11.0 Specialized and Annual Immunization Protocols (in alphabetic order)

- **Palivizumab for Respiratory Syncytial Virus (RSV) prevention**
  - Synagis® Protocol
  - Appendix A - Synagis® Registration Form
  - Appendix B - Synagis® Consent
  - Appendix C - Synagis® Report Form
  - Appendix D - Synagis® Procedure for OOT cases
  - Appendix E - Synagis® Program Flow Chart

Protocol for Synagis®

(Palivizumab)

Purpose	Provide information and guidance for the Synagis® Program in Nunavut.
Objective	Reduce Respiratory Syncytial Virus (RSV) related morbidity and mortality
Indication	Infants at high risk for serious morbidity and mortality secondary to RSV infection.
Eligibility	➢ Premature infants born at ≤ 35 weeks and 6 days gestation AND ≤ 6 months of age; (born July 1 or later) at the start or during the RSV season. Nunavut season: January 1 to May 31 ➢ Children < 12 months of age at the beginning of the RSV season with: • Chronic lung disease of prematurity (CLD, is defined as a need for oxygen at 36 weeks GA) currently requiring ongoing supplemental oxygen and/or medical therapy (diuretics, bronchodilators, steroids). • Hemodynamically significant congenital heart disease requiring supplemental oxygen and/or ongoing medical therapy (diuretics, bronchodilators, steroids) ➢ Children < 24 months of age at the beginning of the RSV season with: • Bronchopulmonary dysplasia/chronic lung disease of prematurity requiring ongoing supplemental oxygen or were weaned off supplemental oxygen in the past three months ➢ Prophylaxis may be considered for children < 24 months with immunodeficiencies, Down syndrome, cystic fibrosis, upper airway obstruction or chronic pulmonary disease other than CLD, **only if**, they are on home oxygen, have prolonged hospitalization for severe pulmonary disease or are severely immunocompromised.
Product	
Vaccine Type	Synagis® is a humanized monoclonal antibody that provides passive immunity.
Vaccine components	Clinically relevant: chloride, glycine and histidine Synagis® does not contain Thimerosal or trace antibiotics.
Formats available	Synagis® is supplied in 50 mg/0.5mL and 100 mg/1 mL vials of solution for injection.
Manufacturer	Boehringer Ingelheim (BI) Pharma KG and distributed by Abbvie Laboratories, Ltd.
Administration	Intramuscular (IM) injection (typically in the anterolateral thigh)
Dose Series	Administer 15 mg/kg (if >1 mL give as divided dose). Administer first dose as early in January as possible. Note: The Nunavut season is January to May. For children born after January 1, their first dose should be given as soon as possible after birth. Give every 4 weeks during anticipated periods of community RSV risk to a **maximum of 5 doses,** unless specified by the Office of the Chief Medical Officer of Health (OCMOH). If a dose is delayed, give dose as soon as possible and administer subsequent doses every 4 weeks after this dose. Infants starting Synagis® outside of Nunavut will be reviewed on a case by case basis.

	NOTE: Synagis provides passive immunity, thus missed doses leave patients unprotected. Ensure all doses are administered on time for maximum protection.
Booster Dose	N/A
Vaccine interchangeability	N/A
Contraindications	Do NOT administer if there is a known hypersensitivity to any component of Synagis® or to other humanized monoclonal antibodies.
Precautions and Additional Notes	Minor illnesses (e.g. common cold) proceed to administer Synagis® if meets eligibility criteria. Defer drug administration with moderate to severe illness, with or without fever. *Palivizumab should be discontinued for children with lab-confirmed breakthrough RSV infection.* Synagis® does not interfere with the immune response to vaccines and can be administered at the same time in a separate site i.e. normal childhood immunization schedule can be maintained. Synagis® does not interfere with the immune response to a TST and/or BCG and can be administered at the same time in a separate site.
Special Instructions	**Process*** **Registration** ○ Practitioners (in and out of territory) identify Synagis® program candidates throughout the year based on eligibility criteria. ○ Complete Annual Synagis® Registration Form (Appendix A). ○ Send registration form to the OCMOH throughout the year for approval (approval in collaboration with pediatrician as required). ○ OCMOH will fax approved registrations to respective RCDC. **Ordering and Administering Synagis®** ○ CHC/PH must obtain consent (Appendix B) and weight. ○ Ensure sufficient stock is on hand for the Synagis® program and order more from the regional pharmacy as needed. ○ Administer Synagis®. **Administration Instructions** **Synagis® Solution for injection** Both the 0.5 mL and 1 mL vials contain an overfill to allow the withdrawal of 50 mg or 100 mg. • **DO NOT DILUTE THE PRODUCT** • **DO NOT SHAKE VIAL** • To administer, remove the tab portion of the vial cap and clean the stopper with 70% ethanol or equivalent. Insert the needle into the vial and withdraw an

