# RSV Maternal and Infant Protection Program

2025 Victorian Immunisation Program - Webinar 2

22 January 2025

**OFFICIAL** 



## RSV Mother & Infant Protection Program (RSV-MIPP)

In collaboration with the Commonwealth, the Victorian Government will implement the Respiratory Syncytial Virus Mother & Infant Protection Program (RSV-MIPP) for pregnant women and infants in 2025.



National Immunisation Program (NIP)
Maternal RSV vaccination (Abrysvo®)

#### From Monday, 3 February 2025

- <u>eligible</u> pregnant women will have access to the free Abrysvo® RSV vaccine under the <u>National Immunisation</u> <u>Program</u>
- a single dose of Abrysvo® RSV vaccine is recommended in pregnancy at 28-36 weeks gestation to protect the infant against RSV



Victorian Government
Victorian funded infant immunisation (nirsevimab)

#### 1 April 2025 - 30 September 2025

A free long-acting RSV monoclonal antibody, Beyfortus™ (nirsevimab) will be available for:

- eligible infants whose mothers did not receive Abrysvo® RSV vaccine during pregnancy, or were vaccinated less than two weeks before delivery, and
- eligible infants and young children most at risk of severe RSV



Department of Health

## NIP Maternal RSV vaccination - Abrysvo®

Commencement date 3 February 2025: eligible pregnant women - 28 weeks to 36 weeks gestation

<u>Australian Immunisation Handbook</u> recommendations:

- a single dose recommended for all pregnant women at 28 36 weeks gestation
- can be given beyond 36 weeks gestation but infant may require nirsevimab if less than 2 weeks prior to delivery
- · not routinely recommended for use less than 28 weeks

**Abrysvo®** is the **only** RSV vaccine approved for use in pregnant women

- women who are breastfeeding but not pregnant are not recommended to receive an RSV vaccine
- advice on use in subsequent pregnancies will be provided when data is available

**NOTE:** Arexvy® vaccine is registered for use in adults aged 60 years and over and should **not be** administered to pregnant women. Report errors to <u>SAEFVIC</u>

NIP Maternal RSV vaccination Abrysvo®



## Abrysvo® vaccine - preparation and administration

#### **Timing**

- Year-round program, Abrysvo® RSV vaccine should be routinely offered at the 28-week antenatal appointment
- All women who are already >28 weeks pregnant at the time of program commencement should be vaccinated as soon as possible
- Administer prior to 36 weeks

#### Co-administration

 Abrysvo® RSV vaccine can be co-administered with other maternal vaccinations including pertussis, influenza and COVID-19 vaccines

#### **Presentation**

- The lyophilised vaccine (powder) must be reconstituted only with the diluent provided using the vial adapter
- The prepared vaccine is a clear and colourless solution

#### Dosage

Single 0.5mL, intramuscular injection into the deltoid muscle

#### **Preparation**

#### Abrysvo® vaccine information



Figure 1. Abrysvo® vaccine

- · Abrysvo® vaccine: 0.5 ml vial
- · Presentation: powder and diluent for solution for injection
- the powder or cake is white.
- the diluent is a clear, colourless liquid
- · Route & dosage:
- Intramuscular (IM) injection into the deltoid muscle
- 0.5ml (1 dose per vial)

#### Packet contents

Vial containing lyophilised Abrysvo® RSVpreF vaccine



Pre-filled syringe containing diluent



Syringe cap Luer lock adapter

No needles are included in the packs.

#### AIR Code

Abrysvo ABRSV

Australian Immunisation Register (AIR) - Reporting is critical to success of RSV-MIPP



#### Neonate program

DOB: 1 April 2025 - 30 September 2025

#### Infants born to:

- mothers who did not receive Abrysvo® RSV vaccine during pregnancy or
- Abrysvo® RSV vaccine was administered <2weeks before birth,</li>
- high risk infants\* regardless of maternal vaccination status

\*Australian Immunisation Handbook | RSV



#### Catch up - 1st season

DOB: 1 October 2024 - 31 March 2025 (up to 8 months of age)

#### Infants born to:

- mothers who **did not receive** maternal Abrysvo® RSV vaccine during pregnancy **or**
- Abrysvo® RSV vaccine was administered <2 weeks before birth,</li>
- high risk infants\* regardless of maternal vaccination status

\*Australian Immunisation Handbook | RSV, age limit not applicable



#### Catch up - 2<sup>nd</sup> RSV season

DOB: on or after 1 October 2023

#### Children vulnerable to severe RSV:

- Aboriginal Torres Strait Islander children
- young children with conditions associated with increased risk of severe RSV disease\*\*

