National reference: CYM-24027

Local reference: PGD 0240A

Patient Group Direction

for the administration of

Modified Vaccinia Ankara Bavarian Nordic (MVA-BN) non-replicating live modified vaccine suspension for injection

by registered health care professionals in accordance with the

recommendations given in Chapter 29: The Green Book for mpox vaccination

in Powys Teaching Health Board (PTHB)

Operational from: 1st December 2024

Review Date: 1st August 2027

Expiry Date: 30th November 2027

Version number: v4.0

PGD for the administration of Modified Vaccinia Ankara Bavarian Nordic (MVA-BN) vaccine suspension for injection by healthcare professionals in accordance with the recommendations in Chapter 29: the Green Book for mpox vaccination

Reference:	Modified Vaccinia Ankara Bavarian Nordic (MVA-BN) vaccine PGD
Version no:	04.00
Valid from:	01 December 2024
Review date:	01 August 2027
Expiry date:	30 November 2027

Welsh Medicines Advice Service has developed this PGD for local authorisation.

Those using this PGD must ensure that it is authorised by the organisation in which they are operating 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 the 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 such action will invalidate the *clinical sign-off* with which it is provided.

As operation of this PGD is the responsibility of service providers, the authorising organisation can decide which staff groups, in keeping with relevant legislation, can work to the PGD.

INDIVIDUAL PRACTITIONERS MUST BE LISTED 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.

Any queries regarding the clinical content of this PGD should be addressed to: welshmedicines.information@wales.nhs.uk

[1] This includes any relevant amendments to legislation (e.g. 2013 No.235, 2015 No.178, 2015 No.323) and 2024 No.729).

Change history

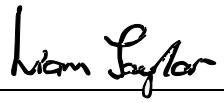
Version number	Change details	Date
01.00	Original PGD template developed	August 2022
01.10	Batch specific variation removed	09 September 2022
02.00	The WMAS national PGD template is updated to: • Incorporate WHO recommended preferred term mpox as a synonym for monkeypox • Include the intradermal (ID) route of administration in the relevant sections: off label use, route of administration, dose and frequency, adverse reactions • Allow the use of US licensed Batch FDP00072 of Jynneos▼® vaccine • Add individuals with keloid scarring to exclusions and dose sections • References update • Delete references to the vaccine being used off label. The vaccine has been authorised for active immunisation against mpox in adults in the UK by the Medicines and Healthcare Products Regulatory Agency (MHRA) • Add observation following vaccination in cautions, patient advice sections and special considerations sections	09 January 2023
03.00	• PGD updated to align with national PGD template. • Update references. • Minor wording and grammar changes and additions to text for consistency. • Removal of intradermal method of administration and reference to individuals with history of keloid scarring. • References updated.	26 March 2024
04.00	• Reference to Jynneos▼® as main vaccine changed and now includes Imvanex▼® product. • Change to legislation no 729 (footer note 1) including registered pharmacy technicians in Section 3 included. • Pharmacy technicians added to list of registered professionals who can work under this PGD. • Additional requirements section updated with links to national minimum standards for immunisation and the competency assessment tool. • Intradermal method of administration included and reference to individuals with history of keloid scarring. • Clinical content reviewed against the UKHSA PGD GOV-17181 and inclusion and exclusion criteria listed.	16 October 2024

1. PGD development

This PGD has been developed by the following health care professionals on behalf of NHS Wales.

This section MUST REMAIN when a PGD is adopted by an organisation

PGD Development

Name	Designation	Signature
Expert Reviewer – Liam Taylor	Deputy Medical Director. Aneurin Bevan University Health Board. Member of the Vaccine Clinical Advisory Group	
Expert Reviewer – Siân Owen	Lead Doctor Immunisation, Betsi Cadwaladr UHB. Member of the Vaccine Clinical Advisory Group	
Main author – Dianne Burnett	National Lead pharmacist Medicines Advice. Welsh Medicines Advice Service, Cardiff and Vale UHB. Member of the Vaccine Clinical Advisory Group	
Expert Reviewer – Nicola Bevan	Nurse Consultant. Deputy Head Vaccine Prevention. Health Protection Team, Public Health Wales.	

This PGD has been peer reviewed by the Vaccine Clinical Advisory Group in accordance with the WMAS PGD Policy and ratified by the All Wales PGD Advisory Board.

Expert Panel – Vaccine Clinical Advisory Group

Name	Designation
Andrew Evans	Chief Pharmaceutical Officer
Dianne Burnett	National Lead Pharmacist Medicines Advice. Welsh Medicines Advice Service, Cardiff and Vale UHB
Christopher Johnson	Head of VPDP, Public Health Wales
Beverley Griggs	Consultant in Health Protection/Communicable Disease Control, Public Health Wales
Liam Taylor	Medical Director representative, Primary Care
Siân Owen	Lead Doctor Immunisation, Associate Specialist in Community Paediatrics, Betsi Cadwaladr UHB
Heather Payne	Senior Medical Officer, Welsh Government
Paul Labourne	Senior Nursing Officer, Office of the CNO, Welsh Government
Nicola Bevan	Nurse Consultant, Deputy Head, Vaccine Prevention, Health Protection Team, Public Health Wales
Kailey Ben-Sassi	Lead Immunisation Pharmacist Betsi Cadwaladr UHB

Date VCAG approval of PGD: 11 December 2024

Date All Wales PGD Advisory Board ratification: 18 December 2024

2. Organisational authorisations

The PGD is not legally valid until it has had the authorisation of the organisation in which the practitioner using it operates.

