Weekly Provider News

December 4, 2014

New Benefit - Oral Nutrition Supplements for Adults

As of May 1, 2014 the Alliance is covering oral nutrition supplements when medically necessary for Medi-Cal eligible adult members (DHCS Policy Letter 14-003).

Prior authorization is required.
Please fax the following information to the Alliance Pharmacy Department at (831) 430-5851:

- Copy of prescribing provider's prescription,
- Complete Treatment Authorization Request (TAR) form, and
- Chart notes that address medical justification for why the member is unable to meet his/ her nutritional needs with standard or modified foods.

The Alliance will not authorize oral nutrition supplements when used for convenience or preference of members or providers.

For a complete explanation of the criteria used to review requests for medical necessity, please see the following pages from Alliance Policy 403-1136 - Enteral Nutrition Products and the Medical Necessity Criteria attachment.

All requests will be reviewed for medical necessity by the Alliance's Registered Dietitian (RD). For questions regarding this expanded benefit, contact Logan Vanderpool, RD at (831) 430-2519.

	POLICIES AND PROCEDURES
Policy #: 403-1136	**Lead Department:** Pharmacy
Title: Enteral Nutrition Products	
Original Date: 05/05/2014	**Last Revision Date:**
Approved by: Utilization Management Work Group (UMWG)	
Effective Date: 05/01/2014	

Purpose:
The purpose of this policy is to define Central California Alliance for Health's, (the Alliance's) requirements for the provision of medically necessary enteral nutrition formulas and supplements.

Policy:
The Alliance will cover enteral nutrition products for Medi-Cal members when medical necessity criteria is met.

Definitions:
BMI: Body Mass Index (BMI) is a simple index of weight-for-height that is commonly used to classify underweight, overweight and obesity in adults. It is defined as the weight in kilograms divided by the square of the height in meters (kg/m^2).
Enteral Nutrition: Involving or passing through the intestine, either naturally via the mouth and esophagus, or through an artificial opening.
Gestational Age: Is the common term used during pregnancy to describe how far along the pregnancy is. It is measured in weeks, from the first day of the woman's last menstrual cycle to the current date. A normal pregnancy can range from 38 to 42 weeks
Oral Nutrition: Nutrients of any form taken my mouth. The terms "Oral Nutrition" and "Enteral Nutrition" may be used interchangeably.
Therapeutic Diet (Regimen): A diet used as part of a treatment of a disease or clinical condition to eliminate, decrease or increase certain substances in the diet.
Tube Fed (Tube Feeding): Tube feeding is when a special liquid food mixture containing protein, carbohydrates (sugar), fats, vitamins and minerals, is given through a tube into the stomach or small bowel. The terms "Tube Feeding" and "Enteral Nutrition" may be used interchangeably.
Weight/Body Weight: actual, measured body weight of an individual.

Procedures:
1. Member Eligibility
   To receive authorization for reimbursement, the beneficiary must be eligible for Medi-Cal on the date of service.
2. Coverage:
   a. Enteral nutrition products may be covered upon authorization when used as a therapeutic diet regimen to prevent serious disability or death in patients with medically diagnosed conditions that preclude the full use of regular food. *(California Code of Regulations (CCR), Title 22, Section 51313.3.)*

b. Enteral nutrition products covered are subject to the Medi-Cal list of enteral nutrition products and utilization controls. *(Welfare and Institutions Code (CWI) Sections 14132.86, 14105.8 and 14105.395)*
c. Medical necessity will be determined using the criteria outlined in the Enteral Nutrition Products Sections of the Medi-Cal Part 2 Pharmacy Provider Manual and as defined in the Alliance's *Procedure and Assessment for Medical Necessity Determination of Enteral Nutrition Products* (Attachment B).
d. If not otherwise specified, the Alliance will cover enteral nutrition products for a minimum of six months.
e. Enteral nutrition products provided to inpatients receiving inpatient hospital services are included in the hospital's reimbursement made under the *CCR, Title 22, Section 51536*. These products are not separately reimbursable.
f. Enteral nutrition products provided to inpatients receiving Nursing Facility Level A services or Nursing Facility Level B services are not separately reimbursable.
g. Enteral nutrition products and infusion nutrients that are provided to beneficiaries during chronic outpatient hemodialysis in renal dialysis centers and community hemodialysis units, or for use during home dialysis are not separately reimbursable. Pharmacies that furnish enteral or infusion nutrition products to hemodialysis centers, community hemodialysis units or to beneficiaries for home dialysis should bill the dialysis provider directly.
h. The Alliance will inform providers about prescription and authorization procedures for the provision of enteral nutrition products, including timeliness standards, requirements for periodic physical assessment and follow-up evaluation, local referral resources and the formulary list of covered enteral nutrition products;
i. The Alliance will inform members about the process and procedures for obtaining medically necessary enteral nutrition products.
j. Food thickener may be considered for members with impaired swallowing function.

