Medical foods: Inborn errors of metabolism and the reimbursement dilemma

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Purpose: Medical foods and pharmacological doses of vitamins are used to treat certain genetic diseases for the duration of a patient's lifetime, which necessitates life-long management of the condition and diet by the patient and a health care provider. However, payment for medical foods and health insurance coverage of medical foods is not uniform. **Methods:** A survey of states' newborn screening (NBS) representatives and a review of state policies (as of 2008) were conducted to ascertain payment and insurance coverage of medical foods. **Results:** According to the NBS representatives, 61% of the states provided or guaranteed medical foods for all or a subset of the population detected by NBS, whereas 82% of states provided or guaranteed medical formulas for the same population. Policies for private health insurance coverage existed in 33/50 states, and range from providing medical food for one specific metabolic condition to providing it for any NBS disorder. In addition, there is variability among states in the specificity of defining what conditions qualify for medical foods. **Conclusion:** This article suggests four options, not mutually exclusive, options for addressing the patchwork of state policies regarding coverage of medical foods, ranging from amending Medicaid legislation to enacting federal legislation, or changing the Food and Drug Administration's stance on oversight of medical foods. *Genet Med* 2010;12(6):364–369.

Key Words: *inborn errors of metabolism, medical food, prescribed solid modified foods, health insurance coverage, state legislation*

A variety of medical foods, and pharmacological doses of vitamins, are used to treat genetic diseases identified by newborn screening and genetic diseases in general. When individuals are identified with inborn errors of metabolism, they are prescribed a special diet appropriate to their particular condition that must be followed for the rest of their life. This requirement also necessitates life-long management with the health care provider of the condition and diet. However, the process of acquiring medical foods (commonly referred to as medical formulas in the clinical setting) to comply with the diet and

finding the funds to pay for the foods, which are more expensive than everyday foods, is complicated by contradictions in payment mechanisms. Private health insurance coverage for medical foods is not uniform across the states and therefore some patients end up receiving very good coverage whereas others receive poor to no coverage. However, the medical foods are particularly important to these patients because they provide the nutrients and balanced diet that they require. In the current climate of health care reform, now is the time to transform how medical foods are reimbursed.

The clinical consequences to a child being “off diet” are exemplified by the following cases and highlight the importance of every diagnosed child maintaining the diet particular to their condition. A child with phenylketonuria (PKU) who does not comply with diet may suffer behavior, mood, and intellectual declines.¹ A child with citrullinemia type I who is not on a diet to maintain a low plasma ammonia concentration may experience hyperammonemia, which results in increased intracranial pressure, seizures, increased neuromuscular tone, loss of consciousness, and death.² A child with Maple Syrup Urine Disease who is untreated will experience encephalopathy, coma, and respiratory failure within 7 to 10 days of age.³

The Food and Drug Administration (FDA) has defined medical foods 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” (section 5(b) of the Orphan Drug Act [21 U.S.C. 360ee (b) (3)]). Although the FDA has a definition of medical foods, it enforces medical foods rules in a manner similar to foods in general rather than drugs or medical products. Medical formulas, prescribed solid modified foods, and nutraceuticals (pharmacological doses of vitamins) are also treated in this fashion, and therefore, medical foods, the term most often used in this article, is used interchangeably with these terms. Medical foods are used to treat disorders identified through newborn screening and other diagnosed genetic conditions, but private insurance coverage of medical foods varies from state to state and from patient to patient. The gaps in insurance coverage for these items leave many families with an insurmountable financial burden for the long-term (i.e., life long) provision of medically necessary foods.

In 2007, 4,315,000 children were born in the United States,⁴ with 98% tested by newborn screening (4,228,700 newborns). Calculations from population-based figures (Table 1) show that approximately 7,200 children per year are being diagnosed with a condition on the newborn screening panel of 29 (not counting those detected with hearing loss, which raises the number to 11,418). Many of these children require medical foods to treat their disorder because the medical foods are specifically formulated to mitigate the effects of the child's inborn error of metabolism by excluding the biological components that the child is incapable of processing because of their condition.

