

Updated: Potential for error: respiratory syncytial virus (RSV) immunisation products



SAFETY NOTICE 014/26

Issue date:	21 September 2026
Replaces:	SN:009/25 – Potential for error: respiratory syncytial virus (RSV) immunisation products
Content reviewed by:	Health Protection NSW, Health and Social Policy Branch, Clinical Excellence Commission
Distributed to:	Chief Executives, Directors of Clinical Governance
KEY MESSAGE:	Ensure clinicians are aware of the different RSV immunisation products available for pregnant women, children and older adults, and their indications for use, to reduce the risk of administration errors.
REQUIRED ACTION:	1. Distribute this Safety Notice to all relevant clinicians and clinical departments where RSV immunisation products are stored, prescribed, dispensed or administered. 2. Continue to report incidents associated with RSV immunisation products into the local incident management system (e.g. ims⁺), to the Therapeutic Goods Administration (TGA) and to the Clinical Excellence Commission at CEC-MedicationSafety@health.nsw.gov.au. 3. Administration errors must be reported to Public Health Units for clinical advice on 1300 066 055.
DEADLINE:	N/A
We recommend you also inform:	Directors, managers and staff of: • Aged Care and Community Health Services. • Child and Family Health Services • Geriatric and Rehabilitation Units • Maternity Services • Medical Services • Neonatal and Paediatric Units (including Paediatric Outpatient Departments) • Nursing/Midwifery Services • Pharmacy Departments • Public Health Units. Drug and Therapeutics Committees. All other relevant clinicians, departments and committees – including ICT teams for electronic Medication Management (eMM) system considerations.
Website:	https://www.health.nsw.gov.au/sabs/Pages/default.aspx http://internal.health.nsw.gov.au/quality/sabs/index.html
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What is updated in this Safety Broadcast from SN:009/25?

This Safety Notice replaces SN:009/25 – Potential for error: respiratory syncytial virus (RSV) immunisation products which has now been **rescinded**. This update reflects the implementation of the NSW RSV Vaccination Program for older adults that provides the RSV vaccine, Arexvy®, for older adults. Specifically, this Safety Notice:

- includes Arexvy® and the risk of selection error between the RSV vaccine funded for older adults and the vaccine funded for use in pregnancy (Abrysvo®)
- consolidates eligibility criteria for the three RSV immunisation products available within NSW Health facilities into a single table
- updates the **Background** to reflect the current program names, the NSW RSV Maternal and Infant Immunisation Program and the NSW RSV Vaccination Program for older adults
- expands the **Recommendations** and **Appendix A** to cover all three RSV immunisation products.

Situation

The recent introduction and availability of multiple RSV immunisation products, each approved and funded (under the National Immunisation Program or by NSW Health) for different age groups and indications, increases the risk of product selection errors. While administration of one of these products outside its funded or approved age group and indication is unlikely to cause harm, patients may not receive the intended protection against RSV.

Background

The NSW RSV Maternal and Infant Immunisation Program aims to protect newborns and at-risk infants against RSV and RSV-associated infections and hospitalisations:

- Pregnant women are offered Abrysvo® to protect their baby from the time of their birth.
- Neonates not protected by maternal immunisation and at-risk infants are offered the RSV monoclonal antibody Beyfortus™ (nirsevimab).

The full eligibility for Abrysvo® and Beyfortus™ (nirsevimab) is available on the NSW Health webpage.

The NSW RSV Vaccination Program for older adults provides Arexvy®, an RSV vaccine for:

- Adults aged 75 years and older; and
- Aboriginal adults aged 60 years and older.

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Assessment

Availability of multiple RSV immunisation products may cause confusion. Clinicians should take the appropriate steps when prescribing, dispensing, and before administering RSV immunisation products to prevent errors and potential harm.

Refer to **Appendix A** for information on RSV immunisation products available in NSW Health facilities.

Recommendations

Clinicians and clinical departments prescribing, dispensing and/or administering RSV immunisation products are to be aware of differences between the available products and the risk of selection error. Local risk mitigation strategies should be employed to minimise the risk of selection errors.

Refer to NSW Health Safety Information 015/25 – Safe management of look-alike, sound-alike medicines in NSW Health facilities for general strategies that reduce the risks associated with the selection and storage of look-alike, sound-alike medicines.

