

Grand Round
webinar series

✶RCPCH

RCPCH Grand Round:

RSV immunisation update 2026

3 July 2026



Presenters

Dr Conall Watson, Consultant Epidemiologist, Public Health Infection Programmes - UK Health Security Agency

Professor Chrissie Jones, Professor in Paediatric Immunity and Infection - University of Southampton

Mandy Matthews, Senior Pharmacy Lead, Specialised Commissioning - NHS England

Laura Wilson, Seasonal Vaccination & Strategy Unit Head - Scottish Government

Nigel Gooding, Consultant Pharmacist - Neonates and Paediatrics and Lead Pharmacist - East of England ODN

Chairs - RCPCH Grand Round Faculty

Dr Yincen Tse, RCPCH Vice President for Education and Workforce, Consultant Paediatric Nephrologist, Newcastle Hospitals NHS Foundation Trust

Dr Hina Rizvi, Paediatric Consultant, The Royal Wolverhampton NHS Trust

Agenda

Item	Presenter
Long-acting mabs in the national RSV immunisation programme	<i>Conall Watson, UK Health Security Agency</i>
JCVI advice on clesrovimab	<i>Chrissie Jones, Southampton / JCVI RSV sub-ctte</i>
RSV LA-mabs policy in the UK nations	<i>Mandy Matthews, NHSE Specialised Commissioning Laura Wilson, Scottish Government Written update, Welsh Government Written update, Dept of Health (NI)</i>
Clinical implementation of LA-mabs	<i>Nigel Gooding, Cambridge/EofE ODN</i>
Practicalities of RSV LA-mab admin	<i>Nigel Gooding, Cambridge/EofE ODN</i>
Q&A	<i>All, chaired by Dr Yincen Tse and Dr Hina Rizvi</i>



UK Health
Security
Agency

Infant monoclonal immunisation within the national RSV programme

Conall Watson MPharm PhD FFPH
Consultant Epidemiologist, RSV lead
Immunisation and Vaccine-Preventable Diseases Division

Declaration of interest

Nil personal.

UKHSA's Immunisation and Vaccine-Preventable Diseases Division provides vaccine manufacturers with post-marketing surveillance reports and analyses to support submissions to licensing authorities. A cost recovery charge is made for these reports. This includes Pfizer for RSV and Sanofi for influenza.

Bivalent pre-F maternal vaccination (Abrysvo[®]) is the mainstay of UK infant RSV protection.

It has an ever-growing body of evidence demonstrating excellent safety and high effectiveness.

Ongoing maternal RSV vaccine safety monitoring

Over 500,000 mother-baby dyads followed-up in England. Matched case-control analyses* of preterm birth and extended perinatal mortality show no signal of concern.

No safety signals in Yellow Card reports to MHRA.

*Matched on maternal age, week of start of pregnancy, (and gest week of birth for mortality); adjusted for ethnicity, region, parity, deprivation, severe immunosuppression and maternal risk group status.

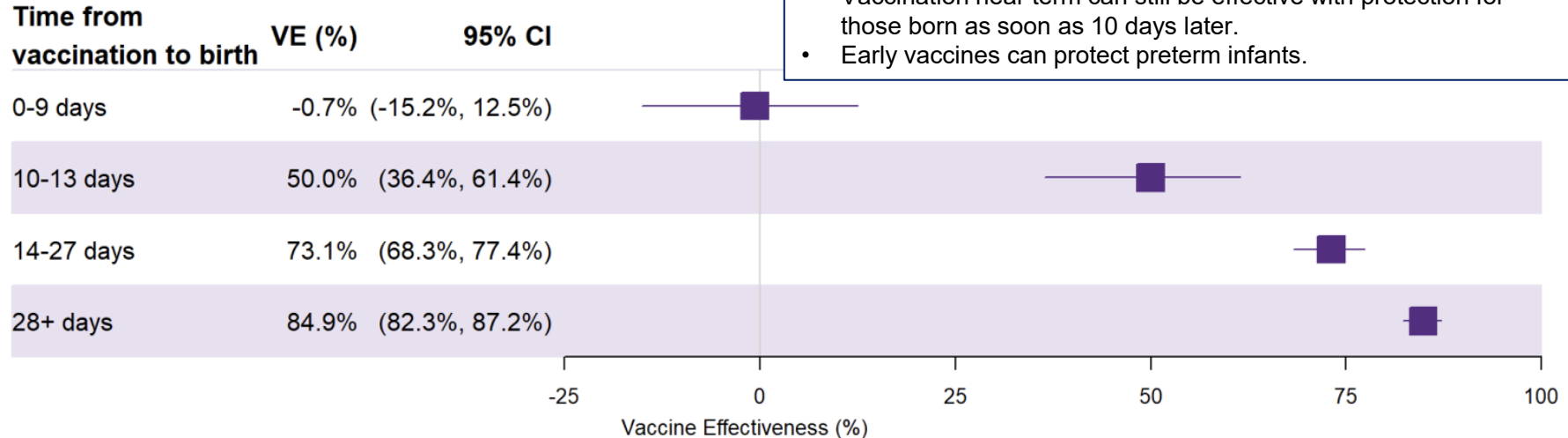
Excellent newborn protection against RSV LRTI admission in an England maternal vaccination cohort

*preliminary,
unpublished*

81.3% (95% CI: 78.9 to 83.4%) effective

The stratified analysis suggests:

- Longer intervals from vaccination to birth may improve protection i.e. ideally give early in approved gestational vaccination windows.
- Vaccination near term can still be effective with protection for those born as soon as 10 days later.
- Early vaccines can protect preterm infants.



