UK Health Security Agency

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Smallpox vaccine Patient Group Direction (PGD)

This PGD is for the administration of the smallpox vaccine, non-replicating, live modified vaccinia virus Ankara - Bavarian Nordic (MVA-BN), to individuals identified for immunisation in response to monkeypox (mpox) in the UK. This PGD allows only the use of US licensed Batch FDP00072 of Jynneos® vaccine.

This PGD is for the administration of smallpox vaccine by registered healthcare practitioners identified in Section 3, subject to any limitations to authorisation detailed in Section 2.

Reference no:	Smallpox vaccine PGD
Version no:	v3.00
Valid from:	15 September 2023
Review date:	1 April 2024
Expiry date:	15 September 2024

The UK Health Security Agency (UKHSA) has developed this PGD to facilitate the delivery of publicly funded immunisation in England in line with national recommendations.

Those using this PGD must ensure that it is organisationally authorised and signed in Section 2 by an appropriate authorising person, relating to the class of person by whom the product is to be supplied, in accordance with Human Medicines Regulations 2012 (HMR2012)[1]. **The PGD is not legal or valid without signed authorisation in accordance with HMR2012 Schedule 16 Part 2.**

Authorising organisations must not alter, amend or add to the clinical content of this document (sections 4, 5 and 6); such action will invalidate the clinical sign-off with which it is provided. In addition, authorising organisations must not alter section 3 'Characteristics of staff'. Only sections 2 and 7 can be amended within the designated editable fields provided.

Operation of this PGD is the responsibility of commissioners and service providers. The final authorised copy of this PGD should be kept by the authorising organisation completing Section 2 for 8 years after the PGD expires if the PGD relates to adults only and for 25 years after the PGD expires if the PGD relates to children only, or adults and children. Provider organisations adopting authorised versions of this PGD should also retain copies for the periods specified above.

Individual practitioners must be authorised by name, under the current version of this PGD before working according to it.

Practitioners and organisations must check that they are using the current version of the PGD. Amendments may become necessary prior to the published expiry date.

Current versions of UKHSA PGD templates for authorisation can be found from:
Immunisation patient group direction (PGD) templates

Any concerns regarding the content of this PGD should be addressed to:
immunisation@ukhsa.gov.uk

Enquiries relating to the availability of organisationally authorised PGDs and subsequent versions of this PGD should be directed to: Contacts listed on page 5 of this PGD

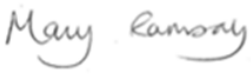
[1] This includes any relevant amendments to legislation.

Change history

Version number	Change details	Date
V1.00	New UKHSA Smallpox vaccine PGD template to: • respond to the outbreak of monkeypox in accordance with the national guidelines; Recommendations for the use of pre and post exposure vaccination during a monkeypox incident and updated Green Book Chapter 29, 21 June 2022 • include information regarding the use of US licensed Jynneos® as there are no stocks of the UK licensed MVA-BN vaccine Imvanex® currently available. Jynneos® is being issued in view of the urgency of the need to manage the monkeypox outbreak. MHRA has granted Batch-Specific Variation to permit the importation of batch FDP00012 of the Jynneos brand of MVA-BN vaccine, which is licensed in the US by the Food and Drug Administration (FDA). Both vaccines are developed by Bavarian Nordic. The conditions of regulatory approval by the MHRA vary slightly from those of the FDA for the US market. At present, there is unlicensed Imvanex® vaccine in use on PSD basis. • include under characteristics of staff additional requirements the condition to be familiar with the Direct Health Professional Communication from manufacturer for Jynneos® vaccine	2 August 2022
V2.00	The UKHSA Smallpox vaccine PGD template is updated to: • allow use of US licensed Batch FDP00072 of Jynneos® vaccine. • delete references to the vaccine being used off-label. The vaccine has been authorised for active immunisation against monkeypox in adults in the UK by the Medicines and Healthcare Products Regulatory Agency (MHRA) • add the use of the intradermal fractional dose route (ID) in the relevant sections: off-label use, route of administration, dose and frequency, adverse reactions • add observation following vaccination in cautions and patient advice sections • add individuals with history of developing keloid scarring in cautions and patient advice sections • reword paragraph relating to co-administration with other vaccines in the off-label section • minor wording changes and additions to text for consistency • updated references	17 October 2022
V3.00	The UKHSA Smallpox vaccine PGD template is updated to: • remove the use of US licensed Batch FD00012 as it has expired • remove national incident recommendations due to step down from incident and aligned to Green Book Chapter 29 • remove gay, bisexual and other men who have sex with men (GBMSM) statement with regard to vaccine dose prioritisation in response to the mpox outbreak • amend supplies section as per Green Book, Chapter 29 • add signposting to accessible information in written information provided • minor wording and grammar changes and additions to text for consistency • updated references	29 August 2023