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Table 1 Incidence of diseases on the ACMG 29 condition newborn screening panel, excluding hearing loss¹⁶

Number	Condition	Incidence per 100,000 screened individuals
1	Biotinidase	2
	Biotinidase (partial)	6
2	Congenital adrenal hyperplasia (includes salt wasting-CAH, simple virilizing-CAH, non-classical CAH, unclassified CAH, and CAH other than 21-OH)	8
3	Cystic fibrosis—classical	20
	Cystic fibrosis—non-classical	2.4
4	Galactosemia (classical)	3
	Galactokinase deficiency (GALK)	0.2
	Galactose epimerase deficiency (GALE)	0.5
	variant GAL	24
5	Homocystinuria	0.6
6	Sickle cell anemia (Hb SS disease)	30
7	Sickle C disease (Hb S/C disease)	16
8	Hb S/B-thalassemia	3.4
9	Phenylketonuria (classical)	5
	PKU—significant variant	2
	PKU—non-significant variant	2
10	Congenital hypothyroidism (primary)	65
	Secondary CH	0.5
	Transient CH	30
	Other types CH	4
11	Maple syrup (urine) disease	0.6
12	Argininosuccinate Lyase Deficiency	0.5
13	Citrullinemia	0.36
14	Tyrosinemia type I	0.04
15	Carnitine uptake defect	0.06
16	Long-chain L-3-OH acyl-CoA dehydrogenase deficiency	0.66 (2006)
17	Trifunctional protein deficiency	4
18	Very long-chain acyl-CoA dehydrogenase deficiency	2 (2006)
19	Medium-chain acyl-CoA dehydrogenase deficiency	2
20	Glutaric acidemia type I	1 (2006)
21	Isovaleric acidemia	0.5
22	3-OH 3-CH₃ glutaric aciduria (HMG)	1.6 (2005)
23	Multiple carboxylase deficiency	0.06
24	Methylmalonic acidemia (mutase deficiency)	0.4
25	3-Methylcrotonyl-CoA carboxylase deficiency	3
26	Methylmalonic acidemia (Cbl A, B)	0.06
27	Propionic acidemia	0.43
28	β-Ketothiolase deficiency	0.06
	Average total incidence	0.024 = 2.4/1,000
	Average total incidence without subconditions	0.017 = 1.7/1,000

The conditions given in bold correspond with those that require medical foods based on current common practice models.
ACMG, American College of Medical Genetics.

However, based on data from the 1990s, the specialized formula can cost between \$5,000 per year (for <18 years) and \$7,000 per year (for all age groups).⁵ The \$5,000–\$7,000 expense is significantly more than the cost of feeding the average child; the 2007 USDA estimate is \$1880 per year to feed a 6–8 year old child in a family earning an average of \$61,000 before income tax⁶ and standard infant formula costs approximately \$1,200 per year.⁷ Because many private insurance companies fail to cover medical foods, out-of-pocket expenses as high as \$7,000 pose a serious challenge for some families.

DETAILS ABOUT VARIABILITY/ NON-CONFORMITY

Lay of the land

State legislation for medical foods coverage is highly variable.⁸ A review of state legislation was reported by Alissa Johnson to the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC) on October 1, 2008. (ACHDNC advises the Secretary of the federal Department of Health and Human Services. The Committee provides advice to the Secretary about aspects of newborn and childhood screening and technical information for the development of policies and priorities that will enhance the ability of the State and local health agencies to provide for newborn and child screening, counseling, and health care services for newborns and children having or at risk for heritable disorders.) State provisions related to private insurance coverage requirements for medical foods and formula to treat disorders identified through newborn screening were collated from each state's laws and regulations in 2008, and measures were found in 33 of 50 states. No private insurance requirements were found in Alabama, District of Columbia, Georgia, Idaho, Illinois, Iowa, Kansas, Michigan, Mississippi, Nebraska, North Carolina, Ohio, Oklahoma, South Carolina, Virginia, West Virginia, Wisconsin, and Wyoming. Provisions for state assistance exist in some of these jurisdictions, but income-eligibility requirements or caps may apply.

As a follow up to the review of state legislation, the American College of Medical Genetics conducted a survey in which 46 states' newborn screening representatives participated. Twenty-eight of the 46 states (60.87%) have state-provided, or guaranteed, medical foods for all or some subset of the newborn screening population; therefore, 39.13% of the states reporting do not have state-provided or guaranteed medical foods. A larger proportion of states, 82.22%, have state-provided, or guaranteed, formulas for all or some subset of the newborn screening population. It is possible that a larger proportion of states provides formulas than food because the formulas are ready-made and cannot be modified, which allows for consistency and control.

