

MEDI-CAL ENTERAL NUTRITION PRODUCT REVIEW PROCEDURES

November 30, 2007

GENERAL INFORMATION

This document describes the Department of Health Care Services' (Department) procedures and criteria (safety, efficacy, misuse potential, essential need, and cost effectiveness) to create a List of Contracted Enteral Nutrition Products. The Department's Pharmacy Benefits Division (PBD) is responsible for the addition, deletion, or retention of enteral nutrition products on the Medi-Cal List of Contracted Enteral Nutrition Products (List).

The authority for contracting for nutrition products is established in *Welfare and Institutions Code Section 14105.8*, chaptered in Fall 2002. The purpose of contracting is to establish a List of Contracted Nutrition Products that meet medical criteria and afford the Department price maximums for pharmacy providers who dispense the product to an eligible Medi-Cal beneficiary. Nutrition products are an optional benefit under Federal Medicaid rules, and prudent Listing and payments in this area are essential to retain the benefit in California. The contracts resulting from this process establish a Maximum Acquisition Cost (MAC) per unit of product, at or below which all Medi-Cal pharmacy providers are guaranteed the ability to purchase the product.

Companies eligible to enter an agreement with the Department, for placement of products on the List must be either (a) the manufacturer of the product or (b) a relabeler, or repackager, with a unique labeler code. The products subject to review must be available for purchase by any Medi-Cal pharmacy providers who dispense to eligible outpatients in California.

The statute exempts this contracting process from a formal government bid approach, and therefore one or more contractors may ultimately enter into contracts with the Department for comparable items.

Confidentiality requirements are applicable to the *Product Category Review* AND the *Individual Petition* processes described in this document. There is no public opening of business proposals, and confidentiality is required of all participants engaged in the contracting process. All anti-trust and collusion laws must be strictly adhered to by all. This includes, but is not limited to:

- **active promotion** of products proposed for addition to the List shall not occur until the provider bulletin is published; AND
- prices proposed to the Department, counter offers from the Department, and final contracted prices shall not be **shared or announced** until the provider bulletin is published; AND
- failure to comply with confidentiality requirements may result in a delay of the addition of products to the List, or cancellation of the contract.

PBD retains all records associated with recommendations and decisions regarding addition, deletion, or retention of enteral nutrition products on the List for a period of two years.

Contracting Procedures

Enteral nutrition products are reviewed in two ways:

Either:

- I. A **Product Category Review (PCR)** considers all contractors' comparable items at once and one or more contractors' products are published to the List;
or
- II. An **Individual Petition**, considers one contractor's newly marketed product when a PCR has already taken place and a List already exists, but the new technology is an important consideration for addition to the List mid-term.

I. Product Category Review (PCR)

Product Category Reviews (PCRs) are Department-initiated, and address comparable products from multiple contractors simultaneously. It is the Department's intent to conclude a PCR within 180 days of the PCR Notification Letter. PCRs result in three year contracts between the Department and one or more contractors, and an established List of contracted products with associated MAC prices. A new PCR will be conducted approximately every three years. Products that do not meet the five criteria, or that are not proposed during a PCR, may be proposed again in a subsequent Individual Petition or PCR.

(During the term of existing three year contracts, products that represent new technology and/or are assigned new Universal Product Numbers (UPN), Universal Product Codes (UPC), or National Drug Code-like numbers (NDCs) will be considered for addition to the List by Individual Petition; see section II. in the Individual Petitions portion of this document.)

PCR Notification Letter

The PCR Notification Letter to contractors includes the following:

- Identification of the defined category for the PCR.
- Identification of the five criteria of: effectiveness, safety, essential need, misuse potential, and cost of the enteral nutrition product (see Appendix A).
- Identification of the Department project manager assigned to coordinate the PCR.
- Scheduled date/s for contractor presentations of the five criteria.

PCR Analytical Process

The Department schedules and hosts a meeting with each contractor's representative/s. The Department's representatives at the meeting will include the Chief of the Contract Branch, the project manager (nutritionist) assigned to coordinate the PCR, and the Nutrition Advisory Committee (NAC) of experts from other programs, the community, and external to Medi-Cal (in person or by conference call). The purpose of this meeting is to discuss the first 4 criteria with emphasis on therapeutic considerations, and studies. The NAC members are excused from the contractor presentation before the business proposal with price information is described by the contractor.

