

Ministry of Health

# Older Adult High-Risk Respiratory Syncytial Virus (RSV) Vaccine Program Fact Sheet - *Health Care Providers*

Version 4.1 – October 10, 2024

## Highlights of Changes

- Update to co-administration section
- Update to eligibility section

This fact sheet for health care providers gives basic information only. It is not intended to provide or take the place of medical advice, diagnosis, or treatment.

## Disease Burden

Respiratory syncytial virus (RSV) is a major cause of lower respiratory illness, particularly among infants, children, and older adults.

Older adults, particularly those with existing comorbid conditions, are more susceptible to severe disease and have an increased risk of RSV-related hospitalization and mortality. In Ontario, most deaths from RSV have occurred in those aged 60 years and older. Older adults in long-term care and retirement homes also tend to have longer hospital stays than the general population due to RSV.

During peak RSV season, hospitals have seen a surge in emergency room visits and admissions of young children and older adults requiring medical care, putting a strain on hospital resources, including beds, staffing, and specialized units.

## Vaccine Products

There are two available vaccine products authorized for individuals 60 years of age and older: Arexvy and Abrysvo™ ([Table 1](#)).

**Table 1. Comparison of RSV Vaccine Products.**

Vaccine	Arexvy	Abrysvo <sup>TM</sup>
<b>Manufacturer</b>	GlaxoSmithKline (GSK)	Pfizer
<b>Date of Authorization (Health Canada)</b>	August 4, 2023	December 21, 2023
<b>Type of Vaccine</b>	Adjuvanted recombinant protein subunit	Bivalent recombinant protein subunit
<b>Dosage</b>	1 dose (0.5 mL)	1 dose (0.5 mL)
<b>Route of Administration</b>	Intramuscular	Intramuscular
<b>Indication</b>	Individuals 60 yrs + to prevent lower respiratory tract disease (LRTD) caused by RSV.	Individuals 60 yrs + to prevent LRTD caused by RSV.  Pregnant individuals from 32 through 36 weeks gestational age to prevent LRTD and severe LRTD caused by RSV in their infants from birth through 6 months of age
<b>Number of Doses (how often)</b>	One dose*	One dose*
<p>Currently, only a single dose is recommended by Health Canada and the National Advisory Committee on Immunization. Studies are ongoing to determine how long the protection lasts with a single dose of vaccine.</p>		

## Dose Recommendations

Evidence supports the use of a single dose of either Arexvy or Abrysvo to help prevent RSV disease in adults 60 years of age and older.

Studies show multi-year protection. As such, if an individual received a dose of RSV vaccine during the 2023-2024 season, they do not need to receive another dose this season. The timing for subsequent doses is unknown at this time. Studies are ongoing to determine the duration of protection.

Arexvy and Abrysvo are authorized by Health Canada and recommended by the National Advisory Committee on Immunization (NACI). Both have demonstrated high effectiveness in preventing severe disease from RSV in clinical trials.

## Co-Administration

NACI suggests it is acceptable and supported to administer both seasonal and non-seasonal vaccines with RSV.

Concurrent administration of RSV to adults 60 years of age and older with other recommended vaccines can be considered in alignment with basic vaccine principles.

When recommending co-administration, health care providers are to consider patient preferences, risk factors or likelihood of patient returning for additional vaccine doses.

## Eligibility

Ontario's publicly funded RSV prevention program is targeted for high-risk individuals and settings. The program includes individuals who are 60 years and older and who are also:

- Residents of long-term care homes, Elder Care Lodges, or retirement homes including similar settings (e.g., co-located facilities)
- Patients in hospital receiving alternate level of care (ALC) including similar settings (e.g., complex continuing care, hospital transitional programs)
- Patients receiving hemodialysis or peritoneal dialysis
- Recipients of solid organ or hematopoietic stem cell transplants
- Individuals experiencing homelessness
- Individuals who identify as First Nations, Inuit, or Métis

## Contraindications and Precautions

- Do not administer RSV vaccine to:
  - Individuals with a history of **severe allergic reaction (anaphylaxis)** to any of the vaccine ingredients, including non-medicinal ingredients or any materials found in the vaccine's packaging (such as the vial cap, aluminum seal, or synthetic rubber stopper).
- Individuals who are **ill**:
  - Those with a severe acute illness with or without a fever should wait until symptoms have subsided before being vaccinated. The presence of a minor illness, such as a cold, should not result in the deferral of vaccination.
- Individuals who have had a **previous RSV infection**:

- If an individual has had an RSV infection, they may be offered vaccination against RSV once they are clinically well. There is no specific interval that is recommended between RSV infection and RSV vaccination.
- Individuals who have had a transplant (solid-organ or stem cell):
  - It is recommended that patients wait 3-6 months post-transplant to receive an RSV vaccination. However, a minimum of 1 month post-transplant may be practiced at the discretion of the provider.

Please refer to the product monographs ([Arexvy](#), [Abrysvo](#)) for detailed information on contraindications and precautions.

