Queensland Health

The Queensland Paediatric Respiratory Syncytial Virus Prevention Program

Clinical Guidance for Immunisation Service Providers

Version 2.0 | 20 January 2025

The Queensland Paediatric Respiratory Syncytial Virus (RSV) Prevention Program provides free RSV immunisation during pregnancy and to eligible infants and young children living in Queensland.

From 1 December 2024, Queensland's Program will offer both:

- **Abrysvo,** an RSV vaccine administered between 28 and 36 weeks of pregnancy to protect newborn infants against severe RSV disease from birth for up to 6 months.
- **Nirsevimab** (brand name Beyfortus), a long-acting monoclonal antibody provides infants and young children protection against severe RSV disease for at least 5 months from administration.

Infants protected by RSV immunisation (Abrysvo) in utero do not routinely require nirsevimab, further information is provided below.

Program eligibility

Refer to the *eligibility table* (below) and *eligibility flow chart* (in appendix 3) for further information on cohorts and recommended products.

See Table 2 for dosing recommendations for each eligible cohort.

Table 1 - Eligibility

Abrysvo RSV vaccine	
A single dose of Abrysvo is recommended during pregnancy between 28 and 36 weeks gestation.	• **This dose should be offered year-round (non-seasonally).** • Abrysvo is the only vaccine approved for use in pregnancy. Do not use other brands of RSV vaccine. • This dose should be administered at least 14 days before delivery to ensure protection for the infant at time of birth. • If Abrysvo is not administered before 36 weeks gestation, it should be given as soon as possible, and remains funded under this program. • Some newborn infants may still be eligible for nirsevimab, see below.

Nirsevimab (Beyfortus) RSV Immunisation Product	
Infants **from birth# to less than 8 months** of age are recommended to receive a dose of nirsevimab if they meet one of the listed eligibility criteria.	• Recommended for all infants where: – the infant is not protected by Abrysvo from birth. This may include: 1. Abrysvo was not administered during pregnancy, **or** 2. Infant was delivered within 14 days of Abrysvo administration, **or** 3. where Abrysvo immunisation status is unknown, **or** – the infant has a condition associated with increased risk of severe RSV disease*, **or** – may have suboptimal RSV antibodies#. • **This dose should be offered year-round (non-seasonally).** • This dose should be offered prior to discharge from the birthing hospital. Eligible infants not immunised in hospital can access nirsevimab through primary care immunisation providers. • **Once an infant reaches 8 months of age,** they will no longer be eligible for this dose.
Infants and young children with a condition associated with increased risk of severe RSV disease* **from 8 months to less than 24 months of age**, ahead of their second RSV season.	• Infants or young children with a condition associated with increased risk of severe RSV disease* are eligible for this dose. • This dose should be given regardless of maternal RSV vaccination status and at least 6 months from a previous dose of nirsevimab (note that some infants and young children will be eligible for more than one dose of nirsevimab under this program). • **Immunisation providers are encouraged to consider the timing of this dose to ensure that the duration and level of protection are maximised over the peak months of the infant or child's 2nd RSV season.** • **Once an infant reaches 24 months of age,** they will no longer be eligible for this dose.
#see appendix 3 for nirsevimab decision support flow chart ***see appendix 2 for list of conditions associated with increased risk of severe RSV disease**	

- **Eligible infants and young children who have had prior laboratory confirmed RSV remain eligible for nirsevimab under this program.**
- **Eligible infants or young children who are moderately or severely unwell, with or without a fever, including those who have documented current RSV infection should defer receiving nirsevimab until they have recovered.**
- **Repeated dosing of nirsevimab within the same RSV season is not required unless the child is undergoing cardiac surgery with cardiopulmonary bypass (see below).**

Nirsevimab (Beyfortus) Key Information

Recommendations for pre-term infants

Pre-term infants (<32 weeks gestational age) should receive nirsevimab at their chronological age using the same guidance for full-term infants and young children, regardless of maternal vaccination status.

There are limited data available for use of nirsevimab in extremely preterm infants (gestational age less than 29 weeks) less than 8 weeks of age. No clinical data are available in infants with a postmenstrual age (gestational age at birth plus chronological age) of less than 32 weeks.

Dosing in infants with a body weight from 1kg to less than 1.6kg is based on extrapolation, no clinical data are available. Administration in infants less than 1kg is anticipated to result in exposure to higher concentrations of nirsevimab than in those infants weighing more. The benefits and risks of nirsevimab use in infants less than 1kg should be carefully considered in consultation with the clinical team providing care for the infant.

