11.0 Specialized and Annual Immunization Protocols (in alphabetic order)

- Palivisumab for Respiratory Syncitial 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®

(Protocol for Synagis® (Palivizumab)

## Purpose
Provide information and guidance for the Synagis® Program in Nunavut.

## Objective
Reduce Respiratory Syncitial 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 < 24 months of age at the beginning of the RSV season with:
  - Bronchopulmonary dysplasia/chronic lung disease of prematurity requiring oxygen and/or ongoing medical therapy for that illness in the previous 6 months OR
  - Hemodynamically significant congenital heart disease OR
  - Other pulmonary disorders requiring oxygen therapy e.g. recurrent aspiration OR
- Other medical conditions as identified by a specialist and approved in collaboration with pediatrician as required.

## Product

<table>
<thead>
<tr>
<th>Vaccine Type</th>
<th>Synagis® is a humanized monoclonal antibody that provides passive immunity.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vaccine components</td>
<td>Clinically relevant: Glycine, Histidine and Mannitol. Synagis® does not contain Thimerosal or trace antibiotics.</td>
</tr>
<tr>
<td>Formats available</td>
<td>Synagis® is supplied in 50 or 100 mg vials of sterile lyophilized powder for reconstitution with sterile water.</td>
</tr>
<tr>
<td>Manufacturer</td>
<td>Boehringer Ingelhein (BI) Pharma KG and distributed by Abbvie Laboratories, Ltd.</td>
</tr>
<tr>
<td>Administration</td>
<td>Intramuscular (IM) injection (typically in the anterolateral thigh)</td>
</tr>
<tr>
<td>Dose Series</td>
<td>Administer 15 mg/kg (if &gt;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.</td>
</tr>
<tr>
<td>Booster Dose</td>
<td>N/A</td>
</tr>
<tr>
<td>Vaccine interchangeability</td>
<td>N/A</td>
</tr>
</tbody>
</table>

*Note: Synagis provides passive immunity, thus missed doses leave patients unprotected. Ensure all doses are administered on time for maximum protection.*
other humanized monoclonal antibodies.

<table>
<thead>
<tr>
<th>Precautions and Additional Notes</th>
<th>Defer drug administration with moderate to severe illness, with or without fever.</th>
</tr>
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<tbody>
<tr>
<td><strong>Special Instructions</strong></td>
<td>Children who become infected with RSV while taking Synagis® prophylaxis should continue to receive their scheduled monthly doses of Synagis® throughout the RSV season, because RSV infection itself does not confer protective immunity. Minor illnesses (e.g. common cold) proceed to administer Synagis® if meets eligibility criteria. 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.</td>
</tr>
</tbody>
</table>

**Process**

**Registration**
- Practitioners (in and outside the 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®

**Synagis® Documentation and Reporting**
- Document Synagis® administration on the chart, HER 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.

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 registration and reporting procedures for those eligible infants from Nunavut can be found in Appendix D.

*See Appendix E Synagis® Program Flow Chart

**Preparation:**
1. **Very slowly** inject (drip along inside of vial) sterile water using aseptic technique.
2. Gently swirl vial for 30 seconds to dissolve powder to ensure that all the Synagis® has been saturated by the sterile water. **Do NOT shake or vigorously agitate the vial. Do NOT invert the vial during the reconstitution process.**

3. Let prepared solution stand at room temperature for at least 20 minutes until the solution clarifies or becomes opalescent. **Use within 3 hours of reconstitution as there is no preservative.**

4. Invert vial for about 30 seconds prior to drawing up solution.

### 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 (in the vaccine section).

### 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 Effects
Report all serious adverse events requiring medical attention, unusual/unexpected events, or medication errors to RCDC.

The Nunavut policy is:

- Adverse Events Following Immunization (AEFI) should be used **only** for the reporting of serious adverse events following immunization. The form is available in the Nunavut Immunization Manual Section 3 (3.5.5). Is also available online at: [Adverse Event Following Immunization (AEFI) Form](#).

- The unusual Occurrence Report should be used for reporting medication errors and other events. The report can be found in the Nunavut Community Health Nursing Administration Manual, Policy 05-004. A copy of the incident report must be faxed to RCDC.

If there is an AEFI **and** a vaccination error, both AEFI and Unusual Occurrence Report forms should be completed.

All completed forms should be faxed to RCDC at the numbers listed below:
Qikiqtaaluk: 867-975-4833; Kitikmeot: 867-983-4088; Kivalliq: 867-645-8272

### Vaccine Coverage and Reporting
Compliance is based on returned Synagis® Report Forms.
A final compliance report is created annually.