PCR Evaluation

The Department next conducts a debriefing meeting with the NAC, followed by an internal meeting to review and evaluate the enteral nutrition product/s. Discussion of each enteral nutrition product is initiated by the project manager assigned to the PCR. A format is utilized for documenting consideration of each enteral nutrition product. This format includes the following information at a minimum:

- Contractor of the enteral nutrition product.
- Brief documentation of each of the five criteria of safety, efficacy, essential need,

- misuse potential, and cost.
- Pertinent medical literature or other information.
- NAC recommendations to the Department.

PCR Negotiations

Upon arriving at a decision to List or not List each product, the Department next presents a price counter offer, for some, or all of the proposed products to the contractor. The contractor may accept, reject, or present an alternative to the counter offer within the time frame requested by the Department.

PCR Decision

The project manager coordinates the Department's review of each enteral nutrition product. If during the internal review additional information is needed, the project manager will contact the contractor. The Department then makes a final decision about which products to add to or retain on the List.

PCR Decision Notification

When negotiations are concluded, the Department sends a communication to the contractor of the product.

When the decision is that a contractor's product will be added to, or retained on, the List, the Department asks for labeler code and legal signee information and sends a contract, with agreed products and prices inserted, to the contractor. Once the Department receives the contract signed by the contractor's legal representative, the Department instructs the Department's fiscal intermediary to inform providers of changes to the List, to publish products in the provider manual, and to take action for processing provider claims for these enteral nutrition products.

Contractors may contact the project manager to find out the proposed effective dates of the enteral nutrition product addition. The effective date to add an enteral nutrition product is not official until the Medi-Cal provider bulletin is published. Therefore, contractors must not announce an effective date prior to Medi-Cal bulletin publication. The term of the resulting contract will be three years.

The transition from non-contracted to Listed, contracted-only product availability is a 60 to 90 day process in which providers may dispense and claim either, in order to exhaust old inventory for their Medi-Cal customer base.

PCR Appeals

Contact your contract manager for information about appeals.

II. Individual Petition Review

To accommodate new enteral nutrition product technology or new product numbers, an Individual Petition may be submitted for review and evaluation *during* the term of existing three year contracts.

Individual Petition reviews occur as a result of contractor requests, physician or pharmacist requests, or Department initiation. The Department will not begin an Individual Petition review unless a product is available on the market (established retail presence is required by law).

The Department tracks written requests of Individual Petitions received from contractors and coordinates a review of products as time permits, and in priority order based on essential need (see Appendix A). Individual Petitions may be deferred to a PCR if a review is anticipated.

Individual Petitions

To be considered complete, a contractor must submit an Individual Petition that contains at least the following information regarding the product:

- A letter specifically requesting addition to the List.
- Evidence of existing retail presence.
- Description of the unique technology not currently represented on the contracted List for the category.

The above minimum information is sufficient for the Department to consider the review and initiate the evaluation of a single product. However, the Department will require additional information during the review process. Contractors are encouraged to provide the Department with detailed therapeutic (e.g., clinical studies), five criteria (see Appendix A) information, and cost proposals as early as possible in the process. It is the Department's intent to conclude an Individual Petition review within 180 days of the Individual Petition Notification Letter (see next section), but other in-progress PCRs have priority and can significantly affect this timeframe.

Individual Petition Notification Letter

The Department will notify contractors that a review has been initiated. The Individual Petition Notification includes at least the following:

- Identification of the five criteria (effectiveness, safety, essential need, misuse potential, and cost) used to evaluate the product (see Appendix A).
- Identification and phone number for the Department project manager assigned to coordinate the review.

Individual Petition Analytical Process

The Department schedules and hosts a meeting in person or by phone, with the contractor. The Department's representatives at the meeting will generally include the Chief of the Contract Branch and the project manager (nutritionist) assigned to coordinate the review. *In some cases* a Nutrition Advisory Committee member, or members, best suited to assist the Department with an evaluation of the five criteria (see PCR Analytical Process) for your product will participate. The purpose of this meeting is to discuss the first 4 criteria with emphasis on therapeutic considerations, and studies. The NAC members are excused from the contractor presentation before the business proposal containing pricing information is described by the contractor.

