Protecting Infants and High-Risk Children during RSV Season

FOR HEALTHCARE PROVIDERS

Respiratory Syncytial Virus (RSV) is one of the most common respiratory viruses 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 RSV season with emergency department visits, hospitalizations and intensive care unit admissions.

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 is one of the first provinces to do so.

What has changed with Ontario's RSV prevention program for infants?

1. For the 2024-25 RSV season, the Ministry of Health is transitioning from the current high-risk infant prophylaxis program using Palivizumab (SYNAGIS®, AstraZeneca), to a universal infant and high-risk children RSV prevention program using Nirsevamib (BEYFORTUS™, Sanofi).

2. Similarly to Synagis, Beyfortus is a monoclonal antibody (mAb) product and has Health Canada authorization to help protect infants and young children from lower respiratory tract infections caused by RSV through passive immunization that offers immediate protection.

3. The RSVpreF (ABRYSVO™, Pfizer) vaccine will also be available this 2024-25 RSV season and has Health Canada authorization to be given during 32 to 36 weeks in pregnancy to protect infants from RSV.

4. Beyfortus is the recommended approach for the protection of infants as per the National Advisory Committee on Immunization (NACI), with Abrysvo to be considered on a case-by-case basis.

What are the eligibility criteria for Beyfortus?

For the 2024/25 season in Ontario, Beyfortus is publicly funded for infants and young children:

- Born in 2024 prior to the RSV season*
- Born during the 2024/25 RSV season
- Up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season (refer to Ministry of Health Beyfortus Guidance Document for details).

The RSV season is generally from November to April but varies by region and year. The Ministry of Health declares a start and end date to the RSV season annually.

*NACI recommends infants 8 months of age or less be immunized.

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

Synagis requires monthly dosing, whereas Beyfortus requires one dose to provide protection to the infant/child for the duration of the RSV season. Product transition and expansion will protect more infants/children and preserve health system capacity, particularly by preventing RSV-related hospitalizations.

BEYFORTUS

What is the duration of protection provided by Beyfortus?

Protection is most effective for six months after Beyfortus is given. 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.

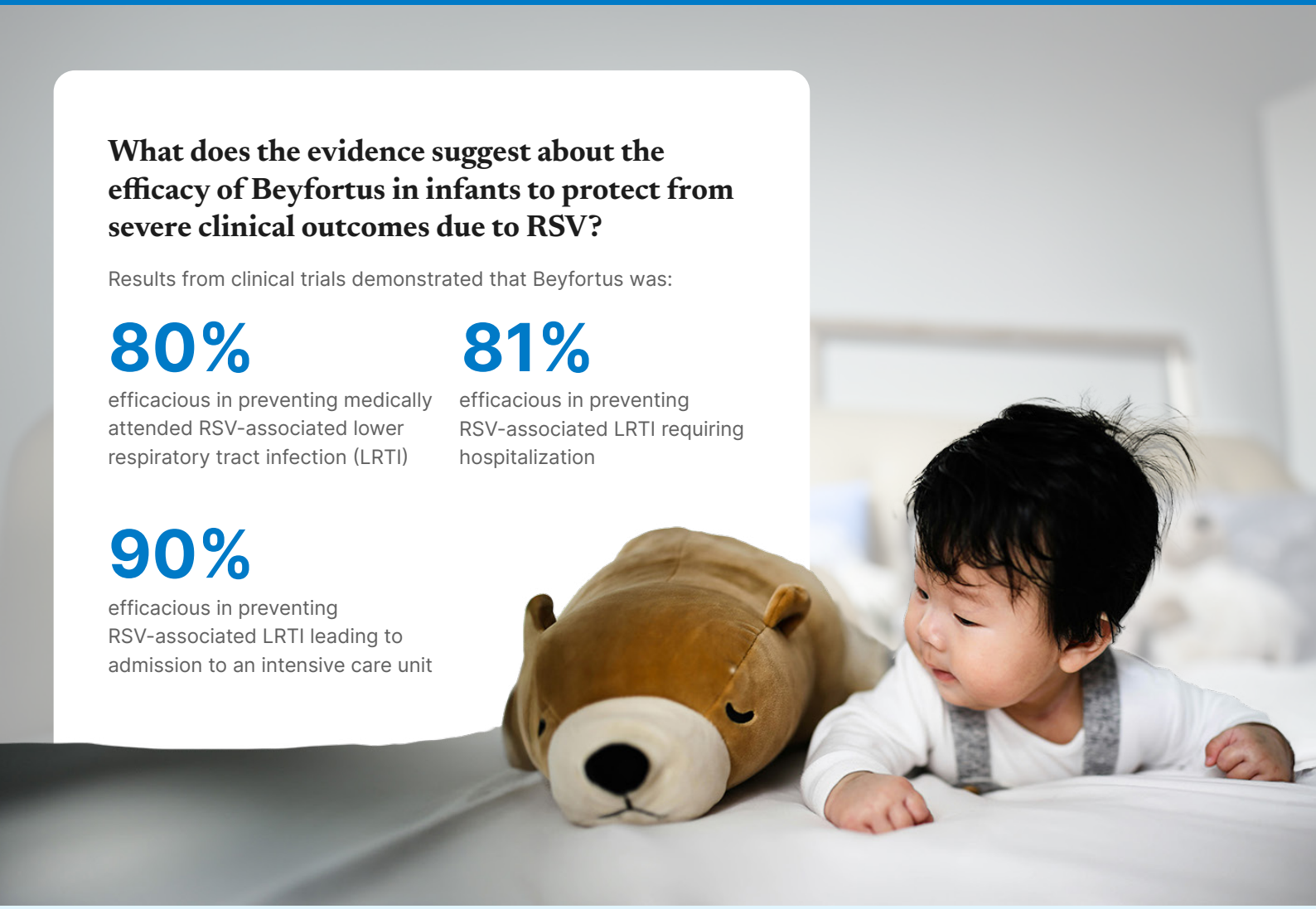
What does the evidence suggest about the efficacy of Beyfortus in infants to protect from severe clinical outcomes due to RSV?

