Development of a State Condition-Readiness Tool for Disorders Not on the Recommended Uniform Screening Panel

2017 Newborn Screening and Genetic Testing Symposium

September 11, 2017

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Michigan Newborn Screening Follow-Up Program

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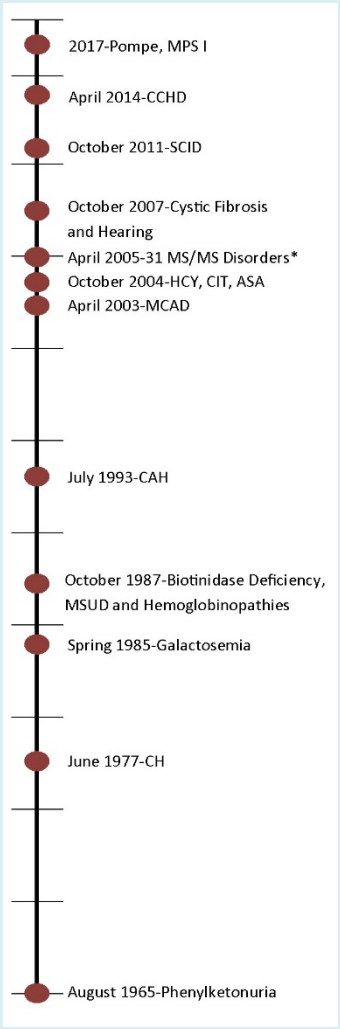
MICHIGAN Newborn Screening

MDHHS Michigan Department of Health & Human Services

RICK SNYDER, GOVERNOR | NICK LYON, DIRECTOR

How Michigan adds conditions

- Michigan historically has followed the recommendations of the Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC)
- State of Michigan Public Health Code mandated formation of Newborn Screening Quality Assurance Advisory Committee (NBS QAAC) in 2006
  - "The [NBS QAAC] shall also include in the report recommendations to revise the list to include additional newborn screening tests that are nationally recognized in the scientific literature or national standards for conditions that can be ameliorated or treated if identified by a newborn screening test…"



Michigan Approval Process for Addition of New NBS Disorders

Legislative Review by both chambers (45 days from session)
No action = approved

Effective 6 months from approval

MDHHS Director approves; forwards to Michigan Legislature (30 days)

QAAC reviews, discusses, forms recommendation, votes

TAC reviews, discusses, revises, votes on recommendations, MDHHS presents to QAAC

Michigan Legislature – Health Policy Committees
Senate Chair and House Chair

Michigan Department of Health and Human Services
Director

Population Health Administration
Senior Deputy Director

NBS QAAC
Newborn Screening Quality Assurance Advisory Committee

NBS Technical Advisory Committee (TAC)

- Pompe Disease & MPS I Advisory Committee
- Cystic Fibrosis Quality Improvement Committee
- Pediatric Endocrinology Advisory Committee
- Primary Immunodeficiency Disorders Quality Improvement Committee
- Metabolic Disorders Quality Improvement Committee
- Hemoglobinopathy Quality Improvement Committee
- Critical Congenital Heart Disease Advisory Committee
- X-ALD Quality Improvement Committee

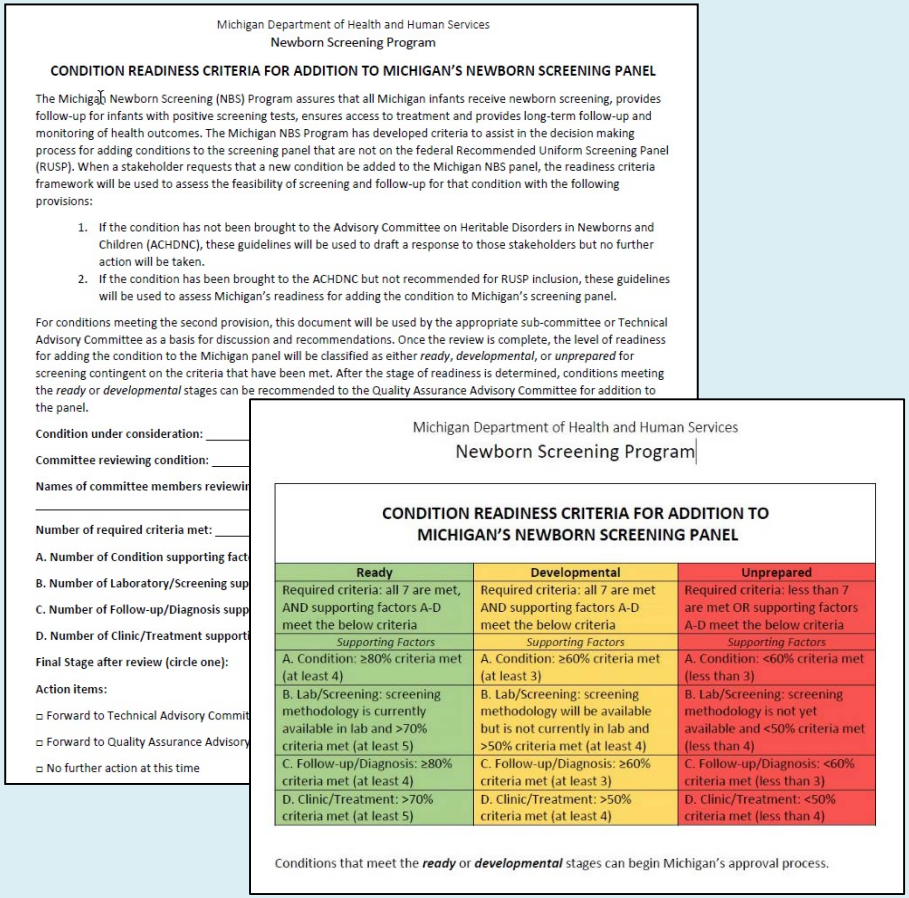
Subcommittee reviews, discusses, formulates recommendation, presents to TAC

