

Nutritional Support Enteral Formula, Medical Foods and Feeding Equipment and Supplies

Medical Coverage Policy

UTILIZATION * ALERT*

- Prior to use of this MCP for evaluation of medical necessity, benefit coverage MUST be verified in the member's EOC or benefit document.
- Please refer to state issued guidelines for Medicaid Members.
- Please review the Medicare coverage database for Medicare Advantage members. CMS guidelines for DME (Medicare) covers enteral nutrition under the prosthetic devices benefit.
- Note: After searching the Medicare Coverage Database, if no LCD/LCA is found, then use the policy referenced above for coverage guidelines.

I. Service: Outpatient Nutritional Support Therapies

II. **Diagnosis:** Numerous congenital or acquired conditions including:

Malformations and malfunctions of mouth and/or esophagus

Dysfunction of gastro-intestinal (GI) system including swallowing

Congenital or acquired food metabolism conditions, per state mandate

III. Definitions

- A. Enteral formulas are liquid nutrition delivered via tube feeding.
- B. Amino Acid Formulas are specialized liquid nutrition delivered by mouth through normal oral intake or via tube.
- C. Medical foods are special foods used for treating inborn metabolism errors, to restrict the intake of certain amino acids in the member's diet

IV. Pediatric Conditions

Newborns and children can have different structural, developmental, or metabolic conditions which require specialized diet to meet their caloric requirement for adequate growth and development.

A. Pediatric enteral supplies and equipment

Medical equipment and supplies are covered for pediatric members who meet the following criteria for enteral feeding:

- 1. Inability to ingest adequate nutrition due to:
 - a. Structural malformation of the mouth, esophagus, throat, or GI tract;
 - b. Congenital or genetic anomalies (including autism) which impairs food intake;
 - c. Significant food aversion resulting in failure to thrive;



Nutritional Support Enteral Formula, Medical Foods and Feeding Equipment and Supplies

Medical Coverage Policy

- d. Reduced cardiac or pulmonary stamina, malabsorption or increase caloric needs; or
- e. Congenital or acquired food metabolism disorders; or
- f. Inability to maintain adequate nutrition through oral intake.
- 2. Supplies and equipment are covered when the member meets the criteria for pediatric enteral supplies, regardless of whether the formula is covered by the member's plan.
- 3. Coverage of supplies may be of single use (disposable) or multiple use.
- 4. Enteral feeding pumps must be supported by sufficient medical documentation to establish their medical necessity.

B. Pediatric formulas (including enteral formula) and medical foods

- 1. Coverage of amino acid formulas and medical foods vary by state mandate and are covered as described in the member's evidence of coverage (EOC).
- 2. Enteral formula is covered when the following criteria are met:
 - a. Structural malformation of the mouth, esophagus, throat, or GI tract; or
 - b. Inability to swallow secondary to neurological or other disorder
- 3. Approval of amino acid formulas for mild protein enteropathies requires documentation that the member has tried and failed extensively hydrolyzed formula.

C. Pediatric coverage

- Maryland and Virginia Medicaid members with normal food metabolism have coverage of formula for tube feeding or oral intake when medically necessary. Expert physician opinion must be obtained to determine the medical necessity of both oral and enteral feeding nutritional support for these members.
- 2. KPMAS does not cover banked breast milk for any method of delivery.

V. Adult Conditions

A. Adult enteral supplies and equipment

- 1. Enteral equipment and supplies are covered when the member meets the following criteria for enteral feeding:
 - a. Structural malformation of the mouth, esophagus, throat, or GI tract;
 - b. Inability to swallow secondary to neurological or other disorder; or
 - c. Inability to maintain adequate nutrition through oral intake.
- 2. Covered supplies may be of single use (disposable) or multiple use.
- 3. Enteral feeding pumps must be supported with sufficient medical documentation to establish that the pump is medically necessary, i.e., gravity feeding is not sufficient due to aspiration or dumping syndrome.

B. Adult formulas (enteral, oral) and medical foods coverage



Nutritional Support Enteral Formula, Medical Foods and Feeding Equipment and Supplies

Medical Coverage Policy

- 1. Enteral formula is covered for a patient who has a OR b, c, AND d
 - Non-function or diseases of the structures that normally permit food to reach the small bowel;
 OR
 - b. Disease of the small bowel which impairs digestion and absorption of an oral diet, AND
 - c. Requires tube feeding to maintain weight and strength commensurate with the patient's overall health status. AND
 - d. The patient's condition must be of a long and indefinite duration (ordinarily at least 3 months). The condition could either be anatomic (obstruction due to head and neck cancer, reconstructive surgery, etc.) or a motility disorder (e.g., severe dysphagia following a stroke, etc.).
- 2. Medical foods given internally or orally are covered as described in the member's EOC and state mandates.
- 3. Oral nutritional supplements are not covered.

