# Manitoba's Paediatric Respiratory Syncytial Virus(RSV) Immunoprophylaxis Program Training Module 2025

### September 2025

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## **Overview**

- 1) Burden of RSV
- 2) Symptoms /Transmission
- 3) RSV Prevention Practices
- Manitoba's Paediatric Respiratory Syncytial Virus(RSV) Immunoprophylaxis Program
- 5) What is Nirsevimab (Beyfortus®)?
- 6) Storage and Handling
- 7) Nirsevimab (Beyfortus®) Ordering and Supply Information
- 8) Pre- administration
- 9) Nirsevimab (Beyfortus®) Administration
- 10) Post- Administration
- 11) Documentation
- 12) Resources

# **Land Acknowledgment**

### We acknowledge

We acknowledge we are gathered on Treaty 1 Territory and that Manitoba is located on the Treaty Territories and ancestral lands of the Anishinaabeg, Anishininewuk, Dakota Oyate, Denesuline and Nehethowuk Nations.

We acknowledge Manitoba is located on the Homeland of the Red River Métis.

We acknowledge northern Manitoba includes lands that were and are the ancestral lands of the Inuit.

We respect the spirit and intent of Treaties and Treaty Making and remain committed to working in partnership with First Nations, Inuit and Métis people in the spirit of truth, reconciliation and collaboration.



### 1. Burden of RSV Disease

- RSV: enveloped single-stranded RNA virus (Paramyxoviridae).
- Causes recurring respiratory infections; yearly outbreaks (late fall-early spring in Canada).
- Usually mild in healthy older children and adults (cold-like symptoms).
- Leading cause of bronchiolitis and pneumonia in infants and young children.
- Severe outcomes in older adults, especially with comorbidities.
- RSV outcomes are more severe in high-risk children (premature, chronic lung disease, congenital heart disease, immunocompromised) and may require hospitalization.

In Canada, RSV is the #1 cause of hospital admissions among children in their first year of life.

### **Burden of RSV Disease**

# 6 out of 1,000

In Canada, an estimated 6 out of every 1,000 children under 2 years of age are hospitalized with RSV each year.

### 50%

About 50% of children are infected with RSV by less then 6 months of age, and 20 –40% of those infected will develop bronchiolitis or pneumonia.

# ~100% Infected by Age 2

RSV continues to infect nearly all children (~100%) by the age of 2 years.

- RSV reinfections occur throughout life as an RSV infection produces only partial and temporary immunity.
- An estimated 5–17% of RSV-related hospitalizations occur among individuals from remote communities.

# **Burden of RSV Disease in Manitoba**

Percentage of RSV Positive Admissions by Age to Children's Hospital 2024-25 Season



45% of the admissions were < 6months of age of the 288 admissions

## **Burden of RSV Disease**





Data from 65 infants born at 25-26 weeks gestational age (GA)(n+-26) or 29-32 weeks GA (n+45). Adapted from Salow et al. Ped Was 1986;26(9): 899-904.

# **Burden of RSV Disease**Table: RSV Hospitalization Statistics in Canada – Children < 5 Years</p>

Age Group	Estimated Hospitalization Rate
<6 months	15–25 per 1,000
6–11 months	6–10 per 1,000
12–23 months	2–4 per 1,000
24–59 months	<1 per 1,000
All children <2 yrs	~6 per 1,000
Annual burden (Canada)	~5,000–7,000 hospitalizations/year

Sources: Canadian Paediatric Society (2023); CIHI; Public Health Agency of Canada (PHAC); National Advisory Committee on Immunization (NACI); Manitoba Health RSV Reports

# **Burden of RSV Disease in Canadian Infants**

Category	Estimated Rate / Incidence
ER/Clinician Visits	~10 – 20% of respiratory infections; ~20–64 visits per 1,000 infants/year
Hospitalization	~6 – 8.6 per 1,000 infants (<2 yrs); up to 28 per 1,000 in <6 mo
ICU Admission	~5 – 13% of hospitalized infants
Mortality	~6.9 per million live births (~0.0007%); ~0.2% mortality within 30d of hospitalization

#### Sources:

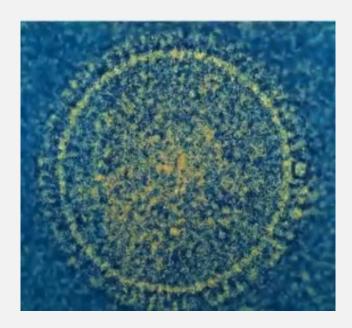
- 1. Public Health Agency of Canada (PHAC), RSV Surveillance Reports
- 2. Canadian Institute for Health Information (CIHI), Hospitalization Data
- 3. CMAJ Open 2018;6(4):E535–E544. doi:10.9778/cmajo.20180020 (PMID: 29788036)
- 4. Canadian Communicable Disease Report (CCDR) 2024, Vol 50-3: RSV Updates
- 5. Paediatric Child Health. 2000;36(4):343-345 (PMID: 10949905)
- 6. rethinkrsv.ca RSV burden and prevention resource hub

## 2. Symptoms /Transmission

- ➤ RSV Symptoms and Lower Airway Disease in Infants
- ➤ RSV Symptom Progression in Infants
- ➤ How is RSV Transmitted?

## Symptoms /Transmission RSV Symptoms and Lower Airway Disease in Infants

- Initial Presentation:
  - Symptoms usually begin 3–5 days after exposure and may appear like a cold at first.
    - Runny or stuffy nose, mild fever, decreased feeding/appetite, dehydration/dry or less frequent wet diapers.
    - Around 1–3 days later, a cough might develop, often followed by sneezing and wheezing.
- Progression to Lower Respiratory Tract (LRT) Involvement
  - By 2–4 days into illness, infection often spreads from the upper airway to the bronchioles, leading to bronchiolitis.
    - Symptoms include tachypnea, wheezing, subcostal or intercostal retractions, nasal flaring, and grunting.

