UK Health Security Agency

NHS

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mpox vaccine Patient Group Direction (PGD)

This PGD is for the administration of the non-replicating, live modified vaccinia virus Ankara - Bavarian Nordic (MVA-BN), to individuals identified for immunisation in response to preventing the spread of monkeypox virus (MPXV). **This PGD allows the use of Imvanex® vaccine and where Jynneos® is supplied, this PGD only enables the use of US licensed Batch FDP00072, expiry 31 July 2025.**

This PGD is for use by registered healthcare practitioners identified in section 3, subject to any limitations to authorisation detailed in section 2.

Reference no:	mpox (monkeypox) vaccine PGD (previously titled as Smallpox vaccine PGD)
Version no:	v4.0
Valid from:	10 October 2024
Review date:	30 November 2026
Expiry date:	30 April 2027

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). **Sections 2 and 7 can be edited within the designated editable fields provided, but only for the purposes for which these sections are provided, namely the responsibilities and governance arrangements of the NHS organisation using the PGD. The fields in section 2 and 7 cannot be used to alter, amend or add to the clinical content. Such action will invalidate the UKHSA clinical content authorisation which is provided in accordance with the regulations.**

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

[1] This includes any relevant amendments to legislation.

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

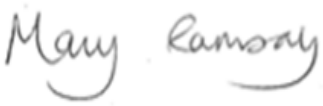
Enquiries relating to the availability of organisationally authorised PGDs and subsequent versions of this PGD should be directed to your local screening and immunisation team

Change history

Version number	Change details	Date
v1.00 and v2.00	See earlier versions of this PGD for specifics	2 August 2022 to 29 August 2023
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
v4.0	UKHSA mpox vaccine PGD amended to include: • reference to Chapter 29 amendments, made in response to the Clade I mpox virus (MPXV) infection guidance • change of PGD title from Smallpox vaccine PGD, to mpox (monkeypox) vaccine PGD, in line with other UKHSA circulars • reference to the disease as mpox, not monkeypox (in line with other UKHSA publications and WHO advice) • Imvanex®, in line with anticipated vaccine supplies • a revised definition of severely immunosuppressed (changed from Chapter 7 of the Green Book to Chapter 28a). Reference to immunosuppressed individuals as severely immunosuppressed • updated advice for needle length in intradermal administration, in line with the recently reissued BCG PGD • enabling intradermal (ID) administration to individuals under 18 years of age during supply constraints, within the context of an outbreak response (previously ID administration not recommended under any circumstances for this age group) • minor rewording, layout and formatting changes for consistency with other UKHSA PGDs • updated references • inclusion of additional Expert Panel members	9 October 2024

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)	Christina Wilson Lead Pharmacist Immunisation Programmes – design, implementation and clinical guidance, UKHSA		4 October 2024
Doctor	Dr Mary Ramsay CBE Director of Public Health Programmes and Consultant Epidemiologist, Immunisation and Vaccine Preventable Diseases Division, UKHSA		4 October 2024
Registered Nurse (Chair of Expert Panel)	David Green Nurse Consultant for Immunisation, Immunisation Programmes – design, implementation and clinical guidance, UKHSA		4 October 2024

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

Expert Panel (continued overleaf)

Dr Nicholas Aigbogun	Consultant in Communicable Disease Control, Yorkshire and Humber Health Protection Team, UKHSA
Dr Gayatri Amirthalingam	Deputy Director of Public Health Programmes and Consultant Epidemiologist, Immunisation and Vaccine Preventable Diseases Division, UKHSA
Alison Campbell	Screening and Immunisation Coordinator, Clinical, NHSE Midlands
Jodie Crossman	Clinical Nurse Specialist – GU Medicine, Brighton SHAC and Co-Chair-Sexually Transmitted Infections Foundation
Jane Freeguard	Deputy Director of Vaccination – Medicines and Pharmacy, NHSE
Rosie Furner	Advanced Specialist Pharmacist – Medicines Governance (Patient Group Directions and Medicines Mechanisms), Medicines Use and Safety, NHS Specialist Pharmacist Services (SPS)
Ed Gardner	Advanced Paramedic Practitioner/Emergency Care Practitioner, Primary Care Based, Southbourne Surgery
Greta Hayward	Consultant Midwife – Immunisation Programmes – design, implementation and clinical guidance, UKHSA
Gemma Hudspeth	Senior Health Protection Practitioner, North East Health Protection Team Regions Directorate, UKHSA
Jacqueline Lamberty	Medicines Governance Consultant Lead Pharmacist, UKHSA
Michelle Jones	Principal Medicines Optimisation Pharmacist, NHS Bristol North Somerset and South Gloucestershire Integrated Care Board

Elizabeth Luckett	Senior Screening and Immunisation Manager, NHSE South West
Dr Vanessa MacGregor	Consultant in Communicable Disease Control, East Midlands Health Protection Team, UKHSA
Dr 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 Programmes – design, implementation and clinical guidance, UKHSA
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.

