

RSV in Babies and Pregnancy

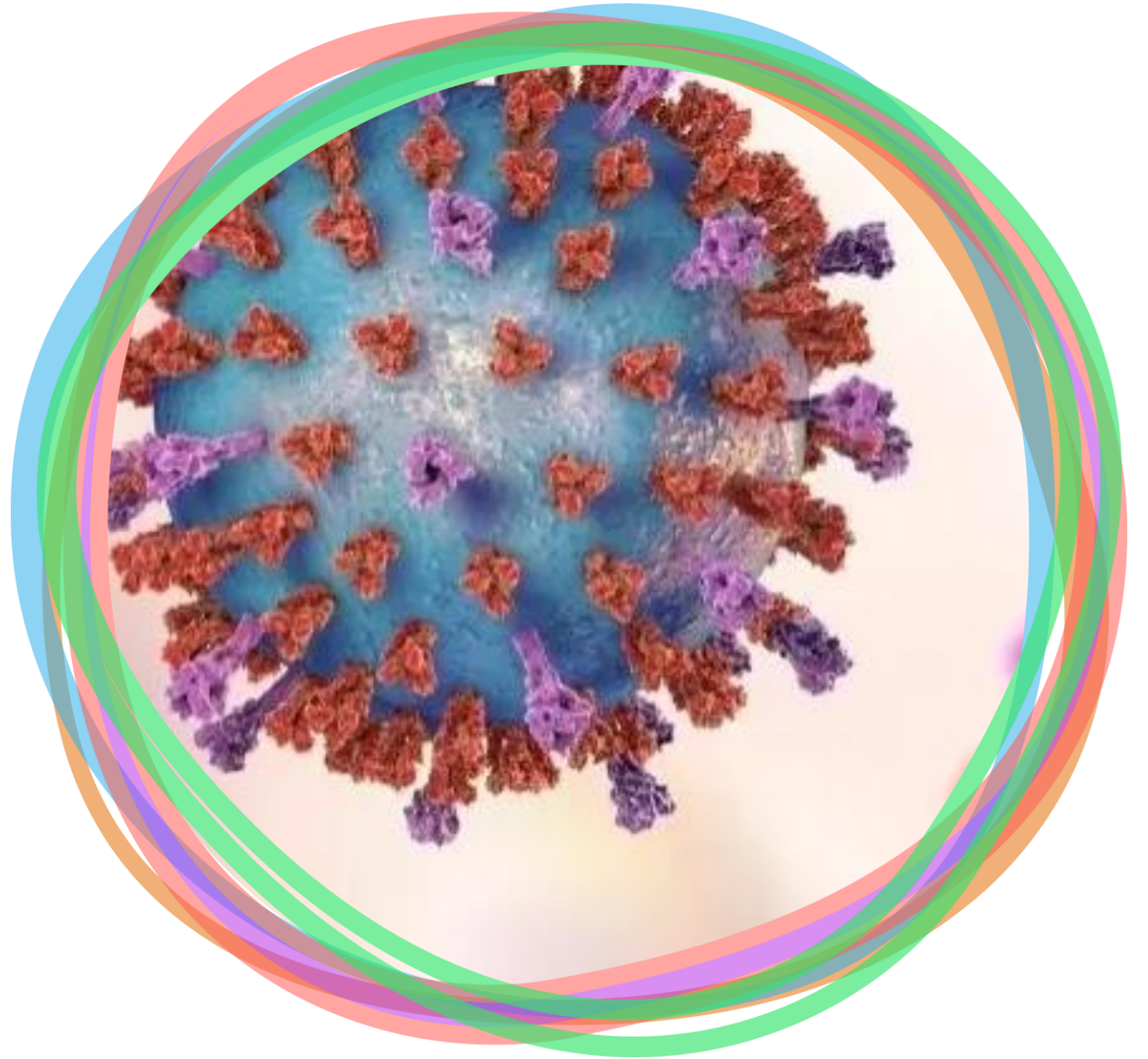
Ale Heddon

Rita Ha

Dr. Lara Rosenberg

October 17, 2024*

*updated October 24, 2024



Agenda

1. RSV impact
2. Options for RSV prevention
3. Beyfortus MOA, precautions, dosing
4. Beyfortus vs Abrysvo
5. Publicly funded Beyfortus, Abrysvo
6. RSV at NYFHT - EMR assets, QI program
7. Patient resources

RSV impact

- RSV infects almost all infants by 2 years of age
- Respiratory tract infection, lasting 1-2 wks
 - Nasal congestion
 - Cough
 - Low grade fever
 - Loss of appetite
- 20-30% of infants with RSV develop bronchiolitis or pneumonia
- Croup or otitis media may also occur