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

Powys Teaching Health Board authorises this PGD for use by the services or providers listed below.

Authorised for use by the following organisations and/or services
Powys Teaching Health Board Powys Teaching Health Board GP Practices: role, organisation, name, signature and date must be added to indicate adoption
Limitations to authorisation

Organisational approval (legal requirement)			
Role	**Name**	**Sign**	**Date**
Lead Doctor for PTHB	Dr Kate Wright	DocuSigned by: Kate Wright 1F267952823F473...	1/16/2025
Chief Pharmacist for PTHB	Jacqueline Seaton	Signed by: Jacqueline Seaton 71E8089DE3634C4...	1/16/2025
Executive Director of Nursing and Midwifery for PTHB	Claire Roche	DocuSigned by: Claire Roche F07413E114E04B1...	1/17/2025

Additional signatories according to locally agreed policy			
Role	**Name**	**Sign**	**Date**
Clinical Governance Lead for PTHB: Assistant Director for Innovation and Improvement	Amanda Edwards	DocuSigned by: Amanda Edwards 74A4E51A42E9473...	1/23/2025

Local enquiries regarding the use of this PGD may be directed to [Medicines Management on 01874 712641.

Assembly, final preparation and administration of vaccines supplied and administered under this PGD must be subject to NHS governance arrangements and standard operating procedures that ensure that the safety, quality or efficacy of the product is not compromised. The assembly, final preparation and administration of the vaccines should also be in accordance with the manufacturer's instructions in the product's UK Summary of Product Characteristics and/or in accordance with official national recommendations.

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

Details of local policy or guidance that should be read in conjunction with this PGD
PTHB Additional local appendix (attached to the end of this PGD)

Retention statement

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.

3. Characteristics of staff

Qualifications and professional registration	**Practitioners must only work under this PGD where they are competent to do so.** Practitioners working to this PGD must also be one of the following registered professionals who can legally supply and administer under a PGD (see Patient Group Directions: who can administer them): ➢ Nurses and midwives currently registered with the Nursing and Midwifery Council (NMC). ➢ Pharmacists and pharmacy technicians currently registered with the General Pharmaceutical Council (GPhC). ➢ Chiropodists/podiatrists, dieticians, occupational therapists, orthoptists, orthotists/prosthetists, paramedics, physiotherapists, radiographers and speech and language therapists currently registered with the Health and Care Professions Council (HCPC). ➢ Dental hygienists and dental therapists registered with the General Dental Council (GDC). ➢ Optometrists registered with the General Optical Council (GOC). Practitioners must also fulfil all the additional requirements. Check Section 2 limitations to authorisation to confirm whether all the registered practitioners listed above have organisational authorisation to work under this PGD.
Additional requirements (continued over page)	Additionally: ➢ practitioners must be employed by, or providing services on behalf of PTHB or a PTHB GP Practice. ➢ practitioners must be authorised by name as an approved practitioner under the current terms of this PGD before working to it. ➢ practitioners must be competent in the use of PGDs (see NICE Competency framework for health professionals using PGDs). ➢ practitioners must be familiar with the vaccine products and alert to changes in the package insert for Jynneos▼®, the Summary of Product Characteristics (SmPC) for Imvanex▼®, Immunisation Against Infectious Disease (the 'Green Book'), and national and local immunisation programmes (the Welsh Health Circulars and Public Health Wales). ➢ practitioners must have undertaken appropriate training for working under PGDs for supply/administration of medicines. ➢ practitioners must have undertaken training appropriate to this PGD as required by local policy and health board standard operating procedures and in line with the mpox training recommendations available at Mpox - Information for health professionals - Public Health Wales (nhs.wales).

Additional requirements (continued)	➢ if practitioners are new to immunisation the national minimum standards and core curriculum for immunisation training for registered healthcare practitioners apply. Practitioners delivering training should adapt the curriculum (the topics covered and the level of detail required) to the specific needs of the workforce depending on the nature of their role in terms of delivering the mpox vaccine programme. ➢ if a practitioner has not received any vaccine update training in the past year, it is recommended that they also undertake the administration, storage and legal aspects e-learning modules available in the Immunisation programme - Public Health Wales (nhs.wales). This page offers support on how to access these resources via ESR, or for staff outside of NHS Wales via the learning@Wales platform. Training resources and guidance documents are also available to view here: Resources for health and social care professionals - Public Health Wales Immunisation training resources and events - Public Health Wales Mpox - Information for health professionals - Public Health Wales (nhs.wales) ➢ all new mpox immunisers should complete a competency assessment, for formal assessment and sign-off of their clinical competency. The competencies required will depend on the individual service area and the role of the immuniser. The RCN competency assessment tool is available here: Immunisation Knowledge and Skills Competence Assessment Tool. ➢ the competency assessment tool is also useful for more experienced immunisers to self-assess and identify if there are any areas where they need to update or further their knowledge and skills. ➢ practitioners must be competent to undertake immunisation and to discuss issues related to immunisation. ➢ practitioners must be competent in the handling and storage of vaccines, and management of the cold chain. ➢ practitioners must be competent in the recognition and management of anaphylaxis. ➢ practitioners must have access to the PGD and associated online resources. ➢ practitioners 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.**

