VERMONT

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The Department of Vermont Health Access Clinical Criteria

Subject: Nutritional Supplementation and Support:

- **Metabolic Nutrition,**
- **Nutritional Therapy (Enteral Nutrition and Parenteral Nutrition), and**
- **Liquid Oral Supplementation**

Last Review: October 26, 2023*
Past Revisions: N/A

***Please note: Most current content changes will be highlighted in yellow.**

Description of Service or Procedure

Metabolic Nutrition:
An inherited metabolic disease is a disease caused by an inherited abnormality of body chemistry for which the State screens newborn infants. The Department of Vermont Health Access (DVHA) covers medical foods and low protein modified food products for the treatment of inherited metabolic diseases.

Medical foods include an amino acid modified preparation that is intended to be used under the direction of a physician for the dietary treatment of an inherited metabolic disease.

Low protein modified food products are specifically formulated to have less than one gram of protein per serving and are intended to be used under the direction of a physician for the dietary treatment of a metabolic disease.

Nutritional Therapy (Enteral Nutrition and Parenteral Nutrition) in the Home Setting:
According to the American Society for Parenteral and Enteral Nutrition (ASPEN) (2020):

- Enteral Nutrition: System of providing nutrition directly into the gastrointestinal tract via a tube, catheter, or stoma that bypasses the oral cavity.
- Parenteral Nutrition: The intravenous administration of nutrients. (Parenteral nutrition is used in preference to “parenteral feeding.”) • Central: Parenteral nutrition delivered into a large-diameter vein, usually the superior vena cava adjacent to the right atrium. • Peripheral: Parenteral nutrition delivered into a small-diameter peripheral vein, usually of the hand or forearm.

Pumps are a rented item.

Liquid Oral Supplementation:

In some patients, nutritional supplementation to a standard diet with high-caloric density and/or high nutrient supplementation may be medically necessary to avoid hospitalization and/or a significant weight loss/decline, and specifically in the pediatric population to correct a relevant change in the growth trend.

All liquid supplements are subject to the FDA definition of medical foods as defined in section 5(b)(3) ofthe Orphan Drug Act (21 U.S.C. 360ee(b)(3)). Please note that medical foods, per the FDA, "are distinguished from the broader category of foods for special dietary use by the requirement that medical foods be intended to meet distinctive nutritional requirements of a disease or condition, used under medical supervision, and intended for the specific dietary management of a disease or condition. Medicalfoods are not those simply recommended by a physician as part of an overall diet to manage the symptoms or reduce the risk of a disease or condition."

This policy is not intended to provide coverage for standard infant formula or infant formulas found over-the-counter. The prior authorization form, Nutritionals Request Form, for pediatric liquid oral supplementation nutritional products can be found at the Pharmacy Prior Authorization Request Forms and Order Forms page at: https://dvha.vermont.gov/forms-manuals/forms/pharmacy-prior-authorization-request-forms-and-order-forms

Disclaimer

Coverage is limited to that outlined in Medicaid Rule or Health Care Administrative Rules that pertain to the member's aid category. Prior Authorization (PA) is only valid if the member is eligible for the applicable item or service on the date of service.

Medicaid Rule

Medicaid and Health Care Administrative Rules can be found at https://humanservices.vermont.gov/rules-policies/health-care-rules/health-care-administrative-rules-hcar/adopted-rules

7102	Prior Authorization
7508.2	Prosthetics Devices Covered Services
4.101	Medical Necessity for Covered Services
4.104	Medicaid Non-Covered Services
4.106	Early and Periodic Screening, Diagnostic and Treatment (EPSDT) Services
4.207	Prescribed Drugs
4.209	Durable Medical Equipment

State Statute- 8 V.S.A. § 4089e. Treatment of inherited metabolic diseases

Nutritional support is covered for low protein modified food products for treatment of an inherited metabolic disease, as required by Act 128 of the 1998 legislative session when it is consistent with the patient's medical condition and plan of care.

Coverage Position

Nutritional supplementation and support may be covered for members:

- When the supplement is prescribed by a licensed medical provider, enrolled in the Vermont Medicaid program, operating within their scope of practice as described on the Vermont Office of Professional Regulation's website*, Statute, or rule who is knowledgeable regarding nutritional supplementation and support, and who provides medical care to the member AND
- When the clinical criteria below are met.

* Vermont's Office of Professional Regulation's website: https://sos.vermont.gov/opr/

Coverage Criteria

Nutritional supplementation and support may be covered for members who met the criteria located in the Preferred Drug List (PDL). *Please note: Metabolic coverage criteria is listed below and not in the PDL.*

- **Pharmacy Benefit Coverage:** NDC, HRI, or UPC needed. See Preferred Drug List for criteria used to determine medical necessity Prior authorization is required, and can be requested with Nutritional Prior Authorization PA forms.

- **Medical Benefit Coverage: Generally** Enteral or parenteral formulas. HCPCS code needed. See Preferred Drug List. Please see the Fee Schedule for PA requirements.

