Summary of RSV immunisation product efficacy and safety as at 30 July 2025

Since 2023, multiple RSV immunisation products have either been approved or reached the final stages of development and/or approval globally. Data on the efficacy and safety of these products have come from clinical trials, and post-licensure data are becoming available. The tables in this document summarise the main findings to date:

- Table 1: Efficacy and effectiveness of RSV immunisation products in infants and young children
- Table 2: Efficacy and effectiveness of RSV vaccines in adults aged 60 years and over
- Table 3: Safety of RSV prevention products.

Note: *These are not direct comparisons for each product.*

Formal recommendations regarding the use of RSV immunisation products in Australia can be found in the Australian Immunisation Handbook RSV chapter.

Table 1: Efficacy and effectiveness of RSV immunisation products in infants and young children

This table summarises how well RSV immunisation products for infants and young children performed against severe disease in clinical trials and real-world effectiveness studies.

It includes products that are either approved or in the final stages of development or approval globally and indicates the current status of these products in Australia.

It includes data for both monoclonal antibodies (for use in infants only*)* and the Abrysvo vaccine (for use in pregnant women only).

Note: *These are not direct comparisons for each product.*

RSV product (company)	Study trial population	Schedule and dose	Main vaccine efficacy (VE) or effectiveness findings	Current status in Australia
Abrysvo (Pfizer)	Vaccination of women with singleton pregnancies at 24–36 weeks gestation for the protection of infants	1 dose	VE against hospitalisation of infants from birth to 180 days = **56.8%** (99.17% CI 10.1, 80.7) VE against severe LRTI in infants from birth to 180 days = **69.4%** (97.58% 44.3, 84.1)	Approved by the TGA Recommended and National Immunisation Program (NIP)-funded for pregnant women from 28 weeks gestation as part of the National RSV Mother & Infant Protection Program (RSV-MIPP)
Beyfortus (nirsevimab); (Sanofi & AstraZeneca)	Monoclonal RSV antibody administered to infants aged ≤1 year (>50% ≤3 months of age) who had been born ≥35 weeks gestation (healthy term/ex late pre-terms) and are entering their first RSV season	1 dose	Efficacy against hospitalisation for RSV-associated LRTI in infants through 150 days after injection compared with placebo: **76.8%** (95% CI 49.4, 89.4) Efficacy against very severe medical attended RSV-associated LRTI through 150 days after injection compared with placebo:† **78.6%** (95% CI 48.8, 91.0)	Approved by the TGA Recommended in certain infants and children; available through state-and-territory-funded programs as part of the National RSV Mother & Infant Protection Program (RSV-MIPP)
Beyfortus (nirsevimab); (Sanofi & AstraZeneca)	Monoclonal RSV antibody administered to infants aged <1 year (median aged 4.5 months) who had been born ≥29 weeks gestation who were not eligible to receive palivizumab (healthy at term/preterm) and entering their first RSV season	1 dose	Efficacy against hospitalisation for RSV-associated LRTI in infants through 6 months after injection compared with standard care: **83.2%** (95% CI 67.8, 92.0)	Approved by the TGA Recommended in certain infants and children; available through state-and-territory-funded programs as part of the National RSV Mother & Infant Protection Program (RSV-MIPP)

