Respiratory Syncytial Virus (RSV) Vaccines for Adults FAQ

The Nova Scotia Publicly Funded Vaccine/Immunoglobulin Eligibility Policy and Publicly Funded Vaccine Eligibility for Individuals at High Risk of Acquiring Vaccine Preventable Disease policies were updated in September 2024 to include an active Respiratory Syncytial Virus (RSV) vaccine.

1. What products are available in Canada to protect against RSV?

- There are three Health Canada authorized active immunizing agents (vaccines) to protect against RSV; Abrysvo™ (RSVpreF), Arexvy (RSVPreF3), and mRESVIA® (RSV mRNA). Although Health Canada authorized mRESVIA® in November 2024, mRESVIA® is not anticipated to be comercially available in Canada until 2025.
    - Abrysvo™ (RSVpreF), Arexvy (RSVPreF3), and mRESVIA® are authorized for those 60 years of age and older.
    - Arexvy (RSVPreF3) is also authorized for adults 50 through 59 years who are at increased risk for RSV disease.
    - Abrysvo™ (RSVpreF) is also authorized for use in pregnancy between 32 and 36 weeks of gestation to provide passive protection to the infant from birth to 6 months of age through transplacental transfer of antibodies.
        - Arexvy (RSVPreF3) and mRESVIA® CANNOT be substituted for Abrysvo™ (RSVpreF) in pregnant individuals.

2. Which RSV vaccine is publicly funded in Nova Scotia for adults?

- Abrysvo™ (RSVpreF) is publicly funded for individuals 60 years of age and older residing in long-term care (LTC) facilities, nursing homes and residential care facilities [RCF], and for individuals 60 years of age and older who are hospital inpatients awaiting placement in a LTC facility.
- Abrysvo™ (RSVpreF) is not publicly funded for use in pregnancy.*
  * Nova Scotia has a publicly funded high risk monoclonal antibody program for premature infants.
- Arexvy (RSVPreF3) and mRESVIA® are not publicly funded.

3. Which populations of older adults should consider RSV vaccine?

- RSV vaccine is recommended for individuals 60 years of age and older who are residents of LTC facilities and RCFs as they are at highest risk for severe outcomes from RSV disease.
- NACI also recommends RSV vaccine for individuals 75 years and older, particularly those at increased risk of severe RSV disease (see question 4).
- In Nova Scotia, individuals over 60 years of age residing in LTC, nursing homes and RCFs, or in hospital awaiting placement in LTC are included in the publicly funded program.
- Those who are not eligible for publicly funded Abrysvo™ (RSVpreF) vaccine may consider purchasing the RSV vaccine privately.
    - As duration of protection from one dose is unclear (although data to date supports protection for at least two RSV seasons), and additional doses (i.e., booster doses) are not recommended at this time, deferring vaccination to a future time when the individual may be at greater risk of severe RSV disease and the vaccine may confer greater benefit should be discussed.
    - Adults who live in or are part of some First Nations, Métis, and Inuit communities may consider RSV vaccination at a younger age given the evidence for an increased burden of illness due to social, environmental, and economic factors, rooted in the history of colonization and systemic racism.

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4. What health conditions in older adults lead to increased risk for severe RSV disease?

- Cardiac or pulmonary disorders (includes chronic obstructive pulmonary disease [COPD], asthma, cystic fibrosis, and conditions affecting ability to clear airway secretions)
- Diabetes mellitus and other metabolic diseases
- Moderate and severe immunodeficiency
- Chronic renal disease
- Chronic liver disease
- Neurologic or neurodevelopmental conditions (includes neuromuscular, neurovascular, neurodegenerative [e.g., dementia], neurodevelopmental conditions, and seizure disorders, but excludes migraines and psychiatric conditions without neurological conditions)
- Class 3 obesity (defined as BMI of 40 kg/m^2 and over)

5. When is the best time to get an RSV vaccine?

- In Nova Scotia, the RSV season usually begins in late fall and continues until early spring.
- In older adults, the optimal time to get an RSV vaccine is just before the start of the RSV season.
- Administration of Abrysvo™ (RSVpreF) to pregnant people should be considered in advance of, or during the RSV season. Abrysvo™ (RSVpreF) is authorized in pregnancy between 32 and 36 weeks of gestation to provide protection to the infant from birth to 6 months of age through transplacental transfer of antibodies. Abrysvo™ (RSVpreF) needs to be administered at least 2 weeks before birth for optimal immune response and transplacental transfer of antibodies.

