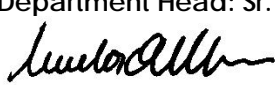
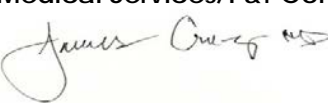


Policy Title: Therapeutic Enteral Formulas		POLICY #: 70.2.84	
		Line of business: ALL	
Department Name: Utilization Management	Original Date 5/15	Effective Date 5/19	Revision Date 12/18
Department Head: Sr. Director, UM 			Date: 3/21
Medical Services/P&T Committee: (If Applicable) PHP CMO 			Date: 3/21

PURPOSE

To establish and define mechanisms for Blue Shield of California Promise Health Plan’s (Blue Shield Promise) Utilization Management (UM) Department to provide medically necessary therapeutic enteral formulas for infants, children, and adults when medically indicated, and in accordance with current regulatory guidelines.

POLICY

There are patients who, because of chronic illness or trauma, cannot be sustained through oral feeding. These people must rely on either enteral or parenteral nutritional therapy, depending upon the particular nature of their medical condition. Blue Shield Promise Health Plan will provide and/or arrange for all services that are categorically medically necessary and a part of therapeutic regimen in patients with medically diagnosed conditions that preclude the use of regular food.

Blue Shield Promise shall provide enteral nutrition products and affiliated services in an amount no less than that which is offered to beneficiaries as a covered benefit for Medi-Cal and Medicare.

DEFINITIONS:

Medically Necessary Covered Services: are those that are reasonable and necessary to protect life existence, living potentials, prevent significant illness or significant disability, or alleviate severe pain through the diagnosis or treatment of disease, illness, or injury, in accordance with title 22, CCR 51303 (a).

Infant Formula – is food which intends to be or is represented for special dietary use solely as a food for infants by reasons of its simulation of human milk or its suitability as a complete or partial substitute for human milk.

Therapeutic Medical Food – one that is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation.

PROCEDURE

- I. Guidelines for Enteral Nutritional Products:
 - a. The UM Department shall ensure consistent application of medical necessity criteria for therapeutic enteral formula for specific medical conditions, through regular review, updating of criteria, and clear documentation of reasons for decisions.
 - b. The UM Department shall ensure provision of medically necessary therapeutic enteral formulas and the equipment/supplies necessary for delivery of these indicated products.
 - c. Blue Shield Promise shall provide enteral nutrition products and affiliated services in an amount no less than that which is offered to beneficiaries under Medi-Cal and Medicare Benefits.
 - d. Medical Necessity and Benefit determinations to include amounts supplied shall be derived from the following guidelines:
 - i. Medi-Cal Provider manual Part 2 – Durable Medical Equipment and Medical Supplies (DME) 2 – Enteral Nutrition Products March 2015: http://files.medi-cal.ca.gov/pubsdoco/manuals_menu.asp
 - ii. Medi-Cal Part Pharmacy Provider Manual, Enteral products Section the product identification numbers are included in the approved list of enteral nutrition: [Pharmacy Provider Manual](#)
 - iii. National Coverage Determination (NCD) for Enteral and Parenteral Nutritional Therapy (180.2)
 - e. There will be an adequate time period, not to exceed 120 days, for new Blue Shield Promise members to continue receiving a current therapeutic formula regimen until medical necessity is determined by new plan.
 - f. The authorization process for all available enteral nutrition benefits shall not include any requirement for the patient to have first attempted blenderized foods.
- II. **Exemptions**
 - a. Enteral nutrition products for similar diagnoses and intended uses that are not on the approved Medi-Cal list are not a covered Medi-Cal Benefit
 - b. Some patients require supplementation of their daily protein and caloric intake. Nutritional supplements are often given as a medicine between meals to boost protein-caloric intake or the mainstay of a daily nutritional plan. Nutritional supplementation is not covered under Medicare Part B.
 - c. Beneficiaries covered under the Early and Periodic Screening, Diagnostic, and Treatment Program (EPSDT) shall be exempt from the aforementioned limitation of non-approval listed enteral nutrition products
 - d. WIC Program services are not covered under the Medi-Cal enteral nutrition product service.
- III. **Review Process:**
 - a. To properly process the medical necessity of enteral nutritional services for eligible beneficiaries, Blue Shield Promise shall require a Treatment Authorization Request (TAR).
 - b. The required information will be utilized to demonstrate that both medical criteria and product criteria are met.
 - c. Criteria:

