

Metabolic Food & Formula Program



Program Report (FY 2017)
July 1, 2016 – June 30, 2017





Congenital & Inherited Disorders



Iowa Department of Public Health *Advancing Health Through the Generations*

Terry Branstad
Governor

Kimberly Reynolds
Lt. Governor

Gerd Clabaugh
Director

Authorized State Official for this contract:
Brenda Dobson, Interim Director, Division of Health Promotion and
Chronic Disease Prevention (515) 281-3104

University of Iowa Stead Family Department of Pediatrics
(319) 356-7248

Val Sheffield, MD, PhD
Lisa Neff-Letts

Program Director
Program Coordinator



**In collaboration with the
Iowa Department of Public Health
&
The Stead Family Department of Pediatrics
Division of Medical Genetics
University of Iowa Children's Hospital**

WHAT IS THE METABOLIC FOOD AND FORMULA PROGRAM?

Babies born in Iowa are tested for a variety of disorders 24-48 hours after birth. This testing is called newborn screening. Many of the diseases tested for are life threatening and/or disabling and require immediate intervention. One category of diseases screened for are called “inborn errors of metabolism”. Patients with these types of disorders require lifelong medications and/or specialized, restrictive diets.

The Metabolic Formula Program was created over 20 years ago to assist families of Iowan’s diagnosed with Inborn Errors of Metabolism with the cost of the metabolic formula. 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 to them as insulin is to a 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. Even when insurance pays a portion of the cost of the formula, the cost to the patient is still significant. With the Metabolic Formula Program, the patients benefit from the buying power/contracts of the University of Iowa.

The Metabolic Formula Program is funded from three sources – 1) insurance reimbursement / patient payments; 2) \$4 from each Iowa newborn screen; and 3) any remaining allocation from the food portion of the program.

The Metabolic Food Program was established in November 2005 from a State of Iowa appropriation to the Iowa Department of Public Health. The funding priority is for the purchase of metabolic food, with any remaining funds being used to cover the deficit for the Metabolic Formula Program. Prior to this funding source, patients had to purchase low protein food with personal funds. Many patients went without low protein foods because the foods are very expensive (i.e. a loaf of low protein bread can cost as much as \$10).

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

To be eligible for the Metabolic Food and Formula Program, the patient must:

- be a resident of Iowa with an inborn error of metabolism.
- complete the Metabolic Food and Formula Program application annually.
- be followed in a metabolic genetics clinic on a regular basis (as defined by the medical director).
- follow the treatment plan and recommendations.

IMPACT OF PROGRAM FOR PATIENTS

We have a number of adults with PKU who were either born before newborn screening began or treated for a few years and then taken off the special diet as was recommended then. Due to either the late diagnosis or being taken off the diet at an early age, these individuals have varying degrees of intellectual disabilities. Some are able to live on their own while others need additional assistance either in a group home setting or a nursing home.

Since the recommendation for PKU treatment is diet for life, we have attempted to find those individuals and encourage them to go back on diet. Even though going back on diet does not reverse the intellectual disability, reducing phenylalanine levels into the treatment range helps with the mental health issues these individuals face such as anxiety, brain “fogginess”, and agoraphobia. As you can imagine, if a person is used to eating a regular diet including high protein foods like meat, chicken, fish, cheese, eggs, and milk products and is asked to eliminate these items from their diet and instead begin to drink a formula that provides 80-90% of their protein needs, many find this difficult. They appreciate having low protein substitutes for these foods that make the diet more palatable. The majority of these patients have done well in making this change and we have seen good results in reduction of psychiatric medications as well as improvement in their general well being. One individual in a group home is non verbal and before starting the diet did not welcome any human interaction. After being on the diet and getting her levels down, she now welcomes hugs and other human interaction which makes life more pleasant for her as well as her family and staff. All of these individuals have benefited greatly from having access to the Metabolic Food and Formula Programs.

