Preventing RSV in Infants: Current Immunization Options

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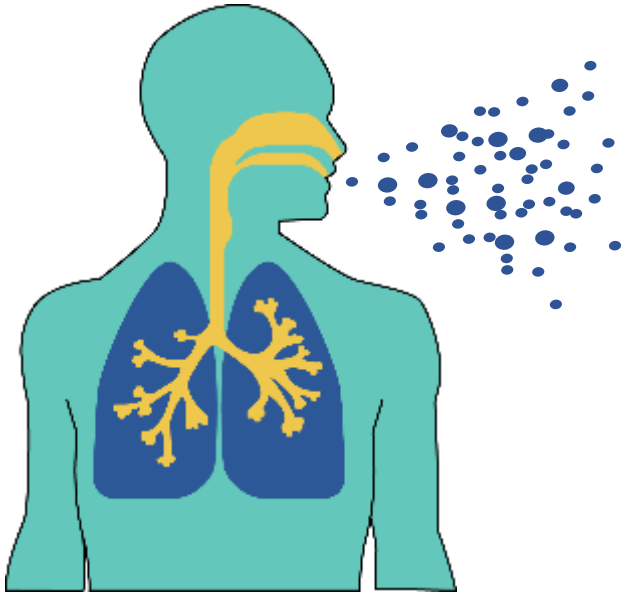
October 7, 2024

Objectives

- Review the burden of RSV
- Available products including Beyfortus and Abyrsvo
- Who is eligible
- NACI recommendations for implementation and pathways to administration

RSV is a Common Respiratory Virus Transmitted Through Respiratory Droplets



RSV is transmitted by respiratory droplets and surfaces is considered highly contagious[1,2]

R_0 of 4.5
mean R_0 ranging from 1.7–8.2[3]

RSV is a Pneumoviridae virus in the Paramyxoviridae family with seasonal peaks similar to cold and flu, typically in the winter months[1,4-6]

- Two antigenic subgroups exist: A and B[1]

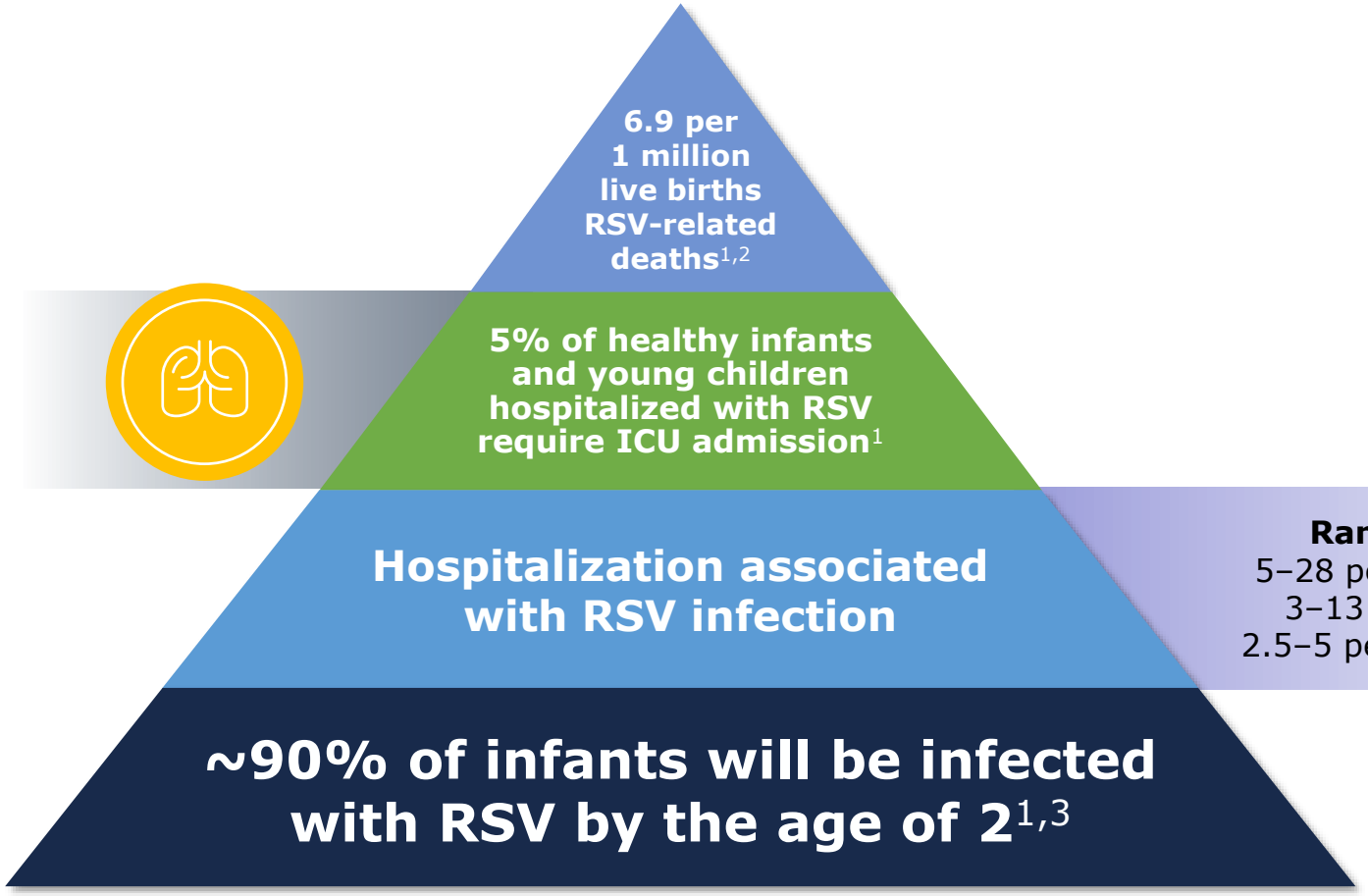
While RSV infection causes mild, cold-like symptoms for many people, infants and at-risk individuals can develop serious respiratory symptoms[4]

RSV is the most common cause of bronchiolitis and pneumonia in infants [4]

R_0=basic reproduction number; RSV=respiratory syncytial virus.

