Protecting Infants and High-Risk Children During the RSV Season

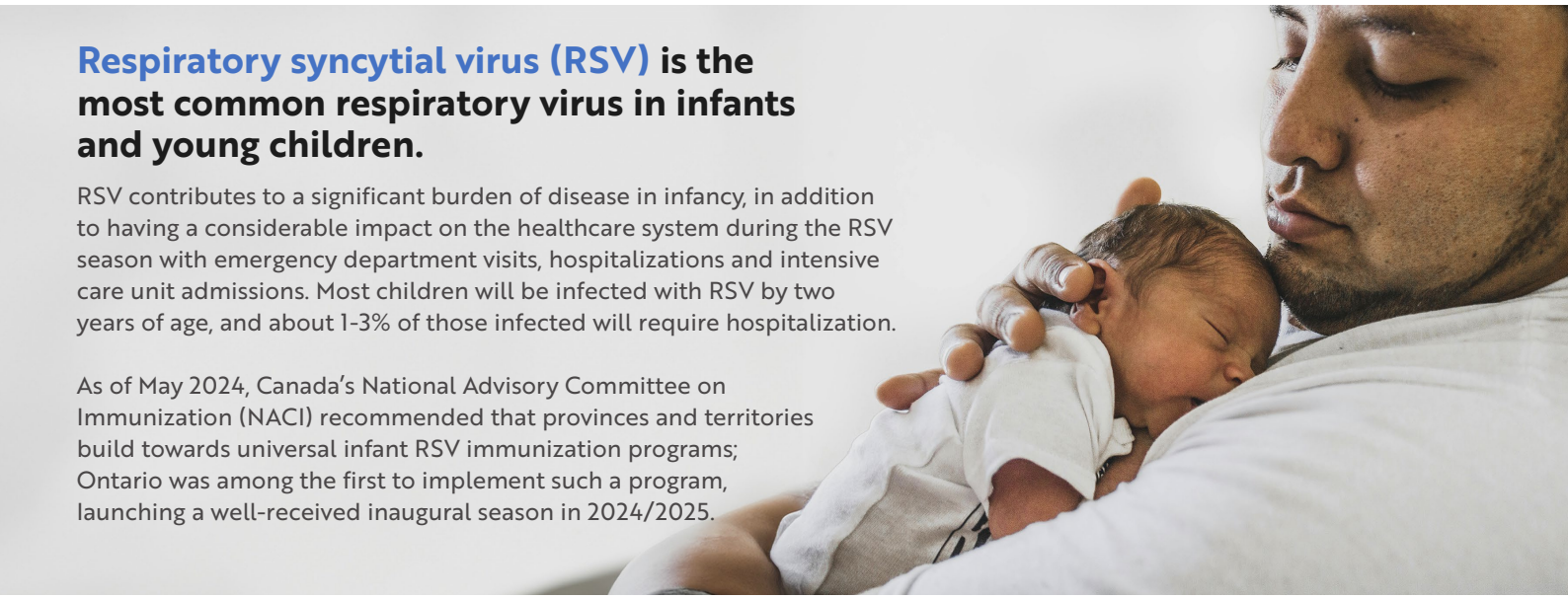
FOR HEALTHCARE PROVIDERS

Provincial Council for Maternal and Child Health

Respiratory syncytial virus (RSV) is the most common respiratory virus in infants and young children.

RSV contributes to a significant burden of disease in infancy, in addition to having a considerable impact on the healthcare system during the RSV season with emergency department visits, hospitalizations and intensive care unit admissions. Most children will be infected with RSV by two years of age, and about 1-3% of those infected will require hospitalization.

As of May 2024, Canada's National Advisory Committee on Immunization (NACI) recommended that provinces and territories build towards universal infant RSV immunization programs; Ontario was among the first to implement such a program, launching a well-received inaugural season in 2024/2025.



What do I need to know about Ontario's approach to protecting infants from RSV?

1. In 2024, the Ministry of Health (MOH) transitioned from a high-risk infant RSV prophylaxis program using palivizumab (SYNAGIS®, AstraZeneca), to a universal prevention program for all infants and high-risk children using nirsevimab (BEYFORTUS®, Sanofi).

