

Payment Policy 36 Hydrolyzed Enteral 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.

Policy Overview

Affected CPT codes: B4161, B4153

An amino acid-based elemental formula is a type of formula which is regulated by the U.S. Food and Drug Administration (FDA) and is prescribed for infants or children with specific medical or dietary problems. An amino acid-based formula contains proteins which are broken down into their simplest (elemental) form making it easier for the body to process and digest. While a protein may elicit an allergic reaction and may not be absorbed, elemental amino acids do not elicit the same reaction and are more easily absorbed. An infant or child may be placed on an amino acid-based formula if he/she is unable to digest or tolerate whole proteins found in other formulas, due to certain allergies or gastrointestinal conditions.

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 are 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 outlines clinical guidelines appropriate for the majority of individuals with specific diseases, illnesses, or conditions. However, each member's medical needs are unique, and coverage determinations may require individualized review based on the submitted clinical documentation.

If a diagnosis is not listed within this policy, providers may submit comprehensive medical records to support review of medical necessity.

Unless otherwise specified by the provider's contract, an itemized invoice is required when submitting claims for these services. The itemized invoice must align with all of the required billing standards/guidelines as required within the DMS provider type 90 billing manual.

Note: The list of diagnosis codes below is provided as reference only and may not be all inclusive.

ICD-10 Code	Description	ICD-10 Code	Description
E40	Kwashiorkor	E72.2	Urea cycle metabolism disorders
E41	Nutritional marasmus	E72.20	Urea cycle disorder, unspecified
E42	Marasmic kwashiorkor	E72.21	Argininemia
E43	Severe protein-calorie malnutrition	E72.22	Arginosuccinic aciduria
E44.0	Moderate protein-calorie malnutrition	E72.23	Citrullinemia
E44.1	Mild protein-calorie malnutrition	E72.29	Other disorders of urea cycle metabolism
E46	Unspecified protein-calorie malnutrition	E72.3	Lysine and hydroxylysine metabolism disorders
E70.0	Classical phenylketonuria	E72.4	Ornithine metabolism disorders
E70.1	Other hyperphenylalaninemias	E72.5	Glycine metabolism disorders
E70.2	Disorders of tyrosine metabolism	E72.50	Glycine metabolism disorder, unspecified
E70.20	Disorder of tyrosine metabolism, unspecified	E72.51	Non-ketotic hyperglycinemia
E70.21	Tyrosinemia	E72.52	Trimethylaminuria
E70.29	Other disorders of tyrosine metabolism	E72.53	Primary hyperoxaluria
E70.330	Chediak–Higashi syndrome	E72.59	Other glycine metabolism disorders
E70.331	Hermansky–Pudlak syndrome	E72.8	Other specified AA metabolism disorders
E70.40	Histidine metabolism disorder, unspecified	E72.9	Unspecified AA metabolism disorder
E70.41	Histidinemia	E74.21	Galactosemia
E70.49	Other disorders of histidine metabolism	E77.8	Other disorders of glycoprotein metabolism
E70.5	Disorders of tryptophan metabolism	E84.0	Cystic fibrosis with pulmonary manifestations
E70.8	Other disorders of aromatic amino-acid metabolism	E84.1	Cystic fibrosis with intestinal manifestations
E70.9	Aromatic amino-acid metabolism disorder, unspecified	E84.11	Meconium ileus in Cystic fibrosis
E71.0	Maple syrup urine disease	E84.19	Cystic fibrosis with other intestinal manifestations
E71.1	Other disorders of branched-chain AA metabolism	E84.8	Cystic fibrosis with other manifestations
E71.11	Branched-chain organic acidurias	E84.9	Cystic fibrosis, unspecified
E71.110	Isovaleric acidemia	E88.09	Other disorders of plasma-protein metabolism, NEC
E71.111	3-methylglutaconic aciduria	E88.9	Metabolic disorder, unspecified
E71.118	Other branched-chain organic acidurias	K20.0	Eosinophilic esophagitis
E71.12	Disorders of propionate metabolism	K21.9	GERD without esophagitis
E71.120	Methylmalonic acidemia	K50.00–K50.919	Crohn's disease (all types)
E71.121	Propionic acidemia	K51.00–K51.919	Ulcerative colitis (all types)
E71.128	Other disorders of propionate metabolism	K52.2	Allergic and dietetic gastroenteritis and colitis
E71.19	Other branched-chain AA metabolism disorders	K52.21	Food protein–induced enterocolitis syndrome (FPIES)
E71.2	Branched-chain AA metabolism disorder, unspecified	K52.22	Food protein–induced enteropathy
E71.3	Fatty-acid metabolism disorders	K52.29	Other allergic and dietetic gastroenteritis and colitis
E71.30	Fatty-acid metabolism disorder, unspecified	K52.81	Eosinophilic gastritis or gastroenteritis
E71.31	Fatty-acid oxidation disorder	K52.82	Eosinophilic colitis
E71.310	Long chain/very long chain acyl-CoA dehydrogenase deficiency	K59.00	Constipation
E71.311	Medium chain acyl-CoA dehydrogenase deficiency	K90.0	Celiac disease
E71.312	Short chain acyl-CoA dehydrogenase deficiency	K90.3	Pancreatic steatorrhea
E71.313	Glutaric aciduria type II	K90.41	Non-celiac gluten sensitivity
E71.314	Muscle carnitine palmitoyltransferase deficiency	K90.49	Malabsorption due to intolerance, NEC
E71.318	Other disorders of fatty-acid oxidation	K90.89	Other intestinal malabsorption
E72.0	Disorders of amino-acid transport	P78.1	Other neonatal peritonitis
E72.00	AA transport disorder, unspecified	P78.3	Noninfective neonatal diarrhea
E72.01	Cystinuria	P92.0–P92.9	Feeding problems of newborn
E72.02	Hartnup's disease	R62.51	Failure to thrive
E72.03	Lowe's syndrome	R63.30–R63.39	Feeding difficulties
E72.04	Cystinosis	R63.30–R63.39	Feeding difficulties
E72.09	Other AA transport disorders	T78.0XXA	Food-induced anaphylaxis
E72.1	Disorders of sulfur-bearing AA metabolism	T78.1XXA	Other adverse food reaction
E72.10	Sulfur-bearing AA metabolism disorder, unspecified	Z91.011	Allergy to Milk products
E72.11	Homocystinuria	Z91.012	Allergy to Eggs
E72.12	Methylenetetrahydrofolate reductase deficiency	Z91.018	Allergy to other foods
E72.19	Other sulfur-bearing AA metabolism disorders		

