Respiratory Syncytial Virus (RSV) Monoclonal Antibody BEYFORTUS® (nirsevimab) Supplier: Sanofi Pasteur Limited

(50 mg/0.5 mL presentation; 100 mg/1 mL presentation)

INDICATIONS:

- See 2025-2026 Infant RSV Program Eligibility Criteria [A]

BEYFORTUS® is not indicated for children over 2 years of age. Infants less than 1.6 kg or less than 34 weeks post-menstrual age (PMA) [B] should not receive BEYFORTUS® until they are greater than or equal to 1.6 kg and greater than or equal to 34 weeks PMA.

Those not eligible through BC's Infant RSV Program may be able to purchase BEYFORTUS® privately.

DOSES AND SCHEDULE: [C]

- Infants and children in their first RSV season 1.6 kg to less than 5 kg: 1 dose given as 0.5 mL (50 mg) **IM**.
- Infants and children in their first RSV season 5 kg or greater: 1 dose given as 1 mL (100 mg) **IM**.
- Infants and children in their second RSV season 5 kg to less than 10 kg:1 dose given as 1 mL (100 mg) **IM**.
- Infants and children in their second RSV season 10 kg or greater: 2 mL (200 mg) dose, given as two 1 mL (100 mg) doses **IM** at same visit.
- Infants and children who had cardiopulmonary bypass surgery after receiving BEYFORTUS®:[D]
    - If within 90 days of the prior BEYFORTUS® dose, follow weight-based seasonal dosing above to administer another dose.
    - If greater than 90 days since the prior BEYFORTUS® dose:
        - Infants and children less than 10 kg: 1 dose given as 0.5 mL (50 mg) **IM**.
        - Infants and children 10 kg or greater: 1 dose given as 1 mL (100 mg) **IM**.

[A] Eligibility outside of this list may be determined by the Infant RSV Program (RSV@cw.bc.ca).

[B] Post-menstrual age (PMA) is the time elapsed between the first day of the last menstrual period and birth (gestational age) plus the time elapsed after birth (chronological age). PMA is usually described in number of weeks and is most frequently applied during the perinatal period beginning after the day of birth. For example, a preterm infant born at a gestational age of 33 weeks who is currently 10 weeks old (chronological age) would have a PMA of 43 weeks.

[C] For infants and children hospitalized since birth throughout the RSV season (e.g., a very premature infant born in January and discharged in August), the subsequent RSV season is considered to be their first season. Those who were discharged from hospital prior to or during the previous season are considered to be in their second RSV season, regardless of RSV immunoprophylaxis receipt during the previous season. Note: In BC, the RSV season typically lasts from October to March. The RSV season in northern BC usually starts and ends later than other regions of BC.

[D] Those who have undergone cardiopulmonary bypass surgery and are discharged home during the RSV season require re-immunization, as bypass surgery diminishes circulating antibodies.

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ADMINISTRATION:

- BEYFORTUS® is available in 2 pre-filled syringe presentations: 50 mg (50 mg/0.5 mL) pre-filled syringe with purple plunger rod and 100 mg (100 mg/1 mL) pre-filled syringe with light blue plunger rod.
- Keep the pre-filled syringe in the outer carton in order to protect from light. Remove pre-filled syringe from packaging immediately prior to use.
- Store between 2°C - 8°C. Although BEYFORTUS® may be kept at room temperature (20°C - 25°C) for a maximum of 8 hours, it is recommended that this product be stored at 2°C - 8°C until use. If BEYFORTUS® is not used within 8 hours at room temperature, it must be discarded.[A]
- BEYFORTUS® is a clear to opalescent, colourless to yellow solution. Do not administer if cloudy, discoloured, or contains large particulate matter.
- Do not dilute or shake solution.

RE-IMMUNIZATION IN SUBSEQUENT RSV SEASONS:

Children with certain chronic health conditions may be recommended for re-immunization in a subsequent RSV season if under 2 years of age. See 2025-2026 Infant RSV Program eligibility criteria for more information.

SEROLOGICAL TESTING:

Serological testing is not recommended before or after immunization.

CONTRAINDICATIONS:

1. History of anaphylactic reaction to a previous dose of BEYFORTUS® or to any component of BEYFORTUS®, or to other humanized monoclonal antibodies.

PRODUCT COMPONENTS:

Potential allergens: polysorbate 80, L-arginine hydrochloride.

Other components: L-histidine, L-histidine hydrochloride, sucrose.

PRECAUTIONS:

- BEYFORTUS® can be administered at the same time as, or at any time before or after, other immunization products. Monoclonal antibody administration does not interfere with the immune response to other vaccines.

SPECIAL CONSIDERATIONS:

- **Hospital Settings**: Refer to the Provincial Nirsevimab for Immunoprophylaxis of Respiratory Syncytial Virus (RSV) Infection procedure document for guidance related to acute care sites.
- BEYFORTUS® can be provided to infants who have already had a documented RSV infection (hospitalized or not), although the benefit of BEYFORTUS® is likely to be significantly reduced.

[A] Cold chain incidents should be reported to the Infant RSV Program (RSV@cw.bc.ca).

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SPECIAL CONSIDERATIONS (continued):

- A mild febrile illness, such as a mild upper respiratory infection, is not usually a reason to defer administration of BEYFORTUS®; delaying BEYFORTUS® could pose a greater risk of being susceptible to RSV infection. However, a moderate or severe acute infection or febrile illness may warrant delaying the use of BEYFORTUS®. See Appendix C – Contraindications and Precautions for Immunization for more information.
- Infants whose birthing parent received RSV vaccine, ABRYSVO™, do not need BEYFORTUS® unless the infant meets the medical criteria for increased risk for a second RSV season or the infant is born less than 2 weeks after administration of ABRYSVO™. See 2025-2026 Infant RSV Program eligibility criteria for more information. There is no expected additional benefit to using both ABRYSVO™ and BEYFORTUS® for healthy infants.

ADVERSE EVENTS:

Local: rash, redness, soreness.

Systemic: fever.

For adverse event reporting of BEYFORTUS®, notify the Infant RSV Program (RSV@cw.bc.ca) and see Part 5 – Adverse Events Following Immunization, section 3 Reporting Adverse Events.