Nirsevimab
Newborn use only

2025

Alert	On 10 November 2024, the Australian Government announced that the Abrysvo® vaccine for the prevention of RSV would be made available to eligible pregnant women under the National Immunisation Program (NIP) in 2025. **From 3 February 2025,** a new RSV maternal vaccine, Abrysvo®, will be available on the National Immunisation Program (NIP) for pregnant women from 28 to 36 weeks gestation. **From 17 March 2025,** infants not protected from RSV by maternal vaccination or who have certain medical risk factors for severe RSV disease, will be offered nirsevimab, a monoclonal antibody. Due to international supply, eligibility criteria are rapidly changing and are dependent upon state-based funded programs in Australia. Please refer to relevant Ministries/Departments of Health for up-to-date eligibility information for your State or Territory.
Indication	Prevention of severe Respiratory Syncytial Virus (RSV) disease
Action	Long-acting recombinant neutralising human IgG monoclonal antibody that binds to the F1 and F2 subunits of the F protein of the RSV protein. Provides passive immunity against severe RSV infection.
Drug type	Monoclonal antibody
Trade name	Beyfortus
Presentation	1. Beyfortus 50mg in 0.5mL (100mg/mL) in single dose prefilled syringe (purple plunger rod) 2. Beyfortus 100mg in 1mL (100mg/mL) in single dose prefilled syringe (light blue plunger rod)

Dose	**Eligible infants***
	***Eligibility criteria vary across states. Please refer to relevant Ministries/Departments of Health for up-to-date eligibility information for your State or Territory.**
	
	<u>New South Wales RSV prevention program 2025</u>
	To be implemented throughout the year, not just seasonal.
	All pregnant women between 28-36 weeks gestation to receive a single dose of RSV vaccine Abrysvo.
	Eligible infants for Nirsevimab in NSW
	• Any neonate whose mother either was not vaccinated during pregnancy or vaccinated ≤2 weeks prior to delivery
	• Any high-risk neonate regardless of maternal vaccine status:
	  ○ Preterm birth <32 weeks
	  ○ Haemodynamically significant congenital heart disease
	  ○ Significant immunosuppression
	  ○ Chronic lung disease requiring ongoing respiratory support
	  ○ Neurologic disease with impaired respiratory function
	  ○ Cystic fibrosis
	  ○ Trisomy 21 or other genetic disease associated with increase in RSV
	• Any neonate born to mothers with severe immunosuppression, where the immune response to maternally administered RSV vaccine was impaired
	• Any neonate born to mothers who received RSV vaccine in pregnancy but have subsequently undergone a treatment, such as cardiopulmonary bypass or extracorporeal membrane oxygenation, that has led to loss of maternal antibodies
	Can be co-administered with birth or infant vaccines
	For extreme preterm infants in the NICU with low RSV outbreaks within the NICU – clinicians may choose to administer Nirsevimab prior to hospital discharge.
	
	Dose during their first RSV season[15,16,17]

Body weight at time of dosing	Recommended dose
< 5 kg	50 mg IM once
≥ 5 kg	100 mg IM once

Dose during their second RSV season[15]

200 mg IM once (given by 2 intramuscular injections (2 × 1 mL of the 100 mg/mL formulation) at 2 different sites (preferably separate limbs, or else separated by 2.5 cm) during the same visit).

