

Protocol for SYNAGIS®

(Palivizumab) 2021-2022

Purpose	To provide information and guidance for the SYNAGIS® program in Nunavut.
Objective/Indication	Infants at high risk for serious morbidity and mortality secondary to Respiratory Syncytial Virus (RSV) infection.
Eligibility	<ul style="list-style-type: none"> • Premature infants born at ≤ 35 weeks and 6 days gestation AND ≤ 6 months of age; (born June 1 or later) at the start or during the RSV season. <ul style="list-style-type: none"> ○ Nunavut RSV season for this year is December 1 to April 31 • Children < 12 months of age at the beginning of the RSV season with: <ul style="list-style-type: none"> ○ Chronic lung disease of prematurity (CLD- defined as a need for oxygen at 35 weeks GA) currently requiring ongoing supplemental oxygen and/or medical therapy such as diuretics, bronchodilators, or steroids; ○ Hemodynamically significant congenital heart disease requiring supplemental oxygen and/or ongoing medical therapy such as diuretics, bronchodilators, or steroids. • Children < 24 months of age at the beginning of the RSV season with: <ul style="list-style-type: none"> ○ Bronchopulmonary dysplasia/chronic lung disease of prematurity requiring ongoing supplemental oxygen or who 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.¹ <p>Nunavummiut starting SYNAGIS® outside of Nunavut will be reviewed on a case by case basis. All applications received from out of territory need the signature of Nunavut’s Chief Public Health Officer (CPHO) on them, regardless of if they have been signed by a pediatrician from out of territory.</p> <p>Please note: The safety and effectiveness of SYNAGIS® in children older than 24 months of age at the start of dosing have not been established. SYNAGIS® is NOT for adults or for children older than 24 months of age at the start of dosing.</p> <p>It is recommended that children receiving SYNAGIS® who become infected with RSV continue to receive monthly doses of SYNAGIS® throughout the RSV season.</p>
Product	SYNAGIS® is a humanized monoclonal antibody, given by injection every 4 weeks.
Vaccine Type	Passive Immunizing Agent
Vaccine Components	<p>Medicinal ingredients: palivizumab</p> <p>Clinically relevant non-medicinal ingredients: chloride, glycine, histidine, and water for injection.</p>
Formats Available	SYNAGIS® is supplied in 50 mg/0.5mL and 100 mg/1 mL vials of solution for injection.

Manufacturer	AstraZeneca Canada Inc. 1004 Middlegate Road Mississauga, Ontario L4Y 1M4
Dose Series	<p>Note: The Nunavut RSV season is December 1 to April 31</p> <p>Dose: Administer 15 mg/kg, rounding off to the nearest mg. Administer dose q 4 weeks. Max dose 1 mL; doses > 1 mL should be divided.</p> <p>Administer the first dose as early in December as possible. For children born after December 1, their first dose should be given as soon as possible after birth.</p> <p>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 Public Health Officer (OCPHO). If a dose is delayed, give a dose as soon as possible and administer subsequent doses every 4 weeks after this dose.</p> <p>It helps with compliance to coordinate SYNAGIS® injections with routine well-child visits where possible.</p>
Administration	<p>Intramuscular (IM) injection (typically in the anterolateral thigh)</p> <p>The dose per month = [patient weight (kg) x 15 mg/kg ÷ 100 mg/mL of SYNAGIS®]</p> <p>**Injection volumes over 1mL should be given as a divided dose. This means that no more than 1mL of SYNAGIS® can be given in a single injection into a muscle.</p> <ul style="list-style-type: none"> • Both the 0.5mL and 1 mL vials contain overfill to allow the withdrawal of 50 mg or 100 mg. <p>DO NOT DILUTE THE PRODUCT. DO NOT SHAKE VIAL.</p> <ul style="list-style-type: none"> • 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. • Single-use vial. If you need to re-enter the vial, use a new sterile needle, otherwise discard unused content. • SYNAGIS® should not be mixed with any other medications or diluents. <p>NOTE: SYNAGIS® provides passive immunity, thus missed doses leave patients unprotected. Ensure that all doses are administered on time for maximum protection.</p>
Contraindications	Do NOT administer if there is a known hypersensitivity to any component of SYNAGIS® or to other humanized monoclonal antibodies.
Consent	Consent forms must be reviewed and signed by the parent/guardian prior to administration of the first dose of SYNAGIS®. There are translated versions of the consent form (Appendix B) for reference with patients.
Precautions and Additional Notes	<ul style="list-style-type: none"> • Typically, for minor illnesses, proceed to administer if client meets the eligibility criteria. • Defer drug administration only with moderate to severe illness, with or without fever. • SYNAGIS® does not interfere with the immune response to vaccines and can be administered

