

Ontario Infant and High-Risk Children RSV Prevention Program:

Supplementary Clinical Guidance for Health Care Providers

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Disclaimer: This guidance was developed by the experts listed above to supplement, not replace, Ministry of Health guidance. It provides additional clinical context and is current as of the date listed.

Introduction

Respiratory Syncytial Virus (RSV) is one of the most common respiratory viruses in infants and young children and contributes to a significant burden of disease and substantial impact on the healthcare system during the RSV season through emergency department visits, hospitalizations and intensive care unit admissions.

In May 2024, Canada's National Advisory Committee on Immunization (NACI) recommended that provinces and territories work toward universal infant RSV immunization programs. Ontario was among the first to implement such a program, launching its inaugural universal season in 2024/2025.

Thus, in 2024, Ontario's Ministry of Health (MOH) transitioned from a high-risk infant RSV prophylaxis program using palivizumab (Synagis®) to a publicly funded universal prevention program for all infants and high-risk children using Nirsevimab (Beyfortus®). Like Synagis, Beyfortus is a monoclonal antibody (mAb) product authorized by Health Canada to help protect infants and young children from lower respiratory tract infections caused by RSV through passive immunization that offers immediate protection. The RSVpreF maternal vaccine (Abrysvo™, Pfizer) is another available product and is authorized by Health Canada for administration during 32 to 36 weeks of pregnancy to help protect infants from RSV.

Ontario's program publicly funds Abrysvo™ for pregnant individuals and Beyfortus® for infants and high-risk children under two years of age at the start of the RSV season. Prenatal care providers should share information on both products to support informed consent. NACI preferentially recommends Beyfortus® for infant protection due to its effectiveness, long-lasting protection, and positive safety profile. Routine administration of both products is not recommended, except in specific circumstances.

Purpose

This **Supplementary Clinical Guidance for Health Care Providers** is designed to answer frequently asked questions and support best practices in the implementation of Ontario's Infant and High-Risk Children RSV Prevention Program, complementing the Ontario MOH guidance.

The Ontario MOH [Infant and High-Risk Children Respiratory Syncytial Virus \(RSV\) Prevention Program Factsheet for Health Care Providers](#) provides information on:

- RSV immunizing agents available in Ontario
- Eligibility criteria under the publicly funded program
- Product preparation and administration practices, including schedule and dosing
- Co-administration with vaccine products
- Contraindications and precautions
- Reporting of side effects and adverse events following immunization (AEFIs)
- Ordering process to access the publicly funded supply

Frequently Asked Questions

Sections:

1. Additional Program Eligibility and Accessibility Considerations
2. Timing of the RSV Season and the Infant RSV Program
3. Considerations for Children with Complex Medical Conditions
4. Other Program and Vaccine Administration Considerations

Section 1: Additional Program Eligibility and Accessibility Considerations

Who is eligible for RSV prophylaxis with Beyfortus®?

Refer to the MOH [Infant and High-risk Children RSV Prevention Program Factsheet for HCPs](#) for eligibility under the publicly funded program. To be eligible for the program, the infant or child must be a resident of Ontario and meet the program's listed clinical criteria.

Prior to the start of each prophylaxis season, the MOH updates the program's eligibility requirements. Of note, immigrants to Ontario are eligible for prophylaxis if they are resident in Ontario at the start of the RSV season and do not have a health card/Ontario Health Insurance Plan (OHIP). This eligibility may also extend to high-risk children who have been transferred from other countries to one of Ontario's hospitals and are receiving prolonged treatment over several months and may have multiple exposures to RSV while in hospital during the season.

Do premature infants born between November 1, 2024, and March 31, 2025, qualify for prophylaxis in the 2025-2026 RSV season, if they are discharged home after April 1st?

These infants are not eligible for prophylaxis unless they have BPD or chronic lung disease. However, if an infant has experienced a very complicated neonatal course with multiple medical problems, the decision to administer Beyfortus® remains under the discretion of the responsible pediatric specialist.

Should premature infants who are over the age of 8 months receive RSV prophylaxis?

