

MEDICAL FOODS INSURANCE COVERAGE ACT
Act of Dec. 20, 1996, P.L. 1492, No. 191
AN ACT

Cl. 40

Providing for certain health insurance policies to cover the cost of formulas necessary for the treatment of phenylketonuria and other disorders. (Title amended Oct. 22, 2014, P.L.2564, No.158)

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The General Assembly of the Commonwealth of Pennsylvania hereby enacts as follows:

Section 1. Short title.

This act shall be known and may be cited as the Medical Foods Insurance Coverage Act.

Section 2. Declaration of policy.

The General Assembly finds and declares as follows:

(1) Phenylketonuria (PKU), branched-chain ketonuria, galactosemia and homocystinuria are aminoacidopathies that are rare hereditary genetic metabolic disorders.

(2) Lacking in these aminoacidopathies is the body's ability to process or metabolize amino acids, and, if left untreated or without proper therapeutic management, these disorders cause severe mental retardation and chronic physical disabilities.

(3) The only form of treatment is by restricting food intake in order to remove the problem amino acids, which are necessary in the diet, and then replenishing them in carefully controlled measured amounts of a nutritional food substitute.

(4) In an attempt to encourage the development of new products, increase availability and reduce cost, formulas were removed from the Federal prescription list and reclassified as medical foods. An unfortunate side effect has been the reluctance of many insurance companies to cover the cost of these formulas. In instances where coverage is provided, it is random and subject to inconsistent interpretation.

(5) The intent of this legislation is not to require insurance coverage for normal food products used in dietary management of these disorders, but to provide for such coverage of formulas that are equivalent to a prescription drug medically necessary for the therapeutic treatment of such rare hereditary genetic metabolic disorders and administered under the direction of a physician.

(6) In recognition by the General Assembly that such formulas are medically necessary and critical to the well-being of individuals afflicted with rare hereditary genetic metabolic disorders, it shall be required that health

insurance policies issued in this Commonwealth shall include such coverage.

Section 3. Definitions.

The following words and phrases when used in this act shall have the meanings given to them in this section unless the context clearly indicates otherwise:

"Health insurance policy." Except for specified disease and accident-only policies, the term shall mean any group health insurance policy, contract or plan or any individual policy, contract or plan with coverage for prescription drugs which provides medical coverage on an expense-incurred, service or prepaid basis. The term includes the following:

(1) A health insurance policy or contract issued by a nonprofit corporation subject to 40 Pa.C.S. Chs. 61 (relating to hospital plan corporations) and 63 (relating to professional health services plan corporations) and the act of December 14, 1992 (P.L.835, No.134), known as the Fraternal Benefit Societies Code.

(2) A health service plan operating under the act of December 29, 1972 (P.L.1701, No.364), known as the Health Maintenance Organization Act.

Section 4. Medical foods insurance coverage.

(a) Nutritional supplements.--Except as provided in section 7, any health insurance policy which is delivered, issued for delivery, renewed, extended or modified in this Commonwealth by any health care insurer shall provide that the health insurance benefits applicable under the policy include coverage for the cost of nutritional supplements (formulas) as medically necessary for the therapeutic treatment of phenylketonuria, branched-chain ketonuria, galactosemia and homocystinuria as administered under the direction of a physician.

(b) Amino acid-based elemental medical formula.--Except as provided in section 7, any health insurance policy which is delivered, issued for delivery, renewed, extended or modified in this Commonwealth by any health care insurer shall provide that the health insurance benefits applicable under the policy include coverage for infants and children for the usual and customary cost of amino acid-based elemental medical formula ordered by a physician as medically necessary and administered orally or enterally for food protein allergies, food protein-induced enterocolitis syndrome, eosinophilic disorders and short-bowel syndrome. An amino acid-based elemental formula covered under this section is a formula made of 100% free amino acids as the protein source.

(4 amended Oct. 22, 2014, P.L.2564, No.158)

Section 5. Delivery of policy.

Except as provided in section 7, if a health insurance policy provides coverage or benefits to a resident of this Commonwealth, it shall be deemed to be delivered in this Commonwealth within the meaning of this act, regardless of whether the health care insurer issuing or delivering the policy is located within or outside this Commonwealth.

Section 6. Cost-sharing provisions.

(a) Applicability.--Benefits for nutritional supplements (formulas) as medically necessary for the therapeutic treatment of phenylketonuria, branched-chain ketonuria, galactosemia and homocystinuria as administered under the direction of a physician shall be subject to copayment and coinsurance provisions of a health insurance policy to the extent that other medical services covered by the policy are subject to those provisions.

(a.1) Amino acid-based elemental medical formula.--Benefits for amino acid-based elemental medical formula ordered by a physician as medically necessary for food protein allergies, food protein-induced enterocolitis syndrome, eosinophilic disorders and short-bowel syndrome shall be subject to copayment and coinsurance provisions of a health insurance policy to the extent that other medical services covered by the policy are subject to those provisions.

(b) Exemption.--Benefits for nutritional supplements (formulas) as medically necessary for the therapeutic treatment of phenylketonuria, branched-chain ketonuria, galactosemia and homocystinuria as administered under the direction of a physician shall be exempt from deductible provisions in a health insurance policy. This exemption must be explicitly provided for in the policy.

(6 amended Oct. 22, 2014, P.L.2564, No.158)

Section 7. Exemption.

Notwithstanding sections 4 and 5, this act shall not be construed to require a health insurance policy to include coverage for nutritional supplements (formulas) as medically necessary for the therapeutic treatment of phenylketonuria, branched-chain ketonuria, galactosemia and homocystinuria as administered under the direction of a physician for an individual who is a resident of this Commonwealth if all of the following apply:

(1) The individual is employed outside this Commonwealth.

(2) The individual's employer maintains a health insurance policy for the individual as an employment benefit.

Section 8. Regulations.

The Department of Health and the Insurance Department may promulgate regulations as necessary and appropriate to implement this act.

(8 amended Oct. 22, 2014, P.L.2564, No.158)

Section 9. Applicability.

This act shall apply as follows:

(1) For health insurance policies for which either rates or forms are required to be filed with the Insurance Department or the Federal Government, this act shall apply to any policy for which a form or rate is first filed on or after the effective date of this section.

(2) For health insurance policies for which neither rates nor forms are required to be filed with the Insurance Department or the Federal Government, this act shall apply to any policy issued or renewed on or after 180 days after the effective date of this section.

(9 amended Oct. 22, 2014, P.L.2564, No.158)

Section 10. Effective date.

This act shall take effect in six months.