	<p>at the same time in a separate site; routine childhood immunization schedule can be maintained.</p> <ul style="list-style-type: none"> • SYNAGIS® does not interfere with the immune response to Tuberculosis Skin Tests (TSTs) and/or Bacillus Calmette-Guérin (BCG), and can be administered at the same time in a separate site.
Side Effects	<ul style="list-style-type: none"> • Very common: fever, rash. • Common: redness or swelling at the injection site, temporary pause in breathing or other breathing difficulties. • Uncommon: cough, runny nose, wheeze, vomiting, diarrhea, pain, viral infections and liver function abnormality. • Very rare: severe allergic reactions, anaphylactic shock.
Reportable Adverse Events/Side Effects	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.
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.
Storage	<ul style="list-style-type: none"> • Store in monitored vaccine refrigerator between 2°C and 8°C. • Protect from light. • If product arrives frozen or warm, separate the affected product under cold chain conditions, label “Do Not Use” and contact regional pharmacy for further instructions.
Vaccine Supply and Distribution	Pharmacy will send enough stock to each community prior to the start of the program to ensure all of those who registered will be covered. Thereafter, stock doses can be ordered as needed on the regular community pharmaceutical requisition form (GN Drug Formulary).
Special Instructions	<p>Registration for SYNAGIS® Program:</p> <ul style="list-style-type: none"> • 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 OCPHO throughout the year for approval via email or fax. • Clinical consultation with a pediatrician may be carried out as part of the review process, but the final approval of applications will be at the discretion of the CPHO. The approved registrations will be faxed by the OCPHO to the respective RCDCs or RSV representatives OOT. <p>Ordering and Administering SYNAGIS®:</p> <ul style="list-style-type: none"> • Community health centres/public health must obtain informed consent (Appendix B) and weight before administering SYNAGIS® (done at each new visit). • Ensure sufficient stock is available in clinic for the SYNAGIS® program and order more SYNAGIS® from the Regional pharmacy as needed. • Administer SYNAGIS®. <p>SYNAGIS® Documentation and Reporting:</p> <ul style="list-style-type: none"> • Document SYNAGIS® administration on the chart, Meditech electronic health record, and on the client’s immunization record.

