

Ministry of Health

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

Version 3.0 – September 28, 2026

Highlights of Changes

- Updated product information.
- Updated timing for vaccination in pregnancy.

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 respiratory syncytial virus (RSV) prevention program, two products are available for the prevention of RSV illness during the RSV season. Nirsevimab (Beyfortus®) is a monoclonal antibody (mAb) and may be administered to eligible infants and high-risk children less than 24 months of age who remain at increased risk of severe RSV disease. The RSVpreF vaccine (Abrysvo®) may be administered during pregnancy to provide passive immunity to infants after birth. Health care providers caring for pregnant women should provide information on both RSVpreF (Abrysvo®) and nirsevimab (Beyfortus®) to support informed decision-making and obtain informed consent.

With the significant positive outcomes (i.e. high uptake and reduced hospitalizations) observed through Ontario's RSV prevention program over the past two respiratory illness seasons, Ontario will continue to offer nirsevimab (Beyfortus®) for eligible infants and high-risk children based on demonstrated effectiveness and duration of protection.

For those interested in an alternative approach, RSVpreF (Abrysvo®) vaccination during pregnancy is also an effective option for infant RSV protection. Emerging evidence suggests RSVpreF (Abrysvo®) and nirsevimab (Beyfortus®) provide similar protection against severe RSV disease in infants. Product use should be discussed with a health care provider.

Administration of RSVpreF (Abrysvo®) to the pregnant woman and nirsevimab (Beyfortus®) to the infant is **NOT** recommended, except under specific circumstances (see eligibility criteria).

RSV immunization agents

Monoclonal Antibody

Nirsevimab (Beyfortus®) is an injectable mAb used in Ontario's RSV prevention program to help protect infants and eligible high-risk children from lower respiratory tract disease caused by RSV.

Unlike vaccination or natural infection, monoclonal antibodies (mAbs) do not stimulate an immune response (active immunization). Instead, they provide direct and immediate protection against RSV through the administration of RSV-specific antibodies (passive immunization).

Protection from nirsevimab (Beyfortus®) wanes over time as the administered antibodies gradually degrade, however, nirsevimab (Beyfortus®) is expected to provide protection for up to six months and may provide protection throughout an entire RSV season.

Nirsevimab (Beyfortus®) provides protection to infants during the period when they are at greatest risk of severe RSV disease. The risk of severe illness from RSV significantly decreases with age in otherwise healthy infants, making protection during early infancy particularly important.

RSV Vaccine for Pregnant Women

The RSVpreF vaccine (Abrysvo®) is administered during pregnancy to help protect infants against severe RSV illness in early life. RSVpreF (Abrysvo®) actively immunizes pregnant women and promotes the development and transplacental transfer of RSV-specific antibodies to the fetus, providing infants with passive protection after birth.

Due to the gradual decline of passively transferred antibodies in infants over time, the protective effect of RSVpreF (Abrysvo®) is expected to wane and may not extend beyond the first six months of life. While the pregnant woman who receives RSVpreF (Abrysvo®) may have protection that persists for multiple years, vaccination during pregnancy 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:

Nirsevimab (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 at the time of immunization.
- Children less than 24 months of age who remain vulnerable to severe RSV disease, following a discussion with their pediatric specialist 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 less 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

RSVpreF Vaccine (Abrysvo®)–

Under the Ontario RSV prevention program, RSVpreF (Abrysvo®) is available to pregnant women between 28 and 36 weeks gestation who are expected to deliver during the RSV season, following a discussion with a health care provider. While RSVpreF (Abrysvo®) is authorized by Health Canada for use in pregnant persons between 32 and 36 weeks gestation, the National Advisory Committee on Immunization (NACI) recommends that RSVpreF may be administered between 28 and 36 weeks gestation. This recommendation is supported by available safety and efficacy data, supports broader access and opportunities for immunization, and aligns with recommendations by the World Health Organization. Administration before 32 weeks gestation is considered off-label and is subject to the sole clinical judgment of the health care provider.

NOTE: Administration of both RSVpreF (Abrysvo®) during pregnancy and nirsevimab (Beyfortus®) to the infant is **NOT** routinely recommended, except in the following circumstances:

- Infants born less than 14 days after administration of RSVpreF (Abrysvo®)
- OR**
- Infants at increased risk of severe RSV disease, including:
 - All premature infants (i.e., less than 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, with activity typically peaking in December. The timing and epidemiology of RSV may vary across regions in Ontario and from year to year. Due to the seasonal nature of RSV and to ensure optimal protection, both nirsevimab (Beyfortus®) and RSVpreF (Abrysvo®) should be administered shortly before and during the active RSV season. Pending product availability, administration of nirsevimab (Beyfortus®) and RSVpreF (Abrysvo®) for the infant program can begin October 1 each year.

The RSV season typically concludes on March 31, and RSV immunizing agents for the infant program should not be administered after this date. If seasonal epidemiology warrants a change, the ministry will provide notice of the revised infant prevention program end date.