3. Non-Coverage: The following nutrition products are not covered by the Alliance under this policy:
   a. Regular food including solid, semi-solid, blenderized, and pureed foods
   b. Common household items
   c. Regular infant formula as defined in the Federal Food, Drug and Cosmetic Act (FDC Act) to meet the normal needs of healthy infants, regardless of the route of administration, or reduced iron content, or thickened form;

d. Shakes, cereals, thickened products, puddings, bars, gels, and other non-liquid products;
e. Any products for assistance with weight loss;
f. Vitamin and/or mineral supplements, except for pregnancy and birth up to 5 years of age;
g. Nutrition products used orally as a convenient alternative to preparing and/or consuming regular solid or pureed foods.

4. Requirements for Authorization:

a. The enteral nutrition product must be prescribed by a licensed provider;
b. Authorization of all enteral nutrition products requires the provider to submit an Authorization Request (AR) Form.
c. Medical authorization procedures and review for approval of enteral nutrition products shall be supervised by the Alliance's Registered Dietitian (RD).
d. Only the Alliance's Chief Medical Officer or the Medical Director/ Physician designee may make a denial.

5. Documentation

To demonstrate member meets medical necessity criteria for Enteral Nutrition Products, the following clinical information, as documented in the beneficiary's medical record, must be submitted with the AR via the Alliance's *Enteral Nutrition Product Authorization Request Form* (Attachment A) along with any additional pertinent clinical documentation.

NOTE: The documentation must be dated within 3 months at the time of AR or submission.

a. Member's full name;
b. Member's Alliance ID Number;
c. Member's date of birth (with gestational age at birth if applicable to request); and
d. Medical diagnosis related to the request for enteral or oral nutrition product coverage.
    i. For disease-specific products, documentation must also include the product's disease-specific indication (diagnosis name) and ICD-9/ICD-10 code as documented in the beneficiary's medical record.

e. Secondary Medical diagnosis and code if applicable to disease-specific or specialized formula being requested and statement why standard formula not appropriate.
f. Current Anthropometric measurements: Weight, Height (length), body mass index (BMI), head circumference (if <2 years old), amount of recent weight change, and time frame of recent weight change.
    i. Attach growth charts of height, weight, and BMI for age if member 2-21 years of age. Attach growth charts of weight, length, and head circumference for age if member 0-2 years of age.
g. Daily Nutritional Needs: Calories, protein and fluid requirement; as determined by whom, and on what date.
h. Biochemical, clinical and/or dietary indicators related to the request for a product.
i. Prior Treatments (failed or successful; duration and outcome).
j. Estimated duration of need for the formula or supplement product. Complete nutrition care plan will also be accepted.
k. Product label name being prescribed
    i. Product 11-digit Medi-Cal billing number,
    ii. Product package size (ml or gm),
    iii. Product caloric density (kcal/ml or kcal/gm),
    iv. Units per day needed,
    v. Anatomical route of administration, and
    vi. Indicate whether product will provide member with primary or secondary source of nutrition.
l. For Diabetes products: Hemoglobin A1c (HgbA1c) value measured within 6 months of the authorization request submission.
    i. If HgbA1c not available, please provide results from multiple blood glucose tests indicating consistent presence of hyperglycemia.
m. For renal products: One of the following measured within 6 months of the authorization request submission:
    i. Blood serum potassium,
    ii. BUN levels (> than 20 mg/dL for approval),
    iii. Urine Creatinine (> 26 mg/kg/day for men, or >20 mg/kg/day for women), or
    iv. Glomerular Filtration Rate (GFR) (< 60 mL/min/1.73m2 for approval).
n. For Hepatic products: Results of Liver Function Tests measured within 6 months of the authorization request submission.