Ongoing training and competency	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 Continuing Professional Development (CPD). ➢ be aware of any updates to relevant national guidelines from Public Health Wales, NHS Wales, Welsh Government Welsh Health Circulars (WHC) and other sources of medicines information. ➢ be aware of any updates made to the product in its SmPC or BNF entries or in the Green Book. ➢ as registered professionals, be professionally accountable and must work within their competence. A record of training and competence must be maintained. ➢ have demonstrated competence in Basic Life Support skills including resuscitation skills and the management of anaphylaxis, in line with the published requirements for provision of this service. 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

Clinical condition or situation to which this PGD applies	Modified Vaccinia Virus Ankara Bavarian Nordic (MVA-BN) vaccine is indicated for the pre and post exposure immunisation of individuals against mpox virus, in accordance with the recommendations given in Smallpox and mpox: the green book chapter 29 and subsequent official correspondence or publications.
Inclusion Criteria (continued over page)	MVA-BN vaccine should be used in accordance with the recommendations given in Smallpox and mpox: the green book chapter 29. **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** MVA-BN vaccine can be given to: ➢ 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 Smallpox and mpox: the green book chapter 29, namely: o a recent history of multiple sexual partners o participation in group sex o attendance at sex-on-premises venues o acquiring a bacterial sexually transmitted infection (STI) in the last 12 months ➢ individuals (irrespective of gender or sexual orientation) who have frequent close and intimate contact with the GBMSM network at risk of mpox, such as o 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.** MVA-BN vaccine can be given to: ➢ 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). ➢ individuals, in the event of local detection of a case or cluster of Clade I MPXV, who are identified as being within a 'ring' of an exposed

Inclusion Criteria

(continued)

individual and where standard infection control measures are anticipated to be ineffective or challenging, as outlined in box 1.

- 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 small numbers of designated healthcare staff who will be directly assessing and/or managing suspected mpox cases (see Smallpox and mpox: the green book chapter 29).
- other individuals or groups not covered elsewhere and identified following risk assessment by the local Health Protection Team and / or Incident Management Team.

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 day care 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)

MVA-BN vaccine can be given to:

- an individual who 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**:
  - they present within 4 days of the last exposure.

  OR

  - they present within 14 days of the last exposure and are in a group at higher risk of complications, for example:
    - individuals aged under 5 years including infants from birth.
    - individuals who are pregnant.

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Inclusion Criteria (continued)	▪ individuals 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** ○ they present after 4 days, but the ongoing exposure level is high or has increased over the elapsed period since the original exposure. **OR** ○ the exposed individual presents after 4 days, but lives with high-risk household members (outlined 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.** MVA-BN vaccine can be given: ➢ to an individual who 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**: ○ 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 inclusion criteria). **OR** ○ 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 post-exposure vaccination and appendix C for information).

Exclusion Criteria[2]	MVA-BN vaccine should not be given to: ➢ individuals for whom no valid consent has been received or 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). The Patient Information Leaflet (PIL) for Modified Vaccinia Ankara Bavarian Nordic (MVA-BN) vaccine (Imvanex▼®) OR the package insert for Jynneos▼® should be available to inform consent. ➢ individuals who have had a confirmed anaphylactic reaction to a previous dose of the MVA-BN vaccine. ➢ individuals who have had a confirmed anaphylactic reaction to any component of the MVA-BN vaccine or residues from the manufacturing process.[3] ➢ individuals who are suffering from acute severe febrile illness. The presence of a minor infection is not a contraindication for immunisation. ➢ individuals who received the first dose less than 4 weeks ago. ➢ individuals where the date of their exposure is greater than 14 days. ➢ 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 inclusion criteria, individuals who require vaccination for occupational health reasons, such as laboratory workers and staff working in High Consequence Infectious Disease (HCID) units or laboratories see Smallpox and mpox: the green book chapter 29. **Post-exposure specific exclusion criteria** ➢ individuals who have been classed as a category I (low risk) exposure to Clade I or II MPXV. ➢ who 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. ➢ who 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), where their completing dose has been given less than 6 months before an exposure event.

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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 for administration of vaccine will be required

[3] Contains tromethamine, chicken protein, benzonase, gentamicin and ciprofloxacin. Refer to the Summary of Product Characteristics (SmPC) and package inserts for a full list of excipients

Exclusion Criteria

(continued)

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

Category and risk of exposure	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

Cautions

Refer to the Summary of Product Characteristics (SmPC) for Imvanex▼® and package insert for Jynneos▼® for full details of special warnings and precautions for use.

Individuals with atopic dermatitis can develop more local and general symptoms after vaccination. For further information see management of adverse reactions section and Smallpox and mpox: the green book chapter 29.

Bleeding disorder

Individuals with a thrombocytopenia or a bleeding disorder may develop a haematoma at the injection site (see route of administration).

Keloid scarring

Individuals with a history of developing keloid scarring may be offered a 0.5 mL sub cutaneous or intramuscular dose of MVA-BN in preference to a fractional dose intradermally.

Syncope

Syncope (fainting) can occur following, or even before, any vaccination 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 that procedures are in place to avoid injury from faints.

