Worcestershire Acute Hospitals NHS Trust

Diagnosis and Management of Congenital CMV Infection: Maternal & Neonatal Guideline

This guidance does not override the individual responsibility of health professionals to make appropriate decision according to the circumstances of the individual patient in consultation with the patient and /or carer. Health care professionals must be prepared to justify any deviation from this guidance.

Introduction:

Congenital CMV is the leading non-genetic cause of sensorineural hearing loss. Worldwide, the birth prevalence of CMV is estimated at 7 per 1000 births. Approximately 10% of infected newborns are symptomatic at birth and of those around half will have significant impairment in their neurodevelopment. Of infants who are asymptomatic at birth approximately 15% go on to have long term sequelae including sensorineural hearing loss in childhood.

This guideline is for use by the following staff groups :

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Approved by *Neonatal Guidelines Review Meeting* on:	11th November 2022
Review Date This is the most current document and should be used until a revised version is in place:	11th November 2025

Key amendments to this guideline

Date	Amendment	Approved by:
November 2022	Document approved for 3 years with no amendments	Dr Gregory/ Neonatal Guidelines Review Meeting

Congenital CMV (cCMV)

Congenital CMV is the leading non-genetic cause of sensorineural hearing loss. Worldwide, the birth prevalence of CMV is estimated at 7 per 1000 births. Approximately 10-15% of infected newborns are symptomatic at birth and of those around half will have significant impairment in their neurodevelopment. Of infants who are asymptomatic at birth approximately 15% go on to have long term sequelae including sensorineural hearing loss in childhood.

Vertical transmission of CMV infection can be intrauterine, intrapartum, and postnatal. Intrauterine transmission is the most important route as it may result in major neurological sequelae. Symptoms of congenital CMV can range from mild transient symptoms to severe multi system dysfunction and death.

Epidemiology

In-utero transmission of CMV can occur either following primary or secondary maternal CMV infection. Secondary infection is either by reactivation of prior CMV infection or by reinfection of seropositive mothers with a different strain.

Transmission is more likely following primary maternal infection in pregnancy than following secondary infection. Infants born to mothers with primary infection have a risk of congenital infection of 30-40% (of which 13% will be symptomatic at birth). Following secondary maternal infection, the risk of congenital infection is 1-2%. Despite this, in populations with high seroprevalence the majority of cases of congenital CMV result from secondary infection.

The risk of congenital infection increases with advancing gestation (30% in the first trimester, increasing to 47% in the third trimester), However, although the risk of transmission is lower in the first trimester the proportion of cases with a prenatal diagnosis of severe infection is higher when infection occurs in the first compared to the third trimester.
While to risk of transmission is lower in the first trimester, the cases of severe fetal infection are disproportionally higher when compared with cases acquired in the third trimester.

The majority of mothers acquiring a primary CMV infection will be asymptomatic, a minority experience symptoms such as; fever, malaise myalgia and cervical lymphadenopathy. Mild asymptomatic hepatitis (isolated raised ALT) is common

CMV can remain dormant (usually in the salivary glands) lifelong and be reactivated at any time, including during pregnancy

Antenatal Detection and Screening

CMV screening does not meet several of the criteria for an effective screening test and screening is not currently offered outside a research setting.
Serological testing should be offered to women who are symptomatic of CMV infection and/or where there is ultrasound detection of anomalies consistent with possible fetal CMV infection including:

- Intrauterine Growth Restriction (IUGR) or Small for Gestational Age (SGA)
- Intracranial ventriculomegaly / calcification, microcephaly
- Hydrops fetalis
- Ascites, pleural or pericardial effusions
- Oligohydramnios or polyhydramnios
- Hepatomegaly or splenomegaly
- Intra-abdominal calcification
- Echogenic bowel
- Placentomegaly >40mm

Maternal Tests

Maternal serology for CMV IgG/IgM is the mainstay for the diagnosis of maternal infection. Fetal infection is diagnosed through identification of the virus in the amniotic fluid following amniocentesis (PCR).

- Both IgG and IgM negative: unlikely to be CMV infection
- IgG positive, IgM negative: past maternal infection. **NOTE**: ***a negative IgM close to term does not exclude the possibility of primary infection the first trimester.***
- IgG positive, IgM positive: possible primary infection
- IgM positive is not necessarily diagnostic of recent, maternal primary infection as IgM can persist many months after primary infection, may be detected in secondary infection, cross react with other viral illnesses such as EBV or be a non-specific false-positive.
- IgG avidity testing is used to better define the timing of primary infection. It can be performed on any IgG positive blood sample
- The avidity index is a measure of how strongly bound antigen is to antibody. Antibody avidity increases ("becomes stronger") over time as the immune response matures.
- A high avidity index (>60%) is highly suggestive of a past (>3 month ago) or secondary infection
- A low avidity index (<30%) is highly suggestive of a recent primary infection.
- Therefore the diagnosis of primary CMV in pregnancy requires either 1) the appearance of CMV specific IgG in a woman who was previously seronegative or CMV IgM with low IgG avidity.
- The diagnosis of secondary CMV is difficult and can only be confirmed by invasive testing (amniocentesis or fetal blood sampling).