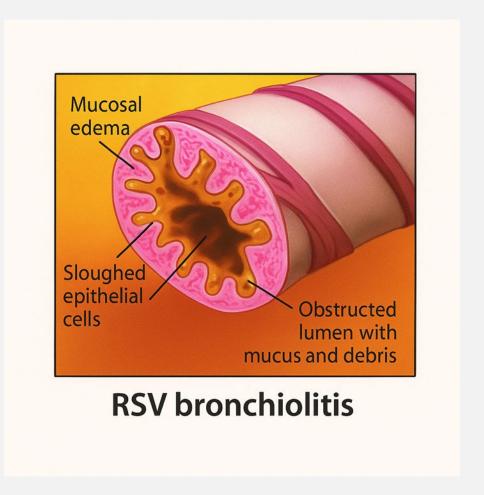


Source ACIP 2023

## Symptoms /Transmission RSV Symptoms and Lower Airway Disease in Infants Con't

#### 3. Severe LRT Illness

- In severe cases, infants may develop:
  - Bronchiolitis: airway obstruction from mucus and cell debris.
  - Pneumonia: alveolar involvement from fluid-filled air spaces.
  - Apnea: particularly in infants under 6 months.
  - Poor oxygenation, requiring supplemental oxygen or ventilation in ~10% of hospitalized infants.



### Symptoms /Transmission Summary Table: RSV Symptom Progression in Infants

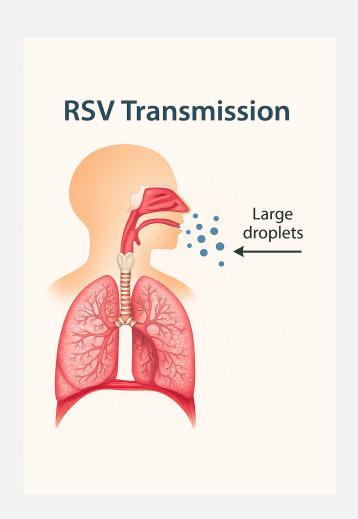
Phase	Key Symptoms & Findings
Early Upper Respiratory Infection ( URI)	Nasal congestion, runny/stuffy nose, mild fever, poor feeding, sometimes cough
Middle phase	Cough intensifies, sneezing, low-grade fever, onset of wheezing
Late/LRT disease	Tachypnea, nasal flaring, grunting, retractions, severe wheezing, apnea, poor oxygenation
Severe disease	Bronchiolitis, possible pneumonia, hypoxia, respiratory failure requiring hospitalization

Support parent/caregiver to contact/visit doctor/health care provider/facility if they feel that there is a concern with their baby or child.

## **Symptoms / Transmission**

#### **How is RSV Transmitted?**

- Primarily through large respiratory droplets.
- Droplets are expelled by coughing, sneezing, or talking.
- Infection occurs via contact with eyes, nose, or mouth.
- Close contact with an infected person increases risk.
- RSV can survive for hours on surfaces (e.g., toys, tables, hands).
- Indirect transmission can occur by touching contaminated objects.
- Most common in daycares, households, and healthcare settings.



## 3. RSV Preventive Practices

#### Caregiver Tips to Reduce RSV Risk:

- RSV prophylaxis (e.g., nirsevimab, Beyfortus®)
- Avoid direct contact with anyone who has cold symptoms.
- Avoid crowded areas during RSV season.
- Provide a smoke-free environment.
- Offer breast/chest milk if possible.
- Stay home when sick, even with mild cold symptoms.
- Disinfect frequently touched surfaces and objects.
- Keep up with routine vaccinations, including fluand COVID-19 vaccines.

# HAND WASHING! HAND WASHING!

All infants and young children are susceptible to RSV.

# 4. Manitoba's Paediatric RSV Immunoprophylaxis Program

- Manitoba's Paediatric RSV Immunoprophylaxis Program Expansion
- ➤ Manitoba's Eligibility Criteria
- ➤ Nirsevimab (Beyfortus®) Access Pathways for Infants Born October 1,2025 March 31, 2026
- ➤ The Role of Public Health in Nirsevimab (Beyfortus®) Access

### Manitoba's Paediatric RSV Immunoprophylaxis Program Expansion

Expansion of existing High-Risk Infant RSV Immunoprophylaxis Program to include all infants born between October 1 and March 31.

Based on NACI recommendations for nirsevimab (Beyfortus®) use in infants.

Aims to reduce RSV-related illness and hospitalizations.

Ensures equitable access across Manitoba in alignment with national guidance.

- Start date :
  - October 1, 2025

- End Date:
  - March 31, 2026

# Manitoba's Paediatric RSV Immunoprophylaxis Program

### Manitoba's Eligibility Criteria

- All infants born between October 1,2025 and March 31,2026 are eligible to receive one dose of nirsevimab (Beyfortus®).
- Infants and children with the following high-risk conditions may also be eligible in consultation with the Manitoba High-Risk RSV Immunoprophylaxis Program.
  - Preterm infants born before 33 weeks gestational age between April 1 and September 30, 2025.
  - Children with cardiac conditions < 2 years of age on October 1, 2025 (in consultation with pediatric cardiology).
  - Children with chronic lung conditions, typically requiring supplemental oxygen treatment, and are < 2 years of age on October 1, 2025.</li>
  - Other patients in consultation with the Manitoba High-Risk RSV Immunoprophylaxis Program.

