Ontario

Ministry of Health

Infant and High-risk Children Respiratory Syncytial Virus (RSV) Prevention Program Factsheet for Health Care Providers

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This guidance document for health care professionals provides basic information only. It is not intended to provide or replace medical advice, diagnosis, or treatment.

Under Ontario's infant RSV program, there are two products that can be used for the prevention of disease during the RSV season. Beyfortus® can be given to infants and high-risk children up to 24 months of age, and Abrysvo™ can be given to pregnant individuals to subsequently protect their infants. Health care providers caring for pregnant individuals should provide information on the RSV vaccine and monoclonal antibody to ensure informed consent.

The National Advisory Committee on Immunization (NACI) preferentially recommends the use of Beyfortus® for infant protection due to its effectiveness, long-lasting protection, and positive safety profile. NACI will continue to monitor the evolving evidence and will update recommendations as needed.

Administration of both the vaccine to the pregnant individual and a monoclonal antibody to the infant is **NOT** recommended except under specific circumstances (see eligibility criteria).

RSV immunization agents

The Ontario RSV program uses two Health Canada authorized products to help prevent respiratory syncytial virus (RSV) lower respiratory tract disease in infants and high-risk children:

1. A monoclonal antibody (Beyfortus®) given to infants just prior to or during their first RSV season or high-risk children in their second season.
2. A vaccine (Abrysvo™) given during pregnancy.

Monoclonal Antibody

Beyfortus® is an injectable monoclonal antibody (mAb) used to help protect infants and young children from lower respiratory tract disease caused by RSV.

Monoclonal antibodies do not activate the immune system, as would occur with infection or vaccination (active immunization). Instead, the injected antibodies provide direct and immediate protection against disease (passive immunization).

Protection from Beyfortus® wanes over time as the antibodies degrade. Beyfortus® is efficacious through five months of age and may provide full season protection. Beyfortus® does not provide long-term immunity to RSV disease but helps to protect infants when they are most at risk of severe RSV disease. As children get older, they are less likely to develop severe symptoms from RSV infection.

RSV Vaccine for Pregnant Individuals

Abrysvo™ is an RSV vaccine authorized for pregnant persons between 32-36 weeks gestation who will deliver during the RSV season. It is used to actively immunize pregnant individuals, providing infants with passive maternal antibodies that helps protect them from severe RSV illness. Due to waning effects of the passively transferred antibodies in neonates over time, the protective effect may not last beyond six months of age in infants. While the parent who received Abrysvo™ may have multi-year protection, it does not provide the infant with long-term immunity.

Eligibility criteria

The following products are publicly funded for eligible individuals who are Ontario residents and meet the following criteria:

Beyfortus® - infants and children who meet any one of the following criteria:

- Infants born April 1 or after **and** less than 8 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, following a discussion with a healthcare provider, including children with:
    - Chronic lung disease (CLD), including bronchopulmonary dysplasia (BPD), defined by need for ongoing respiratory support and supplemental oxygen therapy at 36 weeks postmenstrual age (gestational age at birth plus chronological age) or discharged home, if earlier.
        - Note: Children who were < 12 months of age and approved for coverage in the previous RSV season for chronic lung disease and bronchopulmonary dysplasia remain eligible, irrespective of their clinical status in the second RSV season.
    - Hemodynamically significant cyanotic or acyanotic congenital heart disease (CHD) defined as infants requiring corrective surgery or are on cardiac medication for congestive heart failure or diagnosed with moderate to severe pulmonary hypertension.
    - Severe immunodeficiency
    - Down syndrome/Trisomy 21
    - Cystic fibrosis with recurrent pulmonary exacerbations requiring hospitalization, deteriorating pulmonary function and/or severe growth delay

    - Neuromuscular disease impairing clearing of respiratory secretions
    - Severe congenital airway anomalies impairing the clearing of respiratory secretions

Abrysvo™ – pregnant persons between 32-36 weeks gestation who will deliver during the RSV season, following a discussion with a health care provider.

