

# PALIVIZUMAB (PVZ) FOR IMMUNOPROPHYLAXIS OF RESPIRATORY SYNCYTIAL VIRUS (RSV) INFECTION

## PROCEDURE

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### Site Applicability

This Procedure and Decision Support Tool is applicable to all clinical areas at Children's and Women's, and is relevant to the RSV Clinic.

### Practice Level/Competencies

#### Foundational Skill:

The administration of the immunoprophylactic agent, palivizumab (PVZ), *with a provider order*, is a foundational skill for nurses. Nurses follow all medication administration practices and this decision support tool. Competency to recognize and address anaphylaxis is required. RN's and physicians may administer intramuscular injections that are within their scope and competencies.

#### Advanced Skill: Registered Nurse

##### Nurse Independent Activity (NIA)

Independent administration of PVZ to prevent respiratory syncytial virus (RSV) infection is considered an advanced skill for RNs. RNs may autonomously administer PVZ to approved patients (see inclusion/exclusion criteria below) *without a provider order* if they have the competencies and follow this approved decision support tool. Competencies required are:

#### Knowledge

- Demonstrates an understanding of the rationale & benefit of RSV immunoprophylaxis
- Demonstrates a general understanding of the immune system
- Differentiates between passive immunity (i.e. from a monoclonal antibody like nirsevimab) versus active immunity (e.g. from a traditional vaccine)
- Explains how RSV immunoprophylaxis works using basic knowledge of the immune system
- Demonstrates understanding of RSV immunization schedule & Program eligibility criteria
- Demonstrates an understanding of reporting responsibilities for adverse events/drug reactions (as per the Canadian Adverse Effects reporting system)

#### Skill

- Applies knowledge of components/properties of RSV immunoprophylaxis for safe & effective practice
- Assesses clients' health status (& immunization history); not unique in the sense the assessment is required to evaluate whether to proceed with injection on that visit. (see ["Judgement"](#) section below)
- Recognizes & responds to the unique immunization needs within BC's RSV Program
- Implements the BCCDC provincial guidelines when [storing/handling/transporting immunizing agents](#)
- Prepares & administers immunizing agents correctly
- Provides education to client's family re: [RSV, standard prevention/precautions](#), & [post immunization /symptom care](#)

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### Judgement

- Anticipates, identifies, & manages reactions following immunization
- Determines need for appropriate referral to physician or NP
- Documents information relevant to immunization in accordance with RSV Program guidelines & institutional policies, including consent.
- Determines need to postpone immunization (i.e., if child has been ill)

### Attitude

- Acts in accordance with legal & high ethical standards
- Respects individual choices & beliefs
- Demonstrates self-awareness of own beliefs, values, & practice limitations

Nurse Independent Activities (NIAs) are advanced competencies for nurses and require nurses to have the knowledge, skill and competency to perform the activity and manage the intended and possible unintended outcomes that can be reasonably anticipated.

Nurses performing NIAs are recommended to complete Autonomous Scope of Practice education. Refer to the Learning Hub course: [Understanding Autonomous Practice & Nurse Independent Activities \(NIA\) / Nurse-Initiated Protocols \(NIP\)](#)

### Policy Statement(s)

All healthcare providers administering PVZ must have the appropriate resources and plan in place to manage anaphylactic reactions or other potential adverse events. All healthcare providers ensure consent is obtained in alignment with the [PHSA Consent to Health Care Policy](#) and the BC Immunization Manual, Appendix A: Informed Consent. Completion of RSV program Authorization for Treatment form prior to administration of palivizumab (PVZ) is required.

Nurse Independent Activities (NIAs) and Nurse Initiated Protocols (NIPs) are supported at BCCH/BCW and are defined by policy: [Nurse Independent Activities \(NIAs\) and Nurse Initiated Protocols \(NIPs\).pdf](#)

A prescriber order takes precedence over a Nurse Independent Activity or Nurse Initiated Protocol.

As per the [BCCNM scope of Practice](#), RNs who compound, dispense or administer immunoprophylactic agents for the purpose of, preventing respiratory syncytial virus infection, must possess the competencies as outlined in this document and follow this decision support tool.

### Equipment & Supplies

- Refer to [Palivizumab preparation](#) Standard Work
- Refer to [vaccine-management](#) BCCDC [How to Pack an Insulated Cooler](#)
- Refer to [Storage and handling](#) BCCDC. Report suspected cold chain breaks immediately to the RSV desk at [rsv@cw.bc.ca](mailto:rsv@cw.bc.ca). The RSV 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.