See Eligibility Criteria for Publicly-Funded Vaccines for more information: <a href="https://www.manitoba.ca/health/publichealth/cdc/vaccineeligibility.html">https://www.manitoba.ca/health/publichealth/cdc/vaccineeligibility.html</a>

# Manitoba's Paediatric RSV Immunoprophylaxis Program

#### Nirsevimab (Beyfortus®) Access Pathways

Nirsevimab (Beyfortus®) will be made available at various sites throughout the province to offer a dose to all infants born October 1, 2025, to March 31, 2026.

- Infants born in birthing facilities should receive nirsevimab (Beyfortus®) prior to discharge.
  - If an infant does not receive a dose prior to discharge, parents can be directed to the following locations where providers can administer a dose:
    - Local public health office or post-partum home visit by the public health nurse.
    - A First Nations/provincial nursing station or health centre.
    - Designated Walk-In Connected Care Clinics (WICC) at Access Centres in Winnipeg https://wrha.mb.ca/locations-services/walk-in-connected-care/
      - Call the clinic first to confirm availability.
    - Infants born in Ode'imin Birth Centre or home births attended by midwives can receive a dose during post natal follow up visits.
    - High risk eligible infants can receive a dose arranged by Manitoba High Risk RSV Program.

# Manitoba's Paediatric RSV Immunoprophylaxis Program

#### Role of the Public Health Nurses in Nirsevimab (Beyfortus®) Access

- Frontline Access Point
  - Birthing hospitals are the primary access point, providing nirsevimab (Beyfortus®) prior to infant discharge.
  - Public health nurses play a key role in ensuring infants who did not receive nirsevimab (Beyfortus®) in hospital still have timely access.
- Home and Community Delivery
  - Doses can be administered during postpartum home visits or at local public health offices, providing convenient and equitable access for families.
- Care Coordination
  - PHNs guide families by directing them to appropriate sites (e.g., nursing stations, health centres, designated walk-in connected care clinics) if nirsevimab cannot be given during the home visit.
- Continuity of Care
  - Midwives provide nirsevimab (Beyfortus®) at the post-natal visit for infants born in their care (delegated task through Dr. Chiu, Manitoba High-Risk RSV Infant Program).
  - PHNs collaborate with midwives to confirm administration and ensure follow-up as needed.

# 5. What is Nirsevimab (Beyfortus®)?

- ➤ How does Nirsevimab (Beyfortus®) Work?
- Efficacy of Nirsevimab (Beyfortus®)
- ➤ Nirsevimab (Beyfortus®) Safety Profile

# What is Nirsevimab (Beyfortus®)?

# How Does Nirsevimab (Beyfortus®) Work?

- Not a vaccine does not rely on the infant's immune response.
- It binds to the RSV fusion (F) protein, blocking the virus from entering respiratory cells.
- Provides immediate passive immunity with ready-made antibodies.
- A single dose protects infants from RSV for 5–6 months.
- Especially valuable for young infants and children or those at high risk of severe disease (e.g., premature infants, those with certain cardiac or respiratory conditions, or immunocompromised infants).
- Weight-based dosing ensures appropriate protection.

Source: NACI Reference: Section 2.1, Background on RSV and Product Characteristics and Section 2.2, Immunogenicity and Mechanism of Action

## What is Nirsevimab (Beyfortus®)?

#### **Efficacy of Nirsevimab (**Beyfortus®)

- A meta-analysis of randomized controlled trials found that nirsevimab (Beyfortus®) RSV-associated hospitalizations by approximately 81% (95% CI: 64–90%) compared to placebo in healthy infants entering their first RSV season.
- A Phase IIIb study in healthy term infants showed similar findings: 83.2% efficacy (95% CI: 67.8–92.0%) in reducing hospitalizations compared to standard care.
- In Quebec (2023–24), real-world data showed nirsevimab (Beyfortus®) was highly effective—86% against ER visits, 89% against hospitalizations, and 88% against ICU admissions, with protection exceeding 80% across all groups. An estimated 41 at-birth or 58 catch-up doses were needed to prevent one RSV hospitalization. Current coverage prevented over half of RSV-related hospitalizations and ICU admissions, with potential to exceed 75% through earlier and broader catch-up coverage.

Source: NACI statement: Recommendations on the use of nirsevimab for the prevention of respiratory syncytial virus (RSV) disease in infants. May 15, 2024.

Canadian Immunization Guide (CIG) — Part 4: RSV (Nirsevimab & Palivizumab) Government of Canada, Updated May 2024.https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-4-active-vaccines/respiratory-syncytial-virus.html

Clinical trial data (RCTs & Phase IIIb); Carazo et al., 2025. medRxiv preprint <a href="https://doi.org/10.1101/2025.07.27.25332262">https://doi.org/10.1101/2025.07.27.25332262</a>

# What is Nirsevimab (Beyfortus®)?

### Safety Data: Nirsevimab NACI Summary (2024 statement)

- No increased risk of severe adverse events vs. placebo or palivizumab.
- Most adverse events mild or moderate.

#### **Most Common Side Effects**

(from product monograph <u>00070439.PDF</u>, within 7–14 days post-dose):

Adverse Event	Nirsevimab	Placebo
Rash	0.7 %	0.3 %
Fever (pyrexia)	0.5 %	0.6 %
Injection-site reaction	0.3 %	0 %

# 6. Storage and Handling

- ➤ Cold Chain & Storage- Immunization Stations
- ➤ Storage and Handling of Nirsevimab (Beyfortus®)

# **Storage and Handling**

#### **Cold Chain and Storage**

The Cold Chain refers to the process used to maintain optimal conditions during the transport, storage, and handling of products, starting at the manufacturer and ending with the administration of the product to the client.