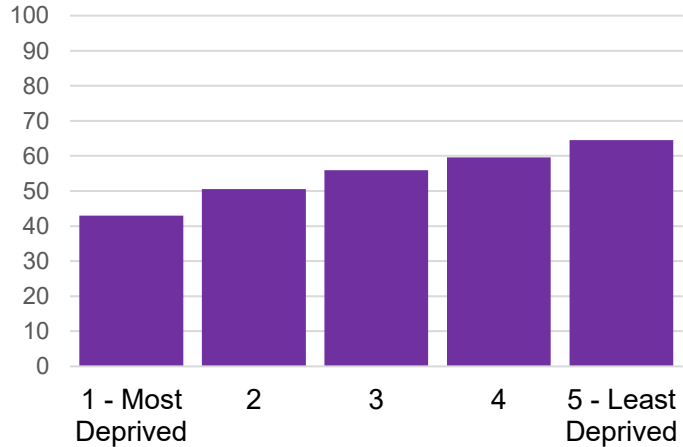
Vaccine effectiveness was **69.4%** (59.0, 77.6) in pre-term babies

Matt Wilson and colleagues, presented at ESCMID [gov.uk/government/news/rsv-maternal-vaccine-cuts-baby-hospital-admissions-by-up-to-85](https://www.gov.uk/government/news/rsv-maternal-vaccine-cuts-baby-hospital-admissions-by-up-to-85)

Adjusted for seasonality, infant age, region and parity.

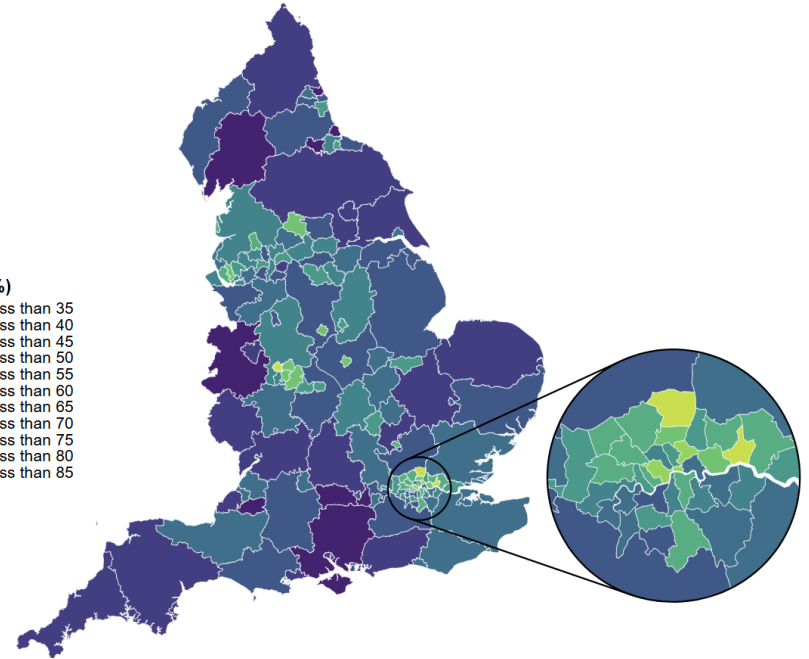
Benefits are not evenly distributed: please support local maternity services vaccinating/signposting pregnant women

Maternal vaccine uptake (%) by Scottish Index of Multiple Deprivation



Vaccine uptake (%)

- 30 to less than 35
- 35 to less than 40
- 40 to less than 45
- 45 to less than 50
- 50 to less than 55
- 55 to less than 60
- 60 to less than 65
- 65 to less than 70
- 70 to less than 75
- 75 to less than 80
- 80 to less than 85



Jan 2026 births protected by RSV vaccination (%), by Local Authority in England
<https://www.gov.uk/government/statistics/respiratory-syncytial-virus-rsv-maternal-vaccination-coverage-in-england>

<https://scotland.shinyapps.io/phs-vaccination-surveillance/>

Current Green Book clinical high-risk groups carry forward previous recommendations

Recommendations for the use of the passive immunisation

The objective of the passive immunisation is to protect ~~at-risk infants for whom RSV infection is likely to cause serious illness or death, and all children less than 24 months of age with severe combined immunodeficiency syndrome (SCID). Based on an analysis of the cost effective use of Palivizumab prophylaxis, Synagis® is recommended for use in all children in the following groups.~~

1. High Risk due to Bronchopulmonary dysplasia (BPD) – (also known as chronic lung disease)
 - a) 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 age¹. Children who fall into the light and dark green shaded area of Table 1 should be offered prophylaxis
 - b) 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

Respiratory
syncytial virus
September 2015

2. High Risk due to Congenital Heart Disease (CHD)
 - a) 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 green shaded area in Table 1.
 - b) Cyanotic or acyanotic CHD plus significant co-morbidities particularly if multiple organ systems are involved.
3. High Risk due to Severe Combined Immunodeficiency Syndrome (SCID)
 - a) 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.