NHS England authorises this PGD for use by the services or providers listed below:

Authorised for use by the following organisations and/or services
All NHS England commissioned immunisation services within the NHS England South East Region.
Limitations to authorisation
This patient group direction (PGD) must only be used by the registered healthcare practitioners identified in Section 3 who have been named by their organisation to practice under it. The most recent in-date final version authorised by NHS England (South East) must be used. This PGD includes vaccination of individuals across the national immunisation programme. Users of this PGD should note that where they are commissioned to immunise certain groups this PGD does not constitute permission to offer immunisation beyond the groups they are commissioned to immunise.

Organisational approval (legal requirement)			
Role	**Name**	**Sign**	**Date**
Medical Director System improvement and Professional Standards	**Dr Shahed Ahmed**		**30/10/24**

Additional signatories according to locally agreed policy			
Role	**Name**	**Sign**	**Date**

Local enquiries regarding the use of this PGD may be directed to insert local contact

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	**All practitioners should only administer vaccination where it is within their clinical scope of practice to do so. Practitioners must also fulfil the additional requirements and continued training requirements to ensure their competency is up to date, as outlined in the section below.** Practitioners working to this PGD must also be one of the following registered professionals who can legally supply and administer under a PGD: • nurses and midwives currently registered with the Nursing and Midwifery Council (NMC) • pharmacists and pharmacy technicians 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) 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 healthcare 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 intramuscular and subcutaneous injection techniques (plus intradermal in the event of constrained vaccine supply) • 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, 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 (continued over page)	**Availability of the MVA-BN vaccine at the time of assessment may determine whether the individual should be offered a deferral of the second primary dose or (in post-exposure cases) whether prioritisation should be given to higher risk individuals.** **a) Pre-exposure vaccination** (i) individuals who identify as gay, bisexual or a man who has sex with other men (GBMSM) **and** they are assessed as being at risk of mpox exposure as outlined in Chapter 29, namely - a recent history of multiple sexual partners - participation in group sex - attendance at sex-on-premises venues - acquiring a bacterial sexually transmitted infection (STI) in the last 12 months (ii) individuals (irrespective of gender or sexual orientation) who have frequent close and intimate contact with the GBMSM network at risk of mpox, such as - staff working in sex-on-premises venues frequented by GBMSM individuals and who are regularly exposed to surfaces or linen likely to be contaminated with body fluids or skin cells (such as in saunas) **Vaccination during outbreaks and incidents** **The decision to vaccinate an individual or group will be following a risk assessment by the Incident Management Team and/or Health Protection Team.** (iii) individuals in a specific setting or population type where multiple unlinked clusters are observed and where it is deemed more appropriate than managing as separate post-exposure cases. Individuals may be considered for a single dose of vaccine based on local risk assessment and epidemiology (such as the groups outlined in Box 1) (iv) in the event of local detection of a case or cluster of Clade I MPXV, individuals who are identified as being within a 'ring' of an exposed individual and where standard infection control measures are anticipated to be ineffective or challenging, as outlined in Box 1 (v) healthcare workers: in a wider outbreak response consider an extension of pre exposure vaccination recommendations. This is to protect health workers in settings or with populations where an outbreak is happening. This may need to be limited to a small numbers of designated healthcare staff who will be directly assessing and/or managing suspected mpox cases (see Chapter 29) (vi) other individuals or groups not covered elsewhere and identified following risk assessment by the local Health Protection Team and/or Incident Management Team

Criteria for inclusion

(continued)

Box 1: Local detection of a case or cluster of Clade I MPXV: populations for consideration for pre-exposure vaccination

- are household contacts of an individual assessed as having had a significant exposure
- are members (irrespective of gender or sexual orientation) of a sexual network with multiple casual sexual partners, such as sex workers and clients working from identified premises or a particular street or other public or semi-public location; members of a semi-closed sexual network associated with a specific venue
- regularly attend venues where close contact is anticipated, such as schools, pre-school nurseries, contact sport clubs and societies and daycare settings
- congregate in closed settings such as boarding schools, homeless shelters and hostels, care homes, residential facilities and prisons and other detained settings
- most of the exposed population is vulnerable to severe disease or less able to access healthcare, such as children under 5 and people experiencing homelessness
- members of a geographically defined area or community with a documented high risk of exposure to mpox (such as a village or defined postcode)

b) Post exposure vaccination (see Chapter 29 and mpox contact tracing guidance for most up-to-date advice)