RSV product (company)	Study trial population	Schedule and dose	Main vaccine efficacy (VE) or effectiveness findings	Current status in Australia
Beyfortus (nirsevimab); (Sanofi & AstraZeneca) (cont.)			Efficacy against very severe RSV-related LRTI through 6 months after injection compared with standard care:‡ **75.7%** (95% CI 32.8, 92.9)	
Beyfortus (nirsevimab); (AstraZeneca)	Monoclonal RSV antibody administered to infants with a median age of 1.4 months and entering their first RSV season	1 dose	Effectiveness against hospitalization for RSV-associated LRTI (observation period 120–150 days): **87.6%** (95% CI 67.7, 95.3) Effectiveness against RSV-associated ICU admission (observation period 60–90 days): **92.1%** (95% CI 64.0, 98.3)	Approved by the TGA Recommended in certain infants and children; available through state-and-territory-funded programs as part of the National RSV Mother & Infant Protection Program (RSV-MIPP)
Beyfortus (nirsevimab); (AstraZeneca)	Monoclonal RSV antibody administered to infants <6 months (median age 88–106 days) and entering their first RSV season	1 dose	Effectiveness against hospitalisation for RSV-associated LRTI (observation period 122 days): **87.6%** (95% CI 82.1, 91.4) Effectiveness against RSV-associated ICU admission (observation period 122 days): **90.1%** (95% CI, 76.3, 95.9)	Approved by the TGA Recommended in certain infants and children; available through state-and-territory-funded programs as part of the National RSV Mother & Infant Protection Program (RSV-MIPP)

RSV product (company)	Study trial population	Schedule and dose	Main vaccine efficacy (VE) or effectiveness findings	Current status in Australia
Beyfortus (nirsevimab); (AstraZeneca)	Monoclonal RSV antibody administered to infants <6 months (median age 4 months) and entering their first RSV season	1 dose	Effectiveness against hospitalisation for RSV-associated LRTI (observation period 97 days): **82.0%** (95% CI 65.6, 90.2)	Approved by the TGA Recommended in certain infants and children; available through state-and-territory-funded programs as part of the National RSV Mother & Infant Protection Program (RSV-MIPP)
Synagis (palivizumab); (Sobi)	Monoclonal RSV antibody administered to infants or toddlers with conditions that increase the risk of severe RSV disease, including: • infants born preterm and aged <6 months • infants aged <2 years with bronchopulmonary dysplasia • infants aged ≤2 years with haemodynamically significant congenital heart disease	5 doses (once-monthly for 5 months)	Relative risk reduction in RSV-associated hospitalisations compared with placebo: **51%** (3 trials, RR 0.49 [95% CI 0.37,0.64]) Relative risk reduction in ICU admissions compared with placebo: **50%** (2 trials, RR 0.50 [95% CI 0.30,0.81])	Approved by the TGA and used in certain medically at-risk infants since 1999

RSV product (company)	Study trial population	Schedule and dose	Main vaccine efficacy (VE) or effectiveness findings	Current status in Australia
Clesrovimab (MK-1654); (MSD)	Monoclonal RSV antibody administered to infants up to 12 months, including: • early or moderate pre-term infants without medical risk conditions for severe RSV disease (≥29 to <35 weeks gestational age) and late pre-term or full-term infants without medical risk conditions for severe RSV disease (≥35 weeks gestational age) entering their first RSV season	1 dose	Efficacy against RSV-associated hospitalisation in infants through 6 months after injection compared with placebo: **81.3%** (95% CI 62.5, 90.7) Efficacy against severe medically-attended LRTI in infants through 6 months after injection compared with placebo:^ **91.7%** (95% CI 62.9, 98.1)	N/A

CI=confidence interval; LRTI/LRTD=lower respiratory tract infection/disease; MALRI=medically attended lower respiratory infection; RSV=respiratory syncytial virus; VE=vaccine efficacy

† Very severe, medically attended, RSV-associated LRTI was defined as infection for which hospitalisation and supplemental oxygen or intravenous fluids were warranted.

‡ Very severe RSV-related LRTI was defined as patients whose oxygen level is under 90% and require oxygen supplementation

^ Severe medically attended LRTI was defined as: severe hypoxemia (oxygen saturation <90% on room air at sea level; <87% on room air at altitude ≥1800m) or the need for high flow nasal cannula, oxygen mask, or mechanical ventilatory support

Table 2: Efficacy and effectiveness of RSV vaccines in adults aged 60 years and over

This table summarises how well RSV vaccines performed against severe outcomes in clinical trials in adults aged 60 years and over and real-world effectiveness studies. It only includes those vaccines in the final stages of development or approval globally; it also indicates their current status in Australia.

