Government of **Western Australia**
Department of **Health**

Consent form for JYNNEOS® vaccination

Version 4: 13 February 2023

Before you fill out this form, make sure you read the patient information sheet.

About JYNNEOS® vaccination against mpox (monkeypox)

JYNNEOS® (modified vaccinia virus Ankara – Bavarian Nordic, MVA-BN) is a vaccine used to prevent infection with smallpox and mpox viruses. It is manufactured by Bavarian Nordic. It is made using weakened live vaccinia virus and cannot cause smallpox or mpox.

A primary vaccination course with JYNNEOS® requires two doses, given at least 28 days apart.

Standard administration of JYNNEOS® is by subcutaneous injection (under the skin).

JYNNEOS® is most effective when it is used to vaccinate a person before exposure to mpox. JYNNEOS® may also be given to a person after they have been exposed to a mpox case, preferably as soon as possible after first exposure. Vaccination within 14 days after first exposure is expected to reduce severity of the disease.

People who have previously had a smallpox vaccine, including any doses of JYNNEOS® may still get mpox if they are exposed to a mpox case. If you develop any symptoms of mpox, you must still follow all health advice you are given by your state or territory public health staff.

People at high risk of mpox infection who have received a smallpox vaccine dose more than ten years ago are recommended to receive only one dose of JYNNEOS®.

Who can get the vaccine?

Individuals 18 years and older:

JYNNEOS® vaccine is indicated for use in adults aged 18 years and older considered at risk for mpox infection.

Individuals under 18 years:

JYNNEOS® has not been formally studied in children aged under 18 years and is not currently registered for use in this age group in countries where JYNNEOS® is licensed. However, there are clinical study data on safety in children on MVA (the active substance in this vaccine), which has been used as a vaccine component in 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 risks and benefits of vaccination with their immunisation provider.

JYNNEOS® has not been studied in pregnant or breastfeeding women however, there are no expected safety concerns. JYNNEOS® is considered safe to use in people with atopic dermatitis (eczema) and in people with weakened immune systems.

Co-administration with other vaccines

JYNNEOS® may be given at the same time as other vaccines.

It is not known if JYNNEOS® is associated with a risk of myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining of the heart). Spacing JYNNEOS® and a COVID-19 vaccine apart by several weeks may be considered for people with increased risk of myocarditis and/or pericarditis after an mRNA COVID-19 vaccine, such as young adult males.

Who should not get this vaccine?

JYNNEOS® should not be given to people with anaphylaxis (severe allergic reaction) to a previous dose or to a component of the vaccine. JYNNEOS® contains modified vaccinia Ankara – Bavarian Nordic live virus (active substance), trometamol, sodium chloride, and small amounts of benzonase, gentamicin and ciprofloxacin (antibiotics), chicken host-cell DNA and chicken protein. In people with a severe allergy or anaphylaxis to egg, there is a possible risk of allergic reaction. Tell your health care provider if this is a concern.

People who have had mpox virus infection during the 2022 outbreak are not recommended to be vaccinated at this time as their immunity will be boosted by natural infection.

Vaccine side effects

Safety data on JYNNEOS® is available from 22 clinical studies with a total of over 7,800 JYNNEOS® vaccine recipients. Most side effects are mild, short-lived and occur within a few days of receiving the vaccine. Common adverse events include injection site pain, redness, swelling, induration (hardness) and itch, muscle aches, headache, fatigue, nausea, chills and fever. There are no notable serious side effects from the clinical studies.

People with atopic dermatitis (eczema) may be more likely to have side effects after vaccination compared to those without this condition.

Tell your health care provider if you have any side effects after vaccination that you are worried about. You or your immunisation provider should report adverse events to the state or territory health department or to the Therapeutic Goods Administration (TGA).

More information is available on the TGA website.

You may be contacted by SMS or email in the week after you have the vaccine to see if you have had any side effects, as part of vaccine safety surveillance.

You should call an ambulance (dial 000) if you think you are having a serious allergic reaction after vaccination and have symptoms such as difficulty breathing, wheezing, chest pain or 'fluttering' (irregular heartbeat).

Reporting serious side effects in Western Australia

Anyone who experiences a significant reaction following vaccination should first seek medical attention from a health professional.

The Western Australian Vaccine Safety Surveillance (WAVSS) system is the central reporting service in Western Australia (WA) for any significant side effects (adverse events) following vaccination.

You should report:

- Any significant event following immunisation.
- Any reaction to a vaccine which requires assessment by a doctor or nurse
- Any reaction that has affected you or your family's confidence in future immunisation.

If you have experienced any significant side effect to a vaccine, you can report it either:

- Online at https://www.safevac.org.au/, or
- Over the phone, by calling WAVSS on (08) 6456 0208 (8.30am to 4.30pm Mon to Fri).

By reporting serious side effects, you can help provide more information on the safety of this vaccine.

You can call HealthDirect on 1800 022 222 (24 hours) for non-urgent advice on managing side effects if needed

Further information

JYNNEOS® vaccine is not registered for use in Australia and has not been formally assessed by the Therapeutic Goods Administration (TGA) but has been made available via a special emergency pathway under section 18A of the *Therapeutic Goods Act 1989 (Commonwealth)*. JYNNEOS® is licensed in the United States of America for adults aged 18 years and older and the equivalent product, with the same formulation and strength of JYNNEOS®, is registered for use in adults in Europe as IMVANEX® and in Canada as IMVAMUNE®. All currently available information on the safety and efficacy of JYNNEOS® has been evaluated by ATAGI.

