National Women & Infants Health Programme

Training Programme

Nirsevimab

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

National Clinical Programme for Paediatrics and Neonatology
National Women and Infants Health Programme

View Training Video Online Here

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Aim of the Respiratory Syncytial Virus Immunisation, Nurse & Midwife Training

- The aim of this training session is to facilitate Midwives and Nurses employed by the Health Service Executive (HSE) and Voluntary Hospitals to develop, maintain and update the requisite knowledge, skills and competencies to safely and effectively administer RSV Immunisations in Maternity Units/Hospitals nationally.

Learning outcomes of this training programme

At the end of the programme you should be able to:

- Understand what RSV is and why is it important to offer immunisation.
- Understand the background to the launch of RSV immunisation programme here in Ireland.
- Understand the importance of obtaining consent, correct documentation and record keeping for administering the RSV immunisation.
- Manage the safe and effective administration of RSV immunisations to infants.

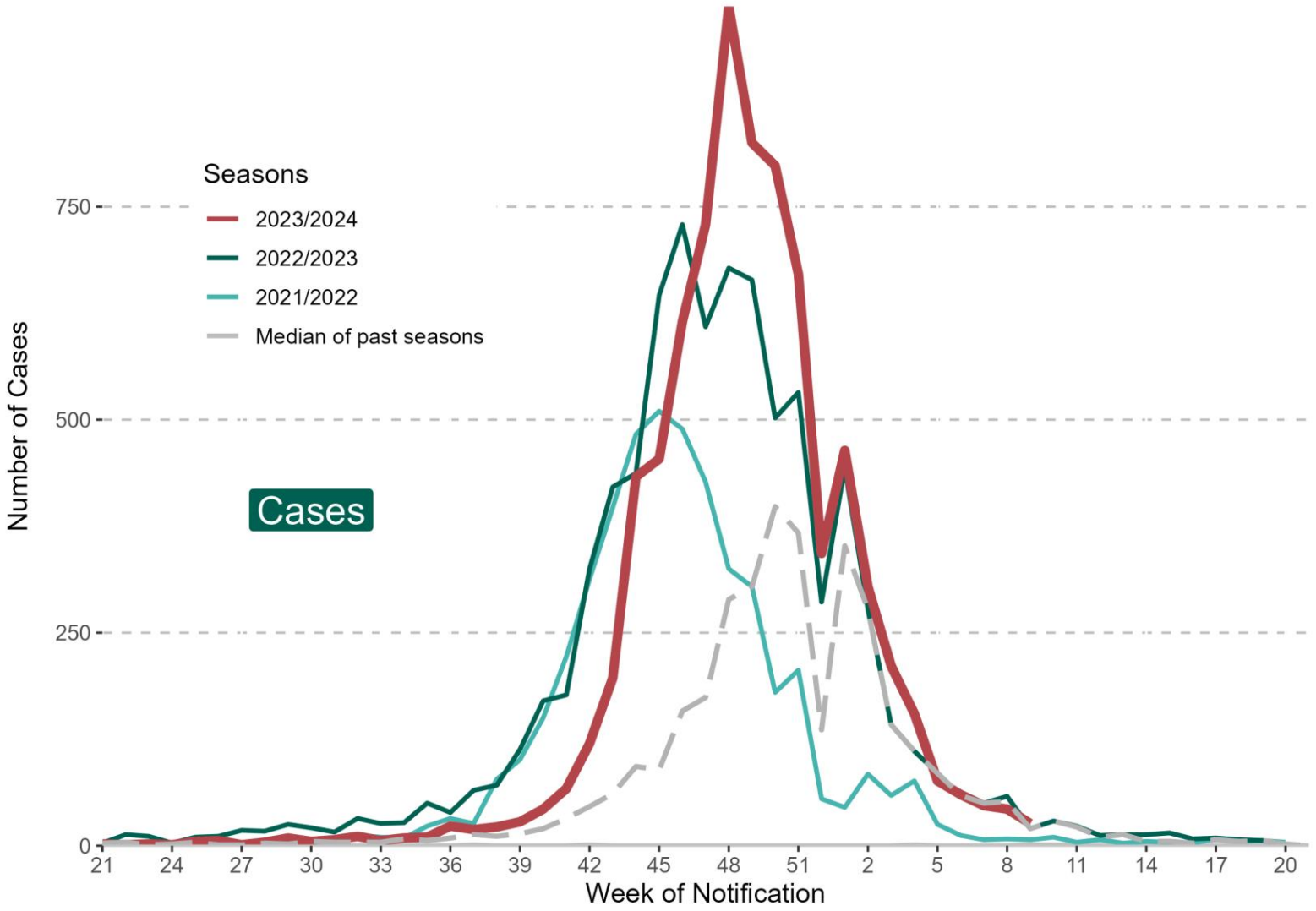
Eligibility Criteria to Administer the RSV Immunisation

