November 27, 2024

HIROC: Emerging Trends Bulletin, Ontario (Number 31)

In keeping with HIROC's commitment to serving our valued Subscribers, HIROC's Emerging Trends Bulletin intends to bring Subscribers consistent information, guidance, and support on evolving matters.

Because of recent announcements in Ontario recommending Nirsevimab-alip (Beyfortus) as the product to protect infants from RSV, this bulletin is for the benefit of Ontario Subscribers.

Within this bulletin we aim to promote consistent information and provide considerations to your questions regarding:

- Maximizing the protection of infants against RSV
- Delegation and medical directives
- Supervision and location of the dose administration
- HIROC Coverage/CMPA eligibility for assistance
- Documentation and record retention
- Appendices

As a reminder, you can request an email copy of previous HIROC bulletins by replying to this email or sending a request to communications@hiroc.com.

We encourage you to reach out at any time if you need clarity around any risk, safety, claims, or insurance coverage issues.

In answering some insurance questions, we are, of course, summarizing HIROC's – and in certain circumstances, our excess insurers' policy coverages. The policy wording is not changed by this overview. As always, the facts and circumstances of each claim will determine if, and how, coverage under the HIROC policy would apply.

We will continue to provide information around coverage and risk considerations.

As your trusted healthcare safety advisor, we encourage you to reach out any time—we're here for you!

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Respiratory Syncytial Virus (RSV) infection is a major cause of respiratory tract illness, particularly among infants and young children. The Canadian National Advisory Committee on Immunization has recommended *Nirsevimab-alip* (Beyfortus) as the product to protect infants from RSV. Beyfortus is currently funded in Ontario for residents who meet the criteria set by the Ministry of Health. For information on RSV and protective immunization, please refer to the Public Health Agency of Canada's RSV vaccines: Canadian Immunization Guide and NACI Statement.

Delegation of the administration of *Nirsevimab-alip* (Beyfortus) to midwives through medical directives is an option to support preventative efforts against RSV.

HIROC covers insured:

- Registered Midwives to administer *Nirsevimab-alip* (Beyfortus) to newborns pursuant to medical directives
- Healthcare organizations/hospitals for claims arising from the administration of *Nirsevimab-alip* (Beyfortus) to newborns pursuant to medical directives.

Maximizing the protection of infants against RSV

When deciding how to facilitate the maximum number of healthcare providers to administer Beyfortus, thereby increasing its uptake for the benefit of vulnerable populations (such as infants), Subscribers and physicians may wish to consider delegation. Delegation enables a regulated health professional – who is authorized and competent to perform the controlled act (e.g., physicians and nurse practitioners) – to grant temporary authority to another provider/group (e.g., Registered Midwives) who are not currently legally authorized to perform the act independently (Ref: College of Physicians and Surgeons of Ontario (CPSO), 2024; Ontario and College of Nurses of Ontario (CNO), n.d., HPRO, n.d.).

Specifically, HIROC is aware that Registered Midwives as regulated health professionals with specialized training in perinatal and neonatal care do not, in the absence of an authorized medical delegation, have a pathway under current legislation to administer Beyfortus under their own authority.

HIROC is aware of the public health risk of RSV, particularly for infants, as well as the general risks and system benefits attending the judicious use of medical directives. From a risk perspective, HIROC's coverage and risk management advice is available to support the development of healthcare organization/hospital-approved medical directives permitting credentialed midwives to administer Beyfortus to newborns prior to discharge from the hospital and in primary care settings.

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Delegation and medical directives

Delegation of a controlled act is permissible via a direct order (order for treatment or intervention for one patient) or medical directive (refer to Appendix A for a sample medical directive from Hamiliton Health Sciences Centre). Unlike a direct order, medical directives are written orders from an authorized healthcare provider for the performance of treatments, interventions or procedures for particular patients (more than one) when specified criteria are met. They are intended to optimize timely, effective and efficient patient care. Medical directives may be utilized within an acute care facility/hospital (e.g., emergency departments) as well as in the community (e.g., long-term care facilities; emergency medical services) and primary care settings (e.g., clinic settings; client's home).

Physicians' and nurse practitioners' authority to delegate controlled acts in Ontario are derived through their respective provincial regulatory authority/college (CPSO, 2021; CNO, n.d.). Both the College of Physicians and Surgeons of Ontario and the College of Nurses of Ontario provide clear guidelines for delegation and use of medical directives (e.g., when to delegate, when not to delegate, what to delegated, how to delegate, consent requirements, etc.).