Infants with prolonged birth hospitalisations related to prematurity or other causes should receive nirsevimab before discharge from hospital.

If an infant is in a Neonatal Intensive Care Unit or Special Care Nursery, the clinical team should perform a clinical/risk assessment and administer accordingly. Seek specialist advice for further recommendations.

Recommendations for infants who are receiving palivizumab

Transition from palivizumab to nirsevimab for eligible children should have occurred in 2024 under the Queensland Paediatric Respiratory Syncytial Virus Prevention Program.

For any children still receiving palivizumab, a single dose of nirsevimab can be administered 28 days after a previous dose of palivizumab. Repeated dosing of nirsevimab within the same season, as is done with palivizumab, is not required. Palivizumab should not be administered to infants who have already received nirsevimab in the same season. For further guidance seek specialist advice.

Product appearance

Nirsevimab is presented as a prefilled syringe containing either 0.5mL or 1mL.

- Nirsevimab (Beyfortus) 50mg in 0.5mL is a prefilled syringe with a **purple plunger** rod.
- Nirsevimab (Beyfortus) 100mg in 1mL is a prefilled syringe with light **blue plunger** rod.

Dosing recommendations – Nirsevimab (Beyfortus)

The recommended dose for infants and young children is weight and age dependant. Nirsevimab is given as a single dose.

Note the dosing weight refers to an infant's or young child's weight at the time of administration, not their birth weight.

Immunisation providers should weigh all infants or young children prior to administration if they do not have a recent weight recorded.

Refer to eligibility criteria prior administration

Refer to appendix 4 for information on administration of nirsevimab.

Table 2 – Dosing

Age and weight	Dose	Number of syringes to administer
Infant <5kg **and** <8 months of age	50mg	**Give 1 x 50mg prefilled syringe** via intramuscular injection. **Volume for IM injection = 0.5mL**
Infant ≥5kg **and** <8 months of age	100mg	**Give 1 x 100mg prefilled syringe** **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**
Infants and young children **8 to <24 months, 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**

****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.
- The 100mg prefilled syringes will be supplied for infants and young children who require a 200mg dose. DO NOT use 4 x 50mg prefilled syringes for the administration of 200mg.
- There is currently no information available regarding the need for dose adjustment in ECMO, renal impairment and hepatic impairment. Seek specialist advice.

Additional dose recommendations for children undergoing cardiac surgery with cardiopulmonary bypass

For children undergoing cardiac surgery with cardiopulmonary bypass, an additional dose of nirsevimab is recommended as soon as the child is stable after surgery to ensure adequate nirsevimab serum levels. This dose should be given regardless of maternal vaccination status.

For infants <8 months of age:

- If surgery is within 90 days after receiving nirsevimab, the additional dose should be based on body weight at the time of the additional dose. Refer to **Table 2** for weight-based dosing.
- If more than 90 days have elapsed since receiving nirsevimab, the additional dose should be 50mg regardless of body weight.

Infants and young children 8 to <24 months,

- If surgery is within 90 days after receiving nirsevimab, the additional dose should be 200mg, regardless of body weight.
- If more than 90 days have elapsed since receiving nirsevimab, the additional dose should be 100 mg, regardless of body weight.

If an infant or young child has not received any prior doses of nirsevimab, refer to table 2.0 for age/weight-based dosing recommendations.

For more information on **Nirsevimab** including precautions, contraindications and co-administration with other vaccines, refer to the ***Australian Immunisation Handbook***

Abrysvo (RSV vaccine) Key Information

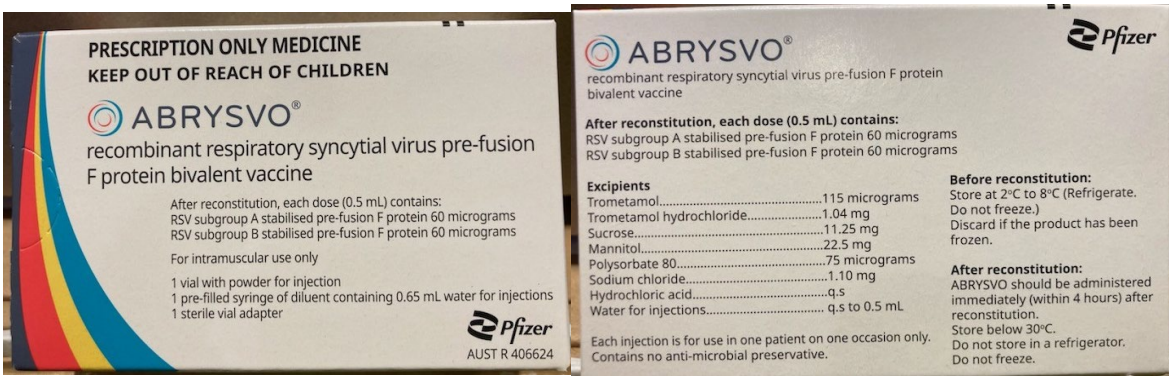
Product appearance

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 dose of Abrysvo (0.5mL).

