BC Infant Respiratory Syncytial Virus (RSV) Immunoprophylaxis Program
Questions and Answers for Immunization Providers
November 2024

This resource was developed in collaboration with the BC Infant RSV Immunoprophylaxis Program.

1. What is Respiratory Syncytial Virus (RSV)?

RSV is an enveloped single-stranded RNA virus from the *Paramyxoviridae* family. RSV is a common cause of respiratory tract infections that recur throughout life. It is the most common cause of bronchiolitis and pneumonia among infants and young children, and is associated with severe clinical outcomes among older adults, particularly among those with comorbidities.[1]

Consistent with many other respiratory viruses, RSV is seasonal, with infections being more common in the winter. Each jurisdiction within Canada defines their RSV season based on local epidemiology to determine the right time for their immunization.[2] In BC, RSV infections often occur between the mid-fall to the early spring.[3]

2. Who is at high risk of developing severe RSV?

RSV infects almost all infants by 2 years of age. In infants and young children, the younger the child, the higher the risk of hospitalization. The risk of medically attended RSV appears to be higher in infants with comorbidities compared to healthy term infants entering their first RSV season. However, the majority of infants and young children who require medical office or emergency department visits associated with RSV are born at term with no underlying comorbidities.[1]

A number of conditions increase the risk of severe RSV infection in an infant, including a younger age (i.e., under 6 months), prematurity, chronic respiratory and cardiac diseases or deficits of the immune system.

Geography could also be considered a risk factor. Although there is limited data, both Canadian surveillance data and primary literature demonstrates a higher burden of RSV admissions in northern and remote settings compared to the rest of Canada.[4]

It is also important to highlight that older adults are also another group at risk of severe RSV disease. However, this resource will focus on prevention of RSV in infants and young children.

For more information, visit Respiratory syncytial virus (RSV) vaccines: Canadian Immunization Guide.

3. What products protect infants against RSV?

Immunization products to protect infants against RSV include:

1. **Infant monoclonal antibody preparations:** BEYFORTUS™ (nirsevimab) and SYNAGIS® (palivizumab) are administered directly to infants.

2. **Maternal vaccine:** ABRYSVO™ (RSVpreF) subunit vaccine is administered during pregnancy between 32 and 36 weeks gestation to protect the infant through the passive transfer of maternal antibodies.[1]

See Table 1 below for product information and availability in BC.

Table 1: SUMMARY OF PRODUCTS TO PROTECT INFANTS FROM RSV[5]				
PRODUCT	**PRODUCT TYPE**	**APPROVED BY HEALTH CANADA FOR**	**AVAILABILITY IN BC**	**PUBLICLY FUNDED IN BC**
SYNAGIS® (palivizumab)	Short-acting infant monoclonal antibody medication (IM injection)	Newborns, infants, and children up to 2 years of age who are at high risk for severe RSV infection (such as those born prematurely or who have a chronic lung disease)	Yes, if registered with and eligible through the BC RSV Infant Program	Yes, if registered with and eligible through the BC RSV Infant Program
BEYFORTUS™ (nirsevimab)	Long-acting infant monoclonal antibody medication (IM injection)	1. Newborns and infants who will be experiencing their first RSV season (RSV season in Canada is during the fall and winter months, which is when the virus is most active) 2. Children up to 2 years of age who are at risk for severe RSV infection (such as those born prematurely or who have a chronic lung disease)	Yes, if registered with and eligible through the BC RSV Infant Program, however (product availability in BC remains limited in 2024)	Yes, if registered with and eligible through the BC RSV Infant Program
ABRYSVO™ (RSVpreF)	Maternal vaccine	People who are 32 to 36 weeks pregnant	Yes, for purchase at some pharmacies	No

4. What are monoclonal antibodies and how do they protect against RSV?

Monoclonal antibodies are not vaccines.[6, 7] Monoclonal antibodies are passive immunizing agents. The two RSV monoclonal antibody preparations, nirsevimab and palivizumab can help protect infants from RSV disease by giving the infant antibodies via direct injection.[1]

Palivizumab and nirsevimab are monoclonal antibodies that specifically recognize and target RSV to help prevent severe RSV infection.[5] They do not activate the immune system as would occur with infection or vaccination (active immunity). Rather, the antibodies themselves protect against disease (i.e., passive immunity).[6, 7]

