

Eight out of 10 infants and newborns in Canada have access to RSV prevention with Beyfortus® this season

- Six provinces and three territories to provide universal immunization programs for Respiratory Syncytial Virus (RSV) infant protection this respiratory season
- Beyfortus will also be reimbursed through select private health insurance providers
- Beyfortus demonstrated the ability to reduce the risk of RSV lower respiratory tract infections by 74.5%, including hospitalizations in infants entering their first RSV seasonⁱ

TORONTO, Nov. 10, 2025 /CNW/ - This RSV season, eight out of 10 Canadian newborns and infants will have access to Beyfortus, the first and only protective antibody approved in Canada for the prevention of RSV lower respiratory tract disease in babies through their first RSV seasonⁱ. Initially offered in 2024 in Quebec, Ontario, Yukon, Northwest Territories and Nunavut, Beyfortus is now also available in Saskatchewan, Manitoba, Nova Scotia and Prince Edward Island through provincial universal immunization programs, aiming to protect eligible infants from RSV.



A highly contagious virus, Respiratory Syncytial Virus or RSV impacts 90% of babies before their second birthdayⁱⁱ. RSV circulates seasonally between November and April and causes a high burden of bronchiolitis, pneumonia and hospitalizations in infants and newborns. Sanofi has worked closely with provinces and territories to make Beyfortus available this RSV season to help protect all infants entering their first RSV season and some infants entering their second season who remain vulnerable to RSV.

Beyfortus will be provided in hospital prior to discharge for babies born during the RSV season and in some provinces Beyfortus will also be available through primary care providers or public health offices for infants born before the RSV season.

Beyfortus is publicly funded and available free of charge for all infants in Ontario, Quebec, Nova Scotia, Prince Edward Island, Nunavut, Northwest Territories and Yukon; Manitoba and Saskatchewan will provide Beyfortus free of charge to all infants born during the RSV season, and British Columbia, Alberta, New Brunswick and Newfoundland and Labrador will provide Beyfortus free of charge to high-risk infants only. Reimbursement for Beyfortus is also available through select private health insurance providers for those with private coverage. Healthcare providers can contact their local health authority to obtain more information about Beyfortus.

"Through real-world evidence we have seen the significant impact Beyfortus can have on reducing the risk of RSV in infants and babies, and as a result on helping to alleviate the burden RSV has on the Canadian healthcare system every year," said Delphine Lansac, General Manager Vaccines. "Equally as important, is the confidence it gives parents to know that they have taken a positive step in helping to protect their baby from RSV."

The National Advisory Committee on Immunization (NACI) and Quebec's National Institute of Excellence in Health and Social Services (INESSS) recommended Beyfortus to protect all newborns and infants from RSV.^{iii iv} Beyfortus has been approved in Canada since April 2023.

About RSV

RSV, a highly contagious virus, can lead to respiratory illness in babies, including lung infections such as bronchiolitis and pneumonia.^v Approximately 2 out of 3 infants are infected by RSV by their first birthday and almost all infants are infected by the age of 2.^{vi} Infants under 1 year are on average almost 16 times more likely to be hospitalized for RSV than for influenza.^{vii} The majority of RSV hospitalizations occur in infants without risk factors. A recent study showed among infants hospitalized for RSV, 80% were previously healthy and born at term.^{viii} As highlighted by NACI, each year, between 10% and 20% of RSV cases among healthy infants require medical care including physician office, urgent care, emergency room visits and hospitalizations.^{ix} Until now, only a small fraction of infants born in Canada have been eligible to receive RSV protection.

About Beyfortus

Beyfortus is the first immunization designed for all infants to help prevent RSV lower respiratory tract disease through their first RSV season. Beyfortus is also indicated for children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season. Beyfortus offers timely protection against RSV lower respiratory tract disease lasting at least 5 months, to coincide with the RSV season.

As a single-dose, long-acting antibody provided directly to newborns and infants, Beyfortus offers rapid protection to help prevent lower respiratory tract disease caused by RSV without requiring activation of the immune system.

Beyfortus demonstrated statistically significant efficacy in reducing the relative risk of respiratory syncytial virus lower respiratory tract infections, including hospitalizations, by 74.5% vs. placebo in term and late preterm infants (gestational age greater than or equal to 35 weeks) entering their first RSV season (95% CI: 49.6-87.1; $p < 0.0001$).^x

About Sanofi

Sanofi is an R&D driven, AI-powered biopharma company committed to improving people's lives and delivering compelling growth. We apply our deep understanding of the immune system to invent medicines and vaccines that treat and protect millions of people around the world, with an innovative pipeline that could benefit millions more.

Sanofi is the largest biopharma manufacturer in Canada, and the only company investing, innovating and operating across the full life sciences value chain. We are 2,000+ employees strong, invest 20% of our revenue annually in biopharma research, and are on track to deliver over \$2 billion in new infrastructure investments by 2028. Sanofi is committed to our community and is working with partners to foster a long-term sustainable ecosystem and build a healthier Canada.

ⁱ BEYFORTUS Product Monograph, Sanofi Pasteur Limited, June 14, 2024

ⁱⁱ Simoes EAF. *Lancet* 1999; 354: 847-852

ⁱⁱⁱ An Advisory Statement, National Advisory Committee on Immunization (NACI), Statement on the prevention of Respiratory Syncytial Virus (RSV) disease in infants, April 2024.

^{iv} Institut national d'excellence en santé et en services sociaux: BEYFORTUS^{MC}: Prévention des infections graves par le virus respiratoire syncytial chez l'enfant.

^v Public Health Agency of Canada. Accessed 21 February 2024. [Respiratory syncytial virus \(RSV\): Canadian Immunization Guide - Canada.ca](https://www.canada.ca/en/public-health/services/immunization/canadian-immunization-guide/canadian-immunization-guide-respiratory-syncytial-virus-rsv.html)

^{vi} Simoes EAF. *Lancet* 1999; 354:847-852

^{vii} Demont C et al. *BMC Infect Dis* 2021; 21(1) : 730, Sanchez-Luna M et al. *Curr Med Res Opin* 2016; 32(4) : 693-698, Kobayashi Y et. Al. *J Infect Dis* 2022; 226 :386-395, Yu J et al. *Emerg Infect Dis* 2019; 25(6) : 1127-1135, Thwaites R et al. *Eur J Pediatr* 2020; 179(5): 791-799, Arriola C et al. *J Pediatric Infect Dis Soc* 2020; 8(12): 2048.

^{viii} Pisesky et al. *PLoS one* 11.3 (2016): e0150416

^{ix} Abrams EM, Doyon-Plourde P, Davis P, Brousseau N, Irwin A, Siu W, et al. Burden of disease of respiratory syncytial virus in infants, young children and pregnant women and people. *Canada Communicable Disease Report*. 2024 Feb;50(1/2):1-15. <https://doi.org/10.14745/ccdr.v50i12a01>.

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