

Pocket Guide for Immunizers:

RSV Vaccines and Immunizing Agents

The purpose of this pocket guide is to serve as a tool for health care providers to learn more about respiratory syncytial virus (RSV) vaccines and monoclonal antibody medications, enabling them to make strong recommendations to their patients.

Respiratory syncytial virus (RSV) is a common seasonal cause of acute lower respiratory tract infections in people of all ages. It is common for people to become infected with RSV multiple times throughout their life. RSV is a common transmissible disease globally, and virtually all children will be exposed to it and infected by the age of two. Approximately 2% of Canadian infants are hospitalized with RSV during the first year of their lives, and estimates show that around 20% of admitted children will be transferred to an intensive care unit.

Adults 75 years of age and older, especially those with chronic health conditions, are also at high risk of severe disease from RSV. They can have serious complications, including hospitalization, admission to an intensive care unit, and death.

There are both active (vaccine) and passive (monoclonal antibody) immunizing agents available to help prevent RSV disease and reduce the severity of infections. Immunization is our best tool for keeping children and adults safe from this widespread and potentially serious virus.



This pocket guide references recommendations made in the [Canadian Immunization Guide Chapter on Respiratory Syncytial Virus \(RSV\) Vaccines](#) from the National Advisory Committee on Immunization (NACI) and commentary made by expert reviewers.

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What immunizing agents are available?

There are currently three different vaccines and two different monoclonal antibody medications authorized for use in Canada for the prevention of RSV, as detailed in the table below.

The RSV monoclonal antibody products are approved for use in newborns, infants, and children up to 2 years of age, and are recommended for providing immediate passive protection to infants and young children.

One RSV vaccine is approved for use in adults 50 years of age and older,

whereas the other two are approved for use in adults 60 years of age and older. The vaccines are particularly recommended for use in adults 75 years of age and older, adults with chronic health conditions, and adults 60 years of age and older living in nursing homes or other care facilities. Additionally, the RSVpreF vaccine is approved for use between 32 and 36 weeks of pregnancy, to be administered to pregnant women and pregnant people as a means of passing on antibodies to their infant.

Table 1: Preparations authorized for use in Canada

Class Name	Class Details	Authorized Ages for Use	Product Name	Product Code
Monoclonal antibodies	Monoclonal antibodies recommended for pediatric use	Newborns, infants, and children up to 2 years of age	SYNAGIS®	palivizumab
			BEYFORTUS™	nirsevimab
Vaccine	Vaccines recommended for adult use	Adults 50 years of age and older	AREXVY	RSVPreF3
		Adults 60 years of age and older	mRESVIA™	mRNA-1345
		Adults 60 years of age and older	ABRYSVO™	RSVpreF

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Class Name	Class Details	Authorized Ages for Use	Product Name	Product Code
Vaccine	Vaccines recommended for adult use	Women and people who are 32 to 36 weeks pregnant	ABRYSVO	RSVpreF

Note: Throughout the rest of this guide, products will be referred to by product code when there is a specific recommendation within the class, and by class name when there is not.

What is the recommended dosage and how is it given?

Palivizumab is administered intramuscularly (IM) at a dose of 15 mg/kg of body weight, approximately every 28 days, during RSV season, for a total of 4 or 5 doses.

For infants entering their first RSV season, nirsevimab is administered intramuscularly (IM) as a single dose of either 50 mg (0.5 mL) or 100 mg (1 mL). Infants weighing under 5 kg should receive the 50-mg dose. Infants weighing 5 kg or more should receive the 100-mg dose.

For most children entering their second RSV season who are at ongoing risk of

severe RSV disease, a total of 200 mg of nirsevimab is administered intramuscularly (IM) as two separate 100-mg (1ml) injections at two different injection sites. However, if the child weighs less than 10 kg entering their second RSV season, consideration can be given to administering a single dose of 100 mg, at clinical discretion.

RSVpreF, RSVPreF3, and mRNA-1345 are each administered intramuscularly (IM) as a single 0.5-ml dose.



How do I choose which immunizing agent to give?