Note: *These are not direct comparisons for each product.*

RSV vaccine (company)	Study trial population	Schedule and dose	Main vaccine efficacy (VE) or effectiveness findings	Current status in Australia
Arexvy (GSK)	Vaccination of adults aged ≥60 years without risk conditions for severe RSV disease*	1 dose	VE against LRTD¶ (season 1: median follow up of 6.7 months) = **82.6%** (95% CI 57.9, 94.1) VE against LRTD¶ (season 2: median follow up of 6.3 months) = **56.1%** (95% CI 28.2, 74.4) VE against severe^ LRTD (season 1: median follow up of 6.7 months) = **94.1%** (95% CI 62.4, 99.9) VE against severe^ LRTD (season 2: median follow up of 6.3 months) = **64.2%** (95% CI 6.2, 89.2) Effectiveness against hospitalisation (from 14 days following vaccination) = **83%** (95% CI 73, 89)	Approved by the TGA for adults aged ≥60 years and adults aged 50–59 years with risk conditions# Recommended in all adults aged ≥75 years, First Nations adults and adults with risk conditions aged ≥60 years Not currently NIP-funded Funded in Victoria for residents aged ≥60 years in public and Aboriginal community-controlled aged care services

RSV vaccine (company)	Study trial population	Schedule and dose	Main vaccine efficacy (VE) or effectiveness findings	Current status in Australia
Abrysvo (Pfizer)	Vaccination of healthy adults aged ≥60 years without risk conditions for severe RSV disease*	1 dose	VE against MA† LRTD (season 1; median follow up not reported) = **84.6%** (95% CI 32.0, 98.3) VE against LRTD with 3 or more symptoms (season 1: mean follow up of 7.1 months) = **88.9%** (95% CI 53.6, 98.7) VE against LRTD with 3 or more symptoms (season 2: mean follow up of 7.6 months) = **77.8%** (95% CI 51.4, 91.1) Effectiveness against hospitalisation (from 14 days following vaccination) = **73%** (95% CI 52, 85)	Approved by the TGA Recommended in all adults aged ≥75 years, First Nations adults and adults with risk conditions aged ≥60 years Received a positive recommendation from PBAC but not currently NIP-funded

RSV vaccine (company)	Study trial population	Schedule and dose	Main vaccine efficacy (VE) or effectiveness findings	Current status in Australia
mRESVIA (Moderna)	Vaccination of adults aged ≥60 years without risk conditions for severe RSV disease*	1 dose	VE against LRTD with 3 or more signs/ symptoms [PDF] (median follow-up of 18.8 months) = **49.9%** (95% CI 27.8, 65.6)	Approved by the TGA

CI=confidence interval; LRTI/LRTD=lower respiratory tract infection/disease; MA=medically attended; MALRI=medically attended lower respiratory infection; RSV=respiratory syncytial virus; VE=vaccine efficacy

* May have one or more clinically stable chronic medical conditions

¶ Lower respiratory tract disease (LRTD) was defined as 2 or more lower respiratory symptoms/signs (including ≥1 lower respiratory sign) or 3 or more lower respiratory symptoms, lasting 24 hours or longer

^ Severe disease was determined in accordance with either of two case definitions: (1) on the basis of clinical signs or investigator assessment; or (2) on the basis of receipt of supportive therapy.

† Medically attended, RSV-associated LRTD was defined as LRTD prompting any healthcare visit such as hospitalisation, emergency department visit, home health care services, general practitioner visit, specialist visit, other visit or telehealth consultation.

There are no efficacy or effectiveness data on RSV vaccines in adults aged 50–59 years. Clinical trial data have shown that the immune response following vaccination with Arexvy in adults aged 50–59 years was similar compared to adults aged 60 years and over.

Table 3: Safety of RSV prevention products

Clinical trials of RSV vaccines and RSV monoclonal antibodies have demonstrated them to be safe.

Across all RSV vaccines, in older adults and pregnant women, local adverse events were more common after the vaccine when compared to placebo. There was more variability in the systemic responses to the vaccine. Australian post-market surveillance data from AusVaxSafety show most adverse events experienced following RSV vaccination in older adults who have completed an AusVaxSafety survey to date have been local adverse events.

