



# SUMMARY OF NATIONAL ADVISORY COMMITTEE ON IMMUNIZATION (NACI) RAPID RESPONSE OF SEPTEMBER 23, 2022

Updated interim guidance on Imvamune® in the  
context of ongoing monkeypox outbreaks



**TO PROMOTE AND PROTECT THE HEALTH OF CANADIANS THROUGH LEADERSHIP,  
PARTNERSHIP, INNOVATION AND ACTION IN PUBLIC HEALTH.**

— Public Health Agency of Canada

Également disponible en français sous le titre :  
Résumé de la réponse rapide du CCNI : Mise à jour des directives provisoires sur l'Imvamune<sup>MD</sup>  
dans le contexte des éclosions actuelles de variole simienne

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# OVERVIEW

- On September 23, 2022, the Public Health Agency of Canada (PHAC) released updated guidance from the National Advisory Committee on Immunization (NACI) on the use of the Imvamune® vaccine in the context of ongoing monkeypox outbreaks in Canada.
- This updated guidance is based on current evidence and NACI's expert opinion and builds on NACI's interim guidance on the use of Imvamune® in the context of monkeypox outbreaks in Canada published on June 10, 2022.
- This updated guidance includes recommendations on the use of Imvamune® for pre-exposure vaccination and dose-sparing strategies that may be considered to maximize vaccine coverage when supply is limited.
- In developing these recommendations, NACI considered the epidemiology of ongoing Canadian and international monkeypox outbreaks, the growing evidence on the safety and protection offered by the Imvamune® vaccine against monkeypox, the current and projected supply of Imvamune® in Canada and feedback from stakeholder groups representing individuals considered most at risk for infection.
- **In the context of an active monkeypox outbreak, NACI recommends that the Imvamune® vaccine should be offered as pre-exposure vaccination to individuals with highest risk of monkeypox\*. Pre-exposure vaccination is when Imvamune® is administered before known exposure to the virus. After considering the current and projected outbreak epidemiology, NACI recommends the following individuals be considered for pre-exposure vaccination (*Strong NACI Recommendation*):**
  - Men who have sex with men (MSM)\*\*, and individuals who have sex with MSM, and who meet at least one of the following criteria:
    - Having two or more sexual partners or who are in a relationship where at least one of the partners has other sexual partners
    - Having had a confirmed sexually transmitted infection in the past year
    - Engaging in sexual contact in sex-on-premises venues
  - Individuals who self-identify as sex workers, regardless of self-identified sex/gender
  - Staff or volunteers in sex-on-premises venues where workers may have contact with objects or materials that may be contaminated with the monkeypox virus without the use of personal protective equipment

\*Those with a history of monkeypox infection do not need to be vaccinated.

\*\*Within its men who have sex with men (MSM) definition, NACI includes any man or Two-Spirit-identifying individual who has sex with another person who identifies as a man, including but not limited to: individuals who self-identify as trans-gender, cis-gender, two spirit, gender-queer, intersex, and non-binary who also identify as gay, bisexual, or pansexual.

- **In the context of the ongoing monkeypox outbreaks and limited vaccine supply, dose sparing strategies, including extended dosing intervals and fractional dosing, should be considered to maximize vaccine coverage for those at highest risk of exposure to the monkeypox virus. (Strong NACI Recommendation)**
  - First doses of Imvamune® can be prioritized for immunocompetent adults at highest risk of exposure to the virus. Second doses should be offered as soon as demand for first doses has been met. This may result in an extended interval strategy, where the second dose is offered beyond the minimum authorised interval of 28 days.
  - Individuals at highest risk of exposure who are moderately to severely immunocompromised should be prioritized to receive two doses of Imvamune® with 28 days between each dose.
  - Off-label intradermal administration of a fractional dose (1/5<sup>th</sup> volume) can be offered to immunocompetent adults for a second dose, following a first full dose administered subcutaneously.
  - Individuals at highest risk of exposure who are under 18 years of age, at risk of keloid scars or moderately to severely immunocompromised should only be offered the vaccine using the subcutaneous route of administration.
- **When vaccine supply is adequate, NACI recommends that Imvamune® pre-exposure vaccination should be offered as a two-dose primary series, with at least 28 days between doses, to individuals at highest risk of monkeypox. (Strong NACI Recommendation)**

For the full rapid response, including supporting evidence and rationale, please see [NACI Rapid Response: Updated interim guidance on Imvamune® in the context of ongoing monkeypox outbreaks.](#)

- **NACI continues to recommend the use of Imvamune® as post-exposure vaccination for individuals who have had a high risk exposure to a probable or confirmed case of monkeypox, or within a setting where transmission is happening.**

For more information on this recommendation, please see the June 10, 2022 [NACI Rapid Response: Interim guidance on the use of Imvamune® in the context of monkeypox outbreaks in Canada.](#)

