NSW Health

RSV (Respiratory Syncytial Virus) Vulnerable Babies Program

Clinician Guide

NSW GOVERNMENT

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The NSW Ministry for Health acknowledges the traditional custodians of the lands across NSW. We acknowledge that we live and work on Aboriginal lands. We pay our respects to Elders past and present and to all Aboriginal people.

Further copies of this document can be downloaded from the NSW Health webpage www.health.nsw.gov.au

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Contents

What the guide contains

This guide has been developed to support the implementation of the respiratory syncytial virus (RSV) Vulnerable Babies Program in NSW to reduce RSV-associated infections and hospitalisations. The guide is for clinicians that will order and/or administer Beyfortus™ (nirsevimab), a new RSV monocolonal antibody (mAB) in NSW Health and private health facilities.

Clinicians must administer Beyfortus™ (nirsevimab) in line with **the Therapeutic Goods Administration (TGA) Product Information** and this guide.

The guide includes information about:

- RSV
- Infants and young children at greater risk of requiring hospitalisation with RSV
- RSV vaccine and mAB for infants and young children
- Eligibility for 2024 state funded Beyfortus™ (nirsevimab)
- Ordering 2024 state funded Beyfortus™ (nirsevimab)
- Beyfortus™ (nirsevimab) storage and cold chain management
- Beyfortus™ (nirsevimab) presentation and administration
- Beyfortus™ (nirsevimab) efficacy
- Beyfortus™ (nirsevimab) safety
- Reporting adverse events following immunisation (AEFI)
- Reporting and monitoring administration encounters
- Useful links
- Contact
- Reference

RSV

RSV is a common respiratory virus that can infect people of all ages and usually causes mild, cold-like symptoms. Most people recover in a week or two, but RSV can be serious. Infants and older adults are more likely to develop severe RSV and need hospitalisation. RSV is recognised as one of the most common causes of childhood illness and is the most common cause of hospitalisation in infants. RSV can cause a range of respiratory illness from a mild cold to severe conditions such as bronchiolitis in infants and pneumonia. RSV is spread through droplets from an infected person's cough or sneeze.

RSV Vulnerable Babies Program

Beyfortus™ (nirsevimab) was approved by the TGA in November 2023 for use in neonates and infants in Australia. The NSW RSV Vulnerable Babies Program offers this RSV mAB from March 2024 to September 2024 to infants who are at high-risk of RSV lower respiratory tract infections (LRTI).

The program is available in a phased approach during the 2024 RSV season. The targeted cohorts in each phase are as follows:

Phase 1 (commencing on 25 March 2024)

Infants meeting eligibility criteria currently in public hospitals (administered at discharge).

Phase 2 (commencing the week beginning 8 April 2024)

Infants meeting eligibility criteria in the remainder of the cohorts.

Authority for Authorised Registered Nurse/Midwife Immunisers to Supply Poisons and Restricted Substances and Authorised Registered Nurse/ Midwife Vaccination Standards are available on the **NSW Health webpage** to allow Authorised Nurse and Midwife Immunisers to independently administer Beyfortus™ (nirsevimab).

Infants and young children at greatest risk of requiring hospitalisation with RSV

Infants and young children at greatest risk for serious RSV disease include:

- Young children aged 2 years and under with medical conditions such as chronic lung disease or congenital heart disease

- Infants and young children aged 2 years and under who were born pre-term or with a low birth weight
- Aboriginal and/or Torres Strait Islander infants and young children aged 2 years and under
- Infants aged 12 months and under, especially those aged 6 months and under.

RSV vaccines and mAB for infants and young children

A range of RSV vaccines and mAB have been approved or are being assessed by the TGA for use in Australia. Further information on evaluation of and expected access to new RSV vaccines and long-acting mAB in Australia is available on the **National Centre for Immunisation Research and Surveillance (NCIRS) website.**

The following two RSV mAB are currently available in Australia for administration to infants:

- Beyfortus™ (nirsevimab)
  A new long-acting mAB was approved by the TGA in November 2023 for use as a single injection in infants.
- Synagis (palivizumab)
  It has been registered in Australia for use in infants aged 24 months and under since 1999. However, it needs to be given monthly during an RSV reason. Each dose provides around one month of protection.

Eligibility for Beyfortus™ (nirsevimab)

Beyfortus™ (nirsevimab), a long-acting mAB was approved by the TGA in November 2023 for use in neonates and infants in Australia. NSW Health has secured a supply for vulnerable babies and the program will run from March 2024 to September 2024.

