

BC RSV Immunoprophylaxis Program

ADMINISTRATIVE MANUAL AND DECISION SUPPORT TOOL

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While every attempt has been made to ensure the information contained herein is clinically accurate and current, the BC RSV Immunoprophylaxis Program acknowledges this information may change over time as evidence becomes available.
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MANDATE & VISION STATEMENT

The BC RSV Immunoprophylaxis Program (“the RSV Program” / “the Program”) is a Provincial Health Services Authority program whose mandate is to determine eligibility for funded RSV immunoprophylaxis and administer doses to those so identified; and 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.

PURPOSE OF THIS MANUAL / DECISION SUPPORT TOOL

This manual primarily exists to elaborate on BC’s RSV Program and on the guidelines for enrolment. As the Program is evidence based, details regarding eligibility for RSV immunoprophylaxis and clinic practice may be subject to minor change, and therefore this annually updated manual keeps BC’s clinics apprised.

As a decision support tool this resource also provides an evidence-based guide regarding the administration of immunoprophylaxis for RSV, as well as the enrolment of high-risk infants into BC’s RSV Program. When making clinical decisions this tool is to be used in conjunction with clinical judgment, available evidence, discussion with colleagues, and consideration of client needs and preferences.

STRUCTURE

The RSV Program’s **EXECUTIVE COMMITTEE** comprises:

- The Chair of the Advisory Committee;
- The Children’s & Women’s Pharmacy Coordinator;
- The Program Administrative Director;
- The Program Medical Director; and
- The Provincial Clinic Coordinator.

The **ADVISORY COMMITTEE** comprises:

- A Chair, elected by the Advisory Committee in three-year terms;
- All RSV Program Executive Committee members (listed above);
- Applicable paediatric subspecialty representatives when available, e.g.:
 - Cardiology,
 - Immunology,
 - Infectious Diseases,
 - Neonatology, and
 - Respirology
- Two nursing representatives of the RSV Clinics; and
- Representatives of each BC Health Authority.

The **ADJUDICATION PANEL** comprises:

- Three Program-aligned physicians; and
- A fourth alternate member.

Further information regarding the structure of the RSV Program and its members can be found in the program Terms of Reference in Appendix V.i and the contact lists in Appendices V.ii/V.iii.



INFORMATION SHARING AND RELATIONSHIP WITH BC'S HEALTH AUTHORITIES

An Information Sharing Plan (ISP) has been completed by the RSV Program in consultation with:

- The Information Privacy Offices of the Fraser Health Authority;
- The Interior Health Authority;
- The Northern Health Authority;
- The Provincial Health Services Authority;
- The Vancouver Coastal Health Authority; and
- The Vancouver Island Health Authority.

The approved ISP forms part of - and is subject to the terms and conditions of - the General Health Information Sharing Agreement (GHISA).

ARMS-LENGTH RELATIONSHIPS

In support of the RSV Program mandate and in alignment with the Canadian Paediatric Society (CPS) recommendations, no member of the Program's Advisory Committee or of the Adjudicator Panel shall have either a real, potential, nor perceived Conflict of Interest (as defined in the glossary on pages 19-20).

This preserves the objectivity and credibility of the guidelines and the RSV administration processes. For greater clarity, no one with a relationship or interest in a pharmaceutical vendor that manufactures palivizumab shall participate in the development of the guidelines or in the adjudication process.

APPLYING FOR ENROLMENT

- Assess for Program eligibility (as per the Eligibility Criteria on Page 06)
- Discuss risks and benefits with the family
- Complete the RSV Program's Application Form and submit to RSV Desk, either via:
 - Email: rsv@cw.bc.ca (preferred method).
 - Fax: 604-875-2879 or toll-free 1-877-625-7555.

PROTOCOL FOR APPLYING

- Email applications should only be sent from secure hospital/Health Authority addresses. Requests originating outside of secure locations must be faxed.
- Application Forms must include supporting clinical rationale.
- If the patient is in hospital after 01-Nov-2020, the discharge date may be estimated.
- Final approval of all applications is dependent on at least one signature from a health care professional on a faxed completed Authorization for Treatment Form.

ADJUDICATIONS OF APPLICANTS NOT MEETING AUTOMATIC ELIGIBILITY

An adjudication occurs when an enrolment request (i.e., an Application Form) is submitted for a high-risk infant who does not meet criteria for automatic eligibility.

WHEN SUBMITTING AN APPLICATION FOR ADJUDICATION

Applications for adjudication may be made prior to discussion with the family.

To submit an application for adjudication:

- Fill out and submit Application Form and Authorization for Treatment Form as normal.
- Attach up-to-date relevant medical records.
- Attach a supporting letter from either an Infectious Disease Specialist, a Neonatologist, or Respirologist. If a supporting letter cannot be obtained due to limited accessibility to a specialist in one of the above fields, this should be clearly stated on the Application Form.
- Describe the applicant's specific medical illness detailing the clinical rationale for the application. Provide sufficient clinical details as it relates to the applicant and risk for severe RSV disease.
- Briefly and specifically describe the general health of the applicant, especially with respect to respiratory conditions. Mention any medications they are taking.

PANEL STRUCTURE & PRACTICE

- Adjudication will be conducted by a panel of three physicians and resolved with a majority vote.
- The panel will have the capacity for a fourth alternate, for in the event of an absence in the panel.
- Adjudicators will have no real, potential, nor perceived conflict of interest (as defined in the glossary on pages 19-20).
- No adjudicator may adjudicate their own patients, and must recuse themselves from the panel of three with respect to that case.

ADJUDICATION PROCESS AND GUIDELINES

- Adjudications will be processed based on receipt of a fully completed Application Form and supporting clinical rationale.
- Although adjudications may be processed without evidence of consent, for final approval, completed Application Forms and Authorization for Treatment Forms are still required. Telephone consent is acceptable if necessary.

[continued on following page]

- Nearly all second-season requests will be adjudicated. First-season requests for complex infants without significant prematurity, chronic lung disease, or significant congenital heart disease will still require adjudication.
- Adjudications will generally be processed within five working days. The adjudication process will be audited in real-time for time-to-response, and each variance will be pursued and reported.
- Infants with significant congenital heart disease will not require adjudication for their first year as long as the application is supported by their cardiologist, with adequate documentation.

FORMS AND REPORT-BACK

The forms included in this manual are mandatory, each providing a benefit to the patient or to the Program's ability to collect long-term data. This enables outcome review, without which the Program cannot function, and ensures consent has been obtained by a person responsible, and to facilitate parental consent for audit and follow up.

The forms for parents (in Appendices III.ii–III.iv) should be given to any parent whose child is identified at high risk for RSV infection this season.

Forms related to the application process and patient tracking are in Appendix II. The program requires standard reporting on all infants receiving palivizumab throughout the RSV Season and at season end. All forms can be either sent by email to rsv@cw.bc.ca, or by fax at 604-875-2879 or toll free at 1-877-625-7555. The health care professional should also document palivizumab information as per organization policy.

Please submit applications as soon as feasible. RSV Program forms include the following:

Form	Timeline of submission	Purpose
Application Form	Prior to enrolment	Confirms eligibility
Authorization for Treatment Form	Prior to enrolment	Confirms informed consent
Hospitalization Data Form	Each time patient is hospitalized throughout RSV season	To report respiratory admissions
Patient Log	End of each clinic	Facilitates tracking/inventory

SEASON DURATION

RSV-related illness normally has a consistent November-March trend. The RSV Executive Committee determines the commencement date for RSV immunoprophylaxis annually.

The 2020/21 RSV Season (i.e., dosing of RSV immunoprophylaxis) will begin on November 09 and ends the following March 31 with the following exceptions:

- Infants may receive one dose in the first two weeks of April if they meet all of the following criteria:
 - Discharged home for first time between April 01-April 14; AND
 - Otherwise automatically eligible for palivizumab due to prematurity/chronic lung disease; and
 - Under 35 weeks gestational age (GA) at birth.
- Clinics in the NHA have an adjusted season schedule (as detailed below).

INFANTS RESIDING IN NORTHERN HEALTH REGIONS

The RSV season in northern BC usually starts and ends later. To reflect this, the executive committee acknowledges some differences for clinics in the Northern Health Authority. In these areas the season start date will be three weeks later than other regions, and the season end date is one month later (on April 30). No palivizumab will be given after that time.

Infants 29-34 weeks GA age at birth who reside in NHA regions will be awarded 20 Risk Factor points for discharge in March / 10 points for discharge in April (instead of 10 points / 0 points, in other BC regions).

ELIGIBILITY CRITERIA

Palivizumab is not recommended or funded for prevention of health care-associated RSV disease (i.e., in-hospital outbreaks or transmission), nor for treatment of RSV illness.

There are two avenues to meet eligibility for enrolment:

- The infant has a pre-approved indication (as detailed below); or
- An application for adjudication is approved by the adjudicator panel.

MAXIMUM AGE FOR CONSIDERATION FOR PALIVIZUMAB

No one born prior to 01-Nov-2018 will be eligible, regardless of their clinical condition. Most children 2+ years of age have antibodies to RSV, and within this population there is no evidence of benefit.

PRE-APPROVED INDICATIONS

The following infants will automatically be eligible for prophylaxis:

- Ex-premature infants with Bronchopulmonary Dysplasia / Chronic Lung Disease (i.e., O₂ or CPAP at > 28 days) and born on or after 01-Nov-2019 and requiring continuous O₂ on or after 01-Jul-2020 due to chronic lung disease (i.e., O₂- or CPAP-dependent at 28 days of age or 36 weeks corrected age)
- Infants born at < 29 weeks GA and discharged home on or after 01-Sep-2020
- Infants born between 29 weeks to 34^{6/7} weeks GA without Bronchopulmonary Dysplasia and discharged home on or after 01-Oct-2020 and with a risk factor score of ≥ 42 points
- Infants requiring home respiratory support (e.g., home O₂, CPAP, tracheostomy) on or after 01-Nov-2020 and born on or after 01-Nov-2018
- Hemodynamically significant congenital heart disease AND born on or after 01-Nov-2019 (i.e., less than 1 year of age on 01-Nov-2020)¹
- Multiple of an approved child and under 35 weeks GA at birth and born on or after 01-Nov-2019 (i.e., < 1 year age at season start)
- Infants with Down Syndrome and DOB on or after 01-April-2020

INDICATIONS REQUIRING ADJUDICATION

Infants with the following conditions require adjudication (may not be an exhaustive list):

- Progressive neuromuscular disease and inability to clear secretions and DoB on/after 01-Nov-2018
- Severe immunodeficiency (i.e., stem cell transplantation, infant ALL/AML, infant brain tumor intensive protocol, SCIDS, ICE protocol) and born on or after 01-Nov-2018
- Significant cardiopulmonary disability (i.e., pulmonary hypertension, pulmonary hypertension, severe
- Bronchopulmonary Dysplasia, symptomatic Cystic Fibrosis, cardiac palliation, other) and DoB on or after 01-Nov-2018

NOTE:

- The presence or absence of risk factors is relevant to all adjudication requests.
- Infants under 2 years of age on 01-Nov-2020 who are on home oxygen or home ventilation, remain automatically eligible.
- Applications for infants with congenital heart disease should be supported by the infant's cardiologist (include the physician's name) as well as details on the type of heart disease, date of surgery/ surgeries, medications, or other medical support. Please describe this clinical reasoning on the Application Form.

¹ NOTE: The application for such infants must be supported by their cardiologist with clinical details

RISK FACTORS

- Regular attendance at home or facility-based group (in first 3 months after discharge)²: 22 points
- Discharged home in December, January, or February³: 20 points
- Discharged home in November or March³: 10 points
- Female not receiving human milk⁴, or Male (all): 8 points
- GA age at birth = 29-30^{6/7} weeks: 10 points
- Other child < 5 years old living in the same household (not including multiples of applicant):... 14 points
- ≥ 6 people residing in the household (including applicant and multiples of applicant): 12 points
- Infants residing in a remote location⁵:
(i.e., > 100 km by ground transport to nearest hospital able to provide paediatric care): 10 points
- Birth weight ≤ 10th percentile for GA at birth: 8 points
- ≥ 2 smokers in the household⁶: 8 points

For premature infants 29-34^{6/7} weeks of age with no chronic lung disease, the RSV Program will continue to apply a risk scale that cumulatively scores risk factors, and will again require a minimum of 42 points to meet eligibility.

² Day care is strongly discouraged in the first year, especially in those at increased risk.

³ For infants residing in Northern Health regions, **20 points** are awarded for discharge in March; **10 points** for discharge in April.

⁴ "Receiving breast milk": Refers to any regular consumption of human milk, including by bottle.

⁵ "Remote Location": Refers to 100 km OR 1 hour by ground transport to nearest hospital/point of care.

⁶ Exposure to cigarette smoke is contra-indicated for all infants.

ASSESSMENT

During a clinic day, perform a brief assessment of patient's health to identify any considerations or contraindications to RSV Immunoprophylaxis. Defer RSV Immunoprophylaxis when appropriate and according to the BC Guidelines for RSV Infection and Immunoprophylaxis (on Pages 4-7). It is the responsibility of the health care professional to assess benefit vs. risk of delaying Immunoprophylaxis.

CONSIDERATIONS:

- A mild febrile illness, such as a mild upper respiratory infection, is not usually a reason to defer administration of palivizumab; withholding palivizumab entails a greater risk. However, a moderate or severe acute infection or febrile illness may warrant delaying the use of palivizumab.
- Administration of RSV Immunoprophylaxis to patients with thrombocytopenia or any coagulation disorder needs to be given with 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 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.

CONTRAINDICATIONS:

- Patients with known hypersensitivity to palivizumab or any of its excipients;
- Patients with known hypersensitivity to other humanized monoclonal antibodies;
- Patients who react with a severe hypersensitivity reaction (at which point administration of palivizumab should be permanently discontinued); and
- Hospitalized patients (i.e., only administer to outpatients and inpatients ready for discharge).

TO NOTE:

- If further questions are needed to be addressed, contact the RSV Desk at rsv@cw.bc.ca.
- During the clinic visit, the clinician will need to support parents' efforts to implement pain management techniques (see the pamphlet in Appendix III.iii).
- Since the monoclonal antibody is specific for RSV, palivizumab is not expected to interfere with the immune response to vaccines, including live viral vaccines. Therefore, routine immunizations may be given concurrently with palivizumab.

The below table shows an example of an assessment tool:

<p>1) Assess patient wellness – recent or current illnesses/surgery/hospital admissions <i>Is your child well today? Has s/he been recently ill? Has s/he required surgery or been admitted to a hospital?</i></p>
<p>2) Identify and confirm allergies <i>Does your child have any allergies? or My records indicate that your child is allergic to... or Have there been any additional reactions or changes?</i></p>
<p>3) Review current medication <i>Is your child on any medications? Have there been any medication changes since his/her last visit?</i></p>
<p>4) Review recent vaccinations <i>Has your child received any vaccines/needle injections in the last 24 hours?</i></p>
<p>5) Identify adverse reactions <i>How did your child respond to his/her last injection? Any reactions noted?</i></p>
<p>6) Obtain child's weight</p> <ul style="list-style-type: none"> • Consider utilizing a recent weight, within the last 48 hours, if done by a health care professional; ensure child was weighed naked / with dry diaper, depending on your policy. • Address concerns/questions that can be discussed while weighing the child.

CLIENT EDUCATION

Palivizumab must be administered on schedule throughout the season in order to maintain the serum concentration at a level sufficient to provide protection against RSV; while the infant may still experience morbidity due to RSV illness after receiving palivizumab, the effect is less severe.
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There are many ways to reduce a child's risk of contracting RSV. Discussing and reviewing these measures with the family/guardians is required. Communicating with parents the benefit of palivizumab in reducing RSV-associated illness and hospitalizations may also increase compliance.

Appendix III includes tips regarding how best to communicate with families and hand-outs for parents.

CONSULTATION / OUT OF PROVINCE REFERRAL

The RSV Program liaises with similar programs in other provinces and territories. In the event an infant whose health care is covered by another province requires dosage in BC, then, with the understanding the home province would reimburse the RSV Program, the Program would provide doses as per the eligibility requirements of that infant's home province (regardless of whether they would be eligible for doses under the auspices of BC's guidelines).

All requests for dosage by the RSV Program must be forwarded to the RSV desk at rsv@cw.bc.ca for review. All referrals will be reviewed for eligibility. Only referrals that have received approval and are issued a provincial registration number will be eligible to receive RSV Immunoprophylaxis.

There are two scenarios in which a patient from out-of-province may require a dose of palivizumab:

1. The patient is in a BC hospital (e.g., in NICU) and does not have prior approval in their home province or territory; and requires a dose of palivizumab prior to discharge home. The program will forward the referral to the patient's province or territory of residency. Once approval has been decided by the home province or territory, the program will notify the site of the approval.

NOTE: Eligibility criteria is decided by the patient's home province or territory, and may differ from BC's criteria.

2. The patient has travelled to BC and has already been approved for RSV Immunoprophylaxis in their home province or territory. The RSV Program needs to be aware of such situations. The RSV Program will contact the clinic coordinator or appropriate liaison in the patient's home province, to obtain documentation of approved status prior to treatment. A copy of the approval will be sent to the clinic where palivizumab is to be given.

In either scenario, after the dose has been given, the providing clinic must notify the program with the following information, in order to recover vials from the patient's home province/territory:

- Name of patient
- Patient Weight
- Date dose was given
- Amount given (mg)
- Number of vials used
- Lot #
- Expiry date of vials

DECISION-MAKING CRITERIA

An infant/child eligible for RSV immunoprophylaxis progresses through the following sequential steps.

1. Identification
An infant or young child potentially eligible for RSV Immunoprophylaxis is identified.
2. Referral/Eligibility
A referral is initiated and submitted to the RSV Program for review to confirm patient's eligibility as per Program eligibility criteria. (See Appendix II for the Application and Authorization for Treatment forms, etc.)
3. Enrolment (consent and registering)
The child's eligibility is confirmed by the RSV Program as per the BC guidelines (or otherwise approved by the RSV Program's Adjudication Panel) and the parents/legal guardians provide consent for RSV Immunoprophylaxis.
4. Provision of RSV Immunoprophylaxis (hospital/community based, in-patient and out-patient)
The eligible child is registered and receives a reference number to obtain RSV Immunoprophylaxis.
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5. Tracking

Tracking of the eligible patient starts when they are first identified and continues until:

- They receive all of their appropriate doses, or
- The parents/legal guardians withdraw the patient's enrolment from the RSV Program.

FOLLOW UP

Quality control and outcome evaluation are integral components of the RSV Program. The Program requires standard reporting related to all infants receiving palivizumab. Approximately one month after season end, all active clinics are required to connect with their patients' family/guardian to confirm whether any hospital readmission for respiratory illness occurred (as referenced on the bottom of the Patient Log). If an admission occurred, collect the appropriate information on the Hospitalization Data Form. These forms need to be emailed to rsv@cw.bc.ca or faxed to 604-875-2879.

INFORMED CONSENT

The health care professional will ensure informed consent is obtained from parent/legal guardian for eligible patients. This is a mandatory step for approval to receive palivizumab from the RSV Program. To ensure consent is informed, it is essential for parents/legal guardians to have access to educational material regarding RSV Immunoprophylaxis and for them to understand this material. Refer to Appendix III for further information regarding how to discuss RSV Immunoprophylaxis with families.