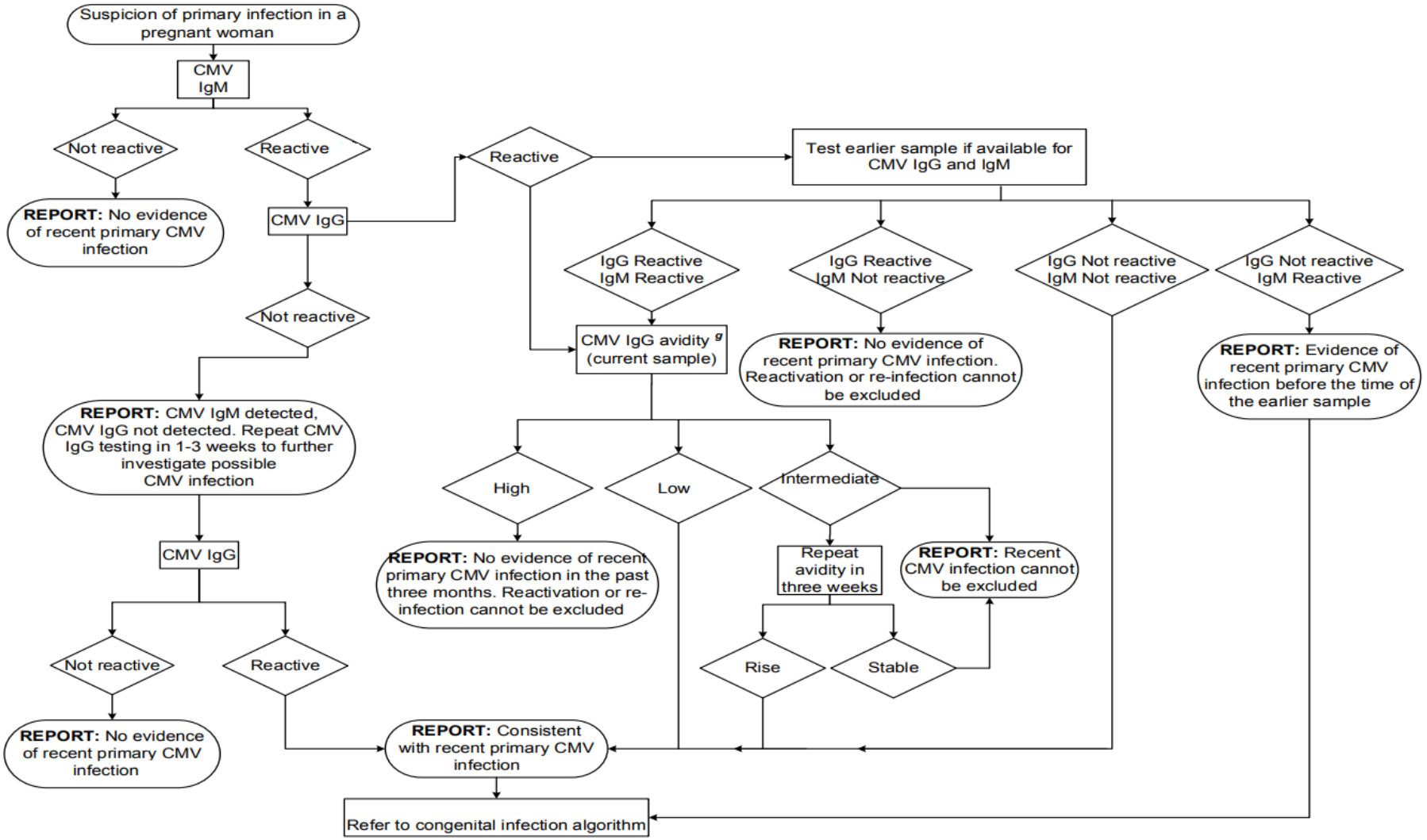
NOTE: *Passively acquired CMV IgG may be detectable in patients who have recently received blood or blood products, including anti-D immunoglobulins, leading to misinterpretation of the CMV infection status through false seropositive or seroconversion results. Passively acquired immunoglobulins decrease over time, with a half-life of approximately 3 weeks.*

Blood Sampling

Maternal serology for CMV IgG/IgM should be taken in a 'gold top' tube (serum separating tube). Avidity can be requested on any sample which is IgG positive and is requested following discussion with the laboratory. Maternal booking blood samples are stored by the laboratory and can be tested retrospectively if this can help establish the timing of primary maternal infection.

