

HAMILTON HEALTH SCIENCES	Authorizing Mechanisms
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Title: MAC - MD - No. 44015 Respiratory Syncytial Virus (RSV) Prophylaxis Medical Directive	



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.

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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

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- 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 $150 \times 10^9/L$), 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.

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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.

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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 occurrence 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.

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2024 Developed and Agreed to by:

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Resources/References:

- Pediatric Nursing Procedures, Third Edition, V R Bowden & C Smith- Greenberg 2012.
- NACI RSV Infant Statement. May 17th, 2024. Cat.: HP40-355/1-2024E-PDF
- Beyfortus Monograph. May 29th 2023; ATC Code: J06BD08: © AstraZeneca Canada Inc. 2023.
- Nirsevimab for Prevention of Hospitalizations Due to RSV in Infants. Drysdale SB et al. N Engl J Med. 2023 Dec 28;389(26):2425-2435.
- Single-Dose Nirsevimab for Prevention of RSV in Preterm Infants. Griffin MP et al. N Engl J Med. 2020 Jul 30;383(5):415-425.
- Nirsevimab for Prevention of RSV in Healthy Late-Preterm and Term Infants. Hammitt LL et al. N Engl J Med. 2022 Mar 3;386(9):837-846.
- Safety of Nirsevimab for RSV in Infants with Heart or Lung Disease or Prematurity. Domachowske J et al. N Engl J Med. 2022 Mar 3;386(9):892-894.
- 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