PROCEDURAL CHECKLIST

1. Obtain verbal consent, either via direct contact or telephone
2. Fill out and submit Authorization for Treatment Form (via rsv@cw.bc.ca or fax at 604-875-2879).
3. Obtain consent for end-of-season telephone follow-up (required for audit).

NECESSARY COMPONENTS OF INFORMED CONSENT INCLUDE THE FOLLOWING:

- An explanation of RSV-related illness (including education on prevention measures);
- Identification of the drug (including administration requirements);
- A discussion of benefits versus risks (including potential side effects);
- Addressing of any family concerns; and
- Accommodation of language/literacy barriers and special needs.

INTENDED OUTCOMES

RSV Immunoprophylaxis can reduce the hospitalization rate and severity of illness for eligible infants. Palivizumab injections are generally well tolerated with minimal adverse effects. Overall the most common adverse events include rash, ear infection, runny nose, soreness around injection site, and fever. If these adverse effects occur they are generally minor and do not last for long periods.

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 system found in Appendix IV.ii.
- Suspected cold chain breaks should be reported immediately to the RSV desk at 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. The product should be quarantined until further direction is received. Refer to Appendix IV.iii for more details.

Palivizumab (PVZ), brand name Synagis[®], a specific monoclonal antibody against RSV, has been demonstrated to decrease the likelihood of hospital admission due to RSV bronchiolitis in specific high-risk patient populations. It does not appear to prevent upper respiratory tract infection and may not prevent apneas associated with RSV in very young children. It is expensive and has not been shown to be cost effective, even in infants at moderately high risk. In Canada, each province creates eligibility guidelines for government funded RSV prophylaxis with PVZ.

PRODUCT DETAILS

- A Humanized monoclonal antibody produced by recombinant DNA technology.
- PVZ is supplied as 50 mg vials of prediluted, preservative-free liquid.
- PVZ vials also contain chloride, glycine, and histidine.
- PVZ vials must be kept refrigerated and stored between 2° C and 8° C in the original container. Do not freeze.
- The concentration is 100 mg/mL.
- The solution is maximized if inverted for 10-20 minutes prior to administration and should be used within three hours after the first puncture.
- Cluster administration to several patients is standard in order to minimize wastage. Partially used vials should be shared between patients using standard aseptic techniques. Discard unused vial contents after three hours.
- PVZ is not expected to interfere with the immune response to vaccines, including live viral vaccines. Routine immunizations may be given concurrently with PVZ.

CONTRAINDICATIONS

- Known hypersensitivity to PVZ or any of the additional components of the medication.
- Known hypersensitivity to other humanized monoclonal antibodies.

PRECAUTIONS

- Anaphylaxis has rarely occurred; be prepared to treat with epinephrine in appropriate paediatric dosage as per individual agency policy.
- As with any intramuscular injection, use with caution on patients with thrombocytopenia or any coagulation disorder, or who are on anti-coagulation therapy. Use a fine gauge needle of appropriate length and apply firm pressure, without rubbing, for five minutes following injection.

Please see Appendix IV.iii which elaborates on how best to handle, store, and transport palivizumab.

AUTONOMOUS RN ADMINISTRATION OF PALIVIZUMAB

The British Columbia College of Nurses and Midwives includes palivizumab (PVZ) as a medication RNs can autonomously administer (as seen in Scope of Practice on Pg's 39&63) without a client-specific order by a physician, to any patient that has been approved by the BC RSV Immunoprophylaxis Program. In order to be able to administer PVZ without a client-specific order two conditions must be met:

- 1) The registered nurse has the required competencies (as detailed on Pg 39&63); and
- 2) The registered nurse's hospital or agency has approved the practice in their facility.

DOSE

- Dosage calculation: patient weight (kg) X 15 mg/kg = mg to be administered.
- Round off dose to the nearest mg.
- mg to be administered / 100 mg/mL = mL to be administered.
 - * Example: If weight = 4.300 kg, then dosage to be administered is 64.5 mg. (4.3kg x 15mg) This is rounded to 65 mg. These 65 mg are contained in 0.65 mL.
- Dosage ceilings:
 - Infant with no cardiac disease and no CLD and premature $\geq 29w$Max. 3 doses
 - Infant with cardiac disease or with CLD or premature $< 29w$Max. 4 doses
- As a matter of policy, no PVZ will be administered to hospitalized infants unless and until they are ready for discharge.
- Multiples of enrolled children may only be given PVZ if they were born prematurely and qualifying twin is discharged for the first time.
- Once a child is RSV+ (whether hospitalized or not), they are no longer eligible for dosing. Severe immunocompromised pts may be an exception once reviewed.
- Hospitals in other provinces will receive reimbursement for dosage of BC-residing patients only within the limits of the BC guidelines; and that reimbursements will be equivalent to the appropriate dosing regimen indicated by the guidelines indicated by the most current version of the RSV Program's Administrative Manual.
- For ambulatory patient care, it is strongly recommended children receive their palivizumab doses from the central site in their region, through same-day, centralized, hospital-based outpatient clinics, in order to cluster dose and avoid wastage.

INTERVALS AND DATES

For eligible infants discharged home before 09-Nov-2020 (or November 30th 2020 for infants in NHA regions), outpatient RSV clinics will commence that week.

- For eligible infants still in hospital on or after 09-Nov-2020, Dose 1 is ideally administered 1-3 days prior to discharge home; or up to 7 days if discharge date is certain (to allow for cluster dosing and to minimize wastage).
- Dose 2 is given 3-4 weeks after Dose 1.
- Any doses after dose 2 are administered at 4-5 week intervals (up to the prescribed dose amount).

The three-to-four dose regimen will continue to be applied, with the exception of qualifying children with cardiac conditions, who undergo repair under bypass and are discharged home up to 31 March 2021; infants in this group will receive a post-operative dose of PVZ once medically stable and ready for discharge, as long as they still qualify for PVZ prophylaxis, even if this is a fifth seasonal dose. This fifth dose will not require a separate adjudication.

Administration of PVZ for potentially eligible children who remain in hospital is not supported by the medical literature, and therefore not supported by the RSV Program.

No doses are to be administered after 31 March 2021, unless the infant was premature (i.e., less than 35 weeks GA) at delivery and otherwise eligible and discharged within the first two weeks of April; these infants may receive a single dose of PVZ before going home.

PROCEDURE FOR ADMINISTERING

Administration of palivizumab for eligible children who remain in hospital is not supported by the RSV Program.

- Palivizumab is administered via intramuscular route only. The preferred site for injection is the vastus lateralis. Maximum volume of 1 mL per site in infants, dependent on assessed muscle mass, is recommended by BCCDC. Doses greater than 1 mL must be divided.

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. Refer to Page 11 for more product information.

Clinic instructions and provider expectations are detailed on the following page.

ROUTE

- PVZ is administered via the intramuscular route only. Preferred site for injection is the vastus lateralis.
- Maximum volume is 1 mL per site, as outlined above. Doses greater than 1 mL must be divided.

CLINIC INSTRUCTIONS & PROVIDER EXPECTATIONS FOR PALIVIZUMAB ADMINISTRATION

Quality control and outcome evaluation are integral components of the RSV Program. As such, the Program requires standardized documentation and reporting. This requirement is part of official agreements between the PHSA and the Health Authorities.

The RSV Program has the following expectations of all sites administering government-funded PVZ:

- 1) Education on RSV, standard infection control measures, and the benefits and risks of PVZ are all part of the authorization process. Education pamphlets are available in Appendix III.
- 2) Program enrolment requires a fully completed Application Form, Program approval, and a signed and completed Authorization for Treatment Form.
 - For patients meeting pre-approved criteria, the Authorization for Treatment may be submitted with the Application Form.
 - For patients requiring adjudication, the Authorization for Treatment Form should be completed and submitted after approval has been received by the requesting health care professional.
- 3) Providers maintain accurate records of all doses given to each patient, using the Patient Log.
 - For patients who get their first dose while still in hospital, or who 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, and the program must also be notified.
 - The sending site must confirm the receiving site has received the transfer information.
 - In every case where a patient transfer occurs and a dose of PVZ is administered, The RSV Desk at the Children's & Women's Pharmacy must be notified at rsv@cw.bc.ca or by fax at 604-875-2879.
 - At the end of every clinic day, copies of the Patient Log from every patient seen during that day must be submitted to the RSV Desk at rsv@cw.bc.ca or by fax to 604-875-2879 (for the purposes of quality control and outcome evaluation throughout the season).
- 4) Clinics stay in touch with their patients for the duration of the season and report any hospital admissions for respiratory illness to the RSV Program using the Hospitalization Data Form. At season end, a final contact is made with the family, documented on the Patient Log, and faxed to the RSV Program.
- 5) A completed Facsimile Cover Sheet must be used for **all** faxed Program communications.

WHEN ADMINISTERING

(as per BC Centre for Disease Control regarding administration of vaccines, etc.)

Document the following:

- Trade name of the product
- Disease(s) against which it protects
- Date given (day, month and year)
- Site and route of administration
- Lot number and expiry dates
- Name and title of person administering the vaccine

When a scheduled immunization is not given, record the following:

- The reason why the dose was not given
- The planned follow-up action.

Examples:

- Parent/guardian refusal
- Severe illness
- Contraindication to vaccine to be offered

Appendix IV.iii details handling of vaccines and other immunoprophylaxis with care.

Centralized RSV Clinics should be organized at sites expecting more than five patients annually. The purpose of the RSV Clinics is to maximize program penetration and patient/family compliance with the immunoprophylaxis schedule, in order to achieve optimal results. It is recognized attendance at a centralized clinic is not always possible due to distances involved so there are a limited number of physician offices or community health centres that see single patients.

NOSOCOMIAL (HOSPITAL-ACQUIRED) INFECTIONS

RSV may be transmitted in the hospital setting and can cause serious disease in high-risk infants, though it is not as infectious as many other viruses. In high-risk hospitalized infants, the foremost means to prevent RSV disease is strict observance of infection control practices, including rapid means to identify and cohort RSV-infected infants. If an RSV outbreak is documented in a high-risk unit, accepted guidelines indicate primary emphasis should be placed on proper infection control practices. There is no data supporting palivizumab (PVZ) use in controlling hospital outbreaks or for treatment of established RSV.

RSV DISEASE PREVENTION

Chronologic young age (i.e., below three months) is the single most important risk factor for RSV hospitalization.

General measures are the most effective way for preventing RSV Infection, as most admissions for RSV occur in previously healthy late pre-term and term infants who are not considered candidates for PVZ. Selection criteria to identify late pre-term and term infants at increased risk of RSV disease do not exist; no jurisdiction provides PVZ for this group. There is also a continued need for data regarding infants who currently do not qualify.

Parent education should be a core component of discharge teaching. Prevention of all respiratory viral infections, including RSV, includes careful hand washing, the use of alcohol based hand rubs, and avoidance of contagious settings such as child care centres and crowded public places (especially in the first six months). Breastfeeding and avoidance of exposure to tobacco smoke are also strongly recommended.

Guides for discussing RSV with parents and pamphlets for parents to take home are available in Appendix III.

RSV PROGRAM QUALITY CONTROL

Quality control and outcome evaluation are essential components of the RSV Program. The information about PVZ administration and patient admissions required from the Clinics is at the core of the Program's outcome review, without which the Program cannot function.

The Program requires standard reporting related to all infants receiving PVZ:

- The Program requires a faxed Authorization for Treatment Form which includes additional consent for telephone follow-up as well as appropriate contact information, to facilitate audit at season end. Established clinics, physician offices, and other applicable points of care must co-operate with data collection.
- The information required from the RSV Clinics after each session is mandatory. **Fully** completed application/authorization forms expedite the request process and the delivery of the drug, and receipt of Patient Logs is required in order to activate the continuous supply of PVZ to the Clinics.

VIAL SHARING

PVZ is an exceptionally expensive medication. The goal of the BC RSV Immunoprophylaxis Program is to provide palivizumab, to qualifying infants, with maximum efficiency.

As such, the RSV Program expects PVZ will be administered in such a way as to maximize product utilization. RSV Clinics should be organized to provide clustered administration of PVZ to the largest number of patients possible. Vial sharing has been in place in BC and in most jurisdictions in Canada for many years, and is integral to the RSV Program.

A study by the RSV Program demonstrated the greater the number of patients treated during a “clinic” day, the lower the cost for administering doses per mg delivered. For this reason, doses within BC Children’s Hospital and BC Women’s Hospital + Health Centre are coordinated as much as possible with scheduled outpatient clinic days in order to maximize effective utilization.

There are occasions when, due to clinical circumstances, doses must be administered outside of scheduled clinic days. It is encouraged, when possible, to coordinate other doses to maximize utilization.

Another important contribution to cost savings is the overfill in the 50 mg vials of palivizumab, which results in the ability to retrieve **55 mg (0.55 mL)** from each 50 mg vial when handled appropriately.

An example of the savings using vial sharing on one typical day at BC Children’s Hospital is outlined below. This example is taken from a real day at BC Children’s Hospital and represents both the doses given in the outpatient clinic and doses given on an inpatient unit.

EXAMPLE GIVEN

Total number of patients receiving a dose of PVZ = 13

Total number of mgs prescribed = 1232 mg

Total number of vials required to provide all doses with **no** vial sharing = 29 vials

Total cost to provide all doses with no vial sharing = \$21,750

Total number of vials required to provide all doses with vial sharing = 23 vials

Total cost to provide all doses with vial sharing = \$17,250

Amount of medication wasted with no vial sharing = **418 mg**

Cost savings with vial sharing for one clinic = **\$4,500**

IS VIAL SHARING SAFE?

Vial sharing is practiced in many jurisdictions. Palivizumab should be used within 3 hours after the vial is first punctured.

CLUSTER DOSING AND VIAL SHARING ON IN-PATIENT UNITS

In the majority of cases, the plan for discharge home is known a few days ahead of time and can be coordinated with the outpatient clinic.

There are instances when discharge is sudden, or when an approval has been received late and a patient requires a dose immediately. In such cases there may be other eligible patients known to be going home within a short period of time. It is then possible to give more than one dose should doing so minimize wastage.

[Vial sharing information continued on following page]

HOW TO DETERMINE THE MOST EFFICIENT USE OF PALIVIZUMAB

The example below demonstrates how vial sharing and consideration of the **actual yield of 55 mg** from a 50 mg vial can maximize clinic efficiency.

EXAMPLE GIVEN

Wherein 3 patients require a dose of PVZ:

- Patient 1: 45 mg
- Patient 2: 95 mg
- Patient 3: 75 mg

The total amount of PVZ to be given is 215 mg. This can be obtained from sharing 4 vials due to known overfill in the 50 mg vials. This will eliminate the need to open a 5th vial, increasing the efficiency of PVZ use by 20%.

1. Remove from refrigeration and label each vial with the time. Invert for 10-20 minutes before withdrawing any medication.
2. Coordinate the timing of each dose so all PVZ is used within the 3-hour timeframe.
3. Withdraw PVZ from each vial sequentially (i.e., use all contents of one vial before withdrawing from another). This reduces the number of times a vial is accessed.
4. If there will be short delays between dosing each infant, then, to minimize the chance of contamination, store the vials in the medication fridge.
5. Discard unused PVZ after 3 hours.



BRITISH COLUMBIA COLLEGE OF NURSES AND MIDWIVES – LIMITS/CONDITIONS

Registered nurses who compound, dispense, or administer immunoprophylactic agents for the purpose of preventing respiratory syncytial virus infection must possess the competencies and follow decision support tools established by the PHSA.

RNs can autonomously administer PVZ to approved patients without a client specific order if they meet the British Columbia College of Nurses and Midwives (BCCNM's) condition of practice and their employer policy supports and infrastructure are in place. Systems must be in place in outpatient clinics to manage anaphylaxis. It is recommended there be a second RN available during the scheduled clinic time to provide assistance if possible.

The registered nurse must be familiar with the Core Nursing Competencies for RSV Immunoprophylaxis as outlined by the PHSA (as seen below).

Authorization for Treatment must be obtained from the parent or guardian prior to administration of palivizumab (PVZ). All health care providers administering PVZ must have the appropriate resources and plan in place to manage anaphylactic reactions or other potential adverse events.

Core Nursing Practice Competencies for RSV Immunoprophylaxis

KNOWLEDGE	<ul style="list-style-type: none"> • Demonstrates an understanding of the rationale & benefit of RSV immunoprophylaxis • Demonstrates a general understanding of the immune system • Differentiates between passive & active immunity • 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	<ul style="list-style-type: none"> • 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 "Judgment" 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 symptoms/care
JUDGMENT	<ul style="list-style-type: none"> • 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 as per employer policy) • Determines need to postpone immunization (i.e., if child has been ill)
ATTITUDE	<ul style="list-style-type: none"> • Acts in accordance with legal & high ethical standards • Respects individual choices & beliefs • Demonstrates self-awareness of own beliefs, values, & practice limitations

SCOPE OF PRACTICE

Under the Health Professions Act RNs can autonomously administer immunoprophylactic agents...

8(1)(a.1) in respect of a drug specified in Schedule I of the Drug Schedules Regulation, [including to]:

- (i) compound the drug,
- (ii) dispense the drug, or
- (iii) administer the drug by any method for the purpose of...

(iv) preventing disease using immunoprophylactic agents and post exposure chemoprophylactic agents.⁷

⁷ BCCNM's "Scope of Practice for Registered Nurses: Pg.39&63": https://www.bccnm.ca/Standards/RN_NP/StandardResources/RN_ScopeofPractice.pdf

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, develops the disease, 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. A vaccine stimulates a primary response against the antigen without causing symptoms of the disease.

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.

Conflict of Interest (COI)

A Conflict of Interest occurs when there is a potential divergence between a person's personal interests and professional obligations, such that the public or patients might reasonably question whether the professional actions or decisions were influenced by personal gain, financial or otherwise. Personal interests may include business, commercial, or financial interests, as well as personal matters and career interests.

With respect to the RSV Program, a COI includes any relationship or interest with a pharmaceutical firm that makes palivizumab. Examples of such relationships or interests include:

- Membership on an advisory board or equivalent;
- Member of a Speaker Bureau;
- Payment from the pharmaceutical firm, including consulting fees, honoraria, salaries, etc.;
- Grants, industry-sponsored clinical trial, or other research funding;
- Holding a patent for a product that is marketed by the pharmaceutical firm;
- Investments; and/or
- Other relationships.

The Program's no-COI position is in alignment with the Canadian Paediatric Society (CPS) position statement, Preventing Hospitalizations for Respiratory Syncytial Virus Infection, which states the following recommendation:

A panel of experts should be convened in each province or territory to review annually the palivizumab program guidelines and outcomes. People servicing on these panels should not have conflicts of interest, including research funding, participation in a speaker's bureau or financial links, with the pharmaceutical firm that makes palivizumab.⁸

Humanized monoclonal antibody

An antibody produced by a single clone of cells. As such, a monoclonal antibody is a single, pure type of antibody. Monoclonal antibodies can be made in large quantities in the laboratory and are the cornerstone of immunology.

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.

[glossary continued on following page]

⁸ Robinson, J, Le Saux, N, Canadian Paediatric Society, Infectious Diseases and Immunization Committee. [Preventing hospitalizations for respiratory syncytial virus infection](#). Paediatric Child Health 2015; 20(6):321-26.