### Documentation
All doses given should be documented on the chart and the Immunization Record.

### Materials and A Few Facts
- RSV Protocol found in the Nunavut Communicable Disease Manual
| Resources | Synagis® Registration Form (Revised November 2014)  
| Synagis® Consent Form (Revised November 2014)  
| Synagis® Report Form (Revised November 2014)  
| Synagis® Program Flow Chart (Revised November 2014) |


| Prescription for program administration | Administer Synagis® according to the criteria above and in accordance with the Nunavut RSV season.  
Name of prescriber: Dr. Maureen Baikie, Chief Medical Officer of Health November 2014.  
This protocol is in effect for all eligible Nunavut children until rescinded or modified by CMOH. |
Appendix A

Annual Synagis® Registration Form

Fill in OR affix addressograph here

Last Name: _____________________
First Name: _____________________
Sex:        □ Male       □ Female
Date of Birth: ___(DD)______(month)____(YYYY)
Chart#: ________________________
Health Card #: ________________________
Community of Residence: __________________

Eligibility criteria (check all applicable):

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

☐ Children < 24 months of age at the beginning of the RSV season with:
  ☐ Bronchopulmonary dysplasia/Chronic lung disease of prematurity requiring oxygen and/or ongoing medical therapy for that illness in the previous 6 months
  ☐ Hemodynamically significant congenital heart disease
  ☐ Other pulmonary disorders requiring oxygen therapy e.g. recurrent aspiration

☐ Other medical conditions as identified by a specialist and approved in collaboration with pediatrician as required (specify condition and attach letter from physician):

________________________________________________________________________
________________________________________________________________________
________________________________________________________________________

Practitioner Name_____________________________________________________________
Signature___________________________________________________________________

CMOH /DCMOH or Designated Pediatrician
Signature: __________________________
Date: ___(DD)______(month)____(YYYY)
Comments____________________________________________________________________
____________________________________________________________________________
____________________________________________________________________________

Fax to Office of CMOH 1-867-979-3190
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
  - Very rare: severe allergic reactions

☐ 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) _____(month) _____(YYYY)
**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.

<table>
<thead>
<tr>
<th>Dose</th>
<th>Community &amp; contact number</th>
<th>Date given (d/m/y)</th>
<th>Lot #(s)</th>
<th>Next dose due (d/m/y)</th>
<th>Synagis® discontinued (e.g. last dose, moved out of Nunavut, declined consent)</th>
</tr>
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<tbody>
<tr>
<td>1</td>
<td></td>
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<td></td>
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<td>Specify:</td>
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<td>6*</td>
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<td>Specify:</td>
</tr>
<tr>
<td>7*</td>
<td></td>
<td></td>
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<td></td>
<td>Specify:</td>
</tr>
</tbody>
</table>

* 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.

<table>
<thead>
<tr>
<th>Date</th>
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Use extra sheets if you need to write more notes.
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 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 Coordinators

Qiiktaaluk Region:

Barbara Beattie RN, BN
Regional Communicable Disease Coordinator
Nunavut Department of Health
Phone (867)975-4811
Fax (867)975-4833
Email: bbeatte@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

Children's Hospital of Eastern Ontario
Annie Stephens
Phone 613- 737-7600 ext 2406
Fax 613-738-4329
Email: astephens@cheo.on.ca

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Kivalliq Region

Cielo Smith, RN
A/ Regional Communicable Disease Coordinator
Nunavut Department of Health
Phone No: 867-645-8072
Fax No: 867-645-8272
Email: csmith@gov.nu.ca

Winnipeg

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

Frances Uwazie
Regional Communicable Disease Coordinator
Nunavut Department of Health
Phone (867)983-4508
Fax (867)983-4088
Email: fuwazie@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

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

Synagis® Program Flow Chart

Practitioners identify Synagis® program candidates and complete Annual Synagis® Registration Form

CMOH reviews

OCMOH consults with designated pediatrician as required

OCMOH faxes approved registrations to RCDC

Pharmacy

Receive Synagis® orders from CH/PH or from OOT

Ship Synagis®

Ensure Synagis® stock on hand in CHC

Synagis® Inventory Control (including wastage)

CHC/PH

Obtain consent and complete Synagis® Consent Form

Ensure Synagis® in stock or order from Pharmacy

Administer Synagis® and document

Fax Synagis® Report Form to RCDC

RCDC reviews Synagis® Report Form and put in a forward file

Keeps track of compliance per child Links with OOT Synagis® Coordinators

Fax Synagis® Report Form to OCMOH

Assess Synagis® coverage/compliance at mid & end of season and produce final report

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

Nunavut RSV and Synagis® Program (November 2014)