	appropriate volume of solution into the syringe. • Synagis® does not contain a preservative and should be administered immediately after drawing the dose into the syringe. • If you need to re-enter the vial, use a new sterile needle, otherwise discard unused content. **Synagis® Documentation and Reporting** ○ Document Synagis® administration on the chart, electronic health record (EHR) where applicable and the Immunization Record. ○ Complete Synagis® Report Form and fax it to RCDC. ○ RCDC will review Synagis® Report and put it in a forward file. ○ RCDC will fax Synagis® Report Form to OCMOH. ○ OCMOH will assess Synagis® coverage/compliance at mid-season and end of season and produce a final report. Input from frontline staff will be requested in order to review the overall Synagis® program. **Synagis® Documentation and Reporting--Travel Related** ○ Ensure children travelling out of their community (including out of the territory) for healthcare or visiting are accompanied with a copy of their Synagis® Report Form (Appendix C). ○ Additional information on out of territory (OOT) registration and reporting procedures for those eligible infants from Nunavut can be found in Appendix D. ***See Appendix E Synagis® Program Flow Chart**
Vaccine Supply and Distribution	Pharmacy will send enough stock to each community prior to the start of the program to ensure all those registered will be covered. Thereafter, stock doses can be ordered as needed on the regular community pharmaceutical requisition form (GN Drug Formulary).
Storage	Store in monitored vaccine refrigerator between 2°C and 8°C. Protect from light. If product arrives frozen or warm segregate damaged product keeping the cold chain protocol and inform regional pharmacy.
Consent	Consent forms must be reviewed and signed by the parent/guardian prior to vaccination.
Anaphylaxis	Review the principles of the emergency management of anaphylaxis in the Nunavut Immunization Manual Section 3 (3.7). Further information can be found in Anaphylaxis: Initial Management in Non-Hospital Settings found in the Canadian Immunization Guide.
Side Effects	• Commonly: fever, redness or swelling at the injection site • Less commonly: colds, coughs, runny nose, wheeze, vomiting, rash, diarrhea, pain, viral infections and liver function abnormality • Rare: pause in breathing or other breathing difficulties • Very rare: severe allergic reactions
Reportable Adverse Events/Side	Report all serious adverse events requiring medical attention, unusual/unexpected events, or medication errors to RCDC. Review section 3.5 in the Nunavut Immunization Manual.

Effects	
Vaccine Coverage and Reporting	Compliance is based on returned Synagis® Report Forms. A final compliance report is created annually.
Documentation	Document Synagis® administration on the chart, electronic health record (EHR) where applicable and the Immunization Record.
Materials and Resources	A Parent's Guide to Prevention of RSV Infection in Babies. Abbvie booklet. (4 languages) RSV Protocol found in the Nunavut Communicable Disease Manual Appendix A. Synagis® Registration Form (Reviewed October 2018) Appendix B. Synagis® Consent Form (Reviewed October 2018) Appendix C. Synagis® Report Form (Revised October 2018) Appendix D. Synagis® Procedure for Eligible Out of Territory (OOT) Infants from Nunavut (Revised November 2018) Appendix E. Synagis® Program Flow Chart (Reviewed October 2018)
References	1. Preventing hospitalizations for respiratory syncytial virus infection. Infectious Diseases and Immunization Committee, Canadian Pediatric Society. Pediatric Child Health. Updated February, 2018. 2. Synagis® Product Monograph. Boehringer Ingelheim (BI) Pharma KG. April, 2018. 3. Public Health Agency of Canada. Canadian Immunization Guide – Evergreen Edition (2013). Available at: http://www.phac-aspc.gc.ca/publicat/cig-gci/index-eng.php 4. Canada Communicable Disease Report (2003). National Advisory Committee Statement on the Recommended Use of Monoclonal Anti-RSV Antibody (Palivizumab); 29 (ACS-7, 8).
Prescription for program administration	Administer Synagis® according to the criteria above and in accordance with the Nunavut RSV season. Name of prescriber: Dr. Michael Patterson, Deputy Chief Medical Officer of Health. October 2018. This protocol is in effect for all eligible Nunavut children until rescinded or modified by DCMOH.