Passive Immunity

The transfer of active immunity, in the form of ready-made antibodies, from one individual to another. Passive immunity can occur naturally, when maternal antibodies are transferred to the fetus through the placenta, and can also be induced artificially. Artificially acquired passive immunity is a short-term immunization by the injection of antibodies, such as gamma globulin, which are not produced by the recipient's cells.

Recombinant DNA technology

A series of procedures used to join together (recombine) DNA segments. A recombinant DNA molecule is constructed from segments of two or more different DNA molecules. Under certain conditions, a recombinant DNA molecule can enter a cell and replicate there, either on its own or after it has been integrated into a chromosome.

Respiratory Syncytial Virus (RSV)

A major cause of respiratory illness in young children. RSV causes infection of the lungs and breathing passage, which may cause bronchiolitis or pneumonia. While most infants will only express mild respiratory symptoms, it can lead to other more serious illnesses in premature babies and infants/children with diseases that affect the heart, lungs, and immune system. RSV infections often occur in epidemics that last from late autumn through early spring. 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.

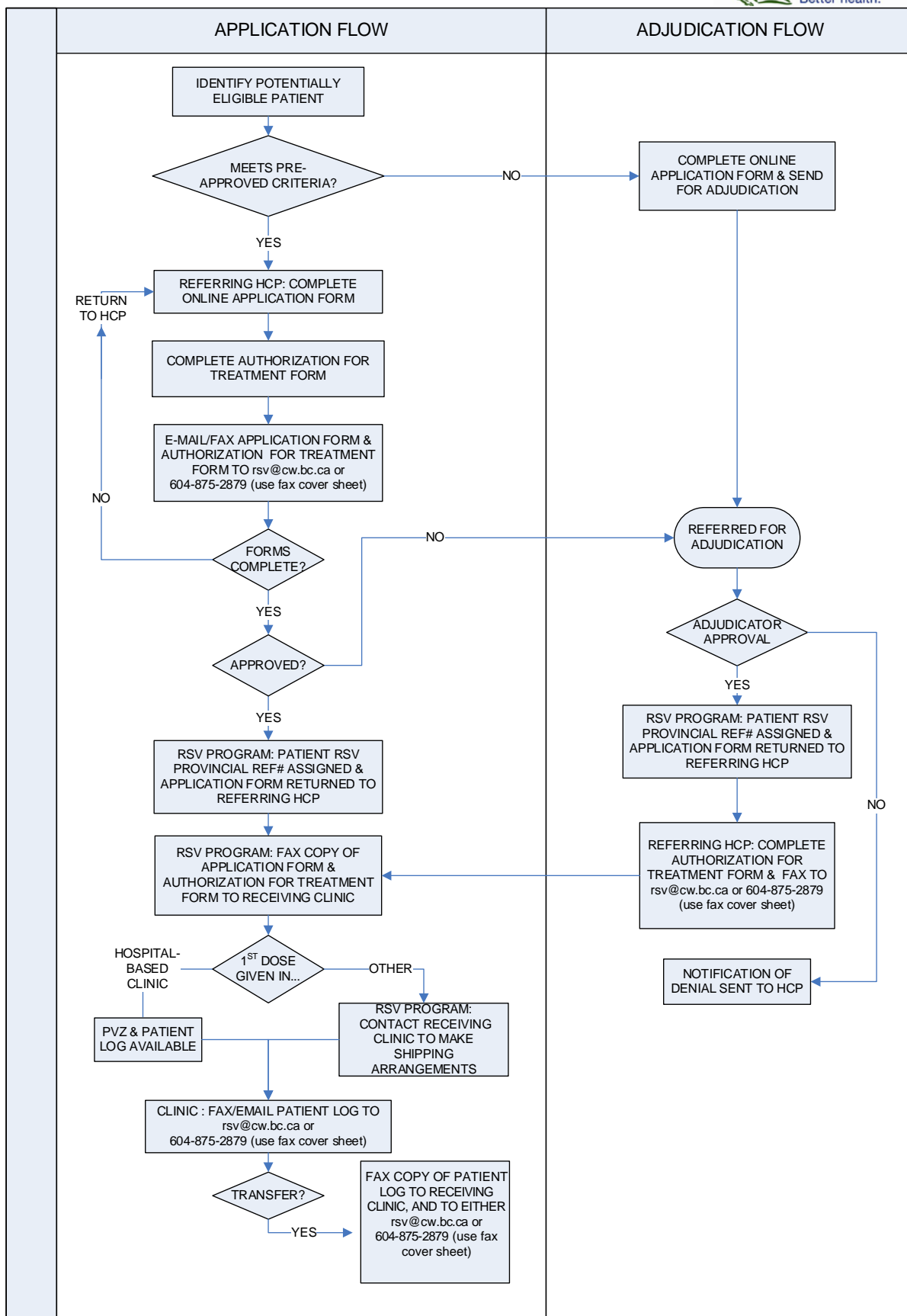
RSV infects almost all children by 2 years of age. While most infants will only express mild respiratory symptoms, RSV infection is responsible for most of the approximately 12,000 hospitalizations for respiratory illness per year in children younger than two years of age in Canada. In BC the RSV season typically lasts from November to April. The overwhelming majority of hospital admissions occur in term and late preterm infants with no pre-existing risk factors in the first year of life. Younger children are more likely to have a prolonged hospital admission and more likely to be admitted to the intensive care unit. Young infants with underlying cardiac or pulmonary disease are at highest risk of admission.

Vaccination

A type of immunoprophylaxis involving the injection of a killed microbe in order to stimulate the immune system against the microbe, thereby preventing disease.

NOTE: palivizumab is not a vaccine.

RSV Program – Enrolment Flow Diagram



BC RSV Immunoprophylaxis Program

Guidelines by Comparison - Indications

Condition	BC 2014	AAP 2014	CPS 2015	BC 2020
Preterm infants without CLD born before 29w+0d GA	Up to 4 doses per season, if date of discharge after 01 Sep and GA at birth <29w	Recommended for infants born before 29w+0d gestation who are < 12 mos at start of RSV season.	Reasonable (but not essential) for infants born <30w+0d when <6 mos of age at start of RSV season,	Up to 4 doses per season, if date of discharge after 01 Sep and GA at birth <29w
Infants born after 29w+0d and under 35w+0d GA	Up to 3 doses per season, if date of discharge after 01 Oct AND have >41 points in the BC Risk Score	Not recommended for healthy infants born at 29w+0d GA or later.	PVZ should not be prescribed for infants after 30w+0d weeks.	Up to 3 doses per season, if date of discharge after 01 Oct AND have >41 points in the BC Risk Score
CLD - first year of life	CLD/BPD (defined as a need for oxygen or CPAP for more than 28 days) AND <12 mos at start of season AND on oxygen after 01 July	Recommended for CLD of prematurity defined as gestational age <32w+0d and a requirement for >21% O ₂ for at least the first 28 days after birth.	CLD is defined as a need for oxygen at 36 weeks' GA who require ongoing diuretics, bronchodilators, steroids or supplemental oxygen. PVZ if <12 mos of age at start of RSV season.	Same as previous years. To be adjudicated if >12 mo age by 01 Nov
CLD - second year of life	CLD/BPD (defined as a need for oxygen or CPAP for more than 28 days) AND >12 mos at start of season AND on oxygen after 01 July	Only if continue to require medical support (chronic corticosteroid therapy, supplemental oxygen, diuretic therapy) during 6-mo pe- riod prior to start of second RSV season.	Only indicated in the second year in those still on or weaned off of supplemental oxygen in the past 3 mos.	To be adjudicated if >12 mo age by 01 Nov
Significant pulmonary disability	Significant pulmonary disability (pulmonary hypertension, pulmonary malformations, severe BPD, progressive neuromuscular disease) AND <24 mos by 01 Nov			To be adjudicated
Upper airway obstruction, or chronic pulmonary disease other than CLD	Funded only if severe and after adjudication by single expert, if age <12 mos		Should not routinely be offered PVZ.	To be adjudicated
<24 mos of age on home oxygen for severe pulmonary disease	Funded after adjudication by single expert, if age <12 mos		Consider prophylaxis	Up to 4 doses per season if continuous home O ₂ /ventilation on or after 01 Nov 20 and DoB on or after 01 Nov 18
Hemodynamically significant CHD	PVZ if they are <24 mos of age at the start of RSV season AND have hemodynamically significant CHD on or after 01 Nov	May administer to <12 mos with acyanotic heart disease receiving medication to control congestive heart failure and will require cardiac surgical procedures; and infants with moderate to severe pulmonary hypertension. Infants with cyanotic heart defects in the first year of life, in consultation with a pediatric cardiologist.	PVZ if they are <12 mos of age at the start of RSV season. PVZ is not indicated during the second RSV season for infants with CHD	PVZ if <12 mos as of 01 Nov 20 AND hemodynamically significant CHD: i.e., acyanotic heart disease receiving medication to control CHF and requires cardiac surgical procedures; and infants with moderate to severe pulmonary hypertension. Infants with cyanotic heart defects in the first year of life, in consultation with a pediatric cardiologist.
CHD, special circumstances	Extra post operative dose after cardiac bypass.	Extra post operative dose after cardiac bypass. ECMO or transplant during RSV season AND <24 mos.		Extra post operative dose after cardiac bypass, ECMO or transplant during RSV season AND < 24 mos.

BC RSV Immunoprophylaxis Program

Guidelines by Comparison - Indications

Condition	BC 2014	AAP 2014	CPS 2015	BC 2020
CHD - Complex patients being carried over with single ventricle palliations and <24mo			PVZ if they are <12 mos of age at the start of RSV season. PVZ is not indicated during the second RSV season for infants with CHD	To be adjudicated
CHD clarification		PVZ not indicated: hemodynamically insignificant CHD(*), lesions adequately corrected by surgery unless requiring medication for CHF, mild cardiomyopathy not requiring medical therapy.		To be adjudicated if PVZ for any of these is requested
Cystic Fibrosis	If symptomatic and DoB after 01 Jan	Only if clinical evidence of CLD and/ or nutritional compromise in the first year of life. PVZ in second year only if severe lung disease or weight for length less than the 10th percentile.	Should not routinely be offered PVZ.	To be adjudicated
Down Syndrome	If hemodynamically significant CHD is not present, then approved only if date of discharge after 01 Oct and BC Risk Factor score	Only if with qualifying heart disease, CLD, airway clearance issues, or prematurity (<29 weeks, 0 days' gestation) is present.	Should not routinely be offered PVZ.	Up to 4 doses if DOB on or after 01 April
Neuromuscular disease and inability to clear secretions	By adjudication	Neuromuscular disease or congenital anomaly impairing ability to clear secretions from the upper airway because of ineffective cough may be considered for prophylaxis during the first year of life.		To be adjudicated
Solid organ or hematopoietic stem cell transplantation; and severely immunocompromised children <24 mos	Consider if <24 mos of age AND profoundly immunocompromised during the RSV season: AML, stem cell transplant, infant ALL, infant brain tumor intensive protocol, SCIDS, ICE protocol AND <24 mos	Consider if <24 mos of age AND profoundly immunocompromised during the RSV season.		To be adjudicated
Other immunocompromised children	PVZ should not routinely be offered to other diagnoses including most cancer patients		PVZ should not routinely be offered	To be adjudicated
Administration to multiple	Multiples of enrolled children approved for same number of doses	Not considered	Not in the CPS guideline	PVZ if <35w and qualifying twin discharged for first time
Breakthrough RSV infection.	Continuation of monthly PVZ is not recommended	Discontinue monthly PVZ	Continuation of monthly PVZ is not recommended	Continuation of PVZ not funded

* Hemodynamically insignificant CHD: secundum ASD, small VSD, pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, and PDA

BC RSV Immunoprophylaxis Program


Guidelines by Comparison - Miscellaneous

Circumstance	BC 2014	AAP 2014	CPS 2015	BC 2020
Teaching for parents	Education advocated, but not formalized in Program documentation		Young infants (and their siblings) should not be in contact with individuals with respiratory tract infections whenever practical. A Cochrane review suggests that hand hygiene in the home decreases the spread of respiratory tract infections in children. Breastfeeding and avoidance of cigarette smoke are also presumed to decrease the incidence and/or severity of viral respiratory tract infections.	While PVZ is beneficial in reducing RSV risks, very important measures for relieving and lowering the risk of viral respiratory tract infections include the following: <ul style="list-style-type: none"> * Whenever possible, keep your child (and their siblings) away from people who have respiratory tract infections. * Frequent handwashing or use of alcohol hand sanitizer. * Breast milk. * Avoidance of cigarette smoke. * Discouraging daycare, especially <1yo
Maximum number of doses per season	4 doses, except for post pump after which an extra dose is given	Up to 5; last dose in March	Programs should administer a maximum of 3-5 doses, with 4 doses probably being sufficient in all risk groups if PVZ is started only when there is RSV activity in the community, especially if doses 2, 3, and 4 are given 38 days apart.	4 doses, except post pump after which an extra dose is given
When first dose	For eligible infants being discharged home for the first time during RSV season, start just before discharge.	48-72 hours prior to discharge	For eligible infants being discharged home for the first time during RSV season, start just before discharge.	For eligible infants being discharged home for the first time during RSV season, start just before discharge.
Greater than 5 doses	Not funded	Not considered	No evidence to support giving >5 doses in one RSV season	Not funded
Use to prevent nosocomial infection	Not funded	Not recommended	Expensive strategy that is not recommended.	Not funded
PVZ as RSV therapy	Not funded	Not effective; not approved	PVZ as RSV therapy is no indicated	Not funded
>24 mos	Not funded	Not considered	No evidence to support administration to any child >24mo age	Not funded
Use of Risk Score system	BC RSV Risk Score used for >29w without CLD	Not discussed	Not discussed	BC RSV Risk Score will remain in place
Cluster administration	PVZ wastage should be minimized by cluster administration to the largest number of patients possible			PVZ wastage should be minimized by cluster administration to the largest number of patients possible

BC RSV Immunoprophylaxis Program

Guidelines by Comparison - Miscellaneous

Circumstance	BC 2014	AAP 2014	CPS 2015	BC 2020
Infants in remote communities who would require air transportation for hospitalization	10 pts per BC risk score; otherwise not a factor	RSV disease and costs associated with transport from remote locations may result in a broader use in special populations	If born before 36 + 0 weeks' GA and <6 mos of age at start of RSV season should be offered PVZ. Not clear if this should apply only to Inuit infants, to all Aboriginal infants or to all infants in remote communities. However, first priority should be to provide PVZ to infants with prematurity, CLD or CHD.	10 pts per BC risk score; otherwise not a factor
Program Review	Arms length program with no funding or participation by vendor.		A panel of experts should be convened in each province or territory to review annually the PVZ program guidelines and outcomes. People serving on these panels should not have COI, including research funding, participation in a speaker's bureau or financial links, with the pharmaceutical firm that makes PVZ.	No member of advisory committee or adjudicator panel to have a COI (real or perceived). Adjudication is conducted by a panel of 3. No adjudication of one's own patients.

STANDARD WORK	 Provincial Health Services Authority Province-wide solutions. Better health.		Title: <u>Palivizumab Preparation</u> Role performing Activity: Nurse/physician/nurse practitioner	
	Location: Established clinics and doctors' offices		Department: BC RSV Immunoprophylaxis Program	
	Document Owner: Cheryl Christopherson			
	Date Prepared: July 1, 2014		Last Revision: September 2017	

Note the following:

- Vials of palivizumab NO LONGER REQUIRE RECONSTITUTION but may still contain a small overfill.
- Barring the use of controlled and validated aseptic conditions, palivizumab should be used within 3 hours of opening.

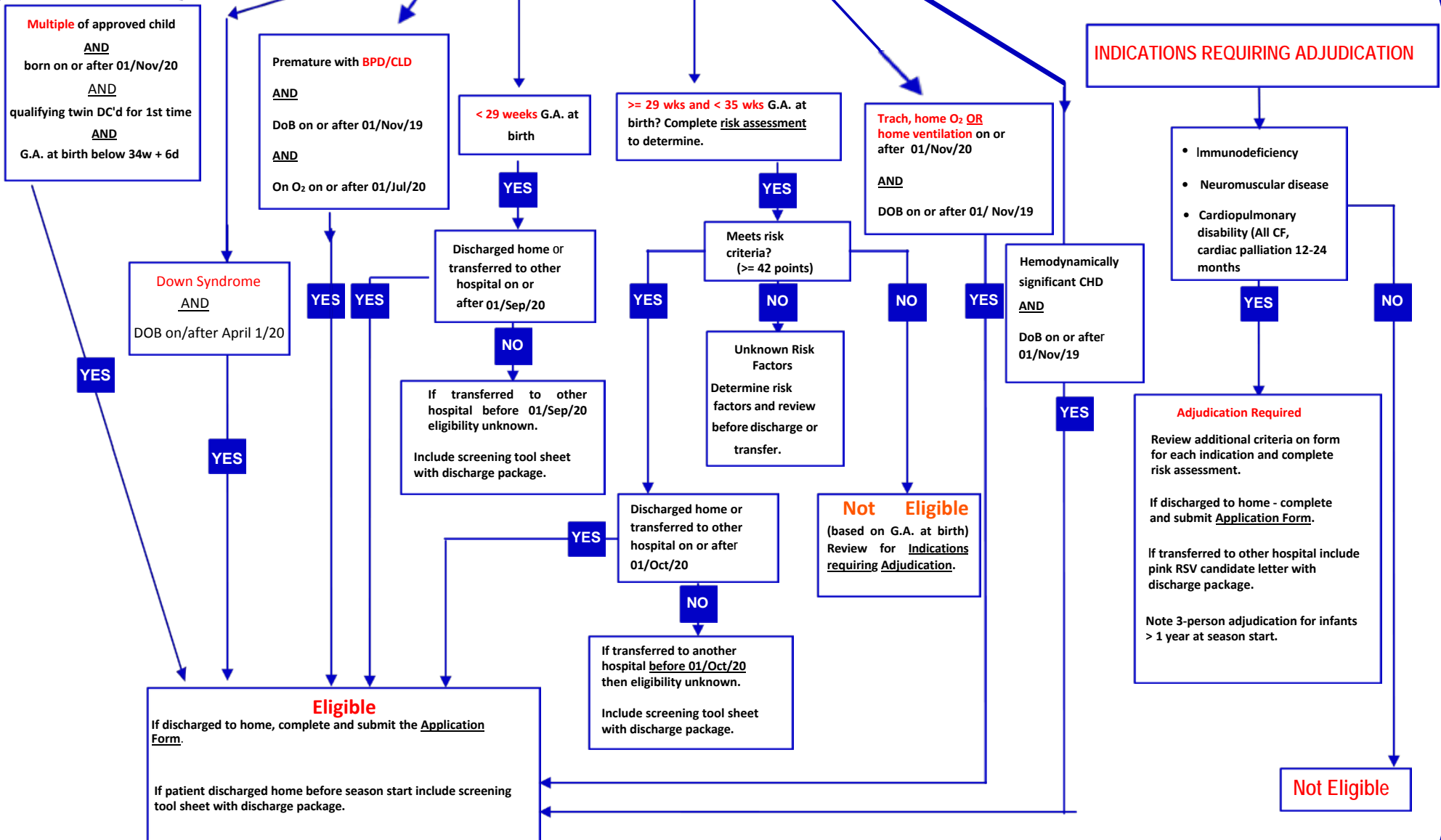
Items needed:

- Alcohol swabs
- Dry gauze pads (or equivalent)
- 1ml syringe
- Needles

Task Sequence	Essential Tasks
1	Place contents of package on a clean surface.
2	Wash hands thoroughly.
3	Invert palivizumab vial and leave upside down for 10-20 mins to allow maximum medication to top of vial. Do not dilute or shake solution.
4	Prepare 1ml syringe for withdrawal of pre-diluted medication
5	Using antiseptic technique, remove tab portion on vial cap and clean rubber stopper with 70% ethanol (or equivalent).
6	Insert needle carefully into the vial. To minimize foaming, slowly withdraw medication along inner side of vial. Do not mix with any other medications prior to administration.

