Cal Rx website.

DHCS will not review a product unless the proposed product's 11-digit NDC-like billing code is active within DHCS' primary price reference source, currently First Data Bank (FDB), and is available for purchase in the California pharmacy provider marketplace by Medi-Cal Rx pharmacy providers.

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) annually, or as part of a Product Category Review (PCR) every three years, and considers five statutory-required criteria (Welfare and Institutions (W&I) Code 14105.8 (b)(1)):

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 Product Category Review (PCR) process approximately every three years to determine if products will be retained on, added to, or deleted from the List. Contracted MAC prices, coverage criteria and utilization controls are also reviewed during this time. The PCR process may result in contract cost negotiations with DHCS for product placement on the List. DHCS sends a notification and invitation letter to companies (Petitioners) that manufacture, re-label, and distribute enteral nutrition products to participate in the PCR process. Interested companies and current contracting partners are responsible for notifying DHCS of changes to company information, contact names, email addresses, and phone numbers 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. These meetings are voluntary.

INDIVIDUAL PRODUCT PETITION (IPP)

To accommodate new products, new formulations or line extensions, and changes to currently contracted products, an Individual Product Petition (IPP) may be submitted annually outside of the PCR process. DHCS reviews and evaluates IPPs yearly during the State Fiscal Year (July 1 – June 30). Petitioners interested in submitting an IPP must submit all the required petition documents on or before **June 30** to be eligible for review and addition to the List, which usually occurs by the following January 1. This effective date is not guaranteed and is at the Department's determination.

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 to the List. The Petitioner 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.

Petitioners may submit an IPP as a petition packet containing the information outlined in the "List of Required Documents" below for new products the Petitioner is interested in adding to the List. An IPP package should be submitted electronically to medicalsupplies@dhcs.ca.gov or by mail to:

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

DHCS will notify the Petitioner by email within 30 days of receipt of the IPP request that either the product review has been initiated or the IPP is being deferred for later review (W&I Code 14105.475 (c-g)). IPPs may be deferred until the next PCR process if the PCR is currently scheduled or planned, and the proposed products do not offer any significant clinical benefit

over products currently on the List. For previously petitioned and denied products, the Petitioner must wait until the next PCR, to re-petition the same product. Documentation of the previous denial by the Department, reasons for the denial, and any changes to the product since the denial should be included in the re- submission packet. Please refer to the *Decision Notification* section below for additional information.

PRODUCT REVIEW CRITERIA

Enteral nutrition products reviewed, evaluated, and considered for coverage by Medi-Cal Rx are those liquid or readily reconstitute-able enteral nutrition formula 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)). Regular foods, including solid, semi-solid, and pureed foods are excluded from coverage by the California Medicaid State Plan. 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 consider 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 consider 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 consider 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 consider 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 consider 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 Petitioner related to:

- The comparison of two or more treatment alternatives having identical outcomes (Cost-Minimization Analysis); or
- 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 Contracted 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.

All the documents and information listed below are required from the Petitioner when a petition is submitted, and a product is reviewed for either the PCR or the IPP. Upon receipt and review by the project lead, DHCS will conduct an internal meeting to evaluate the product.

LIST OF REQUIRED DOCUMENTS

1. **Company Contact Information**
   a. "Letter of Intent to Contract", on company letterhead, signed by a person with legal authority, for the addition of proposed products to the *Medi-Cal Rx List of Contracted Enteral Nutrition Products*.
   b. Company's legal name (as it will appear on the contract)
   c. Contract signature – name, title, and address of person with legal authority to sign agreement (contract)

      Contract delivery is by DocuSign – name, title, and email address of person to receive by DocuSign the agreement (contract) if not the same as contract signee.

   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.)
   e. Petitioner's primary point of contact name, title, address, email, and phone number.

i. **The Department requires one point of contact for each Petitioner**.
ii. If the point of contact is a third-party representative, documentation from the manufacturer, re-labeler, or distributor must be included specific identifying the third-party representative as the official Petitioner's primary point of contact.

2. **Signed Contractor's Certification**
3. **Product Specifications and Cost Proposals** --Please see item # 6 for a detailed listing of required information for discussion. Submit product specifications and cost proposals on an Excel spreadsheet, using the column headings outlined below including information discussed in point #6.
   a. Product Label Name (product name, kCal amount per gram or milliliter, size of individual container, flavor)
   b. Pharmacy Billing Number (11-digit billing number (NDC-like number) as it is listed in First Data Bank)
   c. Universal Product Code (UPC) Number (item) – as it appears on the individual package.
   d. UPC Number (case) – as it appears on the case package.
   e. 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 as a long-term, single source of nutrition, without additional macronutrient or micronutrient supplementation other than water.

   f. Caloric Density (kcal/gram or milliliter)
   g. Protein Density (mg/gram or milliliter)
   h. Detailed list of ingredients. NOTE: Formula may not contain common allergens (e.g. lactose) in measurable quantities

      - List source(s) of carbohydrates
      - List source(s) of protein
      - List source(s) of fat, ratio of chains, and specific amounts per gram or mL
      - Ingredients and Nutritional Composition (per gram or milliliter)
      - Vitamins, minerals, and elements
      - Other ingredients

   i. Proposed MAC (price) per gram or milliliter. Please include the Healthcare Common Procedure Coding System (HCPCS) assigned by the Centers for Medicare and Medicaid Services (CMS) for each product.
4. **Manufacturing documentation 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. 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

5. **Proof of compliance with the US Bioterrorism Act, FFRM, FDA form 3537** – provide a copy of the US FDA certification document registration. This is one time only registration and uses FDA form 3537.
6. **Product information** – for each product proposed, provide a brief written discussion for all of the following:
   a. Indication, use, benefits, and efficacy. Include leading authorities (e.g. ASPEN, NIH) recommendation for use and dosage and any pertinent medical literature.
   b. Category the petitioned product would fit into, if applicable:

