Congenital Cytomegalovirus (cCMV) Screening Protocol

Guidance for Oregon Licensed Hospitals and Birthing Centers

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Purpose

To provide a standard protocol for expanded targeted congenital cytomegalovirus (cCMV) screening at licensed hospitals and birthing centers to support the health and wellbeing of newborns in Oregon.

Congenital Cytomegalovirus (cCMV) Overview

Cytomegalovirus (CMV) is a common infection in newborns with an estimated 1 in 200 babies infected at birth. CMV spreads easily, especially in settings with children such as childcare, and often has no symptoms. Babies born with CMV and diagnosed within 21 days of age are considered to have congenital cytomegalovirus (cCMV) which can cause long-term health impacts. Of newborns infected with cCMV, around 10% are symptomatic at birth while around 90% are asymptomatic. While most babies with cCMV will grow and develop typically, some may experience serious and permanent health issues, including problems with their brain, eyes, and inner ears that can be present at birth or develop later in childhood. In rare cases, cCMV may cause death.

Hearing loss is among the most frequent long-term impacts of cCMV. It is the most common non-hereditary cause of sensorineural hearing loss in children, accounting for 20% of diagnoses at birth and 25% by age four. Hearing loss from cCMV can be progressive or late-onset, making ongoing monitoring by a child's primary care provider and audiologist essential to support communication, language acquisition, and developmental outcomes.

Screening newborns for cCMV risk factors and clinical signs within 21 days of age helps with early detection, access to care, and enrollment in early intervention services to support long-term health outcomes for these infants. This timing helps determine whether the infection was acquired congenitally (present at birth) or postnatally (acquired after birth). Postnatal infections are generally not associated with serious health concerns, whereas congenital infections can impact long-term development.

Following a positive test result from cCMV screening, newborns should complete additional diagnostic lab-based testing and imaging as well as further evaluation by various health care professionals for possible treatment and ongoing monitoring.

Congenital Cytomegalovirus (cCMV) Screening Rules

Oregon licensed hospitals and birthing centers must screen newborns for cCMV pursuant to Oregon Administrative Rules 333-020-0125 through 333-020-0187. The hospital or birthing center must conduct cCMV screening based on this protocol, which includes:

- assessing each newborn for known risk factors and clinical signs of cCMV, and
- as necessary, based on the presence of one or more of the risk factors or clinical signs, conduct CMV testing.

The screening must be completed prior to discharge or within 14 days of age, whichever occurs earlier, unless parents or guardians refuse in writing. If the hospital or birthing center is part of a licensed Health Maintenance Organization facility, screening must occur within 14 days of age.

cCMV Screening and Testing Overview

Hospitals and birthing center must assess a newborn for the following risk factors and clinical signs:

- Birth parent diagnosed with primary CMV infection during pregnancy
- Did not pass the newborn hearing screening (one or both ears)
- Symmetric small for gestational age: birth weight <10th percentile
- Microcephaly: head circumference <3rd percentile based on gestational age, recommend remeasuring 24 hours after delivery
- Unexplained petechial rash or blueberry muffin rash
- Unexplained abnormal red reflex, retinitis, or cataracts
- Unexplained fetal hydrops or ascites, abdominal calcifications, or thickened bowel on prenatal ultrasound
- Unexplained or persistent hepatomegaly, splenomegaly, or elevated liver function tests (AST or ALT >100 U/L or direct bilirubin >1.0 mg/dL)

- Unexplained abnormal brain imaging including ventriculomegaly, intracerebral calcifications, white matter changes, periventricular echogenicity, cortical or cerebellar malformations, or migration abnormalities
- Unexplained thrombocytopenia (platelets <100,000/mm3)

For newborns transferred from one facility to another or admitted to the neonatal intensive care unit (NICU), please see the section on Special Populations.

If any of the risk factors or clinical signs above are present, the hospital or birthing center must conduct CMV testing using Polymerase Chain Reaction (PCR) testing of urine or saliva specimens, with urine being the preferred specimen due to its higher diagnostic reliability. All specimens for CMV testing shall be collected prior to discharge. If saliva PCR testing is used and returns a positive result, a confirmatory urine PCR test should be performed within 21 days of age to confirm diagnosis.

Hospitals and birthing centers are encouraged to inform parents or guardians at the time of discharge about the status of the newborn's CMV testing (e.g., results pending, test not completed). If results are not yet available at discharge, facilities are encouraged to provide information on recommended follow-up steps should the test return positive.

Parents or guardians of the newborn must be informed of positive PCR test results through direct personal communication as specified in OAR 333-020-0175, prior to discharge. Additionally, the newborn's primary care provider (PCP) on record must be informed of a positive CMV test result through direct personal communication to PCP or their designated staff as specified in OAR 333-020-0175. All communications must be documented in the newborn's medical record.