Beyfortus™ (nirsevimab) is listed on the NSW Medicines Formulary, restricted to use "*as per the NSW Health RSV vulnerable babies program*".

Infants without prior laboratory-confirmed RSV infection in 2024 and in the following risk categories will be eligible for Beyfortus™ (nirsevimab) prior to October 2024:

- All premature infants (<37 weeks gestation at birth) born after 31 October 2023
- All Aboriginal and Torres Strait Islander infants born after 31 October 2023
- Other vulnerable infants including:
  - Chronic neonatal lung disease (neonates requiring home oxygen/other respiratory support ≥ 36 weeks corrected age, <12months of age
  - Infants with haemodynamically significant congenital heart disease, <24 months of age
  - Other**:
    - Combined Immunodeficiency <24 months of age AND not yet received curative treatment
    - Trisomy 21, <12 months of age
    - Other paediatric chronic and complex conditions that significantly impair respiratory function, <12 months of age
    - Children with 28 days before hematopoietic stem cell transplantation (HSCT) or prior to engraftment after HSCT, <24 months of age

** at clinician's judgement in consultation with specialist paediatric infectious diseases physician, specialist in paediatric immunisation, or designated Beyfortus™ (nirsevimab) program lead at a NSW Health facility. This group will include a variety of children with conditions/disorders requiring continuous home oxygen/respiratory support including neurological conditions, congenital malformations of the upper and/or lower airways, chronic suppurative lung diseases including cystic fibrosis with severe respiratory function impairment.

Additional points:

- Infants who have already received palivizumab, and who meet the above eligibility criteria, can receive Beyfortus™ (nirsevimab) 28 days later, instead of their next palivizumab dose. Palivizumab should then be discontinued.
- Infants who have had prior laboratory-confirmed RSV infection in 2024 are excluded.

Ordering funded Beyfortus™ (nirsevimab)

All state and National Immunisation Program (NIP) funded vaccines can be ordered through the **NSW Vaccine Centre (SVC)**. Providers are required to have a Vaccine Account Number (VAN) to order vaccines. In local health districts (LHDs) this is generally managed by the pharmacy department however individual services in some cases will have their own account.

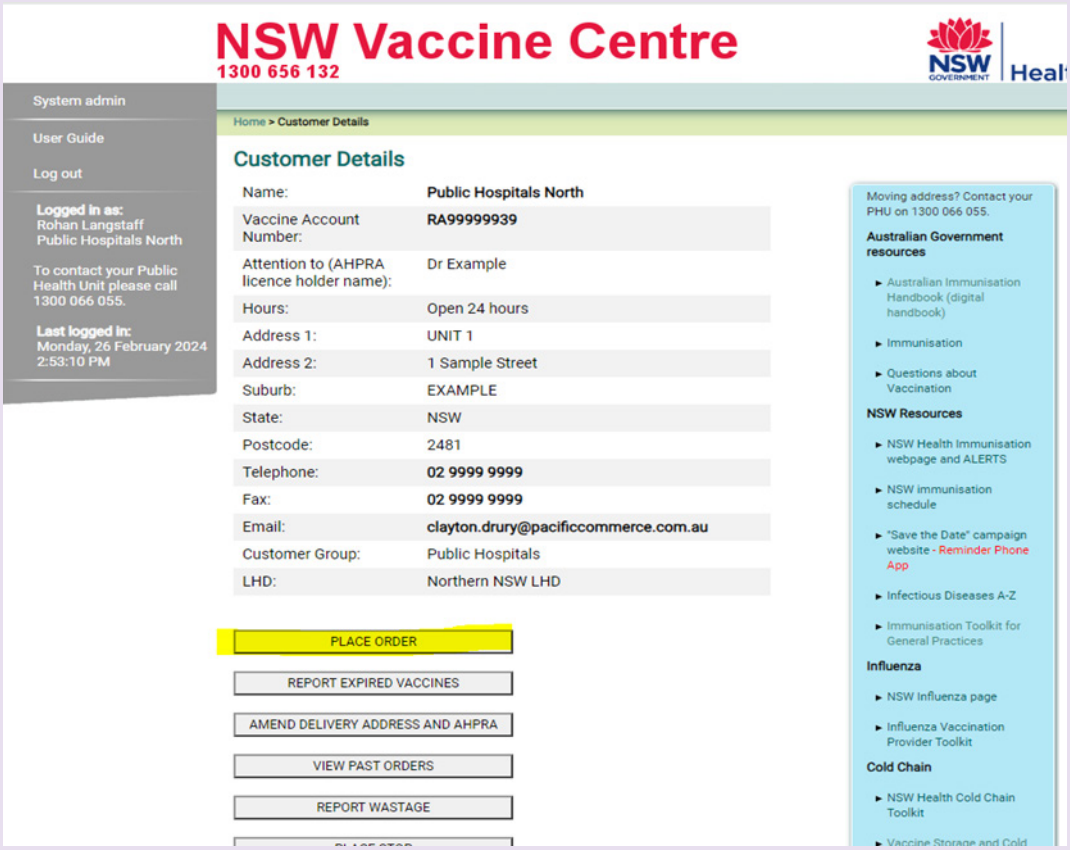
Beyfortus™ (nirsevimab) is available to order in the following formulations from the SVC:

- 50 mg in 0.5mL solution (prefilled syringe)
- 100 mg in 1mL solution (prefilled syringe)

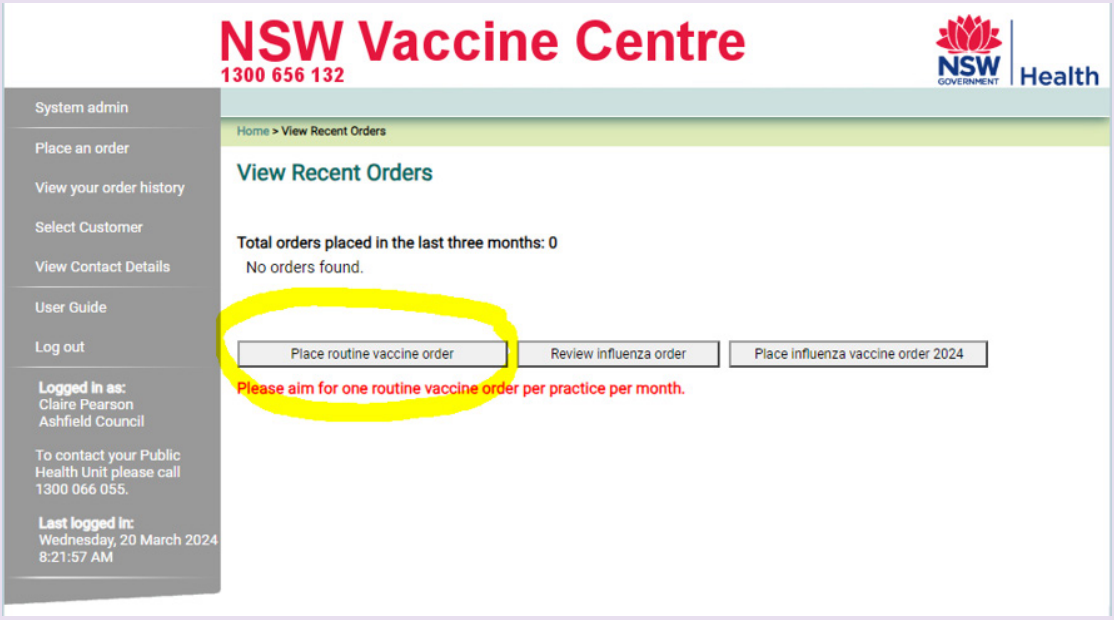
Supply may be limited in line with availability of Beyfortus™ (nirsevimab).

The ordering process is as follows:

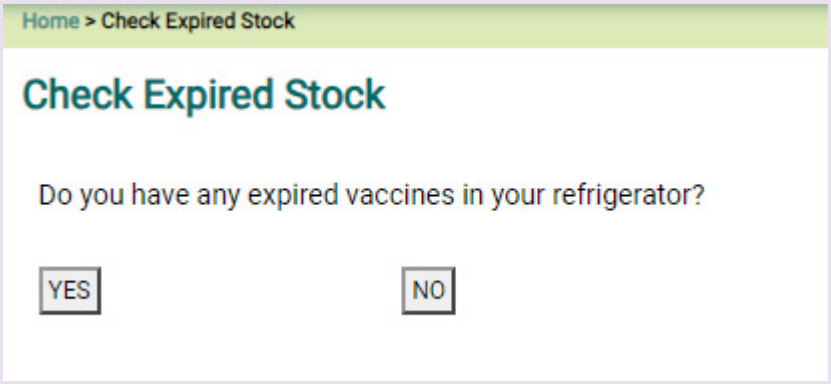
STEP 1: to place an order, log into the NSW Vaccine Centre and select “PLACE ORDER”