## Observation Period Following Immunization

NACI recommends a 15-minute post-vaccination observation period, as specified in the [Canadian Immunization Guide](#) (CIG). If there is a specific concern about possible vaccine allergy, 30 minutes is a safer interval.

## Side Effects

Like any other vaccine or medication, RSV vaccines may have some side effects, which in most cases are mild and last only a few days. Common side effects after an RSV vaccine can include pain, redness, and swelling where the shot is given, fatigue, fever, headache, nausea, diarrhea, and muscle or joint pain.

Early safety data from surveillance systems in the United States suggest a potential increased rate of Guillain-Barré syndrome after RSV vaccination in adults 60 years of age and older. However, these events are rare and the available data cannot confirm an association at this time. This issue will continue to be monitored closely.

## Adverse Events Following Immunization (AEFI)

As per s.38 of the *Health Protection and Promotion Act*, those administering this vaccine should ensure that the vaccine recipients or their substitute decision-makers are aware of the need to immediately report AEFIs to their health care provider.

Vaccine recipients should be advised to go to the nearest emergency department if severe reactions develop, including the following:

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

Health care providers (e.g., physicians, nurses, and pharmacists) are required by law (i.e., *Health Protection and Promotion Act*, s.38) to report AEFIs associated with the RSV vaccine to their local public health unit. Reports should be made using the [Ontario AEFI Reporting Form](#) and submitted to their local public health unit.

## Storage and Handling

See [Table 2](#) below for an overview of the storage and handling for the two RSV vaccine products. Please refer to the product monographs for reconstitution instructions and for more information on storage and handling.

For additional information on provincial vaccine storage and handling requirements, please refer to the [Vaccine Storage and Handling Guidelines](#).

**Table 2. Storage and Handling of Arexvy and Abrysvo.**

Vaccine	<a href="#">Arexvy</a>	<a href="#">Abrysvo</a>
Packaging	<ul style="list-style-type: none"> <li>• <b>10-pack</b>; 10 single-dose vials of lyophilized antigen (powder) and 10 vials of the adjuvant (suspension).</li> <li>• <b>1-pack</b>; one single-dose vial of lyophilized antigen (powder) and one vial of the adjuvant (suspension).</li> </ul>	<ul style="list-style-type: none"> <li>• <b>10-pack</b>; 10 vials of powder, 10 pre-filled syringes of diluent and 10 vial adapters.</li> <li>• <b>1-pack</b>; one vial of powder, one pre-filled syringe of diluent and one vial adapter.</li> </ul>
Storage	<p>Unopened Vials</p> <p>Store between +2°C and +8°C in original carton to protect from light.</p> <p>Do not freeze. Discard if vial has been frozen.</p> <p>MUST be reconstituted prior to administration<sup>1</sup></p> <p><b>After Reconstitution:</b> 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.</p>	<p>Unopened Vials</p> <p>Store between +2°C and +8°C in original carton to protect from light.</p> <p>Do not freeze. Discard if vial has been frozen.</p> <p>MUST be reconstituted prior to administration.</p> <p><b>After Reconstitution:</b> Administer vaccine immediately (within 4 hrs). Store reconstituted vaccine between +15°C and +30°C. Do not store reconstituted vaccine in the refrigerator. Do not freeze. If not used within 4 hrs, discard.</p>

## Vaccine Administrators

Physicians, nurse practitioners (NP), registered nurses (RNs), registered practical nurses (RPNs), and certain pharmacy professionals can administer the RSV vaccine.

Before administering an RSV vaccine, health care professionals should discuss administration with their employer as certain practice settings may not allow it due to laws or employer preferences and policies. Also, prior to administering the RSV vaccine a health care professional must ensure they have the required authority, such as a direct order, medical directive or delegation, and the competency, to administer the vaccine.

## Ordering Vaccine

Vaccine providers should order vaccine from their usual vaccine source (e.g., public health unit or the OGPMS).

## Reducing Vaccine Wastage

For information on vaccine waste reduction best practices, please refer to the [Vaccine Storage and Handling Guidelines](#).

## Individuals Not Eligible for a Publicly Funded Vaccine

Individuals aged 60 years and older who do not qualify for the publicly funded RSV vaccine program can obtain the vaccine at a pharmacy with a prescription from their primary care provider. Individuals who obtain the RSV vaccine at their local pharmacy will be required to pay out of pocket from the private market. The ministry does not reimburse for publicly funded vaccines or vaccines purchased from the private market. Some private insurers may cover all or part of the cost of the vaccine. Please ensure that your patients are aware of this if they are choosing to purchase an RSV vaccine from the private market.

## Additional Resources

- Ontario Ministry of Health: [Respiratory Syncytial Virus \(RSV\) prevention programs](#) – for health care providers
- Ontario Ministry of Health: [Respiratory Syncytial Virus](#) – for individuals, parents, and caregivers
- [Abrysvo Product Monograph](#)
- [Arexvy Product Monograph](#)