Government of **Western Australia**
Department of **Health**

Respiratory Syncytial Virus (RSV) infant immunisation program

Fact sheet – for providers

What is RSV?

RSV, or Respiratory Syncytial Virus, causes illness in people of all ages, but infants aged less than 6 months are at a higher risk of severe disease.

RSV infections are often mild with symptoms similar to a common cold. RSV is one of the most frequent causes of coughs, colds and earaches. However, patients with RSV may also deteriorate rapidly, resulting in:

- bronchiolitis (chest infection)
- pneumonia (lung infection)
- croup (voice box and windpipe infection).

Globally, deaths due to RSV are 5-times higher than deaths from influenza among children under 1 year.

Why is an RSV infant immunisation program being introduced in WA?

RSV is the leading cause of infant hospitalisation in Australia. Each year, between 900–1300 infants are hospitalised in WA. Aboriginal infants are twice likely to be hospitalised with RSV then that of non-Aboriginal infants. While babies born prematurely and those with lung, heart or immune problems are at increased risk, studies show that 4 out of 5 infants and children admitted to hospital with RSV were previously healthy, with no underlying conditions.

It is difficult to predict which babies will develop serious illness requiring hospitalisation.

The Australian Therapeutic Goods Association (TGA) has recently approved a preventative monoclonal antibody called nirsevimab (available in Australia under the brand name Beyfortus®). Nirsevimab is an antibody that provides immediate protective immunity against RSV infection and has been shown to be 80 per cent effective at decreasing infant hospitalisations due to RSV.

Given the high burden of disease in young infants, the WA Department of Health is implementing a nirsevimab infant immunisation program this year. This time-limited program will run from early April to 30 September 2024.

Please note that Beyfortus® is currently not on the Pharmaceutical Benefits Scheme or National Immunisation Program.

What is the difference between a monoclonal antibody and a vaccine?

A vaccine stimulates your immune system to mount a response, which includes making antibodies, a process referred to as 'active immunisation'. This process can take up to 2 weeks after you get vaccinated and may require more than one exposure to the antigen(s) in the vaccine.

In contrast, nirsevimab contains pre-formed antibodies against a protein on the surface of the RSV virus that can prevent the virus from entering cells. This 'passive immunisation' does not require an immune response in the recipient and can provide protection almost immediately after administration.

Are monoclonal antibodies new technology?

No, another RSV preventative antibody, palivizumab, has been used to protect select high-risk infants in Australia since 2015.

Who is eligible for nirsevimab and where can they have the immunisation?

The below 4 cohorts are eligible for nirsevimab immunisation under this program.

From 1 April 2024 to 30 September 2024, nirsevimab will be offered:

- as a catch-up program for babies born from 1 October 2023 to 30 April 2024
- to all Aboriginal children born from 1 October 2022 to 30 September 2024

- to some medically at-risk children in their second RSV season born from 1 October 2022 to 30 September 2023 (for the full list of medical risk conditions, please see RSV immunisation).

In addition:

- at birth to all babies born between 1 May and 30 September 2024.

While the program is available until September, providers are urged to prioritise immunisation in April and May, prior to the start of the RSV season.

This program is delivered through participating birth hospitals, general practices, Aboriginal Medical Services, and community health immunisation clinics. Nirsevimab is not offered through community pharmacies.

How is nirsevimab administered?

Nirsevimab is given as a single intramuscular (IM) injection, usually in the outer part of the upper thigh.

What is the recommended dosage?

For babies aged younger than 8 months of age including those with medical risk conditions, dosage is determined by weight (50mg for infants <5kg and 100mg for infants ≥5kg).

For children aged 8 months and older including those with medical risk conditions (regardless of weight): dosage is 200 mg (2x100mg doses).

What is the recommendation for using nirsevimab in preterm infants?

Pre-term infants should receive nirsevimab at their chronological age using the same guidance for full-term infants and young children.

How long does the protection provided by nirsevimab last?

One dose of nirsevimab protects infants for at least 5 months, the length of an average RSV season.

Can nirsevimab be co administered with other childhood vaccines?

