National Clinical Programme for Paediatrics and Neonatology

PAEDIATRICS

National Women & Infants Health Programme

Standard Operating Procedure

Nirsevimab

To Reduce Respiratory Syncytial Virus (RSV) and Associated Hospitalisations in Infants

Developed by:

National Clinical Programme for Paediatrics and Neonatology
National Women and Infants Health Programme
HSE National Health Protection Office

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Disclaimer

The National Implementation Working Group acknowledges that there may be changes required to the operationalisation of this SOP following implementation. If you have any feedback or wish to raise concerns in relation to the SOP please email them to rsvpathfinderprogramme@hpsc.ie or nwihp.corporate@hse.ie. The information provided within this document is in relation to Beyfortus™ (**Nirsevimab) (prevention of RSV in newborn infants)** and therefore should not be used for any other purposes. This is not part of a national immunisation programme nor is it a substitute for professional care.

0.0 Version Control

National Policy ☐ National Procedure ☒ National Protocol ☐ National Guideline ☐ National Clinical Guideline ☐ **HSE National Procedure on Nirsevimab to reduce RSV and associated hospitalisations in Infants**	
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[1] Records the senior management roles involved in the governance and development of the document.

Lead responsibility for national implementation:	Dr Ciaran Browne HSE Access and Integration Co-Chair - RSV 2.0 Nirsevimab Pathfinder Programme National Steering Group
Lead responsibility for national monitoring and audit:	Dr Ciaran Browne HSE Access and Integration Co-Chair - RSV 2.0 Nirsevimab Pathfinder Programme National Steering Group
Development Group Name:	RSV 2.0 Pathfinder Programme National Implementation Working Group
Development Group Chairperson:	Dr Augustine Pereira - Chair Dr Ciara Martin - Vice Chair Prof John Murphy - Vice Chair

Additional headings can be inserted as required	

DOCUMENT MANAGEMENT [2]			
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Note: HSE National 3PGs should be formally reviewed every 3 years, unless new legislative/regulatory or emerging issues/research/technology/audit etc. dictates sooner.			

VERSION CONTROL UPDATE [3][4]

[2] Records the control information about the document.
[3] Records details when a document is reviewed, even if no changes are made.
[4] Records the document information required for publication on the HSE National Central Repository.

Version No. (most recent version first)	Date reviewed (most recent date first)	Comments (1 sentence max, if required)
3.0	16/07/2025	Pathfinder Programme 2.0 (2025) Original document approved at Implementation Working Group meeting
2.0	11/09/2024	Added information on Home births, (page 16), pathway for Nirsevimab Administration to Preterm Infants (page 23), Preparation for Administration of Intramuscular Injection section - use of alcohol swab (page 25) as well as addition of new appendices 8 to 12.
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Short summary:

This Standard Operating Procedure (SOP) has been developed to support Clinicians in the implementation of the respiratory syncytial virus (RSV) Immunisation Pathfinder Programme 2.0. The SOP is for clinicians and seeks to provide direction, information and support for Midwives, Nurses, Pharmacists/Pharmaceutical Technicians, Neonatologists, and Paediatricians working in Maternity Hospitals/ Units, Neonatal Units and Paediatric settings.

Description:

The guide includes information about:

- RSV
- Newborn Infants at greater risk of requiring hospitalisation with RSV
- RSV immunisation and Monoclonal Antibody (mAB)for newborn infants and young children

1.0 Aim of Standard Operating Procedure (SOP)

This Standard Operating Procedure (SOP) has been developed to support the implementation of the respiratory syncytial virus (RSV) pathfinder programme 2.0 by administering the monoclonal antibody, nirsevimab, to reduce RSV – associated infections and hospitalisations. The SOP is for clinicians (Midwives/Nurses, Doctors, Pharmacists/Pharmaceutical Technicians and other vaccinators working with the HSE Mobile Vaccination Teams) that will order or administer nirsevimab, or be involved in the medication management process, promotion and administration of nirsevimab. The SOP seeks to provide direction, information and support for staff working in Maternity Hospitals/ Units, Neonatal Units, Paediatric and community settings, including Mobile Vaccination Teams.

This SOP includes recommendations for standard practice. It does not describe management that may be offered if an infant's clinical assessment deviates from normal parameters. Clinicians will need to refer to specific local policy, procedures, protocols, and guidelines for escalation pathways and more specific details. It is the responsibility of the healthcare professional to escalate care to the multidisciplinary team when deviations from the normal/expected ranges are identified, in line with national guidelines[1].

The National Immunisation Oversight Group and the National Steering Group for RSV 2.0 pathfinder for the Implementation of Beyfortus™ (nirsevimab) agreed to use the name 'nirsevimab' as the product/trade name in the Republic of Ireland.

Nirsevimab should be administered in line with European Medicine Agency (EMA) Product Information. https://www.ema.europa.eu/en/documents/product-information/beyfortus-epar-product-information_en.pdf

The guide includes information about:

- RSV
- Newborn Infants at greater risk of requiring hospitalisation with RSV
- RSV immunisation and mAB for newborn infants and young children
- Eligibility for 2025 state funded nirsevimab
- Ordering 2025 state funded nirsevimab

- Nirsevimab storage and cold chain management
- Nirsevimab presentation and administration
- Nirsevimab efficacy
- Nirsevimab safety
- Reporting suspected adverse events following immunisation
- Reporting and monitoring administration encounters
- Useful links
- Useful contact details
- References

2.0 Key Terms and Acronyms

RSV	Respiratory Syncytial Virus
NIAC	National Immunisation Advisory Committee
LRTI	Lower Respiratory Tract Infection
CLD	Chronic Lung Disease
HPRA	Health Product Regulatory Authority
CI	Confidence Interval
NNT	Number Needed to Treat
HSPC	Health Surveillance Protection Centre
mAB	Monocolonal Antibody (mAB)
SOP	Standard Operating Procedure
PICU	Paediatric Intensive Care Unit

NICU	Neonatal Intensive Care Unit
SCBU	Special Care Baby Unit
SmPC	Summary of Product Characteristics

3.0 Stakeholder Involvement

Stakeholders are people who have a common interest in improving health services. This includes persons that are responsible for delivering and those who receive services related to the clinical SOP. It is comprised of health care professionals with a special interest and expertise in maternity services, public health, neonatal and paediatric services.

A SOP Development Group as outlined in Table 1 reviewed and drafted the SOP and the wider Implementation Working Group included in Table 2 were consulted on the contents of the SOP.

Table 1: SOP Writing Group

Name	Role
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Dr Ciara Martin (Vice Chair)	National Clinical Advisor and Group Lead for Children and Young People
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Table 2: Implementation Working Group

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Kate Cassidy	Immunisation Lead and General Manager, HSE Dublin and South East
Corrina Broderick	Clinical Lead, HSE Immunisation Service

4.0 Use of Language

Within this SOP, the terms 'woman' and 'women's health' are used. However, it is important to acknowledge that people who do not identify as cis-gender women are excluded from this descriptor, including people who identify as transgender, gender diverse and gender nonbinary[2]. It is appreciated that there are risks to desexing language when describing female reproduction[3] [4]. Services and delivery of care must be appropriate, inclusive and sensitive to the needs of people whose gender identity does not align with the sex they were assigned at birth.

5.0 Respiratory Syncytial Virus (RSV)

Respiratory syncytial virus (RSV) causes annual epidemics during autumn and winter in temperate climates and continues to exert a significant toll on public health and healthcare systems. It is a leading cause of respiratory tract infections and places vulnerable populations, including infants, older adults, and immunocompromised individuals, at increased risk.

Almost all infants will have had an RSV infection by two years of age, however those aged less than six months are at highest risk for severe disease. Infection induced immunity is not fully protective and repeated lifelong infections are common. RSV causes a considerable socioeconomic burden, due to the impact of infant infections and hospitalisations on health care systems and caregivers.

RSV is highly contagious. Transmission occurs through contact with aerosolised viral particles generated through sneezing and coughing, or from contaminated surfaces or fomites. Large particle droplets can survive on contaminated surfaces for up to six hours, making handwashing the most effective infection control procedure. The frequent occurrence of mild or asymptomatic infection in otherwise healthy individuals makes infection control challenging.

Incubation is usually 2-8 days. Infected individuals shed RSV for 3-8 days but immunocompromised patients with severe infection may shed virus for up to four weeks. There are no effective treatments available for RSV infection in either adults or children, supportive care is the mainstay of treatment.

In infants, RSV typically causes a self-limiting upper respiratory tract infection (URTI) with rhinorrhoea, pharyngitis, nasal congestion, coughing, sneezing, tachypnoea, and decreased appetite. Lower respiratory tract disease occurs as bronchiolitis or

pneumonia, with fever in<50% of infections, increased work of breathing, hyperinflation, croup (laryngotracheobronchitis), and wheeze. Typically, between 1% and 3% of infants with RSV infection require hospitalisation. Treatment is supportive (supplemental oxygen and feeding support).

