



Hydrolyzed Eternal Formula – Diagnosis

Purpose

This policy is intended to ensure correct provider reimbursement and serves only as a general resource regarding Molina Healthcare's reimbursement policy for the services described in this policy. It is not intended to address every aspect of a reimbursement situation, nor is it intended to impact care decisions. This policy was developed using nationally accepted industry standards and coding principles. In a conflict, federal and state guidelines, as applicable, and the member's benefit plan document supersede the information in this policy. Also, to the extent of conflicts between this policy and the provider contract language, the Provider contract language will prevail. Coverage may be mandated by applicable legal requirements of a State, the Federal government or the Centers for Medicare and Medicaid Services (CMS). References included were accurate at the time of policy approval. If there is a state exception, please refer to the state exception table listed below.

Policy Overview

Affected CPT codes: B4161, B4153

An amino acid-based elemental formula is regulated by the U.S. Food and Drug Administration (FDA) and prescribed for infants or children with specific medical or dietary issues. This type of formula contains proteins broken down into their simplest (elemental) form, making them easier for the body to process and digest. Unlike whole proteins that may cause allergic reactions and absorption issues, elemental amino acids do not elicit the same reaction and are more readily absorbed. Infants or children who cannot digest or tolerate whole proteins due to allergies or gastrointestinal conditions may be placed on an amino acid-based formula.

Policy

Coverage is subject to the specific terms of the member's benefit plan.

Patients with a Definitive Diagnosis

The use of oral amino acid-based elemental formula (B4161, B4153) may be considered appropriate, and the codes will be payable when one of the following conditions is present on the submitted claim:

- Cystic fibrosis
- Amino acid, organic acid, and fatty acid metabolic and malabsorption disorders (e.g., phenylketonuria, maple syrup urine disease, homocystinuria, tyrosinemia, methylmalonic acidemia, and propionic acidemia)
- IgE-mediated allergies to food proteins
- Food protein-induced enterocolitis syndrome
- Eosinophilic esophagitis
- Eosinophilic gastroenteritis
- Eosinophilic colitis

Covered ICD-10 Code List:

This policy is designed to address medical guidelines appropriate for most individuals with a particular disease, illness, or condition. Each person's unique clinical circumstances may warrant individual consideration, based on a review of applicable medical records.

- K52.2 - Allergic and dietetic gastroenteritis and colitis
- K52.21 - Food protein-induced enterocolitis syndrome
- K52.22 - Food protein-induced enteropathy
- K52.81 - Eosinophilic gastritis or gastroenteritis
- K52.82 - Eosinophilic colitis
- E70 - Disorders of aromatic amino-acid metabolism

Covered ICD-10 Code List Continued:

- E70.0 - Classical phenylketonuria
- E70.1 - Other hyperphenylalaninemia's
- E70.2 - Disorders of tyrosine metabolism
- E70.20 - Disorder of tyrosine metabolism, unspecified
- E70.21 - Tyrosinemia
- E70.29 - Other disorders of tyrosine metabolism
- E70.330 - Chediak-Higashi syndrome
- E70.331 - Hermansky-Pudlak syndrome
- E70.40 - Disorders of histidine metabolism, unspecified
- E70.41 - Histidinemia
- E70.49 - Other disorders of histidine metabolism
- E70.5 - Disorders of tryptophan metabolism
- E70.8 - Other disorders of aromatic amino-acid metabolism
- E70.9 - Disorder of aromatic amino-acid metabolism, unspecified
- E71 - Disorders of branched-chain amino-acid metabolism & fatty-acid metabolism
- E71.0 - Maple-syrup-urine disease
- E71.1 - Other disorders of branched-chain amino-acid metabolism
- E71.11 - Branched-chain organic acidurias
- E71.110 - Isovaleric acidemia
- E71.111 - 3-methylglutaconic aciduria
- E71.118 - Other branched-chain organic acidurias
- E71.12 - Disorders of propionate metabolism
- E71.120 - Methylmalonic acidemia
- E71.121 - Propionic acidemia
- E71.128 - Other disorders of propionate metabolism
- E71.19 - Other disorders of branched-chain amino-acid metabolism
- E71.2 - Disorder of branched-chain amino-acid metabolism, unspecified
- E71.3 - Disorders of fatty-acid metabolism
- E71.30 - Disorder of fatty-acid metabolism, unspecified
- E71.31 - Disorders of fatty-acid oxidation
- E71.310 - Long chain/very long chain acyl CoA dehydrogenase deficiency
- E71.311 - Medium chain acyl CoA dehydrogenase deficiency
- E71.312 - Short chain acyl CoA dehydrogenase deficiency
- E71.313 - Glutaric aciduria type II
- E71.314 - Muscle carnitine palmitoyl transferase deficiency
- E71.318 - Other disorders of fatty-acid oxidation
- E72 - Other disorders of amino-acid metabolism
- E72.0 - Disorders of amino-acid transport
- E72.00 - Disorders of amino-acid transport, unspecified
- E72.01 - Cystinuria
- E72.02 - Hartnup's disease
- E72.03 - Lowe's syndrome
- E72.04 - Cystinosis
- E72.09 - Other disorders of amino-acid transport
- E72.1 - Disorders of sulfur-bearing amino-acid metabolism