1. PGD development

This PGD has been developed by the following health professionals on behalf of the UKHSA:

Developed by:	Name	Signature	Date
Pharmacist (Lead Author)	Suki Hunjunt Lead Pharmacist Immunisation Services, Immunisation and Vaccine Preventable Diseases Division, UKHSA		30 August 2023
Doctor	Mary Ramsay Consultant Epidemiologist, Immunisation and Vaccine Preventable Diseases Division, UKHSA		30 August 2023
Registered Nurse (Chair of Expert Panel)	David Green Nurse Consultant for Immunisation, Immunisation and Vaccine Preventable Diseases Division, UKHSA		30 August 2023

This PGD has been peer reviewed by the UKHSA Immunisations PGD Expert Panel in accordance with the UKHSA PGD Policy. It has been ratified by the UKHSA Medicines Governance Group.

Expert Panel

Nicholas Aigbogun	Consultant in Communicable Disease Control, Yorkshire and Humber Health Protection Team, UKHSA
Gayatri Amrithalingham	Consultant Epidemiologist, Immunisation and Vaccine Preventable Diseases Division, UKHSA
Alison Campbell	Screening and Immunisation Coordinator,Public Health Commissioning NHS England (NHSE) Midlands
Rosie Furner	Pharmacist - Medicines Governance, Specialist Pharmacist Services (SPS)
Ed Gardner	Advanced Paramedic Practitioner/Emergency Care Practitioner, Medicines Manager, Proactive Care Lead
Jacqueline Lamberty	Lead Pharmacist, Medicines Governance, UKHSA
Michelle Jones	Principal Medicines Optimisation Pharmacist, Bristol North Somerset and South Gloucestershire Integrated Care Board
Shamez Ladhani	Paediatric Infectious Disease Consultant, UKHSA
Elizabeth Luckett	Senior Screening and Immunisation Manager NHSE South West
Vanessa MacGregor	Consultant in Communicable Disease Control, East Midlands Health Protection Team, UKHSA
Sema Mandal	Deputy Director, Blood Safety, Hepatitis, STI, and HIV Division Consultant Epidemiologist in Immunisation and Hepatitis, UKHSA
Lesley McFarlane	Lead Immunisation Nurse Specialist Immunisation and Vaccine Preventable Diseases Division, UKHSA
Nicola Philbin	Screening and Immunisation Manager, Vaccination and screening programmes – Public Health Commissioning NHSE Midlands
Laura Smeaton	IDPS Programme Projects Manager and Registered Midwife, NHS Infectious Diseases in Pregnancy Screening (IDPS) Programme, NHS England (NHSE)
Tushar Shah	Lead Pharmacy Adviser, NHSE London

2. Organisational authorisations

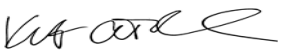
The PGD is not legally valid until it has had the relevant organisational authorisation.

It is the responsibility of the organisation that has legal authority to authorise the PGD, to ensure that all legal and governance requirements are met. The authorising body accepts governance responsibility for the appropriate use of the PGD.

NHSE North East and Yorkshire authorises this PGD for use by the services or providers listed below:

Authorised for use by the following organisations and/or services
NHS England (NHSE) commissioned immunisation services or NHS Trust providing immunisation services.
Limitations to authorisation
Authorisation is limited to those registered practitioners listed in Section 3 who are employed by organisations/providers commissioned by NHSE North East and Yorkshire (NEY) to deliver immunisation programmes within the whole of the NHSE region of North East and Yorkshire

Organisational approval (legal requirement)			
Role	**Name**	**Sign**	**Date**
Assistant Medical Director and Responsible Officer, **NHS England –NEY**	**Dr James Gossow**		**11th September 2023**

Additional signatories according to locally agreed policy			
Role	**Name**	**Sign**	**Date**
NHSE NEY PGD Governance assurance review (Medicines Optimisation Pharmacist Lead, NHS NECS	**Kurt Ramsden**		**11th September 2023**
Screening and Immunisation Coordinator Public Health Programme Team – Yorkshire and the Humber NHS England (NE and Yorkshire)	**Laura Brown**		**7th September 2023**

Local enquiries regarding the use of this PGD may be directed to your local screening and immunisation teams. See area-specific contacts below:

For North East and North Cumbria Area (i.e. Northumberland, Tyne & Wear, Durham Darlington and Tees and North Cumbria) use the following:

NHS England Screening and Immunisation Team:

email england.cane.screeningimms@nhs.net

or NECS Medicine Optimisation Pharmacists: Kurt Ramsden: kurtramsden@nhs.net

or Sue White: sue.white14@nhs.net

Please note - All North East and North Cumbria PGDs can be found at:

https://medicines.necsu.nhs.uk/resources/patient-group-directions/

For Yorkshire and Humber Area use the following:

West Yorkshire - england.wysit@nhs.net

South Yorkshire and Bassetlaw - england.sybsit@nhs.net

North Yorkshire and Humber ENGLAND.NYAHSIT@nhs.net

or the Health Protection Team Acute Response Centre (ARC): Contact Number: 0113 3860 300.