- the individual has been risk assessed as a category 3 (high risk) exposure to Clade I or Clade II MPXV (or, when the supply chain is unaffected, a category 2 (medium risk) exposure to Clade I) **and either**:

(i) they present within 4 days of the last exposure
or

(ii) they present within 14 days of the last exposure and are in a group at higher risk of complications, for example

- aged under 5 years
- are pregnant
- living with HIV and who have a CD4 count of less than 200 cells per mm^3 or are otherwise severely immunosuppressed (as defined in Chapter 28a of the Green Book)

or

(iii) they present after 4 days, but the ongoing exposure level is high or has increased over the elapsed period since the original exposure
or

(iv) the exposed individual presents after 4 days, but lives with high risk household members (outlined in b(ii) above). Vaccinate these high-risk individuals (particularly if the exposure is significant)

c) Routine booster doses

Routine booster doses are not generally advised, except in limited specific circumstances.

The individual has previously completed a 2 dose primary dose of the MVA-BN vaccine (or 1 dose of MVA-BN and 1 dose of live smallpox vaccine) **and either:**

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Criteria for inclusion (continued)	(i) they are immunocompetent healthcare workers at ongoing risk from mpox exposure, whose last primary dose was over 10 years ago **and** who are eligible under extended pre-exposure vaccination recommendations in wider outbreak management (as outlined in criteria for inclusion) **or** (ii) they are severely immunosuppressed (as defined in Chapter 28a), are eligible for pre-exposure immunisation and whose last primary dose was over 2 years ago. Where a post-exposure dose is indicated, this may be given 6 months from the previous dose (see dose and frequency of indication [c)post-exposure vaccination] and Appendix 1 for information).
Criteria for exclusion[2]	Individuals who have not given valid consent (or for whom a best-interests decision in accordance with the Mental Capacity Act 2005, has not been obtained). For further information on consent, see Chapter 2 of the Green Book and written information to be given to individual or carer section. 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 • have completed the primary course of vaccination with 2 doses of MVA-BN or 1 dose of live smallpox vaccine and 1 dose of MVA-BN in the last 2 years • are travelling to areas affected by an MPXV outbreak or incident overseas. If the individual is eligible for the vaccine by being in the inclusion criteria then they can be vaccinated. • with the exception of healthcare workers as detailed in the criteria for inclusion, individuals who require vaccination for occupational health reasons, such as laboratory workers and staff working in High Consequence Infectious Disease (HCID) units (see Chapter 29: people at occupational risk of exposure). **Post-exposure specific exclusion criteria** • have been classed as a category I (low risk) exposure to Clade I or II MPXV • are immunocompetent and who completed a 2 dose course of MVA-BN (or 1 dose of live smallpox vaccine and 1 dose of MVA-BN), where their completing dose has been given less than 2 years before an exposure event • are severely immunosuppressed and who completed a 2 dose course of MVA-BN (or 1 dose of live smallpox vaccine and 1 dose of MVA-BN),

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[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.

Criteria for exclusion

(continued)

where their completing dose has been given less than 6 months before an exposure event

	No supply issue with MVA-BN	Supply issue with MVA-BN
Clade I category 1 (low risk) exposure	Vaccination not indicated	Vaccination not indicated
Clade I category 2 (medium risk) exposure	Vaccinate if inclusion criteria met	Vaccination not indicated
Clade I category 3 (high risk) exposure	Vaccinate if inclusion criteria met	Vaccinate if inclusion criteria met
Clade II category 1 (low risk) exposure	Vaccination not indicated	Vaccination not indicated
Clade II category 2 (medium risk) exposure	Vaccination not indicated	Vaccination not indicated
Clade II category 3 (high risk) exposure	Vaccinate if inclusion criteria met	Vaccinate if inclusion criteria met

Table 1: Summary of interventions based on Clade type and stratification of exposure risk (also refer to Chapter 29 and mpox contact tracing guidance)

Cautions including any relevant action to be taken

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 UK).

Individuals with atopic dermatitis develop more local and general symptoms after vaccination with MVA-BN vaccine. See identification and management of adverse reactions section for more information.

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 premises. However, as fainting can occur following vaccination, all those vaccinated with MVA-BN should be advised to not drive for 15 minutes after vaccination.

