Universal Congenital Cytomegalovirus (cCMV) Newborn Screening

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Connecticut Children's

What is a Clinical Pathway?

An evidence-based guideline that decreases unnecessary variation and helps promote safe, effective, and consistent patient care.

Objectives of Pathway

- Create an easily assessable standardized protocol that aligns with current expert guidance on the testing and work up for cCMV in newborns

- Collaborate with the Connecticut newborn screening program to ensure all infants are appropriately screened for cCMV and receive standard-of-care follow up

Why is Pathway Necessary?

- As of July 1, 2025 our state is now conducting universal congenital Cytomegalovirus (cCMV) screening on all infants
- This is a shift in how our state tests for congenital CMV, which may create confusion and questions
- A clinical pathway is needed to help standardize guidelines for the follow up of testing results and next steps
- Awareness around congenital CMV is increasing and provider knowledge is important

Setting

- Where will this pathway be used?
    - Well baby nursery
    - NICU
    - Outpatient primary care pediatric office

Background

- cCMV occurs in 0.4-2% of live births and is the leading cause of congenital infections worldwide[1,2]
    - Connecticut is estimated to diagnosis up to 175 cases/year within our state if all infants are screened at birth

- cCMV is the leading cause of non-genetic sensorineural hearing loss (SNHL), causing 20% of all hearing loss present at birth and increasing to 25% by age 4 years [2,3]

cCMV Symptoms

- Premature birth
- Sensorineural hearing loss (neonatal or delayed onset)
- Small size or low birth weight
- Jaundice
- Enlarged liver or spleen
- Microcephaly
- Feeding issues
- Hypotonia
- Abnormal reflexes
- Rash (petechiae)
- Seizures
- Eye abnormalities

Background

- Early detection of cCMV infection and treatment with oral valganciclovir in those who are moderate to severely symptomatic can reduce the risk of development or progression of sensorineural hearing loss and improves developmental outcomes[4,5]

- Recently, there is a new recommendation from the AAP for treatment of clinically inapparent infants with only hearing loss to improve hearing outcomes[6]

Background

- In 2016, Connecticut implemented House Bill 5525, An Act Concerning Cytomegalovirus
  - Mandated targeted cCMV screening
  - Targeted Screening = testing an infant for cCMV with a saliva or urine PCR test if they refer (do not pass) their newborn hearing screen

- Because not all infants are symptomatic at birth (10%), but can go on to develop hearing loss, targeted screening will not detect all infants who are congenitally infected
  - Fowler et al reported that 43% of infants who developed postnatal hearing loss went unidentified in their 2007-2012 multicenter study[3]

Background

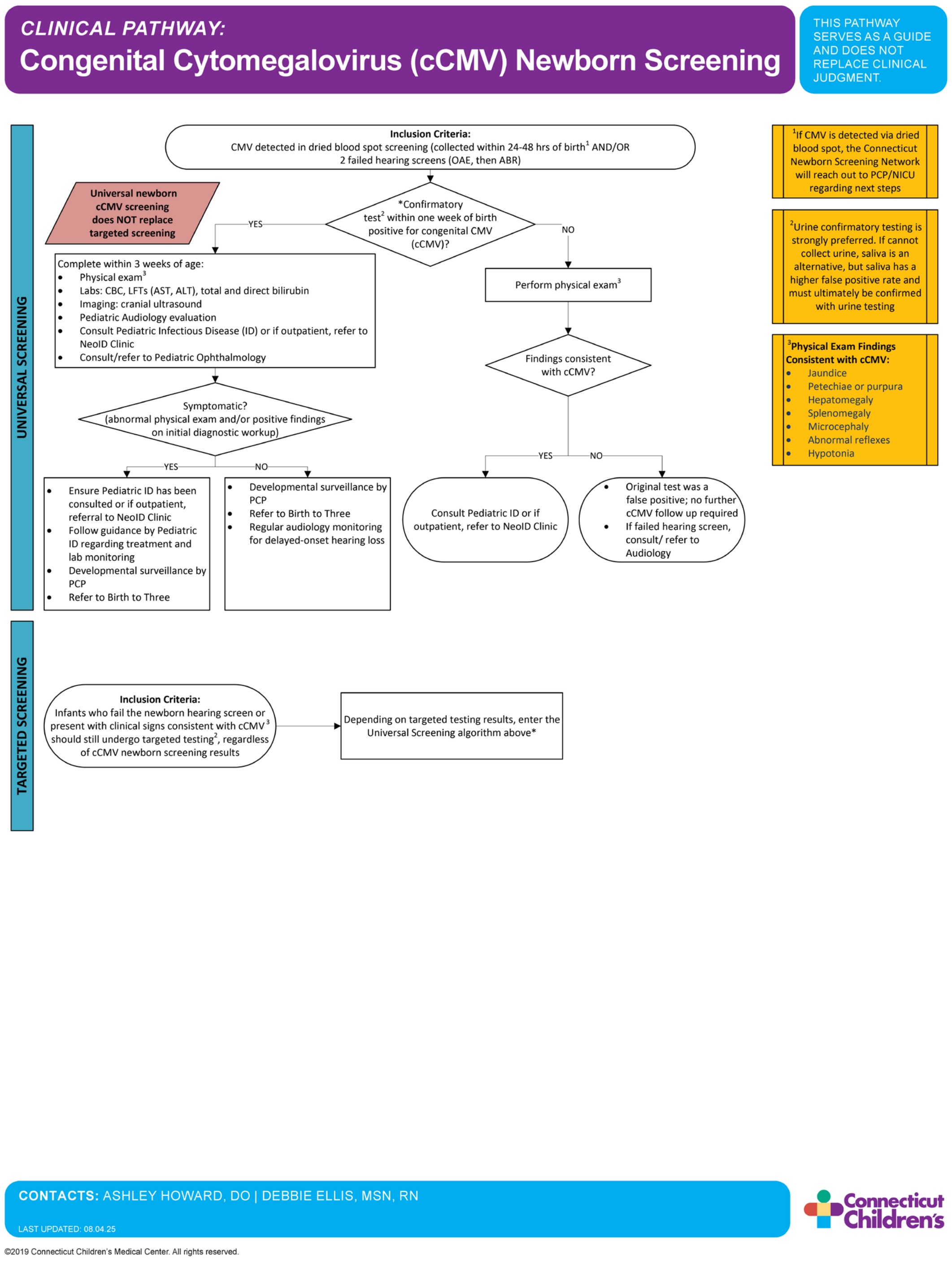
- Connecticut is now the second state to implement a law mandating universal screening (Started 7/1/2025)
  - What does this look like?
  - A blood spot for PCR testing is collected before discharge from the birth hospital and sent to the state laboratory