- E72.10 - Disorders of sulfur-bearing amino-acid metabolism, unspecified
- E72.11 - Homocystinuria
- E72.12 - Methylene tetrahydrofolate reductase deficiency
- E72.19 - Other disorders of sulfur-bearing amino-acid metabolism
- E72.2 - Disorders of urea cycle metabolism
- E72.20 - Disorder of urea cycle metabolism, unspecified
- E72.21 - Argininemia
- E72.22 - Arginosuccinic aciduria
- E72.23 - Citrullinemia
- E72.29 - Other disorders of urea cycle metabolism
- E72.3 - Disorders of lysine and hydroxylysine metabolism
- E72.4 - Disorders of ornithine metabolism
- E72.5 - Disorders of glycine metabolism
- E72.50 - Disorder of glycine metabolism, unspecified
- E72.51 - Non-ketotic hyperglycinemia
- E72.52 - Trimethylaminuria
- E72.53 - Hyperoxaluria
- E72.59 - Other disorders of glycine metabolism
- E72.8 - Other specified disorders of amino-acid metabolism
- E72.9 - Disorder of amino-acid metabolism, unspecified
- E84 - Cystic fibrosis
- E84.0 - Cystic fibrosis with pulmonary manifestations
- E84.1 - Cystic fibrosis with intestinal manifestations
- E84.11 - Meconium ileus in cystic fibrosis
- E84.19 - Cystic fibrosis with other intestinal manifestations
- E84.8 - Cystic fibrosis with other manifestations
- E84.9 - Cystic fibrosis, unspecified

Procedure Codes (CPT & HCPCS) Code	Code Description
B4161	Enteral formula, for pediatrics, hydrolyzed/amino acids and peptide chain proteins, includes fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit
B4153	Enteral formula, nutritionally complete, hydrolyzed proteins (amino acids and peptide chain), includes fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit

Documentation History

Effective Date	Revision Date	Revision Description
11/20/2020		
	08/16/2023	Verified links, updated page numbers for links- CS
	12/12/2024	Verified links, updated page numbers for links and Template

References

Government Agencies

CMS-

<https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Recovery-Audit-Program/Approved-RAC-Topics-Items/0015-Enteral-Nutrition-TherapyMedical-Necessity-and-Documentation-Requirements>

“Enteral nutrition is considered reasonable and necessary for a patient with a functioning gastrointestinal tract who, due to pathology to, or non-function of, the structures that normally permit food to reach the digestive tract, cannot maintain weight and strength commensurate with his or her general condition. Documentation will be reviewed to determine if claims for enteral nutrition, with dates of service prior to November 12, 2020, meet coverage criteria and/or are medically reasonable and necessary.”

Government Agencies Continued:

CMS-

<https://www.cms.gov/regulations-and-Guidance/guidance/manuals/downloads/pim83c05.pdf>

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“For any DMEPOS item to be covered by Medicare, the patient’s medical record must contain sufficient documentation of the patient’s medical condition to substantiate the necessity for the type and quantity of items ordered and for the frequency of use or replacement (if applicable). The information should include the patient’s diagnosis and other pertinent information including, but not limited to, duration of the patient’s condition, clinical course (worsening or improvement), prognosis, nature and extent of functional limitations, other therapeutic interventions and results, past experience with related items, etc.”

