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1. BACKGROUND

1.1. About this document

This Protocol provides information on JYNNEOS, a vaccine indicated for the prevention of smallpox and mpox disease in adults 18 years of age and older. JYNNEOS has been made available in Australia under Section 18A of the *Therapeutic Goods Act 1989 (Cth)*.

Vaccination will be offered to those who are determined to be at high risk of mpox infection, or susceptible to detrimental sequelae should they develop disease. At the direction of the NSW Chief Health Officer (CHO), vaccination may be advised for those at occupational risk of smallpox or mpox exposure, including staff working in high level biocontainment facilities or laboratory workers who are likely to be in close contact / care of patients or handling biohazardous samples from infected patients.

This Protocol is for use by health practitioners who have been identified by the CHO as vaccination providers and will order or administer the Vaccine. Compliance with this Protocol is mandatory.

Authorised settings for administration of the Vaccine are limited to those designated by the CHO. Vaccination in other settings is not legally permitted.

This Protocol contains protocols for:

- JYNNEOS vaccine administration

The requirements set out in this Protocol are directions of the CHO for the purposes of the *Therapeutic Goods (Medicines – MVA-BN) (Emergency) Exemption) (No.3) 2022* (as amended from time to time).

1.2. Key definitions

CHO	The New South Wales Chief Health Officer.
Medication	Used singularly throughout the Protocol to describe a drug, medicine, pharmaceutical preparation, therapeutic substance, and vaccine.
Public Health Organisation	A local health district, or statutory health corporation, or an affiliated health organisation in respect of its recognised establishments and recognised services.
Public Hospital	Any public hospital as defined in the Health Services Act 1997 (NSW)
S100 Prescriber	A medical practitioner authorised to prescribe section 100 highly specialised drugs under the *National Health Act 1953*, including but not limited to HIV and hepatitis B & C therapeutics.
Supply	Includes to administer medications to a group or a specific patient and is consistent with the definition of supply in section 4 of *the Poisons and Therapeutic Goods Act 1966*. Includes administration of a single dose for prophylaxis by an authorised health practitioner.
Vaccine	The JYNNEOS vaccine, a 3rd generation smallpox vaccine manufactured by Bavarian Nordic.

1.3. Training requirements

The following training requirements must be met by medical practitioners and any registered nurses acting under the direction of a medical practitioner prior to administration of the JYNNEOS vaccine

- current cardio-pulmonary resuscitation (Basic Life Support) competency.
- received prior training to recognise and manage anaphylaxis including the use of adrenaline (epinephrine).
- remain up to date on any new advice from the Australian Technical Advisory Group on Immunisation (ATAGI) or Therapeutic Goods Administration (TGA) regarding additional precautions or consent requirements. The Public Health Organisation or sexual health service will ensure up to date resources are provided to the service.

2. IMPLEMENTATION OF PROTOCOL

2.1. Prerequisites for medical practitioners administering the Vaccine

Medical practitioners operating under this Protocol must:

- Have read and understood this Protocol and comply with the Protocol in relation to the administration of the Vaccine and the selection of targeted persons to receive the Vaccine.
- Practice in accordance with any practice conditions imposed by the person's place of employment and the endorsements, notations and conditions on the person's registration.
- Ensure informed consent is obtained from the patient by a medical practitioner prior to Vaccine administration. The medical practitioner may direct a registered nurse to conduct consenting procedures on their behalf where the medical practitioner supervises and ensures that the consent was properly obtained. For the avoidance of doubt, supervision by the medical practitioner can occur by telehealth.
- Ensure records relating to the administration of the Vaccine are retained in the medical record and are uploaded to the Australian Immunisation Register (AIR) unless the patient makes a specific request that their vaccination is not recorded in the AIR.

2.2. Public Health Organisations and S100 Prescribers

The Vaccine may be administered by registered nurses only at the direction and under the authority of a medical practitioner.

Public Health Organisations and S100 prescriber settings must ensure that consent has been obtained from the patient and that the registered nurse administers a Vaccine on the direction of a medical practitioner.

Public Health Organisations and S100 prescriber settings must have processes in place to periodically assess compliance with this Protocol and take appropriate action where any aspect of non-compliance is identified. The CHO may request evidence of the compliance with this Protocol and relevant records which Public Health Organisations and S100 prescribers are required to keep under this Protocol.