### Contraindications

- known hypersensitivity to PVZ or any components of the medication
- known hypersensitivity to other humanized monoclonal antibodies
- Patients who exhibit a severe hypersensitivity reaction (permanent discontinuation is advised)

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### Special Considerations

- A mild febrile illness, such as a mild upper respiratory infection, is not usually a reason to defer administration of PVZ; withholding PVZ entails a greater risk. However, a moderate or severe acute infection or febrile illness may warrant delaying the use of PVZ.
- Administration of PVZ to patients with thrombocytopenia or any coagulation disorder requires caution (refer to individual hospital policy). Use a fine gauge needle of appropriate length and apply firm pressure, without rubbing, for 5 minutes following injection.
- If a patient, who has started RSV Immunoprophylaxis, is readmitted to hospital for a condition other than RSV infection, for a short period, and is due a routine dose, then one dose may be given.

### Unintended Outcomes

Anaphylaxis has rarely occurred. In the event of anaphylaxis, be prepared to treat with epinephrine in appropriate paediatric dosage; follow employer policy for emergency treatment of anaphylaxis.

To report any adverse reactions:

1. Notify RSV Program directors.
2. Report the adverse reaction to your local health authority after reviewing BCCDC guideline for Canadian Adverse Effects: [reporting adverse events](#)
  - Adverse events following receipt of a passive immunizing agent such as PVZ; including in instances where a vaccine is given at the same visit, and the adverse event cannot be specifically associated with any given product administered at that visit, should be reported using the procedures for reporting an adverse drug reaction to the [Canadian Adverse Drug Reaction Monitoring Program at Health Canada](#)

### Inclusion Criteria for RSV prophylaxis

- Infants approved and registered, in the BC RSV program, to receive outpatient dosing in the current season.
- No doses are to be administered after end of season, unless the infant was premature (i.e., less than 35 weeks GA) at delivery, and otherwise eligible, and discharged for the *first time* within two weeks of end of season. These infants may receive a single dose of PVZ before going home.

### Exclusion Criteria

- Healthy term infants and Infants > 2 years of age at start of season
- Hospitalized eligible infants, unless and until ready for discharge
- RSV+ (hospitalized or not). Note: severe immunocompromised patients may be considered.

### Special Considerations

Potentially eligible infants discharged pre-season will be tracked, enrolled, then dosed, if approved, once outpatient RSV clinics commence.

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- For eligible infants, still in hospital at season start, administer **Dose 1**, 1-3 days prior to discharge home. Up to 7 days prior is acceptable if discharge date is certain and to allow for cluster dosing to minimize wastage.
- Administer **Dose 2**, 3-4 weeks after Dose 1.
- After Dose 2**, administer at 4-5 week intervals (up to the prescribed dose number).
- A 3-4 dose regimen will apply, with the exception of qualifying children with cardiac conditions, who undergo repair under bypass, and discharged home within season. Infants in this group will receive a post-operative dose of PVZ, even if this is a fifth dose; once medically stable, ready for discharge, and *they still qualify for PVZ prophylaxis*. This additional dose will **not** require a separate adjudication.
- Patients who receive palivizumab in a given season should only continue to receive palivizumab until the end of the season, and should not receive the other RSV immunoprophylaxis nirsevimab in the same season. Reciprically, patients who received nirsevimab in a given season should not receive palivizumab in the same season.

## Procedure for Administering PVZ

STEPS	RATIONALE
<ol style="list-style-type: none"> <li>Administer PVZ via the intramuscular route only. <ul style="list-style-type: none"> <li>Preferred site: vastus lateralis.</li> <li>Maximum volume: 1ml per site in infants</li> </ul> </li> </ol>	As recommended by <a href="#">BCCDC</a>
<ol style="list-style-type: none"> <li>Cluster dosing and vial sharing is encouraged and practiced.</li> <li>Each 50mg vial has an approx. 10% overfill resulting in 55mg obtainable when vial handled appropriately.</li> </ol> <p>Remove from refrigeration and label each vial with the time. Invert for 10-20 minutes before withdrawing any medication.</p>	<p>PVZ is an exceptionally expensive medication. The goal of the BC RSV Immunoprophylaxis Program is to provide PVZ to qualifying infants, with maximum efficiency.</p> <p>For ambulatory patient care: it is strongly recommended children receive PVZ doses from the central site in their region, through same-day, centralized, hospital-based outpatient clinics, in order to cluster dose and avoid wastage.</p>
<ol style="list-style-type: none"> <li>PVZ vials should be used within 6 hours after first puncture.</li> </ol>	Coordinate the timing of each dose so all PVZ is used within the 6 hour timeframe. Discard unused PVZ after 6 hours.
<p>Dose Calculation</p> <ul style="list-style-type: none"> <li>Patient weight (<b>kg</b>) X 15 mg/kg = X mg to be administered.</li> <li>Round dose to the nearest <b>mg</b>.</li> </ul>	<p>X mg to be administered / 100 mg/mL = XmL to be administered.</p> <ul style="list-style-type: none"> <li>* Example: If weight = <b>4.3kg</b> (4.3kg x 15mg=64.5mg) dosage calculated is <b>64.5 mg</b></li> <li>* Rounded dose to administer = <b>65mg</b></li> </ul>
Dosage ceilings:	A 3-4 maximum dose regimen will apply to all approved registrants.