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Cautions (continued)	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/clinic. However, as fainting can occur following vaccination, all those vaccinated with MVA-BN should be advised to not drive for 15 minutes after vaccination. **Immunocompromised** Individuals with immunosuppression or taking immunosuppressant medication may have a reduced response to vaccination but they should still be vaccinated. Further vaccination may need considering. See Smallpox and mpox: the green book chapter 29). 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/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 in accordance with recommendations, as these individuals are at significant risk of the complications of mpox (see Smallpox and mpox: the green book 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/mm3 are not considered 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. Whether prior mpox infection protects against future infection is unclear but based on analogy from smallpox infection and from live smallpox vaccine, it is 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 recommended that vaccination of confirmed cases is deferred. If supply allows, vaccination may be considered for those at on-going risk once fully recovered. **Pregnancy** ➢ While the vaccine is not recommended in pregnancy, there is no theoretical reason for concern in pregnancy (non-replicating virus). ➢ The adverse effect profile is expected to be similar to that in non-pregnant individuals. ➢ Any concerns need to be weighed against the maternal risk of exposure to mpox in later pregnancy, such as a risk of more severe disease from

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Cautions (continued)	viral infections in the third trimester, and consequent foetal risk 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.
Action to be taken if the individual is excluded or declines (continued over page)	➢ Seek appropriate advice from a clinical supervisor, immunisation co-ordinator, the local immunisation team or the individual's clinician where appropriate. ➢ Explain the reasons for exclusion and any advice or action taken and document in the individual's patient record. ➢ 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. ➢ In case of postponement due to acute illness and who are not at immediate risk of exposure, advise when the individual can be vaccinated and ensure another appointment is arranged. ➢ 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. ➢ 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, or are severely immunosuppressed and require a post-exposure dose, which may be considered 6 months after the last dose was given. ➢ If the individual has a long-term condition or they take medicines that affect their immune system and they are exhibiting rapidly worsening symptoms of mpox, they should be referred for a clinical assessment to be appropriately advised. ➢ Informed consent, from the individual or a person legally able to act on the person's behalf, must be obtained for each administration. Where a person lacks the capacity, in accordance with the Mental Capacity Act 2005, a 'Best Interests' decision to vaccinate may be made for the individual and be equivalent to the requirement for informed consent for

Action to be taken if the individual is excluded or declines (continued)	administration. For further information on consent see chapter 2 of the Green Book. ➢ If the individual declines, advise about the protective effects of the vaccine and the consequences of not receiving it. ➢ The risk to the individual of not being immunised should be considered. The indications for mpox vaccination are not exhaustive, and practitioners should consider the risk of mpox exacerbating any underlying disease that an individual may have, as well as the risk of serious illness from mpox itself and refer individuals to an appropriate medical professional for immunisation or a Patient Specific Direction (PSD) obtained where appropriate.
Arrangements for referral for medical advice	If there is any doubt about the administration of the vaccine or an individual's suitability to receive the vaccine, an appropriate medical professional should be consulted.

5. Description of treatment

Name, strength & formulation of drug	MVA-BN vaccine suspension for injection. **Jynneos▼®** Each 0.5 mL 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 the time of administration, this PGD only enables the use of US licensed Jynneos▼® vaccine: batch number FDP00072 (expiry date 31 July 2025).** **Imvanex▼®** Each 0.5 mL dose contains no less than 5 x 10^7 infectious units.
Legal category	POM - Prescription Only Medicine
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	The use of MVA-BN vaccine is off label in children, however, 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 Smallpox and mpox: the green book chapter 29 to children considered to be at risk, as children seem to have a more severe presentation of mpox. **Both Imvanex▼® and Jynneos▼® are only licensed for subcutaneous use. However, the Smallpox and mpox: the green book 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 (0.1 mL), the intradermal route is now recommended during periods of supply constraints and where there is a need to preserve doses. TWO 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 Small pox and mpox: the green book 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 vaccines at the same time as other vaccines. However, it can be co-administered with other vaccines in accordance with Smallpox and mpox: the green book chapter 29. Vaccines should be stored according to the conditions detailed in the storage section in this document. However, in the event of an inadvertent or unavoidable deviation of these conditions refer to section 5 (storage) and section 11 (incident) of advisory document on ordering storage and handling of vaccines.

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Off-label use (continued)	Where vaccine is 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, as part of the consent process, consider informing the individual or their parent/carer that the vaccine is being offered in accordance with national guidance but that this is outside the product licence.
Route / method of administration (continued over page)	The vaccine can be given subcutaneously (SC), intramuscularly (IM) or intradermally (ID). **Individuals aged less than 18 years**: Administer through the SC or IM route. By exception the ID route **can be used** for individuals aged under 18 during an outbreak, when supplies of MVA-BN are limited. Check the expiry date or beyond use date. **For SC or IM routes.** A dose of 0.5 mL is withdrawn into a syringe for injection and administered by the deep SC route or IM route (see Green Book chapter 4). The preferred sites for SC or IM immunisation are the deltoid muscle of the upper arm or the 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 Welsh Government or NHS Wales, with the exception of the following groups, who should continue to be offered a full 0.5 mL dose by IM or SC injection: ➢ Individuals who are severely immunosuppressed (of any age). ➢ Individuals with keloid scars. Withdraw a fractional dose of 0.1 mL. Use the correct needle and syringe for withdrawing the fractional dose. An ID 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).