According to NACI "a dose of the RSV monoclonal antibody nirsevimab is recommended for all infants less than 8 months of age, entering, or born during, their first RSV season." However, infants over 8 months of age who are diagnosed with BPD, chronic lung disease, or another medical condition that places them at high risk for severe RSV illness are recommended to receive RSV prophylaxis.

Which complex medical disorders are eligible for Beyfortus® in the second RSV season?

In the past under the Synagis program, complex medical disorders were adjudicated by the Advisory Board to the MOH who determined need for RSV prophylaxis. Currently, the decision for prophylaxis rests with healthcare providers (HCPs) (i.e., pediatric specialists experienced in RSV prophylaxis) who can best determine the severity of a child's existing conditions that merit prophylaxis.

Children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season, may include but is not limited to children with:

- Hemodynamically significant congenital heart disease (HS-CHD) as per definition listed below
- Bronchopulmonary dysplasia/chronic lung disease (BPD/CLD) as per definition listed below
- Down syndrome/Trisomy 21 (Both healthy infants/children and those with comorbidities)
- Severe immunodeficiency: Children with both primary (e.g., severe combined immunodeficiency, Wiskott-Aldrich syndrome, interleukin receptor deficiencies) and secondary (acquired) immunodeficiencies (e.g., cytotoxic chemotherapy, bone marrow/stem cell/solid organ transplant, HIV infection)
- Cystic fibrosis with recurrent pulmonary exacerbations requiring hospitalization, deteriorating pulmonary function and/or severe growth delay <10th percentile
- Neuromuscular disease: This group includes infants/children with conditions that impair clearing of secretions such as general hypotonia and those with hypotonia associated with hypoxic-ischemic encephalopathy, syndromes (Prader-Willi), chromosomal disorders and migration and demyelinating conditions and infants/children with specific primary myopathies such as spinal muscular atrophy, muscle disorders (e.g., myotonic dystrophy, centronuclear and nemaline myopathy), mitochondrial and glycogen storage myopathies or arthrogryposis
- Severe congenital airway anomalies impairing the clearing of respiratory secretions. These include:
 - 1) upper airway anatomical anomalies involving the nasal passage (e.g., choanal atresia or severe stenosis), laryngo-tracheo-bronchomalacia, and primary vocal cord paralysis, extending to the subglottic region, and
 - 2) lower airway abnormalities extending from the subglottic area to pulmonary airway malformations (e.g., aplasia, congenital pulmonary airway malformation [CPAM], pulmonary sequestration, lung cysts, lobar emphysema). Additionally, many children who have chronic upper airway obstruction, airway anomalies and underlying complex medical disorders, may require a tracheostomy to facilitate airway clearance of secretions and prevent aspiration. This surgical procedure poses an increased risk for RSV-related hospitalization, and these infants/children should be considered for prophylaxis.

Are children > 2 years eligible for prophylaxis with Beyfortus®?

Despite not meeting eligibility under the publicly funded program, children over the age of 24 months who remain high-risk for severe RSV illness may benefit from prophylaxis with Beyfortus. The highest risk for RSV-related hospitalization pertains to children who are chronologically < 6 months of age and more specifically to those < 2 months. The incidence of hospitalization declines after 6 months with some variation annually as noted during and immediately post the COVID-19 pandemic. The safety and efficacy of Beyfortus® in children > 2

years of age has not been established and neither has the effective dose to prevent disease been determined based on body weight. Children in the MEDLEY second RSV season clinical trial ranged in median weight from 9.7 (range: 6.1–15.7) kg and received 200 mg of Beyfortus® for prophylaxis.

Clinically, children with the following medical conditions remain at risk for severe RSV disease beyond 2 years of age:

- Severe immunocompromise
- Hemodynamically significant heart disease awaiting cardiac transplant
- BPD/CLD and ongoing pulmonary hypertension
- Down syndrome who have severe medical complications
- Severe myopathies

However, decisions to provide 200 mg Beyfortus® prophylaxis for children up to 16 kg, should be made on a case-by-case basis by a pediatric specialist involved in their care. As a guideline utilizing first season data, but not supported by pharmacokinetic evidence, children weighing 17-21 kg can receive 250mg (2.5 ml) Beyfortus® and those between 22-26 kg can be administered 300mg (3.0 ml) ®.

