

## POLICY AND PROCEDURE

<b>POLICY NAME:</b> Reviews for Nutritional Products	<b>POLICY ID:</b> FL.UM.20
<b>BUSINESS UNIT:</b> Sunshine State Health Plan	<b>FUNCTIONAL AREA:</b> Utilization Management
<b>EFFECTIVE DATE:</b> 06/2015	<b>PRODUCT(S):</b> Managed Medical Assistance (MMA), Child Welfare (CW), and Long Term Care (LTC), CMS, Serious Mental Illness (SMI)
<b>REVIEWED/REVISED DATE:</b> 06/2015; 08/2016, 12/2017, 02/19, 05/20, 07/2021, 07/2022, 9/2022, 2/2023, 02/2024	
<b>REGULATOR MOST RECENT APPROVAL DATE(S):</b> Please refer to system of record – Archer	

**POLICY STATEMENT:**

It is the policy of Sunshine Health to cover nutritional products when medically necessary and covered under the member’s specific benefit plan. Nutritional products include enteral supplements and oral nutritional supplements. Sunshine Health considers coverage of nutritional products when appropriate and consistent with good medical practice, and after review on an individual basis, for the specific indications outlined in this policy.

**PURPOSE:**

Sunshine Health’s Review of Nutritional Products clinical policy supports the management of the MMA, CW, CMS, SMI and LTC benefit for private duty nursing as described in the Florida Agency for Health Care Administration (AHCA) Provider Handbook along with the Category Lists for the HCPCS Codes for Enteral Formula.

**SCOPE:**

Sunshine Health Utilization Department for Managed Medical Assistance (MMA), Child Welfare (CW), CMS Serious Mental Illness (SMI) and Long Term Care (LTC) product lines. This policy applies to all directors, officers, and employees of Centene Corporation, its affiliates, health plans, and subsidiary companies (collectively, the “Company”).

**DEFINITIONS:**

**Enteral nutrition** is commonly administered as tube feedings. Enteral nutrition/supplements provide sole/supplemental nutritional needs via absorption through the stomach and small intestine. Enteral support is considered reasonable and medically necessary in certain disease states in which a member is unable to maintain adequate oral nutritional intake for an extended period of time. In such cases, the recipient is unable to absorb sufficient nutrients to maintain weight and strength.

**Oral Nutritional Product** is any product prescribed to be ingested by the oral route for the purpose of restoring or maintaining nutrition, weight, and strength commensurate with the member’s overall health status

**Nutritional Product Benefits**

- Enteral nutritional supplements - If a physical illness or injury causes the inability to eat, nutrition must be supplied in a different way. One method is enteral nutrition, which is commonly administered as tube feedings. Enteral nutrition/supplements provide sole supplemental nutritional needs via absorption through the stomach and small intestine. Enteral support is considered reasonable and medically necessary in certain disease states in which a member is unable to maintain adequate oral nutritional intake for an extended period of time. In such cases, the recipient is unable to absorb sufficient nutrients to maintain weight and strength. Medical documentation such as hospital records, dietician evaluation and clinical findings must provide the basis for the request for supplements. Tube feedings included nasogastric, percutaneous gastrostomy or jejunostomy tubes.
- Oral nutritional supplements - There are many physical conditions that cause inability to eat enough food to maintain health. Some examples are decreased appetite, difficulties in swallowing, or any type of surgery that interferes with eating. In conditions where eating is still possible, oral nutritional products can be used with the purpose of restoring or maintaining adequate nutritional status, weight, or strength for the maintenance of overall health. Many oral nutritional products are widely available through commercial retail; however, there are some products that require prescription of a doctor.

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The review and criteria for parenteral and drug infusion pumps and supplies is considered independent of this nutritional product policy.

## **PROCEDURE:**

### **Review Process**

To assist in determining the medical necessity of nutritional products, the clinical criteria established in this policy will be applied. A request for medical necessity review is consistent with Sunshine Health medical policies:

- FL.UM.02.01 - Medical Necessity Review and Continuity of Care
- FL.UM.02- Use of Clinical Criteria
- Any decision to deny, reduce, suspend, or terminate services must be made by a Sunshine Health Medical Director as outlined in the policy Use of Clinical Criteria FL.UM.02
- Determinations and provider notifications will be made according to the expediency of the case as described in the Timeliness of UM Decisions and Notifications FL.UM.05

### **Information Required for the Initial Review**

The treating provider must submit to Sunshine Health's utilization management department the following information when initially requesting nutritional products:

- Physician's signed order or prescription not greater than three (3) months old
- Product name
- Administration rate
- Route of administration
- Complete description of clinical circumstances which justifies the requested product
- Diagnoses or physical anomalies of member which are causing the need for the supplemental nutritional products
- Deficiencies in member's nutritional status due to diagnosis
- Documentation of permanent gastrointestinal impairment in cases where this applies
- Documentation of the presence of an inborn error of metabolism, or inherited metabolic disorder, when such justification exists
- Estimated duration of therapy
- An account of the current member's nutritional status, including height and weight and current percentiles in pediatric members
- Change in member's weight and current height, weight, and body mass index with at least 2 index points over the last three (3) months
- An explanation of why shelf products will not meet nutritional needs in any request for a special need's formula
- An attestation that the member's nutritional needs cannot be met using dietary modifications, including trials and failures

## **Specific Clinical Information/Criteria**

### **Initial Review**

Upon receipt of the information provided by the treating physician, the review for medical necessity for nutritional products will consider but is not limited to the following:

- The primary source of nutrition is via an enteral tube feeding.
- The member has a metabolic disorder that requires specialty feeding.
- All requests must include current height, weight, and body mass index at least 2 index points
- The length of the initial approval is for up to three (6) months.

### **Criteria to support need for nutritional product**

If member is an adult (over the age of 21):

- Current BMI:
  - BMI < 18.5 kg/m
  - BMI < 20kg/m and is associated with an unintentional weight loss of greater than 5% in the past 3 months
- Unintentional weight loss of greater than 10% in the past 3-6 months
- Anticipated inadequate oral intake over a period greater than 7 days (e.g., chemotherapy)
- Documented current diagnosis that may be associated with need for nutritional support/supplement, including:

- GI cancers
- Ulcerative colitis
- Ischemic bowel disease
- Intractable nausea/vomiting
- Alzheimer's disease
- Dysphagia
- CVA with inability to eat/swallow
- Short gut syndrome
- Jaw fracture
- HIV
- Renal Failure
- Respiratory Failure

If member is a child (birth to up to age 21):

Documented pediatric diagnosis, as listed below, that may be associated with need for nutritional support/supplement:

- Inability to ingest adequate nutrition orally
- Disorders of sucking and swallowing
- Prematurity
- Neurologic and neuromuscular disorders (e.g., cerebral palsy)
- Congenital diseases of the GI tract
- Tumors
- Trauma to the head and neck
- Inability to take oral intake (e.g., ventilator)
- Disorders of digestion and absorption
- Cystic fibrosis
- Short bowel syndrome
- Inflammatory bowel disease
- Congenital GI tract abnormalities
- Enteritis
- Autoimmune enteropathy
- Immunodeficiency (e.g., AIDS, severe combined immunodeficiency)
- Graft versus host disease
- Chronic liver disease (e.g., biliary atresia)
- Food allergy
- Enterocolitis evidenced by Protracted vomiting (generally 1-3 hours after feeding and diarrhea (often bloody to BOTH milk-based and soy-based formula
- Enteropathy evidenced by protracted diarrhea, often fatty, to cow's milk, soy and other foods. Celiac disease may be a cause- which should be proven
- Food protein-induced proctocolitis as evidenced by blood-streaked stools to breast milk, milk, and soy formulas
- Allergic eosinophilic esophagitis evidenced by chronic GERD, food refusal, abdominal pain, dysphagia. Most is due to cow's milk intolerance. Often associated with asthma and atopic dermatitis. Requirement: allergy testing completed, and results provided, and an elimination diet trial completed with results provided
- Diseases that require specific dietary restrictions
  - Inborn errors of metabolism e.g., phenylketonuria
  - Need for a ketogenic diet in epilepsy

### **Redetermination**

Prior to the expiration of the initial authorization period, the requesting provider must submit to Sunshine Health's utilization management department information on the member's status in order for a review for a subsequent approval. Required information for continued authorization must be submitted per "Specific Clinical Information/Criteria" and "Information Required for the Initial Review" as outlined in this policy.

### **Limitations**

The limitations or exclusions for authorization of nutritional / enteral products are described below:

- Enteral products for members who are institutionalized are not covered.
- Enteral products for weight reduction, bodybuilding, athletic performance enhancement, anorexia, or bulimia are not covered.
- Banked human breast milk is not covered.

- Standard milk and soy based infant formulas are not covered.
- Ketogenic products are covered only for patients with a diagnosis of seizures.
- Products for inborn errors of metabolism are covered, with documentation of appropriate diagnosis.
- Elemental diets are covered only with a documented diagnosis of a malabsorption condition.
- Modular products are covered for conditions other than failure to thrive. The 50% of Calories requirement does not need to be met for modular products.