Requirements range from mandates for private health insurers to provide medical food for one specified metabolic condition (e.g., phenylketonuria, PKU) (e.g., Alaska, California) with those that require private health insurers to provide coverage for modified low protein foods (one form of prescribed solid modified foods) to treat any newborn screening disorder (e.g., Arizona) identified by the state program. State policies also vary from those that only cover conditions tested by newborn screening with those that cover any genetic disease with a dietary requirement, regardless of whether it is tested for by the newborn screen or not. Because state policies run the gamut from mentioning a specific disease to a broader definition of disorders for which medical foods provide therapeutic benefit, even fam-

ilies that live in states with insurance coverage requirements may receive very different degrees of assistance. Additionally, within the provisions of what must be covered, there is opportunity for insured individuals to be excluded or for insurers to impose "reasonable contract limitations" (without refusing coverage based on a preexisting condition or requiring a covered individual pay a higher deductible or copayment than another condition or illness).

The policies also range in the specificity of language with regard to defining medical foods. Some statutes list conditions by name, but others are written in broader terms (e.g., Arizona: "inherited metabolic disorders and diseases screened for under the newborn screening program"). The main themes addressed in the laws and resolutions are (1) who is responsible for covering the individual (e.g., health insurance, health department, or state funds), (2) what disorder(s) is/are covered, (3) the benefit limit of what is covered (e.g., Arizona: \$5000 insurance coverage, Arkansas: \$2400 tax credit, California: insurance coverage "to the extent that the cost of the necessary formulas and special food products exceeds the cost of a normal diet"), (4) whether the medical food must be ordered by a physician, (5) until what age the coverage is applicable, (6) whether deductibles and copayments are applicable, and (7) income eligibility requirements for public programs.

However, having a state insurance mandate does not translate into harmonization of reimbursement amounts or support. The types of medical foods covered by an insurance company differ from state to state, and state laws have variable levels of enforcement.^{5,8} A major concern is that nearly 60% of individuals with private insurance are covered by employment-based health plans, which are exempt from state insurance laws, as are federal insurance programs (e.g., Tricare).

One counterpoint to the lack of harmonization of reimbursement policies is the availability of resources from companies that produce treatments for conditions that require medical foods. Biomarin, which manufactures treatment for PKU, in partnership with the National Organization for Rare Disorders has a patient and physician support program that is designed to not only help patients obtain coverage and minimize out-of-pocket expenses but also "find alternative financial assistance for treatment."⁹ Additionally, Ross Medical Nutritionals Patient Assistance Program, provided by Abbott Laboratories, offers a preset list of nutritionals at no cost with those who are eligible for their program.

In support of the evidence provided by the review of state policies, we present three real life vignettes. The first demonstrates what a family endured when they moved from one state to another keeping the same insurance. The second highlights what happened to a family whose coverage changed from 1 year to the next even though they maintained the same insurance company. The last vignette illustrates the effort a family must put in to acquire insurance coverage in a state with existing regulations about medical foods reimbursement.

Vignette 1

A family in Georgia has private insurance that will cover 90% of their formula (medical foods) costs after their family deductible is paid. However, another family with the same private insurance is living in Texas, and the insurance will not cover any of the medical foods. Although Texas has a law mandating insurance coverage, this particular insurance plan is through the employer and is self-funded; therefore, the insurance company will not change their policy and told the family that the employer must amend the plan or make an exception to obtain coverage.

Vignette 2

A family in Georgia was previously given coverage of formula (medical foods) through their private insurance. The plan given to their employer for 2009 was said to be the same as previous years, but it did not include coverage for medical foods. The 2009 plan omitted one line stating “exceptions made for individuals with PKU.” This deletion was not caught by the family or their employer until summer of 2009 when the bills for the patient’s medical foods were sent to the family. Because Georgia has no legislation for medical foods, the family was forced to negotiate with the insurance company. The company immediately refused payment because of the fact that the new plan did not cover medical foods. The family then went to the company’s Human Resources Department to notify them of the error, and, after several months of negotiating, the family was able to receive coverage for 2009.

Vignette 3

A family moved to New York and immediately asked for coverage for formula (medical foods) for their son who was affected with PKU. Although there is legislation in New York requiring coverage, the employer was self-insured and would not change the plan to include treatment for PKU. Eventually, the family switched insurance to that of the other parent’s employer and was able to obtain coverage. The experience has left the family in a state of anxiety over the cost of formula and continued medical care and coverage for their son.

