Northern Territory of Australia

Medicines, Poisons and Therapeutic Goods Act 2012

Mpox Vaccination SSTP
Revocation and Approval

I, Christopher Paul Burgess, Chief Health Officer:

(a) under section 254(5) of the Medicines, Poisons and Therapeutic Goods Act 2012, (the Act), revoke the instrument titled "[Vaccine for Human Therapeutic Use – Monkeypox/smallpox SSTP -Revocation and Approval" dated 13 April 2023; and

(b) under section 254(1) of the Act, approve each Scheduled substance treatment protocol specified in Schedule A;

(c) under section 254(3) of the Act, state that each Schedule substance treatment protocol specified in Schedule A remains in effect for a period of 2 years on and from the date of this instrument.

Dated

30 June 2025

EDOC2025/163508

Chief Health Officer

Schedule A

Title	Publication Date	Author
JYNNEOS® Vaccine for Prevention of Mpox (previously known as monkeypox) Disease SSTP	23/06/2025	Center for Disease Control, Northern Territory Government, Department of Health

Scheduled Substance Treatment Protocol (SSTP)

JYNNEOS® Vaccine for Prevention of Mpox (previously known as monkeypox) Disease SSTP

Areas Applicable	NT Wide
Health Professionals authorised by this SSTP	Nurses Midwives Aboriginal and Torres Strait Islander Health Practitioners Pharmacists
Scheduled Substance(s)	JYNNEOS® Vaccine (modified vaccinia Ankara– Bavarian Nordic, or MVA-BN)
Indication	People at risk of Mpox including primary preventive vaccination (PPV) and post-exposure preventive vaccination (PEPV) as outlined by Australian Technical Advisory Group on Immunisation (ATAGI) or as directed by NT Health.
Contraindications, and/or Exclusions (including relevant drug interactions)*	**JYNNEOS® is contraindicated in:** • People who have had anaphylaxis after a previous dose of JYNNEOS® vaccine or to any component of a JYNNEOS vaccine: -10 mM Tris (tromethamine), 140 mM sodium chloride, residual amounts of chicken host-cell DNA (≤ 20 mcg), chicken protein (≤ 500 mcg), benzonase (≤ 0.0025 mcg), gentamicin (≤ 0.163 mcg) and ciprofloxacin (≤ 0.005 mcg). • People with an acute febrile illness **Exclusions to this protocol** • Pharmacists may only administer vaccines to patients aged 5 years and above. • Refer individuals with severe egg/chicken protein allergies to an immunologist or allergist expert **Considerations** • Individuals with atopic dermatitis reported a higher frequency of local and general symptoms after vaccination compared with those without this condition. However the vaccine is considered safe to use in people with eczema/atopic dermatitis. • There are no data on the immune response to JYNNEOS® in other immunosuppressed individuals but the vaccine is considered safe in people who are immunocompromised. • JYNNEOS® vaccine is considered safe in pregnancy and breast feeding although no formal evaluations in these groups have occurred. • 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, such as young adult males.

NORTHERN TERRITORY GOVERNMENT

Dose and Route*	Subcutaneous – 0.5mL (1 dose per vial) OR Intradermal – 0.1mL (up to 5 doses per vial) **Administration:** Appropriate equipment (as per the Australian Immunisation Handbook - Preparing an anaphylaxis response kit) – must be available to initiate treatment for adverse events if required. Subcutaneous injection preferably into the upper arm (deltoid). The intradermal route is not recommended for people with severe immunocompromise, and not preferred for the first dose of post-exposure prophylaxis. Intradermal administration is preferably into the volar aspect (inner side) of the forearm, with the deltoid also an acceptable intradermal site. Intradermal technique must only be used by trained and competent immunisers to minimise errors. If an intradermal dose is administered incorrectly (e.g. inadvertently given subcutaneously), administer a repeat dose as soon as possible, namely a 0.5mL dose subcutaneously (withdrawn from a new vaccine vial). If a vaccine course is commenced using the subcutaneous route for the first dose, it can be completed by intradermal injection for the second dose, and vice versa. Allow the vaccine to thaw and reach room temperature before use. Do not refreeze. When thawed, JYNNEOS® is a milky, light yellow to pale white coloured suspension. Swirl the vial gently before use for at least 30 seconds.
Dose Frequency*	2 doses at least 28 days apart
Monitoring requirements*	Post vaccination procedures should be followed as per the current Australian Immunisation Handbook. All patients must be monitored post vaccination for 15 minutes unless they withdraw consent to be monitored. Ensure withdrawn consent is documented in the person's clinical record. Report any adverse event during or post vaccination to the NT Centre for Disease Control using the 'Adverse event following vaccination' form available online at Immunisation Program NT Health
Health Professional Accreditation Requirements	Health professionals using this guideline must meet the requirements outlined by the NT Chief Health Officer: ***Nurses and Midwives:*** • Be registered with the Nursing and Midwifery Board of Australia with no conditions, undertakings or notations which may limit delivery of clinical services directly to patients

	Aboriginal Health Practitioners: • Be registered with the Aboriginal and Torres Strait Islander Health Practice Board of Australia with no conditions or undertakings which may limit delivery of clinical services directly to patients ***Pharmacists*** • Be registered with the Pharmacy Board of Australia with no conditions or undertakings which may limit delivery of clinical services directly to patients **All health professionals administering vaccines from this protocol must have completed and hold a current qualification in:** • A program of study accredited by Health Education Services Australia (HESA) or; • A program of study approved by the Chief Health Officer or; • Completed the assessment of an immuniser program of study that meets the curriculum content requirements of the National Immunisation Education Framework for Health Professionals And Must: • Maintain continuing professional development related to skills and competencies required for the delivery of medicines and vaccines including the use of multi-dose vials and management of anaphylaxis • Hold a current Cardiopulmonary Resuscitation (CPR) certificate
Documentation *(including necessary information to the patient)*	Patient consent (written or verbal) for vaccination must be recorded. Records of this should be maintained by the clinical service. The health professional must: • Complete all clinical documentation requirements as outlined by the Health Service. • Enter the mandatory fields in the Australian Immunisation Register within 24 hours and no later than 10 days after administration. For many vaccine providers this involves entry into routine clinical information systems for automatic upload A provider may abstain from reporting to AIR where a provider reasonably believes that reporting a vaccination would pose a risk to the health or safety of the individual. In these cases there is an onus on the provider to be able to provide supporting evidence should it be requested.
Related Documents	• Immunisation program | NT Health • The Australian Immunisation Handbook (health.gov.au) • National vaccine storage guidelines - Strive for 5, 3rd edition (health.gov.au) • ASCIA_HP_Guidelines_Acute_Management_Anaphylaxis_2024.pdf (allergy.org.au)

	• ATAGI clinical guidance on the use of vaccines for prevention of Mpox • Product information Package Insert - JYNNEOS (fda.gov)		
Chief Health Officer	**Signature**	**Name**	**Date**
	EDOC2025/163506	Adj Prof Paul Burgess	30/06/2025
Period of effect	This SSTP remains in force until 30/06/2027 unless revoked earlier		

References:

* The medicine information provided is to act as a guide to outline the limits of legal dealing with the named scheduled substances. Further information reference should be made to the full manufacturer's product info and other reliable sources of medicines information. If contraindications or exclusions are present, health professionals must refer the matter to an authorised prescriber for an administration order.