Refer to appendix 5 for information on reconstitution and administration of Abrysvo.

Some batches of Abrysvo have received an extension by the TGA on their printed shelf-life, refer to appendix 6 for information on the affected batches and updated expiry.



For more information on **Abrysvo** including timing of vaccination during pregnancy, precautions, contraindications and co-administration with other vaccines recommended in pregnancy, refer to the ***Australian Immunisation Handbook***

Recording administration of nirsevimab and Abrysvo

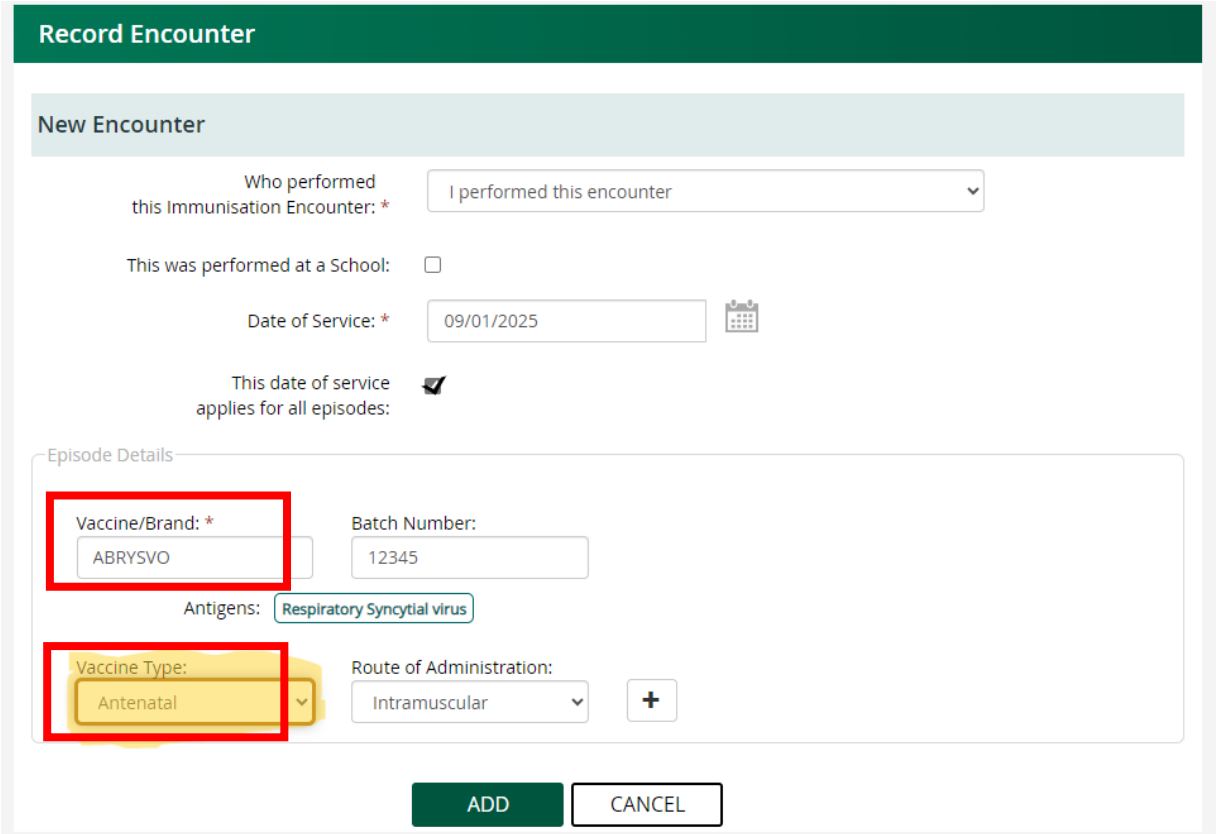
Personal Health Record (Red Book)