- How is this different from targeted screening?
  - Infants will no longer only be tested if they refer on their hearing screen

- *Universal screening does not take place of targeted screening*
  - If a hearing screen is not passed, do not wait for the blood spot results
  - Collect a urine PCR (preferred) over a saliva PCR for CMV

This is the cCMV Clinical Pathway.

We will be reviewing each component in the following slides.



CLINICAL PATHWAY:

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UNIVERSAL SCREENING

Inclusion Criteria:
CMV detected in dried blood spot screening (collected within 24-48 hrs of birth[1] AND/OR 2 failed hearing screens (OAE, then ABR)

Universal newborn cCMV screening does NOT replace targeted screening

*Confirmatory test[2] within one week of birth positive for congenital CMV (cCMV)?

YES

Complete within 3 weeks of age:
- Physical exam[3]
- Labs: CBC, LFTs (AST, ALT), total and direct bilirubin
- Imaging: cranial ultrasound
- Pediatric Audiology evaluation
- Consult Pediatric Infectious Disease (ID) or if outpatient, refer to NeoID Clinic
- Consult/refer to Pediatric Ophthalmology

Symptomatic?
(abnormal physical exam and/or positive findings on initial diagnostic workup)

YES
- Ensure Pediatric ID has been consulted or if outpatient, referral to NeoID Clinic
- Follow guidance by Pediatric ID regarding treatment and lab monitoring
- Developmental surveillance by PCP
- Refer to Birth to Three

NO
- Developmental surveillance by PCP
- Refer to Birth to Three
- Regular audiology monitoring for delayed-onset hearing loss

NO

Perform physical exam[3]

Findings consistent with cCMV?

YES

Consult Pediatric ID or if outpatient, refer to NeoID Clinic

NO
- Original test was a false positive; no further cCMV follow up required
- If failed hearing screen, consult/ refer to Audiology

TARGETED SCREENING

Inclusion Criteria:
Infants who fail the newborn hearing screen or present with clinical signs consistent with cCMV[3] should still undergo targeted testing[2], regardless of cCMV newborn screening results

Depending on targeted testing results, enter the Universal Screening algorithm above*

[1] If CMV is detected via dried blood spot, the Connecticut Newborn Screening Network will reach out to PCP/NICU regarding next steps

[2] Urine confirmatory testing is strongly preferred. If cannot collect urine, saliva is an alternative, but saliva has a higher false positive rate and must ultimately be confirmed with urine testing

[3] **Physical Exam Findings Consistent with cCMV:**
- Jaundice
- Petechiae or purpura
- Hepatomegaly
- Splenomegaly
- Microcephaly
- Abnormal reflexes
- Hypotonia

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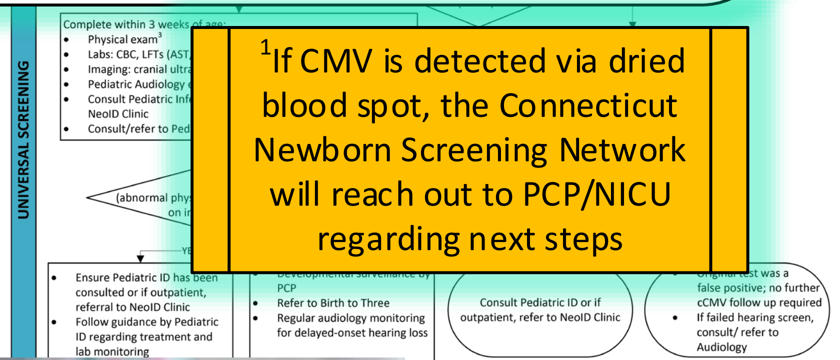
- As part of the new Universal Screening process, all patients will be tested for cCMV at birth via dried spot screening
- A patient qualifies for this clinical pathway if the cCMV spot test is positive

AND/OR

- The newborn has 2 failed hearing screens (OAE and ABR)
- If the newborn test is positive, the Connecticut Newborn Screening Network will reach out to the primary care provider or NICU provider regarding next steps



