RSV Maternal and Infant Protection Program Toolkit Tasmania 2025

Protecting infants from severe RSV through maternal and infant immunisation

Clinical Guidance for Immunisation Service Providers

Version 1.0 – February 2025

Department of Health

Tasmanian Government

Contents

Disclaimer

Please note that any change(s) to this toolkit will be communicated by email with an updated version.

Introduction

Respiratory syncytial virus (RSV) causes upper and lower respiratory tract infections. RSV is highly infectious and is spread via respiratory droplets or through contact with contaminated surfaces.

Symptoms of RSV infection often include runny nose, cough and fever. RSV is a common cause of acute respiratory tract infections which are usually mild and self-limiting. It is understood that almost all children experience at least one RSV infection within their first two years of life.

The virus can sometimes lead to more severe illness and hospitalisation, especially in very young infants. In infants, RSV can cause pneumonia, bronchitis or bronchiolitis (inflammation and narrowing of the small airways in the lungs), which can lead to significant breathing difficulties. RSV is the most common cause of hospitalisation in infants and young children.

In Tasmania, the RSV season typically occurs from May to September, with year-to-year variation.

Program Overview

The Therapeutic Goods Administration (TGA) has approved two immunisation products to protect infants and young children from severe RSV. In Tasmania in 2025, both products are offered as part of a comprehensive RSV maternal and infant protection program.

- **Maternal program:** From 3 February, a single dose of Abrysvo® is funded under the National Immunisation Program (NIP) and recommended in pregnancy from 28 – 36 weeks' gestation to protect the infant against RSV from birth through to approximately six months of age.
- **Infant program:** From 1 April to 30 September, eligible infants will have access to a state-funded long-acting monoclonal antibody product (Beyfortus® (nirsevimab)).

Table 1. Overview of Maternal and Infant Protection Program and Eligibility

	Maternal vaccination - Abrysvo® (Pfizer)	Infant immunisation - Beyfortus® (nirsevimab) (Sanofi)
Funding	NIP	State-funded
Program duration	Year-round	Seasonal, 1 April to 30 September 2025
Providers	Medical Practitioners, Nurse Practitioners and Authorised Immunisers	Medical Practitioners, Registered Nurses, Midwives and Enrolled Nurses on receipt of a prescription
Setting	General practice, community pharmacy, antenatal clinics, hospitals and local government immunisation clinics	Hospitals, general practice
Registered for use	In pregnancy from 24 – 36 weeks, however it is not recommended by ATAGI for use earlier than 28 weeks' gestation until additional safety and efficacy data is available.	In children <24 months of age
Clinical guidance and program eligibility*	A single dose of Abrysvo® is recommended in pregnancy from **28 – 36 weeks' gestation** to protect the infant. If a pregnant woman is not vaccinated before 36 weeks' gestation, they should receive the vaccine as soon as possible. Infants are not expected to be adequately protected unless they are born at least two (2) weeks after the mother has received the vaccine. Verbal confirmation from the pregnant woman is sufficient to establish gestational age (formal evidence is not required).	A single dose of Beyfortus® (nirsevimab) is recommended for: • **Eligible infants entering their first RSV season** born from 1 April to 30 September 2025 – see *Appendix 1* • **Catch up program – first RSV season** for infants **(<8 months of age**) born from 1 October 2024 – 31 March 2025 – see *Appendix 1* • **Catch up program – second RSV season** for children (**<24 months of age)** born from 1 October 2023 and with conditions associated with *(continued)*

Table 1 *(continued).* Overview of Maternal and Infant Protection Program and Eligibility

	Maternal vaccination - Abrysvo® (Pfizer)	Infant immunisation - Beyfortus® (nirsevimab) (Sanofi)
Clinical guidance and program eligibility *(continued)*	Advice on repeat vaccination during subsequent pregnancies will be provided in the future as clinical guidance is updated.	increased risk of severe RSV disease* – see *Appendix 2*. • Infants born to mothers with severe immunosuppression, where the immune response to maternally administered RSV vaccine was impaired (see People who are severely compromised) ± • infants whose mothers have received RSV vaccine in pregnancy but have subsequently undergone a treatment, such as cardiopulmonary bypass or extracorporeal membrane oxygenation, that has led to loss of maternal antibodies±
Dose	The dose of Abrysvo® is 0.5 mL, given by intramuscular injection only, preferably in the deltoid region of the upper arm. Single dose administered in pregnancy (third trimester).	A single dose, administered by intramuscular (IM) injection, once per season - see dose recommendations in *Table 2*. For low birthweight/extremely preterm infants and children undergoing cardiac surgery with cardiopulmonary bypass, see Beyfortus® (nirsevimab) Product Information for further information.
Co-administration with other vaccines	Pregnant women can receive Abrysvo® at the same time as, or separate to, dTpa, influenza and COVID-19 vaccines. Data on co-administration in pregnant women are still emerging, but there are no theoretical concerns.	Beyfortus® (nirsevimab) can be safely administered with other routine childhood vaccines.
Presentation	Each box of Abrysvo® contains a vial for reconstitution, a vial adapter and a pre-filled diluent syringe. **This product requires reconstitution prior to administration. Do not administer without reconstituting.** After reconstitution, the syringe will contain a single 0.5mL dose of Abrysvo®.	Beyfortus® (nirsevimab) is presented as a prefilled syringe containing either 0.5mL or 1mL. • Beyfortus® (nirsevimab) 50mg in 0.5mL is a prefilled syringe with a **purple plunger** rod. • Beyfortus® (nirsevimab) 100mg in 1mL is a prefilled syringe with light **blue plunger** rod.
Storage	Store between +2°C and +8°C and protect from light.	Store between +2°C and +8°C and protect from light.