Route / method of administration (continued)	A correctly given ID injection results in a tense, blanched, raised bleb of around 7 mm diameter following a fractional dose of 0.1 mL ID injection. It is easier to administer this correctly with a 1 mL graduated syringe fitted with a 25G or 26G short needle (9 to 12 mm 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. 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. Allow the vaccine to thaw. The vaccine should be allowed to reach room temperature before use. 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'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 particulate matter and/or variation of physical aspect being observed, the vaccine should be discarded. Swirl the vial gently before use for at least 30 seconds, including when fractional doses are being used. 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 2.5 cm apart. The site at which each vaccine was given should be noted in the individual's records. Individuals with bleeding disorders may be vaccinated IM if, in the opinion of a doctor familiar with the individual's bleeding risk, vaccines or similar small volume IM 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 receive IM vaccination. If the individual receives medication / treatment to reduce bleeding, for example treatment for haemophilia, IM vaccination can be scheduled shortly after such medication / 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 or their parent/carer should be informed about the risk of haematoma from the injection.

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Route / method of administration (continued)	For individuals with an unstable bleeding disorder (or where IM injection is otherwise not considered suitable), vaccines normally given by an IM route may be given by deep SC injection instead. If in any doubt, consult with the clinician responsible for prescribing or monitoring the individual's anticoagulant therapy. When vaccinating mpox contacts, follow Public Health Wales infection prevention and control (IP&C) measures for suspected and confirmed cased of Mpox in healthcare settings in Wales. Administration should be under conditions where management of severe hypersensitivity reactions, such as anaphylaxis, is possible. It is recommended that individuals should be observed for immediate adverse effects post vaccination. The Summary of Product Characteristics (SmPC) for Imvanex▼® and package insert for Jynneos▼® provides further guidance on administration.
Dose and frequency of administration (continued over page)	**a) Pre-exposure vaccination** **Individuals previously not vaccinated against smallpox.** Administer a course of TWO doses with at least a 28-day interval between doses. Dose intervals of less than 4 weeks should be avoided. **Immunocompetent adults and children.** ➢ 0.5 mL dose of MVA-BN per administration for IM or SC injection. ➢ during supply constraints, a fractional dose of 0.1 mL of MVA-BN per administration for ID 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** ➢ 0.5 mL dose of MVA-BN per administration for IM or SC injection. In the event of an outbreak or incident, it is highly unlikely that there will be sufficient time to offer pre-exposure vaccination with two doses for those at risk of occupational exposure. In this case, a single dose of vaccine should be offered immediately. Completion of the primary course with a second dose at least 28 days later should be considered on assessment of ongoing risk of exposure. Where the second dose of MVA-BN is given beyond 28 days, the first dose should not be repeated (see Smallpox and mpox: the green book chapter 29). **Individuals previously vaccinated against smallpox.** Administer a single dose of MVA-BN.

Dose and frequency of administration (continued)	**Immunocompetent adults and children** ➢ 0.5 mL dose of MVA-BN per administration for IM or SC injection. ➢ during supply constraints, a fractional dose of 0.1 mL of MVA-BN per administration for ID 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** ➢ 0.5 mL dose of MVA-BN per administration for IM or SC injection. **b) Post-exposure vaccination** Administer a single dose of MVA-BN immediately. For those with ongoing risk, a second dose maybe administered at a minimum interval of 28 days. **Immunocompetent adults and children.** ➢ 0.5 mL dose of MVA-BN per administration for IM or SC injection. ➢ during supply constraints, a fractional dose of 0.1 mL of MVA-BN per administration for ID 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** ➢ 0.5 mL dose of MVA-BN per administration for IM or SC injection. To maximise the chance of preventing infection, MVA-BN should preferably be administered within 4 days from the date of exposure to mpox. The objectives of immunisation are to provide protection against infection and to modify disease severity in individuals following an identified exposure. Post-exposure vaccination should be offered within 4 days of exposure, although it may be offered up to 14 days after exposure for those who are at high risk of the complications of mpox. This includes children below the age of five years, pregnant women and individuals with immunosuppression as outlined in Smallpox and mpox: the green book chapter 29. Individuals who have previously received a two-dose course of MVA-BN, with the second dose given in the past two years, do not need a further dose of vaccine after exposure (post exposure dose). The exception is those who are severely immunosuppressed, who may have made a lower or less durable immune response, where an additional dose can be considered from 6 months after their second dose (Smallpox and mpox: the green book chapter 29).

(continued over page)

Dose and frequency of administration

(continued)

Booster vaccination

Table 1: Summary table for booster doses (pre-exposure indications)

Cohort	Dose	Notes
Severely immunosuppressed individuals	0.5 mL 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)	0.5 mL[#] IM or SC if last completing dose given over 10 years ago	

[#] during times of supply constraint, a fractional dose of 0.1 mL ID administration can be used.

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:

- for eligible immunocompetent health workers (who meet the inclusion criteria) 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 of MVA-BN.

Immunocompetent adults and children

- 0.5 mL dose of MVA-BN per administration for IM or SC injection.
- during supply constraints, a fractional dose of 0.1 mL of MVA-BN per administration for ID 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

- 0.5 mL dose of MVA-BN per administration for IM or SC injection.