- Be a Registered Nurse and or Registered Midwife, on an active register maintained by NMBI.
- Have completed this education programme on the Respiratory Syncytial Virus Immunisation for infants.
- Have successfully completed in the past 2 years the 8th edition of the American Academy of Pediatrics: Neonatal Resuscitation Programme.
- Have successfully completed a recognised Medication Safety programme for Nurses and Midwives in the past 2 years.

Background

- RSV is a common respiratory virus that can infect people of all ages and usually causes mild, cold-like symptoms. Most people recover in a week or two, but RSV can be serious.
- RSV is highly infectious in young infants. RSV is spread through droplets from an infected person's cough or sneeze.
- Typical clinical symptoms in infants are a runny nose, cough, wheezing, mild temperature, and poor feeding. In more severe cases added features include tachypnoea, grunting, chest recessions, cyanosis, and intermittent apnoea .
- It is the leading cause of hospital admission in young infants during the winter months. The RSV season extends between October and March, the rate of new cases peaking in week 45 (Nov 4-10).

Number of RSV cases weekly trends for recent seasons and age-specific rates



Cases					
Age (years)	**W08**	**W09**		**Number (season)**	**Rate (season)**
<1	6	8	■	2,843	4,919.0
1-4	7	5	■	2,125	894.3
5-14	4	1	■	397	55.4
15-24	0	4	■	104	14.8
25-34	0	2	■	134	23.6
35-44	0	1	■	187	23.5
45-54	1	1	■	212	29.7
55-64	2	2	■	306	52.8
65+	16	9	-44% ▼	1,357	174.8
All ages	**43**	**26**	**-40% ▼**	**7,666**	**148.9**

Number and age-specific rate per 100,000 notified RSV cases cumulative for current season (2023, Wk40 onwards).

Burden of RSV in Ireland, 2019/20-2023/24

- 23,848 laboratory confirmed RSV cases notified 
- 104 confirmed RSV outbreaks notified 
- 10,348 notified laboratory confirmed RSV hospitalisations 

- 1,397 RSV hospitalisations in infants under one year of age, and the majority of these of (1,017) were less than 6 months of age. In winter 2023/2024, there were 118 paediatric intensive care units admissions of infants under the age of one year of age attributed to RSV (Brennan & Patterson, 2022).

Background

- Secondary to these findings, a working group was established by the National Health Protection Office on the request of National Immunisation Advisory Committee (NIAC) and the Department of Health (DOH). It recommended the introduction of a pathfinder programme for infants born during this coming RSV season.
- The Minister of Health announced on June 18, 2024 that funding has been made available for the administration of Nirsevimab through an infant Respiratory Syncytial Virus (RSV) Immunisation Pathfinder Programme, to all infants born in Ireland during the six months (September ’2024 – February ’2025).
- A pathfinder programme is a (pilot programme) process where solutions are applied to provide an item of medical care in the most effective way. Agencies and professionals including the HSE, Midwives and Nurses, NWIHP, the faculty of Paediatrics and hospital Pharmacists have been involved in this programme.
- The immunisation will be offered to an estimated 28,000 infants during this period.
- National Health Protection Office in conjunction with the National Women and Infants Health Programme have developed this training package.

Nirsevimab

- Nirsevimab, a monoclonal antibody for the prevention of RSV lower respiratory tract infection, will now be available for administration to infants 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.
- Nirsevimab begins to provide protection against RSV immediately after injection. It takes 6 days after injection for Nirsevimab concentration to reach its peak.
- The duration of effect of Nirsevimab has been verified in clinical trials at 5 months. Pharmacokinetic data suggests protection against RSV could be as long as one year.

Nirsevimab Safety & Efficacy

- 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 administration. The majority of rash cases were mild to moderate in intensity.
- Additional, pyrexia and injections site reactions were reported at a rate of 0.5% and 0.3% per 1000 within 7 days post dose and 0.9% for 14 days respectively. Injection site reactions were non-serious EMA (2022).