3. VACCINE INFORMATION

3.1. General Information

JYNNEOS is a 3rd generation smallpox vaccine. It is a live vaccine produced from the strain modified vaccinia Ankara-Bavarian Nordic (MVA-BN), an attenuated, non-replicating orthopoxvirus, and cannot replicate in the human body. The Vaccine is expected to protect against both the smallpox and mpox viruses.

JYNNEOS is considered safe to use in people who are immunocompromised, in pregnant women and while breastfeeding. It is indicated for use in adults aged 18 years and older considered at risk for mpox infection.

JYNNEOS has not been formally studied in children aged under 18 years. However, there are trial data on safety in children of MVA-BN used as the vaccine delivery platform for a small number of childhood vaccines.

The Australian Technical Advisory Group on Immunisation (ATAGI) advises that vaccination with JYNNEOS in children can be considered, especially for individuals in high-risk groups aged 16 years and older, after discussing the benefits and the potential harms of vaccination with their immunisation provider.

Vaccination with JYNNEOS may be used for both pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP).

JYNNEOS must only be administered by subcutaneous injection in the deltoid.

For PrEP, a complete vaccination course with JYNNEOS requires two doses, which must be given at least 28 days apart.

If a vaccine course was commenced using the intradermal route for the first dose, it can be completed by subcutaneous injection for the second dose.

There is evidence showing that the first dose may provide a moderate level of protection after around two weeks. Optimal coverage is reached two weeks after the second dose.

People who have previously had a smallpox vaccine, including any doses of JYNNEOS, may still get mpox if they are exposed to an infected person. People at high risk of mpox infection who have received a smallpox vaccine dose more than ten years prior are recommended to receive a booster dose.

For PEP, a single dose is recommended for protection against contracting mpox infection and attenuating disease/symptoms. It is ideally offered within 4 days of last exposure, although may be offered up to 14 days in those at ongoing risk, or those who are at higher risk of the complications of mpox.

3.2. Supply and use

JYNNEOS is supplied with a package of 20 single-dose vials. The dimensions of the pack are: L: 9.8 x W: 12.90 x H: 4.7 cm.

JYNNEOS must be supplied and used ONLY at the direction of the CHO in accordance with this Protocol. The requirements set out in this Protocol are the directions of the CHO for the purposes of the *Therapeutic Goods (Medicines – MVA-BN) (Emergency) Exemption) (No.3) 2022* (as amended from time to time).

3.3. Storage, distribution and handling

JYNNEOS will either be stored frozen or at +2°C to +8°C prior to distribution. It should be stored in its original packaging to protect from light. Once de-frosted it must not be re-frozen.

JYNNEOS will be distributed at the direction of the CHO to locations within NSW.

For distribution, the Vaccine will be transported either frozen or at +2°C to +8°C to designated vaccination providers or the hospital pharmacy.

If received frozen, the Vaccine can be stored frozen at -20°C or -50°C. Otherwise the Vaccine must be stored at +2°C to +8°C, it must not be re-frozen. It is stable for 24 weeks if it is brought to this temperature directly from prior storage at -50°C. [Note: storage for 24 weeks at +2°C to +8°C is based on advice from officers of the Commonwealth Department of Health, and it is different to advice in the JYNNEOS® Package Insert FDA (appendix A) which advises that once thawed, the Vaccine may be kept at +2°C to +8°C (+36°F to +46°F) for 12 hours].

If frozen, before use the Vaccine must be thawed at room temperature for approximately 10 minutes. Vials must not be re-frozen once they have been thawed.

The Vaccine must not be used after the expiration date shown on the vial/carton label, nor beyond 24 weeks after thawing from -50°C (or 12 hours if thawed from -20°C).

The Vaccine can only be moved from one provider to another in accordance with the conditions set out in the "Licence to supply by wholesale poisons and restricted substances – Licence No LHD 005" dated 20 December 2022 (as amended from time to time) (**Licence**). The Licence requires the licensee to comply with the directions regarding the Vaccine as set out in this Protocol (as amended from time to time at the direction of the CHO).

Cold chain breaches should be reported to the public health unit (PHU) who must send the details of the breach to MOH-VaccReports@health.nsw.gov.au for further advice.