	Note: • The closer administration is to the RSV season, the more effective is the seasonal protection. • Infants born just before or during the RSV season can be offered nirsevimab as soon as possible after birth. However, if an infant is in NICU/SCN, the clinical team can perform a risk assessment and administer accordingly. • For infants born after the RSV season, the committee recommends offering nirsevimab before the start of their first RSV season. • Infants who have already had confirmed RSV infection this season are ineligible.
Dose adjustment	Therapeutic hypothermia – Not applicable. ECMO – No information. Renal impairment – No information. Hepatic impairment – No information.
Maximum dose	Not applicable.
Total cumulative dose	Not applicable.
Route	IM
Preparation	Prefilled syringe
Administration	IM injection into the anterolateral aspect of the thigh. When 2 injections are required to make up a dose (e.g., 200 mg = 2 x 100mg injections), injections should be administered at 2 different sites (preferably separate limbs, or else separated by 2.5 cm) at the same visit.[17]
Monitoring	Monitor for at least 15 minutes after administration for any hypersensitivity reactions. Immunisation providers to have appropriate equipment and protocols to initiate treatment for adverse events if required.
Contraindications	Nirsevimab is contraindicated in individuals with a history of severe allergic reaction (e.g., anaphylaxis) to the active substance or to any of the excipients of the product.
Precautions	Hypersensitivity to nirsevimab. When administering to infants with an increased risk for bleeding such as those with thrombocytopenia, any coagulant disorders or those on anticoagulation therapy.
Drug interactions	Not applicable.
Adverse reactions	Rash, fever, and injection site reactions (e.g., pain, swelling, redness). Hypersensitivity reaction: There is a risk of rare hypersensitivity reactions, including urticaria, dyspnoea, cyanosis, hypotonia and/or anaphylaxis after receiving nirsevimab. Monitor for at least 15 minutes after administration for any hypersensitivity reactions. Immunisation providers to have appropriate equipment and protocols to initiate treatment for adverse events if required. Carers of infants and young children should be informed about potential signs and symptoms of hypersensitivity reactions, including anaphylaxis, and advised to seek immediate care if these occur.
Overdose	No specific treatment.
Compatibility	Not applicable.
Incompatibility	Do not mix with any other vaccines in the same syringe or vial.
Stability	May be kept at room temperature (below 25°C) for a maximum of 8 hours. Nirvesimab must then be used within these 8 hours or discarded.
Storage	Refrigerate between 2-8°C. Do not freeze. Protect from light. Do not shake or expose to heat.
Excipients	Histidine, histidine hydrochloride monohydrate, arginine hydrochloride, sucrose, polysorbate 80 ad water for injection.
Special comments	**Co-administration with vaccines** Nirsevimab can be administered concomitantly with routine childhood vaccines, in a separate syringe and at different site. **Co-administration with immunoglobulin products (e.g. palivizumab)**

	No information is available on co-administration of nirsevimab with other immunoglobulin preparations. Infants who have received palivizumab and meet the eligibility criteria for nirvesimab can receive nirvesimab 28 days later, instead of their subsequent palivizumab dose. Palivizumab should then be discontinued.[16]
Evidence	**Background** Respiratory syncytial virus (RSV) infects nearly all infants at least once by their second birthday.[2] In New South Wales, a pre-covid study over a 10-year period (2001-2010) showed distinct seasonality of acute lower respiratory tract infections and RSV hospitalisations in NSW. The peak in RSV-coded hospitalisations was between May and August of each year with 81% of the total RSV -coded hospitalisations recorded between these months.[3] This study found an incidence of 4.9 per 1000 child years for RSV hospitalisations among children<5 years. This incidence was highest at 25.6/1000 child years in 0-3 month old, particularly in children<3 month with BPD, incidence was 239/1000 child years. This incidence was 11/1000 child-years for indigenous children, 81.5 for children with BPD, 39 for preterm children with GA <28 weeks. The mean cost of each episode of RSV hospitalisation in children aged <5 years was AUD 6350. For Indigenous children the mean cost for each episode of RSV hospitalization was AUD 9190. The mean cost associated with each episode of hospitalization for children with BPD, preterm children and children born with low birthweight were AUD 12731 and AUD 6664 respectively. The mean cost for all other term children was AUD 5649. The mean annual inpatient hospital cost associated with RSV hospitalisation in NSW was AUD 9080000.[3] Nirsevimab is a monoclonal antibody that binds to F1 and F2 subunits of the F protein of RSV. Nirsevimab is now the preferred agent for passive immunity against RSV.[15,16,17] **Efficacy** **NOTE:** For the purpose of this evidence summary, ANMF summarised the trial findings into 2 groups based on first or second RSV season: (1) otherwise healthy preterm and term infants (i.e. general infant population) and (2) at-risk infants – These are the infants who are considered at higher risk of severe RSV disease by the clinicians, e.g. preterm infants with chronic lung disease (CLD), infants with congenital heart disease (CHD). **First RSV season – Otherwise healthy infants (general infant population) - Nirsevimab versus placebo/standard care** **A 2023 systematic review and meta-analysis** of otherwise healthy infant population showed that among infants, nirsevimab resulted in (1) 74% reduction in medically attended RSV-related infection (RR 0.26; 95% CI 0.18-0.38), and 76% reduction in the risk of hospitalisation due to RSV (RR 0.24; 95% CI 0.13-0.47). This meta-analysis showed the risk of death and risk of any special adverse events from nirsevimab were not statistically different between 2 groups.[5] This meta-analysis included This meta-analysis included 2 randomised controlled trials (RCTs) with a total population of 2,943 infants, 1,963 from the treatment arm and 980 from the placebo arm. **These 2 RCTs were Nirsevimab study 2020 (Phase 2b trial)[6] and phase 3 MELODY 2022 RCT.[7]** Both these RCTs showed statistically significant protection against medically attended RSV lower respiratory tract infections over a 5-month period with nirsevimab use. These two efficacy trials enrolled distinct populations by gestational age: the phase 2b trial enrolled otherwise healthy preterm infants ≥29 to <35 weeks and MELODY enrolled otherwise healthy term or late preterm infants≥35 weeks. Both these trials excluded at-risk infants who were eligible for existing RSV prophylaxis (e.g. palivizumab) as per their local guidelines. **Nirsevimab study group 2020 RCT** (also titled as phase 2b trial) included 1453 otherwise healthy **preterm** infants (29^{+0}-34^{+6} wks at birth).[6] The study excluded at-risk infants who would have been eligible for RSV prophylaxis as per their local guidelines. The trial was conducted at 164 sites in 23 countries in Europe, USA and South Africa. Infants were randomly assigned in a 2:1 ratio to receive nirsevimab, at a dose of 50 mg in a single intramuscular injection, or placebo at the start of an RSV season. The primary end point was medically attended RSV-associated lower respiratory tract infection through 150 days after administration of the dose. The secondary efficacy end point was hospitalization for RSV-associated lower respiratory tract infection through 150 days after administration of the dose. The study also determined the serum concentrations of nirsevimab on days 91, 151, and 361 after nirsevimab was administered. Medically attended RSV infection occurred in 2.6% in Nirsevimab group, compared to 9.5% in placebo group. RSV hospitalisation was 0.8% in nirsevimab group, compared to 4.1% in placebo group. Over the entire 150-days after administration of the dose, nirsevimab group had a lower risk of medically