Please note: Medical Nutrition Therapy service by Registered Dietitians see criteria, located-https://dvha.vermont.gov/forms-manuals/forms/prior-authorizations-tools-and-criteria/procedure-criteria

Metabolic Nutrition

Metabolic nutrition may be covered for a beneficiary who:

- Has a diagnosis of an inherited metabolic disease caused by an inherited abnormality of body chemistry. AND
- Requires a low protein modified food product:
    - which is specifically formulated to have less than one gram of protein per serving and
    - is intended to be used under the direction of a physician for the treatment of the inherited metabolic disease OR
- Requires an amino acid modified food that is intended to be used under the direction of a physician for the dietary treatment of an inherited metabolic disease.

Prior Authorization may be required for products that are not found on this list: Drug Coverage Lists | Department of Vermont Health Access

Nutritional Therapy (Enteral Nutrition and Parenteral Nutrition) in the Home Setting

Nutritional support (enteral or parenteral) may be covered for neonatal, pediatric, and adult members when:

Enteral

- There is a functioning gastrointestinal tract, **AND**

- The member has a diagnosis for which enteral nutrition products are indicated when a member cannot eat enough food because of an illness (i.e., dysphagia, neuromuscular illness, head and neck cancers, and gastroparesis, **AND**
- The member has a nasogastric, jejunostomy or gastrostomy tube (selection of appropriate route must consider the expected duration of treatment, clinical condition of patient and level of consciousness of the patient), **AND**
- The clinical documentation supports need for enteral nutrition (lab measurements demonstrating malnutrition, height, weight, BMI, past treatments and estimated duration of need), **AND**
- The member has a caregiver who has been trained to provide the feedings OR the member is able to independently administer the feedings.

Parenteral

- The members cannot eat or absorb enough food through tube feeding formula to maintain good nutrition status, **AND**
- The member has a diagnosis of a disorder or disease process which impairs absorption of sufficient nutrients to preserve weight such as short bowel syndrome, GI fistulas, or bowel obstruction) **AND**
- Clinical documentation supports need for parenteral nutrition (lab measurements demonstrating malnutrition, height, weight, BMI and past treatments), **AND**
- The member has a caregiver who has been trained to provide the feedings OR the member is able to independently administer the feedings.

Considerations: Home Health Agencies should have clearly defined policies and procedures in place to ensure appropriate care.

Liquid Oral Supplementation

Liquid oral supplementation may be covered for beneficiaries under the age of 21 for the shortestmedically necessary period when:

- There is a functioning gastrointestinal tract. **AND**
- Anatomic causes for malnutrition have been evaluated and treated (ex.: gastro-esophageal refluxdisease, etc.); **AND**
- Social causes for malnutrition have been evaluated and treated (ex.: child neglect, etc.); **AND**
- The clinical documentation supports the need for enteral nutrition (lab measurements demonstrating malnutrition, height, weight, BMI, past treatments and estimated duration of need).

AND ONE OR MORE OF THE BELOW

- A chronic medical condition exists resulting in nutritional deficiencies, and a three-month trial is required to prevent gastric tube placement, **OR**
- The beneficiary has a documented diagnosis of an inborn error of metabolism that cannot be accommodated by standard foods with a modified diet, **OR**
- Weaning from TPN or feeding tube, **OR**
- Supplementation to regular diet or meal replacement is required, and the beneficiary's weight is below the 5th percentile for sex and corrected age with one of the following, **AND**
- Weight-to-length ratio has fallen below the 10th percentile, **OR**

- There has been a sustained decrease in growth velocity demonstrated by weight-for-age or weight-for-length fall on the growth curve by two major percentiles (percentile markers 95, 90, 75, 50, 25, 10, and 5) over time. (As defined by the World Health Organization for children less than 2 years of age and the Centers for Disease Control for children greater than 2 years of age)

Early and Periodic Screening, Diagnostic and Treatment (EPSDT) exception: Vermont Medicaid will provide comprehensive services and furnish all Medicaid coverable, appropriate, and medically necessary services needed to correct and ameliorate health conditions for Medicaid members under age 21.

Please note, Vermont Medicaid Clinical Criteria is reviewed based on available literature, evidence- based guidelines/standards, Medicaid rule and policy, and Medicare coverage determinations that may be appropriate to incorporate when applicable.

Clinical criteria for repeat service or procedure

- The same criteria applies as for the initial use.
- Therapy could be for a short period of time or a lifetime.
- Pumps are a rented item.

Type of service or procedure not covered (this list may not be all inclusive)

Nutritional support is not covered for non-medical foods.

Oral liquid supplementation is not covered:

- For healthy infants and newborns without a clinical disease or condition.
- For children whose need is nutritional rather than medical including an unwillingness to consume solid or pureed foods.
- As an alternative to preparing or consuming regular foods.
- Because of an inability to afford food and supplements.
- For food allergies that can be accommodated by alternative foods and supplements commonly available at retail grocers.

For resources related to infant formula or food assistance, see the website for Women, Infants and Children at HealthVermont.gov and 3SquaresVT.