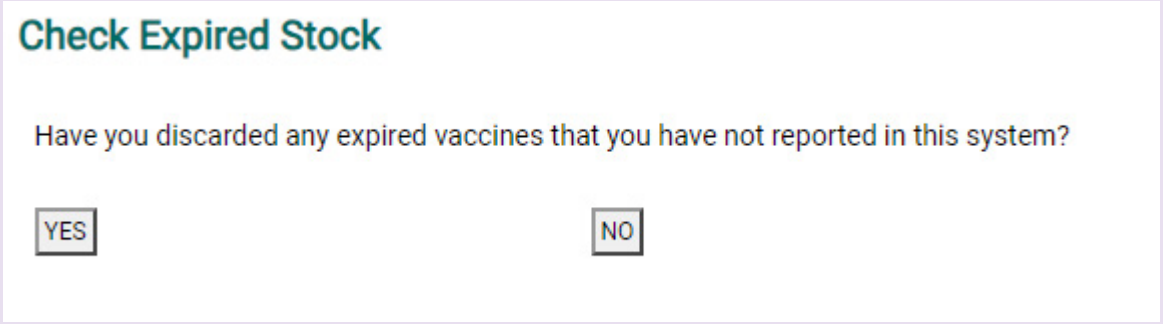
STEP 2: select “PLACE ROUTINE VACCINE ORDER”



STEP 3: answer yes or no to the following question



STEP 4: answer yes or no to the following question



STEP 5: enter the number of Beyfortus™ (nirsevimab) doses that you require and the number of Beyfortus™ (nirsevimab) that you have in stock (when placing subsequent orders). Please note there may be a restricted allocation for each provider per month, depending on supply and availability of Beyfortus™ (nirsevimab).

RSV Beyfortus (Nirsevimab) 100mg	• Infants 5kg and over. • All premature infants (< 37 weeks gestation at birth) born after 31 October 2023. • All Aboriginal and Torres Strait Islander infants born after 31 October 2023. • Other vulnerable infants including: • Chronic neonatal lung disease(neonates requiring home oxygen/other respiratory support ≥ 36 weeks corrected age) <12 months of age. • Infants with haemodynamically significant congenital heart disease, <24 months of age. • Other: Combined Immunodeficiency <24 months of age AND not yet received curative treatment. • Trisomy 21, <12 months of age. • Other paediatric chronic and complex conditions that significantly impair respiratory function, <12 months of age. • Children within 28 days before hematopoietic stem cell transplantation (HSCT) or prior to engraftment after HSCT, < 24 months of age.		
RSV Beyfortus (Nirsevimab) 50mg	• Phase 1- public hospital inpatients. • Infants less than 5 kg. • All premature infants (< 37 weeks gestation at birth) born after 31 October 2023 . • All Aboriginal and Torres Strait Islander infants born after 31 October 2023. • Other vulnerable infants including: • Chronic neonatal lung disease(neonates requiring home oxygen/other respiratory support ≥ 36 weeks corrected age) <12 months of age. • Infants with haemodynamically significant congenital heart disease, <24 months of age. • Other: Combined Immunodeficiency <24 months of age AND not yet received curative treatment. • Trisomy 21, <12 months of age. • Other paediatric chronic and complex conditions that significantly impair respiratory function, <12 months of age. • Children within 28 days before hematopoietic stem cell transplantation (HSCT) or prior to engraftment after HSCT, < 24 months of age.		

Beyfortus™ (nirsevimab) storage and cold chain management

Beyfortus™ (nirsevimab) must be stored at +2°C to +8°C and protected from light at all times. It may be kept at room temperature (below 25°C) for a maximum of 8 hours. After removal from the vaccine fridge, Beyfortus™ (nirsevimab) must be used within 8 hours or discarded. Do not shake or expose to heat. For further information, please refer to **the TGA Product Information**.

Vaccines are sensitive medicines that must be protected from light and temperature fluctuations outside of +2°C to +8°C. All immunisation providers responsible for ordering, storing, receiving and administering vaccines must understand the principles of vaccine storage. The **National Vaccine Storage Guidelines: Strive for 5** provide best practice guidelines for storing vaccines and managing the cold chain. The NSW Health **Vaccine Storage and Cold Chain Management Policy** also provides mandatory requirements for the storage and management of vaccines in LHD facilities. The policy directive includes a **Vaccine Refrigerator Protocol**.

