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 Public Health: National Health Protection

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Contents

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National Clinical Programme for Paediatrics and Neonatology
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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. 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
- Eligibility for 2024 state funded nirsevimab
- Ordering 2024 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
- Contact
- References

1.0 Aim of Standard Operating Procedure (SOP)

This Standard Operating Procedure (SOP) has been developed to support Clinicians in the implementation of the respiratory syncytial virus (RSV) Immunisation Pathfinder Programme. 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.

Subject to deliberation and review of products available in the market the National Clinical Oversight Group 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

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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

The SOP Development Group was made up of health care professionals with a special interest and expertise in maternity services, public health and neonatal pharmaceutical care.

The table below outlines stakeholders' involvement

Name	Role
Dr John Murphy Co-Chair	National Neonatal Lead, NWHIP
Dr Augustine Pereira Co-Chair	National Health Protection
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Aoife Morrissey	HSE Communication
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Michelle Waldron	NMPDU Officer, NMPDU Dublin and South East

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 non-binary.[1] It is appreciated that there are risks to desexing language when describing female reproduction.[2] [3] 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.

6.0 Effects of RSV

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).

7.0 Transmission

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.

8.0 Incubation Period

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.
RSV season extends between September and the end of February, with the rate of new cases usually peaking between November/December. During the 2023/2024 winter RSV season, there were over 3300 hospitalisations due to RSV across all age groups, of which approximately 1400 RSV hospital admissions were in children under one year of age in Ireland.
Nirsevimab, a monoclonal antibody for the prevention of RSV lower respiratory tract infection, will now be available for administration to newborn infants from autumn 2024.

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.

9.0 Nirsevimab Safety and Efficacy

Clinical trials and real world data demonstrate that nirsevimab is very effective in preventing hospitalisation from RSV infection. Across all endpoints, a single dose of nirsevimab has demonstrated sustained and consistent reduction in severe RSV 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 reported is the development of 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 administration 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 is sufficient to cover 150 days, equalling the entire RSV season. Nirsevimab begins to provide protection against RSV immediately after the injection is

administered. It takes 6 days after the administration for nirsevimab concentration to reach its peak levels in circulation. 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, Canada in April 2023, and USA 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;

The MELODY trial [5] assessed the safety and efficacy of Nirsevimab in a cohort 1490 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 trial [6] 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 trial [7] 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 trial [7] 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 trial [8] 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.

The NIRSE-GAL longitudinal population-based study [8] 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. conducted a test-negative case-control study [10] 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. 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. [11] 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. conducted a test-negative case-control study [12] 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.[13] 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 [14]. 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).

The picture that emerges is that nirsevimab leads to an 80% reduction in RSV hospitalisations in infants. It has the potential to substantially reduce the morbidity in infants associated with RSV each winter. It will alleviate the seasonal pressures on paediatric units throughout the country. The NNT (number needed to treat) to prevent a hospitalisation is 25.

10.0 National Immunisation Advisory Committee (NIAC) Recommendations for the Passive Immunisation of Infants against RSV during the 2024/2025 Season (16/04/2024) [15]

1. NIAC recommends the passive immunisation with nirsevimab of all infants who are born during the RSV season. These infants should receive nirsevimab ideally prior to discharge home from a maternity hospital. [1]
2. 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.
3. NIAC recommends the passive immunisation with nirsevimab of all infants who are aged ≤6 months at the start of the 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 in their second season 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 or programmatic limitations youngest infants (those born during the RSV season) 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. Assuming the 24/25 season follows a similar pattern, the programme should start in late September 2024 and finish at the end of February 2025. If no catch-up program is planned, an earlier start to the programme (September 1st) should be considered to capture those who will be aged under three months at the peak of the RSV season. The definitive end date for the program should be determined by levels of circulating RSV and may need to be adjusted.
8. Nirsevimab should be administered as follows: • Infants <5kg: A single dose of 50mg (0.5ml) administered intramuscularly • Infants ≥5kg: A single dose of 100mg (1.0ml) administered intramuscularly Children up to 24 months entering their second season: 200 mg given as 2 x 100mg (1.0ml) intramuscular injections.

[1] Infants currently eligible for palivizumab as outlined in Chapter 18a of NIAC Immunisation Guideline of

*Children with CLD (defined as those who required at least 28 days of supplement oxygen after birth and who continue to require medical intervention (supplementation oxygen, 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 1.0kg to > 1.6kg is based on extrapolation: no clinical data are available. Exposure in infants < 1kg is anticipated to yield higher exposure than in those weighting more. The benefits and risks of nirsevimab use in infants <1kg should be carefully considered.

*For additional dosing recommendations in those post cardiac surgery requiring cardiopulmonary bypass please consult the SPC

11.0 SOP Key Recommendations

- It is recommended that the governance and process for administration be overseen by the maternity hospital's/units Drugs & Therapeutics Committee similar to all other hospital medications and in line with hospital medication management guidelines. A template for a midwifery/nursing medication protocol for nirsevimab is attached. (Appendix 2)

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

- All staff involved in procurement, handling or administration of Nirsevimab should receive training on the safety/efficacy of Nirsevimab to reduce RSV hospitalisations. (Training Programme Nirsevimab to Reduce RSV and Associated Hospitalisation in Infants). (Appendix 6)

- It is recommended that all units create a workflow for the following scenarios:
    - Ensuring that all infants born between the September 2024 and February 2025 are offered Nirsevimab prior to discharge.
    - Ensure a process of documentation is in place which should include the data collection process required for public health monitoring and the process for documenting consent. (See RSV Nirsevimab Data Collection Form in Appendix 3)

- Midwife/Nurse Training Requirements:
    - Be a registered Nurse and or Registered Midwife, on an active register maintained by NMBI. Student midwives must act under the direct supervision of a registered midwife or nurse
    - To have completed the Training Programme Nirsevimab to Reduce RSV and Associated Hospitalisation in Infants. (Appendix 6)
      This training programme is a voice over PowerPoint presentation and will take 20 minutes to complete.
    - Have completed the 8th edition of the American Academy Heart Association/ Neonatal Resuscitation Programme in the last two years.
    - Have successful completed a recognised Medication Safety Programme for Nurses and Midwives
- 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 guardian should also be given written and verbal information following birth. Written information is available in a number of languages and these can be downloaded https://www.healthpromotion.ie/

- It is recommended that verbal consent be obtained in line with other vaccine programmes. Standard processes for obtaining consent from a parent or guardian for neonatal immunisation should be followed. The key steps include:

    - Information & advice provided at antenatal clinics.
    - HSE Parent information leaflet given to each parent. The QR codes in the patient information leaflet will direct to the EMA patient information page and the HSE RSV webpage.
    - HSE RSV FAQ will also be provided.
    - The English version of the patient information leaflet from manufacturer Sanofi attached to the injection box will be given to the parent.
    - Verbal consent would be sought after providing information and offering advice, which will be documented in the clinical notes – see section 24.
    - Documentation would include that Nirsevimab was administered, date batch, number and signature of the midwife.
    - Should a parent or guardian decline to have their infant immunised, the decision not to immunise should be documented in the Health Care Record.

- Parent and guardian may have additional questions. A number of frequent asked questions has been developed. (Appendix 5)

- Should a parent or guardian decline to have their infant immunised prior to discharge she should be informed that this product is not administered by PHN/GP. Local arrangements will vary across the 19 units with some units unable to facilitate infants to return.

- RSV immunisation is available to all eligible infants born within the dates of the programme. This includes **infants born at home (HSE homebirth service/private midwives)**. The RSV immunisation should be provided in settings where facilities for neonatal anaphylaxis are available. In the instances of homebirths, we recommend that Nirsevimab be administered in the maternity hospital/unit **opportunistically at either baby check or hearing screening visit** where facilities for management of neonatal anaphylaxis are available.

12.0 Contraindications

• Anaphylaxis to any of the monoclonal antibody constituents listed in the Summary of Product Characteristics (SmPC). (https://www.medicines.ie/medicines/synagis-solution-for-injection-33895/spc

• Serious hypersensitivity reaction to previous immunisation with Nirsevimab or palivizumab.