attended RSV-associated lower respiratory tract infection than placebo group (hazard ratio, 0.26; 95% CI, 0.16 to 0.43), as well as a lower risk of RSV hospitalization (hazard ratio, 0.19; 95% CI, 0.08 to 0.44). On day 151, serum concentrations in 97.9% of the nirsevimab recipients were above the targeted 90% effective concentration threshold of 6.8 µg/mL. The types and frequencies of adverse events that occurred during the trial were similar in both groups.[6]

MELODY study 2022 RCT included 1490 healthy **late preterm and term** infants of ≥35^{+0} weeks at birth from 20 countries in Europe, USA, South Africa, and Asia.[7] Participants were randomly assigned, in a 2:1 ratio, to receive either placebo or single IM dose of 50 mg of nirsevimab if they weighed <5 kg or 100 mg if they weighed ≥5 kg. The primary efficacy end point was medically attended RSV-associated lower respiratory tract infection through 150 days after the injection, and the secondary efficacy end point was RSV-hospitalization during the same period. Medically attended RSV-associated lower respiratory tract infection occurred in 1.2% in the nirsevimab group and 5.0% in the placebo group – this corresponds to an efficacy of 74.5% (95% CI 49.6 to 87.1; P<0.001) for nirsevimab. RSV- associated hospitalization occurred in 0.6% in the nirsevimab group and 1.6% in the placebo group (efficacy, 62.1%; 95% CI, −8.6 to 86.8; P =0.07). Serum concentrations of nirsevimab decreased linearly over time. The mean (±SD) half-life of nirsevimab was 68.7±10.9 days. On day 151, mean nirsevimab serum concentrations were 19.6±7.7 µg/mL among infants <5 kg and 31.2±13.7 µg/mL among infants ≥5 kg.

Harmonie study group 2023 RCT included 8058 infants ≥29^{+0} weeks at birth who were entering their first RSV season at 235 sites in France, Germany, or the United Kingdom.[8] This study excluded infants who were otherwise eligible for RSV prophylaxis with palivizumab. Participants were given in a 1:1 ratio, either single IM dose of nirsevimab (50 mg for infants weighing <5 kg and 100 mg for infants weighing ≥5 kg) or standard care before or during RSV season. Hospitalisation for RSV-associated lower respiratory tract infection was 0.3% in the nirsevimab group and 1.5%) in the standard-care group, corresponding to nirsevimab efficacy of 83.2% (95% CI, 67.8 to 92.0; P<0.001). Very severe RSV-associated lower respiratory tract infection occurred in 0.1% in the nirsevimab group and 0.5% in the standard-care group, which represented a nirsevimab efficacy of 75.7% (95% CI, 32.8 to 92.9; P = 0.004). The limitation of this study is that efficacy duration was available for only up to 3 months in majority of participants by the time of publication. The trial is ongoing with a planned follow up for at least 12 months after randomisation.

