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Your Health Connection

PUBLIC HEALTH ALERT

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Infant and High-Risk Young Children Respiratory Syncytial Virus (RSV) Immunization Program

Attention: Physicians, Nurses and Nurse Practitioners, Walk-In Clinics/Urgent Care Clinics, Family Health Teams, Ontario Health Teams, Hospitals, Infection Prevention & Control Practitioners, Indigenous Health Care & Community, Midwives, Ontario Health Central

Date: September 5, 2024

As announced in July, the Ministry of Health is expanding the Respiratory Syncytial Virus (RSV) immunization program for infants and young children for the 2024-25 season. RSV remains a significant cause of respiratory illness among infants and young children. In Ontario in the 2022/23 season there were 3,850 hospitalizations in children under two years old, with 538 requiring intensive care.

There are currently three products authorized by Health Canada to help prevent RSV infections in infants:

- two monoclonal antibody (mAb) immunizing agents (Beyfortus® or Synagis®) given to infants just prior to or during RSV season (generally from November to April) that provides best protection for 6 months, and
- a vaccine (Abrysvo™) administered to pregnant individuals 32 to 36 weeks gestation to protect the infant when they are born for 6 months with maternal antibodies.

Beyfortus® will be the publicly funded mAb product available for eligible infants in Ontario for 2024/2025.

The RSV vaccine, Abrysvo™, is also available in Ontario for pregnant individuals from 32 to 36 weeks gestation, in consultation with their health care provider. The **National Advisory Committee on Immunization (NACI) recommends primary immunization for the infants with the mAb product Beyfortus® over the vaccination of pregnant individuals based on efficacy, duration of protection, and safety profile**. **If it is anticipated that Beyfortus® will be administered to a healthy infant, then Abrysvo™ in pregnancy is not recommended.**

NACI states some studies have found an increase in preterm births among Abrysvo™ vaccine recipients compared to placebo recipients. This was not observed in high-income countries like Canada. It is unclear whether there is a causal relationship with the vaccine; the currently available data are inconclusive. By limiting vaccine administration to 32 through 36 weeks gestation, the potential risk of preterm birth is reduced. NACI will continue to monitor the Abrysvo™ vaccine safety data and will update its recommendation if needed. NACI therefore currently recommends the vaccine's use on a case-by-case basis in pregnancy.

Pregnant individuals and their health care providers should discuss the use of the vaccine in cases where the mAb would not be agreed to or available (e.g., not giving birth in Ontario).

If a pregnant individual chose to receive Abrysvo, and their newborn was born within 2 weeks of them receiving the Abrysvo or their newborn is in one of the high-risk groups noted in the third bullet below, then it is recommended that the newborn also receive Beyfortus.

For the 2024/25 RSV season, Beyfortus®, is publicly funded for the following infants and children:

- Born in 2024 prior to the RSV season
- Born during the 2024/25 RSV season
- Children up to 24 months of age who are high-risk for severe RSV disease through their second RSV season with:
    - Chronic lung disease (CLD), including bronchopulmonary dysplasia, requiring ongoing assisted ventilation, oxygen therapy or chronic medical therapy in the six 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
    - Neuromuscular disease impairing clearing of respiratory secretions
    - Severe congenital airway anomalies impairing the clearing of respiratory secretions

The administration of Beyfortus® will occur through multiple channels to reach all eligible infants. This includes hospital administration of Beyfortus® to newborns during the RSV season before discharge, ensuring immediate protection for in-season births. Primary care providers will be provided Beyfortus® for infants born out-of-season or those born outside the hospital system (e.g., home births). Public health will also provide Beyfortus® to infants born out of season who do not have a primary care provider. Additionally, pediatric specialists, primary care providers, and outpatient hospital clinics will be important in reaching infants up to two years of age who are at high risk for severe RSV disease during their second season.

Beyfortus® Product Information:

- Product comes in a prefilled syringe and is fridge stable at 2ºC-8ºC.
- Intramuscular injection: Anterolateral thigh for < 12 months, Deltoid muscle for 12 months and older.
- Can be co-administered on the same day or any time before or after other vaccines.

Table 1: Beyfortus® Administration Guidelines for Infants and Children

Category	Weight	Dose	Timing
Infants born during the 2024/25 RSV season	< 5 kg	50 mg in 0.5 mL (100 mg/mL)	Administered from birth
	≥ 5 kg	100 mg in 1 mL (100 mg/mL)	Administered from birth
Infants born outside of the 2024/25 RSV season	< 5 kg	50 mg in 0.5 mL (100 mg/mL)	Shortly before the start of the RSV season
	≥ 5 kg	100 mg in 1 mL (100 mg/mL)	Shortly before the start of the RSV season
Children at continued high-risk from RSV infection entering their second season	N/A	200 mg (two 1 mL injections of 100 mg/mL)	Shortly before the start of their second RSV season

Children undergoing cardiac surgery with cardiopulmonary bypass should receive an additional dose as soon as they are stable after surgery to ensure adequate Beyfortus® serum levels. Refer to the Infant RSV Guidance for Health Care Providers - Beyfortus® for additional details.

For more detailed information about the use of Beyfortus® in infants, refer to the product monograph or the following Ministry resources:

- Infant RSV Guidance for Health Care Providers - Beyfortus®
- RSV Fact Sheet
- Immunity Fact Sheet
- Beyfortus® Fact Sheet for Patients
- Canadian Immunization Guide - RSV vaccines

For more detailed information about the use of the Abrysvo™ vaccine in pregnant individuals, refer to the product monograph or the following Ministry resources:

- Infant RSV Guidance for Health Care Providers - Abrysvo™
- Abrysvo™ in Pregnancy Fact Sheet for Patients

Ordering the Beyfortus® and Abrysvo™

It is anticipated that Beyfortus® will be available in early October. To order Beyfortus® or Abrysvo™ for the Infant & High-Risk Children RSV immunization program, please use the following order form and the health unit will fill your order as soon as the product is received. The majority of our vaccine supply is in single dose boxes so consider vaccine fridge capacity when ordering. Package dimensions are noted on the order form.

If you have any concerns, please contact the Immunization Program at 705-721-7520 ext. 8806.