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Department of Health
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Ministère de la Santé

Appendix A

Fill in OR affix addressograph here

Last Name: _____
First Name: _____
Sex: □ Male □ Female
Date of Birth: ___(DD) _____(MM) _____(YYYY)
Chart#: _____
Health Card #: _____
Community of Residence: _____

Annual Synagis® Registration Form

Submission date: (DD) (MM) (YYYY)

Eligibility criteria (check all applicable):

□ Premature infants ≤ 35 weeks + 6 days gestation AND ≤ 6 months of age (born July 1 or later) at the start or during the RSV season (season: January 1 to May 31). Gestational age at birth :_____

□ Children < 12 months of age at the beginning of the RSV season with:

□ Chronic lung disease of prematurity (CLD, is defined as a need for oxygen at 36 weeks) currently requiring ongoing supplemental oxygen and/or medical therapy (diuretics, bronchodilators, steroids).

□ Hemodynamically significant congenital heart disease requiring supplemental oxygen and/or ongoing medical therapy (diuretics, bronchodilators, steroids)

□ *Children < 24 months of age at the beginning of the RSV season with*:

□ Bronchopulmonary dysplasia/chronic lung disease of prematurity requiring ongoing supplemental oxygen or were weaned off supplemental oxygen in the past three months

□ Prophylaxis may be considered for children < 24 months with immunodeficiencies, Down syndrome, cystic fibrosis, upper airway obstruction or chronic pulmonary disease other than CLD **only if,** they are on home oxygen, have prolonged hospitalization for severe pulmonary disease or are severely immunocompromised.

(If infants don't meet any of the above criteria, please include health care provider letter of support for inclusion in the program and relevant clinical documents on the case).

_____

_____

Practitioner Name_____ **Signature**_____

Contact information _____

CMOH /DCMOH or Designated Pediatrician

Signature: _____

Date: ___ (DD) _____ (MM) _____ (YYYY)

Fax to Office of CMOH 1-867-979-3190

Appendix B

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Department of Health
Munaqhiliqiyitkut
Ministère de la Santé

Fill in OR affix addressograph here

Last Name: ______________________
First Name: ______________________
Sex: □ Male □ Female
Date of Birth: ____(DD) _______(MM) _____(YYYY)
Chart#: _________________________
Health Card #: _________________________
Community of Residence: __________________

Synagis® Consent Form

Review information with parent/guardian

- Synagis® (palivizumab) provides protection against Respiratory Syncytial Virus (RSV), the cause of potentially serious respiratory illnesses
- The protection that each dose of Synagis® provides against RSV **wears off in 3-4 weeks**
- To decrease the chance of your child getting sick from RSV it is **important that they get all Synagis® doses on schedule**
- Be aware your child may not get Synagis® if they have:
  - Known hypersensitivity to Synagis® components or other humanized monoclonal antibodies
  - Moderate to severe illness, with or without fever (call the health center to inform them and schedule next dose for as soon as possible)
- Adverse Events:
  - Commonly: fever, redness or swelling at the injection site
  - Rare: pause in breathing or other breathing difficulties

☐ I have read the above information or had it read to me and understand it.
☐ I understand to best protect my child from RSV I must bring them on time for all doses.
☐ I have asked questions and had them answered to my satisfaction.

Child's current weight (kg) ______________________

Parent/Guardian Name: _______________________________

Signature: _______________________________ Date: ____ (DD) _______ (MM) ______ (YYYY)

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Munaqhiliqiyitkut
Ministère de la Santé

Appendix C

Fill in OR affix addressograph here

Last Name: ____________________
First Name: ____________________
Sex: □ **Male** □ **Female**
Date of Birth: ____(DD) ________(MM) _____(YYYY)
Chart#: _______________________
Health Card #: _______________________
Community of Residence: _________________

Synagis® Report Form

Complete and submit as soon as a Synagis® dose is given or you become aware child is not in community of residence for the next dose.