Following receipt of results, hospital and birthing center staff are encouraged to:

- document all CMV test results in the newborn's medical record,
- inform PCP that confirmatory urine PCR testing is needed following a positive saliva PCR test to confirm diagnosis,
- inform PCP of inconclusive CMV test results through direct personal communication to PCP or their designated staff and document all interactions in the newborn's medical record, and

- add the diagnosis “Congenital CMV Infection” (ICD-10 code is P35.1) to the problem list in the newborn’s medical record if positive results are received prior to the newborn’s discharge.

Expanded Targeted Congenital Cytomegalovirus (cCMV) Screening Process Map

To view the Expanded Targeted Congenital Cytomegalovirus (cCMV) Screening Process Map, please refer to the attachment at the end of this document or visit Oregon.gov/CMV.

Additional Health Professional Recommendations

Hospital and Birthing Center Recommendations

Hospital and birthing centers are encouraged to:

- Establish protocols for data collection and recording of CMV testing results.
- Ensure adequate training for all testing personnel to conduct CMV testing effectively using recommended methods and procedures and ensure the maintenance of comprehensive training records.
- Develop facility processes for placing the order for CMV testing following a newborn meeting the screening criteria for cCMV. Facilities may consider adopting a standing order policy to reduce delays and improve compliance.

Primary Care Provider Recommendations

For detailed recommendations on cCMV diagnostic testing and care, review OHA’s Congenital Cytomegalovirus (cCMV) Diagnostic Testing and Care Protocol listed on Oregon.gov/CMV. For brief overview, see the information below.

Following receipt of positive urine CMV test results within 21 days of age, the newborn’s primary care provider is encouraged to complete the following to evaluate for further evidence and extent of cCMV disease as soon as possible:

- Complete Blood Count (CBC) with differential
- Complete Metabolic Panel (CMP)
- Head Ultrasound (HUS)

- Physical exam with height, weight, and head circumference measurements
- Referral to audiology for diagnostic audiology evaluation
- Referral to Early Intervention services

Referrals

The primary care provider may consider the following referrals:

- Pediatric Infectious Disease
    - When possible, it is preferred that results from CBC with differential, CMP, HUS (or other brain imaging), physical exam, and diagnostic audiology evaluation be available prior to being seen by Pediatric Infectious Disease specialist for clinical management.
- Pediatric Otolaryngology (ENT) if hearing loss is identified by audiology
- Pediatric Neurology if abnormal imaging, microcephaly, hearing loss, or abnormal neurological exam
- Pediatric Ophthalmology or Pediatric Optometry
    - When possible, indicate any abnormal eye findings, hearing loss, or abnormal neurological exam on referral.

Ongoing Monitoring

PCPs should consider frequent monitoring of child's growth and development due to progressive symptoms. Children with cCMV may have difficulties with hearing, vision, communication, growth, cognition, learning, and motor coordination.

All children with cCMV are recommended to be monitored by an audiologist, even if they pass the newborn hearing screening, because they are at risk of progressive hearing loss. For children with cCMV, families should plan for audiology visits every 3 months until 1 year of age, then every 6 months until 3 years of age, then yearly until 6 years of age. More frequent evaluations may be needed based on audiologist recommendation.

Reporting Requirements

cCMV is not a reportable condition in Oregon.

Special Populations

Hospital Transfers and Neonatal Intensive Care Unit (NICU) Patients

If a newborn is transferred from one facility to another prior to cCMV screening occurring, then it is the responsibility of the receiving facility to ensure that cCMV screening is completed. If the newborn was screened for cCMV prior to transfer, the transferring facility must provide the status of cCMV screening to the receiving facility upon transfer.

For newborns where a hearing screening cannot be accomplished prior to 14 days of age due to gestational age or other medical reasons, the newborn shall be screened for the other risk factors and clinical signs, as listed in this protocol, to determine if CMV testing is recommended.

For newborns that have one or more risk factors and clinical signs of cCMV and CMV testing cannot be accomplished prior to 14 days of age for medical reasons, testing for CMV is left to the discretion of the medical practitioner caring for the newborn and should be considered up to 21 days of age.

If a newborn tests positive for CMV and remains in care, the hospital is encouraged to order additional diagnostic testing and follow care recommendations outlined in the Congenital Cytomegalovirus (cCMV) Diagnostic Testing and Care Protocol.

Multiple Births

In cases where a pregnant individual gives birth to multiple infants (e.g., twins, triplets), it is possible for one or more infants to be infected with CMV, while others may not be. If any one infant in a multiple birth presents with risk factors or clinical signs that meet the criteria for CMV testing outlined in this protocol, then all other infants from the same pregnancy must also be tested, regardless of whether they individually meet the screening criteria.

