East of England Neonatal ODN
(Hosted by Cambridge University Hospitals)

Clinical Guideline: Respiratory Syncytial Virus (RSV) immunisation guideline

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Date of meeting	

Respiratory Syncytial Virus (RSV) Immunisation

1. Introduction

RSV is a common cause of respiratory tract infections. It usually causes a mild self-limiting respiratory infection in adults and children, but it can be severe in infants and older adults who are at increased risk of acute lower respiratory tract infection (LRTI), including bronchiolitis in infants.
Predisposing clinical risk factors for severe RSV disease amongst infants include congenital heart disease, chronic lung disease, chromosomal abnormalities, neuromuscular disorders, large airway abnormalities, and immunodeficiency, particularly multimorbidity.
In children considered high risk due to prematurity or chronic respiratory disease, hospitalisation with RSV has a risk of death of around 3%. Compared to full-term infants, those born very prematurely (<32 weeks) are three times more likely to be admitted and ten times more likely to need critical care due to RSV.

RSV monoclonal antibody immunisation using palivizumab was first approved for use in infants in European countries in 1999, providing passive protection. Its high cost and moderate effectiveness meant that cost-effectiveness was only demonstrated for high-risk infants. The UK selective immunisation programme has been led in secondary care by paediatric services.

Clesrovimab (Enflonsia®) and nirsevimab (Beyfortus®), are both approved by the MHRA for the prevention of RSV LRTI in infants. Clesrovimab and nirsevimab are recombinant monocolonal antibody with an extended half life and a duration of protection of at least 5 months following a single dose.

The Joint Committee on Vaccination and Immuisation (JCVI) has advised that high risk infants and young children receive either nirsevimab (February 2023 advice) or clesrovimab (October 2025 advice), or palivizumab if neither first line monoclonal antibody immunisation is available.

JCVI has advised (2024 and 2025) that in a universal programme of maternal vaccination, clesrovimab or nirsevimab immunisation should be considered for very and extremely preterm infants (born before 32 weeks), who are unlikely to benefit from maternal vaccination, to be offered in or immediately preceding their first RSV season.

NHSE have approved both the use of clesrovimab and nirsevimab from the RSV season 2026-27.

2. Recommendations for the use of RSV monocolonal antibodies

Criteria for use of RSV monoclonal antibody medicines (clesrovimab and nirsevimab) are published in the Green Book: Immunisation against infectious disease, based on JCVI recommendations. The drugs are funded by NHSE and therefore must only be used in line with the commissioning criteria defined by NHSE each season. The aim of the RSV immunisation programme is to lower the incidence and severity of RSV LRTI in:

- infants, through maternal vaccination as part of the routine immunisation schedule.
- very and extremely preterm infants (born <32 weeks gestation) through selective immunisation.
- Infants (under 12 months of age) and young children at high risk of severe RSV disease through selective immunisation

Current criteria for use of clesrovimab and nirsevimab includes

a) Selective immunisation of very and extremely preterm infants

To reduce the risk of severe disease, infants born very or extremely prematurely (less than 32 weeks) are recommended to receive a single dose of either clesrovimab (Enflonsia®) or nirsevimab (Beyfortus®) during or preceding their first RSV season.

- Typically, infants being discharged from hospital for the first time between mid-September and the end of February should be immunised with either clesrovimab or nirsevimab whilst an inpatient. ***It is important to note that babies who remain an infant on a neonatal unit are not commissioned to receive clesrovimab or nirsevimab as an inpatient until there is a clear imminent plan for discharge home. In most cases for infants on a neonatal unit the dose should be administered 1 week before the planned discharge date.***
- Those leaving hospital for the first time from the start of March to first half of September (preceding an RSV season) should be invited for outpatient immunisation scheduled in the second half of September or first half of October.

b) Selective immunisations for high risk infants and young children.

To reduce the risk of severe disease, eligible high-risk infants and young children are recommended to receive RSV monoclonal antibody immunisation seasonally. This should be offered regardless of whether the mother was vaccinated during the pregnancy.

- Typically, infants being discharged from hospital for the first time between mid-September and the end of February, during the RSV season, should be immunised with either clesrovimab or nirsevimab while an inpatient. ***It is important to note that babies who remain an infant on a neonatal unit are not commissioned to receive clesrovimab or nirsevimab as an inpatient until there is a clear imminent plan for discharge home. In most cases for infants on a neonatal unit the dose should be administered 1 week before the planned discharge date.***
- Those leaving hospital of the first time from the start of March to first half of September (preceding an RSV season) should be invited for outpatient immunisation scheduled in the second half of September or first half of October

All children in the following high-risk groups (Box 1) are recommended to receive RSV monoclonal antibody immunisation with either clesrovimab or nirsevimab (or palivizumab if long acting monoclonal antibody is unavailable). Note that most of the infants meeting the high risk eligibility will also be eligible under the very and extremely preterm selective immunisation programme: only a single dose of clesrivomab or nirsevimab is required for protection in a season.