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- PCP
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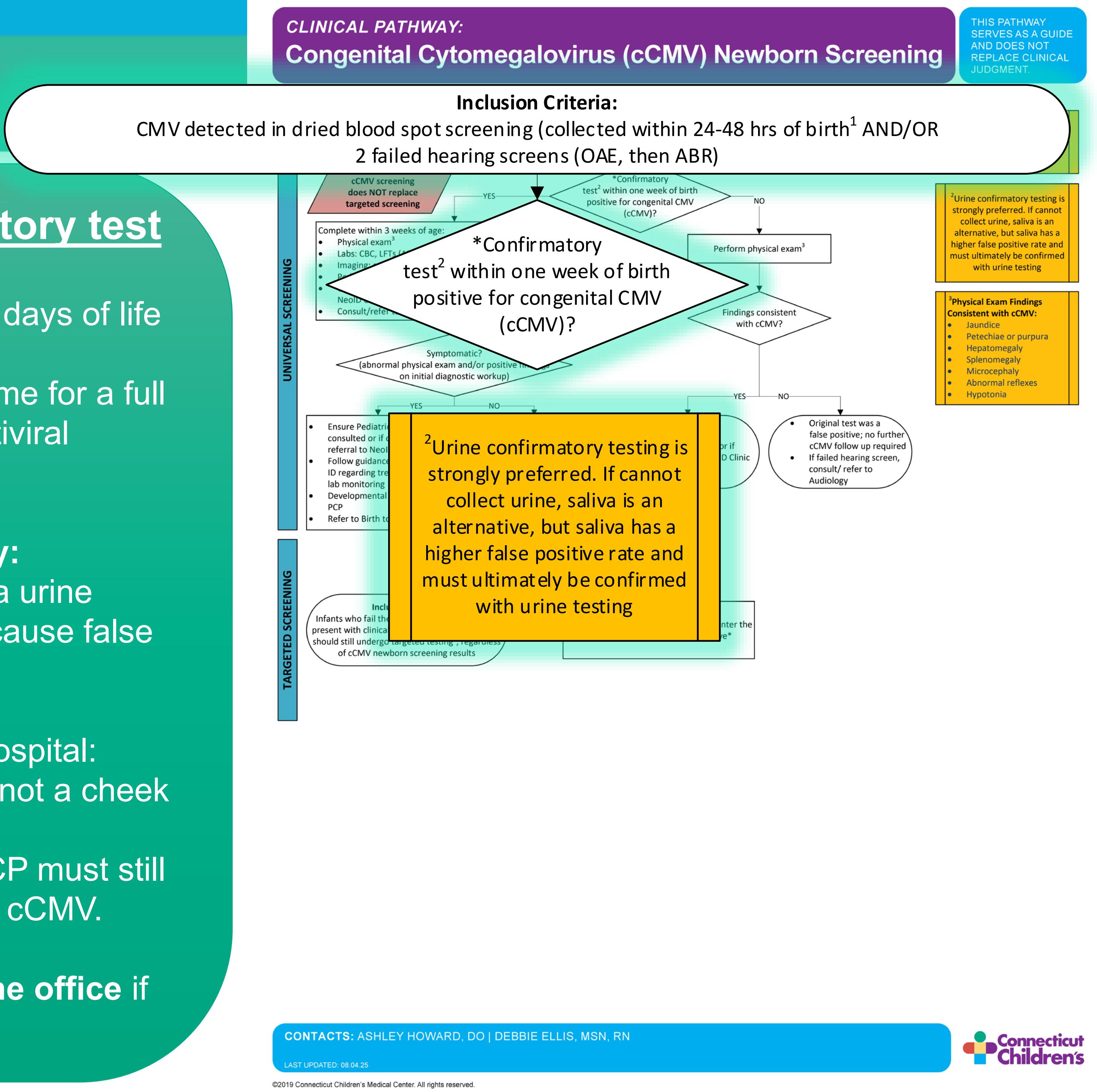
The next step is to obtain a <u>urine confirmatory test</u>

- A positive urine CMV PCR result within the first 21 days of life is diagnostic for cCMV
    - **Ideal timing: within 7 days of life** to allow time for a full evaluation and decision-making regarding antiviral therapy.

- **Saliva tests (cheek swabs) are not confirmatory:**
    - A positive saliva test must be confirmed with a urine PCR, as maternal CMV from breastmilk can cause false positives in saliva.

- If a baby fails the newborn hearing screen in the hospital:
    - The hospital should order a urine CMV PCR, not a cheek swab.
    - If a cheek swab is mistakenly ordered, the PCP must still order a urine CMV PCR to confirm or rule out cCMV.

- Please **assist families with urine collection in the office** if needed.