Dose	**Community & contact number**	**Date given** (dd/mm/yyyy)	**Lot #(s)**	**Next dose due** (dd/mm/yyyy)	**Synagis® discontinued** (e.g. last dose, moved out of Nunavut, declined consent)
1					Specify:
2					Specify:
3					Specify:
4					Specify:
5					Specify:
6*					Specify:
7*					Specify:

*** Within Nunavut, 5 doses are routinely administered. There may be exceptions in consultation with the RCDC.**

Notes below: e.g. Baby travels out of the community around the time of next dose.

Date	

Use extra sheets if you need to write more notes.

Fax to RCDC
Kitikmeot: 867-983-4088
Kivalliq: 867- 645-2409
Qikiqtaaluk: 867-975-4833

Appendix D

Synagis® Procedure for Eligible Out of Territory (OOT) Infants from Nunavut

1. Fax Annual Synagis® Registration Form (Appendix A) to Office of Chief Medical Officer of Health (OCMOH).

2. OCMOH faxes approved registration to Regional Communicable Disease Coordinator (RCDC).

3. OOT Synagis® Coordinator orders Synagis® from Nunavut Pharmacy 1-867-975-8600 ext. 2306.

4. Once Synagis® is administered, OOT Synagis® Coordinator fills out *Synagis® Report Form* (Appendix C) and faxes to RCDC.

5. If the infant returns to Nunavut, RCDC will fax *Synagis® Report Form (Appendix C)* to home community.

Synagis® Procedure for Eligible Infants Transferred to Out of Territory (OOT) Health Facilities

1. Community Health Center/Public Health advises RCDC using the *Synagis® Report Form (Appendix C)*.

2. RCDC advises the OOT Synagis® Coordinator.

3. OOT Synagis® Coordinator orders Synagis® from Nunavut Pharmacy 1-867-975-8600 ext. 2306.

4. Once Synagis® is administered, OOT Synagis® Coordinator fills out *Synagis® Report Form* (Appendix C) and faxes to RCDC.

5. If the infant returns to Nunavut, RCDC will fax *Synagis® Report Form (Appendix C)* to home community.

Synagis® Contact Information for Nunavut Regional CDC and Out of Territory (OOT) Coordinators

Qiqiktaaluk Region

Barbara Beattie RN, BN
Regional Communicable Disease Coordinator
Nunavut Department of Health
Phone (867)975-4811
Fax (867)975-4833
Email; bbeattie@gov.nu.ca

Kate Darling BSN MPH
Regional Communicable Disease Coordinator
Nunavut Department of Health
Phone (867)975-4814
Fax (867)975-4833
Email; kdarling1@gov.nu.ca

Ottawa

Coralee Boileau
RSV Clinic
Ambulatory Care
Children's Hospital of Eastern Ontario
Phone 613- 737-7600 ext 2406
Pager (613) 593-4249
Fax 613-738-4329
Email; cboileau@cheo.on.ca

Kivalliq Region

Lourdes Hernandez, RN
A/ Regional Communicable Disease Coordinator
Nunavut Department of Health
Phone No: 867-645-2171 ext 1503
Fax No: 867-645-2409
Email; kivalliq_RCDC@gov.nu.ca

Winnipeg

Winnipeg Children's Hospital
Rose Paulley, BN
Manitoba RSV Prophylaxis Program
Phone: 204-787-2535
Fax: 204-787-2545
Email : rpaulley@exchange.hsc.mb.ca

Kitikmeot Region

Frances Digout
Regional Communicable Disease Coordinator
Nunavut Department of Health
Phone (867)983-4508
Fax (867)983-4088
Email: fdigout@gov.nu.ca