Why implement a tool?

- Michigan Newborn Screening Program is occasionally approached by families, state legislators, or clinicians to consider adding other disorders not included on the ACHDNC Recommended Uniform Screening Panel (RUSP)
- Needed a systematic approach to review requests

Tool Development

- Review of ACHDNC resources
- Current ACHDNC evaluation process
- Other resources
  - Washington State's 2016 APHL presentation
  - Ontario's process



Michigan Department of Health and Human Services
Newborn Screening Program

CONDITION READINESS CRITERIA FOR ADDITION TO MICHIGAN'S NEWBORN SCREENING PANEL

The Michigan Newborn Screening (NBS) Program assures that all Michigan infants receive newborn screening, provides follow-up for infants with positive screening tests, ensures access to treatment and provides long-term follow-up and monitoring of health outcomes. The Michigan NBS Program has developed criteria to assist in the decision making process for adding conditions to the screening panel that are not on the federal Recommended Uniform Screening Panel (RUSP). When a stakeholder requests that a new condition be added to the Michigan NBS panel, the readiness criteria framework will be used to assess the feasibility of screening and follow-up for that condition with the following provisions:

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For conditions meeting the second provision, this document will be used by the appropriate sub-committee or Technical Advisory Committee as a basis for discussion and recommendations. Once the review is complete, the level of readiness for adding the condition to the Michigan panel will be classified as either *ready*, *developmental*, or *unprepared* for screening contingent on the criteria that have been met. After the stage of readiness is determined, conditions meeting the *ready* or *developmental* stages can be recommended to the Quality Assurance Advisory Committee for addition to the panel.

Condition under consideration: _____

Committee reviewing condition: _____

Names of committee members reviewir

_____

Number of required criteria met: _____

A. Number of Condition supporting fact

B. Number of Laboratory/Screening sup

C. Number of Follow-up/Diagnosis supp

D. Number of Clinic/Treatment support

Final Stage after review (circle one):

Action items:

□ Forward to Technical Advisory Commit

□ Forward to Quality Assurance Advisory

□ No further action at this time

Michigan Department of Health and Human Services
Newborn Screening Program

CONDITION READINESS CRITERIA FOR ADDITION TO MICHIGAN'S NEWBORN SCREENING PANEL

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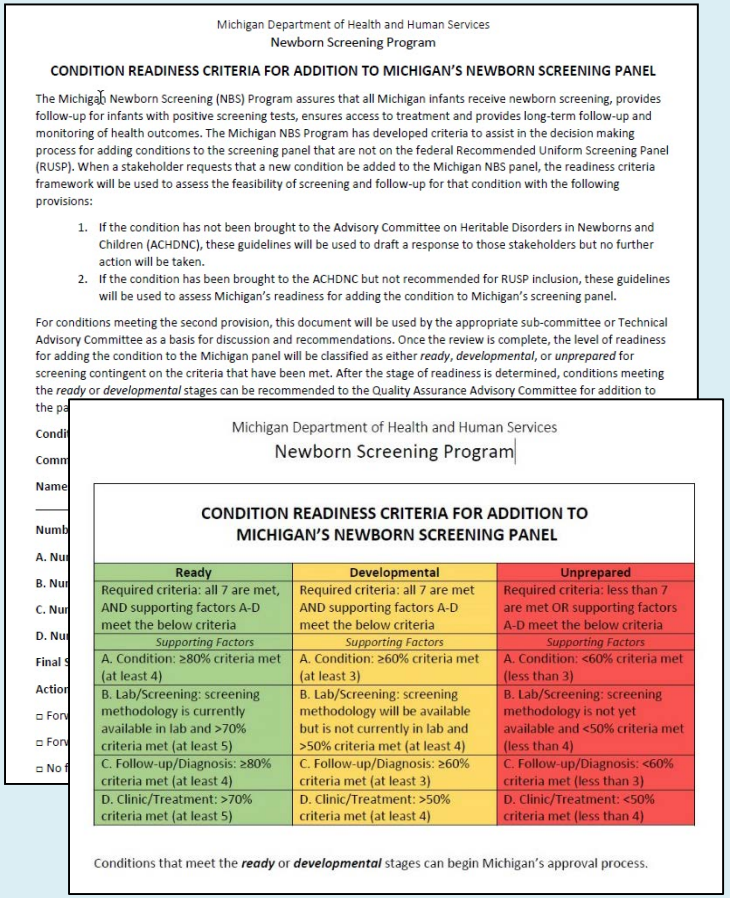
Conditions that meet the ***ready*** or ***developmental*** stages can begin Michigan's approval process.

Tool Development

- Collaboration from
  - NBS follow-up program staff
  - NBS laboratory staff
  - NBS Coordinating Center staff
  - NBS Technical Advisory Committee
  - NBS Quality Assurance Advisory Committee



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Michigan Department of Health and Human Services
Newborn Screening Program

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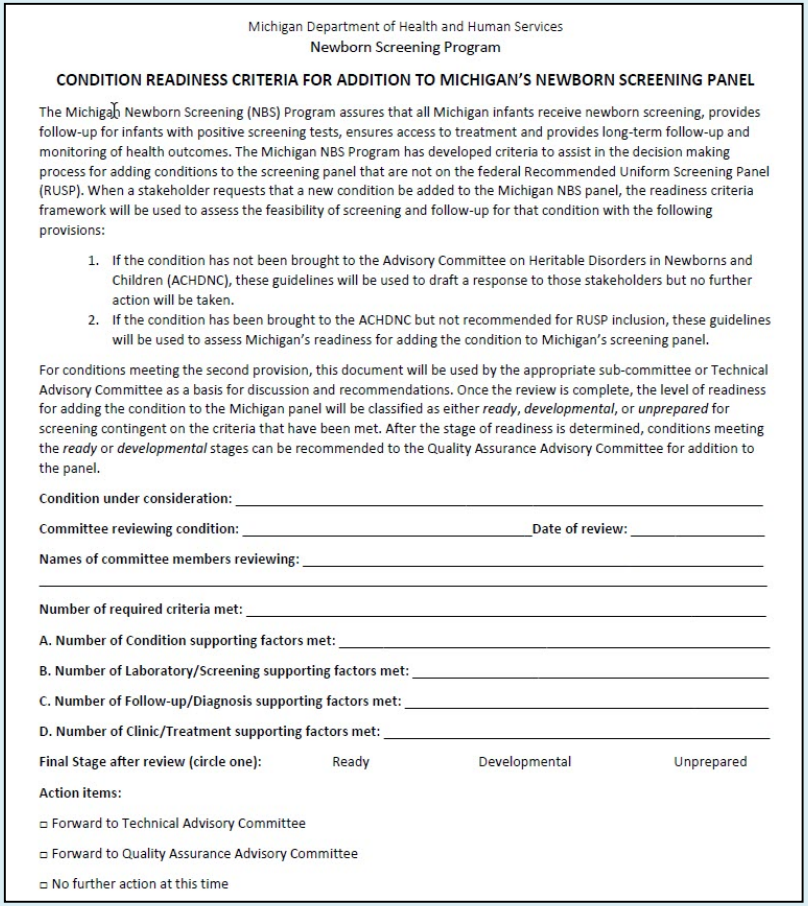
Conditions that meet the ***ready*** or ***developmental*** stages can begin Michigan's approval process.

How does Michigan use the tool?