Because monoclonal antibodies are passive immunizing agents, protection is short-lived and most effective the weeks after the monoclonal antibody is given. No memory is created and protection wanes over time.[6, 7] As children get older, they are less likely to get severe symptoms from RSV infection.[6, 7] Compared to palivizumab, nirsevimab has a longer duration of protection and, if administered at birth, protection is high in the first months of life when infants are most at risk for RSV. Nirsevimab is efficacious for at least 5 months after administration, which is generally sufficient to provide protection for the entire RSV season in BC. Palivizumab has a shorter duration of protection compared to nirsevimab and requires monthly doses.[1]

Read more about Nirsevimab to reduce infant morbidity from respiratory syncytial virus.

5. What are the National Advisory Committee on Immunization (NACI) recommendations for the prevention of RSV disease in infants?

Nirsevimab is preferred over palivizumab and the RSVpreF (ABRYSVO™) maternal vaccine.[1]

Table 2: SUMMARY OF NACI RECOMMENDATIONS FOR PREVENTION OF RSV IN INFANTS BY STRENGTH[4]	
Strong recommendation	Considering the significant burden of disease in all infants from RSV and the impacts of RSV on the Canadian health system, NACI recommends building towards a universal RSV immunization program for all infants. Program introduction could occur in stages depending on access to supply, cost-effectiveness, and affordability of available options.
	NACI recommends RSV immunization programs use nirsevimab to prevent severe RSV disease. Programs can build and expand over time depending on access to supply, cost-effectiveness, and affordability of available options. Priority 1: • Infants entering, or born during, their first RSV season who are at increased risk of severe RSV disease, including those who are born at less than 37 weeks gestational age (wGA). • Infants entering their second RSV season and at ongoing increased risk of severe RSV disease. • Infants entering, or born during, their first RSV season whose transportation for severe RSV disease treatment is complex, and/or whose risk of severe RSV disease intersects with established social and structural health determinants such as those experienced by some Indigenous communities across First Nations, Métis and Inuit populations. Priority 2: • Any infant less than 8 months of age entering, or born during, their first RSV season through universal immunization programs to prevent severe RSV disease.
Discretionary recommendation	NACI recommends ABRYSVO™ (RSVpreF) vaccine may be considered as an individual decision by a pregnant woman or pregnant person together with information from their pregnancy care provider, in advance of, or during, the RSV season, to prevent severe RSV disease in their infant. At the present time, NACI does not recommend an immunization program for ABRYSVO™ (RSVpreF). More data and information are expected to emerge over time and NACI will reconsider this recommendation in the future.

For summary of evidence and rationale, and further considerations surrounding these recommendations, review the NACI Statement on the prevention of respiratory syncytial virus (RSV) disease in infants which is consistent with the Society of Obstetricians and Gynecologists of Canada (SOGC) Position Statement.

6. What is the BC Infant RSV Immunoprophylaxis Program and how is it being expanded?

Children who meet palivizumab criteria (detailed on the 2024-2025 BC RSV Immunoprophylaxis Program Palivizumab Application Form) should continue to receive palivizumab this year.

The BC Infant RSV Immunoprophylaxis Program ("the Program") is a Provincial Health Services Authority program run by BC Children's Hospital whose mandate is to determine eligibility for funded RSV immunoprophylaxis and administer doses to those so identified. Doses are administered through a distributed network of clinics as well as physician offices to approved children. In addition, the program aims to promote health education aimed at reducing RSV hospital admission. The Program's Eligibility criteria are evidence-based, centered in clinical rationale, and reviewed annually.[8] Case surveillance by the Program determines when immunoprophylaxis starts and ends. The Program's Executive Committee determines the commencement date for RSV immunoprophylaxis based on surveillance data, each year. The Program has been in operation for over 15 years coordinating the administration of SYNAGIS® (palivizumab) to high-risk children under two years of age.