NOTE: Administration of both the vaccine to the pregnant individual and a monoclonal antibody to the infant is **NOT** recommended except under specific circumstances:

- Infants born less than 14 days after administration of Abrysvo™ **OR**
- Infants who meet the medical criteria for increased risk of severe RSV disease:
    - All premature infants (i.e., <37 weeks gestation)
    - Infants who meet any of the above high-risk criteria

RSV season

The RSV season is generally from November 1 to March 31, peaking in December, with regional variation across Ontario and between years. 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. The upcoming RSV season will begin November 1. Pending product availability, administration of either Beyfortus® or Abrysvo™ for the infant program can begin in early October.

Product preparation and administration

See the individual product monographs and packaging for step-by-step directions on administration and expiry dates. Refer to Table 1 in the Publicly Funded Immunization Schedules for Ontario for assistance in selecting the appropriate needle length and gauge.

Product storage and handling

The Ontario Vaccine Storage and Handling Guidelines provide details on provincial requirements for the storage and handling of refrigerated vaccines which should also be applied to Beyfortus®. Please also refer to the product monographs (hyperlinked in Table 4 of the Appendix) for additional information.

Administration schedule

Timing

Beyfortus® should be offered to new cohort of infants and high-risk children beginning **early October** of each year, based on specific timing of product availability and should continue to be administered throughout the RSV season. For infants born in hospital Beyfortus® should be administered prior to discharge. Infants with prolonged hospitalization (e.g., preterm infants) should be immunized shortly before discharge or immediately after. Administration information

is limited for extremely preterm infants (gestational age under 29 weeks) who are less than 8 weeks old, and no clinical data exist for infants with a postmenstrual age (gestational age at birth plus chronological age) of 32 weeks.

Abrysvo™ should be offered to pregnant individuals between 32 and 36 weeks gestation that will deliver during RSV season beginning **early October** of each year, based on specific timing of product availability and throughout the RSV season.

Route

Both Beyfortus® and Abrysvo™ are administered intramuscularly. The preferred site of administration for Beyfortus® depends on the age of the child. For infants under 12 months of age, the preferred site is the anterolateral thigh region. For high-risk children between 12 and 24 months of age, the preferred administration site is the deltoid region. For pregnant individuals receiving Abrysvo™, the vaccine should be administered in the deltoid region.

Beyfortus® and Abrysvo™ should not be administered intravenously, intradermally, or subcutaneously.

Number of Doses

Beyfortus® dosing is dependent on the age and weight of the recipient:

- **Infants born during the RSV season:** A single dose is administered based on the infant's weight at the time of administration.
    - Infants < 5kg: 50 mg in 0.5 mL (100 mg/mL)
    - Infants ≥ 5kg: 100 mg in 1.0 mL (100 mg/mL)
- **Infants born outside of the RSV season** (includes those infants born from April 1 up to the start of their first RSV season (i.e., less than 8 months): A single dose is recommended based on the infant's weight at the time of administration.
    - Infants < 5 kg: 50 mg in 0.5 mL (100 mg/mL)
    - Infants ≥ 5 kg: 100 mg in 1.0 mL (100 mg/mL)

Administration should be targeted shortly before the start of the RSV season but can continue to be administered during the season.

- **Children at continued high-risk entering their second RSV season (up to 24 months of age):** Administration of a one-time 200 mg dose given as two 1.0 mL intramuscular injections of 100 mg/mL of Beyfortus® administered in two separate injection sites should be targeted shortly before the start of their second RSV season (i.e., early October), but can be administered during the season if necessary. For children weighing less than 10 kg, a single dose of 100 mg may be considered based on clinical discretion.
- **Children who have received Beyfortus® and are undergoing cardiac surgery with cardiopulmonary bypass:** An additional dose should be administered as soon as the individual is stable after surgery to ensure adequate Beyfortus® serum levels. If **within 90**

days after receiving the first dose of Beyfortus®, the additional dose during the first RSV season should be 50 mg or 100 mg according to body weight or 200 mg during the second RSV season. If **more than 90 days** have elapsed since the first dose, the additional dose should be a single dose of 50 mg regardless of body weight during the first RSV season or 100 mg during the second RSV season to cover the remainder of the RSV season.