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Dose and frequency of administration (continued)	**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. 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	See dosage schedule above. This PGD only allows for the duration stated in the dosage schedule above. 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. 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 administered	Single 0.5 mL dose per SC or IM administration. Single 0.1 mL fractional dose per ID 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▼® has been 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. NHS standard operating procedures should be followed for appropriate ordering, storage, handling, recording, preparation, administration and waste minimisation. Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see storage and transportation section below).
Storage (continued over page)	Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see storage and transportation section below). Store in a freezer at -20ºC (+/-5ºC). 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 2-8°, 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▼®). After thawing at room temperature, the vaccine should be used immediately. 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.

Storage (continued)	Refer to: ➢ advisory document on ordering storage and handling of vaccines section 5 (storage). ➢ Green Book chapter 3, and relevant local vaccine policy or guidance. ➢ vaccine incident guidance: responding to vaccine errors. ➢ local Medicines Advice Service for advice. Any loss of vaccines due to expiry date, wastage or fridge failure/breaches in cold chain must be reported following local procedure and documented on WIS (if appropriate), ImmForm and via DatixCymru incident reporting system.
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 designation as genetically modified organism (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 Smallpox and mpox: the green book chapter 29.) ➢ Any unused product or waste material should be disposed of in accordance with local requirements. ➢ Equipment used for immunisation, including used vials, ampoules, or discharged vaccines in a syringe or applicator, should be disposed of at the end of a session by sealing in a UN-approved puncture-resistant 'sharps' box, according to local authority regulations and guidance in the Welsh Health Technical Memorandum 07-01 Safer management of healthcare waste.
Drug interactions	Currently, there are no data on administering Jynneos▼® or Imvanex▼® vaccine at the same time as other vaccines. However, it can be co-administered with other vaccines in accordance with Smallpox and mpox: the green book chapter 29. 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 the vaccine with any immunoglobulin including Vaccinia Immune Globulin (VIG) has not been studied and should be avoided.
Identification & management of adverse reactions (continued over page)	If individuals or their parent / carer are concerned about their health at any time, they should seek advice from their GP or NHS 111 Wales. A detailed list of adverse reactions is available in the Summary of Product Characteristics (SmPC) for Imvanex▼® and package insert for Jynneos▼®. The DHPC from Bavarian Nordic, the manufacturer, signposts to the Imvanex▼® information on the MHRA website.

Identification & management of adverse reactions (continued)	**Hypersensitivity reactions** have been reported with administration of MVA-BN vaccines and are very rare. If signs or symptoms of a clinically significant hypersensitivity reaction or anaphylaxis occur which include any of the following: nausea, chills, dizziness (or syncope), rash, urticaria and flushing initiate appropriate medications and/or supportive care. See special precautions section. The most frequently reported adverse effects (affecting between 1 in 10 people and 1 in 100 people) include: ➢ injection site reactions, including pain, redness, swelling, induration, itching. ➢ systemic reactions, including chills, fever (≥38ºC), muscle pain, fatigue, headache, nausea. Reactions were mild to moderate in intensity and resolved without intervention within 7 days following vaccination. ID injection has been associated with a higher rate of itchiness and local reactions such as erythema and induration when compared to SC injection, although pain at the injection site was less common than after SC 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 (Smallpox and mpox: the 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 moderate in intensity and usually resolve without sequelae. **Anxiety-related reactions** Anxiety-related reactions, including vasovagal reactions (syncope), hyperventilation or stress-related reactions (e.g. dizziness, palpitations, increases in heart rate, alterations in blood pressure, paraesthesia, hypoaesthesia and sweating) may occur in association with the vaccination process itself. Stress-related reactions are temporary and resolve on their own. Individuals or their parent / carer should be advised to bring symptoms to the attention of the vaccination provider for evaluation. It is important that precautions are in place to avoid injury from fainting. ➢ Advise the individual or their parent / carer that they should refrain from driving or operating machinery for 15 minutes after vaccination.

Reporting procedure for suspected adverse reactions	Any adverse reaction to the product should be documented in the individual's medical records and their GP should be informed. Report ALL suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) or by using the Yellow Card reporting scheme or search for MHRA Yellow Card in the Google Play or Apple App store. All serious adverse reactions and those considered avoidable should also be reported on the DatixCymru incident reporting system.
Written information to be given to individual or their parent / carer	Provide the individual or their parent/carer with: ➢ Patient Information Leaflet (PIL). DHPC from Bavarian Nordic advises healthcare professionals to provide Jynneos▼® package insert included in the outer packaging to individuals receiving a vaccine. ➢ If the individual is pregnant, a patient information leaflet is available to support them in their decision to have the vaccine. Available at: Mpox (monkeypox) - Public Health Wales (nhs.wales). ➢ Leaflets recommended by Public Health Wales are available at Mpox vaccination resources Public Health Wales.
Patient or parent / carer advice / follow up (continued over page)	Inform the individual or their parent / carer: ➢ with a full explanation of risks and benefits to the individual or their parent/carer in order to obtain informed consent. ➢ of any possible side effects and their management. ➢ that they may experience a mild fever, which usually resolves within 7 days. This is a common, expected reaction. Feeling generally unwell, shivery, achy and tired is common and usually resolves without treatment, but paracetamol can be given if necessary to relieve any of these symptoms. ➢ 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 / clinic. ➢ not to drive for 15 minutes after vaccination as fainting can occur following vaccination. ➢ that the vaccine cannot cause mpox infection. ➢ 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. ➢ when they can be vaccinated another time if they have to postpone because of illness. ➢ when subsequent doses are due if appropriate. ➢ if they get any side effects, to talk to their doctor, or pharmacist, including side effects not listed in the leaflet. ➢ to seek medical advice in the event of a severe adverse reaction.