Testing Refusal

Parents or guardians of a newborn may refuse cCMV screening. Hospital and birthing center staff must obtain a signed refusal form at the time of the screening, and it

should be retained in the child's medical record for the period of time defined by the hospital or birthing center policy.

Additional Resources

To find more information and resources about Cytomegalovirus (CMV) prevention, testing, and care in Oregon, visit Oregon.gov/CMV.

American Academy of Audiology on Congenital Cytomegalovirus: https://www.audiology.org/consumers-and-patients/hearing-and-balance/congenital-cytomegalovirus-cmv-infection/

American Academy of Pediatrics on Congenital Cytomegalovirus: https://www.aap.org/en/patient-care/congenital-cytomegalovirus-ccmv

American College of Obstetricians and Gynecologists on Cytomegalovirus in Pregnancy: https://www.acog.org/clinical-information/physician-faqs/cytomegalovirus-in-pregnancy

Center for Disease Control (CDC) on Congenital Cytomegalovirus in Newborns: https://www.cdc.gov/cytomegalovirus/congenital-infection/index.html

National CMV Foundation: https://www.nationalcmv.org/

Acknowledgements and Contributors

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You can get this document in other languages, large print, braille or a format you prefer free of charge. Contact the Early Hearing Detection and Intervention (EHDI) Program at Oregon.EHDI@odhsoha.oregon.gov or 888-917-4327. We accept all relay calls.

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OREGON HEALTH AUTHORITY

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Oregon.gov/CMV

Expanded Targeted Congenital Cytomegalovirus (cCMV) Screening Process Map

Hospital and Birthing Center Responsibilities

OREGON HEALTH AUTHORITY

Oregon.gov/CMV

Screen

All newborns must be screened for the following risk factors and clinical signs associated with congenital cytomegalovirus (cCMV) within 14 days of age and prior to discharge, whichever occurs earlier:

- Birth parent diagnosed with primary CMV infection during pregnancy
- Did not pass the newborn hearing screening (one or both ears)
- Symmetric small for gestational age: birth weight <10th percentile
- Microcephaly: head circumference <3rd percentile based on gestational age, recommend remeasuring 24 hours after delivery
- Unexplained petechial rash or blueberry muffin rash
- Unexplained abnormal red reflex, retinitis, or cataracts
- Unexplained fetal hydrops or ascites, abdominal calcifications, or thickened bowel on prenatal ultrasound
- Unexplained or persistent hepatomegaly, splenomegaly, or elevated liver function tests (AST or ALT >100 U/L or direct bilirubin >1.0 mg/dL)
- Unexplained abnormal brain imaging including ventriculomegaly, intracerebral calcifications, white matter changes, periventricular echogenicity, cortical or cerebellar malformations, or migration abnormalities
- Unexplained thrombocytopenia (platelets <100,000/mm3)

Step 1

Test

Any newborns presenting with one or more of the risk factors and clinical signs must receive CMV testing within 14 days of age and prior to discharge, whichever occurs earlier, unless the parents or guardians refuse in writing.

Collect urine for CMV PCR test. Urine is the preferred specimen for testing due to its higher diagnostic reliability. If unable to collect urine, saliva CMV PCR test may be used. If saliva is used, wait at least 1 hour after consumption of breastmilk to avoid false positives. Saliva CMV PCR tests that return a positive result should follow up with urine CMV PCR testing within 21 days of age to confirm diagnosis.

Step 2

Inform

It is encouraged to inform parents or guardians of newborn at discharge of the status of CMV testing (e.g. pending results, not completed, etc.). If results have not been received prior to discharge, it is encouraged to include follow up steps in the event of a positive results.

Step 3

Document and Alert

Requirements upon receipt of positive PCR test results:

- Inform the newborn's primary care provider (PCP) on record of any positive CMV test results through direct personal communication to PCP or their designated staff. Document all interactions in the newborn's medical record.
- Inform the newborn's parent or guardians of newborn of any positive CMV test result, through direct personal communication if possible. Document all interactions in the newborn's medical record.

Recommendations upon receipt of results:

- All results (e.g. positive, negative, contaminated, etc.) should be included in the newborn's medical record.
- Inform PCP that confirmatory urine PCR testing is needed following a positive saliva PCR test to confirm diagnosis.
- Inform PCP of inconclusive CMV test results through direct personal communication to PCP or their designated staff. Document all interactions in the newborn's medical record.
- If a positive PCR test result is received prior to newborn's discharge, add the diagnosis "Congenital CMV Infection" (ICD-10 code is P35.1) to the problem list in the newborn's medical record.

Step 4