Table 1: Beyfortus® Administration Guidelines for Infants and Children

Category	Weight	Dose	Timing
Infants born during the current RSV season∞	< 5 kg	50 mg in 0.5 mL (100 mg/mL)	Administered from birth
	≥ 5 kg	100 mg in 1 mL (100 mg/mL)	Administered from birth
Infants born April 1 or after and less than 8 months of age up to the end of the RSV season	< 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 over 8 months and up to 24 months of age and at continued high-risk from RSV infection during second RSV season	N/A	200 mg (two 1 mL injections of 100 mg/mL)†	Shortly before or during the RSV season∞
∞ Due to the seasonality of the RSV virus, Beyfortus® should be administered shortly before and during the active RSV season. Beyfortus® should be offered to eligible infants and children beginning early October of each year, based on specific timing of product availability and throughout the RSV season.			
†If a child weighs less than 10 kg entering their second RSV season, consideration can be given to administering a single dose of 100 mg at the clinical discretion of the health care provider.			

Table 2: Beyfortus® Re-immunization Administration Guidelines for Children Undergoing Cardiac Surgery with Cardiopulmonary Bypass*∞

Time Since First Dose	Weight	Dose
< 90 days after the first dose		
• First season	< 5 kg	50 mg
	≥ 5 kg	100 mg
• Second season	Any weight	200 mg
≥ 90 days after the first dose		
• First season	Any weight	50 mg
• Second season	Any weight	100 mg
*Dosing applies to infants who have already received their dose of Beyfortus® for the season and then undergo cardiac surgery with cardiopulmonary bypass. The surgical procedure causes a drop in serum concentration. All doses should be administered as soon as the individual is stable post-surgery. ∞Although not indicated in the product monograph, NACI indicates that reimmunization can also be considered at the conclusion of extracorporeal membrane oxygenation.		

Abrysvo™ is approved and recommended for administration as a single 0.5 mL dose.

Co-administration with vaccine products

Beyfortus® can be administered on the same day or any time before or after routine childhood vaccines, including seasonal vaccines (such as influenza). No minimum interval is necessary between the administration of Beyfortus® and live vaccines (such as MMR and varicella).

Co-administration of Beyfortus® and vaccine products is not expected to interfere with the immune response to vaccine products. In clinical trials, when Beyfortus® was given concomitantly with routine childhood vaccines, the safety and reactogenicity profile was similar as when the childhood vaccines were given alone. When administered concomitantly with injectable vaccines, they should be given with separate syringes and at different injection sites.

Abrysvo™ may be given on the same day as tetanus, diphtheria, acellular pertussis, COVID-19, and influenza vaccines. If another immunization must be given at the same visit, they should be administered in different limbs to reduce any risk of increasing pain or other local reactions.

Contraindications and precautions

Beyfortus® or Abrysvo™ should not be given to those with known hypersensitivity or a history of a severe allergic reaction (e.g., anaphylaxis) to any product ingredients, including non-medicinal ingredients or materials in the product's packaging.

Administration of Beyfortus® or Abrysvo™ should be postponed in persons suffering from severe acute illness. Immunization should not be delayed because of minor acute illness, with or without fever.

Please refer to the Beyfortus® and the Abrysvo™ product monographs for detailed information on contraindications and precautions.

Product safety

Beyfortus® and Abrysvo™ are authorized for use in Canada and are safe and well tolerated. As with other immunizing agents, they must be authorized for use by the Canadian regulator, Health Canada, following review of a product's safety and how well it works (e.g., clinical trial and other evidence).

Adverse events

Like vaccines or medications, Beyfortus® and Abrysvo™ may have some side effects in the recipient, which are mild and last only a few days.

