

Respiratory Syncytial Virus Prophylaxis Program Saskatchewan Protocol 2019-2020 Season

Respiratory Syncytial Virus (RSV) is the most common cause of lower respiratory tract illness and hospitalization for infants worldwide. Those at highest risk of hospitalization or even death include premature infants (<35 weeks gestational age), infants and children with chronic lung diseases (CLD) like bronchopulmonary dysplasia or cystic fibrosis, and infants and children with unstable congenital heart diseases.

Palivizumab (Synagis®), a humanized monoclonal antibody, was approved in Canada in 2002 for the prevention of serious lower respiratory disease caused by RSV. It has been shown to significantly reduce hospitalizations due to RSV infection in young children.¹

RSV Season

In Canada the RSV season usually runs from November/December to March/April. The season is determined by reports of positive isolates in the Health Canada Respiratory Virus Weekly Detection Report or from Provincial Virology Laboratories.

Eligibility

Saskatchewan eligibility criteria are based on recommendations by the Canadian Pediatric Society and the Public Health Agency of Canada's *Canadian Immunization Guide*. Saskatchewan infants and children meeting at least one of the following criteria are eligible to receive Synagis®:

1. Premature infants born at < 30 weeks gestation, on/after June 1, 2019
2. Premature infants born at < 33 weeks gestation, on /after September 1, 2019
4. Children < 2 years of age with bronchopulmonary dysplasia/chronic lung disease and who have required oxygen within the 6 months preceding the RSV season.
3. Children < 2 years of age with hemodynamically significant heart disease as assessed by cardiology.
4. Children < 1 year of age with Cystic Fibrosis.
5. Infants born at < 36 weeks gestation during the current RSV season (Nov – Feb), with a high risk score according to the Risk Score Tool (Appendix B).
6. Infants born at < 36 weeks gestation during the RSV season that are living in or north of La Ronge.
7. Others. A letter from the requesting physician providing medical justification for request is required. Approval from the authorized medical specialist is required.

¹ Impact-RSV Study Group. Palivizumab, a humanized respiratory syncytial virus monoclonal antibody, reduces hospitalization from RSV infection in high risk infants. *Pediatrics* 1998; 102(3): 531-7.

Procedure

- 1. Identify Infants and children who are at risk.** All requests for Synagis must be forwarded to the RSV Coordinators to ensure eligibility requirements are followed. The RSV Coordinators identify most eligible infants because of their admission to the neonatal intensive care unit at Regina General Hospital (RGH) or Royal University Hospital (RUH). In addition, Pediatricians, Pediatric Cardiologists, Pediatric Pulmonologists, and Nurse Practitioners may refer to the program. Questions regarding eligibility should be forwarded to the RSV Coordinators in your area.
- 2. Ensure the infant or child meets the eligibility criteria** as outlined in this protocol.
- 3. Complete the RSV Prophylaxis Referral Form** (Appendix A), **Risk Score Tool** (Appendix B) if indicated, and **Medical Justification letter** (Appendix C: if referring under the “Other” category) to be approved by an authorized medical specialist.
- 4. Send** the RSV Prophylaxis Referral Form to either:

Northern Saskatchewan RSV Prophylaxis Program

(Former Saskatoon, Heartland, Kelsey Trail, Prairie North, Prince Albert Parkland, Keewatin Yatthe, Mamawetan Churchill River, and Athabasca Health Regions)

Office: 306-655-0679

Cell: 306-321-5610

Fax: 306-655-1224

Email an electronic copy to RSV@saskatoonhealthregion.ca

Submit through the EMR system.

Southern Saskatchewan RSV Prophylaxis Program

(Former Regina Qu'appelle, Five Hills, Cypress, Sunrise, and Sun Country Health Regions)

Phone: 306-766-4574

Fax: 306-766-3461

Email: southsaskrsvprogram@rqhealth.ca

The RSV coordinators and Medical Specialist will then determine approval.

- 5. The first dose** of Synagis® may be administered in hospital (NICU, PICU, Pediatrics), or through community resources (e.g. primary care clinics.)
- 6. The second and subsequent doses** are given every 4 weeks (28 days) until the end of RSV season. A maximum of 5 doses are given per season.
7. While hospitalized, the first dose should be given prior to discharge or transfer to another unit. The second dose would be given 4 weeks after the first dose (in hospital or in the community).
- 8. Follow up arrangements** will be made by the RSV Coordinators for the immunization to be administered either in hospital or by community resources. The RSV Coordinators arrange shipment of Synagis® to locations as required.
- 9. After each dose**, fill out the Synagis® Injection Record (Appendix D) and fax to the RSV Coordinator for your area.