1 Post-menstrual age is calculated by adding the time elapsed between the first day of the last menstrual period to the day of delivery plus the time elapsed from birth.

2 The definition of LTV is 'any child who when medically stable, continues to require a mechanical aid for breathing, after an acknowledged failure to wean three months after the institution of ventilation' (Jardine and Wallis, 1998)

Current Green Book clinical high-risk groups carry forward previous recommendations

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.

- Clesrovimab (Enflonsia™) or nirsevimab (Befortus®) are the recommended first-line immunisations, if available. Choice of long-acting monoclonal antibody may depend on local and national NHS arrangements.
- Palivizumab (Synagis®) is recommended if neither of the first line products is available.

Chronological age (months)	Gestational age at birth (weeks ⁺ days)						
	≤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							

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

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.

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 clesrovimab or nirsevimab (first-line, if available) or palivizumab could be considered during the RSV season.

Child RSV risk groups need systematic clinical evidence: paediatric health professionals are key

- There are limits to analyses based on routinely collected health data*
- Single sub-speciality case series etc do not allow ready comparability across conditions and severities.

Clesrovimab in the UK RSV programme: JCVI assessment

Chrissie Jones

Professor of Paediatric Immunity and Infection
University of Southampton
c.e.jones@soton.ac.uk

Declaration of interest

- Member, JCVI Respiratory Syncytial Virus (RSV) Subcommittee.
 - The views and opinions expressed in this presentation are entirely my own. They do not necessarily reflect the official policy, position, or endorsement of the JCVI, the UK Health Security Agency (UKHSA), or the Department of Health and Social Care.
 - No under-embargo committee data or restricted policy deliberations are disclosed in this presentation.
- I conduct studies on behalf of University of Southampton and University Hospital Southampton NHS Foundation Trust funded by vaccine manufacturers, including Pfizer, Minervax and Moderna,, but receive no personal funding from these sources.

JCVI assessment, October 2025

“Overall, the data presented indicated that **clesrovimab was likely to be as good as nirsevimab in terms of efficacy and safety** although here had been no head-to-head studies comparing the two products.

The sub-committee had advised that **clesrovimab and nirsevimab should be treated as equivalent products** for the selective immunisation programme.

The products could also be considered equivalent if there was a competitive tender for a universal programme based JCVI’s previous advice that there was no strong preference between nirsevimab and the maternal RSV vaccine.




The Committee agreed with the advice of the RSV sub-committee.”

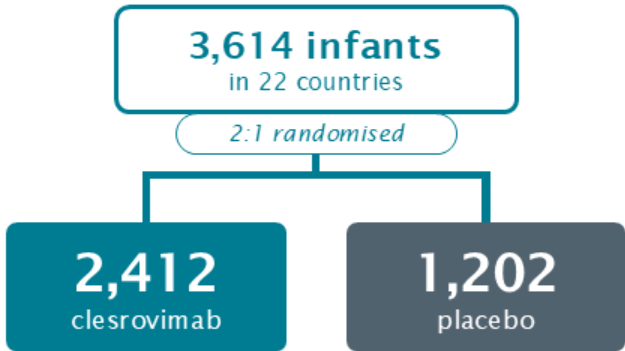
Minutes via gov.uk:

<https://app.box.com/s/iddfb4ppwkmtjusir2tc/file/2044018962188>

Clesrovimab & nirsevimab: phase 3 trial designs




Clesrovimab CLEVER trial

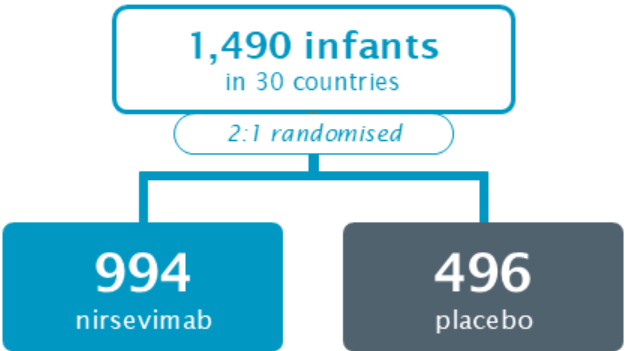
-  Phase 3 — efficacy & safety
-  Healthy infants, ≥ 29 weeks
-  105 mg IM, single dose



Zar NEJM 2025

Nirsevimab MELODY trial

-  Phase 3 — efficacy & safety
-  Healthy infants, ≥ 35 weeks
-  50 mg (<5 kg) / 100 mg (≥ 5 kg) IM



Hammitt NEJM 2022

Clesrovimab & nirsevimab: efficacy endpoints

Clesrovimab CLEVER trial

Outcomes to 150 days:

Primary: RSV associated (PCR+) Medically attended lower respiratory infection (MA LRI) with:

- Cough or difficulty breathing
- AND ≥ 1 of: wheezing, chest-wall retractions, rales or crackles, hypoxemia, tachypnea, or dehydration caused by respiratory symptoms

Secondary: hospitalisation for RSV PCR+ respiratory illness

Outcome to 180 days

- **Secondary:** RSV PCR+ MA LRTI

Nirsevimab MELODY trial

Outcomes to 150 days:

Primary: RSV associated (PCR+) Medically attended lower respiratory infection (MA LRI) with:

- **at least one physical exam finding** of rhonchi, rales, crackles, or wheeze AND
- **at least one of the following clinical signs:**
 - Increased respiratory rate at rest OR
 - Hypoxemia OR
 - Clinical signs of severe respiratory disease
 - (e.g. acute hypoxic or ventilatory failure, new onset apnea, nasal flaring, intercostal, subcostal or supraclavicular retractions, grunting) or dehydration secondary to inadequate oral intake due to respiratory distress

Secondary: hospitalisation for RSV PCR+ MA LRTI

Clesrovimab / nirsevimab: results

Clesrovimab CLEVER trial

RSV Outcome	Endpoint	Efficacy (95%CI)
MA LRI 150d	Primary	60.4 (44.1 to 71.9)
MA LRI 150d 2+ indicators	<i>Post-hoc</i> MELODY-aligned	88.0 (76.1 to 94.0)
Respiratory hospitalisation 150d	Secondary	84.2 (66.6 to 92.6)
MA LRTI 180d	Secondary	59.5 (43.3 to 71.1)
Arm	Deaths (%)	
Mab	7 (0.29%)	
Placebo	3 (0.25%)	

Nirsevimab MELODY trial

RSV Outcome	Endpoint	Efficacy (95%CI)
MA LRTI 150d	Primary	74.5 (49.6 to 87.1)
Hospitalisation MA LRTI 150d	Secondary	62.1% (-8.6 to 86.8)
Arm	Deaths (%)	
Mab	3 (0.30%)	
Placebo	0	

CLEVER trial, all efficacy endpoints

A Efficacy through 150 Days (5 mo) after Injection

RSV-Associated End Point	End-Point Designation	Clesrovimab (N=2398)		Placebo (N=1201)		No. Needed to Immunize (95% CI)	Efficacy (95% CI)		
		Total No. of cases	Total follow-up time Incidence rate	Total No. of cases	Total follow-up time Incidence rate				
		mo	percent	mo	percent		percent		
Severe medically attended LRI	Tertiary	2	11,882.0	0.1	12	5906.4	1.0	108 (60–226)	91.7 (62.9–98.1)
Hospitalization for LRI	Tertiary	5	11,874.1	0.2	27	5862.8	2.3	48 (32–76)	90.9 (76.2–96.5)
Hospitalization	Secondary	9	11,864.8	0.4	28	5859.0	2.4	50 (33–84)	84.2 (66.6–92.6)
Medically attended LRI with ≥2 indicators of LRI or disease severity	Post hoc	10	11,855.2	0.4	41	5810.8	3.5	33 (24–48)	88.0 (76.1–94.0)
Medically attended LRI with ≥1 indicator of LRI or disease severity	Primary	60	11,685.6	2.6	74	5710.5	6.5	26 (18–42)	60.4 (44.1–71.9)
Acute respiratory infection	Tertiary	148	11,387.7	6.5	148	5467.3	13.5	15 (11–21)	52.0 (39.5–61.9)

B Efficacy through 180 Days (6 mo) after Injection

RSV-Associated End Point	End-Point Designation	Clesrovimab (N=2398)		Placebo (N=1201)		No. Needed to Immunize (95% CI)	Efficacy (95% CI)		
		Total No. of cases	Total follow-up time Incidence rate	Total No. of cases	Total follow-up time Incidence rate				
		mo	percent	mo	percent		percent		
Severe medically attended LRI	Tertiary	2	14,226.1	0.1	12	7072.2	1.0	108 (60–225)	91.7 (62.9–98.1)
Hospitalization for LRI	Tertiary	5	14,215.2	0.2	28	7012.7	2.4	46 (31–72)	91.2 (77.2–96.6)
Hospitalization	Tertiary	11	14,201.1	0.5	29	7007.8	2.5	50 (33–85)	81.3 (62.5–90.7)
Medically attended LRI with ≥2 indicators of LRI or disease severity	Post hoc	11	14,190.9	0.5	42	6947.5	3.6	32 (23–47)	87.2 (75.1–93.4)
Medically attended LRI with ≥1 indicator of LRI or disease severity	Secondary	64	13,970.8	2.7	77	6813.6	6.8	25 (18–40)	59.5 (43.3–71.1)
Acute respiratory infection	Tertiary	161	13,580.4	7.1	154	6495.0	14.2	15 (11–21)	50.0 (37.4–60.1)

Efficacy maintained at 6 months

Nirsevimab phase 3B and post-marketing

HARMONIE

Drysdale NEJM 2023

1:1 infants 29wk+ in GB FR DE
(4037 vs 4021)

Primary: hospitalised RSV LRTI:
83.2% (95%CI: 67.8 to 92.0)

Secondary: severe, above with
sats<90%, needing supp. oxygen:
75.7% (32.8 to 92.9)

Observational RWE SR MA

Lee Thorax 2025

Effectiveness against confirmed RSV
clinical endpoints:

- 80.7% (95%CI: 75.7% to 85.7); ED visits; seven studies
- 80.7% (76.1% to 85.2%) against hospital admissions; 17 studies
- 75.6% (63.3% to 87.9%) against ICU admissions; eight studies.