RSV Program Screening Decision Tree

PRE-APPROVED INDICATIONS (WITH CRITERIA)



Northern Health Authority regions:

SEASON START November 30

SEASON END April 30

Other regions of BC:

SEASON START November 09

SEASON END March 31

Last day of dosing for *eligible infants first discharged from the NICU (Between April 01-14) **April 14**

**Premature, <29 weeks GA, or <35 weeks with high risk score, discharged for the first time.*

NOTE: Although the RSV Season is extended in NHA regions, the maximum number of doses remains three or four per infant depending on indication).

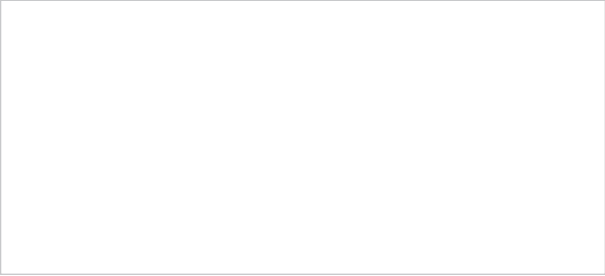
BC RSV IMMUNOPROPHYLAXIS PROGRAM APPLICATION FORM

The BC RSV Immunoprophylaxis Program only covers high risk children who meet the risk criteria established by the Program.

No child > 2 years of age by 01 November, 2020 is eligible.

Please COMPLETE THIS FORM ONLINE, save it and submit it to rsv@cw.bc.ca as an attachment to an email from a Health Authority (i.e., hospital) email account. Print a copy for your records.

To contact the RSV Program, please email rsv@cw.bc.ca, telephone 1-877-625-7888, or 604-875-2867 or fax 1-877-625-7555 or 604-875-2879



Section 1 - PATIENT INFORMATION

Last Name:		First Name:		PHN:	
Date of birth: (dd/mmm/yyyy)		Gest age at birth (w + d):		Date first discharged home: (dd/mmm/yyyy)	
Age at time of request (mos):		Birth weight (g):		Birth weight percentile:	
<input type="checkbox"/> Male <input type="checkbox"/> Female		Current weight (g):		Parent / Guardian's First & Last Name:	
Parent / Guardian phone numbers:		Second Parent / Guardian's First & Last Name:			
Home		Cell		City of Residence:	

Section 2 - REQUESTING PHYSICIAN

First and Last Name:		Person completing form (Name/Number):			
Physician Phone:		Physician Fax:		Physician Email:	

Section 3 - COMMUNITY PHYSICIAN

First and Last Name:		Office Address or Institution Name:			
Phone:		Fax:		Physician Email:	

Section 4 - PRODUCT DELIVERY INFORMATION

Hospital name for initial dose:		Hospital name for subsequent doses:			
[For Pharmacy Use Only] Number of 50 mg vials to be shipped now:		[For Pharmacy Use Only] Number of 50 mg vials required for season:			

Note: Dose of palivizumab is 15 mg/kg, as per Product Monograph

Approval

Approved for maximum 4 doses / season
 Approved for maximum 3 doses / season
 Not approved

Adjudicator Name & Signature:

Date:

[For Pharmacy Use Only]

AbbVie Ref. #:	Patient Initials:	PHSA / C&W PO #:	Provincial Ref. #:
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Section 5 - PRE-APPROVED INDICATIONS

- Prem with BPD/CLD(O2 or CPAP more than 28d) AND DoB on or after 01 Nov 2019 AND On continuous O2 on or after 01 July 2020
- GA at birth below 29w + 0 days AND discharged home on or after 01 Sep 2020
- GA at birth 29w + 0d to 34w + 6d AND discharged home on or after 01 Oct 2020 AND risk factor score greater than 41 points*
- Tracheostomy / continuous home oxygen / ventilation on or after 01 Nov 2020 AND born on or after 01 Nov 2018
- Multiple of approved child AND qualifying twin qualifies under prematurity
- Hemodynamically significant CHD AND DoB on or after 01 Nov 2019 (clinical details/name of supporting cardiologist below)
- Down Syndrome AND DoB on or after 01 April 2020

Section 6 - INDICATIONS REQUIRING ADJUDICATION

- Progressive neuromuscular disease with inability to clear secretions AND DoB on or after 01 Nov 2018 (clinical details below)
- **Severe immunodeficiency (e.g., stem cell transplantation) AND DoB on or after 01 Nov 2018
- **Significant cardiopulmonary disability (pulmonary hypertension, pulmonary malformations, severe BPD, symptomatic CF, cardiac palliation, other) AND DoB on or after 01 Nov 2018 (clinical details below)

* The risk factors below will be important to facilitate adjudication in all borderline cases
** Summarize clinical course and level of disability in the space below or in separate sheet

Section 7 - ADDITIONAL CLINICAL INFORMATION REQUIRED (to be completed for ALL requests)

Risk factors present in this child at discharge:

Yes	No		
<input type="checkbox"/>	<input type="checkbox"/>	Will attend daycare regularly during first 3 months after discharge	22 pts
<input type="checkbox"/>	<input type="checkbox"/>	Discharged home in Dec or Jan or Feb	20 pts
<input type="checkbox"/>	<input type="checkbox"/>	Discharged home in Nov or Mar	10 pts
<input type="checkbox"/>	<input type="checkbox"/>	Gestational age at birth 29 weeks + 0 days to 30 weeks + 6 days	10 pts
<input type="checkbox"/>	<input type="checkbox"/>	Other child younger than 5 years living at home (not including multiples of applicant)	14 pts
<input type="checkbox"/>	<input type="checkbox"/>	6 or more people at home (including applicant and multiples of applicant)	12 pts
<input type="checkbox"/>	<input type="checkbox"/>	Remote residence (Over 1 hour travel time or >100 km in Google maps to the nearest hospital)	10 pts
<input type="checkbox"/>	<input type="checkbox"/>	Girl not receiving breastmilk, or Boy (any)	8 pts
<input type="checkbox"/>	<input type="checkbox"/>	SGA (BW less than 10th percentile)	8 pts
<input type="checkbox"/>	<input type="checkbox"/>	2 or more smokers living at home	8 pts
			TOTAL:

Summarize clinical course to date with current/proposed Rx below or on separate sheet *Adjudicator comments will be e-mailed*

AUTHORIZATION FOR ADMINISTRATION OF PALIVIZUMAB AND FOLLOW-UP

The benefits and risks of this medication have been explained to parent/guardian and information provided on reducing the risk of respiratory infections. Parent/guardian CONSENTS DECLINES child receiving Palivizumab as per the BC RSV immunoprophylaxis program guidelines and to contact for follow-up.

Application form details and contact information are confirmed, and patient meets pre-approval criteria for funded prophylaxis.

If consent not obtained above, or adjudication required, a separate authorization for treatment and follow up must be submitted following approval. (Telephone consent is ok).

Signature of health-care provider

Date

Printed name

Contact number



Patient Name: _____ DOB (dd/mmm/yyyy): _____

Prov. Health #: _____ Registration #: _____

Parent / Legal Guardian Name (Print): _____

Phone: _____ Other Phone / Contact: _____

Authorization for Administration of Palivizumab and Follow-Up

The benefits and risks of this medication have been explained to me and I have received information on reducing the risk of respiratory infections. I consent to my child receiving Palivizumab as per the BC RSV Immunoprophylaxis Program Guidelines and to contact for follow-up.

Signature of Parent/Guardian: _____ Date: _____

This section for Physician/Nurse providing care

The application form's details and contact information have been confirmed above and the patient is eligible for funded prophylaxis. I have provided information on the RSV program and have answered questions. I confirm that consent for treatment and follow-up has been obtained (*telephone consent is acceptable*).

Signature of Physician/Nurse obtaining consent

Signed on [this date]: [dd/mmm/yyyy]

Printed name of Physician/Nurse

Contact telephone number of Physician/Nurse

(For use by clinic / point of care as an individual administration record)

Patient Name: _____ **DoB (dd/mmm/yyyy):** _____

Parent / Legal Guardian Name: _____ **Provincial Health #:** _____

Phone: _____ **Provincial Reference #:** _____

Other Phone / Contact: _____

Circle #doses approved

3 4

Dosing 15mg/kg
2nd dose 3-4 weeks after 1st
Subsequent doses 4-5 weeks apart

Consent obtained? NO YES

Course complete? NO YES

Eligibility Criteria:

Dose #	When Taken	Where Dose Was Administered	Date (dd/mmm/yy)	Lot Number	Weight (kg)	Expiry Date	Dose (mg)	Admitted with any respiratory infection in previous month?	Admitted with RSV+ infection in previous month?	Clinic for next dose?
1		<input type="checkbox"/> No <input type="checkbox"/> Yes, at: _____						<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Unknown	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Unknown	<input type="checkbox"/> No <input type="checkbox"/> Yes, to: _____
2	3-4 weeks after Dose 1	<input type="checkbox"/> No <input type="checkbox"/> Yes, at: _____						<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Unknown	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Unknown	<input type="checkbox"/> No <input type="checkbox"/> Yes, to: _____
3	4-5 weeks after Dose 2	<input type="checkbox"/> No <input type="checkbox"/> Yes, at: _____						<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Unknown	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Unknown	<input type="checkbox"/> No <input type="checkbox"/> Yes, to: _____
<i>*NOTE: the standard administration is three to four doses; a fifth dose may only be given to patients who have undergone cardiac bypass surgery.</i>										
4 th ?	4-5 weeks after Dose 3	<input type="checkbox"/> No <input type="checkbox"/> Yes, at: _____						<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Unknown	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Unknown	<input type="checkbox"/> No <input type="checkbox"/> Yes, to: _____
5 th ?		<input type="checkbox"/> No <input type="checkbox"/> Yes, at: _____						<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Unknown	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Unknown	<input type="checkbox"/> No <input type="checkbox"/> Yes, to: _____
Final f/up		<input type="checkbox"/> No <input type="checkbox"/> Yes, at: _____						<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Unknown	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Unknown	<input type="checkbox"/> No <input type="checkbox"/> Yes, to: _____

At the end of each day, fax this page to the RSV Program and to any clinic that the patient attends. 604-875-2879 or 1-877-625-7555

If the patient has been hospitalized for any respiratory infection, then please fill out a Hospitalization Data form and send to

rsv@cw.bc.ca. BC RSV Immunoprophylaxis Program, as of 2020/21 Season



This form to precede all RSV Forms submitted via fax

This facsimile communication is intended only for the use of the addressee and may contain information that is privileged and confidential. Any dissemination, distribution, or copying of this communication by unauthorized individuals or for unauthorized purposes are strictly prohibited.

If you received this communication in error, please notify us immediately via telephone at 604-875-2867 or toll free at 1-877-625-7888, and return to the original to us by regular mail.

Date: _____

To BC RSV Immunoprophylaxis Program.... Grace Burns/Cheryl Christopherson

at Fax Number: _____1-877-625-7555 or 604-875-2879_____

From:

Contact Information: _____

Number of pages (including this page): _____

Notes:



For Respiratory Infection in Infants approved for Palivizumab and admitted for Respiratory Illness up to April 30, 2021

Name of Patient: _____ DoB: _____

Provincial Reference #: _____ PHN: _____

Admitting Hospital: _____ Attending Physician: _____

Admitted (dd/mmm/yyyy): _____ Discharged (dd/mmm/yyyy): _____

If Transferred:

Name of Hospital: _____ Attending Physician: _____

Admitted (dd/mmm/yyyy): _____ Discharged (dd/mmm/yyyy): _____

Reason(s) for Hospitalization (e.g., apnea, respiratory distress): _____

Final RSV test result: Negative Positive Unknown

Other significant viruses/bacteria isolated: _____

Medical support while in hospital

Supplemental O2: No Yes: Number of days: _____

NG feeding: No Yes: Number of days: _____

IV fluids: No Yes: Number of days: _____

PICU admission: No Yes: Number of days: _____

CPAP: No Yes: Number of days: _____

Intubated/Ventilated: No Yes: Number of days: _____

Other treatments? Please specify: _____

Please complete as much information as possible, then fax to 604-875-2879, or toll-free 1-877-625-7555.

RSV Program – Tracking and Screening Tool



NOTE: This form is a tool to track eligible infants during the off season, with particular attention to infants <35 weeks gestational age **or** with chronic lung disease **or** who may qualify under the “Indications Requiring Adjudication” category below.

Patient Information

Discharge to home (dd/mmm/yy): _____

Last Name: _____

First Name: _____

Date of Birth (dd/mmm/yy): _____

PHN: _____

Gender: _____ Gestational Age at Birth (weeks + days): _____

Birth Weight: _____ grams

Transfer to other Hospital? If yes, name: _____ on (dd/mmm/yy) _____

Parent/Guardian Name: _____ Parent/Guardian Telephone: _____

Accepting Physician Name: _____ Accepting Physician Telephone: _____

Pre-Approved Indications

- Premature with BPD/CLD (O₂ or CPAP for >28 days) **and** DoB on or after 01-Nov-19 **and** continuous O₂ requirements on or after 01-Jul-20
- Premature (<29w) discharge home on or after 01-Sep-20
- Premature (29w–34w+6days) without BPD discharged home on or after 01-Oct-20 **and** Risk Factor Score ≥ 42 points
- Home respiratory support (e.g., home oxygen, CPAP, tracheostomy) on or after 01-Nov-20 and born on or after 01-Nov-18
- Multiple of approved child **and** under 35 weeks gestation at birth **and** DoB on or after 01-Nov-19
- Hemodynamically significant CHD **and** born on or after 01-Nov-19
- Down Syndrome **and** DoB on or after 01 April 2020

Risk Factor Assessment

- Discharged home Dec, Jan, or Feb+20 points
 - Discharged home Nov or Mar+10 points
 - Female infant not receiving breastmilk+8 points
 - GA at birth 29w or 30w + 6 days+10 points
 - ≥2 smokers in household+8 points
 - Male infant+8 points
 - Other <5 year old in home (not including multiples)+14 points
 - Regular daycare in first 3 mos after discharge*+22 points
 - Remote residence (>1hr or 100 km to hospital able to provide paediatric care)+10 points
 - 6+ people in household (including multiples)+12 points
 - SGA (birth weight <10th percentile)+8 points
- Total Points: _____

Indications Requiring Adjudication (Note: also complete risk factor assessment above.)

- Significant cardiopulmonary disability** **and** DoB on or after 01 Nov 2018
- Severe immunodeficiency **and** DoB on or after 01-Nov-18
- Progressive neuromuscular disease and inability to clear secretions **and** DoB on or after 01-Nov-18
- Other: _____

Additional Relevant Information:

* i.e., home or facility-based group daycare with 4 or more children

** i.e., pulmonary hypertension, pulmonary malformation, severe BPD, progressive neuromuscular disease, other diagnosis

This form is for clinicians.

- Begin a conversation using consent language, such as, “Do you have a few minutes?”
- *Tell them who you are* (e.g., that you work with Cardiology, or another program); and that you work with BC’s RSV (Prevention) Program.
- Ask the parent/guardian *whether they have heard of RSV*; if not, reassure them *most people haven’t*. Tell them that it *stands for Respiratory Syncytial Virus* and is a respiratory virus.
- Explain the following:
 - RSV is one of many viruses that become more common in winter months, and the majority of babies have had it by age 1, and almost all by age 2.
 - For adults and older children it’s like a cold; but some can get quite sick from RSV, especially if born prematurely, have heart or lung problems, or have trouble clearing their airways.
 - Because it’s a virus treatments like antibiotics do not work, though oxygen and IV hydration have been used as supportive therapies.
- Introduce reason for the conversation, such as by saying: “One of the reasons I’m calling you is because there is a medicine that can help prevent RSV. This medicine, called palivizumab, is for a select group of babies and your baby has qualified because of their heart defect/prematurity/etc.”
- Explain that because palivizumab is an antibody and not a vaccine, it doesn’t prevent RSV, but helps support the immune system so infants don’t get as sick from it, keeping the virus away from the lower airway, where it can cause more problems.
- Explain that sometimes babies who have had palivizumab still come to the hospital with RSV, but the hope is palivizumab makes it less severe.
- Quote studies that determine a 55% reduction in hospitalizations in premature babies and a 45% reduction in cardiac patients after receipt of palivizumab.
- Address other ways to prevent RSV, such as hand-washing around the baby, and avoiding:
 - Large crowds (e.g., malls, buses)
 - Second-hand smoke
 - Sick people
 - Kissing your baby on the face, particularly when parent is experiencing symptoms
 Express these measures are the best ways to prevent the spread of RSV infection.
- Explain it is an injection that goes into the baby’s muscle in their thigh and, can be a total of 3 injections (4 where applicable). It takes one injection every month during the cold season which is from November to March/April. The first two doses are given three weeks apart; subsequent doses are administered thereafter at four to five weeks apart, up to the limit prescribed by the guidelines of BC’s RSV Program.
- Palivizumab is generally well tolerated. There are usually no side effects, but like any medication there may be some side effects linked to the immune response, most commonly:
 - ↳ The baby seems “a bit off”;
 - ↳ Not feeding well;
 - ↳ Runny nose and other cold-like symptoms (with or without a fever);
 - ↳ An ear infection; and
 - ↳ A rash.
 There is always a risk of serious reaction, like any medicine someone has not had (in studies, less than 1 in 100,000 cases of serious reaction to palivizumab have been identified.) If a fever lasts more than 24 hours, it is recommended a doctor see the baby, in case something else is going on.

- Gently explain RSV gets worse before it gets better (usually around day 3-5). Watch the baby closely at this time because babies do not have a lot of reserve. The baby should be seen by a doctor if you are concerned, especially if the baby appears to be having difficulty breathing. This gives the doctor a chance to assess the baby and also get a baseline of what the baby looked like in case he/she gets worse.
- Tell the family that their baby has already been approved by Cardiology/their physician/etc. for palivizumab, and ask whether they are interested. (Spell out any unrecognized terms if they wish to research the subject.)
- If they agree to proceed, explain the follow-up portion of the authorization:
 - The details of each dose given will be sent to the program (date, dosage, and weight).
 - A final follow-up telephone call will be made in April or May to ask how the patient has done for the remainder of the winter / early spring.
 - If the patient is hospitalized with RSV-related illness, we may contact the family to ask permission to access information from the hospitalization record (at which point no further doses will be administered).

FREQUENTLY ASKED QUESTIONS

“Can I have my baby’s four-month immunizations done there in the clinic?”

Unfortunately not. Babies’ immunizations can be arranged through the public health nurse. Paediatricians often do not administer immunizations, as public health nurses are very informed on the latest in immunization policies, and their capacity to document is much more consistent.