1. Drajac C, et al. *J Immunol Res.* Published online 9 November 2017. doi:10.1155/2017/8734504 2. Centers for Disease Control and Prevention. Accessed 26 July 2022. https://www.cdc.gov/rsv/about/transmission.html 3. Reis J, et al. *Infect Dis Model.* 2018;3:23-34. 4. Public Health Agency of Canada. Accessed 4 May 2023. https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-4-active-vaccines/respiratory-syncytial-virus.html. 5. Centers for Disease Control and Prevention. Accessed 9 August 2022. https://www.cdc.gov/flu/about/season/flu-season.htm 6. Graham BS. *Curr Opin Virol.* 2017;23:107-112.

RSV is a seasonal disease with a high annual burden in infants younger than 12 months of age[1]



Range of hospitalizations by age:[1]
5–28 per 1,000 in infants less than 6 months
3–13 per 1,000 in infants 6 to 12 months
2.5–5 per 1,000 in children 1 to 5 years of age

ICU=intensive care unit; **RSV**=respiratory syncytial virus.

References: 1. Abrams EM, et al. *Canada Communicable Disease Report* 2024;50(1/2):1–15. **2.** Reichert H, et al. *The Journal of Infectious Diseases* 2022;15(226, Supplement 2):S246–54. **3.** Simões EAF. *Lancet* 1999;354:847–52.

Majority of RSV hospitalizations occur in infants without risk factors

Severe RSV disease is unpredictable[2]

Any infant can be hospitalized in their first season whether born[2]…

At term | **Premature** | **With underlying health conditions**

In fact, among infants hospitalized for RSV

were previously healthy and born at term[3]

- Based on a Canadian study validating an algorithm for hospital admissions at the Children's Hospital of Eastern Ontario (Ottawa) between January 2010 and December 2011 to apply to the provincial health administrative data across Ontario.
- Extrapolated data identified that among 19,815 hospitalized infants between April 2005 – March 2013, 15, 482 (80.0%) of infants <3 years did not have any of the following risk factors: CHD, prematurity, BPD, Trisomy 21

RSV=respiratory syncytial virus.

- **References: 1.** Hall CB, et al. *Pediatrics* 2013;132:e34–8. **2.** Bianchini S, et al. *Microorganisms* 2020;8(12):2048. **3.** Pisesky, et al. *PloS one 2016;*11(3):e0150416.

RSV risk by birth month

Apr	May	Jun	Jul	Aug	Sep	Oct	**Nov**	**Dec**	**Jan**	**Feb**	**Mar**

68%

of hospitalized infants were born **before the RSV season**[1]

32%

of hospitalized infants were born **during the RSV season**[1]

Babies born before the RSV season also need to be protected before entering their first RSV season[1-3]

RSV=respiratory syncytial virus.

- **References: 1.** Reeves RM et al. J Infect. 2019;78(6):468–475. **2.** Tregoning JS, Schwarze J. Clin Microbiol Rev. 2010;23(1):74–98. **3.** Drajac C, et al. J Immunol Res. 2017;2017:8734504.

Differentiating Active vs. Passive immunity

Active immunity is protection produced by a person's own immune system. The immune system is stimulated by an antigen to produce antibody-mediated and cell-mediated immunity. Active immunity usually lasts for many years, often for a lifetime.[1-3]

Passive immunity is protection by antibody or antitoxin produced by one animal or human and transferred to another. Passive immunity provides immediate protection against infection, but that protection is temporary.[1-3]

Monoclonal antibodies (mAb) are synthetic proteins engineered to emulate the body's natural defense mechanism against pathogens, including RSV. mAbs act by targeting and neutralizing specific pathogens, which can prevent or limit disease progression. Authorized options include palivizumab (for infants at high risk of RSV only) and nirsevimab.[1-4]

Vaccines are an antigen that trigger the body's immune system to produce its own protective response. RSVPreF is available as an option for pregnant individuals.[1-4]

RSV=respiratory syncytial virus.

- **References: 1.** Centers for Disease Control and Prevention. Epidemiology and Prevention of Vaccine-Preventable Diseases. Hall E, et al., eds. 14th ed. Washington, D.C. Public Health Foundation, 2021. **2.** World Health Organization. Monoclonal Antibodies (mAbs) for Infectious Diseases. Available at: https://www.who.int/teams/immunization-vaccines-and-biologicals/product-and-delivery-research/monoclonal-antibodies-(mabs)-for-infectious-diseases. Accessed: March 14, 2024. **3.** Castelli MS, et al. *Pharmacol Res Perspect* 2019;7(6):e00535. **4.** Government of Canada. Respiratory syncytial virus (RSV): Canadian Immunization Guide. Available at: https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-4-active-vaccines/respiratory-syncytial-virus.html. Accessed on March 25, 2024.