13.0 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.

• As with any other intramuscular injections, Nirsevimab should be given with caution to infants with thrombocytopenia or any coagulation disorder.

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

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 **R**SV = **R**ight. 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.

15.0 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.

16.0 Eligibility for Nirsevimab

For the 2024-25 RSV Immunisation pathfinder programme, the HSE recommends Nirsevimab for all healthy term infants and all high-risk infants previously eligible for Palivizumab as recommended by NIAC.

NIAC recommends the passive immunisation with nirsevimab of all healthy term infants born in the RSV season September to end of February inclusive. This recommendation includes:

- All preterm infants (<37 weeks' gestation at birth) born September 2024 and February 2025 inclusive.
- All infants with chronic lung disease
- All infants with congenital heart disease.

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.

17.0 Ordering Nirsevimab

Funding for nirsevimab is being provided centrally by the HSE. No charges will be incurred by hospital pharmacies for the product or deliveries. Based on the volume of births, each hospital will need to estimate their likely weekly Nirsevimab stock ordering levels. To prevent hospitals 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 below. Please note that as demand rates settle into a stable pattern, each hospital will, over time, be able to adjust their delivery quantities.

Hospital	2023 Births	Nirsevimab 50mg Per Day (Total)	Nirsevimab 50mg Per Week (Total)	Nirsevimab 50mg Per 28 Day Month (Total)
National	54,484	136	953	3,812
Rotunda Hospital	8,442	21	146	583
Coombe Women and Infants University Hospital	6,974	17	120	481
National Maternity Hospital	6,856	17	118	473
Cork University Maternity Hospital	6,464	16	112	446
UMH Limerick	3,938	10	68	272
Our Lady of Lourdes Hospital	2,770	7	48	191
Galway University Hospitals	2,605	6	45	180
MRH Mullingar	1,804	4	31	125
UH Waterford	1,654	4	29	114
Letterkenny University Hospital	1,577	4	27	109
Wexford General Hospital	1,567	4	27	108
MRH Portlaoise	1,402	3	24	97
Portiuncula University Hospital	1,384	3	24	96
Mayo University Hospital	1,369	3	24	95
St. Luke's General Hospital Kilkenny	1,340	3	23	93
Cavan General Hospital	1,263	3	22	87
Sligo University Hospital	1,211	3	21	84
UH Kerry	1,137	3	20	78
Tipperary University Hospital	727	2	13	50
CHI Crumlin	N/A	2	13	50

*These estimates will form the basis for initial stock ordering levels that will be given to Uniphar/Durbin to deliver to each hospital around mid-August. This can be updated directly with Uniphar/Durbin as demand levels become clearer.

While the vast majority of Nirsevimab doses delivered will be the 50mg formulation (for neonates < 5kg birth weight), hospitals 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 2024.

18.0 Nirsevimab Storage and Cold Chain Management

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 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 patient information leaflet.

Nirsevimab) must be protected from light and temperature fluctuations outside of +2°C to +8°C. To protect the medication from light exposure it must be stored in a medication refrigerator inside the 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 at local level to ensure that medication storage fridges:

- 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 temperature record must be maintained.

19.0 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.

20.0 Nirsevimab Presentation

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 2024/25 RSV season, EMA licensed stock will be provided. However, the presentation will be in either French or Spanish language. English language patient information leaflet will be made available.

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. The minimum gauge of needle that should be used is 25G. If local practice

is to use a wider bore for administration of IM injections to neonates, then a 23G needle can be used. 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.

The French language product of nirsevimab will contain 25G needles of lengths 16mm and 25mm, whereas the Spanish language product will not; these needles will need to be sourced locally.

21.0 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 100 mg intramuscular injections.

22.0 Nirsevimab Administration to Preterm Infants

Background:
A selective programme for the administration of Palivizumab (Synagis) to high-risk preterm infants has been in place for over 20 years. The infants who received Palivizumab were those less than 30 weeks' gestation or birthweight less than 1.25 Kg.

The pathway for RSV protection for preterm infants
Preterm infants will be administered Nirsevimab instead of Palivizumab. Its advantages are that it requires only one injection and it has greater efficacy.
Preterm infants who are discharged home from the forthcoming 1st September will be administered nirsevimab prior to discharge from the neonatal unit.
The preterm infants who were discharged home prior to this forthcoming RSV season and were due to receive Palivizumab at home, will instead receive Nirsevimab at home through TCP Homecare.

23.0 TCP Homecare Service for Nirsevimab

The introduction of the Respiratory Syncytial Virus (RSV) Immunisation Pathfinder Programme via maternity units will only offer Nirsevimab to babies born in hospital after the 1st of September, where the baby will receive the injection prior to discharge home.

High-risk babies previously eligible for palivizumab will now be offered Nirsevimab. This includes high risk babies born out of RSV season i.e. between the end of March 2024 and the beginning of September 2024 as well as all high risk babies entering their second season (year 2 of their life). These babies at high-risk from RSV Infection include the following:

1. Premature babies born at ≤29 weeks gestational age
2. Chronic Lung Disease - Bronchopulmonary dysplasia a serious complication of prematurity resulting from poor lung growth and lung injury.
3. Congenital Heart - Preterm babies have more than twice as many congenital heart defects as term neonates.

TCP Homecare will provide an at-home injection service to these high-risk babies born during the period March to September 2024. This service will include the following elements:

a. Direct communication with all Paediatric Hospitals notifying them of this service for at-risk Out of Season Babies.

b. Implementation of a robust referral process to facilitate service registration and the provision of prescriptions for Nirsevimab for all babies registered to the programme.

c. Provision of a Pharmacy Dispensing Service

d. Provision of a Direct to Patient home delivery service of the dispensed Nirsevimab via our validated and verifiably monitored fleet of cold-chain vehicles (@ 2° - 8°C).

e. Provision of appropriately trained Paediatric Nurses to administer the Nirsevimab IM Injection in the baby's home.

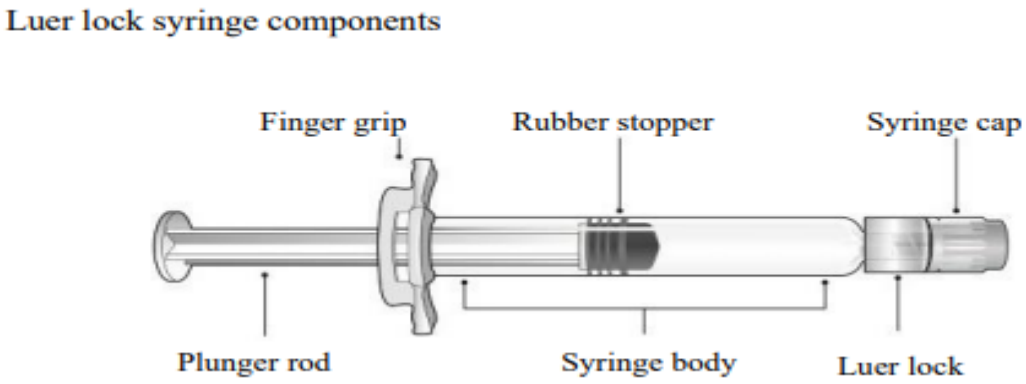
f. Removal of all Clinical Waste associated with the administration of Nirsevimab.

Hospitals wishing to refer babies to this 'At Home Injection Service' will need to complete the Nirsevimab Referral Form (See Appendix 10) and the prescription form provided (see Appendix 12) and return to TCP Homecare (details are provided on the forms).

Note: it is critical that the prescription provided clearly states the actual dose to be administered i.e. 50mg for a baby less than 5KG and 100mg for a baby 5KG or more. It is recommended that 2nd season babies receive a 200MG dose of Nirsevimab.