VI. Adult and Pediatric Enteral Formulas and Medical Foods for District of Columbia (DC) situs members

- A. Conditions covered for enteral formulas and medical foods under DC mandate:
 - 1. Inflammatory bowel disease:
 - 2. Gastroesophageal reflux disease that is nonresponsive to standard medical therapies;
 - 3. Immunoglobulin E and non-Immunoglobulin E-mediated allergies to food proteins:
 - 4. Food protein-induced enterocolitis syndrome;
 - 5. Eosinophilic disorders, including eosinophilic esophagitis, gastroenteritis, colitis, and post-transplant eosinophilic disorders;
 - 6. Impaired absorption of nutrients caused by disorders affecting the absorptive surface, functional length, and motility of the gastrointestinal tract, including short bowel syndrome and chronic intestinal pseudo-obstruction:
 - 7. Malabsorption due to liver or pancreatic disease;
 - 8. Inherited metabolic disorders; and
- B. Any other diseases or conditions as determined by the current DC Mayor through rule making.



Nutritional Support Enteral Formula, Medical Foods and Feeding Equipment and Supplies

Medical Coverage Policy

References

- 1. Bandon JJ, Goutet JM, Biran-Mucignat V et al. Assessment of dysphagia in infants with facial malformations, *Eur J Pediatric* 2009 168:187-93
- 2. Baudon RF Galliani JJ et al. Facial, lingual, and pharyngeal electromyography in infants with Pierre Robin sequence, *Muscle & Nerve*, Jun 2011; 43, Issue 6: 866-71
- 3. CMS Medicare Coverage Database: Enteral and Parenteral Nutritional Therapy (180.2). Accessed 9/29/2014.
- 4. Guo Z, Wu R, Zhu W et al. Effect of Exclusive Enteral Nutrition on Health-Related Quality of Life for Adults with Active Crohn's Disease, *Nutrition in Clinical Practice*. July 2013; 28: 499
- Hall BT, Englehart M, Blaseg K et al. Implementation of a Dietitian-Led Enteral Nutrition Support Clinic Results in Quality Improvement, Reduced Readmissions, and Cost Savings. *Nutr Clin Pract*, Oct 2014;29:5 pp. 649-55
- 6. Leder SB, Suiter DM, Warner HL et al. Success of recommending oral diets in acute stroke patients based on passing a 90-cc water swallow challenge protocol, Topics in Stroke Rehabilitation, Jan/Feb 2012; 19:1 40-4
- 7. Lev-Tzion R, Turner D. Is pediatric IBD treatment different than in adults? *Gastroenterol Dietol* Jun 2012; 58(2):137-50
- CMS.gov. Local Coverage Determination (LCD) Parenteral Nutrition (L33798). Accessed 08/17/2019. https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33798&ver=12&DocID=L33798&bc=qAAABAAAAAAA
- CMS.gov. Local Coverage Determination (LCD) Enteral Nutrition (L33783). Accessed 08/17/2019. https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33783&ver=14&Date=&DocID=L33783&bc=iAAAABAAAAAAA
- 11. Nugent B, Lewis S, O'Sullivan JM. <u>Enteral feeding methods for nutritional management in patients with head and neck cancers being treated with radiotherapy and/or chemotherapy</u> (Review), The Cochrane Collaboration, 2013.
- 12. Olieman JF, Penning C, Jsselstijn HI et al. Enteral Nutrition in Children with Short-Bowel Syndrome: Current Evidence and Recommendations for the Clinician, *J of the American Dietetic Association*, 2010; 110: 3:420-26
- 13. Peterson J, Kerner JA New Advances in the Management of Children with Intestinal Failure. *Journal of Parenteral and Enteral Nutrition*. January 2012: 36: Supplement 1. 36S-42S.
- Review: A systematic review of the cost and economic outcomes of home enteral nutrition by Wong, A; Goh, G.; Banks, M.D; Bauer, J.D. In Clinical Nutrition. April 2018 37(2):429-442 Language: English. DOI: 10.1016/J.CLNU 2017.06.019, Database: Science Direct.
- 15. Tighe MP, Cumming JR, Afzal NA. Nutrition, and inflammatory bowel disease: primary or adjuvant therapy, *Clinical Nutrition and Metabolic Care*, Sept 2011; 14:5:491-6.
- 16. Original article: Malnutrition risk predicts recovery of full oral intake among older adult stroke patients



Nutritional Support Enteral Formula, Medical Foods and Feeding Equipment and Supplies