For the 2024-2025 season, the Program has expanded the reach of its RSV immunoprophylaxis program. Health Canada recently authorized Beyfortus™ (nirsevimab) to protect infants and children from RSV.[4] The Program has secured limited doses of nirsevimab. Starting in the 2024-2025 RSV season, all infants born after March 31, 2024 who reside in certain remote BC communities will be assessed for nirsevimab. In addition, some groups of high-risk medically complex children under 2 years old who do not qualify for palivizumab, such as those with Down syndrome, can receive nirsevimab. Children under 2 years of age eligible for palivizumab who live in difficult-to-access BC areas may also receive nirsevimab.

Regional Health Authorities and the First Nations Health Authority will be supporting the expansion of the BC Infant RSV Immunoprophylaxis Program by:

- identifying eligible infants,
- registering infants into the Program, and
- administering nirsevimab to approved clients.

7. Why are infants living in remote BC communities being prioritized for nirsevimab?

Infants living in remote BC communities affected with RSV are at increased risk of requiring hospitalization. Additionally, remote communities may have significant barriers accessing timely care (e.g., geographical and transportation barriers).

While data are limited, both Canadian surveillance data and primary literature demonstrates a higher burden of RSV admissions in northern and remote settings compared to the rest of Canada. Canadian administrative hospitalization data (from September 2014 to August 2023) generally show higher rates of hospitalizations for the territories compared to the rest of Canada in most RSV seasons among infants and young children. In addition, there is a greater cost of RSV care to the healthcare system in these remote locations due to the need for air transportation of infants to regional hospitals or to tertiary care settings.[2]

Broader efforts are ongoing provincially to delineate what an ideal infant RSV immunoprophylaxis program could look like for BC in the future seasons.

8. Who is eligible for nirsevimab and how can they be registered for it?

The BC Infant RSV Immunoprophylaxis Program has secured limited doses of nirsevimab. Table 3 outlines eligible and potentially eligible groups and how they can register for nirsevimab.

Table 3: ELIGIBILITY FOR NIRSEVIMAB

Eligible and potentially eligible groups	How to register
All infants born after March 31, 2024 who reside in certain **remote BC communities** (see map). If you are unsure of whether a client is eligible based on this criteria, contact the BC RSV Immunoprophylaxis Program for clarification at rsv@cw.bc.ca.	Children can be registered by any health care provider (e.g., public/community health nurse, maternity care provider) using this Redcap link. **Health care providers should ensure that client identifiers, including personal health numbers (PHNs) are entered accurately.** Register infants as soon as possible to facilitate timely distribution of nirsevimab doses in communities where infants are located.
Some groups of high-risk medically complex children under 2 years old who do not qualify for palivizumab, such as those with Down syndrome can also receive nirsevimab. Children under 2 years of age eligible for palivizumab who live in difficult-to-access BC areas may receive nirsevimab.	For all potentially eligible, medically complex children, please submit a BC 2024-2025 RSV Immunoprophylaxis Program Palivizumab Application Form on the PHSA Shared Hospital Organization Portal (SHOP). Provide as much relevant clinical information as possible in the 'Summary clinical course' section of this form to facilitate adjudication of available doses.

9. What should I know before registering a client in Redcap?

Before registering a client in Redcap, health care providers should note the following:

- Due to the significant cost of the product and logistical considerations surrounding its distribution to remote BC communities and to minimize product wastage, informed consent should be obtained from the client **prior** to registering them in Redcap for a dose of nirsevimab. As part of your informed consent discussion, inform the family that the infant will be registered in the BC Infant RSV Immunoprophylaxis Program and upon approval from the program, arrangements will be made for administration of nirsevimab. Informed consent must also be re-affirmed immediately prior to administration of nirsevimab.

- Maternal RSV vaccination status should be confirmed before discussing nirsevimab eligibility for a healthy child. Nirsevimab is not required if the birthing parent has received an RSV vaccine during pregnancy at least 2 weeks prior to the birth of the infant and in these cases, the infant should not be registered in Redcap.

- The Redcap survey will ask for the following details:
  - Client and parent/guardian information
  - Information about the health care provider making the request
  - Child's weight in grams
  - Maternal RSV vaccination status and date if vaccinated
  - Whether the client meets the criteria for Immunoprophylaxis

- If you are a health care provider registering an infant but will not be the provider administering the product, please ensure you indicate where the infant will be receiving the product (e.g., the community health centre/public health unit) to ensure the product is available at the correct location.