* Conditions associated with increased risk of severe RSV disease in infants and young children are listed in the Australian Immunisation Handbook and *Appendix 2*.
± For advice regarding maternal immunosuppression and where women have undergone treatment leading to a loss of maternal antibodies refer to the Australian Immunisation Handbook and *Appendix 1*

Note: The adjuvanted RSV vaccine **Arexvy® (GSK)** is not registered for use in pregnant women or persons <60 years and must not be used in this cohort.

RSV Beyfortus® (nirsevimab) Dose Recommendations ^

Table 2: Beyfortus® (nirsevimab) Dose Recommendations

Eligibility	Weight	Dose	Number of syringes to administer
Infants entering their 1st RSV season in 2025 (born from 1 October 2024 AND <8 months of age at time of administration) *Once an infant reaches 8 months of age, they will no longer be eligible for this dose*	Infants <5kg **(at the time of administration)**	50mg	**Give 1 x 50mg prefilled syringe** via intramuscular injection. **Volume for IM injection = 1x 0.5mL**
	Infant ≥5kg **(at the time of administration)**	100mg	**Give 1 x 100mg prefilled syringe** via intramuscular injection. **Volume for IM injection = 1 x 1mL** **OR** *If supply constrained or no 100mg syringes are available* **Give 2 x 50mg prefilled syringes**** via separate intramuscular injections. (Administer both syringes at the same appointment/during the same encounter.) **Volume for IM injection = 2 x 0.5mL**
Children entering their 2nd RSV season with an increased risk of severe RSV disease* (born from 1 October 2023 AND <24 months of age at time of administration) *Once a child reaches 24 months of age, they will no longer be eligible for this dose*	All infants and children, regardless of weight with conditions associated with increased risk of severe RSV disease*	200mg	**Give 2 x 100mg prefilled syringes**** via separate intramuscular injections. (Administer both syringes at the same appointment/during the same encounter.) **Volume for IM injection = 2 x 1mL**

^See Australian Product Information Beyfortus® (nirsevimab)
*See the Australian Immunisation Handbook – conditions associated with increased risk of severe disease in infants and young children
**Note:

- Immunisation providers may be supplied both 50mg and 100mg prefilled syringes as part of their order.
- If 100mg prefilled syringes are unavailable, immunisation providers can administer 2 x 50mg prefilled syringes for a 100mg dose.
- 100mg prefilled syringes are suitable for infants and young children requiring a 200mg dose. **DO NOT** use 4 x 50mg prefilled syringes to administer a 200mg dose.

Clinical Documentation

Documentation of both maternal vaccination and infant immunisation is particularly important in this program, given the multiple providers across maternal and infant care.

Abrysvo®

The mother's RSV vaccination status must be reviewed as part of the eligibility assessment of the baby, therefore it is imperative that all maternal Abrysvo® vaccination encounters are reported to the Australian Immunisation Register (AIR), as the mother's vaccination status directly influences the baby's immunisation requirements at birth. Maternal vaccination should also be recorded in relevant antenatal clinical records.

Pregnant women should be advised to bring their digital AIR Immunisation History Statement with them to their antenatal appointments and to the hospital at delivery, to confirm their vaccination history.

Beyfortus® (nirsevimab)

Prior to administration of Beyfortus® (nirsevimab) all immunisation providers must review the AIR history of both the mother and infant.

Please report all infant doses of Beyfortus® (nirsevimab) to the AIR and record in the Immunisation Section of the Childhood Personal Health Record (PHR - Blue Book) and on hospital discharge summary documentation. This is important during transitions of care (e.g. hospital to primary care), to ensure eligible infants receive the immunisation and to avoid inadvertent duplicate doses of Beyfortus® (nirsevimab) being administered.