3.4. Record-keeping and disclosure

Vaccine administration must be recorded into the eMR and / or other specific vaccination record for loading the information up to the Australian Immunisation Register (AIR). Patients without a Medicare Card can be registered via the Individual Health Identifier (IHI) process. If Vaccine administration is not recorded on AIR, clinics must be able to provide a record of Vaccine use.

Suspected adverse events following immunisation (AEFI) can be reported by contacting the local PHU on 1300 066 055 or by reporting it directly to the TGA. It is advised to report all uncommon, serious or unexpected AEFI. The form can be found in Appendix G. Further information about AEFI can be found here.

The CHO will keep records relating to the quantity, location, storage, transportation, supply, use and disposal of the Vaccine. Providers will keep a record of Vaccine received, used and disposed and these are required to be provided to the CHO upon request.

3.5. Disposal

Unusable Vaccine and Vaccine waste products will be disposed of in designated clinical waste bins for destruction. The CHO will direct unused vaccine to another designated vaccination provider of increased need.

4. Vaccination priority groups and vaccination sites

4.1. Vaccine eligibility

As a result of receiving additional vaccine supplies, NSW now has sufficient vaccine to vaccinate the following persons at greatest risk of mpox:

- All sexually active gay and bisexual men (cis and trans)
- Sexual partners of the people above
- Sex workers
- Anyone at greater risk of a poor clinical outcome from mpox infection, such as individuals with a compromised immune system.

4.2. Additional groups for vaccination

The following groups should also be prioritised for vaccination:

- Post Exposure Prophylaxis for close contacts of known mpox cases (ideally within 4 days of last exposure but up to 14 days since last exposure)
- Laboratory workers that are performing mpox virus culture where the virus is amplified
- Health care workers who may be involved in the care of persons with mpox.

This is applicable as at the date of this Protocol; however, it is subject to revision.

4.3. Designated locations for vaccination

Vaccination (including for PEP) can occur at any of the following locations:

- S100 prescriber sites as designated by the CHO
- Publicly funded NSW sexual health and community centres as designated by the CHO
- Publicly funded NSW Mpox vaccination clinics as designated by the CHO
- Justice Health and Forensic Mental Health Network approved vaccination sites as designated by the CHO
- A designated NSW Health vaccination clinic sanctioned by a Local Health District.

Vaccination for PEP can also occur at any Public Hospital. The public health unit of the LHD is responsible for determining how PEP can be delivered safely in the Public Hospital, in consultation with the LHD Director of Clinical Governance, and the relevant facility general manager. These pathways must be developed in advance and may include the direction of the person to an Emergency Department. This includes identification of separate patient waiting areas, streamlined administration to reduce risk of transmission and follow up pathways.

For additional guidance on the provision of PEP refer to the Post exposure prophylaxis (PEP for mpox in NSW protocol at Appendix F).

Providers should maintain familiarity with the Australian Technical Advisory Group on

Immunisation clinical guidance for mpox vaccination.

5. ADRENALINE (EPINEPHRINE) FOR ANAPHYLAXIS

Anaphylaxis must be managed as per the *Anaphylaxis after vaccination* guidance, found in Appendix E.

In addition, advice in the Australian Immunisation Handbook must be followed.

6. PROTOCOL FOR ADMINISTRATION OF THE JYNNEOS VACCINE

Below is the protocol for administration of the JYNNEOS smallpox/mpox vaccine for people 18 years of age and over, in authorised settings.

TITLE	Protocol for JYNNEOS® vaccine
Drug(s)	**JYNNEOS smallpox vaccine**
Presentation[1]	If the Vaccine is received frozen, it must be allowed to thaw at room temperature before administration. Once thawed, it should not be frozen again. Store vials at +2 to +8 °C. (Refrigerate. Do not freeze. Discard after 24 weeks if defrosted from -50°C or 12 hours if thawed from -20°C) One vial provides one dose subcutaneously of 0.5 mL. Once thawed, JYNNEOS® is a milky, light yellow to pale white colored suspension. It should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. If either of these conditions exists, the Vaccine should not be administered. **Always maintain cold chain storage and protect from light.**
Indication[2]	• see section 4.1
Contraindications[1]	Hypersensitivity to the active substance or to any of the excipients (tromentalmol, sodium chloride, water for injections) or trace residues (chicken protein, benzonase, gentamicin and ciprofloxacin).
Precautions[1]	• Persons who experienced a severe allergic reaction following a previous dose of JYNNEOS® or following exposure to any component of JYNNEOS may be at increased risk for severe allergic reactions after JYNNEOS. The risk for a severe allergic reaction should be weighed against the risk for disease due to mpox • Immunocompromised persons, including those receiving immunosuppressive therapy, may have a diminished immune response to JYNNEOS. They should receive Vaccine subcutaneously. • Vaccination with JYNNEOS may not protect all recipients • Persons should be screened for symptoms of mpox to ensure that they do not already have clinical illness • JYNNEOS may be given concomitantly with other vaccines. Whether JYNNEOS is associated with a risk of myocarditis is uncertain. For PrEP