If you have any questions, please email: rsv@cw.bc.ca.

10. Will eligible infants born during RSV season be offered nirsevimab before they are discharged home?

The BC Infant RSV Immunoprophylaxis Program is engaging with maternity care units in hospitals across BC. However, product availability may vary depending on region.

11. What is the protective efficacy of BEYFORTUS™ (nirsevimab), SYNAGIS® (palivizumab), and ABRYSVO™ (RSVpreF) against RSV?

Table 4: PROTECTIVE EFFICACY OF RSV PRODUCTS FOR INFANTS[1]

	Infant Monoclonal Antibodies		Maternal RSV Vaccine
	BEYFORTUS™ (nirsevimab)	SYNAGIS® (palivizumab)	ABRYSVO™ (RSVpreF) vaccine in pregnancy
Reduction in RSV associated hospital admission	~80%[4]	38-86%[8]	57%
Reduction in medically attended RSV respiratory tract infection in healthy infants	80%	Not Available	51% in their first RSV season
Protective efficacy	Protective efficacy of monoclonal antibodies is immediate.		Protective efficacy takes some time to develop. Optimally administered at least 2 weeks before birth to allow for transplacental transfer of protective antibodies. Efficacy is high in the first months of life when infants are most at risk for RSV during the RSV season.
Duration of protection	Longer duration of protection compared to palivizumab; a single dose protects for the entire season.	Shorter duration of protection compared to nirsevimab.	Due to waning of passively transferred antibodies in neonates over time, the protective effect may not exceed 6 months of age in infants.

12. Are healthy infants of a person who received ABRYSVO™ (RSVpreF) vaccine during pregnancy eligible for BEYFORTUS™ (nirsevimab)?

The ABRYSVO™ (RSVpreF) vaccine may be considered by a pregnant woman or pregnant person, together with their care provider, in advance of or during the RSV season, to prevent RSV disease in their infant.(1)

Most healthy infants whose immunocompetent birthing parent received an RSV vaccine at least 14 days prior to delivery are considered sufficiently protected, and do not require nirsevimab.

Medically complex infants will be identified through the BC Infant RSV Immunoprophylaxis Program for eligibility for nirsevimab. Health care providers do not need to register medically complex infants for nirsevimab through Redcap. If you have any questions, please email: rsv@cw.bc.ca.

13. What public-facing resources are available for RSV infection, ABRYSVO™ (RSVpref) vaccine, BEYFORTUS™ (nirsevimab) and SYNAGIS®(palivizumab)?

Table 5: RSV INFECTION, RSV VACCINE AND MONOCLONAL ANTIBODIES RESOURCES FOR THE PUBLIC	
BEYFORTUS™ (nirsevimab)	BC Children's Hospital/BC Women's Hospital + Health Centre: • Information for Parents about Nirsevimab (Beyfortus®) Immunize Canada: • Preventing RSV in infants: Know your product options
SYNAGIS® (palivizumab)	BC Children's Hospital/BC Women's Hospital + Health Centre: • Information for Parents about Synagis
RSV infection	BC Children's Hospital/BC Women's Hospital + Health Centre: • Respiratory Syncytial Virus (RSV) and your child Immunize Canada: • Preventing RSV in infants: What you need to know
ABRYSVO™ (RSVpreF) vaccine	ImmunizeBC: • Respiratory Syncytial Virus (RSV) vaccine Immunize Canada: • RSV vaccines in pregnancy: What you need to know

14. Which resources can be used to provide standard information to support informed consent discussions for nirsevimab?

Immunization providers may utilize resources from BC Children's Hospital/BC Women's Hospital + Health Centre:

- Respiratory Syncytial Virus (RSV) and your child
- Information for Parents about Nirsevimab (Beyfortus®)

15. Is a client-specific order required for nurses to administer nirsevimab?

Yes, for the 2024-2025 RSV season, nurses will require a client-specific order from an authorized prescriber for the administration of nirsevimab. The provision of client-specific orders will be facilitated through the BC Infant RSV Immunoprophylaxis Program. Additional regulatory amendments are needed to support autonomous provision of nirsevimab to infants and children.

