# CONTENTS

# 1. BACKGROUND

## 1.1. About this document

This Protocol provides information on JYNNEOS, a vaccine indicated for the prevention of smallpox and mpox disease.

JYNNEOS has been made available in Australia under the Therapeutic Goods (Medicines – MVA-BN) (Emergency) Exemption) 2023 (as amended from time to time), which is an instrument made under section 18A of the Therapeutic Goods Act 1989 (Cth). The requirements set out in this protocol are directions of the CHO for the purposes of the Therapeutic Goods (Medicines – MVA-BN) (Emergency) Exemption) 2023 (as amended from time to time).

This protocol is subject to revision and may be updated in the future.

Key definitions

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| **Authorised nurse/midwife immuniser** | Nurses and midwives authorised under the NSW *Registered Nurses and Registered Midwives Authority*, given under the *Poisons and Therapeutic Goods Act 1966* and its Regulation to supply the specified poisons and restricted substances. |
| **CHO** | The New South Wales Chief Health Officer. |
| **Health institution** | A health institution as defined in the *Health Services Act 1997* (NSW) |
| **Health service** | A health service as defined in the *Health Services Act 1997* (NSW) |
| **Medication** | Used singularly throughout the Protocol to describe a drug, medicine, pharmaceutical preparation, therapeutic substance, and vaccine. |
| **Pharmacist immuniser** | Pharmacists authorised under NSW Pharmacist Vaccine Authority given under the *Poisons and Therapeutic Goods Act 1966* and its Regulation to supply by administration the specified vaccines. |

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| **Public Hospital** | Any public hospital as defined in the *Health Services Act 1997* (NSW). |
| **S100 Prescriber** | A medical practitioner or nurse practitioner authorised to prescribe section 100 highly specialised drugs under the *National Health Act 1953 (Cth)*, including but not limited to HIV and hepatitis B & C therapeutics. |
| **Standing order** | Authorises a registered nurse to administer and / or supply for administration specified medications and sets out procedures for ordering, dispensing, supplying and administering medications for the purpose of treatment or of prophylaxis against certain conditions as per local health district or speciality network policy. |
| **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 a treating authorised prescriber. |
| **Treating authorised practitioner** | A medical practitioner, nurse practitioner, authorised nurse/midwife immuniser and pharmacist immuniser working within their authorised scope of practice to supply the Vaccine. |
| **Vaccine** | The JYNNEOS vaccine, a 3rd generation smallpox vaccine manufactured by Bavarian Nordic. |
| **Vaccination setting** | A type of healthcare or clinical setting as specified in the protocol, such as s100 GP clinics or NSW Health publicly funded sexual clinics, that can provide Vaccine |
| **Vaccination site** | An individual clinic that is approved to be a Vaccine provider |

## 1.2. Training requirements

The following training requirements must be met by health practitioners 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), Australian Immunisation Handbook (appendix A) and Therapeutic Goods Administration (TGA) regarding JYNNEOS vaccine.

# 2. IMPLEMENTATION OF PROTOCOL

## 2.1. Prerequisites for supplying the Vaccine

The Vaccine can be supplied and administered by treating authorised prescribers. Registered and enrolled nurses, who are not authorised nurse/midwife immunisers, may administer at the direction and under the authority of a medical practitioner or under a medication standing order allowing the administration of the Vaccine.

Health 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 as a health practitioner.
- Have read and understood the Australian Immunisation Handbook recommendations for usage of JYNNEOS vaccination, including contraindications and precautions for usage.
- Authorised registered nurse and midwife immunisers must practice in accordance with the NSW Registered Nurses and Registered Midwives Authority and the NSW Registered Nurses and Midwives Vaccination Standards.
- Pharmacist immunisers must practice in accordance with the NSW Pharmacist Vaccine Authority and the NSW Pharmacist Vaccination Standards.
- 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 person requests that there vaccination is not recorded on the AIR. If the patient requests that their vaccination is not recorded on the AIR, authorised vaccination providers must be able to provide a record of Vaccine use.

# 3. VACCINE INFORMATION

Information on JYNNEOS Vaccine is available in the Australian Immunisation Handbook Mpox (previously known as monkeypox) chapter.

## 3.1. Storage, distribution and handling

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 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 to authorised vaccination sites within NSW in accordance with this protocol.

For distribution, the Vaccine will be transported either frozen or at +2°C to +8°C to authorised vaccination site 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 B) 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 beyond 24 weeks at +2ºC to +8ºC after thawing from -50°C.

Only an LHD or speciality network may move the Vaccine from one authorised vaccination setting to another and only in accordance with section 3.2. Records must be maintained of any Vaccine redistribution.

