

CHEO Corporate Medical Directive

1. Name of the Medical Directive: *Initiation and Administration of Nirsevimab by CHEO Nurses*

Approval Status (Dates)

Version/Revision	MDC Submission	MDC Approval
Version 1	September 2024	October 2024
Version 2	October 2025	October 2025

Effective Date: March 2026

Directive Number: 2217

Renewal Frequency: ☐ 3 years

☒ Other (1 year): Annually

2. Purpose Statement

- To administer Nirsevimab IM injection prophylaxis for the prevention of RSV infection
- To prevent serious disease caused by respiratory syncytial virus (RSV) in pediatric patients

3. Personnel Authorized to Implement the Medical Directive

- Nurses at CHEO authorized to use this directive must complete training and demonstrate knowledge (medication, side effects and technique of administration), skills and judgement related to the procedure prior to applying the medical directive.
- Nurses caring for newborns/infants in hospital or outpatient clinics where Nirsevimab is available for administration and who are authorized to use this directive

4. Patient Population and Indications

- All Ontario patients who have been referred to the RSV clinic, are patients in ambulatory care or are admitted, who meet the Ontario Ministry of Health and Long Term Care (MOHLTC) risk assessment criteria for RSV prophylaxis (**Appendix 1**) and/or who have otherwise met criteria to receive prophylaxis.
- All Nunavut patients who meet the Nunavut Department of Health and Social Services criteria (**Appendix 2**) and who have been approved by the Nunavut Chief Medical Officer of Health (CMOH)
- All Quebec patients who meet the Quebec criteria as determined by the Ministère de la Santé et des Services Sociaux (**Appendix 3**) and who have been approved to receive prophylaxis.

5. Contraindications

- Patient is clinically unwell or has a fever over 38.0 degrees Celsius.
 - The nurse will screen for signs and symptoms of febrile illness and have the physician assess the patient
 - The Physician will assess the patient and document
- Known sensitivity to Nirsevimab or to any of its excipients, including non-medicinal ingredients or materials in product's packaging
- Hypersensitivity to other humanized monoclonal antibodies.
- History of a previous clinically relevant adverse reaction, which can be attributed to the vaccine.
- History of a clinically relevant drug interaction involving the vaccine that has not been previously discussed with the prescribing physician. The Nurse should contact the prescribing Physician to discuss the drug interaction.
- History of documented and lab confirmed RSV infection within the last 12 months

Precautions

- Caution for individuals with bleeding disorders
- Individuals who have a moderate or severe acute illness, with or without fever, should delay immunization until they have recovered before receiving Nirsevimab.

6. Description of the Procedure

Prior procedure:

- Ensure the anaphylaxis kit is available and easily accessible in the clinic.
- Check allergy status with parents or any delayed symptoms relative to a previous dose for those returning patients.
- Perform a medication history
 - Verify if infant is on Anti-Thrombotic Therapy (eg: Enoxaparin) and when the last dose was given. The information given may alert the nurse to the need for added precautions regarding bleeding post injection
- Marked allergies and medications as reviewed in Epic
- Prescribe in Epic under the Medical Directive Nirvesimab entry
 - Obtain a weight and temperature to determine whether the infant is well enough to receive Nirsevimab and to determine the dose required:
 - Infants born during the current RSV season
 - For infants < 5kg: 50mg*
 - For infants ≥ 5kg: 100mg**
 - For infants born after April 1 before the current RSV season starts (up to 8 months of age)
 - For infants < 5kg: 50mg*
 - For infants ≥ 5kg: 100mg**
 - For children over 8 months and up to 24 months of age, at continued high-risk from RSV infection:
 - 200mg (2 x 100mg divided dose given at separate site of injection)**
 - For returning patients, between 8 months and up to 24 months of age, weighing less than 10kg, a 100mg (instead of 200mg)** dose may be considered
- Administer oral analgesics (24% Sucrose for procedural pain management and Nursing Initiated Order)
- Enter dose given in the patient's EHR (Electronic Health Record) and on their immunization record.
- For doses given while the infant is hospitalized, ensure that the parent and their PCP is aware that it has been administered to avoid any duplication
- Administer the IM injection as per Mosby Nursing Skills procedure

*: Nirvesimab (Beyfortus) is available in pre-filled syringes format of 50 mg in 0.5 mL (100 mg/mL)

** : Nirvesimab (Beyfortus) is available in pre-filled syringes format of 100 mg in 1 mL (100 mg/mL)

Post procedure:

- Monitor the patient for a minimum of 15 minutes after the injection for adverse reactions including but not limited to wheeze, dyspnea, urticaria, angioedema, itching, hypotonia, injection site reaction.
- If patient is on anti-thrombotic therapy, ensure pressure is applied at injection site for long enough to ensure hemostasis.