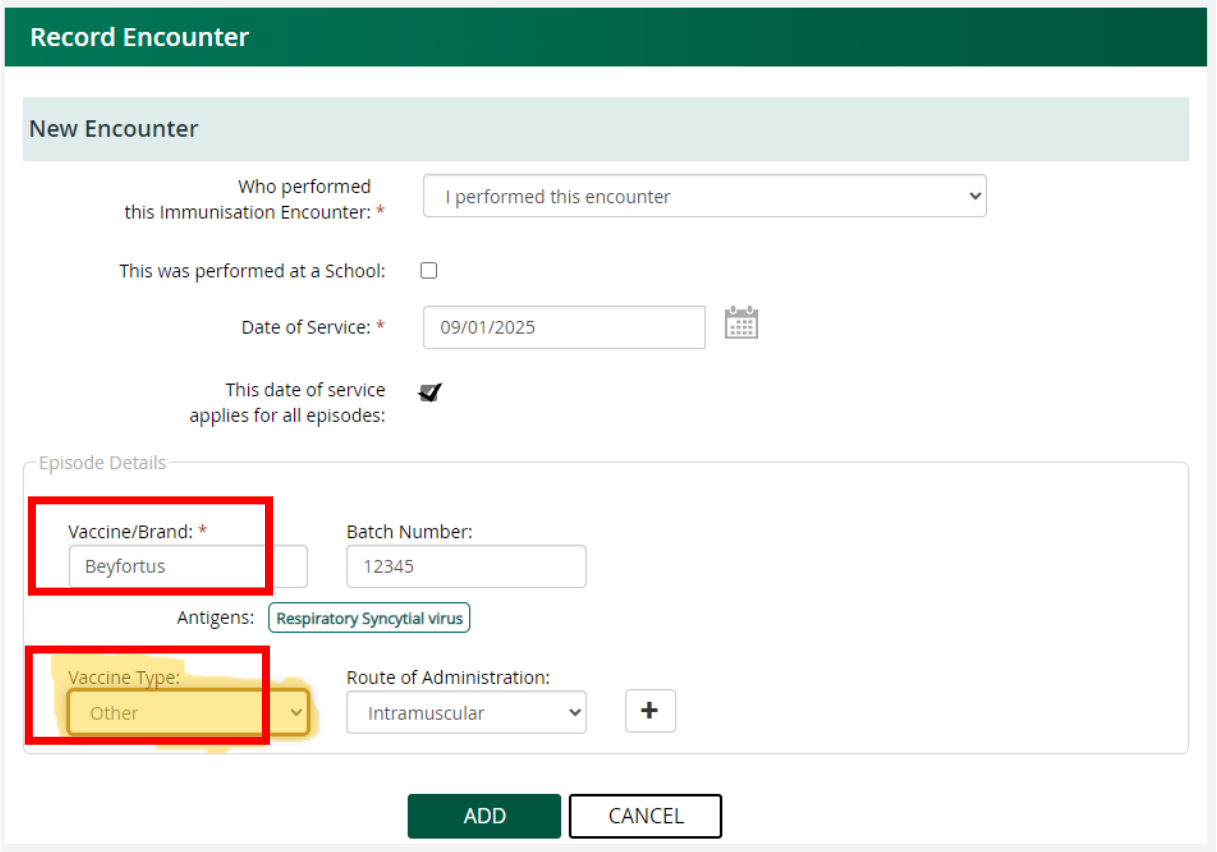
Doses of nirsevimab can be recorded in the Immunisation section of the Personal Health Record by removing the adhesive batch label from the prefilled syringe and affixing it to the Vaccination record page. If no label is available, clearly record all required details in the book.

Australian Immunisation Register (AIR)

Recording immunisations to the AIR is critical to ensure all Queenslanders have a complete record from birth and is a mandatory requirement for all National Immunisation Program (NIP) immunisations. The Australian Immunisation Register (AIR) has been updated to allow for the recording of nirsevimab (Beyfortus) and Abrysvo.

For infants and young children who may require two syringes of nirsevimab to be administered at the same time (i.e. 2 x 50mg or 2 x 100mg), they should only have a **single** dose of nirsevimab recorded on AIR.





Ordering

Nirsevimab and Abrysvo given as part of the Queensland Paediatric Respiratory Syncytial Virus Prevention Program can be ordered through the Queensland Health Immunisation Program (QHIP) as part of regular fortnightly orders.

For more information on how to place an order with QHIP visit our website Order, store and manage immunisations | Queensland Health.

Providers should complete their stock on hand count when submitting orders. QHIP may need retrieve unused stock for re-distribution to other sites.