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.

## 3.2. Disposal

To reduce wastage, LHDs or speciality networks may move unexpired, unused Vaccine to authorised vaccination settings within LHDs and speciality networks subject to:

- compliance with the **"**Licence to supply by wholesale poisons and restricted substances – Licence No LHD 005" dated 20 December 2022 (as amended from time to time) or, if that licence has been revoked, a subsequent licence issued under the Poisons and Therapeutic Good Act 1996 which has the effect of replacing the aforementioned licence (Licence)**,** and
- maintenance of cold chain during storage and transportation, and
- records being maintained of the Vaccine redistribution, and
- if the Vaccine will be moved to a different LHD or specialty network, approval by the Director of Communicable Disease Branch, Executive Director of Health Protection NSW or the CHO.

Unusable Vaccine and Vaccine waste products must be disposed of in designated clinical waste bins for destruction and records kept of Vaccine disposal.

## 3.3. Record-keeping and disclosure

Vaccine administration should be recorded in an appropriate medication record system and the Australian Immunisation Register (AIR) (unless a patient opts out of the Vaccine being recorded on AIR). Patients without a Medicare Card should be registered via the Individual Health Identifier (IHI) process. If Vaccine administration is not recorded on AIR, authorised vaccination providers must be able to provide a record of Vaccine use.

Processes must be in place in authorised vaccination sites 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 all vaccination sites are required to keep under this Protocol.

Suspected adverse events following immunisation (AEFI) must 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. 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 must keep a record of Vaccine received, used and disposed and these are required to be provided to the CHO upon request.

## 3.4. Vaccine eligibility

Primary preventive vaccination (PPV) against mpox is only available for:

- people self-identifying as belonging to one of the following groups at risk of exposure:
  - sexually active gay, bisexual or other men who have sex with men (GBMSM)
  - sexually active transgender and gender diverse people, if at risk of exposure
  - sex workers, particularly those whose clients are at risk of mpox exposure
  - people who are attending sex on premises venues (SOPVs)
  - people living with HIV, if at risk of mpox exposure
  - sexual partners of GBMSM, sex workers and people living with HIV
  - laboratory personnel working with orthopoxviruses.
- healthcare workers at risk of exposure to patients with mpox in Australia, including staff in sexual health clinics, high consequence infectious disease units, and other workers as appropriate. The risk of transmission should be minimised by using infection control measures in the first instance
- healthcare workers and other humanitarian workers at risk of occupational mpox exposure working internationally in countries with mpox outbreaks
- anyone at risk of mpox exposure and greater risk of a poor clinical outcome from mpox infection, such as individuals with a compromised immune system
- anyone (regardless of sexual orientation or gender identity) with travel planned to a country with ongoing transmission of clade I mpox and planning to undertake sexual activities within the country which may put them at risk of exposure.

Post-exposure preventive vaccination (PEPV) is available for people categorised by a Public Health Unit or medical practitioner as a high or medium risk mpox contact as per the NSW Health Control Guidelines for mpox a within the past 14 days. Risk assessment for people exposed to mpox (contacts) who are being assessed for PEPV is stratified by high, medium or low risk.

Eligible people under the age of 16 for both PPV and PEPV must only have vaccination administered after a risk assessment by a medical practitioner and vaccine administration should occur by an LHD or speciality network with paediatric services.

## 3.5. Authorised vaccination settings and sites

The Vaccine may only be administered to patients in an authorised vaccination setting or site. All authorised vaccination settings and sites must comply with this protocol. Authorised vaccination settings or sites must have or establish a system to order from the NSW State Vaccine Centre.

The following authorised vaccination settings may order and administer the Vaccine in compliance with this protocol:

- NSW publicly funded sexual health clinics
- Public hospitals
- Health institutions controlled by a Local Health District or Speciality Network at which health services are provided
- Sites where s100 prescribers practice.

Individual vaccination sites can be approved by the Director of Communicable Disease Branch, Executive Director of Health Protection NSW or the CHO provided that the approver is satisfied that:

- the site is in an area with insufficient vaccination provider numbers, and/or
- the site has clients who fit the eligibility criteria.

These sites may include non-s100 GP practices, community pharmacies or additional sites as deemed suitable vaccination settings. Community pharmacies may only supply PPV against mpox via subcutaneous injection to non-pregnant eligible individuals aged 16 years and over as per the NSW Pharmacist Vaccination Standards. Authorised vaccination sites approved under a previous version of this protocol remain approved unless revoked by the CHO.

All public hospitals should have pathways in place to offer PEPV after-hours if required. These pathways must be developed in advance and are the responsibility of the public health unit in consultation with the LHD or speciality network Director of Clinical Governance.