Administration

1. Determine if patient has any contraindications to receiving Synagis®. These would include hypersensitivity to Synagis® or any of its components, or hypersensitivity to other humanized monoclonal antibodies. A mild febrile illness is NOT a contraindication to receiving Synagis®.
2. Synagis® is administered at a dose of **15 mg/kg** body weight every 28-30 days by intramuscular (IM) injection.
3. Synagis® is provided in 0.5 mL vials at a concentration of 100 mg/mL (50 mg/vial)
4. A current weight must be obtained prior to calculating the dose of Synagis®.
5. Calculate the dose using the current weight:

$$\text{Dose} = \frac{\text{Patient Weight (kg)} \times 15 \text{ mg/kg}}{100 \text{ mg/mL (Concentration)}}$$

Example using a dosing weight of 4.5 kg:

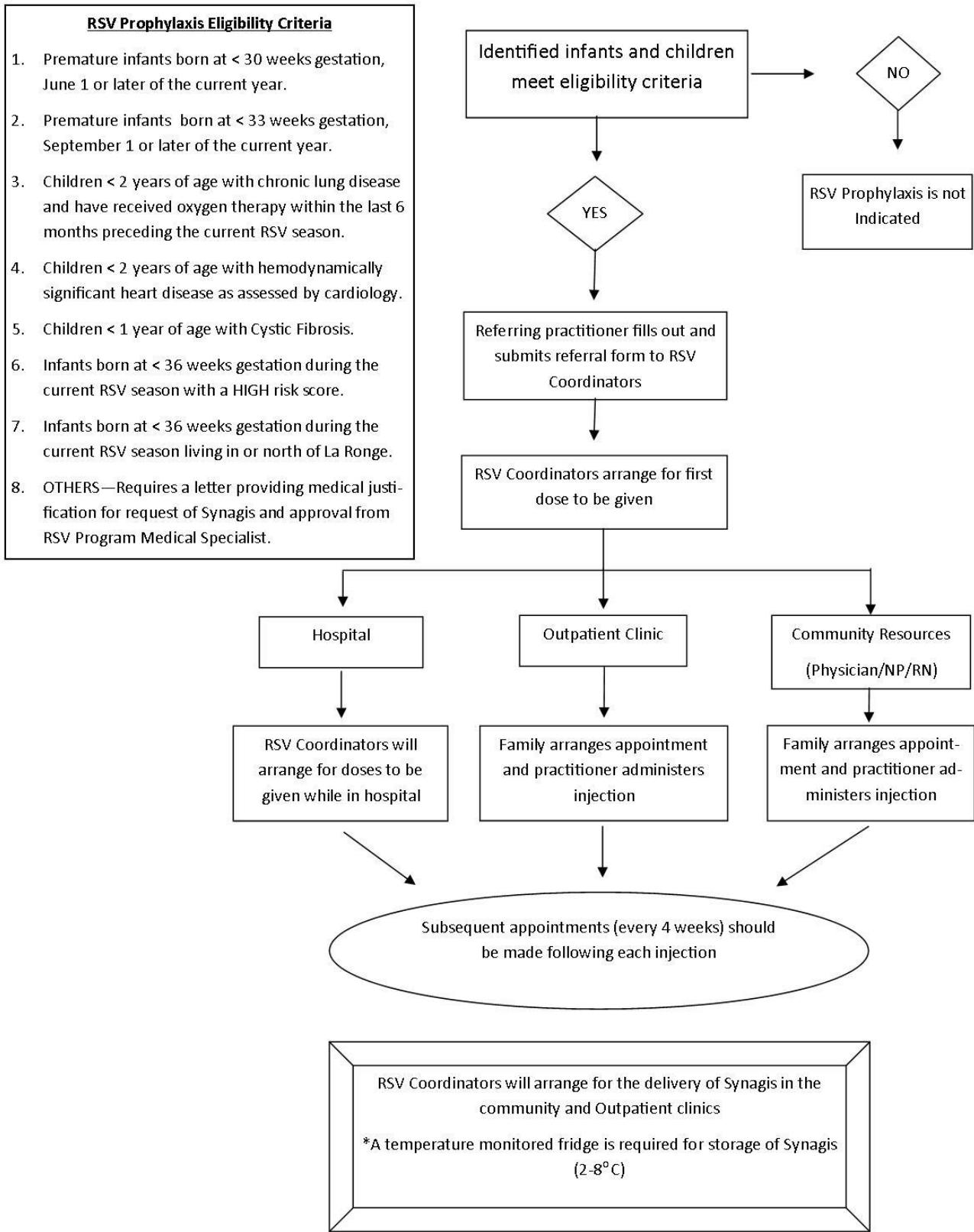
$$\frac{4.5 \text{ kg} \times 15 \text{ mg/kg}}{100 \text{ mg/mL}} = \frac{67.5 \text{ mg}}{100 \text{ mg/mL}} = 0.675 \text{ mL or } 0.68 \text{ mL (rounded to the nearest 0.01mL)}$$

