Ontario

Ministry of Health

Monkeypox Vaccine (Imvamune®) Guidance for Health Care Providers

Version 1.0 – June 14, 2022

This guidance provides basic information only. This document is not intended to provide or take the place of medical advice, diagnosis or treatment, or legal advice.

Ontario continues to monitor for cases of monkeypox and is working collaboratively with health care providers, Public Health Ontario (PHO) and the Public Health Agency of Canada (PHAC) to address health risk(s). New guidance will continue to emerge as new information becomes available and the epidemiology of this situation evolves.

Imvamune® Vaccine

Imvamune® is a live attenuated, non-replicating vaccine that is approved in Canada for protection against smallpox, monkeypox, and other orthopoxvirus related illness; it is 3rd generation smallpox vaccine. It is produced from the Modified Vaccinia Ankara-Bavarian Nordic (MVA-BN) strain of orthopoxvirus and was developed to provide an alternative for the vaccination of immunocompromised individuals and those with atopic dermatitis, who could not safely receive earlier generation (replicating) smallpox vaccines.

Health Canada first approved the use of this vaccine for active immunization against smallpox in a public health emergency in 2013. In 2020, Health Canada expanded approval of Imvamune® to include additional indications, specifically monkeypox and related orthopoxvirus infections in adults 18 years of age and older at high risk of exposure. The use of Imvamune® has not been studied in individuals less than 18 years of age or in those who are pregnant or breastfeeding.

Imvamune® can be used as post exposure prophylaxis (PEP) in individuals with a recent high-risk monkeypox exposure. This is based on evidence extrapolated from animal studies and historical experience with smallpox vaccine in humans which suggest that vaccination after an exposure to monkeypox infection may prevent infection or lessen disease severity in those who become infected.

Individuals who are hypersensitive to this vaccine or to any ingredient in the formulation or component of the container should not receive the vaccine. A list of ingredients (e.g., gentamicin, ciprofloxacin) can be found in the product monograph.

Individuals with signs or symptoms of monkeypox infection should not receive the vaccine as the vaccine is not indicated in the treatment of monkeypox infection.

Use of Imvamune® in Ontario

Given the current limited supply, Ontario is using a ring vaccination approach using a single dose of Imvamune® in locations with confirmed cases. This is to limit ongoing transmission with the explicit goal of preventing exportation of monkeypox to unaffected areas. This approach is continually being evaluated as the epidemiology evolves and vaccine supply expands.

Imvamune® should be considered for the following:

1) **For the Purposes of Pre-Exposure Prophylaxis (PrEP) in locations with confirmed cases**

Trans- or cis-gender individuals who self-identify as belonging to the gay, bisexual and other men who have sex with men (gbMSM) community AND at least one of the following:

- Have received a diagnosis of bacterial STI (i.e., chlamydia, gonorrhea, syphilis) in the past 2 months;
- Have had 2 or more sexual partners within the past 21 days or may be planning to;
- Have attended venues for sexual contact within the past 21 days (i.e., bath houses, sex clubs) or may be planning to, or who work/volunteer in these settings;
- Have had anonymous sex in the past 21 days (e.g., using hookup apps) or may be planning to;
- Engage in sex work or may be planning to, and their sexual contacts.

Individuals who are immunocompromised, pregnant, or breastfeeding may be at higher risk for severe illness from a monkeypox infection. These individuals should contact their local public health unit for consideration of PrEP if they are at risk for contracting monkeypox.

2) For the Purposes of Post-Exposure Prophylaxis (PEP) throughout Ontario

The provision of Imvamune® for PEP requires an assessment of the risk of exposure by the public health unit. **A single dose** of the vaccine should be offered ideally within 4 days (up to 14 days) from the date of the last exposure to individuals who are a high risk contact of a confirmed or probable case of monkeypox.

Any one who self-identifies as a high risk contact of a confirmed or probable case of monkeypox should contact their the local public health unit for further assessment to see if PEP would be recommended.

Intermediate risk contacts may also be offered PEP, following the public health unit's assessment of individual risks and benefits (i.e., to balance the risks from exposure, protection from vaccination and potential side effects from the vaccine).

Low risk contacts are also not recommended for PEP.

Table 1. Recommendations for Post-exposure Prophylaxis (PEP) according to risk of infection

Risk of exposure[1]	**PEP**
High	Recommended
Intermediate	May be recommended based on the public health unit's assessment of risks and benefits
Low	Not recommended
No/very low	Not recommended

[1] Monkeypox Virus: Interim Case and Contact Management Guidance for Local Public Health Units

