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

V1.1

March 2019
## Summary

<table>
<thead>
<tr>
<th>SETTING</th>
<th>Children with congenital heart disease and neonates with chronic lung disease needing Palivizumab</th>
</tr>
</thead>
<tbody>
<tr>
<td>FOR STAFF</td>
<td>Medical &amp; Nursing staff</td>
</tr>
<tr>
<td>PATIENTS</td>
<td>Paediatric congenital heart disease patients and neonates with chronic lung disease who are eligible for Palivizumab</td>
</tr>
</tbody>
</table>
1. **Aim/Purpose of this Guideline**
Aimed at clinical staff who are involved in managing neonates and infants with chronic lung disease and congenital heart disease

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)
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 Blueteq.

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.

2.3 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.

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.

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 deter administration of palivizumab. If an individual is acutely unwell, immunisation may be postponed until they have fully recovered.

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 (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 anyone competent in administering intramuscular injections. Where ever possible this could be carried out in Primary care in agreement with GP practice to make this easy for the family and minimise trips to hospital. The Paediatrician with expertise in Cardiology and Paediatric Pharmacist will work in conjunction to initiate the process with Primary care. Infants who need to have this administered in hospital will be arranged to come in to an appointment as a palivizumab clinic.

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

<table>
<thead>
<tr>
<th>Element to be monitored</th>
<th>Key Changes to practice</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lead</td>
<td>Dr Sam Padmanabhan</td>
</tr>
<tr>
<td>Tool</td>
<td>Audit</td>
</tr>
<tr>
<td>Frequency</td>
<td>As dictated by audit findings</td>
</tr>
<tr>
<td>Reporting arrangements</td>
<td>Child Health Directorate Audit and Neonatal Clinical Guidelines</td>
</tr>
<tr>
<td>Acting on recommendations and Lead(s)</td>
<td>Dr Sam Padmanabhan Consultant pediatrician and neonatologist</td>
</tr>
<tr>
<td>Change in practice and lessons to be shared</td>
<td>Required Changes in Practice will be identified and actioned within 3 months</td>
</tr>
</tbody>
</table>

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 & Human Rights 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

<table>
<thead>
<tr>
<th>Document Title</th>
<th>Palivizumab For Neonatal Chronic Lung Disease and Congenital Heart Disease Clinical Guideline V1.1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date Issued/Approved:</td>
<td>19&lt;sup&gt;th&lt;/sup&gt; December 2018</td>
</tr>
<tr>
<td>Date Valid From:</td>
<td>March 2019</td>
</tr>
<tr>
<td>Date Valid To:</td>
<td>March 2021</td>
</tr>
</tbody>
</table>
| Directorate / Department responsible (author/owner): | Dr Sam Padmanabhan  
Consultant paediatrician and neonatologist |
| Contact details: | 01872255081 |
| Brief summary of contents | Identification and administration of Palivizumab to at risk babies |
| Suggested Keywords: | Palivizumab RSV Congenital heart disease, chronic lung disease Respiratory syncytial virus |
| Target Audience | RCHT | CFT | KCCG |
| Executive Director responsible for Policy: | Medical Director |
| Date revised: | 19<sup>th</sup> December 2018 |
| This document replaces (exact title of previous version): | Palivizumab For Neonatal Chronic Lung Disease and Congenital Heart Disease Clinical Guideline V1.0 |
| Approval route (names of committees)/consultation: | Neonatal Guidelines Group |
| Divisional Manager confirming approval processes | Debra Shields, Care Group General Manager |
| Name and Post Title of additional signatories | ‘Not Required’ |
| Name and Signature of Divisional/Directorate Governance Lead confirming approval by specialty and divisional management meetings | {Original Copy Signed}  
Name: Caroline Amukusana |
| Signature of Executive Director giving approval | {Original Copy Signed} |
| Publication Location (refer to Policy on Policies – Approvals and) | Internet & Intranet  
☑️ Intranet Only |
Palivizumab For Neonatal Chronic Lung Disease and Congenital Heart Disease Clinical Guideline V1.1

**Ratification):**

**Document Library Folder/Sub Folder**

Clinical / Neonatal

**Links to key external standards**

- The Green book. Respiratory syncytial virus. Chapter 28a

  [http://www.medicines.org.uk/emc/medicine/30629](http://www.medicines.org.uk/emc/medicine/30629)