Table 3: Common Side Effects

	Beyfortus®	Abrysvo™
Rash	✓	✓
Fever	✓	✓
Pain, swelling or redness at injection site	✓	✓
Nausea		✓
Headache		✓
Muscle aches		✓

Guidance on reporting side effects post-administration

To ensure the ongoing safety of vaccines in Ontario, reporting of Adverse Events Following Immunization (AEFIs) by physicians, nurses, pharmacists, or other persons authorized to administer an immunizing agent is mandatory under the *Health Promotion and Protection Act*. Vaccine providers are asked to report AEFIs through local public health units using the Ontario AEFI Reporting Form. A list of local public health units is available at: https://www.ontario.ca/page/public-health-unit-locations.

As Beyfortus® is a monoclonal antibody and not a vaccine, s.38 of the *Health Protection and Promotion Act* requiring the follow-up and reporting of suspected adverse events following immunization does not apply to providers administering this product. As a health product with less than five years market experience, it is recommended that these incidents do not need to be reported to the local public health unit and should be managed as per practices and organizational policies for other medicines and therapeutics.

Where no organizational policy exists, it is recommended that organizations, providers, and/or parents/guardians report all suspected side effects to Health Canada, especially those that are:

- Unexpected, regardless of their severity (i.e., not consistent with product information or labelling)
- Serious, whether expected or not
- Reactions to health products on the market less than five years, regardless of their nature or severity.

To report a side effect of Beyfortus®, please see the Health Canada, *Side Effect Reporting Form*. This form may be completed online, downloaded, faxed, or mailed using the information on their website.

Those administering vaccines or monoclonal antibodies should ensure that the recipients or their parents or guardians are aware of the need to immediately report any adverse event to their health care provider. Subsequently, health care providers should report any adverse events temporally related to immunization to their local public health unit or Health Canada, based on the immunization product as described above.

Parents and guardians or patients should be advised to go to the nearest emergency department if the recipient develops severe reactions after receiving the immunization, including the following:

- Hives
- Swelling of the mouth or throat
- Trouble breathing, hoarseness or wheezing
- High fever (over 40°C or 104°F)
- Seizures
- Other serious reactions

Observation period following immunization

Recipients should be observed for at least 15 minutes after immunization. A 30-minute observation period is preferred should concerns regarding possible allergies arise.

Administration after RSV infection

Beyfortus® is generally not necessary or recommended for an infant 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, as the risk of rehospitalization in the same season is very low. However, consideration may be given to severely immunocompromised infants who may not mount an adequate immune response to the RSV infection.

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

Ordering information

Health care providers should order Beyfortus® or Abrysvo™ from their usual vaccine source (i.e., Public Health Unit or the Ontario Government Pharmaceutical and Medical Supply Service (OGPMSS).

Additional information and resources

Health care providers looking for more information about RSV, the mAb product, the RSV vaccine, or the province's RSV prevention program can refer to the ministry's RSV website and the appropriate product monograph.

Appendix

Table 4: Infant, high-risk and pregnancy immunization products

Vaccine	Infant or high-risk children (up to 24 months of age)	Pregnant individuals in third trimester
Product monograph	Beyfortus®	Abrysvo™
Manufacturer	Sanofi	Pfizer
Protects against	RSV	RSV
Product type	monoclonal antibody	vaccine
Eligibility Criteria	• Infants born April 1 or after **and** less than 8 months of age up to the end of the RSV season • Children up to 24 months of age who remain vulnerable from severe RSV disease through their second RSV season	Pregnant individuals 32-36 weeks gestation that will deliver during RSV season
Dosage	Based on weight • 50 mg in 0.5 mL (100 mg/mL) • 100 mg in 1.0 mL (100 mg/mL)	0.5 mL
Route of administration	Intramuscular injection (IM)	Intramuscular injection (IM)
Package format	Pre-filled syringe • 1 unit per pack	One vial of powder with pre-filled syringe with diluent and vial adapter • 1 unit per pack • 10 units per pack
Package size (cm) **L x W x H**	14.4 x 5.1 x 2.4 (both 50 mg and 100mg doses)	1 pack: 11.7 x 3.8 x 7.4 10 pack: 23.6 x 13.2 x 7.8
Reconstitution	N/A	Lyophilized vaccine must be reconstituted using vial adapter and only with diluent provided