Please note - All Yorkshire and Humber PGDs can be found at: https://www.england.nhs.uk/north-east-yorkshire/our-work/information-for-professionals/pgds /

Section 7 provides a practitioner authorisation sheet. Individual practitioners must be authorised by name to work to this PGD. Alternative practitioner authorisation sheets may be used where appropriate in accordance with local policy, but this should be an individual agreement or a multiple practitioner authorisation sheet as included at the end of this PGD.

3. Characteristics of staff

Qualifications and professional registration	Registered professional with one of the following bodies: • nurses and midwives currently registered with the Nursing and Midwifery Council (NMC) • pharmacists currently registered with the General Pharmaceutical Council (GPhC) (Note: This PGD is not relevant to privately provided community pharmacy services) • paramedics and physiotherapists currently registered with the Health and Care Professions Council (HCPC) The practitioners above must also fulfil the Additional requirements detailed below. Check Section 2 Limitations to authorisation to confirm whether all practitioners listed above have organisational authorisation to work under this PGD.
Additional requirements	Additionally, practitioners: • must be authorised by name as an approved practitioner under the current terms of this PGD before working to it • must have undertaken appropriate training for working under PGDs for supply/administration of medicines • must be competent in the use of PGDs (see NICE Competency framework for health professionals using PGDs) • must be familiar with the vaccine product and alert to changes in the Summary of Product Characteristics (SPC), Immunisation Against Infectious Disease (the 'Green Book'), and national and local immunisation programmes • must have undertaken training appropriate to this PGD as required by local policy and in line with the National Minimum Standards and Core Curriculum for Immunisation Training • must be competent to undertake immunisation and to discuss issues related to immunisation • must be competent in the handling and storage of vaccines, and management of the cold chain • must be competent in the recognition and management of anaphylaxis • must have access to the PGD and associated online resources • must have read and be familiar with the contents of the Direct Healthcare Professional Communications from Bavarian Nordic on the differences between the Imvanex® brand and Jynneos® brand (licensed in US) of Live Modified Vaccinia Virus Ankara • should fulfil any additional requirements defined by local policy **The individual practitioner must be authorised by name, under the current version of this PGD before working according to it.**
Continued training requirements	Practitioners must ensure they are up to date with relevant issues and clinical skills relating to immunisation and management of anaphylaxis, with evidence of appropriate Continued Professional Development (CPD). Practitioners should be constantly alert to any subsequent recommendations from the UKHSA and/or NHSE and other sources of medicines information. Note: The most current national recommendations should be followed but a Patient Specific Direction (PSD) may be required to administer the vaccine in line with updated recommendations that are outside the criteria specified in this PGD.

4. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	Indicated for the pre and post exposure immunisation of individuals against mpox virus, in accordance with the recommendations given in Chapter 29, Immunisation Against Infectious Disease: The 'Green Book' and the mpox vaccination programme.
Criteria for inclusion	Individuals who: • are recommended immunisation as a contact of a case of monkeypox • are at risk of mpox exposure as defined in Chapter 29 Use in accordance with the recommendations given in Green Book, Chapter 29
Criteria for exclusion[2]	Individuals for whom valid consent has not been obtained (for further information on consent see Chapter 2 of 'The Green Book'). Individuals who: • have had a confirmed anaphylactic reaction to a previous dose of MVA-BN vaccine or to any component of the vaccine (including trace residues from the manufacturing process such as chicken protein, benzonase, gentamicin and ciprofloxacin) • are acutely unwell. Immunisation may be postponed until they have fully recovered. Minor illnesses without fever or systemic upset are not valid reasons to postpone immunisation. This is to avoid confusing the differential diagnosis of any acute illness by wrongly attributing any signs or symptoms to the adverse effects of the vaccine All healthcare workers (HCWs) are excluded from this PGD. Under the NHSE mpox specification, all HCWs are excluded from receiving mpox vaccine as part of the NHS service. HCWs will therefore need to be vaccinated as part of an occupational health (OH) service using a PSD or Written Instruction in accordance with the NHSE guidance for the delivery of vaccination for mpox.
Cautions including any relevant action to be taken Continued over page	Facilities for management of anaphylaxis should be available at all vaccination sites (see Chapter 8 of the Green Book) and advice issued by the Resuscitation Council. Individuals with atopic dermatitis develop more local and general symptoms after vaccination with MVA-BN vaccine. For further information see Green Book Chapter 29. Individuals with a history of developing keloid scarring may be offered a 0.5ml SC/IM dose of MVA-BN in preference to a fractional dose intradermally. Syncope (fainting) can occur following, or even before, any vaccination especially in adolescents as a psychogenic response to the needle injection. This can be accompanied by several neurological signs such as transient visual disturbance, paraesthesia and tonic-clonic limb movements during recovery. It is important procedures are in place to avoid injury from faints. There is no routine requirement for observation following MVA-BN administration, but individuals should be observed for any immediate reactions whilst receiving any verbal post vaccination information and exiting the centre. However, as fainting can occur following vaccination, all those vaccinated with MVA-BN should be advised to not drive for 15 minutes after vaccination.

