



## PROVIDER POLICIES & PROCEDURES

### MEDICAL FOODS

The primary purpose of this document is to assist providers enrolled in the Connecticut Medical Assistance Program (CMAP) with the information needed to support a medical necessity determination for medical foods. By clarifying the information needed for prior authorization of services, HUSKY Health hopes to facilitate timely review of requests so that individuals obtain the medically necessary care they need as quickly as possible.

The FDA, in section 5(b)(3) of the Orphan Drug Act (21 U.S.C. 360ee(b)(3)), defines medical food 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.” The FDA, further states “Medical foods are distinguished from the broader category of foods for special dietary use by the requirement that medical foods be intended to meet distinctive nutritional requirements of a disease or condition, used under medical supervision, and intended for the specific dietary management of a disease or condition. Medical foods are not those simply recommended by a physician as part of an overall diet to manage the symptoms or reduce the risk of a disease or condition. Not all foods fed to patients with a disease, including diseases that require dietary management, are medical foods. Instead, medical foods are foods that 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.”

Please refer to the [DSS MEDS – Miscellaneous fee schedule](#) for the list of items requiring prior authorization.

This policy addresses coverage of medical foods for non-inborn and inborn errors of metabolism under the HUSKY Health Program medical benefit. Please refer to [the HUSKY Health Medical Equipment, Devices, and Supplies \(MEDS\) benefit grid](#) for additional information on nutritional formulas covered under the HUSKY Health Program Pharmacy benefit.

#### Benefit and Prior Authorization Requirements:

- Prior authorization is required for medical foods for non-inborn errors of metabolism (HCPCS code S9432)
- Prior authorization is required for medical foods for inborn errors of metabolism (HCPCS code S9435)

#### CLINICAL GUIDELINE

Coverage guidelines for medical foods are made in accordance with the DSS definition of Medical Necessity. The following criteria are guidelines *only*. Coverage determinations are based on an assessment of the individual and their unique clinical needs. If the guidelines conflict with the definition of Medical Necessity, the definition of Medical Necessity shall prevail. The guidelines are as follows:

Please note that authorization is based on medical necessity at the time the authorization is issued and is not a guarantee of payment. Payment is based on the individual having active coverage, benefits and policies in effect at the time of service. <sup>1</sup>

To determine if a service or procedure requires prior authorization, CMAP Providers may refer to the *Benefit and Authorization Grids* summaries on [www.ct.gov/husky](http://www.ct.gov/husky) by clicking on “For Providers” followed by “Benefit Grids”. For a definitive list of benefits and service limitations, CMAP Providers may access the CMAP provider fee schedules and regulations at [www.ctdssmap.com](http://www.ctdssmap.com).

Medical foods may be considered medically necessary when:

- A. The product is a medical food for oral or tube feeding that is prescribed by a physician, advanced practice registered nurse (APRN), or physician assistant (PA); and
- B. The individual has a diagnosis of an inborn error of metabolism that interferes with the metabolism of specific nutrients for which there are distinctive nutritional requirements to avert the development of serious physical or mental disabilities, including but not limited to one of the following conditions:
  - Phenylketonuria (PKU)
  - Maple syrup urine disease
  - Homocystinuria
  - Urea cycle disorders
  - Organic acidemias
  - Histidinemia
  - Tyrosinemia
  - Von Gierke's disease (Type 1 glycogen storage disease)
  - Pyruvate dehydrogenase deficiency.

**Investigational and Not Medically Necessary**

Medical foods for conditions other than inborn errors of metabolism are typically considered investigational and therefore not medically necessary. Requests for medical foods for these conditions will be reviewed on a case-by-case basis.

**NOTE: EPSDT Special Provision**

Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) is a federal Medicaid requirement that requires the Connecticut Medical Assistance Program (CMAP) to cover services, products, or procedures for Medicaid enrollees under 21 years of age where the service or good is medically necessary health care to correct or ameliorate a defect, physical or mental illness, or a condition identified through a screening examination. The applicable definition of medical necessity is set forth in Conn. Gen. Stat. Section 17b-259b (2011) [ref. CMAP Provider Bulletin PB 2011-36].

**PROCEDURE**

Prior authorization for medical foods is required. Requests for coverage are reviewed in accordance with procedures in place for reviewing requests for medical equipment, devices, and supplies (MEDS). Coverage determinations are based upon a review of requested and/or submitted case-specific information.