RSV season extends between September and the end of February, in the 2023/2024 RSV season 7,827 cases of RSV were notified in Ireland, with new cases peaking in week 48 (Nov 26 – Dec 2). This included 3,308 hospitalisations, with the highest number of admissions in infants under one year accounting for 43% (1,431 cases) of all hospitalisations and 78% of all RSV related ICU admissions (118 cases)[5].

Nirsevimab, a monoclonal antibody for the prevention of RSV lower respiratory tract infection, will now be available for administration to all infants in accordance with NIAC recommendations from this autumn.

Nirsevimab works by preventing the virus entry into the host cell by binding the F1 and F2 subunits of the RSV fusion (F) protein on the surface of RSV.

6.0 Nirsevimab Safety, Efficacy & Effectiveness

Clinical trials and real world data demonstrate that nirsevimab is very effective in preventing infant hospitalisation from RSV infection. Across all endpoints, a single dose of nirsevimab has demonstrated sustained and consistent reduction in RSV respiratory tract infections in infants. The picture that emerges is that nirsevimab leads to an 80% reduction in RSV hospitalisations in infants.

Nirsevimab is well tolerated with a favourable safety profile. The most frequent adverse reaction was a skin rash (0.7%) occurring within 14 days post dose. The majority of cases were mild to moderate in intensity. Additionally, pyrexia and injection site reactions were reported at a rate of 0.5% and 0.3% within 7 days post dose and 0.9% for 14 days respectively. Injection site reactions were reported to be non-serious. https://www.ema.europa.eu/en/documents/product-information/beyfortus-epar-product-information_en.pdf

Nirsevimab has an extended half-life greater than 3 times that of typical monoclonal antibodies. One dose provides protection for at least 5 months, the entire RSV season. Nirsevimab begins to provide protection against RSV immediately after injection is administered and reaches peak concentration in approximately 6 days. Pharmacokinetic data suggests protection against RSV could be as long as one year.

Nirsevimab was approved by the EMA (European medicines agency) in October 2022, HPFB, Canada in April 2023, and FDA in July 2023. The National Immunisation Advisory Committee) (NIAC) on 12/10/23 recommended the passive immunisation of all infants in Ireland against RSV during their first RSV season.

Clinical trials and real-world trials have demonstrated the safety and efficacy of nirsevimab in infants.

A summary of the international clinical trial and real-world evidence is included in the appendices.

In Ireland in October 2023, the National Immunisation Advisory Committee (NIAC) recommended the passive immunisation of all infants against RSV during their first RSV season[6]. In June 2024 the HSE established an RSV Immunisation Pathfinder Programme – a pilot programme to offer nirsevimab to all infants born between 1st September 2024 and 28th February 2025, in addition to clinically high-risk infants aged less than 12 months (including pre-term infants born <30 weeks gestation, congenital heart disease, chronic lung disease of prematurity, and immunocompromised infants). The pilot programme commenced on 1st September 2024 and nirsevimab was offered to infants in all 19 maternity hospitals, in Children's Health Ireland and to clinically high-risk infants at home by Temperature Controlled Pharmaceuticals (TCP) Homecare.

Between 1st September 2024 and 28th February 2025 uptake of immunisation with nirsevimab in infants nationally was 83% with 22,444 infants immunised in total. Routine surveillance data of RSV among infants born in this period showed a significant reduction in the number of cases in this cohort compared to previous seasons as summarised in Table 3.

Table 3. Summary of RSV cases notified among those born between 1st September and 28th February by RSV season, Ireland, 2018/2019 – 2024/2025

RSV season	ED Presentation	Hospitalised	Non-ICU	ICU[a]	Total cases[b]
2018/2019	240 (24%)	501 (52%)	-	-	967 (100%)
2019/2020	263 (26%)	573 (58%)	-	-	996 (100%)
2020/2021	2 (100%)	0 (0%)	-	-	2 (100%)
2021/2022	340 (42%)	400 (50%)	-	-	801 (100%)
2022/2023	468 (47%)	488 (49%)	-	-	997 (100%)
2023/2024	395 (35%)	676 (59%)	587 (51%)	89 (8%)	1142 (100%)
2024/2025[c]	169 (42%)	164 (41%)	133 (33%)	31 (8%)	398 (100%)

a) Surveillance of RSV in ICU began in October 2023
b) All laboratory confirmed RSV notifications (including primary care and outpatients)
c) **This data only covers up to Week 16, 2025**

RSV surveillance data until week 16 2024-25 showed a 65% reduction in total cases, 57% reduction in ED presentations, 76% reduction in hospitalisations and a 65% reduction in ICU admissions during 2024-25 season compared with 2023-24 season (Figure 1).

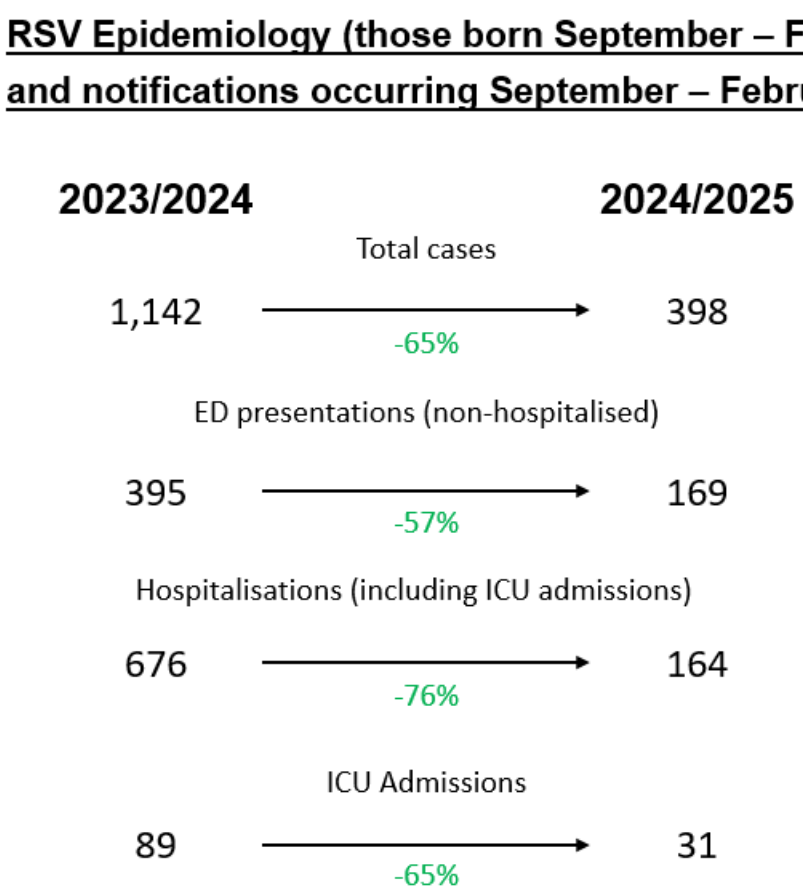


Figure 1: Change in RSV cases in infants born 1st September to 28th February in 2024/2025 season compared to 2023/2024 season

The impact of RSV immunisation on healthcare service utilisation, including hospitalisations and ICU admissions, in the 2024/2025 was estimated as part of an evaluation of the Pathfinder 1.0 Programme. Two methods were used to estimate cases averted in these settings.

The first method used case notifications amongst infants born between 1st September 2024 and 28th February 2025 up to 3rd March 2025 to estimate hospitalisation averted. It estimated that 430 hospitalisations and 79 ICU admissions were averted in this cohort due to immunisation. The evaluation included data until 3 March and as it was not possible to include RSV case notification for the full RSV season, it was noted as an underestimate of true effect.

The second method used observed data of RSV cases in infants born between 1st September 2024 and 28th February 2025 and compared it to modelled predictions of

RSV cases, based on previous RSV seasons, to estimate the impact of nirsevimab on hospitalisations in the 2024/2025 season. This method estimated 532 (95% CI:369-695) averted hospitalisations in this cohort in the 2024/2025 season and is more likely to reflect the true impact of immunisation than the first method as it used modelled data for the full season.

The Health Products Regulatory Authority were just aware of one adverse reaction relating to nirsevimab – erythema following double administration.

Two medication safety incidents have been reported to the central programme team to date relating to the double administration of nirsevimab. This was likely due to a breakdown in communication between teams when the infants were transferred between wards, and it was unclear if the child had already received nirsevimab or not.

There was at least one incident where the incorrect dose was given to an infant (i.e. 100mg given to a child <5kg). No adverse reaction occurred, and the parents were informed of the error.

The picture that emerges is that nirsevimab leads to an 80% reduction in RSV hospitalisations in infants. It has the potential to reduce the morbidity in infants associated with RSV each winter, as was seen in Ireland during the 2024-25 season with a programme for newborn infants only. With the extension of the programme to a catch-up cohort in 2025-26 it has the potential to substantially alleviate the seasonal pressures on paediatric units and emergency departments throughout the country. Modelling estimates predict up to 800 hospitalisations could be averted with uptake rates similar to what was achieved in Ireland last year.