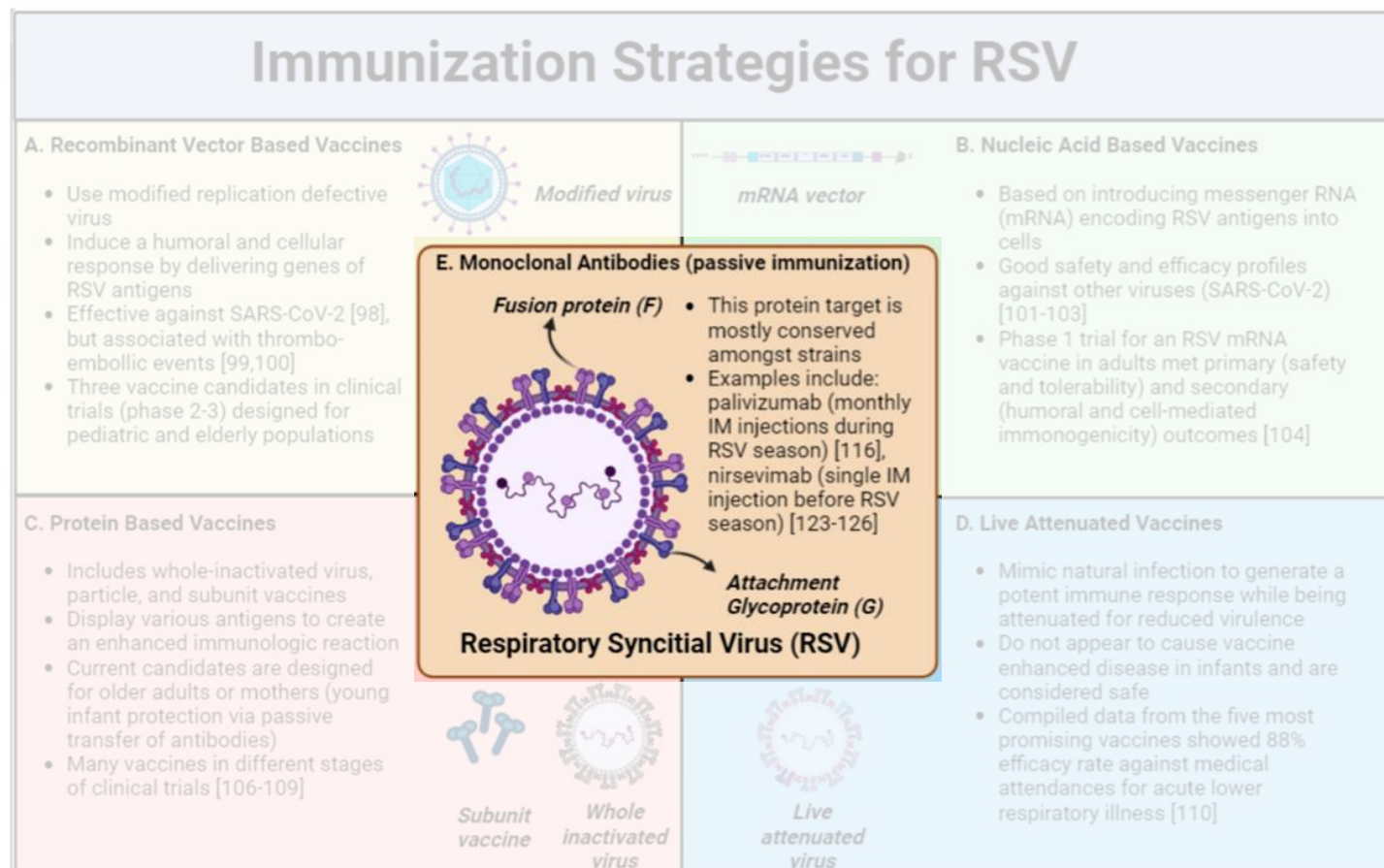
Options for RSV prevention

Monoclonal antibodies

- Synagis (palivizumab)
- **Beyfortus (nirsevimab)**

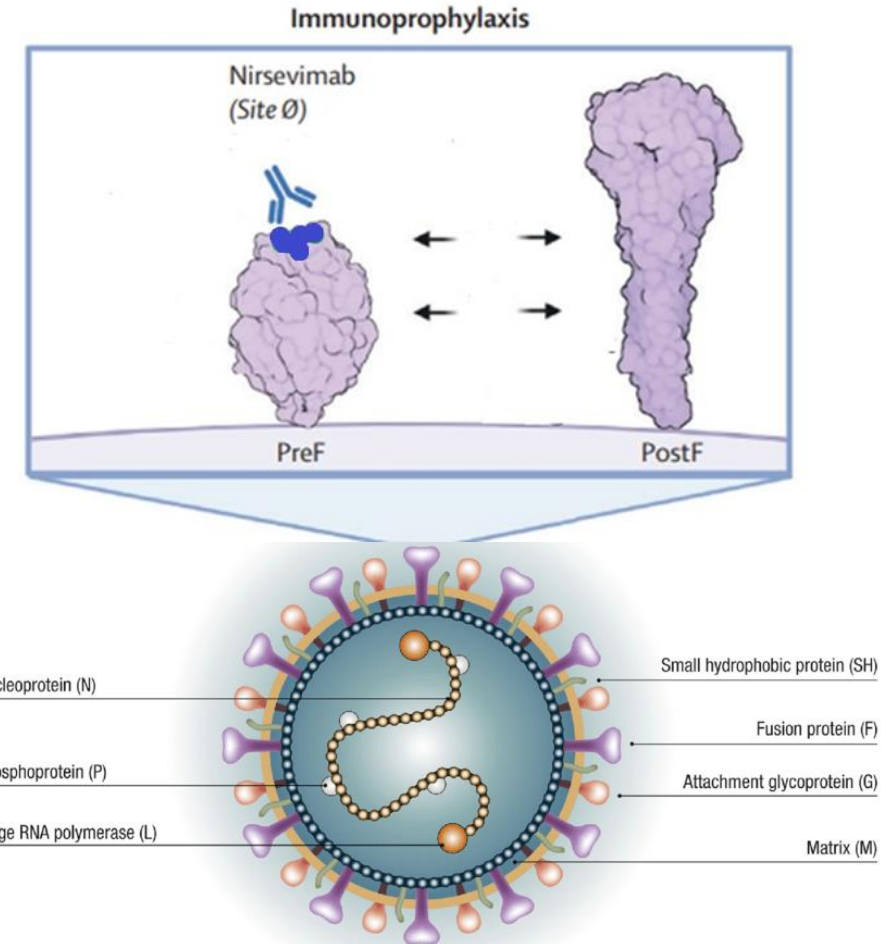
RSV vaccines

- Arexvy (RSVPreF3)
- Abrysvo (RSVpreF)