[2] Exclusion under this PGD does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation will be required

Cautions including any relevant action to be taken (continued)	The immunogenicity of the vaccine could be reduced in immunosuppressed subjects. Vaccination should proceed in accordance with the national recommendations. However, re-immunisation may need to be considered. Seek medical advice as appropriate (see Chapter 29). **Pregnancy** Although MVA-BN has not formally been evaluated in pregnancy, animal studies (3 studies in female rats) identified no vaccine related fetal malformations. Use of MVA-BN in pregnant women is limited to less than 300 pregnancies without leading to any adverse events on pregnancy. As it is a non-replicating vaccine, there is no theoretical reason for concerns in pregnancy and the adverse events profile would be expected to be similar to that in non-pregnant vaccinees. Whilst it is not recommended for use in pregnancy, any theoretical risk needs to be weighed against the maternal risks of exposure to mpox in late pregnancy (such as a risk of more severe disease from viral infections in the third trimester) and any consequent fetal risks from maternal infection in early pregnancy. **Breastfeeding** It is not known whether MVA-BN is excreted in human milk, but this is unlikely as the vaccine virus does not replicate effectively in humans. Women who are breastfeeding and have a significant exposure to mpox should therefore be offered vaccination, after discussion about the risks of mpox to themselves and to the breast-fed child. **Immunosuppression including HIV infection** MVA-BN is a replication defective virus and should pose no risk to those who are immunosuppressed. The safety and immunogenicity of MVA-BN in persons living with HIV infection (with CD4 cell counts above 100 cells/mm3) has been demonstrated (Greenberg et al, 2013). However, the immune response to the vaccine could be reduced in severely immunosuppressed individuals, so additional precautions may be needed. Vaccination should generally proceed in accordance with recommendations, as these individuals are also at significant risk of the complications of mpox (see Green Book Chapter 29). Individuals living with HIV who are virally suppressed and have a CD4 count above 200 cells/mm3 are not considered immunosuppressed for the purposes of this guidance. **Current or previous mpox infection** If an individual is acutely unwell, including those with symptoms or signs of possible mpox infection, immunisation should be postponed until they have fully recovered. This is to both reduce risks of exposing others and to avoid wrongly attributing any signs or symptoms to the adverse effects of the vaccine. Whether prior mpox infection protects against future infection is currently unknown but based on analogy from smallpox infection and from live smallpox vaccine, it seems likely that re-infection will be unusual, particularly in the short term. Although previous mpox infection is not a contra-indication to vaccination, in a situation of constrained vaccine supply, it is therefore recommended that vaccination of confirmed cases is deferred. If supply allows, vaccination may be considered for those at on-going risk once fully recovered.
Action to be taken if the patient is excluded Continued over page	If a confirmed anaphylactic reaction has been experienced after a previous dose of MVA-BN or any of its components, specialist advice should be sought.

Action to be taken if the patient is excluded (continued)	If the individual is a potential contact of mpox and is suffering from acute severe febrile illness, they should be referred for a clinical assessment to be appropriately advised. Other individuals with febrile illness who are not at immediate risk of exposure, and who are suffering acute severe febrile illness may postpone immunisation until they have recovered. Immunisers should advise when the individual can be vaccinated, and ensure another appointment is arranged at the earliest opportunity. Monkeypox contact tracing guidance provides principles for risk assessment and follow up of contacts of confirmed mpox cases. It is intended to support risk assessment and categorisation of contacts to ensure they are offered appropriate isolation advice and vaccination. Seek appropriate advice from the local Screening and Immunisation Team, local Health Protection Team or the individual's clinician as required. The risk to the individual of not being immunised must be taken into account. Document the reason for exclusion and any action taken in the individual's clinical records. Inform or refer to the individual's clinician as appropriate.
Action to be taken if the patient or carer declines treatment	Informed consent, from the individual or a person legally able to act on the individual's behalf, must be obtained for each administration. Advise the individual/parent/carer about the protective effects of the vaccine, the risks of infection and potential complications. Document the advice given and the decision reached. Inform or refer to the individual's clinician as appropriate.
Arrangements for referral for medical advice	As per local policy