ISSUES

The above analysis highlights the patchwork of state policies that currently exists regarding coverage of medical foods. The spectrum ranges from states with measures that provide comprehensive support to other states that provide almost no support. In the states where state funding is limited, other means of federal resources have been tapped.

Demonstrating financial need

In the past, funds have been drawn from the Women, Infants and Children program, the Health Resources and Services Administration Title V Block grant funds, funds from state newborn screening programs, Medicaid, Centers for Medicare and Medicaid Services, and private donors.¹⁰ However, to draw funds from many of these sources, a financial need must be demonstrated. If an individual or family does not qualify for support based on the needs requirements of the program, there is no option to appeal, and the prospect of finding funds elsewhere is bleak.

Coverage issues for patients reaching majority age

A second critical issue related to the coverage of metabolic foods is the transition of the patient from childhood to adulthood. Children with metabolic conditions that require medical foods supplementation have the condition for their lifetime. However, state and federal support for reimbursement of medical foods does not necessarily address coverage of adult-age patients. Therefore, some children transition out of the coverage requirement, if one exists in their state, when they reach 18–21 years of age and have minimal bargaining power for the continued coverage for their medically necessary food because laws or regulations do not compel insurance companies to address the needs of individuals ages 18–21 and older.

FDA classification of medical foods

Finally, medical foods were not designated pharmaceutical agents by the FDA in part because of the prohibitive cost of clinical trials in a small population (the disorders treated by medical foods are rare). Thus, medical foods were designated as a separate category that can be marketed at lower cost and do not require a doctor’s written prescription. Insurance companies typically do not provide reimbursement for medical elements that are not doctor-prescribed, and FDA approval for an agent typically translates into insurance reimbursement. The tension between nonpharmaceutical agents, FDA approval, and insurance reimbursement highlights the precarious position that medical foods are in—one of contradictory treatment under the law as both medically necessary but not federally mandated for coverage or reimbursement. Therefore, patients/parents are required to work with their insurance carrier to educate them about the nature and necessity of the medical foods to have any hope of obtaining coverage and/or reimbursement.

The recommendation for a national uniform panel of newborn screening conditions to be tested in newborns was reported in 2006.¹¹ In the intervening 3 years, no national recommendations have been put forward for states to use as models for legislative support for insurance coverage and reimbursement for medical foods; rather, a patchwork of state statutes and regulations exist. However, the near unanimous adoption of the panel of 29 conditions by the states makes now an ideal time for states to collectively revisit their policies.

A PRIMER: CURRENT US HEALTHCARE FINANCING OPTIONS

The current morass of health care financing in the United States requires a multi-pronged approach/solution. Before considering possible solutions, a primer of current US health care financing options will be presented.

The primary purpose of health insurance is to provide financial coverage for preventive and primary health care services. Medicare and Medicaid provide health care services and are administered by the federal government, but Medicaid is a program based on income eligibility (i.e., low income) and is state-administered whereas Medicare is a program based on entitlement. Medicaid also administers a buy-in program, whereby families with private insurance coverage can buy enhanced benefits for an underinsured child. In addition to Medicaid, there is also the Children’s Health Insurance Program, which offers health insurance coverage to uninsured children in families with incomes up to 200% of the federal poverty level. As with Medicaid, Children’s Health Insurance Program is jointly administered by the federal government and by individual states. A third federally funded option is Title V, a Maternal and Child Health block grant program. Title V awards money to states, which then have flexibility in determining health priorities and allocating the funds.

Private health insurance options are those typically provided by employers or unions. Private health insurance policies differ in their premium amount and in how comprehensive the health insurance coverage is. Some private health insurers provide “premium assistance,” whereby states can use public funds to pay for a portion of the premium costs of employer-sponsored insurance for eligible persons. Given that the entities listed above can be available on their own or can be supplemented by additional funding (e.g., buy in or premium assistance programs), it is not surprising that confusion exists about which entity is/can be responsible for covering the cost of medical

foods. The default response has been that medical foods are being covered by a patchwork of regulations and by a variety of entities.