In order to safely delegate, the delegator is responsible to ensure the delegate has the requisite skills and training to carry out the delegated act. In a hospital environment, this responsibility may be shared between the delegating physicians/nurse practitioners and the healthcare organization. In the community primary care settings, the delegate midwife(midwives) may be expected to provide the delegating physician(s)/nurse practitioner(s) with information regarding their current qualifications and experience to administer Beyfortus. Subscribers may wish to use a standardized tool to track such information (e.g., Health Profession Regulators of Ontario's 'Implementer Performance Readiness Form – Group' is show in Appendix B).

Supervision and location of the dose administration

With some exceptions (e.g., infants with prolonged hesitation or those who are extremely preterm), infants born during RSV season may receive their dose of Beyfortus "in the hospital after delivery prior to discharge, or a primary care provider clinic" (MOH, 2024). No recommendations have been provided for infants born outside of RSV season.

Direct supervision of the delegate by the delegator may not be required in all circumstances (CMPA, 2022; CPSO, 2024). Delegation, where the delegator is not readily available in all locations where the delegate is providing care, may be appropriate where "the risk of the delegation is low, and/or the circumstances make it impractical or impossible to be onsite"

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(CPSO, 2024). The level of supervision depends on factors such as "the act being delegated and the risk it entails" (CMPA, 2022).

The use of medical directives in the hospital/healthcare facility setting is well established. However, HIROC recognizes that some Subscribers may have specific questions regarding delegation for the community and primary care settings (e.g., ensuring medical directives address the management of anaphylaxis in all administration locations). We ask that you please connect with us at riskmanagement@hiroc.com with any questions. Physicians who may have questions are encouraged to contact CMPA at inquiries@cmpa.org.

HIROC Coverage/CMPA eligibility for assistance

HIROC is aware of healthcare organizations that have already developed, or are in the process of developing, medical directives to delegate the administration of Beyfortus to credentialed Registered Midwives.

As outlined in HIROC's Composite Insurance Policy, HIROC's coverage extends to Subscribers (midwives, healthcare organizations and their employees and directors and officers) in relation to the administration of *Nirsevimab-alip* (Beyfortus), by Registered Midwives, to infants in the hospital prior to discharge or at primary care settings through the use of approved medical directives. For additional questions on your HIROC policy please contact inquiries@hiroc.com.

Physicians are encouraged to follow CMPA's advice regarding delegation in doing so (e.g., When can you safely delegate?). HIROC is also advised that with respect to CMPA assistance, a member named in an action or complaint related to the practice of medicine (including delegation) would generally be eligible for the Association's assistance.

Documentation and record retention

Midwives administering Beyfortus pursuant to an approved medical directive are encouraged to document the following (but not limited to) each time the directive is enacted:

- Indications for the administration
- Assessment of the patient
- Consent to treatment
- Date/time and location of the administration
- Name and number of the medical directive
- Signature of the midwife enacting the directive
- The patient's response to the administration

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- Specific actions taken in response to anaphylactic reaction or emergencies in response to the administration of Beyfortus

Subscribers and physicians should retain a copy of the medical directive in line with retention guidelines for physician orders (assuming orders are retained as part of the neonatal record).

To capture the names of all delegators (physicians and nurse practitioners) and delegates (Registered Midwives), Subscribers and physicians may wish to use Authorization Approval and Delegate(s)/Implementer(s) Approval forms. Both lists should be updated/amended annually (at the time of initial appointment and reappointment). Templates are included in Appendix C and D. These tools and template medical directive provide basic information only. They are not intended to take the place of medical advice, diagnosis, or treatment.

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Appendix A Sample Beyfortus Medical Directive – McMaster Children's Hospital's MAC - MD - Respiratory Syncytial Virus (RSV) Prophylaxis Medical Directive (accessed from the Association of Ontario Midwives website 07-OCT-24)

HAMILTON HEALTH SCIENCES	Authorizing Mechanisms
Issue Date: 2016 10 13 **Last Renewal Date:** 2018 02 15; 2022 12 14; 2024 09 11	Page 1 of 6
Title: MAC - MD - No. 44015 Respiratory Syncytial Virus (RSV) Prophylaxis Medical Directive	

Hamilton Health Sciences

AUTHORIZING MECHANISM
Medical Directive

Title: MAC - MD - Respiratory Syncytial Virus (RSV) Prophylaxis Medical Directive