Patient or parent / carer advice / follow up (continued)	➢ to seek advice from their doctor, or a pharmacist if common side effects do not spontaneously resolve 7 days after vaccination. ➢ that they should report side effects directly to the Yellow Card reporting scheme. ➢ that the PIL will be provided. For more information go to: Immunisation and Vaccines - Public Health Wales (NHS. Wales). ➢ to visit the NHS 111 Wales website for more information.
Special considerations / additional information (continued over page)	The practitioner should have immediate access to adrenaline (epinephrine) 1 in 1,000 injection and access to a telephone at the time of vaccination. See chapter 8 of the Green Book and advice issued by the Resuscitation Council. An age appropriate protocol for the management of anaphylaxis and an anaphylaxis pack must always be available. Immediate treatment should include early treatment with: ➢ 12 years and above: 500 micrograms IM (0.5 mL of 1:1000 or 1 mg/mL adrenaline). ➢ if individual is small or prepubertal: 300 micrograms IM (0.3 mL of 1:1000 or 1 mg/mL adrenaline). ➢ 6 years to 11 years: 300 micrograms IM (0.3 mL of 1:1000 or 1 mg/mL adrenaline). ➢ 6 months to 5 years: 150 micrograms IM (0.15 mL of 1:1000 or 1 mg/mL adrenaline (epinephrine). ➢ under 6 months: 150 micrograms IM (0.15 mL of 1:1000 or 1 mg/mL adrenaline (epinephrine). ➢ with an early call for help and further IM adrenaline every 5 minutes. See chapter 8 of the Green Book and advice issued by the Resuscitation Council. For children under the age of 16 years, those assessed as Gillick competent can self-consent (for further information on consent see chapter 2 of the Green Book). **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

Special considerations / additional information (continued)	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 (including infants from birth) and severely immunosuppressed individuals. Those eligible for pre-exposure doses (such as GBMSM with multiple sexual partners) should be prioritised for vaccination. 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 (continued over page)	Record: ➢ that valid informed consent was given. ➢ how the individual met or did not meet the inclusion/exclusion criteria of the PGD. ➢ name of individual, address, date of birth and the GP with whom the individual is registered. ➢ allergies and previous adverse events. ➢ name and signature of the health professional administering the vaccine (if recording on paper). If recording directly into electronic patient record, name only as signature will be replaced by electronic logging of the user ➢ details of the vaccine such as name and brand (where applicable) of the vaccine, dose, strength, form, quantity, route and site of administration ➢ date of and time of administration. ➢ batch number and expiry date of vaccine. ➢ information provided to the individual or their parent/carer, including side effects and advice given if excluded or declines immunisation. ➢ details of any adverse drug reactions and actions taken. ➢ referral arrangements (if any). Records should be signed and dated (or password-controlled immuniser's record on e-records). All records should be clear, legible and contemporaneous.

Records (continued)	All records, electronically or otherwise must be kept in accordance with NHS Wales record keeping. See: records management code of practice for health and social care 2022. For pregnant women, also record immunisation in the hand held and electronic maternity record if available. 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.

GIG CYMRU NHS WALES

Appendices

Appendix A: *References*

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Appendix B: *Practitioner authorisation sheet*

Patient Group Direction for the administration of Live Modified Vaccinia Virus Ankara Bavarian Nordic (MVA-BN) Vaccine suspension for injection by health care professionals

Valid from: 01 December 2024 Expiry: 30 November 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. Signed copies of these sheets should be kept in accordance with the retention statement in section 2.

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 PTHB or a PTHB GP Practice for the above-named health care 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 in accordance with the retention statement in the organisational authorisation section.

Appendix C: *Summary 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 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 days interval between doses	A single dose	A single dose if indicated (see below)
Immunocompetent children and adults (including those with atopic eczema)	0.5 mL IM or SC Fractional dose of 0.1 mL ID during supply constraints (for children, only within the context of an outbreak response)	0.5 mL IM or SC Fractional dose of 0.1 mL 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	0.5 mL IM or SC	0.5 mL 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

Additional local appendix for vaccination PGDs, detailing PTHB PGD requirements

Section of PGD	Additional requirements
Characteristics of staff	Practitioner must have completed Patient Group Directions training (available via eLfH PGD eLearning programme. PTHB staff to access via ESR). Evidence of ongoing PGD training to be submitted to Line Manager annually– this should include an annual completion certificate of PGD e-learning or a dated screenshot of the PGD e-learning assessment results as proof of completion. The practitioner must update at least every 2 years on the administration/use, contra-indications and adverse effects of the medication. Practitioners must make a self-declaration of competency on PADR (if relevant). The **personal development plan** (yellow) section of the PADR booklet should be used to record completion of Statutory and Mandatory training, including annual PGD e-learning. Individuals operating under this PGD must be assessed as competent -refer to the practitioner authorisation sheet and the PTHB competency checklist. Must be competent in the recognition, management and reporting of recognised adverse reactions, including anaphylaxis. Must be competent in the administration of adrenaline and have up to date Basic Life Support skills. Compliance with all mandatory NHS training (if relevant), including safeguarding at the level relevant to the role. Practitioners should be constantly alert to changes in the BNF and Summary of Product Characteristics, and any subsequent recommendations from Welsh Government and/or Public Health Wales and/or NHS Wales and UKHSA and other sources of medicines information. If relevant, HEIW provide training in Wales (CPPE in England). Must be familiar with All Wales Advisory document on Ordering Storage and Handling of Vaccines, and must have completed: • immunisation training (also see National Minimum Standards and Core Curriculum for Immunisation). Please contact PTHB Immunisation coordinator for further information. • cold chain training (also available via ESR). **It is the responsibility of the healthcare professional to maintain their own competency to practice within this PGD.**
Clinical Condition: Situation	**It is the responsibility of the administering/supplying healthcare professional to ensure that the individual is within the inclusion criteria, and that there are no reasons for exclusion before proceeding. If there is any reason for concern, seek medical advice.**