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 abnormalities. 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

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Cautions including any relevant action to be taken (continued)	pregnancy and the adverse events profile would be expected to be similar to that in non-pregnant individuals. Whilst the vaccine is not recommended for use in pregnancy, any theoretical risk needs to be weighed against the maternal risks of exposure to mpox in later 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 as the vaccine may be considered to be inactivated. The safety and immunogenicity of MVA-BN in individuals living with HIV infection (with CD4 cell counts above 100 cells/mm^3) 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 via the subcutaneous or intramuscular route. Severely immunosupressed individuals are at significant risk of the complications of mpox (see Chapter 29). Data on the intradermal route is lacking in this population. Individuals living with HIV who are virally suppressed and have a CD4 count above 200 cells/mm^3 are not considered to be severely 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. Although previous mpox infection is not a contraindication to vaccination, deferring vaccination of confirmed cases is recommended where supply is constrained. If supply allows, vaccination may be considered for those at continued risk once fully recovered.

Action to be taken if the individual is excluded	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. 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. Individuals seeking vaccination solely for the purpose of travel should be advised that MVA-BN is not currently recommended. Direct the individual towards the latest risk reduction advice on NaTHNaC. UK healthcare and laboratory workers, plus UK humanitarian aid workers wishing to travel to overseas areas affected by an MPXV outbreak should be directed to an occupational health service, as outlined below. Occupational health provision is not routinely covered under NHS commissioned services and remains an employer responsibility. With the exception of healthcare workers responding directly to mpox outbreaks as outlined in the criteria for inclusion, individuals requiring vaccination for occupational health purposes should be referred to their employer. In line with advice in Chapter 29, most health and social care workers will not require routine pre-exposure vaccination, particularly where appropriate PPE and environmental containment measures are utilised. Mpox 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. Individuals who are deemed to be in a lower risk category following an outbreak of mpox should be reassured and advised (where applicable and practical) to maintain isolation and hygiene measures where practical and adhere to standard infection control measures until 21 days have elapsed. Where applicable, provide the individual with an information sheet for contacts of confirmed mpox cases. Individuals who have been previously vaccinated with 2 doses of MVA-BN or 1 dose of MVA-BN and 1 dose of live smallpox vaccine should be reassured that the immunity afforded from a complete course offers long-lasting protection against future exposures, unless they are at a prolonged ongoing risk and a booster dose is recommended (see criteria for inclusion), or are severely immunosuppressed and require a post-exposure dose, which may be considered 6 months after the last dose was given. 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 individual 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 and recorded appropriately. Where a person lacks the capacity, in accordance with the Mental Capacity Act 2005, a decision to vaccinate may be made in the individual's best interests. For further information on consent, see Chapter 2 of the Green Book. Advise the individual, parent or 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 for injection. • **Jynneos®** 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- where Jynneos® is the local vaccine available at time of administration, this PGD only enables the use of US licensed Jynneos® vaccine: batch number FDP00072 (expiry date 31 July 2025).** • **Imvanex®** Each 0.5ml dose contains no less than 5 x 10^7 infectious units.
Legal category	Prescription only medicine (POM) See batch specific information above under name, strength and formulation section.
Black triangle▼	Yes. As new vaccine products, the MHRA has a specific interest in the reporting of adverse drug reactions for both vaccines. All suspected adverse drug reactions should be reported using the MHRA Yellow Card Scheme.
Off-label use	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 Chapter 29 to children considered to be at risk, as children seem to have a more severe presentation of mpox. Both Jynneos® and Imvanex® are only licensed for subcutaneous use. However, Chapter 29 allows the vaccine to be used subcutaneously, intramuscularly or intradermally. In August 2022, following evidence of efficacy of the intradermal route and fractional dosing (0.1ml), the intradermal route is now recommended during periods of supply constraints and where there is a need to preserve doses. 2 doses of MVA-BN are recommended for primary vaccination. The recommendation that only one dose of MVA-BN is required for exposed and at-risk individuals during an outbreak of mpox is off-label but in line with recommendations in Chapter 29, given that comparable vaccine efficacy has been seen when one and 2 doses are administered. Currently, there are no data on administering MVA-BN at the same time as other vaccines. However, it can be co-administered with other vaccines in accordance with Chapter 29. The 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 vaccines are assessed in accordance with these guidelines as appropriate for continued use, this would constitute off-label administration under this PGD. 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 outside of product licence.
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. By exception,