Resources

- Queensland Paediatric Respiratory Syncytial Virus Prevention Program | Queensland Health.
- RSV Immunisation Nirsevimab – information for parent and carers
- RSV Vaccination in Pregnancy (health.qld.gov.au)
- First Nations RSV Immunisation Nirsevimab – information for patients and carers
- Queensland Health Nirsevimab consent form
- QHIP online training courses
- Immunisation Schedule Queensland
- RSV – Australian Immunisation Handbook
- Extended Practice Authorities
- National Vaccine Storage Guidelines 'Strive for 5'
- National Centre for Immunisation Research and Surveillance RSV FAQs
- Recommended sites for childhood vaccination resource | NCIRS

For more information about this program contact:

Queensland Health Immunisation Program

Email: immunisation@health.qld.gov.au

References

Australian Government, Department of Health and Aged Care (Jun 2024). *Australian Immunisation Handbook – Respiratory syncytial virus (RSV).* Viewed Sept 2024. https://immunisationhandbook.health.gov.au/contents/vaccine-preventable-diseases/respiratory-syncytial-virus-rsv

Australian Government, Department of Health and Aged Care (Aug 2024). *Administration of vaccines.* Viewed Sept 2024. https://immunisationhandbook.health.gov.au/contents/vaccination-procedures/administration-of-vaccines

Australian Government Department of Health and Aged Care (Jun 2018). *Managing anaphylaxis*. Viewed Sept 2024. https://immunisationhandbook.health.gov.au/resources/publications/managing-anaphylaxis

Australian Government, Department of Health and Aged Care (Nov 2023). Viewed March 2024. https://immunisationhandbook.health.gov.au/contents/vaccination-procedures/after-vaccination

Australian Government, Department of Health and Aged Care (Apr 2020). *National Vaccine Storage Guidelines 'Strive for 5'*. Viewed Sept 2024. https://www.health.gov.au/resources/publications/national-vaccine-storage-guidelines-strive-for-5

Therapeutic Goods Administration. *Product and Consumer Medicine Information- ABRYSVO.* Viewed Sept 2024. https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/PICMI?OpenForm&t=&q=abrysvo&r=/

Therapeutic Goods Administration. *Product and Consumer Medicine Information- BEYFORTUS.* Viewed Sept 2024. https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/PICMI?OpenForm&t=&k=B&r=/

Australian Government, Department of Health and Aged Care. *Using the Australian Immunisation Register*. Viewed Sept 2024. https://www.health.gov.au/topics/immunisation/immunisation-information-for-health-professionals/using-the-australian-immunisation-register

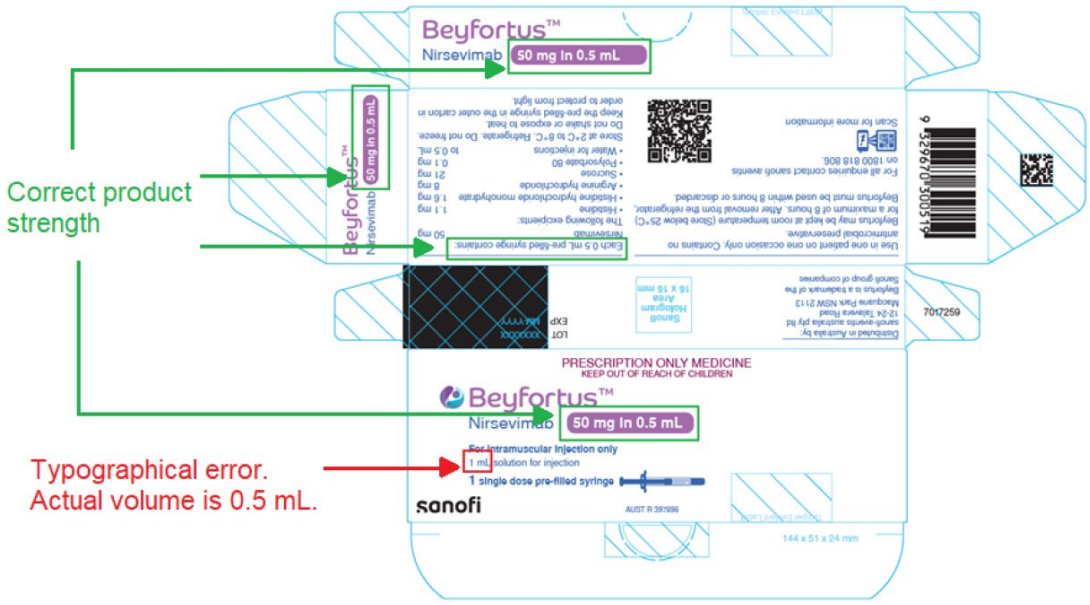
Queensland Government (Mar 2024). *Respiratory syncytial virus (RSV)*. Viewed Sept 2024. https://www.qld.gov.au/health/condition/infections-and-parasites/viral-infections/respiratory-syncytial-virus-rsv