The nurse who is administering the product must follow the Medication practice standard and be competent to give an injection. Nurses who are acting on a client-specific order to immunize and meet BC College of Nurses and Midwives (BCCNM) standards do not need to meet all of the competencies established by BC Centre for Disease Control (BCCDC) before administering nirsevimab.[9]

Although additional education is not required for nurses administering immunoprophylactic agents with an order, completion of additional educational resources may be required by organizations/employers for those who have not completed the BCCDC Immunization Competency Course. Please check with your organization/employer for any additional requirements.

Additional resources from BCCNM:

- Medication Practice Standard
- Acting with client-specific orders Standard
- Acting on a client specific order thinking tool

16. What resources should nurses refer to for management of anaphylaxis?

Per BC College of Nurses and Midwives' (BCCNM's) Medication Practice Standard, before administering a medication, nurses ensure they have the competence to:

a. Monitor the client's response to the medication, and
b. Recognize and manage intended and adverse outcomes of the medication

While anaphylaxis is extremely rare, every immunization carries an associated risk of producing an anaphylactic reaction. Advise recipients of any biological product to remain under supervision for at least 15 minutes after immunization; regardless of whether or not they have had the particular product previously.

For nurses who have not completed the BC Immunization Competency Course and do not routinely use Part 3: Management of Anaphylaxis in a Non-Hospital Setting of the BC Immunization Manual, nursing professionals may also follow the provincial decision-support tool (DST), Anaphylaxis: Initial Emergency Treatment by Nurses (Adult and Pediatric). The clinical content and protocol in these two DSTs is identical however Part 3: Management of Anaphylaxis in a Non-Hospital Setting, includes important immunization-specific information including background information and vaccine reporting regulations.

For those who have not completed the BC Immunization Competency course, the Anaphylaxis Initial Emergency Treatment by Nurses (Adult & Pediatric) course is a learning module designed to support and provide the necessary information for nurses (registered nurses (RN), registered psychiatric nurses (RPN), and licensed practical nurses (LPN)) to diagnose anaphylaxis and to initiate the appropriate nursing interventions in the event of an anaphylactic reaction in an adult or pediatric client, within scope

of practice. Completion of this course is a requirement for RPNs and LPNs to autonomously administer immunoprophylactic agents.

17. How and where should I document the administration of nirsevimab?

The client-specific order must be documented in the client's permanent record e.g., the provincial immunization registry (PIR).

Nirsevimab administration must be documented in the client record and should also be recorded in the following form: RSV PROGRAM: PATIENT DOSING LOG DOCUMENT: NIRSEVIMAB. Submit the completed form to BC Infant RSV Immunoprophylaxis Program via e-mail (rsv@cw.bc.ca) or fax (604-875-2879 or 1-877-625-7555).

Additionally, provide the family with a record (i.e., Child Health Passport) of the dose provided.

If a dose of nirsevimab is offered and not provided, ensure to document the reason why the dose was not given and the planned follow-up action.

18. What do I need to know for the administration of nirsevimab?

Nirsevimab is available in 2 pre-filled syringe presentations: 50 mg (50 mg/0.5 mL) pre-filled syringe with purple plunger rod and 100 mg (100 mg/1 mL) pre-filled syringe with light blue plunger rod. Dosing is based on weight. The appropriate dose for the client will be indicated within the client-specific order received from the RSV Program.

The following resources have been developed for BC Children's and BC Women's Hospital staff, however they contain valuable information and can be a useful guide for nurses in other settings:

- Nirsevimab preparation
- Nirsevimab for immunoprophylaxis of RSV infection

Nirsevimab should be administered intramuscularly (IM). Refer to the BC Immunization Manual Appendix B: Administration of Biological Products for direction on the recommended site, needle length and maximum volume for intramuscular injection based on the client's age (p.17).