	purposes only, spacing JYNNEOS and an mRNA COVID-19 vaccine apart by several weeks may be considered for people with increased risk of myocarditis and/or pericarditis following an mRNA COVID-19 vaccine, (e.g. young adult males). • Bleeding disorders or anticoagulation are not a contraindication. • Pregnancy and breastfeeding are not contraindications.
Dose[1]	0.5 mL suspension administered subcutaneously for patients 18 years and older.
Dose frequency[1]	Post-exposure prophylaxis: a single dose Pre-exposure prophylaxis: two doses - a second dose should be administered at least four weeks after a first dose**.**
Administration[1]	Swirl the vial gently before use for at least 30 seconds. **Subcutaneous injection:** Withdraw a dose of 0.5 mL into a sterile syringe for injection. Administer JYNNEOS by **subcutaneous injection**, preferably into the upper arm (in the region of the deltoid muscle).
Drug Interactions[1]	No interaction studies with other vaccines or medicinal products have been performed.
Adverse effects[1]	JYNNEOS has a good safety profile. The main adverse events seen in clinical trials include local injection site irritation (increased frequency in people with atopic dermatitis), myalgia, fatigue, fever, chills, nausea, and headache. For further information on adverse effects, please refer to the product information.
Documentation[3]	• Explain risks and possible adverse effects, provide patient information sheet on the JYNNEOS vaccine and obtain informed consent. • Advise patient they may be contacted by SMS or email in the following week to check for side effects, as part of Vaccine safety surveillance. • Record vaccination on the Australian Immunisation Register (AIR) and advise patient their vaccination record can be accessed through the Express Plus Medicare mobile app, MyGov, or My Health Record. • Report adverse events to the TGA using AEFI form (see appendix).

[1] The drug information provided in this protocol is to act as a guide only. For comprehensive information, refer to the latest manufacturer's product information. If any contraindications, precautions or other concerns in relation to suitability for treatment are identified, refer to a medical practitioner.

[2] Emergency approval granted based on overseas known efficacy and safety data. Continued approval depends on the evidence of longer-term efficacy and safety from ongoing assessment.

[3] Informed consent must be obtained by a medical practitioner.

If expert advice is needed, the medical officer can contact the NSW Immunisation Specialist Service (NSWISS) on 1800 679 477.

7. PROCEDURE FOR VACCINE ADMINISTRATION

7.1. Procedure for preparing for vaccine administration

This Protocol allows for administration of the Vaccine where the patient does not have a relevant precaution or contraindication to treatment. Where a relevant precaution or contraindication exists, treatment (JYNNEOS vaccination) can only proceed under the direct authority of a medical practitioner.

The following steps must be followed when preparing for Vaccine administration.

All assessments and details relating to the administration of the Vaccine must be documented.

Procedure:

- Practice according to this Protocol for JYNNEOS administration and its supporting documents (see Appendices)
- Arrange the supply of the Vaccine from the designated supply point. The immuniser must ensure an anaphylaxis kit is available. This includes adrenaline (epinephrine),1mL syringes, 23g needles and cotton swabs. Adrenaline may be administered by an Authorised nurse/midwife immuniser working under the Authority for registered nurses and midwives or by a nurse/midwife if it is at the direction of a medical practitioner, and the nurse/midwife who is administering the adrenaline at the direction of a medical practitioner must be working within their scope of practice (that is, have the necessary skills to administer adrenaline). They must also be familiar with the adrenaline (epinephrine) treatment protocol, found in the online version of The Australian Immunisation Handbook
- Provide the patient with the relevant patient information sheet:
  - Refer to Appendix D
- Determine whether the patient meets the criteria for the Protocol by:
  - reviewing the patient-completed screening tool in the consent form, and performing a focussed medical history related to any “Yes” answer. Identify any language or communication barriers that may prevent informed consent, before proceeding. Refer the patient for further assessment by a medical practitioner should any health concerns or questions be identified. This assessment should be documented. **Note: there is no prescription requirement for a person to receive the Vaccine.**
  - providing information in relation to the benefits and risks of the JYNNEOS vaccine. Explain the rationale and purpose of the Vaccine to the patient/ /guardian. Ensure if there are any questions/concerns, the patient / guardian has had the opportunity to discuss benefits and risks with a medical practitioner using the latest available benefits and risks information and advice from the Australian Technical Advisory Group on Immunisation (ATAGI).
  - documenting all assessments and details relating to the administration of the Vaccine.