Once the Nirsevimab Referral forms & prescriptions are received into TCP Homecare, each parent / guardian will be contacted, details of a delivery date for the Nirsevimab injection will be agreed with the parent / guardian and a Nurse Home Visit date confirmed. (See Appendix 8 for TCP Homecare SOP)

24.0 Preparation for Administration of Intramuscular Injection



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

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

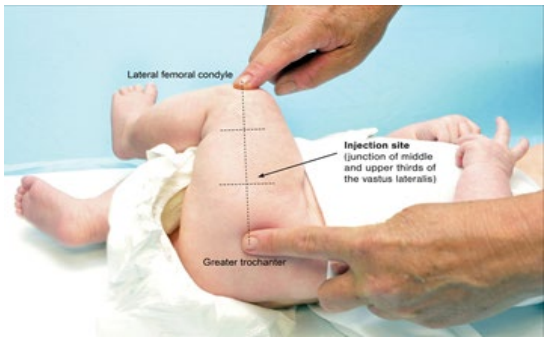
Step 3: Hold the syringe body with one hand and carefully pull the needle cover straight off with the other hand. Do not hold the plunger rod while removing the needle cover or the rubber stopper may move. Do not touch the needle or let it touch any surface. Do not recap the needle or detach it from the syringe. (SmPC) (https://www.medicines.ie/medicines/synagis-solution-for-injection-33895/spc

Step 4. 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 5. Infants must be clinically well prior to the administration Nirsevimab. Infants with extended post birth hospitalisation (including SCBU/NICU/HDU admissions) should receive nirsevimab shortly before discharge.

Step 6. If the injection site is visibly dirty, it should be cleaned with soap and water. If an alcohol swab is used, the injection should be delayed for 30 seconds, to ensure the alcohol has evaporated (NIAC Immunisation Guidelines Chapter 2).

Step 7. 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.



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 virtually no risk of anaphylaxis associated with administration of this product. [17].

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

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 guardian. (Appendix 1)

25.0 Record of Immunisation Interaction

The essential concept about informed consent is that the parent(s) of the infant should be informed of all the known risks, the exact purpose of the immunisation jab and be provided with the various leaflets (patient information leaflet, product information leaflet and FAQ) and any further information such that the parent(s) have an informed choice to make concerning the immunisation of the child. Documentation is crucial and therefore it is important to maintain excellent records of each immunisation interaction with the parent(s).

The RSV Nirsevimab data collection form (appendix 3) provides a standardised way to document the administration of Nirsevimab. These data are required to target specific public health messaging and also required by the HSE (and specifically the Health Protection Surveillance Centre (HPSC)) for service evaluation and to monitor the epidemiological impact of this pathfinder programme.

- An agreed data collection form (appendix 3) has been designed and should be completed by each maternity unit.
- The four 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 and The National Maternity Hospital.
- For all other maternity hospitals (non-MN-CMS sites) and CHI, a multi-par paper data collection form (appendix 3) 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 into a central repository of data. Each unit will be required to develop a process on how this will be managed.

- The HSE are currently developing a Central repository of data and further instructions will issue in this regard and meanwhile each unit is requested to securely store these data collection forms.
- 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) have been 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
- Adverse events are managed as per standard Health Product Regulatory Authority (HPRA). Please visit www.hpra.ie/report to report a side effect. [i]

PAEDIATRICS

National Women & Infants Health Programme

Appendix 1: Parent/ Legal Guardian Information Leaflet

Protect your new born baby against Respiratory Syncytial Virus (RSV)

Protect your baby against RSV

You can now protect your new born 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 one in two new born babies will get RSV and many will need medical care from their GP or the emergency department of a children's hospital. Four out of a hundred new born babies are hospitalised due to RSV, with some babies needing special treatment in intensive care units.

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

29/07/2024 13:08

Cén chaoi ar féidir liom mo naíonán a chosaint ar RSV?

Tá imdhíonadh ar a dtugtar nirsevimab á mholadh do gach leanbh a bheirtear idir Meán Fómhair 2024 agus Feabhra 2025. Cosnóidh sé seo do naíonán ar ionfhabhtú RSV le linn míonna an gheimhridh.

Is instealladh aonair é nirsevimab a thugtar isteach i matán leise an naíonáin. Tá sé saor in aisce. Tairgfear an t-imdhíonadh do do naíonán sula rachaidh sibh abhaile ón ospidéal máithreachais.

Céard is nirsevimab ann agus cén chaoi a n-oibríonn sé?

Is antasubstaint é Nirsevimab ar féidir leis cosaint a thabhairt i gcoinne RSV. Ní hionann é agus vacsaín, a spreagann an córas imdhíonachta le hantasubstaintí a tháirgeadh. Ina áit sin, tugann nirsevimab na hantasubstaintí féin go díreach do do naíonán. Ní chuireann nirsevimab isteach ar vacsaíní ná ar chógais eile a thugtar do naíonáin agus is féidir é a thabhairt ag an am céanna le hinstealltaí eile.

Céard iad na buntáistí a bhaineann le mo naíonán a chosaint ar RSV?

Tá nirsevimab an-éifeachtach agus cuireann sé cosc ar níos mó ná 80% d'ionfhabhtuithe RSV. Laghdaíonn sé freisin an baol go mbeidh ar do leanbh dul chuig an ospidéal chun cóir leighis a fháil nó go dtiocfaidh aimhréidheanna eile air nó uirthi de dheasca ionfhabhtú RSV.

Oibríonn sé láithreach bonn, rud a fhágann go mbeidh do naíonán cosanta agus sibh ag fágáil an ospidéil agus ag dul isteach i dtimpeallachtaí a bhféadfadh RSV a bheith ag scaipeadh iontu, amhail an baile nó an pobal.

Cosnóidh nirsevimab do naíonán ar RSV go ceann cúig mhí ar a laghad thar thréimhse an gheimhridh, tráth a mbíonn ardleibhéal RSV ag dul thart.

Tá an Roinn Sláinte, Feidhmeannacht na Seirbhíse Sláinte (FSS) agus an Coiste Comhairleach Náisiúnta um Imdhíonadh ag moladh nirsevimab in Éirinn. Tá imdhíonadh RSV á mholadh i dtíortha eile san Eoraip, sna Stáit Aontaithe agus san Astráil freisin.

An bhfuil nirsevimab slán sábháilte do mo naíonán?

Mar thoradh ar thrialacha cliniciúla mionsonraithe, staidéir mhóra eolaíocha agus taithí ó chláir eile imdhíonta nirsevimab san Eoraip, is eol dúinn go bhfuil nirsevimab idir shlán sábháilte agus éifeachtach. Rinne an Ghníomhaireacht Leigheasra Eorpach (EMA) nirsevimab a cheadúnú in 2022.

Céard iad na fo-iarmhairtí?

Níl fo-iarmhairtí coitianta. Ní thuairiscítear iarmhairtí éadroma ná mion-iarmhairtí ach i níos lú ná 1% de na naíonáin a fhaigheann nirsevimab. Ina measc siúd tá:

- deirge sa chraiceann san áit a bhfuair an naíonán an t-instealladh
- teocht éadrom,
- gríos éadrom.

Is annamh a thuairiscítear frithghníomhuithe ailléirgeacha

nó hipiríogaireacht. Déanfar dlúthmhonatóireacht ar do naíonán tar éis dó nó di an t-instealladh a fháil.

Níl aon RSV in imdhíonadh nirsevimab agus ní féidir leis a bheith ina chúis le haon bhreoiteacht a bhaineann le RSV.

Beidh do dhochtúir nó do chnáimhseach in ann aon cheist atá agat a fhreagairt.

Céard iad na roghanna eile?

Má dhéanann tú an cinneadh gan nirsevimab a thabhairt do do naíonán, ní bheidh sé nó sí cosanta ar RSV.

Beidh RSV ag scaipeadh i measc leanaí agus daoine fásta mar sin féin agus beidh an seans ann go dtolgfaidh do naíonán é agus go n-éireoidh sé nó sí breoite dá bharr.

Má dhéanann tú an cinneadh gan do naíonán a imdhíonadh in aghaidh RSV, d'fhéadfadh sé go mbeadh ort an baol go dtolgfaidh do naíonán RSV a laghdú ar bhealaí eile:

- lámha a ní i gceart
- fanacht glan ar áiteanna plódaithe
- teorainn a chur le teagmháil le daoine a bhfuil comharthaí slaghdáin nó ionfhabhtuithe eile orthu.

Cé na daoine nár cheart dóibh nirsevimab a fháil?

