Health Plan of San Joaquin | Mountain Valley Health Plan

POLICY AND PROCEDURE	
Policy # and TITLE: PH19 Nutritional Supplements for Medical Conditions	
Primary Policy owner: Pharmacy	**POLICY #:** PH19
Impacted/Secondary policy owner: Select the department(s) that are responsible for compliance with all, or a portion of the policy or procedure as outlined	
1) ☐All Departments 2) ☐Behavioral Health (BH) 3) ☐Benefits Administration (BA) 4) ☐Care Management (CM) 5) ☐Claims (CLMS) 6) ☐Community Marketplace & Member Engagement (MAR) 7) ☐Compliance (CMP/HPA) 8) ☐Configuration (CFG) 9) ☐Provider Contracting (CONT) 10) ☐Cultural & Linguistics (CL) 11) ☐Customer Service (CS)	12) ☐Facilities (FAC) 13) ☐Finance (FIN) 14) ☐Human Resources (HR) 15) ☐Information Technology / Core Systems (IT) 16) ☒Pharmacy (PH) 17) ☐Provider Networks (PRO) 18) ☐QI Health Equity (GRV/HE/HEQ/PHM/QM) 19) ☐ Utilization Management (UM)
PRODUCT TYPE: ☒Medi-Cal	**Supersedes Policy Number:** N/A

I. PURPOSE

To establish standards for criteria review of physician administered therapeutic enteral nutritional supplement requests.

II. POLICY

A. Physician administered enteral nutrition supplements are covered through San Joaquin County Health Commission (“Commission”), operating, and doing business as Health Plan of San Joaquin and Mountain Valley Health Plan (“Health Plan”)’s medical 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). The Health Plan 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 who are eligible for state subsidized (WIC) supplemental food services will be referred to WIC per the Health Plan's Policy UM52, Women, Infants and Children (WIC) Supplemental Food Program.

C. If a member has coverage through Medicare, CCS, another payer, requires custodial care in home, or has an AIDS diagnosis; reimbursement will be sought through the other payer or through the appropriate Medi-Cal program.

D. Decisions and appeals regarding therapeutic enteral formulas when reviewed under the medical benefit via the Utilization Management (UM) team 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 72 hours for services that following the standard timeframe could seriously jeopardize the member's life or health or ability to attain maximal function.

   3. Routine 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

A. The following products are considered benefit exclusions and are not covered by the Health Plan:

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

III. PROCEDURE

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 Health Plan's authorization process.
2. All therapeutic 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 the Health Plan's Pharmacist.

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 formula powder *(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 OR have documented age <6 months at time of review.
   c. Weight must be less than the 10th percentile on the growth chart, adjusted for gestational age OR less than 25th percentile with a severe medical condition.
3. Hypoallergenic formula powder (*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,

      iv. Or age <6 months at time of review.

   4. Non-allergenic infant formula powder *(e.g., Neocate, Elecare)*
      a. Documented failure or contraindication to hypoallergenic infant formula powder formulations.

D. **Pediatrics (Age 1 – 17 years) <u>with</u> 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) <u>without</u> 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) that is not covered via CCS in addition to:
         i. Weight-for-age, weight-for-length, body mass index (BMI) < 5th percentile
      b. Diagnosis of failure to thrive in addition to:
         i. (1) weight-for-age, (2) weight-for-length, or (3) BMI < 5th percentile, based on World Health Organization growth standards for toddlers < 2 years old, or CDC growth references for children > 2 years old
            A. Documentation of failure to gain weight after dietary intervention (e.g. consultation with a dietician)
            B. 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 the Health Plan will be conducted.

2. If medical necessity criteria are not met, the provider and member will be informed in writing through the Health Plan's denial process. See Table 1. Decision and Notification Timeframes for further details.

ADULTS (>17 YEARS OLD) PROCEDURES

A. **California Children's Services (CCS) Responsibility:**
   1. CCS covers children <21 years of age. 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 the Health Plan 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:
      a. That the patient has a "permanently inoperative internal body organ or function thereof."
      b. Enteral nutrition is not covered under part B in situations involving temporary impairments.

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 <u>without</u> 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. Documentation of at least two consultations with a dietician
2. Or have a high nutrient requirement disease state:
   a. Chronic Kidney Disease (Please see the Nutrition in CKD policy document).
   b. Inborn errors of metabolism (if age > 21) (e.g., cystic fibrosis, organic acidemias, PKU (phenylketonuria), 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

B. Severe weight loss due to a severe medical condition (cancer, HIV/AIDS, or immunological condition) that is being actively treated or managed.