6. Should RSV active vaccines be given annually?

- No. Individuals who have previously received an RSV vaccine should not receive another dose.
- The efficacy of RSV vaccines in older adults beyond the first RSV season is not yet clear but data suggests protection is maintained for at least two RSV seasons.
- There are no recommendations on additional (booster) doses.

7. Can RSV vaccines be given concurrently with other vaccines?

- RSV vaccines can be administered at the same time or at any time before or after, other vaccines.
- NACI suggests that, *if possible*, to avoid inadvertently attributing an adverse event from another vaccine to the RSV vaccine, RSV vaccine should be spaced by at least 6 weeks before or after non-seasonal vaccines (e.g. shingles, Td).

8. Can RSV vaccines be given to individuals under the age of 60?

- Health Canada authorized Abrysvo™ (RSVpreF) for pregnant individuals between weeks 32-36 of pregnancy and Arexvy (RSVPreF3) is authorized for adults 50 through 59 years who are at increased risk for RSV disease.

9. Is spacing required between an RSV vaccine and lab-confirmed RSV infection?

- Primary infection with RSV does not confer protective immunity against reinfections.
- Even with a history of RSV infection, RSV vaccination can help prevent future respiratory disease from RSV.
- RSV vaccines may be administered to those with prior RSV infection provided they have recovered from their illness.

10. What are the similarities and differences between Abrysvo™ (RSVpreF) and Arexvy (RSVPreF3)?

- Abrysvo™ (RSVpreF) and Arexvy (RSVPreF3) are similar in the following ways:
  - Both vaccines are authorized in adults 60 years of age and older.
  - Both vaccines are non-live protein subunit vaccines.
  - Neither vaccine contains preservatives or natural rubber latex.
  - There have been no head-to-head trials but limited data suggests Abrysvo™ (RSVpreF) and Arexvy (RSVPreF3) result in similar reductions in hospitalization associated with RSV and medically attended RSV respiratory tract infection (RTI) for adults 60 years of age and older.
- Abrysvo™ (RSVpreF) and Arexvy (RSVPreF3) differ in the following ways:
  - Abrysvo™ (RSVpreF) is authorized for people who are 32 to 36 weeks pregnant.
  - Arexvy (RSVPreF3) is authorized for adults 50 through 59 years who are at increased risk for RSV disease.
  - Abrysvo™ (RSVpreF) contains tromethamine (also found in other common vaccines e.g. mRNA COVID-19 vaccines).
  - Arexvy (RSVPreF3) contains the adjuvant AS01$_E$.
  - Common, mild side effects such as pain at the injection site, headache, fatigue, and myalgia are reported more with Arexvy (RSVPreF3).
- NACI does not recommend one vaccine over the other for older individuals. Only Abrysvo™ (RSVpreF) is publicly funded for select populations in Nova Scotia.

11. What is an adjuvant?

- In a vaccine, an adjuvant is a substance that helps elicit an increased immune response to an antigen.
- Arexvy (RSVPreF3) contains an adjuvant called AS01$_E$. This is the same adjuvant used in the herpes zoster (shingles) vaccine Shingrix®, but Arexvy (RSVPreF3) contains half the adjuvant dose.

12. How are Abrysvo™ (RSVpreF) and Arexvy (RSVPreF3) administered?

- Both Abrysvo™ (RSVpreF) and Arexvy (RSVPreF3) are administered as a single 0.5 mL intramuscular injection.

13. How is Abrysvo™ (RSVpreF) supplied and prepared?

- Abrysvo™ (RSVpreF) is supplied as a reconstitution kit containing 1 vial of antigen power, 1 prefilled syringe of diluent and 1 vial adapter.
- Instructions on preparation (with photos) can be found in Section 4 of the product monograph and an instructional video can be found on the product website (see minutes 0 to 2:37).

14. How is Arexvy (RSVPreF3) supplied and prepared?

- Arexvy (RSVPreF3) is supplied as 1 single dose vial of antigen powder and 1 single dose vial of adjuvant suspension.
- Instructions on preparation (with photos) can be found in Section 4 of the product monograph.

