Respiratory Syncytial Virus (RSV) Prophylaxis for High-Risk Infants Program – Frequently Asked Questions

This fact sheet provides basic information only. It must not take the place of medical advice, diagnosis or treatment. Always talk to a health care professional about any health concerns you have, and before you make any changes to your diet, lifestyle or treatment.

Who is eligible for RSV prophylaxis with palivizumab?
To be eligible for the RSV Prophylaxis for High-Risk Infants Program (the “Program”), the infant must be a resident of Ontario, insured under the Ontario Health Insurance Plan (OHIP) and meet the Program’s listed clinical criteria. Prior to the start of each prophylaxis season, the Ministry updates the Program’s eligibility requirements and provides additional information through the RSV Prophylaxis Season Information to Health Care Professionals communiqué.

When is the start date for RSV prophylaxis in Ontario?
The RSV prophylaxis start date is determined by the Ministry of Health and Long-Term Care and usually begins in the third week of November for southern and central Ontario. Northern Ontario’s prophylaxis season traditionally starts later by a month or more. Prior to the start of each prophylaxis season, the Ministry will communicate the start date through RSV Prophylaxis Season Information to Health Care Professionals communiqué. The RSV season is influenced by local RSV activity and seasonal factors. The Ministry uses this information in consultation with the Ontario RSV Advisory Group to determine the start date. However, the RSV season in any given regional area may be delayed as it relates to the actual local RSV activity. Ministry funding of palivizumab is provided between the start and end date of the RSV prophylaxis season.

When is the end date for RSV prophylaxis in Ontario? Can palivizumab be given after season end?
The end date to the RSV prophylaxis season is normally around April 1st and is communicated through the RSV Season End communiqué. However, the date may change based on RSV activity trend in various regions of Ontario and tracking through the Public Health Agency of Canada (PHAC) Respiratory Virus Detection Surveillance System reports. However, for areas of North Western Ontario such as Thunder Bay, the RSV season typically ends near the end of April to early May.

Doses of palivizumab should not be given after the RSV season has ended as declared by the Ministry. If doses are required after the season end, the Program may consider those requests on a case-by-case basis but only where the local RSV season is definitely active and ongoing. The RSV season is considered ongoing when there are TWO or more local RSV related
HOSPITALIZATIONS per week for TWO consecutive weeks. The requesting physician must state on the submitted request the current status of the LOCAL RSV season. It is important to confirm the status of your RSV season by contacting your local or regional hospital’s pediatric infectious disease department. Please fax your case-by-case requests to the fax number listed on the enrolment or order form.

Can palivizumab be administered out of season and will the Ministry provide appropriate funding?
Palivizumab should not be administered to high risk infants beyond the Ontario RSV season and funding for such infants will not be provided by the Ministry. Similarly, prophylaxis cannot be started before the season has officially commenced without approval by the Ministry, even if the child is deemed by the physician to be at extremely high risk based on risk factors.

How should palivizumab be administered?
NOTE: AbbVie has introduced palivizumab solution for injection for the 2016-2017 season. The new formulation is available in single-use vials containing 0.5 mL or 1.0 mL of solution for injection, both with a concentration of 100 mg/mL. This new formulation does not have to be reconstituted before use. Clinics or physician offices with remaining stock of palivizumab lyophilized powder are reminded to use up this stock since unused vials cannot be returned to AbbVie. Please note that the solution for injection and lyophilized powder formulations should not be mixed.

Palivizumab solution for injection
Palivizumab solution for injection should not be mixed with any medications or diluents. The solution should be withdrawn based on the product monograph. Since the single-use vial does not contain a preservative, palivizumab solution for injection should be administered immediately after drawing the dose into the syringe.

Palivizumab lyophilized powder
Palivizumab lyophilized powder should be reconstituted for intramuscular injection based on the product monograph. Following reconstitution the product is stable for up to 6 hours when left at room temperature. However, since the single dose vial does not contain a preservative, it is optimal to administer the product within 3 hours of reconstitution, unless it is reconstituted under controlled and validated aseptic conditions.

