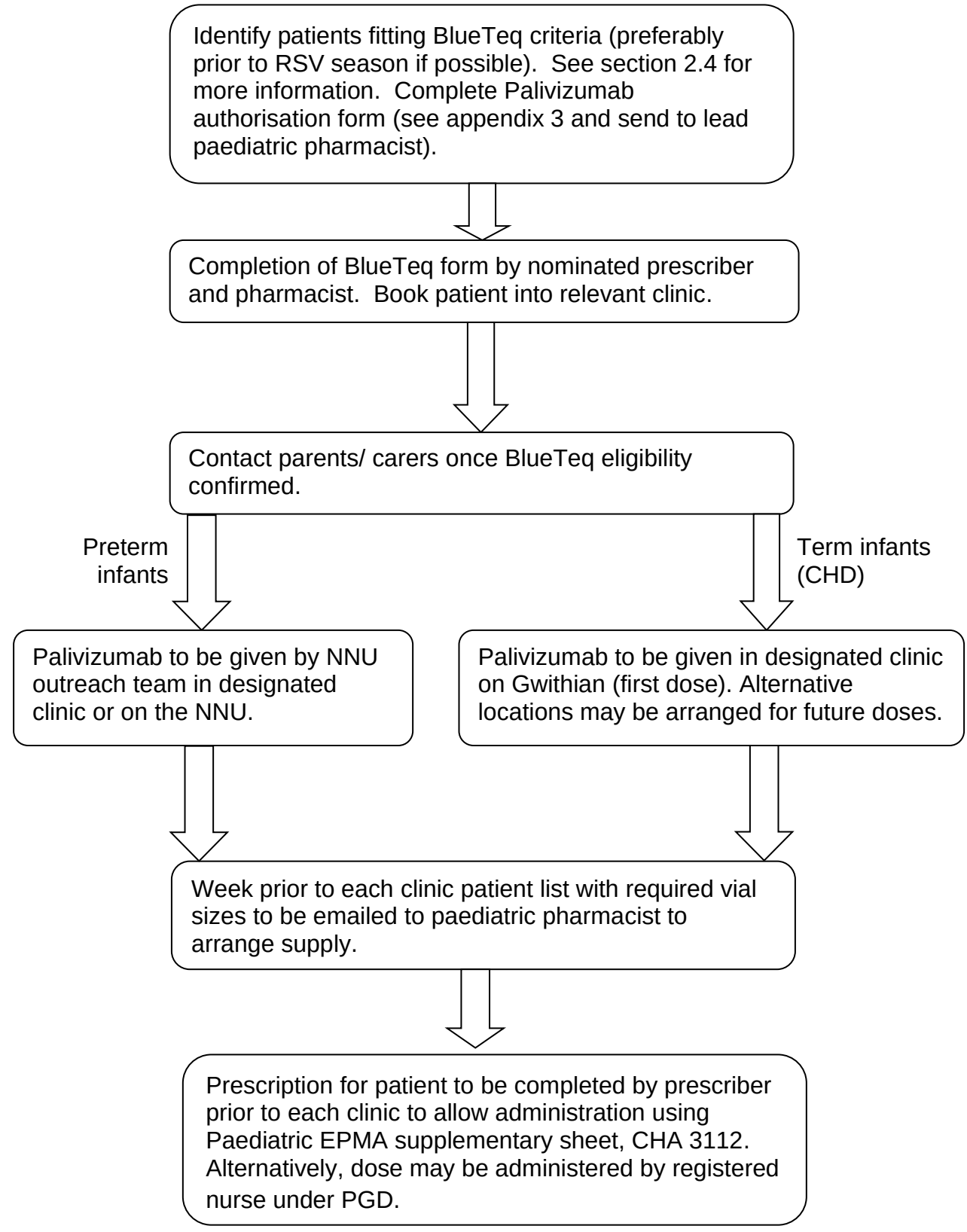
Royal Cornwall Hospitals
NHS Trust

Palivizumab for Neonatal Chronic Lung Disease and Congenital Heart Disease Clinical Guideline

