Immunization Protocol for Imvamune®

Purpose	To provide information and guidance for monkeypox immunization in Nunavut for providers. Refer to the Canadian Immunization Guide (CIG), product monograph, or insert for additional information.
Objective	To protect at-risk Nunavummiut from the disease and potential health complications of the monkeypox virus
Indication	Nunavut's publicly funded program is offered to all Nunavummiut who meet eligibility criteria.

Eligibility	Individuals who meet the following criteria:
	• 18 years of age and older
	• Asymptomatic
	
	<u>Pre-exposure vaccination</u>
	• 18 years of age and older
	• Asymptomatic
	• 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 being in a relationship where at least one of the partners has other sexual partners
	  ○ Having had a confirmed sexually transmitted infection acquired in the last year
	  ○ Engage in sexual contact in sex-on-premises venues
	
	OR:
	• Individuals who self-identify as sex workers regardless of self- identified sex/gender
	
	OR:
	• Staff or volunteers in sex-on-premises venues where workers may have contact with fomites potentially contaminated with monkeypox, without the use of personal protective equipment
	
	<u>Post-exposure vaccination</u>
	• 18 years of age and older
	• Asymptomatic
	• Close contacts of a probable or confirmed case (in consultation with Chief Public Health Officer (CPHO)) or within a setting where transmission is known to be occurring.
	
	<u>Please see *Special Populations* section of this protocol for specific exceptions to the above criteria and additional information,</u>

Product	Imvamune®

Vaccine Type	Imvamune® is a live attenuated, non-replicating vaccine.
Vaccine Composition	Each vial of liquid-frozen Imvamune® is formulated to have a titer of at least 0.5 x 10^8 infectious units (Inf.U) per 0.5 mL (1 dose). <u>Non-medicinal Ingredients:</u> • Tris buffer (10 mM Tris containing 140 mM NaCl, pH 7.7): Tris-hydroxymethyl-amino methane, sodium chloride, water for injection and hydrochloric acid • Trometamol (0.61 mg/dose) (Tris-hydroxymethyl-amino methane), • Sodium chloride, • water for injection The product contains no preservatives and no adjuvants.
Formats available	Imvamune® is supplied as a single 0.5 mL dose in a 2 mL type I borosilicate glass vial closed with a sterile bromobutyl rubber stopper, crimped with an aluminum cap and covered with a polypropylene closure.
Manufacturer	Bavarian Nordic A/S Philip Heymans Alle 3 DK-2900 Hellerup Denmark
Vaccine ordering	Requests for the release of Imvamune® by the territorial pharmacy should be directed to the Regional Communicable Disease Coordinator (RCDC) who will consult with the office of the CPHO if there are questions or concerns about eligibility.
Storage	Imvamune® will be shipped to the health centre at -20°C ± 5°C. Once received, Imvamune® can be stored at -20°C ± 5°C for up to 3 months and should not be used after the date indicated by the Territorial Pharmacy in the shipping container. The vaccine can also be placed in the fridge and stored at 2°C – 8°C for up to 2 weeks prior to use. Do not use after the expiry date provided by the Territorial Pharmacy or after the date shown on the label, whichever is sooner. Do not refreeze a vial once it has been thawed. Store in the original package in order to protect from light.
Handling	Imvamune® should be thawed at room temperature. The single dose vial should be swirled gently (not shaken) for at least 30 seconds to ensure homogeneity upon thawing. The vaccine should appear as a semi-opaque white coloured homogenous suspension. The vaccine must not be used if any foreign particulate matter is visible. Reconstitution is NOT required.
Consent	Consent forms must be reviewed and signed by the individual receiving the vaccine prior to vaccine administration.
Administration	Subcutaneous (SC) injection in the outer aspect of the upper arm. Each vial is for single use only and should not be used for more than one individual. The entire contents of the vial should be injected.
Dose Series	The primary vaccination schedule consists of two doses of 0.5 mL four weeks apart administered by the subcutaneous route. Post-exposure prophylaxis (PEP) should be offered as soon as possible and within 4 days of last exposure but can be considered up to 14 days since last exposure.