- Insulated containers (coolers) with ice packs and cold gel packs can be used to temporarily store products at an off-site location.
- Health Care Providers are responsible to ensure appropriate temperature storage of products is maintained according to the manufacturer's requirements.
  - Insulating material should be used as a barrier to prevent direct contact between the product and the cold packs.
  - Cold gel packs should be replenished to ensure cold chain of products are maintained.
- Products should be kept in their original packaging until ready to prepare and administer to protect against breakage, exposure to light, and prevent direct contact with refrigerated gel packs.
- Cold Chain Protocol- Vaccines and Biologics: <a href="https://www.gov.mb.ca/health/publichealth/cdc/protocol/ccp.pdf">www.gov.mb.ca/health/publichealth/cdc/protocol/ccp.pdf</a>

# **Storage and Handling**

- Storage Conditions:
  - Refrigerate at 2°C 8°C
  - Keep in original carton to protect from light
  - May be kept at room temperature (20°C 25°C) for up to 8 hours
  - After removal from refrigerator, must be used within 8 hours or discarded
  - Do NOT freeze, shake, or expose to heat
- Handling:
  - No reconstitution required
  - Supplied as a sterile, preservative-free solution
  - Appearance: clear to opalescent, colourless to yellow
- Expiry:
  - Valid until the last day of the month listed

# 7. Nirsevimab (Beyfortus®) Ordering and Supply Information

- All participating locations may order nirsevimab (Beyfortus®) directly from the Provincial Vaccine Warehouse using the Manitoba Health Vaccines and Biologics Order Form <a href="https://www.gov.mb.ca/health/publichealth/cdc/protocol/vaccinebiologics.pdf">www.gov.mb.ca/health/publichealth/cdc/protocol/vaccinebiologics.pdf</a>.
- Applies to doses for all eligible infants (see "Program Eligibility").
  - If ordering for a high-risk infant / child, make note of high-risk status in the special delivery instructions section on the form.
- PHIMS Registered Users: Ordering can also be completed directly through PHIMS.
  - More information: PHIMS Inventory Support <a href="https://phimsmb.ca/support-tools/public-health/inventory/">https://phimsmb.ca/support-tools/public-health/inventory/</a>

- Informed Consent
- Pre-administration Counselling
  - ➤ Contraindications and Precautions

#### **Informed Consent**

Informed consent requires that the client, parent/guardian or legal decision maker must be provided with the information necessary to make a decision whether to have or to refuse treatment such as:

- Expected benefits and risks of the immunizations;
- Risks of the disease in the absence of product administration;
- Any other information (e.g., common side effects, contraindications, route of administration) that a reasonable person in the same circumstances would require in order to make a decision about the immunization.

Consent can be obtained verbally (and documented by the health care provider) or written onto the paper consent form by the client, parent/guardian or legal decision-maker. For Manitoba child/ adolescent immunization consent form see: <a href="https://www.manitoba.ca/health/publichealth/cdc/div/docs/child-immunization-consent-form.pdf">https://www.manitoba.ca/health/publichealth/cdc/div/docs/child-immunization-consent-form.pdf</a>.

Provincial Informed Consent Guidelines for Immunization are located at: <a href="https://www.manitoba.ca/health/publichealth/cdc/protocol/consentguidelines.pdf">www.manitoba.ca/health/publichealth/cdc/protocol/consentguidelines.pdf</a>

Prior to administration, the immunizer should:

- Screen for Eligibility
  - Confirm whether the infant's birthing parent received the RSV vaccine during pregnancy (check PHIMS or obtain verbal report).
    - If yes: Nirsevimab (Beyfortus®) is generally not recommended unless the infant is high risk (e.g., prematurity, chronic lung disease, significant congenital heart disease, or other qualifying conditions) or born <14 days after maternal vaccination. In such cases, consult the Manitoba High-Risk RSV Immunoprophylaxis Program.
    - If No: Nirsevimab (Beyfortus®) is recommended.

#### Check for Previous Nirsevimab (Beyfortus®) Administration

- Review immunization history carefully to avoid accidental duplicate dosing (safety data on repeat doses is limited).
- Verify through:
  - RSV Monoclonal Antibody Administration Reporting Form for Health Care Providers
  - Postpartum referral form
  - Infant referral form
  - Hospital discharge summary
  - Parent/legal guardian report
- If nirsevimab (Beyfortus®) was given in hospital: The RSV Monoclonal Antibody Administration Form should be sent along with the postpartum referral to Public Health as the record of administration.
- If uncertain whether the infant already received nirsevimab (Beyfortus® )→ do not administer.
- If confirmed not given in hospital → proceed with administration.

#### **General Pre-Administration Checks**

- Ensure proper client identification (two identifiers such as name and birthdate).
- Assess current state of health.
- Review contraindications and precautions (e.g., history of immediate or anaphylactic hypersensitivity to a previous dose or product components).
- Provide information on benefits and risks of receiving or not receiving nirsevimab (Beyfortus®).
- Ensure informed consent is obtained from parent/guardian or legal decision maker (or mature minor, if applicable).

# Pre-Administration Contraindications and Precautions- Nirsevimab (Beyfortus®)

Before administering nirsevimab (Beyfortus®), assess the client's health history (e.g., allergies, underlying medical conditions) and current health status to determine if it is safe for them to receive the product.

