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| **Medical Directive Title:** | **Respiratory Syncytial Virus Prophylaxis** | |
| **Lead Contact Person:** | **Erin Fleischer RN (EC) NP- Paediatrics** | |
| **Physician Lead:** | **Dr. April Price** | |
| **Program:** | **Children's Hospital and Women's Care** | |
| **Approval By:** | **Medical Advisory Committee** | |
| **Original Effective Date:** | **Revised Date:**<br>*Will be assigned by Medical Affairs* | **To Be Reviewed Date:**<br>*Will be assigned by Medical Affairs* |

**This Medical Directive applies to the following sites** *(click the relevant check box)*

☐ **All LHSC sites** ☐ **LHSC-UH** ☒ **LHSC-VH** ☐ **LRCP** ☐ **BFMC** ☐ **VFMC**

☐ **Other:** _____

**This Medical Directive Applies to the following patient population sites** *(click the relevant check box)*

☒ **In-Patients** ☒ **Out-Patients** ☐ **Adults** ☒ **Paediatrics** ☒ **Neonates**

**Order (***Identify the Order(s)/Treatment(s)/Intervention(s) Specifically in a narrative paragraph format for an overview / rational of this directive)*

1. **Name and description of the procedure, treatment, or intervention being ordered.**

Beyfortus™ (Nirsevimab) is approved by Health Canada for the prevention of RSV disease in newborns and infants. This includes those who are born healthy, whether at term or preterm, as well as those with specific health conditions. It is publicly funded for all infants as indicated in the recipient section.

https://www.ontario.ca/page/respiratory-syncytial-virus-rsv-prevention-programs

A single intramuscular (IM) dose of Beyfortus™ is administered in the preferred site of the anterolateral thigh for infants who are less than 12 months old. For children over 12 months of age, the recommended site is deltoid muscle in the upper arm.

| Category | Weight | Dose | Optimal Timing |
|---|---|---|---|
| Infants born during the current RSV season | <5kg | 50mg in 0.5ml (100mg/ml) | Administered soon after birth |
| | ≥5kg | 100mg in 1ml (100mg/ml) | Administered soon after birth |
| | <5kg | 50mg in 0.5ml (100mg/ml) | At the start of RSV season (October 1) |

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| Infants born April 1 of the current year before start of RSV season | ≥5kg | 100mg in 1ml (100mg/ml) | At the start of RSV season (October 1) |
| Children Under 24 months of age who are at continued high-risk from RSV infection entering their second RSV season (as determined by subspecialist) | N/A | 200mg (two 1ml injections of 100mg/ml) | At the start of the 2nd RSV season (October 1) |

Oral sucrose 24% (1 mL dose) may also be administered to the tip of the infant's tongue, if required, to transiently reduce pain and distress during administration of RSV prophylaxis. Sucrose is not a substitute for comfort measures.

Appendix Attached? ☒Yes ☐No
Please ensure you include appendix with your Medical Directive submission

**Recipient Patients** *(In broad terms Identify which patients may receive the order including the clinical and situational conditions required)*

- Infants born during the current RSV season (October 1-March 31) either in hospital or in the community under their care of their midwife
- Infants born prior to the current RSV season either on or after April 1, who will be receiving care either in the hospital or in community with their midwife
- Infants whose mother received maternal immunization but were born less than 14 days after injection, or Maternal immunization status unknown or; those infants born less than 37 weeks gestation

**Authorized Implementers** *(Identify individuals or groups of individuals by position and qualifications who will be involved in implementing the medical directive on behalf of the MRP*);

| Position / Title | Qualifications / Certifications |
|---|---|
| Nurses-assigned to RSV immunization clinic; PMDU; OBCU; PPCU; Paediatric ED; BFMC; VFMC; Paediatric Cardiology, Paediatric ENT | Registration with the College of Nurses of Ontario (CNO), practicing within LHSC |
| Registered Midwife | College of Midwives of Ontario |

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**Indications & Contraindications**

- Indications: Identify **specifically** when and under what conditions the directive applies.
- Contraindications: Identify conditions that would preclude implementation of the order or delegation. Identify what actions should be taken.

Indications:

- Please see recipient list for all indications

Contraindications:

Respiratory Syncytial Virus Prophylaxis cannot be implemented under authority of this medical directive if:

- The patient's SDM does not consent to this procedure
- For those infants where the pregnant person received maternal immunization and 14 days has passed since the injection was given

BEYFORTUS (Nirsevimab) is contraindicated in the following patients who:

- Have a history of severe hypersensitivity reactions, including anaphylaxis, to this drug or to any ingredient in the formulation, including any non-medicinal ingredient, or component of the container.
- Have a fever/temperature greater than 37.5 degree Celsius (If Nurse/Midwife has clinical concerns about a patient's clinical stability - for inpatients notify Physician/Midwife/NP MRP and for outpatients send to Emergency Department, Urgent Care Centre or community health care provider for assessment as appropriate).
- Have thrombocytopenia (platelets less than 150 x $10^9$ /L), any coagulation/bleeding disorder such as hemophilia or are on anticoagulation therapy and Physician/Midwife MRP has advised patient should not have IM injections

**Medication / Drug Table** *(Please identify any additional medications/drugs, using the chart below, which are included under this medical directive by listing the AHFS classification and then identifying which drugs are **INCLUDED and specific to your practice**)*

| **Drug Name (GENERIC) LIST INCLUSIONS** | **Indications** | **Route of Administration** | **Special Consideration (e.g. monitoring, lab tests)** |
|---|---|---|---|
| **Nirsevimab** | RSV Prophylaxis | Intramuscular | Allergies, age eligibility |
| **Sucrose 24%** | Analgesia | oral | |
| for formulary listings see - https://pharmapp.lhsc.on.ca/formulary_prod/public/search.php | | | |

**Consent**

Informed consent will be obtained prior to ordering/implementing the medical directive as per the College of Nurses of Ontario Practice Guideline: Consent, College of Midwives of Ontario Guide to the Health Care Consent Act and the Corporate Policy: Consent to Treatment

Nurse or Midwife to obtain verbal consent from care partner or substitute decision-maker.

