

Metabolic Food & Formula Program



Annual Report
July 1, 2009 through June 30, 2010





Congenital & Inherited Disorders

Division of Health Promotion & Chronic Disease Prevention

Phone: 1-800-383-3826

www.idph.state.ia.us/genetics/default.asp



In collaboration with the
Iowa Department of Public Health
&
The Department of Pediatrics
Division of Medical Genetics
University of Iowa

WHAT IS THE METABOLIC FOOD AND FORMULA PROGRAM

Babies born in Iowa are tested for a variety of disorders 24-72 hours after birth. This testing is called newborn screening – known by many as the “heel stick” test. Many of the diseases tested for are life threatening and/or disabling and require immediate intervention. One category of diseases screened for are inborn errors of metabolism which requires life long medications and/or specialized, restricted diets.

The **metabolic formula program** was developed to assist Iowans diagnosed with specific inborn errors of metabolism. These patients are on very rigid restricted diets. In order to get the nutrients they need to survive and thrive, they must drink specialized formulas, and eat specially modified foods. These special foods and formulas are as essential as insulin is to the diabetic person. However, unlike insulin, some insurance companies will not cover the cost of these foods and formulas because they are considered a dietary supplement - not a medication. The metabolic formula program was created to assist families with the cost of the formula even as the state has worked to improve insurance coverage. With the metabolic formula program purchasing the formula, patients benefit from the buying power/contracts of the University of Iowa.

Anyone with an inborn error of metabolism who legally resides in Iowa is eligible for the metabolic food and formula program. Patients must enroll annually by completing an application, receive regular care in a metabolic genetics clinic, and follow a recommended treatment plan.

The formula program is funded from three sources – insurance payments, patient payments, and \$3 designated from each newborn screening fee that is collected by the state

The **metabolic food program** was started in November, 2005 from an appropriation to the Iowa Department of Public Health. The funding priority is for the purchase of metabolic food, but patients can use a portion of their food appropriation to help offset formula costs as well. Prior to this funding source, patients had to purchase low protein food from personal funds. Many patients went without low protein foods in their diet because the foods were cost prohibitive.

WHO IS ELIGIBLE TO PARTICIPATE IN THE METABOLIC FOOD AND FORMULA PROGRAM

To be eligible for the metabolic low protein food and formula program, the patient must:

- Reside in the State of Iowa
- Complete Metabolic Food/Formula Program Application
- Be followed in a metabolic genetics clinic on a regular basis (as defined by the medical director)
- Follow treatment plan and recommendations

PATIENT STORIES

“Dan” is a young adult from Clinton with PKU that has been enrolled in our food/formula program since his birth. Dan is a former National PKU Foundation Scholarship winner and is now pursuing a Master’s degree. He and his parents credit his success in part due to the excellent clinical care he received as well as easy access to metabolic formula and low protein foods

“Mateo” is a 10 year old boy with MSUD that moved to Iowa from Washington DC during FY10. Mateo’s condition has proven to be a little harder to control than Dan’s. Mateo and his family rely on low protein food to keep his condition stable. They are thankful that Iowa has a low protein food program because they know it makes a big difference in the management of his disease and helps decrease visits to the doctor and hospitalizations.

“Lourdes” is a 16-year-old girl from Des Moines with intellectual disability due to PKU. Lourdes was born in Mexico where they did not screen for PKU. Because they did not screen for PKU, she wasn’t put on the appropriate diet of low protein foods and formula which resulted in her intellectual disability. Lourdes is an example of the positive impact the low protein food program has on patients and the course of their disorder. Lourdes’ allocation to purchase food was used up by the time she was seen in clinic in April 2010. When she came back for a clinic appointment 6 months later, her levels were double what they were in April 2010 (a higher number indicates the disorder is not under good control). When the higher levels were discussed with the family, they felt that her levels were high because she had not been eating any low protein foods since her food allocation ran out earlier in the year. They indicated they did not have the money to buy low protein foods on their own – they rely each year on the money allotted to them from the food program. Once the allocation is used up, Lourdes is not able to eat any low protein foods that help keep her disease stable.