Number: 44015

Activation Date: 2016 10 13 **Next review due by:** 2025 09 11

Approved by: MAC **Date:** 2024 09 11

Sponsoring/Contact Person(s): Dr. Jenn Twiss, Medical Director RSV Clinic, Ext. 73591; Dr. Sarah Khan, Head of Service, Infectious Diseases, Ext. 77577; Kim Felker, Director Women's and Newborn Health, Ext 73830; Karen Margallo, Director, Child & Youth Ambulatory Service, Ext. 75629; Catherine Duffin, Director, Community Programs, Ext. 11332

Order/Description of Procedure: Respiratory Syncytial Virus (RSV) Prophylaxis
Authorized Controlled Act and Procedure (CAP): yes ☒ no ☐
Delegated Controlled Act (DCA): yes ☐ no ☒
Authorized Non-Controlled Act and Procedure (Non-CAP): yes ☒ no ☐

Respiratory Syncytial Virus (RSV) Prophylaxis procedure includes the administration of a long-acting monoclonal antibody to prevent serious lower respiratory tract infections caused by RSV in infants who are less than 24 months of age at the start of the RSV season. RSV illness severity and related hospitalization are highest among infants under six months of age and children under 24 months of age with chronic conditions such as bronchopulmonary dysplasia, congenital heart disease, compromised immune systems, or neuromuscular disorders.

For infants entering their first RSV season, the recommended dose of BEYFORTUS® (nirsevimab) is:

- Infant weight less than 5kg - 50mg (50mg/0.5mL) x 1
- Infant weight 5 kg or greater - 100mg (100mg/1mL) x 1

For children who remain vulnerable to severe RSV disease entering their second RSV season, the recommended dose of BEYFORTUS® (nirsevimab) is:

- Children aged 24 months or less - a single dose of 200mg given as two intramuscular injections (100 mg/1mL) x 2

The IM injection is used to puncture the dermis of the patient's vastus lateralis to deliver the appropriate dose. The above procedure is an Authorized Controlled Act "performing a procedure beneath the dermis" and is based on the patient meeting all enrollment criteria.

The drug is only available during the active RSV season generally from November to April, as declared by the Ministry of Health (MOH).

Oral Sucrose 24% (up to a 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 the prophylaxis injection. Sucrose is not a substitute for comfort measures.

For administration of the seasonal immunoprophylaxis BEYFORTUS® (nirsevimab) to infants/pediatric inpatients and outpatients at McMaster Children's Hospital (MCH), McMaster University Medical Centre (MUMC) and West Lincoln Memorial Hospital (WLMH) sites:

Nurses (RNs and RPNs), Physician Assistants and Midwives at Hamilton Health Sciences (HHS) may administer the monoclonal antibody BEYFORTUS® (nirsevimab) IM, supplied in pre-filled syringes, to:

- **Pediatric Outpatients** at McMaster Children's Hospital, 2G Ambulatory Clinic:
  - up to 24 months of age or less in their first or entering their second RSV season
  - For high-risk patients greater than 24 months of age, requests will be approved or denied through an internal adjudication process
- **Infants/Pediatric Inpatients** in the Neonatal Intensive Care Unit/Level 2 Nursery, MUMC L&D, 4C Postpartum, Midwifery Care Unit and WLMH Obstetrics Unit:
  - Infants entering their first RSV Season:
    - 2024-2025 RSV season - all infants born as of January 1, 2024
  - Children who remain vulnerable to severe RSV disease entering their second RSV season and are aged 24 months or less
  - For high-risk patients greater than 24 months of age, requests will be approved or denied through an internal adjudication process

according to conditions set out in this directive.

Authorized by:
Sponsoring Physician/Health Professional(s):
Dr. Jennifer Twiss, Medical Director RSV Clinic
Approving Physician(s)/Health Professional(s) to Whom this Directive Applies:
Dr Jennifer Twiss, MD, FRCPC, is the authorizing physician for all infant/pediatric inpatients and outpatients at HHS.

