STATE OF IOWA DEPARTMENT OF
Health AND Human
SERVICES

Medical Foods
DME-023

Iowa Medicaid Program:	Prior Authorization	**Effective Date:**	7/15/2022
Revision Number:	3	**Last Rev Date:**	7/19/2024
Reviewed By:	Medicaid Medical Director	**Next Rev Date:**	7/18/2025
Approved By:	Medicaid Clinical Advisory Committee	**Approved Date:**	7/15/2022

Descriptive Narrative

Medical food is defined in section 5(b) of the Orphan Drug Act (21 U.S.C. 360ee (b) (3) as: "A food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation".

Frequently Asked Questions guidance on medical foods from the FDA states that "not all foods used for supplementing the diet of someone, even a person with a disease requiring dietary management are medical foods. Instead, medical foods are specially formulated and processed (as opposed to a naturally occurring foodstuff used in a natural state) for a patient who requires use of the product as a major component of a disease or condition's specific dietary management". **Naturally occurring foods and food typically available at the local grocery store would not meet the FDA definition of a medical food.**

Medical foods and dietary restriction comprise the major elements of treatment for a class of diseases called inborn errors of metabolism (IEM). The FDA indicates that many IEM can be managed without medical foods, however others cannot. "For these IEM, a medical food is required in addition to a specific dietary modification in order to obtain adequate levels of essential nutrients (e.g., essential amino acids, essential fatty acids) that are restricted by modifying the normal diet".

Inborn Errors of Metabolism (IEM)

IEM are a large group of rare genetic disorders that result from a defect in an enzyme or transport protein causing the blockage of a metabolic pathway. Illness and symptoms result from toxic accumulations of substrates before the blockage, intermediate products from alternative metabolic pathways, defects in energy production and use caused by a deficiency of products beyond the blockage, or a combination of these metabolic deviations.

The incidence of IEM collectively, is estimated to be as high as 1 in 800 live births, but it varies greatly and depends on the population. Phenylketonuria (PKU) and medium-chain acyl-CoA

dehydrogenase (MCAD) deficiency with respective incidences of 1 in 10,000 and 1 in 20,000 are among the most prevalent.

Optimal outcome for children with IEM depends upon early recognition of the signs and symptoms of metabolic disease and prompt evaluation and referral to a center familiar with the management of these disorders. The clinical manifestations in many of these disorders can be prevented if diagnosis is achieved early and necessary treatment with dietary protein or amino acid restriction is instituted immediately. Delay in diagnosis may result in acute metabolic decompensation, progressive neurologic injury, or death.

Treatment may include restriction of specific amino acids, restriction of total nitrogen intake, or supplementation of certain substances. For some IEM, special formulas and medical foods have been developed which eliminate the amino acid that cannot be metabolized from the protein context of the food. As adults, patients must avoid certain foods as well.

There are three major categories of IEM: protein disorders, fatty acid oxidation disorders, and carbohydrate disorders. Special food products are required to treat inborn errors of metabolism to avoid long-term complications. IEM are considered present at birth and permanent.

Not all IEM require nutritional supplementation through medical foods. Members with the following IEM are eligible for reimbursement:

- Phenylketonuria (PKU),
- Maple syrup urine disease (MSUD),
- Homocystinuria,
- Urea cycle disorders,
- Organic acidemias (e.g., Isovaleric Acidemia, propionic academia, methylmalonic academia),
- Histidinemia,
- Tyrosinemia,
- von Gierke's disease,
- Pyruvate dehydrogenase deficiency,
- Lysinuric protein intolerance.

Please refer to Enteral Products and Supplies criteria for coverage of those products.

Criteria

Medical foods are considered medically necessary when **ALL** the following are met:

1. The member must have a diagnosis of an IEM that interferes with the metabolism of specific nutrients; **AND**
2. The condition must be present at birth and considered a permanent condition; **AND**
3. The food is prescribed by or authorized by a licensed healthcare practitioner; **AND**
4. A nutritional plan must be submitted by a dietician.

Not Covered

Foods that are available in a supermarket are considered a noncovered benefit.

Coding

The following list of codes is provided for reference purposes only and may not be all inclusive. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment, nor does the exclusion of a code imply that its association to the HCPCS/CPT code is inappropriate.

HCPCS	Description
S9435	Medical foods for inborn errors of metabolism.

Compliance

1. Should conflict exist between this policy and applicable statute, the applicable statute shall supersede.
2. Federal and State law, as well as contract language, including definitions and specific contract provisions or exclusions, take precedence over medical policy and must be considered first in determining eligibility for coverage.
3. Medical technology is constantly evolving, and Iowa Medicaid reserves the right to review and update medical policy on an annual and as-needed basis.

Medical necessity guidelines have been developed for determining coverage for member benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. Criteria are revised and updated annually, or more frequently if new evidence becomes available that suggests needed revisions.

References

Optum EncoderPro.

U.S. Food and Drug Administration. Regulatory Information. Section 5 (b) of the Orphan Drug Act (21 U.S.C. 360ee (b) (3)). Content current as of January 25, 2022. Available at: http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/MedicalFoods/default.htm.

Frequently Asked Questions about Medical Foods. Second Edition. Food and Drug Administration. Center for Food Safety and Applied Nutrition. May 2016. https://www.fda.gov/media/97726/download.

Sutton V Reid. Inborn errors of metabolism: Epidemiology, pathogenesis, and clinical features. UpToDate. Last updated February 01, 2022.

Weiner Debra L. Inborn Errors of Metabolism. Medscape. Updated September 20, 2017.

Recommended Uniform Screening Panel. Federal Advisory Committee. Health Resources and Services Administration. Core and Secondary Conditions (as of July 2018). https://www.hrsa.gov/advisory-committees/heritable-disorders/rusp/index.html.

Development of utilization management criteria may also involve research into other state Medicaid programs, other payer policies, consultation with experts and review by the Medicaid Clinical Advisory Committee (CAC). These sources may not be referenced individually unless they are specifically published and are otherwise applicable to the criteria at issue.

Criteria Change History

Change Date	Changed By	Description of Change	Version
Signature			

Change Date	Changed By	Description of Change	Version
Signature			

Change Date	Changed By	Description of Change	Version
7/19/2024	CAC	Annual review.	3
Signature William (Bill) Jagiello, DO			
Change Date	**Changed By**	**Description of Change**	**Version**
7/21/2023	CAC	Annual review.	2
Signature William (Bill) Jagiello, DO			

Criteria Change History

Change Date	Changed By	Description of Change	Version
7/15/2022	CAC	Criteria implementation.	1

Signature
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