- Guidelines used for non-RUSP conditions
- Tool assists in drafting response to stakeholders requesting addition of a new condition to Michigan's NBS panel
- If the condition has never been brought to ACHDNC attention, draft response but no further action
- If the condition has been brought to ACHDNC and not recommended for RUSP, guidelines can be used to assess Michigan's readiness to add
- Conditions added prior to development of tool are grandfathered in
- Tool will be reviewed every 3 years



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Condition under consideration: _____

Committee reviewing condition: _____ **Date of review:** _____

Names of committee members reviewing: _____

_____

Number of required criteria met: _____

A. Number of Condition supporting factors met: _____

B. Number of Laboratory/Screening supporting factors met: _____

C. Number of Follow-up/Diagnosis supporting factors met: _____

D. Number of Clinic/Treatment supporting factors met: _____

Final Stage after review (circle one): Ready Developmental Unprepared

Action items:

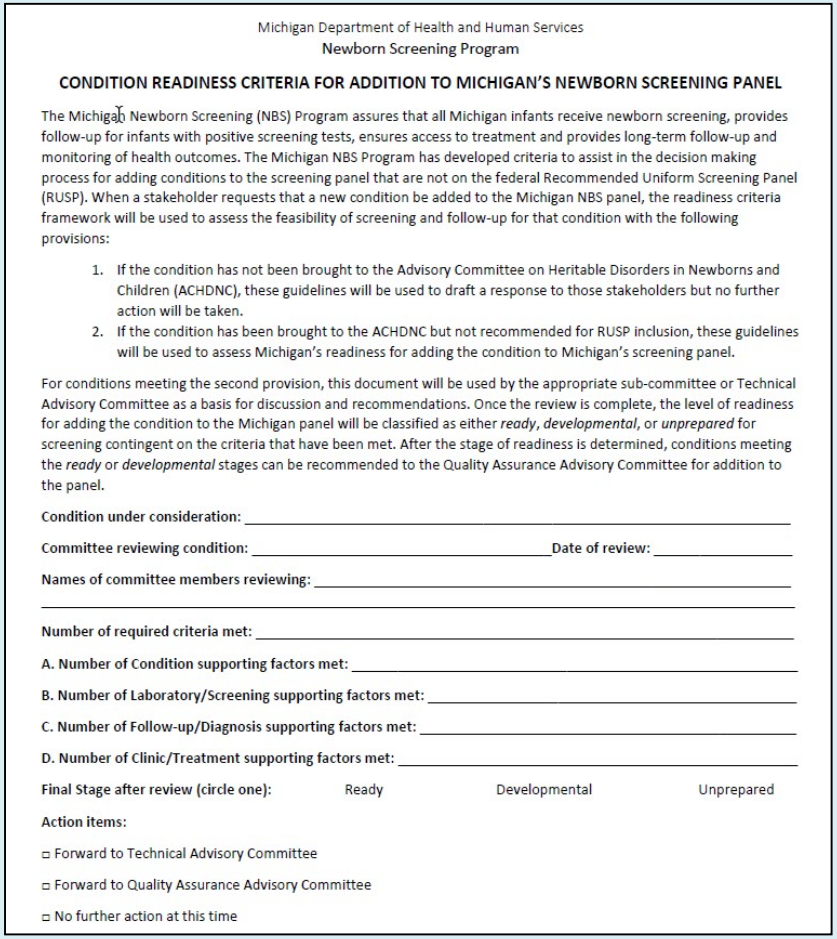
□ Forward to Technical Advisory Committee

□ Forward to Quality Assurance Advisory Committee

□ No further action at this time

How does Michigan use the tool?

- Utilize committee structure
  - Subcommittee reviews, discusses, formulates recommendation and presents to TAC
  - TAC recommends approval to QAAC
  - QAAC makes final recommendation
  - Legislature process follows



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Action items:

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Readiness Table

- Total for each section determines status of condition
- Conditions meeting ready or developmental stages can go through Michigan's approval process

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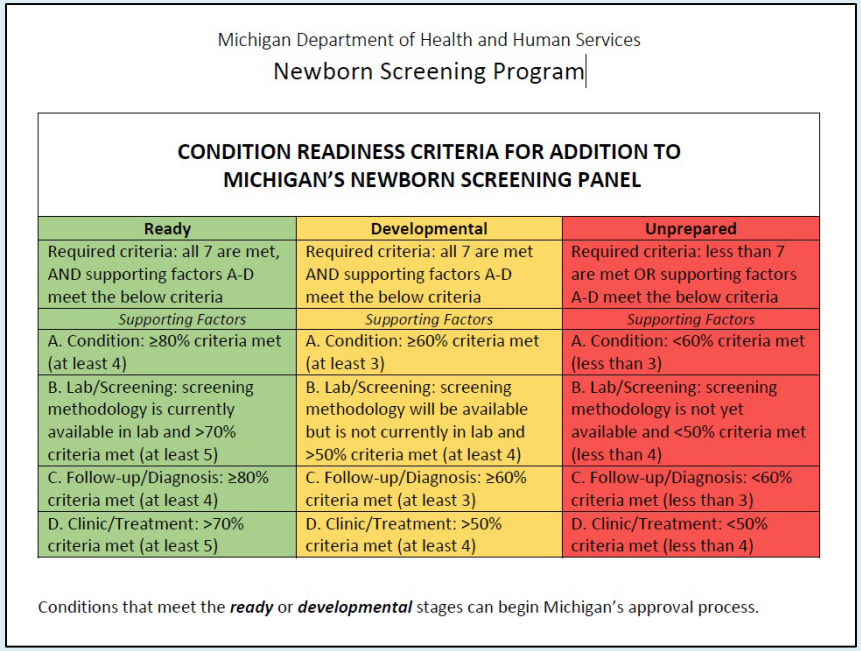
Conditions that meet the ***ready*** or ***developmental*** stages can begin Michigan's approval process.