Beyfortus MOA

- Engineered human monoclonal antibody
- Binds to prefusion protein for RSV A and RSV B (bivalent) and inhibits membrane fusion for viral entry to host cell
- Injected antibodies provide direct and immediate protection against disease
- Does not activate the immune system
- Protection wanes as antibodies degrade
- Effective for 6 months



Mazur 2023. [RSV prevention within reach: the vaccine and monoclonal antibody landscape.](#)
Azzari 2021. [Epidemiology and prevention of RSV infections in children in Italy.](#)

Beyfortus Precautions

When not to give it

- Current RSV infection
- History of RSV infection in current RSV season (except immunocompromised infants)
- Healthy infant (no risk factors) with mother who received Abrysvo during pregnancy
- Moderate to severe illness, with or without fever – consider defer with clinical discretion

Side effects

- Rash (mild-moderate)
- Fever
- Injection site reactions
- Overall rates of adverse events were comparable with placebo

Beyfortus Administration

First RSV season:

For neonates and infants based on **body weight at the time of dosing**¹

 Weight **<5 kg**
1 x 50 mg dose



 Weight **≥5 kg**
1 x 100 mg dose



Second RSV season:

For children who remain **vulnerable to severe RSV disease**, up to 24 months of age¹

 **Regardless of body weight**
200 mg administered as
2 x 100 mg in a single appointment

Different injection sites should be used

Beyfortus is for IM injection only.
Preferably in the anterolateral aspect of the thigh.

Can be given at the same time as, or at any time before or after other immunization products.

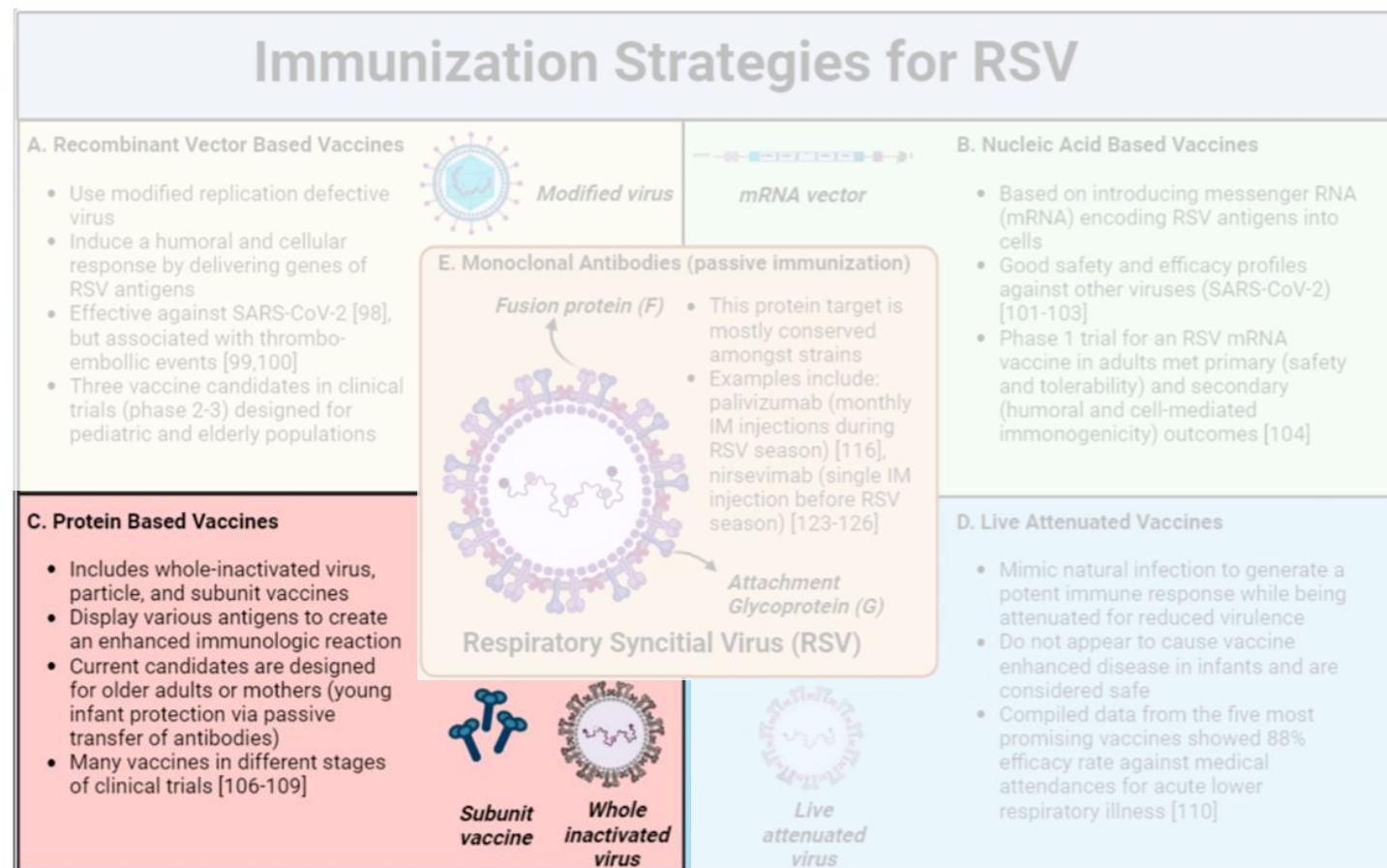
Options for RSV prevention

Monoclonal antibodies

- Synagis (palivizumab)
- Beyfortus (nirsevimab)