Nirsevimab (Beyfortus®) should **NOT** be administered to:

- Individuals who currently have an acute, febrile illness. Administration should be postponed until the individual has recovered.
- Individuals who are allergic to any active substance in nirsevimab (Beyfortus®) or to any ingredient in its formulation. Refer to the nirsevimab (Beyfortus®) product monograph for a complete list of ingredients <u>00070439.PDF</u>.
- Individuals with a history of anaphylaxis following a previous dose of nirsevimab (Beyfortus®).
- Infants whose birth parent received the RSV vaccine during pregnancy should not routinely receive nirsevimab (Beyfortus®), unless the infant is considered high risk (e.g., prematurity, chronic lung disease, significant congenital heart disease, or other qualifying medical conditions) or was born less than 14 days after maternal vaccination. In these situations, consultation with the Manitoba High-Risk RSV Immunoprophylaxis Program is recommended.

#### **Contraindications and Precautions**

Key resources to reference for contraindications and precautions include:

- <u>Nirsevimab</u> Passive Immunizing Agent (Human Monoclonal Antibody) Quick Reference Guide <u>Guide https://www.gov.mb.ca/health/publichealth/diseases/docs/nirsevimab-qrg.pdf</u>
- Nirsevimab fact sheet https://www.gov.mb.ca/health/publichealth/factsheets/nirsevimab-rsv-monoclonal-antibody.pdf
- Beyfortus® (nirsevimab) product monogragh https://pdf.hres.ca/dpd\_pm/00070439.PDF
- Respiratory syncytial virus (RSV) vaccines: Canadian Immunization Guide
   https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-4-active-vaccines/respiratory-syncytial-virus.html

# 9. Nirsevimab (Beyfortus®) Administration

- Infection Prevention and Control (IP&C)
- > 8 Rights of Administration
- Immunization Counselling and Comfort Measures
- Administration Supplies
- Assessing the Injection Site
- Landmarking for Vastus Lateralis
- Landmarking Deltoid Muscle
- Intramuscular Injection Technique
- Multiple Immunization Administration
- Beyfortus® (nirsevimab) Preparation
- Dosing

#### Infection Prevention and Control (IP&C)

- Staff providing immunizations in any setting should follow routine practices at all times and perform a Point of Care Risk Assessment (PCRA) to determine what Personal Protective Equipment (PPE) is required: <a href="mailto:sharedhealthmb.ca/files/routine-practices-protocol.pdf">sharedhealthmb.ca/files/routine-practices-protocol.pdf</a>.
- PPE must be available for all staff (medical grade masks, eye protection, N95 respirators)
  if required.
- Please visit <u>www.gov.mb.ca/health/publichealth/cdc/ipc.html</u> to review the *Immunization Program Clinics -Infection Prevention and Control (IP&C) Procedures/Processes* and for additional guidelines and resources.

#### 8 Rights of Administration

As part of preparation and administration of nirsevimab (Beyfortus®), the health care provider is responsible for checking the following rights:

- ✓ Right client obtain 2 client identifiers to ensure the product is being given to the correct client (e.g., date of birth (DOB), and/or contact information such as address and/or phone number).
- ✓ Right product (e.g., not expired)
- ✓ Right dose review client's age, weight and product information for correct dosage (i.e., 0.5 mL or 1 mL).
- Right time/schedule meets the minimum or recommended interval for the client to receive the product in order for it to be an effective and valid dose.
- ✓ Right route optimum route this immunization should be given (e.g., intramuscular).
- ✓ Right injection site optimum location chosen for administration based on age or product type (i.e., deltoid vs vastus lateralis).
- ✓ Right reason (e.g., meets eligibility criteria)
- Right documentation- ensure all the key documentation requirements have been completed.

#### **Immunization Counselling**

During each interaction, immunizers should encourage questions, address concerns/misinformation and provide valid/evidence-based information. Building trust is especially important with clients or parents who are hesitant to receive immunizations themselves or for their child.

The following link provides resources for immunization counselling and immunization hesitancy:

Counselling the Public | immunizecanada

#### **Pain Management and Comfort Measures**

- Comfort Positioning
  - Hold infant/child securely in upright position on caregiver's lap.
- Distraction Techniques
  - Use age-appropriate distraction: singing, talking, toys.
  - Engage caregiver to maintain calm presence.
- Topical Analgesia (Optional)
  - Apply topical anesthetic (e.g., lidocaine-prilocaine cream) prior to injection, if feasible.
- Breastfeeding or Sweet Solutions
  - Skin-to-skin contact during immunization injection (≤1 month of age).
  - Breastfeed during or immediately after injection.
  - For non-breastfed infants: offer sucrose solution (per regional protocol).
- Skilled Injection
  - Use appropriate needle size for age/weight.
- Post-Injection Comfort
  - Gentle rocking or holding.

For more information and resources on immunization pain management and comfort measures: Pain management <a href="https://immunize.ca/pain-management-children">https://immunize.ca/pain-management-children</a>, C.A.R.D (Comfort, Ask, Relax, Distract) – <a href="https://www.aboutkidshealth.ca/card/?topic=cardfamilies">https://www.aboutkidshealth.ca/card/?topic=cardfamilies</a>

#### **Supplies for Administration**

- Alcohol-based hand sanitizer or soap and water for hand hygiene
- Pre-filled nirsevimab (Beyfortus®) syringe(s)
- Appropriate safety engineered Luer Lock needle (size determined by infant's age/size & clinical judgement)
- Infant scale (for accurate weight-based dosing)
- Sterile alcohol swabs (for skin preparation)
- Cotton ball or gauze pad (to apply light pressure after injection)
- Adhesive bandage (if needed, though not routinely required)
- Sharps disposal container
- Anaphylaxis management kit (must be available on-site)
- Personal protective equipment (as per regional protocols)
- Documentation tools (RSV Monoclonal Antibody Administration Form <a href="https://www.gov.mb.ca/health/publichealth/cdc/div/manual/docs/rsv-monoclonal-ab-administration-form.pdf">https://www.gov.mb.ca/health/publichealth/cdc/div/manual/docs/rsv-monoclonal-ab-administration-form.pdf</a> chart, EMR, immunization record)

#### **Assessing the Injection Site**

- The vastus lateralis (anterolateral thigh) is the preferred injection site for infants under 1 year of age
  or who are not yet walking. For children over 1 year of age or walking, the deltoid muscle may be
  used, with clinical judgment applied to ensure the muscle is adequately developed to receive the
  product.
- When choosing the appropriate injection site, inspect the skin's surface for bruises, inflammation and palpate the site for masses, edema, or tenderness.
- Do not inject if any of these are found as there may be interference with absorption of the product.
- If unavoidable, product may be administered through a superficial birthmark.

