

HEALTH PLAN OF SAN JOAQUIN					
<b>Subject: Nutritional Supplements for Medical Conditions</b>					
<b>Department:</b> Medical Management / Pharmacy				<b>Policy #:</b> PH19	
<b>Effective Date:</b> 06/01/2007	<b>Committee/Approval Date:</b> P&T 02/16/16	<b>Review/Revision Dates:</b> 12/07, 09/2014, 09/15, 2/16			
Applies To:	Medi-Cal	Yes	X	No	
	MCAP	Yes	X	No	
	TPA	Yes		No	X

**POLICY**

- A. Enteral nutrition supplements are covered through the Medi-Cal pharmacy benefit when used as a medically necessary therapeutic regimen to prevent serious disability or death in patients with medically diagnosed conditions that preclude the use of regular food. (22 CCR 51313.3 (e)(2). HPSJ is responsible for arranging for medically necessary covered enteral supplementation as explained in the following procedure.
- B. Infant formula required for normal healthy infants and children is not a benefit under the Medi-Cal, CCS, or Genetically Handicapped Persons Program. Members of the Health Plan of San Joaquin (HPSJ) who are eligible for state subsidized (WIC) supplemental food services will be referred to WIC per HPSJ Policy UM52.
- C. If a member has coverage through Medicare, CCS, or another payer, resides in a long term care facility, requires custodial care in home, or has an AIDS diagnosis; reimbursement will be sought through the other payer or through the appropriate Medi-Cal waiver program.
- D. Decisions and appeals regarding therapeutic enteral formulas shall be performed in a timely manner based on the severity of medical conditions as follows:
  - 1. Emergency requests and continuation requests will not require PA, but will be approved for 30 working days and reviewed for medical necessity using the expedited request time frame. (Welfare and Institutions Code Section 14103.6);
  - 2. Expedited requests will be reviewed within 3 working days for services that following the standard timeframe could seriously jeopardize the member’s life or health or ability to attain maximal function. When supplied through the pharmacy benefit nutritional supplements will follow the standard pharmacy timelines.
  - 3. Non-emergency requests will be reviewed within 5 working days. If additional information is needed, additional information will be requested from the prescriber.
  - 4. Requests for continuation of therapy will be reviewed within 5 working days for review of a currently provided regimen as consistent with urgency of the member’s medical condition (Health and Safety Code Section 1367.01)

## **BENEFIT EXCLUSIONS**

The following products are considered benefit exclusions are not covered by HPSJ:

- Regular foods, including solid, semi-solid, and pureed foods
- Common household items
- Standard infant formulas
- Shakes, cereals, thickened products, puddings, bars, gels, and other non-liquid products
- Thickeners (e.g. Thick-It)
- Weight-loss products (e.g. Slim-Fast)
- Enteral Nutrition products used orally as a convenient alternative to preparing and/or consuming regular solid or pureed foods
- Medical foods (e.g. probiotics)

## **PEDIATRICS (AGE 0-17) PROCEDURES**

### **A. Identification and Referral**

1. Following appropriate medical evaluation, and referral for comprehensive nutritional services, a primary care provider (PCP) or licensed specialist provider may request nutritional supplementation through the HPSJ pharmacy authorization process.
2. All enteral nutrition supplements require prior authorization except in emergency or continuation of prior care situations

### **B. Medical Necessity Determination**

1. All requests for nutritional supplementation will be evaluated by a HPSJ Pharmacist. The Medical Director is ultimately responsible for all determinations.
2. The following medical necessity criteria will be used:
  - a. Enteral nutrition supplements covered must be intended for the specific management of a disease or condition for which distinctive nutritional requirements based on scientific principles are established by medical evaluation.
3. Age specific medical necessity criteria must be met for approval (see below)
4. If medical necessity criteria are met, the supplement will be approved.

### **C. Infants(Age 0-12 months)**

1. Standard Infant Formula
  - a. Not a covered benefit. See “benefit exclusions” section. May be covered by WIC if eligible.
2. Premature enriched infant formulas (*e.g., Neosure, Enfacare*)
  - a. Maximum approval for 12 months post-discharge.
  - b. Member must be “premature” as documented by birth before 37 gestational weeks

- c. Weight must be less than the 10<sup>th</sup> percentile on the growth chart, adjusted for gestational age OR less than 25<sup>th</sup> percentile with a severe medical condition.
- 3. Hypoallergenic formula (*e.g., Alimentum, Nutramigen*)
  - a. Must meet ONE of the following criteria:
    - i. Severe IgE-associated cow milk protein allergy symptoms (*e.g.* angioedema, anaphylaxis, urticaria),
    - ii. Non-IgE associated allergy symptoms (*e.g.* esophagitis, enterocolitis),
    - iii. Other IgE associated symptoms, including documented failure/contraindication to soy-based formula OR age < 6 months.
- 4. Non-allergenic infant formula (*e.g., Neocate, Elecare*)
  - a. Documented failure or contraindication to hypoallergenic infant formula

**D. Pediatrics (Age 1 – 17 years) with a feeding tube**

- 1. Documentation of use of enteral feeding tube (*i.e.* gastric, nasogastric, or jejunostomy tubes) is required for coverage.
- 2. Reassessment every 6 months may be required based on medical necessity. (See definition below)