Sample volumes: each test (IgM, IgG and IgG avidity) requires AT LEAST 200µl of clotted blood. Thus it is recommended that a minimum sample volume of 600µl is sent to the laboratory. Use a gold top tube.

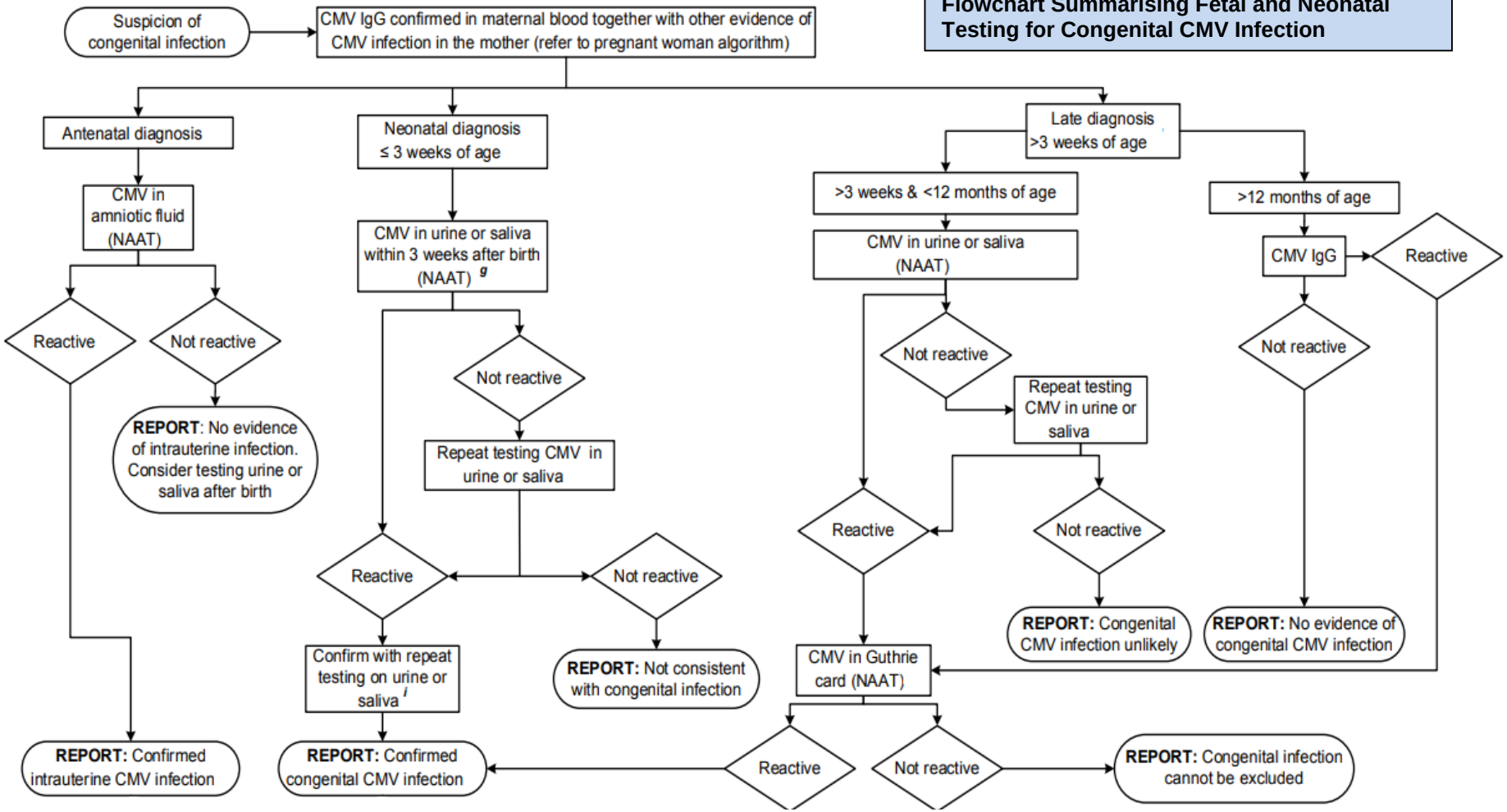
EDTA blood samples (purple top tubes) are required for CMV viral load testing. These are NOT recommended, except as directed by an infection specialist, as results can be difficult to interpret.



Diag

Give.. booking blood collected at c. 12/40 gestation is usually available and can be very helpful when testing in parallel with samples from later in pregnancy.

Flowchart Summarising Fetal and Neonatal Testing for Congenital CMV Infection



Fetal and neonatal testing

- Amniocentesis for PCR depends on viral excretion in the fetal urine, therefore it should be performed after 20/40 (once fetal urination is well established) AND after a sufficient period of time for the fetus to become infected after maternal primary infection (at least 6 weeks).
- Repeat testing of CMV in neonatal urine or saliva is only required if clinical findings are inconsistent with the laboratory result

Prenatal Prognostic Indicators

The risk of vertical transmission increases with gestation, whereas cCMV acquired in early pregnancy is more likely to be associated with severe disease.

