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2025/2026 Respiratory Syncytial Virus (RSV) Immunization Program for Adults and Infants

Attention: Physicians, Nurse and Nurse Practitioners, Walk-In Clinics/Urgent Care Clinics, Family Health

Teams, Ontario Health Teams, Hospitals, Infection Prevention & Control Practitioners, Long term care homes, Retirement homes, Indigenous Health Care & Community, Ontario Health

Central, Municipalities

Date: September 15, 2025

Older Adult RSV Vaccine Program

The following groups are eligible for Ontario's Older Adult RSV vaccine program for the 2025-26 fall season:

- New: all individuals aged 75 and older
- Individuals 60 to 74 years of age who are also:
 - residents of long-term care homes, Elder Care Lodges, or retirement homes including similar settings (e.g., co-located facilities).
 - o patients in hospital receiving alternate level of care (ALC) including similar settings (for example, complex continuing care, hospital transitional programs)
 - patients with glomerulonephritis (GN) who are moderately to severely immunocompromised
 - o patients receiving hemodialysis or peritoneal dialysis
 - recipients of solid organ or hematopoietic stem cell transplants
 - individuals experiencing homelessness
 - o individuals who identify as First Nations, Inuit, or Métis

Individuals who have had a transplant (solid-organ or stem cell) are recommended to wait 3-6 months post-transplant to receive RSV vaccine, however, a minimum of 1-month post-transplant may be considered.

Those who have previously received a dose of RSV vaccine are not recommended or eligible to receive another dose this season. Studies on the duration of protection are ongoing and continue to show multi-year protection. The timing for booster doses is unknown.

Pharmacists cannot administer publicly funded RSV vaccine. Those who are eligible will need to access the vaccine from their primary care provider, facility, or outpatient hospital program. Those without a primary care provider can book an appointment at a health unit clinic.

View all current Public Health Alerts by visiting the Health Professional Resources page at: http://www.smdhu.org/PHA

Table 1. Comparison of RSV Vaccine Products

Vaccine	Arexvy®	Abrysvo™	
Manufacturer	GlaxoSmithKline (GSK)	Pfizer	
Dosage	1 dose (0.5 mL)	1 dose (0.5 mL)	
Route of Administration	Intramuscular Intramuscular		
Publicly Funded Eligibility	Older adults 75+	Older adults 75+	
	Individuals 60 to 74 yrs who meet eligibility (see above)	Individuals 60 to 74 yrs who meet eligibility (see above)	
		Pregnant individuals from 32 through 36 weeks gestation to prevent LRTD and severe LRTD caused by RSV in their infants from birth through 6 months of age	
Vaccine Packaging	1-pack : one vial of lyophilized antigen (powder) and one vial of adjuvant (suspension).	10-pack : 10 vials of powder, 10 pre- filled syringes of diluent, and 10 vial adapters to use when reconstituting.	
		1-pack : one vial of powder, one prefilled syringe, and one vial adapter to use when reconstituting.	
Vaccine Storage & Handling	Store between +2°C and +8°C in original carton to protect from light.	Store between +2°C and +8°C in original carton to protect from light.	
	Do not freeze. Discard if vial has been frozen.	Do not freeze. Discard if vial has been frozen.	
	MUST be reconstituted prior to administration	MUST be re-constituted prior to administration.	
	After Reconstitution: Administer vaccine immediately (within 4 hrs.). Store reconstituted vaccine in the refrigerator between +2°C and +8°C or at room temperature up to +25°C. If not used within 4 hrs., discard.	After Reconstitution: Administer vaccine immediately (within 4 hrs.). Store reconstituted vaccine between +15°C and +30°C. Do not store reconstituted vaccine in the refrigerator. If not used within 4 hrs., discard.	

The Abrysvo[™] vaccine comes with a vial adapter which is used to reconstitute the vaccine without requiring a needle. Pfizer has created a video demonstrating how to use this adapter which can be viewed at the following link: https://abrysvomaternal.pfizerpro.com/about-abrysvo/reconstitution

For more information, refer to the <u>Ministry of Health Older Adult High-risk RSV Vaccine Program Fact Sheet for Health Care Providers</u>.