6. Authorization Request Review Process
   a. Authorization Request Review Time Frames
      i. The Alliance will perform decisions and appeals regarding enteral nutrition products in a timely manner based in the sensitivity of the medical conditions as follows:
         1) **Routine (Non-Emergency) Requests:** The Alliance will process non-emergency requests for service within five (5) working days when the proposed treatment meets objective medical necessity criteria and is not contraindicated.
         2) **A Regimen Already in Place:** The Alliance will process a regimen of services already in place within five (5) working days as consistent with the urgency of the member's medical condition, as required by Health and Safety Code (CCHS) Section 1367.01.
         3) **Expedited Requests:** The Alliance will provide for expedited requests on services and process within three (3) working days when a provider or the Alliance determines that the standard timeframes above could seriously jeopardize the member's life or health or ability to attain, maintain or regain maximum function.
         4) **Emergency Requests:** The Alliance will not require prior authorization of service when there is a bona fide emergency requiring immediate treatment as required by CWI, Section 14103.6.
      ii. If the Alliance determines there is insufficient information to render a medically appropriate decision, the Alliance may extended the request process for fourteen (14) calendar days from the date of receipt.
      iii. The decision may be deferred an additional fourteen (14) calendar days at the request of the member or the member's provider. The Alliance may also defer the decision for the same time period when the need for additional information is in the member's interest.
      iv. If the Alliance delays any decision past 28 calendar days, the request is considered approved and shall by immediately processed as such.
   b. Notification of Determination
      i. Approval of an authorization request is communicated to the member through their provider. Providers are notified of approval via fax.
      ii. The Alliance will provide written notification to any provider and member when an Enteral Nutrition Product authorization has been extended,

deferred, denied or modified in an amount, duration, or scope that is less than what is submitted in the original requested.

iii. Written notification of determination will contain procedures for appeals for both providers and members.

7. Quantity Restrictions
   Claims billed for each dispensing of authorized enteral or oral nutrition products benefit are limited to no more than a 31-day supply. A 31-day supply is defined as the patient's daily caloric requirement for product (specified by licensed prescriber on the prescription), multiplied by 31 days, divided by caloric density of product (kcal/milliliter of liquid product, or kcal/gram of powdered product), **and rounded up to the smallest available package size (can, bottle, bag, or brikpak). Rounding up does not include rounding up** to six packs or full cases of product.

8. Referrals to Woman, Infants and Children's (WIC) Program:
   a. WIC Program services are not covered under the Medi-Cal enteral nutrition product service. However, the Alliance maintains Memorandum of Understanding with WIC to promote member utilization of WIC services through member inquiries and provider and community agency referrals;
   b. As part of the referral process, providers shall periodically provide the WIC Program with a current hemoglobin or hematocrit laboratory value. Providers shall also document laboratory values and the referral in the beneficiary's medical record; and
   c. As part of the beneficiary's initial health assessment, or as part of the initial evaluation of pregnant beneficiaries, providers shall refer and document the referral of pregnant, breastfeeding, or postpartum beneficiaries, or a parent/guardian of a child under the age of five to the WIC Program as mandated by Title 42 Code of Federal Regulations (CFR) Section 431.63(c).

9. Informing Providers and Members:
   a. The Alliance shall inform providers about prescription and authorization procedures for the provision of enteral nutrition products, including timeliness standards, requirements for periodic physical assessment and follow-up evaluation, local referral resources, and the formulary list of covered enteral nutrition products (formulas) annually via the Provider Manual.
   b. The Alliance shall inform members about the processes and procedures for obtaining medically necessary enteral nutrition products annually via the Member

Handbook Evidence of Coverage.

References:

Alliance Policies:

405-1201 - Memoranda of Understanding (MOU)
402-1207 - Perinatal Services
404-1201 - Authorization Request Process

Regulatory:

OIL131-14
22 CCR, Section 51313.3
44 CFR, Section 431.63(c)
CWI, Section 14132.86
CWI, Section 141.32.86 paragraph (ab) (1-4)
CWI, Section 14105.395
CWI, Section 14105.8
CCHS, Section 1367.01
FDC Act, Chapter IV; Section 412

Contractual:

Legislative:

MMCD Policy Letter:

Policy Letter 14-003

Supersedes:

Other References:

Attachment A: Alliance Enteral Nutrition Product Authorization Request Form
Attachment B: Procedure and Assessment for Medical Necessity Determination of Enteral Nutrition Products

Lines of Business This Policy Applies To	LOB Effective Dates
☒ Medi-Cal	(01/01/1996 – present)
☐ Healthy Families	(07/01/1998 – 01/31/2014)
☐ Healthy Kids Santa Cruz	(07/01/2004 – present)
☐ Alliance Care IHSS	(07/01/2005 - present)
☐ Access for Infants and Mothers	(02/01/2009 – present)
☐ Individual Conversion Plan	(01/01/2005 - 01/01/2014)
☐ Santa Cruz County LIHP	(01/01/2012 – 12/31/2013)
☐ Monterey County LIHP	(03/01/2013 – 12/31/2013)

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Revision History:

Review Date	Revised Date	Changes Made By	Approved By

MEDICAL NECESSITY CRITERIA

Purpose:
The purpose of this procedure is to outline the medical necessity criteria that Central California Alliance for Health (the Alliance) follows to determine medical appropriateness for the authorization of enteral nutrition formulas and supplements. These criteria do not pertain to the supplies necessary for delivery of enteral nutrition formulas and supplements. For supplies, please reference the DME Prior Authorization list, as delineated in DHCS Policy Letter 14-003

Program Coverage:
Enteral nutrition products may be covered upon authorization when used as a therapeutic regimen to prevent serious disability or death in patients with medically diagnosed conditions that preclude the full use of regular food and when medically necessary.

