

902 KAR 4:035. Cost reimbursement for specialized food products.

RELATES TO: KRS 205.560(1)(c), 213.141(2), 304.17A-258, 7 C.F.R. 246.2, 246.10

STATUTORY AUTHORITY: KRS 194A.050(1), 205.560(1)(c)

CERTIFICATION STATEMENT:

NECESSITY, FUNCTION, AND CONFORMITY: KRS 194A.050(1) requires the secretary of the Cabinet for Health and Family Services to promulgate administrative regulations necessary to operate the programs and fulfill the responsibilities vested in the cabinet. KRS 205.560(1)(c) requires the cabinet to cover the cost of products for the treatment of inborn errors of metabolism or genetic, gastrointestinal, and food allergic conditions, consisting of therapeutic food, formulas, supplements, amino acid-based elemental formula, or low-protein modified food products that are medically necessary and administered under the direction of a physician. This administrative regulation establishes the application and cost reimbursement procedures for specialized food products.

Section 1. Definitions.

- (1) "Amino acid-based elemental formula" is defined by KRS 304.17A-258(1)(c).
- (2) "Low-protein modified food" is defined by KRS 304.17A-258(1)(b).
- (3) "Patient" means a person with one (1) or more of the metabolic conditions listed in KRS 205.560(1)(c).
- (4) "Program" means the Kentucky Metabolic Foods and Formulas program operated by the Cabinet for Health and Family Services, Department for Public Health.
- (5) "Specialized food product" means a therapeutic food or formula, supplement, amino acid-based elemental formula, or low-protein modified food product, which is medically indicated for therapeutic treatment.
- (6) "Uninsured patient" means a patient who does not meet the criteria to receive Medicaid, K-CHIP, Medicare, or WIC benefits, or whose private insurance coverage is exhausted or denied.
- (7) "Vendor" means an individual or entity authorized to fill a prescription for specialized food product for an uninsured patient.
- (8) "WIC" is defined by 7 C.F.R. 246.2.

Section 2. Eligibility.

- (1) An individual meeting the definition of an uninsured patient shall be eligible to receive approval for financial coverage of a specialized food product by the program.
- (2) An uninsured patient seeking financial coverage of a specialized food product shall submit to the program:
 - (a) Kentucky Metabolic Food and Formula Provision Financial and Release of Information Form; and
 - (b) Written verification that an application for WIC, Medicaid, Medicare, or K-CHIP was denied, and that private health insurance has been exhausted or denied.
- (3) On behalf of an uninsured patient seeking financial coverage of a specialized food product, a licensed or certified healthcare practitioner with prescriptive authority shall submit to the program:
 - (a)
 1. A Kentucky Metabolic Disease Program Physician's Statement of Medical Necessity – Metabolic Disease Therapy form; or
 2. A certificate of medical necessity; and
 - (b) A prescription for the specialized food product.
- (4) Eligibility for financial coverage shall be renewed annually by submitting the documentation as required by subsection (2) of this section.
- (5) The cost of the formula for a patient who is eligible for WIC shall be covered by the WIC Program in accordance with 7 C.F.R. 246.10(e)(3)(i).

(6) The cost for food and formula for a patient covered by private health insurance shall be paid under the terms of the individual insurance policy, which shall meet or exceed the limit established in KRS 304.17A-258.

Section 3. Cost Reimbursement.

(1) Cost reimbursement shall be made directly to the vendor filling a prescription for a specialized food product.

(2) To receive reimbursement of the actual cost plus twenty (20) percent, a vendor shall submit the following documents to the program:

- (a) A prescription for the specialized food product from a licensed or certified healthcare practitioner with prescriptive authority;
- (b) A completed Authorization for Services, MFF-100; and
- (c) An invoice from the supplier with the patient name, service date, and cost to the vendor.

Section 4. Incorporation by Reference.

(1) The following material is incorporated by reference:

- (a) "Kentucky Metabolic Disease Program Physician's Statement of Medical Necessity - Metabolic Disease Therapy", Rev. 2/19;
- (b) "Authorization for Services", MFF-100, 2/19; and
- (c) "Kentucky Metabolic Food and Formula Provision Financial and Release of Information Form", FRI-100, Rev. 2/19.

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(27 Ky.R. 3477; Am. 28 Ky.R. 393; eff. 8-15-2001; 379; 890; eff. 11-16-2005; 45 Ky.R. 3557; eff. 8-19-2019; Crt eff. 7-1-2026.)