PALIVIZUMAB

Based on Chapter 27a of Green Book
(Note that Nirsevimab is first line for RSV from September 2025)

DEFINITION

Palivizumab is a humanised 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 light and dark shaded area in **Table 1** (at start of RSV season 1st October)
- Babies with respiratory disease who are not necessarily pre-term but are aged <2 yr and who remain on oxygen at start of RSV season 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;
- **and** including those receiving long-term ventilation at the start of the season

High risk congenital heart disease (CHD) defined as:

- Preterm babies with haemodynamically significant, acyanotic CHD at the chronological ages at the start of RSV season 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 syndrome
- preterm delivery (<35 weeks)
- BPD/CLD
- pulmonary hypertension
- immune deficiency – DiGeorge, combined immune-deficiency
- heart failure – diuretic therapy, oral inotropic therapy
- cyanosis with SpO_2 <85%
- those due transplantation or cardiac surgery

Children with severe combined immunodeficiency syndrome (SCID)

- Children aged <2 yr who have SCID until immune reconstituted

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							

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 BPD
- Children aged >2 yr

PROCEDURE

- Identify babies eligible for palivizumab prophylaxis at discharge from NNU – document in discharge summary
- Babies eligible for palivizumab will also be eligible for annual influenza vaccination if aged >6 months by early October
- advise GP in advance to include in annual influenza vaccination programme
- inform parents of benefits and risks of prophylaxis at follow-up clinics before RSV season
  - provide leaflet and discussion with consultant and neonatal community outreach team (NCOT)
  - obtain verbal consent
- Consultant will complete **Blueteq** form for each patient meeting the criteria above
- if the consultant considers a baby outside of the above criteria would benefit from palivizumab treatment, an application for approval should be made through the regional individual funding request process
- Paediatric cardiology team at Birmingham Children's Hospital will:
- identify late preterm/term babies with CHD meeting criteria for prophylaxis
- complete **Blueteq** form
- notify local team (including **Blueteq** approval number)
- 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 7 doses 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