Immunisation Advisory Centre

VERSION 3

Mpox vaccine (Jynneos)

Guidance for healthcare professionals

From 11 September 2024, Jynneos vaccine was provisionally approved for use in NZ for the prevention of mpox. The vaccine may be administered under the National Immunisation Programme (NIP) by authorised vaccinators, who are required to complete the IMAC online education. They will not require a prescription to administer to the eligible population when following the guidance in the datasheet.

Sections of this factsheet with a blue background give guidance specifically to prescribers on areas where clinical guidance differs from the datasheet. Authorised vaccinators will require a prescription/standing order and written informed consent for any off-label use.

Brand names: Jynneos; also known as MVA-BN, Imvamune and Imvanex, MPV

Manufacturer: Bavarian Nordic

Type: Live, non-replicating Modified Vaccinia virus Ankara (MVA). Third generation smallpox and mpox (monkeypox) vaccine.

Protects against smallpox and mpox for pre-exposure vaccination in groups at highest risk of being exposed to individuals with infection and for post-exposure vaccination of close contacts of cases.

Jynneos is currently provisionally approved by Medsafe for those aged 18 years and over. A prescription and written informed consent are required for anyone under 18 years of age following a risk-benefit assessment with the prescriber.

Table 1: Vaccine summary – Jynneos

Age for use	Aged 18 years and over. See below for guidance on use in those under 18 years and discussion for use in pregnancy.
Presentation	Single dose vial containing 0.5mL
Volume/strength	At least 0.5×10^8 infectious units/0.5mL single dose
Schedule	2 doses of Jynneos 0.5mL separated by a minimum of 4 weeks
Administration route	Subcutaneous (SC) injection (or intradermal (ID) if appropriate)
Ingredients	0.5 to 3.95×10^8 infectious units of Modified Vaccinia Ankara-Bavarian Nordic virus
Excipients	Tris (tromethamine); and Sodium chloride May contain trace amounts of chicken host-cell DNA, chicken protein, benzonase, gentamicin and ciprofloxacin.

Background

Jynneos is a third-generation orthopoxvirus (smallpox and mpox) vaccine containing a replication-defective Vaccinia virus. Although the vaccine virus is considered live, it cannot replicate so is safe to use in those with immunocompromise. It has also been used as a viral vector, expressing recombinant antigens for other infectious disease and cancer vaccines.

Jynneos vaccine is being used globally throughout the current mpox outbreaks. In Aotearoa New Zealand, Jynneos is approved for use in eligible adults aged 18 years and older.

This vaccine may be suitable for individuals who are at high risk of mpox infection:

- Population groups outlined below in Table 2
- Post-exposure vaccination, preferably within 4 days (but up to 14 days) of exposure to a confirmed mpox case.
- Adolescents aged under 18 years who meet the criteria for being at high risk of mpox exposure (as listed below) are highly recommended MPV vaccination, to be administered with a **prescription and written informed consent**.

Table 2: Pre- and post-exposure vaccination	

Pre-exposure vaccination	Population groups considered at higher risk of exposure or further transmission, including:
	• Gay, bisexual and other men who have sex with men (GBMSM), transgender or non-binary people who in the past 6 months have had one of the following:
	  ○ A new diagnosis of a sexually transmitted disease
	  ○ More than one sex partner
	  ○ Sex at a commercial venue
	  ○ Sex in association with a large public event in an area where mpox transmission is likely to occur
	• People living with HIV, if at risk of mpox exposure
	• Those at occupational risk of mpox exposure:
	  ○ Laboratory staff working with orthopoxviruses
	  ○ Health workers at risk of repeated exposures to patients with mpox
	  ○ Sex workers, particularly for those with clients who are risk of exposure to mpox
	• Sexual partners of those at increased risk of mpox infection
	• People who anticipate experiencing any of the above.

Post-exposure vaccination	• Close contacts of people infected with mpox (e.g., intimate partners) • People whose occupation might put them at increased risk and if there is a breach of protective personal equipment (PPE) (i.e., healthcare workers caring for those infected with mpox and laboratory workers handling mpox swabs).
• This vaccine can be given to individuals with immunocompromising medical conditions or therapy, including those living with HIV infection (PWHIV). It can also be given to those taking HIV pre-exposure prophylaxis (PrEP) medication. • This vaccine is not available for travel purposes, to areas with an active outbreak, unless the individual is at high risk of infection due to occupational or sexual activities.	

Storage and preparation

- Jynneos is provided as a single-dose vial of 0.5mL in suspension
- Vaccine supply is stored centrally at minus 50°C. It is defrosted when packaged for delivery to site and expiry date recorded on the box
- Unopened vials should be stored in their box at +2 to +8°C for up to 24 weeks (or to expiry date, whichever is sooner)
- Do not re-freeze
- On site storage +2 to +8°C
- Vaccines are prepared only as needed
- Allow vaccine to reach room temperature before use
- Before drawing up the vaccines, swirl vial gently for at least 30 seconds
- Follow guidance in IMAC factsheet "*Subcutaneous (SC) vaccine preparation: mpox Jynneos*" for details of preparation and administration of SC vaccines.

