

Dear Commissioner Malcolm,

Following the passage of the Vivian Act, the Advisory Committee on Heritable and Congenital Disorders has been reviewing congenital cytomegalovirus (cCMV) as a candidate condition for addition to the Minnesota newborn screening panel. A scientific/technical work group was assembled consisting of physicians with specific expertise and who would be directly impacted by the addition of this condition, including primary care providers, audiologists, laboratorians, and infectious disease specialists. This work group met three times to complete the Condition Readiness Criteria document (enclosed). This document was previously developed and adopted by this committee to establish a mechanism for the evaluation of disorders being considered for addition to the Minnesota panel. In October, we listened to presentations from a parent of a child with cCMV, Dr. Mark Schleiss (local infectious disease specialist), and Dr. Sheila Dollard (laboratory director for viral diseases at the CDC). During the Committee's January 11th, 2022 meeting, we heard from the Newborn Hearing Screening Advisory Committee chair, Newborn Screening unit supervisors about MDH's readiness and needs, and then used the Condition Readiness Criteria document and matrix (enclosed) to discuss the readiness of cCMV for addition to Minnesota's newborn screening panel.

A few key elements of the discussion are highlighted below:

- Advisors stressed the importance of education about the advantages and limitations of screening, including the specific need to educate primary care providers on how to provide uniform follow-up using the best standards of care.
- Advisors wanted to ensure that the \$43 fee increase will not only cover the cost to implement but would also sustain the screening, follow-up, and education efforts as well.
- Some advisors expressed concern over the 75% sensitivity rate as well as the high number of cases that are asymptomatic and will require ongoing surveillance. Other advisors felt that 75% is a lot better than 0% and that the testing would improve a pediatrician's ability to monitor patients.
- There was a request for an update on the availability of vaccines and how that would impact their decision and screening. A representative from the National CMV Foundation shared that Moderna is the furthest along, but that she doesn't expect mass vaccination to be available within the next few years.
- Although advisors knew there are only modest benefits obtained by administration of Valganciclovir (antiviral medication) for symptomatic newborns, focus was on the advantages of the interventions for hearing loss.

Following discussion completion, the Committee elected to proceed with a vote on the following:

Do you recommend that the Commissioner of Health add congenital cytomegalovirus (cCMV) to the Minnesota Newborn Screening panel?

No, it is not ready for addition at this time = 3

Yes, I recommend its addition = 16

With a majority vote and pending your approval, the Committee has recommended the addition of cCMV to Minnesota's newborn screening panel.

Thank you for your consideration.

/s/

Sincerely,
Jan Larson, J.D.
Chairperson