Health Plan of San Mateo
Policy & Procedure Manual

Policy: RX.030		Title: Nutritional Supplements for Medical Conditions	Original Effective Date 01/01/2019
Revision: 4	Last Reviewed: 06/28/2019	Dept: Pharmacy Services	Page 1 of 5

Approval By: P&T Committee, Director of Pharmacy, Chief Medical Officer	Date: 7/10/2019
Annual Review Date: 06/30/2020	
Authored by: Lead Clinical Pharmacist	
Pursuant To: ☒ DHCS Contract Provision ☐ Health and Safety (H&S) Code ☐ CFR ☒ APL / DPL	 ☐ W & I Code ☐ California Title # ☐ Organization Need ☐ Other
Departments Impacted: Pharmacy Services	

Purpose

The purpose of this policy is to outline coverage for nutritional supplements related to a medical condition. This includes infant formulas, oral nutritional supplements, and enteral nutritional supplements.

Scope

This policy applies to (check all that apply):

☐ All LOBs/Entire Organization	☐ CCS	☒ Medi-Cal Expansion
	☐ Healthy Kids	☒ Medi-Cal Adults
☐ ACE	☐ HealthWorx	☒ Medi-Cal Children
☒ CA-CMC / MMP	☒ Medi-Cal	☒ Other (specify) NCQA

Responsibility and Authority

- The Director of Pharmacy, or designee, is responsible for overseeing the development, review, and administration of this policy and procedure.
- Pharmacy team members, including pharmacists, technicians, and other pharmacy department staff are responsible for overseeing and administering operations in accordance to the details outlined in this policy and procedure.

Definitions

Plan – Refers to the Health Plan of San Mateo unless otherwise indicated.

Nutritional Supplement – Refers to infant formula, oral nutritional supplements, or enteral nutritional supplements.

Chronic Medical Condition – Refers to a medical condition expected to last more than 3 months in duration.

Oral Nutritional Supplements – Refers to liquid nutritional supplements usually taken by mouth (e.g. Ensure, Boost). Does not include liquid infant formulas.

Enteral Nutrition Supplements – Refers to liquid nutritional supplements administered via a tube (G-tube, NG tube, J-tube) to the gastrointestinal (GI) tract to deliver part or all of a person's caloric

requirements.

Infant Formulas – Refers to nutritional supplements (liquid or powder) which are manufactured and specifically designed and marketed to babies and infants less than 12 months of age.

Therapeutic Infant Formulas – Refers to infant formulas specifically designed for use in those with specific medical conditions. These include products intended for premature and low birth weight infants, human milk fortified products, extensively hydrolyzed products, amino acid-based products, renal products, and chylothorax or long-chain 3-hydrxyacyl-CoA dehydrogenase deficiency (LCHAD) products. Therapeutic infant formulas are generally not covered by the WIC program.

Standard Infant Formulas – Refers to infant formulas used solely as a food for infants by reason of its simulation of human milk or its suitability as a complete or partial substitute for human milk and not intended for use for infants with inborn errors of metabolism or low birth weight, or who otherwise have unusual medical or dietary problems. Standard infant formulas are coverable for those members who qualify for the WIC program.

WIC Program – Refers to Woman's, Infants, and Children Program. The WIC program provides basic preventive education, supplemental foods, and individual group education to qualified participants to reinforce diet therapy provided by the health care system.

Corrected Age (Infants) – Refers to the adjusted age for a premature infant based on the chronological age minus the number of weeks or months he or she was born. For example, a one-year-old who was born three months early would have a corrected age of nine months.

Failure to Thrive – Refers to pediatric patients with insufficient weight gain or inappropriate weight loss, resulting in the failure to grow and maintain weight.

Policy

1.0 **HPSM will cover all nutritional supplements for medical conditions when medical necessity is established, including but not limited to products under the metabolic, specialized (diabetic, modular, lipid, modular protein, pulmonary, hepatic), and specialty infant categories. This coverage applies to nutritional supplements products not listed on the formulary when they are determined to be medically necessary.**

2.0 **Infant formulas, oral nutritional supplements, or enteral nutritional supplements are coverable if ALL of the following conditions are met:**

2.1 A physician has prescribed or ordered the nutritional supplementation.

2.2 Documentation is provided to substantiate the request such as the member's BMI, height, weight, history of dietary/nutrition consultation, supporting lab documentation, diagnosis, and the percentage weight loss over a defined period of time.

2.3 The member has a chronic medical condition which necessitates the use of nutritional supplementation.

2.4 The member has met the criteria as outlined below based on the following age categories:

2.4.1 **Infants (Age 0-12 months):**

2.4.1.1 Standard infant formula products (e.g. Enfamil Infant, Gentlease, ProSobee, A.R., Reguline) are not covered by the Plan. Members shall be referred to the California WIC program for details regarding potential coverage.

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2.4.1.2 Authorization for therapeutic infant products is restricted through the age of 12 months or based on the corrected age of 12 months for premature infants.

2.4.1.3 Approval of therapeutic infant products will be for the powder formulation of a product, where applicable. Approval of liquid formulations will require clinical justification as to why powders are unsuitable for treatment of the member's condition.

