WISCONSIN NEWBORN SCREENING (NBS) PROGRAM – CONDITION NOMINATION

Nomination of a Condition to the Wisconsin Newborn Screening Panel

Date of Nomination

3/26/25

NOMINATOR	
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CO-SPONSORING ORGANIZATION #1 (as appropriate, additional sponsors may be included on page 5)	
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Condition	**STATEMENT**
Nominated Condition	Mucopolysaccaridosis type II (MPS II)
Description of Disorder	Mucopolysaccharidosis type II (MPS II, also called Hunter syndrome) is an X-linked lysosomal storage disorder caused by a deficiency of iduronate-2-sulfatase (I2S) due to pathogenic variants in the iduronate-2-sulfatase (IDS) gene. As an X-linked disorder males are predominantly affected; few affected females have been reported in cases of skewed X-inactivation or X chromosome abnormalities. This enzymatic defect results in progressive accumulation of two glycosaminoglycans (GAGs, also known as mucopolysaccharides), dermatan and heparan sulfate, in various body tissues, causing a multisystem disorder with highly variable age of onset, rate of progression, and disease severity. Primary clinical features include progressive airway disease, cardiac disease, skeletal involvement, and central nervous system (CNS) involvement in the form of progressive cognitive decline. MPS II is characterized clinically as “severe” or “attenuated” (previously “neuronopathic” and “non-neuronopathic”) depending on the presence or absence of neurological involvement. Approximately two-thirds of affected individuals have the severe form of MPS II. Other common features in both forms of MPS II include: short stature; macrocephaly with or without communicating hydrocephalus; macroglossia; hoarse voice; conductive and sensorineural hearing loss; hepatosplenomegaly; dysostosis multiplex; spinal stenosis; and carpal tunnel syndrome.” (Scarpa et al., GeneReviews) Without treatment, individuals with the severe form typically live only into their second decade. Individuals with the attenuated form may live into their fifth or sixth decade. (Wraith et al., 2008)

Screening Method	Measurement of iduronate-2-sulfatase enzyme activity in dried blood spot (DBS) followed by glycosaminoglycan (GAG) analysis in DBS as a 2nd tier test when enzyme is low.
Gene	iduronate-2-sulfatase (IDS)
OMIM or other names for condition	Mucopolysaccaridosis type II (MPS II; 309900); other names: HUNTER SYNDROME IDURONATE 2-SULFATASE DEFICIENCY IDS DEFICIENCY SULFOIDURONATE SULFATASE DEFICIENCY SIDS DEFICIENCY
Case Definition	1) low/absent iduronate-2-sulfatase activity* and 2) elevated dermatan and heparan sulfate in urine to rule out I2S biochemical pseudodeficiency. *Note: clinical confirmatory testing should include normal measurement of at least one other sulfatase to rule out multiple sulfatase deficiency

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

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.* While the earliest signs and symptoms of MPS II may be present in the first year or two of life, there will generally not be any clinical signs in the newborn period to distinguish an affected infant from an unaffected infant. A publication using data from the Hunter Outcome Survey (HOS) found that the only clinical findings evident in a majority of affected individuals prior to age two were otitis media and abdominal hernia – both very nonspecific features unlikely to raise concern for MPS II in isolation. (Wraith et al., 2008) Individuals on the severe end of the disease spectrum manifest features between 2-4 years of age and experience rapid neurological decline resulting in severe cognitive impairment. Individuals with an attenuated phenotype can develop similar somatic manifestations at the same or later ages but with no or minimal CNS involvement. An analysis of ERT-treated (n=800) and untreated (n=95) patients from the HOS reported that the median ages of symptom onset in the two groups (ERT-treated and untreated) were 1.6 years and 1.5 years, respectively, and the median ages at diagnosis were 3.3 years and 3.2 years, respectively. (Burton et al., 2017)
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?* The birth prevalence of MPS II, as assessed prior to newborn screening, is unclear. One study reported a birth prevalence of 0.26 per 100,000 in the United States based on 1995-2005 National MPS Society Membership, though as this a voluntary registry the number is likely an underestimate. (Puckett et al., 2021) The ACHDNC review assumed an incidence of clinically detected MPS II (either attenuated or severe) of 0.67 per 100,000 births. (Kemper et al., 2022) Updated birth prevalence data is emerging as states have implemented newborn screening for MPS II. Illinois described a birth prevalence of 1 in 73,290 or 1.4 per 100,000 based on screening 586,323 infants between December 12, 2017 and April 30, 2022. (Burton et al., 2023) Missouri reported summary data at a recent MPS conference that described a birth prevalence of 1 in 96,297 or 1.0 per 100,000 based on screening 288,892 infants between November 1, 2018 and December 31, 2022. (Klug, 2023) The ACHDNC review assumed an overall incidence after NBS of 1.6 per 100,000 births. (Kemper et al., 2022)