V3.0

October 2023

Summary


Identify patients fitting BlueTeq criteria (preferably prior to RSV season if possible). See section 2.4 for more information. Complete Palivizumab authorisation form (see appendix 3 and send to lead paediatric pharmacist).
Completion of BlueTeq form by nominated prescriber and pharmacist. Book patient into relevant clinic.
Contact parents/ carers once BlueTeq eligibility confirmed.
Preterm infants
Term infants (CHD)
Palivizumab to be given by NNU outreach team in designated clinic or on the NNU.
Palivizumab to be given in designated clinic on Gwithian (first dose). Alternative locations may be arranged for future doses.
Week prior to each clinic patient list with required vial sizes to be emailed to paediatric pharmacist to arrange supply.
Prescription for patient to be completed by prescriber prior to each clinic to allow administration using Paediatric EPMA supplementary sheet, CHA 3112. Alternatively, dose may be administered by registered nurse under PGD.
NNU- Neonatal Unit.
RSV- Respiratory syncytial virus.
CHD- Congenital heart disease.
EPMA- Electronic prescribing and medicines administration.

1. Aim/Purpose of this Guideline

1.1. Aimed at clinical staff who are involved in managing neonates and infants with chronic lung disease and congenital heart disease.

1.2. This version supersedes any previous versions of this document.

Data Protection Act 2018 (UK General Data Protection Regulation – GDPR) Legislation.

The Trust has a duty under the Data Protection Act 2018 and UK General Data Protection Regulations 2016/679 to ensure that there is a valid legal basis to process personal and sensitive data. The legal basis for processing must be identified and documented before the processing begins. In many cases we may need consent; this must be explicit, informed, and documented. We cannot rely on opt out, it must be opt in.

Data Protection Act 2018 and UK General Data Protection Regulations 2016/679 is applicable to all staff; this includes those working as contractors and providers of services.

For more information about your obligations under the Data Protection Act 2018 and UK General Data Protection Regulations 2016/679 please see the Information Use Framework Policy or contact the Information Governance Team.

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2. The Guidance

Those paediatric cardiac patients and neonates with chronic lung disease who fit the following criteria.

2.1. High risk due to chronic lung disease (Broncopulmonary dysplasia (BPD).

2.1.1. Pre-term infants who have moderate or severe BPD. Moderate or severe BPD is defined as ‘preterm infants with compatible x-ray changes who continue to receive supplemental oxygen or respiratory support at 36 weeks post-menstrual age’. Children who fall into the light and dark green shaded area of Table 1 should be offered prophylaxis.

2.1.2. Infants with respiratory diseases who are not necessarily pre-term but who remain in oxygen at the start of the RSV season are also considered to be at higher risk. These infants may include those with conditions including:

- Pulmonary hypoplasia due to congenital diaphragmatic hernia.
- Other congenital lung abnormalities (sometimes also involving congenital heart disease or lung malformation).
- Interstitial lung disease and including those receiving long term ventilation at the onset of the season.

2.2. High Risk due to Congenital Heart Disease (CHD):

2.2.1. Preterm infants with haemodynamically significant, acyanotic CHD at the chronological ages at the start of the RSV season and gestational ages at birth covered within the light shaded area in Table 1.

2.2.2. Cyanotic or acyanotic CHD plus significant co-morbidities particularly if multiple organ systems are involved.

2.2.3. Respiratory Syncytial Virus

Table 1- Cost effective use of Palivizumab (shaded area).

	Gestational Age At Birth (weeks + days)						
Chronological Age (Months)	**≤24+0**	**24+1 to 26+0**	**26+1 to 28+0**	**28+1 to 30+0**	**30+1 to 32+0**	**32+1 to 34+0**	**≥34+1**
<1.5							
1.5 to <3							
3 to <6							
6 to <9							
≥9							

2.2.3.1. The table above shows chronological age (months) at the start of the RSV season (beginning of October) and gestational age at birth (weeks). The gestational ages are based on whole weeks so parts of weeks should be rounded up. This is based on an analysis of the cost effective use of Palivizumab prophylaxis.