	<ul style="list-style-type: none"> • Complete SYNAGIS® Report Form (Appendix C) and fax it to the RCDC. • RCDC will review SYNAGIS® Report and file it for next steps. • RCDC will fax SYNAGIS® Report Form to OCPHO. • OCPHO will assess SYNAGIS® coverage/adherence at mid-season and end of season. <p>SYNAGIS® Documentation and Reporting for Travel:</p> <ul style="list-style-type: none"> • Ensure children travelling out of their community (including out of the territory) for healthcare or other reasons are given a copy of their SYNAGIS® Report Form (Appendix C) to take with them. • Additional information on out of territory registration and reporting procedures for those eligible infants from Nunavut can be found in Appendix D.
Vaccine Coverage and Reporting	Adherence is based on returned SYNAGIS® Report Forms.
Documentation	Document SYNAGIS® administration on the report form, Meditech electronic health record, and on the client’s immunization record.
Materials and Resources	<ul style="list-style-type: none"> • Appendix A. SYNAGIS® Registration Form (Reviewed November 2021) • Appendix B. SYNAGIS® Consent Form (Reviewed November 2021) • Appendix C. SYNAGIS® Report Form (Revised November 2021) • Appendix D. SYNAGIS® Procedure for Eligible Out of Territory (OOT) Infants from Nunavut (Revised November 2021) • AstraZeneca (2021). SYNAGIS® Patient Medication Information from Product Monograph. Retrieved from synagis-consumer-information-leaflet-en (gov.nt.ca)
References	<ol style="list-style-type: none"> 1. Infectious Diseases and Immunization Committee (2016). <i>Preventing hospitalizations for respiratory syncytial virus infection</i>. Canadian Pediatric Society: 2021. Updated May 12, 2016. Reaffirmed January 1, 2021. Retrieved from https://cps.ca/documents/position/preventing-hospitalizations-for-rsv-infections. 2. AstraZeneca (2021). SYNAGIS® Product Monograph. Retrieved from https://www.astrazeneca.ca/content/dam/az-ca/downloads/productinformation/synagis-product-monograph-en.pdf on November 9, 2021. 3. Public Health Agency of Canada (2021). <i>Canadian Immunization Guide- Evergreen Edition</i>. Retrieved from Canadian Immunization Guide - Canada.ca. 4. National Advisory Committee on Immunization Statement on the Recommended Use of Monoclonal Anti-RSV Antibody (palivizumab). <i>Can Commun Dis Rep</i>. 2003 Sep 15;29:1-15.
Prescription for Program Administration	Administer SYNAGIS® according to the criteria above and in accordance with the Nunavut RSV season. Name of the prescriber: Dr. Michael Patterson, Chief Medical Officer of Health. November 2021. This protocol is in effect for all eligible Nunavut infants until rescinded or modified. This protocol was reviewed and approved by Dr. Patterson on November 10, 2021.

Appendix A

Annual SYNAGIS® Registration Form

Submission date: (DD) (MM) (YYYY)
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Last Name:	_____
First Name:	_____
Sex:	<input type="checkbox"/> Male <input type="checkbox"/> Female
Date of Birth:	_____ (DD) _____ (MM) _____ (YYYY)
Chart #:	_____
Health Card #:	_____

Eligibility Criteria (check all applicable):

- Premature infants ≤ 35 weeks + 6 days gestation AND ≤ 6 months of age (born June 1 or later) at the start or during the RSV season (season: December 1 to April 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 do not 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:
Contact Information:

Signature:

CPHO/DCPHO Signature:			
Date:	(DD)	(MM)	(YYYY)

Appendix B

Annual SYNAGIS® Consent Form

Review information with parent/guardian:

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

- 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 centre to inform them and schedule next dose for as soon as possible).
- Side effects/adverse events:
 - Very common: fever, rash.
 - Common: redness or swelling at the injection site, pause in breathing or other breathing difficulties.
 - Very rare: severe allergic reactions, anaphylactic shock.

- 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: _____

ፎልዶ ቦ
ፍላጎት ለሌሎች SYNAGIS® ለማግኘት
ርዕስ ስም

Last Name: _____

First Name: _____

Sex: Male Female

Date of Birth: _____ (DD) _____ (MM) _____ (YYYY)

የግብይት ስም

Chart #: _____

የግብይት ስም

Health Card #: _____

የሌሎች ጭቅቶች/የሌሎች ስም:

- SYNAGIS® (palivizumab) ለአጭር ጊዜ ወይንም ለጊዜ ገደብ Respiratory Syncytial Virus (RSV), ለአጭር ጊዜ የሚጠበቅ የሆነ ነው።
- ለአጭር ጊዜ ለጊዜ የሚጠበቅ የሆነ SYNAGIS® ለአጭር ጊዜ የሚጠበቅ የሆነ ነው።
- ለአጭር ጊዜ የሚጠበቅ የሆነ ለጊዜ ገደብ ለጊዜ የሚጠበቅ የሆነ ነው።
- የአጭር ጊዜ የሚጠበቅ የሆነ ለጊዜ ገደብ ለጊዜ የሚጠበቅ የሆነ ነው።