PATIENT STATISTICS

Patient Ages

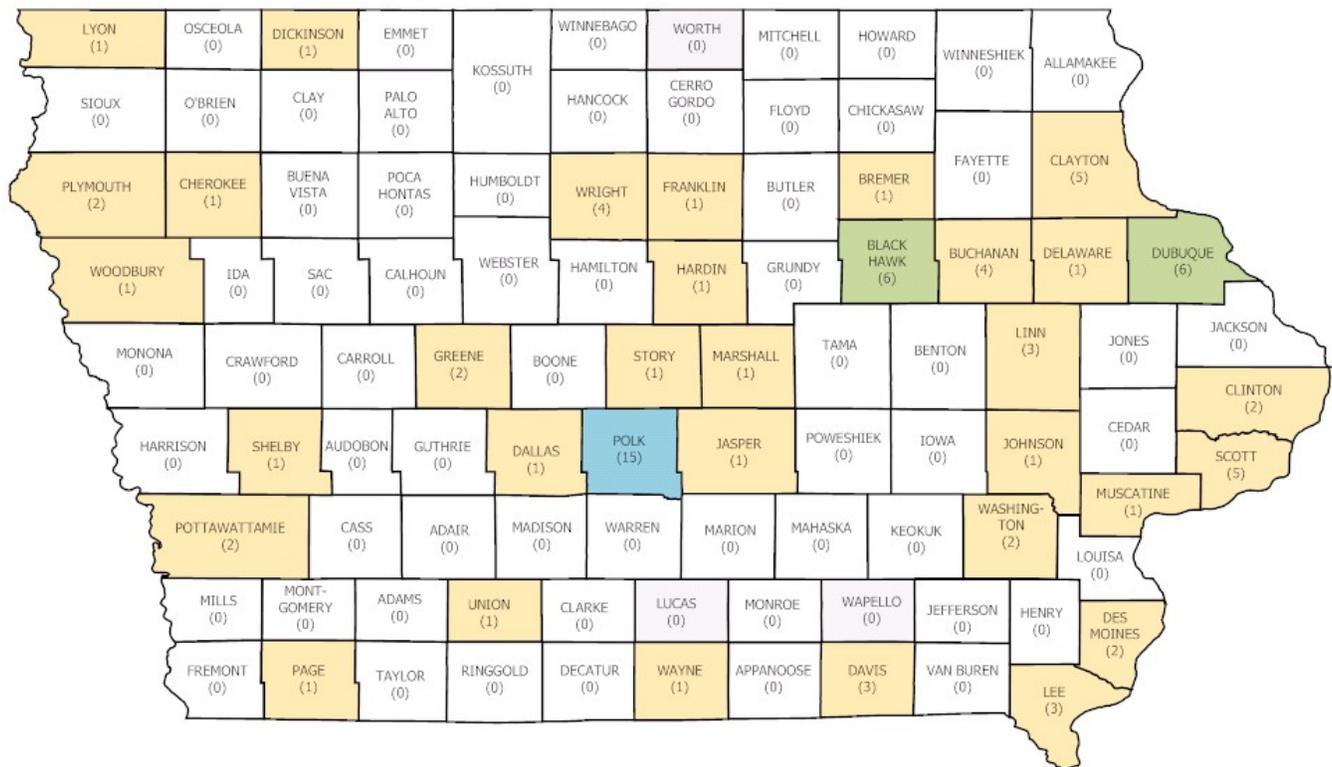
Age/Category	Number of Patients In Formula/Food Program FY 08	Number of Patients in Formula/Food Program FY 09	Number of Patients in Formula/Food Program FY 10
Children 0-17	59	59	59/69
Adults 18-on	23	29	32/40
TOTAL	82	88	91/109