Who should communicate with caregivers of infants regarding Beyfortus® eligibility and how should this be done?

Ideally, this should be done by the infants' regular clinician/healthcare practitioner or delegate. They can inform caregivers, that all infants who are born on or after April 1st and are aged less than eight months at the time of administration are eligible for RSV prophylaxis under the publicly funded program. Recommendations regarding Beyfortus® in the second season (8-24 months of age) should only be conveyed to parents after a clinician/healthcare practitioner has carefully reviewed the status of the child with pre-existing comorbidities and deems that the severity of the medical condition merits RSV prophylaxis. If the clinician is unsure about eligibility, it is advised that they seek a second opinion before providing information to caregivers.

How are out-of-province patients treated?

Every province and territory in Canada individually administers and funds their own RSV prophylaxis program (e.g., some programs are targeted, while others are universal). The eligibility criteria differs among provinces and territories.

International children are not eligible under the publicly funded program, unless in those cases of prolonged hospital stays during the RSV season. Of note, immigrants to Ontario are eligible for prophylaxis based on the criteria, if they are resident in Ontario at the start of or during the RSV season and **do not have** a health card/Ontario Health Insurance Plan. If an Ontario infant/child is travelling to another province/territory, or another country during RSV season, the infant/child should preferably be immunized prior to travel.

Are doses provided for Ontario infants/children travelling outside of Canada?

Funding of Beyfortus® is only provided to Ontario infants/children while they are residing within Canada. Beyfortus® is available in other countries but alternative funding, such as private payment, privately purchased doses will not be reimbursed by MOH.

What if an infant/child is ineligible for Ontario's RSV Prophylaxis Program?

The evidence-based eligibility criteria identify infants and young children at risk of hospitalization due to RSV. If an infant or child is ineligible for the RSV program, this means that experts believe that their risk of developing severe forms of RSV is less when compared with eligible infants/young children. If their parents or guardians and physicians still wish to proceed with RSV prophylaxis, Beyfortus® can be purchased privately or may be available for coverage through a private insurance plan. Beyfortus® is currently being covered by the following private insurers: Sun Life, Manulife, Medavie Blue Cross, Canada Life, GreenShield, ClaimSecure, and Desjardins. Approximately 39 percent of Canadians with access to a private insurance plan have a plan that would cover Beyfortus®. Patients can either reach out to their insurance providers for confirmation or check with a pharmacy.

In Ontario, a prescription is required. Parents or guardians, with the assistance of their physicians, may contact their pharmacy to determine how long it would take to order the product. Patients may use their insurance coverage or pay out-of-pocket at the time of purchase of the product.

Is Beyfortus® covered for patients under the Interim Federal Health (IFH) Program?

Beyfortus® 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 link for more information regarding coverage under the IFH program including medication coverage: [Interim Federal Health Program: Summary of Coverage](#).

Section 2: Timing of the RSV Season and the Infant & High-Risk Children RSV Program

When does the RSV season begin?

The RSV season is generally from November 1 to March 31, peaking in December, with regional variation across Ontario and between years. The RSV season is influenced by local RSV activity and seasonal factors. Typically, the RSV season begins in November for southern, central and eastern Ontario. Northern Ontario's season traditionally starts later by a month or more. However, the RSV season in any given regional area may be delayed as it relates to the actual local RSV activity.

When is the start date for RSV prophylaxis in Ontario?

Due to the seasonality of the RSV virus and to ensure optimal protection, Beyfortus® and Abrysvo™ should be administered shortly before and during the active RSV season. Pending product availability, administration of either Beyfortus® or Abrysvo™ for the infant program can begin in early October.

When is the end date for RSV prophylaxis in Ontario? Can Beyfortus® be given after season end?

The end date to the RSV prophylaxis season is normally March 31st and is communicated in program materials developed by the MOH. For some areas of Northern Ontario, the RSV season typically may end near the end of April to early May. 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.