Box 1

High Risk due to chronic lung disease of prematurity (CLD), also known as bronchopulmonary dysplasia (BPD)

Pre-term infants who have moderate or severe CLD. Moderate or severe CLD 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'.[1] Children who fall into the light and dark red shaded area of Table 1 should be offered prophylaxis

Infants (children less than 12 months of age) 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 (LTV) at the onset of the season.[2]

High Risk due to Congenital Heart Disease (CHD)

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 red shaded area in Table 1.

Infants (children less than 12 months of age) with cyanotic or acyanotic CHD plus significant co-morbidities particularly if multiple organ systems are involved.

High Risk due to Severe Combined Immunodeficiency Syndrome (SCID)

Children less than 24 months of age with SCID – the most severe form of inherited deficiency of immunity, who are unable to mount either T-cell responses or produce antibody against infectious agents – until immune reconstituted.

Table 1: Recommended use of monoclonal antibodies in risk patients by gestational age

	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							

Light red shaded area denotes eligibility for premature infants with haemodynamically significant acynanotic congenital heart disease; light or dark red areas denote eligibility for preterm infants with chronic lung disease. See text in box 1 for further details including eligibility for other conditions. Note that most infants under consideration for eligiblity in this table are also eligible through the very and extremely preterm criteria.

3. Identification of patients requiring RSV immunisation

a) The following patients, coming into their **first** RSV season in the community, should be identified to receive a pre-season catch up dose of clesrovimab or nirsevimab from mid-Sept (and to be administered by mid-October).

- Identify infants born <32 weeks gestation from the previous September who were not discharged from hospital until after March.

b) Identify any patients in the high risk groups in box 1 and arrange to receive a dose of either clesrovimab or nirsevimab in the pre-season clinic from mid-Sept (and to be administered by mid-Oct)

c) During September to end of February (of current season), identify any inpatient infants born <32 weeks gestation and any inpatient infants in the high risk groups (box 1), that are planned for discharge and administer a single dose of either clesrovimab or nirsevimab prior to discharge.

NOTE: Inpatients on a neonatal unit are not commissioned to receive a dose of clesrovimab or nirsevimab until they are ready for discharge. National consensus is that these infants are of low risk of catching RSV whilst in a neonatal unit. In most cases for infants on a neonatal unit the dose should be administered 1 week before the planned discharge date.

4. Use of Blueteq to register prior approval use of clesrovimab or nirsevimab with NHSE

Any patients that receive either clesrovimab or nirsevimab, **must** be registered via Blueteq and meet the clinical criteria on the registration form.

4 different Blueteq forms for use of each drug are available.

- Infants with bronchopulmonary dysplasia
- Infants with congenital heart disease
- Infants with severe combined immunodeficiency syndrome
- Infants born very or extremely prematurely (<32 weeks gestation)

If a patient meets the high risk group patient criteria (box 1) then the appropriate form for that indication should be used in preference to the form for infants born <32 weeks gestation. The <32 weeks gestation form must only be used if the neonatal only meets this criteria for use.

Please ensure that the infant's weight, gestational age (at birth) and chronological age is included in the Blueteq registration.

5. Prescribing and administration information

5.1 Clesrovimab

5.1.1 Presentation

Clesrovimab is supplied as a 105mg in 0.7mL pre-filled syringe

Pre-filled syringes should be stored in a fridge (2 – 8ºC)

Pre-filled syringes can be kept at room temperature (20 – 25oC) when protected from light for a maximum of 48 hours. After which time the syringe must be discarded.

5.1.2 Dose

For all infants: 105mg as a single intramuscular dose

5.1.3 Administration

Select 105mg/0.7mL pre-filled syringe

Visually inspect the product for particulate matter and discoloration prior to administration. The medicinal product is a clear to opalescent, colourless to yellow solution.

Do not inject if the liquid is cloudy, discoloured, or it contains large particles of foreign particulate matter.

Do not use if the pre-filled syringe has been dropped or damaged.

Step 1: Hold the syringe barrel in one hand and unscrew the tip cap by twisting it counter-clockwise with the other hand. Do not remove the Luer lock adaptor and the finger flange extender.

Step 2: Attach a sterile Luer lock needle by twisting in a clockwise direction until the needle fits securely on the syringe. If not provided, due to the viscosity of the product, use a 25 gauge or larger needle.

Step 3: Inject the entire contents of the pre-filled syringe intramuscularly, in the anterolateral aspect of the thigh. The medicinal product should not be injected in the gluteal area or areas where there may be a major nerve trunk and/or blood vessel.

Step 4: Dispose of the used syringe immediately, together with the needle, in a sharps disposal container or in accordance with local requirements.

5.2 Nirsevimab

5.2.1 Nirsevimab is supplied in either a 50mg in 0.5mL or 100mg in 1mL pre-filled syringe

Pre-filled syringes should be stored in a fridge (2 – 8ºC)

Pre-filled syringes can be kept at room temperature (20 – 25oC) when protected from light for a maximum of 48 hours. After which time the syringe must be discarded.