7.0 National Immunisation Advisory Committee (NIAC) Updated Recommendations for the Passive Immunisation of Infants against RSV during the 2025/2026 Season (25/03/2025)[7]

1. NIAC recommends the passive immunisation with nirsevimab of all infants who are born during the RSV season (i.e., the birth cohort). These infants should receive nirsevimab ideally prior to discharge home from a maternity hospital.
2. NIAC recommends the passive immunisation with nirsevimab of all infants who are aged ≤6 months at the start of the RSV season (i.e., the catch-up cohort). These infants should receive nirsevimab prior to the start of the RSV season.
3. NIAC recommends the passive immunisation with nirsevimab of all *high-risk infants aged ≤12 months at the start of their first RSV season. These infants should receive nirsevimab prior to the start of the RSV season.
4. NIAC recommends the passive immunisation with nirsevimab of all ex-preterm infants under 24 months of age with †chronic lung disease (CLD) in their second RSV season. Infants who will be severely immunocompromised during the RSV season may also be considered for nirsevimab in consultation with their treating specialist. These infants should receive nirsevimab prior to the start of the RSV season.
5. In the event of short supply, the youngest infants and *high-risk infants in their first RSV season should be prioritised.
6. ‡Neonates with prolonged hospitalisation from birth due to prematurity or other reasons should receive nirsevimab shortly before discharge from hospital if they are being discharged during or shortly before the RSV season.
7. The RSV season in Ireland typically starts in calendar weeks 38-40 and ends around calendar week 8 of the following year. Immunisation of the birth cohort should aim to start shortly before the onset of the RSV season and finish at the end of the RSV season. The catch-up cohort should aim to be immunised shortly before the onset of the RSV season.
8. § Nirsevimab should be administered as follows: • Infants<5kg: A single dose of 50 mg administered intramuscularly • Infants ≥5kg: A single dose of 100 mg administered intramuscularly • Children up to 24 months entering their second season: 200 mg given as 2 x 100 mg intramuscular injections. **Recommendations may be updated when more information becomes available.**

* Infants currently eligible for palivizumab as outlined in Chapter 18a of NIAC Immunisation Guidelines of Ireland.

† Children with CLD (defined as those who required at least 28 days of supplemental oxygen after birth) and who continue to require medical intervention (supplemental oxygen, chronic corticosteroid, or diuretic therapy) for 6 months preceding the RSV season.

‡ Earlier inpatient administration may be considered if infant is considered at risk of RSV exposure in hospital. Dosing in infants with a body weight from 1.0 kg to <1.6 kg is based on extrapolation; no clinical data are available. Exposure in infants <1 kg is anticipated to yield higher exposures than in those weighing more. The benefits and risks of nirsevimab use in infants <1 kg should be carefully considered.

§ For additional dosing recommendations in those post cardiac surgery requiring cardiopulmonary bypass please consult the summary of product characteristics (SPC.)

8.0 Eligibility for Nirsevimab

NIAC recommends the passive immunisation with nirsevimab to the following:

- **All infants born in the RSV season September to end of February inclusive** (i.e. the **birth cohort**)
- **All infants aged ≤6 months at the start of the RSV season** (i.e. the **catch-up cohort**).
- **All high-risk infants aged ≤12 months at the start of their first RSV season**.
- **All ex-preterm infants under 24 months of age with †chronic lung disease (CLD) in their second RSV season** and **severely immunocompromised infants** during the RSV season for whom nirsevimab is deemed necessary in consultation with their treating specialist.

9.0 Adverse Reactions

The most frequent adverse reaction was rash (0.7%) occurring within14 days post dose. The majority of cases were mild to moderate in intensity. Additionally, pyrexia and injection site reactions were reported at a rate of 0.5% and 0.3% within 7 days post dose, respectively. Injection site reactions were non-serious.

Local: common: injection site reactions.

General: common: rash, pyrexia.

In the event of an adverse reaction, please refer to section 24 - process for reporting adverse reaction to HPRA.

10.0 Contraindications

Nirsevimab is contraindicated in infants with a history of severe hypersensitivity reactions, including anaphylaxis, to the active substance or to any of the following ingredients listed in the Summary of Product Characteristics (SmPC): L-histidine, L-histidine hydrochloride, L- arginine hydrochloride, Sucrose, Polysorbate 80 (E433), water for injections.

Serious hypersensitivity reaction to previous immunisation with nirsevimab or palivizumab.

Infants of a mother or father who have a strong history of hypersensitivity is not a contraindication to immunisation with nirsevimab.

11.0 Precautions

Serious hypersensitivity reactions, including anaphylaxis, have been observed with monoclonal antibodies. If signs and symptoms of a clinically significant hypersensitivity reaction or anaphylaxis occur, immediately discontinue administration and initiate appropriate medicinal products and/or supportive therapy.

Individuals with a bleeding disorder or receiving anticoagulant therapy may develop haematomas at IM injection sites. Prior to vaccination, inform the recipient about this risk. For those with thrombocytopenia (platelet count $<50x10^9$/L) consult the relevant specialist.

NIAC Immunisation Guidelines (Chapter 2) detail the technique for IM injections in persons with bleeding disorders as follows:

- Only one injection per muscle mass should be given at each visit. Use a 23 or 25 gauge needle to reduce the pressure gradient and cause less trauma to the tissue. The vaccine should be injected slowly (≥5 seconds) to reduce the risk of tissue damage.
- Firm pressure should be applied to the site for 5 to 10 minutes after injection.
- Stabilisation of the limb will reduce the risk of a haematoma.
- The site should not be rubbed or massaged.
- Instruct the patient/parent to monitor the injected limb and to report any concerns to their treating specialist.

12.0 Target Users

This SOP is a resource for all Midwives, Nurses, Doctors, Pharmacists/Pharmaceutical Technicians, and other healthcare vaccinators who provide care to infants. The services will be delivered in **maternity and paediatric settings,** and through **HSE Mobile Vaccination Teams**.

This SOP is also applicable to staff delivering immunisation to infants delivered in a community setting under the **HSE Homebirth Service**.

Staff providing care to high-risk infants ≤12 months at the start of their first RSV season and **ex-preterm infants under 24 months of age with chronic lung disease in their second RSV season** should also be aware of this SOP, including healthcare staff providing at home injection services to high-risk infants.

13.0 Ordering Nirsevimab

Funding for nirsevimab is being provided centrally by the HSE and Uniphar will supply the product via their subsidiary called Durbin. No charges will be incurred by hospital or Mobile Vaccination Team pharmacies for the product or deliveries. Based on the volume of births, each site will need to estimate their likely weekly Nirsevimab stock ordering levels.

Community based services are required to register with Uniphar/Durbin in advance of ordering stock and arrangements to be made for decommissioning the product for community services. Contact vaccineorders@durbinireland.ie .

Maternity settings

To prevent maternity hospitals/units from holding excessive amounts of stock, the maximum weekly orderable amount of Nirsevimab 50mg formulation for a hospital is limited to 150% of their anticipated normal weekly usage figure as per the column titled "Nirsevimab 50mg Per Week (Total)" in the **Table 4** below. Please note that as demand rates settle into a stable pattern, each hospital will, over time, be able to adjust their delivery quantities.

Table 4: 2024 Live Births by Hospital in HSE Regions

HSE Region	Hospital	2024 Births	Nirsevimab per Week (Total)	Nirsevimab per 28 day month (Total)
National		**53,056**	**1020**	**4081**
Dublin and North East	Rotunda Hospital	8,458	163	651
	OLOLH Drogheda	2,665	51	205
	Cavan General Hospital	1,205	23	93
	Coombe Women and Infants University Hospital	6,506	125	500

Dublin and Midlands	MRH Mullingar	1,693	33	130
	MRH Portlaoise	1,371	26	105
Dublin and South East	National Maternity Hospital	6,591	127	507
	UH Waterford	1,541	30	119
	Wexford General Hospital	1,492	29	115
	St Luke's General Hospital Kilkenny	1,341	26	103
	Tipperary University Hospital	675	13	52
South West	Cork University Maternity Hospital	6594	127	507
	University Hospital Kerry	989	19	76
Mid West	UMH Limerick	3,900	75	300
West and North West	Galway University Hospitals	2,631	51	202
	Letterkenny University Hospital	1,475	28	113
	Mayo University Hospital	1,389	27	107
	Portiuncula University Hospital	1,311	25	101
	Sligo University Hospital	1,229	24	95

While the vast majority of nirsevimab doses delivered will be the 50mg formulation (for neonates < 5kg birth weight), maternity hospitals/units will need to maintain a standing stock of the 100mg formulation for infants ≥ 5 kg birth weight. Hospital pharmacies will need to monitor stock levels of the 100mg formulation and top-up as necessary on an ongoing basis. It is estimated that approximately 1% of newborn babies might require the 100mg/1ml dose. Orders will be managed and distributed via Durbin (specialised vaccines unit within Uniphar).