2.2.3.2. This current guidance also states;

‘Where clinical judgement of other individual patient circumstances strongly suggests that prophylaxis would prevent serious RSV infection in infants who are at particular risk of complications from RSV, use of Synagis® could be considered during the RSV season.’

2.2.3.3. The patients that may come into the latter statement are infants aged 1 year or younger with documented haemodynamically significant congenital cardiac disease. {Haemodynamically significant CHD is defined as one where the child is symptomatic, on medication or is cyanosed.}

2.2.4. Process for identifying patients

2.2.4.1. During August, a list of paediatric congenital heart disease patients in Cornwall, who fulfil the criteria for palivizumab treatment is generated after discussion with visiting Paediatric Tertiary cardiologist who would have received a list from Bristol Paediatric Cardiology. Additions to this list will occur throughout the RSV season. Notify neonatal outreach nurses for the Chronic Lung Disease (CLD) patients, and the Gwithian nursing staff for the cardiac babies.

2.2.4.2. For patients at home, the neonates with chronic lung disease meeting BlueTeq criteria are identified by the Consultant Paediatrician in charge of each case, for the neonatal inpatients, the service consultant identifies them and completes the Palivizumab authorisation form (appendix 3), which is sent to the lead paediatric pharmacist for organisation of Blue Teq completion.

2.2.5. Funding

Prior approval needed to be via BlueTeq and is funded by NHS England. The Paediatrician with Expertise in Cardiology and Consultant Paediatrician looking after the infant will request this approval on BlueTeq.

2.2.6. In special circumstances the RSV season may be extended, or additional groups of patients may be identified (e.g., during the COVID pandemic). This will be communicated via the Joint Committee on Vaccination and Immunisation (JCVI), National Health Service England (NHSE) or another appropriate government body. Where this occurs information will be disseminated by the lead paediatric pharmacist.

2.3. DRUG INFORMATION

Indicated for the prevention of serious lower respiratory tract disease requiring hospitalisation caused by RSV in children at high risk of RSV disease. It is licensed for children less than 2 years of age with haemodynamically significant congenital heart disease.

2.3.1. Class of Drug

A humanised monoclonal antibody produced using recombinant DNA techniques in mouse myeloma host cells.

2.3.2. Mechanism of Action

The infectivity of RSV is determined by 2 surface glycoproteins, G and F. The G protein enables the virus to attach itself to the host cell. The F protein promotes fusion of the virus with the host cell as well as fusion of infected host cells with one another, facilitating cell-cell transmission. Palivizumab is directed against an epitope in the A antigen site of the F protein of RSV. It provides passive immunity against RSV.

2.3.3. Preparation

50mg and 100mg vial.

2.3.4. Presentation

Solution for injection. It is a clear to slightly opalescent liquid. Supplied in 0.5ml or 1ml vials. The concentration of palivizumab in each vial is 100mg/ml. The vials contain an overfill to allow the withdrawal of the correct dose. This solution for injection should not be further diluted and should not be shaken.

2.3.5. Administration

By intramuscular injection preferably in the anterolateral aspect of the thigh. The gluteal muscle should not be used routinely as an injection site because of the risk of damage to the sciatic nerve. Injection volumes over 1ml should be given as a divided dose.

It can be given at the same time as vaccines administered as part of the routine childhood immunisation programme. The vaccines should be given at separate sites, preferably in a different limb.

Batch number and expiry date of the vial should be documented on the prescription chart at the time of administration.

2.3.6. Dose

15mg/kg once a month during periods of RSV risk for a maximum of 5 months. Where possible, the first dose should be administered prior to commencement of the RSV season, ideally being offered the last week of September or first week of October, unless otherwise advised.