Administration

Pre-exposure
For those aged 18 years and over, two doses of Jynneos 0.5mL is administered subcutaneously for all eligible population, separated by a minimum of 4 weeks.

Post-exposure

- To maximise chance of preventing infection, Jynneos should be administered preferably within 4 days from date of mpox exposure.
- Asymptomatic individuals may still be offered vaccination up to 14 days after exposure to mpox with the aim of reducing severity of symptoms.
- If Jynneos vaccine is administered post-exposure and consumer remains asymptomatic, then a second dose should be administered a minimum of 4 weeks after the first dose.

Note: Those aged under 18 years will require written informed consent and a prescription.

Subcutaneous (SC) administration guidance

The current recommendation is that all doses be given via the subcutaneous (SC) route while the vaccine supply is sufficient to meet demand. If demand in NZ is higher than currently anticipated, there remains an option to revert to fractional intradermal (ID) administration. If a vaccine course was commenced using the ID route for the first dose, it can be completed by SC route for the second dose, and vice versa.

Second doses

Second doses are administered at least 4 weeks after first dose. Completion of the two-dose series should be encouraged to ensure longer lasting immunity. Delays in administering the second dose do not require restarting the series.

Co-administration

Due to lack of data, the datasheet currently says to avoid co-administration with other vaccines.

Based on first principles, there is minimal risk of interference between Jynneos and other vaccines. However, if the timing of mpox or COVID-19 vaccination is not urgent, consider allowing a gap of 4 weeks between Jynneos and Comirnaty. This is particularly relevant for young males and those who have a history of cardiac inflammation.

Since this cohort are likely to benefit from administration of additional vaccines such as HPV and MMR, it is recommended that vaccine histories are checked and where possible co-administration of these vaccines is offered, supported by a **standing order or prescription and documented informed consent**. If this is not possible, offer to rebook or add to recall lists.

Effectiveness

Studies of antibody responses, preclinical studies and real-world data show Jynneos is most effective when given pre-exposure. Studies reported in 2022[1,2,3] showed good protection following one or two doses of Jynneos. A systematic review found vaccine effectiveness against mpox infection to be 76% (95% CI 64-88%) after one dose and 82% (72-92%) after two doses in predominantly GBMSM aged 18-49 years.[3] Effectiveness is similar regardless of administration route.

Breakthrough cases following vaccination are mostly mild with low number of lesions and no or minimal prodromal symptoms. Reinfection has also been described. The vaccine can decrease severity of illness, risk for hospitalisation, and even death among those who are immunocompromised.

Further research is needed to better understand the efficacy of mpox vaccine for post-exposure prophylaxis. Current evidence shows that post-exposure vaccination offers some protection against mpox. The incidence rate of mpox in those vaccinated post-exposure was shown to be 14 times lower than those who were unvaccinated in an observational study in the US.[4] It is likely to be most effective if given within 4 days of exposure, if given later it may reduce the severity of illness.

Consumers should be aware they could still contract and transmit mpox after vaccination and should consider avoiding or reducing intimate contact with people who have or may have mpox and seek medical care if they develop symptoms that could be mpox.

Contraindications and precautions

Contraindications:

- Jynneos should not be given to anyone with a history of anaphylaxis to a previous dose of Jynneos or any component of the vaccine.
- Jynneos is contraindicated in subjects with known hypersensitivity to any of the vaccine's excipients or trace residues (chicken or egg protein, gentamicin, ciprofloxacin, or benzonase). The datasheet also says "the risk for a severe allergic reaction should be weighed against the risk for disease due to monkeypox". It is recommended that you seek guidance from 0800 IMMUNE or a prescriber. If vaccinated, **written informed consent** is required and consumer should be observed for a longer period of at least 30 minutes following vaccination.
- Jynneos should not be given to anyone with myocarditis or pericarditis following a previous dose of Jynneos.

Precautions:

- Anyone with previous myocarditis or pericarditis should have a risk-benefit discussion.
- Postpone vaccination in individuals who are acutely unwell with a fever over 38°C. Do not delay immunisation in those with a minor infection and/or low-grade fever.

Vaccine safety

Potential responses – subcutaneous

Common adverse events in clinical trials include local site reactions: pain (85%), redness (61%), swelling (52%), induration (46%) and itching (43%); and systemic symptoms: muscle pain (43%), headache (35%), fatigue (30%), nausea (17%) and chills (10%).[5]

Responses are mainly mild to moderate in intensity and resolve without intervention within seven days following vaccination.

Frequency of adverse events, particularly local site reactions, are higher in those who have received previous live smallpox (vaccinia) immunisation.

Active surveillance in New Zealand from the Post Vaccine Symptom Check (PVSC) of the Jynneos vaccine (mainly administered ID during the survey period) showed the rate of adverse events was similar or less than during clinical trials. Of the PVSC day-7 survey participants, 68% reported at least one adverse event, 4% reported missing work or other daily activities, and fewer than 2% sought medical care. Local reactions and fatigue were most commonly reported.