2. 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 and longer-lasting protection.

3. The RSVpreF 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.

4. NACI preferentially recommends Beyfortus over Abrysvo for infant protection due to its efficacy, longer-lasting protection and positive safety profile. Use of both products together is not recommended except under specific circumstances.

What are the eligibility criteria for Beyfortus?

Beyfortus can be administered during the active RSV season and is publicly funded for Ontario residents who meet one of the following criteria:

- Infants born April 1 or after **and** less than eight months of age up to the end of the RSV season
- Children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season (see the MOH Infant and High-Risk RSV Prevention Program Fact Sheet for Health Care Providers for details)

The RSV season generally runs from November 1 to March 31, typically peaking in December, though it can vary by region and year. Beyfortus or Abrysvo may be offered starting in early October to provide protection just ahead of the season, depending on product availability.

Why was the publicly funded infant product transitioned from Synagis to Beyfortus?

Synagis requires monthly dosing, whereas Beyfortus requires only a single dose to provide protection for the entire RSV season. The product transition and expansion aimed to protect more infants and children and preserve health system capacity, particularly by preventing RSV-related hospitalizations and emergency room visits.

BEYFORTUS

What is the duration of protection provided by Beyfortus?

Protection is most effective for five months following Beyfortus administration. If Beyfortus is administered soon after birth during the RSV season, protection would be for the duration when the infant is most at risk of getting severe RSV disease.

What does the evidence suggest about the effectiveness of Beyfortus in infants to protect from severe clinical outcomes due to RSV?

Consistent with clinical trial results, Beyfortus has demonstrated strong real-world effectiveness in reducing RSV-related morbidity in infants. A systematic review and meta-analysis of real-world studies found that, among infants aged 0-12 months, receipt of Beyfortus was associated with:

83%
lower odds of RSV-related hospitalization

81%
lower odds of intensive care unit (ICU) admission

75%
lower odds of lower respiratory tract infection (LRTI)

Are there side effects associated with Beyfortus?

- Side effects from Beyfortus are rare, usually mild and last only a few days. The most common include redness, swelling and pain at the injection site.
- The clinical trials demonstrated that the most frequent adverse reactions were rash, pyrexia and injection site reactions. Few participants experienced adverse systemic events, but none were related to treatment with Beyfortus.

! Healthcare professionals, organizations and patients are recommended to report suspected side effects to Health Canada. Refer to the Beyfortus product monograph for detailed information on contraindications and precautions.

What was Beyfortus uptake at birth in Ontario?

From November 1, 2024 to March 31, 2025, 68.8% of newborns in Ontario* received Beyfortus at birth before discharge. The main reasons for not receiving it were parent/caregiver declined, prenatal receipt of Abrysvo, or discharge before being offered/missed opportunity.

*This sample includes births from all birthing hospitals across Ontario and represents approximately 94% of births during this time period. Source: BORN Ontario

How is Beyfortus administered and at what dosage and frequency?

A single dose of Beyfortus is administered intramuscularly with the preferred site dependent on the age of the child (e.g., anterolateral thigh for infants <12 months of age). The recommended dose is based on the infant/child's weight at the time of administration, as follows:

Category	Weight	Dose	Optimal Timing
Infants born during the current RSV season	< 5 kg	50 mg in 0.5 mL (100 mg/mL)	Administered soon after birth
	≥ 5 kg	100 mg in 1 mL (100 mg/mL)	Administered soon after birth
Infants born on or after April 1 before the current RSV season starts	< 5 kg	50 mg in 0.5 mL (100 mg/mL)	Shortly before or during the RSV season
	≥ 5 kg	100 mg in 1 mL (100 mg/mL)	Shortly before or during the RSV season
Children at continued high-risk from RSV infection during the second RSV season (up to 24 months of age)	N/A	200 mg (two 1 mL injections of 100 mg/mL)	Shortly before or during the RSV season

For children undergoing cardiac surgery with cardiopulmonary bypass, please refer to the MOH Infant and High-Risk RSV Prevention Program Fact Sheet for Health Care Providers for information.