Queensland Government (Jun 2024). *Adverse event following immunisation*. Viewed Sept 2024. https://www.health.qld.gov.au/clinical-practice/guidelines-procedures/diseases-infection/immunisation/service-providers/adverse-event

Appendix 1 – Typographical error on carton of 50mg/0.5mL prefilled syringe

It has been identified that there is a typographical error on the carton of some batches of the single dose prefilled syringe for the 50mg/0.5mL presentation of nirsevimab. The total volume of the syringe is printed as 1mL instead of 0.5mL on the front of the carton face as shown below:

Figure 1: Carton Label (50 mg in 0.5 mL)



- Product strength (50mg in 0.5mL) is correctly stated on all faces of the carton.
- Product strength (50mg in 0.5mL is correctly stated on the syringe label.
- The syringe contains 0.5mL for solution for injection.
- **The contents of the entire syringe should be administered to deliver a single dose of 50mg.**

This typographical error has no impact on the product quality and stock is suitable to continuing using.

There is no error on the carton for the 100mg in 1.0mL nirsevimab product.

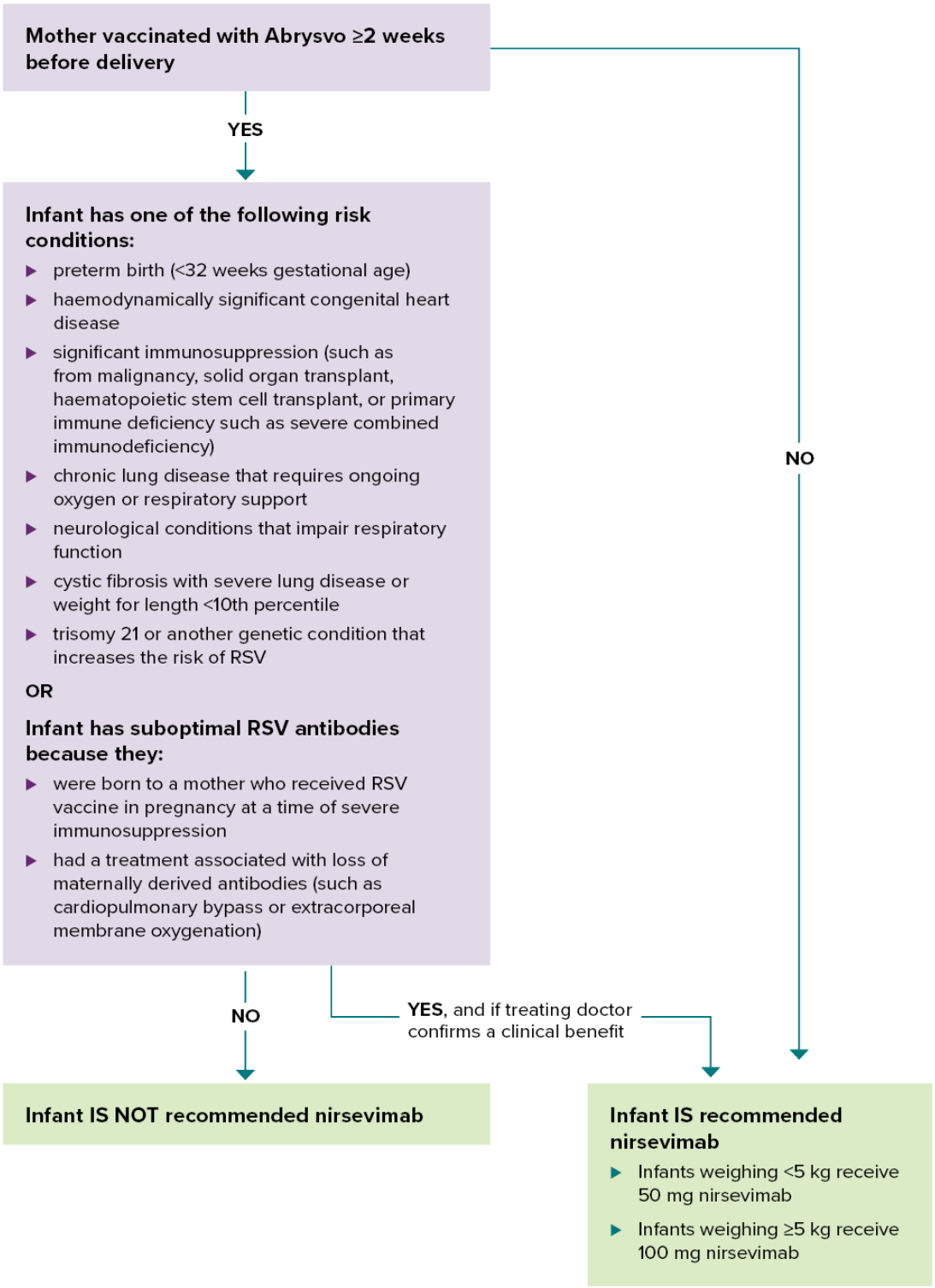
Please contact immunisation@health.qld.gov.au if you have any questions.