To place an order either send an email to vaccineorders@durbinireland.ie or telephone 01-4687669.

Deliveries will arrive in cardboard boxes via a refrigerated van. Hospital pharmacies will not need to return refrigerated boxes.

There will be an option of twice weekly deliveries for hospitals with larger usage volumes (Rotunda, Coombe, NMH, CUMH, UMHL, OLOLH, and UHG). There will be once weekly deliveries to all other hospitals. Orders placed on Day 1 will be delivered on Day 3. Uniphar/Durbin will liaise with individual hospital pharmacy departments to set pre-agreed delivery days for each hospital. However, out of schedule / urgent orders will be facilitated. In consultation between Uniphar/Durbin and individual hospitals, a system of weekly standing orders can be established for hospitals with larger usage volume. First deliveries will begin in middle to end of August 2025.

Paediatric/ community settings

Paediatrics settings providing RSV immunisation for catch up cohorts will need to hold a supply of 50mg and 100mg doses.

Pharmacy support to services providing nirsevimab in the community will be agreed on a regional basis.

Sites may order supplies on a weekly basis with weekly estimates initially based on the eligible cohort in each region.

Table 5: Estimated number of infants in the catch-up cohort eligible for nirsevimab in 2025/2026, by HSE Region*

HSE Region	Infants Eligible for Catch-Up Nirsevimab
Dublin and North East	6,164
Dublin and Midlands	4,785
Dublin and South East	5,820
South West	3,792
Mid West	1,950
West and North West	4,018

*based on 2024 live births

14.0 Nirsevimab Storage and Cold Chain Management

Nirsevimab must be stored in a refrigerator at +2°C to +8°C. Keep the pre-filled syringe in the outer container in order to protect from light at all times. Do not freeze or expose to direct heat. **It may be kept at room temperature (below 25°C) for a cumulative maximum of 8 hours**. An example in practice would be a situation where nirsevimab is removed from a fridge for 1 hour, at which point the parent then declines consent or it is not appropriate to administer nirsevimab to the infant. The product can then be returned to a fridge, but with a 7-hour expiry time in the temperature range >8C to ≤25C for subsequent excursions to room temperature, instead of an 8-hour

expiry time. It is recommended in such a scenario to clearly document on the outer packaging of the product that the new expiry time out of the fridge is reduced from 8 hours to 7 hours. There is no limit on the number of permitted temperature excursions in the range >8C to ≤25C, so long as the product administered to an infant has not been stored in the range of >8C to ≤25C for longer than 8 hours in total. However, standard practice should be to remove nirsevimab from a fridge only when the parent has consented to their infant receiving the immunisation and it is clinically appropriate for them to receive it. For further information, please refer to the patient information leaflet.

Nirsevimab must be protected from light. To protect the medication from light exposure it must be stored in a purpose-built immunisation refrigerator inside their original cardboard packaging. Immunisations must not be removed from their original cardboard packaging to increase refrigerator capacity.

All immunisation providers responsible for ordering, storing, receiving and administering nirsevimab must understand the principles of refrigerated medication storage.

Arrangements must be put in place to ensure that medication storage fridges:

- Pharmaceutical grade refrigerator
- Are of sufficient size to store the anticipated volume of stock
- Are maintained well and serviced at least annually
- Have an associated remote temperature monitoring system in place. In the meantime, while establishing such a technological solution, at the minimum a manual twice daily maximum and minimum temperature record must be maintained.
- For further guidance see the HSE Guidelines for maintenance of cold-chain in fridges.

In the event of cold-chain failure greater than 8 hours please contact the Irish representative of the Marketing Authorisation Holder – sanofi-aventis Ireland T/A SANOFI, Tel: + 353 (0) 1 4035 600 (SmPC). All cold-chain failures should be reported to the Public Health Lead for RSV Pathfinder Programme 2.0.

15.0 Handling Requirements

Nirsevimab is a pre-filled syringe and occupational exposure is unlikely. There is no information that suggests nirsevimab has characteristics of a hazardous medicine. Preclinical studies of nirsevimab have not identified the product as a special hazard for humans (there are no known or suspected cytotoxic, genetic or reproductive toxicities). Refer to local policies and procedures for safe handling of monoclonal antibodies of this nature.

16.0 Nirsevimab Presentation and administration

Nirsevimab is available in a 50mg 0.5mL pre-filled syringe with a purple plunger rod and a 100mg in 1mL prefilled syringe with a light blue plunger rod. For the 2025/26 RSV season, HPRA licensed stock will be provided. The required English language patient information leaflet will be contained in each box.

Clinicians should use a needle long enough to reach deep into the muscle to ensure the

product is deposited within the proper tissue layer; an appropriate length and gauge of needle must be selected based on clinical judgment. The appropriate needle sizes for use are either 25G x 16mm or 25G x 25mm. If local practice is to use a wider bore for administration of IM injections to neonates, then a 23G needle can be used and if required must be sourced locally. Depending on local practice for administration of IM injections to neonates, a 16mm length needle can be used for administration to preterm infants and infants weighing less than 5.0kg while a 25mm length needle can be used for infants weighing ≥ 5.0kg

17.0 Dosing Recommendations

NIAC recommended dose for Nirsevimab that should be administered is as follows:

- Infants weight<5kg: A single dose of 50mg (0.5ml) administered intramuscularly (Purple Syringe)
- Infants weight≥5kg: A single dose of 100mg (1.0ml) administered intramuscularly (Blue Syringe)
- Children up to 24 months entering their second season:
    - 200 mg given as 2 x 100mg (1 ml) intramuscular injections.

18.0 Preparation for Administration of Intramuscular Injection

All infants must be clinically well prior to the administration nirsevimab. Newborn infants that are being monitored for sepsis, low blood sugars, or jaundice must be seen and deemed clinically well by a paediatrician before nirsevimab is prescribed. Infants with extended post birth hospitalisation (including SCBU/NICU/HDU admissions) should receive nirsevimab shortly before discharge.

Where there are clinical concerns in relation to the immunisation of infants attending community settings the vaccinator should liaise with the infant's paediatrician for advice before administering nirsevimab.

Check the infant's weight and consult the ensure the correct dose of nirsevimab has been selected.

Step 1. Visually inspect the syringe prior to administration. Nirsevimab is a clear to opalescent, colourless to yellow solution. Do not use if the liquid is cloudy, discoloured or contains foreign particulate matter. Do not use if the pre-filled syringe has been dropped or damaged.

Step 2. Ensure the correct dose 50mg or 100mg has been selected.

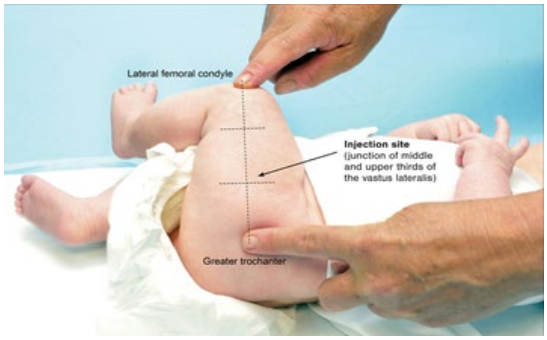
Step 3. Holding the Luer lock in one hand, (avoid holding the plunger rod or syringe body) unscrew the syringe cap by twisting it counterclockwise with the other hand.

Step 4. 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. Both Beyfortus® presentations (50mg in 0.5mL and 100mg in 1mL) will contain a 25G x 16mm and a 25G x 25mm needle. Select the appropriate length needle depending on the patient's size. A 23G needle may also be used in line with local practice, however this must be sourced locally.

Step 5. 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 6. If the skin at the injection site is visibly dirty it should be cleaned with soap and water. There is no need to use a disinfectant e.g. alcohol swabs. If an alcohol swab is used, injection should be delayed for ≥30 seconds, to ensure the alcohol will have evaporated.

Step 7. Nirsevimab is administered intramuscularly 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. If two injections are required, different injection sites should be used.



Step 8. Recipients should be passively observed for 15 minutes after the administration of nirsevimab in line with other low risk procedures such as scheduled childhood vaccinations.

Studies have shown extremely low risk of anaphylaxis associated with administration of this product[8].

Facilities for management of infant anaphylaxis should be available in all areas where nirsevimab is being administered.

Step 9. Staff must adhere to the principles of safe handling and disposal of sharps. Each pre-filled syringe is for single use only.

Step 10. It is important that the parent or guardian receives a record of the immunisation give to share with her GP and PHN. The patient information leaflet contains a section where this can be recorded and given to the parent or legal guardian. A copy of the product information leaflet should also be given to the parent or legal guardian. (Appendix 3)

19.0 Co-administration with Vaccines , Immunoglobulins and Vitamin K (Phytomenadione)

Nirsevimab can be given at the same time as routine childhood vaccines or any interval from routine vaccines and routine vaccines should not be delayed by having received Nirsevimab.