Authorized/delegated to:
Under the authority of this medical directive, RSV Prophylaxis may only be implemented:

- By nurses, physician assistants and midwives who have completed the education component and signed off an annual review of the medical directive

Indications:
Nurses, Physician Assistants and Midwives may implement RSV Prophylaxis under authority of this medical directive when:

- The patient's Substitute Decision Maker (SDM) has consented to this procedure
- The following conditions are met:
  - Infants entering their first RSV Season:
    - 2024-2025 RSV season - all infants born as of January 1, 2024
    - Infant is clinically stable, greater than or equal to 30 weeks + 0 days corrected gestational age and weight greater than 1800 grams
  - Children up to 24 months of age who remain vulnerable to severe RSV disease entering their second RSV season, related to the following conditions, but is not limited to:
    - Chronic lung disease of prematurity (CLD/bronchopulmonary dysplasia)
    - Hemodynamically significant congenital heart disease (CHD)
    - Immunocompromised conditions
    - Down syndrome
    - Cystic fibrosis
    - Neuromuscular disease
    - Congenital airway anomalies

- Patient is afebrile (mild cough and/or upper respiratory tract infection (URTI) symptoms are not a contraindication)

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
- 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° C (If Nurse/Physician Assistant/Midwife has clinical concerns about a patient's clinical stability - for inpatients notify Physician/Midwife 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

Process for Implementing the Procedure:
Steps
The Nurse/Physician Assistant/Midwife will offer BEYFORTUS® (nirsevimab) to all eligible patients who do not have contraindications to receiving the RSV prophylaxis. Optimal timing for prophylaxis is from October to December but may be offered up to the end of March or while supplies last or when the MOH announces the RSV season end. The Nurse/Physician Assistant/Midwife may begin prophylaxis once the start of the RSV season is announced by the MOH as per the steps below:

1. Prefilled syringes must be stored in a refrigerator (2°C - 8°C). After removal from the refrigerator, BEYFORTUS® must be used within 8 hours or discarded.
   - Keep the pre-filled syringe in the outer carton in order to protect from light.
2. Substitute Decision Maker (SDM) of the patients receiving the immunization must be informed in language understandable to them, the nature of the procedure, the expected benefits, reasonably foreseeable associated risks, complications or side effects anticipated as a result of taking or not taking BEYFORTUS®. Nurse/Physician Assistant/Midwife should confirm with SDM that they understand that this is **NOT** a vaccine but an antibody that protects against RSV infection.
3. Obtain verbal consent from the patient's Substitute Decision Maker (SDM).
4. Identify patient by using two identifiers, e.g. name, DOB, Health Card Number
5. Obtain a naked weight using infant scale.
6. Two minutes prior to IM injection, apply up to 1 mL of Sucrose 24% to the tip of the infant's tongue and post procedure as needed.
   - Maximum dose is 4 mL in 24 hrs; use lowest dose necessary.
   - **Note:** Sucrose is not a substitute for comfort measures. The administration of oral Sucrose 24% is intended for transiently reducing pain response during a minor painful procedure. Additional measures such as non-nutritive sucking, breastfeeding, swaddling to minimize limb movement, skin to skin contact with primary caregiver, holding, cuddling, and or distraction may also help in reducing distress.
7. Verify the product, supplied in a pre-filled syringe, is not expired.

8. Cleanse the thigh(s) with chlorhexidine/alcohol swab as per unit/clinic protocol, administer BEYFORTUS® by injecting into the vastus lateralis muscle using 25 G 5/8 needle. Apply a band-aid post injection.
9. Administer remaining Sucrose 24% if needed
10. Observe for any adverse effects for 20 minutes post injection (see below)
11. Prior to discharge or leaving the Clinic, advise the SDM to contact their community health care provider immediately **if symptoms (see below) persist longer than 2 days**, and that they may be having a reaction to BEYFORTUS®.

Management of Untoward Outcomes
Management of Anaphylaxis:

- In case of immediate allergic reactions such as skin rash (hives) pruritus, dyspnea, facial and peripheral edema, bronchospasm, stridor, chest tightness and pain and or hypotension following immunization:
  - The Nurse/Physician Assistant/Midwife will:
    - Take vital signs as appropriate
    - Call a Pediatric Code Blue for pediatric outpatients in Clinic
    - Call Code Pink for newborn/neonatal inpatients (Infants in NICU/Level 2 Nursery, MUMC L&D, 4C, Midwifery Care Unit and WLMH Obstetrics Unit)
    - Notify the Physician/Midwife MRP and authorizing physician if/when an allergic reaction occurs

Prior to discharge or leaving the Clinic, advise the SDM to contact their community health care provider immediately if symptoms (see below) persist longer than 2 days, and that they may be having a reaction to BEYFORTUS®:

- **Local reaction:** The most frequent side effect of immunoprophylaxis is soreness at the injection site that lasts less than 2 days. This local reaction is generally mild and rarely interferes with the patient's ability to conduct usual daily activities.
- **Minor reactions:** These include fever and a possible rash.