Doses should be rounded as per the table on the following page:

Weight range (kg)			Palivizumab dose
2.0	to	< 2.2	30mg
2.2	to	< 2.5	35mg
2.5	to	< 3.0	40mg
3.0	to	< 3.7	50mg
3.7	to	< 4.4	60mg
4.4	to	< 5.0	70mg
5.0	to	< 5.7	80mg
5.7	to	< 6.4	90mg
6.4	to	< 7.0	100mg
7.0	to	< 7.7	110mg
7.7	to	< 8.4	120mg
8.4	to	< 9.0	130mg
9.0	to	< 9.7	140mg
9.7	to	< 10.4	150mg
10.4	to	< 11.0	160mg
11.0	to	< 11.7	170mg
11.7	to	< 12.4	180mg
12.4	to	< 13.0	190mg
> 13.0			200mg

RSV infection is clearly identified winter virus, usually occurring in the UK within the period October to March.

Where courses have started midseason, continue until the end of February. If a patient has had surgical correction, then palivizumab will only continue whilst the patient is on medication post operatively. The half-life in the body is in the range 18-21 days. Monthly injections are required to maintain its concentration at a protective level.

2.3.7. Cardio-pulmonary bypass

Patients should have their planned monthly palivizumab doses up to 1 week prior to surgery and have the dose repeated post bypass as soon as stable after surgery, as the drug is partially ‘washed out’ during bypass. Then the patient should resume normal monthly injections.

2.3.8. Side effects

Common side effects include:

- Fever.
- Injection site reactions.
- Rash.

2.3.9. Contra-indications

Confirmed anaphylactic reaction to previous dose of palivizumab, to any of its components or another humanised monoclonal antibody.

2.3.10. Warnings and precautions

Allergic reactions including very rare cases of anaphylactic shock have been reported with palivizumab. As with any intramuscular injection, palivizumab should be given with caution to patients with thrombocytopenia or any coagulation disorder. A mild febrile illness, such as mild upper respiratory infection, is not usually reason to defer administration of palivizumab. If an individual is acutely unwell, immunisation may be postponed until they have fully recovered.

Patients should be observed for a few minutes after administration in case of reactions.

2.3.11. Interactions

There are no known interactions that have been described to date. Since palivizumab is specific for RSV, it is not expected to interfere with the immune response to vaccines. Routine immunisations do not need to be rescheduled or deferred.

2.3.12. Adverse reactions

Can be reported to Medical and Healthcare products Regulatory Agency (MHRA) using the yellow card reporting scheme: (http://www.yellowcard.gov.uk/).

2.3.13. Compatibility

Should not be mixed with any other products. Do not dilute the product.

2.3.14. Storage

Store in a refrigerator (2°C to 8°C) in original packaging and protected from light.

2.3.15. Excipients

Histidine, glycine, and water.

2.3.16. Palivizumab clinics

This can be administered by a nurse that has completed their immunisation training.

Neonatal clinics will be held on Gwithian wherever possible and seen by the neonatal outreach team those eligible for palivizumab due to their prematurity.

All other babies will be seen on Gwithian by suitably trained staff for their first dose. Further doses may be given in external clinic locations.

2.3.17. Parents Counselling

RSV is a common cause of respiratory infection in infants and small children. Transmission occurs by contact with infectious secretions through hand contamination and self-inoculation of eye, nose, and mouth. Hand washing should be encouraged.

3. Monitoring compliance and effectiveness

Information Category	Detail of process and methodology for monitoring compliance
Element to be monitored	Key Changes to practice.
Lead	Dr. Sam Padmanabhan.
Tool	Audit using WORD or Excel spreadsheet.
Frequency	As dictated by audit findings.

Information Category	Detail of process and methodology for monitoring compliance
Reporting arrangements	Child Health Directorate Audit and Neonatal Clinical Guidelines.
Acting on recommendations and Lead(s)	Consultant pediatrician and neonatologist.
Change in practice and lessons to be shared	Required Changes in Practice will be identified and actioned within 3 months.