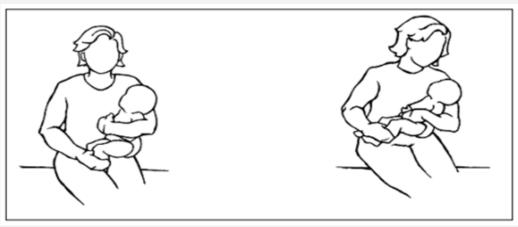
#### Intramuscular Injection Site Selection by Age

https://www.canada.ca/en/public-health/services/canadian-immunization-guide.html

Age Group	Preferred Site	Rationale	
Birth – 12 months	Vastus lateralis (anterolateral thigh)	Largest muscle at birth; safe distance from major nerves and vessels; best absorption.	
12 – 18 months	Vastus lateralis (primary) Deltoid (secondary, if adequate muscle mass)	Many still receive in the vastus lateralis unless deltoid muscle is well developed.	
18 months — 3 years  Public Health Agency of Canada. Canadian I. Information — Vaccine Administration Practic	Vastus lateralis or deltoid mmunization Guide: Part 1 — Key Immunization tess. Government of Canada. Updated 2024.	Choice depends on muscle mass and child's comfort.	

- Proper positioning ensures correct administration site.
- Guide parent/guardian to hold child so site is visible, and movement minimized.
- Older children: sit straight, deltoid exposed, arms/hands relaxed on thighs.

Examples of positioning for injection in the vastus lateralis:

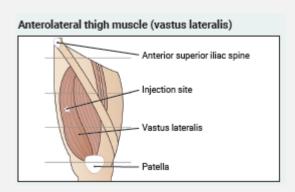


Source BC CDC

### **Identifying Injection Site for Vastus Lateralis:**

- Divide the space between the femoral trochanter and the top of the knee into three equal parts.
- Draw a horizontal median line along the outer surface of the thigh.
- The injection site is located in the middle third, just above this horizontal line.

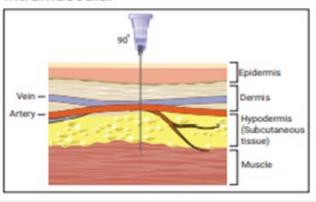




#### **Intramuscular Injection Technique**

- Perform hand hygiene by washing hands with soap and water or alcohol-based hand sanitizer.
- Cleanse the injection site with a new alcohol swab by circling from the center of the site outward for 1-2 inches. Allow to dry to avoid a burning sensation on insertion of the needle.
- If client's muscle mass is small, bunch or squeeze the muscle between the non-dominant thumb and fingers before and during the injection to increase muscle mass and minimize the chance of striking underlying bone.
- Alternatively, place your thumb and forefinger on either side of the site of injection and press the area flat. This method is recommended when clinical judgement has deemed a 5/8" needle appropriate for use based on client assessment.
- Insert the needle quickly at a 90° angle into the muscle.
- Do not aspirate (do not pull back on the plunger).
- Inject the product while maintaining stability of the limb and needle.
- Remove the needle in a swift motion.
- Activate the safety mechanism and discard into the sharp's container.
- A cotton ball can be used to apply pressure to the injection site to minimize bruising. Do not massage the injection site as this may damage underlying tissue. Use of adhesive bandages is not routinely recommended.

#### Intramuscular



#### **Multiple Immunization Administration**

There are many advantages of administering multiple immunizations at one visit:

- There is no delay in protection as it ensures individuals are protected against serious diseases earlier rather than later.
- There are fewer immunization visits which saves time for clients, parents/legal decision makers and health care professionals, is more cost efficient, and enhances immunization compliance.
- There are fewer periods of discomfort for the individual due to the lower number of immunization visits.

Some level of anxiety should be expected from parents or caregivers when their infant is receiving immunizations or other products. Immunizers should be prepared to use strategies that help reduce both injection pain for the infant and anxiety for the parent.

#### **Multiple Immunization Administration**

Immunizers should consider the following practices when administering multiple immunizations/products:

- Immunizations/products that are intended for separate administration should never be combined in the same syringe.
- It is best practice to draw up/prepare the multiple immunizations required for the individual client all at the same time; this ensures the client/parent does not have to wait for each product to be prepared between injections.
- Syringes should be labelled to identify which immunization/product each syringe contains.
- The site of administration of each immunization/product should be recorded, so that if an injection site reaction occurs, the associated immunization/product can be identified (e.g., deltoid, vastus lateralis).

### **Multiple Immunization Administration**

- When more than one immunization/product is to be administered in the same visit, it is preferable to use separate anatomic injection sites (different limbs) for each vaccine/product, but it is not necessary.
- When administering 2 or more immunizations in the same limb, separate the injection sites by as much distance as possible. A separation of at least 2.5 cm (1 inch) is preferred so local reactions are unlikely to overlap.