Appendix 2 - *List of conditions which increase the risk of severe RSV disease in infants and young children

Infants and young children with any of the following conditions listed below are eligible for nirsevimab under this program regardless of maternal vaccinations status:

- Preterm birth <32 weeks gestational age.
- Haemodynamically significant congenital heart disease.
- Significant immunosuppression, such as from solid organ transplant, haematopoietic stem cell transplant, infants and young children receiving active chemotherapy, 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.
- Other infants less than 24 months of age with a condition associated with increased risk of severe RSV disease, after discussion with a Paediatric Infectious Diseases Specialist.

Appendix 3 - #Flow chart for determining nirsevimab eligibility for infants <8 months of age



For more information refer to the Australian Immunisation Handbook.

Image source - Figure. Flowchart to guide which infants should receive nirsevimab in their 1st RSV season | The Australian Immunisation Handbook (health.gov.au)

Appendix 4 – Administering nirsevimab

Refer to the Australian Immunisation Handbook for detailed information on IM injection techniques in paediatrics.

All strengths of nirsevimab should be administered by intramuscular (IM) 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.

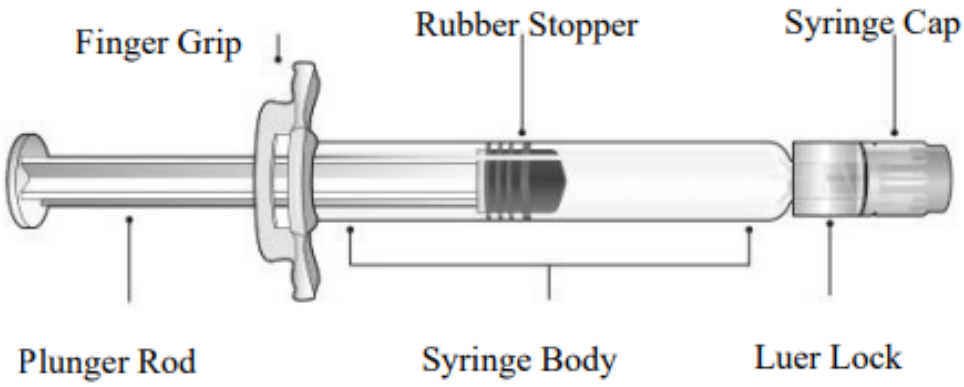
Do not administer nirsevimab intravenously, intradermally, or subcutaneously.

Needles are not included with this product, refer to the Australian Immunisation Handbook for detailed information on recommended needle size, length and angle for administering immunisations.

Nirsevimab is available in both 50mg in 0.5mL and 100mg in 1mL prefilled syringes. Each prefilled syringe is for single use in one patient only. Check the labels on the carton and prefilled syringe to make sure you have selected the correct strength and that it is within the expiry date prior to administration.

Visually inspect the nirsevimab syringe for particulate matter and discolouration prior to administration. Nirsevimab is a clear to opalescent, colourless to yellow solution. Do not inject nirsevimab if the liquid is cloudy, discoloured or it contains large particles or foreign particulate matter.

Figure 1 - Luer lock syringe components



Ensuring that appropriate hand hygiene is performed, use the following steps to administer the nirsevimab syringe/s:

- **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 an appropriately sized Luer lock needle to the prefilled syringe by gently twisting the needle clockwise onto the prefilled 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 prefilled syringe as an intramuscular injection.

- **Step 5:** Dispose of the used syringe immediately.
- **Step 6:** Monitor for at least 15 minutes after administration for any adverse events.

If two injections are required, repeat above steps at a different injection site, if the same limb is used ensure the injections are separated by 2.5cm.