Consistent with SR MA by Sumsuzzman *et al* Jun 2025 Lancet Child Adoles H

Clesrovimab: safety in CLEVER Study

Adverse Event	Clesrovimab (N=2409) <i>no. of infants (%)</i>	Placebo (N=1202)	Estimated Difference (95% CI) [‡] <i>percentage points</i>
Overall adverse events [‡]			
Any adverse event			
≥1 Adverse event	1861 (77.3)	932 (77.5)	-0.3 (-3.1 to 2.7)
Related to clesrovimab or placebo	696 (28.9)	344 (28.6)	0.3 (-2.9 to 3.4)
Any serious adverse event	278 (11.5)	149 (12.4)	-0.9 (-3.2 to 1.3)
Related to clesrovimab or placebo	1 (<0.1)	1 (0.1)	0.0 (-0.4 to 0.2)
Death [§]	7 (0.3)	3 (0.2)	0.0 (-0.5 to 0.4)
Solicited adverse event or fever on days 1–5 after inj			
Injection-site reaction			
Erythema	274 (11.4)	141 (11.7)	-0.4 (-2.6 to 1.8)
Pain	107 (4.4)	43 (3.6)	0.9 (-0.6 to 2.2)
Swelling	156 (6.5)	96 (8.0)	-1.5 (-3.4 to 0.2)
Solicited systemic adverse event	77 (3.2)	38 (3.2)	0.0 (-1.3 to 1.2)
Decreased appetite	726 (30.1)	375 (31.2)	-1.1 (-4.3 to 2.1)
Irritability	131 (5.4)	73 (6.1)	-0.6 (-2.3 to 0.9)
Somnolence	517 (21.5)	264 (22.0)	-0.5 (-3.4 to 2.3)
With fever	333 (13.8)	192 (16.0)	-2.2 (-4.7 to 0.3)
	13 (0.5)	14 (1.2)	-0.6 (-1.4 to -0.0)
Adverse event of special interest on days 1–42 after inj			
Anaphylaxis or hypersensitivity	1 (<0.1)	0	0.0 (-0.3 to 0.2)
Rash	11 (0.5)	4 (0.3)	0.1 (-0.4 to 0.5)

Adverse events similar in clesrovimab arm and placebo arms.
No deaths considered related

Clesrovimab: SMART study

- Phase 3 safety trial in **high-risk infants**, >100 sites in 29 countries
- Population: **palivizumab-eligible** infants <1 year born prematurely (≤ 35 weeks) with CLD, hemodynamically significant congenital heart disease, and entering their first RSV season.
- Intervention: randomly assigned in a 1:1 ratio to single 105-mg dose of clesrovimab or monthly palivizumab
- Primary objectives: **safety and tolerability**

SMART safety

Adverse Event	Clesrovimab (N=445) <i>number of infants (percent)</i>	Palivizumab (N=450)	Estimated Difference (95% CI) [‡] <i>percentage points</i>
All adverse events			
Any adverse event			
≥1 Adverse event	335 (75.3)	358 (79.6)	-4.3 (-9.8 to 1.2)
Drug-related [‡]	141 (31.7)	163 (36.2)	-4.5 (-10.7 to 1.7)
Serious adverse events			
Any	99 (22.2)	112 (24.9)	-2.6 (-8.2 to 2.94)
Drug-related [‡]	0	2 (0.4)	-0.4 (-1.6 to 0.4)
Deaths [§]	8 (1.8)	4 (0.9)	0.9 (-0.7 to 2.7)
Solicited adverse events or fever			
Injection-site adverse events			
Erythema	69 (15.5)	76 (16.9)	-1.4 (-6.2 to 3.5)
Pain	31 (7.0)	27 (6.0)	1.0 (-2.3 to 4.3)
Swelling	35 (7.9)	51 (11.3)	-3.5 (-7.4 to 0.4)
Pain	29 (6.5)	24 (5.3)	1.2 (-2.0 to 4.4)
Systemic adverse events			
Decreased appetite	180 (40.4)	195 (43.3)	-2.9 (-9.3 to 3.6)
Irritability	59 (13.3)	59 (13.1)	0.1 (-4.3 to 4.6)
Somnolence	133 (29.9)	154 (34.2)	-4.3 (-10.4 to 1.8)
With fever	88 (19.8)	103 (22.9)	-3.1 (-8.5 to 2.3)
With fever	4 (0.9)	6 (1.3)	-0.4 (-2.1 to 1.1)
Adverse events of special interest			
Anaphylaxis or hypersensitivity	0	0	0.0 (-0.8 to 0.9)
Rash	3 (0.7)	1 (0.2)	0.5 (-0.6 to 1.8)

Adverse events similar in clesrovimab arm and placebo arms
 No deaths considered related

Summary

- A single intramuscular dose of **either Clesrovimab or Nisrevimab is safe and provide significant protection** against RSV-associated lower respiratory infections across a range of disease severities in the first RSV season



JCVI advice, published in the Green Book

Immunisation against infectious disease

3 June 2026

Respiratory syncytial virus

JCVI has advised that high risk infants and young children (see later) 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.