PATIENT STATISTICS

Patient Ages

Age/Category	Number of Patients in Formula/Food Program FY 16	Number of Patients in Formula/Food Program FY 17
Children 0-17	72	73
Adults 18-on	57	59
TOTAL	129	132

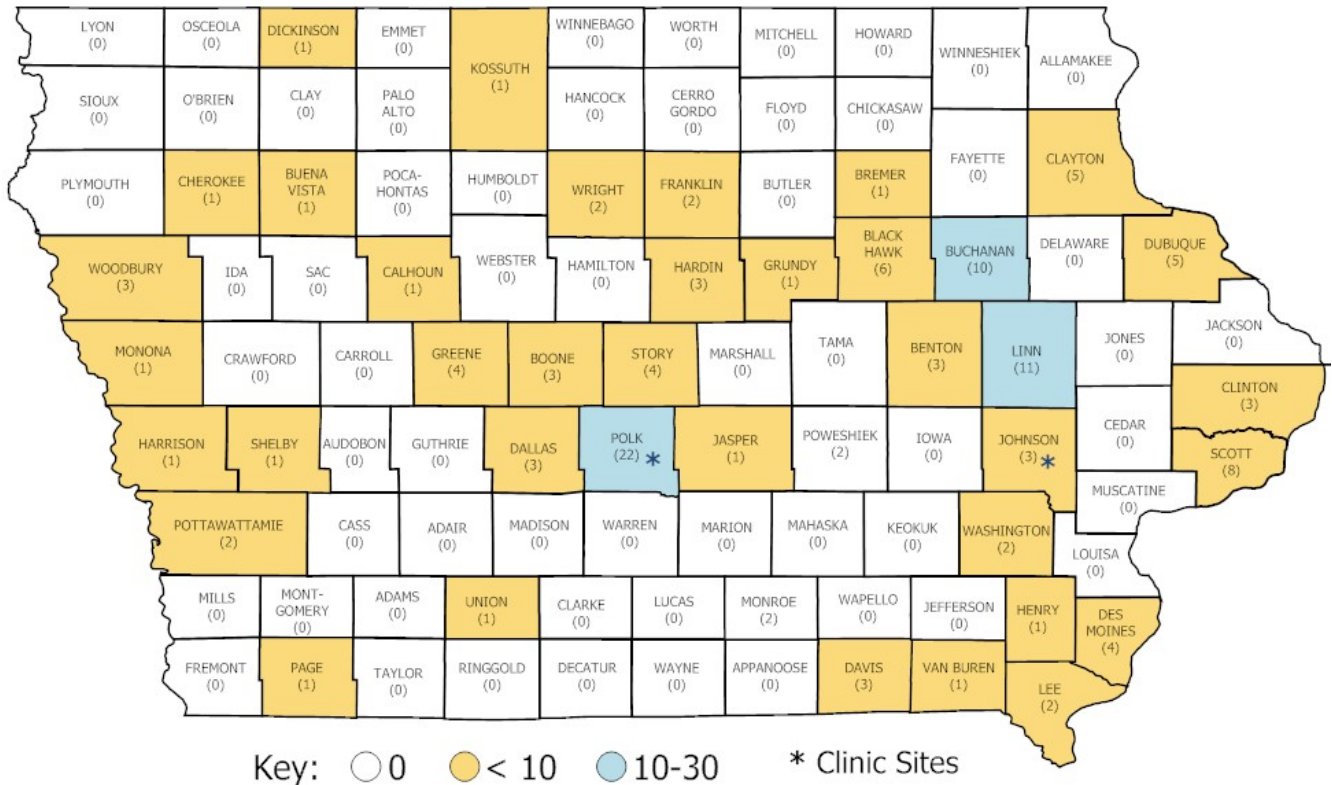
This table shows enrollment numbers for FY16 and FY17. The number is from the program’s patient spreadsheet. This spreadsheet captures everyone who has returned a completed application to the program. All patients who qualify for WIC receive their formula locally through their county WIC office or through a home healthcare agency. Some patients receive their formula locally, but still complete an application so that they qualify to order/receive low protein foods from the program.

There were 5 new patients added to the program this fiscal year. This includes 4 new babies diagnosed with PKU and 1 new adult who moved to Iowa.

PATIENTS SERVED BY COUNTY

FY 2017 (132 patients)

FY 2017 Formula Program Patient Breakdowns by County



PROGRAM OPERATIONS

Patients are enrolled into the program by self-referral or by being identified with an inborn error of metabolism in our metabolic clinic, usually through a positive newborn screening result.