Immunization options for infants currently available in Canada

Monoclonal antibodies

- Palivizumab
  SYNAGIS™
- Nirsevimab
  BEYFORTUS™

Vaccination during pregnancy

- RSV PreF Vaccine
  ABRYSVO™

Infant RSV Prophylaxis options prior to 2024

Palivizumab SYNAGIS™

WHAT:

The only existing option for RSV prophylaxis in Canada ***until recently***

Approved by Health Canada in 2002

WHO:

Limited indications:

- Premature infants born at less than 32 weeks GA
- Infants 33-35 weeks gestation and ages less than 6 months during the RSV season who have a risk assessment tool score of 49-100
- Infants 33-35 weeks gestation and ages less than 6 months during the RSV season who live in remote communities with lack of access to medical care
- Children under 24 months of age with comorbidities

HOW:

Risk Scoring tool

Monthly dosing schedule with up to 5 doses required in a given season

Infant RSV Prophylaxis options in the 2024-2025 Season

Nirsevimab BEYFORTUS™

WHAT:

***2nd* Monoclonal antibody**

Approved by Health Canada April 2023

WHO:

Nirsevimab is indicated for:

Neonates and infants born during or entering their first RSV season

Children up to 24 months of age who remain vulnerable to severe RSV during their second RSV season[1]

HOW:

A single dose before or during the RSV season

RSVpreF ABRYSVO™

WHAT:

Vaccine for pregnant individuals

Approved by Health Canada December 2023

WHO:

INDICATION

Active immunization of all pregnant individuals

TO PROTECT

Infants from birth through to 6 months of age

Prevention of lower respiratory tract disease caused by RSV in individuals 60 years of age and older by active immunization.

HOW:

A single dose between 32-36 weeks GA

Summary: Available immunization options to protect infants

Nirsevimab (Long-acting antibody)

Approved by Health Canada in 2023

WHO: ALL INFANTS

- Neonates and infants during their first RSV season.
- Children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season, which may include but is not limited to children with:
  - Chronic lung disease of prematurity (CLD)
  - Hemodynamically significant congenital heart disease (CHD)
  - Immunocompromised states
  - Down syndrome
  - Cystic fibrosis
  - Neuromuscular disease
  - Congenital airway anomalies.

Palivizumab (Short-acting antibody)

Approved by Health Canada in 2002

WHO: High Risk Infants

- Premature infants born at less than 32 weeks GA
- Infants 33-35 weeks gestation and ages less than 6 months during the RSV season who have a risk assessment tool score of 49-100
- Infants 33-35 weeks gestation and ages less than 6 months during the RSV season who live in remote communities with lack of access to medical care
- Children under 24 months of age with comorbidities

RSVPreF (Maternal Vaccine)

Approved by Health Canada in 2023

WHO: PREGNANT INDIVIDUALS

- Active immunization of pregnant individuals from 32 through 36 weeks gestational age for the prevention of lower respiratory tract disease (LRTD) and severe LRTD caused by respiratory syncytial virus (RSV) in infants from birth through 6 months of age.
- Prevention of lower respiratory tract disease caused by RSV in individuals 60 years of age and older by active immunization.

What's the difference between Health Canada and NACI?

	HEALTH CANADA	NATIONAL ADVISORY COMMITTEE ON IMMUNIZATION (NACI)
Purpose	Authorize specific indications for use that are expected to be safe, immunogenic, efficacious, and of suitable quality for individuals	Recommend vaccination strategies to promote health, prevent and control infectious diseases, and prepare for or respond to public health emergencies
Focus	Individual use of product	Use of product for public programs and population health and individual recommendations.
What data is reviewed	Pre-clinical and clinical trial data and manufacturing information submitted by manufacturers, and post-marketing monitoring	All relevant/available evidence for specific vaccines and similar vaccine formulations in the context of public health considerations, including existing vaccine programs and schedules, disease burden and distribution, and outbreak management

- **Reference:** Adapted from Public Health Agency of Canada: Role of the National Advisory Committee on Immunization (NACI) in COVID-19 Vaccine. https://www.canada.ca/en/public-health.html Planning chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://nccid.ca/wp-content/uploads/sites/2/2021/02/Foundations2_NACI_Role.pdf

National Immunization Committee on Immunization (NACI) Recommendations for RSV Prevention in Infants[1].

1

STRONG RECOMMENDATION

Considering the significant burden of disease in all infants from RSV and the impacts of RSV on the Canadian health system, NACI recommends **building towards a universal RSV immunization program** for all infants. Program introduction could occur in stages depending on access to supply, cost-effectiveness, and affordability of available options.

2

STRONG RECOMMENDATION

NACI recommends RSV immunization programs use nirsevimab to prevent severe RSV disease. Programs can build and expand over time depending on access to supply, cost-effectiveness, and affordability of available options.

3

DISCRETIONARY RECOMMENDATION

NACI recommends **RSVpreF may be considered as an individual decision** by a pregnant woman or pregnant person together with information from their pregnancy care provider, in advance of, or during, the RSV season, to prevent severe RSV disease in their infant. At the present time, NACI does not recommend an immunization program for RSVpreF.

- **Reference: 1.** An Advisory Committee Statement (ACS) National Advisory Committee on Immunization (NACI). Statement on the prevention of respiratory syncytial virus (RSV) disease in infants. Available at: https://www.canada.ca/content/dam/phac-aspc/documents/services/publications/vaccines-immunization/national-advisory-committee-immunization-statement-prevention-respiratory-syncytial-virus-disease-infants/naci-statement-2024-05-17.pdf. Accessed: May 27, 2024.

