

Hydrolyzed Elemental Formula Diagnosis Policy

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 plans 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-CM 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
- 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 - Methylenetetrahydrofolate 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 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 |

Reimbursement Guidelines

Molina Healthcare will monitor compliance with this policy and take corrective action as necessary to ensure ongoing adherence to coding and billing standards.

This policy ensures that Molina Healthcare operates in a manner that is compliant with all applicable laws and regulations and maintains the integrity and accuracy of billing and coding practices.

Supplemental Information

State Exceptions

| State | Exception |
|----------|---|
| Medicare | Exclude Rev Code 80X Exclude Modifier AY Exclude HCPCS code J0604 |
| IL | Exclude CPT J0606 |
| OH | Exclude Modifier 1: AY, 59, 91 Exclude CPT: J0606, 80047, 80048, 80051, 80053, 80069, 80076, 82306, 82330, 82575, 83550, 84466, 84540, 85046, 87075, 87081, J0604, J0610, J0882, J0887, J1200, J1270, J1756, J1940, J2501, J2916, Q0163, Q4081, Q5105 Exclude Rev Code: 0800, 0801, 0802, 0803, 0804, 0809, 0820, 0821, 0822, 0823, 0824, 0825, 0826, 0829, 0830, 0831, 0832, 0833, 0834, 0835, 0839, 0840, 0841, 0842, 0843, 0844, 0845, 0849, 0850, 0851, 0852, 0853, 0854, 0855, 0859, 0880, 0881, 0882, 0889, 800, 801, 802, 803, 804, 809, 820, 821, 822, 823, 824, 825, 826, 829, 830, 831, 832, 833, 834, 835, 839, 840, 841, 842, 843, 844, 845, 849, 850, 851, 852, 853, 854, 855, 859, 880, 881, 882, 889 |
| SC | SC Medicaid does not pay ESRD (End Stage Renal Disease) PPS |

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| WA | Exclude claims paid Medicaid method services in the Medicaid fee schedule. Reports should include: Contract description, Contract term description Term type for both claims to aid in determining any special contract language. |
| WI | Exclude claims with Custom contracts 'MP - HOSP - HSHS' for WI |

Documentation History

| Type | Date | Action |
|-----------------------|------------|---|
| Initial Creation Date | 04/26/2024 | New Policy |
| Revised Date | 07/09/2024 | Updated Template |
| Revised Date | 12/16/2024 | Updated Template |
| Revised Date | 08/04/2025 | Updated Template |
| Revised Date | 09/02/2025 | Added verbiage to Reimbursement Guidelines; Added Supplemental Information headline; re-formatted PI number and pages; reformatted Definitions; reformatted References. |
| Revised Date | 09/19/2025 | Updated Reference links |

References

This policy was developed using:

- CMS
- State Medicaid Regulatory Guidance
- State Contracts

| Reference | Link |
|-----------|---|
| CMS | MEDICARE PROGRAM INTERGRITY MANUAL |
| FDA | GUIDANCE FOR INDUSTRY |
| JAMA | JAMA PEDIATRICS |
| FL | FLORDIA MEDICAID MANUAL |
| ID | SUPPLIERS PROVIDER CHECKLIST |
| KY | SENATE BILL 193 |
| MI | MEDICAID PROVIDER MANUAL |
| MS | PPS CONSOLIDATED BILLING LIST |
| NY | DME PROCEDURE CODES & COVERAGE GUIDELINES |
| OH | RULE 5160-10-26 DMEPOS: NUTRITION PRODUCTS |
| SC | DME: SERVICES PROVIDER MANUAL |
| WA | ENTERAL NUTRITION BILLING GUIDE |

***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.