Predicted Impact of Immunising Infants

ESTIMATE OF REDUCTION IN HOSPITALISATIONS				
Age group	Hospitalisations (2023-24)	Reduction in Hospitalisations admissions expected	ICU admissions (2023-24)	Reduction in ICU admissions expected
<6mo	1017	453	107	48

- Nirsevimab leads to an 80% reduction in RSV hospitalisations in infants and it has the potential to substantially reduce the morbidity associated with RSV each winter Paireau et al (2024). It is anticipated that infant RSV immunisation during the pilot period will alleviate the seasonal pressures on paediatric units throughout the country.

Talking with Parents/Guardians about Nirsevimab

- Women attending antenatal appointments, antenatal classes or having antenatal care in their home should be offered the Nirsevimab Parent Information Leaflet along with verbal information on the use of Nirsevimab to reduce severe disease and hospitalisation caused by RSV.
- Following birth, the parent or guardian should also be offered written and verbal RSV information.
- Every effort should be made to encourage the uptake of Nirsevimab.

Protect your newborn baby against Respiratory Syncytial Virus (RSV)

Protect your baby against RSV

You can now protect your newborn baby against Respiratory Syncytial Virus (RSV).

What is RSV and why should I protect my baby against it?

RSV is a common virus that causes respiratory infections in young babies. Babies under three months old get sicker with RSV than older children.

Each winter in Ireland, four out of every 100 new born babies are hospitalised due to RSV, with some babies needing special treatment in intensive care units. A further one in two new born babies in Ireland will get RSV in winter and many will need medical care from their GP or the emergency department of a children's hospital.

Nirsevimab is the best way to protect your baby from RSV.

Talking with Parents/Guardians about Nirsevimab

1

Start the Conversation

It's your decision whether to give the RSV immunisation, Nirsevimab, to your baby when they are born. My role is to share the latest information and advice to help you make this decision

2

Give a recommendation

We **recommend** Nirsevimab to protect your baby against RSV

3

Provide information on the reasons why

Each winter in Ireland, four out of every 100 new born babies are hospitalised due to RSV, with some babies needing special treatment in intensive care units.

Nirsevimab is very effective and prevents more than 80% of RSV infections. It also reduces the risk of your baby needing hospital treatment and other complications due to RSV infection.

Detailed clinical trials, large scientific studies and experiences from other nirsevimab immunisation programmes in Europe, have found nirsevimab to be safe and effective.

4

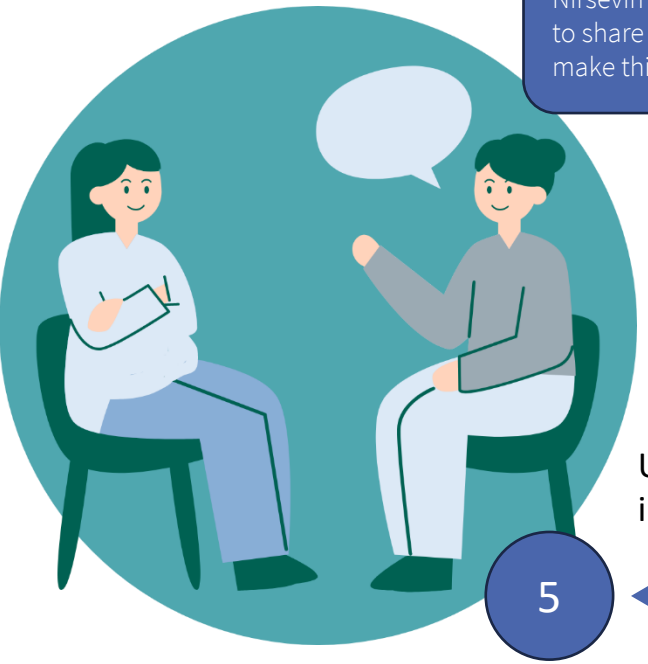
Ask about and address their concerns

The nirsevimab injection does not contain RSV and cannot cause RSV or related illnesses.