For members aged 21 and older:

- Standard 1 – 2 kcal/ml products are covered if product is the member’s sole source of nutrition.
- Member must have documented diagnosis of a barrier to ingestion, digestion, and/or absorption of regular food, or a diagnosis of renal failure or hepatic failure.
- Elemental products are covered only with a documented diagnosis of a malabsorption condition.
- Modular products and nutritionally incomplete products are not covered.
- Pregnant and lactating women who are eligible for the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program must receive nutritional products through WIC.
  - No verification of coverage needed through WIC for Kate Farms Products. All Kate Farms Products are reviewed by the plan.

Members under age 21:

- For MMA, CW and LTC members, the EPSDT process in policy FL.UM.08 Management of Requests as part of EPSDT or as a Potential Benefits followed.
- Commercial enteral products are covered if such products constitute 50% or more of total patient caloric intake. Products are not approved to augment normal dietary sources of nutrition.
- Member must have medical condition that limits his or her ability to ingest, digest, or absorb regular food.
- Enteral products will not be approved for the diagnosis of “failure to thrive.”
- For members under five years of age, the WIC program must be the primary provider of nutritional products if member is WIC eligible.
  - No verification of coverage needed through WIC for Kate Farms Products. All Kate Farms Products are reviewed by the plan.
- Feeding supply kits must correspond to the method of administration.

**REFERENCES:**

AHCA Provider Handbook.  
 FL.UM.05 Timeliness of UM Decisions and Determinations policy and procedure  
 FL.UM.02 Use of Clinical Criteria  
 FL.UM.02.01 Medical Necessity Review  
 FL.UM.08 Management of Requests as part of EPSDT or as a Potential Benefit  
 Freijer K, Bours MJ, Nuijten MJ, Poley MJ, Meijers JM, Halfens RJ, Schols JM. The economic value of enteral medical nutrition in the management of disease-related malnutrition: a systematic review. J Am Med Dir Assoc. 2014 Jan; 15(1):17-29. doi: 10.1016/j.jamda.2013.09.005. Epub 2013 Nov 13  
 Florida Medicaid Handbook for Enteral Nutrition. Updated July 2014  
 American Academy of Pediatrics Committee on Nutrition. Reimbursement for medical foods for inborn errors of metabolism. Pediatrics. 1994; 93(5):860.  
 ASPEN. American Society for Parenteral and Enteral Nutrition Board of Directors. Standards of Practice for Home Nutrition Support. Journal of Parenteral and Enteral Nutrition, Volume 33, Number 2, March/Apri/2009 122-167. Available at <http://pen.sagepub.com> Accessed June 3, 2013.  
 Cabre Gelada E. Enteral nutrition in gastrointestinal disease. Gastroenterol Hepatol. 1998; 21(5):245- 256.  
 DeWitt RC, Kudsk KA. Enteral nutrition. Gastroenterol Clin North Am. 1998; 27(2):371-386.  
 Forchielli M, Bines J. Enteral Nutrition 68, 766-775. Abbot Nutrition Health Institute. Available at [http://anhi.org/learning/pdfs/bcdecker/Enteral\\_Nutrition.pdf](http://anhi.org/learning/pdfs/bcdecker/Enteral_Nutrition.pdf). Accessed June 3, 2013.

**ATTACHMENTS:** N/A

**ROLES & RESPONSIBILITIES:** Utilization Management

**REGULATORY REPORTING REQUIREMENTS:** State review and approval required for any substantial changes and upon request

**REVISION LOG**

<b>REVISION TYPE</b>	<b>REVISION SUMMARY</b>	<b>DATE APPROVED &amp; PUBLISHED</b>
New Policy Document	Policy Created	06/02/2015
Annual Review	Reference to FL.UM.02.02 updated to reflect new condensed policy FL.UM.02 Practice Guidelines and Clinical Criteria policy and procedure; Removed code B4140SC not a valid 2016 HCPC code	07/01/2016
Annual Review	Annual review: added reference to UM.14 Management of Requests as part of EPSDT or as a Potential Benefit Removed <b>Nutritional Supplement Codes and Limits</b>	12/2017
Annual Review	Archer Upload- No review or revision conducted	02/2019
Annual Review	Fixed policy numbers and names, and changed approver 3 to VP, Medical Affairs	05/2020
Annual Review	No changes needed	07/2021
Annual Review	No changes needed	07/25/2022
Update	Kate Farms Exception for WIC added	09/01/2022
Policy Update	Add CMS and SMI to product line. Increase the length of the initial formula reviews for our members from 3 months to 6.	2/27/2023
Annual Review	Updated Policy ID Added Policy ID and Name to "Footer" Made minor grammatical changes	02/2024

### **POLICY AND PROCEDURE APPROVAL**

The electronic approval retained in RSA Archer, the Company's P&P management software, is considered equivalent to a signature.