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<ul style="list-style-type: none"> <li>Infant with no cardiac disease and no CLD and premature <math>\geq 29w</math> +Risk Factors <math>&gt; 41</math> .....Max. 3 doses</li> <li>Infants approved under all other criteria .....Max. 4 doses</li> </ul>	<p><u>Note:</u> The exception of qualifying Cardiology patients under the following circumstances:</p> <ul style="list-style-type: none"> <li><i>Surgical repair under cardiac bypass, <b>and</b> discharged home within season.</i></li> <li>Infants in this group will receive a post-operative dose of PVZ, even if this is a fifth dose. Dosing given once medically stable, ready for discharge, and <i>they still qualify for PVZ prophylaxis.</i></li> <li>This additional dose will <b>not</b> require a separate adjudication.</li> </ul>
<p>Monitor all children for 15-20 minutes after each dose to assess for hypersensitivity and/or anaphylaxis. If the family/guardian chooses not to remain under supervision after immunization, inform them of any signs or symptoms of anaphylaxis and instruct them to obtain immediate medical attention should symptoms occur.</p>	
<p>Document PVZ administration as per the <a href="#">Medication Administration Policy</a> in the patient health record.</p>	
<p>Complete required RSV <a href="#">Dosing log</a> and return to RSV program. Include</p> <ul style="list-style-type: none"> <li>Trade name of the product</li> <li>Date given (day, month and year)</li> <li>Site and route of administration</li> <li>Lot number and expiry dates</li> <li>Name and title of person administering the vaccine</li> </ul>	<p>Quality control and outcome evaluation are integral components of the RSV Program, requiring standardized documentation and reporting. This requirement is part of official agreements between the PHSA and the Health Authorities.</p> <p>Providers maintain accurate records of all doses given, using the RSV Dosing Log.</p> <p>For patients who get their first dose while still in hospital, or are transferred between sites, an up-to-date copy of the Patient Log will be forwarded to the clinic administering the remainder of the doses, <b>and</b> the RSV Program at the Children's &amp; Women's Pharmacy</p> <ul style="list-style-type: none"> <li>* The sending site must confirm the receiving site has received the transfer information.</li> </ul> <p>Submit completed copies of the Patient Log from every patient seen during each day to the RSV Program at <a href="mailto:rsv@cw.bc.ca">rsv@cw.bc.ca</a> or by fax to 604-875-2879 (for inventory management and outcome evaluation)</p>
<p>When a scheduled immunization is not given, record the following:</p> <ul style="list-style-type: none"> <li>The reason why the dose was not given</li> </ul>	

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<ul style="list-style-type: none"> <li>The planned follow-up action. Examples: <ul style="list-style-type: none"> <li>Parent/guardian refusal</li> <li>Severe illness</li> <li>Contraindication to vaccine to be offered</li> </ul> </li> </ul>	
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## Glossary & Definitions

### Active Immunity

An immune capacity produced within and by the host body. Naturally acquired active immunity occurs when the person is exposed to a live pathogen, and becomes immune as a result of the primary immune response. Artificially acquired active immunity can be induced by a vaccine, a substance that contains the antigen – i.e. one or more components of the pathogen. A vaccine stimulates a primary response against the antigen without causing the typical disease associated with the pathogen.

### Clinic

Any site where a patient receives a dose of palivizumab (PVZ), even if there is only one patient attending, and includes the child's home as well as a physician's office.

### Humanized monoclonal antibody

An antibody produced by commercial cells, in a manufacture or lab setting. As such, a monoclonal antibody is a single, pure type of antibody. Monoclonal antibodies can be made in large quantities in the laboratory.