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 nirsevimab (Beyfortus®). Please also refer to the product monographs (hyperlinked in Table 4 of the Appendix) for additional information.

Administration schedule

Timing

Nirsevimab (Beyfortus®) should be offered to newly eligible cohorts of infants (i.e. those born after April 1st) and eligible high-risk children beginning **October 1** each year, subject to product availability, and should continue to be administered to infants born throughout the RSV season.

For infants born in hospital, nirsevimab (Beyfortus®) should be administered prior to discharge. Infants with prolonged hospitalization (e.g., preterm infants) should be immunized with nirsevimab (Beyfortus®) shortly before or immediately after discharge.

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

RSVpreF (Abrysvo®) can be offered to pregnant women who are 28 to 36 weeks' gestation and expected to deliver during RSV season. As RSVpreF (Abrysvo®) is authorized by Health Canada for use between 32 and 36 weeks' gestation; administration before 32 weeks' gestation

is considered off-label and should be solely based on the clinical judgment of the health care provider. Administration of RSVpreF (Abrysvo®) may begin October 1 each year, subject to product availability, and should continue throughout the RSV season.

RSVpreF (Abrysvo®) is approved and recommended for administration as a single 0.5 mL dose.

There is currently no evidence on repeat vaccination with RSVpreF (Abrysvo®) in subsequent pregnancies. Pregnant women should discuss with a health care provider. To provide RSV protection to infants born in subsequent pregnancies, health care providers should consider administration of a nirsevimab (Beyfortus®) to the infant after birth.

Route

Both nirsevimab (Beyfortus®) and RSVpreF (Abrysvo®) are administered intramuscularly. The preferred site of administration for nirsevimab (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 women receiving RSVpreF (Abrysvo®) the vaccine should be administered in the deltoid region.

Nirsevimab (Beyfortus®) and RSVpreF (Abrysvo®) should not be administered intravenously, intradermally, or subcutaneously.

Number of Doses

Nirsevimab (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.

- **Infants and children who are at continued high-risk and between 8 and 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 nirsevimab (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.

- **Infants and children who have received nirsevimab (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 nirsevimab (Beyfortus®) serum levels. If **within 90 days after receiving the first dose** of nirsevimab (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: Nirsevimab (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 at the time of immunization	< 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 less than 24 months of age and at continued high-risk from RSV infection	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, nirsevimab (Beyfortus®) should be administered shortly before and during the active RSV season. Nirsevimab (Beyfortus®) should be offered to eligible infants and children beginning October 1 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: Nirsevimab (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 nirsevimab (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.		

Co-administration with vaccine products

Nirsevimab (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 nirsevimab (Beyfortus®) and live vaccines (such as MMR and varicella).

Co-administration of nirsevimab (Beyfortus®) and vaccine products is not expected to interfere with the immune response to vaccine products. In clinical trials, when nirsevimab (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.

RSVpreF (Abrysvo®) may be administered on the same day as tetanus, diphtheria, acellular pertussis, COVID-19, and influenza vaccines. If multiple immunizations are being given at the same visit, they should be administered in separate limbs to reduce any risk of increasing pain or other local reactions.

Contraindications and precautions

Nirsevimab (Beyfortus®) and RSVpreF (Abrysvo®) should not be administered 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 used in the product's packaging.

Administration of nirsevimab (Beyfortus®) and RSVpreF (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 nirsevimab ([Beyfortus®](#)) and RSVpreF ([Abrysvo®](#)) product monographs for detailed information on contraindications and precautions.

Product safety

Nirsevimab (Beyfortus®) and RSVpreF (Abrysvo®) are authorized for use in Canada and are safe and well tolerated. Like all authorized immunizing agents, they have undergone a rigorous review by Health Canada to assess their safety, efficacy and quality prior to authorization, based on evidence from clinical trials and other available data.

Adverse events

Like vaccines or medications, nirsevimab (Beyfortus®) and RSVpreF (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 nirsevimab (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 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 nirsevimab (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

Administration of a nirsevimab (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 nirsevimab (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 nirsevimab (Beyfortus®).

Ordering information

Health care providers should order nirsevimab (Beyfortus®) or RSVpreF (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, mAbs, RSVpreF (Abrysvo®), 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 women
Product monograph	Beyfortus®	Abrysvo®
Manufacturer	Sanofi	Pfizer
Protects against	RSV	RSV
Product type	monoclonal antibody (mAb)	Bivalent (RSV A and B) stabilized prefusion F protein subunit vaccine (RSVpreF)
Eligibility Criteria	- Infants born April 1 or after and less than 8 months of age at the time of immunization. - Children less than 24 months of age who remain vulnerable to severe RSV disease, following a discussion with a pediatric specialist.	Pregnant women 28-36 weeks gestation that will deliver during RSV season. Note: Administration before 32 weeks gestation is considered off-label and is solely subject to the clinical judgment of the health care provider.
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: 10.7 x 3.7 x 7.4 10 pack: 20.7x 8 x 13.1
Reconstitution	N/A	Lyophilized vaccine must be reconstituted using vial adapter and only with diluent provided