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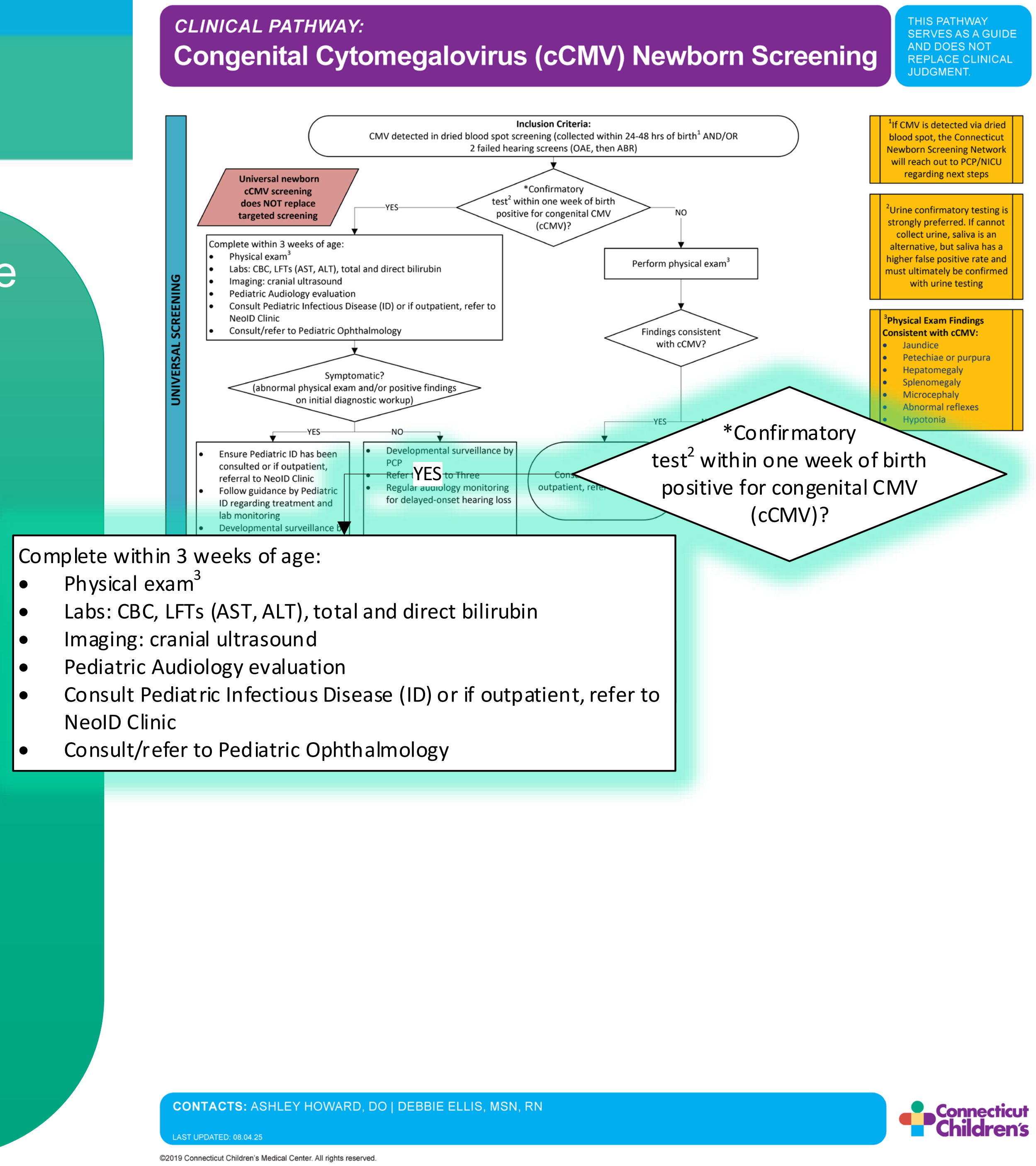
If confirmatory urine CMV test is positive, please complete the following within 21 days of life:

- ☐ Physical examination by PCP
- ☐ CBC
- ☐ Liver Function Tests: AST and ALT
- ☐ Bilirubin
- ☐ Head Ultrasound
- ☐ Audiology Evaluation
- ☐ Ophthalmology Referral
- ☐ Infectious Disease Referral



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Symptomatic?
(abnormal physical exam and/or positive findings on initial diagnostic workup)

YES

- Ensure Pediatric ID has been consulted or if outpatient, referral to NeoID Clinic
- Follow guidance by Pediatric ID regarding treatment and lab monitoring
- Developmental surveillance b

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- Developmental surveillance by PCP
- Refer to Three
- Regular audiology monitoring for delayed-onset hearing loss