**The following information is needed to review requests for medical foods:**

- 1. Fully completed authorization request via on-line web portal or fully completed Outpatient Prior Authorization Request form; and
- 2. An ICD 10-CM diagnosis code for an inborn error of metabolism clearly written on or entered in the authorization request; and
- 3. (For conditions other than an inborn error of metabolism), clinical documentation supporting medical necessity; and
- 4. Pricing information as outlined in the [DSS Pricing Policy for MEDS Items](#).

**EFFECTIVE DATE**

This policy for the prior authorization for medical foods for individuals covered under the HUSKY Health Program is effective August 01, 2024.

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## LIMITATIONS

N/A

## CODES:

Code	Description
S9432	Medical foods for non-inborn errors of metabolism
S9435	medical foods for inborn errors of metabolism

## DEFINITIONS

1. **HUSKY A:** Connecticut children and their parents or a relative caregiver; and pregnant women may qualify for HUSKY A (also known as Medicaid). Income limits apply.
2. **HUSKY B:** Uninsured children under the age of 19 in higher income households may be eligible for HUSKY B (also known as the Children's Health Insurance Program) depending on their family income level. Family cost-sharing may apply.
3. **HUSKY C:** Connecticut residents who are age 65 or older or residents who are ages 18-64 and who are blind, or have another disability, may qualify for Medicaid coverage under HUSKY C (this includes Medicaid for Employees with Disabilities (MED-Connect), if working). Income and asset limits apply.
4. **HUSKY D:** Connecticut residents who are ages 19-64 without dependent children and who: (1) do not qualify for HUSKY A; (2) do not receive Medicare; and (3) are not pregnant, may qualify for HUSKY D (also known as Medicaid for the Lowest-Income populations).
5. **HUSKY Health Program:** The HUSKY A, HUSKY B, HUSKY C, HUSKY D and HUSKY Limited Benefit programs, collectively.
6. **HUSKY Limited Benefit Program or HUSKY, LBP:** Connecticut's implementation of limited health insurance coverage under Medicaid for individuals with tuberculosis or for family planning purposes and such coverage is substantially less than the full Medicaid coverage.
7. **Medically Necessary or Medical Necessity:** (as defined in Connecticut General Statutes § 17b-259b) Those health services required to prevent, identify, diagnose, treat, rehabilitate or ameliorate an individual's medical condition, including mental illness, or its effects, in order to attain or maintain the individual's achievable health and independent functioning provided such services are: (1) Consistent with generally-accepted standards of medical practice that are defined as standards that are based on (A) credible scientific evidence published in peer-reviewed medical literature that is generally recognized by the relevant medical community, (B) recommendations of a physician-specialty society, (C) the views of physicians practicing in relevant clinical areas, and (D) any other relevant factors; (2) clinically appropriate in terms of type, frequency, timing, site, extent and duration and considered effective for the individual's illness, injury or disease; (3) not primarily for the convenience of the individual, the individual's health care provider or other health care providers; (4) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the individual's illness, injury or disease; and (5) based on an assessment of the individual and his or her medical condition.
8. **Prior Authorization:** A process for approving covered services prior to the delivery of the service or initiation of the plan of care based on a determination by CHNCT as to whether the requested service is medically necessary.

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## REFERENCES

- Camp KM, Lloyd-Puryear MA, Huntington KL. Nutritional treatment for inborn errors of metabolism: indications, regulations, and availability of medical foods and dietary supplements using phenylketonuria as an example. *Mol Genet Metab.* 2012;107(1-2):3-9. doi:10.1016/j.ymgme.2012.07.005
- Frequently Asked Questions about Medical Foods. Second Edition. Food and Drug Administration. Center for Food Safety and Applied Nutrition. May 2016. Available at: <https://www.fda.gov/media/97726/download>. Accessed on February 8, 2024.
- Weiner Debra L. Inborn Errors of Metabolism. Medscape. Updated September 20, 2017.
- U.S. Food and Drug Administration (FDA). Guidance for Industry: Frequently Asked Questions About Medical Foods - Third Edition. March 2023. Available at: <https://www.fda.gov/regulatory-information/search-fdaguidance-documents/guidance-industry-frequently-asked-questions-about-medical-foodsthird-edition> Accessed on February 14, 2024.
- 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 March 1, 2023. Available at: <https://www.fda.gov/food/guidance-documents-regulatory-information-topic-food-and-dietary-supplements/medical-foods-guidance-documents-regulatory-information>. Accessed on February 8, 2024.

## PUBLICATION HISTORY

Status	Date	Action Taken
Original Publication	June 2024	Approved at the June 12, 2024 CHNCT Medical Reviewer meeting. Approved at the June 17, 2024 CHNCT Clinical Quality Subcommittee meeting. Approved by DSS on June 26, 2024.

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