RSV vaccines

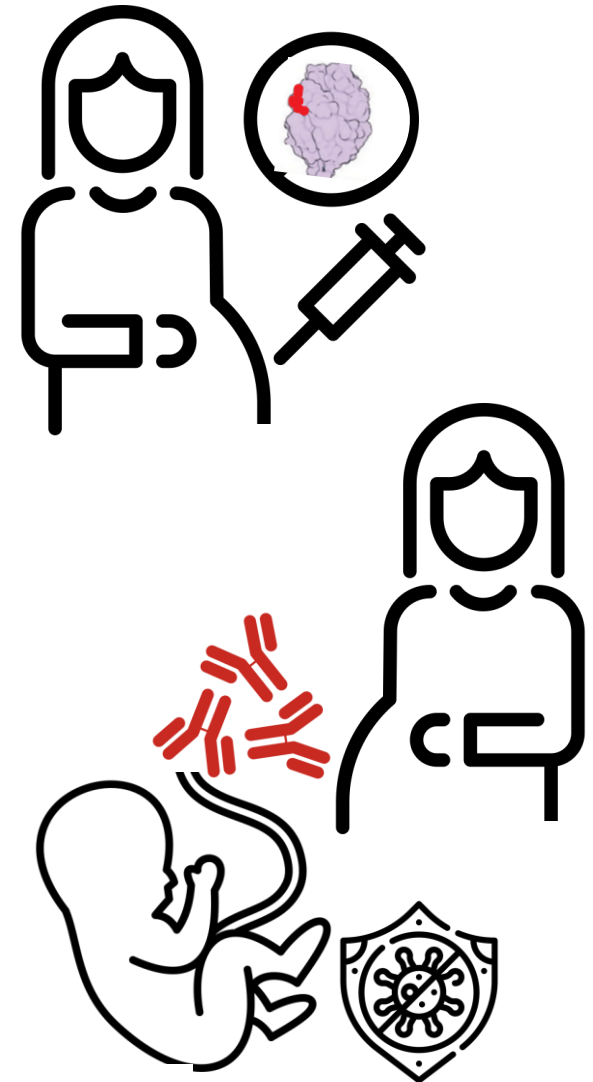
- Arexvy (RSVPreF3)
- **Abrysvo (RSVpreF)**



Gatt 2023. [Prevention and treatment strategies for RSV.](#)

Abrysvo (RSVPreF)

- Prefusion F antigens elicit immune response (active immunization)
- Maternal immune response develops neutralizing antibodies
- Antibodies are passively transferred from mother to infant
- Infant is born with passive immunity against RSV
- Maternal immunization confers passive immunity to infants without fully functional immune system



Abrysvo [product monograph]. https://pdf.hres.ca/dpd_pm/00073900.PDF
Terstappen 2024. [The RSV vaccine and monoclonal antibody landscape.](#)
Patel 2024. [Use of the Abrysvo vaccine in pregnancy to prevent RSV in infants](#)

NACI RSV guidelines

Beyfortus (nirsevimab)

- Reduce hospital admission by 81-83%
- Reduce MA RSV LRTI in healthy infants by 80%

Abrysvo

- Reduce hospital admission in infants by 57%
- Reduce MA RSV RTI in infants by 51%

NACI RSV guidelines

- 1) Beyfortus is recommended for all infants entering, or born during, their first RSV season
- 2) Beyfortus is recommended over Abrysvo due to Beyfortus' superior efficacy, duration of protection and available safety data.
- 3) Infants whose gestational parent received Abrysvo, still need Beyfortus if:
 - Infant meets criteria for high risk of severe RSV disease
 - Infant born less than 2 weeks after administration of Abrysvo

Publicly funded RSV programs

Beyfortus (monoclonal antibody) for infants

Eligible patients:

- Born in 2024 prior to the RSV season (i.e. entering their first RSV season)
- Born during the 2024/25 RSV season (November-April)
- Children up to 24 months of age who remain vulnerable from severe RSV disease through their second RSV season
 - Chronic lung disease
 - Congenital heart disease
 - Severe immunodeficiency
 - Down syndrome/Trisomy 21
 - Cystic fibrosis
 - Neuromuscular disease impairing clearing of respiratory secretions
 - Severe congenital airway anomalies impairing the clearing of respiratory secretions

Publicly funded RSV programs

Abrysvo (RSV vaccine) for pregnant individuals

Eligible patients:

- Pregnant individuals (32-36 wks gestational) who will deliver prior to or during RSV season (November-April)



Publicly funded RSV programs


Vaccine Ordering Details:

Submit [Toronto Provider RSV Vaccine Order Form](#) (updated October 2024)

Send completed forms to vaccineorder@toronto.ca

Do not batch order

Toronto Public Health will be monitoring orders and may contact HCPs if clarifications on their orders are required.

 **Toronto Provider RSV Vaccine Order Form**

Email your vaccine order to vaccineorder@toronto.ca Ministry Use Only – Order no. _____

• Maintain no more than a one month supply in your vaccine fridge at any time.
• Complete ALL fields to avoid a delay in processing your vaccine order.
Please visit the [QPS webpage](#) for more information on public health unit locations and contact information

Client no. _____ Customer Requisition no. _____ Date of requisition (yyyy/mm/dd): _____

Order placed by
Last Name _____ First Name _____

Telephone No. _____ Fax No. _____ Email Address _____

Vaccinating Facility

Long-Term Care Home _____ Retirement Home _____

Indigenous Long Term Care Home (Elder Care Lodge) _____ Hospital _____

Primary Care Office _____ Obstetrician _____

Midwife* _____ Other (specify) _____

Ship to Address
Unit No. _____ Street No. _____ Street Name _____ PO Box _____

City/Town _____ Province _____ Postal Code _____

*Midwives must have a direct order, medical directive or delegation to administer Beyfortus® as specified in O. Reg. 188/24 under the Midwifery Act, 1991.

Shipping Instructions
Alternative delivery sites must have a monitored refrigerator for vaccine storage that has been inspected by your local public health unit. Staff must be available to receive the vaccine order on the scheduled delivery day. If the office is closed (e.g., closed for lunch, etc.), your order will NOT be redelivered until your NEXT scheduled delivery day.