OPTIONS FOR ADDRESSING POOR ACCESS TO COVERAGE

There are four options presented here to address the poor access to and coverage for medical foods. However, these four options are not mutually exclusive; no one proposed solution fixes all the existing problems. They can be combined and/or modified to create the most beneficial solution.

One option to improve the coverage of medical foods is to amend Medicaid's legislation (i.e., Title XIX of the Social Security Act) to broaden coverage of medical foods by state Medicaid programs, which aligns with the Secretary's ACHDNC recommendation 2. (Secretary's ACHDNC recommendation 2 reads: Medicaid's enabling legislation [Title XIX of the Social Security Act] be amended to ensure more uniform coverage by state Medicaid programs of medical foods and foods modified to be low protein for those conditions recommended by the Committee. Medical foods are not mentioned in the federal Medicaid statute allowing significant variation across states with respect to the coverage of medical foods. Amending 1905(a) of the federal statute would encourage best practices and ensure greater uniformity.) Currently, medical foods are not mentioned in the Medicaid legislation: there is no mandate for coverage. Additionally, as noted above, states vary in their terms of coverage for medical foods. If the Medicaid legislation was amended to include medical food coverage, then there would be less variation among states. However, if the "improved" Medicaid legislation ends up being more restrictive than what some of the states currently have in place, then the new legislation would actually be doing a disservice to some patients because their coverage would be reduced. This problem could be addressed by requiring states to meet or exceed the regulation, or to not decrease coverage to the regulation level if it is vastly different.

A second option is to develop a model state Medicaid coverage policy or a model state insurance law. The purpose of this option is to harmonize the mechanism by which coverage is provided (i.e., as a home health benefit, as durable medical equipment, or as a clinic benefit) and/or to determine whether it is a medical benefit or a pharmacy benefit. Model laws and policies have the advantage of providing structure and uniformity, with avenues for legal action and meaningful penalties in cases of noncompliance.

A third option is to enact federal legislation to require third party payer health insurers offer coverage of medical foods, which aligns with the Secretary's ACHDNC recommendation 1. (Secretary's ACHDNC recommendation 1 reads: Federal legislation be enacted to establish a uniform requirement that health plans offer coverage of medical foods and foods modified to be low protein for those conditions recommended by the Committee. Health plans would include Federal insurance programs coverage plans [Children's Health Insurance Program, Tricare, and Medicaid] and those plans governed by the Employment Retirement Income Security Act and would not be subject to state exclusions.) Third party payer plans are exempt from state mandates, but they are similar to state mandates in that they exhibit variability in coverage of medical foods. Therefore, a federal law could require a specific mandate for coverage of medical foods, which would serve a similar purpose to a model

state insurance law but would be federally regulated rather than state based.

There is also the option to work with health insurance companies to improve reimbursement policies and procedures. Reimbursement codes that are specific to billing and payment for medical foods need to be developed. In addition, health insurance companies can streamline the payment/problem-resolution process by providing easy-to-use information or procedure manuals to assist those patients who do have coverage for medical foods in obtaining the reimbursement that is owed to them. This could be as simple as providing the name and contact information for the point person in the company who handles all medical foods questions and claims. However, experience is that these situations are rarely resolved below the level of the medical director. In addition, the considerable cost in time and effort of working through the system to find the point person in the company also has been a hindrance.

A further change that could enhance the coverage of medical foods would be for the FDA to change its stance on their oversight. The broad area of dietary supplements has been seen as too large and lacking in clear distinctions between classical drug therapeutics and the dietary supplements for everything from vitamins to specialized diets for weight loss. However, the potential does exist for the FDA to consider its role in the oversight of the medical foods that are tied to the conditions that are recommended for newborn screening by the federal Advisory Committee on Heritable Disorders of Newborns and Children.

There is a spectrum of options and solutions from those that can change one part of the reimbursement system with those that can alter the reimbursement system more broadly. When proposing a solution, it is worthwhile to consider whether revamping the whole system is the most beneficial approach or whether a parsimonious approach that changes fewer elements of the system is more likely to be met with success. Reducing confusion will benefit the providers and the patients. To ensure access to medical foods, which are part of daily management for people diagnosed with certain genetic conditions, the solution needs to be properly aligned with the needs of the patients. We are joining other organizations that have recognized the need for reimbursement of medical foods,^{12–14} as well as the legislation that has been introduced into the 111th Congress,¹⁵ and attempt with this article to advance the discussion toward solutions.

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