Doses of Beyfortus® should not be given after the RSV season has ended. If doses are required after the season end, requests will be considered on a case-by-case basis but only where the local RSV activity is ongoing. The requesting prescriber must communicate with their local public health unit and then they will distribute the product as appropriate.

The RSV season is considered ongoing when there are TWO or more local RSV related HOSPITALIZATIONS per week for TWO consecutive weeks OR the first day of 2 consecutive weeks when at least two of 10–19 specimens tested each week are positive for RSV antigen or when at least 10% of ≥20 tests are reported to be RSV positive.

Can Beyfortus® be administered out of season and will MOH provide appropriate funding?

Beyfortus® should not be administered to infants/children under the publicly funded program beyond the Ontario RSV season. Similarly, prophylaxis cannot be started before the season has officially commenced, even if the child is deemed by the prescriber to be at extremely high risk.

Section 3: Considerations for Children with Complex Medical Conditions

Can midwives administer Abrysvo™ and Beyfortus®?

Under current legislation, midwives are only approved to prescribe and administer Abrysvo™. The College of Midwives of Ontario has proposed a regulatory amendment to add Beyfortus® to the list of drugs and substances that midwives can prescribe and administer.

How is hemodynamically significant congenital heart disease (HS-CHD) defined?

HS-CHD is defined as uncorrected or palliated cyanotic or acyanotic CHD associated with documented: Pulmonary hypertension (systolic pulmonary arterial pressure 40 mm Hg or resting mean pulmonary arterial pressure > 20 mm Hg) or a requirement for daily medication to manage congestive heart failure or severe failure to thrive based specifically on CHD status. The definition must be met for prophylaxis under the high-risk criteria for children both in the first season (less than 8 months of age) and in the second season (8-24 months of age) diagnosed with HS-CHD.

Does RSV prophylaxis with Beyfortus® need to continue after cardiac surgery?

Refer to the Ontario MOH [Infant and High-risk Children RSV Prevention Program Factsheet for HCPs](#) section on children undergoing cardiac surgery with cardiopulmonary bypass (Table 2: Beyfortus® Re-immunization Administration Guidelines for Children Undergoing Cardiac Surgery

with Cardiopulmonary Bypass). RSV prophylaxis is not recommended after the post-surgery dose has been received.

What supporting documentation is required to confirm a diagnosis of pulmonary hypertension?

Only moderate and severe pulmonary hypertension independently or specifically associated with bronchopulmonary dysplasia should be considered for RSV prophylaxis in the second RSV season under the publicly funded program. An echocardiogram and consultation with a cardiologist are strongly recommended to confirm evidence of hypertension and guide prophylaxis with Beyfortus®.

What is the definition of bronchopulmonary dysplasia/chronic lung disease (BPD/CLD)?

The following table defines BPD for a preterm infant < 32 completed weeks gestational age based on the mode of respiratory support and FiO₂ at 36 weeks postmenstrual age or discharge home, if earlier:

BPD Severity	Breathing in room air	NC < 1 L/min	NC 1-3L/min	NC > 3L/min, nCPAP, or NIPPV	Invasive PPV
No BPD	21%	21%	21%	-	-
Grade 1	-	22-70%	22-29%	21%	-
Grade 2	-	71-100%	30-100%	22-29%	21%
Grade 3	-	-	-	30-100%	22-100%

Abbreviations: bronchopulmonary dysplasia (BPD), fraction of inspired oxygen (FiO₂), nasal cannula (NC), nasal continuous positive airway pressure (nCPAP), nasal intermittent positive pressure ventilation (NIPPV), positive pressure ventilation (PPV)

For infants > 32 completed weeks gestation age with BPD/CLD the same criteria as above can be adopted with the proviso that the assessment occurs at > 28 days of age but < 56 days or at time of discharge.

If the definition of BPD/CLD is met in the first RSV season, the infant should continue to receive prophylaxis in the second RSV season, irrespective of clinical status or the Grade of BPD/CLD.

Section 4: Other Program and Vaccine Administration Considerations

Should a child still get the “flu” shot if they received RSV prophylaxis?