Severity of Disease	*Morbidity, disability, mortality, spectrum of severity, natural history*. Much of the data outlining the natural history of MPS II has come from the Hunter Outcome Survey (HOS), a voluntary registry including patients who are untreated, have been treated with enzyme replacement therapy (ERT) or hematopoietic stem cell transplant (HSCT), as well as retrospective data on patients who passed away prior to study entry. From the ACHDNC review of MPS II: "An initial report of the first 263 MPS II patients registered in the HOS describes the prevalence of initial symptom characteristics, with age of onset. Of these patients, 24% were receiving idursulfase (ERT) at the time of enrollment in the HOS and had a median age of 12.2 years. Table 1 in the Supplemental Materials document (enclosed with nomination form) summarizes those features reported by at least 30% of patients in this HOS report, in order of median age of onset. Over 80% of patients registered in the Hunter Outcome Survey (HOS) reported at least one neurological (84%) or cardiovascular (82%) symptom, as well as involvement in the abdomen, head and neck, skeletal, ear, mouth, and chest and lungs, and at least 60% of patients additionally reported throat, skin, nose and gastrointestinal symptoms." (Kemper et al., 2022) Without treatment, individuals with the severe form typically live only into their second decade. Individuals with the attenuated form may live into their fifth or sixth decade. (Wraith et al., 2008)

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? Urgent in a severely affected individual, but not emergent. Treatment initiation will be based on clinical evaluation, with the best outcomes if treatment is started before somatic and cognitive concerns manifest. See Table 2 in Supplemental Materials document for a summary of eight subjects receiving ERT <1 year of age (Lampe et al., 2014)
Efficacy (Benefits)	Extent of prevention of mortality, morbidity, disability. Treatment limitations, such as difficulty with acceptance or adherence. Intravenous enzyme replacement therapy (ERT) is the most commonly used available treatement for MPS II. Idursulfase (Elaprase; Takeda Pharmaceutical Company Limited) was approved by the FDA in 2006 and is a once-weekly IV infusion. A significant limitation of idursulfase is that it does not cross the blood-brain barrier so it cannot impact GAG accumulation in the brain or progression of central nervous system disease. A 2024 systematic review found that idursulfase consistently demonstrates improvements in urinary GAG levels, hepatosplenomegaly, and left ventricular myocardial index (but not all cardiac manifestations such as valve disease). Respiratory outcomes are not consistently improved across studies. Improvments in 6-minute walk test are commonly reported, however, this is a challenging test to administer in young children or those with cognitive or physical impairments which may mean it is not a reliable metric to use in the youngest and most severely affected patients. (Al-Hertani et al., 2024) See Table 3 in the Supplemental Materials document for a comparison of outcomes for sibships with earlier and later ERT initiation. Hematopoietic stem cell transplantation (HSCT) could provide sufficient enzyme activity to slow or stop the progression of the disease; however, no controlled clinical studies have been conducted in individuals with MPS II and existing clinical outcomes data do not clearly delineate benefits of HSCT over ERT. Emerging therapies for MPS II that cross the blood-brain barrier (BBB) or otherwise address the central nervous system disease manifestations are under investigation or approved in other countries, including intracerebroventricular ERT, IV ERT engineered to cross the BBB, and gene therapies. See ClinicalTrials.gov for existing study details: https://clinicaltrials.gov/search?cond=Mucopolysaccharidosis%20II&aggFilters=status:not%20rec%20act%20com%20enr%20ava,studyType:int%20exp