2.4.1.4 Requests for premature infant formulas (e.g. Neosure, Enfacare) shall be approved if **ALL** of following is met:

2.4.1.4.1 Documentation that the member is a premature infant (<37 weeks gestational age); **AND**

2.4.1.4.2 Documentation that the member's corrected weight/age is ≤50% based on the World Health Organization (WHO) growth chart.

2.4.1.5 Requests for hypo- or non-allergenic infant formulas (e.g. Alimentum, Nutramigen) for those members ≤12 months of age shall be approved if any **ONE** of the following is met:

2.4.1.5.1 Documentation that the member has cow milk protein allergy; **OR**

2.4.1.5.2 Documentation that the member has intolerance to breastmilk; **OR**

2.4.1.5.3 Documentation that the member has intolerance to standard infant formula.

2.4.2 **Pediatric Patients (1-21 years):**

2.4.2.1 Requests for nutritional supplements (e.g. Pediasure, Nutren Junior, Boost Kid Essentials) for those members between 1-21 years of age shall be approved if the following is met:

2.4.2.1.1 Documentation provided to indicate that the patient has undergone nutritional assessment conducted by a provider every 12 months; **AND**

2.4.2.1.2 Documentation that adequate nutrition is not possible or nutritionally sufficient with dietary adjustment, a diet of regular or altered consistency foods (soft or blenderized foods); **AND**

2.4.2.1.3 Documentation that the member has a severe medical condition (e.g. cancer, AIDS, e.g. cerebral palsy); **OR**

2.4.2.1.4 For toddlers between 1-2 years of age: Documentation that the member has a failure to thrive as indicated by weight-for-age or weight-for-length <5th percentile or a drop in 2 growth chart lines in 6 months for weight-for-age or weight-for-length based on World Health Organization growth standards; **OR**

2.4.2.1.5 For children ≥2 years of age: Documentation that the member has a failure to thrive as indicated by a weight-for-age or BMI-for-age <5th percentile according to the CDC growth references chart; **OR**

2.4.2.1.6 Documented oral motor or sensory feeding issues as indicated by an occupational therapist/speech language pathologist evaluation AND documentation that the patient will be receiving or is receiving feeding therapy for the condition.

2.4.2.2 Requests for infant formula for those members >12 months of age shall be approved if **ALL** of the following is met:

2.4.2.2.1 Documentation to indicate patient has met the criteria outlined under Section 1.4.2.1; **AND**

2.4.2.2.2 Documentation provided to indicate why the member cannot be transitioned to oral or enteral pediatric nutritional supplementation.

2.4.3 **Adult Patients (>21 years):**

2.4.3.1 Requests for oral and enteral nutritional supplements (e.g. Boost, Ensure, Jevity) for those members >21 years of age shall be approved if the following is met:

2.4.3.1.1 Documentation to indicate adequate nutrition is not possible or nutritionally sufficient with dietary adjustment or a diet of regular or altered consistency foods (soft or blenderized foods); **AND**

2.4.3.1.2 Documentation that the patient's BMI<18.5; **OR**

2.4.3.1.3 Involuntary weight loss >5% in 1 month, >7.5% in 3 months, or >10% in 6 months; **OR**

2.4.3.1.4 Documentation that the patient has chronic kidney disease with an albumin level of less than <4.0 and documentation member has consulted with a renal dietitian; **OR**

2.4.3.1.5 Documentation that the patient has a medical condition (e.g. cystic fibrosis, organic acidemias, PKU, maple syrup disease) requiring nutritional supplementation; **OR**

2.4.3.1.6 Documentation that the patient has an intestinal malabsorption disorders (e.g. Crohn's disease, ulcerative colitis) requiring nutritional supplementation; **OR**

2.4.3.1.7 Documentation that the patient has any other condition which may require nutritional supplementation (e.g. cancer of the mouth, injury of the head or neck, chronic neurological disorders, severe craniofacial abnormalities).

3.0 **Approval shall be granted for those members with documented current use of an enteral feeding tube (e.g. gastric, nasogastric, or jejunostomy tubes).**

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4.0 For disease-specific products, documentation is required to indicate that the member has a medical diagnosis specific to the product requested and that they have met one of the standard product's medical criteria for use.

5.0 Enteral nutrition products (e.g. Jevity, Isosource, Osmolite, Fibersource TwoCal, Nutren) taken orally based on convenience or member preference alone will not be approved as medically necessary. Approval shall be granted only for members transitioning from parenteral or enteral tube feeding to an oral diet or if other clinical justification is provided.

6.0 Approval quantities for nutritional and enteral supplements may be subject to limitations based upon medical necessity.

7.0 All requests shall be reviewed and a decision rendered no later than 5 working days and consistent with the urgency of the member's medical condition.

8.0 Exceptions may be granted on a case-by-case basis in consultation with a clinical pharmacist, director of pharmacy, or medical director.

Related Documentation

- None

Attachments

- None

Log of Revisions	
Revision Number	Revision Date
0	01/28/2019
1	01/31/2019
2	04/09/2019
3	04/18/2019
4	06/28/2019
5	11/05/2019