Beyfortus® clinical trial study designs

	Study 3 (Ph 2b)[1]	MELODY (Ph 3)[2]	MEDLEY (Ph 2/3)[3]
Design	Randomized Control Trial		Randomized Control Trial
Population	Healthy Preterm Infants (29–35 weeks gestational age)	Healthy Term Infants (≥35 weeks gestational age)	Infants with congenital heart disease (CHD), chronic lung disease (CLD) or Prematurity
Intervention	50 mg single dose of Nirsevimab	50 mg/100 mg single dose of Nirsevimab	50 mg/100 mg single dose of Nirsevimab
Comparator	Placebo		Palivizumab
Primary Outcome	Medically attended RSV LRTI		Safety
Secondary Outcome	RSV LRTI Hospitalizations		Medically attended RSV LRTI (both inpatient & outpatient)

MATISSE Trial (NEJM April 2023)

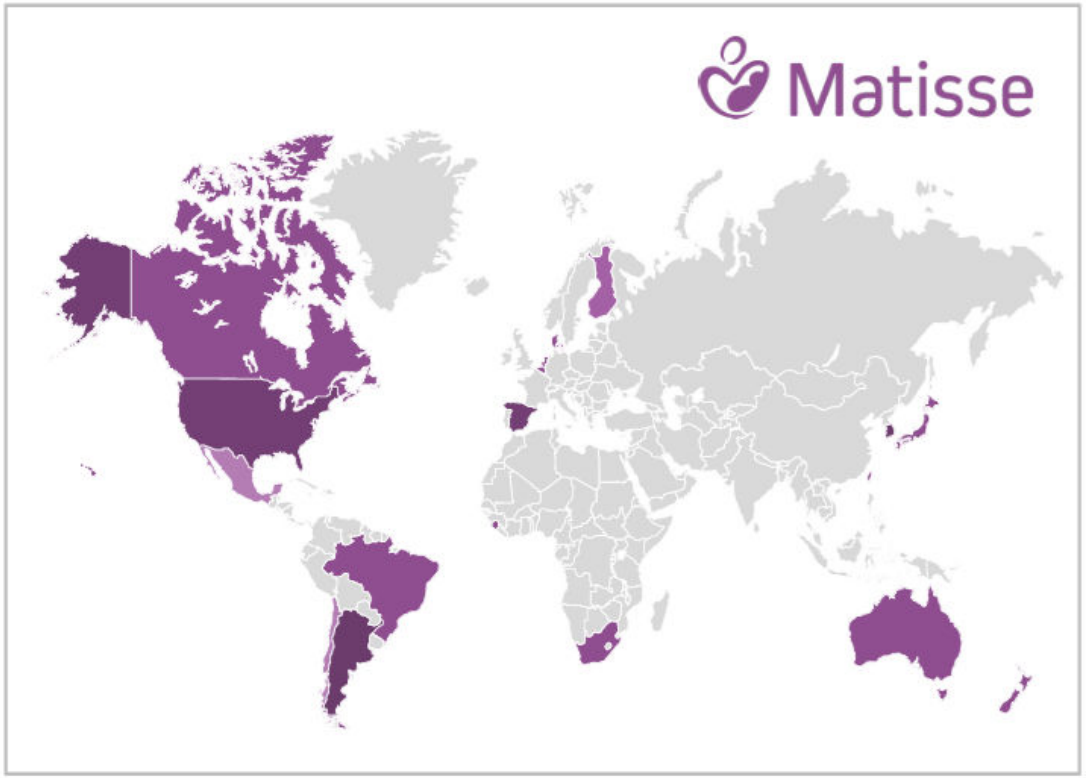
Vaccination during pregnancy

MATISSE: A Phase 3 Trial to Evaluate the Efficacy and Safety of RSVpreF in Infants Born to Women Vaccinated During Pregnancy

7,392 Maternal Participants in 18 Countries
Randomized 1:1 RSVpreF 120µg or Placebo

Pregnant persons ≤49 years between ≥24 and ≤36 weeks gestation

7,128 Infants enrolled



Presented at CDC ACIP meeting February 20, 2023. Slides available from:
https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2023-02/slides-02-23/RSV-Pediatric-06-Munjal-508.pdf

NACI Meta-analysis on Efficacy and Duration of Protection[1]

Clinical Trial Results compared to placebo for protection in the infant[1]

	Nirsevimab (up to 150 days after administration)	**RSVPreF** (up to 180 days after birth) Reflects the trial dosing interval of 24 to 36 weeks gestation rather than the approved dosing interval of 32 to 36 weeks gestation
Medically Attended RSV RTI	**80%**[b] 95% CI: 70 to 87%	**51%**[a] 97.58% CI: 29 to 67%
RSV RTI with Hospitalization	**81%**[b] 95% CI: 64 to 90%	**57%**[b] 99.17% CI: 10 to 88%
RSV RTI with ICU Admission	**90%**[b] 95% CI: 54 to 98%	**43%**[c] 95% CI: -125 to 88%
Development of effect	Immediately	At least 2 weeks between administration and birth
Duration of Protection	• "Efficacious through the first 5 months and may provide full season protection"[1] • "Expected to be effective up to 8 months after administration"[1] (based on PK data)	• "Somewhat efficacious the first 5 months"[1] • "Protection is not expected to last more than 4 to 5 months"[1]

GRADE Certainty evaluated by NACI: [a]High; [b]Moderate; [c]Low

Note 1: Results from the phase IIIb open label trial (HARMONIE) comparing use of nirsevimab (n=4,037) to the standard of care (no intervention, n=4,021) were not available at the time of the GRADE analysis but are described in other components of the NACI statement
Note 2: Confidence Intervals (CI) are as presented as reported in NACI Tables 4 and 7
ICU *Intensive Care Unit;* ***NACI*** *National Advisory Committee on Immunizations;* ***PK*** *Pharmacokinetic;* ***RSV*** *Respiratory Syncytial Virus;* ***RTI*** *Respiratory Tract Infection*

1. National Advisory Committee on Immunizations (NACI): Statement on the prevention of respiratory syncytial virus (RSV) disease in infants. 2024

Beyfortus dosing and administration guidelines

Neonates and infants born during or entering their first RSV season

- 50 mg if <5 kg in body weight
- 100 mg if ≥5 kg in body weight

Children up to 24 months of age who remain vulnerable to severe RSV during their second RSV season

- 200 mg

Administer as an **IM injection**, preferably in the anterolateral aspect of the thigh. The gluteal muscle should not be used as an injection site because of the risk of damage to the sciatic nerve.