Potential Harms	Potential medical or other ill effects from treatment. Infusion-based ERT treatments are time- and resource-intensive, requiring the patient to travel to an infusion center once a week and considerable coordination and administrative work from the clinical team. However infusion centers are already identified in Wisconsin and this mode of treatment is familiar to metabolic centers that would be managing MPS II. The majority of treated patients experience at least one infusion-related reaction, but these are typically minor (most commonly: pyrexia, rash, urticaria, vomiting) and can be managed clinically without the need to discontinue ERT. (Giugliani et al., 2014) Additionally, approximately 50% of participants in the pivitol idursulfase trial had positive IgG anti-idursulfase antibodies and while this attenuated the reduction in urine GAG levels, it did not increase adverse infusion-related reactions or impact clinical outcomes. (Muenzer et al., 2011)
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.* Treatment is typically through FDA-approved ERT, described above.
Availability	*Describe scope of availability and note any limitations.* Infusion centers are already identified and in use around the state of Wisconsin for ERT for other lysosomal storage disorders.
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.* Consistent with existing Wisconsin NBS practices, the state NBS laboratory at WSLH will communicate the positive MPS II screening result to the primary care provider and the metabolic center designated to engage in confirmatory testing and short term follow-up. The metabolic geneticist will reach out to the primary care provider to provide further consultation and center staff will reach out to the baby's family to offer an appointment where confirmatory testing will be performed. Confirmatory testing will consist of enzyme analysis of iduronate-2-sulfatase to confirm deficiency along with another sulfatase enzyme to rule out multiple sulfatase deficiency, urine GAGs to confirm elevated dermatan and heparan sulfate, and - following those results - genetic testing of IDS to confirm the diagnosis and rule out pseudodeficiency. Infants with normal iduronate-2-sulfatase activity, normal GAGs, and/or a known pseudodeficiency IDS variant will be discharged from clinic as false positive and/or unaffected (in the case of pseudodeficiency), having received comprehensive genetic counseling to facilitate understanding of their designation as false positive/unaffected.
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.* I2S activity will be measured using a modification of the NeoLSD MSMS. I2S activity reference range will be based on percent of daily median I2S activity. The assay will be performed on Revvity QSight MD210 mass spectrometer. Analysis of this enzyme activity is to be multiplexed with current platform being used for Pompe disease sceening. GAG analysis will be performed on the DBS specimen as a second-tier screening test when I2S enzyme acivity is low.
Modality of Screening	*Dried blood spot, physical or physiologic assessment, other* Dried Blood Spot
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* DBS specimens with reduced I2S enzyme activity will be confirmed by send-out GAG testing performed on the DBS specimen as a second-tier test. This test is available through Mayo Clinic Laboratories as a laboratory developed test. Outcomes data from the states and countries doing MPS II newborn screening have shown that the incidence of pseudodeficiency is higher than predicted and represents the majority of abnormal newborn screen cases. Several studies have shown that performing second-tier GAG analysis on the DBS reduces the false positive rate as it reliably distinguishes affected patients from those with pseudodeficiency. (Arunkumar et al., 2021)

Clinical Validation	*Location, duration, size, preliminary results of past/ongoing pilot study for clinical validation, positive predictive value, false positive rate, analytical specificity, sensitivity.* Pilot studies have been performed in Illinois and Missouri; see Summary of Population-based Pilot Studies below for details.
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.* Pilot studies from Missouri and Illinois using enzyme activity have been analytically validated for MPS2 newborn screening. These tests are defined as laboratory developed tests. The Missouri pilot study demonstrated a limit of detection of 1.88 µmol/L/h and a linear range of 7.6 to 59.7 µmol/L/h. The Missouri pilot study used two reference ranges: a retest cutoff that required repeat analysis of the specimen and a high-risk cutoff that initiated 2nd-tier testing. The retest cutoff was initially 40 µmol/L/h, but was changed to 25 µmol/L/h. The high-risk cutoff was changed from 35 µmol/L/h to 20 µmol/L/hr. The Illinois pilot study used two references ranges, as well. These ranges were based on percent of daily median enzyme activity. Illinois used a positive cutoff of 10% of the daily median and a borderline cutoff of 13% of the daily median. Detection rates for these pilots are detailed in Summary of Population-based Pilot Studies. Proficiency testing, quality control, and linearity materials have been obtained from the CDC and can be assessed alongside multiplexed screening assays.

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?* Multiple sulfatase deficiency (MSD) could be indirectly identified as a result of the abnormal newborn screen, but only following clinical confirmatory testing. The I2S enzyme activity and GAG analysis being performed on the NBS DBS specimen are insufficient to indicate MSD specifically. Only when an additional sulfatase is assayed though clinical confirmatory testing might this ultra- rare disorder be suspected and subsequently confirmed by identification of bialleic variants in SUMF1. As such, the NBS lab will not have a role in disclosing MSD results. If MSD is identified, it will be only once an infant is already in the care of the metabolic center so there will already be a provider relationship established to provide ongoing care and counseling. MSD has an estimated incidence of 1 in 1.4 million. (Schlotawa, GeneReviews) Using the 2023 Wisconsin birth rate of ~59,000, we would expect to find only one individual with this condition on average over a 20+ year time period.
	• *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?* There are no clinically-available treatments for MSD.