The main prognositic indicator is the presence of cerebral abnormalities, when ultrasound is used in conjunction with fetal MRI in the third trimester when a fetus is known to be affected, there is a 95% sensitivity for the detection of CNS anomalies. In fetuses without cerebral anomalies, the prognosis is generally good.

Pre-natal therapy

Options have traditionally consisted of conservative management (continuation of the pregnancy) or termination of pregnancy.

More recently treatment options to reduce the risk of fetal transmission have been explored; these include anti-viral drugs and CMV hyperimmune globulin (HIG).

Valaciclovir, when taken by a mother with primary CMV, has been shown to reduce the risk of fetal transmission. It has an excellent safety profile, however treatment has not been subjected to a randomised control trial, therefore should only be used under the direction of the fetal medicine team.

Fetuses with intermediate risk may benefit from treatment (see Table 1).

The evidence for HIG is conflicting and it appears to be associated with an increased risk of poor obstetric outcomes and is therefore not recommended.

See the flow chart below for a proposed management of cCMV.

Flowchart for Management of CMV

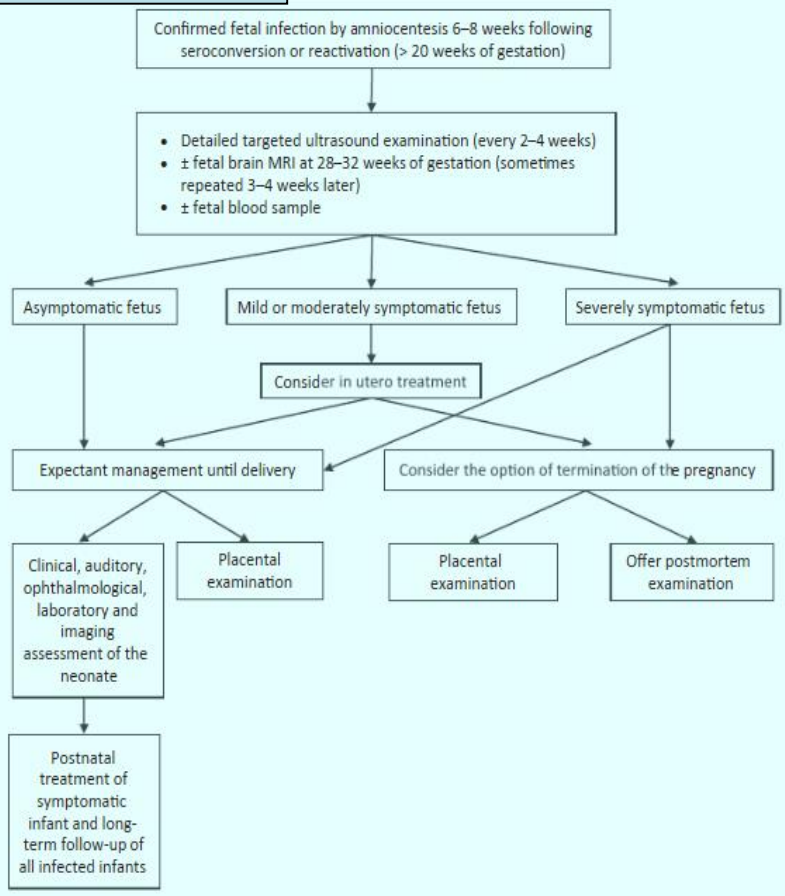


Table of Antenatal Scan and Lab Findings in Congenital CMV

At least one extracerebral abnormality compatible with fetal CMV infection
Fetal growth restriction
Abnormal amniotic fluid volume
Ascites and/or pleural effusion
Skin oedema
Hydrops
Placentomegaly > 40 mm
Hyperechogenic bowel
Hepatomegaly > 40 mm
Splenomegaly > 30 mm
Liver calcifications

And/or one isolated cerebral abnormality
Moderate isolated ventriculomegaly (< 15 mm)
Isolated cerebral calcification
Isolated intraventricular adhesion
Lenticulostriate vasculopathy

And/or laboratory findings of generalised CMV infection in fetal blood
Fetal viraemia > 3000 copies/ml
Fetal platelet count < 100 000/mm^3

Postnatal

15% of babies born with congenital CMV will be symptomatic at birth. 6-23% of the asymptomatic neonates will develop Sensorineural Hearing Loss (SNHL).

