

DIET FOR LIFE WORK GROUP

Meeting #3: Review of Recommendations

January 13, 2014

Overview of today's meeting

- ▶ Welcome and Introductions
- ▶ Family Member Presentations
- ▶ Background Statement (How the Work Group came about)
- ▶ Review of Work Group Objectives
- ▶ Recap of Work Group Process
- ▶ Presentation of a proposed model for a Michigan Nutritional Treatment Initiative for Inborn Errors of Metabolism
 - Present components of model
 - Worksheet of action items related to each component (Self-tally)
 - Members vote on components
- ▶ Conclusion and Next Steps
- ▶ Wrap-up Meeting for Family Members

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Background

- ▶ Due to changing demographic patterns, increased costs, and diet for life treatment recommendations, the Newborn Screening Program no longer has sufficient resources to supply medical formula for patients as in the past;
- ▶ Therefore, Michigan is in need of a multi-part solution that provides feasible options to enable patients of all ages to obtain lifelong dietary treatment for inborn errors of metabolism.

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Work Group Objectives

- ▶ To identify and understand existing clinical best practice guidelines for lifelong dietary treatment of individuals with inborn errors of metabolism detected through newborn screening
- ▶ To describe facilitators and barriers to dietary compliance in order to assure the best possible outcomes
- ▶ To recommend feasible solutions that enable patients of all ages to receive appropriate metabolic formulas in light of Newborn Screening Program budgetary constraints
- ▶ To suggest long term strategies for assisting families in obtaining insurance coverage and reimbursement for metabolic foods

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The Work Group Process

Meeting 1

- ▶ Reviewed best practices in treatment
- ▶ Heard testimony from patients and family members

Meeting 2 (adult focus) & 3 (child focus)

- ▶ Reviewed models in other states
- ▶ Formulated strategies to address needs

Today

- ▶ Move from ~40 possible strategies to a work group recommendation

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From Possible Strategies to a Recommendation

- ▶ Work Group formulated ~40 strategies
- ▶ Strategies were sorted into 7 broad categories (components of a state plan)
- ▶ Work Group members will:
 - Rank importance of strategies within each of the 7 components and "other" category
 - Vote on each component to include in recommendation to MDCH

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A proposed model for Michigan's nutritional treatment initiative

► **Would include the following components:**

- A coordinated metabolic treatment program
- Family education and advocacy
- Maximum use of 3rd party insurance benefits
- Increased access to low protein modified foods
- A safety net
- Coordination with state and federal supplemental food programs
- Possible legislation, if needed

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Strategies for Component #1: A Coordinated Metabolic Treatment Program

A.	Maintain a comprehensive metabolic disease treatment program supported by MDCH to assure qualified clinic personnel are available to provide appropriate diagnostic and follow-up services for all patients with inborn errors of metabolism
B.	Develop policies that strive to minimize disruption of current system for providing medical formula/food shipped directly to the patient's home based on metabolic dietitian and physician recommendations
C.	Establish a centralized DME as a single source supplier for medical foods*
D.	Establish a centralized pharmacy as a single source supplier for medically necessary single amino acids, amino acid mixtures and vitamins*

* Part of consensus recommendation to establish a centralized DME as a single source supplier for nutritional treatment products, as identified at November work group meetings

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Questions raised about DME	What we have learned
Investigate if single source contract possible for DME to provide nutritional treatment products through CSHCS	MDCH can explore ways to support a single DME provider to serve all patients with IEM, but cannot require all insurance plans to use it
Investigate if MDCH can become DME (like Louisiana and Washington)	Appears MDCH cannot be a DME
Investigate if State of Michigan can become part of multistate collaborative to purchase formula	Volume purchase discounts not greater than current pricing through CHM
Determine if and why Michigan DME is required (or can Michigan go directly to suppliers?); is DME needed for all three sub-types of treatment?	Medicaid/CSHCS and some insurance plans require billing for formula through a DME; amino acids supplied through pharmacies; low protein modified foods not covered by Medicaid/CSHCS, therefore do not need to be supplied through DME for those patients
Determine if DMEs can provide multiple types of medical foods (or only types to be administered through tube feeding or only cheapest forms)	DMEs provide formulas per prior approvals; low protein modified foods not covered by Medicaid/CSHCS.