Individual Petition Evaluation

The Department next conducts a debriefing meeting with the NAC (if applicable), followed by an internal meeting to review and evaluate the enteral nutrition product/s. Discussion of each product is initiated by the project manager assigned to the PCR. A format is utilized for documenting consideration of each product. This format includes the following information at a minimum:

- Contractor of the enteral nutrition product.
- Brief documentation of each of the five criteria of safety, efficacy, essential need, misuse potential, and cost.
- Contractor's input.
- Pertinent medical literature or other information.
- NAC recommendations to the Department.

Individual Petition Negotiations

If the Department arrives at a decision to List the proposed product (based on the first four criteria), the Department next presents a price counter offer, for the proposed product to the contractor. The contractor may accept, reject, or present an alternative to the counter offer within the time frame requested by the Department.

Individual Petition Decision

When negotiations are concluded, the Department sends a communication to the contractor of the product.

When the decision is that a contractor's product will be added to, or retained on, the List, the Department asks for labeler code and legal signee information and sends a contract, with agreed products and prices inserted, to the contractor. Once the Department receives the contract signed by the contractor's legal representative, the Department instructs the Department's fiscal intermediary to inform providers of changes to the List, to publish products in the provider manual, and to take action for processing provider claims for these enteral nutrition products.

Contractors may contact the project manager to find out the proposed effective dates of the enteral nutrition product addition. The effective date to add an enteral nutrition product is not official until the Medi-Cal provider bulletin is published. Therefore, contractors must not announce an effective date prior to Medi-Cal bulletin publication. The term of the resulting contract will be three years.

The transition from non-contracted to Listed, contracted-only product availability is a 60 to 90 day process in which providers may dispense and claim either, in order to exhaust old inventory for their Medi-Cal customer base.

Individual Petition Appeals

Contact your contract manager for information about appeals.

APPENDIX A

Product Review Criteria

The Department shall, when evaluating a decision to execute a contract, and when evaluating enteral nutrition products for addition to, retention on, or deletion from, the List of contracted enteral nutrition products, use all of the following criteria:

- (1) The safety of the enteral nutrition product.
- (2) The effectiveness of the enteral nutrition product.
- (3) The essential need for the enteral nutrition product.
- (4) The potential for misuse of the enteral nutrition product.
- (5) The cost effectiveness of the enteral nutrition product.

The deficiency of an enteral formula when measured by one of these criteria may be sufficient to support a decision that the enteral nutrition product should not be added or retained, or should be deleted from the list. However, the superiority of an enteral nutrition product under one criterion may be sufficient to warrant the addition or retention of the enteral nutrition product, notwithstanding a deficiency in another criterion.

The Department's consideration of the five criteria follows:

(1) *Safety* means the relative freedom from contamination and side effects, and is determined by reviewing the indications for use, precautions, warnings, and adverse effects of the enteral nutrition product. Evaluation of safety may take into account such factors as handling requirements, packaging, form, 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.

(2) *Efficacy* means 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) *Essential Need* means that the availability of an enteral nutrition product through the List is necessary to protect life or prevent significant disability. 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) *Misuse Potential* means the opportunity for unjustified, inappropriate, irresponsible, or improper use of an enteral nutrition product. Evaluation of unjustified, inappropriate, or irresponsible use 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. Medical literature, professional expertise, audits and investigations, and provider experience are utilized to confirm what uses are inappropriate.

(5) *Cost effectiveness* means the immediate or long-term cost effectiveness of the product. Evaluation of cost effectiveness may involve a single enteral nutrition product or comparisons between two or more enteral nutrition products. This may take into account such factors as the net cost of the product to the Department, as well as fiscal impact resulting from improvements in emergency room use, acute facility use, the time for the medical condition to achieve resolution, and/or the reduced utilization of ancillary therapeutic agents.

As part of the cost evaluation, the Department considers data presented by the contractor 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 guidelines for reviewing models/studies relative to evaluating the cost criterion are as follows:

1. Studies used to support claims must be of sufficient scientific rigor to assure confidence in the claimed effects. Study designs and measurements must reflect current scientific standards.
2. Baseline data should be reflective of the population served by the Medi-Cal program.
3. Baseline data should be reflective of the Medi-Cal program.
4. Cost data should be reflective of the Medi-Cal program's reimbursement methods.

Realistic offsets for enteral nutrition product displacement should be included along with data quantifying product category growth.