Since nirsevimab is a monoclonal antibody, a passive immunisation specific for RSV, **it is not expected to interfere with the active immune response to co-administered vaccines.** There is limited experience of co-administration with vaccines. In clinical trials, when nirsevimab was given with routine childhood vaccines, the safety and

reactogenicity profile of the co-administered regimen was similar to the childhood vaccines given alone. Nirsevimab can be given concomitantly with childhood vaccines. 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.

Nirsevimab may be administered at the same time as IM vitamin K (phytomenadione) as long as administration occurs into a different limb. Depending on local practice in each maternity unit, vitamin K and nirsevimab may be given in different wards/clinical areas of the hospital within a short space of time. To mitigate the risk of both IM injections being given into the same limb, the RSV Immunisation Pathfinder Programme strongly recommend that a systematic approach be taken to co-administration whereby nirsevimab should be administered into the anterolateral aspect of the right thigh, while vitamin K should be administered into the left thigh. A useful mnemonic to remember is RSV = Right. However, this approach should not replace appropriate documentation of site of administration in the infant's healthcare record. In the event that the site of administration of vitamin K has not been appropriately documented and there is no way to identify which limb it was administered into, consideration should be given to delaying administration of nirsevimab by 24 hours.

20.0 Consent

- **Informed consent must be obtained from the parent/legal guardian of the infant prior to immunisation.**
- All women attending antenatal appointments and antenatal classes or antenatal care in the home should be give written and verbal information on nirsevimab and its role in the prevention of RSV in newborns and infants.
- The parent or legal guardian should also be given written and verbal information following birth on the postnatal ward.
- The parent or legal guardian should be given written and verbal information at any clinical interaction prior to the catch-up programme.
- The parent or legal guardian should also be given written and verbal information in the catch-up clinics.
- **Written information is available in 11 languages on the HPSC website**, where information is not available in a language spoken by the parent/legal guardian an interpreter should be organised.

Valid parental or legal guardian consent should be obtained in accordance with the HSE National Consent Policy 2022.

- Further information on who can give consent for vaccination of a young person aged under 16 years is available from the HSE guidance on legal guardianship.
- In the maternity setting verbal informed consent should be obtained from the mother and clearly documented in the infant's medical records by the midwife/nurse providing the immunisation.
- In the community setting verbal informed consent should be obtained from the parent/legal guardian of the infant. In the case of Mobile Vaccination Teams written informed consent is recommended as there is no clinical record of the infant to record verbal informed consent.
- Consent of the infant's parent/legal guardian should be documented in the relevant section of the consent form by the vaccinator prior to immunisation of the infants (Appendix 3).
- All community immunisation records will be stored in line with the HSE National Records Retention Policy.
- Should a parent or legal guardian decline to have their infant immunised, the decision not to immunise should be documented in the Health Care Record or in the case of Mobile Vaccination Teams, in the data collection form.
- Should a parent or legal guardian decline to have their infant immunised prior to discharge she should be informed how he/she can get the immunisation should she change her mind in line with local policy.

21.0 Record of Immunisation Interaction

The RSV Nirsevimab data collection form (**Appendix 3**) provides a standardised way to document the clinical interaction and administration of Nirsevimab. Documentation is crucial and therefore it is important to maintain excellent records of each immunisation interaction with the parent(s)/legal guardian(s).

Additionally real time data is required to target public health messaging for groups with poor vaccine uptake and data is also required by Health Protection Surveillance Centre (HPSC) for monitoring epidemiological impact.

Maternity settings:

• An agreed data collection form has been designed and should be completed by each maternity unit (Appendix 3).

• The six maternity units that use the Maternal-Newborn Clinical Management System (MN-CMS) will be in a position to report data electronically using the MN-CMS reporting functionality. These are Cork University Maternity Hospital, University Hospital Kerry, The Rotunda Hospital, The National Maternity Hospital, University Hospital Limerick and The Coombe Hospital.

• For all other maternity hospitals (non-MN-CMS sites) and CHI, a multi-par paper data collection form has been developed to facilitate those units that do not have electronic records. One original version of the paper data collection form should be stored in the infants file and one copy should be stored securely by the hospital, for later reporting centrally. Each unit will be required to develop a process on how this will be managed.

Paediatric/ Community settings:

- An agreed data collection form has been designed and should be completed by each unit (Appendix 3).
- All community immunisation records will be stored in line with the HSE National Records Retention Policy.

Adverse events – managed in the usual way as per HPRA guidance – no need for additional pathways/processes to be established The Health Products Regulatory Authority (hpra.ie)

22.0 Monitoring Uptake

In order to monitor the overall uptake of Nirsevimab in real-time, the HPSC have developed a short online survey for all hospitals to complete each week. Detailed instructions (and the link to the online survey) will be emailed to all maternity hospitals and CHI via Regional Executive Officers (REOs) for each Region. The online survey should be completed each Tuesday for data on the previous Monday-Sunday.

- Each maternity hospital will be required to report on the following each week:
    - Number of live births in each maternity hospital during the reporting week
    - Number of infants immunised during the reporting week
- CHI will be required to report on the following each week:
    - Number of eligible infants offered Nirsevimab in CHI (Crumlin & Temple Street) during the reporting week

- Number of infants immunised in CHI (Crumlin & Temple Street) during the reporting week

Further instructions on monitoring uptake for catch up cohort will be issued via REOs.

23.0 Other Key Recommendations

- It is recommended that the governance and process for administration be overseen by the hospital's Drugs & Therapeutics Committee similar to all other hospital medications and in line with hospital medication management guidelines.

- In the community setting where HSE Mobile Vaccination Teams are administering nirsevimab it is recommended that the governance and process for administration be overseen in accordance with locally agreed policies and guidelines.

- It is recommended that pharmacy processes for ordering, distribution, storage and clinical pharmacy review of immunisations are in line with local guidelines/SOP.

- All staff involved in procurement, handling or administration should receive training on the safety/efficacy of nirsevimab to reduce RSV hospitalisations.

- It is recommended that all units create a workflow for the following scenarios:
  - Ensuring that all infants born between the beginning of September 2025 and end of February 2026 receive nirsevimab) prior to discharge.
  - Ensure a process of documentation is in place including data required for public health monitoring. (See appendix for data collection form)

- Qualification and Training Requirements for Healthcare Professionals administering nirsevimab

  All healthcare professionals administering nirsevimab to infants must fulfil the following requirements:

- Appropriate registration with their professional oversight organisation
  - Midwife/Nurse: Be a registered Nurse and or Registered Midwife, on an active register maintained by NMBI;
  - Doctor: Registered Doctor, listed on Irish Medical Council register;
  - A registered pharmacist: listed on PSI register
  - A registered dentist: listed on dental council of Ireland register
  - an advanced paramedic: registered with the Pre-Hospital Emergency Care Council
  - A paramedic: registered with the Pre-Hospital Emergency Care Council
  - An emergency medical technician: registered with the Pre-Hospital Emergency Care Council
  - A person registered with CORU (regulator for health and social care professionals), including Physiotherapists, Radiographers, and other appropriate health and social care professionals

- Healthcare professionals administering nirsevimab to the birth cohort must have completed the following training within the last 2 years:
  - HSE RSV Nirsevimab online training module
  - 8th edition of the American Academy Heart Association/ Neonatal
  - Resuscitation Programme
  - A recognised Medication Safety training module/class for Nurses and Midwives

- Healthcare professionals administering nirsevimab to the catch-up cohort must have completed the following training within the last 2 years:
  - HSE RSV Nirsevimab online training module
  - Training in paediatric basic life support and the recognition and initial management of anaphylaxis. This training must be delivered by a recognised body and aligned with current Resuscitation Guidelines UK Anaphylaxis Algorithm and European Resuscitation Guidelines.
  - For nurses, midwives and student nurses/midwives, to have completed a recognised Medication Safety training module/class for Nurses and Midwives

All healthcare professionals administering nirsevimab must be:

  - Competent in the administration of intramuscular injection to infants
  - Competent in the indications and administration of intramuscular epinephrine injection in infants

- As part of the communications campaign particular attention should be given to patient groups where a lower uptake of nirsevimab was observed during RSV Pathfinder 1.0, including younger mothers, multiparous women, infants from less affluent areas and underserved population groups.

Appendix 1 Summary of International Clinical Trial and Real-world Evidence

The MELODY[1] trial assessed the safety and efficacy of nirsevimab in a cohort 1490 term and late preterm born infants after 35 weeks' gestation. The MELODY trial assessed the safety and efficacy of nirsevimab in a cohort of1490 term and late preterm born infants after 35 weeks' gestation. Infants were randomised to receive either nirsevimab (n=994) or placebo (n=496).