      - Elemental and semi-elemental (contain partially or fully broken-down macronutrients)
      - Metabolic (indicated for inborn errors of metabolisms diagnosis)
      - Specialized (disease-specific diagnosis or conditions)
      - Standard (contain intact macronutrients and nutritionally complete; can provide long-term sole-source nutrition without the need of additional macronutrients or micronutrient supplementation other than water)

   c. Dosage form: powder, liquid, or tablet (ONLY acceptable for Inborne Errors of Metabolism (IEM) protein equivalent replacements in tablet form). Medi-Cal Rx only covers contracted enteral nutrition formula. Special programs exist for coverage of non-formula medical foods which could be a covered benefit through the member's medical benefit, through CCS, GHPP, CalFresh, or WIC. Our team does not oversee or contract for these foods and manufacturers, re-labelers, or distributors should contact the individual programs for more information.

      NOTE: Medi-Cal Rx only covers products in liquid or powder (to be reconstituted as liquid) form and can be administered in a size 11 or smaller feeding tube. Please include documentation of smallest feeding tube size compatible with the formula petitioned.

   d. Compare product with other similar/like contracted products and discuss product advantages. If there are none, please include this point and document "innovative, non-comparable contracted products".
   e. List other state Medicaid or federal programs, managed care plans or other health coverage organizations that currently cover the products and provide the current coverage policy.
7. **For new Products proposed, provide all of the following additional information:**

   a. Copies of all relevant published clinical studies of efficacy and other information for each proposed product.
   b. A PDF of the package label showing all the product information as it appears in distribution.
   c. The product's published detailed product description and the link to it's publication online.
   d. Brief written product presentation providing a summary of your product(s), how they would be useful to Medi-Cal Rx beneficiaries and are medically necessary, and discussing each of the five review criteria:

- Safety – the relative freedom from side effects that is determined by reviewing the contraindications, precautions, warnings and adverse effects.
- Efficacy – the speed, duration and extend to which the product will alleviate, control, or cure the medical condition for which it is indicated.
- Essential need – the incidence, severity, and prognosis of the medical conditions for which it is indicated.
- Misuse Potential – the likelihood for unjustified, inappropriate, irresponsible or improper use.
- Cost Effectiveness – the immediate or long-term cost effectiveness.

8. First Data Bank (FDB) Listing – the 11-digit code from First Data Bank (Medi-Cal billing number) for reach product package size proposed **must be listed and active in FDB at the time of submission.** Include PDF from FDB showing the 11-digit billing code petitioned is available and active in FDB's drug pricing resource, OR
9. Include an email from FDB showing FDB email addresses, validating the petitioned 11-digit billing code is available and active in FDB's drug pricing resource or a PDF of FDB's product listing.
10. If items above are "not applicable," please explain via placeholder.

NOTE: FDB's Prizm database is NOT acceptable as Medi-Cal Rx only uses FDB's drug pricing resource and does not have access to Prizm.

NEGOTIATIONS

DHCS may present a price counteroffer following the product evaluation meeting. The Petitioner may accept, reject, or present an alternative to the counteroffer 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 product pricing with stakeholders.

DECISION NOTIFICATION

Upon review and cost negotiations to add or retain an enteral nutrition product on the List, DHCS will send a contract via DocuSign to the Petitioner. Once DHCS receives the contract signed by the authorized representative, DHCS will instruct its fiscal intermediary to inform providers of changes to the List and to take action for processing provider claims for these enteral nutrition products by the contractual effect date.

The project lead will notify the Petitioner 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 Rx provider bulletins. **Petitioners must not announce an effective date prior to the Medi-Cal Rx provider bulletin publications.**

DENIALS

If DHCS decides not to contract for a product, a notification letter regarding such a decision will be sent to the Petitioner. If a petition of a product is denied, the Petitioner must wait until the next product category review (PCR), to re-petition the same product.

If significant changes have been made to the product since the denial, a petition of a previously denied product may be petitioned again prior to the next PCR. The Petitioner should send a letter to the lead consultant (Victoria.Tereschenko@dhcs.ca.gov) including the following:

- An email requesting to petition the product prior to the PCR.
- Prior petition and denial dates and appeal dates (if applicable)
- Products petitioned and previously denied
- DHCS reason the products were denied
- Changes that have been made since the denial addressing the original denial reasons and included documentation.

A re-petition outside the PCR requires the above-referenced items and does not guarantee the petition will be reviewed. The team will consider and review the request and supporting documentation included and respond within 30 days of the email request:

- The team will move forward and review the individual product petition; or
- The team will defer the request to the next PCR.

A Petitioner of an enteral nutrition product denied a contract with the Department for admission to the List may file an appeal of that decision within 30 days of the Department's written decision. A final decision on the appeal will be issued by The Department within 60 calendar days of the date of the appeal request W&IC 14105.475 (k)(2).

The Appeal request should include:

- An email or letter requesting an appeal of the denial.
- Reasoning for the appeal and what was not considered or missed in the initial review and denial.
- Additional information supporting re-consideration for admission as outlined in bullet point #2 .
- An appeal should not be requested unless there is substantial supporting documentation not considered or included in the initial review. It is important Petitioners include all relevant information and justification for admission to the List in their petitions to avoid possible denials.

The team will review the appeal request along with the original petition, the denial, and any supporting documentation included or available with the appeal submission and issue a response within 60 calendar days of the receipt of the appeal request. The appeal decision made by the team is final. The Petitioner must wait until the next product category review (PCR), to re-petition the same product.

To learn more about the Medi-Cal Program and to view the Medi-Cal Rx *List of Contracted 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.