- Explain the expected adverse effects of the Vaccine and the use of simple over the counter medication in the 24-48 hours following vaccination if required. Provide post-vaccination care advice as per the latest ATAGI advice, including the period during which symptoms should be carefully monitored, symptoms to look out for, and when to seek medical attention. Provide advice to immediately seek medical review for any new or unexpected or severe symptoms.
- Provide written post-vaccination advice.
- For each person, document the following details:
  - Name
  - Address
  - Date of birth
  - Sex
  - Phone number
  - Whether the person has any relevant conditions, including precautions or contraindications, established above
  - That they have received the relevant information sheet and appropriate post-immunisation advice
  - The date and time the Vaccine was administered, batch number, serial number, site of Vaccine injection, route of injection and name of vaccination service provider and supervising medical practitioner (if provider is a RN).
- Following vaccination, observe the patient for 15 minutes, and check the patient has no signs or symptoms requiring clinical review prior to discharge.
- Record the administration of each Vaccine.

APPENDICES – RELEVANT LINKS

Appendix A - JYNNEOS Package Insert (FDA)

www.fda.gov/media/131078/download

Appendix B – Link to ATAGI Clinical Guidance on Vaccination against Mpox

www.health.gov.au/resources/publications/atagi-clinical-guidance-on-vaccination-against-mpox

Appendix C - Link to JYNNEOS Consent form

www.health.gov.au/resources/publications/mpox-mpx-consent-form-for-jynneosr-vaccination

Appendix D – Mpox vaccine information sheet - JYNNEOS (MVA-BN)

www.health.gov.au/resources/publications/mpox-mpx-information-on-jynneosr-vaccine

Appendix E – Anaphylaxis after vaccination

www.health.nsw.gov.au/Infectious/covid-19/vaccine/Documents/management-of-anaphylaxis.pdf

Appendix F – Post exposure prophylaxis (PEP) for mpox in NSW

www.health.nsw.gov.au/Infectious/factsheets/Pages/mpxv-pep.aspx

Appendix G – AEFI reporting form

www.tga.gov.au/form/national-adverse-events-following-immunisation-aefi-reporting-form

Appendix H – Document history

Version	Date	Areas updated
2	2 September 2022	1.3 Training requirements 3.4 Record keeping for LHD mass vaccination clinics 4.3 Locations where Vaccine can be administered expanded 4.4 Addition of intradermal route of administration 7. Revised to include intradermal route, additional precautions for all Appendix F included – post-exposure prophylaxis
3	12 September 2022	Update to links in Appendices Update to consideration around immunocompromised
4	10 October	2.1 Medical practitioner can provide supervision via Telehealth
5	14 October	3.4 Reporting daily data to NSW Health 4.1 Expanded eligibility criteria for the Vaccine 4.3 Adding additional designated clinics 7 Additional guidance on use of insulin syringes
6	29 November	2.1 Electronic consent via VAM 3.3 Movement of vaccine 3.4 VAM downtime 4.1 Vaccine eligibility 4.3 Additional designated clinics 6. Additional sites for ID vaccination 7. Administration of adrenaline by nurses in the event of an adverse event
7	19 December	4.3 Additional designated clinics (Justice Health)
8	23 January 2023	3.3 Movement of the Vaccine 4.3 Addition of Taree Vaccination clinic 4.4 Removal of intradermal route of administration

9	9 February 2023	4.3 Additional designated clinics (S100 prescriber sites)
10	**7 September 2023**	**Monkeypox renamed to Mpox** **3.4 Removal of the vaccination administration management system (VAM) and record keeping requirements updated** **4.3 Updated designated Vaccine sites**