19. What are the contraindications to receiving nirsevimab?

Nirsevimab is contraindicated for the following individuals with:

- Known hypersensitivity to nirsevimab or any components of the medication such as polysorbate 80.
- Known hypersensitivity to other humanized monoclonal antibodies
- Patients who exhibit a severe hypersensitivity reaction

20. Should nirsevimab be delayed if the child is experiencing an illness?

Minor illnesses such as the common cold, with or without fever, are not contraindications to nirsevimab. However, moderate to severe illness, with or without fever, is a reason to consider deferring

administration. The decision to delay administration of nirsevimab will depend on the severity and etiology of the underlying disease as well as the risk of not receiving nirsevimab. Furthermore, due to the unique nature of this program, supply and access may also be a factor to consider.[1]

If you have questions e-mail the BC Infant RSV Immunoprophylaxis Program at rsv@cw.bc.ca.

21. What are the common adverse events following nirsevimab administration?

Adverse events following administration of RSV monoclonal antibodies are uncommon.

In randomized controlled trials, the rates of local and systemic adverse events were similar for those receiving either nirsevimab or palivizumab as for those receiving a placebo.[1]

In infants, fever and/or rash at the injection site occurred at a rate of 0.5% within 7 days following administration of RSV monoclonal antibodies. For nirsevimab, the most frequent adverse reaction was rash, occurring within 14 days of administration, reported in 0.7% of subjects receiving nirsevimab and 0.3% in placebo recipients. Fever and injection site reactions (including redness, pain and swelling) were reported at a rate of 0.5% (0.6% in placebo) and 0.3% (0% in placebo), respectively, within 7 days of administration.[10]

Compared with placebo, nirsevimab does not increase the risk of severe systemic adverse events in infants.[1]

22. How should adverse events following receipt of nirsevimab be reported?

If an adverse event occurs following receipt of nirsevimab, notify the BC Infant RSV Immunoprophylaxis Program Directors at rsv@cw.bc.ca.

Adverse events following administration of passive immunizing agents such as nirsevimab should also be reported to the Canada Vigilance Program using the online Side Effect Reporting Form as an adverse drug reaction.

If an adverse event occurs in an individual who received both vaccine(s) and nirsevimab and the health care provider is uncertain about which product was associated with the event, the event should be reported both as a vaccine-related Adverse Event Following Immunization (AEFI) to the local public health unit, and as an adverse drug reaction to the Canada Vigilance Program. When reporting the AEFI, indicate that nirsevimab was concomitantly administered as a passive immunizing agent in the medical history section (rather than the immunization data section) of the AEFI form. For more information, see Part 5 – Adverse Events Following Immunization of the BC Immunization Manual.

23. How should nirsevimab be stored and handled, and where should I report a suspected cold chain break?

Store nirsevimab in a temperature monitored refrigerator (2°C - 8°C). Keep the pre-filled syringe in the outer carton to protect from light. Nirsevimab may be kept at room temperature (20°C - 25°C) for a maximum of 8 hours. After removal from the refrigerator, nirsevimab must be used within 8 hours or discarded. Do not freeze, shake or expose to heat. Do not mix with other products.

Report suspected cold chain breaks immediately to the BC Infant RSV Immunoprophylaxis Program at rsv@cw.bc.ca. The BC Infant RSV Immunoprophylaxis Program will forward details of the suspected cold chain break to the product manufacturer/distributor as soon as possible to determine product stability. Place the product in refrigerated quarantine until advised.

For more information on vaccine management, visit the following BC Centre for Disease Control pages:

- Vaccine Management
- Packing an Insulated Cooler
- Vaccine storage and handling

24. Can RSV monoclonal antibodies be given concurrently with routine vaccines?

Nirsevimab and palivizumab are passive immunizing agents directed specifically against RSV. These monoclonal antibodies do not interfere with the immune response to vaccines. Nirsevimab or palivizumab can be administered at the same time as, or at any time before or after, other immunization products.[1]

25. Where can I find additional resources?

Refer to the BEYFORTUS® (nirsevimab) Product Monograph.

The following resources have been developed for BC Children's and BC Women's Hospital staff, however they contain valuable information and can be a useful guide for nurses in other settings:

- Nirsevimab preparation
- Nirsevimab for immunoprophylaxis of RSV infection

If you are a health care provider and have reviewed all the information and resources in this health care provider Q&A and still have questions, e-mail the BC Infant RSV Immunoprophylaxis Program at rsv@cw.bc.ca.

References:

1. Respiratory syncytial virus (RSV) vaccines: Canadian Immunization Guide. 2023.

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