Is féidir leis na cnáimhseacha nó leis na dochtúirí comhairle a thabhairt duit má bhraitheann siad nár cheart do do naíonán nirsevimab a fháil. Caithfidh an tsláinte a bheith go maith ag do naíonán nuair a thugtar nirsevimab dó nó di. I gcás go bhfuil monatóireacht á déanamh ar do naíonán le haghaidh aon riocht, amhail fadhbanna leis an bhfuil, ionfhabhtú, deacrachtaí análaithe nó leibhéal íseal siúcra san fhuil, d'fhéadfadh sé go gcuirfí siar nirsevimab go dtí go dtiocfaidh biseach ar do naíonán.

Cén áit ar féidir liom teacht ar a thuilleadh eolais?

Labhróidh na cnáimhseacha nó na dochtúirí leat faoin imdhíonadh nirsevimab agus freagróidh aon cheisteanna atá agat. Má dhéanann tú an cinneadh do naíonán a chosaint ar RSV, iarrfar ort toiliú ó bhéal a thabhairt go dtabharfaí an t-instealladh dó nó di.

Le tuilleadh eolais a fháil ó HSE
www.hse.ie/RSV

Chun féachaint ar fhaisnéis othar ó Ghníomhaireacht Leigheasra na hEorpa tabhair cuairt ar:
www.ema.europa.eu/en/medicines/human/EPAR/beyfortus

Cosain do naíonán nuabheirthe ar an Víreas Sincítiach Riospráide (RSV)

Cosain do naíonán ar RSV

Is féidir leat do naíonán nuabheirthe a chosaint ar an Víreas Sincítiach Riospráide (RSV) anois.

Céard is RSV ann agus cén fáth ar chóir dom mo naíonán a chosaint air?

Is víreas coitianta é RSV is cúis le hionfhabhtuithe riospráide i naíonáin óga. Is breoite a bhíonn naíonáin faoi bhun trí mhí d'aois nuair a tholgann siad RSV ná leanaí atá níos sine.

Gach geimhreadh in Éirinn, cuirtear ceathrar as gach 100 naíonán nuabheirthe san ospidéal de dheasca RSV, agus teastaíonn cóireáil speisialta in aonad dianchúraim i roinnt cásanna. Ina theannta sin, tolgann duine amháin as gach beirt naíonán nuabheirthe in Éirinn RSV sa gheimhreadh agus caithfidh an-chuid acu cúram leighis a fháil ó dhochtúir teaghlaigh nó sa rannóg éigeandála in ospidéal leanaí.

Is é nirsevimab an bealach is fearr le do naíonán a chosaint ar RSV.

29/07/2024 13:08

How can I protect my baby from RSV?

An immunisation called nirsevimab is being recommended for your baby. This will protect your baby from severe RSV infection over the coming months.

Nirsevimab is a single injection into the baby's thigh muscle. It is free of charge. You will be offered the immunisation for your baby before you go home from the maternity hospital.

What is nirsevimab and how does it work?

Nirsevimab is an antibody that can protect against RSV. It is different from a vaccine, which stimulates the immune system to produce antibodies. Instead, nirsevimab provides antibodies directly to protect your infant. Nirsevimab does not interfere with other infant vaccines or medicines and can be given at the same time as other injections.

What are the benefits of protecting my baby from RSV?

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

It works straight away so your baby is protected when they leave hospital and enter environments where RSV could be spreading such as the home or in the community.

Nirsevimab will protect your baby against RSV for at least five months over the winter period when RSV levels are highest.

In Ireland, nirsevimab is recommended by the Department of Health, HSE and the National Immunisation Advisory Committee (NIAC). RSV immunisation is also recommended in other countries in Europe, the USA and Australia.

Is nirsevimab safe for my baby?

Detailed clinical trials, large scientific studies and experiences from other nirsevimab immunisation programmes in Europe, have found nirsevimab to be safe and effective. Nirsevimab was licensed by the European Medicines Agency (EMA) in 2022.

What are the side effects?

Side effects are uncommon. Mild and minor effects are reported in fewer than 1% of babies who receive nirsevimab. These include:

- redness of the skin where the baby got the injection
- mild temperature,
- a mild rash.

Allergic reactions or hypersensitivity are rarely reported. Your baby will be monitored closely after the injection.

The nirsevimab immunisation does not contain RSV and cannot cause RSV related illness.

Your doctor or midwife will answer any queries you have.

What are the alternatives?

If you choose not to give nirsevimab to your baby, they won't be protected against RSV.

RSV will still be circulating in children and adults and your baby may get infected and become unwell.

If you choose not to immunise your baby against RSV you may need to reduce the risk of your baby getting RSV by:

- cleaning hands properly
- avoiding crowded places
- and limiting contact with people who have cold-like symptoms or other infections.

Who should not get nirsevimab?

Your team of midwives or your doctor can advise if they feel that your baby should not get nirsevimab. Your baby must be well when nirsevimab is given. If your baby is being monitored for any condition such as problems with their blood, infection, breathing difficulties or low blood sugar, nirsevimab might be delayed until your baby is well.

Where can I learn more?

Your team of midwives or your doctor will talk to you about the nirsevimab immunisation and they will answer any questions that you may have. If you decide to protect your baby from RSV, you will be asked to give verbal consent for your baby to get the injection.

For more information from the HSE
www.hse.ie/RSV

To view patient information from the Europe Medicine Agency visit:
www.ema.europa.eu/en/medicines/human/EPAR/beyfortus

Date:
Batch No:

Appendix 2: Medicine Protocol

Medicine Protocol for the Administration of Nirsevimab to infants for the prevention of Respiratory Syncytial Virus (RSV) by registered nurses and midwives

This medicine protocol is a specific written instruction for the administration of nirsevimab to infant recipients by registered nurses, midwives and student midwives (under supervision) without a prescription from a registered prescriber. This medicine protocol is valid for the 2024/2025 RSV Immunisation Pathfinder Programme. This medicine protocol enables registered nurses and midwives, and student midwives (under supervision) employed in the voluntary and statutory services of the HSE who have undertaken the required education and training programmes to administer nirsevimab to infants 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 for Nirsevimab To Reduce Respiratory Syncytial Virus (RSV) and Associated Hospitalisations in Infants, National Immunisation Advisory Committee (NIAC), and in accordance with the Summary of Product Characteristics (SmPC) for Beyfortus™ available at www.ema.europa.eu/en/homepage.

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).

Medicine Protocol for the administration of Nirsevimab to infant recipients

Document reference number:	NWIHP RSV SOP24
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. This medicine protocol applies to registered nurses and midwives, and student midwives (under supervision) working in maternity/paediatric services involved in the administration of nirsevimab to infant recipients
Date the medicine protocol comes into effect	September 2024

Date for review of medicine protocol	May 2025
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: **Master / CEO** Signature:_____ Name: **Director of Midwifery / Nursing** Signature: _____ **Name: Director / Clinical Lead for Neonatology** Signature: _____ Name: **Pharmacist Executive Manager / Chief Pharmacist** Signature: _____
2.0 Clinical Criteria	
Clinical condition for use of	The clinical condition for which this medicine protocol has been developed is for the passive immunisation of infant recipients against RSV for the 2024/2025 RSV Pathfinder Programme

the medicine protocol	
Inclusion criteria for infant immunisation recipients receiving nirsevimab under medicine protocol	NIAC recommends the passive immunisation with nirsevimab of all healthy term infants born in the RSV season September to end of February inclusive. Infants must be clinically well at the time of administration. 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. **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. • As with any other intramuscular injections, nirsevimab should be given with caution to infants with thrombocytopenia or any coagulation disorder.