Australian Immunisation Register

The person giving your vaccination should record it on the Australian Immunisation Register (AIR). Collection of your personal information for this purpose meets the requirements of the *Privacy Act 1988 (Cth)*. You can view your vaccination record through your Medicare Online account via:

- Express Plus Medicare mobile app
- MyGov
- My Health Record (you can register for this with a Medicare number or an individual healthcare identifier).

Collection of your vaccination information on the AIR ensures that you have a complete immunisation record. This means you and your health care provider can keep track of vaccines you have received and when you are due for any subsequent doses. Your immunisation provider can also report other mpox or smallpox vaccines that you may have received overseas to the AIR.

On the day of your vaccine

Before you get vaccinated, tell the person giving you the vaccination if you have had:

- A severe reaction to a previous dose of JYNNEOS® or to one of its ingredients*
- Anaphylaxis (severe allergic reaction) to any vaccine
- A known or possible exposure to mpox in the last 14 days
- A previous smallpox vaccine ever
- A smallpox or mpox vaccine recently (e.g. overseas)
- Have previously had mpox virus infection
- A current medical condition that lowers your immunity
- A history of keloid scarring
- A new rash.

*JYNNEOS® contains trace residues of benzonase, gentamicin and ciprofloxacin (antibiotics), chicken host-cell DNA and chicken egg protein. In people with confirmed anaphylaxis to egg, there is a possible risk of allergic reaction. See above (Who should not get this vaccine?) for complete list.

Screening questionnaire

Yes	No	
		Have you ever had a severe reaction to a previous dose of JYNNEOS® or to one of its ingredients*?
		Have you ever had a severe reaction following any vaccine or medication (e.g., anaphylaxis)?
		Do you have a history of severe allergies, including anaphylaxis (to anything)?
		Have you had a known or possible exposure to mpox in the last 14 days?
		Do you have a bleeding disorder or take any medicine to thin your blood (an anticoagulant therapy)?
		Do you have a condition that lowers immunity (e.g., leukaemia, cancer, uncontrolled HIV) or are you receiving treatment that lowers immunity?
		Have you ever had eczema (atopic dermatitis) or any other skin conditions?
		Have you ever had keloid scarring (a specific type of wound scarring)?
		Do you have a history of myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining around the heart)?
		Are you pregnant, planning to become pregnant or breastfeeding?
		Have you been sick with a fever or are feeling sick in another way?
		Do you currently have a rash (this could look like bumps, blisters or pimples) or any sores anywhere on your body, including in your mouth or your anus?
		Have you had a JYNNEOS® vaccine, or other mpox or smallpox vaccine before? If so, vaccine name (if known):____ Date: _____
		Have you had a COVID-19 vaccine in the last 4 weeks, or do you plan to receive one in the next 4 weeks?
		Have you received any other vaccinations in the last 4 weeks?

*JYNNEOS® contains modified vaccinia Ankara – Bavarian Nordic live virus (active substance), trometamol, sodium chloride, and small amounts of benzonase, gentamicin and ciprofloxacin (antibiotics), chicken host-cell DNA and chicken egg protein. In people with confirmed anaphylaxis to egg, there is a possible risk of allergic reaction.

If you answered YES to any of the above questions, you may still be able to receive JYNNEOS®, however you should talk to your immunisation provider first to discuss the best timing of vaccination and whether any additional precautions are needed.

Patient information

Name:										
Medicare number:										
Medicare Individual Reference Number:										
Individual Health Identifier (IHI) if applicable:										
Date of birth:										
Phone contact number:										
Email address:										

Next of kin (in case of emergency):	
Name:	
Phone contact number:	

Consent to receive JYNNEOS® vaccine

I confirm I have received and understood information provided to me on JYNNEOS® vaccination.

I confirm that none of the above conditions apply to me, or I have discussed these conditions and any other special circumstances with my regular health care provider and/or immunisation provider.

I confirm that I understand the risks and benefits of the JYNNEOS® vaccine.

☐ I agree to receive a course of JYNNEOS® vaccine / I agree to receive a booster of JYNNEOS® vaccine

Active follow up for monitoring JYNNEOS® side effects post vaccination

The WA Department of Health actively monitors adverse events following JYNNEOS® vaccination to ensure the continued safety of vaccines used in WA. Your information will remain confidential and personal information will not be disclosed to anybody else, unless you have given consent, or are authorised or required to do so by law. Your *de-identified* responses will also contribute to the national mpox active vaccine safety surveillance called AusVaxSafety.

SCAN ME

For more information about the WA Health active follow up after JYNNEOS® vaccination, please visit https://www.healthywa.wa.gov.au/Articles/J_M/Monkeypox

I understand if I do not wish to be contacted for post vaccination follow up, I am still able to receive the vaccine, and this does not impact my care.

☐ I give permission to WA Department of Health to contact me by SMS and to actively monitor vaccine safety.

☐ I give permission to WA Department of Health to contact me when my second dose of JYNNEOS® vaccine is due.

Patient's name:	
Patient's signature:	
Date:	

I am the patient's parent, guardian or substitute decision-maker, and agree to JYNNEOS® vaccination of the patient named above.

Parent/guardian/substitute decision-maker's name:	
Parent/guardian/substitute decision maker's signature:	
Date:	

This document can be made available in alternative formats.