Clinical trials for the RSV monoclonal antibodies have shown them to be safe, and Synagis (palivizumab) has been used in infants in Australia since 1999.

Across clinical trials, most side effects were mild to moderate in severity and lasted a few days.

There is ongoing global monitoring of the safety of RSV prevention products, including monitoring for rare adverse events. Early post-market surveillance data from the US suggest a very rare higher than expected rate of GBS in adults aged 65 years and over following Abrysvo or Arexvy (e.g. one analysis estimates an excess 9 cases of GBS per million doses of Abrysvo, and 7 cases per million doses of Arexvy [noting analyses do not currently compare the two vaccines against each other]). The US FDA has updated their prescribing information for both vaccines to include the rare risk of GBS, however, available evidence remains insufficient to establish a causal link. Active monitoring is ongoing to understand this signal; NCIRS will publish updates as they become available.

RSV product (company)	Population	Schedule and dose	Main safety findings from clinical trials
For protection of older adults			
Arexvy (GSK)	Vaccination of healthy adults aged ≥60 years	1 dose	Serious adverse events: any up to 6 months following vaccination (median follow-up time not reported) *Vaccine:* **4.2%** (95% CI 3.8, 4.6) *Placebo:* **4.0%** (95% CI 3.7, 4.4) Systemic adverse events: up to 4 days following vaccination *Vaccine:* **49%** (no CI provided) *Placebo:* **23%** (no CI provided) *Fatigue, headache, muscle pain and joint pain most common* Local adverse events: up to 4 days following vaccination *Vaccine:* **62%** (no CI provided) *Placebo:* **10%** (no CI provided) *Injection site pain most common* Adverse event of special interest (AESI) (GBS) *Preliminary findings from post-market surveillance in the US are monitoring the rare AESI of GBS in people aged 65 years and over. In one analysis they estimate an excess of 7 cases per million doses of Arexvy. Other analysis in those aged 60 years and over found the observed rate ranged from 1.1 to 9.5 per million doses.*

RSV product (company)	Population	Schedule and dose	Main safety findings from clinical trials
For protection of older adults			
Arexvy (GSK)	Vaccination of adults aged 50–59 years with risk conditions	1 dose	Serious adverse events: any up to 6 months following vaccination (median follow-up time not reported) *Vaccine:* **3.6%** (95% CI 2.0, 6.0) *Placebo:* **2.1%** (95% CI 0.6, 5.3) Fatigue (most common systemic adverse event): up to 4 days following vaccination *Vaccine:* **36%** (95% CI: 31.0, 40.9) *Placebo:* **19%** (95% CI: 13.7, 25.4) Injection site pain (most common local adverse event): up to 4 days following vaccination *Vaccine:* **75%** (95% CI: 70.5, 79.5) *Placebo:* **14%** (95% CI: 9.2, 19.6)

RSV product (company)	Population	Schedule and dose	Main safety findings from clinical trials
For protection of older adults			
Abrysvo (Pfizer)	Vaccination of healthy adults aged ≥60 years	1 dose	Serious adverse events: any up to 10.2 months following vaccination (median follow-up time not reported) *Vaccine:* **2.3%** (95% CI 2.1,2.5) *Placebo:* **2.3%** (95% CI 2.0, 2.5) Systemic adverse events: up to 7 days following vaccination *Vaccine:* **27.4%** (no CI provided) *Placebo:* **25.7%** (no CI provided) *Fatigue, headache, and muscle pain most common* Local adverse events: up to 7 days following vaccination Vaccine: **12.1%** (no CI provided) Placebo: **6.6%** (no CI provided) *Injection site pain most common* Adverse event of special interest (AESI) (GBS) *Preliminary findings from post-market surveillance in the US are monitoring the rare AESI of GBS in people aged 65 years and over. In one analysis, they estimate an excess of 9 cases per million doses of Abrysvo. Another analysis, in those aged 60 years and over, found the observed rate ranged to be 4.6 per million doses of Abrysvo.*