The primary study endpoint was medically-attended RSV-associated lower respiratory tract infection (LRTI) in the 150 days following nirsevimab administration. The number of medically attended RSV infections was 12/994 (1.2%) of infants in the nirsevimab group compared to 25/496 (5.0%) in the placebo group. The reported efficacy against nirsevimab against medically-attended RSV-associated LRTI was 74.5% (95% confidence interval (CI), 49.6-87.1, p<0.001.

The HARMONIE[2] trial assessed the safety and efficacy of nirsevimab in healthy infants born after 29 weeks' gestation. The primary end point was hospitalisation with RSV. There were 8058 infants randomised to either nirsevimab (4037 infants) or no intervention/standard care (4021 infants). 11/4037 (0.27%) infants were hospitalised with RSV in the nirsevimab group and 60/4021 (1.49%) infants in the control group. The reported efficacy of nirsevimab against hospitalisation for RSV-associated LRTI was 83.2% (95% CI, 67.8-92.0, p<0.001).

The MEDLEY[3] trial compared nirsevimab and palivizumab among RSV high risk-preterm infants <35 weeks, infants with chronic lung disease of infancy (CLD), and infants with congenital heart disease. Infants were randomised to receive either a single dose of nirsevimab 50mg or five doses or palivizumab 15mgs/kg. The number of cases of RSV in the 150 days following administration was 4/616 (0.6%) in the nirsevimab infants and 3/309 (1.0%) in the palivizumab infants.

The D5290C00003[3] trial assessed the safety and efficacy of nirsevimab in preterm infants born between 29- and 35-weeks' gestation, randomised to receive either nirsevimab (969 infants) or placebo (484 infants). The primary study endpoint was medically-attended RSV-associated lower respiratory tract infection (LRTI) in the 150 days following nirsevimab administration. The number of medically attended RSV infections was (2.6%) of infants in the nirsevimab group compared to (9.5%) in the placebo group. Incidence of medically attended RSV was 70.1% lower (95% CI, 52.3-81.2, p<0.001) in the nirsevimab group (25/969 infants, 2.3%) compared to the placebo group (46/484 infants, 9.5%).

The MUSIC[4] trial evaluated the safety and efficacy of nirsevimab in immunocompromised infants and children ≤24 months with ≥1 immunocompromising condition. Out of 100 trial participants, 46 were infants aged less than one year old in their first RSV season. A single dose of nirsevimab was well tolerated with no safety concerns arising over 361 days follow-up. No treatment-related serious adverse events or new onset chronic diseases were observed. Nirsevimab serum exposure was consistent with previous studies in healthy children and supportive of efficacy in this immunocompromised population. Some children with underlying protein-losing conditions had a rapid decline in nirsevimab serum concentrations.

Real-world data from Spain, France, and the United States indicate that nirsevimab is effective against RSV-associated hospitalisations and illness in infants. The NIRSE-GAL[5] longitudinal population-based study aimed to assess the effectiveness of nirsevimab in preventing hospitalisations in Galicia, Spain. Of the 10,259 eligible infants 9408 received nirsevimab, which represents a 91.7% uptake. The number of hospitalisations for RSV-associated LRTI in infants who received nirsevimab was 30/9408 (0.3%) compared to 16/851 (1.9%) of infants who did not receive nirsevimab. This corresponded to an effectiveness of 82.0% (95% CI 65.6-90.2). RSV-related LRTI hospitalisations were reduced by 89.8% (Interquartile range (IQR), 87.5-90.3). In previous RSV seasons (2016-23) prior to the introduction of nirsevimab, 3-5 infants out of every 100 were hospitalised with RSV.

Agüera et al.[6] conducted a test-negative case-control study to evaluate the effectiveness of nirsevimab in preventing hospitalisations from RSV bronchiolitis.

The authors included 234 infants hospitalised with bronchiolitis across three hospitals in Catalonia and Andorra, Spain, between November 2023 and February 2024. RSV was detected in 141/234 cases, with fewer RSV-positive hospitalisations in infants who had received nirsevimab compared to infants who had not received nirsevimab (37% vs 75%, p<0.001).

López-Lacort et al.[7] conducted a case-control study using two methodological designs (screening and test-negative) to estimate the effectiveness of nirsevimab against hospitalisation for RSV-associated LRTI. The authors included 166 infants hospitalised between October 2023 and January 2024 across three regions in Spain, of whom 95 had an RSV-positive LRTI. The effectiveness of nirsevimab against RSV-positive LRTI hospitalisations was estimated to be 70.2% (95% CI, 38.3-88.5). No protection against RSV-negative LRTI hospitalisations was shown.

Paireau et al.[8] conducted a test-negative case-control study using PICU surveillance data to estimate the effectiveness of nirsevimab against severe cases of RSV bronchiolitis requiring hospitalisation in France. The authors included 288 infants reported by 20 PICUs between September 2023 and February 2024, of whom 238 were RSV-positive (cases). The number of RSV-positive hospitalisations for infants who received nirsevimab was 37/238 (15.5%), compared to 201/238 (84.5%) for infants who did not receive nirsevimab. Overall nirsevimab effectiveness against RSV hospitalisation was estimated to be 75.9% (95% CI, 48.5-88.7).

The VISION Vaccine Effectiveness Network research collaboration used a test-negative design to assess nirsevimab effectiveness against RSV-associated emergency department (ED) encounters and hospitalisations from October 2023 to March 2024[9]. The number of RSV-positive hospitalisations for an RSV-like illness in infants who received nirsevimab was 4/93 (4.3%), compared to 601/927 (64.8%) for infants who did not receive nirsevimab. The number of RSV-positive ED encounters for an RSV-like illness in infants who received nirsevimab was 63/442 (14.3%), compared to 1988/4610 (43.1%) for infants who did not receive nirsevimab. Effectiveness rates of nirsevimab against RSV-related hospitalisations and ED encounters in this cohort were 98% (95% CI, 95-99) and 77% (95% CI, 69-83), respectively.

The New Vaccine Surveillance Network (NVSN) is a population-based, prospective surveillance platform for infant and paediatric acute respiratory illness[10]. Using a test-negative design, the NVSN evaluated nirsevimab effectiveness against RSV-associated hospitalisation among infants between October 2023 and February 2024. Among 699 infants hospitalised with acute respiratory illness, 59 (8%) received nirsevimab ≥7 days before symptom onset. Nirsevimab effectiveness against RSV-associated hospitalisation was 90% (95% CI, 75-95).

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Appendix 2 Medicine Protocol

Master Medicine Protocol for the Administration of Nirsevimab (Beyfortus® 50mg/0.5mL and 100mg/mL) Solution for Injection in Pre-filled Syringe to Infants and Children

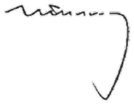
This medicine protocol is a specific written instruction for the administration of nirsevimab to infant recipients by registered nurses, midwives, student nurses/midwives (under supervision), along with HCPs included in Statutory Instrument S.I. No. XXX of 2025 who are registered with their respective regulatory body. This medicine protocol is valid for the 2025/2026 RSV Immunisation Pathfinder Programme 2.0. This medicine protocol enables the above HCPs employed in the voluntary and statutory services of the HSE who have undertaken the required education and training programmes to administer nirsevimab to infants or children for the prevention of RSV. This is with reference to and guidance from the Nursing & Midwifery Board of Ireland (NMBI), the HSE/NWIHP Standard Operating Procedure (SOP) for Nirsevimab To Reduce Respiratory Syncytial Virus (RSV) and Hospitalisations in Infants, National Immunisation
Advisory Committee (NIAC), and in accordance with the Summary of Product Characteristics (SmPC) for Beyfortus™ available at https://www.medicines.ie/medicines/beyfortus-50-mgsolution-for-injection-in-pre-filled-syringe-36322/spc#tabs

The NMBI defines medicine protocols as "written directions that allow for the supply and administration of a named medicinal product by a nurse or midwife in identified clinical situations. A medicine protocol involves the authorisation of the nurse/midwife to supply and administer a medicine to groups of patients in a defined situation meeting specific criteria and who may not be individually identified before presentation for treatment (NMBI 2020, page 6).

The HSE's RSV Immunisation Pathfinder Programme has developed this medicine protocol to facilitate infant and child immunisation against RSV using the monoclonal antibody nirsevimab according to NIAC recommendations endorsed by the Department of Health and The National Women and Infants Health Programme (NWIHP).

The professional groups using this medicine protocol must ensure that it is organisationally authorised by an appropriate authorising person or persons, relating to the professional cohort of healthcare workers by whom the immunisation is to be administered, including requirements of registration, education, training and assessment of competency.