RSV Immunisation update 2026/27 - England

Mandy Matthews, Senior Pharmacy Lead
(Specialised commissioning, NHS England)

3 July 2026



Policy position in England

In line with the Green Book, NHS England will commission clesrovimab and nirsevimab for

- very and extremely preterm infants (born before 32 weeks gestation)
- infants and young children at high risk of severe RSV disease, due to:
 - Chronic Lung Disease of prematurity (CLD), also known as bronchopulmonary dysplasia (BPD) (children less than 12 months of age)
 - Congenital Heart Disease (CHD) (children less than 12 months of age)
 - Severe Combined Immunodeficiency Syndrome (SCID) (Children less than 24 months of age)
- Both drugs are available on a Medicines Procurement and Supply Chain framework
- Both drugs are reimbursed in the fixed 'block' allocation
- Communications to regional commissioners and providers will follow this webinar

Supply:

- Clesrovimab:
 - Phased supply from July to December 2026, via Alliance Healthcare
 - Order accordingly
- Nirsevimab:
 - French packaged stock, bagged with an English leaflet, will be used initially for 100mg vials (to use up supply from last year)
 - English 100mg vials available once French stock used up
 - Stock will be distributed across the Phoenix network



Prior Approval (Blueteq)

- Four forms for clesrovimab
- Four forms for nirsevimab
- If the individual meets the criteria for one of the high-risk cohorts (BPD, CHD or SCID) ensure the relevant prior approval form is submitted
- Only complete the very/extremely preterm prior approval form if none of the high-risk forms are relevant
- Forms will be enabled 1 August 2026
- Prior approval data is used for analysis and may inform future procurement requirements, so please use correct form for 26/27 and include
 - Infant's chronological age (at time of treatment)
 - Infant's gestational age (at birth in weeks + days)



Sample prior approval form (England)

26/27 NHS England - Initial Funding Application - Clesrovimab to reduce the risk of respiratory syncytial virus (RSV) in infants with severe combined immunodeficiency syndrome (SCID) for the 26/27 season

1. I confirm the patient is under the age of 24 months and has severe combined immunodeficiency syndrome (SCID)

Note: clesrovimab is licenced for neonates and infants so use in children aged >12 months to 24 months is off-label therefore Trust policy regarding unlicensed medicines should apply.

2. Please record the following information:

Infant's weight:

Infant's chronological age (at time of treatment):

Infant's gestational age (at birth in weeks + days):

3. I confirm that the patient will be treated in line with the Green Book



Sample prior approval form (England)

(26/27) NHS England - Initial Funding Application – xxxxx to reduce the risk of severe respiratory syncytial virus (RSV) disease in infants born very or extremely prematurely

1. I confirm that the infant was born very or extremely prematurely (less than 32 weeks).

Please note that separate prior approval forms should be used for clesrovimab used in infants with bronchopulmonary dysplasia (also known as chronic lung disease of prematurity), infants with congenital heart disease or infants with severe combined immunodeficiency syndrome

2. I confirm that the infant (defined as less than 12 months age) is receiving a dose of clesrovimab during or preceding their first RSV season 3. Please record the following information:

Infant's weight:

Infant's chronological age (at time of treatment):

Infant's gestational age (at birth in weeks + days):

4. I confirm that the patient will be treated in line with the Green Book

Scotland - Winter 2026

- Scotland's tender for RSV MABS in train, managed by NHS Public Service Delivery Scotland (PSDS)
- Tender due to conclude shortly
- Outcome of tender and associated implications for delivery will be communicated to the system at the nearest available opportunity
- Update to the programme Chief Medical Officer (CMO) letter, upon conclusion of the tender
- SLWG meets next week to discuss programme delivery – includes paediatric & neonatal specialists from across Scotland
- Programme eligibility & delivery as per winter 2025/26



Scottish Government
Riaghaltas na h-Alba
gov.scot

Wales

Clesrovimab and Nirsevimab will both be available through the NHS Wales medicines framework for purchase from **6th July**.

Orders should be placed in line with advice from the Joint Committee on Vaccination and Immunisation (JCVI), who have advised that high risk infants and young children receive either nirsevimab or clesrovimab.

Eligibility information is contained within the RSV Greenbook chapter.



Llywodraeth Cymru
Welsh Government

Northern Ireland

In Northern Ireland, policy is still in development with relation to the introduction of Clesrovimab for passive immunisation against RSV in at risk infants.

The latest policy information with relation to the introduction of Nirsevimab (2025) is available on the Department of Health website



Department of
Health

An Roinn Sláinte

Mánnystrie O Pousté

Clinical implementation of long-acting monoclonal antibodies

Presented by Nigel Gooding, Consultant Pharmacist
on behalf of Dr Anoo Jain and Dr Thomas Williams

Eligibility; High risk of severe RSV

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 age¹

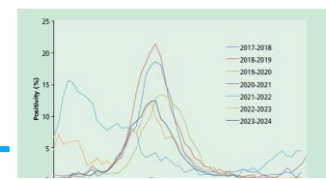
Chronological age (months)	Gestational age at birth (weeks ^{+days})						
	≤24+0	24+1 to 26+0	26+1 to 28+0	28+1 to 30+0	30+1 to 32+0	32+1 to 34+0	≥34+1
<1.5	Light red	Light red	Light red	Light red	Light red	Dark red	Light green
1.5 to <3	Light red	Light red	Light red	Light red	Dark red	Light green	Light green
3 to <6	Light red	Light red	Dark red	Light green	Light green	Light green	Light green
6 to <9	Dark red	Light green	Light green	Light green	Light green	Light green	Light green
9	Light green	Light green	Light green	Light green	Light green	Light green	Light green