For this report, we decided to show two enrollment numbers to you. The first number is the number that the UIHC billing system reports and the second number is from the program’s patient spreadsheet. The UIHC numbers are lower because the system only captures data from those patients who have ordered formula and have had formula claims submitted to insurance and bills processed through UIHC. The second number is from our program’s spreadsheet. This spreadsheet captures everyone who has returned a completed food/formula application to the program. The differences in the numbers are because not all

patients receive their formula through our program. Most patients who qualify for WIC receive their formula locally through their county WIC office or through a home health care agency. Some of our patients who reside in an assisted living facility or nursing home also receive their formula through a home health care agency. Finally, because of changes in shipping rules from the Mead-Johnson Company (a major supplier of metabolic formula), some patients chose to order their formula from their local pharmacy rather than having to drive to Iowa City to pick it up. The patients who receive their formula locally still fill out an application so that they qualify to order/receive low protein foods from the program.

The program added 12 new patients this year. Three newborns were identified with PKU and two adults with PKU decided to go back on diet. One child moved from Washington DC to Iowa who has MSUD. A three year old was diagnosed with OTC deficiency. A adult female with OTC deficiency went back on diet during her pregnancy. A newborn was diagnosed with isovaleric acidemia. Another newborn was diagnosed with a fatty acid oxidation disorder, and yet another newborn was diagnosed with CPT II deficiency. A child diagnosed with gyrate atrophy (a non-metabolic disorder) was placed on a protein restricted diet because it helps the management of her condition.

PATIENTS SERVED BY COUNTY FY 10



Key: ○ 0 ● 1-5 ● 6-9 ● >10

PROGRAM OPERATIONS

Patients are enrolled into the food/formula program either by self-referral or by being identified with a metabolic disorder in our metabolic clinic, usually through a positive newborn screening result.

Patients receive a prescription for the appropriate amount and type of low protein food and formula through the medical program at the University of Iowa. The metabolic food and formula programs are discussed during the initial visit, patients are enrolled in the program, and subsequently families/patients call the dietitian to initiate the order for formula.

For formula, the dietitian places the order with the appropriate vendor and through a special purchasing arrangement, and the formula is delivered directly to the patient. The program is billed for the cost of the formula and a claim is submitted to the insurance company. Once the claim is resolved, the sliding fee schedule is applied (see below), and the patient is billed for the balance of the formula when applicable.

Mead-Johnson no longer ships formula directly to those patients using a Mead-Johnson product. Program staff pleaded with the company to reverse this decision with no success. All Mead-Johnson formula must be shipped directly to the program. Patients either pick it up the same day they come to a clinic appointment or drive to Iowa City to pick it up. This has been a significant burden to the patients and has made extra work for program staff as well. Some patients have elected to get the formula locally, which means the sliding fee scale cannot be applied to the cost of the formula and they often have to submit claims to insurance on their own. Some patients have found that their local pharmacy refuses to order the product because of the high cost or require payment in full *before* ordering the product. Recently, we tried shipping formula via Federal Express from UIHC to the patient's home and invoicing the patient separately for the shipping charges. This has been working well and most patients are now choosing to use the Federal Express option rather than driving or getting the formula locally.

The food program is administered somewhat differently. The food program appropriation is divided equally amongst program participants. For FY10, the allocation was \$900/patient. Order forms for the low protein food vendors are given to the patient. The patient fills out the form and sends the order to the program. The clerk reviews and then places the order, and enters the total cost of the order into a spreadsheet. The food is then delivered directly to the patient and the program is billed for the cost of the food ordered. Once the patient has spent their allotted amount of money on low protein food, no more orders are accepted, and the patient must order and pay for the low protein food out of their personal funds. This year, any unspent funds reverted back to the program to help offset the deficit in the formula program.