Reference: 1. Beyfortus® Product Monograph, June 14, 2024.

NACI: Concurrent Administration with Other Vaccines

Nirsevimab: Can be given concurrently with other pediatric immunizations[1]

- Not expected to interfere with other immunizations
- Co-administration of pediatric vaccines* to healthy preterm and term infants on the same day, ±7 days, or ±14 days had similar safety and reactogenicity profiles as vaccines given alone

RSVpreF: Can be given concurrently with other non-live vaccines during pregnancy[1]

Coadministration in healthy non-pregnant women with Tdap

Component	Non-inferiority? (immunogenicity)
Pertussis	Non-inferiority was not established
Tetanus	Yes
Diphtheria	Yes
RSV A & B	Yes

Coadministration in healthy participants with influenza vaccine

- RSVpreF vaccine was safe and well-tolerated but influenza immune responses trended lower across all strains

*7 prespecified vaccine groups (tuberculosis vaccine; influenza vaccine; measles/mumps/rubella/varicella vaccine; rotavirus vaccine; polyvalent diphtheria, pertussis, tetanus [DPT]-containing vaccine; pneumococcal vaccine; and Hepatitis B vaccine)
Tdap tetanus, diphtheria, and acellular pertussis vaccine

1. National Advisory Committee on Immunizations (NACI): Statement on the prevention of respiratory syncytial virus (RSV) disease in infants. 2024

Abrysvo Vs. Beyfortus: when to use both?

As per NACI Nirsevimab is preferred over RSVpreF

- "If anticipated that nirsevimab will be administered to a healthy infant, then RSVpreF in pregnancy may not provide added benefit for the healthy infant"[1]

If RSVpreF was administered to the gestational parent, NACI recommends that nirsevimab should still be administered in the following two scenarios:[1]

- Infants who meet medical criteria for increased risk of severe RSV disease*

  OR

- Infants who are born less than 2 weeks after administration of RSVpreF

***Infants at increased risk of severe RSV disease during their first RSV season:** All premature infants (i.e., born less than 37 wGA); Chronic lung disease, including bronchopulmonary dysplasia, requiring ongoing assisted ventilation, oxygen therapy or chronic medical therapy in the 6 months prior to the start of the RSV season; Cystic fibrosis with respiratory involvement and/or growth delay; Haemodynamically significant chronic cardiac disease; Severe immunodeficiency; Severe congenital airway anomalies impairing clearing of respiratory secretions; Neuromuscular disease impairing clearing of respiratory secretions; Down syndrome
Infants at ongoing risk of severe RSV disease during their second RSV season: All those listed above, except for infants born at less than 37 wGA and infants with Down syndrome who do not have another medical condition on the list

1. National Advisory Committee on Immunizations (NACI): Statement on the prevention of respiratory syncytial virus (RSV) disease in infants. 2024

Safety profile of Beyfortus in clinical trials

Adverse Reaction, %	Safety*	
	Nirsevimab (n=2570)	Placebo (n=1284)
Rash† (occurring within 14 days post-dose)	0.9%	0.6%
Injection site reactions (occurring within 7 days post-dose)	0.3%	0%
Fever (occurring within 7 days post-dose)	0.5%	0.6%

- **References: 1.** Beyfortus® Product Monograph, June 14, 2024. **2.** Domachowske JB, et al. *N Engl J Med* 2022;386:892–4. Domachowske JB, et al. for the MEDLEY Study Group, Safety of Re-dosing Nirsevimab Prior to RSV Season 2 in Children With Heart or Lung Disease, Journal of the Pediatric Infectious Diseases Society, Volume 12, Issue 8, August 2023, Pages 477–480, https://doi.org/10.1093/jpids/piad052.

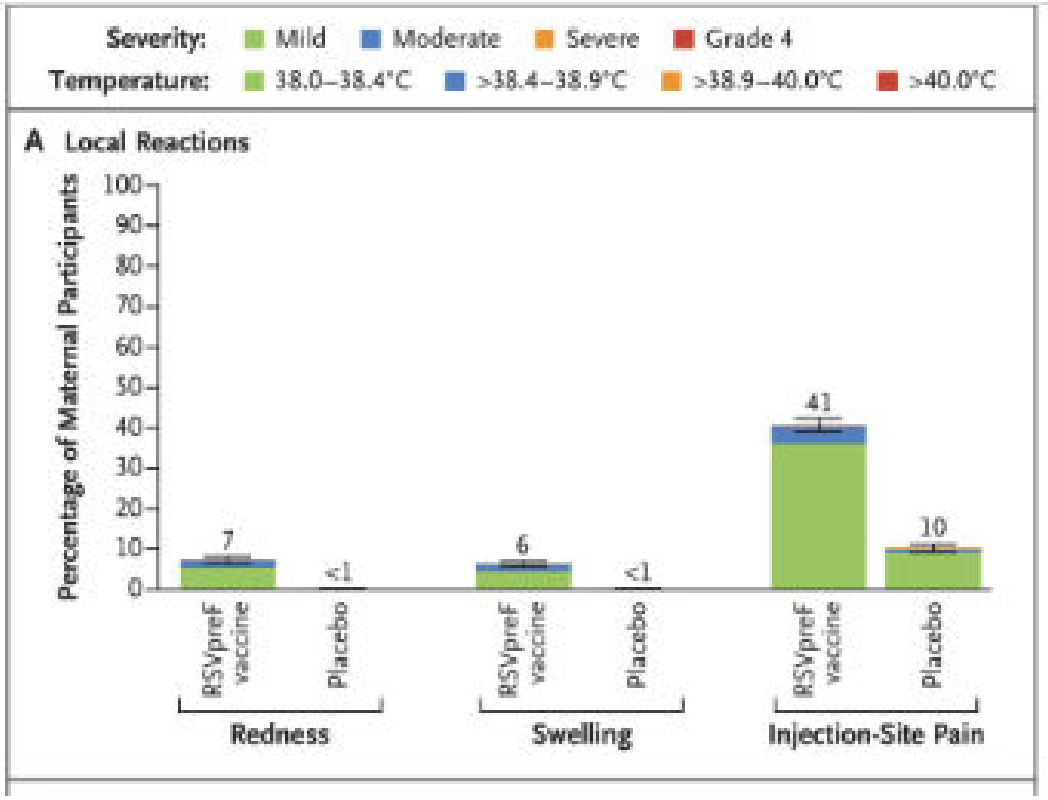
Safety Profile of Abrysvo in Clinical Trials