“Can my baby have his/her RSV shot on the same day as his/her immunizations?”

There is no contraindication to administering them at the same time, but it is recommended to give them separately, especially on the first dose; that way, if there’s an adverse reaction, it’s clear which one caused it.

“Should I give my baby Tylenol before or after? How much?”

Giving your baby Tylenol is really the discretion of the parent or caregiver. Dosage is based on age/weight group, as detailed on the bottle. We do not have Tylenol to provide you; it can be found at your local pharmacy.

“Does *Emla* help decrease the pain of the injection?”

While *Emla* helps to decrease the surface pain associated with needles, it doesn’t really make a difference deep in the muscle where the medication is being injected. It’s your choice.

“My child’s application was denied; who can I talk to about this?”

If you and your doctor strongly feel that s/he should have been approved, it is recommended your doctor fill out another request form giving even more detailed information as to why s/he believes your child is a candidate.

“Can my baby feed immediately after the shot?”

Absolutely. In fact, many moms breastfeed while the baby receives their shot to help comfort them.

“Can my baby get their RSV shot at the same time they see their paediatrician in the Medical Day Unit?”

If an RSV Clinic is running on the same day, then the RSV nurse can easily administer the dose with the paediatrician’s permission; if there isn’t, this will have to be coordinated with the MDU charge nurse and is at their discretion.

“Can someone other than the RSV nurse give a shot of palivizumab?”

Yes. While it is suggested the RSV nurse give the dose when possible (to keep the left-over palivizumab in their clinic), a bedside nurse can also administer a dose when necessary to approved infants.

Information for Parents about Respiratory Syncytial Virus or RSV



The Pharmacy Department
4480 Oak Street, Vancouver, BC V6H 3V4
604-875-2867 • 1-877-625-7888
www.bcchildrens.ca

Is RSV serious?

Most children that get RSV will experience a minor cold which will go away in 1 to 2 weeks. In a small number of children, RSV can develop into a more severe infection, especially in children who:

- Are born premature
- Have chronic lung disease
- Have heart disease
- Are less than 6 months old

What is Respiratory Syncytial Virus (RSV)?

RSV is a virus that affects the lungs and airways. It is one of the most common viruses in infancy and childhood. Researchers say that almost all children have had RSV by the time they are three. It is the most frequent cause of lower respiratory tract infection in children. You can learn more about the lungs and the respiratory system at: www.aboutkidshealth.ca/BCCH/En/HowTheBodyWorks

How do you catch RSV?

RSV is very easy to catch. It is spread by contact such as touching, kissing, or shaking hands with a person infected with RSV. It can also be spread by touching countertops, toys, Kleenex or any other surfaces. RSV viruses can last for hours on these objects after an infected person has touched them. You can catch the infection when infectious material touches your mouth, nose or eyes. You can also catch it by inhaling droplets from a sneeze or cough from an infected person. RSV is around all year but is most active from November to April.

There is an increased chance of catching RSV if your child:

- Attends day care.
- Has a sibling who attends day care.
- Lives in a household with 5 or more people.
- Is exposed to second hand smoke.
- Is exposed to crowded environments.

What are the symptoms of RSV?

The symptoms of RSV are often like that of the common cold:

- Runny or stuffy nose
- Cough
- Low grade fever (less than 38.5° C or 101° F)
- Not feeling hungry

The symptoms can get worse if the virus moves lower and causes inflammation of the lungs. Symptoms could include:

- Difficulty breathing or rapid breathing
- Unusual or long pauses of breathing
- Wheezing
- Difficulty feeding

When should I take my child to the doctor?

If your child seems to be getting sicker, with more rapid breathing, a wheezy sound, high temperature or is having a harder time feeding they should be seen by a doctor. If they are having a lot of trouble breathing they should be taken to emergency as soon as possible.

How do I protect my child against RSV?

- **Clean your hands** each time before touching your baby and ask others to do the same. You can use warm water and soap or an alcohol based cleanser. More information about good hand washing is available at: http://www.cw.bc.ca/library/pdf/pamphlets/PHSA311_HowToHandRubWash_2010_Dec17.pdf
- Keep your child away from people who have colds or who are sick. **This includes saying “No visiting” to family and friends if they are ill.**
- Try to avoid crowded places such as church, daycare centres, and shopping malls during the RSV season (from November to April).
- Keep your child away from second hand smoke, smokers who have recently smoked, and clothes that smell of smoke.
- Do not share personal items such as cups, washcloths, and towels with people who are ill.
- Breastfeed your child. It may help protect your child from catching RSV.

Information for Parents about Synagis



The Pharmacy Department
4480 Oak Street, Vancouver, BC V6H 3V4
604-875-2867 • 1-877-625-7888
www.bcchildrens.ca

What is Synagis®?

It is a medication that helps a child's body fight off a serious respiratory syncytial virus also called RSV. It is given every month for 3 to 5 months during the RSV season. In BC the RSV season is November to April.

Why has my child been prescribed Synagis®?

Your child has more risk of developing a severe RSV infection. Your doctor has asked that your child receive Synagis®.

How is Synagis® given?

It is given by needle into the thigh muscles. If your child needs more than 1 ml of Synagis® the amount is split and your child will receive a shot in each thigh.

Is Synagis® a vaccine like the other immunizations my child receives?

No. There is no vaccine available for RSV. Synagis® is a type of antibody. It works like antibodies that your child's body makes naturally to fight an infection. The antibodies from Synagis® help your child for about one month.

Is Synagis® a blood product?

No. There is also no chance of your child getting an infection from Synagis®.

Does my child need to receive all of the monthly injections?

Yes! It is very important that your child get all of the injections. Each injection protects your child from a serious RSV infection for about 30 days. It is very important that you bring your child to her or his appointment every month during the RSV season. If you miss an appointment then contact your clinic to reschedule as soon as possible.

What are the side effects of Synagis®?

Synagis® has few side effects. If side effects develop they are usually mild and do not last very long. Side effects may include:

- a mild fever
- a rash
- redness and soreness at the injection site.

Severe side effects are very rare.

Can my child still receive their other immunizations?

Yes, Synagis® does not interfere with other immunizations. It can be given on the same day.

If my child is sick can they still receive their Synagis®?

Usually yes. If your child is very sick with a high fever you should contact your doctor. Your doctor may want to wait until your child is well. On the other hand your doctor may feel that waiting to give the Synagis® may be a greater risk for your child. A mild fever or cold is usually not a reason to wait.

Can my child still get RSV even if they are receiving Synagis®?

Yes, but the chance of getting so sick that she or he needs to be admitted to hospital is reduced. It is also important to know that Synagis® will not prevent other viral infections.

Remember – it is very important that your child receive all of her or his injections **on time** to be protected for the entire RSV season.

Protect your child by coming every month for her or his Synagis injection.

呼吸道合胞病毒嚴重嗎？

大部分感染了呼吸道合胞病毒（本文簡稱合胞病毒）的兒童都會在1至2周內出現輕微傷風的病徵。少數兒童則會出現較嚴重感染。這些兒童包括：

- 早產者
- 有長期肺病
- 有心臟病
- 未滿6個月大

何謂呼吸道合胞病毒（合胞病毒）？

合胞病毒是一種影響肺部和氣道的病毒，是嬰兒和兒童期間最常見的病毒之一。研究人員表示，幾乎所有兒童在屆滿3歲前均曾感染合胞病毒。這種病毒是引致兒童下呼吸道感染的最普遍成因。如要更詳盡了解肺部和呼吸道，可上網至：

www.aboutkidshealth.ca/BCCH/En/HowTheBodyWorks（英文網站）。

如何感染合胞病毒？

合胞病毒十分容易傳染。只要觸摸、親吻合胞病毒感染者，或與他們握手，病毒便會透過這些接觸傳播。另外，接觸工作枱、玩具、紙巾或任何其他表面，亦可以是傳播病毒的途徑。感染者接觸過的物件，便有合胞病毒在表面停留數小時。如果你的口、鼻或眼睛接觸到帶病毒的物件，或者你吸入患者打噴嚏或咳嗽濺出的飛沫，亦有機會受感染。合胞病毒全年均有，但在十一月至四月期間最為活躍。

如果你的子女屬於以下情況，便有較大機會感染合胞病毒：

- 上日託中心。
- 有兄弟姐妹上日託中心。
- 家中有5名或以上成員。
- 會接觸二手煙。
- 處身於稠密的環境。

呼吸道合胞病毒有何病徵？

呼吸道合胞病毒的病徵與普通傷風類似：

- 流鼻水或鼻塞
- 咳嗽
- 發低燒（低於38.5°C（攝氏）或101°F（華氏））
- 不會感到飢餓

如果病毒向下蔓延，引致肺部發炎，病徵便會惡化。徵

狀包括：

- 呼吸困難或急速
- 呼吸異常或間歇很長
- 發出喘聲
- 難於餵食

我何時要帶小孩看醫生？

如果小孩病情惡化，例如呼吸更急速、發出喘聲、發高燒或更難於餵食，你便須要帶小孩看醫生。如果小孩呼吸十分困難，你便要盡快帶他／她到急救部門。

我如何保障子女避免呼吸道合胞病毒？

- 清潔雙手然後才觸摸嬰兒，其他接觸嬰兒的人亦須要先洗手。你可以用溫水加肥皂，或者用含酒精的清潔劑。要了解如何能徹底清潔雙手，可上網至：http://www.cw.bc.ca/library/pdf/pamphlets/PHSA311_HowToHandRubWash_2010_Dec17.pdf（英文網站）。
- 小孩要與傷風病患或感到不適者保持距離。換言之，如有家人或親友不適，請他們“不要到訪”。
- 合胞病毒高峰期間（十一月至四月）盡量避開人多聚集的地方，例如教會、日託中心及商場。
- 小孩應避開二手煙、剛剛吸煙或衣物仍有煙味的人士。
- 不要與患病不適者共用個人物品，例如杯、洗滌布及毛巾等。
- 母乳餵哺小孩有助保護他／她免受呼吸道合胞病毒感染。

甚麼是Synagis®？

Synagis®是一種藥物，專門幫助兒童身體抵抗一種名為呼吸道合胞病毒（簡稱合胞病毒）的嚴重病毒。在合胞病毒高峰期間，兒童每個月接受這種藥物一次，為期3至5個月。卑詩省的合胞病毒高峰期為十一月至四月。

為何我的子女需要接受Synagis®？

你的子女有較大機會出現嚴重的呼吸道合胞病毒感染。你的子女需要接受Synagis®，是出於醫生的指示。

Synagis®如何服用？

Synagis®以針筒注射在大腿上。如果你的子女需要的Synagis®劑量多於1 ml（毫升），藥物會分成兩份，分別注射在兩邊大腿上。

Synagis®是否類似子女接受的其他免疫注射？

不是。現在並無疫苗預防合胞病毒。Synagis®是一種抗體，功能類似兒童抵抗感染時天然製造的抗體。Synagis®的抗體可幫助兒童抵抗病毒約一個月。

Synagis®是血液產品嗎？

不是。你的子女不會因接受Synagis®而受感染。

我的子女需要在整個高峰期每月接受一次注射嗎？

是！你的子女接受所有注射是很重要的。每次注射能保障小孩在約為30天內不至感染嚴重的呼吸道合胞病毒。在合胞病毒高峰期間，你必須帶小孩每個月接受注射。如果你未能按時赴約，請盡快聯絡診所重新預約時間。

Synagis®有甚麼副作用？

Synagis®的副作用很少。如果有，一般也很輕微，而且不會持續長久。副作用或包括：

- 輕微發燒
- 出疹
- 注射部位發紅和疼痛。

嚴重的副作用非常罕見。

我的子女仍能接受其他免疫注射嗎？

可以。Synagis®不會干擾其他免疫注射。小孩可以同日接受疫苗。

如果我的子女感到不適，仍能接受Synagis®嗎？

一般均可以。如果子女感到非常不適，並發高燒，你便要帶她／他看醫生。醫生或要求小孩痊癒後才接受注射。但另一方面，醫生亦可能覺得拖延注射Synagis®對小孩構成更大風險。一般來說，輕微發燒或傷風，都不足以構成延遲注射的理由。

子女接受Synagis®後仍會感染呼吸道合胞病毒嗎？

可以，但嚴重不適以至需要入院治理的機會便可減低。家長須要知道，Synagis®不能預防其他病毒感染。

請緊記—子女在整個呼吸道合胞病毒高峰期，均需**按時**接受所有注射，才能獲得保障。

保障子女，每月安排他們接受Synagis注射。

ਕੀ ਆਰ.ਐੱਸ.ਵੀ. ਗੰਭੀਰ ਹੈ?

ਆਰ.ਐੱਸ.ਵੀ. ਵਾਲਿਆਂ ਜ਼ਿਆਦਾਤਰ ਬੱਚਿਆਂ ਨੂੰ ਮਾਮੂਲੀ ਜਿਹਾ ਸਰਦੀ ਜ਼ੁਕਾਮ ਹੋ ਸਕਦਾ ਹੈ ਜੋ 1 ਤੋਂ 2 ਹਫ਼ਤਿਆਂ ਵਿੱਚ ਚਲਾ ਜਾਂਦਾ ਹੈ। ਕੁੱਝ ਬੱਚੇ ਜਿਹੇ ਬੱਚਿਆਂ ਵਿੱਚ ਆਰ.ਐੱਸ.ਵੀ. ਜ਼ਿਆਦਾ ਗੰਭੀਰ ਇਨਫੈਕਸ਼ਨ ਬਣ ਸਕਦੀ ਹੈ ਖਾਸ ਕਰ ਉਹ ਬੱਚੇ:

- ਜੋ ਸਮੇਂ ਤੋਂ ਪਹਿਲਾਂ ਪੈਦਾ ਹੋਏ ਹੋਣ
- ਜਿਨ੍ਹਾਂ ਨੂੰ ਫੇਫੜਿਆਂ ਦੀ ਪੱਕੀ ਬਿਮਾਰੀ ਹੈ
- ਜਿਨ੍ਹਾਂ ਨੂੰ ਦਿਲ ਦਾ ਰੋਗ ਹੈ
- ਜੋ 6 ਮਹੀਨਿਆਂ ਤੋਂ ਘੱਟ ਉਮਰ ਦੇ ਹਨ

ਰੈਸਪੀਰੇਟਰੀ ਸਿੰਸੀਸ਼ੀਅਲ ਵਾਇਰਸ (ਆਰ.ਐੱਸ.ਵੀ.) ਕੀ ਹੈ?

ਆਰ.ਐੱਸ.ਵੀ. ਇੱਕ ਵਾਇਰਸ ਹੈ ਜੋ ਫੇਫੜਿਆਂ ਅਤੇ ਸਾਹ ਨਲੀ ਤੇ ਅਸਰ ਕਰਦਾ ਹੈ। ਬਚਪਨ ਦੀ ਉਮਰ ਵਿੱਚ ਇਹ ਇੱਕ ਆਮ ਵਾਇਰਸ ਹੈ। ਅਨੁਸੰਧਾਨ ਕਰਨ ਵਾਲਿਆਂ ਦਾ ਕਹਿਣਾ ਹੈ ਕਿ 3 ਸਾਲ ਦੀ ਉਮਰ ਤੱਕ ਤਕਰੀਬਨ ਸਾਰੇ ਬੱਚਿਆਂ ਨੂੰ ਆਰ.ਐੱਸ.ਵੀ. ਦਾ ਅਸਰ ਹੁੰਦਾ ਹੀ ਹੈ। ਬੱਚਿਆਂ ਦੀ ਸਾਹ ਨਲੀ ਦੇ ਹੇਠਲੇ ਹਿੱਸੇ ਵਿੱਚ ਇਨਫੈਕਸ਼ਨ ਦਾ ਕਾਰਨ ਜ਼ਿਆਦਾਤਰ ਇਹੀ ਵਾਇਰਸ ਹੁੰਦਾ ਹੈ। ਤੁਸੀਂ ਫੇਫੜਿਆਂ ਅਤੇ ਸਾਹ ਪ੍ਰਣਾਲੀ ਬਾਰੇ ਹੋਰ ਜ਼ਿਆਦਾ ਜਾਣਕਾਰੀ www.aboutkidshealth.ca/BCCH/En/HowTheBodyWorks ਵੈੱਬਸਾਈਟ ਤੋਂ ਲੈ ਸਕਦੇ ਹੋ।

ਆਰ.ਐੱਸ.ਵੀ. ਕਿਵੇਂ ਹੋ ਜਾਂਦਾ ਹੈ?

ਆਰ.ਐੱਸ.ਵੀ. ਬੜੀ ਆਸਾਨੀ ਨਾਲ ਲੱਗ ਜਾਂਦਾ ਹੈ। ਇਹ ਆਰ.ਐੱਸ.ਵੀ. ਦੀ ਇਨਫੈਕਸ਼ਨ ਵਾਲੇ ਵਿਅਕਤੀ ਨੂੰ ਛੂਹਣ, ਚੁੰਮਣ ਜਾਂ ਹੱਥ ਮਿਲਾਉਣ ਨਾਲ ਫੈਲਦਾ ਹੈ। ਇਹ ਕਾਊਂਟਰਟਾਪ, ਖਿਡਾਉਣੇ, ਕਲੀਨੈਕਸ ਜਾਂ ਕਿਸੇ ਵੀ ਹੋਰ ਸਤਹ ਨੂੰ ਛੂਹਣ ਨਾਲ ਫੈਲ ਸਕਦਾ ਹੈ। ਕਿਉਂਕਿ ਇਨਫੈਕਸ਼ਨ ਵਾਲੇ ਵਿਅਕਤੀ ਦੁਆਰਾ ਇਹ ਚੀਜ਼ਾਂ ਛੂਹਣ ਤੋਂ ਬਾਅਦ ਆਰ.ਐੱਸ.ਵੀ. ਵਾਇਰਸ ਇਨ੍ਹਾਂ ਤੇ ਕਈ ਘੰਟਿਆਂ ਤੱਕ ਰਹਿ ਸਕਦਾ ਹੈ। ਜਦੋਂ ਦੂਸ਼ਿਤ ਚੀਜ਼ਾਂ ਤੁਹਾਡੇ ਮੂੰਹ, ਨੱਕ ਜਾਂ ਅੱਖਾਂ ਨੂੰ ਛੂਹਦੀਆਂ ਹਨ ਤਾਂ ਇਨਫੈਕਸ਼ਨ ਤੁਹਾਨੂੰ ਹੋ ਸਕਦੀ ਹੈ। ਇਨਫੈਕਸ਼ਨ ਵਾਲੇ ਵਿਅਕਤੀ ਦੁਆਰਾ ਨਿੱਛ ਮਾਰਨ ਜਾਂ ਖੰਘਣ ਨਾਲ ਹਵਾ ਵਿੱਚ ਫੈਲੀਆਂ ਬੂੰਦਾਂ ਸਾਹ ਨਾਲ ਅੰਦਰ ਜਾ ਕੇ ਵੀ ਤੁਹਾਨੂੰ ਇਨਫੈਕਟ ਕਰ ਸਕਦੀਆਂ ਹਨ। ਆਰ.ਐੱਸ.ਵੀ. ਤਕਰੀਬਨ ਸਾਰਾ ਸਾਲ ਹੀ ਰਹਿੰਦਾ ਹੈ ਪਰ ਨਵੰਬਰ ਤੋਂ ਅਪ੍ਰੈਲ ਤੱਕ ਜ਼ਿਆਦਾ ਸਰਗਰਮ ਹੁੰਦਾ ਹੈ।

ਤੁਹਾਡੇ ਬੱਚੇ ਨੂੰ ਆਰ.ਐੱਸ.ਵੀ. ਹੋਣ ਦੇ ਜ਼ਿਆਦਾ ਚਾਂਸ ਹਨ ਜੇ:

- ਉਹ ਡੇ ਕੇਅਰ ਵਿੱਚ ਜਾਂਦਾ ਹੈ।
- ਉਸ ਦਾ ਛੋਟਾ ਭਰਾ/ਭੈਣ ਡੇ ਕੇਅਰ ਜਾਂਦਾ ਹੈ।
- ਉਹ 5 ਜਾਂ ਇਸ ਤੋਂ ਵੱਧ ਜੀਆਂ ਵਾਲੇ ਪਰਵਾਰ ਵਿੱਚ ਰਹਿੰਦਾ ਹੈ।
- ਉਸ ਨੂੰ ਤਮਾਕੂ ਦੇ ਪੁੱਠੇ ਵਿੱਚ ਸਾਹ ਲੈਂਦਾ ਹੈ।
- ਉਸ ਨੂੰ ਭੀੜ ਵਾਲੇ ਵਾਤਾਵਰਨ ਵਿੱਚ ਰਹਿੰਦਾ ਹੈ।

ਆਰ.ਐੱਸ.ਵੀ. ਦੇ ਰੋਗ ਲੱਛਣ ਕੀ ਹਨ?