Route and method of administration (continued)	the ID route can be used for individuals aged under 18 during an outbreak, when supplies of MVA-BN are limited. 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. The vaccine should be allowed to reach room temperature before use. Swirl the vial gently before use for at least 30 seconds, including when fractional doses are being used. The vaccine's normal appearance is a light yellow to pale white milky suspension. The suspension should be visually inspected for foreign particulate matter and other variation of expected appearance prior to preparation and administration. Should either occur, or in the event of any damage to the vial, do not administer the dose and discard the vaccine in accordance with local procedures. 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 the 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 muscle 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 the ID route** The ID route of administration should only be used during periods of constrained vaccine supply when communicated by UKHSA and/or NHSE, with the exception of the following groups, who should continue to be offered a full 0.5ml dose by IM or SC injection: • individuals who are severely immunosuppressed (of any age) • individuals with keloid scars Withdraw a fractional dose of 0.1ml. Use the correct needle and syringe for withdrawing the fractional dose. A 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 to 4 inches below the antecubital fossa (the same site as normally used for Mantoux testing). 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 25G or 26G short needle (9 to 12mm length), ideally with a short bevel. 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 the ID route is used, provide the Intradermal mpox vaccination patient information leaflet.

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Route and method of administration (continued)	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 (2 months for Imvanex®). Do not re-freeze a vial once it has been thawed. The vaccine must not be mixed with other medicinal products. 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 into different limbs. If given into 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. Individuals with bleeding disorders may be vaccinated intramuscularly if, in the opinion of a clinician familiar with the individual's bleeding risk, vaccines or similar small volume intramuscular injections can be administered with reasonable safety by this route. Individuals on stable anticoagulation therapy, including individuals on warfarin who are up to date with their scheduled INR testing and whose latest INR was below the upper threshold of their therapeutic range, can be vaccinated via the intramuscular route. If the individual receives medication or other treatment to reduce bleeding, for example treatment for haemophilia, intramuscular vaccination can be scheduled shortly after such medication or other treatment is administered. A fine needle (equal to 23 gauge or finer calibre such as 25 gauge) should be used for the vaccination, followed by firm pressure applied to the site (without rubbing) for at least 2 minutes. The individual, parent or carer should be informed about the risk of haematoma from the injection. For individuals with an unstable bleeding disorder (or where intramuscular injection is otherwise not considered suitable), vaccines normally given by an intramuscular route may be given by deep subcutaneous injection instead.
Dose and frequency of administration (continued over page)	**a) 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. **Immunocompetent adults and children** • 0.5ml dose of MVA-BN per administration for intramuscular or subcutaneous injection or • during supply constraints, a fractional dose of 0.1ml of MVA-BN per administration for intradermal injection (for children, this applies only in outbreak response) **Severely immunosuppressed individuals (as defined in Chapter 28a) and individuals of any age with a history of keloid scarring** • 0.5ml dose of MVA-BN per administration for intramuscular or subcutaneous injection **b) Pre-exposure vaccination of individuals previously vaccinated against smallpox** Administer a single dose **Immunocompetent adults and children** • 0.5ml dose of MVA-BN per administration for intramuscular or subcutaneous injection or • during supply constraints, a fractional dose of 0.1ml of MVA-BN per administration for intradermal injection (for children, this applies only in outbreak response)

Dose and frequency of administration

(continued)

Severely immunosuppressed individuals (as defined in Chapter 28a) and individuals of any age with a history of keloid scarring

- 0.5ml dose of MVA-BN per administration for intramuscular or subcutaneous injection

c) Post-exposure vaccination

Administer a single dose.

For those with ongoing risk, a second dose may be administered at a minimum interval of 28 days.

Immunocompetent adults and children

- 0.5ml dose of MVA-BN per administration for intramuscular or subcutaneous injection or
- during supply constraints, a fractional dose of 0.1ml dose of MVA-BN per administration for intradermal injection (for children, this applies only in outbreak response)

Severely immunosuppressed individuals (as defined in Chapter 28a) and individuals of any age with a history of keloid scarring

- 0.5ml dose of MVA-BN per administration for intramuscular or subcutaneous injection

Post-exposure vaccination of occupational or community contacts should be offered to individuals with the highest exposure risks and given within 4 days of exposure. Post-exposure vaccination may be offered up to 14 days after exposure for those who are at higher risk of the complications of mpox. This includes children under 5 years of age, pregnant women and individuals with severe immunosuppression as outlined in Chapter 29.