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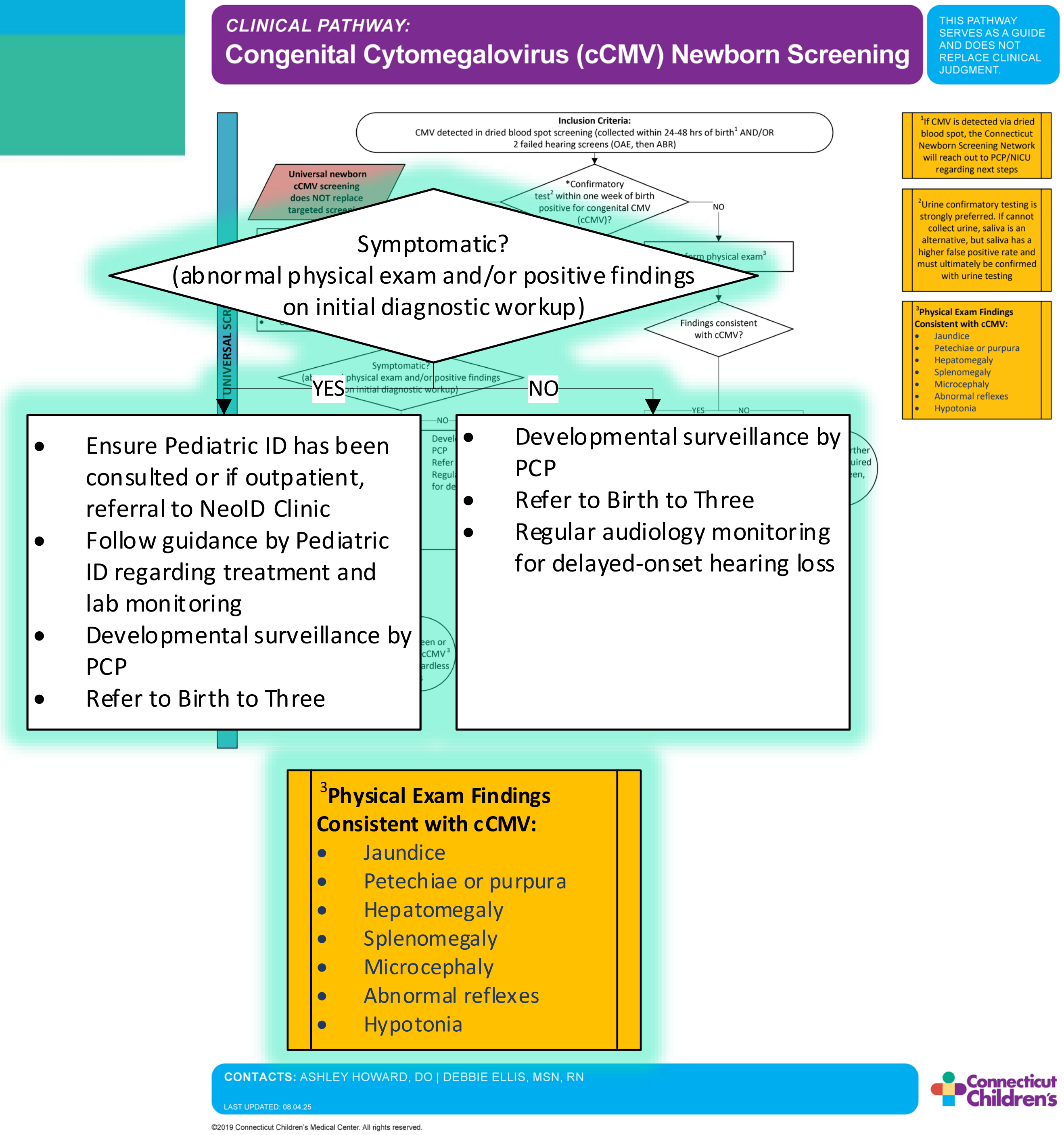
Instructions for next steps are outlined for both symptomatic and asymptomatic patients with positive confirmatory testing



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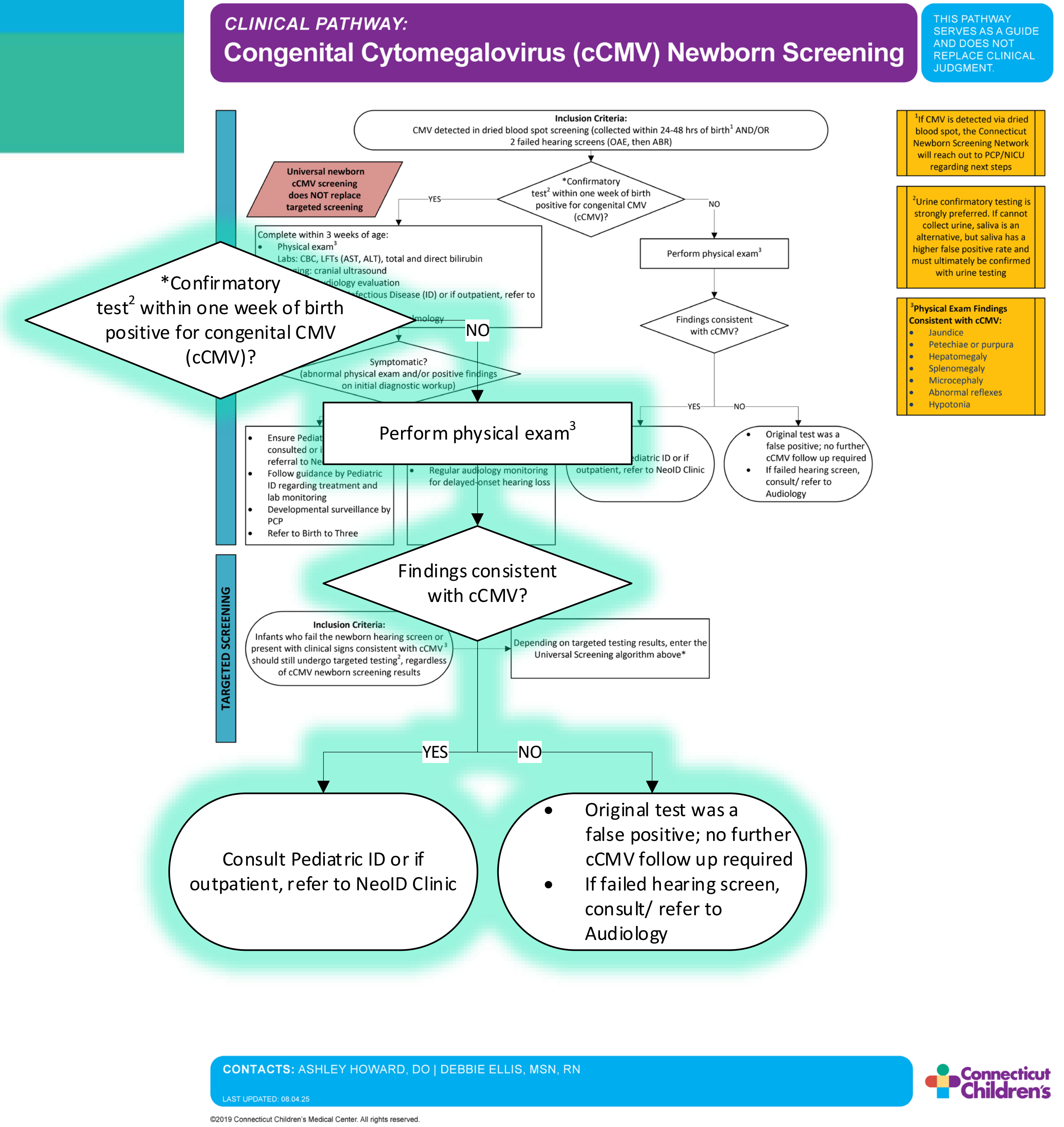
- For patients with *negative* confirmatory testing but physical exam findings consistent with cCMV infection, please consult with ID either by inpatient consult or referral to NeoID Clinic