Local reactions:

- Injection Site pain (41% vs 10%)
- Redness (7% vs 0.2%)
- Swelling (6.2% vs 0.2%)

Systemic Reactions:

- Headache 31% vs 28%
- Muscle pain 17% vs 7%



Kampmann, B., Madhi, S. A., Munjal, I., Simões, E. A. F., Pahud, B. A., Llapur, C., Baker, J., Pérez Marc, G., Radley, D., Shittu, E., Glanternik, J., Snaggs, H., Baber, J., Zachariah, P., Barnabas, S. L., Fausett, M., Adam, T., Perreras, N., Van Houten, M. A., … Gurtman, A. (2023). Bivalent prefusion F vaccine in pregnancy to prevent RSV illness in infants. *New England Journal of Medicine*, *388*(16), 1451–1464.

Real World Evidence on Nirsevimab from the 2023/24 season

HARMONIE Study: Real World Data from Europe 2023

HARMONIE Cohort: N=8,058

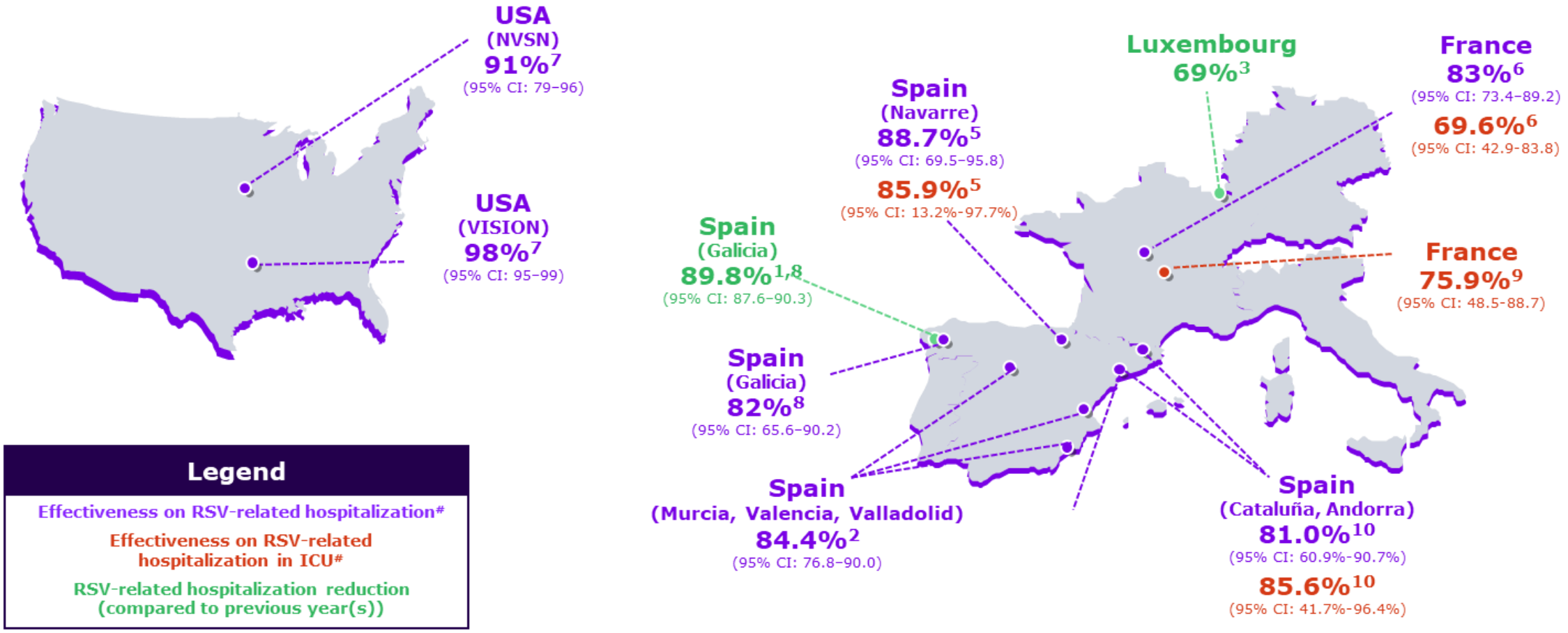
Efficacy through RSV Season

Definition	No Intervention (N=4021)		Nirsevimab (N=4037)		Efficacy	
	n	%	n	%	Efficacy	95% CI
RSV LRTI Hospitalization	60	1.5	11	0.3	**83.2**	67.8-92.0
Very Severe RSV LRTI	19	0.5	5	0.1	**75.4**	34.0-90.8
All-Cause LRTI Hospitalization	98	2.4	45	1.1	**58.0**	39.7-71.2

CI=confidence interval; **LRTI**=lower respiratory tract infection; **RSV**=respiratory syncytial virus.
Very severe=hospitalized patients whose oxygen level is under 90% and require oxygen supplementation.