References

American Society for Parenteral and Enteral Nutrition (ASPEN). (2018, May). *Definition of Terms, Style, and Conventions Used in ASPEN Board of Directors–Approved Documents*. Www.nutritioncare.org. https://www.nutritioncare.org/uploadedFiles/Documents/Guidelines_and_Clinical_Resources/ASPEN%20Definition%20of%20Terms

Berry, S. A., Brown, C. S., Greene, C., Camp, K. M., McDonough, S., & Bocchini, J. A. (2020). Medical Foods for Inborn Errors of Metabolism: History, Current Status, and Critical Need. *Pediatrics*, *145*(3), e20192261. https://doi.org/10.1542/peds.2019-2261

Boullata, J. I., Carrera, A. L., Harvey, L., Escuro, A. A., Hudson, L., Mays, A., McGinnis, C., Wessel, J. J., Bajpai, S., Beebe, M. L., Kinn, T. J., Klang, M. G., Lord, L., Martin, K., Pompeii-Wolfe, C., Sullivan, J., Wood, A., Malone, A., & Guenter, P. (2016). ASPEN Safe Practices for Enteral Nutrition Therapy. *Journal of Parenteral and Enteral Nutrition*, *41*(1), 15–103. https://doi.org/10.1177/0148607116673053

Camp, K. M., Lloyd-Puryear, M. A., & Huntington, K. L. (2012). Nutritional treatment for inborn errors of metabolism: Indications, regulations, and availability of medical foods and dietary supplements using phenylketonuria as an example. *Molecular Genetics and Metabolism*, *107*(1-2), 3–9. https://doi.org/10.1016/j.ymgme.2012.07.005

Center for Food Safety and Applied Nutrition. (2023). *Frequently Asked Questions About Medical Foods; Third Edition Guidance for Industry*. U.S. Department of Health and Human Services. https://www.fda.gov/media/97726/download

Centers for Medicare and Medicaid Services. (2017). *Early and Periodic Screening, Diagnostic, and Treatment | Medicaid*. Medicaid.gov. https://www.medicaid.gov/medicaid/benefits/early-and-periodic-screening-diagnostic-and-treatment/index.html

Cook, S., Weitzman, M., Auinger, P., Nguyen, M., & Dietz, W. H. (2003). Prevalence of a Metabolic Syndrome Phenotype in Adolescents. *Archives of Pediatrics & Adolescent Medicine*, *157*(8), 821. https://doi.org/10.1001/archpedi.157.8.821

Druyan, M. E., Compher, C., Boullata, J. I., Braunschweig, C. L., George, D. E., Simpser, E., & Worthington, P. A. (2011). Clinical Guidelines for the Use of Parenteral and Enteral Nutrition in Adult and Pediatric Patients. *Journal of Parenteral and Enteral Nutrition*, *36*(1), 77–80. https://doi.org/10.1177/0148607111420157

Durand, C., Pairaudeau, P., & Walter, J. (2006). *Inherited metabolic disease* . https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2066048/pdf/A89.pdf

Duryea, T. (2023, July 26). *Poor weight gain in children younger than two years in resource-abundant settings: Etiology and evaluation*. UpToDate. https://www.uptodate.com/contents/poor-weight-gain-in-children-younger-than-two-years-in-resource-abundant-settings-etiology-and-evaluation

Ford, E. S., Giles, W. H., & Dietz, W. H. (2002). Prevalence of the Metabolic Syndrome Among US Adults. *JAMA*, *287*(3), 356. https://doi.org/10.1001/jama.287.3.356

Hayes, Inc. Search and Summary. *Metabolic Foods for the Treatment of Inborn Errors of Amino Acid Metabolism.* Landsdale, PA: Hayes, Inc,; June, 2, 2016.

Homan, G. J. (2016). Failure to Thrive: A Practical Guide. *American Family Physician*, *94*(4), 295–299. https://www.aafp.org/pubs/afp/issues/2016/0815/p295.html

Krugman, S. D., & Dubowitz, H. (2003). Failure to Thrive. *American Family Physician*, *68*(5), 879–884. https://www.aafp.org/pubs/afp/issues/2003/0901/p879.html

McCabe-Sellers, B. J. (2010). Position of the American Dietetic Association: Integration of Medical Nutrition Therapy and Pharmacotherapy. *Journal of the American Dietetic Association*, *110*(6), 950–956. https://doi.org/10.1016/j.jada.2010.04.017

Olsen, E. M., Petersen, J., Skovgaard, A. M., Weile, B., Jorgensen, T., & Wright, C. M. (2006). Failure to thrive: the prevalence and concurrence of anthropometric criteria in a general

infant population. *Archives of Disease in Childhood*, *92*(2), 109–114. https://doi.org/10.1136/adc.2005.080333

Saudubray, J. M., Narcy, C., Lyonnet, L., Bonnefont, J. P., Poll The, B. T., & Munnich, A. (1990). Clinical Approach to Inherited Metabolic Disorders in Neonates. *Neonatology*, *58*(Suppl. 1), 44–53. https://doi.org/10.1159/000243299

Wells Mulherin, D., Walker, R., Holcombe, B., & Guenter, P. (2020). ASPEN Report on Nutrition Support Practice Processes With COVID-19: The First Response. *Nutrition in Clinical Practice*, *35*(5). https://doi.org/10.1002/ncp.10553

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