Master Medicine Protocol for the Administration of Nirsevimab to Infant Recipients

Document reference number:	NWIHP RSV SOP25
1.0 Critical Elements	
Name of health service provider where medicine protocol applies	Health service providers across the voluntary and statutory services of the HSE, non-HSE healthcare facilities, HSE mobile vaccination clinics and community vaccination centres. This medicine protocol applies to: • Registered nurses and midwives, and student nurses/midwives (under supervision) working in maternity/paediatric services involved in the administration of nirsevimab to infant/child recipients in a secondary care or community care setting • Healthcare professionals (HCP)s who are registered with their respective regulatory body in healthcare professions included in S.I. No. XXX of 2025 employed in the voluntary and statutory services of the HSE and who are involved in the administration of nirsevimab to infant recipients
Date the medicine protocol comes into effect	From 1st August 2025
Date for review of medicine protocol	June 2026
Document prepared by	RSV Immunisation Pathfinder Programme
Names and signatures of the employing authority who is authorising the implementation of the medicine protocol ***"On behalf of the authority employing professionals authorised to administer under this medicine protocol, I have read this medicine protocol and authorise its implementation"***	Name: **Dr. Éamonn O'Moore,** Director of National Health Protection, HSE Signature:  Name: **Dr. Colm Henry,** Chief Clinical Officer, HSE Signature: 

2.0 Clinical Criteria	
Clinical condition for use of the medicine protocol	The clinical condition for which this medicine protocol has been developed is for the passive immunisation of infant and child recipients against RSV for the 2025/2026 RSV Pathfinder Programme 2.0 For the purposes of this protocol and in line with WHO definitions: neonate = 0 – 28 days of age; infant = 29 days to < 12 months of age; child = ≥ 12 months and < 24 months of age
Circumstances in which this medicine protocol applies	Immunisation programme against RSV in infants and children in the following cohorts / settings: • "Birth Cohort" of term neonates born in maternity units between 1st September 2025 to 28th February 2026 and administered in maternity units • "Birth Cohort" of term neonates born at home under the care of HSE home birth services, self-employed community midwives and private midwives between 1st September 2025 to 28th February 2026 and administered in the home setting • "Birth Cohort" of neonates who were born between 1st September 2025 and 28th February 2026 who have been transferred to the care of a paediatric unit shortly after birth and did not receive nirsevimab in a maternity unit • "Catch-up Cohort" of neonates and infants aged ≤ 6 months entering the 2025-26 RSV season and administered in: ○ Paediatric or maternity units ○ Community settings • "High-risk Cohort" of infants aged ≤ 12 months entering the 2025-26 RSV season and administered in: ○ Paediatric units ○ Community settings *High-risk defined as infant born before 30 weeks, 0 days' gestation, preterm infants with chronic lung disease (CLD) of prematurity, haemodynamically significant heart disease,

	cyanotic heart disease, pulmonary disease, neuromuscular disease, infants < 1 year age who will be profoundly immunocompromised during the RSV season. • Ex-preterm children under 24 months of age with chronic lung disease. Children who will be severely immunocompromised during the RSV season may be considered for nirsevimab. These infants should receive nirsevimab prior to the start of the RSV season in: ○ Paediatric units ○ Community settings
Inclusion criteria for infant immunisation recipients receiving nirsevimab under medicine protocol	Passive immunisation against RSV in infants and children based on NIAC recommendations • Neonate / infant / child must be clinically well at the time of administration. • S.I. No XXX of 2025 covers nurses, midwives, student nurses/midwives (under supervision) and HCPs who are registered with their respective regulatory body and employed in the voluntary and statutory services of the HSE to administer nirsevimab to infants in the "Birth Cohort" and "Catch-up Cohort" only. Administration of nirsevimab to infants in the "High-risk" cohort and to children who are ex-preterm or post cardiac surgery requiring cardiopulmonary bypass, in line with this medicine protocol, must only be performed by a registered nurse. **Precautions:** • Childhood vaccines may be co-administered at the same time or at any interval as nirsevimab. 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. • From post-marketing data, serious hypersensitivity reactions, including anaphylaxis, have been reported very rarely (< 1 in 10,000) with the exact frequency unknown. If signs and symptoms of a clinically significant hypersensitivity reaction or anaphylaxis occur, immediately discontinue administration and initiate appropriate medicinal products and/or supportive therapy. • Individuals with a bleeding disorder or receiving anticoagulant therapy may develop haematomas at IM injection sites. Prior to vaccination, inform the recipient about this risk. For those with thrombocytopenia (platelet count <$50x10^9$/L) consult the relevant specialist.

	NIAC Immunisation Guidelines (Chapter 2) detail the technique for IM injections in persons with bleeding disorders as follows: • Only one injection per muscle mass should be given at each visit. Use a 23 or 25 gauge needle to reduce the pressure gradient and cause less trauma to the tissue. The vaccine should be injected slowly (≥5 seconds) to reduce the risk of tissue damage. • Firm pressure should be applied to the site for 5 to 10 minutes after injection. • Stabilisation of the limb will reduce the risk of a haematoma. • The site should not be rubbed or massaged. • Instruct the patient/parent to monitor the injected limb and to report any concerns to their treating specialist.

Exclusion criteria for infant immunisation recipients receiving nirsevimab using this medicine protocol	For all cohorts: • Hypersensitivity to the active substance or any of the excipients listed in the Summary of Product Characteristics (SmPC) https://www.medicines.ie/medicines/beyfortus-50-mg-solution-forinjection-in-pre-filled-syringe-36322/spc#tabs • Serious hypersensitivity reaction to previous immunisation with nirsevimab or palivizumab. Exclusion in the Birth Cohort (only within a maternity unit): • Infants less than 36 weeks gestation at birth; nirsevimab must be prescribed in this instance • Infants with extended post birth hospitalisation (including SCBU/NICU/HDU admissions). These infants should have nirsevimab prescribed shortly before discharge if deemed clinically appropriate
Actions to be taken for those who are excluded from receiving the immunisation under medicine protocol	• Refer to / discuss with the relevant neonatologist, paediatrician, medical practitioner or clinical lead for an individual assessment • Document action in patient's healthcare record • Where nirsevimab is prescribed following medical assessment, the person administering the immunisation may administer within their scope of practice

Action to be followed for parent(s) of infant immunisation recipients who do not wish to receive nirsevimab	Advise the parent or guardian that their infant/child will not be protected against RSV, the virus will be circulating in children and adults in the community and their infant/child may get infected and become unwell, with a risk of hospitalisation. Provide advice regarding measures to minimise risk of their infant/child contracting RSV such as hand hygiene, avoiding crowded places, limiting contact with people who have cold-like symptoms or other infections. Refer parent/guardian to the HSE information resource on RSV https://www2.hse.ie/conditions/rsv/
Description of circumstances and referral arrangements when further advice or consultation is required	Refer to / discuss with the relevant neonatal/paediatric/medical team or clinical lead, as per local policy, if there are clinical concerns as outlined in exclusion criteria
Documentation required to support implementation of the medicine protocol	It is the responsibility of each professionally registered HCP to be familiar with the appropriate documentation to support the safe administration of nirsevimab which includes the following: • Check for and ensure verbal informed consent has been obtained and documented • This medicine protocol • RSV immunisation information leaflets • HSE/NWIHP SOP for Nirsevimab to Reduce RSV and Hospitalisations In Infants • HSE/NWIHP approved training programme module for nirsevimab • SPC for Beyfortus® found at https://www.medicines.ie/medicines/beyfortus-50-mg-solution-forinjection-in-pre-filled-syringe-36322/spc#tabs • National Immunisation Advisory Committee (2025) *Updated Recommendations for the Passive Immunisation of Infants against Respiratory Syncytial Virus (RSV)* • HPRA Adverse Reaction Reporting Forms available at http://www.hpra.ie • Local clinical incident report form

3.0 Name of Medicine	
Name of Medicine	Beyfortus® (Nirsevimab) 50mg in 0.5ml and 100mg in 1mL solution for injection in pre-filled syringe
Storage	Nirsevimab must be stored in a refrigerator at +2°C to +8°C and protected from light at all times. It may be kept at room temperature (below 25°C) for a **cumulative** maximum of 8 hours. Product that has been stored outside of a refrigerator for longer than 8 hours cumulative total must be discarded. There is no limit on the number of permitted temperature excursions in the range >8^{0}C to ≤25^{0}C, so long as the product administered to an infant has not been stored in the range of >8^{0}C to ≤25^{0}C for longer than 8 hours in total. However, standard practice should be to remove Nirsevimab from a fridge only when the parent has consented to their infant/child receiving the immunisation and it is clinically appropriate for them to receive it. Do not shake or expose to heat. For further information, please refer to the Summary of Product Characteristics (SmPC). To protect the medication from light exposure it must be stored in a refrigerator inside the original cardboard packaging. Immunisations must not be removed from their original cardboard packaging to increase refrigerator capacity.
Dose and Route of Administration	• Infants < 5kg: A single dose of 50mg (0.5mL) administered intramuscularly (purple syringe) • Infants ≥ 5kg: A single dose of 100mg (1mL) administered intramuscularly (blue syringe) • Children ≤ 24 months of age entering their second RSV season: A single dose of 200mg (2 x 100mg/1mL) administered intramuscularly into two different injection sites • For additional dosing recommendations in those post cardiac surgery requiring cardiopulmonary bypass please consult the SmPC.