Summary of Population-based Pilot Study(ies)

Location of Prospective Pilot	Two states, Illinois and Missouri, have published their experience with MPS II newborn screening. See Tables 4 and 5 in Supplemental Materials document for metrics. Illinois publication: Burton et al, 2023 Missouri publication: Bilyeu et al, 2020 (Numbers below are updated from the publication and came from a presentation at the 2023 MPS Conference in Minnesota (Klug, 2023))
Number of Newborns Screened	IL: 586,323 MO: 288,892

Number of Positive Results	*Positive by primary test versus 2nd tier test if applicable.* IL: 76 positive referred out (low I2S; no 2nd-tier testing performed by state lab) MO: 65 primary results (low I2S) sent for 2nd tier, 34 positive referred out due to abnormal 2nd tier (abnormal GAGs)
False Positive Rate; False Negative Rate (if known)	*False positive by primary test versus 2nd tier test if applicable.* IL: total false positives (including pseudodeficiency): 62 MO total false positives (including pseudodeficiency): 12 (Note: an additional 16 cases are considered "diagnostically uncertain" due to IDS variants of uncertain significance)
Number of Infants Confirmed with Diagnosis	*How are diagnosis confirmed [clinical, biochemical, molecular]?* IL: 8 confirmed diagnoses, confirmed with enzyme, GAG, and molecular analyses MO: 3 confirmed diagnoses, confirmed with enzyme, GAG, and molecular analyses
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.* No
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* Incorporation of second-tier GAG analysis prior to calling out an abnormal NBS case is expected to greatly decrease referrals, thereby decreasing laboratory and consultant/clinician time and preventing families from experiencing undue stress and concern in cases that will ultimately be deemed false positive with normal GAG analysis Pilot studies in other states and worldwide have demonstrated that female carriers are not identified. Confirmatory testing for MPS II is analagous to that which is recommended for many other metabolic NBS indications and no more invasive (blood draw, urine collection, saliva or buccal collection for genetic testing).
Is test FDA cleared/approved	*Include availability of information, sole source manufacturer, etc.* No. The proposed first-tier assay is an FDA-modified test. The components of the first-tier test are manufactured by Revvity. The send out second-tier testing is a laboratory developed test that is proposed to be performed by Mayo Clinic Laboratories.
List all CLIA or CAP certified labs offering testing in the US	*Link to GeneTests, and Genetic Test Reference if applicable.* https://www.ncbi.nlm.nih.gov/gtr/all/tests/?term=mps2&filter=location:840

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.* Follow-up will follow the process already used for other metabolic NBS call-outs. The NBS lab at WSLH will communicate the positive MPS II screening result to the primary care provider and the metabolic center designated to engage in confirmatory testing and short term follow-up. At the center, the metabolic geneticist will reach out to the primary care provider to provide further consultation and subsequently center staff will reach out to the baby's family to offer an appointment where confirmatory testing will be performed. Confirmatory testing will consist of enzyme analysis of iduronate-2-sulfatase to confirm deficiency along with another sulfatase enzyme to rule out multiple sulfatase deficiency, urine GAGs to confirm elevated dermatan and heparan sulfate, and - following those results - genetic testing of IDS to confirm the diagnosis and rule out pseudodeficiency. Infants confirmed to have MPS II will require multidiscplinary clinical care and routine surveillance, including with ophthalmology, ENT, dental, audiology, orthopedics, pulmonology, cardiology, neurology, neurosurgery, GI, and other specialties on case-by-case bases. Families benefit from supportive care in the form of social work referrals, mental health check-ins, and connection to local and national MPS organizations for fraternal support. Infants should be assessed for the benefit of ERT or other treatments based on disease severity. Individuals on ERT begin their infusions at an infusion center and later transition - when possible and approved by their insurance - to home infusion.
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	Screening will require purchase of additional reagents and sendout second-tier testing for GAGs. This change will require a $6 increase in the NBS card fee.
Confirmatory testing	Confirmatory testing will be billed to insurance following standard healthcare practices.
Treatment	Treatment will be billed to insurance following standard healthcare practices.
Counseling	Counseling and ongoing clinical care will be supported by a combination of the Congenital Disorders Grant funding at designated centers and billing to insurance following standard healthcare practices.
False positives	Care for false positive cases, which will include confirmatory testing and at least one appointment with metabolic consultants for assessment and counseling, will be supported by a combination of the Congenital Disorders Grant funding at designated centers and billing to insurance following standard healthcare practice.
Mechanism of funding	NBS will be funded through the NBS card fee.