Table 2: Use of Imvamune® in Special Populations

Special Population:	Imvamune® use indication
Immunocompromised	Clinical trials of Imvamune® have included people living with human immunodeficiency virus (HIV) with a CD4 count of equal or greater than 100. There is less experience in individuals with severe immunosuppression. Additional risk/benefit discussion is indicated for those with severe immunosuppression prior to receiving vaccine as PEP.
Pregnancy and Breastfeeding:	There are very limited data on the use of Imvamune® in pregnancy. No clinical trials have been conducted in pregnant individuals, although approximately 300 pregnancies have been reported to the manufacturer with no safety issues identified. There is no data on whether the vaccine is excreted in breastmilk, although this is unlikely as the vaccine is nonreplicating. Additional risk/benefit discussion is indicated for those who are pregnant or breastfeeding prior to receiving vaccine as PEP.
Children and Youth	Imvamune® vaccine is not authorized for use in persons under 18 years of age, and has not been studied in this age group, although it has been offered to children as PEP in previous United Kingdom monkeypox incidents as cited in UK PEP guidance. Clinical trials have studied other vaccines (TB and malaria) using Modified Vaccinia Ankara (MVA) as a vector in children with a reassuring safety profile. Additional risk/benefit discussion is indicated for persons under 18 years of age prior to receiving vaccine as PEP.
Persons with Atopic Dermatitis	Persons with atopic dermatitis may have more frequent and more intense reactions after vaccination. This population was specifically studied in clinical trials as those with a history or presence of atopic dermatitis are contraindicated to receive the previous generation of smallpox vaccine (ACAM2000).

3) Potential Side Effects of Imvamune®

The most common side effects include reactions at the injection site like pain, erythema, induration and swelling. The most common systemic reactions observed after vaccination are fatigue, headache, myalgia, and nausea. Most of the reported adverse drug reactions observed in clinical trials were of mild to moderate intensity and resolved within the first seven days following vaccination.

Older generation (i.e., replicating) smallpox vaccines have been associated with myocarditis. No case of myocarditis or pericarditis was identified in clinical trials of Imvamune®, however post market surveillance of vaccine recipients identified cardiac adverse events of special interest (AESIs) including asymptomatic troponin elevation, abnormal ECG findings, tachycardia, and palpitations. Cardiac AESIs were reported to occur in 1.4% (91/6,640) of Imvamune® recipients and 0.2% (3/1,206) of placebo recipients who were smallpox vaccine-naïve. Individuals should be counselled to seek medical attention if cardiac symptoms (i.e., chest pain, shortness of breath, palpitations) develop following vaccination with Imvamune®.

Informed Consent

The *Health Care Consent Act, 1996* provides specific information as to the consent required for treatment. According to the HCCA, and the College of Nurses of Ontario (CNO) and College of Physicians and Surgeons of Ontario (CPSO) standards, nurses and physicians are accountable for obtaining consent when providing treatment. It is therefore the responsibility of the health practitioner who is proposing the treatment to take reasonable steps to ensure that informed consent for that treatment is obtained.

According to the HCCA, consent to treatment for a capable person is informed if, before giving the consent:

a. the person received the information about the treatment that a reasonable person in the same circumstances would require to make a decision; and
b. the person received responses to his/her requests for additional information about the treatment.

This information must include:

- The nature of the treatment
- The expected benefits of the treatment
- The material risks of the treatment
- The material side effects of the treatment
- Alternative courses of action

- The likely consequences of not having the treatment.

The elements required for consent to treatment include:

- The client must have the capacity to consent
- The consent must relate to the treatment
- The consent must be informed
- The consent must be given voluntarily
- The consent must not be obtained through misrepresentation or fraud.

Evidence of Consent:

Although the HCCA states that consent to treatment may be expressed or implied (i.e., written or verbal), the CNO and CPSO strongly advise nurses and physicians to document that consent was obtained from the client. Examples include: 1) a signed consent form and/or 2) documented consent in the client's health records.

How to order Imvamune®

To order the vaccine, the local public health unit must email the Ministry of Health Emergency Operations Centre at EOCoperations.MOH@ontario.ca or call the Healthcare Provider Hotline at 1-866-212-2272.

Clinicians who think they have a patient (i.e., a contact of a case) who might be recommended to receive PEP using the criteria above should contact their local public health unit.

Co-Administration of Imvamune®

Data on co-administration of Imvamune® and other vaccines are not available. Therefore, it is recommended to not co-administer Imvamune® with other vaccines, and to reschedule any other vaccines until at least 14 days after administration of Imvamune®.

The administration of Imvamune® as post-exposure prophylaxis **should not be delayed** in an individual who has recently received another vaccine.

Storage Conditions

Please see Monkeypox Virus (gov.on.ca) for information on storing Imvamune®.

Reporting Adverse Events Following Immunization

Reports of any Adverse Event Following Immunization (AEFI) following Imvamune® vaccine should be made using the Ontario AEFI form and sent to the local public health unit. Please see Public Health Ontario's vaccine safety webpage and Fact Sheet –Adverse Event Following Immunization Reporting for Health Care Providers in Ontario for additional guidance.

Where can I get more information?

Imvamune® Product Monograph

Ontario Ministry of Health

Public Health Ontario

Public Health Agency of Canada

Additional Resources

Ontario - Monkeypox Virus (gov.on.ca)

World Health Organization – Monkeypox information

World Health Organization - Monkeypox Q&A (who.int)

European Centre for Disease Prevention and Control - Factsheet for health professionals on monkeypox (europa.eu)

United States Centers for Disease Control - Monkeypox | Poxvirus | CDC

Public Health Ontario - Monkeypox Case and Contact Management