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Strategies for Component #2: Family Education and Advocacy

A.	Clarify timeline for implementation of changes with families
B.	Clarify out of pocket expenses for families- how much they should expect to contribute
C.	Address concerns re: CSHCS from families of children with IEM
D.	Develop metabolic clinic process to work with each family to assess insurance coverage and explain available options
E.	Assist families with appeal process for denied claims, as needed <ul style="list-style-type: none"> • Educate individuals and families about calling helplines such as beneficiary line for Medicaid • Develop factsheet for parents and individuals with IEM regarding tips to approach payers; consider adapting National PKU recently developed factsheet on tips for families in dealing with payers; consider what is incentive for families to approach payers.
F.	Disseminate work group's recommendations and solicit feedback from other MI families and individuals with IEM
G.	Continue Diet for Life work group or similar group to implement recommendations and continue to address needs of MI individuals and families with IEM who require nutritional treatment

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Strategies for Component #3: Maximum Use of 3rd Party Insurance Benefits

A.	Develop and implement process for families of children under 21 to enroll in CSHCS
B.	Develop and implement process for eligible individuals to apply for Medicaid and Healthy Michigan enrollment <ul style="list-style-type: none"> • Assure income-eligible women of reproductive age are enrolled prior to pregnancy
C.	Assess implications for Medicaid Health Plans; consider "carve out" for IEM nutritional treatments
D.	Bill all existing public or private insurance for all forms of nutritional treatment*
E.	Assign MDCH staff to assist clinic and families with payer and billing issues regarding nutritional treatment for individuals with IEM
F.	Assign metabolic clinic staff to become billing expert and liaison for families and payers (i.e. "insurance navigator") regarding nutritional treatment for individuals with IEM
G.	Attempt to find at least one contact at each health plan that is aware and knowledgeable about this issue
H.	Develop methods for metabolic clinic to track results of all attempted billing-including rates of coverage, denials, reimbursement levels, health plan responses, problems with DME, etc.
I.	Summarize current coverage and gaps in coverage for all three sub-types and various patient types and payer types

* Consensus recommendation to have clinic start billing insurance, as identified at November work group meetings

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Questions raised about use of insurance benefits	What we have learned
Determine what Medicaid and Healthy Michigan Plan (Medicaid expansion) can provide for the three treatment sub-types	Medicaid covers metabolic formulas and amino acids; may cover vitamins. Does not cover non-formula medical foods or low protein foods. Healthy Michigan expected to provide same coverage as Medicaid.
Confirm that CSHCS, Medicaid and Healthy Michigan Plan cover all medically necessary single amino acids, amino acid mixtures, vitamins and other compounds as a pharmacy benefit (with prior authorization)	CSHCS does cover; Medicaid covers amino acids, maybe vitamins depending on specific case

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Strategies for Component #4: Increased Access to Low Protein Modified Foods	
A.	Develop centralized single source supplier for low protein modified foods (to leverage group purchasing power) <ul style="list-style-type: none"> Use "metabolic food store" model or DME
B.	Investigate possibility of providing a monthly low protein modified basic food package based on patient's age and dietary needs, with annual review of covered medical food products <ul style="list-style-type: none"> Consider placing limits on quantities of food provided (rather than limits on types and/or sources of food)
C.	Investigate if fundraising is possible to support a medical food store (like Colorado)

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Strategies for Component #5: A Safety Net	
A.	Develop and implement process for coverage when other means exhausted <ul style="list-style-type: none"> Consider developing process of payment and receipt for nutritional treatments when ineligible for coverage by payers or state programs (similar to Kentucky) Determine what NBS (or other state) funds can be used for nutritional treatment
B.	Provide nutritional treatment based on diagnosis without means testing
C.	Investigate sliding scale for costs related to nutritional treatment for families
D.	Explore whether CSHCS would be able to cover adults with IEM (like adults with cystic fibrosis and hemophilia)
E.	Investigate hardship programs offered by pharmaceutical companies, product manufacturers and others