Reporting to the AIR

It is mandatory for all NIP vaccination encounters to be reported to the AIR within a timely manner. This is a requirement under the Australian Immunisation Register Act 2015 and Australian Immunisation Register Rule 2015.

The AIR has been updated to accept records of Beyfortus® (nirsevimab) (BFRSV) and Abrysvo® (ABRSV). All vaccination and immunisation encounters should be reported to the AIR.

Reporting to the AIR will be an essential component in determining eligibility for infant immunisation and in preventing administration errors. Reporting to AIR will also be essential for program monitoring and evaluation.

Antenatal vaccinations

The collection of antenatal data is important to enable the monitoring of vaccination uptake and the effectiveness and safety of maternal vaccines and vaccination programs. Abrysvo® (ABRSV) vaccination encounters should be identified as 'antenatal' when submitting to AIR. Depending on the update status of clinical software and the AIR site, select either:

> Vaccine type = 'NIP/Commonwealth' AND Antenatal indicator = 'Yes'
>
> OR
>
> Vaccine type = 'Antenatal'

From 1 March 2025, it will be mandatory under the AIR Rule 2015 to report to the AIR if an individual is pregnant at the time of vaccination.

Infant immunisations

Beyfortus® (nirsevimab) (BFRSV) immunisation encounters should be submitted to AIR by selecting:

Vaccine type = 'Other'

Recording multiple doses of Beyfortus® (nirsevimab) in the AIR

The dose of nirsevimab for older children entering their 2nd RSV season is 200 mg, given as two intramuscular injections (2 × 100 mg/mL doses) at two different sites (preferably separate limbs, or else separated by 2.5 cm) during the same visit. However, AIR does not record this as multiple doses.

The AIR does not allow vaccination providers to record the same vaccine brand, administered to the same individual, on the same date (as it's assumed as a reporting error/duplicate data). Services Australia recommends that vaccination providers report this scenario to the AIR as a single dose (this is expected to change in the coming months). Where multiple injections are administered, they should have the same batch number.

RSV Product Ordering for Providers

All RSV immunisation products will be available to order online via the Tasmania Vaccine Ordering system or via Sigma (for pharmacists – Abrysvo® only). Providers are required to have a Tasmanian vaccine account to order the products. For assistance or details on obtaining a vaccine account, please contact the Immunisation Team via immunisation@health.tas.gov.au or 1800 671 738 (option 4).

Cold Chain Management

RSV immunisation products require storage in a purpose-built vaccine refrigerator between **+2°C and +8°C** and always protected from light. Temperature deviations outside of this range (except for up to 12°C for <15 minutes) must be reported to the Immunisation Team.

Report cold chain breaches as per established pathways for other government-funded vaccines, by contacting the Immunisation Team on 6166 0632 or after hours to the on-call nurse on 1800 671 738.

Refer to the *National Vaccine Storage Guidelines 'Strive for 5'* for more information on best practice guidelines for immunisation storage and cold chain management.

More details on reporting cold chain breaches can be found online at Immunisation providers | Tasmanian Department of Health.

Reporting Adverse Events Following Immunisation and Administration Errors

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". All AEFIs and vaccine administration errors (VAEs) must be reported to the Immunisation Team. This is particularly important for serious or unexpected AEFIs, or VAEs, as this will enable immunisation safety issues to be identified and managed appropriately and in a timely manner.

AEFIs and VAEs must be reported to the Immunisation Team by completing an Adverse Events Following Immunisation Reporting Form.

Please refer to the Department of Health website on Adverse Events Following Immunisation for more information around reporting AEFIs and VAEs.