Documentation/Communication Requirements for Medical Directives

The Nurse/Physician Assistant/Midwife implementing the Directive will document the following in the patient's health record:

- Verbal consent was obtained
- Order entered in electronic medical record for RSV prophylaxis as per medical directive # 44015 with acknowledgment that consent was obtained from Substitute Decision Maker (SDM)
- Physician/Midwife MRP has been notified of administration of RSV prophylaxis
- On the electronic Medication Administration Record (eMAR) - dose, route, site of the injection, date and time administered, brand name and lot number and expiry date, administration of Sucrose 24% (if used) and the name and designation of the individual administering the BEYFORTUS® and/or Sucrose 24%
- Corresponding documentation should be completed on the Personal Immunization Card if available during patient encounter
- Patient's response to RSV Prophylaxis.
- Any serious adverse events, complete an electronic Safety Occurrence Report. Report any occurence to Physician/Midwife MRP and RSV Medical Director.
- Instructions for post-discharge were given to SDM

Reporting Serious Adverse Events Following RSV Prophylaxis

Serious adverse events associated with BEYFORTUS® (nirsevimab) should be reported to the Physician/Midwife MRP and clinical pharmacist and entered into RL Solutions as an ADR SOR with Health Canada Serious Adverse Drug Reaction Form for Hospitals completed and notification of Drug Information Centre in Pharmacy (ext 76019 or DrugInfo@hhsc.ca). Drug Information Centre Pharmacist will submit report to Health Canada on behalf of HHS following review of report.

Quality Monitoring Processes:

The following processes will be used to maintain appropriate implementation of the directive/delegation and guide action if inappropriate, unanticipated and/or untoward outcomes result:

a) The staff member who identifies any inappropriate, untoward or unanticipated outcomes resulting from implementation will immediately notify the Physician/Midwife responsible for care of the patient or the RSV Medical Director, as appropriate and the Clinical Manager. The Clinical Manager, in collaboration with the authorizing physician will immediately trigger an ad hoc review as per AMPDM - Authorizing Mechanisms Protocol.

b) This medical directive will be reviewed routinely one year after initial activation and then every year thereafter according to the processes identified in the AMPDM - Authorizing Mechanisms Protocol.

c) This medical directive will be reviewed by the Medical Director for the RSV Clinic along with other stakeholders on an annual basis to ensure correct processes are being followed for its implementation and updates are made to reflect most current practices and guidelines. Any SORs that result from the implementation or lack of implementation of this medical directive will be a part of the quality monitoring review process.

d) This medical directive can be placed on hold if routine quality monitoring processes are not completed, or if indicated for an ad hoc review. During the hold, staff cannot perform the procedure under authority of the directive. Program and Medical Directors or designates will notify staff of any hold on the directive/delegation.

e) Nurses/Physician Assistants/Midwives will be authorized to implement the directive with annual review/certification of the medical directive.

2024 Developed and Agreed to by:

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Dr. Sarah Khan, Infection Prevention and Control
Dr. Esther Huisman, Medical Director, Neonatal Nurseries
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Resources/References:

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- NACI RSV Infant Statement. May 17th, 2024. Cat.: HP40-355/1-2024E-PDF
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- Early lessons from the implementation of universal respiratory syncytial virus prophylaxis in infants with long-acting monoclonal antibodies, Galicia, Spain, Martinon-Torres F et al. Euro Surveill 2023 Dec;28(49):2300606.

Related Policies and Procedures:

AMPDM - Authorizing Mechanisms Protocol
Health Canada Serious Adverse Drug Reaction Form for Hospitals

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Appendix B – Implementer Performance Readiness Form - Group (source: Health Profession Regulators of Ontario)

Implementer Performance Readiness Form - Group

Name and Number of Directive, Delegation or Practice:

Unit/Area: **# of pages:**

List Completed by:
(Authorizer or Educator's Name, Position, Signature and Initials)

Date Submitted: **For Period:**

Name of Implementer	Signature	Date	Authorizer or Educator's Initials

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Appendix C – Authorization Approval Form (source: Health Profession Regulators of Ontario)

Authorizer Approval Form

Title and Number of Directive/Delegation: _____

Name of Physicians or Authorizers	Signature	Date

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Appendix D – Implementer Approval Form (source: Health Profession Regulators of Ontario)

Implementer Approval Form

Title and Number of Directive/Delegation: _____

Name of Implementers	Signature	Date

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Disclaimer

These tools and template medical directive provide basic information only. It is not intended to take the place of medical advice, diagnosis, or treatment.

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Citations/Resources

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