Based on NHS England's commissioning criteria June 2021

DEFINITION

Palivizumab is a monoclonal antibody produced by recombinant DNA technology used to prevent severe disease caused by Respiratory Syncytial Virus (RSV)

INDICATIONS

High risk – bronchopulmonary dysplasia (BPD) [also known as chronic lung disease (CLD)]

- Moderate or severe BPD in preterm babies defined as:
- preterm babies with compatible X-ray changes who continue to receive supplemental oxygen or respiratory support at 36 weeks' post-menstrual age and
- in the shaded area in Table 1 (age on 1st October)
- Babies with respiratory disease who are not necessarily preterm but are aged <2 yr and who remain on
 oxygen on 1st October are considered to be at higher risk. This may include those with conditions
 including:
- pulmonary hypoplasia due to congenital diaphragmatic hernia
- other congenital lung abnormalities (sometimes involving heart disease or lung malformation)
- interstitial lung disease; including those receiving long-term ventilation at the start of the season

Table 1: Chronological age cut off for palivizumab

	Gestational age at birth (whole weeks)						
Chronological age (months)	≤24 ⁺⁰	24 ⁺¹ -26 ⁺⁰	26 ⁺¹ -28 ⁺⁰	28 ⁺¹ -30 ⁺⁰	30 ⁺¹ -32 ⁺⁰	32 ⁺¹ -34 ⁺⁰	>34 ⁺¹
<1.5							
1.5 to <3							
3 to <6							
6 to <9							
≥9							

High risk congenital heart disease (CHD) defined as:

- Preterm babies with haemodynamically significant, acyanotic CHD at the chronological ages on 1st
 October and gestational ages covered by light grey shaded area in Table 1
- Cyanotic or acyanotic CHD plus the following significant co-morbidities, particularly if multiple organ systems are involved:
- Down's syndrome
- preterm delivery (<35 weeks)
- CLD
- pulmonary hypertension
- immune deficiency DiGeorge, combined immune-deficiency
- heart failure diuretic therapy, oral inotropic therapy
- cyanosis with SpO₂ <85%
- those due transplantation or cardiac surgery

The following co-morbidities are NOT acceptable under the guidance (little/no evidence for RSV prophylaxis)

- Haemodynamically insignificant CHD (no therapy)
- Repaired CHD
- Arrhythmias
- Recovered from CLD
- Children aged >2 yr

Children with severe defects in cell-mediated immunity

 Children aged <2 yr who have severe combined immunodeficiency syndrome (SCID) until immune reconstituted

Children on long-term ventilation (LTV)

• Children aged <2 yr on LTV are eligible if on air entrained LTV at the start of the season

PROCEDURE

• Consultant will complete **Blueteq** form for each patient meeting the criteria above

PALIVIZUMAB • 2/2

- if the consultant considers a baby outside of the above criteria would benefit from palivizumab treatment, an application for approval to be made through the regional individual funding request process
- 5 doses monthly in RSV season at the beginning of October, November, December, January and February. If the RSV season is prolonged the course may be extended to a maximum of 7doses in total
- give appointment for subsequent doses at palivizumab clinic (if held)
- where possible, administer first dose before start of RSV season
- 15 mg/kg by IM injection into antero-lateral aspect of thigh
- Order palivizumab injection from local community or hospital pharmacy (this can take some days)
- Palivizumab must be stored at 2–8°C. Full administration instructions are provided in the 'Summary of product characteristics' (SPC)
- Split between 2 sites if >1 mL (final concentration when reconstituted 100 mg/mL)

DOCUMENTATION

- After immunisation, document the following in case notes as well as in Child Health Record (Red Book):
- consent gained from parents
- vaccine given and reasons for any omissions
- site of injection(s) in case of any reactions
- batch number of product(s)
- expiry date of product(s)
- legible signature of person administering immunisations
- adverse reactions
- Sign treatment sheet
- Update problem sheet with date and immunisations given
- Document all information on discharge summary and medical case notes including recommendations for future immunisations and need for any special vaccinations, e.g. influenza, palivizumab, etc.