Preparation for Administration of IM Injection	Prior to administration ensure the infant/child is clinically well. Check the infant/child's weight (refer to the guideline for weighing infants listed in the appendices of the national SOP for nirsevimab) **Step 1:** Visually inspect the pre-filled syringe for discolouration or particulate prior to administration. Nirsevimab is a clear to opalescent, colourless to yellow solution. Do not use if the liquid in the syringe is cloudy, discoloured, or contains large particles. Do not use if the pre-filled syringe has been dropped or damaged. Take care when handling as nirsevimab is a high-cost medication **Step 2:** Ensure the correct dose 50mg in 0.5mL or 100mg in 1.0mL has been selected **Step 3:** 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 4:** Attach a Luer lock needle 25G x 16mm or 25G x 25mm to the pre-filled syringe by gently twisting the needle clockwise onto the prefilled syringe until slight resistance is felt. Both Beyfortus® presentations (50mg in 0.5mL and 100mg in 1mL) will contain a 25G x 16mm and a 25G x 25mm needle. Select the appropriate length needle depending on the patient's size. A 23G needle may also be used in line with local practice, however this must be sourced locally. **Step 5:** 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, as 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 6.** If skin at the injection site is visibly dirty, it should be cleaned with soap and water. There is no need to use a disinfectant e.g.

	alcohol swabs. If an alcohol swab is used, the injection should be delayed for 30 seconds, to ensure the alcohol has evaporated **Step 7.** Nirsevimab is administered intramuscularly in the anterolateral aspect of the thigh in infants/children. The gluteal muscle should not be used routinely as an injection site because of the risk of damage to the sciatic nerve. If two injections are required, different injection sites should be used. **Step 8.** Recipients should be passively observed for 15 minutes after the administration of nirsevimab in line with other low risk procedures such as scheduled childhood vaccinations. Monitoring involves observing the infant for difficulty in breathing or swallowing, swelling of the face, lips, tongue, or rash. Facilities/equipment for management of infant anaphylaxis should be available in all areas where nirsevimab is being administered, including in the home birth setting **Step 9.** Staff must adhere to the principles of safe handling and disposal of sharps. **Step 10.** It is important that the parent or guardian receives a record of the immunisation give to share with her GP and PHN. The patient information leaflet contains a section where this can be recorded and given to the parent or legal guardian. A copy of the product information leaflet should also be given to the parent or legal guardian.

Documentation	The order for, and administration of, nirsevimab must be recorded in the relevant sections of the infant/child's medication record, along with the batch number and expiry of nirsevimab, which is an immunoglobulin product. Data is required to target specific public health messaging and for the Health Protection Surveillance Centre (HPSC) to monitor

	epidemiological impact. An RSV Nirsevimab data collection form is required to be completed at the time of administration. There are two different forms: one for the Birth Cohort and one for the Catchup/High-Risk/ex-Preterm cohorts. These can be found in the appendices of the HSE/NWIHP Standard Operating Procedure for Nirsevimab. One copy of the data collection form is stored in the infant/child's file and one copy given to the person who is responsible for populating the data centrally.
Potential Adverse Reactions	The most frequent adverse reaction reported is rash (0.7%) occurring within 14 days post dose. The majority of cases are mild to moderate in intensity. Additionally, pyrexia and injection site reactions have been reported at a rate of 0.5% and 0.3% within 7 days post dose, respectively. Reported injection site reactions were non-serious. Local: common: injection site reactions. General: common: rash, pyrexia.
Procedure for reporting adverse drug reactions to the HPRA	The HCP should report to the HPRA any suspected adverse reactions, in accordance with criteria outlined by the HPRA. This reporting may be carried out on line at http://www.hpra.ie or through use of the yellow card system, which is available in a downloadable format from the HPRA website, or on request from the HPRA. The infant/child recipient's GP should be informed of any reported adverse reaction. In the event of an anaphylactic reaction, the incident and all actions taken must be promptly recorded in accordance with local policy
Procedure for the reporting and documentation of errors and near misses involving the medicine	In the case of medication errors that directly involve the recipient, i.e. wrong medication/dose/route given, duplicate dose administered or another medication error, a registered nurse or midwife must remain with the recipient and closely monitor them for any adverse reactions. Vital signs should be recorded and the recipient should be monitored or moved to an appropriate treatment location if necessary. The incident must be reported to the relevant line

	manager as soon as possible. The incident and all actions taken must be recorded and the relevant local clinical incident form completed as soon as is practicable after the event and reported to the local risk manager as per local policy. The parent or guardian of the recipient should be informed of the incident. Any suspected adverse reactions associated with medication errors must be reported to the HPRA as outlined above.

3.0 Staff Authorised to Use This Medicine Protocol	
Professional qualifications, training, experience and competence required prior to using this medicine protocol	<u>Birth Cohort</u> This medicine protocol covers the following HCPs to administer nirsevimab to term neonates in the birth cohort: • Registered midwives and nurses on the active register maintained by the NMBI • Student midwives under the direct supervision of a registered midwife or nurse The above HCPs must have completed within the past two years: • NWIHP education programme on Nirsevimab To Reduce Respiratory Syncytial Virus (RSV) and Hospitalisations in Infants • 8th edition of the American Academy Heart Association/ Neonatal Resuscitation Programme • A recognised Medication Safety training module/class for Nurses and Midwives <u>Catch-up Cohort</u> This medicine protocol, in conjunction with S.I. No. XXX of 2025 covers the following HCPs to administer nirsevimab to neonates and infants in the catch-up cohort: • Registered nurses and midwives on the active register maintained by the NMBI, including paediatric nurses • Student paediatric nurses under the direct supervision of a registered paediatric nurse • Student midwives under the direct supervision of a registered midwife or nurse, for administration to neonates 0 – 28 days only • HCPs who are registered with their respective regulatory body and employed in the voluntary and statutory services of the HSE and are listed in S.I. No. XXX of 2025

	The above HCPs must have completed within the past two years: • NWIHP education programme on Nirsevimab To Reduce Respiratory Syncytial Virus (RSV) and Hospitalisations in Infants • Training in paediatric basic life support and the recognition and initial management of anaphylaxis. This training must be delivered by a recognised body and aligned with current Resuscitation Guidelines UK Anaphylaxis Algorithm and European Resuscitation Guidelines. • For nurses, midwives and student nurses/midwives, to have completed a recognised Medication Safety training module/class for Nurses and Midwives <u>High-Risk / ex-Preterm / post-cardiac surgery Cohorts</u> This medicine protocol covers the following HCPs to administer nirsevimab to infants in the high-risk / ex-Preterm cohorts: • Registered nurses The above HCPs must have completed within the past two years: • NWIHP education programme for on Nirsevimab To Reduce Respiratory Syncytial Virus (RSV) and Hospitalisations in Infants • Training in paediatric basic life support and the recognition and initial management of anaphylaxis. This training must be delivered by a recognised body and aligned with current Resuscitation Guidelines UK Anaphylaxis Algorithm and European Resuscitation Guidelines. • To have completed a recognised Medication Safety training module/class for Nurses and Midwives

4.0 Organisational Authorisation	
Appropriate authorising person(s) include the Master of a maternity hospital, Clinical Director of Paediatric Services, Regional Clinical Director, Regional Nurse Director, Director of Midwifery/Nursing, Director of Nursing, Pharmacist Executive Manager / Pharmacy Services Manager, Director of Clinical Speciality, Clinical Lead in Community Settings Where only one of the above is present in an organisation then one signature is sufficient	
Name of Organisation	
Authorising Person:	Name: Title: Date: Signature:
Authorising Person:	Name: Title: Date: Signature:
Authorising Person:	Name: Title: Date: Signature:
Authorising Person:	Name: Title: Date: Signature:

References

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National Clinical Guideline No. 30 (2023) – Infection Prevention and Control (IPC) https://www.gov.ie/en/publication/a057e-infection-prevention-and-control-ipc/.

HSE/NWIHP Standard Operating Procedure for Nirsevimab To Reduce Respiratory Syncytial Virus (RSV)

Summary of Product Characteristics (SmPC) for Beyfortus™ available at www.ema.europa.eu/en/homepage

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Appendix 3 Implementation Tools and Resources

Implementation tools and resources are available on the HPSC website and include the following:

- Parent Information Leaflet – birth cohort & catch up cohort
- Consent Form- for Mobile Vaccination Teams
- Guidance for Weighing of Infants for Nirsevimab Administration at Mobile Vaccination Clinics
- Data collection Form – maternity
- Data collection form – catch up
- Summary of Product Characteristics (SmPC)
- FAQs
- Talking to Parents about Nirsevimab
- Guidance on collecting Ethnicity data
- Training Programme – Elearning Module (You Tube video)
- Homecare service SOPs. (tbc- after confirmation from TCP)

Click on the following link to access these resources on the HPSC website - https://www.hpsc.ie/a-z/respiratory/respiratorysyncytialvirus/immunisation/

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