## WHAT YOU NEED TO KNOW

- In May 2022, cases of monkeypox were reported in a number of countries where it is not usually seen. In June 2022, in response to the outbreaks in Canada, NACI provided guidance on the use of the Imvamune® vaccine for post-exposure vaccination.
- Provinces and territories experiencing ongoing monkeypox outbreaks have built on NACI's initial guidance in order to respond to the reality of the outbreaks. Jurisdictions experiencing active outbreaks have expanded eligibility for the Imvamune® vaccine beyond post-exposure use due to the difficulty in offering the vaccine after a potential exposure.
- In light of the ongoing outbreaks and the currently limited supply of the Imvamune® vaccine, Canadian provinces, territories and vaccine stakeholders indicated a need for updated guidance on the use of Imvamune® for pre-exposure vaccination and dose-sparing strategies that may be considered to maximize vaccine coverage when supply is limited.
- Evidence and details continue to emerge with regard to the 2022 monkeypox virus outbreaks, including symptoms, modes of transmission and groups who are at highest risk of exposure. Available information suggests that infection may be transmitted via close physical contact with someone who has monkeypox symptoms or through objects contaminated with the virus.
- The epidemiology of Canadian and international outbreaks has helped identify individuals and groups at highest risk of exposure to the virus. Men who have sex with men (MSM) and individuals who have sex with MSM have the highest risk of being exposed to the monkeypox virus, especially if they have multiple sex partners, have had a recent sexually transmitted infection or engage in sexual contact at sex-on-premises venues. Individuals who self-identify as sex workers and individuals who volunteer or work at sex-on-premises venues may also be at higher risk of exposure to the monkeypox virus.
- Although evidence is limited, one dose of Imvamune® is likely to provide some protection against monkeypox in the short-term when provided before exposure.
- Imvamune® is typically given subcutaneously, in the fatty tissue just under the skin.
- In the context of ongoing outbreaks and limited vaccine supply, one approach is to quickly and broadly offer a first full dose subcutaneously to people at highest risk and to consider a smaller intradermal dose (i.e., 1/5<sup>th</sup> volume) for second doses, once demand for first doses has been met. A smaller intradermal dose, administered between layers of the skin, is expected to generate a similar immune response to a full dose administered subcutaneously. This unique solution balances what is known about different vaccination strategies, principles of vaccinology, and feasibility of vaccination programs. It may take time to train immunizers in the intradermal technique, which can be done while first doses are rolling out.

- Modelling based on Canadian supply projections suggest that expanding vaccine coverage by extending dose intervals and using one full dose of Imvamune® administered subcutaneously followed by one fractional dose (1/5<sup>th</sup> volume) administered intradermally could have short-term public health benefits and prevent infections when vaccine supply is limited.
- The United States Food and Drug Administration has authorised emergency use of fractional intradermal doses for immunocompetent adults who are not at risk of keloid scars, based on a clinical trial from 2015.
- NACI continues to recommend that Imvamune® may be offered to people who are immunocompromised, pregnant or breastfeeding or under the age of 18 if they are at highest risk of exposure, or following known exposure to the virus.
- Although data on the use of Imvamune® in these groups is limited, there are no known safety signals and people in these populations may particularly benefit from receiving the vaccine as they may be at increased risk for severe disease. An individual benefit-risk analysis should be conducted by a healthcare provider when offering the vaccine.
- Recommendations to consider Imvamune® for children under 18 years of age are off-label and should follow an individual benefit-risk analysis conducted by a healthcare provider.
- Immunocompetent individuals recommended for Imvamune® vaccination should receive a single dose if they have already been vaccinated with a live replicating 1st or 2nd generation smallpox vaccine. Individuals who are moderately to severely immunocompromised should receive two doses of Imvamune®, regardless of previous smallpox vaccination.
- Informed consent should include a discussion about the benefits, risks and uncertainties associated with the use of the Imvamune® vaccine against monkeypox.
- Provinces and territories continue to closely monitor and investigate outbreak dynamics and will determine how to best use the Imvamune® vaccine, informed by this NACI advice, in their jurisdictions.
- NACI continues to monitor the evolving epidemiology of the current monkeypox outbreaks, as well as the safety and effectiveness of the Imvamune® vaccine against monkeypox, and will update guidance as needed.

For the full rapid response, including supporting evidence and rationale, please see [NACI Rapid Response: Updated interim guidance on Imvamune® in the context of ongoing monkeypox outbreaks.](#)

For more information on post-exposure recommendations, please see the June 10, 2022 [NACI Rapid Response: Interim guidance on the use of Imvamune® in the context of monkeypox outbreaks in Canada.](#)

## QUOTES

“We have been closely following this outbreak over the summer, and learning from the Canadian experience. NACI is now recommending pre-exposure vaccination with Imvamune® vaccine for key populations where we anticipate it will help protect individuals who have been consistently at highest risk of exposure to monkeypox. When supply is constrained, NACI recommends that a “first dose fast” strategy will improve health equity by providing protection broadly within affected communities. After first doses of the vaccine are provided, another option that may be considered by provinces and territories is to provide second doses as fractional intradermal doses. The aim would be to use less supply, create more opportunities for vaccination, and provide a similar immune response as would be seen with the authorised dose.

All jurisdictions have shown flexibility in the outbreak response, responding to the reality of the outbreak in their jurisdiction, and leveraging strong partnerships with communities to implement the vaccine programs to date. We are prepared for continued flexibility and updates as we learn more about this disease and the best ways to prevent it.”

- Dr. Robyn Harrison, NACI Vice-Chair

“Canada continues to experience monkeypox virus outbreaks with the vast majority of cases occurring in the gay, bisexual and other men who have sex with men community. As we learn more, we are refining our response and control strategies, including vaccination approaches. Experience to date has demonstrated that offering the Imvamune® vaccine after a potential exposure is difficult to implement. However, we are able to offer the Imvamune® vaccine to populations at highest risk for exposure before a potential exposure occurs to provide better protection to these groups, including gay, bisexual and other men who have sex with men. In addition, vaccine dose-sparing strategies, such as extended dose intervals (and offering a 1/5<sup>th</sup> dose intradermally as the second dose), will be useful for provinces and territories to consider when vaccine supply is limited. These strategies can help maximize vaccination coverage among those at highest risk of exposure, while vaccine supply continues to increase over time. PHAC continues to support provinces and territories and communities in their efforts to manage monkeypox outbreaks.”

- Dr. Theresa Tam, Chief Public Health Officer