- For those without any physical exam finding, no further cCMV follow up is necessary
    - However, if infant failed hearing screen, please refer to Audiology



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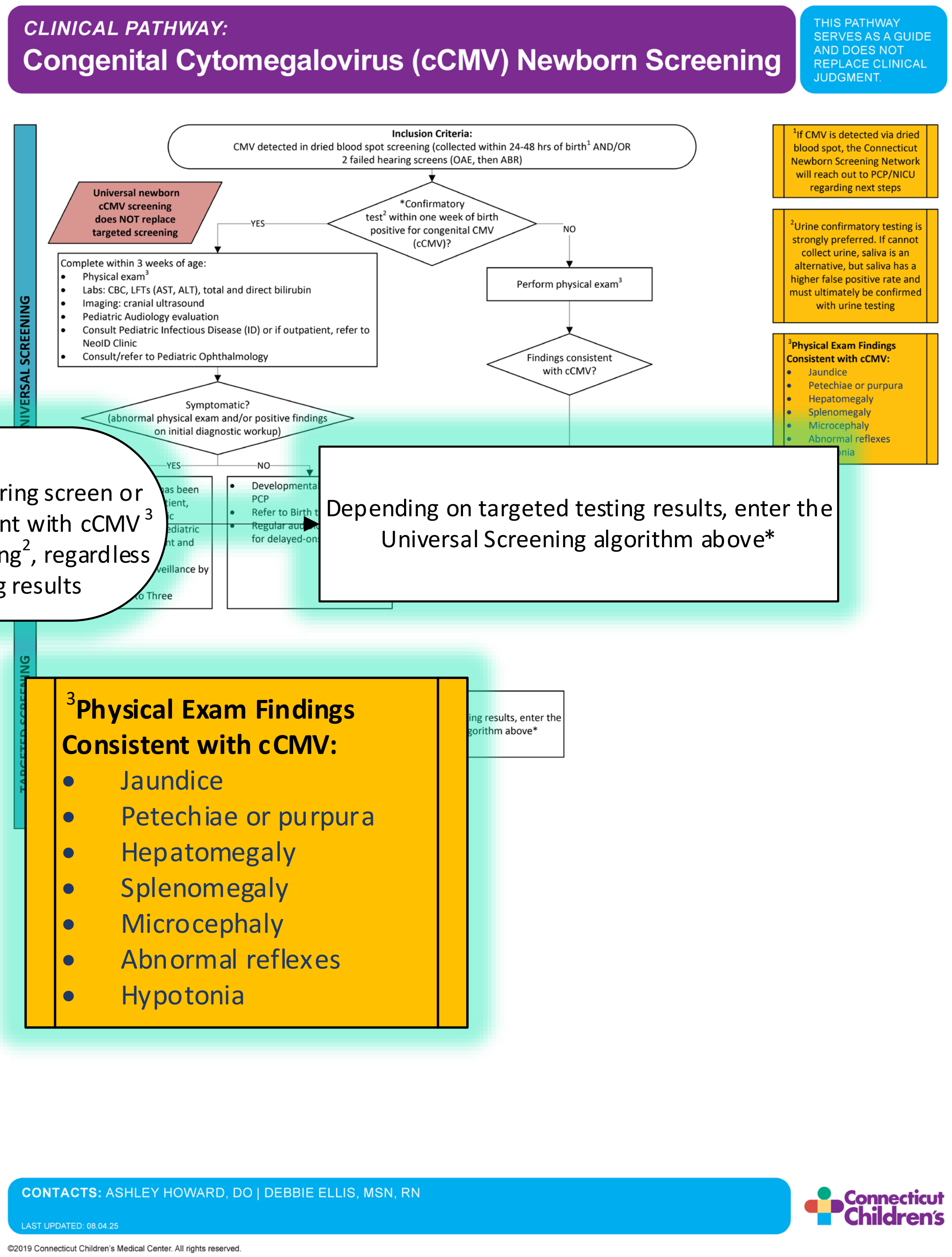
Targeted Screening:

Targeted screening is still appropriate any time a newborn fails the hearing screen or has clinical signs consistent with cCMV even if the cCMV newborn screen results were negative