Features of Neonatal Infection

Examination

- Petechiae/purpura/Blueberry muffin rash
- Hepatomegally or splenomegaly
- Microcephaly (HC<2SD for gestational age)
  (consider if symmetrically small for gestational age (Bwt <2SD for gestational age))

Bloods

- Prolonged Jaundice with transaminitis
- Conjugated hyperbilirubinaemia
- Unexplained thrombocytopenia (leucopenia or anaemia)

Imaging

- Intracranial calcification (often periventricular)
- Ventriculomegaly without explanation

Opthalmology

- Chorioretinitis
- Congenital Cataract

Audiology

- Failed hearing screen

Other

- Seizures with no other explanation
- Severe pneumonia
- Bacteraemia-like illness un-responsive to antibiotics

Indications for testing

Antenatal

Evidence of maternal primary CMV infection in pregnancy
Antenatal ultrasound suggestive of congenital CMV (cCMV): ventriculomegaly, calcifications, periventricular cysts, echogenic bowel, pericardial effusion, ascites and fetal hydrops, SGA (birthweight <3rd centile), oligohydramnios or polyhydramnios.

Neonatal

Petechiae/purpura/Blueberry muffin rash
Hepatomegally or splenomegaly
Prolonged Jaundice with transaminitis
Conjugated hyperbilirubinaemia
Unexplained thrombocytopenia (consider if leucopenia or anaemia)
Microcephaly (HC<2SD for gestational age)
Intracranial calcification (often periventricular)
Ventriculomegaly without explanation
Chorioretinitis
Congenital Cataract
Seizures with no other explanation
Severe pneumonia

Neonatal Testing

- CMV PCR urine (Bag or cotton wool in the nappy) (sensitivity 100% & specificity 99% for congenital CMV infection, provided taken within first 3 weeks of life).(**Preferred test).**
  or
  CMV PCR saliva (Take >1 hour after breast feed – formula fed anytime)

  Soak mouth swab in saliva for 1 min; send in viral transport medium to regional laboratory.
  If negative and high-risk CMV also send urine.

- CMV PCR on dried blood spot
  (if diagnosed after 3 weeks- false negatives occur (sensitivity approx. 84%) & parental consent needed (See Appendix 1)

Consider other congenital infection screen depending on features including:
- Toxoplasma (hydrocephalus, microcephaly, convulsions, generalised infection)
- Syphilis (rash, rhinitis, hepatosplenomegaly, jaundice, thrombocytopenia)
- Rubella (cataract, deafness, microcephaly)
- Zika (maternal/paternal travel, microcephaly)

CMV Positive

Further investigations
- Full blood count - unexplained thrombocytopenia (nadir 2 weeks)
- Renal function
- Bilirubin - conjugated hyperbilirubinaemia (may increase in first 2 weeks)
- Liver enzymes - elevated Transaminases (may increase in first 2 weeks)
- Blood CMV viral load
  if unknown whether infection is congenital request initial bloodspot card to be tested for CMV PCR
- Ophthalmic assessment
- Audiology: brainstem-evoked response
- Head ultrasound - if ultrasound head abnormal or seizures,
- MRI head

Management & Treatments

Note that postnatally acquired CMV does not require treatment. There is little evidence that treating mild cCMV is beneficial and there is no consensus regarding the treatment of moderate cCMV [3].

A modest benefit on both 2-year hearing and neurodevelopmental outcomes was shown with the 6-month treatment course. The longer treatment course improved likelihood of better hearing outcomes most notably in those with pre-existing CNS involvement.

No antiviral drugs are currently licensed for the treatment of cCMV.

Mild cCMV
- Asymptomatic **–** no CNS involvement, including sensorineural hearing loss
- isolated IUGR
- hepatomegaly with normal liver enzymes
- isolated raised ALT/AST

- mild thrombocytopenia
- No treatment

Moderate cCMV

- Discuss with infectious diseases specialist if:
  - >2 weeks mild features
  - >2 mild features

Severe cCMV

- Significant organ involvement:
- significant liver enzyme abnormalities
- marked hepatomegaly
- Any CNS disease
- isolated sensorineural hearing loss
- retinitis
- microcephaly
- cranial ultrasound or MRI brain abnormalities

Treatment Options

- **Valganciclovir 16 mg/kg oral 12-hrly for 6 months**

  *if **not** tolerating oral feeds,*
- **Ganciclovir 6 mg/kg IV [prepared by pharmacy (cytotoxic)] over 1 hr, 12-hrly for 6 weeks**

The side effects vs benefits should be discussed with parents:
Advantages: potential reduced risk of deafness and developmental delay. Degree not clear.
Disadvantages: during treatment reversible blood dyscrasia; long-term unknown risk to fertility and malignancy.

Aim to start treatment as soon as possible. If the diagnosis I delayed treatment can be started up to the age of 1 month.

Feeding

- Do not discourage infected women from breastfeeding their own uninfected, term babies (CMV can be transmitted via breastfeeding, but benefits of feeding outweigh risks posed by breastfeeding as a source of transmission)
- Avoid breastfeeding of premature baby if mother is positive and baby asymptomatic

Follow-up

All these babies should be entered on CMV surveillance register (discuss with paediatric infectious disease specialist).