5

Use available resources to support an informed decision

Refer to the Patient information leaflet (Printed, or in different languages via HSE website)
Refer to Frequently asked questions on HSE website
And HSE.ie/RSV



Consent for a Minor

- Parents or legal guardians are generally considered to be best placed to make decisions in the best interests of their children. This means that the consent of parent(s) who are legal guardians and other legal guardian(s) to an intervention for children under the age of 16 years will generally be both necessary and legally effective.
- Consent of one parent (When the child's parents are married) or legal guardian is sufficient.

Refusal of Consent

- All reasonable efforts should be made to recognise and respect the views of parent(s) or legal guardian(s) as regards what is in the best interests of the child, including when these views differ from those of the service provider.
- Where parent(s) or legal guardian(s) refuse to consent to an intervention which the healthcare worker reasonably believes to be in the best interests of the child, every effort should be made to reach a consensus position as regards the best interest of the child. This may require involving one or more other healthcare workers, including the provision of independent second opinions, as well as mediation or other external supports (if these are available) HSE (2022).
- When consent is refused this should be clearly documented in the infants medical notes and data collection form.

Eligibility Criteria for Nirsevimab

- NIAC recommends the passive immunisation with Nirsevimab of all healthy term infants born in the RSV season September 2024 to end of February 2025 inclusive. This recommendation includes:
- All preterm infants (<37 weeks' gestation at birth) born September and February inclusive.
- All infants with chronic lung disease
- All infants with congenital heart disease.

Contraindications & Caution with Nirsevimab

- Infants must be clinically well prior to the administration of Nirsevimab.
- Infants with extended post birth hospitalisation (including SCBU/NICU/HDU admissions) should receive Nirsevimab shortly before discharge.
- A New born infant of a parent who has a strong history of hypersensitivity can receive Nirsevimab. If there are any clinical concerns advice should be sought from a senior Consultant/Register Neonatology/Paediatrics.
- As with any other intramuscular injection, Nirsevimab should be given with caution to newborn infants whose parents has a medical history of thrombocytopenia or any coagulation disorder.

Guidance for Nurses and Midwives on Nirsevimab Management and Administration

- Nirsevimab must be stored in a medication fridge that has been assessed for suitability and has at least twice daily temperature monitoring in place.
- Nirsevimab must be stored 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 maximum of 8 hours.
- After removal from the medication fridge, Nirsevimab must be used within 8 hours or discarded. Do not shake or expose to heat. For further information, please refer to the European Medication Agency.
- For the 2024/25 season, the supply of Nirsevimab that will be issued to Irish Maternity units will come in either French or Spanish language packaging however an English language patient leaflet will be made available. The RSV Immunisation Pathfinder Programme, in consultation with the HPRA have deemed these formulations to be acceptable to use in an Irish maternity setting.

Guidance for Nurses and Midwives on Nirsevimab Management and Administration

- 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)

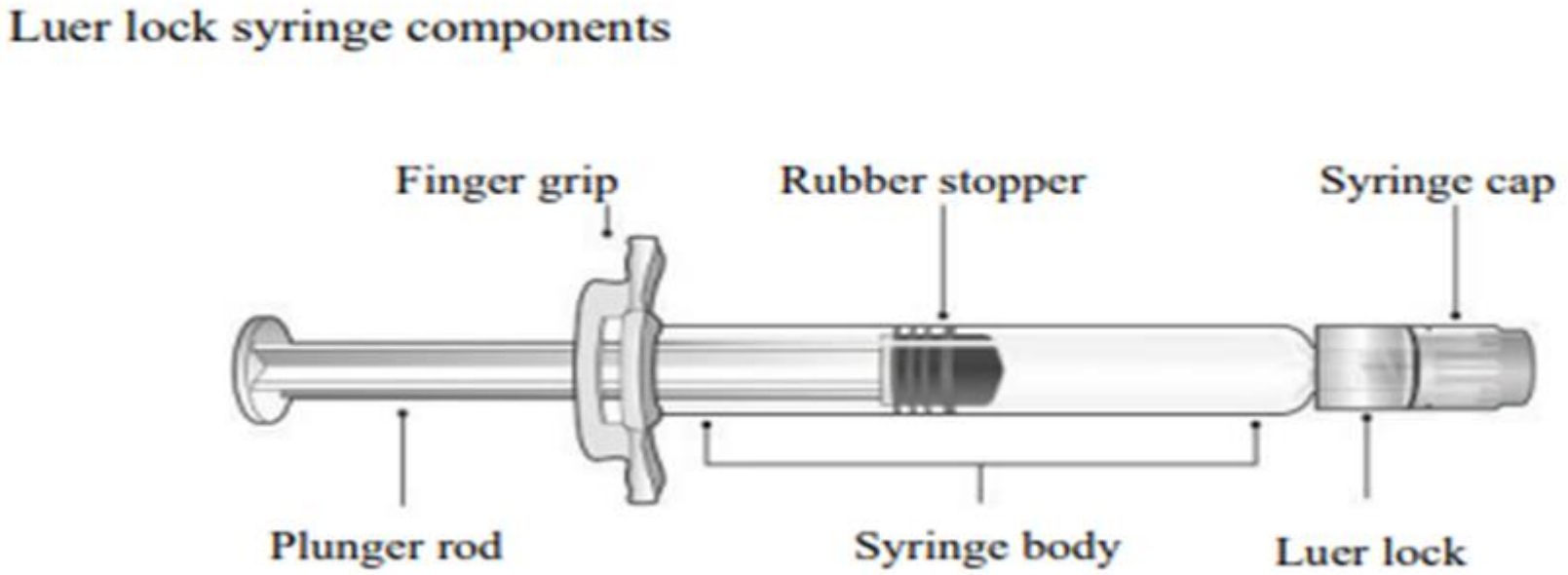
Guidance for Nurses and Midwives on Nirsevimab Management and Administration