To receive authorization for reimbursement, a member must be eligible for Medi-Cal and meet other program and medical criteria on the date of service.

The authorization request for enteral nutrition products will be reviewed for medical necessity and approval by The Alliance's Registered Dietitian (RD). To comprehensively review requests for medical necessity, the following clinical data must be submitted along with an Authorization Request (AR) as summarized through chart notes or via completing the Alliance's Enteral and Oral Nutrition Product Authorization Request Form (Attachment A).

1. Member's full name
2. Member's Alliance ID Number
3. Member's date of birth (with gestational age at birth if applicable to requested product)
4. Medical diagnosis related to the request for enteral or oral nutrition product coverage
    a. For disease-specific products, documentation must also include the product's disease-specific indication (diagnosis name) and ICD-9-CM code as documented in the beneficiary's medical record
5. Secondary Medical diagnosis and code if applicable to disease-specific or specialized formula being requested and statement why standard formula is not appropriate.
6. Current Anthropometric measurements: Weight, Height (length), body mass index (BMI), head circumference (if ≤2 years old), amount of recent weight change, time frame of recent weight change.
    a. Attach growth charts of height, weight & BMI for age if member 2-21 years of age. Attach growth charts of weight, length, and head circumference for age if member 0-2 years of age
7. Daily Nutritional Needs: Calories, protein and fluid requirements; as determined by whom, and on what date.
8. Biochemical, clinical and/or dietary indicators related to the request for a product
9. Prior Treatments (duration and outcome: failed or successful)
10. Estimated duration of need for the formula or supplement product and/or attached

complete nutrition care plan

11. Product label name being prescribed
    a. Product 11-digit Medi-Cal billing number
    b. Product package size (ml or gm)
    c. Product caloric density (kcal/ml or kcal/gm)
    d. Units per day needed
    e. Route of administration
    f. Indicate whether product will provide member with primary or secondary source of nutrition.
12. **For Diabetes products:** Member's Hemoglobin A1c (HgbA1c) value measured within 6 months of this request submission.
    a. (If HgbA1c not available, please provide results from multiple blood glucose tests indicating consistent presence of hyperglycemia.)
13. **For Renal products:** One of the following within 6 months of request:
    a. Blood serum potassium
    b. BUN levels (> than 20 mg/dL for approval)
    c. Urine Creatinine (> 26 mg/kg/day for men, or >20 mg/kg/day for women)
    d. Glomerular Filtration Rate (GFR) (< 60 mL/min/1.73m2 for approval)
14. **For Hepatic products:** Results of member's Liver Function Tests measured within 6 months of this authorization request submission.

Authorization Process:

I. Authorization Request Review Process
   a. Authorization Request Review Time Frames
      i. The Alliance will perform decisions and appeals regarding enteral nutrition products in a timely manner based in the sensitivity of the medical conditions as follows:
         1. **Routine (Non-Emergency) Requests:** The Alliance will process non-emergency requests for service within five (5) working days when the proposed treatment meets objective medical necessity criteria and is not contraindicated;
         2. **A Regimen Already in Place:** The Alliance will process a regimen of services already in place within five (5) working days as consistent with the urgency of the member's medical condition., as required by health and Safety Code Section 1367.01;
         3. **Expedited Requests:** The Alliance will provide for expedited requests on services and process within three (3) working days when a provider or the Alliance determines that the standard timeframes above could seriously jeopardize the member's life or health or ability to attain, maintain or regain maximum function.

4. **Emergency Requests:** The Alliance will not require prior authorization of service when there is a bona fide emergency requiring immediate treatment as required by W7I Code Section 14103.6.

ii. If the Alliance determines there is insufficient information to render a medically appropriate decision, the Alliance may extended the request process for fourteen (14) calendar days from the date of receipt.

iii. The decision may be deferred an additional fourteen (14) calendar days at the request of the member or the member's provider. The Alliance may also defer the decision for the same time period when the need for additional information is in the member's interest.

iv. If the Alliance delays any decision on a service beyond the time periods listed above, the request is considered approved and shall by immediately processed as such.

b. Notification of Determination

i. Approval of an authorization request is communicated to the member through their provider. Providers are notified of approval via fax.

ii. The Alliance will provide written notification to any provider and member when an Enteral Nutrition Product authorization has been extended, deferred, denied or modified in an amount, duration, or scope that is less than what is submitted in the original requested.

iii. Written notification of determination will contain procedures for appeals for both providers and members.