- **Reference:** Drysdale SB, et al. *N Engl J Med* 2023;389:2425–35.

Summary of Real-World Effectiveness



CI=confidence interval; **Cov**=coverage; **Eff**=effectiveness; **RSV**=respiratory syncytial virus.

- **References: 1.** NIRSE-GAL research team. Results of implementation of Nirsevimab in Galicia. https://www.nirsegal.es/en. **2.** López-Lacort M. et al Euro Surveill. 2024;29(6):pii=2400046. **3.** Ernst C et al. Euro Surveill. 2024;29(4):pii=2400033. **4.** Coma E. et al, Preprints with the Lancet, https://ssrn.com/abstract=4749763. **5.** Ezpeleta G, et al. Vaccines. 2024, 12: 383. **6.** Assad Z, et al. N Eng J Med 2024, in press. **7.** Moline HL et al., MMWR Morb Mortal Wkly Rep 2024;73:209–214. **8.** Ares-Gómez S et al. Lancet Infectious Diseases, May 1st 2024. **9.** Paireau J et al. Influenza and Other Respiratory Viruses, 2024; 18:e13311 https://doi.org/10.1111/irv.13311. **10.** Zein A. et al. Oral presentation; 22nd of May, 2024, ESPID 2024; Copenhagen, Denmark.

NNV: Clinical Trials vs. Real World Data

Clinical Trials

Through Day 151 post nirsevimab administration	Cases averted per 1000	NNV
Pooled Analysis – Healthy, 29+weeks gestation (Includes all subjects MELODY)[1,2]		
MA RSV LRTI – Primary	50	**20**
MA RSV LRTI with hospitalization – Secondary	21	**48**
MA RSV LRTI (very severe) – Exploratory	19	**53**

Real World Evidence

Effectiveness and impact of universal prophylaxis with nirsevimab in infants against hospitalization for respiratory syncytial virus in Galicia, Spain: initial results of a population-based longitudinal study[3]

"RSV-related LRTI hospitalizations were reduced by 89.8% (IQR 87.5–90.3), and the **number needed to immunize to avoid one RSV-related LRTI hospitalization was 25** (IQR 24–32). No severe adverse events related to nirsevimab were registered."

MA RSV LRTI=medical attended respiratory syncytial virus lower respiratory tract infection; **NNV**=number needed to vaccinate.

- **References: 1.** Dagan (2023 Feb 22-24). Safety and Efficacy of Nirsevimab for Prevention of Medically Attended RSV Lower Respiratory Tract Infection in All Infants Enrolled in the Phase 3 MELODY Trial. ReSiViNET 2023, Lisbon, Portugal **2.** Astra Zeneca and Sanofi. Meeting slides to ACIP (2022). https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-10-19-20/02-RSV-Mat-Ped-Felter-508.pdf **3.** Ares-Gómez S, et al. Effectiveness and impact of universal prophylaxis with nirsevimab in infants against hospitalisation for respiratory syncytial virus in Galicia, Spain: initial results of a population-based longitudinal study. *Lancet* 2024. In press.

Announced Infant RSV programs In Canada (to date)

Ontario programs to prevent RSV in infants

Beyfortus® is currently funded for RSV prophylaxis in infants who are residents of Ontario, and meet any of the following criteria:

- Born in 2024 prior to the RSV season

- Born during the 2024–25 RSV season.

- Children up to 24 months of age who remain vulnerable from severe RSV disease through their second RSV season, with:
    - chronic lung disease of prematurity (CLD), including bronchopulmonary dysplasia, requiring ongoing assisted ventilation, oxygen therapy or chronic medical therapy in the 6 months prior to the start of RSV season
        - 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.
    - hemodynamically significant congenital heart disease (CHD) requiring corrective surgery or are on cardiac medication for congestive heart failure or diagnosed with moderate to severe pulmonary hypertension
    - severe immunodeficiency
    - Down Syndrome / Trisomy 21
    - cystic fibrosis with respiratory involvement and/or growth delay
    - severe congenital airway anomalies impairing the clearing of respiratory secretions

1. Ontario Health. Respiratory Syncytial Virus (RSV) Prevention Programs. Updated Sep 3 2024 Respiratory Syncytial Virus (RSV) prevention programs | ontario.ca

Ontario programs to prevent RSV in infants

Vaccination in pregnancy

In addition, the ministry will make the RSV vaccine, Abrysvo®, available to pregnant residents of Ontario from 32 to 36 weeks gestational age who will deliver near the start of or during the 2024–25 season. When administered during pregnancy, RSV protection is provided to the infant from birth to six months of age.

The National Advisory Committee on Immunization (NACI) recommends Beyfortus® as the preferred product to protect infants, based on its:
•efficacy (how well it works)
•duration of protection
•good safety profile

Only one of these products is recommended to protect infants from RSV and using both is unnecessary except in certain circumstances (for example, a high-risk infant born to someone who received the vaccine).