\*\*Conditions associated with increased risk

Jan 2025 RSV season

Jan 2025 Feb Mar Apr May Jun Jul Aug Sep Oct Nov Dec 2025

Starts 1 April 2025

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Ends 30 September 2025



#### **Neonate program**

DOB: 1 April 2025 - 30 September 2025

#### Infants born to:

- mothers who did not receive Abrysvo® RSV vaccine during pregnancy or
- Abrysvo® RSV vaccine was administered <2weeks before birth,</li>
- high risk infants\* regardless of maternal vaccination status

#### **High risk infants - 1st RSV season**

- Preterm birth <32 weeks gestational age</li>
- 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
- Born to mothers with severe maternal immunosuppression
- Received treatment associated with loss of maternal derived ABs



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<sup>\*</sup>Australian Immunisation Handbook | RSV



#### Catch up - 1st season

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DOB: on or after 1 October 2023

#### Children vulnerable to severe RSV:

- Aboriginal Torres Strait Islander children
- young children with conditions associated with increased risk of severe RSV disease\*\*

\*\*Conditions associated with increased risk

#### High risk children - 2<sup>nd</sup> RSV season

- All Aboriginal and Torres Strait Islander infants
- Preterm birth <32 weeks gestational age</li>
- · 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</li>
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Starts 1 April 2025
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Ends 30 September 2025

## Nirsevimab (Beyfortus™) - preparation and administration

#### **Timing**

Protective benefits maximised if administered:

- shortly after birth for infants born just before or during the RSV season, aim to give before discharge
- may be delayed for neonates in NICUs, SCNs

#### Recommended work practices

- Link to established workflows in maternity units
- Check maternal vaccination AIR access
- Refer to recommendations in the <u>Australian Immunisation</u> <u>Handbook</u> for medical risk conditions and after treatment (such as cardiopulmonary bypass)

#### **Presentation**

- Clear to opalescent colorless to yellow solution in a prefilled syringe
- Each prefilled syringe contains 0.5 mL or 1 mL solution
- Pack size: 1 or 5 single use prefilled syringe(s)\* without needles

#### AIR Code

Beyfortus BFRSV

#### **Formulations**

- Prefilled syringe with a purple plunger rod contains 50mg of nirsevimab in 0.5mL
- Prefilled syringe with a light blue plunger rod contains 100mg of nirsevimab in 1mL

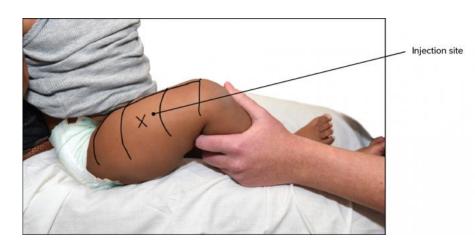
#### **Indications**

Neonate & first RSV season	Second RSV season
Body weight:  • less than 5 kg - 50mg  • 5kg and greater - 100mg	A 200 mg dose administered as <b>two</b> intramuscular injections (2 x 100 mg) at the same visit



## Nirsevimab - route of administration

Administer nirsevimab **intramuscularly (IM)**. The preferred site of administration is the anterolateral thigh region.



Vastus lateralis injection site on the anterolateral thigh

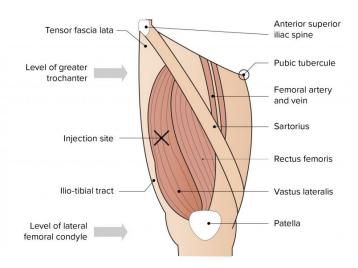


Figure. Anatomical markers used to identify the vastus lateralis injection site on the anterolateral thigh

# Storage of Abrysvo® and nirsevimab



Abrysvo® and nirsevimab **must** be stored in a purpose-built vaccine refrigerator at or between +2°C to +8°C and protected from light at all times



Store in the original cardboard packaging until immediately prior to administration to protect from light



Do not shake or expose to heat



Vaccine refrigerator temperature must be continuously monitored in accordance with the current edition of the National Vaccine Storage Guidelines 'Strive for 5'



A range of resources to support cold chain management are available on the Department of Health Cold Chain Management webpage



## RSV-MIPP: immunisation workforces

- Medical practitioners, nurse practitioners and authorised midwives can already administer Abrysvo® RSV vaccine and nirsevimab to eligible cohorts.
- Additional immunisers have been authorised to administer RSV immunisation products to support implementation and access to the RSV-MIPP.