4. Equality and Diversity

4.1. This document complies with the Royal Cornwall Hospitals NHS Trust service Equality and Diversity statement which can be found in the Equality Diversity And Inclusion Policy or the Equality and Diversity website.

4.2. Equality Impact Assessment

The Initial Equality Impact Assessment Screening Form is at Appendix 2.

Appendix 1. Governance Information

Information Category	Detailed Information
Document Title:	Palivizumab For Neonatal Chronic Lung Disease and Congenital Heart Disease Clinical Guideline V3.0
This document replaces (exact title of previous version):	Palivizumab For Neonatal Chronic Lung Disease and Congenital Heart Disease Clinical Guideline V2.1
Date Issued/Approved:	October 2023
Date Valid From:	October 2023
Date Valid To:	October 2026
Directorate / Department responsible (author/owner):	Dr. Sam Padmanabhan; Consultant Paediatrician and Neonatologist
Contact details:	01872 255081
Brief summary of contents:	Identification and administration of Palivizumab to at risk babies
Suggested Keywords:	Palivizumab. RCV. Congenital heart disease. Chronic lung disease. Respiratory syncytial virus.
Target Audience:	**RCHT:** Yes **CFT:** No **CIOS ICB:** No
Executive Director responsible for Policy:	Chief Medical Officer
Approval route for consultation and ratification:	Neonatal Audit and Guidelines Group. Child Health Audit and Guidelines Group.
Manager confirming approval processes:	Caroline Chappell
Name of Governance Lead confirming consultation and ratification:	Caroline Amukusana

Information Category	Detailed Information
Links to key external standards:	The Green book. Respiratory syncytial virus. Chapter 28a: Respiratory syncytial virus: the green book, chapter 27a - GOV.UK (www.gov.uk) http://www.medicines.org.uk/emc/medicine/30629 British National Formulary for Children (BNFC) 2017-2018
Related Documents:	None required
Training Need Identified?	No
Publication Location (refer to Policy on Policies – Approvals and Ratification):	Internet and Intranet
Document Library Folder/Sub Folder:	Clinical/ Neonatal

Version Control Table

Date	Version Number	Summary of Changes	Changes Made by
8th March 2018	V1.0	Initial Issue.	Dr Sam Padmanabhan. Consultant Paediatrician and Neonatologist.
19 Dec 2018	V1.1	Modification with definition of chronic lung Disease.	Dr Paul Munyard; Consultant.
01 Aug 2020	V2.0	Review of training required to administer. Stream lining of request process.	S Tierney, Pharmacist.
01 Mar 2022	V2.1	Updated eligibility criteria. Addition of dose banding table.	S Tierney, Pharmacist.
13 Sep 2023	V3.0	Full review and update to include external clinic locations.	S Tierney, Pharmacist.

All or part of this document can be released under the Freedom of Information Act 2000.

All Policies, Strategies and Operating Procedures, including Business Plans, are to be kept for the lifetime of the organisation plus 6 years.

This document is only valid on the day of printing.

Controlled Document.

This document has been created following the Royal Cornwall Hospitals NHS Trust The Policy on Policies (Development and Management of Knowledge Procedural and Web Documents Policy). It should not be altered in any way without the express permission of the author or their Line Manager.

Appendix 2. Equality Impact Assessment

Section 1: Equality Impact Assessment (EIA) Form

The EIA process allows the Trust to identify where a policy or service may have a negative impact on an individual or particular group of people.