6. Draw up required dose from vial. Use of a **1 mL syringe** is recommended for accurate dosing.
7. Administer dose by intramuscular (IM) injection in the anterolateral aspect of the thigh. A **5/8" - 1", 25 gauge needle** is appropriate for an IM injection in this age group of children. The needle should be long enough to deposit the medication into the muscle tissue.³ Doses greater than 1 mL total volume should be divided into 2 syringes (2 separate injections, at least 2.5 cm apart if administering in the same limb.)
8. Vials are considered to be single use vials, however, vial sharing is common practice due to the cost of Synagis®. Health Care Providers are encouraged to book all children on the program in their region on the same day if possible and use open vials within 2 hours of initial puncture.
9. Monitor patient for 15 minutes post injection for signs of adverse reactions and/or anaphylaxis. Any severe hypersensitivity reactions should be treated as per your facility's anaphylaxis protocol.³
10. Fill out Synagis® Injection Record (Appendix D) and fax back to the RSV Coordinator for your area.

² Government of Canada. (2018, May 18). Canadian Immunization Guide. *Part 1: Key Immunization Information*. Retrieved from <https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-1-key-immunization-information/page-8-vaccine-administration-practices.html>

³ Abbvie Corporation. (2016, August). Handbook for healthcare professionals. *Contraindications, Warnings, and Precautions*. Canada.

RSV Process Flow Sheet



APPENDIX A

**Saskatchewan RSV Prophylaxis Program
Client Referral Form 2019-2020 Season**

Northern Saskatchewan

Royal University Hospital
Box 87-103 Hospital Drive, Saskatoon, SK S7N 0W8
Office: 306-655-0679 Cell: 306-321-5610 Fax: 306-655-1224
Email: RSV@saskatoonhealthregion.ca

Southern Saskatchewan

Regina General Hospital
C/O Pediatric Outpatients
1440-14th Avenue, Regina, SK, S4P 0W5
Phone: 306-766-4574 Fax: 306-766-3461
Email: southsaskrsvprogram@rghealth.ca

CLIENT IDENTIFICATION

Surname:		Legal Surname:		First Name:	
Date of Birth (d/m/y)		PHN:		Gender:	
Gest. Age @ Birth:	weeks	days	Birth Wt:	kg	Current Wt: kg

PARENT/GUARDIAN CONTACT INFORMATION

Last name:		First Name:			
Address:					
City:		Province:		Postal Code:	
Contact Numbers:			May Contact by Text? Yes ___ No ___		
Other Contact:					
Physician Identification					
Physician Name			Clinic/Health Care Centre:		
Address:		Postal Code:		Phone:	
Verbal Consent obtained from Parent/Guardian: Yes ___ No ___ Date _____					

Eligibility Criteria

- Premature infants born at < 30 weeks gestation, on/after **June 1, 2019**
- Premature infants born at < 33 weeks gestation, on/after **September 1, 2019**
- Children < 2 years of age with chronic lung disease (i.e. BPD) **AND** have received home oxygen therapy within the 6 months preceding the start of the RSV season.
- Children < 2 years of age with hemodynamically significant heart disease as assessed by Cardiology
Indicate specific diagnosis: _____
- Children < 1 year of age with Cystic Fibrosis
- Infants born between 33 – 35 weeks and 6 days during the current RSV Season, with a **HIGH** risk score according to Risk Score Tool *(Please circle Yes or No below)*

YES OR NO	Small for gestational age (<10 th percentile)
YES OR NO	Male
YES OR NO	Born November 1, 2019 to February 28, 2020
YES OR NO	Immediate family all without eczema (No eczema – score YES)
YES OR NO	Infant or siblings attending daycare ≥ 20 hours/week
YES OR NO	6 or more individuals in the home including the infant
YES OR NO	Does anyone smoke in the home
- Infants born between 33 – 35 weeks and 6 days during the current RSV Season living in or north of La Ronge.
- OTHERS: Mandatory:** Requires a letter from the requesting physician providing medical justification for request.