A maximum volume of 1mL of solution for injection/reconstituted product should be drawn up in a 1mL syringe and injected intramuscularly into a single site, using a 25-gauge needle. Volumes over 1mL should be given as a divided dose into two separate sites, unless local hospital nursing guidelines dictate otherwise. It is important to note that reduced muscle mass at the selected injection site may further limit the volume of injectable product into a single site.

How are out-of-province patients treated?
Each province and territory (PT) in Canada individually administers and funds their own RSV prophylaxis program. Out-of-province patients must be enrolled with their home provincial RSV prophylaxis program and assigned an enrolment number. The eligibility criteria for a specific PT may differ from that of Ontario’s and completion of the home provincial enrolment form is required to request enrolment in their program. This process ensures that palivizumab
doses are funded appropriately through the home province, even if the doses are administered in Ontario. Conversely, an Ontario infant travelling to another PT during the season can be treated by enrolling the patient through Ontario’s RSV Prophylaxis Program. The enrolment number assigned to a patient can be used at health facilities across Canada that delivers the RSV Prophylaxis Program.

Once an out-of-province patient has been approved, the enrolment number can be used to order doses of palivizumab which will be delivered to the treating hospital/clinic in Ontario. For further information and listing of provincial contacts to clarify a province’s RSV prophylaxis funding policy and procedures, please visit the Canadian Association of Neonatal Nurses RSV internet site on RSV.

**Are doses provided for Ontario infants travelling outside of Canada?**
Funding of palivizumab is only provided to Ontario infants while they are residing within Canada. Palivizumab is available in other countries but alternative funding, including private payment is required.

**What if an infant is ineligible for Ontario’s RSV Prophylaxis Program?**
The eligibility criteria is supported by evidence-based medicine which identifies infants at high-risk of hospitalization due to RSV. If an infant is ineligible for the Program but parents or guardians wish to proceed with RSV prophylaxis, private funding and access to palivizumab is available and processed as a regular drug prescription. For Ontario, a prescription must be submitted to McKesson Specialty Pharmacy and arrangements made for delivery of drug product while maintaining the cold chain process such that the viability of the product is safely sustained. Parents or guardians can contact McKesson Specialty Prescription Services at 1-888-377-9353 or 416-467-8698 for further information on the process to privately access palivizumab.

**Is Palivizumab covered for patients under the Interim Federal Health (IFH) Program?**
Palivizumab (Synagis) is not a listed standard benefit under the IFH program, but may be considered on an exceptional basis in limited circumstances. Please contact IFH directly and refer to the following links for more information regarding coverage under the IFH program including medication coverage:

[Interim Federal Health Program: Summary of Coverage](#)

[Interim Federal Health Program: Benefit Grid – Prescription Drug Coverage](#)

**Can a child get the ‘flu’ shot?**
Yes, the flu shot prevents influenza which is a different virus. Palivizumab does not offer any protection against influenza. Unless there are medical reasons not to vaccinate against influenza, every individual 6 months of age and older should receive a flu shot (reference PIDAC guidelines and NACI). Flu shots are usually available in the late fall each year. Talk to your child’s pediatrician or family doctor for more information.
Can a child have vaccines or drugs on the same day or in the same week that they receive palivizumab?

Palivizumab is not a vaccine and therefore it does not interact with other vaccines (including live attenuated vaccines i.e., MMR and Varicella) and can be safely administered concomitantly with routine childhood vaccines if the child is well and not febrile. Preferably, palivizumab should be administered 24 hours before or after a routine vaccination. Formal studies have not been conducted to evaluate potential interactions between palivizumab and other drugs but there is no apparent increase in adverse effects when used simultaneously. Please refer to the drug product monograph for full prescribing information.

Where can I get further information on the Ontario RSV Prophylaxis Program?

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

For further information, 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.

Please refer to the following links for information on RSV prophylaxis:

National Advisory Committee on Immunization (NACI)

Canadian Paediatric Society

Canadian Association of Neonatal Nurses

Public Health Agency of Canada – Respiratory Virus Detections in Canada