Resources

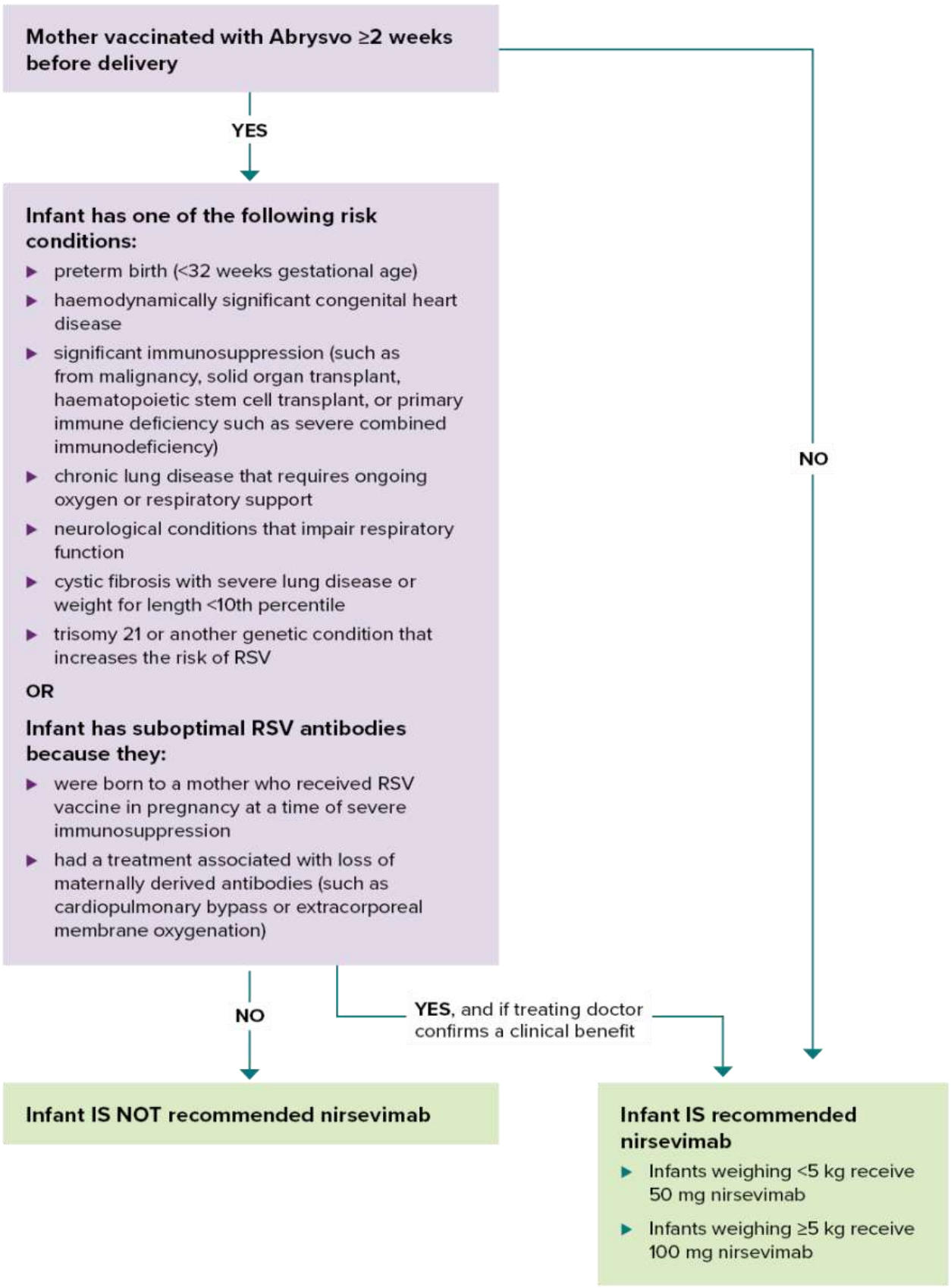
- RSV – Australian Immunisation Handbook
- RSV maternal and infant protection program 2025 – Tasmanian Department of Health
- Health Pathways, For clinicians
- National Vaccine Storage Guidelines 'Strive for 5'
- National Centre for Immunisation Research and Surveillance RSV FAQs
- Department of Health and Aged Care – Immunisation for pregnancy

For more information about this program contact the Immunisation Team

Email: immunisation@health.tas.gov.au

Appendix 1

Flowchart to guide which infants should receive Beyfortus® (nirsevimab) in their first RSV season



Disclaimer: this flowchart is subject to change. Please refer to the Australian Immunisation Handbook – RSV Chapter for current recommendations.

Appendix 2

List of conditions associated with increased risk of severe RSV disease in infants and young children

Infants and young children, assessed by their treating doctor to have any of the following conditions and less than 24 months of age, are eligible for Beyfortus® (nirsevimab) under this program regardless of maternal vaccinations status.

Conditions associated with increased risk of severe RSV disease in infants and young children
• Preterm birth <32 weeks gestational age • Haemodynamically significant congenital heart disease • Significant immunosuppression, such as from solid organ transplant, haematopoietic stem cell transplant, or primary immune deficiencies such as severe combined immunodeficiency (SCID) • Chronic lung disease requiring ongoing oxygen or respiratory support • Neurological conditions that impair respiratory function • Cystic fibrosis with severe lung disease or weight for length <10th percentile • Trisomy 21 or another genetic condition that increases the risk of severe RSV disease

Disclaimer: these conditions are subject to change. Please refer to the Australian Immunisation Handbook – conditions associated with increased risk of severe disease in infants and young children for current risk conditions.