

Nova Scotia Respiratory Syncytial Virus (RSV) Infant Immunization Program

Information for Health Care Professionals NOVEMBER 24, 2025

BACKGROUND

1. What is RSV and why is it important?

Respiratory syncytial virus (RSV) is one of the most common respiratory viruses affecting infants and young children. Nearly all children are infected with RSV before the age of two. RSV, particularly the first infection, can cause serious respiratory illness, such as bronchiolitis and pneumonia, accounting for 10 to 20% of medically attended respiratory tract infections in infants. Severe cases may require intensive care unit (ICU) admission or result in death. While high-risk infants and children have a higher likelihood of severe outcomes, the overall burden of disease is greatest in healthy, full-term infants.

2. Which immunizations protect against RSV in infants?

Currently, no active vaccines are available for direct administration to infants to prevent severe RSV disease. However, three available products can provide passive immunization to temporarily protect infants: two monoclonal antibodies (nirsevimab and palivizumab) and one vaccine for administration during pregnancy (RSVpreF). Nova Scotia's infant immunization program will offer nirsevimab.

PROGRAM ELIGBILITY

3. What is the Nova Scotia RSV infant immunization program?

Nova Scotia will offer nirsevimab to prevent severe RSV disease to:

- All infants under 8 months* old at time of immunization who are entering or born during their first RSV season, and
- High-risk infants under 24 months entering their first or second RSV season (see high-risk criteria below)

This program will run annually during the RSV season only (see Q5) and will replace the highrisk nirsevimab program previously coordinated by the IWK.

* "Months" refers to calendar months. Infants aged 8 months or older at the time of immunization are not eligible unless they meet high-risk criteria. For example, an infant born on May 1, 2025, is less than 8 months until December 31, 2025. On January 1, 2026, the infant is 8 months and is no longer eligible. In another example, an infant born on July 19, 2025, is less than 8 months until March 18, 2026. On March 19, 2026, the infant is 8 months and no longer eligible.

4. Which infants and children are considered at high-risk of severe RSV disease?

Some infants and children aged less than 24 months are considered at high risk and are eligible for immunization during their first and/or second RSV season, even if they are 8 months or older.

Season	High-risk eligibility for infants aged less than 24 months
Infant's first	All premature infants (i.e., born less than 37 weeks gestational age)
RSV season	 Chronic lung disease, including bronchopulmonary dysplasia, that required ongoing assisted ventilation, oxygen therapy or chronic medical therapy in the 6 months prior to the start of the RSV season Cystic fibrosis with respiratory involvement or growth delay Hemodynamically significant chronic cardiac disease Severe immunodeficiency* Severe congenital airway anomalies impairing clearing of respiratory secretions Neuromuscular disease impairing clearing of respiratory secretions Down syndrome
Child's	All those listed above, except for premature infants born at less than
second RSV	37 weeks gestational age and infants with Down syndrome who do not
season	have another medical condition on the list.
* For severe immunodeficiency, the list of immunocompromising conditions developed for	

^{*} For severe immunodeficiency, the <u>list of immunocompromising conditions developed for COVID-19</u> may be used. The following criteria apply for HIV: CD4 less than 750 cells/µL if age less than 1 year or CD4 less than 500 if age 1 to 2 years.

Note for the 2025/26 season: For high-risk infants who are eligible during their *first* season only (e.g., born less than 37 weeks gestational age or with Down syndrome, without other medical conditions on the list), the 2025/26 season can be interpreted as their first season, so long as they were born on or after January 1, 2025, and have not previously received nirsevimab. This approach applies only in this inaugural year, given that DHW has not previously defined the RSV season; in future seasons, eligibility can be assessed based on the defined RSV season.

5. Why is eligibility restricted to less than 8 months for the universal program?

Severe outcomes decrease with chronological age; in general, the older an infant is, the less at risk they are for severe outcomes. Among healthy infants, the rates of hospitalization are highest for infants under 8 months, with risk being highest in the first three months of life and significantly decreasing after the first 6 months of life.

6. What are the 2025/2026 dates for the RSV season and infant RSV immunization program?

For the 2025/26 season, Nova Scotia defines the RSV season as October 15, 2025, to April 30, 2026. Only administer nirsevimab within these dates.

7. If an infant's gestational parent received RSVpreF vaccine during pregnancy, can the infant still receive nirsevimab?

Generally, no, apart from the medical recommendations below. Infants without medical risk factors whose gestational parent received RSVpreF at least two weeks before birth should not receive nirsevimab because they are unlikely to benefit from it. Administer nirsevimab if the gestational parent's vaccination status is unknown.

However, nirsevimab is recommended for:

- High-risk infants regardless of gestational parent's RSVpreF vaccination status
- Infants born less than two weeks after their gestational parent received RSVpreF in pregnancy

8. Can an infant diagnosed with lab-confirmed RSV during the current season receive nirsevimab?

Nirsevimab is not necessary or required for infants with current or previous confirmed RSV infection during the same RSV season, as additional benefit is expected to be minimal. Administer nirsevimab preferably in the absence of confirmed RSV infections. Severely immunocompromised infants with known RSV infections may still benefit as they may not mount an immune response; in this case, seek expert opinion.

Note: Infants who had confirmed RSV infection **prior** to the year's defined RSV season can receive nirsevimab if they meet the other program criteria.

