Northern Territory of Australia

Medicines, Poisons and Therapeutic Goods Act 2012

Vaccine for Human Therapeutic Use – Monkeypox/smallpox SSTP

Revocation and Approval

I, Christine Maree Connors, Acting Chief Health Officer:

(a) under section 254(5) of the *Medicines, Poisons and Therapeutic Goods Act 2012, (**the Act**),* revoke the instrument titled "Declarations and Approvals – Vaccines for human therapeutic use (Monkeypox/Smallpox)" dated 13 October 2022 and published in *Gazette* No.s53 of 14 October 2022; 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 until 03 October 2024

Dated **13/04/2023**

Acting Chief Health Officer

Schedule A

Title	Publication Date	Author
JYNNEOS® vaccine for prevention of monkeypox/smallpox disease Scheduled Substance Treatment Protocol (SSTP)	03/10/2022	Center for Disease Control, Northern Territory Government, Department of Health

JYNNEOS® vaccine for prevention of monkeypox/smallpox disease Scheduled Substance Treatment Protocol (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 vaccine)
Indication	People at risk of monkeypox including pre-exposure (PrEP) and post-exposure prophylaxis (PEP) as outlined by ATAGI or as directed by NT Health.
Contraindications and/or Exclusions*	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 • People under 18 years of age **Exclusions*:** • High risk patient aged between 16 and 18 years ATAGI recommends consideration to receive the vaccination as potential benefits outweigh potential risks. Refer to medical officer before administration. **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. • Lower immune response has been observed in HIV infected individuals compared to healthy individuals, but clinical relevance is unknown. 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
Dose and Route*	Subcutaneous – 0.5ml (1 dose per vial) OR Intradermal – 0.1ml (up to 5 doses per vial)
Dose Frequency*	2 doses at least 28 days apart
Administration*	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.
Drug Interactions*	Nil known
Monitoring requirements*	Observe for 15 minutes post vaccination delivery. If an adverse events occurs an 'Adverse event following vaccination' form must be completed.
Health Professionals Accreditation Requirements	***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:***

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- 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

- Must have completed nationally recognised immunisation training in a program that meets the "National Immunisation Education Framework for Health Professionals 2017" and is nationally accredited and;
- Must holds a current first aid certificate (to be updated every three years) and;
- Must hold a current cardiopulmonary resuscitation certificate (to be updated annually).

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<tr><td>Documentation
(including necessary information to the patient)</td><td>JYNNEOS® vaccines are to be documented in the Australian Immunisation Register (AIR), the client's electronic health record and relevant stock reporting as applicable

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.</td></tr>
<tr><td>Related Documents</td><td>ATAGI statement ATAGI clinical guidance on vaccination against Monkeypox (health.gov.au)
Product information Package Insert - JYNNEOS (fda.gov)</td></tr>
<tr><td>Chief Health Officer</td><td>
<table>
<tr><th>Signature</th><th>Name</th><th>Date</th></tr>
<tr><td>EDOC2022/408965</td><td>Dr Charles Pain</td><td>03/10/2022</td></tr>
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<tr><td>Perioid of effect</td><td>This SSTP is in effect from time of publishing on Agency website until 03/10/24</td></tr>
<tr><td colspan="2">References:
* The drug information provided is to act as a guide only, for further information reference should be made to the full manufacturer's product info and other reliable sources of medicines information. If contraindications/exclusions or interactions are present refer to medical officer before administration</td></tr>
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