FDA-

<https://www.fda.gov/media/97726/download>

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“It is a specially formulated and processed product (as opposed to a naturally occurring foodstuff used in its natural state) for the partial or exclusive feeding of a patient by means of oral intake or enteral feeding by tube, meaning a tube or catheter that delivers nutrients beyond the oral cavity directly into the stomach or small intestine; it is intended for the dietary management of a patient who, because of therapeutic or chronic medical needs, has limited or impaired capacity to ingest, digest, absorb, or metabolize ordinary foodstuffs or certain nutrients, or who has other special medical medically determined nutrient requirements, the dietary management of which cannot be achieved by the modification of the normal diet alone”

<https://www.fda.gov/media/97726/download>

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“Some examples of specific IEMs that medical foods could be used to manage involve amino acid/protein, organic acid, or fatty acid metabolism. These IEMs primarily require significant restriction of particular amino acids and/or total protein such as in phenylketonuria (phenylalanine restriction), ornithine transcarbamylase deficiency (nonessential amino acid restriction), methylmalonic acidemia (isoleucine, methionine, threonine, and valine restriction), or significant modification of fatty acids/total fat such as in very long-chain acyl-CoA dehydrogenase deficiency (long chain fatty acid restriction with an increase in medium chain fatty acid levels)”

Professional Society Guidelines and Other Publications

JAMA-

<https://jamanetwork.com/journals/jamapediatrics/fullarticle/486115>

Comment section

“Prospective controlled trials examining eHFs and partially hydrolyzed whey formulas for allergy prevention among high-risk infants demonstrate significant reductions in the cumulative incidence of atopic disease through the first 1 to 5 years of life compared with feeding CMF. However, based on the studies reported to date, neither eHFs nor pHFs meet the AAP’s8 criteria for allergy prevention because the studies were not consistent in the methods used to score allergic symptoms or confirm reactions, including DBPCFCs. Despite these limitations, the AAP,8 the European Society for Paediatric Allergology and Clinical Immunology,9 and the European Society for Paediatric Gastroenterology, Hepatology and Nutrition26 recommend feeding eHFs to infants at high risk of atopic disease when BF is insufficient. Furthermore, these groups acknowledge that pHFs have a potential role in allergy prevention.

Most of the studies addressed allergy prevention only in high-risk populations. However, in general practice, most infants manifesting atopic symptoms may not have been identified as high risk, whether or not they had a positive family history for the disease. It could be beneficial to broaden the use of eHF or partially hydrolyzed whey formulas for allergy prevention in the general population, weighing potential benefits against the issues of cost, compliance, and palatability. In that regard, although the studies in the literature do not provide overwhelming evidence, they suggest that partially hydrolyzed whey formulas may serve as a reasonable first defense against allergic disease in the general population. Partially hydrolyzed whey formulas are comparable in nutrition, price, and palatability to traditional CMFs and are available as starter formulas for newborns.

Because most studies were conducted in high-risk infants, to determine the potential allergy prevention role in the general population, we need additional prospective randomized controlled trials comparing pHFs, eHFs, and CMFs using clinical scoring systems and DBPCFCs to define atopic disease in the general infant population. In addition, it seems as if different hydrolysate formulas have different potentials for allergy prevention, which appear to depend on factors beyond the degree of protein hydrolysis. Therefore, to demonstrate benefits, specific hydrolysate formulas need to be individually evaluated in clinical trials.”

Other Reviewed Publications

State Medicaid:



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Florida- https://ahca.myflorida.com/medicaid/review/Rules_in_Process/Develop/59G-4.077_Enteral_Parenteral_Nutrition_DME.pdf
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"Florida Medicaid covers the following services in accordance with the American Medical Association's Current Procedural Terminology (CPT) and Healthcare Common Procedure Coding System (HCPCS), and the applicable Florida Medicaid fee schedule(s), or as specified in this policy: Enteral formula and medical supplies: – For recipients of any age when using the product as a sole source of nutrition For recipients under the age of 21 years when using the product as 50% or more of the recipient's caloric intake"

Idaho- <https://www.idmedicaid.com/Provider%20Guidelines/Suppliers.pdf>

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"Enteral nutrition is any method "of caloric delivery that uses the gastrointestinal tract such as feeding tube or oral administration. Enteral nutrition is covered for tube feeding when medically necessary according to the criteria described in the CMS/Medicare DME Coverage Manual. Nutrition received orally, including supplements such as thickener, are covered when necessary to meet the caloric needs of a participant who is unable to maintain growth, weight, and strength through traditional foods alone."