Yes, the flu shot prevents influenza which is a different virus. Beyfortus® does not offer any protection against influenza. Unless there are medical reasons not to vaccinate against influenza, every individual six months of age and older should receive a flu shot (please refer to [Provincial Infectious Diseases Advisory Committee on Infection Prevention and Control](#) (PIDAC-IPC) guidelines and the [National Advisory Committee on Immunization](#) (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 Beyfortus®?

Refer to the Ontario MOH [Infant and High-Risk Children Respiratory Syncytial Virus \(RSV\) Prevention Program Factsheet for Health Care Providers](#) on co-administration with vaccine products posted above.

Beyfortus® is not a vaccine and therefore it does not interact with other vaccines (including live attenuated vaccines i.e., Measles/Mumps/Rubella, Varicella, Rotavirus) and can be safely administered concomitantly with routine childhood vaccines if the child is well and not febrile. Beyfortus® can be administered any time before or after, other immunization products.

Formal studies have not been conducted to evaluate potential interactions between Beyfortus® 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.

Note: Beyfortus should not be mixed with any other vaccine in the same syringe or vial. If Beyfortus is given at the same time as other injectable vaccines, each injection should be given with a separate syringe at a different injection site.

Should Beyfortus® be administered after RSV infection?

Beyfortus® is generally not necessary or recommended for an infant/child who has had a confirmed RSV infection during the current RSV season. The additional benefit of administering Beyfortus® after recovery from RSV is unknown and expected to be low, and the risk of rehospitalization in the same season is very low (<1%). However, consideration may be given to severely immunocompromised infants/children (e.g., those with severe combined immunodeficiency and recent bone marrow transplantation) who may not mount an adequate immune response to the RSV infection.

No specific interval is recommended between RSV infection and receipt of Beyfortus®.

What is the definition of less than 8 months?

To be eligible under Ontario's publicly funded program, infants must be born AFTER the end of the previous RSV season (i.e., April 1 or later) AND less than 8 months of age at the time of administration. For example, an infant born on April 1 would be eligible to receive Beyfortus® only until December 1 of that same year.

Who would qualify as the Most Responsible Healthcare Provider (MRP)?

The term MRP generally refers to the physician, or other regulated healthcare professional, who has overall responsibility for directing and coordinating the care and management of a patient at a specific point in time. This also includes registered midwives and nurse practitioners (NPs).

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

For questions related to local programming and publicly funded product access, delivery, etc., please contact your local [public health unit](#). For questions on hospital order requests, and drug-

related issues (ordering, shipment, storage, reconstitution, administration), please contact your hospital-based pharmacist. For product specific questions (storage and handling, reconstitution, stability, administration) you can also contact the Sanofi Medical Information Portal (Phone #: 1-888-621-1146).

For further information, questions or clarifications on eligibility for Beyfortus and the program policies and processes, please contact the Vaccine Policy and Programs Branch by email at vacpro@ontario.ca.

Additional Resources

Provincial

- Ontario Ministry of Health [RSV Prevention Program](#)
- Public Health Ontario (PHO) [Respiratory Virus Tool](#)
- Provincial Council for Maternal and Child Health (PCMCH) [Multilingual Fact Sheets for Healthcare Providers and Parents/Expectant Parents](#)
- Centre for Effective Practice (CEP) [RSV Prevention Program for infants in Ontario Primary Care Toolkit](#)
- Ontario Medical Association (OMA) [RSV Prevention Program Website](#)
- Association of Ontario Midwives (AOM) [RSV Website](#)
- Ontario College of Family Physicians (OCFP) [RSV Prevention Programs: Summary of Updates](#)

National

- Public Health Agency of Canada (PHAC) [RSV vaccines: Canadian Immunization Guide for Health Professionals](#)
- National Advisory Committee on Immunization (NACI) [May 17, 2024 Statement on the Prevention of RSV in Infants](#)
- Public Health Agency of Canada (PHAC) [Health Infobase RSV Canadian Respiratory Virus Surveillance Report](#)
- Federation of Medical Women of Canada (FMWC) Maternal RSV Task Force [RSV Protect Website](#)
- Praxis Health [RSV Information Hub](#)