	A second dose should NOT be offered to individuals who received a first dose of the vaccine for PEP, are symptomatic and after medical evaluation meet suspect, probable or confirmed monkeypox case definitions. For immunocompetent individuals who have received a live replicating 1st or 2nd generation smallpox vaccine in the past and who are at high risk, a single dose of Imvamune® may be offered (i.e., as a booster dose), rather than the two dose primary vaccine series). This single Imvamune® dose should be given at least two years after the latest live replicating smallpox vaccine dose.
Special Populations	Imvamune® vaccine may be considered in the following populations in consultation with the RCDC based on exposure risk: • Individuals who are immunocompromised due to disease or treatment • Individuals who are pregnant • Individuals who are lactating • Children and youth <18 years of age • Individuals with atopic dermatitis
Booster Dose	Not available currently.
Vaccine interchangeability	There is no vaccine interchangeability for Imvamune®
Contraindications	• Patients who are hypersensitive to this vaccine or to any ingredient in the formulation or component of the container. For a complete listing, see *Vaccine Components* section of this protocol • Individuals who show hypersensitivity reactions after receiving the first dose of the vaccine should not be given the second dose. As with other vaccines, vaccination with Imvamune® must be postponed in persons with acute febrile conditions if used for non-emergency (pre-exposure) prophylaxis.
Drug-Drug Interactions	Use with other vaccines: Interactions with other vaccines have not been established. Therefore, concomitant administration of other vaccines should be avoided. To minimize the potential risk of interactions, it is recommended to administer non-live vaccines > 2 weeks and live or mRNA (including COVID) vaccines ≥ 4 weeks before or after administration of Imvamune®. However, there may be times when it is appropriate for Imvamune® to be given as PEP or PrEP without waiting for the above intervals to elapse. In the event of an urgent or emergency need to provide prophylaxis against Monkeypox, please consult the PHO on-call in instances where Imvamune® is indicated for individuals who have received a vaccine within the timeframes noted above. Use with immunoglobulins: Interaction with concomitant administration of immunoglobulins has not been established. Use with other medications: Interactions with other drugs have not been established.
Precautions and Additional Notes	The benefit of protection against infection should be discussed with a client and weighed against the potential risk of recurrent myocarditis for individuals with a history of myocarditis/pericarditis linked to a previous dose of live replicating 1st and 2nd generation smallpox vaccine and/or Imvamune®. A precautionary approach is warranted at this time until more information is available.[2]

Anaphylaxis	Review the principles of the emergency management of anaphylaxis in the Nunavut Immunization Manual Section 3 (3.7). Further information can be found in the *Anaphylaxis* section of the Canadian Immunization Guide.
Side Effects	The most common local reactions at the injection site after vaccine administration are pain, erythema, induration and swelling. The most common systemic reactions observed after vaccination are fatigue, headache, myalgia, and nausea. Most of the reported side effects were of mild to moderate intensity and resolved within the first seven days following vaccination.
Reportable Adverse Events/Side Effects	Report all serious adverse events, unusual/unexpected events or administration errors to the RCDC. Review section 3.5 (paying close attention to section 3.5.4 *Summary of Reporting Criteria*) in the Nunavut Immunization Manual. A Report of adverse events following immunization (AEFI) (canada.ca) form must be completed and submitted to the RCDC. No trends have been identified suggesting the occurrence of any particular unexpected adverse reactions or classes of adverse reactions following the administration of Imvamune®. During clinical trials, cardiac adverse events were reported to occur in 1.4% Imvamune® recipients and 0.2% of placebo recipients who were smallpox vaccine-naïve. Cardiac adverse events were reported to occur in 2.1% of Imvamune® recipients who were smallpox vaccine-experienced.
Documentation	All immunizations given should be documented on the Immunization Card, chart, personal immunization record, and electronic record.
Materials and Resources	All protocols and materials are available on the Government of Nunavut Department of Health website (www.gov.nu.ca/health) Imvamune® Consent Form Imvamune® Fact Sheet Monkeypox Fact Sheet Nunavut Immunization Manual Manuals / Guidelines | Government of Nunavut Canadian Immunization Guide Canadian Immunization Guide - Canada.ca Report of adverse events following immunization (AEFI) for Report of adverse events following immunization (AEFI) (canada.ca)
Appendices	Appendix A – Instructions for flipping off cap for Imvamune®
References	1. Government of Canada. Health professional risk communication. IMVAMUNE Vaccine: Updated Storage Conditions and Shelf Life. Available at: IMVAMUNE Vaccine: Updated Storage Conditions and Shelf Life - Canada.ca 2. An Advisory Committee Statement (ACS) National Advisory Committee on Immunization (NACI): NACI Rapid Response – Interim guidance on the use of Imvamune® in the context of monkeypox outbreaks in Canada. Available at: guidance-Imvamune-monkeypox-en.pdf (canada.ca)
Approved by the Chief Public Health Officer on October 12, 2022 Department of Health, Government of Nunavut	