Adverse reaction:

- In the event of a reaction the nurse will notify the MRP. Symptoms include, but not limited to wheeze, dyspnea, urticaria, angioedema, itching, hypotonia, injection site reaction.
- Page the assigned physician and dial 4444 to activate the SPOT team as appropriate.
- Prepare Epinephrine IM **only** as per patient specific default dose and **wait** for physician instruction.
- Document on appropriate patient health records.

7. Consent and Documentation

- Obtain informed consent from parents and document consent in patient health record.
- Document Nirsevimab on the appropriate patient health record:
 - Administration of Nirsevimab dosage including the injection site, lot number and expiry date
 - Administration of sucrose
- Document any side effects
- Document any teaching and counseling provided
- Encourage parents to sign up for the CANImmunize app on their phone or PC where they can enter that the dose was administered and keep track of their infant's immunizations

8. Quality Management Process

- Incident reports related to the use of this medical directive will be communicated to the Chief of Infectious Disease Service, Chair of Medical Directive Committee, Ambulatory Care Operations Director and Clinical Manager and Nurse by filling out the on-line Safety Reporting System (SRS).
- Prior to the renewal of this medical directive, an audit will be conducted to verify that the directive is being applied correctly.

9. References and Resources

- CHEO:
 - CHEO Pediatric Doses of Commonly Prescribed Medications
 - CHEO "Do Not Use" List: Abbreviations, Acronyms, and Symbols
 - CHEO 24% Sucrose for Procedural Pain Management policy.
 - Incident Reporting Policy
 - Lexi-Comp online
 - Medical Directives Policy
 - Mosby Nursing Skills procedure: [Medication Administration: Intramuscular Injection \(Pediatric\)](#)
 - Nursing Orientation Policy
 - Out Patient Orders for Nirsevimab
 - Patient Identification Policy
- College of Nurses of Ontario (CNO):
 - Practice Guidelines:
 - [Consent](#) (updated 2023)
 - [Directives](#) (updated 2023)
 - Practice Standards:
 - [Documentation, Revised 2008](#) (updated 2019)
 - [Medication](#) Revised 2023
 - [Scope of Practice](#) (2023)
 - The Regulated Health Professions Act (RHPA): Scope of Practice, Controlled Acts Model (2018)
- College of Physicians and Surgeons of Ontario: [Delegation of Controlled Acts \(CPSO - Delegation of Controlled Acts\)](#) (rev. 2021)
- MOHLTC (Ministry of Health and Long-Term Care): The Respiratory Syncytial Virus (RSV) Prophylaxis for High-Risk Infants Program. ([Respiratory Syncytial Virus | ontario.ca](#)) – Appendix 1 & Quebec – Appendix 3
- Nunavut Department of Health, the office of CMOH (Chief Medical Officer of Health) (link to be added once available) – Appendix 2
- Professional Information of Forwarding Prescriptions. (L'ordre des Pharmaciens du Québec)
- Public Act 1991
- Public Health Agency of Canada; Canadian Immunization Guide. <http://www.phac-aspc.gc.ca/publicat/cig-gci/p02-02-eng.php>

10. Contact Information

Area of Practice: CHEO

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Appendix 1: MOHLTC Ontario Criteria for RSV Prophylaxis

<https://www.ontario.ca/page/respiratory-syncytial-virus-rsv-prevention-programs#section-1>

Appendix 2: Nunavut Department of Health RSV prophylaxis (add once available)

Appendix 3: Héma-Québec criteria's for Nirsevimab

[Ac-VRS : anticorps monoclonal contre le virus respiratoire syncytial \(VRS\) - Immunoglobulines et anticorps monoclonaux - Professionnels de la santé - MSSS \(gouv.qc.ca\)](#)