Medical Criteria:

Approval for enteral nutrition products occurs when products are medically necessary. To be considered medically necessary, there must be sufficient data provided to support the beneficiary's inability to consume regular foods and that his/ her nutritional needs can only be met with oral or enteral nutrition supplements and formulas. To be considered for authorization of any enteral or oral nutrition products, the beneficiary must meet one of the following criteria:

I. Enteral Nutrition Products Administered via Tube:

For enteral nutrition products administered through a tube, the beneficiary must meet one of the following:

1. Enteral nutrition formulas administered via tube are considered medically necessary for individuals with documented medical diagnosis that
    a. interfere with swallowing or
    b. are associated with impaired motility or obstruction of the proximal gastrointestinal tract that requires enteral nutrition products administered through a feeding tube distal to the obstruction
2. Documentation must define whether enteral nutrition formula is being used to
    a. Provide greater than 50% of nutritional needs (primary source of nutrition).

b. Or provides less than 50% of nutrients necessary to prevent malnutrition (secondary source of nutrition) when the formula is used as:
    i. Part of a defined plan of care transitioning off 100% tube feeding regimen
    ii. Supplemental nutrition to meet nutrient needs when member is chronically unable to meet 100% nutritional needs via intake of regular foods by mouth.

3. Authorization requests shall document a medical basis for the inability to maintain appropriate body weight and nutritional status prior to initiating or after discontinuing use of the enteral formula via tube as well as ongoing evidence of response to the implemented enteral nutrition therapy regimen. New documentation supporting current determined nutritional needs (i.e. requested formula type and amount) must be submitted with each new authorization request; even if amount requested does not change.

II. Oral Nutrition Products:

For nutrition products administered orally, beneficiary must meet at least one of the following:

1. A documented chronic medical diagnosis and inability to meet his/her nutritional needs with dietary adjustment of regular or altered-consistency (soft or pureed) foods. There must be clinical indicators identified and documented that supports the beneficiary is nutritionally at risk. Clinical criteria indicative of potential malnutrition and need for oral nutrition supplements include but are not limited to diagnoses of:
    a. AIDS with significant weight loss
    b. Anatomic structures of the GI tract impairing adequate digestion and absorption
    c. Increased metabolic or caloric needs due to excessive burns, infection, trauma or prolonged fever
    d. Chemotherapy or Radiation for cancer treatment with significant weight loss
    e. Crohn's Disease with significant weight loss
    f. Decubitus Ulcers (≥ Stage 3, or ≥Stage 2 also with recent significant weight loss, BMI ≤18.5 or <90% Ideal Body Weight)
    g. Chronic Kidney Disease on Hemodialysis or Peritoneal Dialysis with significant weight loss.
    h. Chronic Pancreatitis with significant weight loss
    i. Neurological disorders that impair swallowing or chewing
    j. Prolonged nutrient loses due to malabsorption syndromes or short/ small/ inadequate bowel syndromes
    k. Radiation enteritis
    l. Treatment with anti-nutrient or catabolic properties

m. Ulcerative colitis with significant weight loss
n. In neonates, infants and children:
    i. Very low birth weight (birth weight <1500g)
    ii. Small for gestational age (SGA)
o. Beneficiaries under 21 years of age with documented clinical signs and symptoms including anthropometric status indicative of (stunting, wasting, or underweight) of nutritional risk. Standard and modified growth charts should be used to document nutritional need and patient deficiency.
p. Severe swallowing or chewing difficulty due to one of the following:
    i. Cancer in the mouth, throat, or esophagus
    ii. Injury, trauma, surgery or radiation therapy involving the head or neck
    iii. Chronic neurological disorders
    iv. Severe craniofacial anomalies
q. Transitioning from parenteral or enteral tube feeding to an oral diet.
r. For beneficiaries over 21 years of age, any other medical condition with associated significant weight loss or underweight status defined by BMI <18.5 kg/m2 or less than 90% Ideal Body Weight will be considered.

III. Disease-Specific Formulas:

Medical necessity criteria for specific disease-based formulas are listed below.

1. **Standard Nutrition Products** will be approved for authorization when the beneficiary meets one of the above-mentioned criteria.