Key References to support each criterion. Please list and attach as PDF(s). If mailing, include hard copies.	
#	**Criterion 1**
	Scarpa M et al., "Mucopolysaccharidosis Type II," in GeneReviews®, ed. Margaret P. Adam et al. (Seattle (WA): University of Washington, Seattle, 1993), http://www.ncbi.nlm.nih.gov/books/NBK1274/. Wraith J et al., "Initial Report from the Hunter Outcome Survey," Genetics in Medicine: Official Journal of the American College of Medical Genetics 10, no. 7 (July 2008): 508–16, https://doi.org/10.1097/gim.0b013e31817701e6
	Burton B et al., "Survival in Idursulfase-Treated and Untreated Patients with Mucopolysaccharidosis Type II: Data from the Hunter Outcome Survey (HOS)," Journal of Inherited Metabolic Disease 40, no. 6 (November 2017): 867–74, https://doi.org/10.1007/s10545-017-0075-x.
	Criterion 2
	Puckett Y et al., "Epidemiology of Mucopolysaccharidoses (MPS) in United States: Challenges and Opportunities," Orphanet Journal of Rare Diseases 16, no. 1 (May 29, 2021): 241, https://doi.org/10.1186/s13023-021-01880-8.
	Kemper A et al., Advisory Committee on Heritable Disorders in Newborns and Children [ACHDNC]. (2022). Evidence-Based Review of Newborn Screening for Mucopolysaccharidosis Type II: Final Report. Retrieved from HRSA website. Burton B et al., "Newborn Screening for Mucopolysaccharidosis Type II: Lessons Learned," Molecular Genetics and Metabolism, March 6, 2023, 107557, https://doi.org/10.1016/j.ymgme.2023.107557. Klug T. "NBS: A deeper dive: State experiences, MO, IL & NY." Presentation at the Mucopolysaccharidosis Newborn Screening Meeting of the MPS Center at the University of Minnesota, Minneapolis, MN, April 10-12, 2023
	Criterion 3
	Lampe C et al., "Enzyme Replacement Therapy in Mucopolysaccharidosis II Patients Under 1 Year of Age," JIMD Reports 14 (February 11, 2014): 99–113, https://doi.org/10.1007/8904_2013_289. Al-Hertani W, Pathak RR, Evuarherhe O, et al. Intravenous Idursulfase for the Treatment of Mucopolysaccharidosis Type II: A Systematic Literature Review. Int J Mol Sci. 2024;25(16):8573. Published 2024 Aug 6. doi:10.3390/ijms25168573
	Giugliani R et al., "A Multicenter, Open-Label Study Evaluating Safety and Clinical Outcomes in Children (1.4–7.5 Years) with Hunter Syndrome Receiving Idursulfase Enzyme Replacement Therapy," Genetics in Medicine 16, no. 6 (June 2014): 435–41, https://doi.org/10.1038/gim.2013.162. Muenzer J et al., "Long-Term, Open-Labeled Extension Study of Idursulfase in the Treatment of Hunter Syndrome," Genetics in Medicine: Official Journal of the American College of Medical Genetics 13, no. 2 (February 2011): 95–101, https://doi.org/10.1097/GIM.0b013e3181fea459.
	Criterion 4
	Criterion 5
	Criterion 6
	Arunkumar N et al., "Diagnosis of Mucopolysaccharidoses and Mucolipidosis by Assaying Multiplex Enzymes and Glycosaminoglycans," Diagnostics 11, no. 8 (August 2021): 1347, https://doi.org/10.3390/diagnostics11081347.

	Burton B et al., "Newborn Screening for Mucopolysaccharidosis Type II: Lessons Learned," Molecular Genetics and Metabolism, March 6, 2023, 107557, https://doi.org/10.1016/j.ymgme.2023.107557. Bilyeu H et al., "Validation and Implementation of a Highly Sensitive and Efficient Newborn Screening Assay for Mucopolysaccharidosis Type II," International Journal of Neonatal Screening 6, no. 4 (October 14, 2020): 79, https://doi.org/10.3390/ijns6040079. Klug T. "NBS: A deeper dive: State experiences, MO, IL & NY." Presentation at the Mucopolysaccharidosis Newborn Screening Meeting of the MPS Center at the University of Minnesota, Minneapolis, MN, April 10-12, 2023 Schlotawa L et al. Multiple Sulfatase Deficiency. 2019 Mar 21. In: Adam MP, Feldman J, Mirzaa GM, et al., editors. GeneReviews® [Internet]. Seattle (WA): University of Washington, Seattle; 1993-2025. https://www.ncbi.nlm.nih.gov/books/NBK538937/
	Criterion 7
	Criterion 8
	Criterion 9

Additional Co-sponsoring Organizations

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

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: Emily Singh, MS, CGC
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Submit Nominations to: DHSWICongenitalDisorders@wisconsin.gov
Or mail to:

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