**Educational Requirements**

- For nurses: successful completion of Corporate Nursing Orientation and unit-specific orientation.
- For Registered Midwives: maintain privileges with the London Health Sciences Centre and be a member in good standing with the College of Midwives of Ontario
- Review medical directive upon roll-out and annually at minimum along with completing RSV iLearn education on a yearly basis
- Product Monograph: Beyfortus
- Infant and High-risk Children Respiratory Syncytial Virus (RSV) Prevention Program Guidance for Health Care Providers – Beyfortus® (Nirsevimab)

Appendix Attached? ☐Yes ☒No
Please ensure you include appendix with your Medical Directive submission

**Documentation & Communication (***Identify all standard documentation requirements for the order(s) or procedure(s) (i.e. documentation standards for the patient health record)*

- Enter and/or confirm weight in EMR for all areas
- Orders will be entered in the electronic health record (EHR) by the nurse approved to use the medical directive. The appropriate order sentence is selected (Nirsevimab), the MRP or RN(EC ) name is documented, and the authorization communication type of *medical directive* is selected during the order's initiation.
- Documentation of the patient's condition meeting inclusion criteria must be reflected within the patient's health record (EMR or paper chart) with rationale provided for initiating the medical directive.
- Document all interventions in the Comfort Measures section, where applicable.
- Medications to be signed off on the medication administration record.
- Nurse is to notify the Most Responsible Provider (MRP) for any concerning changes in the patient's condition, abnormal results and for any additional instructions and/or assessments required outside this medical directive.
- Documentation will be completed as per LHSC and College of Nurses of Ontario documentation standards of practices and College of Midwives of Ontario documentation standards of practice.

**Review and Quality Monitoring Guidelines** *(Identify how issues will be addressed using this directive (e.g. How to address questions or clarification requirements, new information, unanticipated outcomes and identify who to contact and how to proceed).* ***Consider how this medical directive may impact operations and how monitoring impact on utilization will occur.***

If all recipient patient criteria are met and the nurse is unable to complete this medical directive, they will notify the MRP and document on the patient chart.

This medical directive will be reviewed annually by physicians, leaders, clinical educators, midwives, and nurses in all applicable areas.

In the event of a near miss or adverse event of any kind that could be reasonably attributed to the use of this medical directive, the nurse or midwife should complete and document any relevant assessments, notify the MRP, contact their leader, enter a report through the LHSC online safety system (SPEAK) as per LHSC procedure Incident Reporting and Management, and document all events in the patient's health record. Questions or clarification of a medical nature will be raised with the MRP.

**Professional Staff Approvals** *(Identify which Professional Staff group is responsible for patients who may receive an order or procedure under this medical directive on their behalf)*

Department: Paediatrics, Family Medicine, Midwifery

Division: Women' Care, Children's Care, Family Medicine

Program: Women's care (OBCU, PPCU); Children's Care, Family Medical Centre

A complete listing of all Professional Staff who have electronically signed this directive will be published on the online Medical Directive Catalog. Go to https://meddirs.lhsc.on.ca/and click on the directive name and scroll to the signatures section.

Please indicate the specific Professional Staff names below who will be asked to electronically sign this directive as processed by Medical Affairs.

| **NAME**<br>Example Only – Dr. John Doe | **DEPARTMENT / DIVISION**<br>Example Only – Medicine / Nephrology |
|---|---|
| Physicians | Family Medicine |
| Physicians | Community Paediatrics |
| Dr. April Price | Paediatric Respirology |
| Physicians | Paediatric Emergency |
| Erin Fleischer NP | Paediatric Respirology |

# Administrative Authorization Approval Form

Name of Directive: Respiratory Syncytial Virus Prophylaxis

Lead Contact Person (s): Erin Fleischer RN (EC) NP- Paediatrics

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| Chair, LHSC Medical Advisory Committee - Dr. David Steven (Interim) |
| Risk Consultant – Jennifer Hlembizky |
| Corporate Nursing Executive – Deborah Wiseman |
| Director, Nursing Professional Practice – Laura Rashleigh (Interim) |
| Chair, Drug & Therapeutics Committee, LHSC - Dr. Ian Ball |
| Director, Pharmacy Services – Sara Henderson |
| Department Head, Family Medicine – Dr. Scott McKay |
| Department Head, Midwifery – Meagan Furnivall |
| Department Head, Paediatrics – Dr. Craig Campbell |
| Division Head, Paediatric Respirology – Dr. April Price |
| Division Head, Community Paediatrics – Dr. Michelle Danby |
| Program Director / Manager /Coordinator (one must be indicated) –<br><br>Claire Martin, Director, Women's and Children's- PPCU, NICU, expanded midwifery care, MNCYN & Michael Gunning Simulation Centre<br><br>Rajwant Sousa, Director, Children's Services - Acute & Oncology Inpatient and Outpatient Services & NRT<br><br>Amanda Williams, Director, Women's and Children's – OBCU, OB/Gyn Ambulatory, Inpatient Gynecology and Regional Genetics Program |