To enter the baby onto the registry, please contact CCMVET via ccmvnet@gmail.com

For more details please visit the following webpage https://cmvaction.org.uk/news/ccmvet-cmv-registry/

A neurodevelopmental assessment should be carried out aged 1 yr - if delayed development discuss MRI brain with radiology.
Parent can find support at CMV Action charity through https://cmvaction.org.uk/

Blood Monitoring:

- ***Ganciclovir IV:*** FBC, LFT, U&E at least twice weekly
- ***Valganciclovir oral:*** FBC, LFT, U&E weekly for first 4 weeks, then monthly until completion
- CMV viral load monthly on antiviral therapy
- Therapeutic drug monitoring should be considered if:
  - viral load increases >1 log on treatment
  - toxicity suspected
  - abnormal renal function
  - <36 weeks' gestation

Audiology:
3 monthly for first year, then 6 monthly for 3 years, then annually until aged 6 years for both asymptomatic and symptomatic congenitally infected babies

Paediatric Infectious Diseases Specialist referral:
This review should be arranged as soon as possible in first month, then annually until aged 2 years.
Ophthalmology:
Review at least annually until aged 5 years if symptomatic/signs at birth.

Appendix 1: Consent for Blood Spot CMV Testing

This consent form can sent by email with details of the child's name, CHI number, neonatal consultant and email/contact details of the person to whom the report should be sent.

The lab should also be contacted by telephone to ensure the request is processed urgently.

Tel: 0121 333 9905 / 0121 333 9904

Website: http://www.newbornscreening.org/site/laboratory-details.asp

Consent form for the retrieval and use of the Dried Blood Spot Specimen

CHILD'S NAME ……..

MOTHER'S NAME WHEN CHILD WAS BORN …….

CHILD'S DATE OF BIRTH
…….

HOME ADDRESS WHEN CHILD WAS BORN ……

…….

…….

I/we give permission for you to recall the blood spot specimen from the above child to be released for

laboratory investigation for
……

……

NAME OF
PARENT(S)……

PARENTAL
SIGNATURE(S)…….

DATE SIGNED……

Appendix 2:
Consent Form for treatment of valganciclovir or ganciclovir for congenital CMV

Child's Name:

NHS number:

Consultant Neonatologist:

Date:

I understand my child has been diagnosed with congenital cytomegalovirus and I wish them to receive ganciclovir/valganciclovir treatment for this.

I have received and read the parent information leaflet congenital CMV treatment

I understand the course of treatment is 6 months and requires regular blood tests and outpatient appointments as per my child's treatment plan.

I have received a copy of the treatment plan for my child

I understand the risks associated with treatment including potential long term risk as detailed in the parental information leaflet.

Name of doctor responsible for discussion with parents

Signature

Date

Name of parent out guardian

Signature

Date

Appendix 3: Treatment Plan Valganciclovir

Name of Infant

NHS number

Responsible consultant

Congenital CMV infection confirmed

Urine date….. Saliva swab date …….
Newborn blood spot specimen (if applicable) date ……

Pre-treatment investigations completed

Investigation	Result
Full blood count	
U&Es	
Liver function	
Coagulation	
Viral load	
Ophthalmological assessment	
Hearing assessment	

Parental discussion by consultant completed

Parental information leaflet given

Consent form signed

Date of start of treatment Date of end of treatment

First outpatient appointment given

GP contacted

Monitoring

Schedule	Date completed	Test	Results actioned	Weight	Dose adjustment
Week 1		FBC, UEs, LFTs			
Week 2		FBC, UEs, LFTs. Viral load			
Week 3		FBC, UEs, LFTs			
Week 4		FBC, UEs, LFTs, Viral Load			
Week 8		FBC, UEs, LFTs. Viral load			
Week 12		FBC, UEs, LFTs. Viral load			
Week 16 (month 4)		FBC, UEs, LFTs. Viral load			
Week 20 (month 5)		FBC, UEs, LFTs. Viral load			
Week 24 (month 6)		FBC, UEs, LFTs			N/A
Week 28 (month 7)		FBC, UEs, LFTs			N/A

Follow up

Outpatient appointment arranged

GP contacted and ongoing prescription arrangements made

MRI scan arranged

Audiology referral

Ophthalmology referral

Developmental clinic referral

Appendix 4: Treatment Plan Ganciclovir

Name of Infant

NHS number

Responsible consultant

Congenital CMV infection confirmed

Urine date….. Saliva swab date …….
Newborn blood spot specimen (if applicable) date ……

Pre-treatment investigations completed

Investigation	Result
Full blood count	
U&Es	
Liver function	
Coagulation	
Viral load	
Ophthalmological assessment	
Hearing assessment	

Parental discussion by consultant completed

Parental information leaflet given

Consent form signed

Date of start of treatment Date of end of treatment

Reason for ganciclovir treatment

Monitoring

Treatment should be switched to valganciclovir when clinical improvement noted and oral medication tolerated. Monitoring schedule of valganciclovir should then be used for the remaining treatment.