**Needle Selection and Maximum Volume Guidelines** 

Route of Administration	Needle Gauge	Age	Site	Needle Length	Max Volume
Intramuscular (IM)	(IM)	<28 days	Vastus lateralis	5 inch	1mL
90° angle		1 to < 12 months	Vastus lateralis	1 inch	1mL
	>12 months to 3 years	Deltoid muscle	5/8 inch to 1 inch	1mL	
			Vastus lateralis	1 inch to 1¼ inch	2mL

Source :National Advisory Committee on Immunization. (2017, November 3). *Canadian Immunization Guide: Part 1 – Key immunization information: Vaccine administration practices*. Public Health Agency of Canada

#### **Beyfortus® (nirsevimab) Preparation for Administration**

- Beyfortus® (nirsevimab) is supplied as a single-dose prefilled syringe.
- Supplied in doses of 50 mg / 0.5 ml (purple plunger) or 100mg /1 ml (light blue plunger).





- Reconstitution not required (Product is supplied as a sterile solution that is clear to opalescent, colourless to yellow solution).
- Preservative and latex free.
- Do not shake, freeze or expose to heat.
- Attach an appropriately sized sterile needle (based on age, weight, and recommended injection site).
- Confirm the correct dose volume according to age and weight.
- Do not mix with other products in the same syringe or vial.

The following steps outline the correct preparation and administration of Beyfortus® (nirsevimab) pre-filled syringes. To ensure product integrity and patient safety, follow each step carefully, using aseptic technique and observing safe injection practices.

#### Step 1:

Hold the Luer lock securely in one hand (do not hold the plunger rod or syringe body). With the other hand, twist the syringe cap counterclockwise to remove it.

#### Step 2:

Attach a Luer lock needle by gently twisting it clockwise onto the prefilled syringe until slight resistance is felt.

#### Step 3:

With one hand holding the syringe body, carefully pull the needle cover straight off with the other hand. Avoid holding the plunger rod to prevent movement of the rubber stopper. Do not touch the needle or allow it to contact any surface. Do not recap or detach the needle.

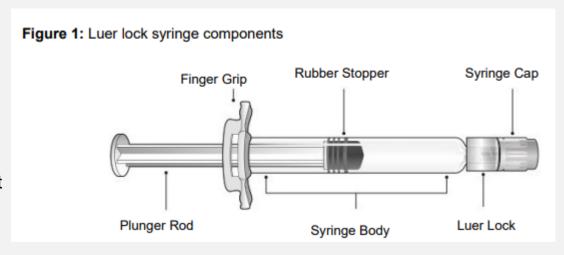
#### Step 4:

Administer the entire contents of the nirsevimab (Beyfortus®) pre-filled syringe as a single intramuscular injection.

#### Step 5:

Immediately dispose of the used syringe and needle in a sharp's disposal container, in accordance with local protocols. If a second injection is required, repeat steps 1–5 at a different injection site.

If two injections are required, repeat steps 1-5 in a different injection site.



Source: Beyfortus® Product Monograph

#### Dosage:

- 0.5 ml (50 mg) for infants < 5 kg</li>
- 1ml (100 mg) for infants ≥5 kg to <10 kg
- 2 ml (200 mg) in divided doses for infants ≥10 kg

#### Interval:

- Single dose
  - can be given concomitantly or at any time before or after childhood immunizations.

#### Note:

\* Nirsevimab (Beyfortus®) doses for Infants/ children in the high-risk category are provided by the Manitoba RSV immunoprophylaxis program. Special circumstances, such as infants undergoing cardiac surgery, may indicate a second dose. Infants/ children in some RSV high risk categories receive a follow up dose in their second RSV season.

When administered concomitantly with injectable immunizations, they should be given with separate syringes and at different injection sites.

- ➤Adverse Events
  - ➤ Anaphylaxis
- ➤ Adverse Event Following Immunization (AEFI) Reporting

#### **Adverse Events**

- Health Canada approves antibody products following a review of their quality and safety and are considered safe for use.
- Side effects are uncommon. If they occur, the most common include:
  - redness, swelling and soreness at injection site.
- All clients should be monitored for 15 minutes post administration to assess for any adverse events that may require immediate attention (i.e., syncope or anaphylaxis).
- There have been no reports of serious allergic reactions with nirsevimab (Beyfortus®), but this is a theoretic possibility.
   Risk of anaphylaxis is approximately 1 out of 1 million. Though very rare, anaphylaxis can occur following the administration of nirsevimab (Beyfortus®) and must be managed quickly and appropriately.
- If anaphylaxis occurs, the majority of cases arise within 15 minutes. However, some cases occur beyond 30 minutes.
- Usually, two body systems will be affected such as cardiovascular and integumentary systems.

#### **Adverse Events**

- Anaphylaxis
- Every provider should be familiar with the signs and symptoms of anaphylaxis and be prepared and equipped with an anaphylaxis kit to act quickly. Well established anaphylaxis response plans should be prepared by the team prior to administering, nirsevimab (Beyfortus®) including determining roles in anaphylaxis response (e.g., initiating emergency response (911), CPR, epinephrine administration, etc.).
- Anaphylaxis Kit

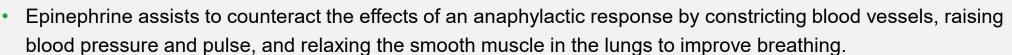
Nirsevimab (Beyfortus®) providers require an <u>anaphylaxis management kit(s)</u> that contain(s):

- Manitoba Provincial Anaphylaxis Protocol and a drug administration record
- Epinephrine dosage by weight and age requirements
- 3 vials of Epinephrine
- Injection supplies: syringes, needles, alcohol swabs, etc.
- In addition, the anaphylaxis kit may also include:
- One way valve face mask
- Stethoscope
- Sphygmomanometer
- Emergency telephone numbers
- Address/location of the clinic
- It is important that all immunizers refer to your region or site-specific anaphylaxis training requirements.
- For further information refer to:
- https://www.gov.mb.ca/health/publichealth/cdc/div/manual/docs/mb-anaphylaxis-protocol.pdf
- <a href="https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-2-vaccine-safety/page-4-early-vaccine-reactions-including-anaphylaxis.html">https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-2-vaccine-safety/page-4-early-vaccine-reactions-including-anaphylaxis.html</a>

#### **Adverse Events**

#### **Epinephrine**

Epinephrine is the lifesaving drug for anaphylaxis.