5. Description of treatment

Name, strength and formulation of drug	MVA-BN suspension Jynneos® packaging states: Each 0.5ml dose contains 0.5 x 10^8 to 3.95 x 10^8 infectious units of non-replicating, live MVA-BN. Note: This PGD allows only the use of US licensed Batch FDP00072 of Jynneos® vaccine.
Legal category	Prescription only medicine (POM) See batch specific information above under name, strength and formulation section.
Black triangle▼	Yes
Off-label use	Where a vaccine is recommended off-label consider, as part of the consent process, informing the individual that the vaccine is being offered in accordance with national guidance but that this is outside the product licence. Although the MVA-BN vaccine is not indicated for children, several paediatric studies of other vaccines using MVA as a vector (often at a considerably higher dose than used in MVA-BN) have been undertaken with a reassuring side effect profile. The vaccine should therefore be offered in accordance with Green Book Chapter 29 to children considered to be at risk, as children seem to have a more severe presentation of mpox. Jynneos® is only licensed for subcutaneous use. However, the Green Book Chapter 29 allows the vaccine to be used subcutaneously, intramuscularly or intradermally. In August 2022, following the emergency use approval by the US Food and Drug Administration (FDA), JCVI endorsed the use of a fractional dose (0.1ml) of MVA-BN given by intradermal injection during periods of supply constraints. Currently, there are no data on administering Jynneos® vaccine at the same time as other vaccines. However, it can be co-administered with other vaccines in accordance with Green Book Chapter 29. Vaccine should be stored according to the conditions detailed in the Storage section below. However, in the event of an inadvertent or unavoidable deviation of these conditions refer to Vaccine Incident Guidance. Where vaccine is assessed in accordance with these guidelines as appropriate for continued use this would constitute off-label administration under this PGD.
Route and method of administration Continued over page	The vaccine can be given subcutaneously (SC), intramuscularly (IM) or intradermally (ID). However, administration for individuals under 18 years of age should be through the subcutaneous or intramuscular route. Allow the vaccine to thaw. Frozen vials should be transferred to 2°C to 8°C to thaw or may be thawed for 15 minutes at room temperatures for immediate use (Chapter 29). The vaccine should be allowed to reach room temperature before use. Swirl the vial gently before use for at least 30 seconds. The vaccine's normal appearance is a light yellow to pale white milky suspension. The suspension should be visually inspected for particulate matter and discoloration before use. In the event of any damage to the vial, foreign

Route and method of administration (continued)	particulate matter and/or variation of physical aspect being observed, the vaccine should be discarded. Check the expiry date or beyond use date. Appropriate infection control and aseptic techniques should be used at all times and is particularly important when using as multi-dose vials for the ID route. Always use a new, sterile needle and syringe for each injection. **For IM and SC route** Withdraw a dose of 0.5 ml into a sterile syringe for injection and administer by the deep subcutaneous route (see Green Book Chapter 4) or intramuscular route. The preferred sites for IM and SC immunisation are the anterolateral aspect of the deltoid area of the upper arm or anterolateral aspect of the thigh . The anterolateral aspect of the thigh is the preferred site for infants under one year old because it provides a large muscle mass into which vaccines can be safely injected. **For ID route** ID route of administration should be used during period of constrained vaccine supply when recommended by UKHSA and/or NHSE, except in the following cases: • children under 18 years • adult individuals who are immunosuppressed • individuals with keloid scars A fractional dose of 0.1ml is withdrawn for injection and administered by the intradermal route. Use the correct needle and syringe for withdrawing the fractional dose. The needle must be attached firmly and the intradermal injection administered with the bevel facing up. A fractional dose intradermal injection for MVA-BN may be administered on the deltoid (the same site recommended for BCG - see Chapter 4 and Chapter 32) or on the volar aspect (palm side) of the forearm around 2-4 inches below the ante-cubital fossa (the same site as normally used for Mantoux testing - see Chapter 29). The immuniser should stretch the skin between the thumb and forefinger of one hand and with the other slowly insert the needle, with the bevel upwards, about 3mm into the superficial layers of the dermis almost parallel with the surface. The needle can usually be seen through the epidermis. A correctly given intradermal injection results in a tense, blanched, raised bleb of around 7mm diameter following a 0.1ml intradermal injection. It is easier to administer this correctly with a 1ml graduated syringe fitted with a 26G or 27G short needle (such as a 0.45mm x 10mm brown needle - see Green Book Chapter 4). If little resistance is felt when injecting and a diffuse swelling occurs as opposed to a tense blanched bleb, the needle is too deep. The needle should be withdrawn and reinserted intradermally before more vaccine is given. Where fractional doses are being used the contents of the vial can remain at room temperature for up to one hour whilst up to 5 doses are used. Each dose should be drawn up and given immediately. Note the time and date when the first puncture is made on the vial and discard after one hour. Where ID route is given, provide the full information as per the Intradermal mpox vaccination Patient Information Leaflet. Vaccines previously stored at -20°C +/-5°C, can be stored at +2°C–+8°C in the dark for up to 8 weeks prior to use. Do not re-freeze a vial once it has been thawed.
Continued over page	The vaccine must not be mixed with other medicinal products.