Schedule	Date completed	Tests	Results actioned
Day 3		FBC, UE , LFT, viral load, ganciclovir levels	
Day 6		FBC, UE, LFTs.	
Day 10		FBC, UE , LFT, viral load, ganciclovir levels	
Day 13		FBC, UE, LFTs	
Day 17		FBC, UE , LFT, viral load, ganciclovir levels	
Day 20 (end of week 3)		FBC, UE, LFTs	
Week 4		FBC, UE , LFT, viral load, ganciclovir levels	
Week 5		FBC, UE , LFT, viral load, ganciclovir levels	
Week 6		FBC, UE , LFT, viral load, ganciclovir levels	

By week 6 most infants should be able to be converted to valganciclovir to complete 6 months of treatment. If the infant is not able to be converted to valganciclovir at this stage seek further advice from consultant virologist and paediatric infectious diseases team.

Date of conversion to valganciclovir …….

Follow up

Outpatient appointment arranged
GP contacted
MRI scan arranged
Audiology referral
Ophthalmology referral
Developmental clinic referral

Treatment plan for ganciclovir

Name of Infant

CHI number

Responsible consultant

Congenital CMV infection confirmed

Urine date….. Saliva swab date …….
Newborn blood spot specimen (if applicable) date ……

Pre-treatment investigations completed

Investigation	Result
Full blood count	
U&Es	
Liver function	
Coagulation	
Viral load	
Ophthalmological assessment	
Hearing assessment	

Parental discussion by consultant completed

Parental information leaflet given

Consent form signed

Date of start of treatment Date of end of treatment

Reason for ganciclovir treatment

Monitoring

Treatment should be switched to valganciclovir when clinical improvement noted and oral medication tolerated. Monitoring schedule of valganciclovir should then be used for the remaining treatment.

Schedule	Date completed	Tests	Results actioned
Day 3		FBC, UE , LFT, viral load, ganciclovir levels	
Day 6		FBC, UE, LFTs.	
Day 10		FBC, UE , LFT, viral load, ganciclovir levels	
Day 13		FBC, UE, LFTs	
Day 17		FBC, UE , LFT, viral load, ganciclovir levels	
Day 20 (end of week 3)		FBC, UE, LFTs	
Week 4		FBC, UE , LFT, viral load, ganciclovir levels	
Week 5		FBC, UE , LFT, viral load, ganciclovir levels	
Week 6		FBC, UE , LFT, viral load, ganciclovir levels	

By week 6 most infants should be able to be converted to valganciclovir to complete 6 months of treatment. If the infant is not able to be converted to valganciclovir at this stage seek further advice from consultant virologist and paediatric infectious diseases team.

Date of conversion to valganciclovir

Follow up

Outpatient appointment arranged
GP contacted
MRI scan arranged
Audiology referral
Ophthalmology referral
Developmental clinic referral

Appendix 5: Parent Information Leaflet

What is Cytomegalovirus (CMV)?

Cytomegalovirus (CMV) is a common virus for people of all ages; however, a healthy person's immune system usually keeps the virus from causing illness.

Is CMV Common?

Over half of adults have been infected with CMV by age 40 and nearly one in three children are already infected with CMV by age five.

How is CMV transmitted?

People with CMV may pass the virus in body fluids, such as saliva, urine, blood, tears, semen, and breast milk. CMV can be spread from an infected person from direct contact with saliva or urine, especially from babies and young children, through sexual contact, from breast milk to nursing infants. It can also be spread through transplanted organs and blood transfusions

What is Congenital CMV?

Congenital CMV is when the mother is infected during pregnancy. The infection can effects the growing baby in different ways

How is CMV diagnosed?

The virus can be detected best in the urine and also in saliva. Occasionally doctors may ask your consent to use the blood spot to confirm the virus was present at birth.

Does congenital CMV affect all babies?

Some babies may not be affected at all. It is thought that babies exposed to CMV during the earlier part of pregnancy have more risk of being affected. If babies catch CMV after birth it rarely causes any problems at all.

Can babies breast feed if their mother has CMV?

Yes. The benefits of breast feeding far out-weigh the risks after birth.

How can congenital CMV affect my baby?

Some babies born with CMV can have brain, liver, spleen, lung, and growth problems. The most common long-term health problem in babies born with

congenital CMV infection is hearing loss, which may be detected soon after birth or may develop later in childhood.

What tests will babies with congenital CMV have to have?

Because of these different effects babies with congenital CMV will be investigated with an USS of the brain (through the soft spot on the baby's head). Sometimes an MRI scan of the head is also checked. The opthalmologists (eye doctors) will be asked to look for cataracts or chorioretinitis, a form of eye disease associated with the virus.