#### **Abrysvo®**

- Will be available for **all immunisation providers** in Victoria
- Nurse immunisers, pharmacist immunisers, intern pharmacist immunisers and Aboriginal and Torres Strait Islander health practitioner (ATSIHP) immunisers are authorised to administer Abrysvo® vaccine for RSV, as recommended in the Australian Immunisation Handbook



#### nirsevimab

- Availability will be limited due to constrained supply
- Nurse immunisers and Aboriginal and Torres Strait Islander health practitioner (ATSIHP) immunisers are authorised to administer nirsevimab to eligible infants and children listed on the department's <u>RSV immunisation webpage</u> and in accordance with the <u>Australian Immunisation Handbook</u>



## Ordering RSV Abrysvo® and nirsevimab

#### **Abrysvo®**

- Ordering opened on 20 January 2025 to ensure all registered immunisation providers have access to the vaccine before commencement of the program
- National Immunisation Program eligibility commences on Monday 3 February 2025
- Order limits for Abrysvo® RSV vaccine are in place to manage demand and ensure equitable distribution
- Order limits may change without notice, providers should refer to their <u>Onelink</u> ordering template for the most up to information
- Account audits will be undertaken to ensure over-ordering does not occur and all doses must be reported to the AIR
- Shelf-life extension to batches LL2636, LL6779, LR6778, this information will be included when affected batches are despatched

#### nirsevimab

- Ordering is anticipated to open in mid-March to ensure that registered immunisation providers have access to nirsevimab before the commencement date of 1 April 2025. More information will be provided closer to the date
- GP's, public and private hospitals, NPs and local councils should refer to their Onelink ordering template
- Due to limited supply strict order limits will be in place to manage demand and ensure equitable distribution
- · Account audits will be undertaken to ensure over-ordering does not occur



# Australian Immunisation Register (AIR) reporting

#### **Preparation – examine records**



- Encourage mothers to bring digital / other copy of Immunisation statement or the Victorian Maternity Record (VMR) to all appointments and when presenting for infant nirsevimab dose
- Check eligibility criteria for risk factors for neonates and 'catch-up' doses

#### **Report doses**



- Check does your clinical software immunisation records automatically interface with the AIR? If not, ensure your service has manual processes in place to report encounters
- · Have you updated your practice software for 2025?
- Ensure correct codes, refer to <u>Services Australia AIR codes</u>
- Read <u>AIR fact sheet for providers</u> to ensure reporting is in line with recommendations

#### Reporting to the AIR



- It is mandatory to report all National Immunisation Program (NIP) vaccinations provided to the AIR
- It is strongly encouraged to report all other vaccinations to the AIR
- Record vaccine information within 24 hours (if practical), otherwise within 10 business days of administration
- Infants not enrolled with Medicare or not eligible for Medicare will be added to the AIR when a vaccination provider reports their vaccination details. This is a manual process and can take up to 5-10 business days
- Individuals who are enrolled with Medicare automatically have an AIR record created for them
- When reporting vaccinations for infants, add as much detail as possible to allow for future matching to a Medicare record and to avoid creating duplicate records
- Refer to <u>AIR Tip | NCIRS</u> for information on how to report newborn vaccinations for infants who are not yet enrolled in Medicare

## Vaccine administration error - RSV

#### **Abrysvo®**



#### Arexvy® - not used in RSV-MIPP





#### **Common administration errors**

- Brand confusion Abrysvo® and Arexvy®
- Indication for use which brand is licenced for which person, reconstitution is required

#### **Avoid administration errors**

- Abrysvo® and Arexvy® are not approved for use in infants and young children
- Abrysvo® is the only RSV vaccine recommended for pregnant people (NIP)
- Arexvy® is registered for people aged 60 years and over (private)

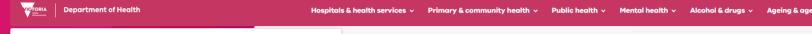
#### Key strategies for safe practice - Vaccine error management

- Right person, right vaccine, right time, right dose
- Clearly label vaccines in vaccine refrigerator keep separate
- Education share information regarding RSV program and products, including preparation
- Report to the Australian Immunisation Register

#### Report adverse events following immunisation (AEFI)

- Report AEFI and vaccine administration error to SAEFVIC, Victoria's safety surveillance service
- Requirement for open disclosure

## Practical tips - resources for health professionals



Home > Public health > Immunisation > Respiratory syncytial virus (RSV) immunisation

#### Information for immunisation providers

- Australian Government RSV Program advice for health professionals
- Department of Health Respiratory syncytial virus (RSV) immunisation website
- Fact sheet Abrysvo® RSV vaccine preparation
- Fact sheet RSV vaccination in pregnancy Abrysvo®
- RSV-MIPP Infant program Toolkit for Immunisation providers
- Uploading to the AIR factsheet for immunisation providers
- NCIRS Respiratory syncytial virus (RSV) FAQ
- Australian Immunisation Handbook Respiratory syncytial virus (RSV)

#### Information for consumers

- RSV vaccination for pregnant women A3 posters
- Fact sheet RSV vaccination in pregnancy
- Fact sheet RSV immunisation for infants and young children Nirsevimab
- Better Health Channel Respiratory syncytial virus (RSV) factsheet
- Australian Government RSV frequently asked questions

# Respiratory syncytial virus (RSV) immunisation

ATAGI recommendations, resources and workforce authorisation information for immunisation providers.

## Accessibility statement and publisher information

To receive this presentation in another format, using the National Relay Service 13 36 77 if required, or email the Immunisation Program < immunisation@health.vic.gov.au >.

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