Nirsevimab
Newborn use only

2024

Alert	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. Medicine information for consumers can be found on Therapeutic Goods and Administration website: https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent=&id=CP-2023-CMI-02633-1&d=20240325172310101&d=20240326172310101
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	Nirsevimab
Presentation	1. Beyfortus 50 mg in 0.5 mL (100 mg/mL) in single dose prefilled syringe (purple plunger rod) 2. Beyfortus 100 mg in 1 mL (100 mg/mL) in single dose prefilled syringe (light blue plunger rod)
Dose	**Eligible* infants entering 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 **Eligible* infants up to 24 months of age entering their second RSV season[15]** 200 mg IM once ***Eligibility criteria are evolving and vary across states as more supply becomes available. Please refer to relevant Ministries/Departments of Health for up-to-date eligibility information for your State or Territory.** **Note:** 1. The closer administration is to the RSV season, the more effective is the seasonal protection. 2. 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. 3. For infants born after the RSV season, the committee recommends offering nirsevimab before the start of their first RSV season. 4. 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^{o}C) for a maximum of 8 hours. Nirvesimab must then be used within these 8 hours or discarded.
Storage	Refrigerate between 2-8^{o}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).

	<u>First RSV season – Otherwise healthy infants (general infant population) - Nirsevimab versus placebo/standard care</u> **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

ATAGI- Australian technical advisory group on immunisation clinical advice (26 March 2024)[17]

1. Nirsevimab can be used to protect all infants against severe disease during or entering their first RSV season, and young children aged <24 months who are vulnerable to severe disease during their second RSV season.
2. Although all infants aged <6 months entering their first RSV season would benefit from nirsevimab, in the setting of supply constraints, it is important to prioritise those with risk conditions that put them at the highest risk of severe RSV disease and hospitalisation.
3. For infants and children up to age 24 months with a high risk of severe RSV disease due to certain medical conditions, use of nirsevimab before their second RSV season can be considered.
4. Nirsevimab is safe and well tolerated in infants and young children. Very rare hypersensitivity reactions may occur with use.
5. Timing of nirsevimab: The RSV season in temperate regions of Australia is usually from April to September. Nirsevimab should be given at birth to infants born just before or during the RSV season. For infants born after the RSV season, take into consideration the likelihood of out-of-season RSV infection and risk of severe disease (Box 1), and consider delaying nirsevimab until just before the next RSV season if appropriate. Older infants and young children who require nirsevimab should receive it just before or early in the RSV season. The pattern of RSV disease in tropical areas is less predictable but may coincide with months of high rainfall. For timing of administration in Australia's tropical regions, seek local advice.
6. It is not available on the National Immunisation Program and is not currently listed on the Pharmaceutical Benefits Scheme. States and territories may have separate availability and funding arrangements, which will be detailed on their relevant department of health websites where appropriate.
7. It is anticipated that the supply of nirsevimab will be limited in coming months to state-based programs. Therefore, the populations that are likely to gain the most benefit should be prioritised to receive nirsevimab according to their risk of severe RSV disease (see Table 1). Those at highest risk

prioritised to receive nirsevimab in a setting of constrained supply are infants 0 to <6 months of age with risk conditions for severe disease (shown in the red box in Table 1). For those at moderate risk, different dosage requirements may need to be considered when prioritising who should receive nirsevimab; for example in newborns at birth compared to children 12 to 24 months of age with risk conditions (see Dosing nirsevimab).

Age	Healthy	Preterm 32<37 weeks	Risk conditions listed in box 1 (includes prematurity <32 weeks)
Birth<6 months*	Moderate risk	Moderate risk	High risk
6-<12 months	Low risk	Low-moderate risk	Moderate risk
12-24 months	Low risk. Nirsevimab not recommended.	Low risk. Nirsevimab not recommended.	Moderate risk

*Risk is particularly increased in infants aged 0 to <3 months.

8. Other considerations when evaluating the benefit from nirsevimab include:
   • Infants with multiple risk factors for severe RSV disease are likely to have an even higher risk of severe outcomes – for example, prematurity and a medical risk condition.
   • The risk of hospitalisation from RSV for Aboriginal and Torres Strait Islander infants is approximately 2 times that of other infants of the same age.
   • Infants who cannot readily access advanced care for severe RSV because they live in remote regions may have greater benefit.
   • The availability and eligibility for palivizumab as an alternate RSV mAb.
9. 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.

10. 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 Grade≥3 Severe AE	86.2 8.0 11.2	86.8 12.5 16.9
Late preterm to term	Any Grade≥3 Severe AE	83.7 3.1 6.3	81.8 3.8 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 (communication on 22 March 2024) - Beyfortus™ (nirsevimab) is funded for the following vulnerable infants:[16]

1. All premature infants (< 37 weeks gestation at birth) born after 31 October 2023.

2. All Aboriginal and Torres Strait Islander infants born after 31 October 2023
3. Other vulnerable infants including:
   Chronic neonatal lung disease (neonates requiring home oxygen/other respiratory support ≥ 36 weeks corrected age), <12 months of age.
   Infants with haemodynamically significant congenital heart disease, <24 months of age
   Other**:
   Combined immunodeficiency <24 months of age AND not yet received curative treatment.
   Trisomy 21, <12 months of age.
   Other paediatric chronic and complex conditions that significantly impair respiratory function, <12 months of age.
   Children within 28 days before hematopoietic stem cell transplantation (HSCT) or prior to engraftment after HSCT, < 24 months of age.
   **at clinician's judgement in consultation with specialist paediatric infectious diseases physician, specialist in paediatric immunisation, or designated nirsevimab program lead at a NSW Health facility. This group will include a variety of children with conditions/disorders requiring continuous home oxygen/respiratory support including neurological conditions, congenital malformations of the upper and/or lower airways, chronic suppurative lung diseases including cystic fibrosis with severe respiratory function impairment.
4. Additional points:
   - Infants who have already received palivizumab, and who meet the above eligibility criteria, can receive nirsevimab 28 days later, instead of their next palivizumab dose. Palivizumab should then be discontinued.
   - Infants who have had prior laboratory-confirmed RSV infection in 2024 are excluded.
   - The program will commence from Monday 25 March 2024 and will be rolled out in 2 phases:
   - Phase 1 (approximately the first four weeks of the program) - hospitalised infants meeting the above eligibility criteria currently in public hospitals
   - Phase 2 - Remainder of cohort.

Western Australia: In 2024 in Western Australia, 3 cohorts will be eligible for nirsevimab:[11]

1. Infants entering their first RSV season: All children born on or after 1 October 2023 to 30 April 2024 will be able to receive a single dose of nirsevimab via their general practitioner (GP), WA Country Health Services (WACHS), metropolitan Child and Adolescent Community Health (CACH) clinics, or Aboriginal Medical Service (AMS). This program will not be available at pharmacies.
2. Children born during RSV season: Nirsevimab will be offered to all babies born in WA from 1 May to 30 September 2024 through birthing hospitals.
3. High risk children entering their second RSV season: Children entering their second RSV season (aged 8 to 19 months) who have a medical condition that places them at-risk for severe RSV disease will be eligible to receive nirsevimab.

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 vulnerable babies program. Memo released on 22 March 2024.
17. Australian technical advisory group on immunisation (ATAGI) clinical advice: Statement on the use of nirsevimab for prevention of severe disease due to respiratory syncytial virus (RSV) in infants. https://www.health.gov.au/sites/default/files/2024-03/atagi-statement-on-nirsevimab-2024.pdf. Issue date: 26 March 2024.

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