- Nurses and Midwives should adhere to the principles of the 10 ‘rights’ of medication administration when administrating any medications to any patient including immunisations (NMBI, 2020)

The 10 ‘rights’ of medication administration	
1. Right patient	6. Right dose
2. Right reason	7. Right form
3. Right medication	8. Right action
4. Right route	9. Right documentation
5. Right time	10. Right response

Guidance for Nurses and Midwives on Nirsevimab Management and Administration

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

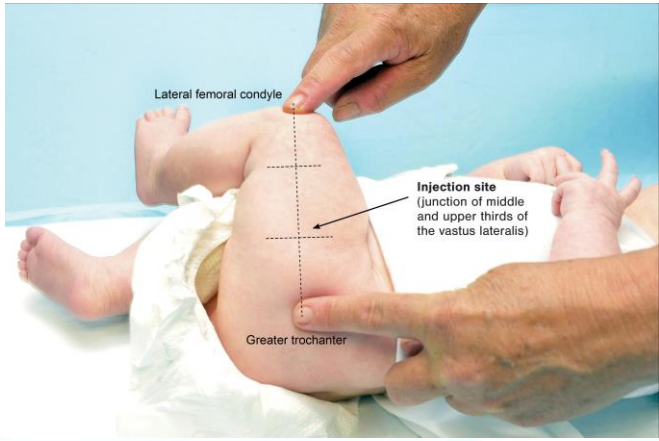


Guidance for Nurses and Midwives on Nirsevimab Management and Administration

- Step 2: Attach a Luer lock needle 25G x 16mm or 25G x 25mm needle to the pre-filled syringe by gently twisting the needle clockwise onto the pre-filled syringe until slight resistance is felt.
- Step 3: Hold the syringe body with one hand and carefully pull the needle cover straight off with the other hand. Do not hold the plunger rod while removing the needle cover or the rubber stopper may move. Do not touch the needle or let it touch any surface. Do not recap the needle or detach it from the syringe.

Guidance for Nurses and Midwives on Nirsevimab Management and Administration

- Step 4. The injection site should be cleaned with an alcohol swab and left to air dry for at least 30 seconds before administration of Nirsevimab.
- Step 5. The midwife or doctor administering the injection should visually inspect the pre-filled syringe for discolouration or particulate prior to administration. 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.
- Step 6. Nirsevimab is administered intramuscularly in the anterolateral aspect of the thigh in newborns infant. 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.



Guidance for Nurses and Midwives on Nirsevimab Management and Administration

- Step 7. Recipients should be passively observed for 15 minutes after the administration of Nirsevimab. If signs of a clinically significant hypersensitivity reaction or anaphylaxis initiate appropriate medical treatment. Facilities for management of neonatal anaphylaxis should be available in all clinical areas where Nirsevimab is being administered. Suspected adverse events following administration of Nirsevimab should be reported to Health Products Regulatory Authority (HPRA) by the Maternity Unit/Hospital.
- Step 8. Staff must adhere to the principles of safe handling and disposal of sharps.
- Step 9. Staff should complete all administration and documentation. The parent or guardian should receive a record of the immunisation to share with her GP/PHN. The information leaflet contains a section where this can be recorded.

