simcoe muskoka DISTRICT HEALTH UNIT
Tel: 705-721-7520
Toll free: 1-877-721-7520
www.simcoemuskokahealth.org
Your Health Connection

PUBLIC HEALTH ALERT

Dr. Charles Gardner, Medical Officer of Health
Dr. Colin Lee, Associate Medical Officer of Health
Dr. Lisa Simon, Associate Medical Officer of Health

Updates on Infant RSV Immunization (Beyfortus®)

Attention: Physicans, Nurse and Nurse Practitioners, Walk-In Clinics/Urgent Care Clinics, Infection Prevention & Control Practitioners, Hospital Pharmacies, Hospital Occupational Health Nurses, Midwives, EMS, Community Health Centres, Family Health Teams, Ontario Health Teams, Ontario Health Central, Indigenous Health Care & Community

Date: October 21, 2024

Beyfortus® (100 mg) is now available in all local hospitals for infants ≥ 5 kg, with the 50 mg format for those less than 5 kg expected to be delivered to local hospitals this week. The health unit has also received a limited supply of the 100 mg format which is being distributed to primary care providers (PCPs), with additional supply expected in the coming weeks.

If you ordered 100mg doses before October 16th, a small supply (1-5 doses depending on the size of the practice) will be available with your order ready for pick up October 23rd. We are unable to track doses remaining from partially filled orders, so please submit a new order for additional doses. It is expected that PCPs will be ordering mainly the 100 mg format, however if you need the 50 mg format for specific infants it can also be ordered.

For babies who were born earlier in 2024 prior to the RSV season, it is best to administer Beyfortus® as soon as feasible so that they have protection before RSV season is in full swing. It also may be convenient for the Beyfortus® to be administered when they see their PCP for their routine vaccines are 2, 4 or 6 months. Beyfortus® can be co-administered at the same visit as any routine vaccine.

RSV Season Start and End

The RSV season is generally from November to April, peaking in December, with variations in various regions in Ontario and between years. **Hospitals and PCPs can start administering Beyfortus® as soon as they receive supply**. We will communicate the end of the RSV season and when Beyfortus® should no longer be administered once the season ends.

Side Effects & Reporting Adverse Events Following Beyfortus®

Like vaccines or medications, Beyfortus® may have some side effects, which are mild and last only a few days.

Common side effects for Beyfortus® are mild or moderate, including local reactions such as redness, swelling, and pain at the injection site. The most frequent adverse reactions in clinical trials were:

- Rash (0.7% vs. 0.3% placebo)
- Pyrexia (0.5% vs. 0.6% placebo)
- Injection site reactions (0.3% vs. 0% placebo) within seven days

Some participants experienced systemic adverse events, such as:

- RSV bronchiolitis (1.3% vs. 2.6% placebo)
- RSV pneumonia (0.7% vs. 0.9% placebo)
- RSV bronchitis (0.5% vs. 1.0% placebo)

As Beyfortus® is a new drug product, its safety and tolerability will continue to be monitored in post-market safety surveillance. As Beyfortus® is a mAb and not a vaccine, reporting of suspected AEFIs to Beyfortus® is not subject to s.38 of the Health Protection and Promotion Act (HPPA). As such, these incidents do not need to be reported to the local public health unit and should be managed as per practices and organizational policies for other medicines and therapeutics. It is recommended that providers and parents report all suspected side effects to Health Canada using the Side Effect Reporting Form.

Clarification: When should Beyfortus® also be administered to an Infant when Pregnant Individuals have Received Abrysvo™:

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.

If a pregnant individual receives Abyrsvo™, Beyfortus® for the infant is only also publicly funded in the following situations:

- Infants born less than 14 days after administration of Abrysvo™ or
- Infants who meet the medical criteria for increased risk from severe RSV disease:
    - All premature infants (i.e., born < 37wGA
    - 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
    - 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.

Refer to the Ministry of Health Infant and High-risk Children RSV Prevention Program Guidance for HCPs for immunization of children undergoing cardiac surgery with cardiopulmonary bypass.

Note: While prematurity is an eligibility factor to receive Beyfortus® when Abrysvo™ was received in pregnancy, it is not a factor for high-risk second season eligibility like the other conditions listed above.

The following updated Administration table has been provided by the Ministry of Health to support HCPs:

Table 1: Beyfortus® Administration Guidelines for Infants and Children

Category	Weight	Dose	Timing
Infants born during the current 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 in 2024 before the current RSV season starts (up to 12 months of age)*	< 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 over 12 months and up to 24 months of age and at continued high-risk from RSV infection	N/A	200 mg (two 1 mL injections of 100 mg/mL)†	Shortly before the start of their second RSV season∞
∞ Due to the seasonality of the RSV virus, Beyfortus should be administered shortly before and during the active RSV season. The RSV season is generally from November to April, peaking in December, with variations in various regions in Ontario and between years.			
*NACI recommends Beyfortus especially for infants less than 8 months of age due to risk of severe outcomes in younger infants.			
†If a child weighs less than 10 kg entering their second RSV season, consideration can be given to administering a single dose of 100 mg at the clinical discretion of the provider.			

For more information, please visit our website at www.smdhu.org/hpportal or contact the Immunization Program at 705-721-7520 or toll free at 1-877-721-7520.

- For questions regarding vaccine orders: ext. 8808 or vaccineorders@smdhu.org
- For all other HCP questions: ext. 8806 or hc.vpd@smdhu.org