Because hearing is most frequently affected, this will be checked every three months for the first year, then six monthly until the baby is two and then yearly until the baby reaches six years of age.

Can babies with congenital CMV be treated?

There is some evidence that treatment with antiviral drugs such as Ganciclovir and Valganciclovir for six months may improve the hearing loss and developmental outcomes at age two, particularly when there is already evidence of neurological involvement.

Are there any risks to treating congenital CMV?

Treatment does have risks; short-term toxicity, including neutropenia (low white cells), can be anticipated in around half of the patients treated with ganciclovir and in one fifth of those on valganciclovir. Low platelets and liver toxicity can also occur in up to 30%. This can require treatment interruption or rarely administration of granulocyte colony-stimulating factor (GCSF) to stimulate the production of blood cells.

Does congenital CMV treatment need monitoring?

To ensure that your baby is not suffering from any of the side effects frequent blood tests will be arranged.

- Ganciclovir: this is given intravenously these tests will be every 3-4 days for the first twenty days and then weekly thereafter
- Valganciclovir: this is given by mouth and tests will be done weekly for the first month and then monthly thereafter.

The bloods can often be taken from a heel prick. The blood count, liver function and kidney function will be checked each time. The viral load (amount of CMV virus in the blood) will be also be checked at intervals.

Are there any long term risks associated with treating congenital CMV?
The long term risks of treatment are not known. There are some potential risks including toxicity, malignancy risk and effects on fertility. Whether these occur in reality has not been proven yet. To help monitor these effectiveness of treatment your doctor may ask your permission to share details of a babies case with a registry.

Are there support groups for parents with babies with congenital CMV?
Yes, there is a UK based group called CMV Action.
https://cmvaction.org.uk/
There is also an American group called The National CMV Foundation
https://www.nationalcmv.org/default.aspx

Monitoring Tool

This should include realistic goals, timeframes and measurable outcomes.

How will monitoring be carried out?

Who will monitor compliance with the guideline?

Page/ Section of Key Document	Key control:	Checks to be carried out to confirm compliance with the policy:	How often the check will be carried out:	Responsible for carrying out the check:	Results of check reported to: *(Responsible for also ensuring actions are developed to address any areas of non-compliance)*	Frequency of reporting:
	WHAT?	**HOW?**	**WHEN?**	**WHO?**	**WHERE?**	**WHEN?**
	These are the 'key' parts of the process that we are relying on to manage risk. We may not be able to monitor every part of the process, but we MUST monitor the key elements, otherwise we won't know whether we are keeping patients, visitors and/or staff safe.	What are we going to do to make sure the key parts of the process we have identified are being followed? (Some techniques to consider are; audits, spot-checks, analysis of incident trends, monitoring of attendance at training.)	Be realistic. Set achievable frequencies. Use terms such as '10 times a year' instead of 'monthly'.	Who is responsible for the check? Is it listed in the 'duties' section of the policy? Is it in the job description?	Who will receive the monitoring results? Where this is a committee the committee's specific responsibility for monitoring the process must be described within its terms of reference.	Use terms such as '10 times a year' instead of 'monthly'.
	Monitoring of treatment	Audit Guideline	3 yearly		Audit meeting	3 yearly

References

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Contribution List

This key document has been circulated to the following individuals for consultation;

Designation
Ophthalmology
Audiology
Pharmacy
Dr Hugh Morton, Consultant Microbiologist

This key document has been circulated to the chair(s) of the following committee's / groups for comments;

Committee
Paediatric QI Meeting

Supporting Document 1 - Equality Impact Assessment Tool

To be completed by the key document author and attached to key document when submitted to the appropriate committee for consideration and approval.

		Yes/No	Comments
1.	**Does the policy/guidance affect one group less or more favourably than another on the basis of:**		
	• Race	NO	
	• Ethnic origins (including gypsies and travellers)	NO	
	• Nationality	NO	
	• Gender	YES	Aimed at pregnant women (i.e. an obstetric guideline) due to the neonatal implications of maternal CMV infection.
	• Culture	NO	
	• Religion or belief	NO	
	• Sexual orientation including lesbian, gay and bisexual people	NO	
	• Age	YES	Also a guideline for management of neonatal CMV infection
2.	**Is there any evidence that some groups are affected differently?**	NO	
3.	**If you have identified potential discrimination, are any exceptions valid, legal and/or justifiable?**	N/A	
4.	**Is the impact of the policy/guidance likely to be negative?**	NO	
5.	**If so can the impact be avoided?**	N/A	
6.	**What alternatives are there to achieving the policy/guidance without the impact?**	N/A	
7.	**Can we reduce the impact by taking different action?**	N/A	

If you have identified a potential discriminatory impact of this key document, please refer it to Human Resources, together with any suggestions as to the action required to avoid/reduce this impact.

For advice in respect of answering the above questions, please contact Human Resources