Nirsevimab is recommended for all infants entering their first RSV season, and for young children at high risk of severe RSV infection entering their second season. Palivizumab should only be administered to infants and young children at high risk of severe RSV infection, and only if nirsevimab is unavailable. Availability of and eligibility for nirsevimab and palivizumab differ by province and territory, as there is no universal RSV immunization program in Canada. Note that palivizumab requires multiple doses per season, given at intervals of several weeks (21 to 28 days between the first and second

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doses, 28 to 35 days between subsequent doses). Nirsevimab, by contrast, requires only a single dose per season.

Immunization with RSVpreF during pregnancy can also be seen as an alternative to infant immunization with either nirsevimab or palivizumab, particularly in cases where nirsevimab is not available or there is a parental preference to vaccinate during pregnancy instead of immunizing the infant. Note that the goal of RSV immunization in pregnancy is entirely for the purpose of passive antibody transfer to the unborn child, as the effectiveness of the vaccine for preventing RSV infection in the pregnant woman or pregnant person has not been evaluated. Immunization of infants with nirsevimab is preferred over immunization in pregnancy with RSVpreF. If, however, RSVpreF was administered during pregnancy, there is no need to administer nirsevimab to the infant during the first RSV season.

For adults 60 years of age and older, there are no product preferences. Either RSVpreF, RSVPreF3, or mRNA-1345 can be used.

When should RSV immunizing agents not be given?

Safety data shows that all RSV immunization products authorized for use in Canada are safe and well tolerated. Severe adverse effects and anaphylaxis are extremely rare with these products. There are, however, some contraindications and situations which warrant extra precautions.

- Individuals who have previously experienced a severe anaphylactic reaction or have a known hypersensitivity to the product or any of its components should not receive the product in question.
- Individuals who have an active or previous confirmed case of RSV infection during the current RSV season should generally not receive nirsevimab or palivizumab, although consideration can be given in the case of severely immunocompromised infants.
- Individuals with known hypersensitivity to other humanized monoclonal antibodies should not receive nirsevimab or palivizumab.
- For individuals with moderate or severe illness, deferring administration of the immunizing agent may be considered, taking into account the severity of the illness and the risk of not immunizing. In the case of minor illness, with or without fever, immunization should proceed normally.

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Who should receive RSV immunizing agents?

<p>Infants entering, or born during, their first RSV season</p> <ul style="list-style-type: none"> • Immunization with nirsevimab is recommended • For infants who are at increased risk of severe RSV infection, immunization with palivizumab is an alternative if nirsevimab is not available • Immunization during pregnancy with RSVpreF may be considered as an alternative • <i>See Table 2 for schedule</i> 	<p>Infants at increased risk of severe RSV infection entering their second RSV season</p> <ul style="list-style-type: none"> • Immunization with nirsevimab is recommended • Immunization with palivizumab is an alternative if nirsevimab is not available • For infants at increased risk, immunization as the second RSV season approaches is recommended, regardless of whether or how they were immunized during their first RSV season • <i>See Table 3 for schedule</i>
<p>Adults aged 75 years and older</p> <ul style="list-style-type: none"> • Immunization with RSVPreF3, RSVpreF, or mRNA-1345 is recommended for adults 75 years of age and older, particularly for individuals who are at increased risk of severe RSV infection • One dose of RSVPreF3, RSVpreF, or mRNA-1345 should ideally be given near the start of the RSV season to provide optimal protection to the vaccine recipient • Further immunization is not recommended during subsequent RSV seasons • <i>See Table 4 for schedule</i> 	<p>Adults at increased risk of severe RSV infection aged 50 to 74</p> <ul style="list-style-type: none"> • Immunization with RSVPreF3, RSVpreF, or mRNA-1345 is recommended for individuals 60 years of age and older living in nursing homes and other chronic care facilities • Immunization for other adults 50 to 74 years of age is considered to be an individual decision, though extra consideration may be warranted for individuals at increased risk of severe RSV infection • Further immunization is not recommended during subsequent RSV seasons • <i>See Table 4 for schedule</i>

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What factors lead to increased risk of severe RSV infection in infants?