Route and method of administration (continued)	When administering at the same time as other vaccines, care should be taken to ensure that the appropriate route of injection is used for all the vaccinations. The vaccines should be given at separate sites, preferably in different limbs. If given in the same limb, they should be given at least 2.5cm apart. The site at which each vaccine was given should be noted in the individual's records Green Book Chapter 4).
Dose and frequency of administration	**Pre-exposure vaccination of individuals previously not vaccinated against smallpox** Administer a course of 2 doses with at least a 28-day interval between doses. **Adults 18 years and above** • 0.5ml dose of MVA-BN per administration for intramuscular or subcutaneous injection or • a fractional dose of 0.1ml dose of MVA-BN per administration for intradermal injection (during supply constraints) **Children under 18 years, immunosuppressed individuals (as defined in Chapter 7) and those with a history of keloid scarring of any age** • 0.5ml dose of MVA-BN per administration for intramuscular or subcutaneous injection Pre-exposure vaccination may also be considered for those about to start providing prolonged or close care for an individual with confirmed mpox. **Pre-exposure vaccination of individuals previously vaccinated against smallpox** Administer a single dose **Adults 18 years and above** • 0.5ml dose of MVA-BN per administration for intramuscular or subcutaneous injection or • a fractional dose of 0.1ml dose of MVA-BN per administration for intradermal injection (during supply constraints) **Children under 18 years, immunosuppressed individuals (as defined in Chapter 7) and those with a history of keloid scarring of any age** • 0.5ml dose of MVA-BN per administration for intramuscular or subcutaneous injection **Post-exposure vaccination** Administer a single dose immediately For those with ongoing risk, a second dose may be administered at a minimum interval of 28 days. **Adults 18 years and above** • 0.5ml dose of MVA-BN per administration for intramuscular or subcutaneous injection or • a fractional dose of 0.1ml dose of MVA-BN per administration for intradermal injection (during supply constraints) **Children under 18 years, immunosuppressed individuals (as defined in Chapter 7) and those with a history of keloid scarring of any age** • 0.5ml dose of MVA-BN per administration for intramuscular or subcutaneous injection To maximise the chance of preventing infection, MVA-BN should preferably be administered within 4 days from the date of exposure to mpox.
Continued over page	The objectives of immunisation are to provide protection against infection and to modify disease severity in individuals of any age with recent

Dose and frequency of administration (continued)	exposure to mpox. Post-exposure vaccination of high risk community contacts is offered, ideally within 4 days of exposure, although may be offered up to 14 days in those at on-going risk (for example during an outbreak) or those who are at higher risk of the complications of mpox - this includes children below the age of 5 years, pregnant women and individuals with immunosuppression. (Green Book Chapter 29). Individuals who have previously received a 2 dose course of MVA-BN, with the second dose given in the past 2 years, do not need a further dose of vaccine after exposure, except those who are immunosuppressed, who may have made a lower or less durable immune response, for whom an additional dose can be considered (Green Book Chapter 29). Additional dose in immunosuppressed individuals should be offered based on specialist clinical judgement under a PSD. **Booster vaccination** Individuals previously vaccinated against smallpox or mpox, who are considered to be at on-going risk or in the event of an exposure incident should receive a booster dose of MVA-BN, no less than two years after the primary course (see Chapter 29). Administer a single dose **Adults 18 years and above** • 0.5ml dose of MVA-BN per administration for intramuscular or subcutaneous injection or • a fractional dose of 0.1ml dose of MVA-BN per administration for intradermal injection (during supply constraints) **Children under 18 years, immunosuppressed individuals (as defined in Chapter 7) and those with a history of keloid scarring of any age** • 0.5ml dose of MVA-BN per administration for intramuscular or subcutaneous injection **Previous incomplete vaccination** If the MVA-BN course is interrupted or delayed, it should be resumed but the first dose does not need to be repeated.
Duration of treatment	See Dose and Frequency section above
Quantity to be supplied and administered	Single 0.5ml dose per subcutaneous or intramuscular administration Single 0.1ml dose per intradermal administration
Supplies	Currently, there are no stocks of Imvanex®, the UK licensed MVA-BN vaccine, available. The US licensed Jynneos® was urgently procured to manage the mpox outbreak. Batch FDP00072 has been granted Batch Specific Variation by the MHRA to allow importation of the FDA-licensed Jynneos® brand of the MVA-BN vaccine. The vaccines are developed by Bavarian Nordic. The conditions of regulatory approval by the MHRA vary slightly from those for the US market. Vaccine is available from UKHSA. Contact the UKHSA. (see Chapter 29). Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see the 'Green Book' Chapter 3).
Storage Continued over page	Keep frozen at -20°C (± 5°C). MVA-BN is supplied frozen in packs of 20 vials. The remaining shelf life at clinic level will depend on previous storage temperature. Frozen vials should be transferred to +2°C to +8°C to thaw or may be thawed for 15 minutes at room temperatures for immediate use.

