

AUSTRALIAN TECHNICAL ADVISORY GROUP ON IMMUNISATION (ATAGI) CLINICAL ADVICE

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STATEMENT ON RESPIRATORY SYNCYTIAL VIRUS (RSV) IMMUNISATION PRODUCTS AND PREVENTION OF ADMINISTRATION ERRORS.

It is important to read this statement in conjunction with the RSV chapter of the <u>Australian Immunisation Handbook</u>, available at immunisationhandbook.health.gov.au

Overview

Recent reports to the Therapeutic Goods Administration (TGA) and state and territory safety surveillance systems, along with data from the Australian Immunisation Register (AIR), indicate that some respiratory syncytial virus (RSV) immunisation products have been used incorrectly.

This statement provides guidance on actions following inadvertent administration of the incorrect product, as well as clinical guidance in Appendix 1. It should be read in conjunction with the RSV chapter of the Australian Immunisation Handbook and information on correct administration published by the TGA.

Providers should always comprehensively <u>screen people before administering immunisation products</u> and ensure they are familiar with all guidance, especially on newer products.

The Australian Technical Advisory Group on Immunisation (ATAGI) emphasises the importance of correct administration of RSV immunisation products. The specific indications for each product are outlined in Table 1.

Table 1: RSV immunisation product indications and recommendations

	Beyfortus (nirsevimab) (Sanofi)	Abrysvo (Pfizer)	Arexvy (GSK)	
Indication	Protection of infants against severe RSV disease during their 1st or 2nd RSV season	Protection of newborn infants against severe RSV disease through maternal antibodies Protection of adults against severe RSV disease	Protection of adults against severe RSV disease	
Product presentation and dosing	Pre-filled syringe of 50 mg or 100 mg. Dose varies by weight of infant and RSV season (1st or 2nd) of use; see the Australian Immunisation Handbook for details.	Powder and diluent to be reconstituted for dosing	Powder and diluent to be reconstituted for dosing	
Recommendations				
Pregnant people from 28 weeks gestation	DO NOT USE	√*	DO NOT USE	
Infants aged <8 months whose mothers were not vaccinated ≥2 weeks before giving birth OR who are at increased risk of severe RSV disease	✓	DO NOT USE	DO NOT USE	

	Beyfortus (nirsevimab) (Sanofi)	Abrysvo (Pfizer)	Arexvy (GSK)	
Infants aged ≥8 to ≤24 months who are at increased risk of severe RSV disease	✓	DO NOT USE	DO NOT USE	
Adults aged ≥75 years	DO NOT USE	\checkmark	✓	
Aboriginal and Torres Strait Islander adults aged ≥60 years	DO NOT USE	✓	✓	
Adults aged ≥60 years with risk factors for severe RSV disease	DO NOT USE	√	✓	
Conditional recommendations				
Adults aged 60-74 years can consider RSV vaccination	DO NOT USE	√	√	
Adults aged 50–59 years with risk factors for severe RSV disease can consider RSV vaccination	DO NOT USE	DO NOT USE	√	

Abrysvo is recommended to be administered as one dose during pregnancy. For detailed recommendations, refer to the Australian Immunisation Handbook. Beyfortus may be used for protection of infants born after subsequent pregnancies.

Current use of immunisation products for preventing RSV disease in Australia

RSV is a common cause of severe respiratory disease, particularly in young infants and elderly people.

In 2025, a comprehensive and nationally coordinated RSV prevention program to protect infants against severe disease was rolled out in Australia. This includes:

- · Abrysvo RSV vaccine administered during pregnancy to prevent disease in infants after birth; and
- Beyfortus (nirsevimab) RSV-specific monoclonal antibody administered to infants and children aged <2 years.

For detailed recommendations, refer to the Australian Immunisation Handbook.

The use of these products has already had a significant impact in reducing RSV disease in infants since their introduction during 2024 and early 2025.^{1,2}

There is no nationally funded RSV vaccination program for older adults. Two RSV vaccines, Abrysvo and Arexvy, are available for protection of older adults via private prescription. Abrysvo has an additional indication for use in pregnant people, whereas Arexvy is only for use in older adults.

Guidance on actions following inadvertent administration of the incorrect product

If an incorrect immunisation product is inadvertently administered to an adult or child:

- 1. Inform the recipient (in keeping with the principle of open disclosure) and monitor for any possible adverse event following immunisation.
- 2. Follow the clinical guidance on RSV immunisation product administration errors.
- 3. Report the error as an adverse event, whether or not any symptoms are apparent, in line with procedures for your state or territory. Contact details are in the <u>Australian Immunisation Handbook</u>.

Practical measures to minimise administration errors

As well as following <u>guidance on vaccination procedures</u>, ATAGI strongly recommends that immunisation providers and associated staff implement additional practical measures to ensure that the correct RSV immunisation product is selected. These may include:

- storing immunisation products for use in infants and children in a separate area of the vaccine refrigerator to products for use in adults
- labelling storage areas or trays for specific indicated populations (such as infants, pregnant people and older adults)
- displaying reminders or warning notices to alert staff to avoid potential error

- developing and implementing a procedure checklist for selecting the correct immunisation product for administering to specific population groups
- checking for and installing updates, and using alert functions, if available, in clinical practice software systems to minimise the risk of administration error.

References

- 1. Bloomfield LE, Pingault NV, Foong RE, et al. Nirsevimab immunisation of infants and respiratory syncytial virus (RSV)-associated hospitalisations, Western Australia, 2024: a population-based analysis. *Med J Aust* 2025;222:568-70. Available from: https://pmc.ncbi.nlm.nih.gov/articles/PMC12167606/.
- 2. Queensland Health. RSV immunisation program reduces hospitalisations among Queensland babies. 2025. Available from: https://www.health.qld.gov.au/newsroom/doh-media-releases/rsv-immunisation-program-reduces-hospitalisations-among-queensland-babies (Accessed 24/06/2025).