2. **Specialized Nutrition Products** are indicated for specific disease states. The beneficiary must meet one of the above-mentioned medical necessity criteria, have a documented medical diagnosis specific to the product requested AND must meet one of the following criteria for:
    a. For *carbohydrate modular* products: there must be documented clinical evidence to support that the beneficiary is unable to meet caloric nutritional need with the current use of nutrition formula or supplement and has an impairment of carbohydrate metabolism.
    b. For *lipid (fat) modular* products:
        i. Has a documented diagnosis of inability to digest or absorb conventional fats
        ii. Has a documented diagnosis of uncontrolled seizure disorder that cannot otherwise be medically managed

c. For *protein modular products*, there must be documented clinical evidence to support the beneficiary is unable to meet protein requirement with current use of a high protein enteral or oral nutrition product.

3. **Elemental or Semi-Elemental Nutrition Products** administered orally or through a feeding tube, will be approved for authorization when the beneficiary meets one of the following:
   a. Have an intestinal malabsorption diagnosis (ICD-9-CM codes 579.0 - 579.9), lactose intolerance alone is excluded
   b. Have a chronic medical diagnosis and presents clinical signs and symptoms of inability to absorb nutrients or to tolerate intact protein that cannot otherwise be medically managed. The beneficiary must have a history of use with a *standard* or *specialized disease-specific* nutrition product that failed to provide adequate nutrition unless such products are medically contraindicated.

ICD-9-CM	DIAGNOSIS: Intestinal Malabsorption
579	**Intestinal Malabsorption**
579.0	**Celiac disease** crisis infantism rickets Gee(-Herter) disease Gluten enteropathy Idiopathic steatorrhea Nontropical sprue **Definition:** Malabsorption syndrome due to gluten consumption; symptoms include fetid, bulky, frothy, oily stools; distended abdomen, gas, asthenia, electrolyte depletion and vitamin B, D and K deficiency.
579.1	**Tropical sprue** Sprue NOS Tropical **Definition**: Diarrhea, occurs in tropics; may be due to enteric infection and malnutrition.
579.2	**Blind loop syndrome** Postoperative blind loop syndrome **Definition**: Obstruction or impaired passage in small intestine due to alterations, from strictures or surgery; causes stasis, abnormal bacterial flora, diarrhea, weight loss, multiple vitamin deficiency and megaloblastic anemia. **TIP**: do not assign additional code 997.4 Digestive system complications.
579.3	**Other and unspecified postsurgical nonabsorption** Hypoglycemia or Malnutrition {following gastrointestinal surgery}
579.4	**Pancreatic Steatorrhea** **Definition:** Excess fat in feces due to absence of pancreatic juice in intestine.

579.8	**Other specified intestinal malabsorption** Enteropathy: Exudative Protein-losing Steatorrhea (chronic)
579.9	**Unspecified intestinal malabsorption** (lactose intolerance alone- excluded) Malabsorption syndrome NOS (lactose intolerance alone, excluded)

4. **Metabolic Nutrition Products** administered orally or through a feeding are restricted to beneficiaries with a diagnosis of inborn errors of metabolism (ICD-9 Codes 270.0-271.1, 271.8, 277.0 & 277.8).

ICD-9-CM CODE	DIAGNOSIS: Inborn Errors of Metabolism (IEM)
270	**Disorders of amino-acid transport and metabolism**
270.0	Disturbances of amino-acid transport
270.1	Phenylketonuria [PKU] **Definition**: Inherited metabolic condition causing excess phenylpyruvic and other acids in urine; results in mental retardation, neurological manifestations—including spasticity and tremors— light pigmentation, eczema and mousy odor.
270.2	Other disturbances of aromatic amino-acid metabolism
270.3	Disturbances of branched-chain amino-acid metabolism
270.4	Disturbances of sulphur-bearing amino-acid metabolism
270.5	Disturbances of histidine metabolism
270.6	Disorders of urea cycle metabolism
270.7	Other disturbances of straight-chain amino-acid metabolism
270.8	Other specified disorders of amino-acid metabolism
270.9	Unspecified disorder of amino-acid metabolism
271	**Disorders of carbohydrate transport and metabolism**
271.0	Glycogenosis **Definition**: Excess glycogen storage; rare inherited trait affects liver, kidneys; causes various symptoms depending on type, though often weakness and muscle cramps.

