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| **DEPARTMENT OF HEALTH SERVICES**  Division of Public Health  F-00986 (03/2014) | **STATE OF WISCONSIN** |
| **WISCONSIN NEWBORN SCREENING (NBS) PROGRAM – CONDITION NOMINATION** | |

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| **Nomination of a Condition to the Wisconsin Newborn Screening Panel** | | |
| Date of Nomination | | |
| **NOMINATOR** | | |
| Name | | Organization |
| Affiliation (i.e., health professional, researcher, clinician, advocate) | | |
| Address | | |
| Email Address | | Telephone Number |
| **CO-SPONSORING ORGANIZATION #1** (as appropriate, additional sponsors may be included on page 5) | | |
| Name | | Organization |
| Affiliation (i.e., health professional, researcher, clinician, advocate) | | |
| Address | | |
| Email Address | | Telephone Number |
| **Condition** | **STATEMENT** | |
| Nominated Condition |  | |
| Description of Disorder |  | |
| Screening Method |  | |
| Gene |  | |
| OMIM or other names for condition |  | |
| Case Definition |  | |

**NOTE:** Please reference each statement/answer with the corresponding reference number listed in **Key References**.

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| **CRITERION** | | |
| **Criterion 1:** Mandated testing should be limited to conditions that cause serious health risks in childhood that are unlikely to be detected and prevented in the absence of newborn screening. | | |
| Timing of Clinical Onset | *Relevance of the timing of newborn screening to onset of clinical manifestations. Must cause serious health risks in childhood that are unlikely to be detected and prevented in the absence of newborn screening.* | |
| **Criterion 2:** For each condition, there should be information about the incidence, morbidity and mortality, and the natural history of the disorder. | |
| Incidence | *Determined by what method(s): pilot screening or clinical identification?* |
| Severity of Disease | *Morbidity, disability, mortality, spectrum of severity, natural history.* |

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| **Criterion 3:** Conditions identified by newborn screening should be linked with interventions that have been shown in well-designed studies to be safe and effective in preventing serious health consequences. | |
| Urgency | How soon after birth must treatment be initiated to be effective? |
| Efficacy (Benefits) | Extent of prevention of mortality, morbidity, disability. Treatment limitations, such as difficulty with acceptance or adherence. |
| Potential Harms | Potential medical or other ill effects from treatment. |
| **Criterion 4:** The interventions should be reasonably available to affected newborns. | |
| Modality | *Drug(s), diet, replacement therapy, transplant, surgery, other. Include information regarding regulatory status of treatment.* |
| Availability | *Describe scope of availability and note any limitations.* |
| **Criterion 5:** Appropriate follow-up should be available for newborns that have a false positive newborn screen. | |
| Follow-up for False Positives | *Define the follow-up process.* |
| **Criterion 6:** The characteristics of mandated tests in the newborn population should be known, including specificity, sensitivity, and predictive value. | |
| Screening test(s) to be used | *Description of the high volume method, instrumentation and if available as part of*  *multi-analyte platform.* |
| Modality of Screening | *Dried blood spot, physical or physiologic assessment, other* |
| Does the screening algorithm include a second tier test? If so, what type of test and availability? | *Dried blood spot, physical or physiologic assessment, other* |
| Clinical Validation | *Location, duration, size, preliminary results of past/ongoing pilot study for clinical validation, positive predictive value, false positive rate, analytical specificity, sensitivity.* |
| Analytic Validation | *Limit of detection/quantitation, detection rate, reportable range of test results, reference range. Include regulatory status of test, information about reference samples and controls required for testing and availability of or potential for external quality assurance system, e.g., QC and PT for both screening and confirmatory tests.* |
| Potential Secondary Findings | *May other disorders be identified by the screening test for the nominated condition?*  Yes  No ***If yes:***   * *How should that identification be handled—should those screening results be disclosed to the physicians or parents?* * *Would that disorder(s) meet the outlined criteria?*  Yes  No   + *If yes, please prepare a separate nomination form for the secondary disorder(s)*   + *If no, what criteria does it not meet?* |
| **Summary of Population-based Pilot Study(ies)** | |
| Location of Prospective Pilot |  |
| Number of Newborns Screened |  |
| Number of Positive Results | *Positive by primary test versus 2nd tier test if applicable.* |
| False Positive Rate; False Negative Rate (if known) | *False positive by primary test versus 2nd tier test if applicable.* |
| Number of Infants Confirmed with Diagnosis | *How are diagnosis confirmed [clinical, biochemical, molecular]?* |
| **Criterion 7:** If a new sample collection system is needed to add a disorder, reliability and timeliness of sample collection must be demonstrated. | |
| Is this a new sample collection system? | *If yes, demonstrate reliability and timeliness of sample collection process, including data collection, analysis, and reporting of new results.* |
| **Criterion 8:** Before a test is added to the panel, the details of reporting, follow-up, and management must be completely delineated, including development of standard instructions, identification of consultants, and identification of appropriate referral centers throughout the state/region. | |
| Considerations of Screening and Diagnostic Testing | *False positives, carrier detection, invasiveness of method, other*      . |
| Is test FDA cleared/approved | *Include availability of information, sole source manufacturer, etc.* |
| List all CLIA or CAP certified labs offering testing in the US | *Link to GeneTests, and Genetic Test Reference if applicable.* |
| Follow-up and management process | *Development of standard instructions, identification of consultants, identification of appropriate referral centers throughout the state/region, follow-up for results, management of ongoing care, education, and outreach.* |
| **Criterion 9:** Recommendations and decisions should include consideration of the costs of the screening test, confirmatory testing, accompanying treatment, counseling, and the consequences of false positives. The mechanism of funding those costs should be identified. Expertise in economic factors should be available to those responsible for recommendations and decisions. | |
| Screening test |  |
| Confirmatory testing |  |
| Treatment |  |
| Counseling |  |
| False positives |  |
| Mechanism of funding |  |

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| **Key References to support each criterion. Please list and attach as PDF(s). If mailing, include hard copies.** | |
| **#** | **Criterion 1** |
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|  | **Criterion 2** |
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|  | **Criterion 3** |
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|  | **Criterion 5** |
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|  | **Criterion 6** |
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|  | **Criterion 7** |
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|  | **Criterion 8** |
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|  | **Criterion 9** |
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**Additional Co-sponsoring Organizations**

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| **CO-SPONSORING ORGANIZATION #2** | |
| Name | Organization |
| Affiliation (i.e., health professional, researcher, clinician, advocate) | |
| Address | |
| Email Address | Telephone Number |
| **CO-SPONSORING ORGANIZATION #3** | |
| Name | Organization |
| Affiliation (i.e., health professional, researcher, clinician, advocate) | |
| Address | |
| Email Address | Telephone Number |
| **CO-SPONSORING ORGANIZATION #4** | |
| Name | Organization |
| Affiliation (i.e., health professional, researcher, clinician, advocate) | |
| Address | |
| Email Address | Telephone Number |
| **CO-SPONSORING ORGANIZATION #5** | |
| Name | Organization |
| Affiliation (i.e., health professional, researcher, clinician, advocate) | |
| Address | |
| Email Address | Telephone Number |

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| **Submission Checklist** | |
|  | Nomination form |
|  | Conflict of Interest Forms completed by Nominator and all Co-Sponsoring Organizations |
|  | PDF(s) or hard copies of references |
| Contact information of Nominator: | |

Submit Nominations to: [DHSWICongenitalDisorders@wisconsin.gov](mailto:DHSWICongenitalDisorders@wisconsin.gov)

Or mail to:

WI Division of Public Health

Newborn Screening Program

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