Criteria sub-sections

- Required criteria
- Supporting factors
  - Condition characteristics
  - Laboratory/Screening
  - Follow-up/Diagnosis
  - Clinic/Treatment availability



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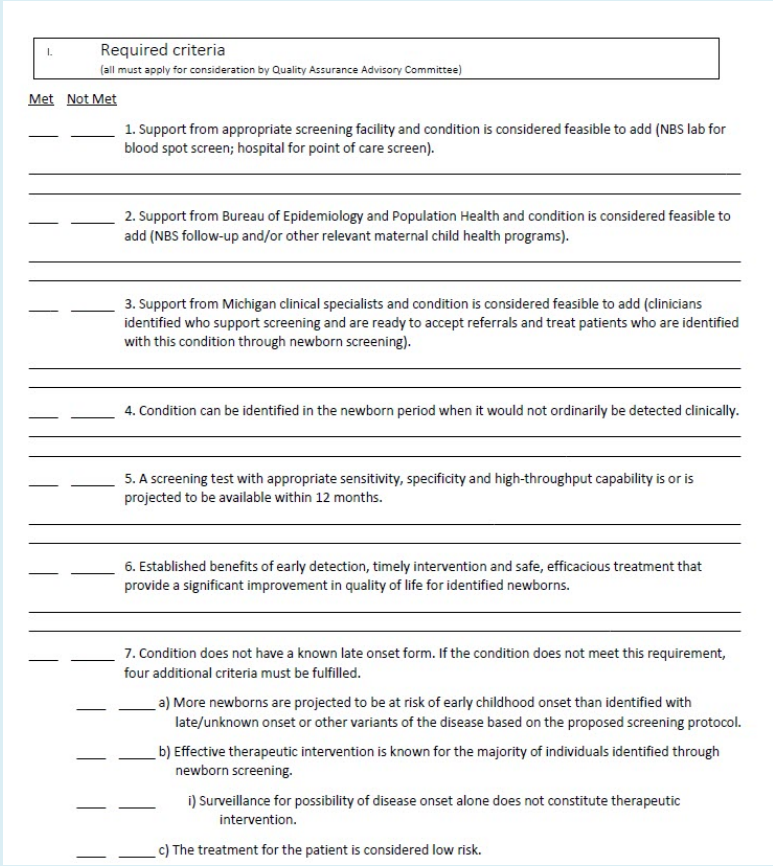
Required Criteria

- All 7 criteria must be met to pass
- Criteria include:
  - Support from NBS lab, follow-up and Michigan clinical specialists
  - Condition is identifiable in newborn period
  - Sensitive, specific, screening test with high-throughput capability
  - Established benefits of early intervention and treatment
  - Condition does not have a known late-onset form (additional caveats must be met if late-onset forms are known)



I. Required criteria
(all must apply for consideration by Quality Assurance Advisory Committee)

Met Not Met

___ ___ 1. Support from appropriate screening facility and condition is considered feasible to add (NBS lab for blood spot screen; hospital for point of care screen).

___ ___ 2. Support from Bureau of Epidemiology and Population Health and condition is considered feasible to add (NBS follow-up and/or other relevant maternal child health programs).

___ ___ 3. Support from Michigan clinical specialists and condition is considered feasible to add (clinicians identified who support screening and are ready to accept referrals and treat patients who are identified with this condition through newborn screening).

___ ___ 4. Condition can be identified in the newborn period when it would not ordinarily be detected clinically.

___ ___ 5. A screening test with appropriate sensitivity, specificity and high-throughput capability is or is projected to be available within 12 months.

___ ___ 6. Established benefits of early detection, timely intervention and safe, efficacious treatment that provide a significant improvement in quality of life for identified newborns.

___ ___ 7. Condition does not have a known late onset form. If the condition does not meet this requirement, four additional criteria must be fulfilled.

___ ___ a) More newborns are projected to be at risk of early childhood onset than identified with late/unknown onset or other variants of the disease based on the proposed screening protocol.