- i. For Medi-Cal LOB, 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
- ii. For Medicare LOB NCD will be utilized to establish medical necessity as listed above Section I. item c.
- iii. Medical Record information shall include:
 - 1. Thorough past medical history
 - 2. Physical examination
 - 3. Nutrition assessment
 - 4. Laboratory testing
 - 5. Feeding observation (when applicable)
 - 6. Evaluation of beneficiary's behavior and home environment
- d. In the event that Blue Shield Promise Health Plan is in receipt of a request for Enteral Nutrition for a child or infant that has been diagnosed with Failure to Thrive (FTT), the case will be referred to a Blue Shield Promise internal California Children's Services Liaison and/or an ambulatory case manager to evaluate the social and environmental conditions related to Failure to Thrive (FTT) infants and children.
- e. Blue Shield Promise will also work with other local, county, and community agencies through the Memorandum of Understanding process, when available, to efficiently evaluate and meet the needs of high-risk beneficiaries.
- f. WIC Program services are not covered under the Medi-Cal enteral nutrition product service. However, Blue Shield Promise shall have procedures to identify and refer eligible beneficiaries to WIC Program services. Please refer to P&P 10.2.100.16 Titled "Women, Infants and Children Supplemental Nutrition Program".
- g. Enteral nutrition must be prescribed by a licensed provider.
- h. A qualified healthcare professional shall supervise the medical authorization procedures and review for approval of enteral nutrition products.
- i. Denials shall be reviewed by a qualified physician.
- j. Blue Shield Promise shall complete authorization decisions regarding enteral nutrition products in a timely manner based on the sensitivity of medical conditions as follows:
 - 1. **Emergency Requests:** Blue Shield Promise shall not require prior authorization of services when there is a bona fide emergency requiring immediate treatment.
 - 2. **Expedited Requests:** Blue Shield Promise shall provide for expedited requests on services and process within 72 hours when a provider or a Blue Shield Promise determines that the standard timeframes above could seriously jeopardize the beneficiary's life, health, or ability to attain, maintain, or regain maximum function.
 - 3. **Routine Requests:** Blue Shield Promise shall process non-emergency requests for services as follows:
 - a. Medi-Cal within five calendar days when the proposed treatment meets objective medical criteria and is not contraindicated.
 - b. Medicare within 14 calendar days when the proposed treatment meets objective medical criteria and is not contraindicated.
 - 4. Requests for a Pre-established Regimen: Blue Shield Promise shall process a regimen of services that have already been established as above for emergent, expedited, and routine to maintain

consistency with the urgency of the beneficiary's medical condition.

5. If Blue Shield Promise is delayed in making a determination for enteral nutrition products or services beyond the time periods outlined above in Procedures I, (3), the service is considered approved and therefore shall immediately be processed as such.
- k. Blue Shield Promise shall provide verbal and written notification to the member and provider requesting the service in compliance with regulatory standards, and as outlined in P&P 10.2.100.16 for Medi-Cal LOB and P&P 50.2.31 for Medicare LOB for approved, modified, deferred or denied decisions.
 - i. Any adverse determination notice shall include detailed information and instruction on Appeal Rights in compliance with California DHCS and CMS requirements.

IV. Informing Providers and Beneficiaries:

- a. Blue Shield Promise shall inform providers about prescription and authorization procedures for the provision of obtaining medically necessary enteral nutrition products through the Blue Shield Promise Provider Manual, access to Blue Shield Promise's Policies and Procedures, and individual training as necessary and/or requested.
- b. Blue Shield Promise contracted IPAs and Medical Groups shall inform providers about authorization procedures for provision of therapeutic enteral formulas, timeliness standards, requirements for periodic physical assessment and follow-up evaluation, local referral resources, formulary list of approved therapeutic formulas, and processes for approval of newly marketed therapeutic enteral formulas; and
- c. Members are informed authorization procedures and enteral products through their Evidence of Coverage, Blue Shield Promise Website, and individual education upon request for information.
- d. Blue Shield Promise IPAs and Medical Groups shall inform members about the processes and procedures for provision of medically necessary therapeutic enteral formulas.

REFERENCES

Policy Letter (PL) 14-003

Welfare and Institutions Code, section 14132.86

Welfare and Institutions Code, Section 14105.8

Welfare and Institutions Code, Section 14105.395

Welfare and Institutions Code, Section 14103.6

Welfare and Institutions Code, Section 14132, subdivision AB

42 Code of Federal Regulations Section 431.63 (c)

Title 22, CCR 51303 (a)

National Coverage Determination (NCD) for Enteral and Parenteral Nutrition Therapy (180.2)