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

Date of birth	Gestational age at birth				
	≤24+0	24+1 - 28+0	28+1 - 32+0	32+1 - 34+0	≥34+1
1 st Jan – 31 st March	☑				
1 st April – 30 th June	☑	☑			
1 st July – 16 th Aug	☑	☑	☑		
17 th Aug – 30 th Sept	☑	☑	☑	☑	
1 st Oct – 31 st Dec	☑	☑	☑	☑	

From Dr Judith Orme, Clinical Lead, Department of Neonatology
Simpson Centre for Reproductive Health, Edinburgh

Clinics 26/27 – 'catch up'; 'in season'



Long-acting monoclonal antibody dosage and schedules

For the selective immunisation of very preterm infants and high-risk children, long-acting monoclonal antibodies are given seasonally, usually in or from the second half of September or first half of October (before RSV becomes prevalent) to the end of February. A single dose is expected to protect for at least 5 to 6 months, a full RSV season. Typically infants being discharged from hospital for the first time between mid-September and the end of February should be immunised with clesrovimab or nirsevimab while an inpatient. Those leaving hospital of the first time from the start of March to first half of September should be invited for outpatient immunisation scheduled in the second half of September or first half of October. Health service operational guidance should be followed. If an infant or child is newly identified as high-risk (see box 1) during the season, a single dose of clesrovimab or nirsevimab should be given, up to the end of February.



Supportive



Innovative



Respectful



Collaborative



University Hospitals
Bristol and Weston
NHS Foundation Trust

Clinics for 26/27 –

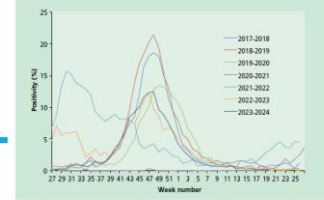


Figure 1. Weekly RSV swab positivity (%) by date of specimen, Respiratory DataMart 2017/18 to 2023/24.

'in season'

- for any inpatient <32 weeks that will be discharged between mid Sep 2026 - end Feb 2027 should get LAMA approx 1 week before discharge from NICU/Paeds

'next season'

- for any <32 weeks baby that will be discharged from March-Sep 2027 should get LAMA in Sep/Oct 2027



Supportive



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Practicalities of administering nirsevimab and clesrovimab

Nigel Gooding, Consultant Pharmacist

Practicalities of administering nirsevimab and clesrovimab

- Doses
- Administration
- Storage
- Adverse effects
- Cautions
- Contraindications
- Catch up clinic & patient selection



Dosing and administration of nirsevimab

- <5kg – 50mg SINGLE DOSE
- ≥5kg – 100mg SINGLE DOSE
- 200mg licensed dose for 2nd season indications is not commissioned
- Dosing in infants 1kg – 1.6kg is based on extrapolation; (risk vs benefit in <1kg)

ADMINISTRATION

Select appropriate 50mg or 100mg prefilled syringe

Visually inspect the product for particulate matter and discoloration

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

- Administer the entire contents of the pre-filled syringe as an intramuscular injection, preferably in the anterolateral aspect of the thigh.

STORAGE

- Store in a fridge (2 – 8°C)
- Do NOT freeze
- Can be kept for max 48 hours at 20 – 25°C when protected from light

ADVERSE EFFECTS

Rash occurring within 14 days post dose

Pyrexia and injection site reactions

RARE serious hypersensitivity reactions following nirsevimab administration have been reported

- Anaphylaxis kit availability



Report all ADR's via Yellow Card!!!

<https://yellowcard.mhra.gov.uk/>

CAUTIONS

Patients with thrombocytopenia or coagulation disorder

CONTRAINDICATIONS

Hypersensitivity to nirsevimab or an excipient
(but no cross contraindication to palivizumab unless an excipient)

Dosing and administration of clesrovimab

- All infants 105mg (0.7mL) single dose
- Only licensed for 1st RSV season
- Dosing in infants 0.5kg – 1.1kg is based on extrapolation; no clinical data is available (risk vs benefit in <1.1kg)

ADMINISTRATION

Select 105mg in 0.7mL pre-filled syringe

Allow to reach room temperature (15 mins)

Visually inspect the product for particulate matter and discoloration

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

- Administer the entire contents of the pre-filled syringe as an intramuscular injection, preferably in the anterolateral aspect of the thigh. Use 25g or larger needle.
- Record batch number of product used

STORAGE

- Store in a fridge (2 – 8°C)
- Do NOT freeze
- Can be kept for max 48 hours at 20 – 25°C

ADVERSE EFFECTS

Rash occurring within 14 days post dose

Injection site reactions (pain, erythema, swelling)

RARE serious hypersensitivity reactions following clesrovimab administration (similar to palivizumab)

- Anaphylaxis kit availability



Report all ADR's via Yellow Card!!!