In the previous fiscal year, we made an attempt to bill insurance companies for low protein food. We were encouraged to do so by the Follow Up and Treatment Subcommittee to US Secretary of Health and Human Services Advisory Committee on Heritable Diseases and Newborn Screening. We discontinued this practice for FY2010 due to our experiences during FY2009. These experiences included that at the end of the fiscal year, we had only received \$11,263 in payments for low protein food. This amount did not cover the personnel effort it

took to complete this task. The final straw that supported our decision to discontinue this practice was when the insurance companies that *had* paid for the food asked for their money back.

Sliding Fee Scale – Formula Program – FY10

The sliding fee scale is based on the yearly poverty guidelines established by the federal government. The guidelines take into account income as well as the number of family members. The sliding fee scale is applied *after* an insurance payment (or denial) is received, but *before* the patient is billed. The reduction is the percent reduction of the charged fee.

	FY 09		FY 10	
<u>Reduction</u>	<u>Number of Patients</u>	<u>% of Total Number of Pts</u>	<u>Number of Patients</u>	<u>% of Total Number of Pts</u>
0%	24	25%	26	24%
25%	3	3%	9	8%
50%	6	6%	5	5%
75%	7	7%	1	1%
100%	45	46%	60	55%
Amish	12	12%	8	7%
	97	100%	109	100%

To clarify, 0% reduction means that the patient is responsible for 100% of the charges; 25% reduction means that the patient is responsible for 75% of the charges and the program absorbs the remaining 25%; 50% reduction means that the patient is responsible for 50% of the charges and the program absorbs the remaining 50%; 75% reduction means that the patient is responsible for 25% of the charges and the program absorbs the remaining 75%; and 100% reduction means that the program absorbs 100% of the cost of the formula after insurance reimbursement. The Amish have a special arrangement with UIHC where 67% is paid for by a third party and 33% is absorbed by the program.

When comparing the sliding fee scale data from FY 09 and FY 10, the percent of patients who qualify for 100% reduction of fees has increased by 15 patients, or 9%. That's a significant increase in expenses for the program. The number of Amish patients decreased by 5 (5%) from FY 09 to FY 10.

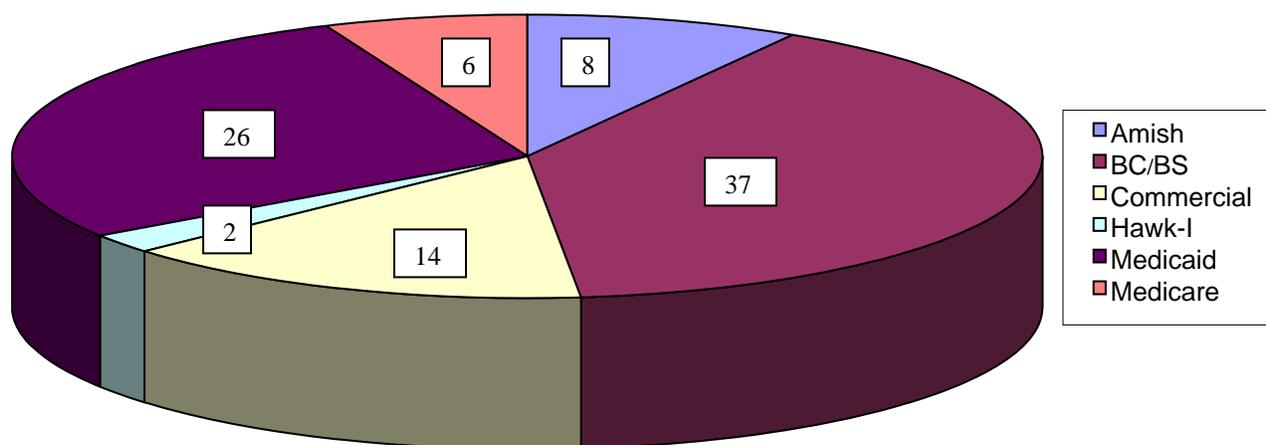
Financial Hardship

Patients enrolled in this program can appeal to the Program Director for special consideration of social and economic factors not considered in the Federal Sliding fee scale – i.e. a hardship waiver. When granted, it changes their status on the sliding fee scale. Often, these patients are those who do not qualify for any reduction using the sliding fee scale. In the past, requests have come from patients who have insurance that does not pay for formula at all. Other circumstances where the hardship clause could be enacted would include catastrophic

illness/death, crop loss, or other similar circumstances. Routine consumer debt is not considered a “hardship”. No patients applied for financial hardship this year.