For additional guidance on the provision of PEPV refer to the Post exposure preventative vaccination (PEPV) for mpox in NSW protocol (Appendix C).

# 4. PROCEDURE FOR VACCINE ADMINISTRATION

Providers should remain up to date on any new advice from the Australian Technical Advisory Group on Immunisation (ATAGI), Australian Immunisation Handbook or Therapeutic Goods Administration (TGA) regarding JYNNEOS vaccine.

In NSW, JYNNEOS must be administered by subcutaneous injection. The preferred site is over the deltoid. In times of vaccination shortage, dose sparing administration by intradermal injection may be permitted if authorised by the CHO.

Treating authorised practitioners must ensure that consent has been obtained from the patient prior to Vaccine administration. A medical practitioner may direct a registered or enrolled 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.

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

- Practice according to this Protocol for JYNNEOS administration and its supporting documents (see Appendices)
- Determine whether the patient meets the criteria for the Vaccine by:
  - Asking the patient if they belong to one of the eligible groups (the patient does not have to disclose which group they belong to).
  - Screening the patient for any contraindications to receiving the Vaccine (Screening questions are included in Appendix A). If any precaution or contraindication exists, ensure the patient is reviewed by a medical practitioner.
  - 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.
  - 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, authorised nurse/midwife immuniser and pharmacist immunisers using the latest available benefits and risks information and advice from the Australian Technical Advisory Group on Immunisation (ATAGI) and Australian Immunisation Handbook.
  - 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. Post vaccination care advice should be given to the patient (details on post vaccination care can be found in Appendix D) and advise the patient to immediately seek medical review for any new or unexpected or severe symptoms.
- 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 practitioner.
- 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 on an appropriate medical record system, and on the Australian Immunisation Register (unless patient has specifically opted-out).

# APPENDICES – RELEVANT LINKS

## Appendix A - Immunisation handbook JYNNEOS

https://immunisationhandbook.health.gov.au/contents/vaccine-preventable-diseases/mpox-previously-known-as-monkeypox

## Appendix B - JYNNEOS Package Insert (FDA)

www.fda.gov/media/131078/download

## Appendix C – Post exposure preventative vaccination (PEPV) for mpox in NSW

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

## Appendix D – Post vaccination care advice

www.health.nsw.gov.au/Infectious/factsheets/Pages/after-mpox-vaccine.aspx

## Appendix E – Document history

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

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| 9 | 9 February 2023 | 4.3 Additional designated clinics (S100 prescriber sites) |
| 10 | 7 September 2023 | Monkeypox renamed to Mpox<br>3.4 Removal of the vaccination administration management system (VAM) and record keeping requirements updated<br>4.3 Updated designated Vaccine sites |
| 11 | 12 February 2024 | 2.2. Update of prescriber settings requirements to Requirements for vaccine administration<br>4.2. Additional groups for vaccination updated<br>4.3 Updated designated Vaccine sites |
| 12 | 02 August 2024 | Authorised nurse/midwife immuniser allowed to order vaccine and amended throughout protocol<br><br>Registered nurses allowed to administer vaccination under a standing order<br><br>Vaccine eligibility updated in line with Australian Immunisation Handbook<br><br>Age recommendation changed to older than 16 in line with Australian Immunisation Handbook<br><br>Clarification throughout protocol that PEPV is only for individuals who have not received a full course of the Vaccine<br><br>PEP changed to PEPV in line with Immunisation Handbook usage of 'post exposure preventative vaccination (PEPV)'<br><br>1.2. Added definition for authorised nurse/midwife immuniser<br><br>7.1. Removal of requirement for completing a written consent form<br><br>Appendix D link updated to Immunisation Handbook |

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| 13 | 18 December 2024 | Age recommendations changed in line with Australian Immunisation Handbook and ATAGI guidance.<br>Expansion of the eligibility criteria to include people who attend SOPVs and gender diverse and transgender people.<br>Enrolled nurses allowed to administer the Vaccine under supervision of a medical practitioner.<br>Pharmacist immunisers allowed to order and administer the Vaccine for PPV to non-pregnant eligible individuals aged 16 years and over.<br>JYNNEOS is now listed in the Australian Immunisation Handbook. Information that duplicates the handbook has been removed and the protocol should be used in conjunction with the AIH.<br>4.2. Vaccination sites no longer require individual CHO approval if they fall into authorised provider settings. |
| **14** | **4 March 2025** | **3.4. PPV recommendations expanded to include travellers at risk of exposure to clade I through sexual activities in line with ATAGI guidance** |