C. 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 THE HEALTH PLAN'S 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).

IV. ATTACHMENT(S)

A. DHCS Medi – Cal Managed Care Plans Definitions (Exhibit A, Attachment I, 1.0 Definitions)
B. Glossary of Terms Link
C. Medi-Cal Managed Care Contract Acronyms List (Exhibit A, Attachment I, 2.0 Acronyms)

V. REFERENCES

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. H&S Code Section 1367.01
E. Hypoallergenic Infant Formulas AMERICAN ACADEMY OF PEDIATRICS. Pediatrics Vol. 106 No. 2 August 2000, pp. 346-349.

F. MMCD Policy Letter 07006
G. Soy Protein-based Formulas: Recommendations for Use in Infant Feeding. AMERICAN ACADEMY OF PEDIATRICS. Pediatrics Vol. 101 No. 1 January 1998, pp. 148-153.
H. Title 22 CCR 51313.3(e)(2)
I. W&I Code Section 14103.6

VI. REVISION HISTORY

*Version 001 as of 01/01/2023

Version*	Revision Summary	Date
000	12/07, 09/2014, 09/15, 02/16, 02/17, 02/18, 05/19, 05/20, 09/21, 09/22	N/A
001	Moved PH19 to new template. Performed annual review and updated the expedite time frame to 72 hours.	9/8/2023
Initial Effective Date: 6/1/2007		

VII. Committee Review and Approval

Committee Name	Version	Date
Compliance Committee	001	2/15/2024
• Privacy & Security Oversight Committee (PSOC)		
• Risk Management		
• Delegation Oversight		
• Policy Review	001	12/20/2024
Quality and Utilization Management		
• Quality Operations Committee		
• Grievance		
Pharmacy & Therapeutics Committee	000	7/19/2023

VIII. REGULATORY AGENCY APPROVALS

Department	Reviewer	Version	Date
Department of Healthcare services (DHCS)	N/A	N/A	N/A
Department of Managed Care (DMHC)	N/A	N/A	N/A

IX. *Approval signature**

Signature	Name Title	Date
	PRC Chairperson	
	Policy Owner	
	Department Executive	
	Chief Executive Officer	

*Signatures are on file, will not be on the published copy

X. ADDENDUM

Table 1. Decision and Notification Timeframes			
Type of Request	**Decision**	**Initial Notification From the Health Plan to Practitioner**	**Written/ Electronic Notification of Denial and Modification to**

		(Notification May Be Oral and/or Electronic)	Practitioner and Member
Routine (Non-urgent) Pre-Service • All necessary information received at time of initial request.	**Within 5 working days of receipt of all information reasonably necessary to render a decision** • Any decision delayed beyond the time limits is considered a denial and must be processed immediately as such. • In this situation, the member has the right to request an appeal with the Health Plan and the Health Plan must send the member written notice of all appeal rights.	Practitioner: Within 24 hours of the decision Member: None Specified	Practitioner: Within 2 working days of making the decision Member: Within 2 working days of making the decision.
Routine (Non-urgent) Pre-Service – Extension Needed ***Additional clinical information*** • Require consultation by an Expert Reviewer • Additional examination or tests to be performed. (AKA: Deferral)	**Within 5 working days from receipt of the information reasonably necessary to render a decision but no longer than 14 calendar days from the receipt of the request** • The decision may be deferred, and the time limit extended an additional 14 calendar days only where the Member or the Member's provider requests an extension, or the Health Plan/ Provider Group can provide justification upon request by the State for the need for additional information and how it is in the Member's interest. • Notify members and practitioner of decision to defer, in writing, within 5 working days of receipt of request & provide 14 calendar days from the date of receipt of the original request for submission of requested information. Notice of deferral should include the additional information needed to render the decision, the type of expert	Practitioner: Within 24 hours of making the decision Member: None Specified	Practitioner: Within 2 working days of making the decision Member: Within 2 working days of making the decision

	reviewed and/or the additional examinations or tests required and the anticipated date on which a decision will be rendered. **Additional information received** • If requested information is received, decision must be made within 5 working days of receipt of information, not to exceed 28 calendar days from the date of receipt of the request for service **Additional information incomplete or not received** • If after 28 calendar days from the receipt of the request for prior authorization, the provider has not complied with the request for additional information, the plan shall make a decision with available information. • Any decision delayed beyond the time limits is considered a denial and must be processed immediately as such. • In this situation, the member has the right to request an appeal with the health Plan and the health Plan must send the member written notice of all appeal rights.		
Expedited Authorization (Pre-Service) • Requests where provider indicates or the Provider Group /Health Plan determines that the standard timeframes could seriously jeopardize the	**Within 72 hours of receipt of the request a decision shall be made in a timely fashion appropriate for the nature of the enrollee s condition, not to exceed 72 hours.** • Any decision delayed beyond the time limits is considered a denial and must be processed immediately as such. • In this situation, the member has the right to request an appeal with the	Practitioner: Within 24 hours of making the decision Member: None Specified	Within 2 working days of making the decision, not to exceed 3 working days from the receipt of the request for service

