STATE OF CONNECTICUT

INSURANCE DEPARTMENT

BULLETIN HC - 60
September 24, 2004

TO: All Health Insurers Authorized To Conduct Business In Connecticut

RE: Public Act 04-173 – An Act Concerning Health Insurance Coverage for Medically Necessary Formula

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Public Act 04-173 amended Connecticut General Statutes 38a-492c and 38a-518c by extending the mandate for health insurance policies to cover specialized formulas for children from age three to age eight and mandating that coverage for those formulas, as well as low protein modified food products and amino acid modified preparations prescribed for the treatment of inherited metabolic diseases, be covered on the same basis as outpatient prescription drugs. Health insurance carriers have previously identified areas of concern regarding the medical necessity criteria for the specialized infant formulas and have now asked for clarification regarding the administration of the newly mandated requirements. The Insurance Department ("Department") is issuing this bulletin to provide guidance.

Medically Necessary Criteria

Sections 38a-492c and 38a-518c each contain two distinct subsections that set forth specific mandate language. Subsection (b) addresses coverage for inherited metabolic diseases and mandates coverage for "amino acid modified preparations or low protein modified food products for the treatment of inherited metabolic diseases if the amino acid modified preparations or low protein modified food products are prescribed for the therapeutic treatment of inherited metabolic diseases and are administered under the direction of a physician." Subsection (c) mandates coverage for "specialized formulas when such specialized formulas are medically necessary for the treatment of a disease or condition and are administered under the direction of a physician." The distinguishing differences between the two subsections are that under subsection (c), coverage for specialized formulas is provided for children up to age eight when medically necessary for the treatment of a disease or condition; they need not suffer from a statutorily specified disease such as a metabolic disorder.

The United States Food and Drug Administration (FDA) regulations exempt infant formula from the general nutritional labeling requirements that apply, with exceptions, to products intended for human consumption (21 CFR § 101. 9(j)(7)). FDA has separate regulations on infant formulas that exempt from labeling requirements formulas that are represented and labeled for use by infants with inborn metabolic disorders, low birth weights, or unusual medical or dietary problems (21 CFR § 107. 3). The FDA distinguishes between two types of exempt formulas - those that are readily available to the general public at retail stores and those that are not. The FDA's intent is that formulas available at a retail store are typically labeled for dietary management of diseases or conditions that are not clinically serious or life-threatening, even

formulas that are not available for general consumer purchase are typically prescribed by a physician and must be requested from a pharmacist. They are labeled solely to provide dietary management for specific diseases or conditions that are clinically serious or life-threatening and generally are required for prolonged periods of time (21 CFR § 107. 50). Unfortunately, the FDA intent is not reflective of actual practice.

The FDA has identified that it does not mandate or regulate which formulas are provided on an "off the shelf" or "behind the counter" basis and that determination frequently happens at the retail level based on space limitations. Consequently, the method of distribution and delivery, i.e., "off the shelf" or "behind the counter" cannot determine whether a formula is exempt and thus subject to the law as a specialized formula. Furthermore, while the FDA does provide a list of the formulas by category classification on their website, they acknowledge that the list is frequently outdated. The Department believes that is it inappropriate for determinations of coverage to be made based primarily on the distinction of whether a formula is "off the shelf" or "behind the counter" while the question of medical necessity is neglected. The Department expects that all health insurers authorized to conduct business in the State of Connecticut will establish reasonable medical necessity criteria against which to evaluate requests for coverage of all infant formula. Criteria need not be submitted to the Department for approval. Any claims denied for not meeting that medical necessity criteria may be appealed through the external appeal process.

Coverage as Outpatient Prescription Drug

Public Act 04-173 amended Sections 38a-492c and 38a-518c by adding a new subsection (d) which provides "Such policy shall provide coverage for such preparations, food products and formulas on the same basis as outpatient prescription drugs." This amendment has raised a number of questions regarding coverage application and claim handling. The following will provide guidance in administering this new provision.