For guidance please refer to the Equality Impact Assessment Policy (available from the document library) or contact the Equality, Diversity, and Inclusion Team rcht.inclusion@nhs.net

Information Category	Detailed Information
Name of the strategy / policy / proposal / service function to be assessed:	Palivizumab for Neonatal Chronic Lung Disease and Congenital Heart Disease Clinical Guideline V3.0
Directorate and service area:	Neonatal
Is this a new or existing Policy?	Existing
Name of individual completing EIA (Should be completed by an individual with a good understanding of the Service/Policy):	Neonatal Audit and Guidelines Group
Contact details:	01872 255081

Information Category	Detailed Information
1. Policy Aim - Who is the Policy aimed at? (The Policy is the Strategy, Policy, Proposal or Service Change to be assessed)	Aimed at clinical staff who manage newborns, (midwifery and neonatal staff) who look after babies with chronic lung disease and congenital heart disease.
2. Policy Objectives	Identification of infants at high risk of respiratory syncytial virus.
3. Policy Intended Outcomes	As above.
4. How will you measure each outcome?	Audit.
5. Who is intended to benefit from the policy?	Neonatal Patients.

Information Category	Detailed Information
6a. Who did you consult with? (Please select Yes or No for each category)	• Workforce: Yes • Patients/ visitors: No • Local groups/ system partners: No • External organisations: No • Other: No
6b. Please list the individuals/groups who have been consulted about this policy.	**Please record specific names of individuals/ groups:** Neonatal Audit and Guidelines Group. Child Heath Audit and Guidelines Group.
6c. What was the outcome of the consultation?	Neonatal Audit and Guidelines Group- 05 October 2023. Child Heath Audit and Guidelines Group- 02 October 2023.
6d. Have you used any of the following to assist your assessment?	**National or local statistics, audits, activity reports, process maps, complaints, staff, or patient surveys:** No

7. The Impact

Following consultation with key groups, has a negative impact been identified for any protected characteristic? Please note that a rationale is required for each one.

Where a negative impact is identified without rationale, the key groups will need to be consulted again.

Protected Characteristic	(Yes or No)	Rationale
Age	No	
Sex (male or female)	No	
Gender reassignment (Transgender, non-binary, gender fluid etc.)	No	
Race	No	Any information provided should be in an accessible format for the parent/ carer's needs- i.e., available in different languages if required/ access to an interpreter if required.

Protected Characteristic	(Yes or No)	Rationale
Disability (e.g. physical or cognitive impairment, mental health, long term conditions etc.)	No	Those parent/ carers with any identified additional needs will be referred for additional support as appropriate- i.e., to the Liaison team or for specialised equipment. Written information will be provided in a format to meet the family's needs e.g., easy read, audio etc.
Religion or belief	No	All staff should be aware of any beliefs that may impact on the decision to treat and should respond accordingly.
Marriage and civil partnership	No	All staff should be aware of any marital arrangements that may have an impact on care (for example: separated parents, domestic abuse).
Pregnancy and maternity	No	
Sexual orientation (e.g. gay, straight, bisexual, lesbian etc.)	No	

A robust rationale must be in place for all protected characteristics. If a negative impact has been identified, please complete section 2. If no negative impact has been identified and if this is not a major service change, you can end the assessment here.

I am confident that section 2 of this EIA does not need completing as there are no highlighted risks of negative impact occurring because of this policy.

Name of person confirming result of initial impact assessment: Neonatal Audit and Guidelines Group

If a negative impact has been identified above OR this is a major service change, you will need to complete section 2 of the EIA form available here:
Section 2. Full Equality Analysis

Appendix 3. Palivizumab Authorisation Form

Not to be kept in patient's notes

Patient CR Number:

Name:

DOB:

NHS number:

GP surgery:

Reason for applying for Palivizumab authorisation: Cardiac/ Neonatal/Other

Please state diagnosis:

Reviewed Pali Guideline for eligibility criteria?

Eligible: Yes / No

Additional Comments:

Lead Consultant:

Date:

Please submit this form to Lead Paediatric Pharmacist through your secretary for authorisation group to review request

Outcome: Accepted/ Rejected

Reason for Rejection:

Informed Consultant: Yes/No

For those Accepted:

BlueTeq from filled (for Pali authorisation group to do): Yes /No

Pali clinic notified (for Pali authorisation group to do): Yes/No

Parents and GP notified (through letter): Yes/No