First RSV season – Infants at higher risk of RSV (e.g. chronic lung disease or congenital heart disease) - Nirsevimab versus palivizumab

A phase 2-3 MEDLEY multicentre RCT reported the safety and pharmacokinetics of nirsevimab through the first RSV season, in comparison to palivizumab.[9] The study enrolled 925 infants who were eligible to receive palivizumab, who were born on or before 35 weeks of gestation, and who did not have congenital heart disease (CHD) or chronic lung disease (CLD) of prematurity (preterm cohort) and infants who had uncorrected, partially corrected, or medically treated CHD or CLD warranting therapeutic intervention within 6 months. Infants were randomly assigned to receive nirsevimab in a single, fixed intramuscular dose of 50 mg if they weighed less than 5 kg and a dose of 100 mg if they weighed 5 kg or more, to be followed by four once-monthly doses of placebo or five once-monthly intramuscular doses of palivizumab (15 mg/kg/dose). This study reported similar safety profile for nirsevimab and palivizumab in infants with CHD or CLD. At day 151, serum levels of nirsevimab were similar in the two cohorts and similar to those reported in the MELODY trial. The antidrug–antibody response at day 151 was low.

Second RSV season

Efficacy: As of March 2024, there are no published reports of efficacy of 2nd dose of nirsevimab in infants entering the 2nd RSV season. The Melody study group is continuing to follow up infants through the 2nd RSV season without second dose for healthy infants.[7] The Harmonie study group is following up infants for at least up to 12 months after the 1st dose.[8]

Safety: Medley study group reported the safety of nirsevimab in comparison to palivizumab among children with CHD or CLD following administration of a 2nd dose of nirsevimab (200 mg) prior to their 2nd RSV season.[10] Nirsevimab had a similar safety profile to that of palivizumab. Second dose also resulted in nirsevimab serum exposures known to be efficacious in preventing RSV LRTI in healthy infants, supporting efficacy in this population at risk of severe RSV disease.[10] There were no cases of medically attended RSV lower respiratory tract infections through 150 days post first Season 2 dose during MEDLEY, but there were only 262 participants in this 2nd dose study.[10]

Current recommendations

Australian Immunisation handbook – Accessed online on 14 January 2025[17]

1. Nirsevimab is recommended for infants who were born:
    - to women who did not receive RSV vaccine during pregnancy
    - within 2 weeks of the mother receiving RSV vaccine during pregnancy
2. Nirsevimab is also recommended for the following infants after assessment by their treating doctor to confirm potential clinical benefit:
    - infants with risk conditions for severe RSV disease, regardless of maternal vaccination:
        - Preterm birth <32 weeks gestational age
        - 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
    - infants born to mothers with severe immunosuppression, where the immune response to maternally administered RSV vaccine was impaired
    - infants whose mothers have received RSV vaccine in pregnancy but have subsequently undergone a treatment, such as cardiopulmonary bypass or extracorporeal membrane oxygenation, that has led to loss of maternal antibodies
3. Administration of nirsevimab is likely to be most effective when given shortly after birth for infants born just before or during the RSV season. See Timing of RSV-specific monoclonal antibodies in infants.
4. Nirsevimab is not recommended for infants during the first 6 months of life if:
    - the infant's mother received RSV vaccine at an appropriate time during pregnancy, and
    - the infant does not have a risk condition for severe RSV disease
5. Timing of RSV-specific monoclonal antibodies in infants
    - The timing of administration of monoclonal antibody should ensure that the duration and level of protection are maximised over the peak months of a child's 1st RSV season. This is typically April to September in temperate regions of Australia, but this may vary for different regions. Local advice should be sought.
    - Nirsevimab offers protection for at least 5 months. Protective benefits can be maximised if it is administered:
        - shortly after birth for infants born just before or during the RSV season. For infants born after the RSV season, consider the likelihood of out-of-season RSV infection and risk of severe disease (see List. Conditions associated with increased risk of severe RSV disease in infants and young children), and consider delaying nirsevimab until just before the next RSV season, if appropriate
        - shortly before the start of their 1st RSV season in older infants that remain at high risk.
        - Young children aged 8 to <24 months who have certain risk conditions for severe RSV disease are recommended to receive RSV-specific monoclonal antibody in their 2nd RSV season
6. Dosing nirsevimab:

    For infants born during or entering their first RSV season:
    a. 50 mg in 0.5 mL if weight is <5 kg
    b. 100 mg in 1 mL if weight is ≥5 Kg.