Passport by Molina Healthcare reimburses for enteral formulas billed under HCPCS B4161 (extensively hydrolyzed formula) and B4153 (semi elemental formula).

While authorization is not required for HCPCS codes B4161 or B4153, claims for enteral formulas billed under HCPCS B4161 or B4153 are subject to be reviewed periodically for medical necessity and documentation compliance. Claims lacking sufficient documentation, appropriate unit calculation, or required invoicing may be denied or adjusted in accordance with Kentucky Medicaid requirements and/or applicable contractual guidelines.

- Claims must be billed with the appropriate HCPCS code and qualifying diagnosis.
- Units billed must reflect the prescribed quantity and caloric requirements.
- Unless otherwise specified in the provider's contract, an itemized invoice is required when submitting claims for these services. The itemized invoice must align with all of the required billing standards/guidelines as required within the DMS provider type 90 billing manual.
- Reimbursement is subject to medical necessity, benefit limits, and contractual guidelines.

Audit and Recovery Process:

- **Review:** Claims will be meticulously examined against Passport by Molina Healthcare's standards.
- **Discrepancy Identification:** Any inconsistencies or errors identified will be documented.
- **Recovery:** Overpayments due to inaccuracies will be recovered either by offsets from future payments or through direct refund requests.
- **Appeals:** Providers reserve the right to contest any claim adjustments or denials. Details of the appeal process will accompany the notification.

Policy Monitoring, Review, and Updates:

- The policy will undergo annual reviews or as required, ensuring its alignment with industry best practices, regulatory mandates, and Passport by Molina Healthcare's operational necessities. Any updates will be promptly communicated to providers.

Supplemental Information

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

Definitions

Term	Definition
CMS	The Centers for Medicare & Medicaid Services. It is a federal agency within the United States Department of Health and Human Services that administers the Medicare program and works in partnership with state governments to administer Medicaid, the Children's Health Insurance Program (CHIP), and health insurance portability standards.
Healthcare Common	A standardized coding system used to describe specific items and services provided in healthcare, including procedures, health services, and durable medical equipment

Procedure Coding System (HCPCS)	(DME). Established by the Centers for Medicare & Medicaid Services (CMS), HCPCS codes are essential for billing and documentation in the healthcare system.
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Documentation History

Type	Date	Action
Effective Date	11/20/23	
Revised Date	12/23/25	Added the following diagnosis: E40, E41, E42, E43, E44.0, E44.1, E46, E74.21, E77.8, E88.09, E88.9, K20.0, K21.9, K50.00, K50.919, K51.00–K51.919, K52.29, K59.00, K90.0, K90.3, K90.41, K90.49, K90.89, P78.1, P78.3, P92.0–P92.9, R62.51, R63.30–R63.39, R63.30–R63.39, T78.0XXA, T78.1XXA, Z91.011, Z91.012, Z91.018. Added Reimbursement Guidelines and Definitions. Updated Overview to Policy Overview and added a note under Policy Overview
Publication Dates	10/11/2023 03/16/2026	
New Effective Date	04/16/2026	

Related Policies

Policy Name

References

CMS-

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

Section 5.9

“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 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:

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.”

This policy is designed to provide guidance and is not a guarantee of payment. Healthcare providers should make medical necessity determinations based on the individual clinical circumstances of each patient.