Yes. Nirsevimab can be safely administered at the same time as other routine childhood vaccines, including Hepatitis B vaccine birth dose.

Are there any contraindications to receiving nirsevimab? Can an infant or young child receive nirsevimab when they are sick?

Nirsevimab is contraindicated in infants and young children with a history of serious hypersensitivity reactions, including anaphylaxis, to nirsevimab or to any of its components. WA Health recommends that nirsevimab immunisation should be deferred for persons with a moderate or severe acute illness, as this precaution avoids causing diagnostic confusion between the underlying illness and potential adverse effects of immunisation. Similar to routine childhood vaccines, mild illness, with or without fever, does not require delaying administration of nirsevimab.

How do I order nirsevimab?

Providers will be contacted via email when nirsevimab is available for ordering.

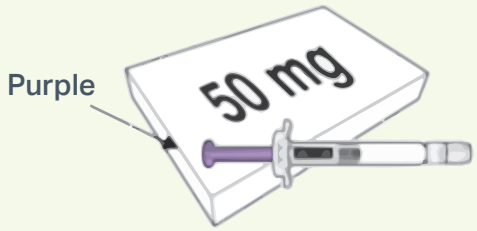
How do I store nirsevimab?

Store at 2°C to 8°C (Refrigerate. Do not freeze). Nirsevimab may be kept at room temperature for a maximum of 8 hours. After removal from the refrigerator, Nirsevimab must be used within 8 hours or discarded. Keep the pre-filled syringe in the outer carton in order to protect from light. Do not shake or expose to heat.

How is nirsevimab supplied?

Each prefilled syringe contains 0.5 mL or 1 mL solution; needles are not included.

BEYFORTUS 50 mg in 0.5 mL
prefilled syringe with a purple plunger rod.



BEYFORTUS 100 mg in 1 mL
prefilled syringe with a light blue plunger rod.

What are the possible side effects of nirsevimab?

In clinical trials, side effects after nirsevimab were uncommon. The most common side effects after nirsevimab are pain, redness, or swelling where the injection is given, and a rash. Almost all reactions were minor and usually resolved within a few days.

In post-marketing surveillance, serious hypersensitivity reactions have been reported following administration of nirsevimab to infants in the United States, where approximately 1.4 million doses of nirsevimab were distributed in 2023 to 2024. These reactions included urticaria, dyspnoea, cyanosis, and/or hypotonia. Anaphylaxis has been observed with human immunoglobulin G1 (IgG1) monoclonal antibodies. Because these reactions are reported voluntarily it is not always possible to establish a causal relationship to drug exposure. As is standard practice at immunisation clinics that provide vaccines, every clinical setting administering nirsevimab should be capable of recognising and treating serious allergic reactions including anaphylaxis.

How do I report adverse events following immunisation (AEFI)?

The WA Department of Health conducts ongoing monitoring of adverse events following immunisation and will do so for nirsevimab immunisation.

The WA Vaccine Safety Surveillance (WAVSS) system is the centralised service in WA for reporting any significant adverse events following immunisation. If you suspect a serious side effect occurred after immunisation, you can report:

- at www.safevac.org.au/Home/Info/WA or
- call WAVSS on (08) 6456 0208 (8:30am to 4:30pm Monday to Friday).

Where can I do the WA Health RSV online education module?

An e-Learning RSV module is being developed for immunisation providers.

More information about education requirements and training can be found on Immunisation education.

Where can I find more information?

The WA Department of Health website and materials will be updated regularly, check this page weekly for up-to-date recommendations and advice for the 2024 RSV immunisation program.

- RSV immunisation – provider website and fact sheet (WA Health)
- RSV – statutory notification alert (WA Health)
- RSV FAQs (NCIRS)
- RSV immunisation – consumer website, fact sheet and FAQs (HealthyWA).

For further information about RSV disease, useful resources on the use of nirsevimab in practice and access to patient education materials, visit Sanofi Australia's RSV page.

Scan the below QR code to view full product information.

This document can be made available in alternative formats.

Produced by Communicable Disease Control Directorate

IMM-014694 MAR'24