Storage (continued)	From the time of thawing and transfer from –20°C (± 5°C) storage to the refrigerator at +2 to +8°C, the vaccine can be stored at +2°C to +8°C in the dark for up to 8 weeks prior to use. Where fractional doses are being used the contents of the vial can remain at room temperature for up to one hour whilst up to 5 doses are used. Note the time and date of the first puncture on the vial. Store in the original package to protect from light. Do not re-freeze a vial once it has been thawed. Do not use the vaccine after the expiry date shown on the vial label. In the event of an inadvertent or unavoidable deviation of these conditions vaccine that has been stored outside the conditions stated above should be quarantined and risk assessed for suitability of continued off-label use or appropriate disposal, refer to Vaccine Incident Guidance.
Disposal	MVA-BN contains genetically modified organisms (GMOs). Sharps waste and empty vials should be placed into yellow lidded waste bins and sent for incineration; there is no need for specific designation as GMO waste. An appropriate virucidal disinfectant should be available for managing spills in all settings where vaccination is administered. Potentially contaminated gloves and aprons can be disposed in yellow/black striped bags for offensive waste (see Chapter 29). Equipment used for immunisation, including used vials, ampoules, or discharged vaccines in a syringe or applicator, should be disposed of safely in a UN-approved puncture-resistant 'sharps' box, according to local authority arrangements and guidance in the technical memorandum 07-01: Safe management of healthcare waste (NHSE, 2022).
Drug interactions	Immunological response may be diminished in those receiving immunosuppressive treatment. Vaccination is recommended even if the antibody response may be limited. The concomitant administration of MVA-BN with any immunoglobulin including Vaccinia Immune Globulin (VIG) has not been studied and should be avoided.
Identification and management of adverse reactions	The most common adverse injection site reactions include pain, redness, swelling, induration, itching and common systemic reactions include chills, fever (temperature ≥ 38°C), muscle pain, fatigue, headache and nausea. Typical for vaccines, reactions which were mild to moderate in intensity resolved without intervention within 7 days following vaccination. Intradermal (ID) injection has been associated with a higher rate of itchiness and local reactions such as erythema and induration when compared to subcutaneous injection, although pain at the injection site was less common than after subcutaneous administration. Some of the local reactions persisted for longer in the ID group and some individuals developed small nodules or discoloration at the injection site 6 months after infection. Systemic reactions were generally similar across both groups Individuals with atopic dermatitis are known to have developed more site-associated reactions and generalized symptoms following MVA-BN vaccination. Individuals in this group therefore need to have a risk assessment before being offered vaccination. The assessment should consider the risk of exposure, the risk of side effects from vaccination and the potential use of alternative preventive interventions (Green Book, Chapter 29). The vaccine may trigger local rashes or more widespread eruptions. Events of rash after vaccination (related cases observed in 0.4% of subjects) tend to occur within the first days after vaccination, are mild to

Continued over page

Identification and management of adverse reactions (continued)	moderate in intensity and usually resolve without sequelae. Hypersensitivity reactions and anaphylaxis can occur after vaccination but are very rare. A detailed list of adverse reactions is available in the Imvanex® SPC. The DHPC from Bavarian Nordic, the manufacturer, signposts to the Imvanex® information on the MHRA website.
Reporting procedure of adverse reactions	Healthcare professionals and individuals are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme or search for MHRA Yellow Card in the Google Play or Apple App Store. Any adverse reaction to a vaccine should be documented in the individual's record and the individual's clinician should be informed.

Written information to be given to patient or carer	Offer marketing authorisation holder's patient information leaflet provided with the vaccine.
	