Medical Coverage Policy

- undergoing enteral nutrition: Secondary analysis of a multicenter survey (the APPLE study) by Nishioka, Shinta; Okamoto, Takatsugu; Takayam, Masako; Urushihara, Maki; Watanabe, Misuzu; Kiriya, Yumiko; Shintani, Keiko; Nakagomi, Hiromi; Kageyama, Noriko. *In Clinical Nutrition*. August 2017 36(4): 1089-1096 Language: English. DOI: 10.1016/j.clnu.2016.06.028.
- 17. Coverage of Enteral Nutrition Therapy OIC. HHS.gov. Accessed 10.02.2018. May 1995 Health and Human Services Enteral Nutrition Support.
- 18. Ukleja, A., Gilbert, K., Mogensen, K. M., Walker, R., Ward, C. T., Ybarra, J., Holcombe, B., & Task Force on Standards for Nutrition Support: Adult Hospitalized Patients, the American Society for Parenteral and Enteral Nutrition (2018). Standards for Nutrition Support: Adult Hospitalized Patients. *Nutrition in clinical practice: official publication of the American Society for Parenteral and Enteral Nutrition*, 33(6), 906–920. https://doi.org/10.1002/ncp.10204
 - https://onlinelibrary.wiley.com/doi/full/10.1002/ncp.10204
- 19. Pironia L, Boeykensb K, Bozzettic F, Jolyd F, Kleke S, Lalf S; Lichotag M, Mühlebachh S, Van Gossumi A, Wantenj G, Wheatleyk C, Bischoffl, S. ESPEN guideline on home parenteral nutrition. *Clinical Nutrition*. Volume 39, Issue 6, June 2020, Pages 1645-1666. https://www.sciencedirect.com/science/article/pii/S0261561420301084
- 20. Gomes F, Baumgartner A, Bounoure L, et al. Association of Nutritional Support with Clinical Outcomes Among Medical Inpatients Who Are Malnourished or at Nutritional Risk: An Updated Systematic Review and Meta-analysis. *JAMA Netw Open.* 2019;2(11): e1915138. doi:10.1001/jamanetworkopen.2019.15138. Accessed 07/08/2020.
 - https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2755665
- 21. Virginia's Legislative Information System. Code of Virginia § 38.2-3418.18. Coverage for formula and enteral nutrition products. Accessed 07/08/2020. https://lis.virginia.gov/cgi-bin/legp604.exe?201+ful+CHAP0214
- 22. Hubbard, G. P., Fry, C., Sorensen, K., Casewell, C., Collins, L., Cunjamalay, A., Simpson, M., Wall, A., Van Wyk, E., Ward, M., Hallowes, S., Duggan, H., Robison, J., Gane, H., Pope, L., Clark, J., & Stratton, R. J. (2020). Energy-dense, low-volume paediatric oral nutritional supplements improve total nutrient intake and increase growth in paediatric patients requiring nutritional support: results of a randomised controlled pilot trial. *European journal of pediatrics*, 179(9), 1421–1430. https://doi.org/10.1007/s00431-020-03620-9
- 23. Roberts, S. B., Franceschini, M. A., Silver, R. E., Taylor, S. F., de Sa, A. B., Có, R., Sonco, A., Krauss, A., Taetzsch, A., Webb, P., Das, S. K., Chen, C. Y., Rogers, B. L., Saltzman, E., Lin, P. Y., Schlossman, N., Pruzensky, W., Balé, C., Chui, K., & Muentener, P. (2020). Effects of food supplementation on cognitive function, cerebral blood flow, and nutritional status in young children at risk of undernutrition: randomized controlled trial. *BMJ* (Clinical research ed.), 370, m2397. https://doi.org/10.1136/bmj.m2397
- 24. Yi, L. J., Tian, X., Shi, B., Pi, Y. P., & Chen, W. Q. (2019). Early enteral nutrition supplemented with probiotics improved the clinical outcomes in severe head injury: Some promising findings from Chinese patients. *Medicine*, *98*(17), e15426.
- 25. Evans, J. C., Hirani, S. P., & Needle, J. J. (2019). Nutritional and Post-Transplantation Outcomes of Enteral



Nutritional Support Enteral Formula, Medical Foods and Feeding Equipment and Supplies

Medical Coverage Policy

versus Parenteral Nutrition in Pediatric Hematopoietic Stem Cell Transplantation: A Systematic Review of Randomized and Nonrandomized Studies. *Biology of blood and marrow transplantation: journal of the American Society for Blood and Marrow Transplantation*, 25(8), e252–e259. https://doi.org/10.1016/j.bbmt.2019.02.023