ਆਰ.ਐੱਸ.ਵੀ. ਦੇ ਰੋਗ ਲੱਛਣ ਆਮ ਤੌਰ ਤੇ ਸਰਦੀ ਜ਼ੁਕਾਮ ਜਿਹੇ ਹੀ ਹੁੰਦੇ ਹਨ:

- ਨੱਕ ਵਗਣਾ ਜਾਂ ਬੰਦ ਹੋਣਾ
- ਖੰਘ
- ਹਲਕਾ ਜਿਹਾ ਬੁਖਾਰ (38.5° C ਜਾਂ 101° F ਤੋਂ ਘੱਟ)
- ਭੁੱਖ ਨਾ ਲੱਗਣੀ

ਜੇ ਵਾਇਰਸ ਕਾਫੀ ਹੇਠਾਂ ਜਾ ਕੇ ਫੇਫੜਿਆਂ ਵਿੱਚ ਸੋਜਸ਼ ਪੈਦਾ ਕਰ ਦੇਵੇ ਤਾਂ ਇਹ ਲੱਛਣ ਗੰਭੀਰ ਹੋ ਸਕਦੇ ਹਨ। ਇਸ ਦੀਆਂ ਨਿਸ਼ਾਨੀਆਂ ਵਿੱਚ ਇਹ ਸ਼ਾਮਲ ਹੋ ਸਕਦੇ ਹਨ:

- ਸਾਹ ਲੈਣ ਵਿੱਚ ਤਕਲੀਫ਼ ਜਾਂ ਸਾਹ ਤੇਜ਼ ਆਉਣਾ
- ਅਸਾਧਾਰਨ ਜਾਂ ਸਾਹ ਕਾਫੀ ਦੇਰ ਬਾਅਦ ਆਉਣਾ
- ਸਾਹ ਵਿੱਚ ਘਰਰ ਘਰਰ ਦੀ ਅਵਾਜ਼ ਹੋਣਾ
- ਖਾਣ ਪੀਣ ਵਿੱਚ ਤਕਲੀਫ਼

ਮੈਂ ਆਪਣੇ ਬੱਚੇ ਨੂੰ ਡਾਕਟਰ ਕੋਲ ਕਦੋਂ ਲੈ ਕੇ ਜਾਵਾਂ?

ਜੇ ਤੁਹਾਡਾ ਬੱਚਾ ਤੇਜ਼ ਸਾਹ, ਸਾਹ ਵਿੱਚ ਘਰਰ ਘਰਰ ਦੀ ਅਵਾਜ਼ ਜਾਂ ਤੇਜ਼ ਟੈਂਪਰੇਚਰ ਨਾਲ ਬਿਮਾਰ ਹੁੰਦਾ ਨਜ਼ਰ ਆਉਂਦਾ ਹੈ ਅਤੇ ਖਾਣ ਪੀਣ ਵਿੱਚ ਬਹੁਤ ਤਕਲੀਫ਼ ਮਹਿਸੂਸ ਕਰਦਾ ਹੈ ਤਾਂ ਬੱਚਾ ਡਾਕਟਰ ਨੂੰ ਦਿਖਾਉਣਾ ਚਾਹੀਦਾ ਹੈ। ਜੇ ਸਾਹ ਲੈਣ ਵਿੱਚ ਜ਼ਿਆਦਾ ਤਕਲੀਫ਼ ਹੋ ਰਹੀ ਹੋਵੇ ਤਾਂ ਜਿੰਨੀ ਜਲਦੀ ਹੋ ਸਕੇ ਅਮਰਜੈਸੀ ਵਿੱਚ ਲੈ ਜਾਣਾ ਚਾਹੀਦਾ ਹੈ।

ਮੈਂ ਆਪਣੇ ਬੱਚੇ ਨੂੰ ਆਰ.ਐੱਸ.ਵੀ. ਤੋਂ ਕਿਵੇਂ ਬਚਾਵਾਂ?

- ਬੱਚੇ ਨੂੰ ਹੱਥ ਲਗਾਉਣ ਤੋਂ ਪਹਿਲਾਂ ਹਰ ਵਾਰ **ਆਪਣੇ ਹੱਥ ਧੋਣੇ** ਅਤੇ ਬਾਕੀਆਂ ਨੂੰ ਵੀ ਇਸ ਤਰ੍ਹਾਂ ਕਰਨ ਲਈ ਕਹੋ। ਇਸ ਲਈ ਤੁਸੀਂ ਗਰਮ ਪਾਣੀ ਅਤੇ ਸਾਬਣ ਜਾਂ ਅਲਕੋਹਲ ਆਧਾਰਤ ਪਦਾਰਥ ਵਰਤੋ। ਚੰਗੀ ਤਰ੍ਹਾਂ ਹੱਥ ਧੋਣ ਲਈ ਹੋਰ ਜ਼ਿਆਦਾ ਜਾਣਕਾਰੀ http://www.cw.bc.ca/library/pdf/pamphlets/PHSA311_HowToHandRubWash_2010_Dec17.pdf ਵੈੱਬਸਾਈਟ ਤੇ ਉਪਲਬਧ ਹੈ।
- ਸਰਦੀ ਜ਼ੁਕਾਮ ਵਾਲੇ ਜਾਂ ਬਿਮਾਰ ਲੋਕਾਂ ਤੋਂ ਆਪਣੇ ਬੱਚੇ ਨੂੰ ਦੂਰ ਰੱਖੋ। **ਇਸ ਵਿੱਚ ਇਹ ਕਹਿਣਾ ਵੀ ਸ਼ਾਮਲ ਹੈ ਕਿ ਉਨ੍ਹਾਂ ਪਰਵਾਰਾਂ ਅਤੇ ਦੋਸਤਾਂ ਨੂੰ ਵੀ “ਮਿਲਨ ਨਹੀਂ ਜਾਣਾ” ਜੋ ਬਿਮਾਰ ਹਨ।**
- ਨਵੰਬਰ ਤੋਂ ਅਪ੍ਰੈਲ ਦੇ ਆਰ.ਐੱਸ.ਵੀ. ਦੇ ਮੌਸਮ ਵਿੱਚ ਭੀੜ ਵਾਲੀਆਂ ਜਗ੍ਹਾਂ ਜਿਵੇਂ ਕਿ ਗੁਰਦੁਆਰਾ/ਮੰਦਰ/ਚਰਚ, ਡੇ ਕੇਅਰ ਸੈਂਟਰ ਅਤੇ ਚੀਜ਼ਾਂ ਖ਼ੀਦਣ ਲਈ ਮਾਲਜ਼ ਵਿੱਚ ਜਾਣ ਤੋਂ ਪਰਹੇਜ਼ ਕਰੋ।
- ਆਪਣੇ ਬੱਚੇ ਨੂੰ ਤਮਾਕੂ ਦੇ ਪੁੱਠੇ, ਜਿਨ੍ਹਾਂ ਨੇ ਹੁਣੇ ਸਿਗਰਟ ਪੀਤੀ ਹੋਵੇ ਅਤੇ ਉਹ ਕੱਪੜੇ ਜਿਨ੍ਹਾਂ ਵਿੱਚੋਂ ਤਮਾਕੂ ਦੇ ਪੁੱਠੇ ਦੀ ਗੰਧ ਆਉਂਦੀ ਹੋਵੇ ਤੋਂ ਦੂਰ ਰੱਖੋ।
- ਬਿਮਾਰ ਲੋਕਾਂ ਨਾਲ ਆਪਣੀਆਂ ਚੀਜ਼ਾਂ ਜਿਵੇਂ ਕਿ ਕੱਪ, ਨਹਾਉਣ ਵਾਲੇ ਕੱਪੜੇ ਅਤੇ ਤੌਲੀਏ ਸਾਂਝੇ ਨਾ ਕਰੋ। ਬੱਚੇ ਨੂੰ ਆਪਣਾ ਦੁੱਧ ਚੁੰਘਾਓ। ਇਸ ਨਾਲ ਤੁਹਾਡੇ ਬੱਚੇ ਦਾ ਆਰ.ਐੱਸ.ਵੀ. ਹੋਣ ਤੋਂ ਬਚਾਅ ਹੋ ਸਕਦਾ ਹੈ।

ਸਾਈਨੇਜਿਸ (Synagis®) ਕੀ ਹੈ?

ਇਹ ਇੱਕ ਦਵਾਈ ਹੈ ਜੋ ਗੰਭੀਰ ਰੈਸਪੀਰੇਟਰੀ ਸਿੰਸੀਸੀਅਲ ਵਾਇਰਸ ਜਿਸ ਨੂੰ ਆਰ.ਐੱਸ.ਵੀ. ਵੀ ਕਹਿੰਦੇ ਹਨ ਦੇ ਵਿਰੁੱਧ ਲੜਨ ਲਈ ਬੱਚੇ ਦੇ ਸਰੀਰ ਦੀ ਮਦਦ ਕਰਦੀ ਹੈ। ਆਰ.ਐੱਸ.ਵੀ. ਦੇ ਮੌਸਮ ਦੌਰਾਨ 3 ਤੋਂ 5 ਮਹੀਨਿਆਂ ਲਈ ਹਰ ਮਹੀਨੇ ਦਿੱਤੀ ਜਾਂਦੀ ਹੈ। ਬੀ.ਸੀ. ਵਿਚ ਨਵੰਬਰ ਤੋਂ ਅਪ੍ਰੈਲ ਤੱਕ ਆਰ.ਐੱਸ.ਵੀ. ਦਾ ਮੌਸਮ ਹੁੰਦਾ ਹੈ।

ਮੇਰੇ ਬੱਚੇ ਨੂੰ ਸਾਈਨੇਜਿਸ ਕਿਉਂ ਤਜਵੀਜ਼ ਕੀਤੀ ਗਈ ਹੈ?

ਕਿਉਂਕਿ ਤੁਹਾਡੇ ਬੱਚੇ ਨੂੰ ਗੰਭੀਰ ਆਰ.ਐੱਸ.ਵੀ. ਇਨਫੈਕਸ਼ਨ ਹੋਣ ਦਾ ਜ਼ਿਆਦਾ ਖਤਰਾ ਹੈ। ਇਸ ਲਈ ਤੁਹਾਡੇ ਡਾਕਟਰ ਨੇ ਬੱਚੇ ਨੂੰ ਸਾਈਨੇਜਿਸ ਲੈਣ ਲਈ ਕਿਹਾ ਹੈ।

ਸਾਈਨੇਜਿਸ ਕਿਵੇਂ ਦਿੱਤੀ ਜਾਂਦੀ ਹੈ?

ਇਹ ਸੂਈ ਨਾਲ ਪੱਟ ਦੇ ਪੱਠਿਆਂ ਵਿਚ ਦਿੱਤੀ ਜਾਂਦੀ ਹੈ। ਜੇ ਤੁਹਾਡੇ ਬੱਚੇ ਨੂੰ 1 ਮਿ.ਲੀ. ਤੋਂ ਜ਼ਿਆਦਾ ਸਾਈਨੇਜਿਸ ਦੇਣ ਦੀ ਲੋੜ ਹੋਵੇ ਤਾਂ ਦਵਾਈ ਨੂੰ ਵੱਡੇ ਕੇ ਦੋਹਾਂ ਪੱਟਾਂ ਵਿਚ ਇਸ ਦਾ ਟੀਕਾ ਲਗਾਇਆ ਜਾਂਦਾ ਹੈ।

ਕੀ ਸਾਈਨੇਜਿਸ ਉਹੋ ਜਿਹਾ ਵੈਕਸੀਨ ਹੈ ਜੋ ਮੇਰਾ ਬੱਚੇ ਇਮਿਊਨਾਈਜ਼ੇਸ਼ਨ ਲਈ ਲੈਂਦਾ ਹੈ?

ਨਹੀਂ। ਆਰ.ਐੱਸ.ਵੀ. ਲਈ ਕੋਈ ਵੈਕਸੀਨ ਉਪਲਬਧ ਨਹੀਂ। ਸਾਈਨੇਜਿਸ ਇੱਕ ਕਿਸਮ ਦੀ ਐਂਟੀਬਾਡੀ (Antibody) ਹੈ। ਇਹ ਉਨ੍ਹਾਂ ਐਂਟੀਬਾਡੀ ਦੀ ਤਰ੍ਹਾਂ ਹੀ ਕੰਮ ਕਰਦੀ ਹੈ ਜੋ ਤੁਹਾਡੇ ਬੱਚੇ ਦਾ ਸਰੀਰ ਇਨਫੈਕਸ਼ਨ ਨਾਲ ਲੜਣ ਲਈ ਕੁਦਰਤੀ ਬਣਾਉਂਦਾ ਹੈ। ਸਾਈਨੇਜਿਸ ਵਿਚਲੀਆਂ ਐਂਟੀਬਾਡੀ ਤੁਹਾਡੇ ਬੱਚੇ ਨੂੰ ਤਕਰੀਬਨ 1 ਮਹੀਨੇ ਲਈ ਮਦਦ ਕਰਦੀਆਂ ਹਨ।

ਕੀ ਸਾਈਨੇਜਿਸ ਖੂਨ ਤੋਂ ਬਣਦਾ ਹੈ?

ਨਹੀਂ। ਸਾਈਨੇਜਿਸ ਤੋਂ ਤੁਹਾਡੇ ਬੱਚੇ ਨੂੰ ਇਨਫੈਕਸ਼ਨ ਹੋਣ ਦਾ ਕੋਈ ਚਾਂਸ ਨਹੀਂ।

ਕੀ ਮੇਰੇ ਬੱਚੇ ਨੂੰ ਮਹੀਨੇ ਵਾਰ ਸਾਰੇ ਟੀਕੇ ਲਵਾਉਣੇ ਪੈਣਗੇ?

ਹਾਂ ਜੀ। ਇਹ ਬੜਾ ਜ਼ਰੂਰੀ ਹੈ ਕਿ ਤੁਹਾਡਾ ਬੱਚਾ ਸਾਰੇ ਟੀਕੇ ਲਵਾਏ। ਹਰ ਇੱਕ ਟੀਕਾ ਆਰ.ਐੱਸ.ਵੀ. ਦੀ ਗੰਭੀਰ ਇਨਫੈਕਸ਼ਨ ਤੋਂ ਤੁਹਾਡੇ ਬੱਚੇ ਨੂੰ ਤਕਰੀਬਨ 30 ਦਿਨਾਂ ਲਈ ਬਚਾਉਂਦਾ ਹੈ। ਇਸ ਲਈ ਇਹ ਬੜਾ ਜ਼ਰੂਰੀ ਹੈ ਕਿ ਆਰ.ਐੱਸ.ਵੀ. ਦੇ ਮੌਸਮ ਵਿਚ ਹਰ ਮਹੀਨੇ ਬੱਚੇ ਦੀ ਐਪੁਆਇੰਟਮੈਂਟ ਤੇ ਤੁਸੀਂ ਬੱਚੇ ਨੂੰ ਲੈ ਕੇ ਆਓ। ਜੇ ਤੁਸੀਂ ਇੱਕ ਵਾਰ ਨਾ ਆ ਸਕੋ ਤਾਂ ਆਪਣੇ ਕਲੀਨਿਕ ਨੂੰ ਸੰਪਰਕ ਕਰ ਕੇ ਜਿੰਨੀ ਜਲਦੀ ਹੋ ਸਕੇ ਦੁਬਾਰਾ ਐਪੁਆਇੰਟਮੈਂਟ ਬਣਾਓ।

ਸਾਈਨੇਜਿਸ ਦੇ ਗੋਣ ਪ੍ਰਭਾਵ ਕੀ ਹਨ?

ਸਾਈਨੇਜਿਸ ਦੇ ਕੁੱਝ ਕੁ ਗੋਣ ਪ੍ਰਭਾਵ ਹਨ। ਜੇ ਗੋਣ ਪ੍ਰਭਾਵ ਪੈਦਾ ਹੋਣ ਤਾਂ ਬਹੁਤ ਮਮੂਲੀ ਹੁੰਦੇ ਹਨ ਅਤੇ ਜ਼ਿਆਦਾ ਦੇਰ ਨਹੀਂ ਰਹਿੰਦੇ। ਗੋਣ ਪ੍ਰਭਾਵਾਂ ਵਿਚ ਇਹ ਸ਼ਾਮਲ ਹੋ ਸਕਦੇ ਹਨ:

- ਹਲਕਾ ਜਿਹਾ ਬੁਖਾਰ
- ਧੱਫੜ (ਰੈਸ)
- ਟੀਕੇ ਵਾਲੀ ਜਗ੍ਹਾ ਲਾਲ ਹੋਣੀ ਅਤੇ ਦੁਖਣੀ।

ਗੰਭੀਰ ਗੋਣ ਪ੍ਰਭਾਵ ਬਹੁਤ ਹੀ ਘੱਟ ਹੁੰਦੇ ਹਨ।

ਕੀ ਮੇਰਾ ਬੱਚਾ ਹੋਰ ਇਮਿਊਨਾਈਜ਼ੇਸ਼ਨ ਵੀ ਲੈ ਸਕਦਾ ਹੈ?

ਹਾਂ ਜੀ। ਸਾਈਨੇਜਿਸ ਹੋਰ ਇਮਿਊਨਾਈਜ਼ੇਸ਼ਨ ਵਿਚ ਰੁਕਾਵਟ ਨਹੀਂ ਪਾਉਂਦਾ। ਇਹ ਉਸੇ ਦਿਨ ਦਿੱਤਾ ਜਾ ਸਕਦਾ ਹੈ।

ਜੇ ਮੇਰਾ ਬੱਚਾ ਬਿਮਾਰ ਹੈ ਤਾਂ ਕੀ ਉਹ ਫਿਰ ਵੀ ਸਾਈਨੇਜਿਸ ਲੈ ਸਕਦਾ ਹੈ?