- የሌሎች ጭቅቶች/የሌሎች ስም
- የሌሎች ጭቅቶች/የሌሎች ስም
- የሌሎች ጭቅቶች/የሌሎች ስም

የሆስፒታል ልክዎት ልክዎት (kg) _____

የሌሎች ጭቅቶች/የሌሎች ስም

የሌሎች ጭቅቶች/የሌሎች ስም

Naunaitkutaa B
Ukiuk Tamaat SYNAGIS®
Angirutikhaq Titiraq

Kingulliq Atia: _____

Hivulliq Atia: _____

Inuuhiriyaa: Angut Arnaq

Annivia: _____ (DD) _____ (MM) _____ (YYYY)

Ilituqhautip Napaa: _____

Aanniaqtailinirmut Takuyaunikut # _____

Ihivriuqtauyukhaq
Naunairutikhangit imaituqarlutik
angajuqqaq/munaqti:

- SYNAGIS® (palivizumab) tunihimaaqtuq munagidjutikharnik talvanga Anirnikkut Aulayunik (RSV), aanniarut aanniaqtitivakhimayuq anirnikkut aanniarninik.
- Tamna munagidjutikhaq havautikhangit talvanga SYNAGIS® havautituqtauvakhimayuq talvanga aaniarutmin RSV piinginaqpaqtuq timingnin 3nik-4nikluuniit havainirnik.
- Aanniarnaitumik nutgat aanniarutmin RSVnik, akhuurutiaqtuq havautituqtauyukhat tamainik SYNAGIS® havautikharnik tikilvikhanga havautituqtaugiaqaligumi.
- Ilihimagukhauyutin nutarat havautituqtaulimaitungnarhiyuq SYNAGIS®nik ayungnautiqagumik inuuhirmini:
 - Ilitarnaqtuq mihingnautiqainagumik havautmun uminga SYNAGIS®nik iluaniitun allanikluuniit havautiqagumik havautinik inuhiangitni ayungnautiqagumik.
 - Aannialaqigumik aanniaryualaqalalakumiklu, kidjakhimaitumik kadjakumikluuniit (hivayaqlugit munarhitkut ilitugipkaklugitlu qanga havautituqpakhimayut qilaminuaq).
- Nakuuhimarman aanniarutit ilanganun inungunun/ihualuangitun aulavakhimayut:
 - Taimailiniartun: kidjarniaqtun, uvinirluklutiklu.
 - Naunaitun: apajaalaginiaqtun puvitlutiklu maqinirmiituni uviniani, anirhaarlungniaqtunluuniit allaniklu anirhaaktariami ajurhautiqarniaqtun.
 - Taimaililualimaitun taimainiartunlu: ayungnautikalarniaqtun inuuhirmini amigiyauyukhanik munarhinin.

- Taigurpagara qangani titiraqhimayut taiguktitavaktagalunniit uvamnun kangikhiyagalu.
- Ilihimagaga ihualuaqtuq munagidjutikhaq nutaramnun talvanga RSVmin takyaqtauvikhangit agitigiyakhatka taima havautitungnagiyaangat tamaini havautikhangit.
- Apigivaktunga apiqutingnik kiuyauvakhimayutlu namagiyamnun.