RSV product (company)	Population	Schedule and dose	Main safety findings from clinical trials
For protection of older adults			
mRESVIA (Moderna)	Vaccination of healthy adults aged ≥60 years	1 dose	Serious adverse events: any (median follow-up time 3.7 months) *Vaccine:* **2.8%** (no CI provided) *Placebo:* **2.8%** (no CI provided) Systemic adverse events: up to 7 days following vaccination *Vaccine:* **47.7%** (no CI provided) *Placebo:* **32.9%** (no CI provided) *Fatigue, headache, muscle pain and joint pain most common* Local adverse events: up to 7 days following vaccination *Vaccine:* **58.7%** (no CIs provided) *Placebo:* **16.2%** (no CIs provided) *Injection site pain most common*
Abrysvo (Pfizer)	Vaccination of healthy women with singleton pregnancies at 24–36 weeks gestation for the protection of infants	1 dose	Serious adverse events: any (maternal) up to 6 months following vaccination (median follow-up time not reported) *Vaccine:* **6.1–16.2%** *Placebo:* **12.0–15.2%** Serious adverse events: any (infants) up to 24 months from birth (median follow-up time not reported) *Vaccine:* **17.5–36.0%** *Placebo:* **17.5–32.8%** Adverse event of special Interest (AESI): preterm (<37 weeks) birth *Vaccine:* **5.3%–5.7%** *Placebo:* **2.6%–4.7%** *Note: There is no statistically significant difference between vaccine and placebo, but the clinical trials were not powered to detect rare events.*

RSV product (company)	Population	Schedule and dose	Main safety findings from clinical trials
For protection of older adults			
Abrysvo (Pfizer) (cont.)	Vaccination of healthy women with singleton pregnancies at 24–36 weeks gestation for the protection of infants	1 dose	*Preliminary findings from post-market surveillance in the US found that the incidence of pre-term births was 4.1% among pregnant women who received Abrysvo during the 2023–2024 respiratory season. This was within the expected range of the incidence of pre-term births at 32–36 weeks' gestation (3.1–6.1%) prior to introduction of this vaccine.* **Adverse event of special interest (AESI) (GBS)** *Preliminary findings from post-market surveillance in the US are monitoring the rare AESI of GBS in people aged 65 years and over. This rare event has not been seen in pregnant women who received the vaccine.* Systemic adverse events (maternal) up to 7 days following vaccination *Vaccine:* **62.2–63.2%** *Placebo:* **59.2–62.4%** *Fatigue most common* Local adverse events (maternal) up to 7 days following vaccination *Vaccine:* **31.6–42.5%** *Placebo:* **13.7–10.4%** *Injection site pain most common*

RSV product (company)	Population	Schedule and dose	Main safety findings from clinical trials
For protection of infants			
Beyfortus (nirsevimab); (Sanofi & AstraZeneca)	Monoclonal RSV antibody administered to infants aged ≤1 year (50% ≤3 months of age) who had been born ≥35 weeks gestation (healthy term/ex late pre-terms)	1 dose	Serious adverse events: any through to 360 days following immunisation (median follow-up time not reported) *Nirsevimab:* **6.3%** (125/1998); no CI provided *Placebo:* **7.4%** (74/996); no CIs provided AESI:†* through to 360 days following immunisation (median follow-up time not reported) *Nirsevimab:* **0.2%** (4/1998); no CI provided *Placebo:* **0%** (0/996); no CI provided
Beyfortus (nirsevimab); (Sanofi & AstraZeneca)	Monoclonal RSV antibody administered to infants aged <1 year (median aged 4.5 months) who had been born ≥29 weeks gestation who were not eligible to receive palivizumab (healthy at term/preterm) and entering their first RSV season	1 dose	Serious adverse events: any through 6 months following immunisation (median follow up time not reported): *Nirsevimab:* **2.2%** (89/4015); no CI provided *Standard care:* **1.7%** (67/4020) no CI provided Serious adverse events: related through 6 months following immunisation (median follow up time not reported): *Nirsevimab:* **<0.1%** (1/4015); no CI provided *Standard care:* **0%** (0/4020); no CI provided AESI† **: through 6 months following immunisation (median follow up time not reported) *Nirsevimab:* 0.1 % (3/4015); no CI provided *Standard care:* <0.1% (1/4020); no CI provided