9. Are out-of-province infants eligible to receive nirsevimab?

Yes, as long as nirsevimab is also publicly funded in the infant's home province. See section 5.2. of the Nova Scotia publicly funded vaccine/immunoglobulin eligibility policy for more details.

PRODUCT INFORMATION

10. What is nirsevimab?

Nirsevimab is a long-acting monoclonal antibody that provides passive, temporary immunity against severe RSV disease in infants. Protection begins immediately upon administration and lasts at least 5 months, potentially covering the full RSV season. Clinical trials demonstrated approximately 80% efficacy in preventing medically attended RSV infections and hospitalizations. Limited data suggest protection against RSV-related ICU admissions as well.

11. What are the safety considerations and contraindications?

Nirsevimab was well tolerated in clinical trials; common side effects are mild to moderate, including rash, fever, and injection site reactions. Nirsevimab is contraindicated in individuals with known hypersensitivity or history of severe allergic reaction (e.g., anaphylaxis) to the product or any of its components.

Given the number of new RSV immunization products now available, it is important to verify that the correct product is administered, and steps should be taken to minimize administration errors.

12. Can nirsevimab be given at the same time as other vaccines?

Yes. Nirsevimab can be administered simultaneously, or at any time before or after routine childhood vaccines. Given that the monoclonal antibody targets a specific antigen, nirsevimab is not expected to interfere with other immunizations. Multiple injections should be given in separate injection sites, and immunization products should never be mixed in the same syringe.

13. What is the administration route, schedule, and dose for nirsevimab?

Nirsevimab is administered by intramuscular injection.

Most infants are eligible for a single dose of nirsevimab in their first RSV season only. Infants younger than 24 months who remain at high-risk of severe RSV disease are eligible for a second dose of nirsevimab in their second RSV season. The dosing is as follows:

Infant's first RSV season:

- Infants less than 5 kg: single 0.5mL dose (50 mg/0.5mL)
- Infants 5 kg or more: a single 1 mL dose (100 mg/1 mL)

High-risk child's second RSV season:

- Standard dose: 200 mg (2 x 100 mg/1 mL, divided between two injection sites)
- For infants less than 10 kg: a single 100mg dose may be considered at clinical discretion

Special scenarios: Reimmunization is indicated for infants undergoing cardiac surgery with cardiopulmonary bypass and can be considered post-extracorporeal membrane oxygenation (ECMO). For additional details, including timing of administration and dosing, see the *Heart disease* subsection of Respiratory syncytial virus (RSV) vaccines: Canadian Immunization Guide.

PROGRAM CONSIDERATIONS

14. When should nirsevimab be administered?

- Infants born during RSV season: Administer nirsevimab before hospital discharge. If missed, or born outside of hospital, administer ideally within the first week of life, or as soon as possible.
- Infants in neonatal intensive care: Timing of administration during the RSV season is at the care team's discretion. At the latest, administer nirsevimab before discharge.
- Infants born before the RSV season: Administer nirsevimab at the start of the RSV season, though it can be given at any time during the RSV season if the infant remains eligible.

15. Where is nirsevimab being offered?

- Hospital-based programs should offer nirsevimab to infants born during the RSV season before discharge.
- Midwives should offer nirsevimab to infants under their care born during RSV season.
- Primary care providers should offer nirsevimab to infants who missed hospital/midwife immunization, were born before the RSV season, or are high-risk entering their second season.
- Nova Scotia Health Public Health will support access to immunization for eligible infants and young children who were not immunized in hospital and do not have a regular care provider.

Community pharmacies will not offer publicly funded nirsevimab during the 2025/26 RSV season.

16. Should RSVpreF vaccine be offered to gestational parents, given the universal nirsevimab program?

RSVpreF vaccine is not publicly funded in Nova Scotia, as nirsevimab is preferred for infant protection. However, pregnant individuals can make an informed decision to privately purchase and receive the RSVpreF vaccine to protect their infants. In these circumstances, consideration should be given to gestational timing and timing of vaccine administration relative to the RSV season. Providers should counsel about nirsevimab eligibility following RSVpreF vaccination in pregnancy.

As with any vaccines administered during pregnancy, RSVpreF vaccine administration should be documented and shared with relevant care providers and Public Health.

17. Do I need to report nirsevimab immunization to Public Health?

It is strongly encouraged to report all immunizations, including nirsevimab, to Public Health to support program evaluation, population immunity assessments, record completeness, and to prevent over-immunization.

18. How should adverse events following immunization (AEFIs) with nirsevimab be reported?

Complete an AEFI form and submit it to Public Health per <u>It's The Law</u>. A de-identified copy should also be sent to <u>Canada Vigilance Program</u>. Although nirsevimab is a passive immunization, reporting any associated AEFIs to Public Health directly supports monitoring the safety of the province's universal immunization programs.

19. How do I bill for administration of this immunization?

Nirsevimab administration is billed as a provincial immunization, and all provincial immunization rules apply. The fee code is 13.59L. RO=RSVM. You will only be reimbursed for administration of nirsevimab doses given during the defined RSV season.

20. How do I order nirsevimab?

Nirsevimab can be ordered utilizing a product specific ordering form which will be shared by the Provincial BioDepot through Shopify emails and faxed communication lists upon program launch.

21. Where can I go for more information?

- Respiratory syncytial virus (RSV) vaccines: Canadian Immunization Guide
- NACI Statement on the prevention of respiratory syncytial virus disease in infants
- Beyfortus (nirsevimab) product monograph