**Ministry of Health and Long-Term Care**

**Ministère de la Santé et des Soins de longue durée**

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Dear Health Care Provider:

**RE: 2018-2019 Season for Respiratory Syncytial Virus Prophylaxis for High-Risk Infants**

This letter details the Respiratory Syncytial Virus (RSV) Prophylaxis for High-Risk Infants Program (Program).

Links to the following can be found on the Program's webpage:

- Enrolment Form,
- Special Clinical Circumstance Medical Justification Form,
- Synagis® Order Form,
- Enrolment and Drug Ordering Process
- Frequently Asked Questions

**Updates for the 2018-2019 RSV Prophylaxis Season:**

Enrolment Form

The table below outlines changes to the enrolment form for the upcoming season:

| Applicable Section of Form | Change to the enrolment form |
|---|---|
| Section 1 | Addition of 'Gestational age at birth' field |
| Section 5 | Addition of diagnoses 'Single Ventricle' and 'Cardiomyopathy' fields, with an additional 'Other' field to provide further conditions |

Special Clinical Circumstance Medical Justification Form

The table below outlines changes to the enrolment form for the upcoming season:

| Applicable Section of Form | Change to the medical justification form |
|---|---|
| Section 2 | An additional section was added to determine if a specialist consultation was sought and the results of the consultation. A reminder was added to attach any further documentation or additional information to the form, such as a letter of support from a specialist, if available. |

## Overview of the Program

### Enrolment Criteria for Approval:

For an infant to be eligible for the Program, the **infant must be an Ontario resident with a valid Ontario health card** and satisfy the criteria as recommended by Ontario's RSV Advisory Group. The funding criteria for the 2018 – 2019 RSV Prophylaxis Season are listed on the enrolment form as follows:

- Infants born prematurely at ≤ 32 completed weeks gestation and aged ≤ 6 months at the start of, or during, the local RSV season; or
- Infants 33 – 35 completed weeks gestation and aged ≤ 6 months at the start of, or during the local RSV season, who DO NOT live in isolated communities AND have a Risk Assessment Tool Score of 49 to 100; or
- Infants 33 – 35 completed weeks gestation and aged ≤ 6 months at the start of, or during the local RSV season and who LIVE IN isolated communities where pediatric hospital care is not readily accessible and ambulance transportation is required for hospital admission; or
- Children < 24 months of age with bronchopulmonary dysplasia/chronic lung disease (BPD/CLD) and who required oxygen and/or medical therapy within the 6 months preceding the RSV season; or
- Children < 12 months of age with hemodynamically significant (HS) cyanotic or acyanotic congenital heart disease (CHD); requiring corrective surgery or is on cardiac medication for HS disease. Children 12 – 24 months of age with ongoing HS CHD will be considered on a case-by-case basis; or
- Children < 24 months of age with Down Syndrome/Trisomy 21, with or without hemodynamically significant congenital heart disease.

### Multiple Birth Sets:

If a high-risk infant of a multiple birth set is approved for the season, the siblings in the same set are also eligible for prophylaxis. Enrolments for the siblings in the same multiple birth set should be submitted on a separate form at the same time as the high-risk infant - irrespective of the discharge date(s) of the individual infants. Under Section 1 of the form, please specify the set (e.g. twins, triplets) and provide the multiple number (e.g. child 1, 2, 3) in the box titled, "Multiple Birth Infant Number". Although there is no specific space available on the form, you may also wish to indicate the Reference Number of the approved infant of the multiple birth set, if available.

### Consideration of Special Clinical Circumstances:

**Infants who are over 2 years of age at the start of the active RSV season will not be approved for funding**. However, enrolment requests for high-risk infants who do not satisfy the above criteria will be considered by the ministry's medical experts in RSV prophylaxis. A complete Special Clinical Circumstance Medical Justification Form (Medical Justification Form) should accompany the enrolment request.

The Medical Justification Form **must state the infant's specific medical illness, provide sufficient clinical details** regarding the risk for severe RSV disease and specify whether an infectious disease specialist, neonatologist or a respirologist has been consulted. If specialist support cannot be obtained because of limited accessibility, this should be clearly stated on the Medical Justification Form. The request will then be considered by the ministry's expert clinicians in RSV who may contact the requesting physician for additional information. When providing

clinical findings/status of the infant, please be as fulsome as possible to avoid delays in the review process. It is important that **no personal health identifiers** (e.g. infant's name, address, health card number, and parents' names) be provided on the Medical Justification Form.