<https://yellowcard.mhra.gov.uk/>

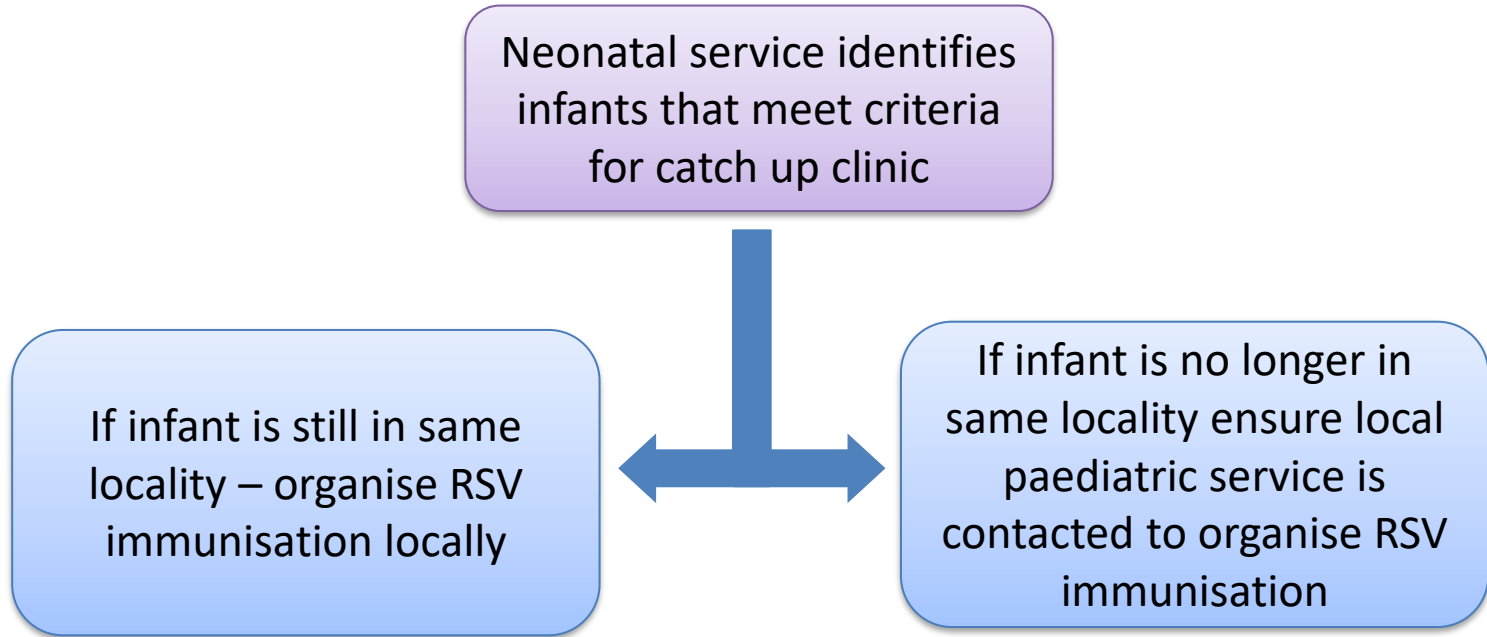
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Catch up clinics and patient selection



Grand Round
webinar series



Q&A session

Pre-submitted questions

Theme	Question
Commissioning	Where do DGH's stand when a tertiary centre advises an uncommissioned use and recommends this to the parents?
	Will use still be commissioned within a block contract payment?
	Why does the blueteq form no longer allow 'clinical judgement'.
Commissioning (cardiology)	<ul style="list-style-type: none"> • Is 2nd dose post cardiac bypass commissioned and what is the recommended dose? • Why were we previously allowed to treat cardiac patients up to the age of 2 years? • Are cardiomyopathy patients included - these are not CHD, but perhaps more vulnerable?
Patient identification	Who is responsible for identifying patients for the catch up clinic that may have been treated in a different neonatal unit and subsequently discharged back to a different locality?
	How did centres manage the definition of 'infant' last season? Noted the BNFC use the definition of 'infant' as 28 days – 24 months of age
	Is a child eligible for a respiratory / cardiac indication if they are < 1 year of age at the start of the season?
Administration timing	There is still some ambiguity regarding eligibility during the season on neonatal units, please clarify: - <ul style="list-style-type: none"> • Can a baby receive immunisation if they were eligible (based on age) at the start of the season, but at the point of discharge they are subsequently too old based on the green book table.
	Please provide guidance on the timing of administration on neonatal units in relation to birth and discharge dates and are there disadvantages of giving earlier in the neonatal inpatient stay?
Supply	Last year there were problems obtaining nirsevimab supply. Will there be assurance that stock is available from the start of this season?
	Can remaining stock of nirsevimab from last year be used this season and funded?

RCPCH campaign for an RSV vaccination programme

Our campaign for an RSV vaccination programme

Following our open letter signed by over 2,000 paediatricians and healthcare professionals, the UK government and devolved administrations have confirmed the delivery of two new respiratory syncytial virus (RSV) vaccination programmes, for older adults and during pregnancy for infant protection. Read our campaign update and FAQs to learn more.

Read more:



Thank you for joining us

We will contact all registrants shortly to share the recording of today's webinar and a link to the online post-webinar evaluation form (survey link also in chat).

We would be very grateful for your feedback. Thank you.