Individuals who have previously received a 2 dose course of MVA-BN, with the completing dose given in the past 2 years do not need a post-exposure dose. The exception is for individuals who are severely immunosuppressed who may have a less durable immune response, where an additional dose can be considered from 6 months after the completing dose.

d) Booster vaccination

Table 2: Summary table for booster doses (pre-exposure indications)

Cohort	Dose	Notes
Severely immunosuppressed individuals	0.5ml IM or SC if last completing dose given over 2 years ago	Give as a single dose. If the booster is in response to a post-exposure event, give this dose within 4 days (up to 14 days post-exposure if at higher risk of mpox complications)
Immunocompetent, eligible healthcare workers (includes individuals living with HIV with a CD4 count above 200mm^3)	0.1ml ID or 0.5ml IM or SC if last completing dose given over 10 years ago	

There is limited evidence supporting the timing and need for booster doses. A booster dose given after 2 years reinforces immune memory from the primary course. Data modelling has predicted the duration of protection is around 10 years. Administration of a reinforcing dose of vaccination **via this PGD** is recommended:

(continued over page)

Dose and frequency of administration (continued)	• for eligible immunocompetent health workers (who meet the criteria for inclusion) at ongoing risk where the primary course was completed over 10 years ago • for severely immunosuppressed individuals where the primary course was completed over 2 years ago Where an outbreak has prompted review of the individual's need for a booster, the dose should be given within 4 days of the exposure event (or 14 days if the individual is at higher risk of mpox complications). Administer a single dose. **Immnunocompetent individuals** • 0.5ml dose of MVA-BN per administration for intramuscular or subcutaneous injection or • during supply constraints, a fractional dose of 0.1ml dose of MVA-BN per administration for intradermal injection (for children, this applies only in outbreak response) **Severely immunosuppressed individuals (as defined in Chapter 28a) and individuals of any age with a history of keloid scarring** • 0.5ml dose of MVA-BN per administration for intramuscular or subcutaneous injection **Previous incomplete vaccination** If the MVA-BN primary course is interrupted or delayed, it should be resumed but the first dose does not need to be repeated. Note that a longer interval between first and second doses increases the duration of protection and may be necessary when supply constraints are present. Evidence suggests individuals vaccinated with MVA-BN who have been previously vaccinated with a live smallpox vaccine manifest an antibody response as good or better than those who are given 2 doses of MVA-BN. A higher rate of side effects in this group would suggest that live vaccines prime effectively for immunity and therefore administering a single dose of MVA-BN following previous vaccination with a live vaccine, irrespective of the elapsed interval is sufficient to complete the primary course. Where a post-exposure dose is recommended for an at-risk individual who would also benefit from pre-exposure vaccination (for example, an individual from the GBMSM community) this dose may be double-counted towards the 2 primary doses.
Duration of treatment (continued over page)	During severe supply constraints, prioritisation should be given to ensuring all high risk individuals are offered a first dose of MVA-BN. Though a 2 dose primary course is advised for previously unvaccinated individuals, this dose may be offered at a longer interval, particularly as longer intervals increase the duration of protection. A 2 to 3 month interval is advised (see recommendations for the use of pre and post-exposure vaccination during an mpox incident). Previously unvaccinated individuals may be offered a 2 dose regime with a minimum 28 day interval between doses. In a post-exposure situation, with the exception of individuals with ongoing high risk exposure, a single dose of MVA-BN will suffice. Individuals who have been vaccinated with the live smallpox vaccine only require a single dose of MVA-BN.

Duration of treatment (continued)	Within the context of a Clade I community outbreak, a single dose should suffice for most eligible individuals identified (irrespective of exposure category), as the foreseeable risk of further exposure to MPXV is unlikely and the first dose of MVA-BN will have offered protection during the incubation period of the original exposure. See dose and frequency of administration section above for specifics.
Quantity to be supplied and administered	Single 0.5ml dose per subcutaneous or intramuscular administration. Single 0.1ml dose per intradermal administration (where supplies of MVA-BN are in severe shortage and the individual is not severely immunosuppressed or does not have a history of keloid scarring).
Supplies	The US-licensed vaccine 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. Depending on what is available from centrally held stocks at the time of ordering, either Jynneos® or Imvanex® will be supplied. Vaccines are available to order via ImmForm. Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see the Green Book Chapter 3).
Storage	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. 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 (2 months for Imvanex®). 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, vaccines that have been stored outside the conditions stated above should be quarantined and risk assessed on a case-by-case basis for suitability of continued off-label use or appropriate disposal. Refer to Vaccine Incident Guidance.
Disposal (continued over page)	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