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15. Can other diluents be used to reconstitute RSV vaccines?

- No, RSV vaccines must not be mixed with other medicinal products, vaccines, or diluents.
    - Abrysvo™ (RSVpreF) must be reconstituted with the prefilled syringe of diluent provided as part of the reconstitution kit.
    - Arexvy (RSVPreF3) must be reconstituted with the accompanying manufacturer supplied suspension which also contains the adjuvant.

16. Can Pharmacists prescribe active RSV vaccines?

- Yes, RSV active vaccines are included in the list of vaccines pharmacists may prescribe as outlined in the NSCP Standards of Practice: Prescribing Drugs.

17. What should I do if Arexvy (RSVPreF3) is administered instead of Abrysvo™ (RSVpreF)?

- **For older individuals:**
    - For adults 60 years of age and older, one dose of either Abrysvo™ (RSVpreF) or Arexvy (RSVPreF3) is recommended.
    - NACI does not recommend one vaccine over another in older individuals, however Abrysvo™ (RSVpreF) is the only publicly funded RSV vaccine in Nova Scotia.
    - If Arexvy (RSVPreF3) is administered instead of publicly funded Abrysvo™ (RSVpreF) in an older individual, do not give additional vaccination with Abrysvo™ (RSVpreF) as both vaccines protect against RSV in older adults.
        - Data are limited, however Abrysvo™ (RSVpreF) and Arexvy (RSVPreF3) appear to result in similar reductions in laboratory confirmed RSV RTI associated hospitalizations and medically attended RSV RTI for adults 60 years of age and older.
        - There are no recommendations on additional (booster) doses.
- **For pregnant individuals**
    - Abrysvo™ (RSVpreF) is the only RSV vaccine approved for active immunization of pregnant individuals from 32 through 36 weeks gestational age for the prevention of LRTD and severe LRTD caused by RSV in infants from birth through 6 months of age.
        - NACI advises that an imbalance in preterm births in the manufacturer's trial was observed. Available data are insufficient to definitively exclude a causal relationship between preterm birth and RSVpreF vaccination. Consequently, at this time, limiting vaccine administration to the Health Canada approved dosing interval of 32 through 36 weeks of gestation reduces the potential risk of preterm birth. NACI will continue to carefully monitor the evidence on the safety of RSVpreF vaccine in pregnant women and people and will update guidance accordingly.
    - There are no data from the use of Arexvy (RSVPreF3) in pregnant individuals and it is not recommended during pregnancy.
        - An assessment of the Vaccine Adverse Event Reporting System (VAERS), a US based passive reporting system between August 2023 and January 2024 identified 113 reports of Arexvy (RSVPreF3) inadvertently administered to pregnant individuals. The majority of reports (103 out of 113, or 91.2%) did not indicate any adverse events.
        - After administration of an investigational *unadjuvanted* RSVPreF3 vaccine (not Arexvy) to 3,557 pregnant people in a single clinical study, an increase in preterm births was observed compared to placebo.

18. Is there an increased risk of Guillain-Barré syndrome (GBS) with RSV vaccinations in older adults?

- Safety data are limited among adults 60 years of age and older. However, early safety data suggest a potential increased rate of inflammatory neurologic events, including GBS, after administration of Abrysvo™ (RSVpreF) or Arexvy (RSVPreF3) in adults 60 years of age and older.
- Current information is insufficient to confirm an increased frequency of these events associated with the vaccines. NACI will continue to monitor safety evidence on Abrysvo™ (RSVpreF) and Arexvy (RSVPreF3) in adults and will update guidance accordingly.

19. Who should I call if I have further questions?

- Privately and publicly funded vaccine clinical questions: NS Health Vaccine Consult Service (8:30am-4:30pm, 7days/week)
    - Phone: 1-833-768-1151, Fax: 1-902-425-6707, Email: VaccineConsult@nshealth.ca
- Publicly funded vaccine ordering, delivery, and storage questions: Provincial BioDepot
    - Phone: 902-481-5813, Email:publichealthvaccineorders@nshealth.ca
- Publicly funded vaccine policy and eligibly questions: Local public health office: Public Health | Nova Scotia Health