Refer to the current [RSV website](#) for Ontario for eligibility criteria

Eligible Older Adults and Eligible Pregnant Individuals					
Product No.	Description	Packages on Hand	Doses/Pkg	Catalogue no.	Packages Required
657123240	Respiratory Syncytial Virus Stabilized Prefusion F Subunit (RSV) Vaccine (Abrysvo 0.5 ml)		1		

Eligible Infant and Children ONLY					
Product No.	Description	Packages on Hand	Doses/Pkg	Catalogue no.	Packages Required
657122000	Passive Immunizing Agent, BEYFORTUS, RSVAb (0.5 ml Prefilled Syringe) ^{1,2}		1		
657124000	Passive Immunizing Agent, BEYFORTUS, RSVAb (1 ml Prefilled Syringe) ^{1,2}		1		
657124001	Passive Immunizing Agent, BEYFORTUS, RSVAb (1 ml Prefilled Syringe) ^{1,2}		5		

¹Each Beyfortus® pre-filled syringe is for single use only.
²Beyfortus® is a passive immunizing agent that must follow the [Vaccine Storage and Handling Guidelines](#). It must be stored in a TPH inspected refrigerator at a temperature between +2°C and +8°C. Please keep the product in the original outer carton until administration to protect it from light. It cannot be frozen, shaken, or exposed to heat. Once removed from the refrigerator, Beyfortus® should be administered immediately.

Customer - Authorized official (please print)
Last Name _____ First Name _____ Signature _____

Note – Questions about recommended immunizations can be directed to Toronto Public Health at immunization@toronto.ca

RSV at NYFHT

EMR assets

QI Program



EMR: RSV prevention macro/stamp

EMR documentation

Macro/stamp

“RSVbeyfortus”

“RSVpregnancy”

- Discussion guide
- Benefits, risks
- Recommendations
- Eligibility for publicly funded RSV program

RSV Publicly Funded Infant Prevention Program 2024/25

Discussed RSV, high-risk populations, and seasonality.

Provided information on changes to Ontario’s RSV prevention program for infants.

Discussed Beyfortus:

- NACI recommended first line; monoclonal antibody providing immediate protection.
- Eligibility: infants born in 2024 before RSV season, infants born during the season, and high-risk children up to 24 months.
- Efficacy: reduces RSV-related hospitalizations by up to 83% and medically attended visit due to RSV by 80% for up to 6 months
- Dose: Single-dose IM injection. Weight based dosing (50 mg if <5 kg, 100 mg if ≥5 kg, 200mg if ≤24 months and high risk).
- Common side effects: injection site reaction, fever, rash. Possible hypersensitivity reactions.

Outcome of Discussion:

«Parent agreeable to receive Beyfortus. Appointment scheduled.»


«Parent agreeable to receive Beyfortus and will call back to schedule appointment.»

«Parent declines Beyfortus immunization.»

«Parent undecided, will follow up.»

PSS - Abrysvo

- Abrysvo


 Be sure to also include Abrysvo receipt in hospital/antenatal record

New treatment for Sam Test

Treatment

Name: Abrysvo (PF) 120 mcg/0.5 mL

Label Instructions: once

 Dosage checking not performed: No quantified dosage entered.

▼ Administering Details

Immunizing Agent: respiratory syncytial virus [RSV] ▼

Site:

Lot:

Expiry Date:

Manufacturer:

Actions & Comments

Refused Treatment

Started/Performed by External Provider

Provider Name:

Comments:

Start/Perform Date:

PSS - Beyfortus

- Not yet available in Medications
- No Immunization Agent option yet

In the meantime

- Use Prescription Favourites
 - Beyf50
 - Beyf100
 - Beyf200

New treatment for Sam Test

Treatment

Name: Beyfortus 100 mg /1 mL IM solution (wt ≥5 kg)

Label Instructions: 1 mL IM as a single dose

⚠ Dosage checking not performed: No quantified dosage entered.

Quantity/Duration: 1 day(s)

Administering Details

Immunizing Agent:

Site:

Lot:

Expiry Date: ← →

Manufacturer:

Choose a Medication

Search Medication Name beyf Search

Suggestions for: beyf

Favourite beyf100: Beyfortus 100 mg /1 mL IM solution (wt ≥5 kg)
Treatment Type: Medication Route: Unknown

Instructions: 1 mL IM as a single dose

Prescription Favourites

- Favourite beyf100: Beyfortus 100 mg /1 mL IM solution (wt ≥5 kg) 1 mL IM as a single dose
- Favourite beyf200: Beyfortus 100 mg/1 mL IM solution (2nd RSV season, high risk) 200 mg IM as single dose (two 100 mg/1 mL IM
- Favourite beyf50: Beyfortus 50 mg/0.5 mL IM solution (wt <5 kg) 0.5 mL IM as a single dose

Accuro - Abrysvo

- Immunization Summary “RSVpreF”
- Select “...” “Abrysvo”
- Enter Immunization Details as usual practice

The screenshot displays the 'Patient Immunization' window. The 'Immunization Age' is set to 'Unknown'. The 'Vaccine' dropdown is currently set to 'RSVpreF'. A search for 'abrysvo' is being performed in the 'Manufactured Drug Search' dialog box, which shows a list of results with 'ABRYSVO 120 MCG/0.5 ML VIAL [025440]' selected. The 'Vaccine Type' is 'Respiratory Syncytial Virus'. The 'Immunization Details' section on the left includes fields for 'Administered Date' (10/), 'Administered By', 'Vaccine Site', 'Vaccine Dose', 'Reaction', 'Note', 'Instructions', and 'Contact Information'. The 'Status' dropdown is set to 'Sta'. The 'PFIZER CANADA U [02544040]' is selected in the dropdown below the search results. The 'OK' and 'Cancel' buttons are visible at the bottom of the dialog and the main window.