RSV product (company)	Population	Schedule and dose	Main safety findings from clinical trials
For protection of infants			
Synagis (palivizumab); (Sobi)	Monoclonal RSV antibody administered to infants aged ≤2 years with haemodynamically significant congenital heart disease	5 once-monthly doses	Serious adverse events: any through 150 days (30 days after last scheduled study injection); (median follow-up time not reported) *Palivizumab:* **55.4%** (354/639); no CI provided Placebo: **63.1%** (409/648); no CI provided (p=0.005) Palivizumab recipients had 12% relative risk reduction in any SAE compared with placebo (RR 0.88 [95% CI, 0.80, 0.96]) Serious adverse events: related through 150 days (30 days after last scheduled study injection); (median follow-up time not reported) *Palivizumab*: **0%** (0/639); no CI provided *Placebo:* **0.5%** (3/648) (p=0.249); no CI provided Palivizumab recipients had statistically non-significant **86%** relative risk reduction in related serious adverse events compared with placebo (RR 0.14 [95% CI, 0.01, 2.80])

RSV product (company)	Population	Schedule and dose	Main safety findings from clinical trials
For protection of infants			
Clesrovimab (MK-1654); (MSD)	Monoclonal RSV antibody administered to infants aged up to 12 months, including: • healthy infants who are an early or moderate pre-term infant (≥29 to 34 weeks and 6 days gestational age) or a late pre-term or full-term infant (≥35 weeks gestational age) entering their first RSV season	1 dose	Serious adverse events: any through 365 days following immunisation (median follow up time not reported): *Clesrovimab:* **11.5%** (278/2409) *Placebo:* **12.4%** (149/1202) Serious adverse events : related through 365 days following immunisation (median follow up time not reported):\ *Clesrovimab:* **0.0%** (1/2409) *Placebo:* **0.1%** (1/1202) AESI: through 42 days following immunisation: *Clesrovimab* Rash **0.5%** (11/2409); anaphylaxis/hypersensitivity **0.0%** (1/2409) *Placebo:* Rash **0.3%** (4/1202); anaphylaxis/hypersensitivity **0%** (0/1202)

RSV product (company)	Population	Schedule and dose	Main safety findings from clinical trials
For protection of infants			
Clesrovimab (MK-1654); (MSD)	Monoclonal RSV antibody administered to infants up to 12 months, including: • infants at risk for severe RSV disease who have been recommended to receive palivizumab	1 dose of clesrovimab 3–5 doses palivizumab	Serious adverse events : any through first RSV season (median follow up time not reported): *Clesrovimab:* **22.2%** (99/445); no CI provided *Palivizumab:* **24.4%** (110/450); no CI provided Serious adverse events : related through first RSV season (median follow up time not reported): *Clesrovimab:* **0%** (0/445); no CIs provided *Plaivizumab:* **0.4%** (2/450) AESI: through 42 days after the first dose (median follow up time not reported): *Clesrovimab* Rash **0.7%** (3/445); anaphylaxis/hypersensitivity **0%** (0/445) *Palivizumab* Rash **0.2%** (1/450); anaphylaxis/hypersensitivity **0%** (0/450)

† Adverse events of special interest (AESI) were hypersensitivity, immune complex disease and thrombocytopenia.

* All four AESI were assessed by the study investigator as related hypersensitivity events and were limited to cutaneous findings. No other anaphylaxis or other serious hypersensitivity were reported.

** Four infants had at least 1 AESI. These events were drug reaction (reported as fever and rash) (1 participant), maculopapular rash (1 participant), allergic dermatitis (1 participant) in the nirsevimab group; and food allergy (1 participant) in the standard care group.