ਆਮ ਤੌਰ ਤੇ ਹਾਂ। ਜੇ ਤੁਹਾਡਾ ਬੱਚਾ ਤੇਜ਼ ਬੁਖਾਰ ਕਰ ਕੇ ਬਹੁਤ ਬਿਮਾਰ ਹੈ ਤਾਂ ਆਪਣੇ ਡਾਕਟਰ ਨੂੰ ਸੰਪਰਕ ਕਰੋ। ਜਦ ਤੱਕ ਤੁਹਾਡਾ ਬੱਚਾ ਠੀਕ ਨਹੀਂ ਹੋ ਜਾਂਦਾ ਤੁਹਾਡਾ ਡਾਕਟਰ ਸ਼ਾਇਦ ਠਹਿਰਨ ਲਈ ਕਹੇ। ਇਹ ਵੀ ਹੋ ਸਕਦਾ ਹੈ ਕਿ ਡਾਕਟਰ ਮਹਿਸੂਸ ਕਰੇ ਕਿ ਸਾਈਨੇਜਿਸ ਲੈਣ ਲਈ ਠਹਿਰਨਾ ਬੱਚੇ ਲਈ ਜ਼ਿਆਦਾ ਖਤਰਨਾਕ ਹੈ। ਮਮੂਲੀ ਬੁਖਾਰ ਜਾਂ ਠੰਢ ਠਹਿਰਨ ਲਈ ਕੋਈ ਕਾਰਨ ਨਹੀਂ ਹਨ।

ਜੇ ਮੇਰਾ ਬੱਚਾ ਸਾਈਨੇਜਿਸ ਲੈ ਰਿਹਾ ਹੈ ਤਾਂ ਕੀ ਉਹ ਫਿਰ ਵੀ ਆਰ.ਐੱਸ.ਵੀ. ਲੈ ਸਕਦਾ ਹੈ?

ਹਾਂ ਜੀ। ਪਰ ਉਸ ਦੇ ਇਤਨਾ ਬਿਮਾਰ ਹੋਣ ਦੇ ਚਾਂਸ ਬਹੁਤ ਘੱਟ ਜਾਂਦੇ ਹਨ ਕਿ ਉਸ ਨੂੰ ਹਸਪਤਾਲ ਦਾਖਲ ਹੋਣਾ ਪਵੇ। ਇਹ ਜਾਣਨਾ ਵੀ ਬੜਾ ਜ਼ਰੂਰੀ ਹੈ ਕਿ ਸਾਈਨੇਜਿਸ ਕਿਸੇ ਹੋਰ ਵਾਇਰਲ ਇਨਫੈਕਸ਼ਨ ਨੂੰ ਨਹੀਂ ਚੋਕੇਗਾ।

ਯਾਦ ਰੱਖੋ - ਇਹ ਬੜਾ ਜ਼ਰੂਰੀ ਹੈ ਕਿ ਆਰ.ਐੱਸ.ਵੀ. ਦੇ ਸਾਰੇ ਮੌਸਮ ਦੌਰਾਨ ਸੁਰੱਖਿਆ ਲਈ ਤੁਹਾਡਾ ਬੱਚਾ ਸਾਰੇ ਟੀਕੇ **ਸਮੇਂ ਸਿਰ** ਲਵਾ ਲਵੇ।

ਹਰ ਮਹੀਨੇ ਬੱਚੇ ਦੇ ਸਾਈਨੇਜਿਸ ਦੇ ਟੀਕੇ ਲਈ ਆ ਕੇ ਆਪਣੇ ਬੱਚੇ ਨੂੰ ਸੁਰੱਖਿਅਤ ਕਰੋ।

As part of BC's RSV Program your child will receive up to 4 doses of palivizumab (brand name Synagis®). Palivizumab is given by intramuscular injection into your child's leg muscle. Depending on your child's weight they may receive 1 or 2 injections with each visit.

Any of these pain management measures may help your child during the injection.

BREASTFEEDING

- The combined aspects of holding your child, skin-to-skin contact, the sweet-tasting milk, and the act of sucking helps to reduce discomfort.
- If possible, start breastfeeding your child a few minutes before the injection and continue to breastfeed during the injection and a few minutes after the injection.

HOLD YOUR CHILD UPRIGHT

- Infants and young children are best held upright, unless breastfeeding (i.e., bear hug on your lap.) Hugging feels comfortable and helps your child stay still.
- Hold and support your child but without using excessive force or restraint.

DISTRACTION

- Distraction can be provided by a parent or health care professional.
- Directing your child's attention away from the procedure can help discomfort, such as to something in the room or something you can show them.
- Choose something that will work for the age of your child. For instance:
 - Babies: toys, bubbles, singing
 - Toddlers: toys, bubbles, pop-up books, songs, party blowers

SUCROSE THERAPY

- This therapy works through activation of sweet taste receptors and distraction.
- It is recommended as an option for children under 12 months old who are not breastfeeding.
- Sucrose therapy should be only used for the management of painful procedures, not for general comfort or as food.
- Please discuss with a member of the RSV team as to where sucrose preparations may be purchased and how they are used.

Please remember these measures are intended to **reduce** or manage your child's discomfort. Measures typically work best when used in combinations. After each injection, watch for your child's response and assess if the measures used are helping your child cope with the discomfort of intramuscular injections. Discuss any concerns with your health care provider.

WHAT IS AN INFECTION?

- An infection is caused by germs (bacteria, viruses or fungi).
- Some germs on or in your body are helpful and some germs are harmful.
- An infection occurs when harmful germs get into body tissues or fluids and grow.

WHAT ARE COMMON SITES OF INFECTION?

Common sites of infection are:

- The bowel;
- The top of the head;
- The lungs;
- The nose;
- The skin;
- The stomach;
- The throat; or
- Inside the middle ear.

BEST WAYS TO AVOID INFECTION

Cleaning your hands and your children's hands is the best way to stop the spread of germs. A thorough, careful wash is even more effective. For best results:

1. Wet hands first.
2. Lather with soap and rub hands for 10 to 15 seconds – about the same amount of time as singing the alphabet. Wash all areas, including between your fingers/thumbs and the backs of your hands.
3. Rinse hands well.
4. Dry with a clean towel.

When water and soap are not available, use a hand sanitizer. Keep hand sanitizer out of reach of young children because they may be harmful if swallowed. To apply hand sanitizer:

1. Put hand sanitizer on the palm of one hand.
2. Rub hands together, covering all surfaces of hands and fingers with the hand sanitizer.
3. Rub until dry.

HOW TO PREVENT AND INFECTION IN THE NOSE, THROAT OR LUNGS

Germs that grow in the nose, throat or lungs are spread:

- in the droplets from a cough
- in the mucus from the lungs or nose

An infection spreads when the droplets or mucus from a person with an infection get in the lining of your child's nose, throat or lungs. An infection can spread to your child when:

- the sick person coughs right into your child's face
- germs from the sick person get onto the hands of someone who then touches your child
- germs from the sick person get onto cups, toys or other objects that your child then touches

[continued on following page]

TO PREVENT YOUR CHILD FROM GETTING AN INFECTION IN THE NOSE, THROAT OR LUNGS:

IN HOSPITAL:

- clean your hands with soap and water or a hand sanitizer before and after caring for your baby
- keep your baby in your hospital room with you as much as possible
- do not allow visitors with colds or flu to visit your baby
- breast feeding helps protect your baby from infections, including RSV

AT HOME:

- Keep baby away from places where there are people with colds such as shopping malls or schools
- Teach children to **cover their coughs**. Turn away and cough into a tissue (or their sleeve if a tissue cannot be found) when they cough or sneeze. Teach them not give baby toys or other objects used by a sick person to infants and to teach them to **clean their hands**.
- **Clean your hands** after blowing your nose/coughing/sneezing/wiping or blowing your child's nose
- Use a tissue (only once)
- Clean your hands after being with a sick person

The best ways to prevent your baby from getting an infection are to clean your hands, keep baby away from people with colds or flu, and get annual influenza shots for family members over 6 months of age!

IF YOU HAVE ANY QUESTIONS CALL:

- Your doctor
- A nurse or nursing station [BC's nurse line can be reached by phoning 811]

*Based on "How to Prevent your Child from Getting or Spreading an Infection",
by the Children's Hospital Patient Education Committee of the Winnipeg Regional Health Authority, ©2011.*

These guidelines are applicable to the BC RSV Immunoprophylaxis Program as well.

IMMUNIZATION SKILLS CHECKLIST

Name: _____

Registration No.: _____

ACTIVITY	DATE
CLINIC SETUP	
<input type="checkbox"/> Ensures anaphylaxis kit is complete and accessible	
<input type="checkbox"/> Sets up supplies and equipment to promote proper body mechanics and OHS standards	
<input type="checkbox"/> Follows provincial guidelines when storing, handling or transporting vaccines	
PERFORMS APPROPRIATE CLIENT ASSESSMENT PRIOR TO IMMUNIZATION	
<input type="checkbox"/> Health status	
<input type="checkbox"/> Contraindications and adverse event history	
<input type="checkbox"/> Vaccine history from client/agency record	
<input type="checkbox"/> Determines high risk eligibility for additional vaccines (e.g. influenza)	
<input type="checkbox"/> Recognizes and responds to the unique immunization needs of certain population groups	
VACCINE(S) TO BE ADMINISTERED	
<input type="checkbox"/> Determines vaccine(s) to be administered according to guidelines of the BCCDC Immunization Program	
OBTAINS INFORMED CONSENT	
<input type="checkbox"/> Discusses the implications of the individual's rights, confidentiality, privacy, informed consent and informed refusal	
<input type="checkbox"/> Explains that consent is obtained for a vaccine series and consent is valid until completion of the series	
<input type="checkbox"/> Refers to appropriate HealthLinkBC File(s) and identifies credible sources of immunization information	
<input type="checkbox"/> Using scientific knowledge, delivers clear, concise messages about the risks of vaccine-preventable diseases and the benefits of vaccines	
<input type="checkbox"/> Describes the nature and purpose of the vaccine(s)	
<input type="checkbox"/> Describes the common and expected reactions following immunization	
<input type="checkbox"/> Reviews possible serious or severe adverse events and their frequency	
<input type="checkbox"/> Reviews contraindications and precautions related to vaccine(s) to be administered	
<input type="checkbox"/> Provides aftercare instructions	
<input type="checkbox"/> Ensures client has opportunity to ask questions	

PREPARES VACCINE CORRECTLY	DATE
<input type="checkbox"/> Cleanses hands	
<input type="checkbox"/> Maintains sterile and aseptic technique	
<input type="checkbox"/> Selects correct vaccine, checks vaccine, expiry date, and dosage X 3 prior to administration	
<input type="checkbox"/> Reconstitutes vaccine	
<input type="checkbox"/> Chooses the correct needle length and gauge for the age and size of the client	
DEMONSTRATES CORRECT VACCINE ADMINISTRATION	
<input type="checkbox"/> Instructs proper positioning either by showing parent to position and hold child appropriately or by instructing adult to sit and relax site of injection	
Demonstrates accurate injection technique and site location	
<input type="checkbox"/> Intramuscular	
<input type="checkbox"/> Subcutaneous	
<input type="checkbox"/> Intradermal	
<input type="checkbox"/> Safely handles and disposes of syringe	
<input type="checkbox"/> Assists parent to comfort child as needed	
<input type="checkbox"/> Demonstrates appropriate knowledge of protocol for the management of anaphylaxis, and describes emergency plan to manage anaphylactic event or a fainting episode	
DOCUMENTATION	
<input type="checkbox"/> Documents consent or refusal for immunization	
<input type="checkbox"/> Documents contraindications	
<input type="checkbox"/> Records an immunization encounter on the appropriate documentation instruments accurately and completely.	
<input type="checkbox"/> Records the reason for and planned follow-up action when a scheduled immunization is not given	
<input type="checkbox"/> Reports adverse events in the electronic registry OR submits adverse events via HLTH 2319 form to the appropriate agency	
<input type="checkbox"/> Provides immunization record to client	
CLIENT REMINDERS	
<input type="checkbox"/> Explains when next vaccines are due	
<input type="checkbox"/> Reminds client to report possible serious or adverse events	

Immunization Evaluator(s): _____ (NAME) _____ (SIGNATURE) _____ (DATE)

_____ (NAME) _____ (SIGNATURE) _____ (DATE)



4.0 REPORTING ADVERSE EVENTS

Vaccine safety is a focus of pre-licensure studies. An acceptable safety profile must be observed in order for vaccines to progress to phase III (clinical) trials in humans. These studies provide frequency data on the occurrence of common adverse events such as local reactions at the injection site or systemic events, and grading of the severity of these events.

Uncommon and rare adverse events are usually not identified in pre-licensure studies and reliance is placed on phase IV studies or post-marketing surveillance; this is especially important in the first year or so following introduction of a vaccine (see Canadian Immunization Guide [2006] Part 2- [Vaccine Safety and Adverse Events Following Immunization](#)).¹

Events that **should not be reported**:

- Local injection site reactions and non-specific systemic reactions (e.g., headache, myalgia) should not be reported as AEFI **unless these are more frequent or severe than expected based on clinical trial findings (rates and severity are typically found in the product monograph)**. However, always counsel clients about expected reactions following immunization and how to manage these reactions.
- Events which have another obvious cause (e.g., co-existing conditions)

Events that **should be** reported include the following (full details in Section 6.0 SUMMARY OF REPORTING CRITERIA)

- Serious events: life threatening or resulting in death; requiring hospitalization; resulting in a residual disability; associated with congenital malformation.
- Event requiring urgent medical attention.
- Unusual or unexpected events:
 - the event that has either not been identified previously (for example, Oculo-Respiratory Syndrome (ORS) was first identified during the 2000/2001 influenza season), or
 - the event has been identified before but is occurring with greater frequency in the population (e.g., extensive local reactions)
- Clusters of events: known or new events that occur in a geographic or temporal cluster (e.g., 6 in a week, or 6 in a Health Service Delivery Area) that require further assessment, even if the total number of AEFIs may not be higher than expected.

Temporal association alone (i.e., onset of an event following receipt of vaccine) is not proof of causation.

When an adverse event follows the administration of a passive immunizing agent (e.g., immune globulin) an AEFI report should not be completed. Instead, please follow the



established procedures for reporting an adverse drug reaction to the [Canadian Adverse Drug Reaction Monitoring Program at Health Canada](#).

When an adverse event follows the administration of an active immunizing agent (e.g., vaccine) that is administered *simultaneously* with a passive immunizing agent (e.g., immune globulin) and/or a diagnostic agent (e.g., tuberculin skin test), complete the [AEFI Report Form](#) and report the event through iPHIS or in Vancouver Coastal Health through PARIS.

4.1 Freedom of Information and Protection of Privacy (FOI/PP)

Inform the client under what authority the information is collected (voluntary, in order to monitor the safety of vaccines at the local, provincial and national level), what will be done with it (reported to BCCDC; reported to the Public Health Agency of Canada after removal of personal identifiers; and reported to the client's health care provider), that it will be handled confidentially and not disclosed without authority, and where it will be housed (electronically, on a server maintained by the Provincial Health Services Authority). As well, inform client of whom to call for more information about FOI issues at the Health Authority (this is a local contact person employed by the HA whose responsibility is ensuring that the HA is in compliance with municipal and provincial FOI/ PP legislation).

5.0 RECOMMENDATIONS FOLLOWING AN ADVERSE EVENT

Health Authorities may determine a process for assessment and decision-making regarding reported adverse events, and which events assessed by a health care provider will require reviewing by the Medical Health Officer. It is within a Registered Nurse (RN) scope of practice to assess adverse events following immunization and determine a course of action that may include decision-making about subsequent doses of the vaccine(s).

The following are **recommended** criteria for events to be reviewed by the Medical Health Officer:

- events which the client's health care provider considers to confer precautions, contraindications or a reason to postpone a future immunization
- all events managed as anaphylaxis
- all neurological events including febrile and afebrile convulsions
- allergic events
- all events where medical attention is required, and
- all events that are serious (resulting in hospitalization, residual disability, death, or congenital malformation)

Recommendations following adverse event review should be discussed with the client and provided to the client's primary health care provider.

STORAGE & HANDLING

- Store vaccine on the middle shelves of fridge; never on the doors or in the crispers.
- Keep vaccines in their original packaging to protect from light.
- Use a separate tray in the refrigerator for opened vaccines and keep them in the original packaging. Use the opened ones before opening new vials/packages.
- Clearly print the date opened on the label of a multi-dose vial. Use a multi-dose vial within 30 days of opening, unless there are specific directions in the product insert for using/discarding sooner.
- Do not reconstitute vaccines or pre-fill syringes until ready to administer.
- Use the correct diluent to reconstitute lyophilized vaccines.

TEMPERATURE

- Maintain a refrigerator temperature of between **2.0° C to 8.0° C**.
- Check refrigerator temperature twice daily (am & pm) and record on a temperature form.
- Store bottles of water (if space allows) on the empty refrigerator shelves and in the door.
- Store ice packs in the freezer.
- Open the refrigerator door only when necessary.
- Do not store food, beverages or lab specimens in the refrigerator.
- Have a refrigerator maintenance check done, at minimum, annually.

TRANSPORTING VACCINES

- Keep vaccines in their original packaging and maintain the packing configuration when removing vaccines from – or returning vaccines to – the cooler.
- Use large coolers for large quantities of vaccine. Either a hard-sided or soft-sided insulated cooler can be used with a tight-fitting lid along with frozen ice packs and insulating material to transport vaccines at all times.
- If the vaccine is in a large cooler for more than 4 hours, monitor cooler temperatures with a minimum-maximum thermometer.
- Use all vaccines in one large cooler before opening the next large cooler.
- Transport vaccines directly from the Health Unit refrigerator to the clinic setting.
- Refrigerate vaccines as soon as transportation is complete.
- Transport diluents separately, unless they have been cooled in the refrigerator for 24 hours prior to transport.

AT THE CLINIC SETTING

- Use small insulated coolers at each work station.
- Maintain the appropriate packing configuration when removing or returning vaccines to the small cooler.
- Avoid pre-loading syringes.
- Mark the date/time of opening on all multi-dose vials.