Request is subject to approval by RSV Program medical specialist Dr. Adamko - Darryl.Adamko@usask.ca

Appendix B

Saskatchewan Respiratory Syncytial Virus Prophylaxis Program Risk for RSV Infection

Scoring Tool for 33 – 35 6/7 Week Gestation Infants

Questions	Yes	No	Score
Small for gestational age (< 10 th Percentile)?	12	0	
Male Gender?	11	0	
Birth month is November, December, January, or February?	25	0	
Immediate family history (mother, father, sibling) without eczema?	12	0	
Infant or siblings attending daycare for ≥ 20 hours per week?	17	0	
6 or more individuals in the home including the infant?	13	0	
Does anyone smoke in the home?	10	0	
TOTAL (Maximum is 100)			

Risk of Hospitalization Due to RSV Infection	Score
Low	0-44
Moderate	45-59
High	60-100

APPENDIX C

**SASKATCHEWAN RSV PROPHYLAXIS
PROGRAM REFERRAL:
Medical Justification for “Other”
Category**

Addressograph

Date: _____

ADDITIONAL INFORMATION REQUIRED PLEASE PRINT

Please addressograph form above

Pediatrician / Family Physician / Nurse Practitioner: _____

Gestational Age @ birth _____ (weeks) Birth Weight (kg): _____ Hospital Discharge date (d/m/y) _____

Current Weight (kg): _____ as of (d/m/y) _____

INDICATION FOR ELIGIBILITY (MANDATORY - This section must be completed)

Upon examination, the above mentioned client presents with the following risk factors and I am therefore requesting Synagis® prophylaxis for the current RSV season. **Please include why the RSV prophylaxis would benefit this client.**

AUTHORIZATION AND CONSENT

Consent Obtained? Yes No

Requesting Physician (print name)

Requesting Physician (signature)

RSV Medical Specialist (signature)

PLEASE SEND/FAX COMPLETED FORM TO THE RSV COORDINATOR FOR YOUR AREA

Northern Saskatchewan RSV Coordinator
Royal University Hospital
Box 87-103 Hospital Drive
Saskatoon, SK S7N 0W8
Office: 306-655-0679 Cell: 306-321-5610
Fax: 306-655-1224

Southern Saskatchewan RSV Coordinator
Regina General Hospital
C/O Pediatric Outpatients
1440 – 14th Ave Regina, SK S4P 0W5
Phone: 306-766-4574
Fax: 306-766-3461

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APPENDIX D

Saskatchewan RSV Prophylaxis Program

After each dose given, fax completed form to the RSV Coordinator for your area:

Northern Saskatchewan

(Former Saskatoon, Heartland, Kelsey Trail, Prairie North, Athabasca, Prince Albert Parkland, Keewatin Yatthe, and Mamawetan Churchill River Health Regions)

Royal University Hospital

Box 87-103 Hospital Drive, Saskatoon, SK S7N 0W8
Office: 306-655-0679 Cell: 306-321-5610

Fax: 306-655-1224

Southern Saskatchewan

(Former Regina Qu'appelle, Sunrise, Cypress, Five Hills and Sun Country Health Regions)

Regina General Hospital

c/o Pediatric Outpatients
1440-14th Avenue, Regina, SK, S4P0W5
Phone: 306-766-4574

Fax: 306-766-3461

SYNAGIS INJECTION RECORD

Health Care site: _____

Client Name: _____

Date of Birth: _____ PHN # _____

Dose # _____

Date dose given: _____

Current Weight (kg): _____ x 15 mg/kg = Dose (mg): _____

Injection Site on Client: _____

Lot # of Vial: _____

Expiry date on Vial: _____

Dose given by: _____ RN NP MD

of Synagis® Vials remaining at your site after giving this dose: _____

Reactions/Comments: _____

FOLLOW UP APPOINTMENT: Date: _____ Time: _____