5.2.2 Dose

For infants <5kg: 50mg as a single intramuscular dose

For infants ≥5kg: 100mg as a single intramuscular dose

5.2.3 Administration

Select appropriate 50mg or 100mg prefilled syringe for the dose prescribed.

Visually inspect the product for particulate matter and discoloration prior to administration. The medicinal product is a clear to opalescent, colourless to yellow solution.
Do not inject if the liquid is cloudy, discoloured, or it contains large particles of foreign particulate matter.

Do not use if the pre-filled syringe has been dropped or damaged.

Step 1: Holding the Luer lock in one hand (avoid holding the plunger rod or syringe body), unscrew the syringe cap by twisting it counter clockwise with the other hand.

Step 2: Attach a Luer lock needle to the pre-filled syringe by gently twisting the needle clockwise onto the pre-filled syringe until slight resistance is felt.

Step 3: Hold the syringe body with one hand and carefully pull the needle cover straight off with the other hand. Do not hold the plunger rod while removing the needle cover or the rubber stopper may move. Do not touch the needle or let it touch any surface. Do not recap the needle or detach it from the syringe.

Step 4: Administer the entire contents of the pre-filled syringe as an 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.

Step 5: Dispose of the used syringe immediately, together with the needle, in a sharps disposal container or in accordance with local requirements.

If two injections are required, repeat steps 1-5 in a different injection site.

5.3 Adverse effects

For both clesrovimab and nirsevimab: -

- Rash occurring within 14 days post dose
- Pyrexia and injection site reactions.
- Serious hypersensitivity reactions following administration have been reported. If signs and symptoms of anaphylaxis or other clinically significant hypersensitivity reaction occur, immediately discontinue administration and initiate appropriate medical products and supportive therapy.

5.4 Cautions

Use clesrovimab and nirsevimab with caution in patients with thrombocytopenia or any coagulation disorder.

5.5 Administration with co-administered vaccines

- Clesroviomab and nirsevimab can be given concomitantly with childhood vaccines.
- Clesroviomab and nirsevimab should not be mixed with any vaccine in the same syringe or vial.
- When administered concomitantly with injectable vaccines, they should be given with separate syringes and at different injection sites.

5.6 Pain relief

Pain relief should also be considered i.e. non-nutritive sucking, sucrose, breast-milk administration and use of paracetamol.

6. Parent / Carer information

The UK Health Security Agency have produced a leaflet for parents and carers. This can be viewed at https://www.gov.uk/government/publications/why-is-my-baby-being-offered-an-rsv-immunisation and should be provided ahead of immunisation

Information for parents on use of paracetamol as a pain relief during immunisation can be found at paracetamol leaflet.

Parents can support their baby during the immunisation process by cuddling them, providing skin to skin, containment holding and talking to their baby.

7. Consent

Parental consent should confirmed and documented before immunisation is undertaken

8. Guidance on the coding and recording of clesrovimab or nirsevimab

RSV immunisation must be correctly recorded and coded in the patient record, and accurately communicated to the individual's GP. The procedure name and procedure code below must be adopted.

SNOMED procedure code advised for the recording of the monoclonal antibody immunisation clesrovimab or nirsevimab:

Programme	Procedure Name	Procedure code - SNOMED
NHS RSV Passive Immunisation Programme	Administration of Respiratory Syncytial virus immune globulin, human (procedure)	117089007

Descriptors and SNOMED codes for the RSV vaccination Abrysvo used for the NHS maternal and older adult RSV programmes MUST NOT be used to record the monoclonal antibody immunisation with clesrovimab or nirsevimab.

It is important that clesrovimab or nirsevimab is not recorded as 'RSV vaccination' or abbreviated to 'RSV immunisation' in infant records where it could be mistakenly interpreted as the RSV vaccine Abrysvo.

Incorrect recording and coding of clesrovimab or nirsevimab can result in unnecessary clinical incident investigation by Trust and general practice providers.

References

Immunisation against infectious disease. UK Health Security Agency. Chapter 27a Respiratory syncytial virus (updated 03/06/2026) https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book

Summary of Product Characteristics: Clesrovimab (Enflonsa®) (last updated 22/06/26) www.medicines.org.uk

Summary of Product Characteristics: Nirsevimab (Beyfortus®) (last updated 21/05/26) www.medicines.org.uk

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Exceptional Circumstances Form

Form to be completed in the **exceptional** circumstances that the Trust is not able to follow ODN approved guidelines.

Details of person completing the form:	
Title:	Organisation:
First name:	Email contact address:
Surname:	Telephone contact number:
Title of document to be excepted from:	
Rationale why Trust is unable to adhere to the document:	
Signature of speciality Clinical Lead: Date:	Signature of Trust Nursing / Medical Director: Date:
Hard Copy Received by ODN (date and sign):	Date acknowledgement receipt sent out:

Please email form to: kelly.hart5@nhs.net requesting receipt.

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