Specific recommendations to prevent errors:

- Ensure all staff are trained about the different RSV immunisation products.
- Prescribe using both **generic** and **brand name**. This applies to both electronic Medication Management (eMM) systems and paper-based prescribing.
- Store the different RSV immunisation products on separate shelves or in separate tubs/containers (including separating the 50 mg and 100 mg presentations of Beyfortus™) within an approved vaccine-specific fridge.
- Check the product name on each component before reconstituting. Abrysvo® and Arexvy® are both supplied as a powder requiring reconstitution, whereas Beyfortus™ (nirsevimab) is supplied as a ready to administer pre-filled syringe.
- Use NSW Health vaccine fridge basket stickers to clearly label the RSV immunisation products. Order stickers via the NSW Immunisation Resource Order Form.
- Check the Australian Immunisation Register and the individual's health record before administering Beyfortus™ (nirsevimab), including whether a dose has already been given this RSV season and whether the mother received Abrysvo® during pregnancy.
- Before administering an RSV immunisation product, clinicians should check they have the:
 - Right RSV immunisation **product** (check product name AND indication)
 - Right **person** (check the person's name and age)
 - Right **dose** (check the dose for the person's age, weight and RSV season, using a measured weight in kilograms rather than a stated or estimated weight)
 - Right **time** (check **eligibility** for the RSV immunisation product).

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If an administration error is identified, please follow the following steps:

- Report the incident to your local Public Health Unit for clinical advice on 1300 066 055.
- Report the incident to the local incident management system (e.g. ims⁺), to the TGA and to CEC-MedicationSafety@health.nsw.gov.au.
- In accordance with NSW Health *Open Disclosure* Policy Directive (PD2023_034), conduct an open disclosure conversation about the incident with the individual/parent or carers.
- Advise the individual/parent or carer to monitor any signs and symptoms of adverse events following immunisation (AEFI) and contact their healthcare provider if required.
- Any AEFIs occurred following an administration error must be reported to the TGA at adr.reports@tga.gov.au by using the National Adverse Event Following Immunisation report form and to your local Public Health Unit on 1300 066 055.

Further information

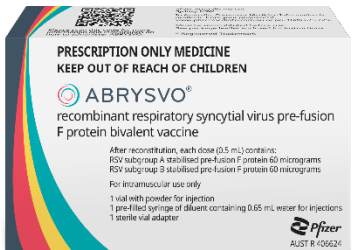
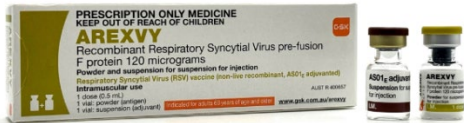
NSW RSV Maternal and Infant Immunisation Program – Information for health professionals at <https://www.health.nsw.gov.au/immunisation/Pages/respiratory-syncytial-virus.aspx>

RSV vaccines and immunisation products at <https://www.health.nsw.gov.au/immunisation/Documents/rsv-product-info-sheet.pdf>

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Appendix A. RSV immunisation products available within NSW Health facilities.

*RSV immunisation product	Eligibility	Indication	Dosing	Additional information
Abrysvo® – RSV vaccine 	Funded under the National Immunisation Program (NIP) for use in pregnant women between 28 to 36 weeks gestation.	Prevention of RSV in infants through the transfer of maternal antibodies to fetus during pregnancy.	Single dose 0.5 mL, given by intramuscular injection only. - Requires reconstitution before administration.	Note this product is registered for use in pregnant women 24-36 weeks and individuals aged 60 and over, however its use within NSW Health facilities is as per the NIP eligibility criteria. Abrysvo® is not registered for use in infants or children.
Arexvy® – RSV vaccine 	Funded under the NIP for people aged 75 years and over and Aboriginal people aged 60 years and over.	For adults at increased risk of RSV.	Single dose 0.5 mL, given by intramuscular injection only. - Requires reconstitution before administration.	Note this product is registered for use in adults aged ≥60 years and adults 50–59 years who are at increased risk, however its use within NSW Health facilities is as per the NIP eligibility criteria. Arexvy® is not registered for use in pregnant women.

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*RSV immunisation product	Eligibility	Indication	Dosing	Additional information
Beyfortus™ (nirsevimab) – RSV monoclonal antibody 50 mg  100 mg 	Funded by NSW Health for: - Neonates and infants born during or entering their first RSV season - Children up to 24 months of age who remain vulnerable to severe RSV disease throughout their second RSV season	Prevention of RSV lower respiratory tract disease in neonates and infants born during or entering their first RSV season, and children up to 24 months of age who remain at risk of severe RSV disease through their second RSV season.	Infants weighing <5 kg, born during or entering their 1st RSV season: 50 mg (0.5 mL), given by intramuscular injection. Infants weighing ≥5 kg born during or entering their 1st RSV season: 100 mg (1 mL), given by intramuscular injection. Children entering their 2nd RSV season: 200 mg, given as two intramuscular injections (2 × 1 mL of the 100 mg/mL formulation)	Note this product is registered for use in neonates, infants and children up to 24 months of age, however its use within NSW Health facilities is as per the NSW RSV Maternal and Infant Immunisation Program. Beyfortus™ (nirsevimab) is not registered for use in adults.

*Other RSV immunisations are approved for use in Australia, however these are not routinely used in NSW Health facilities.