Exclusion criteria for infant immunisation recipients receiving	• All infants less than 36 weeks gestation at birth fall outside the scope of this midwifery/nursing medicine protocol. Nirsevimab must be prescribed for this cohort of infants. • Infants with extended post birth hospitalisation (including SCBU/NICU/HDU admissions). These infants should receive nirsevimab shortly before discharge when deemed clinically well

nirsevimab under medicine protocol	• Anaphylaxis to any of the monoclonal antibody constituents listed in the Summary of Product Characteristics (SmPC) https://www.ema.europa.eu/en/documents/product-information/beyfortus-epar-product-information_en.pdf
Actions to be taken for those who are excluded from receiving the vaccine under medicine protocol	Clinical review by neonatology team. If nirsevimab is subsequently deemed appropriate then a prescription required.
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 will not be protected against RSV, the virus will be circulating in children and adults in the community and their baby may get infected and become unwell, with a risk of hospitalisation. Advice regarding measures to minimise risk of their infant getting RSV such as hand hygiene, avoiding crowded places, limiting contact with people who have cold-like symptoms or other infections
Description of circumstances and referral arrangements when further advice or consultation is required	Refer to/discuss with the neonatal team 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 registered nurse/midwife/midwifery student to be familiar with the appropriate documentation to support the safe administration of nirsevimab which includes the following: • This medicine protocol • RSV Immunisation information leaflets • Check for and ensure that verbal consent has been obtained and documented • HSE/NWIHP Standard Operation Procedure for Nirsevimab To Reduce Respiratory Syncytial Virus (RSV) • HSE/NWIHP Training Programme Module for Nirsevimab • Summary of Product Characteristics (SmPC) for Beyfortus™ available at https://www.ema.europa.eu/en/documents/product-information/beyfortus-epar-product-information_en.pdf • National Immunisation Advisory Committee (2024) *Recommendations for the Passive Immunisation of Infants against Respiratory Syncytial Virus (RSV) during the 2024/2025 season* at: https://www.rcpi.ie/Healthcare-Leadership/NIAC/Advice-Provided-to-the-Department-of-Health • HPRA Adverse Reaction Reporting Forms available at http://www.hpra.ie • Local Clinical Incident Form
Name of medicine	Generic name: Nirsevimab Trade name: Beyfortus™

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 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 Summary of Product Characteristics (SmPC). To protect the medication from light exposure nirsevimab must be stored in the medication refrigerator inside the original cardboard packaging. Immunisations must not be removed

	from their original cardboard packaging to increase refrigerator capacity.
Dose & route of administration	• Infants <5kg birth weight: A single dose of 50mg (0.5ml) administered intramuscularly (Purple Syringe) • Infants ≥5kg birth weight: A single dose of 100mg (1.0ml) administered intramuscularly (Blue Syringe)
Preparation for Administration of Intramuscular Injection	Step 1: Holding the Luer lock in one hand, (avoid holding the plunger rod or syringe body) unscrew the syringe cap by twisting it counter clockwise with the other hand. Step 2: Attach a Luer lock needle 25G x 16mm or 25G x 25mm (23G may be used in line with local practice) to the pre-filled syringe by gently twisting the needle clockwise onto the pre-filled syringe until slight resistance is felt. Step 3: Hold the syringe body with one hand and carefully pull the needle cover straight off with the other hand. Do not hold the plunger rod while removing the needle cover or the rubber stopper may move. Do not touch the needle or let it touch any surface. Do not recap the needle or detach it from the syringe. Step 4. The midwife or nurse 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 5. Infants must be clinically well prior to the administration nirsevimab. Infants with extended post birth hospitalisation (including SCBU/NICU/HDU admissions) should receive nirsevimab shortly before discharge.

	Step 6. If the injection site is visibly dirty, it should be cleaned with soap and water. If an alcohol swab is used, the injection should be delayed for 30 seconds, to ensure the alcohol has evaporated (NIAC Immunisation Guidelines Chapter 2). Step 7. 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. 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 virtually no risk of anaphylaxis associated with administration of this product. Facilities for management of neonatal anaphylaxis should be available in all clinical areas where nirsevimab is being administered. 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 given to share with her GP and PHN. The patient information leaflet contains a section where this can be recorded.
Documentation	The order for, and administration of, nirsevimab must be recorded in the relevant sections of the infant's medication record, along with the batch number and expiry of nirsevimab, which is an immunoglobulin product.

	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. The RSV Nirsevimab data collection form that is required to be completed at the time of administration can be found in the HSE/NWIHP Standard Operating Procedure for Nirsevimab in appendix 3 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.
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 registered nurse or registered midwife 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 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 for neonatal resuscitation

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 being administered or another medication error, the registered nurse or registered 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 as 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	The registered nurse or midwife must have completed all of the following: 1. Be a registered nurse or registered midwife, on the active register maintained by the NMBI. Note student midwives must act under the direct supervision of a registered nurse or midwife 2. NWIHP education programme for registered nurses and registered midwives on *Nirsevimab To Reduce Respiratory Syncytial Virus (RSV) and Associated Hospitalisations in Infants* access (Appendix 6) 3. 8th edition of the American Academy Heart Association/ Neonatal Resuscitation Programme in the last two years Have successfully completed a recognised Medication Safety Programme for Nurses and Midwives

References

NMBI (2020) *Guidance for Registered Midwives and Nurses on Medication Administration* Dublin: Nursing and Midwifery Board of Ireland

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

National Immunisation Advisory Committee (2024) National Immunisation Advisory Committee (2024) *Recommendations for the Passive Immunisation of Infants against Respiratory Syncytial Virus (RSV) during the 2024/2025 season* available at: https://www.rcpi.ie/Healthcare-Leadership/NIAC/Advice-Provided-to-the-Department-of-Health

Nursing and Midwifery Board of Ireland (2021) *Code of Professional Conduct and Ethics for Registered Nurses and Registered Midwives.* Dublin: Nursing and Midwifery Board of Ireland available at: http://www.nmbi.ie/Standards-Guidance/Code

Nursing and Midwifery Board of Ireland (2020) *Guidance for Registered Nurses and Midwives on Medication Administration*. Dublin: Nursing and Midwifery Board of Ireland

Nursing and Midwifery Board of Ireland (2022) *Practice Standards for Midwives.* Dublin: Nursing and Midwifery Board of Ireland available at: http://www.nmbi.ie/Standards-Guidance/Midwives-Standards

Nursing and Midwifery Board of Ireland (2015) *Recording Clinical Practice. Guidance to Nurses and Midwives.* Dublin: Nursing and Midwifery Board of Ireland available at: http://www.nmbi.ie/Standards-Guidance/MoreStandards-Guidance/Recording-Clinical-Practice

Nursing and Midwifery Board of Ireland (2015) *Scope of Nursing and Midwifery Practice Framework.* Dublin: Nursing and Midwifery Board of Ireland available at: http://www.nmbi.ie/Standards-Guidance/Scope-ofPractice/Nursing-Practise-Scope-Definition.

Appendix 3: RSV Nirsevimab Data Collection Form

RSV Nirsevimab Data Collection Form

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 Date of birth: DD / MM / YY Time of birth: _____

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

Admission to neonatal unit? ☐ Y ☐ N ☐ Not known *(If no or unknown skip to section 2)*

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: _____

Maternal parity: ☐ Primparous ☐ Multiparous

Please stick addressograph here or record mother's address:

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

Parent Leaflet and Patient Information Leaflet issued: ☐ Y ☐ N

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			☐ Rt thigh ☐ Lt thigh

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

Signature: _____

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

Signature: _____

RSV Immunisation CC form.indd 1 01/08/2024 11:55

Appendix 4: Summary of Product Characteristics

RSVpreF - Summary of Product Characteristics – [LINK]