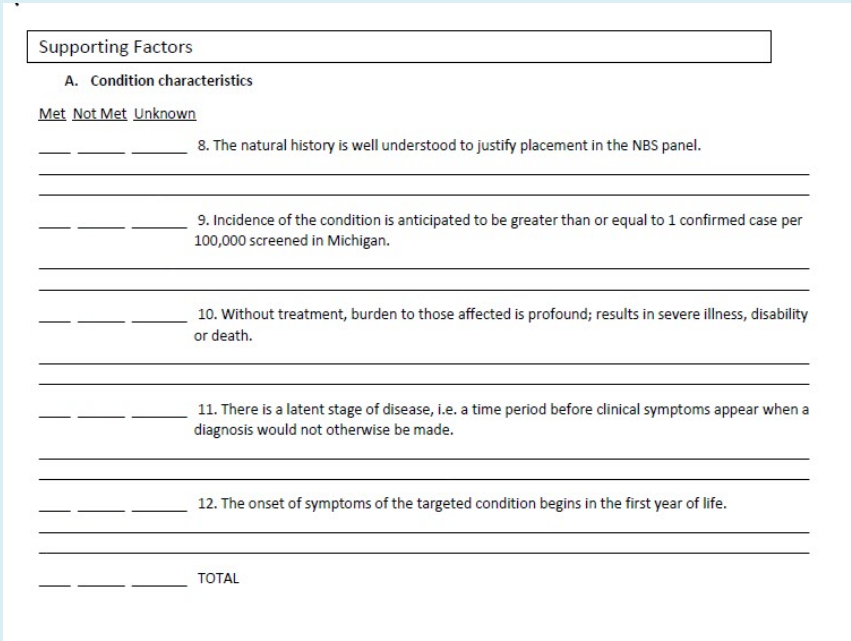
___ ___ b) Effective therapeutic intervention is known for the majority of individuals identified through newborn screening.

___ ___ i) Surveillance for possibility of disease onset alone does not constitute therapeutic intervention.

___ ___ c) The treatment for the patient is considered low risk.

Supporting Factors: Condition characteristics

- Natural history is well understood
- Expected incidence in Michigan
- Profound burden to those affected
- Latent state of disease
- Onset of symptoms in first year of life



Supporting Factors

A. **Condition characteristics**

Met Not Met Unknown

___ ___ ___ 8. The natural history is well understood to justify placement in the NBS panel.

___ ___ ___ 9. Incidence of the condition is anticipated to be greater than or equal to 1 confirmed case per 100,000 screened in Michigan.

___ ___ ___ 10. Without treatment, burden to those affected is profound; results in severe illness, disability or death.

___ ___ ___ 11. There is a latent stage of disease, i.e. a time period before clinical symptoms appear when a diagnosis would not otherwise be made.

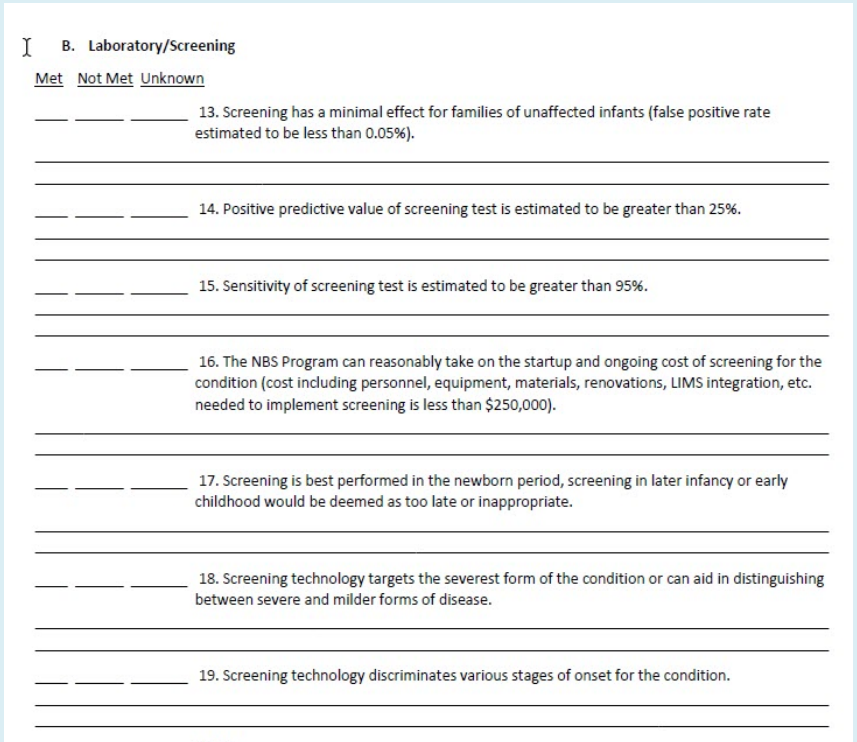
___ ___ ___ 12. The onset of symptoms of the targeted condition begins in the first year of life.