Data Requirements for Public Health Monitoring

- Real time data is required to target specific public health messaging and data is also required by Health Protection Surveillance Centre (HPSC) for monitoring epidemiological impact.

- An agreed minimum data set will be required to be collected by each maternity unit and fed into a central data repository. A multi-par data collection form has been developed to facilitate those units that do not have electronic data base to pull reports. (One copy of the data collection form is stored in the infants file and one copy given to the person who is responsible for populating the data into the central repository. Each unit will be required to develop a process on how this will be managed.

Guidance for Nurses and Midwives on Nirsevimab Management and Administration

Dataset for Infants Offered Nirsevimab

Section 1: Infant's Details

Complete this part for the infant being offered Nirsevimab (PLEASE USE BLOCK CAPITALS)

Infant's First Name: _____ Infant's Surname (Family Name): _____

Infant's MRN/HCRN: _____ Infant Gender: ☐ Female ☐ Male ☐ Indeterminate

Infant's Date of birth: DD / MM / YY Time of birth: _____

Infant's gestational age at birth (Weeks): _____ Infant's birthweight (Kg): _____

Admission to neonatal unit? ☐ Y ☐ N ☐ Not known

Date of admission to neonatal unit: DD / MM / YY Date of discharge: DD / MM / YY

Principal reason for admission to neonatal unit: _____

Section 2: Mother's Details

Mother's First Name: _____

Mother's Surname: _____

Mother's MRN/HCRN: _____

Mother's Date of birth: DD / MM / YY

Mother's Eircode: _____

Please stick addressograph here or record the following details:

Mother's Address:

Maternal parity: ☐ Primparous ☐ Multiparous

Mother's Ethnic or Cultural Background:

A. White
- A.1 ☐ Irish
- A.2 ☐ Irish Traveller
- A.3 ☐ Roma
- A.4 ☐ Any other White Background

B. Black or Black Irish
- B.1 ☐ African
- B.2 ☐ Any other Black background

C. Asian or Asian Irish
- C.1 ☐ Chinese
- C.2 ☐ Indian/Pakistani/Bangladeshi
- C.3 ☐ Any other Asian background

D. Other, including mixed group/ background
- D.1 ☐ Arab
- D.2 ☐ Mixed, write in description

Description _____

E. Prefer not to say
- E.1 ☐

Section 3: Administration Details

Verbal Consent: ☐ Given ☐ Declined Was Nirsevimab administered to the infant? ☐ Y ☐ N

Date of administration	Time of administration	Dose given	Batch number	Expiry date	Injection site
		☐ 50mg ☐ 100mg			

Administered by [Print Name]: _____ PIN/MCRN: _____

Signature: _____

Checked by [Print Name]: _____ PIN/MCRN: _____

Signature: _____

Documentation

- Good record keeping should be undertaken by the Nurse or Midwife administering Nirsevimab as it is part of the professional and legal accountability of registered Nurses and Midwives (NMBI, 2015).

The Recording Clinical Practice document from NMBI should be reviewed which includes guidance on:

- The purpose of good record management.
- Confidentiality.
- Documenting consent to treatment.
- Legal considerations.
- Use of records in research.

References

- Brennan S, Patterson K. Estimation of RSV burden for infants in secondary care hospital records in Ireland 2017-2022 using ICD-10 diagnostic codes. 15th annual IDSI conference.
- HSE National Consent Policy (2022) https://assets.hse.ie/media/documents/ncr/20240524_HSE_Consent_Policy_2022_v1.2.pdf
- Paireau J, Durand C, Raimbault S, Cazaubon J, Mortamet G, Viriot D, et al. Nirsevimab Effectiveness Against Cases of Respiratory Syncytial Virus Bronchiolitis Hospitalised in Paediatric Intensive Care Units in France, September 2023–January 2024. Influenza Other Respir Viruses. 2024 Jun 5;18(6):e13311.
- Product Information European Medicine Agency Product Information and this guide. https://www.ema.europa.eu/en/documents/product-information/beyfortus-epar-product-information_en.pdf
- NMBI (2015) Recording Clinical Practice Guidance to Nurses and Midwives.
- NMBI (2020) Guidance for Registered Nurses and Midwives on Medication Administration


Thank you!