Clinical Condition: Inclusion criteria	Medical and drug history taken, no reason for exclusion. PTHB Consent to Treatment and Examination Policy
Clinical Condition: Exclusion criteria	If relevant, other PTHB PGDs may be found using this link Patient Group Directions (PGDs) - Powys Teaching Health Board (nhs.wales).
Cautions	Check for any other medications that the individual is taking, including topical or inhaled products, food supplements and herbal or homeopathic products. (Refer to BNF/SPC for full list). Under Section 128 and 130 of the Social Services and Wellbeing (Wales) Act 2014, staff have a duty to inform the Local Authority if they have reasonable cause to suspect that an adult or child is at risk. Any vulnerable adult or child protection concerns should be referred to Safeguarding and the PTHB safeguarding policies followed. Consider discussing with GP. Any safeguarding concerns need to be directed to Safeguarding Hub: • to generic email address: PowysTHB.Safeguarding@wales.nhs.uk and • Central Safeguarding number: 01686 252806 • Out of hours: 0345 0544847 Advice can also be sought from local Safeguarding leads
Action to be taken if the individual, parent or carer declines treatment	The patient information leaflet should be available to inform consent. Inform the Child Health department if any vaccination is declined for a child under 19 years, completing the appropriate form. Where appropriate, inform the GP using the local agreed system. If relevant, advise how future immunisation may be accessed if they subsequently decide to receive this.
Description of treatment: Route and method of administration	See Green book chapter 4.
Description of treatment: Supplies	Refer to All Wales Advisory document on Ordering Storage and Handling of Vaccines.
Description of treatment: Storage	Refer to: • MMP 427 Safe and Secure Management of Refrigerated Medicines and Vaccines SOP • All Wales Advisory document on Ordering Storage and Handling of Vaccines Any loss of vaccines due to expiry date or fridge failure/breaches in cold chain must be reported on ImmForm, to PTHB Immunisation Coordinator (Powys.Immunisations@wales.nhs.uk), and via PTHB Datix reporting system Once for Wales Reporting System.

Description of treatment: Disposal	Welsh Health Technical Memorandum 07-01 Safer management of healthcare waste.
Description of treatment: Adverse reactions	Report any suspected adverse reactions to a doctor. In case of an acute anaphylactic reaction occurring, adequate treatment provision must be available for immediate use: Anaphylaxis and resuscitation equipment including adrenaline (1 in 1000) injection and a working telephone. In case of anaphylaxis: • Refer to adrenaline (epinephrine) PGD0017 and anaphylaxis procedure • Request medical assistance urgently. If the GP is not immediately available dial 999 to transfer to A&E • Ensure reaction is fully documented in patient notes • Ensure all patient records are marked **ALLERGIC TO Modified Vaccinia Ankara Bavarian Nordic (MVA-BN) vaccine** (stating the brand) • The individual may be advised to wear a MedicAlert or similar device to alert other healthcare providers • Report via Datix Once for Wales Reporting system
Description of treatment: Written information	Further information for printing and website links suitable for individuals can be found on the Public Health Wales intranet site Public Health Wales Immunisation and Vaccine Preventable Disease Programme, NHS 111 Wales and Health Information Resources.
Description of treatment: Records	Record consultation details as required by local procedures, to include: • Name of representative who gave consent if appropriate. • Medical and drug history taken, including any allergies and previous adverse events • Printed name and signature of healthcare professional • PGD title and version number If a vaccine is administered to a child up to 19 years of age, forward a notification of vaccination given to Child Health Department using the appropriate documentation/pathway as required by any local or contractual arrangement (based in Brecon Hospital for under 5 years and Llandrindod Hospital for school age).

Competency check list for manager or senior team lead to use as part of the authorising process for health professionals to work to a Patient Group Direction (PGD). Review of authorisation will take place on each PGD update and at the individual's annual PADR.

Name: **Role:**		Sign / Initial	Further training identified (Y/N) Specify in " comment	Comments
1	The PGD sign off is for the following PGD:(document the exact title and PGD number) _____			
2	We have discussed the expiry of the PGD and are using a version accessed electronically			
3	The member of staff has the appropriate qualifications and professional registration as outlined in the PGD			
4	The Patient Group Direction has been read in full by the staff member			
5	The identified training has been completed as specified in the PGD and is in date			
6	We have discussed some examples of inclusion criteria and exclusion criteria			
7	The staff member is confident in the administration method and doses			

Staff member print & sign name		Date
Manager or senior team lead to print & sign name		Date

Please send a copy of this completed form to the individual's line manager and to the staff member, in conjunction with the Practitioner authorisation sheet. A copy of this form should also be kept by service lead in the training file.