271.1	Galactosemia **Definition**: Any of three genetic disorders due to defective galactose metabolism; symptoms include failure to thrive in infancy, jaundice, liver and spleen damage, cataracts, and mental retardation.
271.8	Other specified disorders of carbohydrate transport and metabolism (lactose intolerance alone, excluded)
277	**Other unspecified disorders of metabolism**
277.0	Cystic fibrosis **Definition**: Genetic disorder of infants, children and young adults marked by exocrine gland dysfunction; characterized by chronic pulmonary disease with excess mucus production, pancreatic deficiency and high levels of electrolytes in the sweat. **ICD-9-CM Code Cystic Fibrosis Diagnosis** 277.00 Without mention of meconium ileus 277.01 With meconium ileus 277.02 With pulmonary manifestations 277.03 With gastrointestinal manifestations 277.09 With other manifestations
277.8	Other specified disorders of metabolism **ICD-9-CM Code Diagnosis** 277.82 Carnitine deficiency due to inborn errors of metabolism 277.85 Disorders of fatty acid oxidation 277.86 Peroxisomal disorders 277.87Disorders of mitochondrial metabolism

5. **Specialty Infant Nutrition Products** administered orally or through a feeding tube will be approved for authorization when the criteria listed below, specific to the product and/or product type requested, are met.
    a. Premature and low birth weight products:
        i. Products 20 or 22 kcal/ounce are limited to beneficiaries born prior to 37 weeks gestation or birth weight less than 3500 grams
        ii. Products 24 or 30 kcal/ounce are authorized for one month only per request and limited to current weight (at time of dispensing) less than 3500 grams
    b. Human Milk Fortifier products are authorized for one month only per request for beneficiaries with current weight less than 3600 grams and meet one of the following:

i. Fully breast fed or receiving only human milk and no other infant nutrition product (formula) used at the same time.
ii. Breast fed or receiving human milk in combination with infant nutrition product (formula) administered only through a feeding tube.
iii. NOTE: Weight gain is expected to be 33-34 grams/day when calculating 31-day supply limits, to predict weight during an authorization term

c. Extensively hydrolyzed powder liquid products ("hypo-allergenic" or "semi-elemental")
    i. Beneficiary must have a current diagnosis of cow's milk protein allergy or intolerance to breast milk or infant formula
    ii. For liquid form, beneficiary must meet one of the following:
        1. Born less than 34-weeks gestational
        2. Birth weight less than 1800 grams
        3. Currently diagnosed with immune function disorder
        4. Documented intolerance to covered extensively hydrolyzed powdered product
d. Nutramigen with Enlfora LGG Powder (extensively hydrolyzed product with probiotic) is limited ONLY to beneficiaries that meet all of the following:
    i. Current diagnosis of cow's milk protein allergy or intolerance to breast milk or infant formula
    ii. No immune function disorder
    iii. Current body weight greater than 3500 grams
    iv. Documented intolerance to other comparable covered extensively hydrolyzed products without prebiotic in powder or liquid (when qualified) form
e. 100% Amino Acid-Based (100% AA) products are limited to beneficiaries that meet one of the following:
    i. Documented intolerance to breast milk or infant formula
    ii. Extensively hydrolyzed (semi-elemental) products are contraindicated
    iii. Documented in hospital use prior to discharge
f. Fat Malabsorption Products are limited to:
    i. Fat malabsorption diagnosis not effectively addressed by breast milk, regular infant formula, and extensively hydrolyzed protein
g. Renal Products are limited to beneficiaries that meet one of the following:
    i. Renal function impairment
    ii. Hypercalcaemia
    iii. Hypocalcemia due to hyperphosphatemia
h. Enfaport Product (Chylothorax or LCHAD products) are limited to beneficiaries that meet one of the following diagnoses
    i. Chylothorax

   ii. Long-Chain-3-hydroxyacyl-CoA-dehydrogenase deficiency (LCHAD deficiency)
   iii. Cystic Fibrosis
   iv. Diagnosed Mitochondrial Disorder
6. **Thickener.** Food thickener may be considered for members with impaired swallowing function.

Not Medically Necessary:
Under certain circumstances, the Alliance does not consider the use of nutrition products ingested by mouth or via tube to be medically necessary. Examples of such circumstances include, but are not limited to the following:

1. A medical history and physical examination have been performed and other possible alternative interventions have been identified to improve member's nutritional status.
2. The member is identified at nutritional risk with weight loss and or underweight status (as defined below) but has the ability to meet nutritional needs through regular food consumption.
3. The use of the enteral or oral nutrition products are based on the convenience or preference of the member or provider (such as picky eaters) and adequate nutrition status can be obtained through oral intake of standard foods.
4. Oral nutrition products are used as supplements to a normal or regular diet in a member showing no clinical indicators of nutritional risk.
5. When the enteral product is used for individuals with disorders of swallowing where non-medical food is tolerated.
6. The member has food allergies, lactose intolerance or dental problems, but has the ability to meet his or her nutritional requirements through standard food sources.
7. No medical history or physical examination has been taken and there is no documentation that supports need for enteral or oral nutrition products.