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Family Education

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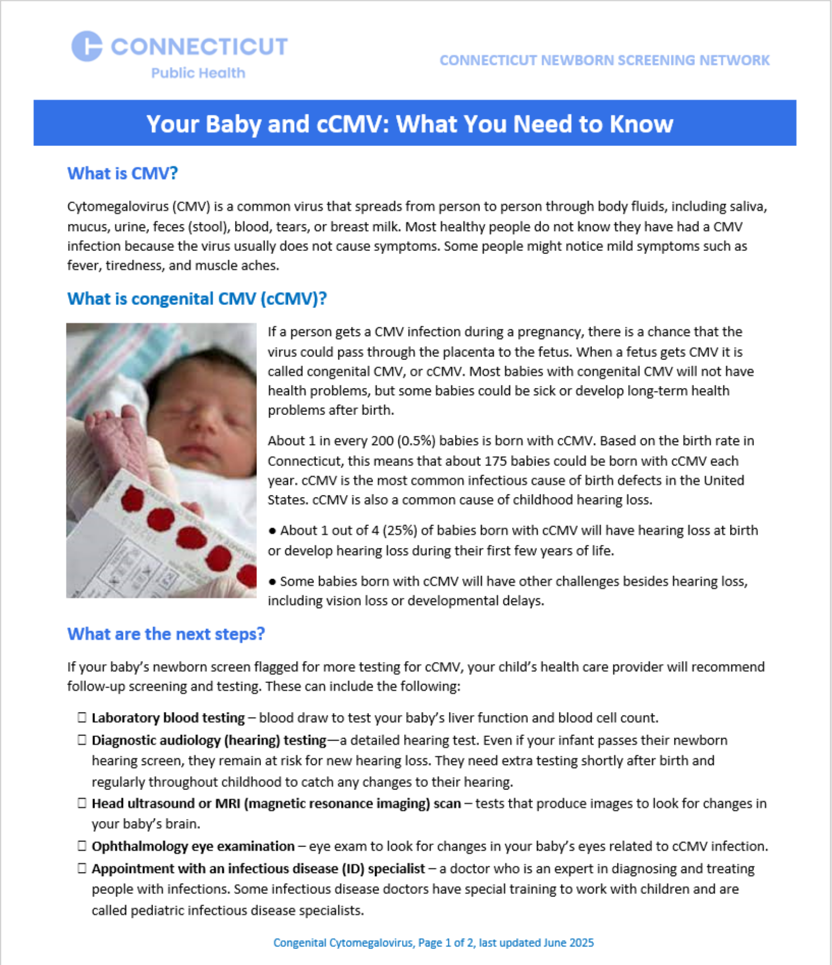
- This info sheet was developed in partnership with families and the national cCMV foundation
- Will be faxed to your office after a positive urine result and offered to families at audiology and ID appointments
- The QR code will scan to a 24 page digital document that will provide comprehensive information about what to expect at appointments, frequently used terms, and resources specific to CT.



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Your Baby and cCMV: What You Need to Know

What is CMV?

Cytomegalovirus (CMV) is a common virus that spreads from person to person through body fluids, including saliva, mucus, urine, feces (stool), blood, tears, or breast milk. Most healthy people do not know they have had a CMV infection because the virus usually does not cause symptoms. Some people might notice mild symptoms such as fever, tiredness, and muscle aches.

What is congenital CMV (cCMV)?

If a person gets a CMV infection during a pregnancy, there is a chance that the virus could pass through the placenta to the fetus. When a fetus gets CMV it is called congenital CMV, or cCMV. Most babies with congenital CMV will not have health problems, but some babies could be sick or develop long-term health problems after birth.

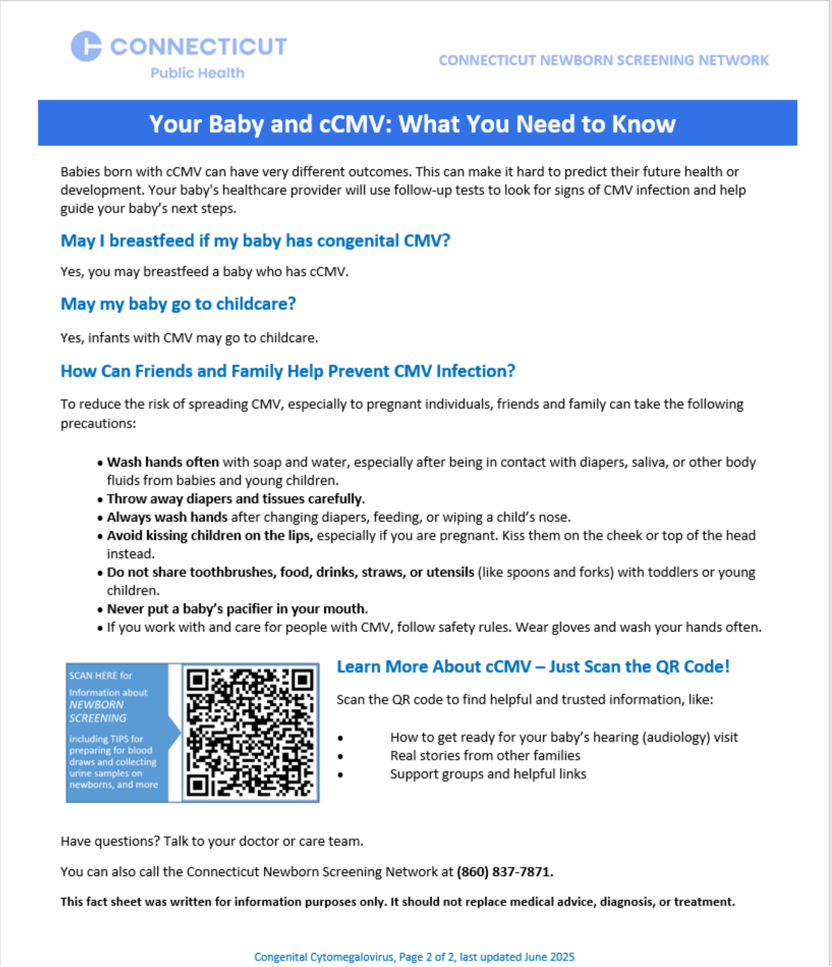
About 1 in every 200 (0.5%) babies is born with cCMV. Based on the birth rate in Connecticut, this means that about 175 babies could be born with cCMV each year. cCMV is the most common infectious cause of birth defects in the United States. cCMV is also a common cause of childhood hearing loss.