	If applicable, inform the individual/parent/carer that the PIL with large print, Braille or audio CD can be ordered from the manufacturer (see electronic medicines compendium).
	• UKHSA Protecting you from monkeypox; information on the smallpox vaccination
	• Intradermal monkeypox vaccination – what you need to know
	• Patient Information Leaflet (PIL)
	The DHPC from Bavarian Nordic advises healthcare professionals to provide the Jynneos® package insert included in the outer packaging to individuals receiving a vaccine
	• Monkeypox vaccination resources:
	  • Monkeypox: waiting for your vaccination
	  • Monkeypox vaccination record card
	  • Intradermal monkeypox vaccination Patient Information Leaflet (PIL)

Patient advice and follow up treatment	Inform the individual of possible side effects and their management. The individual should be advised to seek medical advice in the event of an adverse reaction. There is no routine requirement for observation following MVA-BN administration but following the MVA-BN vaccine administration, individuals should be observed for any immediate reactions whilst receiving any verbal post vaccination information and exiting the centre. As fainting can occur following vaccination, all those vaccinated with MVA-BN should be advised not to drive for 15 minutes after vaccination. Advise the individual when the next dose is due. If administration is postponed advise the individual when to return for vaccination. Provide the individual with further advice and leaflets as recommended in the national guidance mpox (monkeypox) vaccination resources - GOV.UK (www.gov.uk) .
Special considerations and additional information	Ensure there is immediate access to adrenaline (epinephrine) 1 in 1000 injection and access to a telephone at the time of vaccination.
Records Continued over page	Record: • that valid informed consent was given or a decision to vaccinate made in the individual's best interests in accordance with the Mental Capacity Act 2005 • name of individual, address and date of birth

Records (continued)	• name of immuniser • name and brand of vaccine • date of administration • dose, form and route of administration of vaccine • quantity administered • batch number and expiry date • it is a black triangle product • anatomical site of vaccination • advice given, including advice given if excluded or declines immunisation • details of any adverse drug reactions and actions taken • supplied via PGD Records should be signed and dated (or a password-controlled immuniser's record on e-records). All records should be clear, legible and contemporaneous. It is important that vaccinations are recorded in a timely manner on appropriate health care records for the individual. A mpox vaccination card should be completed and given to the individual. A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.

6. Key references

Key references	**Smallpox vaccine** • Immunisation Against Infectious Disease: The Green Book Chapter 29, last updated 26 September 2022 www.gov.uk/government/publications/smallpox-and-vaccinia-the-green-book-chapter-29 • UKHSA-Protecting you from Monkeypox; information on smallpox vaccination www.gov.uk/government/publications/monkeypox-vaccination-resources • Monkeypox: waiting for your vaccination www.gov.uk/government/publications/monkeypox-vaccination-resources • Monkeypox vaccination record card www.gov.uk/government/publications/monkeypox-vaccination-resources • Monkeypox: guidance-information and advice for healthcare professionals and general public www.gov.uk/government/collections/monkeypox-guidance • Intradermal monkeypox vaccination Patient Information Leaflet (PIL) www.gov.uk/government/publications/monkeypox-vaccination-resources • Intradermal monkeypox vaccination – what you need to know www.gov.uk/government/publications/monkeypox-vaccination-resources • Direct Healthcare Professional Communication (DHPC) assets.publishing.service.gov.uk/media/6303a0c1d3bf7f365f4f7e79/Jynneos_UK_HCP_letter_14-Sep-2022.pdf **General** • Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Department of Health 20 March 2013. www.england.nhs.uk/publication/management-and-disposal-of-healthcare-waste-htm-07-01/ • National Minimum Standards and Core Curriculum for Immunisation Training. Published February 2018. www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for-registered-healthcare-practitioners • NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions. Published March 2017 www.nice.org.uk/guidance/mpg2 • NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions. Updated March 2017. www.nice.org.uk/guidance/mpg2/resources • UKHSA Immunisation Collection www.gov.uk/government/collections/immunisation • Vaccine Incident Guidance www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors

7. Practitioner authorisation sheet

Smallpox vaccine PGD v3.00 Valid from 15 September 2023 Expiry: 15 September 2024

Before signing this PGD, check that the document has had the necessary authorisations in section 2. Without these, this PGD is not lawfully valid.

Practitioner

By signing this PGD you are indicating that you agree to its contents and that you will work within it.

PGDs do not remove inherent professional obligations or accountability.

It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

I confirm that I have read and understood the content of this PGD and that I am willing and competent to work to it within my professional code of conduct.			
Name	Designation	Signature	Date

Authorising manager

I confirm that the practitioners named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of insert name of organisation for the above named healthcare professionals who have signed the PGD to work under it.			
Name	Designation	Signature	Date

Note to authorising manager

Score through unused rows in the list of practitioners to prevent practitioner additions post managerial authorisation.

This authorisation sheet should be retained to serve as a record of those practitioners authorised to work under this PGD.