Additionally, vaccines may lose potency if exposed to direct sunlight or ultraviolet (UV) light, including fluorescent light. If a vaccine loses potency, it may become less effective in providing protection against vaccine preventable diseases. To protect vaccines from light exposure they must be stored in the purpose-built vaccine refrigerator inside their original cardboard packaging. Vaccines must not be removed from the original cardboard packaging to increase refrigerator capacity.

Further information on managing the cold chain and protecting vaccines is available on the **NSW Health vaccine storage and cold chain management webpage**.

Beyfortus™ (nirsevimab) presentation and administration

Beyfortus™ (nirsevimab) is available in a 50mg 0.5mL prefilled syringe with a purple plunger rod and a 100mg in 1mL prefilled syringe with a light blue plunger rod. It has either English or German labels as per the following presentations.

German labels

English labels*

* a typographical error has been identified on the packaging of the single dose pre-filled 50mg in 0.5mL of Beyfortus™ (nirsevimab) with English labeling. The outer packaging incorrectly refers to the product as a 1mL solution for injection. The TGA has approved the Section 14 application that Sanofi i.e. manufacturer of Beyfortus™ (nirsevimab) submitted to support the continued use of the product. Further information on this labelling error is available on the **Dear Health Care Professional letter** from Sanofi.

Dosing recommendations

The recommended dosage of Beyfortus™ (nirsevimab) in neonates and infants during or entering the RSV season as per the **TGA product information** is as follows:

Table 1.0

Body weight at time of dosing	Recommended dosage
Less than 5 kg	50mg by intramuscular (IM) injection
5kg and greater	100mg by IM injection

2x 50mg of Beyfortus™ (nirsevimab) can be used for infants with body weight of 5kg and greater.

Infants who have already received palivizumab, and who meet the eligibility for Beyfortus™ (nirsevimab), can receive Beyfortus™ (nirsevimab) 28 days later, instead of their next palivizumab dose. Palivizumab should then be discontinued.

Beyfortus™ (nirsevimab) is administered intramuscularly, 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. If two injections are required, different injection sites should be used.

For general information regarding vaccine administration, please refer to the Australia Immunisation Handbook:

- **Preparing for vaccination**
- **Administering vaccines**
- **After vaccination**

Coadministration with vaccines and immunoglobulins

Beyfortus™ (nirsevimab) can be given at the same time as routine childhood vaccines (in a separate syringe and at a separate site). Since Beyfortus™ (nirsevimab) is a passive immunisation specific for RSV, it is not expected to interfere with the active immune response to co-administered vaccines.

Beyfortus™ (nirsevimab) should not be mixed with any vaccine in the same syringe or vial. When it is co-administered with vaccines, they should be given with separate syringes and at different injection sites.

There is no information regarding co-administration of Beyfortus™ (nirsevimab) with other immunoglobulins.

Handling requirements

Beyfortus™ (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 nirsevimab 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

Beyfortus™ (nirsevimab) efficacy

The clinical trial data on the efficacy of Beyfortus™ (nirsevimab) is available on **the NCIRS website.** Research has shown that a single dose of Beyfortus™ (nirsevimab) provides a consistent level of protection to infants against hospitalisation for RSV-associated LRTI and very severe medically attended LRTI during the RSV season[1,2,3].

Consent for Beyfortus™ (nirsevimab)

Beyfortus™ (nirsevimab) is registered for use in Australia by the Therapeutic Goods Administration (TGA) and use in the NSW Health RSV vulnerable babies program is in accordance with the indications outlined in the Product Information. Standard processes for obtaining consent from a parent or guardian for neonatal immunisation should be followed.

Consent can be verbal or written. After obtaining consent, it is important to document this in the patient's medical record. Documentation should include details of the consent conversation, information provided to the parent or guardian as a part of obtaining consent and the presence of an accredited interpreter (if applicable).

Further information about consenting is available on the **Australian Immunisation Handbook** and **NSW Health Consent to Medical and Healthcare Treatment Manual**.

Beyfortus™ (nirsevimab) safety

Data on the safety of Beyfortus™ (nirsevimab) is monitored by the TGA. The clinical trial data on the safety of Beyfortus™ (nirsevimab) is available on **the NCIRS website**.

Clinical trials have reported the following possible side effects of Beyfortus™ (nirsevimab):

- pain, swelling and redness at the injection site
- Fever
- Rash

Contraindications

Beyfortus™ (nirsevimab) is contraindicated in individuals with a history of severe hypersensitivity reactions, including anaphylaxis, to the active substances or to any of the following ingredients:

- Histidine
- Sucrose
- Histidine hydrocholoride monohydrate
- Polysorbate
- Arginine Hydrochloride
- Water for injections

Precautions for use

Hypersensitivity including anaphylaxis

Recipients should be monitored for at least 15 minutes post administration of Beyfortus™ (nirsevimab). 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 medical treatment.