Where and when will Beyfortus be administered?

The administration of Beyfortus will require multiple channels to effectively reach eligible populations, dependent on geographic location and access to healthcare. This will include:

- **Hospital** administration at birth for infants born during the RSV season, ensuring timely protection before discharge
- **Midwifery, primary care or public health** administration for infants born outside the hospital system (e.g., home births) or outside the RSV season (e.g., spring/summer births)
- **Paediatric specialist, primary care or outpatient hospital clinic** administration for high-risk children up to 24 months of age during their second RSV season

What if my infant/child patient has had a recent RSV infection?

For infants who have had a confirmed RSV infection during the current RSV season, Beyfortus is generally not necessary or recommended due to limited known benefit.

This may differ for severely immunocompromised infants. No specific interval is recommended between RSV infection and Beyfortus administration.

Can Beyfortus be co-administered with other vaccine products?

Beyfortus can be administered on the same day as, or at any time before or after, routine childhood vaccinations (e.g., DTaP-IPV-Hib or MMR).

ABRYSVO

What if my pregnant patient would like to receive the Abrysvo vaccine?

Prenatal care providers should offer information about both the RSV vaccine and the mAb to pregnant patients. However, only one product – either Beyfortus or Abrysvo – is recommended, except in certain circumstances:

- The infant is born less than 14 days after maternal administration of Abrysvo; or
- The infant meets medical criteria for increased risk of severe RSV disease, including:
  - Premature birth (i.e., < 37 weeks gestation)
  - Any of the high-risk conditions outlined in the MOH criteria

Prenatal care providers should counsel patients that Beyfortus is the preferred method for safeguarding infants against RSV over Abrysvo; however, both RSV immunization products are effective.

Results from clinical studies demonstrated that Abrysvo reduced the likelihood of infant hospitalization for RSV by 68-79% within three months after birth and 57-71% within six months.

How is Abrysvo administered and at what dosage and frequency?

Abrysvo is administered as a single dose of 0.5 mL between 32^{+0} and 36^{+6} weeks gestation. The vaccine is used to actively immunize pregnant people, providing infants with passive maternal antibodies that protect them from severe RSV illness from birth to approximately six months of age. Abrysvo can be administered concurrently during pregnancy with other recommended vaccines (e.g., Tdap).

Refer to the MOH Infant and High-Risk RSV Prevention Program Fact Sheet for Health Care Providers for more information and refer to the Abrysvo product monograph for detailed information on product ingredients, contraindications and precautions.

Are there educational resources that can be shared with patients and families?

The Provincial Council for Maternal and Child Health (PCMCH) has developed a fact sheet for parents and expectant parents that is available in English, French and several additional languages. In addition, the Indigenous Primary Health Care Council (IPHCC) and PCMCH have co-developed a tailored fact sheet for Indigenous parents, families and caregivers that is available in English, French and four Indigenous languages.

These resources can be printed or shared electronically with parents and expectant parents to support your shared decision-making conversations about how to protect their infant/child during the RSV season.

What do my patients and families need to know?

Prenatal care providers are encouraged to begin conversations early in pregnancy about RSV and immunization options to protect infants. Key points to guide your discussions with expectant parents may include, but are not limited to:

- **RSV Overview** (e.g., what is RSV, risks to healthy infants and high-risk children, RSV seasonality)
- **Immunization Options** (e.g., mAb or vaccine, Beyfortus as the recommended product)
- **Beyfortus** (e.g., eligibility, timing, frequency, route, safety, efficacy)
- **Abrysvo** (e.g., eligibility, timing, frequency, route, safety, efficacy)
- **Prevention Strategies** (e.g., feeding breast/chest milk, hand hygiene, avoiding smoking and close contact with sick individuals)
- **Documentation** (e.g., Ontario Perinatal Record, keeping immunization records up to date)

Where can I find support for implementing the infant RSV prevention program?

For questions about the program, please contact your local public health unit. The most up-to-date information is available on the MOH RSV prevention program webpage for healthcare providers.

The PCMCH RSV webpage also offers a curated list of additional resources to support you in the integration of this program into your practice.