Appendix 5: Frequently Asked Questions

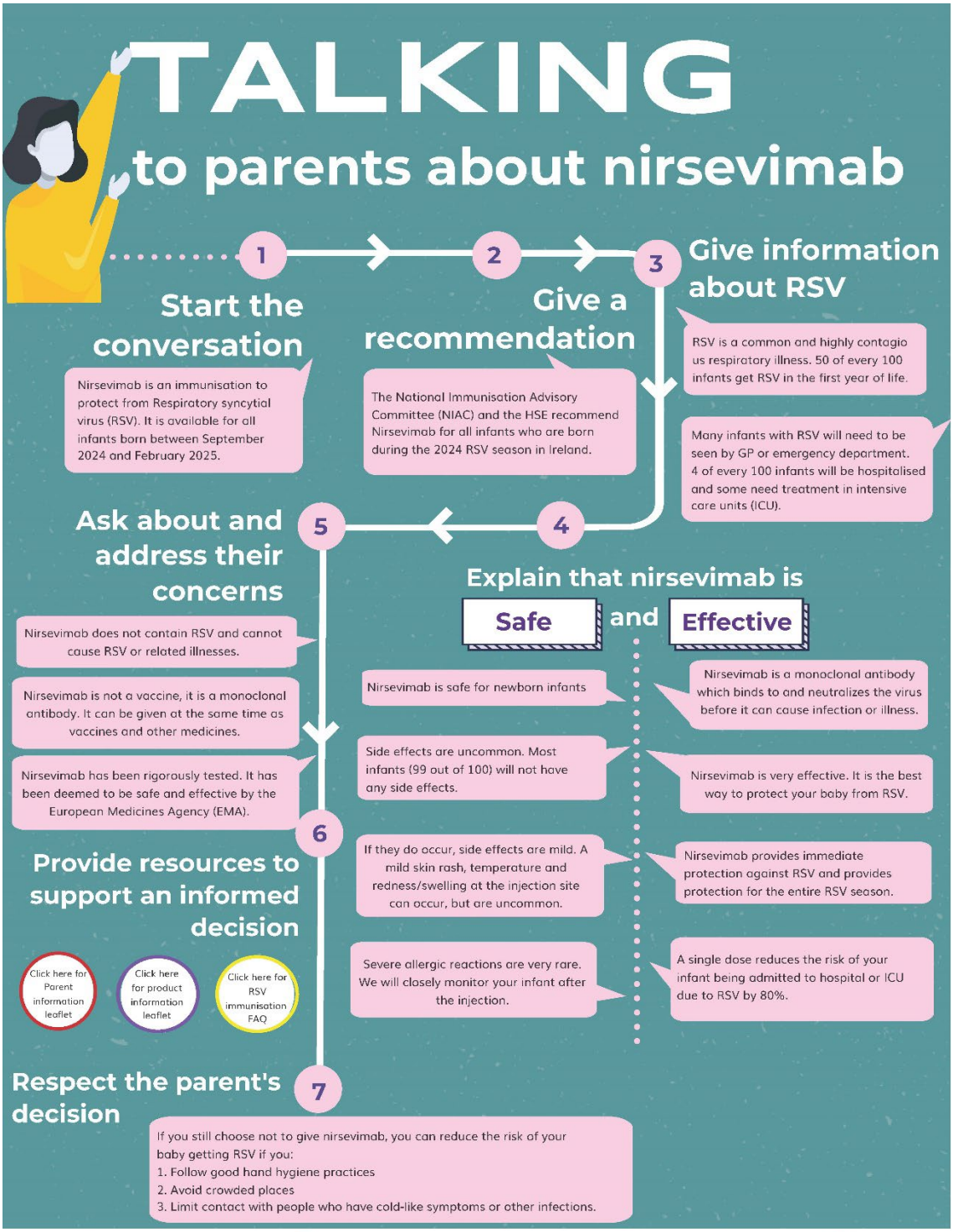
Link to Frequently Asked Questions on HPSC.ie – [https://www.hpsc.ie/a-z/respiratory/respiratorysyncytialvirus/immunisation/]

Appendix 6: Training Programme

Link to Training Programme Slides [PDF]

Link to Training Programme Video [Youtube]

Appendix 7: Talking to Parents about Nirsevimab Resource



Available online at: https://www.hpsc.ie/a-z/respiratory/respiratorysyncytialvirus/resources/

Appendix 8: TCP Homecare Service Nirsevimab SOP

TCP Homecare	Document Name: Beyfortus (Nirsevimab) SOP

Background:

The introduction of the Respiratory Syncytial Virus (RSV) Immunisation Pathfinder Programme will only offer Beyfortus (nirsevimab) to babies born in hospital after the 1st of September, where the baby will receive the injection prior to discharge home.

This leaves a small gap of high-risk babies that will not have direct access to the nirsevimab injection, as they will have been born during the RSV Out of Season period i.e. between the End of March 2024 and the beginning of September 2024.

These babies at high-risk from RSV Infection include the following:

1. Premature babies born at ≤29 wGA
2. Chronic Lung Disease - Bronchopulmonary dysplasia a serious complication of prematurity resulting from poor lung growth and lung injury.
3. Congenital Heart - Preterm babies have more than twice as many congenital heart defects as term neonates.

TCP Homecare are providing an at-home injection service to these high-risk babies born during the period March to September 2024. This service will include the following elements:

a. Direct communication with all Paediatric Hospitals notifying them of this service for at-risk Out of Season Babies.

b. Implementation of a robust referral process to facilitate service registration and the provision of prescriptions for nirsevimab for all babies registered to the programme.

c. Provision of a Pharmacy Dispensing Service

d. Provision of a Direct to Patient home delivery service of the dispensed nirsevimab via our validated and verifiably monitored fleet of cold-chain vehicles (@ 2° - 8°C).

e. Provision of appropriately trained Paediatric Nurses to administer the Beyfortus (nirsevimab) IM Injection in the baby's home.

f. Removal of all Clinical Waste associated with the administration of Beyfortus.

Hospitals wishing to refer babies to this 'At Home Injection Service' will need to complete the Beyfortus Referral Form (See Appendix I) and the prescription form provided (see Appendix II) and return to TCP Homecare (details are provided on the forms).

Note: it is critical that the prescription provided clearly states the actual dose to be administered i.e. 50mg for a baby less than 50KG and 100mg for a baby 5KG or more. It is recommended that 2nd season babies receive a 200MG dose of Beyfortus.

Once the Beyfortus Referral forms & prescriptions are received into TCP Homecare, each parent / guardian will be contacted, details of a delivery date for the Beyfortus Injection will be agreed with the parent / guardian and a Nurse Home Visit date confirmed.

TCP Homecare	Document Name: Beyfortus (Nirsevimab) SOP

1.0 Purpose:

To provide details of the HSE funded Beyfortus Homecare Service. The aim of the Beyfortus (Nirsevimab) Out of Season Home Administration Service is to administer Beyfortus to paediatric patients registered with the service. NIAC recommends the passive immunisation with Beyfortus of all high- risk infants aged less than 12 months at the start of their first RSV season. This includes preterm infants born at less than 29 weeks gestational age, infants with chronic lung disease and infants with congenital heart disease.

Beyfortus is a single dose intramuscular injection given at the onset of RSV season (RSV season extends between September and the end of February).

2.0 Scope:

All TCP Homecare nurses involved in the care of a paediatric patient registered with TCP Homecare who has been prescribed Beyfortus.

3.0 Definitions:

SmPC Summary of Product Characteristics

PIL Patient Information Leaflet

NIAC National Immunisation Advisory Committee

RSV Respiratory Syncytial Virus

4.0 Responsibility:

It is the responsibility of all nurses working with the Beyfortus service to ensure that this procedure is followed.

5.0 Procedure:

5.1 Consent and Data Protection:

- 5.1.1 Ensure the Beyfortus Injection is available in patient's home. Nurse will have contacted parent/guardian night before visit to confirm infant is well and Beyfortus drug has been delivered by TCP Logistics. Advise the parent/Gaurdian to keep the

drug in the fridge until 30mins before nurse planned arrival time. Advise the parent/guardian to always keep the drug in its carton.

- 5.1.2 Log onto tablet and confirm infant's date of birth with parent/guardian
- 5.1.3 Confirm gestational age of infant, any other medication, known allergies
- 5.1.4 Confirm dosage and correct storage of the Beyfortus.
  Beyfortus may be kept at room temperature (20°C - 25°C) when protected from light for a maximum of 8 hours. After this time, the syringe must be discarded
- 5.1.5 Ensure verbal consent for service has been given and that the Parent / Guardian's signature to treatment is captured on the Nurses tablet. Share the Consent to Treatment form (See Appendix III) with infant's parent/guardian
- 5.1.6 Complete risk assessment on tablet
- Complete HSE Data Collection Form (Appendix V) Editable PDF and save in SharePoint drive title 'Beyfortus Data Collection Form'
- Refer to the 'Talking to parents about nirsevimab' (Appendix VI) under Beyfortus Audience on LMS and allow parents to discuss the drug and procedure. Any queries that the nurse is unable to answer the parent should be directed to contact the referring team.