    For children at high risk of severe RSV disease in their 2nd season:

    200 mg administered as 2 × 100 mg (2 mL total) intramuscular injections in different sites (preferably separate limbs, or else separated by 2.5 cm) at the same visit.

7. Safety of nirsevimab: It has favourable safety profile overall. The frequencies of adverse events were similar between nirsevimab and placebo groups.

Population	Adverse event (AE)	Nirsevimab (%)	Placebo (%)
Preterm (born 29 to ≤35 weeks)	Any	86.2	86.8
	Grade≥3	8.0	12.5
	Severe AE	11.2	16.9
Late preterm to term	Any	83.7	81.8
	Grade≥3	3.1	3.8
	Severe AE	6.3	7.4

Food and Drug Administration (FDA) Antimicrobial Drugs Advisory Committee (Briefing document released on 17 May 2023)[15]

1. The PK of nirsevimab is dose proportional.
2. The medium time to maximum concentration of nirsevimab following IM administration is approximately 6 days based on adult data.
3. Nirsevimab did not inhibit a natural immune response to RSV exposure.
4. Exposure-response analyses support the proposed nirsevimab fixed dose by weight band (50 mg for infants weighing < 5 kg or 100 mg for infants weighing ≥ 5 kg) in the first RSV season, with a 200 mg dose proposed in RSV season 2 (based on expected body weight range).
5. There was no difference in PK in infants with CHD or CLD compared to healthy infants. Similar nirsevimab serum concentrations were also achieved in preterm infants < 29 weeks GA.

New South Wales RSV prevention program - Beyfortus™ (nirsevimab) is funded by NSW for the following vulnerable infants:[16]

Eligible infants for Nirsevimab in NSW

Mother either not vaccinated during pregnancy or vaccinated ≤2 weeks prior to delivery

Other high-risk categories irrespective of maternal vaccine status

Preterm birth <32 weeks
Haemodynamically significant congenital heart disease
Significant immunosuppression
Chronic lung disease with respiratory support
Neurologic disease with impaired respiratory function
Cystic fibrosis
Trisomy 21 or other genetic disease associated with increase in RSV

Neonates born to mothers with severe immunosuppression, where the immune response to maternally administered RSV vaccine was impaired

Neonates born to mothers who received RSV vaccine in pregnancy but have subsequently undergone a treatment, such as cardiopulmonary bypass or extracorporeal membrane oxygenation, that has led to loss of maternal antibodies

United States of America – Advisory Committee on Immunization Practices (ACIP) Maternal and Pediatric RSV Work Group – August 2023 recommendations:[1]

- 1 dose of nirsevimab for all infants aged <8 months born during or entering their first RSV season (50 mg for infants weighing <5 kg and 100 mg for infants weighing ≥5 kg.
- 1 dose of nirsevimab (200 mg, administered as two 100 mg injections given at the same time at different injection sites) for infants and children aged 8–19 months who are at increased risk for severe RSV disease and entering their second RSV season.

Swiss consensus recommendations, January 2024:[12]

1. Born April to September → give Nirsevimab in October or as soon as possible thereafter. Nirsevimab can be given concurrently with regular vaccines (DTPa-IPV-Hib-HBV, PCV, meningococcal vaccines, MMR, MMRV) in a separate area of the body (at least 2.5 cm apart).
2. Born October to March → give Nirsevimab in the first post-natal week, ideally at maternity ward or, if hospitalized after birth, preferentially before discharge or earlier at the discretion of the treating physician. Ideally, information about Nirsevimab should be provided to future parents in advance before birth by the gynaecologists/obstetricians, midwives and/or or general practitioners.

	3. Additionally, a second dose of Nirsevimab is recommended for children aged 24 months or younger entering their 2nd RSV season, with chronic congenital or acquired medical conditions associated with a persistent high risk of severe RSV disease, as determined by the attending specialist physician. **Netherlands Health Council Executive summary:**[13] Children born just before or during the RSV season should be offered nirsevimab as soon as possible after birth (within 2 weeks at the latest). For children born after the RSV season, the committee recommends offering nirsevimab before the start of their first RSV season.
Practice points	
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16. New South Wales Health RSV Prevention Program 2025. Memo released in December 2024.
17. Australian Immunisation Handbook. Accessed online on 14 January 2025.

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