Insurance – Formula Program

Insurance Carriers



Blue Cross/Blue Shield (BC/BS)

During FY09, BC/BS made some changes that continue to negatively impact the program.

- 1) They have restricted the amount of formula they will reimburse at any one time to 600 units/month. This becomes a problem for teenage and adult patients who require more than 600 units per month to meet their dietary needs.
- 2) They have restructured the fee schedule reducing the amount they will reimburse. The UIHC Patient Fiscal Services office has been working directly with BC/BS to resolve the lower reimbursement issue, but after several attempts, no resolution has been obtained so far.

These changes create additional administrative cost in managing the program because formula must be ordered/handled more frequently to accommodate the 600 unit limit. The reduced fee schedule shifts the financial burden to the metabolic formula program.

Medicaid of Iowa

Medicaid requires that a prior authorization form is completed and submitted according to their specifications for each patient. The program receives the prior authorization paperwork back with approval for the specific amount of caloric units they will pay for at their set reimbursement rate (which is typically lower than other reimbursement rates). In most cases, the program receives the payment as outlined in the prior authorization form.

Commercial Insurances

Most commercial insurances pay for formula according to individual contract specifications with the exception of certain HMO contracts.

Hawk-I/HMO's/Medicare

These policies do not cover low protein formulas.

Immergruen

Immergruen is an insurance broker used specifically by our Amish patients. Immergruen pays UIHC (the formula program) 67% of the total charges and the program absorbs 33% of the total charges.

No Insurance

We have two siblings with PKU that are not covered by any insurance carrier. Because of the family income and size, they qualify for 100% reduction of fees.

Fiscal Information

Detailed financial information for both programs can be found in a separate fiscal report submitted to the Iowa Department of Public Health.

Medical Director's Statement – Val Sheffield, MD, PhD

Over the past year or so there have been exciting innovations in treatment of Phenylketonuria, the most common of the metabolic disorders that requires dietary therapy. There are currently clinical trials for an investigational drug administered using infusion therapy for the treatment of PKU. Dr. Shchelochkov, our metabolic specialist, is planning to participate in the fourth phase of this clinical trial. Last year, the FDA approved a co-factor with the trade name "Kuvan", that for some PKU patients, allows them to eat small amounts of foods that previously were not allowed on their strict diet. While they may be able to bypass the low protein foods, or eat less of them, they still have a phenylalanine restriction and take metabolic liquid products, like the PKU formulas. As a result, the cost of following this special diet is reduced. However, the medication is incredibly expensive, up to over a \$1000/month, depending on the size of the patient. Fortunately, at this time, most insurance companies will cover it because it is considered a medication (unlike metabolic food/formula).

We have been enrolling different patients into the metabolic food and formula program since we started the expanded newborn screening. More and more patients with fatty acid oxidation defects are being detected. These patients in turn require special medium chain triglycerides that are not accessible in regular foods. They also have to limit the amount of regular fat they ingest.

I anticipate that with time, we will be changing the primary population benefitting from our program, from the predominantly amino acid defects, to those with other limitations to their diet. This population will require our support since the insurance companies have not been willing to assist them to meet their metabolic needs. There will still be the traditional population as well that have already benefitted hugely from the allocation from the state and the newborn screening fee. It is rewarding as a physician to know that not only do I have the support of the hospital where I see patients, but that the State of Iowa also knows the value of good metabolic control and assists us in treating patients to meet the standards of care.