[continued on following page]

INVENTORY MANAGEMENT

- Rotate vaccines according to their expiry date; place those with the longest expiry date at the back.
- Check for expired products every month.
- Never use expired vaccine; always return them to the public health unit/office.
- Keep vaccine stock at a minimum.
- Order only the quantity of vaccine required for one month until the next scheduled pick-up of vaccines.
- For more information, see Section VI, Management of Biologicals, at:
<http://www.bccdc.ca/health-professionals/clinical-resources/vaccine-management>

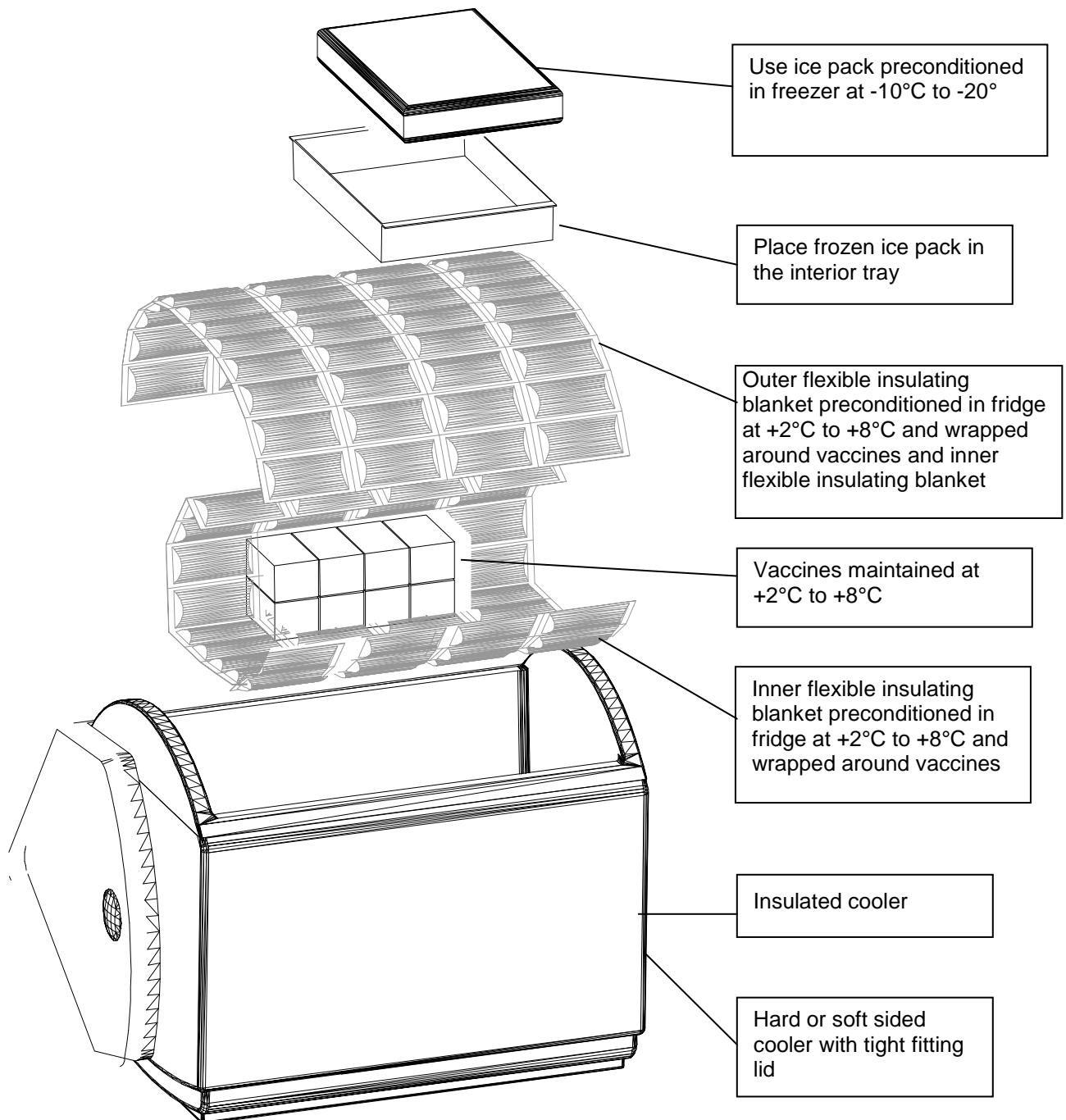
KEY PRINCIPLES

- The insulated coolers used for transport is the “refrigerator” in the clinic setting.
- Open these coolers only when necessary.
- Monitor the temperature in these large coolers.

*Based on “Mass Clinics”, by the BC Centre for Disease Control, at:
<http://www.bccdc.ca/NR/rdonlyres/3F7DE213-BB20-4324-AD8B-E2E3A83D0349/0/MassClinics.pdf>.*

*and
“Vaccine storage and handling”, by the BC Centre for Disease Control, at:
<http://www.bccdc.ca/resource-gallery/Documents/Guidelines%20and%20Forms/Guidelines%20and%20Manuals/Immunization/Cold%20Chain/bccdcoldchainresourcescreen.pdf> These guidelines are applicable to RSV
Immunoprophylaxis as well.*

Packing an Insulated Cooler



Protect the vaccines. Protect your patients.

The BC RSV Immunoprophylaxis Program ('the RSV Program' / 'the Program') is a Provincial Health Services Authority Program administered at BC's Children's Hospital.

1. PURPOSE

- 1.1. To identify and coordinate RSV immunoprophylaxis for eligible infants and children residing in British Columbia;
- 1.2. To evaluate the outcomes of children in the Program;
- 1.3. To measure and track the burden of RSV illness in BC in both children in the Program and children not in the Program;
- 1.4. To make recommendations regarding the functioning and location of palivizumab (PVZ) clinics on the basis of burden of RSV illness and centre size; and
- 1.5. To participate in and encourage / support activities, other than immunoprophylaxis, that may decrease the burden of RSV illness in small children.

2. RESPONSIBILITIES

- 2.1 To develop the annual guidelines for eligibility to the Program;
- 2.2 To develop the educational materials, forms, and processes that will be used to maximize penetration of and compliance with the BC RSV Immunoprophylaxis Program Guidelines ('the Guidelines');
- 2.3 To develop a system of adjudication for admission to the Program of children with defined conditions that require secondary evaluation;
- 2.4 To ensure the Guidelines are evidence based, including based on BC outcomes; To
- 2.5 retrieve complete Health Authority and practitioner outcome information for Program evaluation;
- 2.6 To communicate effectively regarding eligibility or non-eligibility, PVZ shipments and utilization, and Program policies and procedures; and
- 2.7 To facilitate the linking of families to locations where PVZ is administered.

3. GENERAL PRINCIPLES

- 3.1 Prophylaxis typically begins in November and continues through to April; the dates are determined by the Program Advisory Committee (see Item 6).
- 3.2 The referral process is initiated by completion and submission of the Program Application Form; only the Program can approve a patient for funded PVZ administration.
- 3.3 Applications that require adjudication will be adjudicated within five working days.
- 3.4 Confirmation of eligibility or non-eligibility is issued by the PHSA (C&W) Pharmacy to the referral source.
- 3.5 Reconsideration of non-eligibility requires submission of additional clinical information.
- 3.6 The Program only covers children < 2 years of age by November 01 of the season start.
- 3.7 In order to minimize drug wastage, PVZ is generally administered to patient clusters in PVZ clinics.

4. EXECUTIVE SPONSOR

The Executive Sponsor is the Chief Operating Officer, Patient Administration, Children's and Women's Health Centre of British Columbia, who is accountable to the PHSA and the Ministry of Health.

5. PROGRAM EXECUTIVE COMMITTEE

Comprises the Program Medical Director, Chair of the Program Advisory Committee, the Program Administrative Director, the Program Nurse Coordinator, and the Program Pharmacy Coordinator.

Each of these positions is appointed by PHSA, save the Chair of the Program Advisory Committee (see Item 6).

The Executive Committee:

- 5.1 Is chaired by the Program Medical Director;
- 5.2 Reports to the Program’s Executive Sponsor though the Medical Director, the Chair of the Program Advisory Committee, and/or the Program Administrative Director at least three times annually;
- 5.3 Ensures the Program meets its obligations, such as cost, schedule, clinical, and technical;
- 5.4 Meets at least monthly throughout the year;
- 5.5 Builds the foundations of each Program phase, i.e., pre-season, intra-season, post-season;
- 5.6 Manages Program phases and transitions between phases;
- 5.7 Creates and disseminates the documentation required at the end of each phase or process;
- 5.8 Reviews and determines viability, and translates into action the recommendations of the Advisory Committee;
- 5.9 Facilitates the adoption and implementation, at the Health Authority level, of the mechanisms that will allow for the smooth functioning of the Program, including data retrieval for Program management purposes; and
- 5.10 Makes decisions on a consensus basis, but should consensus not be reached, decisions will be made by a majority vote. If necessary, the Program Medical Director will hold ultimate decision-making authority regarding clinical matters.

6. ADVISORY COMMITTEE

Comprising the Program Executive, and relevant Pediatric subspecialty representatives when available, i.e., neonatology, cardiology, pulmonology-CF, immunology, infectious diseases, two nursing representatives of the RSV Clinics, and representatives of each Health Authority: one medical and one administrative; and PHSA Performance Measurement and Reporting.

The Advisory Committee is chaired by one of the subspecialty representatives as elected by the Committee; and:

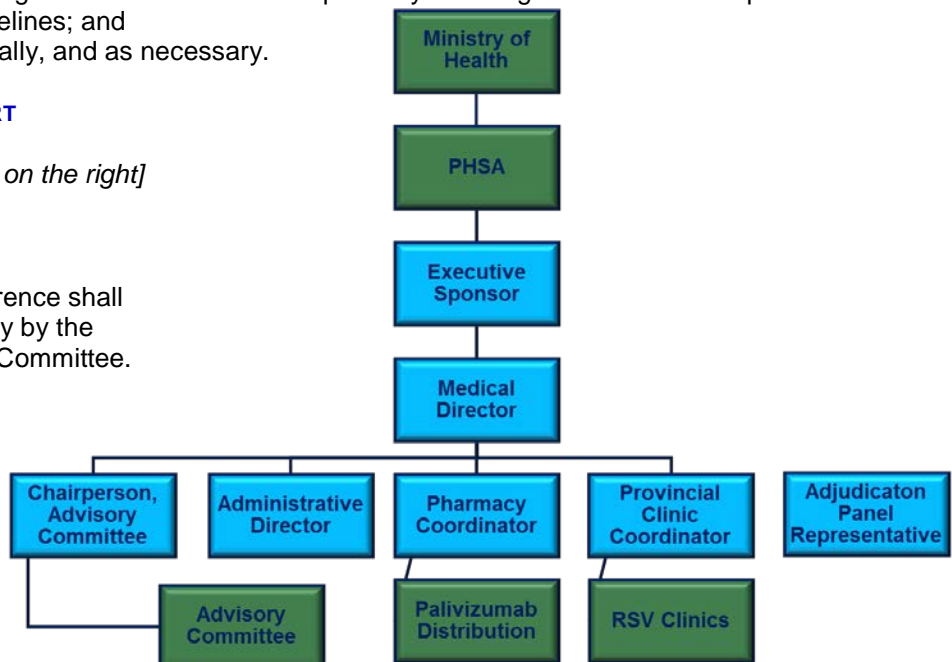
- 6.1 Supports the organizational structure of the Program;
- 6.2 Reviews the report on season outcomes and on new evidence that will inform the subsequent season guidelines;
- 6.3 Provides the guidance and direction required by the Program for the development of the annual guidelines; and
- 6.4 Meets annually, and as necessary.

7. ORGANIZATION CHART

[As per the diagram on the right]

8. AMENDMENTS

These terms of reference shall be reviewed annually by the Program Executive Committee.



RSV Program Clinics – Contact List as of the 2020/21 RSV Season

City	HA	RSV Clinic	Contact name	Email address	Telephone	Fax
B.C. Coordinator	PHSA	C&W	Cheryl Christopherson	cchristop@cw.bc.ca	604-875-2345 x7872	604-875-2703
RSV Desk	PHSA	C&W	Grace Burns	rsv@cw.bc.ca	604-875-2867	604-875-2879
Abbotsford	FH	Abbotsford Regional	Kim McLellan	kim.mclellan@fraserhealth.ca	604-851-4700 x646267	604-851-4787
Abbotsford	FH	Abbotsford Regional	Stacey Atsma	Stacey.Atsma@fraserhealth.ca	604-851-4700 x646267	604-851-4787
Burnaby	FH	Burnaby NICU	Luba Kadnarova	Lubomira.Kadnarova@fraserhealth.ca	604-412-6296/412-6330	604-412-6541
Courtenay/Comox	VIHA	NI Comox Valley	Sarah Heighington	Sarah.Heighington@viha.ca	250-331-5900 x65660	250-331-5924
Duncan	VIHA	Cowichan District	Sarah Byrne	Sarah.Byrne@viha.ca	250-737-2030, x44672	250-709-3020
Kamloops	IHA	Royal Inland NICU	Stacie Schanzenbach	Stacie.Schanzenbach@interiorhealth.ca	250-314-2633	250-314-2155
Kamloops	IHA	Royal Inland	Heather Pehowich	Heather.Pehowich@interiorhealth.ca	250-314-2630	250-314-2629
Kelowna	IHA	Kelowna General	Laura-Lee Regnier	laura-lee.regnier@interiorhealth.ca	250-862-4300 x4431	250-862-4146
Kelowna	IHA	Kelowna NICU	Bonnie Wilkie	bonnie.wilkie@interiorhealth.ca	250-862-4392 or 5593	250 862-4368
Langley	FH	Langley Memorial	Shelley Krautsieder	Shelley.Krautsieder@fraserhealth.ca	604-514-6139	604-539-4334
Nanaimo	VIHA	Nanaimo General	Bev Groenewold	Bev.Groenewold@viha.ca	250-739-5850	250-739-5855
Nanaimo	VIHA	Nanaimo NICU	Lisa Bakker	Lisa.Bakker@viha.ca	250-755-7691 x54783	250-716-7715
New Westminster	FH	Royal Columbian	Katie Goss	Katherine.goss@fraserhealth.ca	604-520-4558	604-520-4112
North Vancouver	VCH	Lion's Gate Peds /NICU	Gina Webb	Gina.webb@vch.ca	604-889-4602 (m)	604-984-5856
Penticton	IHA	Penticton	Tracy Murphy	Tracy.Murphy@interiorhealth.ca	250-492-9030	250-492-9046
Prince George	NHA	UHNBC	Beverly (Bev) Haight	Beverly.Haight@northernhealth.ca	250-645-6164	250-565-5824
Prince George	NHA	UHNBC - NICU			250-565-2328	250-565- 2004
Richmond	VCH	Richmond NICU	Karen Jang-Hugdahl	Karen.JangHugdahl@vch.ca	604-278-9711 x4772	604-233 5629
Surrey	FH	Surrey Memorial	Deb McLaren	Deb.McLaren@fraserhealth.ca	604-585-5666 x774266	604-585-5641
Vancouver	PHSA	C&W NICU	Danielle West	Danielle.west@cw.bc.ca	604-875-2000 x8571	
Vancouver	VCH	St. Paul's NICU	Teaghan Evans	Tevans@providencehealth.bc.ca	604-682-2344 x66029	604-806-9855
Vernon	IHA	Vernon Jubilee	Michelle Rotenburger	michelle.rotenburger@interiorhealth.ca	250-558-1200	250-558-1290
Victoria	VIHA	Victoria General	Margaret Baker	margaret.baker@viha.ca	250-727-4191	250-727-4042



Questions?

If you have any questions about the RSV Program guidelines, or anything else about the Program or administration of PVZ in BC, please contact one of the following members (depending on the nature of your query):

Laurence Bayzand: **Administrative Director**, BC RSV Immunoprophylaxis Program
BC Children's Hospital and BC Women's Hospital + Health Centre
604-875-2337

Grace Burns: **RSV Desk**, BC RSV Immunoprophylaxis Program
Pharmacy Support, Children's & Women's Health Centre of BC
604-875-2867 or toll-free 1-877-625-7888. Fax: 604-875-2879.

Cheryl Christopherson: **Provincial Clinic Coordinator**, BC RSV Immunoprophylaxis Program
Nurse Clinician, Children's & Women's Health Centre of BC
604-875-2345 ext 7872

Alfonso Solimano: **Medical Director**, BC RSV Immunoprophylaxis Program
BC Children's Hospital and BC Women's Hospital + Health Centre
604-875-2135

Richard Taylor: **Chair**, BC RSV Immunoprophylaxis Advisory Committee
Victoria General Hospital
250-727-4531

External Links

Canadian Pediatric Society – Preventing Hospitalizations for Respiratory Syncytial Virus Infection <http://www.cps.ca/en/documents/position/preventing-hospitalizations-for-rsv-infections>

RSV Program Documents (including Application form, Decision Support Tool /Administrative Manual)
https://www.childhealthbc.ca/search?search=RSV&sort_by=search_api_relevance&sort_order=DESC

BC Centre for Disease Control – Vaccine Storage and Handling
[http://www.bccdc.ca/resource-gallery/Documents/Guidelines and Forms/Guidelines and Manuals/Immunization/Cold Chain/bccdccoldchainresourcescreen.pdf](http://www.bccdc.ca/resource-gallery/Documents/Guidelines%20and%20Forms/Guidelines%20and%20Manuals/Immunization/ColdChain/bccdccoldchainresourcescreen.pdf)

BC Centre for Disease Control – Vaccine Management
<http://www.bccdc.ca/health-professionals/clinical-resources/immunization/vaccine-management>

- BC Centre of Disease Control
www.bccdc.ca
- British Columbia RSV Immunoprophylaxis Program Information
www.childhealthbc.ca under “RSV Immunoprophylaxis”
- Canadian Association of Neonatal Nurses:
www.neonatalcann.ca Enter “Respiratory Syncytial Virus (RSV) in the search box
- British Columbia College of Nurses and Midwives (BCCNM)
Practice Standards and Scope of Practice for Registered Nurses
https://www.bccnm.ca/Standards/RN_NP/Pages/Default.aspx
- Manufacturer/distributor website for palivizumab: www.rsvshield.ca
- PVZ monograph:
https://www.abbvie.ca/content/dam/abbvie-dotcom/ca/en/documents/products/SYNAGIS_PM_EN.pdf
- Position Statements: CPS:
www.CPS.ca
- The Public Health Agency of Canada outlines cold chain practices at: <https://www.canada.ca/en/public-health/services/publications/healthy-living/national-vaccine-storage-handling-guidelines-immunization-providers-2015.html>

Recommended Resources:

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. *Preventing hospitalizations for respiratory syncytial virus infection* Paediatric Child Health 2015;20(6):321-26 *Reaffirmed: Feb 28, 2018*
2. Fetus and Newborn Committee. *Palivizumab and Respiratory Syncytial Virus Immune Globulin Intravenous for the Prophylaxis of Respiratory Syncytial Virus Infection in High Risk Infants*. Paediatric & Child Health 1999;4:474-480
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2827759/pdf/pch04474.pdf>
3. Canadian Pediatric Society. *Use of Palivizumab in Children with Congenital Heart Disease*. Paediatric & Child Health 2003;8:631-633

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

Related standards

1. BCCNM Standards of Practice: “Acting without an Order”

This Manual and Decision Support Tool is produced by:

- the **Executive Committee** to the BC RSV Immunoprophylaxis Program
- with the consultation and feedback from **the clinics of BC**.

and is collated and edited by

- **Cheryl Christopherson**

The forms and content herein are reviewed annually and amended as appropriate. At times amendments must take place mid-season. Please consult the [RSV section](#) of the Child Health BC website for the latest version of each RSV Program Resource, including forms, guidelines, and protocols. If you have any questions, please contact rsv@cw.bc.ca or an applicable member of the RSV team on Page 58.

The documents

- *How to Prevent Your Child from Getting or Spreading an Infection* and
- *Pain Management: Helping your Child Cope with the Discomfort of an Injection* are the intellectual property of the Children's Hospital Patient Education Committee of the Winnipeg Regional Health Authority.

The following documents are the intellectual property of the BC Centre for Disease Control:

- *How to Prevent your Child from Getting or Spreading an Infection*
- *Mass Clinics – Immunoprophylaxis-Handling Tips*
- *Handle vaccines with care*
- *Packing an Insulated Cooler*

Thank you all for your support and collaboration. We're always in touch.

cc