Member's life or health or ability to attain, maintain or regain maximum function. • All necessary information received at time of initial request	health Plan and the health Plan must send the member written notice of all appeal rights.		
Expedited Authorization (Pre-Service) - Extension Needed • Requests where provider indicates or the Provider Group /Health Plan determines that the standard timeframes could seriously jeopardize the Member's life or health or ability to attain, maintain or regain maximum function. • Additional clinical information required.	**Additional clinical information required:** Upon the expiration of the 72 hours or as soon as you become aware that you will not meet the 72-hour timeframe, whichever occurs first, notify practitioner and member using the "delay" form, and insert specifics about what has not been received, what consultation is needed and/or the additional examinations or tests required to make a decision and the anticipated date on which a decision will be rendered • Note: The time limit may be extended by up to 14 calendar days if the Member requests an extension, or if the Provider Group / Health Plan can provide justification upon request by the State for the need for additional information and how it is in the Member's interest **Additional information received** • If requested information is received, decision must be made within 1 working day of receipt of information. **Additional information incomplete or not received** • Any decision delayed beyond the time limits is considered a denial and must be processed immediately as such.	Practitioner: Within 24 hours of making the decision Member: None specified	Practitioner: Within 2 working days of making the decision Member: Within 2 working days of making the decision

	• In this situation, the member has the right to request an appeal with the health Plan and the health Plan must send the member written notice of all appeal rights.		
Concurrent review of treatment regimen already in place– (i.e., inpatient, ongoing/ambulatory services) In the case of concurrent review, care shall not be discontinued until the enrollee's treating provider has been notified of the plan's decision, and a care plan has been agreed upon by the treating provider that is appropriate for the medical needs of that patient. CA H&SC 1367.01 (h)(3)	Within 5 working days or less, consistent with urgency of Member's medical condition. NOTE: When the enrollee's condition is such that the enrollee faces an imminent and serious threat to his or her health including, but not limited to, the potential loss of life, limb, or other major bodily function, or the normal timeframe for the decision-making process… would be detrimental to the enrollee's life or health or could jeopardize the enrollee's ability to regain maximum function, decisions to approve, modify, or deny requests by providers prior to, or concurrent with, the provision of health care services to enrollees, shall be made in a timely fashion appropriate for the nature of the enrollee's condition, not to exceed 72 hours after the plan's receipt of the information reasonably necessary and requested by the plan to make the determination (CA H&SC 1367.01 (h)(2)) • Any decision delayed beyond the time limits is considered a denial and must be processed immediately as such. • In this situation, the member has the right to request an appeal with the health Plan and the health Plan must send the member written notice of all appeal rights.	Practitioner: Within 24 hours of making the decision Member: None Specified	Practitioner: Within 24 hours of making the decision Member: Within 2 working days of making the decision
Post-Service / Retrospective Review- All necessary information	Within 30 calendar days from receipt or request	Member & Practitioner:	Member & Practitioner:

received at time of request (decision and notification is required within 30 calendar days from request)		None specified	Within 30 calendar days of receipt of the request
Post-Service - Extension Needed •Additional clinical information required	Additional clinical information required (AKA: deferral) • A decision to defer must be made as soon as the Plan is aware that additional information is required to render a decision but no more than 30 days from the receipt of the request. Additional information received. • If requested information is received, decision must be made within 30 calendar days of receipt of information. • Example: Total of X + 30 where X = number of days it takes to receive requested information	Member & Practitioner: None specified.	Member & Practitioner: Within 30 calendar days from receipt of the information necessary to make the determination.
Hospice - Inpatient Care	**Additional information incomplete or not received.** • If information requested is incomplete or not received, decision must be made with the information that is available by the end of the 30th calendar day given to provide the information within 24 hours of receipt of request	Practitioner: Within 24 hours of making the decision Member: None Specified	Practitioner: Within 2 working days of making the decision Member: Within 2 working days of making the decision