___ ___ ___ TOTAL

Ready	Developmental	Unprepared
A. Condition: ≥80% criteria met (at least 4)	A. Condition: ≥60% criteria met (at least 3)	A. Condition: <60% criteria met (less than 3)

Supporting Factors: Laboratory/Screening

- False positive rate
- Positive predictive value
- Sensitivity
- Cost of screening
- Screening is best done in newborn period
- Targets severest form of condition
- Discriminates states of onset for condition



B. Laboratory/Screening

Met Not Met Unknown

___ ___ ___ 13. Screening has a minimal effect for families of unaffected infants (false positive rate estimated to be less than 0.05%).

___ ___ ___ 14. Positive predictive value of screening test is estimated to be greater than 25%.

___ ___ ___ 15. Sensitivity of screening test is estimated to be greater than 95%.

___ ___ ___ 16. The NBS Program can reasonably take on the startup and ongoing cost of screening for the condition (cost including personnel, equipment, materials, renovations, LIMS integration, etc. needed to implement screening is less than $250,000).

___ ___ ___ 17. Screening is best performed in the newborn period, screening in later infancy or early childhood would be deemed as too late or inappropriate.

___ ___ ___ 18. Screening technology targets the severest form of the condition or can aid in distinguishing between severe and milder forms of disease.

___ ___ ___ 19. Screening technology discriminates various stages of onset for the condition.

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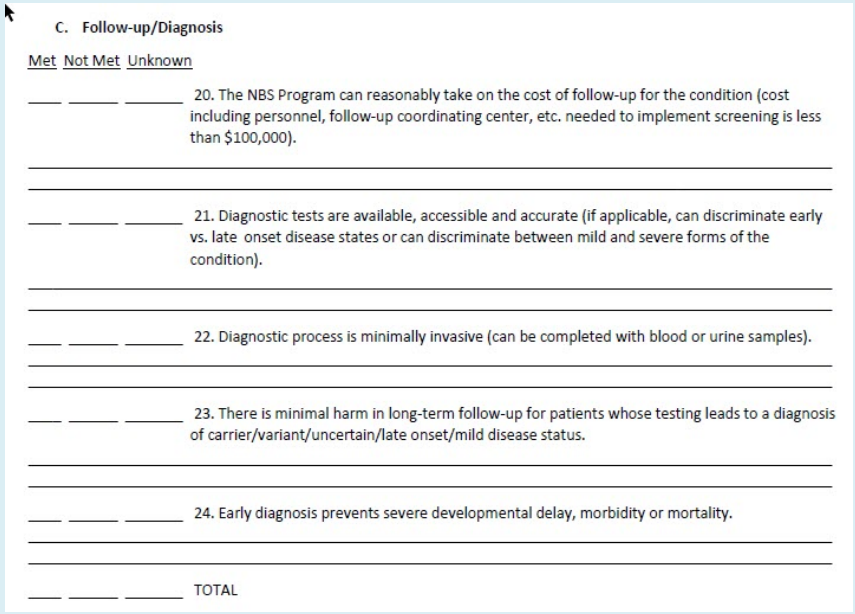
Supporting Factors: Follow-up/Diagnosis

- Cost of follow-up
- Available, accessible and accurate diagnostic tests
- Diagnostic process is minimally invasive
- Minimal harm from follow-up for those diagnosed with carrier/ variant/late onset/mild disease
- Early diagnosis prevents severe developmental delay, morbidity, mortality



C. Follow-up/Diagnosis

Met Not Met Unknown

___ ___ ___ 20. The NBS Program can reasonably take on the cost of follow-up for the condition (cost including personnel, follow-up coordinating center, etc. needed to implement screening is less than $100,000).

___ ___ ___ 21. Diagnostic tests are available, accessible and accurate (if applicable, can discriminate early vs. late onset disease states or can discriminate between mild and severe forms of the condition).

___ ___ ___ 22. Diagnostic process is minimally invasive (can be completed with blood or urine samples).

___ ___ ___ 23. There is minimal harm in long-term follow-up for patients whose testing leads to a diagnosis of carrier/variant/uncertain/late onset/mild disease status.