- 26. Grentzx, L, , Furfari, , Keifer R. and Potter, N . Appetite-guided approach to pediatric enteral tube weaning in the home setting: A pilot study. Journal of Parenteral and Enteral Nutrition (JPEN). 08 May 2022, DOI: 10.1002/jpen.2394. https://doi.org/10.1002/jpen.2394
- 27. Beauchamp-Walters, J et al. Impact of exclusive enteral nutrition on the gut microbiome of children with medical complexity. Journal of Parenteral and Enteral Nutrition (JPEN). 08 May 2022. DOI: 10.1002/jpen.2392. https://doi.org/10.1002/jpen.2392
- 28. U.S. Department of Health and Human Services Food and Drug Administration- Center for Food Safety and Applied Nutrition (2023). Frequently Asked Questions About Medical Foods; Second Edition. Accessed: 07/10/23. https://www.fda.gov/media/97726/download
- 29. Holmes, J. L., Biella, A., Morck, T., Rostorfer, J., & Schneeman, B. (2021). Medical Foods: Science, Regulation, and Practical Aspects. Summary of a Workshop. Current developments in nutrition, 5(Suppl 1), nzaa172. https://doi.org/10.1093/cdn/nzaa172
- 30. Ciampa, B. P., Reyes Ramos, E., Borum, M., & Doman, D. B. (2017). The Emerging Therapeutic Role of Medical Foods for Gastrointestinal Disorders. *Gastroenterology & hepatology*, *13*(2), 104–115.
- 31. U. S. Food and Drug Administration (FDA). Exempt Infant Formulas Marketed in the United States by Manufacturer and Category. Guidance Documents & Regulatory Information by Topic (Food and Dietary Supplements) Infant Formula Guidance Documents & Regulatory Information. 11/2019. https://www.fda.gov/food/infant-formula-guidance-documents-regulatory-information/exempt-infant-formulas-marketed-united-states-manufacturer-and-category
- 32. Stevens J, Wyatt C, Brown P, Patel D, Grujic D, Freedman SD. Absorption and Safety with Sustained Use of RELiZORB Evaluation (ASSURE) Study in Patients with Cystic Fibrosis Receiving Enteral Feeding. J Pediatr Gastroenterol Nutr. 2018;67(4):527-532. doi:10.1097/MPG.000000000002110.
- 33. Holmes, J. L., Biella, A., Morck, T., Rostorfer, J., & Schneeman, B. (2021). Medical Foods: Science, Regulation, and Practical Aspects. Summary of a Workshop. *Current developments in nutrition*, *5*(Suppl 1), nzaa172. https://doi.org/10.1093/cdn/nzaa172
- 34. Podpeskar, A., Crazzolara, R., Kropshofer, G., Hetzer, B., Rabensteiner, E., Meister, B., Obexer, P., & Salvador, C. (2023). Recommendations for Nutritional Supplementation in Pediatric Oncology: A Compilation of the Facts. *Nutrients*, *15*(14), 3239. https://doi.org/10.3390/nu15143239
- 35. Pasini, E., Corsetti, G., & Dioguardi, F. S. (2023). Nutritional Supplementation and Exercise as Essential Allies in the Treatment of Chronic Heart Failure: The Metabolic and Molecular Bases. *Nutrients*, *15*(10), 2337. https://doi.org/10.3390/nu15102337



Nutritional Support Enteral Formula, Medical Foods and Feeding Equipment and Supplies

Medical Coverage Policy

Approval History

Date approved by RUMC*	Date filed with the State of Maryland	Date of Implementation (Ten days after filing)
09/26/2013	09/26/2013	10/07/2013
10/22/2014	10/29/2014	11/10/2014
10/21/2015	10/22/2015	11/02/2015

Approval History

Effective June 01, 2016, state filing is no longer required per Maryland House Bill HB 798 - Health Insurance - Reporting

Date approved by RUMC	Date of Implementation
10/21/2016	10/21/2016
06/01/2017	06/01/2017
05/29/2018	05/29/2018
11/26/2018	11/26/2018
11/20/2019	11/20/2019
11/18/2020	11/18/2020
11/29/2021	11/29/2021
10/20/2022	10/20/2022
09/27/2023	09/27/2023
09/26/2024	09/26/2024

^{*}The Regional Utilization Management Committee received **delegated authority** to review and approve designated Utilization Management and Medical Coverage Policies by the Regional Quality Improvement Committee in 2011.

Note: Kaiser Permanente Mid-Atlantic States (KPMAS) include referral and authorization criteria to support primary care and specialty care practitioners, as appropriate, in caring for members with selected conditions. Whenever possible, Medical Coverage Policies are evidence-based and may also include expert opinion. Medical Coverage Policies are not intended or designed as a substitute for the reasonable exercise of independent clinical judgment by a practitioner in any particular set of circumstances for an individual member.

©2024, Kaiser Foundation Health Plan of the Mid-Atlantic States, Inc. ©2024, Mid-Atlantic Permanente Medical Group, P.C