Accuro - Beyfortus

- Immunization Summary
“RSV mAb”
- **But...Beyfortus “brand” is not available for administration until Accuro update**
- May need to retrospectively re-enter immunization summary (QI project?)

In the meantime:

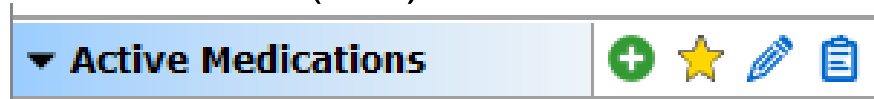
- Enter “nirsevimab” as Active or External Medication
- Enter immunization details in SIG
 - Vaccine Lot:
 - Vaccine expiry date:
 - Administered date:
 - Administered by:
 - Vaccine site:

Accuro - Beyfortus

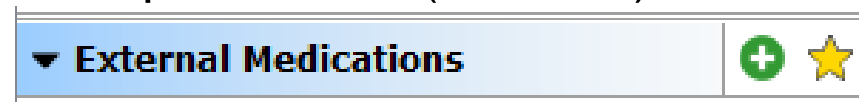
Import Beyfortus as a Prescription Favorite

1. Select ★ for Prescription Favorites.

Prescribers (MD)



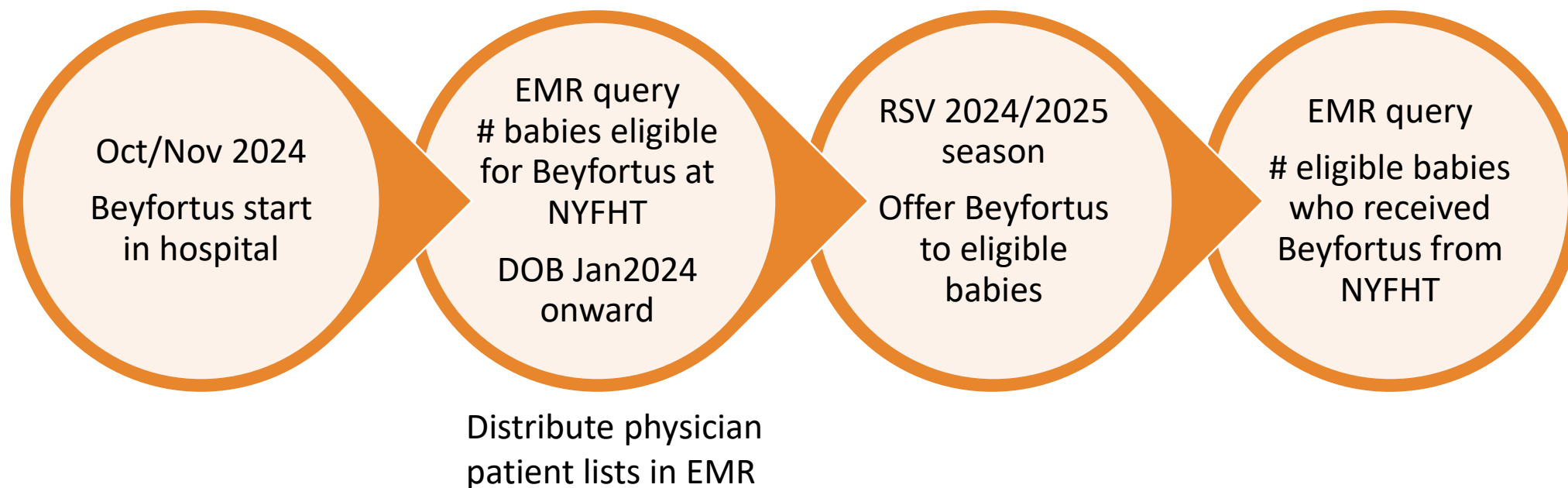
Non-prescribers (RN, IHP)



2. Import Beyfortus prescriptions from another user who has created favorites (e.g. RiHa).
3. Once imported, search and select appropriate RX for your patient in your Favorite Prescription list (Active vs External category).



NYFHT QI: EMR queries



Clinical Resources

Multilingual available

Protecting Your Child from RSV FOR PARENTS AND EXPECTANT PARENTS



What is RSV?

Respiratory syncytial virus (RSV) is a major cause of respiratory illness that affects the airway and lungs, especially in babies and young children.

RSV often causes cold-like symptoms and is the most common cause of a chest infection called bronchiolitis. Babies and young children often have mild illness from RSV and recover quickly. Some babies and young children may develop a severe infection that leads to hospitalization and is life-threatening.

RSV spreads easily from person to person and is most active from late fall to early spring. You and your child can get RSV by having direct contact with a person or surface infected with RSV. You can also get it by being around someone infected with RSV who is coughing or sneezing.



What are the symptoms of RSV?

Symptoms of RSV are similar to those of a cold or flu. They include:

- Cough
- Runny Nose
- Fever
- Drinking or Eating Less
- Low Energy or Being Unusually Tired
- Wheezing
- Irritability

1 Seek medical attention right away if your child is having trouble breathing, is dehydrated, and/or their symptoms are getting worse.

What can I do to protect my infant against RSV?

There are safe and effective ways to keep your child from getting an RSV infection. These include:

- A preventive antibody medication that is given to a child
- A vaccine that is given to a pregnant person

Only one of these options is needed to help protect a child from RSV. Using both the preventive antibody medication and the vaccine is not needed unless recommended by a healthcare provider.

Canada's National Advisory Committee on Immunization (NACI) recommends the preventive antibody medication to be given to a child as the preferred form of protection against RSV infection over the vaccine being given to a pregnant person. This recommendation is based on how well the preventive antibody medication works, how long it provides protection and how safe it is.

Beyfortus™ (also known by the name of nirsevimab) is the preventive antibody medication that is recommended.

It is not a vaccine. Beyfortus works by acting like the antibodies that are made by our bodies to help get rid of germs and harmful substances.