Instruction for flipping off cap for IMVAMUNE.

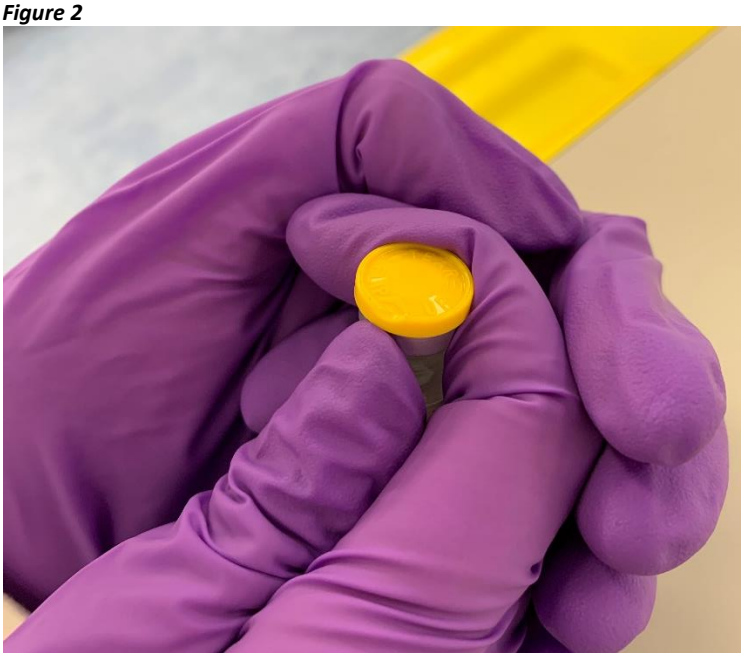
1. On the cap there is a mark for where to flip up the yellow plastic cap, see figure 1a and 1b.

Figure 1a

Figure 1b

2. Hold the vial in your hands and use your thumb to flip up the cap where indicated. See figure 2.

Figure 2



3. Carefully open/flip off the yellow cap to a 90° angel. See figure 3a and 3b.

Figure 3a

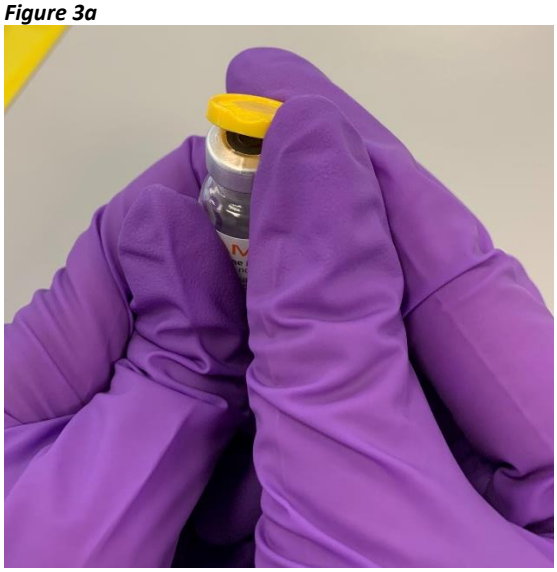


Figure 3b

4. Let the cap stay on the metal crimp cap or alternatively flip it all the way off and let the metal crimp cap stay on the stopper/vial to ensure stopper is still fixed to the vial.
See figure 4.

Figure 4

5. Extract volume for vaccination using a needle and syringe through the indicated circle on the rubber stopper.