To assist the ministry's expert clinicians in contacting the requesting physician if required, please include a direct phone line (back-office number) on the enrolment form, if available.

**Season Start and End:**

**Start**
Due to the seasonality of the RSV virus, palivizumab should only be administered during the active RSV season which for eastern, central and southern Ontario generally occurs from mid-November to March of the following year. As such, Ontario's RSV Advisory Group is recommending that the first dose be administered to eligible infants on or after the week of **November 19th**.

For **northern** Ontario (e.g. Sudbury and further north), the RSV season generally starts later in the year (e.g. December or January) and correspondingly, the end of the season may be delayed (e.g. April or May).

**End**
For most of Ontario, the prophylaxis season will finish at the end of March. However, if continued prophylaxis is required on or after April 1st OR if regional RSV activity persists, the requesting physician must confirm the RSV activity level in the infant's area of residence. The status of the regional activity must be stated on the request as per the definition below.

Regional activity can be confirmed by contacting the local or regional hospital's pediatric infectious disease department to inquire on the status of the season. The RSV season is considered on-going when there are TWO or more LOCAL RSV related hospitalizations per week for two consecutive weeks (Law et al. 2004).

**The ministry will communicate to the community the official start date and a declaration to the end to the RSV season.**

**Dosing Interval:**

The interval between the 1st and 2nd dose should be 21-28 days.

The intervals between the 2nd, 3rd, 4th, and 5th doses should be 28-35 days.

Based on human pharmacokinetic modeling, the 5th dose of palivizumab will provide sufficient antibody levels to protect for at least 6 weeks. **As such, the 5th dose will provide the child protection through the end of April or into the month of May if the usual dosing schedule is followed**.

The Program covers the cost of up to five (5) doses of palivizumab administered during the active RSV season to infants at high-risk for RSV infection. A sixth dose will NOT be covered by the Program except in isolated circumstances which will require approval by the ministry. These requests should be submitted to AbbVie as per the usual process and will be adjudicated by the ministry.

**Palivizumab (Synagis®):**

Palivizumab is a monoclonal antibody that provides passive immunization against the RSV virus and is not expected to interfere with routine vaccinations. However like other vaccinations, palivizumab has the potential to induce an adverse event including but not limited to fevers. For proper monitoring of adverse events, palivizumab can be administered 24 hours before or after a routine vaccination.

Immunization practices that are described in the Canadian Immunization Guide should be followed. Part I of the Guide titled "Key Immunization Information" identifies these practices in the section "National Guidelines for Immunization Practices". In addition, it is important to document the respective lot numbers of doses of palivizumab that are administered to patients.

The costs of 50 mg and 100 mg vials of palivizumab are $752.26 and $1,504.51, respectively. The ministry requests that all health care providers be mindful of the costs such that drug wastage is minimized. The September 2003 Statement on the Recommended Use of Monoclonal Anti-RSV Antibody (Palivizumab) from the National Advisory Committee on Immunization (NACI) recommended that "If an entire vial (500 mg, 1 g) is not required for a patient's monthly injection, physicians should arrange for more than one patient to receive palivizumab within 6 hours in order to minimize product wastage". It is noted that vial sharing is practiced in many jurisdictions and there is literature evidence to demonstrate cost savings associated with this practice.

The ministry is aware that the total number of vials requested for any given clinic date may be less than the calculated number of vials based on total body weight of the infants due to sharing of vials. **The dose of palivizumab is 15 mg per kg of body weight.**

Clinics should not accumulate any extra vials at the end of the season to minimize the possibility of drug spoilage during the off-season (summer months) due to unforeseen circumstances.

For further questions or clarifications on the Program policies and processes, please contact the ministry at RSVProphylaxisProgram@ontario.ca or at 416-327-8109 or 1-866-811-9893. You may also refer to the 'RSV Frequently Asked Questions' document for more program information.

For questions on enrolment status, RSV season reference number, shipment order requests, and drug-related issues (ordering, shipment, storage, stability, administration), please contact the Synagis Coordinator at AbbVie Canada: 1-888-704-8270.

I trust that this information will be helpful in delivering this Program efficiently and effectively through the RSV season.

Sincerely,

*Original signed by*

David Schachow
Director, Drug Programs Delivery Branch