Protecting Infants and High-Risk Children during RSV Season

FOR HEALTHCARE PROVIDERS



Respiratory Syncytial Virus (RSV) is one of the most common respiratory viruses in infants and young children.

RSV contributes to a significant burden of disease in infancy, in addition to having a considerable impact on the healthcare system during RSV season with emergency department visits, hospitalizations and intensive care unit admissions.

As of May 2024, Canada's National Advisory Committee on Immunization (NACI) recommended that provinces and territories build towards universal infant RSV immunization programs; Ontario is one of the first provinces to do so.



What has changed with Ontario's RSV prevention program for infants?

- 1 For the 2024-25 RSV season, the Ministry of Health is transitioning from the current high-risk infant prophylaxis program using Palivizumab (SYNAGIS®, AstraZeneca), to a universal infant and high-risk children RSV prevention program using Nirsevimab (BEYFORTUS™, Sanofi).
- 2 Similarly to Synagis, Beyfortus is a monoclonal antibody (mAb) product and has Health Canada authorization to help protect infants and young children from lower respiratory tract infections caused by RSV through passive immunization that offers immediate protection.
- 3 The RSVpreF (ABRYSVO™, Pfizer) vaccine will also be available this 2024-25 RSV season and has Health Canada authorization to be given during 32 to 36 weeks in pregnancy to protect infants from RSV.
- 4 Beyfortus is the recommended approach for the protection of infants as per the National Advisory Committee on Immunization (NACI), with Abrysvo to be considered on a case-by-case basis.

What are the eligibility criteria for Beyfortus?

For the 2024/25 season in Ontario, Beyfortus is publicly funded for infants and young children:

- Born in 2024 prior to the RSV season*
- Born during the 2024/25 RSV season
- Up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season (refer to [Ministry of Health Beyfortus Guidance Document](#) for details).

The RSV season is generally from November to April but varies by region and year. The Ministry of Health declares a start and end date to the RSV season annually.

*NACI recommends infants 8 months of age or less be immunized.



Why is the publicly funded infant product being transitioned from Synagis to Beyfortus?

Synagis requires monthly dosing, whereas Beyfortus requires one dose to provide protection to the infant/child for the duration of the RSV season. Product transition and expansion will protect more infants/children and preserve health system capacity, particularly by preventing RSV-related hospitalizations.

[PCMCH 09/24](#)

September 2024 | Page 1

How is Abrysvo administered and at what dosage and frequency?

Abrysvo is administered by a single dose of 0.5mL between 32 and 36 weeks gestation. The vaccine is used to actively immunize pregnant individuals, providing infants with passive maternal antibodies that protect them from severe RSV illness from birth to approximately six months of age. Abrysvo can be administered concurrently to pregnant people with their recommended vaccines (e.g., Tdap).

Refer to [Ministry of Health Abrysvo Guidance Document](#) for more information and refer to the [Abrysvo product monograph](#) for detailed information on product ingredients, contraindications and precautions.

Implementation Support

Where should I go with questions regarding implementation?

Direct any questions to your local public health unit. For latest information about the program can be found on the [Ministry's healthcare provider RSV prevention program website](#).

On the [PCMCH RSV webpage](#), you will find a curated list of additional resources to support you with this change in practice.

[PCMCH 09/24](#)

September 2024 | Page 4

ABRYSVO

What if my pregnant patient would like to receive the Abrysvo vaccine?

Prenatal care providers should provide information on both vaccination and mAb products to their pregnant patients; however, only Beyfortus OR Abrysvo is recommended, except in certain circumstances (e.g., a high-risk infant born to someone who received the vaccine).

NACI recommends prioritizing the use of Beyfortus for infant protection due to its efficacy, duration of protection and good safety profile over vaccinating pregnant individuals. Therefore, Beyfortus is the preferred method for safeguarding infants.

Results from clinical trials demonstrated that Abrysvo reduced the likelihood of infant hospitalization for RSV by 88% within three months after birth and 57% within six months.

Communicating with Patients and Families

The Provincial Council for Maternal and Child Health (PCMCH) has developed a parent fact sheet that is available in both [English](#) and [French](#). This resource can be printed out or sent electronically to parents and expectant parents to support your shared decision-making conversations about how to protect their infant/child during RSV season.

What do my patients and families need to know?

Prenatal care providers can begin conversations with their patients early in pregnancy about RSV and immunization options to protect their infants. Key points to guide your discussions with expectant parents may include but are not limited to:

- RSV Overview** (e.g., what is RSV, risks to infants and high-risk children, seasonality)
- Immunization Options** (e.g., mAb or vaccine, Beyfortus as the recommended approach)
- Beyfortus** (e.g., eligibility, timing, frequency, route, safety, efficacy)
- Abrysvo** (e.g., eligibility, timing, frequency, route, safety, efficacy)
- Prevention Strategies** (e.g., avoiding close contact with sick individuals)
- Documentation** (e.g., keeping immunization records up-to-date)

[PCMCH 09/24](#)



<https://www.pcmch.on.ca/wp-content/uploads/pcmch-rsv-provider-fact-sheet.pdf>

<https://www.pcmch.on.ca/wp-content/uploads/pcmch-rsv-parent-fact-sheet.pdf>

Patient Resources



Ministry of Health

Infant and High-risk Children Respiratory Syncytial Virus (RSV) Prevention Program – Immunity, Monoclonal Antibodies and Vaccination

Version 1.0 – August 8, 2024

This fact sheet provides basic information only. It is not intended to provide or replace medical advice, diagnosis, or treatment. You should talk to a health care professional about health concerns and illness.

Immunity

Immunity against diseases is achieved by the presence of antibodies in the body. Antibodies are proteins the body produces to neutralize or destroy harmful organisms, such as viruses and bacteria, that cause disease. These antibodies are specific to each disease (e.g., measles antibodies will only help protect a person exposed to measles).