Disposal (continued)	a UN-approved puncture-resistant sharps box, according to local waste disposal arrangements and NHSE guidance (HTM 07-01): safe and sustainable management of healthcare waste.
Drug interactions	Immunological response may be diminished in those receiving immunosuppressive treatment. Vaccination is recommended even if the antibody response may be limited (see special considerations and additional information section). 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 commonly reported adverse reactions were injection site reactions: pain, redness, swelling, induration, itching and influenza-type reactions, including chills, fever, muscle pain, fatigue, headache and nausea. Such reactions were mild to moderate in intensity and 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 (see 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 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 Direct Healthcare Professional Communication (DHPC) from Bavarian Nordic, the manufacturer, signposts to the Imvanex® information on the MHRA website.
Reporting procedure of adverse reactions	Healthcare professionals, individuals and carers are encouraged to report suspected adverse reactions to the MHRA using the Yellow Card reporting scheme or by searching 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 GP should be informed.
Written information to be given to individual or carer (continued over page)	Offer the marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine. The DHPC from Bavarian Nordic advises healthcare professionals to provide the Jynneos® package insert included in the outer packaging to individuals receiving the Jynneos® vaccine. For resources in accessible formats and alternative languages, please visit Home- Health Publications. • protecting you from mpox (monkeypox); information on the smallpox

Written information to be given to individual or carer (continued)	vaccination • intradermal mpox vaccination – what you need to know • mpox vaccination record card • mpox : waiting for your vaccination • mpox : people who are isolating at home (includes link to easy read guides) • information sheets for contacts (category 2 and category 3) (includes link to easy read guides)
Advice and follow up treatment	Inform the individual, or their parent or carer of possible side effects and their management. The individual, parent or carer should be advised to seek medical advice in the event of an adverse reaction and report this via the Yellow Card reporting scheme. 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. When applicable, advise the individual, parent or carer when the next dose is due. Where administration is postponed, advise the individual, parent or carer when to return for vaccination. Provide the individual, parent or carer with further advice and leaflets as recommended in the national guidance monkeypox vaccination resources.
Special considerations and additional information (continued over page)	Ensure there is immediate access to adrenaline (epinephrine) 1 in 1000 injection and access to a telephone at the time of vaccination. Though protection following immunisation with a single dose of MVA-BN is high, it may take up to 14 days to respond to the vaccine. Appropriate infection control precautions should continue to be followed, particularly for those requiring protection from occupational exposure to mpox. **GBMSM** In line with the JCVI advice on the routine mpox immunisation programme for eligible GBMSM individuals, efforts should be made to equitably offer the MVA-BN vaccine to those at equivalent risk, including gender-diverse individuals who were assigned male at birth and transgender females. **Prioritisation of doses during supply constraints** As the duration of vaccine response improves with a longer dose interval, first primary doses of MVA-BN should be prioritised for individuals at highest risk (such as the GBMSM community at highest risk of exposure). If sufficient vaccine supplies allow, a second dose may be advised 2 to 3 months following the first primary dose to provide longer lasting protection for those at ongoing risk (see recommendations for the use of pre and post exposure vaccination during an mpox incident). Post-exposure vaccination of community contacts should be prioritised for groups at the highest risk of severe disease, such as pregnant individuals, children under 5 years of age and severely immunosuppressed individuals. Those eligible for pre-exposure doses (such as GBMSM with multiple sexual partners) should be prioritised for vaccination. The ID route should also be considered, aside from individuals with keloid scarring and severely immunosuppressed individuals of any age. Except in outbreak cases, where vaccine supply is constrained, individuals under 18

