

Respiratory syncytial virus (RSV) vaccine guideline statement

RSV is responsible for seasonal outbreaks of respiratory tract illness, which in the northern hemisphere peak in January to February. It is not reliably distinguishable from other respiratory tract illness (e.g. influenza) in the absence of laboratory testing. The main population groups at risk of significant disease include: infants <6 months of age (particularly those born premature), children with various comorbidities, and adults age ≥ 60 years with comorbidities and other factors.* The treatment of RSV infection is supportive in general; however, in certain high risk populations there is some evidence to support specific antiviral therapy.

RSV morbidity and mortality. RSV has not been identified as an important HIV-related opportunistic pathogen, although in one jurisdiction, PLWH (persons living with HIV) were found to have a greater risk of hospitalization with RSV infection compared to the general population. Surveillance in North America has shown that among adults aged ≥ 50 years who were hospitalized for RSV infection the mortality rate was 6-8%.

Vaccine efficacy. The first RSV vaccine (Arexvy, Glaxo Smith Kline, GSK) was approved by Health Canada in August of 2023. It is not a live vaccine, but an adjuvanted recombinant stabilized prefusion F protein vaccine. In a large randomized, placebo-controlled study the vaccine was approximately 75% effective in preventing symptomatic, laboratory-confirmed RSV-associated lower respiratory tract infection. The studies done to date have not been powered to clarify the level of protection provided by the vaccine against outcomes such as hospitalization or mortality.

Vaccine safety. Arexvy was generally well-tolerated, although reactogenicity events (e.g., transient inflammation at the injection site) occurred in 3.8% of vaccinees compared to 0.9% of those of who received placebo injections. Until post-marketing surveillance studies are available in a larger number of vaccinees, it remains unclear as to whether there may be rare (occurring in $\geq 1/10,000$ to $< 1/1,000$ of vaccinees), but more serious vaccine-related adverse events. Arexvy may be administered to immunocompromised individuals. It is contraindicated for persons with a history of severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine.

Current role of RSV vaccine. The Canadian National Advisory Committee for Immunizations (NACI) has not yet published their recommendations with respect to RSV vaccination for the 2023/2024 season. However, it has been recommended by the CDC (Atlanta) for older adults (age ≥ 60 years) with various comorbidities.* Specific recommendations with respect to PLWH are not available and it remains unclear as to whether those with a CD4 < 200 cells/ μl (or $< 15\%$) or detectable HIV RNA may respond differently to the vaccine. Given the limited vaccine safety data to date and the incomplete efficacy data for severe RSV outcomes, health care providers are advised to offer the vaccine to those at high risk of RSV aged ≥ 60 years in the context of shared decision-making, including a discussion taking into account the following: risk of disease, patient's values and preferences, and vaccine risk-benefit considerations.

RSV vaccine cost. Currently, in British Columbia, the cost of RSV vaccine is not being covered, at least for the 2023/2024 respiratory virus season; however, individuals with health care benefit

plans may have coverage (the cost for uninsured individuals may be up to \$300 per dose). Individuals who are eligible and interested in receiving the RSV vaccine (Arexvy) can purchase it from [select BC pharmacies](#); appointments can be booked online or by phone.

Recommendation: PLWH (as for the general population) aged ≥ 60 years who are at high risk for severe RSV disease should be offered a single dose of an RSV vaccine (RSVPreF3 [Arexvy, GSK] 0.5 mL IM) by way of shared clinical decision-making.

***RSV risk factors:** comorbidities including: chronic lung (e.g., COPD, asthma) or cardiac disease (e.g., congestive heart failure, coronary artery disease); moderate to severe immunocompromise; diabetes; neurologic or neuromuscular conditions; kidney, liver, or hematologic disorders; and factors associated with increased risk including frailty, advanced age, and residence in a nursing home or long-term care facility.

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