5.2 Prior to administration:

- 5.2.1 Wash hands as per **SOP Infection Control Policy**
- 5.2.2 Assess infant to ensure infant is well enough to receive Beyfortus
- 5.2.4 Check infant's temperature, pulse and respiratory rate and record on tablet
- 5.2.6 Confirm dosage of Beyfortus on prescription against drug available at home

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

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

TCP Homecare	Document Name: Beyfortus (Nirsevimab) SOP

- 5.2.8 Record batch number and expiry date of Beyfortus onto tablet
- 5.2.9 Check the Beyfortus vial, ensuring that it's clear to opalescent, colourless to yellow solution. If there are any issues with vial or contents, contact TCP Pharmacy for instruction

5.3 Administration as per Medication Management SOP & (Appendix IV):

- 5.3.1 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.
  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
- 5.3.2 Beyfortus is administered intramuscularly in the anterolateral aspect of the thigh in infants. 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. The appropriate needle sizes for administration are either 25G x 16mm or 25G x 25mm
- 5.3.3 Sharps to be disposed of in Sharps waste container as per TCP Group Waste Management SOP
- 5.3.4 Check infant's temperature, pulse and respiratory rate a minimum of fifteen minutes post administration of Beyfortus whilst monitoring infant and record on the tablet
- 5.3.5 If the infant exhibits symptoms or signs of anaphylaxis or a severe allergic reaction, follow Management of Anaphylaxis and Acute Allergic Reactions for the management of anaphylaxis (contact emergency services)
- 5.3.6 Any clinical concerns must be reported to the referring team, TCP Clinical Medical Director, Head of Nursing, Lead Nurse
- 5.3.7 Complete visit and close out visit on tablet

TCP Homecare	Document Name: Beyfortus (Nirsevimab) SOP

Instructions for administration

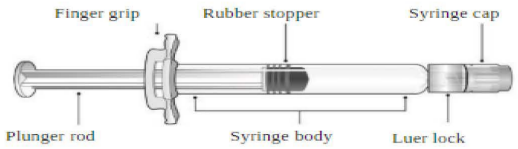
Beyfortus is available in a 50 mg and a 100 mg pre-filled syringe. Check the labels on the carton and pre-filled syringe to make sure you have selected the correct 50 mg or 100 mg presentation as required.

Beyfortus 50 mg (50 mg/0.5 mL) pre-filled syringe with a purple plunger rod.

Beyfortus 100 mg (100 mg/1 mL) pre-filled syringe with a light blue plunger rod.

Refer to Figure 1 for pre-filled syringe components.

Figure 1: Luer lock syringe components



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

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

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

Step 4: Administer the entire contents of the pre-filled syringe as an intramuscular injection, preferably in the anterolateral aspect of the thigh. The gluteal muscle should not be used routinely as an injection site because of the risk of damage to the sciatic nerve.

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

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

TCP Homecare	Document Name: Beyfortus (Nirsevimab) SOP

References:

- HSE National Women and Infants Health Programme Standard Operating Procedure – Nirsevimab – To Reduce Respiratory Syncytial Virus (RSV) and Associated Hospitalisations in Infants (1/08/24)
- Beyfortus (Nirsevimab): Summary of Product Characteristics (19/08/2024)

Appendix 9: TCP Homecare Nirsevimab Home Administration Product Supply

Appendix 10: TCP Homecare Nirsevimab Referral Form

TCP Homecare
BRING HOSPITAL CARE HOME

Useful Contact Information

Beyfortus TCP Homecare Phoneline	**01 427 6022**
Beyfortus TCP Homecare Fax	**01 429 8721**

What is Beyfortus *(nirsevimab)*

Beyfortus is given as a single injection into the thigh muscle. It is given once before the RSV season starts or at birth for infants born during the RSV season. The recommended dose is 50mg for infants weighing less than 5kg and 100mg for infants weighing 5kg or more.

This service is available to high risk babies born during the period March to September 2024

A patient visit report is sent following each home visit. Please supply an email address for visit reports to be forwarded to. If you choose not to provide and email address, this will be taken as an indication that you are declining a visit report.

PAEDIATRICS

National Women & Infants Health Programme

Beyfortus *(nirsevimab)* **Referral Form**

TCP Homecare
BRING HOSPITAL CARE HOME
a PHOENIX company

INFANT DETAILS

Infant's First Name | DOB | M | F

Infant Surname | Parent's Full Name

Telephone (H) | Telephone (M) | Hospital MRN

Home Address

HOSPITAL DETAILS

Hospital Name | Hospital Emergency Tel

Referring Consultant | Consultant Specialty

Hospital Nurse | Nurse Tel Number

Email address(es) for Reports

BEYFORTUS *(nirsevimab)*

Chronic Lung Disease | Prematurity | Please State GA

Congenital Heart Disease | Other | Please Specify

BEYFORTUS REQUIREMENTS

Date of Discharge | Weight of Infant on Discharge | **Current Weight of Infant**

Past Medical History/Allergies

Current Medications

Additional Comments

Any Precautions

TO BE COMPLETED BY THE REFERRING CLINICIAN

Please register the patient for the Beyfortus patient support services. I confirm that I am the patient's consultant OR I am a healthcare professional and have been instructed by the patient's consultant, to discuss the services with the patient's parent, guardian and/or carer (the 'Carer'), and they have consented to receive the services. I understand and have explained to the Carer that in order to participate in these services, the personal data of the patient and the Carer will be passed securely to TCP Homecare patient support service providers, who will provide additional information on the services, complete the patient's enrollment and will contact the Carer by phone to facilitate the above, including the health data set out above in order to ensure that the service provider is able to adequately deliver the Beyfortus home administration service to which they have consented. I agree that the patient remains under the care and responsibility of the referring hospital for the duration of their treatment.

Print Name | Date

Signature

On completion of referral form, please either fax to the Nurse Support Programme on **01 429 8721**
or email the completed form to **homecarepcb@tcp.ie**

Appendix 11: TCP Homecare Consent to Medical Treatment

TCP Homecare Nurse Services –
Consent Form
Our Service to You

Nursing Services and Medical Treatment Consent Form
Our Service to You

Name of the Service: Beyfortus (nirsevimab) Home Injection Service (the "**Service**")

Sponsor of the Service: Health Service Executive

Referring Centre:

On behalf of **TCP Homecare**, we are delighted to be in the privileged position of being invited by the Referring Centre to provide care to you in connection with the Service. The purpose of this consent form is to outline clearly the Service that TCP Homecare nurses will be providing to you and to obtain your consent in connection with the delivery of the Service. **A copy of this form will be left with you following completion.**

Each TCP Homecare nurse is registered with NMBI (Nursing & Midwifery Board of Ireland) and they must adhere to the NMBI Code of Professional Conduct. Accordingly, the NMBI Code of Professional Conduct and Ethics requires that we obtain informed, valid and effective consent from everyone we provide the Services to. In the event that the Service is being provided to a person under the legal age of consent (16 years old), a parent/guardian/ward of court will be required to sign this form.

It is therefore very important that you understand the Service to be delivered by TCP Homecare and are in a position to make an informed decision. In this regard, **please do take time to read all the literature and raise any questions you may have with the TCP Homecare nurse.** Each TCP Homecare nurse will also seek to get your verbal consent upon each visit prior to accessing your home and delivering the Service.

Each TCP Homecare nurse has been trained to deliver a high standard of care and to act at all times in a professional and courteous manner.

What is our Service to You?

Our Service to You is the provision of the Service by TCP Homecare nurses trained to deliver same.

What are you consenting to?