Special considerations and additional information (continued)	years of age should still be offered a full 0.5ml dose via the IM or SC route. Further detail on case prioritisation for vaccination is detailed in recommendations for the use of pre and post-exposure vaccination during an mpox incident. **Severely immunosuppressed individuals** For the purposes of this PGD, individuals living with HIV who are virally suppressed and who have a CD4 count above 200 cells/mm^3 are not considered to be severely immunosuppressed. Individuals who meet the definition of severe immunosuppression as outlined in Chapter 28a (shingles) may be considered for an additional post-exposure dose of MVA-BN. This second dose may be given from 28 days following the first dose as outlined in the dose and frequency of administration section.
Records	The practitioner must ensure the following information is recorded: • 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 • GP with whom the individual is registered (or record if the individual is not registered with a GP) • 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 • anatomical site of vaccination • advice given, including advice given if the individual is excluded or declines immunisation • details of any adverse drug reactions and actions taken • supplied via PGD Records should be signed and dated (or password-controlled on e-records). All records should be clear, legible and contemporaneous. Where the provider is a Sexual Health Service (SHS), the offer and uptake of mpox vaccination should be coded in sexual health services' electronic patient records management system and, in accordance with the service specification, reported to UKHSA with routine GUMCAD STI Surveillance returns. 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. When the vaccine is administered to individuals under 19 years of age, notify the local Child Health Information Service (CHIS) using the appropriate documentation or pathway as required by any local or contractual arrangement. 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	Mpox (monkeypox) vaccine
	• Immunisation Against Infectious Disease: The Green Book Chapter 29, www.gov.uk/government/publications/smallpox-and-vaccinia-the-green-book-chapter-29 • The Medicines and Healthcare products Regulatory Agency (MHRA) Summary of Product Characteristics (Imvanex®), last updated 29 September 2023 https://products.mhra.gov.uk/search/?search=IMVANEX • 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 • Mpox (monkeypox) vaccination record card, published 6 July 2022 www.gov.uk/government/publications/monkeypox-vaccination-resources • Department of Health and Social Care: JCVI statement on mpox vaccination as a routine programme, published 10 November 2023 http://www.gov.uk/government/publications/mpox-vaccination-programme-jcvi-advice-10-november/jcvi-statement-on-mpox-vaccination-as-a-routine-programme • UKHSA Collection - Mpox: guidance, last updated 14 August 2024 www.gov.uk/government/collections/monkeypox-guidance • Intradermal mpox (monkeypox) vaccination for eligible patients www.gov.uk/government/publications/monkeypox-vaccination-resources • Intradermal mpox (monkeypox) vaccination – what you need to know, last updated 6 September 2022 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 • UKHSA Guidance: Clade I mpox virus infection, published 15 August 2024 https://www.gov.uk/guidance/clade-1-mpox-virus-infection • Recommendations for the use of pre and post exposure vaccination during an mpox incident, last updated 12 August 2022 https://www.gov.uk/government/publications/monkeypox-vaccination • Mpox contact tracing guidance: classification of contacts and follow-up advice for non-HCID strains of monkeypox virus (MPXV), published 23 January 2023 https://www.gov.uk/government/publications/monkeypox-contact-tracing **General** • NHSE Health Technical Memorandum 07-01: safe and sustainable management of healthcare waste, updated 7 March 2023 www.england.nhs.uk/publication/management-and-disposal-of-healthcare-waste-htm-07-01/

(continued over page)

Key references (continued)	• National Minimum Standards and Core Curriculum for Immunisation Training, published 7 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 27 March 2017 www.nice.org.uk/guidance/mpg2 • NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions, updated 27 March 2017. www.nice.org.uk/guidance/mpg2/resources • UKHSA Immunisation Collection www.gov.uk/government/collections/immunisation • Vaccine Incident Guidance, updated 7 July 2022 www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors • UK Statutory Instruments 2024, Number 729. The Human Medicines (Amendments relating to Registered Dental Hygienists, Registered Dental Therapists and Registered Pharmacy Technicians) Regulations 2024, published 29 May 2024 https://www.legislation.gov.uk/uksi/2024/729/introduction/made

7. Practitioner authorisation sheet

mpox vaccine PGD v4.0 Valid from 9 October 2024 Expiry: 30 April 2027

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

UK Health Security Agency

NHS

Appendix 1: Summary table of dosing schedules for pre and post-exposure indications

	Previously not vaccinated with any smallpox vaccine (MVA-BN or live smallpox) **(pre-exposure)**	**Previously vaccinated with 1 dose of MVA-BN or live smallpox vaccine** **(pre-exposure or post-exposure)**	**Previously vaccinated with 2 doses of MVA-BN (or with live smallpox vaccine)**
Number of doses indicated	2 dose regime with a minimum 28 day interval between doses.	A single dose	A single dose if indicated (see below)
Immunocompetent children and adults (including those with atopic eczema)	0.5ml IM or SC 0.1ml ID during supply constraints (for children, only within the context of an outbreak response)	0.5ml IM or SC 0.1ml ID during supply constraints (for children, only within the context of an outbreak response)	**Pre-exposure:** if the primary course was completed over 10 years ago **Post-exposure**: if the primary course was completed over 2 years ago
Severely immunosuppressed individuals and those with a history of keloid scarring	0.5ml IM or SC	0.5ml IM or SC	**(Severely immunosuppressed only)** **Pre-exposure**: only indicated if primary course completed over 2 years ago **Post-exposure**: if the primary course was completed more than 6 months ago