Infant RSV Prevention Program

Ontario's Infant RSV prevention program includes two products:

Monoclonal Antibody (mAb) (Beyfortus®): an injectable mAb for infants and young children that provides immediate protection that wanes over time against RSV (passive immunization). 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 protects 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™): an RSV vaccine authorized for pregnant individuals 32 through 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 help 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.

NACI Preferentially Recommends Beyfortus® for Infants over Vaccinating Pregnant Individuals

The National Advisory Committee on Immunization (NACI) preferentially recommends the use of Beyfortus® for infant protection from RSV due to its effectiveness, long-lasting protection, and positive safety profile. If it is anticipated that Beyfortus® will be administered to a healthy infant, then Abrysvo™ in pregnancy is not recommended.

NACI states some studies have found an increase in preterm births among Abrysvo™ vaccine recipients compared to placebo recipients. This was not observed in high-income countries like Canada. It is unclear whether there is a causal relationship with the vaccine; the currently available data are inconclusive. By limiting vaccine administration to 32 through 36 weeks gestation, the potential risk of preterm birth is reduced. NACI therefore currently recommends the vaccine's use on a case-by-case basis in pregnancy. Pregnant individuals and their health care providers should discuss the use of the vaccine in cases where the mAb would not be agreed to or available (e.g., not giving birth in Ontario).

Administration of both the vaccine to the pregnant individual and a monoclonal antibody to the infant is NOT recommended except under the following 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)
 - o Infants who meet any of the below high-risk criteria

Eligibility for the 2025/2026 fall season includes:

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

- Infants born April 1, 2025, 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.
- o Severe immunodeficiency
- o 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
- o 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.

Table 2: 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 theend 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 monthsand up to 24 months ofage 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 duringthe RSV season [∞]

 $[\]infty$ 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 infantsand children beginning early October of each year, based on specific timing of product availability and throughout the RSV season.

Beyfortus® can be administered to the new cohort of infants and high-risk children starting October 1st, 2025.

[†]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 healthcare provider.

Infants born in hospital on or after October 1st should receive Beyfortus® prior to discharge.

Those born before October 1st, those who were born after October 1st who missed receiving prior to discharge, those not born in hospital, and high-risk children entering their second season should receive Beyfortus® in early October. However, administration can continue throughout the season. Beyfortus® can be administered at the same visit as other infant vaccines.

For more information, refer to the Ministry of Health Infant and High-risk Children RSV Prevention Program Fact Sheet for Health Care Providers.

Ordering RSV Vaccine and Beyfortus®

All Fall vaccines are being moved to our online ordering platform. RSV vaccine and Beyfortus® can now be ordered by clicking here.

Adults RSV vaccine

It is anticipated that RSV vaccine for the older adult program will be available in orders being picked up starting Wednesday, October 1st. Click here to order.

NOTE: Most of the older adult RSV vaccine supply will be Arexvy® which is all single dose packaging. Due to packaging size and the high volume of vaccines needing to be stored through the fall season, we recommend that each practice order 10 doses at a time, and order weekly to replenish. If you need to order more than 10 doses for a one-week supply (i.e. having a dedicated clinic), please make a note on your order form and our nurses will review.

Infant RSV - Beyfortus® for Infants & Abrysvo™ for Pregnant Individuals

The Immunization program will coordinate Beyfortus® ordering with hospitals directly.

For distribution to primary care, it is anticipated that **Beyfortus® will be available in orders being picked up starting Wednesday, October 1**st. Click here to order.

If you require a 50 mg dose for an infant under 5 kg who did not receive Beyfortus® at hospital, submit a Beyfortus® 50mg Special Order form.

NOTE: Due to packaging and fridge storage space pressures this time of year, we recommend that each practice order 5 doses of 100mg formulation at a time, and order weekly to replenish. This product has a value of ~\$900 per dose and there was a large amount of wastage unfortunately in the spring, so we do need to monitor supply and orders closely.

RSV vaccine for pregnant individuals (Abrysvo®) can be ordered on the RSV Infant order form.