1. The mandate requires coverage for specialized formulas and amino acid modified preparations or low protein modified food products for the treatment of inherited metabolic diseases in the base policy. The relevant part of Public Act 04-173 reads:

    (b) Each group health insurance ***policy*** (emphasis added) providing coverage of the type specified in subdivisions (1), (2), (4), (6), (11) and (12) of section 38a-469 delivered, issued for delivery or renewed in this state on or after October 1, 1997, shall provide coverage for amino acid modified preparations and low protein modified food products for the treatment of inherited metabolic diseases if the amino acid modified preparations or low protein modified food products are prescribed for the therapeutic treatment of inherited metabolic diseases and are administered under the direction of a physician.

    (c) Each group health insurance ***policy*** (emphasis added) providing coverage of the type specified in subdivisions (1), (2), (4), (6), (11) and (12) of section 38a-469 delivered, issued for delivery or renewed in this state on or after October 1, 2001, shall provide coverage for specialized formulas when such specialized formulas are medically necessary for the treatment of a disease or condition and are administered under the direction of a

physician.

(d) Such ***policy*** (emphasis added) shall provide coverage for such preparations, food products and formulas on the same basis as outpatient prescription drugs.

We read this to mean that the mandate applies to the health policy notwithstanding whether there is prescription drug coverage through a Pharmacy Benefit Manager (PBM), another carrier or no drug coverage. The mandate requires the policy to provide coverage, with the coverage level set at that of the drug benefit. If there is no drug benefit, coverage is governed by the base plan limits.

The same would be applicable for the individual policies.

2. Patient benefits will be subject to the limits of the prescription drug coverage only when the base policy covers prescription drugs or a prescription drug rider is attached to the base policy. If there is no prescription drug coverage, or if benefits are provided by a separate prescription drug policy, whether issued by the same carrier as the base policy or a different carrier, then only the base plan limits apply and no separate prescription drug limit may be imposed in the base policy. Overall base plan annual and/or lifetime maximums may be applied. Carriers may establish base plan cost sharing for this coverage in accordance with currently acceptable copay and coinsurance ranges allowed by the Department. There is no requirement to apply limits or cost sharing to the formula and food products.

   The prescription drug deductible should not be applied towards the base plan deductible.

   The following may be helpful:

Base Policy	**Prescription Drug Coverage**	**Formula and Food Products/Preparations Limits**
Carrier A	Carrier A (in base policy)	Subject to overall Rx coverage design
Carrier A	Carrier A (Rx rider attached to base policy)	Subject to overall Rx coverage design
Carrier A	Carrier A (separate Rx policy)	No separate base plan Rx limit
Carrier A	Carrier B (separate Rx policy)	No separate base plan Rx limit
Carrier A	No coverage	No separate base plan Rx limit

3. Benefits may be subject to prior authorization, but this must be disclosed in the policy.

4. If there is a prescription benefit in the base policy, carriers may establish a separate and distinct tier associated with specialized formulas and the mandated food products and preparations; however, the associated cost sharing provision may not exceed currently acceptable ranges allowed by the Department Allowable copays range from $0 - $40; allowable coinsurance ranges from 0% - 50%.

5. Copays are limited to no more than one per 30 day supply.

6. A determination as to what is a 30 day supply will vary by patient and is to be determined by the physician ordering the formula or food product/preparation. This determination may be subject to the prior authorization review requirements.

7. Managed care organizations may limit this coverage to participating providers unless the plan covers out of network benefits. Plans with out of network benefits must cover out of network purchases as they would any other out of network prescription drug.

8. If preferred provider arrangements have been negotiated, the Department recommends that a direct reimbursement provision also be negotiated.

9. Since the statute refers back to CGS19a-55 which includes PKU, we interpret this to continue to include PKU babies.

10. The mandate implementation date of October 1, 2004 is applicable to policies delivered, issued for delivery or renewed in this state on or after October 1, 2004.

Please contact the Insurance Department Life & Health Division, 860-297-3862 or ctinsdept.lifehealth@po.state.ct.us with any questions about Public Act 04-173 or this bulletin.

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Insurance Commissioner