Clinically significant bleeding disorders

As with any other intramuscular injections, Beyfortus™ (nirsevimab) should be given with caution to infants with thrombocytopenia or any coagulation disorder.

Reporting adverse events following immunisation (AEFI)

An adverse event following immunisation (AEFI) is defined in The Australian Immunisation Handbook as "any untoward medical occurrence that follows immunisation. It does not necessarily have a causal relationship with the vaccine". AEFIs are notifiable conditions under the **NSW Public Health Act** (Schedule 1).

All AEFI notifications are required to be reported to the TGA. To report a suspected AEFI, download the **National Adverse Events Following Immunisation (AEFI) Reporting Form** and contact your local Public Health Unit on 1300 066 055. Further information regarding AEFIs is available on the **NSW Immunisation AEFI webpage**.

If an AEFI occurs at the time of vaccination e.g. anaphylaxis, a report must be made on the NSW Health incident management system IMS+.

Reporting and monitoring administration encounters

The Australian Immunisation Register (AIR) has been updated to accept records of Beyfortus™ (nirsevimab). Vaccination encounters must be reported to the AIR.

The following NSW Health facility record management systems are able to integrate to the AIR to transmit records of Beyfortus (nirsevimab) directly to the AIR. eHealth is working with LHDs and vendors to enable this.

- Cerner eMR – eMeds
- eRIC
- ORION
- SHIP
- MedChart
- MOSAIQ

Providers that utilise other record management systems that are not integrated to the AIR will need to ensure that manual processes are in place to meet reporting requirements.

Further information on how to upload records is available from the **Australian Government web page**.

Private facilities are required to complete a patient reporting template available on the **NSW Health website**.

Useful links

NSW RSV (Respiratory Syncytial Virus) Vulnerable Babies Program webpage:
https://www.health.nsw.gov.au/immunisation/Pages/respiratory-syncytial-virus.aspx?PagePreview=true

Australian Technical Advisory Group on Immunisation (ATAGI) statement on Nirsevimab 2024:
https://www.health.gov.au/resources/publications/atagi-statement-on-nirsevimab-2024?language=en

NSW Immunisation webpage:
https://www.health.nsw.gov.au/immunisation/Pages/default.aspx

NSW Immunisation Schedule:
https://www.health.nsw.gov.au/immunisation/Publications/nsw-immunisation-schedule.pdf

NSW AEFI webpage:
https://www.health.nsw.gov.au/immunisation/Pages/aefi.aspx

NSW vaccine storage and cold chain management webpage:
https://www.health.nsw.gov.au/immunisation/Pages/cold-chain-management.aspx

NSW State Vaccine Centre webpage:
https://nsw.tollhealthcare.com/

National Immunisation Program webpage:
https://www.health.gov.au/our-work/national-immunisation-program

National Vaccine Storage Guidelines: Strive for 5:
https://www.health.gov.au/resources/publications/national-vaccine-storage-guidelines-strive-for-5

Australian Government access to AIR webpage:
https://www.servicesaustralia.gov.au/how-to-set-up-your-access-to-air?context=23401

Australian Immunisation Handbook:
https://immunisationhandbook.health.gov.au/

Respiratory syncytial virus (RSV): Frequently asked questions (FAQs) by the NCIRS: **Respiratory syncytial virus (RSV) FAQs | NCIRS**

The TGA Product Information on Beyfortus™ (nirsevimab):
https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2023-PI-02637-1

Contact

If further information regarding immunisation is required, please contact your local Public Health Unit on 1300 066 055.

Reference

1. Nirsevimab for prevention of RSV in term and late-preterm infants

https://www.nejm.org/doi/10.1056/NEJMc2214773?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed

2. Nirsevimab for prevention of hospitalisation due to RSV in infants **https://www.nejm.org/doi/full/10.1056/NEJMoa2309189**

3. Early Estimate of Nirsevimab Effectiveness for Prevention of Respiratory Syncytial Virus–Associated Hospitalization Among Infants Entering Their First Respiratory Syncytial Virus Season — New Vaccine Surveillance Network, October 2023–February 2024, Morbidity and Mortality Weekly Report, Centres for Disease Control and Prevention **https://www.cdc.gov/mmwr/volumes/73/wr/mm7309a4.htm**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