___ ___ ___ 24. Early diagnosis prevents severe developmental delay, morbidity or mortality.

___ ___ ___ TOTAL

Ready	Developmental	Unprepared
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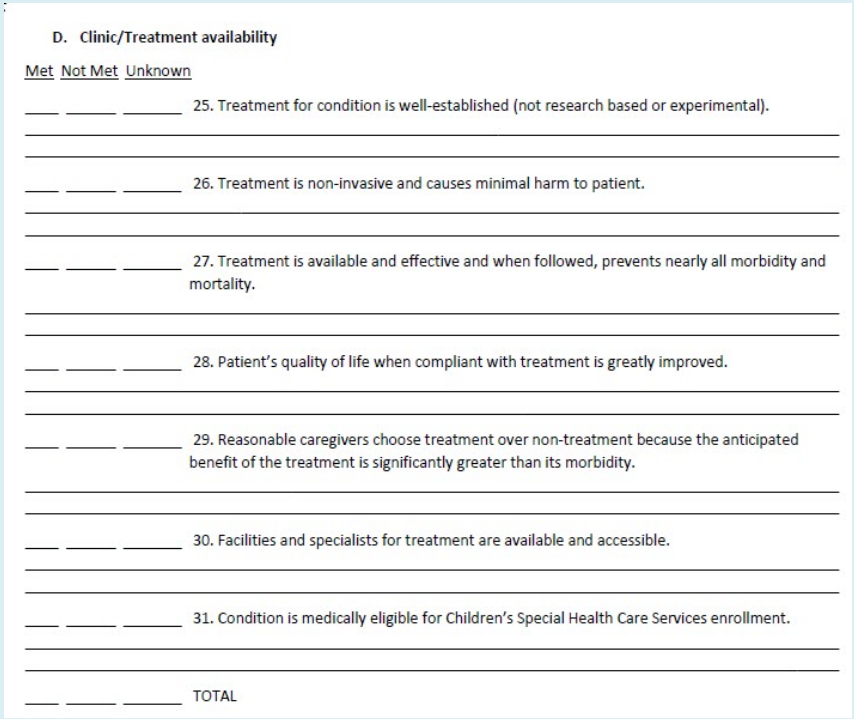
Supporting Factors: Clinic/Treatment availability

- Treatment is well-established
- Treatment is non-invasive (minimal harm)
- Treatment is available and effective
- Treatment improves quality of life
- Caregivers choose to treat
- Facilities and specialists available and accessible
- CSHCS eligibility



D. Clinic/Treatment availability

Met Not Met Unknown

___ ___ ___ 25. Treatment for condition is well-established (not research based or experimental).

___ ___ ___ 26. Treatment is non-invasive and causes minimal harm to patient.

___ ___ ___ 27. Treatment is available and effective and when followed, prevents nearly all morbidity and mortality.

___ ___ ___ 28. Patient's quality of life when compliant with treatment is greatly improved.

___ ___ ___ 29. Reasonable caregivers choose treatment over non-treatment because the anticipated benefit of the treatment is significantly greater than its morbidity.

___ ___ ___ 30. Facilities and specialists for treatment are available and accessible.

___ ___ ___ 31. Condition is medically eligible for Children's Special Health Care Services enrollment.

___ ___ ___ TOTAL

Ready	Developmental	Unprepared
D. Clinic/Treatment: >70% criteria met (at least 5)	D. Clinic/Treatment: >50% criteria met (at least 4)	D. Clinic/Treatment: <50% criteria met (less than 4)

First use of tool: Guanidinoacetate methyltransferase deficiency (GAMT)

- June 2017 – MetQIC meeting to review GAMT deficiency with condition readiness tool

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Supporting Factors	*Supporting Factors*	*Supporting Factors*
A. Condition: ≥80% criteria met (at least 4)	A. Condition: ≥60% criteria met (at least 3)	A. Condition: <60% criteria met (less than 3)
B. Lab/Screening: screening methodology is currently available in lab and >70% criteria met (at least 5)	B. Lab/Screening: screening methodology will be available but is not currently in lab and >50% criteria met (at least 4)	B. Lab/Screening: screening methodology is not yet available and <50% criteria met (less than 4)
C. Follow-up/Diagnosis: ≥80% criteria met (at least 4)	C. Follow-up/Diagnosis: ≥60% criteria met (at least 3)	C. Follow-up/Diagnosis: <60% criteria met (less than 3)
D. Clinic/Treatment: >70% criteria met (at least 5)	D. Clinic/Treatment: >50% criteria met (at least 4)	D. Clinic/Treatment: <50% criteria met (less than 4)

- Detailed notes from MetQIC discussion
- Caveats and comments from discussion listed in meeting minutes
- Developmental result

Unanimous yes vote by all voting members in attendance to forward their findings to TAC

Conclusions

- Criteria were viewed as useful by staff and advisory committees
- Provides a standardized and systematic structure for condition review
- Clarifies factors that need to be considered prior to adding disorders
- Reinforces the importance of a systematic process to evaluate conditions
- Helps direct discussions with professionals

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