Yellowknife

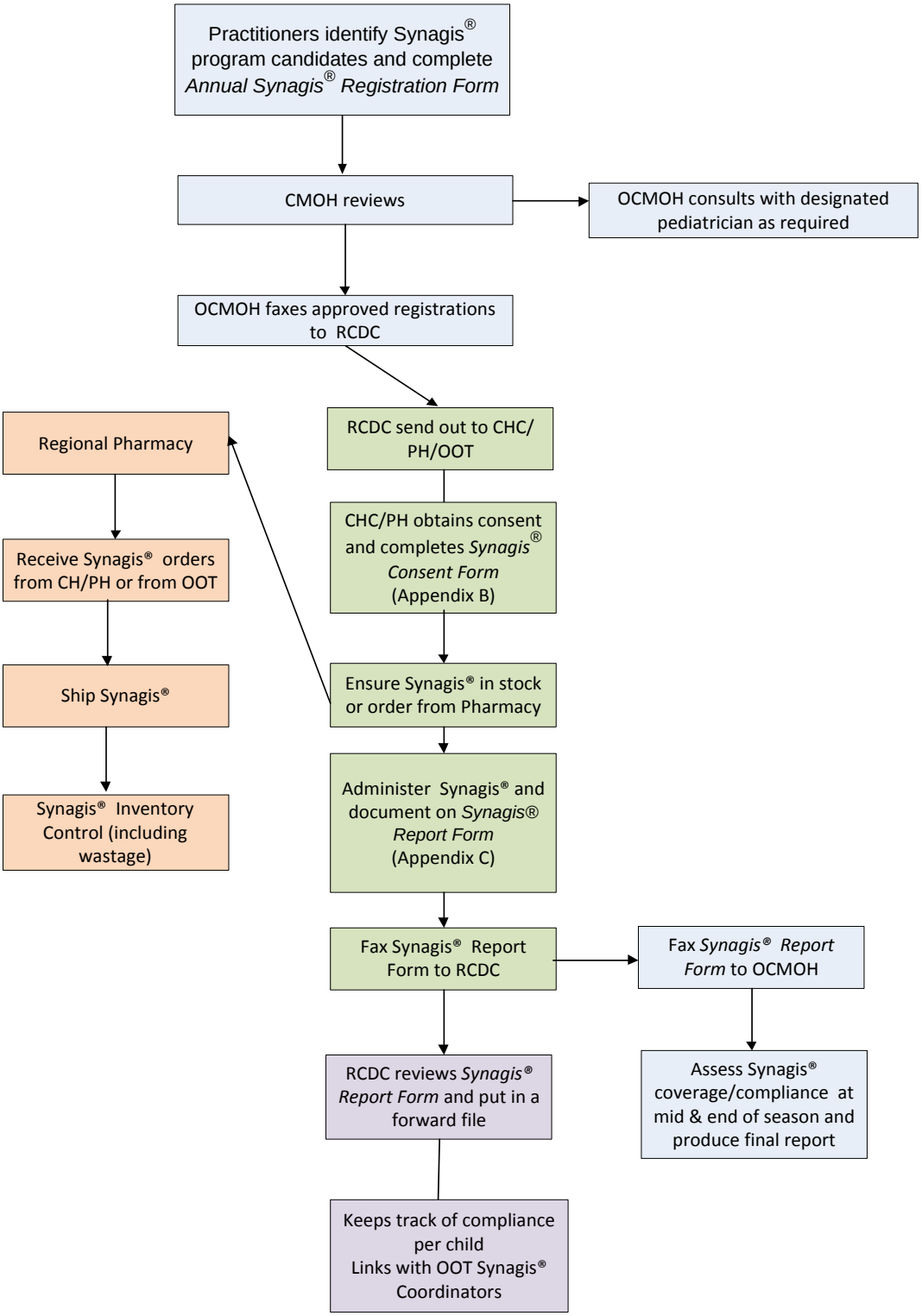
Colin J. Eddie
Manager, Communicable Disease Control Unit
Department of Health and Social Services
Government of the Northwest Territories
Box 1320, Yellowknife, NT, X1A 2L9
Tel: 867-920-3293 / Mobile: 867-444-0059 / Fax 867-873-0442
Email: colin_eddie@gov.nt.ca

Edmonton

Gail Porter-Lai
Royal Alexandra Hospital
Phone 780-735-4205
Fax 780-735-6919
Email : Gail.Porter-Lai@albertahealthservices.ca

Appendix E

Synagis® Program Flow Chart



OCMOH = Office of the Chief Medical Officer of Health
CHC = Community Health Center
PH= Public Health
RCDC= Regional Communicable Disease Coordinator
OOT = Out of Territory