Table 3: Potential vaccine responses of Jynneos	
Common responses	• Injection-site pain, redness, swelling • Muscle pain • Headache • Fatigue • Nausea • Chills
Rare responses	• Fever • Lymphadenopathy
As with any medicine, very rarely a severe allergic reaction (anaphylaxis) can occur following immunisation. Immunisation-stress related responses, including palpitations, tachycardia and fainting (syncope), have been reported.	

Myocarditis/pericarditis

Increased risk for myocarditis (inflammation of heart muscle) and pericarditis (inflammation of lining of the heart) was shown for the older first- and second-generation live smallpox vaccines. No increase in risk has been shown with Jynneos to date, so if there is an association it is likely to be less frequent. Young men are at higher risk for these conditions and the possibility of an increased risk cannot be excluded. Medsafe continues to monitor adverse event reports closely.

Immune-mediated neurologic disorders

Bavarian Nordic has reported that global pharmacovigilance monitoring has detected three episodes of immune-mediated neurological disorders (including optic neuritis) occurring shortly after receipt of this mpox vaccine. It is unknown whether these adverse events were caused by the vaccine. These events are very rare and further assessments are needed. Anyone experiencing neurological symptoms, including blurred vision, following vaccination with Jynneos is advised to seek medical advice.

Reactogenicity in those with atopic dermatitis

Safety for those with atopic dermatitis (AD) has been investigated in a phase II study involving 345 patients with AD. Individuals with AD had more injection site-associated reactions (redness 61% vs 50%, and swelling 52% vs 41%) and generalised symptoms (headache 47% vs 35%, chills 16% vs 8%, nausea 23% vs 15% and fatigue 36% vs 27%) following SC Jynneos vaccination than healthy controls.[6] Reactogenicity with other skin disorders has not been investigated.

Pregnancy and breastfeeding

Mpox can be severe in pregnant people and have adverse effects on the fetus.[7] Animal toxicity studies did not identify any evidence of harm when Jynneos is given prior to or during gestation. As Jynneos is a non-replicating vaccine, adverse events would be expected to be the same as in non-pregnant people. In these situations, the risk from mpox infection to the mother and the infant should be discussed.

Please contact 0800 IMMUNE for guidance, and if vaccinated **written informed consent** is required. Jynneos has not been formally evaluated in lactating people; however, there are no theoretical safety concerns relating to use while breastfeeding.

Under 18 years

Jynneos has not been formally studied in children under 18 years; however, there are trial data on safety in children on MVA used a as the vector for a small number of childhood vaccines and when administered MPV for pre- or post-mpox exposure during outbreaks. Jynneos can be considered in this age group, especially for individuals in high-risk groups and for post- exposure prophylaxis following consultation with prescriber, with a **prescription and written informed consent**.

Safety in people living with HIV

Jynneos is replication defective and, unlike other live vaccines, does not pose a risk to those with immunocompromise. Large numbers of PWHIV have received the vaccine globally and are a priority group for vaccination. Safety was carefully assessed in 91 PWHIV with CD4 counts over 350 cells/mm^3 and was found to be well tolerated.[8] However, immune response to the vaccine could be reduced in those who are severely immunocompromised.

Prior mpox infection

Individuals who have either been diagnosed with laboratory-confirmed mpox prior to vaccination or after the first dose are not recommended vaccination or further doses. This is because mpox infection likely confers adequate immune protection or boosts immunity in those recently vaccinated. For those with immunocompromise and diagnosed with mpox after their first dose of MPV, a second dose of MPV can be considered based on clinical judgement.

For those who have received a smallpox vaccine in the past, a full two-dose course of mpox vaccine is still recommended, particularly for individuals with immunocompromise.

Post-vaccination advice

- Observation period for 20 minutes.
- Observation period of at least 30 minutes for those with a potential increased risk of anaphylaxis.
- Provide written information leaflet *"HP8585 After your mpox vaccine"* to consumer or give them opportunity to photograph it (note: must be June 2025 version)
- Recipients should be warned of the small risk of severe allergic reactions and instructed to call 111 if they develop suggestive symptoms.
- Recipients should be informed about possible local and systemic adverse events as above (Table 3).

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Post-vaccination advice continued...

- Recipients should be informed about possible local and systemic adverse events as above (Table 3).
- Ensure the consumer knows to seek medical advice if they suffer any symptoms including those **suggestive of myocarditis or pericarditis (such as palpitations, chest pain or shortness of breath), or neurological symptoms, including blurred vision**.
- Adverse events should be reported to CARM.
- Refer consumers to phone Healthline (0800 611 116) for advice if they have an adverse reaction or questions about their vaccine site.
- Best protection from mpox vaccine is likely to be from 10 days to two weeks after second dose. Take extra precautions in high-risk situations.
- Consumers should be aware that they could still contract and transmit mpox after vaccination. They should consider avoiding or reducing intimate contact with people who have or may have mpox and seek medical care if they develop symptoms that could be mpox.

Call 0800 IMMUNE (0800 466 863) for clinical advice