1. Ontario Health. Respiratory Syncytial Virus (RSV) Prevention Programs. Updated Sep 3 2024 Respiratory Syncytial Virus (RSV) prevention programs | ontario.ca

Quebec Immunization Program 2024-2025

According to the **Quebec Immunization Program**[1], nirsevimab is covered in hospital (births) and local service points during the RSV season for:

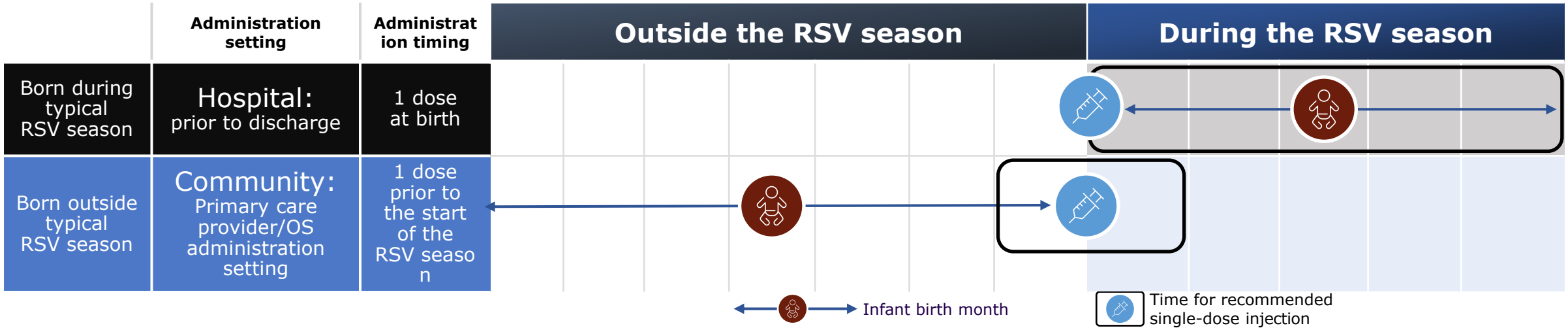
RSV Season	Infants with ***no*** additional risk conditions	Infants ***with*** additional risk conditions*
Going into 1st RSV season	Born on or after April 2nd, 2024	Born on or after February 2nd, 2024 (Includes babies born at less than 37 weeks of pregnancy)
Going into 2nd RSV season	N/A	Born between March 2nd, 2023, and February 1st, 2024

*Conditions include: Cystic fibrosis; Trisomy 21 (Down syndrome); Lung diseases: bronchopulmonary dysplasia, chronic lung disease or moderate or severe pulmonary hypertension; Respiratory problems caused by a muscular disorder or malformation: significant impediment to the evacuation of secretions from the airways, due to a neuromuscular disorder or congenital anomaly of the upper airways; Heart disease or malformation: congenital heart disease or hemodynamically significant cardiomyopathy; Bone marrow, stem cell or solid organ transplant.

1.Gouvernement du Québec. (n.d.). Immunisation contre les infections par le virus respiratoire syncytial (VRS). Gouvernement du Québec . https://www.quebec.ca/sante/conseils-et-prevention/vaccination/immunisation-contre-infections-virus-respiratoire-syncytial-vrs

Timing and administration of Nirsevimab

WHEN: Just prior to start of their 1st RSV season



WHERE:

Hospital: If not given at the hospital prior to discharge, administer Nirsevimab at the first office visit within 1 week of birth

Community: May be given during regularly scheduled 2, 4, or 6-month well-baby visits

New Options in RSV Prevention for Infants: Summary

1. All infants are at risk of RSV, potentially leading to primary care visits, ER, hospitalization, ICU, etc.
2. NACI recommends[1]:
   - Nirsevimab (long-acting antibody) to be used in an universal program for protecting all infants against RSV[1]
     - “Nirsevimab is preferred over RSVpreF given nirsevimab's higher efficacy and possible longer duration of protection”[1]
   - RSVpreF (maternal vaccine) may be considered at an individual level but is currently not recommended for an immunization program[1]
3. Various countries have already implemented publicly funded RSV prophylaxis programs for infants. From the 2023/24 RSV season, nirsevimab has shown effectiveness in reducing RSV hospitalization by 82 to 98%[2-8]. This is consistent with clinical trials showing 81-83% reduction in RSV hospitalization[1]
4. Safety has been studied for these products and continues to be monitored worldwide

1. National Advisory Committee on Immunizations (NACI): Statement on the prevention of respiratory syncytial virus (RSV) disease in infants. 2024; 2. López-Lacort M. et al Euro Surveill. 2024;29(6):pii=2400046; 3. Coma E, et al. Arch Dis Child 2024;0:1–6. doi:10.1136/archdischild-2024-327153; 4. Ezpeleta G, et al. Vaccines. 2024, 12: 383;; 5. Assad Z, et al. NEngl J Med 2024;391:144-54. DOI: 10.1056/NEJMoa2314885 ;6. Payne A., Summary of effectiveness of nirsevimab in infants, ACIP presentation, June 28, 2024, Available at: https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2024-06-26-28/04-RSV-Mat-Peds-Payne-508.pdf, (Accessed on 2July2024); 7. Ares-Gómez S et al. Lancet Infectious Diseases, May 1st2024. 8. Agüera M, et al, Pediatr Allergy Immunol. 2024;35:e14175., https://doi.org/10.1111/pai.14175; 9. Ontario Newsroom, July 25, 2024. https://news.ontario.ca/en/release/1004861/ontario-enhancing-protections-for-more-people-throughout-fall-respiratory-illness-season

For more information

- Local public health unit
- Canadian Immunization Guide
- Ministry factsheets available for providers and families
- PCMCH fact sheet available in English and French