- About 1 out of 4 (25%) of babies born with cCMV will have hearing loss at birth or develop hearing loss during their first few years of life.
- Some babies born with cCMV will have other challenges besides hearing loss, including vision loss or developmental delays.

What are the next steps?

If your baby's newborn screen flagged for more testing for cCMV, your child's health care provider will recommend follow-up screening and testing. These can include the following:

☐ **Laboratory blood testing** – blood draw to test your baby's liver function and blood cell count.
☐ **Diagnostic audiology (hearing) testing**—a detailed hearing test. Even if your infant passes their newborn hearing screen, they remain at risk for new hearing loss. They need extra testing shortly after birth and regularly throughout childhood to catch any changes to their hearing.
☐ **Head ultrasound or MRI (magnetic resonance imaging) scan** – tests that produce images to look for changes in your baby's brain.
☐ **Ophthalmology eye examination** – eye exam to look for changes in your baby's eyes related to cCMV infection.
☐ **Appointment with an infectious disease (ID) specialist** – a doctor who is an expert in diagnosing and treating people with infections. Some infectious disease doctors have special training to work with children and are called pediatric infectious disease specialists.



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Your Baby and cCMV: What You Need to Know

Babies born with cCMV can have very different outcomes. This can make it hard to predict their future health or development. Your baby's healthcare provider will use follow-up tests to look for signs of CMV infection and help guide your baby's next steps.

May I breastfeed if my baby has congenital CMV?

Yes, you may breastfeed a baby who has cCMV.

May my baby go to childcare?

Yes, infants with CMV may go to childcare.

How Can Friends and Family Help Prevent CMV Infection?

To reduce the risk of spreading CMV, especially to pregnant individuals, friends and family can take the following precautions:

- **Wash hands often** with soap and water, especially after being in contact with diapers, saliva, or other body fluids from babies and young children.
- **Throw away diapers and tissues carefully.**
- **Always wash hands** after changing diapers, feeding, or wiping a child's nose.
- **Avoid kissing children on the lips,** especially if you are pregnant. Kiss them on the cheek or top of the head instead.
- **Do not share toothbrushes, food, drinks, straws, or utensils** (like spoons and forks) with toddlers or young children.
- **Never put a baby's pacifier in your mouth.**
- If you work with and care for people with CMV, follow safety rules. Wear gloves and wash your hands often.

SCAN HERE for
Information about
NEWBORN SCREENING
including TIPS for preparing for blood draws and collecting urine samples on newborns, and more

Learn More About cCMV – Just Scan the QR Code!

Scan the QR code to find helpful and trusted information, like:

- How to get ready for your baby's hearing (audiology) visit
- Real stories from other families
- Support groups and helpful links

Have questions? Talk to your doctor or care team.

You can also call the Connecticut Newborn Screening Network at **(860) 837-7871.**

This fact sheet was written for information purposes only. It should not replace medical advice, diagnosis, or treatment.

Review of Key Points

- All infants are now being screened for congenital CMV with new blood spot PCR testing
    - Not all positive infants are visibly symptomatic

- Starting a prompt work up after a positive cCMV result is important
    - Pediatric ID should be involved in starting an antiviral because not all infants will benefit from treatment
    - If an antiviral is indicated, it is most effective if started within one month of life

- There will be false positive and negative results with the blood spot
    - Targeted screening should still be done and does not replace universal screening
    - Infants with signs and symptoms of cCMV should still undergo evaluation

- Pediatric Infectious Disease is always available to help
    - One Call to connect with on call ID provider (860) 837-7741 for clinical questions and urgent referrals
    - CCMC ID office number (860) 545-9490
    - Newborn Screening Network (860) 837-7870

Quality Metrics

Under development

Pathway Contacts

- Debbie Ellis, MSN, RN
  - Connecticut Newborn Screening Network
- Ashley Howard, DO
  - Pediatric Infectious Disease

References

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Thank You!

About Connecticut Children’s Pathways Program

Clinical pathways guide the management of patients to optimize consistent use of evidence-based practice. Clinical pathways have been shown to improve guideline adherence and quality outcomes, while decreasing length of stay and cost. Here at Connecticut Children’s, our Clinical Pathways Program aims to deliver evidence-based, high value care to the greatest number of children in a diversity of patient settings. These pathways serve as a guide for providers and do not replace clinical judgment.