- British National Formulary for Children (BNFC) 2017-2018

**Related Documents:**

None

**Training Need Identified?**

No

**Version Control Table**

<table>
<thead>
<tr>
<th>Date</th>
<th>Version No</th>
<th>Summary of Changes</th>
<th>Changes Made by (Name and Job Title)</th>
</tr>
</thead>
<tbody>
<tr>
<td>8th March 2018</td>
<td>V1.0</td>
<td>Initial Issue</td>
<td>Dr Sam Padmanabhan Consultant paediatrician and neonatologist</td>
</tr>
<tr>
<td>19 Dec 2018</td>
<td>V1.1</td>
<td>Modification with definition of chronic lung disease</td>
<td>Dr Paul Munyard consultant</td>
</tr>
</tbody>
</table>

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**This document is to be retained for 10 years from the date of expiry.**

**This document is only valid on the day of printing**

** Controlled Document**

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## Appendix 2. Initial Equality Impact Assessment Form

*This assessment will need to be completed in stages to allow for adequate consultation with the relevant groups.*

<table>
<thead>
<tr>
<th>Name of the strategy / policy / proposal / service function to be assessed</th>
<th>Name of individual completing assessment: Consultant paediatrician and neonatologist</th>
<th>Directorate and service area: Women Children and Sexual Health</th>
<th>Is this a new or existing Policy?</th>
<th>Telephone: 01872255081</th>
</tr>
</thead>
<tbody>
<tr>
<td>Palivizumab For Neonatal Chronic Lung Disease and Congenital Heart Disease Clinical Guideline V1.1</td>
<td>Dr Sam Padmanabhan</td>
<td>Women Children and Sexual Health</td>
<td>New</td>
<td></td>
</tr>
</tbody>
</table>

1. **Policy Aim**
   *Who is the strategy / policy / proposal / service function aimed at?*
   - 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**
   - Audit

4. *How will you measure the outcome?*
   - Audit

5. **Who is intended to benefit from the policy?**
   - Neonatal Patients

6a Who did you consult with
   - Workforce
   - Patients
   - Local groups
   - External organisations
   - Other
   - X

**Please record specific names of groups**
- Neonatal Guidelines group

**What was the outcome of the consultation?**
- Guidance approved 19th December 2018
7. The Impact
Please complete the following table. **If you are unsure/don’t know if there is a negative impact you need to repeat the consultation step.**

<table>
<thead>
<tr>
<th>Equality Strands:</th>
<th>Yes</th>
<th>No</th>
<th>Unsure</th>
<th>Rationale for Assessment / Existing Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td></td>
<td>X</td>
<td></td>
<td>No areas indicated</td>
</tr>
<tr>
<td>Sex (male, female, trans-gender / gender reassignment)</td>
<td></td>
<td>X</td>
<td></td>
<td>No areas indicated</td>
</tr>
<tr>
<td>Race / Ethnic communities / groups</td>
<td></td>
<td>X</td>
<td></td>
<td>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</td>
</tr>
<tr>
<td>Disability - Learning disability, physical impairment, sensory impairment, mental health conditions and some long term health conditions.</td>
<td></td>
<td>X</td>
<td></td>
<td>Those parent/carer’s 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</td>
</tr>
<tr>
<td>Religion / other beliefs</td>
<td></td>
<td>X</td>
<td></td>
<td>No areas indicated</td>
</tr>
<tr>
<td>Marriage and Civil partnership</td>
<td></td>
<td>X</td>
<td></td>
<td>No areas indicated</td>
</tr>
<tr>
<td>Pregnancy and maternity</td>
<td></td>
<td>X</td>
<td></td>
<td>No areas indicated</td>
</tr>
<tr>
<td>Sexual Orientation, Bisexual, Gay, heterosexual, Lesbian</td>
<td></td>
<td>X</td>
<td></td>
<td>No areas indicated</td>
</tr>
</tbody>
</table>

You will need to continue to a full Equality Impact Assessment if the following have been highlighted:
- You have ticked “Yes” in any column above and
- No consultation or evidence of there being consultation- this excludes any policies which have been identified as not requiring consultation. or
- Major this relates to service redesign or development

8. Please indicate if a full equality analysis is recommended. **Yes** | **No** | **X**

9. If you are **not** recommending a Full Impact assessment please explain why.

No areas indicated
Keep one copy and send a copy to the Human Rights, Equality and Inclusion Lead
c/o Royal Cornwall Hospitals NHS Trust, Human Resources Department, Knowledge Spa, Truro, Cornwall, TR1 3HD

This EIA will not be uploaded to the Trust website without the signature of the Human Rights, Equality & Inclusion Lead.

A summary of the results will be published on the Trust’s web site.

Signed Dr Paul Munyard

Date 19th December 2018