Patients receive dietary prescriptions for the appropriate amount and type of low protein food and formula through the Metabolic Genetics Clinic at the University of Iowa. The Metabolic Food and Formula Program is discussed during the initial visit to the metabolic clinic. Patients are then enrolled in the program. After the first visit, families/patients call the dietitian to initiate the order for formula and fax or email their food orders to the program staff.

All metabolic formulas are purchased through special purchasing arrangements with the University of Iowa. The dietitian places the order with the appropriate vendor for formula. The formula is delivered directly to the patient. The program is billed for the cost of the formula. The University of Iowa Hospitals and Clinics then processes an insurance claim when applicable. Once the claim process is completed, the sliding fee schedule is applied (see below), and the patient is billed for the balance of the formula when applicable.

The food portion of the program is administered somewhat differently. The appropriation for food was divided equally amongst program participants. For FY17, the allocation was \$845 per patient. Effective March 1, 2017 - the Food and Formula allocation was decreased by \$6,177 for FY17. Seven patients in this population have either moved or are no longer in our program and have been removed from the budget for a total of 5,915. One patient will have a balance of \$262 which will be reallocated to the budget (5,915 + 272 = \$6,177) to cover the decrease for this FY.

Order forms for the low protein food vendors were given to the patient. The patient filled out the form and sent the order to the program staff. Our staff reviewed and then placed the orders. The total cost of the orders were then entered into a spreadsheet. Food was delivered directly to the patients and the program was billed for the cost of the food ordered. Once the patient spent their allotted amount of money on low protein food, no more orders were 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 for the Metabolic Formula Program.

Sliding Fee Scale – Formula Program

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 the charge is reduced before it is billed to the patient.

	FY 16		FY 17	
Reduction	Number of Patients	% of Total Number of Pts	Number of Patients	% of Total Number of Pts
0%	34	26%	41	31%
25%	4	3%	5	4%
50%	9	7%	6	5%
75%	0	0%	4	3%
100%	68	53%	60	45%
Amish	14	11%	16	12%
Total	129	100%	132	100%

To clarify, 0% reduction means that the patient is responsible for 100% of the charges (after insurance reimbursement); 25% reduction means that the patient is responsible for 75% of the charges and the program absorbs the remaining 25% (after insurance reimbursement); 50% reduction means that the patient is responsible for 50% of the charges and the program absorbs the remaining 50% (after insurance reimbursement); 75% reduction means that the patient is responsible for 25% of the charges and the program absorbs the remaining 75% (after insurance reimbursement); 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 (ultimately Amish church members) and 33% is absorbed by the program.

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”. One family applied for the hardship clause because both parents have insurance that doesn’t pay for formula. The director accepted their application and gave them a 50% reduction in the cost of the formula.

Insurance – Formula Program

Our program continues to have ongoing difficulties receiving insurance coverage. Currently, it is unknown whether the Managed Care Organization (MCO) will cover the cost of metabolic formula. Medicare and some private insurance companies will not pay for metabolic formula.

Insurance – Food Program

As of now, insurance is not reimbursing for medically modified low protein food.

Fiscal Information

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

Education

Program staff provide educational presentations regarding metabolic disorders and special dietary requirements throughout the fiscal year. Patient education is continuously provided for patients during each clinic visit, as well as when patients contact program staff regarding additional educational needs. Program staff also attend meetings related to metabolic conditions and special dietary needs so that they can provide the most current information and education to the patients they serve.

Meetings Attended:

Name	Title	Meeting Name	Dates
Judy Miller	ARNP	National PKU Alliance Meeting	July 2016

Patient Education Meetings:

Name	Title	Meeting Name	Dates	Location
Judy Miller	ARNP	Grocery Store Tour	August 2016 April 2017	Davenport, IA Waterloo, IA
Cheryl Stimson	Dietitian	Grocery Store Tour	August 2016 April 2017	Davenport, IA Waterloo, IA

Summary

The biggest challenge for the Iowa Metabolic Food and Formula Program continues to be the lack of reimbursement and/or low reimbursement for metabolic formula from certain insurance providers. The National PKU alliance continues to work on a federal level to mandate coverage for prescribed metabolic formulas.

As of July 1, 2017, the allocation for our low protein food has been eliminated due to legislative budget reductions. This is a great loss to our patient population with the youngest newborns to the oldest patient in our population who is 69.

Submitted by Lisa Neff-Letts, Program Coordinator