Non-Coverage:
The following nutrition products are *not* covered by the Alliance's Policy *Enteral Nutrition Products*; ######
1. Regular food, including solid, semi-solid, blenderized and pureed foods
2. Common household items
3. Regular infant formula as defined in the Federal Food, Drug and Cosmetic Act (FD&C Act) to meet the normal needs of healthy infants, regardless of the route of administration, or reduced iron content, or thickened form
4. Shakes, cereals, thickened products, puddings, bars, gels and other non-liquid products
5. Products for assistance with weight loss
6. Vitamin and/or mineral supplements except for pregnancy and birth up to 5 years of age;
7. Nutrition products used orally as a convenient alternative to preparing and/or consuming regular solid or pureed foods.

LA ALIANZA • THE ALLIANCE CENTRAL CALIFORNIA ALLIANCE FOR HEALTH	**MEDICAL NECESSITY CRITERIA**

Definitions:

1. **Underweight:** Defined as EITHER <90% IBW OR BMI <18.5 for adult members (>21 years of age); BMI for age plotted <5th percentile (for pediatric members <21 years of age).
2. **Significant weight loss:**
    - **a.** Adults (>21 years old):
        - **i.** Unintentional loss of 5% or more of usual body weight within 1 month
        - **ii.** Unintentional loss of 7.5% or more of usual body weight within 3 months
        - **iii.** Unintentional loss of 10% or more of usual body weight within 6 months
    - **b.** Pediatric Patients (0-20 years old):
        - **i.** 5% weight loss in 1 month OR
            - **1.** 0-12 months age: no weight gain >1 months
            - **2.** 1-3 years age: no weight gain >3 months
            - **3.** 3-20 years age: no weight gain x 1 year.
3. **Dysphagia:** Difficulty in swallowing
4. **Failure to Thrive:**
    - **a. In Pediatric Patients:** Weight for age that falls below the 5th percentile on multiple occasions, a weight deceleration that crosses two major percentile lines on a growth chart, weight for length below the 10th percentile or weight velocity for age less than the 5th percentile.
    - **b. In Geriatric Members:** syndrome of global decline that occurs in older patients as an aggregate of frailty, cognitive impairment, and functional disability, complicated by medical comorbidities and psychosocial factors.
5. **Malnutrition:** An acute, subacute or chronic state of nutrition, in which a combination of varying degrees of overnutrition or undernutrition with or without inflammatory activity have led to a change in body composition and diminished function.
6. **Medical Food:** A food which 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
7. **Modular Enteral Feeding:** Formulation created by combination of separate nutrient sources or by modification of existing formulations.
8. **Neonate:** An infant during the first 4 weeks (28 days) of life
9. **Nutritionally-at-Risk Neonates:** Neonates should be considered at nutrition risk if they have any of the following:
    - **a.** Low birth weight (<2500 g) even in the absence of gastrointestinal, pulmonary, or cardiac disorders.
    - **b.** Birth weight less than the 10th percentile for gestational age on fetal weight curves.

   c. Weight for corrected gestational age less than the 10th percentile on fetal weight curves.
   d. Acute weight loss of 5% or more.

10. **Nutritionally-at-Risk Children:** Children should be considered at nutrition risk if they have any of the following:
   a. A weight for length or weight for height for sex less than the 10th percentile or greater than the 95th percentile.
   b. Body mass index for age and sex at or below the 10th percentile. Increased metabolic requirements.
   c. Impaired ability to ingest or tolerate oral feedings.
   d. Documented inadequate provision of or tolerance of nutrients.
   e. Inadequate weight gain or a significant decrease in usual growth percentile on growth chart
11. **Nutritionally-at-Risk Adults:** Adults may be considered at nutrition risk if they have any of the following:
   a. Involuntary loss of ≥10% of usual body weight within 6 months, or involuntary loss of ≥5% of usual body weight in 1 month.
   b. Body mass index less than 18.5 kg/m^2 or body weight less than 90% Ideal Body Weight
   c. Increased metabolic requirements.
   d. Altered diets or diet schedules.
   e. Inadequate nutrition intake, including not receiving food or nutrition products for greater than 7 days
12. **Oral Nutrition:** Nutrients taken by mouth.
13. **Therapeutic Diet (Therapeutic Regimen):** A diet used as part of a treatment of a disease or clinical condition to eliminate, decrease, or increase certain substances in the diet**.**
14. **Weight / Body Weight:** Actual, measured body weight of an individual.

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