- premature birth at less than 37 weeks of gestational age (considered a risk factor only during the infant's first RSV season)
- Down syndrome (considered a risk factor only during the infant's first RSV season)
- chronic lung disease which has required assisted ventilation, oxygen therapy, or chronic medical therapy in the previous six months
- cystic fibrosis with respiratory involvement and/or growth delay
- haemodynamically significant chronic cardiac disease
- severe immunodeficiency
- neuromuscular disease or severe congenital airway anomalies impairing clearing of respiratory secretions

What factors lead to increased risk of severe RSV infection in adults aged 50 years and older?

- cardiac or pulmonary disorders (including chronic obstructive pulmonary disease [COPD], asthma, cystic fibrosis, and other conditions affecting the ability to clear airway secretions)
- diabetes mellitus and other metabolic diseases
- moderate and severe immunodeficiency
- chronic renal or liver disease
- neurologic or neurodevelopmental conditions (excluding migraines and psychiatric conditions that are not linked to a neurological condition)
- class 3 obesity (defined as BMI of 40 kg/m² and over)

When is RSV season?

Each province or territory may define their own RSV season based on local data, and the season may shift over time. As a general guideline, RSV season in Canada typically occurs from November through April.



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Can RSV immunizing agents be given at the same time as other vaccines?

All RSV immunizing agents can be given simultaneously with other routine and age-appropriate vaccines.

What about side effects and adverse reactions?

Severe adverse effects are rare following immunization. In randomized controlled trials, adverse effects following immunization with palivizumab were seen at rates similar to placebo.

Some short-term mild to moderate reactions are more commonly seen with nirsevimab, RSVpreF, RSVPreF3, and mRNA-1345:

- soreness at the injection site
- fatigue
- headache
- muscle or joint pain

Remember

In all cases, if products are administered simultaneously, a separate injection site and a different syringe must be used for each.



Should an infant still be immunized in their first RSV season if their mother or birthing parent was vaccinated during pregnancy?

Though immunization of infants with nirsevimab is recommended over immunization during pregnancy with RSVpreF, it is generally not necessary to administer both. Nirsevimab should still be administered, however, if the infant is born less than two weeks after RSVpreF was administered to the pregnant woman or pregnant person, as there will not have been sufficient time for antibody transfer. Nirsevimab should be administered to infants who are at increased risk for severe RSV infection, regardless of immunization in pregnancy with RSVpreF.

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Why might an adult aged 50-74 choose not to be immunized against RSV?

The duration of protection provided by RSV vaccines is not yet known, nor is the effectiveness of repeated booster vaccination in subsequent seasons. Healthy individuals without factors of increased risk can choose to delay initial immunization to a time when they may be at higher risk. Currently, immunization against RSV for this population is not included in all publicly funded programs across Canada.

Immunization Schedules

Table 2: Recommended routine RSV immunization for infants entering, or born during, their first RSV season

Just before the start of RSV season, or at birth for those born during RSV season

One dose of nirsevimab

OR

If nirsevimab is unavailable and the infant is at increased risk for severe RSV infection, one dose of palivizumab every 28 days throughout RSV season, for a total of 4 or 5 doses

*In jurisdictions where nirsevimab will not be available to a newborn or infant entering their first RSV season, healthcare professionals should discuss and encourage administering the RSVpreF vaccine to patients who are pregnant.

Table 3: Recommended RSV immunization for infants at increased risk entering their second RSV season

Just before the start of RSV season

One dose of nirsevimab

OR

If nirsevimab is unavailable, one dose of palivizumab every 28 days throughout RSV season, for a total of 4 or 5 doses

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Table 4: Recommended RSV immunization for adults aged 75 and older, as well as for adults aged 60 to 74 living in nursing homes and chronic care facilities

Just before the start of first qualifying RSV season	One dose of either RSVPreF3, RSVpreF, or mRNA-1345
In subsequent RSV seasons	No further immunization is currently recommended