- It must be administered by intramuscular injection (IM). The preferred administration site is in the vastus lateralis muscle.
- Epinephrine is a short acting drug. Doses may need to be repeated every 5 minutes to a maximum of 3 doses as
  per protocol if assessment warrants. Within a short time period the client will begin to feel relief. Adverse effects of
  epinephrine may include anxiety, nausea and vomiting, headache, and heart palpitations.
- If anaphylaxis is suspected, it should be administered immediately.



- An adverse event following immunization (AEFI) is any untoward medical occurrence (e.g., anaphylaxis, Guillian Barre Syndrome (GBS)) in a
  immunization/antibody product recipient which follows product administration, and which does not necessarily have a causal relationship with the
  administration of the product. AEFIs need to be reported to the regional Medical Officer of Health (MOH) within seven days of the clinician becoming
  aware of the AEFI.
- Of particular interest are those AEFIs which meet one or more of the following criteria:
  - a. Is of a serious nature
  - b. Requires urgent medical attention
  - · c. Is an unusual or unexpected event
- Reporting AEFI's is part of Canada's vaccine safety and surveillance.
- For all serious AEFIs (e.g. anaphylaxis), health care providers must report to the Regional MOH within one business day, which can be done by telephone, followed by the complete report within 72 hours.

#### Review the following resources:

- Report of Adverse Events Following Immunization (AEFI) (AEFI report form)
- <u>User Guide for the Completion and Submission of the AEFI Reports</u> for definitions of a serious AEFI and how to complete the form.

For further information, refer to: Vaccine Safety | Province of Manitoba

### 11. Documentation

➤ Documentation & Reporting – Nirsevimab (Beyfortus®)

# **Documentation and Reporting**

#### Nirsevimab (Beyfortus®)Documentation

- Documentation Tool: RSV Monoclonal Antibody Administration Form <a href="https://www.gov.mb.ca/health/publichealth/cdc/div/manual/docs/rsv-monoclonal-ab-administration-form.pdf">https://www.gov.mb.ca/health/publichealth/cdc/div/manual/docs/rsv-monoclonal-ab-administration-form.pdf</a>
- Information Required for the Client's Official Immunization Record:
  - Client name, birthdate, Manitoba Health registration number, and birthing parent's name (Note: PHIN is typically assigned 4–8 weeks postbirth; Manitoba Health will enter the record once PHIN is available)
  - Immunization name (product and manufacturer)
  - Date of administration
  - Lot number
  - Dose
  - Site and route of administration
  - Name and professional designation of the provider

Immunizing Agent	
Date Given (yyyy/mm/dd)	
Lot Number	
Dosage	
Site of Administration	
Route	
Provider Name	

# **Documentation and Reporting**

### **Documentation & Reporting – Nirsevimab (Beyfortus®)**

- At Birthing Hospital
  - Administer nirsevimab (Beyfortus®)
  - Complete RSV Monoclonal Antibody Administration Form
  - Provide copy to parent / guardian
  - Fax to MB Health (204-945-6482)
    - MB Health enters into PHIMS after PHIN assigned
- If Given by Public Health (PHN)
  - Complete form
  - Fax to MB Health (204-945-6482)
    - MB Health enters into PHIMS after PHIN assigned
- If Infant Returning to Another RHA or FN Community
  - complete form
  - Fax to MB Health (204-945-6482)
    - MB Health enters into PHIMS after PHIN assigned
  - Fax record to local PH office / FN nursing station

Notify primary care provider/pediatrician (if on file)

**Note:** Doses are filed in the order received and entered into PHIMS approximately 3 months from receipt, allowing time for MB Health to create the infant's profile (PHIN assignment).

#### **Key points:**

- Centralized entry prevents duplicate profiles & merges
- Accurate documentation ensures continuity of care, avoids duplicate records, and supports program evaluation.

### 12. Resources

- Respiratory Syncytial Virus (RSV) Manitoba Health Program Website: <a href="https://www.gov.mb.ca/health/publichealth/diseases/rsv.html">https://www.gov.mb.ca/health/publichealth/diseases/rsv.html</a>
- Nirsevimab Quick Reference Guide: <u>https://www.gov.mb.ca/health/publichealth/diseases/docs/nirsevimab-qrg.pdf</u>
- Manitoba Paediatric RSV Immunoprophylaxis Program and Administration Pathways Frequently Asked Questions <a href="https://www.gov.mb.ca/health/publichealth/diseases/docs/paediatric-rsv-immunoprophylaxis-program-admin-pathways-faq.pdf">https://www.gov.mb.ca/health/publichealth/diseases/docs/paediatric-rsv-immunoprophylaxis-program-admin-pathways-faq.pdf</a>
- Beyfortus® (nirsevimab) Product Monograph <a href="https://pdf.hres.ca/dpd\_pm/00070439.PDF">https://pdf.hres.ca/dpd\_pm/00070439.PDF</a>
- Canadian Immunization Guide: <a href="https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-4-active-vaccines/respiratory-syncytial-virus.html">https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-4-active-vaccines/respiratory-syncytial-virus.html</a>