When you sign this consent form you are consenting to the following:

- to allow the TCP Homecare nurse to access your home solely for the purpose of delivering the Service as prescribed by your Doctor;
- to allow the TCP Homecare nurse permission to administer the Service in accordance with the valid prescription from your Doctor ;
- to allow TCP Pharmacy and Logistics to dispense and deliver the Service to your home/place of work;
- to allow TCP Logistics to remove clinical waste or un-required equipment/ medicines relating to the Service from your home/place of work;
- to allow the TCP Homecare nurse/customer care team to contact you via telephone to provide support in relation to the Service;
- to permit the TCP Homecare nurse being accompanied by another member of the TCP Homecare team access to your home solely for the purpose of carrying out the Service as prescribed by your Doctor.

How will our Service to You operate in practice?

You are responsible for ensuring that you are available at the agreed scheduled appointment time and contactable if required, during your full treatment duration. At each visit (if applicable to the Service), you will be assessed by the TCP Homecare nurse and in the majority of instances the TCP Homecare nurse will proceed with carrying out the Service. TCP Homecare will aim to be as flexible as possible to ensure that the delivery of the Service is suited to your individual needs, it being acknowledged that office opening hours are 8:30am to 5pm Monday to Friday (excluding public holidays).

In the event that the TCP Homecare nurse deems that you are clinically unwell and that administering your treatment and/or completing a support visit would put you at risk, the TCP Homecare nurse will contact your treating Doctor or his/her team for instruction. In such a situation, the TCP Homecare nurse will not administer your treatment until the treating Doctor (or such authorised team member) has been contacted and agreed that the treatment is to be provided. Your treating Doctor or his/her team may request that you return to hospital to continue or change your treatment as you shall at all times remain under the clinical responsibility of your treating Doctor.

In the event of any adverse event or adverse reaction (known as side effect), TCP Homecare will share such information with your Doctor and his/her treating team and, may also share (as required by law) certain details (including identifiers such as your initials) of that event with the manufacturer of the product giving rise to the adverse event or adverse reaction, as *is our Legal obligation under the Human Products Regulatory Authority (HPRA)*. TCP Homecare may request follow up information from you in respect of such adverse event or adverse reaction and this would be sought by means of a letter or telephone call. You are not obliged to give any information or follow up information to the manufacturer of the product or to regulatory body, but you should note that any information you can give may help other patients receiving the same medicine.

If, for any reason, you choose to discontinue using the Service at any point, you may do so by discussing this with your Doctor and his/her treating team.

In the unlikely event that a TCP Homecare nurse believes that it is unsafe to continue visiting you at home; TCP Homecare reserves the right to withdraw from providing the Service to you. We will discuss the continuation of your care and treatment regime with your Doctor and his/her treating team and they will be kept fully informed and aware of the circumstances surrounding any such TCP Homecare withdrawal. This will ensure that your care is managed and maintained appropriately. Circumstances that could lead to this action include harassment or discrimination affecting our staff, or any situations that present an unacceptable risk to their personal safety.

Where Medicines are left at your home (if not applicable, please disregard)

A supply of medicine as prescribed by your Doctor is left or may in the future be left within your home for the purpose of carrying out your treatment. Your medicine must be stored in its original packaging at all times at the appropriate temperature and away from damp areas which is out of the reach of children. It must not be tampered with and items must only be removed and used by the attending nurse/under the guidance and instructions of the nurse. You remain responsible at all times for the safe storage of your medicine.

Where a fridge is provided for the storage of your medicine (if not applicable, please disregard)

Where a fridge is provided to you by TCP Homecare in connection with the Service, you will ensure that:

- The fridge is positioned in a suitable place, as agreed with the delivery team;

- The fridge is only used for storage of your medicine that require refrigerated storage prior to administration, as well as any other supplies for administration purposes;
- The fridge is not accessed by anyone other than the delivery driver and your TCP Homecare nurse;
- In the event of an out of temperature excursion, you will contact TCP Homecare as soon as possible;
- In the event of a power failure or any other situation which could have an effect on the correct storage of your medicine, you will contact TCP Homecare as soon as possible; and
- You report any problems to TCP Homecare.

Where sharp bins are provided (if not applicable, please disregard)

You have been supplied with a "Sharps box" in which to place your sharp items once used. Only sharp items relevant to the service must be placed in the sharps bin. This is to comply with EU regulations. This box must be stored in a safe place which is out of the reach of children. When not in use it must be placed in the closed position. You remain responsible at all times for the safe storage and disposal of your sharp items and sharps bin.

Where ancillary items are provided (if not applicable, please disregard)

A supply of ancillary items and equipment has been left within your home for the purpose of carrying out the Service. This box must be stored in an appropriate dry and safe place which is out of the reach of children. This box must not be tampered with and items must only be removed and used by the attending nurse/under the guidance and instructions of the nurse. You remain responsible at all times for the safe storage of the ancillary box and equipment.

Where compliance services are provided (if not applicable, please disregard)

TCP Homecare offers a compliance programme in relation to your individual treatment plan. Patients will be contacted by the TCP Homecare patient Compliance Care Team in relation to your appropriate medication. This will usually be by way of telephone call.

Who can I contact if I have a complaint with the Service?

In the unlikely event that you are dissatisfied with any aspect of the Service, you should contact the Medical Director at TCP Homecare on 01-4291828 or in writing at TCP Homecare, Suite 1 Westland House, Westland Park, Willow Road, Clondalkin, Dublin 12.

What may be done with your personal data?

Please read ***TCP Homecare's Patient Privacy Policy*** which is available for review at **www.tcp.ie**

TCP Homecare Nurse Services –
Consent Form
Our Service to You

Patient Copy:

If you are happy with all the information that you have received and have had the opportunity to ask questions and they have been answered to your satisfaction and wish to be registered with the Service, please sign the form below.

Name of Service:_____

I fully understand the service that TCP Homecare provides as explained to me and would like to be registered with the Service.

I would like however, to decline the following/otherwise not applicable:

Signature of service user: _____

Or

Signature of Legal Guardian: _____ Print Name: _____

Parent ☐ NOK ☐ Ward of Court ☐ Power of Attorney ☐ Other:_____

Patient Name: _____ Date: ____/_____/ 20____

Address: (applicable to both signings)

_____

_____

_____

TCP Homecare Nurse Services –
Consent Form
Our Service to You

TCP Homecare Copy

If you are happy with all the information that you have received and have had the opportunity to ask questions and they have been answered to your satisfaction and wish to be registered with the Service, please sign the form below.

Name of Service:_____ TCP Homecare ID No: _____

I fully understand the service that TCP Homecare provides as explained to me and would like to be registered with the Service.

I would like however, to decline the following/otherwise not applicable:

Signature of service user: _____

Or

Signature of Legal Guardian: _____ Print Name:_____

Parent ☐ NOK ☐ Ward of Court ☐ Power of Attorney ☐ Other:_____

Patient Name: _____ Date: ____/_____/ 20____

Address: (applicable to both signings)

_____

_____

_____

Appendix 12: TCP Homecare Prescription Form

TCP Homecare	Beyfortus (nirsevimab) IM Injection Prescription

PATIENT INFORMATION			
Name:			
Address:			
Patient Weight in Kilograms (date of prescription):			
Telephone No. NOK/Carer:	**Mobile:**	**Date of Birth:**	
	Home:	**Allergies:**	

MEDICATION AND ADMINISTRATION		
Beyfortus (nirsevimab) pre-filled syringe		
DOSE (Tick One Clearly)	**FREQUENCY**	**ROUTE**
50mg ☐ 100mg ☐ Other ☐ _____ mg	**Single Dose**	**Intramuscular injection**

EMERGENCY MEDICATION REQUIREMENTS		
The medications listed below will only be administered to treat an adverse reaction if required		
Medication	**Dose by Age**	**Route**
Epinephrine(Adrenaline) 1:1,000 (1mg/ml)	Aged less than 6 months 0.1mL (100 micrograms) Aged 6 months-5 years 0.15mL (150 micrograms)	IM PRN Up to 3 doses may be given at 5minute intervals

PRESCRIBER INFORMATION			
Consultant/Prescriber:		**Hospital:**	
Email:			
MCRN:		**Phone /Bleep no.:**	
Prescriber signature:		**Date:**	

Please scan a copy of the prescription from a valid Healthmail or HSE email address to pharmacy@tcp.ie and Homecarepcb@tcp.ie

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