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Strategies for Component #6: Coordination with State and Federal Supplemental Food Programs	
A.	Determine supplemental foods (ie naturally occurring low protein foods) available to eligible recipients of WIC, food stamps, school lunch programs, etc.
B.	Develop and implement process for eligible families of children 0-5 and pregnant/post-partum women to enroll in WIC
C.	Approach other state departments (i.e. DHS) about possible food coverage (i.e. food stamps/MI Bridges and MI school breakfast/lunch programs)

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Questions raised about state and federal food programs	What we have learned
Clarify role of WIC with respect to treatment of IEM <ul style="list-style-type: none"> Determine who is eligible and what medical foods and/or formulas are covered by WIC Determine how WIC products are purchased and distributed throughout the state Clarify FDA-exempt food WIC information 	WIC is payer of last resort for exempt infant formulas & medical foods (after Medicaid/CSHCS). Michigan WIC does not currently include metabolic formula or medical food in its automated system. Other food products in WIC package could be supplied to eligible children & pregnant/post-partum women.

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Strategies for Component #7: Possible Legislation, if needed	
A.	Consider state mandate for third-party/private insurers to cover medical foods, regardless of age or gender* <ul style="list-style-type: none"> Include possibility of covering those without insurance coverage as 'protected class' (similar to Kentucky)
B.	Introduce legislation to create a state metabolic food program that provides coverage for all patients with genetic inborn errors of metabolism for all three sub-types of treatment <ul style="list-style-type: none"> Include all patients regardless of age or gender, whether or not detected by NBS Include coverage for shipping or distribution costs, protein reimbursement and family costs
C.	Explore feasibility of amending NBS law to include coverage for nutritional treatments (similar to Wisconsin) <ul style="list-style-type: none"> Could this be added to the Michigan law and still remain budget neutral? Leverage funds from other state programs and/or raise NBS fee?
D.	Investigate introduction of legislation for state tax credit for costs of medical food for families and individuals with IEM

* Consensus recommendation to pursue need for possible state legislation mandating insurance coverage for medical foods used in treatment of IEM regardless of age or gender

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Strategies for Component #7: Possible Legislation, if needed	
E.	If state legislation is pursued, ensure we can demonstrate need, is budget neutral and will be effective <ul style="list-style-type: none"> Investigate if health economic studies have been done and results available regarding nutritional treatment for inborn errors of metabolism Investigate if other states have budget information available to show that their programs are budget neutral or that ultimate savings are beyond actual cost
F.	Monitor federal bills regarding medical food legislation
G.	Determine impact of ACA on nutritional treatment for inborn errors of metabolism and potential impact on current payers if new state legislation introduced
H.	Identify patient advocates to work on nutritional treatment issue and lobby for legislation if needed

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Questions raised about possible legislation	What we have learned
Determine if Medicaid expansion could cover all individuals with IEM via disability-based designation	Medicaid expansion is income-based program; medical review by DHS required for disability determination (federal guidelines?); eligibility ultimately determined by legislature
Clarify current Michigan law regarding NBS to see if nutritional treatment for NBS disorders is covered	Nutritional treatment is not specifically mentioned in current law
Confirm whether Dr. Beth Tarini can assist with a project to address issues related to possible legislation	Dr. Tarini is interested and willing to include as part of her UM/ Center for Healthcare Research & Transformation Policy fellowship

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Other miscellaneous suggestions	
A.	Investigate if restaurants can be more 'IEM-friendly'
B.	Attempt to change reimbursement based on calories amount
C.	Attempt to determine if flavor of medical food can be improved

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Any other ideas that have been missed?

- How important do you feel each of the following areas is to the success of a comprehensive nutritional treatment initiative for Michigan?
- ▶ A coordinated metabolic treatment program
 - ▶ Family education and advocacy
 - ▶ Maximum use of 3rd party insurance benefits
 - ▶ Increased access to low protein modified foods
 - ▶ A safety net
 - ▶ Coordination with state and federal supplemental food programs
 - ▶ Possible legislation, if needed

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Please vote using the following scale

1/A=Not necessary at all, should not be included
 2/B=Not very important
 3/C=Neutral, may or may not be helpful
 4/D=Very important
 5/E=Absolutely essential, must be included