Nutamam uqumaitilaanga tadjakaffuq (kg) _____

Angajuqqaap/Munaqtiup Atia: _____

Atiliurvikhaa: _____

Ublua _____



Annexe B Formulaire de consentement annuel pour SYNAGIS®

annexe

First Name: _____

Sex: Male Female

date de naissance: _____ (DD) _____ (MM) _____ (YYYY)

Chart #: _____

carte Santé #: _____

Lire l'information avec le parent/tuteur :

- SYNAGIS® (palivizumab) fournit une protection contre le virus respiratoire syncytial (VRS), cause de maladies respiratoires potentiellement graves.
- La protection offerte par chaque dose diminue après trois à quatre semaines.
- Pour réduire le risque que votre enfant tombe malade en raison du VRS, il est important qu'il reçoive toutes ses doses de SYNAGIS® au moment prévu.
- Sachez que votre enfant pourrait ne pas recevoir SYNAGIS® s'il a :
 - une hypersensibilité connue aux composantes de SYNAGIS® ou à d'autres anticorps monoclonaux humanisés;
 - une maladie modérée à grave, avec ou sans fièvre (appelez le centre de santé pour planifier la prochaine dose dès que possible).
- Effets secondaires et incidents thérapeutiques :
 - Très courants : fièvre, éruption cutanée.
 - Courants : rougeur ou enflure au point d'injection, pause dans la respiration ou autres difficultés respiratoires.
 - Très rares : réactions allergiques graves, choc anaphylactique.

- J'ai lu ou entendu l'information ci-dessus et je la comprends.
- Je comprends que pour bien protéger mon enfant du VRS, je dois l'amener recevoir toutes ses doses au moment prévu.
- J'ai posé mes questions et reçu des réponses satisfaisantes.

Poids actuel de l'enfant (kg) _____

Nom du parent/tuteur : _____

Signature : _____ Date : _____

Appendix C

Annual SYNAGIS® Report Form

Fax to RCDCs

Qikiqtaaluk: 867-975-4833 (qikiqtaaluk_rcdc@gov.nu.ca)

Kivalliq: 867-645-2409 (kivalliq_rcdc@gov.nu.ca)

Kitikmeot: 867-983-4088 (fdigout@gov.nu.ca)

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

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

Dose	Community & contact number	Dose in mL and date given (dd/mm/yyyy)	Lot #(s)	Next dose due (dd/mm/yyyy)	SYNAGIS® discontinued (e.g. last dose, administered 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/OCPHO.

Notes below (i.e. Baby travels out of the community around the time of next dose):

Appendix D

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

1. Health care providers will fax Annual SYNAGIS® Registration Form(s) (Appendix A) to the Office of the Chief Public Health Officer (OCPHO) or the Regional Communicable Disease Coordinators (RCDCs).
2. OCPHO faxes approved registration forms to RCDCs and keeps a record of them at headquarters.
3. OOT SYNAGIS® Coordinators can order SYNAGIS® from the Nunavut Pharmacy (1-867-975-8600 ext. 2306) or send Nunavut's Pharmacy receipt for the vaccine only **after** the registration form has been approved and signed by the CPHO. This means that SYNAGIS® applications should be approved by the CPHO before any palivizumab is given out of territory.
4. Once SYNAGIS® is administered, OOT SYNAGIS® Coordinator fills out SYNAGIS® Report Form (Appendix C) and faxes it to the RCDC.
5. If the infant returns to Nunavut, RCDC will fax SYNAGIS® Report Form (Appendix C) to home community.

If a child is transferred OOT while enrolled in the program:

- The community health centre/public health advises the RCDC using the SYNAGIS® Report Form (Appendix C).
- The RCDC advises the OOT SYNAGIS® Coordinator, copying the Territorial team for awareness.
- The OOT SYNAGIS® Coordinator orders SYNAGIS® from the Nunavut Pharmacy (1-867-975-8600 ext. 2306) or sends Nunavut Pharmacy receipt for the vaccine.
- Once SYNAGIS® is administered, the OOT SYNAGIS® Coordinator fills out the SYNAGIS® Report Form (Appendix C) and faxes it to the RCDC.
- If the infant returns to Nunavut, the RCDC will fax the SYNAGIS® Report Form (Appendix C) to the infant's home community.