NIRSEVIMAB

Based on Chapter 27a of Green Book

DEFINITION

- Nirsevimab is a humanised monoclonal antibody indicated for the prevention of respiratory syncytial virus (RSV) lower tract respiratory disease
- It is the recommended first-line immunisation for RSV
- only use palivizumab where nirsevimab not available
- Nirsevimab has an extended half-life, duration of protection is at least 5 months after a single dose

INDICATIONS

Selective immunisation of very/extremely preterm babies

- Babies aged <1 yr, born <32 weeks' gestation to receive a single dose of nirsevimab during/preceding their first RSV season (outside of NNU setting) with potential exposure to RSV
- if they were NNU inpatient during their first season this may be the second season of baby's life

Selective immunisation for high-risk babies and children

Babies with chronic lung disease (CLD), also known as bronchopulmonary dysplasia (BPD)

- Preterm babies with compatible X-ray changes who continue to receive supplemental oxygen or respiratory support at 36 weeks' post-menstrual age **and**
- at ages covered 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 preterm but are aged <1 yr and remain on oxygen at start of RSV season, 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)

- 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**
- Babies (aged <1 yr) with cyanotic or acyanotic congenital heart disease **plus** significant co-morbidities (particularly if multiple organ systems are involved) for their first RSV season

Children with severe combined immunodeficiency syndrome (SCID)

- Children aged <2 yr with SCID until immune reconstituted

- Most babies meeting the high-risk eligibility will also be eligible under the very and extremely preterm selective immunisation programme
- Only a single dose of nirsevimab is required for protection in a season
- Offer RSV immunisation regardless of whether the mother was vaccinated during pregnancy

Table 1: Chronological age cut off for nirsevimab

	Gestational age at birth (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–<3							
3–<6							
6–<9							
≥9							

- Light grey shaded area denotes eligibility for premature babies with haemodynamic significant CHD
- Light and dark shaded areas denote eligibility for preterm babies with CLD

PROCEDURE

- Identify babies eligible for nirsevimab prophylaxis before discharge from NNU – document in discharge summary
- If baby first discharged mid-September to end of February, give nirsevimab whilst inpatient
- recommended **1 week before discharge** (or transfer to non-NNU setting) to ensure adequate absorption
- If baby newly identified as high-risk (see above) during the season (up to end of February) give single dose
- If baby transferring to another NNU, immunisation not required before transfer due to low risk of RSV
- document clearly in discharge summary
- Identify babies eligible for nirsevimab prophylaxis who are discharged from the start of March to mid-September and invite to outpatient immunisation scheduled at the start of RSV season
- pre-season clinics between mid-September to mid-October
- document in discharge letter
- Provide information leaflet and obtain verbal consent from parents/carers
- Consultant to complete **Blueteq** form for babies meeting the criteria above
- 4 different forms are available; babies:
  - with BPD
  - with CHD
  - with SCID
  - born very or extremely prematurely (<32 weeks' gestation)
- if baby eligible based on the high-risk criteria, use the corresponding **Blueteq** form [not the preterm (<32 weeks' gestation) form]
- if consultant considers a baby outside of the above criteria would benefit from nirsevimab treatment, an application for approval should be made through the regional individual funding request process

ADMINISTRATION

- Babies <5 kg: 50 mg as single IM injection using 50 mg/0.5 mL pre-filled syringe
- Babies ≥5 kg: 100 mg as a single IM injection using 100 mg/1 mL pre-filled syringe
- IM injection preferably in anterolateral aspect of thigh
- Can be administered concomitantly with injectable vaccines; give in separate syringes and at different injection sites
- Rash may occur within 14 days of dose being given, may cause pyrexia and injection site reactions. If serious hypersensitivity reactions occur immediately discontinue
- Use with caution in babies with thrombocytopenia or any coagulation disorder
- Must be stored in fridge (2–8°C)
- Full administration instructions are provided in the 'Summary of product characteristics'

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

Nirsevimab must be accurately recorded and coded in the patient record under the NHS RSV Passive Immunisation Programme: SNOMED code 117089007