Immunity is divided into two types: **active** and **passive**.

Active immunity arises when the immune system is prompted to produce antibodies in response to exposure to a disease organism. This can happen through natural infection or vaccination.

- Natural immunity develops when a person is exposed to and infected by a disease organism.
- Vaccine-induced immunity occurs when a person is vaccinated with a killed or weakened form of the disease organism or part of it (e.g., protein).

In both cases, the immune system remembers the disease and can quickly produce antibodies if exposed again. Active immunity takes time to develop (usually several weeks) but tends to be long-lasting, sometimes providing life-long protection. However, some diseases, like respiratory syncytial virus (RSV), do not provide long-lasting natural immunity.

Passive immunity is obtained when a person is given ready-made antibodies rather than their immune system producing them.

1



Ministry of Health

Infant and High-risk Children Respiratory Syncytial Virus (RSV) Prevention Program – Monoclonal Antibody for Infants and High-risk Children

Version 1.0 – August 8, 2024

This fact sheet provides basic information only. It is not intended to provide or replace medical advice, diagnosis, or treatment. You should talk to a health care professional about health concerns and illness.

Protecting Your Infant from RSV: Understanding Your Options

Two safe and effective ways to help prevent RSV infections in infants are available in Ontario: vaccination during pregnancy (Abrysvo™) and monoclonal antibodies (Beyfortus™) given after birth.

Generally, only one product is recommended to help protect an infant from RSV. Using both the vaccine and the monoclonal antibody is not necessary, unless the infant is high-risk (e.g., monoclonal antibody is recommended for all infants with certain medical conditions such as cardiac disease) per recommendation by a health care provider.

The National Advisory Committee on Immunization (NACI) recommends the monoclonal antibody product, Beyfortus™, be used over the vaccination of the pregnant individual based on its efficacy (i.e., how well it works), duration of protection, and safety profile.

This fact sheet presents information only for the monoclonal antibody prevention product Beyfortus™. For information about the vaccine available to pregnant persons, please see the *Infant RSV prevention program – Vaccine for pregnant individuals*.

Beyfortus™ Provides Immediate RSV Protection for Infants

Beyfortus™ is an injectable monoclonal antibody given to infants soon after birth during the RSV season, young infants born prior to the RSV season, and high-risk children during their second RSV season. The RSV season is generally from November to April,

1



Ministry of Health

Infant and High-risk Children Respiratory Syncytial Virus (RSV) Prevention Program - Vaccine for Pregnant Individuals

Version 1.0 – August 8, 2024

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The National Advisory Committee on Immunization (NACI) recommends the monoclonal antibody product, Beyfortus™, over the vaccination of the pregnant individual based on its efficacy (i.e., how well it works), duration of protection, and safety profile.

This fact sheet presents information about the Abrysvo™ vaccine for pregnant individuals. For information about the antibody prevention product available to infants, please see the fact sheet, *Infant RSV prevention program – Monoclonal antibody for infants and high-risk children*.

Vaccination for Pregnant Individuals

Health Canada authorized the Abrysvo™ vaccine to be given to pregnant individuals between 32 and 36 weeks of pregnancy if they will deliver near the start of or during RSV season. The RSV season is generally from November to April, peaking in December. In response to the vaccine the pregnant person creates antibodies that are

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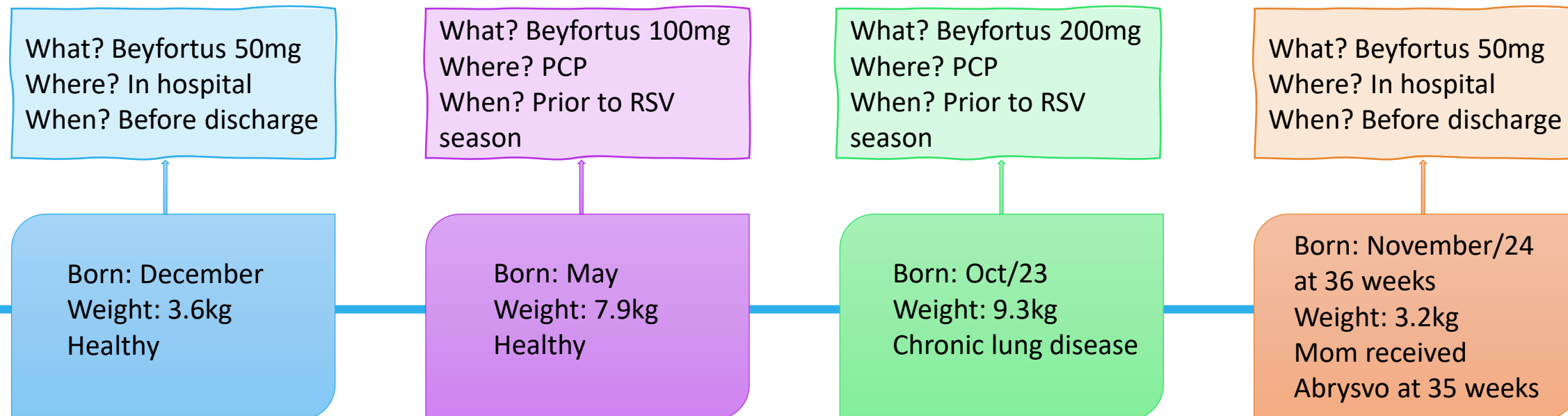


<https://www.ontario.ca/files/2024-08/moh-infant-high-risk-children-rsv-immunity-en-2024-08-29.pdf>

<https://www.ontario.ca/files/2024-08/moh-infant-high-risk-children-rsv-beyfortus-monoclonal-en-2024-08-28.pdf>

<https://www.ontario.ca/files/2024-08/moh-infant-high-risk-children-rsv-abrysvo-pregnancy-en-2024-08-28.pdf>

Case Examples



Questions?