### Immunoprophylaxis

The prevention of disease by the production of active or passive immunity. The use of either vaccines or antibody-containing preparations to provide immune protection against a specific disease.

### Passive Immunity

The transfer of active immunity, in the form of ready-made antibodies. Passive immunity can occur naturally, when maternal antibodies are transferred to the fetus through the placenta, and can also be also be provided therapeutically in the form of antibodies, such as gamma globulin or palivizumab, for short-term immunization.

### Respiratory Syncytial Virus (RSV)

RSV is a major cause of respiratory illness in young children. It causes infection of the lungs and breathing passage, leading to bronchiolitis or pneumonia. While most infants will only express mild respiratory symptoms, children under 3 months of age are at higher risk of requiring hospitalization due to RSV. About 1 - 2% of all children will require hospitalization due to RSV in their first year. Premature babies and infants/children with diseases that affect the heart, lungs and immune system are at higher risk of requiring prolonged hospital admission and to be admitted to the intensive care unit. RSV is typically identified in nasal secretions, which can be collected with a nasal pharyngeal washing. RSV is highly contagious, and can be spread through droplets containing the virus when an individual coughs or sneezes. The virus can persist on surfaces for many hours and for over half an hour on skin. RSV infections often occur in epidemics that last from late autumn through early spring. In BC the RSV season typically lasts from November to April.

### Vaccination

The act of introducing a vaccine into the body to produce protection from a specific disease. Vaccines contain a microorganism or virus in a weakened, live or killed state, or toxins from the organism.

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**NOTE:** palivizumab is not a vaccine.

### Recommended Resources and Related Documents

BCCNM Registered Nurses Scope of Practice: Standards, Limits and Conditions. September 2021.  
[https://www.bccnm.ca/Documents/standards\\_practice/m/RN\\_ScopeofPractice.pdf](https://www.bccnm.ca/Documents/standards_practice/m/RN_ScopeofPractice.pdf)

Related BCCNM standards of Practice

1. [Standards for Acting within autonomous scope of practice](#)
2. [Medication](#)

Cost Effectiveness of Prophylaxis

1. Nuijten MJC, Wittenberg W, Lebmeier M. Cost Effectiveness of Palivizumab for Respiratory Syncytial Virus Prophylaxis in High-Risk Children. *Pharmacoeconomics* 2007;25:55-71

Pain Management

1. <https://bcmj.org/bccdc/reducing-immunization-injection-pain-infants>
2. Taddio A, et al. Reducing Pain of childhood vaccination: An evidence-based clinical practice guideline (summary). *CMAJ*. December 14, 2010, 182(18); 1989-95  
<http://www.cmaj.ca/content/182/18/1989.full.pdf+html>

Position Statements

1. Canadian Pediatric Society (CPS). Preventing hospitalizations for respiratory syncytial virus infection *Paediatric Child Health* 2015;20(6):321-26 Reaffirmed: Jan 1, 2021:  
<https://cps.ca/en/documents/position/preventing-hospitalizations-for-rsv-infections>
2. Canadian Pediatric Society. [Use of Palivizumab in Children with Congenital Heart Disease. \*Paediatric and Child Health\* 2003;8:631-633](#)

Standard Work

[Palivizumab preparation](#)

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### References

- BC Centre of Disease Control  
[www.bccdc.ca](http://www.bccdc.ca)
- British Columbia RSV Immunoprophylaxis Program Information [www.childhealthbc.ca](http://www.childhealthbc.ca) under “RSV Immunoprophylaxis”
- British Columbia College of Nurses and Midwives (BCCNM) Practice Standards and Scope of Practice for Registered Nurses <https://www.bccnm.ca/RN/PracticeStandards/Pages/Default.aspx>
- Canadian Association of Neonatal Nurses: [www.neonatalcann.ca](http://www.neonatalcann.ca) Enter “Respiratory Syncytial Virus (RSV) in the search box
- Canadian Pediatric Society (CPS): Position Statements [RSV](#)
- Manufacturer/distributor website for palivizumab: [www.rsvshield.ca](http://www.rsvshield.ca)
  - PVZ monograph: <https://www.astrazeneca.ca/content/dam/az-ca/downloads/productinformation/synagis-product-monograph-en.pdf>
- The National Advisory Committee on Immunization (NACI). An Advisory Committee Statement (ACS): [Recommended use of palivizumab to reduce complications of respiratory syncytial virus infection in infants](#)
- The Public Health Agency of Canada outlines cold chain practices at: <https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-1-key-immunization-information/page-9-storage-handling-immunizing-agents.html>

### Version History

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