**E. Pediatrics (Age 1 – 17 years) without feeding tube**

- 1. For the coverage of standard nutritional supplements (*e.g.* Pediasure, Nutren Junior, Boost Kid Essentials), one of the following conditions must be met.
  - a. Severe medical condition (*e.g.* Cancer, AIDS, cerebral palsy, CCS Covered Condition)
    - i. Weight-for-age, weight-for-length, body mass index (BMI)
  - b. Diagnosis of failure to thrive in addition to:
    - (a) (1) weight-for-age, (2) weight-for-length, or (3) BMI < 5<sup>th</sup> percentile, based on World Health Organization growth standards for toddlers < 2 years old, or CDC growth references for children > 2 years old
    - ii. Documentation of failure to gain weight after dietary intervention (*e.g.* consultation with a dietician)
    - iii. Evaluation of the home environment and social situation through the San Joaquin County Public Health Maternal Child and Adolescent Health program or an independent social services provider by HPSJ will be conducted.
- 2. If medical necessity criteria are not met, the provider and member will be informed in writing through the HPSJ denial process..

**ADULTS (>17 YEARS OLD) PROCEDURES**

**A. California Children’s Services (CCS) Responsibility**

1. CCS covers children up to age 21. Some members may qualify based on the conditions listed in the section above. Requests for enteral products used to treat a CCS covered condition for members <21 years old will be deferred to CCS.

**B. Medicare responsibility (Part B)**

1. Medicare covered benefits must be billed to Medicare before billing HPSJ for members who qualify as Medicare Part B/Medi-Cal dual-eligible beneficiaries.
2. Coverage of nutritional therapy as a part B benefit is covered under the prosthetic devices benefit provision and requires:
  - i. That the patient have a “permanently inoperative internal body organ or function thereof”
  - ii. Enteral nutrition is not covered under part B in situations involving temporary impairments
3. Members who do not meet coverage criteria of CCS or Medicare, must meet the following criteria:

**C. Adults with feeding tube**

1. Documentation of a medical diagnosis that requires enteral nutrition products to be administered through a feeding tube
2. Documentation of use of an enteral feeding tube.

**D. Adults without feeding tube**

1. Patients must meet all the following criteria
  - a. BMI < 18.5 or involuntary weight loss >5% in 1 month, >7.5% in 3 months, or >10% in 6 months.
  - b. Inability to maintain adequate nutrition with ordinary foods, including soft/pureed/blenderized foods
  - c. documented consultation with a dietician, and (4) one of the following from categories (i) and (ii)
2. High nutrient requirement disease states:
  - a. CKD
    - i. Documentation of renal function tests are required
    - ii. Please see the Nutrition in CKD policy document
  - b. Inborn errors of metabolism (if age > 21) (e.g., cystic fibrosis, organic acidemias, PKU, maple syrup urine disease)
    - i. Documentation of genetic testing and laboratory results are required
  - c. Intestinal malabsorption disorders (e.g. Crohn’s Disease, Ulcerative Colitis)
3. Other Situations:
  - a. Dysphagia/odynophagia due to:

- i. Cancer in the mouth, throat, or esophagus
  - ii. Injury or trauma involving the head or neck
  - iii. Radiation therapy or surgery involving the head or neck
  - iv. Chronic neurological disorders
  - v. Severe craniofacial abnormalities
- E. Severe weight loss due to a severe medical condition (cancer, HIV/AIDS, or immunological condition) that is being actively treated or managed.
- F. Exceptions may be determined on a case-by-case basis for members who do not meet criteria and have special circumstances. Referral to a nutritionist and a treatment plan to wean off nutritional supplement is required. Oral enteral nutrition is considered not medically necessary when the criteria are not met or when use of the enteral product is based on the convenience or preference of the member or provider.

**REQUIRED DOCUMENTATION AND HPSJ PROCESS**

- A. The following information must be submitted for authorization and reauthorization requests.
  - 1. The provider must submit all pertinent patient information including patient age, height, weight, growth charts for infants and children, medical diagnosis, reason(s) for requesting nutritional supplementation, previous nutritional programs attempted, percent of daily caloric intake obtained without supplementation, other food sources, dietary/nutrition consultant information, and supporting lab documentation e.g. albumin level, total lymphocyte count failure-to-thrive workup, etc..
  - 2. Patients referred by their PCP for long-term nutritional supplementation will require an evaluation by a specialist e.g. endocrinologist, gastroenterologist, or qualified nutritionist.
  - 3. Reauthorization will be required every 6 months or as appropriate based on condition.
- B. A denial letter from Medicare, WIC program, or CCS is required (if applicable)

**REFERENCE**

- A. American Academy of Pediatrics Vol 111 No.5, May 2003
- B. DHCS Policy Letter 14-003
- C. DHCS Medi-Cal Provider Manual Part 2 – Pharmacy: Enteral Nutrition
- D. Title 22 CCR 51313.3(e)(2)
- E. MMCD Policy Letter 07006
- F. Soy Protein-based Formulas: Recommendations for Use in Infant Feeding. AMERICAN ACADEMY OF PEDIATRICS. Pediatrics Vol. 101 No. 1 January 1998, pp. 148-153.
- G. 2. Hypoallergenic Infant Formulas AMERICAN ACADEMY OF PEDIATRICS. Pediatrics Vol. 106 No. 2 August 2000, pp. 346-349.

<b>Health Plan of San Joaquin</b>
<b>Approval: Signatures on File</b>

***DHCS Contract Deliverables***

<b><i>Contract Reference</i></b>	<b><i>Date of Approval</i></b>	<b><i>DHCS Unit</i></b>		<b><i>Contract Reference</i></b>	<b><i>Date of Approval</i></b>	<b><i>DHCS Unit</i></b>