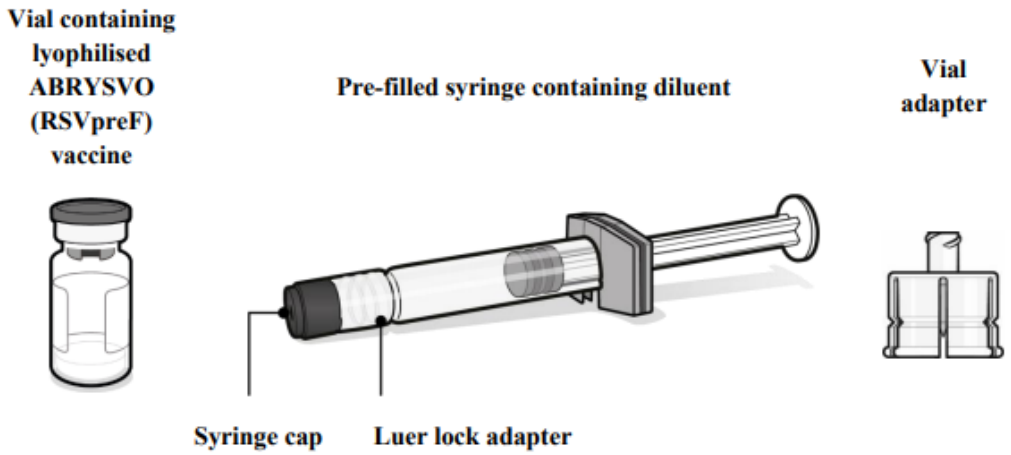
For general information regarding immunisation administration, please refer to the Australia Immunisation Handbook:

- Preparing for vaccination
- Administration of vaccines
- After vaccination

Appendix 5 – Reconstituting and administering Abrysvo

Refer to the Australian Immunisation Handbook for detailed information on pre-screening and IM injection techniques.

This product requires reconstitution, **do not administer without reconstituting**. Each box of Abrysvo should contain the following items:



Ensuring that appropriate hand hygiene is performed, use the following steps to reconstitute and administer Abrysvo:

Step 1: Attach vial adapter

- Peel off the top cover from the vial adapter packaging and remove the flip off cap from the vial.
- While keeping the vial adapter in its packaging, centre the adapter over the vial's stopper and connect with a straight downward push. Do not push the vial adapter in at an angle as it may result in leaking. Remove the packaging.

Step 2: Reconstitute lyophilised vaccine component to form Abrysvo vaccine

- For all syringe assembly steps, hold the syringe only by the Luer lock adapter. This will prevent the Luer lock adapter from detaching during use.
- Twist to remove the syringe cap, then twist to connect the syringe to the vial adapter. Stop turning when you feel resistance.
- Inject the entire contents of the syringe into the vial. Hold the plunger rod down and gently swirl the vial until the powder is completely dissolved (less than 1 minute). Do not shake.

Step 3: Withdraw reconstituted vaccine

- Invert the vial completely and slowly withdraw the entire contents into the syringe to ensure a 0.5 mL dose of the vaccine.
- Twist to disconnect the syringe from the vial adapter.
- Attach a sterile needle suitable for intramuscular injection.

Step 4: Administration of Abrysvo

- Administer the 0.5mL dose via intramuscular injection into the deltoid muscle.
- Dispose of the used syringe immediately.
- Monitor the person for at least 15 minutes after administration for any adverse events.

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

- Preparing for vaccination
- Administration of vaccines
- After vaccination

Appendix 6 – Shelf-life expiry extension for Abrysvo

Pfizer advised on 10 January 2025 that, following the Therapeutic Goods Administration (TGA) approval, the shelf life of the below listed batches of ABRYSVO is extended from 24 to 36 months.

The storage conditions remain unchanged and include the requirement to store ABRYSVO in a refrigerator (2°C - 8°C) prior to reconstitution. For full storage requirements before and after reconstitution, please refer to the ABRYSVO Product Information.

Please refer to the table below for the updated expiry dates.

Batch number	Expiry date on package	Updated expiry date
LL2636	31.07.2025	**31.07.2026**
LR6779	30.06.2025	**30.06.2026**
LR6778	31.05.2026	**31.05.2027**

If you are currently in possession of ABRYSVO stock with batch numbers different to those listed above, the expiry date remains unchanged. Please continue to use the printed expiry date on the packaging.

Should you have any questions regarding this matter, please call Pfizer Medical Information on 1800 675 229 or via www.pfizermedicalinformation.com.acu