Kentucky- <https://apps.legislature.ky.gov/record/16rs/SB193.html>

"Amend KRS 205.560 to add amino acid-based elemental formula to the list of medicines covered by the Cabinet for Health and Family Services for treatment of inborn errors of metabolism or genetic, gastrointestinal, and food allergic conditions; amend KRS 213.141 to add amino acid-based elemental formula to the list of therapeutic foods supplied by the Division of Maternal and Child Health; amend KRS 304.17A-258 to include eosinophilic disorders, food protein allergies, food protein-induced enterocolitis syndrome, and short bowel disorders in the definition of "therapeutic food, formulas, and supplements"; define "amino acid-based elemental formula"; amend KRS 18A.225 to require any policy provided to state employees to cover amino acid-based elemental formulas; declare short title to be "Noah's Law"; EMERGENCY."

Michigan- <https://www.mdch.state.mi.us/dch-medicaid/manuals/MedicaidProviderManual.pdf>

Section 1.11

"NONCOVERED ITEMS Enteral formula to accommodate psychological or behavioral conditions, food preferences, allergies, loss of appetite, or noncompliance with a specialized diet"

Section 2.13.A

"Enteral nutrition (administered orally) may be covered for beneficiaries under the age of 21 when: ♣ A chronic medical condition exists resulting in nutritional deficiencies, and a three month trial is required to prevent gastric tube placement; or ♣ Supplementation to regular diet or meal replacement is required, and the beneficiary's weight-to-height ratio has fallen below the fifth percentile on standard growth grids; or ♣ Physician documentation details low percentage increase in growth pattern or trend directly related to the nutritional intake and associated diagnosis/medical condition. For CSHCS coverage, a nutritionist or appropriate pediatric subspecialist must indicate that long-term enteral supplementation is required to eliminate serious impact on growth and development."

New York- https://www.emedny.org/ProviderManuals/DME/PDFS/DME_Procedure_Codes.pdf

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"Benefit Coverage Criteria is limited to: Members who are fed via nasogastric, gastrostomy or jejunostomy tube. • Members with inborn metabolic disorders. • Children up to 21 years of age, who require liquid oral nutritional therapy when there is a documented diagnostic condition where caloric and dietary nutrients from food cannot be absorbed or metabolized. • Adults with a diagnosis of HIV infection, AIDS, or HIV-related illness, or other disease or condition, who are oral-fed, and who; ❖ require supplemental nutrition, demonstrate documented compliance with an appropriate medical and nutritional plan of care, and have a body mass index (BMI) under 18.5 as defined by the Centers for Disease Control, up to 1,000 calories per day; or ❖ require supplemental nutrition, demonstrate documented compliance with an appropriate medical and nutritional plan of care, have a body mass index (BMI) under 22 as defined by the Centers for Disease Control, and a documented, unintentional weight loss of 5 percent or more within the previous 6 month period, up to 1,000 calories per day; or ❖ require total oral nutritional support, have a permanent structural limitation that prevents the chewing of food, and placement of a feeding tube is medically contraindicated."

State Medicaid Continued:

Ohio- <http://codes.ohio.gov/oac/5160-10-26v1>

"The individual is able to ingest food but cannot derive sufficient energy and nutrients from ordinary food, even if the food is prepared in a liquefied, puréed, or blended form. The individual is unable to ingest food safely but can digest it; or the individual is unable to digest food in the alimentary canal and must obtain nutrition parenterally."

South Carolina- <https://provider.scdhhs.gov/internet/pdf/manuals/dme/Manual.pdf>

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"Enteral Nutrition

Enteral nutrition is the delivery of nutrients through a feeding tube to a normally functioning gastrointestinal tract. A feeding tube must be in place for the provision of nutrients. The formula in enteral feeding must provide nutrition that will maintain the beneficiary's body weight



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and/or provide nutrition for weight gain or healing. Special nutrient formulas are produced to meet unique nutrient needs for specific disease conditions.”

Washington- <https://www.hca.wa.gov/assets/billers-and-providers/Enteral-Nutrition-bi-20200101.pdf>

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“Oral enteral nutrition is a medical benefit for treating medical conditions when no equally effective, less costly alternative is available to treat the client’s condition. It is not a food benefit, such as the Basic Food in Washington and WIC. When commercially available products are prescribed to correct documented nutritional or growth deficiencies, they should be used for the shortest amount of time possible before transitioning to a diet of traditional food or food products with ingredients that can be purchased for the client as grocery products.”

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.