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- #1: A coordinated metabolic treatment program
- ▶ Maintain a coordinated system that maximizes use of appropriate metabolic treatments and minimizes barriers to care by ensuring access to medically necessary nutritional treatment with dietary planning and medical monitoring coordinated by metabolic dietitians and geneticists; incorporates DME that is required to serve all patients

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#1: A coordinated metabolic treatment program

- A. Not necessary at all, should not be included
- B. Not very important
- C. Neutral, may or may not be helpful
- D. Very important
- E. Absolutely essential, must be included

0% 0% 0% 0% 0%

Not necessary at all, should not be included
Not very important
Neutral, may or may not be helpful
Very important
Absolutely essential, must be included

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#2: Family education and advocacy

- ▶ Provide information to patients and families/caregivers and develop a network for improved communication and education about accessing resources for nutritional treatment

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#2: Family education and advocacy

- A. Not necessary at all, should not be included
- B. Not very important
- C. Neutral, may or may not be helpful
- D. Very important
- E. Absolutely essential, must be included

0% 0% 0% 0% 0%

Not necessary at all, should not be included
Not very important
Neutral, may or may not be helpful
Very important
Absolutely essential, must be included

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#3: Maximum use of 3rd party insurance benefits

- ▶ Bill all available insurance carriers for reimbursement of medical food/formula; file appeals when coverage is denied; and assure patients are enrolled in health plans and programs for which they are eligible

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#3: Maximum use of 3rd party insurance benefits

- A. Not necessary at all, should not be included
- B. Not very important
- C. Neutral, may or may not be helpful
- D. Very important
- E. Absolutely essential, must be included

0% 0% 0% 0% 0%

Not necessary at all, should not be included
Not very important
Neutral, may or may not be helpful
Very important
Absolutely essential, must be included

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#4: Increased access to low protein modified foods

- ▶ Decrease costs to families through combined purchasing power in a medical food store or DME; consider provision of monthly low protein food package

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#4: Increased access to low protein modified foods

- A. Not necessary at all, should not be included
- B. Not very important
- C. Neutral, may or may not be helpful
- D. Very important
- E. Absolutely essential, must be included

0% 0% 0% 0% 0%

Not necessary at all, should not be included
Not very important
Neutral, may or may not be helpful
Very important
Absolutely essential, must be included

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#5: A safety net

- ▶ Develop a process for coverage of essential nutritional treatment when 1) other means have been exhausted; and 2) patient is ineligible for coverage by payers or state programs

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#5: A safety net

- A. Not necessary at all, should not be included
- B. Not very important
- C. Neutral, may or may not be helpful
- D. Very important
- E. Absolutely essential, must be included

0% 0% 0% 0% 0%

Not necessary at all, should not be included
Not very important
Neutral, may or may not be helpful
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Absolutely essential, must be included

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#6: Coordination with state and federal supplemental food programs

- ▶ Determine supplemental foods available to eligible recipients of WIC, food stamps, school lunch programs, etc.

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#6: Coordination with state and federal supplemental food programs

- A. Not necessary at all, should not be included
- B. Not very important
- C. Neutral, may or may not be helpful
- D. Very important
- E. Absolutely essential, must be included

0% 0% 0% 0% 0%

Not necessary at all, should not be included
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Very important
Absolutely essential, must be included

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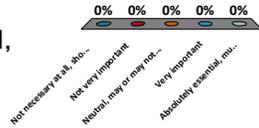
#7: Possible legislation

- ▶ Explore need for state legislation mandating insurance coverage or other approaches to coverage for medical foods used in the treatment of inborn errors of metabolism (IEM) regardless of age or gender

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#7: Possible legislation

- A. Not necessary at all, should not be included
- B. Not very important
- C. Neutral, may or may not be helpful
- D. Very important
- E. Absolutely essential, must be included



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Next Steps

- ▶ Prepare a report that describes the issues, why a change is needed, the work group process, participants and recommendations
- ▶ Make the report available for public comment by families and others
- ▶ Submit the report to directors of the MDCH Public Health and Medical Services Administrations
- ▶ Develop an implementation plan based on departmental response
- ▶ Communicate with families and provide opportunities for continued involvement in implementation

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**THANK YOU FOR YOUR
PARTICIPATION AND IMPORTANT
CONTRIBUTIONS!**