Results from clinical trials demonstrated that Beyfortus was:

80%
efficacious in preventing medically attended RSV-associated lower respiratory tract infection (LRTI)

81%
efficacious in preventing RSV-associated LRTI requiring hospitalization

90%
efficacious in preventing RSV-associated LRTI leading to admission to an intensive care unit



What are the common and serious side effects associated with Beyfortus?

- Common side effects of Beyfortus are usually mild and last only a few days, including 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, with some experiencing systemic adverse events.

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

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 dosage is based on the infant/child's weight at the time of administration, as follows:

Category	Weight	Dose	Optimal Timing
Infants born during the 2024/25 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 in 2024 before start of RSV season	< 5 kg	50 mg in 0.5 mL (100 mg/mL)	Shortly before the start of the RSV season
	≥ 5 kg	100 mg in 1 mL (100 mg/mL)	Shortly before the start of the RSV season
Children at continued high-risk from RSV infection entering their 2nd season	N/A	200 mg (two 1 mL injections of 100 mg/mL)	Shortly before the start of their 2nd RSV season

For children undergoing cardiac surgery with cardiopulmonary bypass, please refer to the Ministry of Health Beyfortus Guidance Document for information.

Where and when will Beyfortus be administered?

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

- **Hospital** administration of Beyfortus to newborns during the RSV season before discharge
- **Primary care provider or public health unit** administration for out-of-season infants or those born outside the hospital system (e.g., home births)
- **Paediatric specialist, primary care provider, or outpatient hospital clinic** administration for children up to two years of age who are at high risk for severe RSV disease during their second 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. There is no recommended interval between RSV infection and receipt of Beyfortus.

Can Beyfortus be co-administered with other vaccine products?

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

ABRYSVO

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

Prenatal care providers should provide information on both vaccination and mAb products to their pregnant patients; however, only Beyfortus OR Abrysvo is recommended, except in certain circumstances (e.g., a high-risk infant born to someone who received the vaccine).

NACI recommends prioritizing the use of Beyfortus for infant protection due to its efficacy, duration of protection and good safety profile over vaccinating pregnant individuals. Therefore, Beyfortus is the preferred method for safeguarding infants.

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

How is Abrysvo administered and at what dosage and frequency?

Abrysvo is administered by a single dose of 0.5mL between 32 and 36 weeks gestation. The vaccine is used to actively immunize pregnant individuals, 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 to pregnant people with other recommended vaccines (e.g., Tdap).

Refer to Ministry of Health Abrysvo Guidance Document for more information and refer to the Abrysvo product monograph for detailed information on product ingredients, contraindications and precautions.

Implementation Support

Where should I go with questions regarding implementation?

Direct any questions to your local public health unit. The latest information about the program can be found on the Ministry's healthcare provider RSV prevention program website.

On the PCMCH RSV webpage, you will find a curated list of additional resources to support you with this change in practice.

Communicating with Patients and Families

The Provincial Council for Maternal and Child Health (PCMCH) has developed a parent fact sheet that is available in both English and French. This resource can be printed out or sent electronically to parents and expectant parents to support your shared decision-making conversations about how to protect their infant/child during RSV season.

What do my patients and families need to know?

Prenatal care providers can begin conversations with their patients early in pregnancy about RSV and immunization options to protect their 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 infants and high-risk children, seasonality)
- **Immunization Options** (e.g., mAb or vaccine, Beyfortus as the recommended approach)
- **Beyfortus** (e.g., eligibility, timing, frequency, route, safety, efficacy)
- **Abrysvo** (e.g., eligibility, timing, frequency, route, safety, efficacy)
- **Prevention Strategies** (e.g., avoiding close contact with sick individuals)
- **Documentation** (e.g., keeping immunization records up-to-date)