NHS Grampian NHS Highland NHS Orkney NHS Shetland NHS Tayside NHS Eileanan Siar Western Isles

Patient Group Direction For The Administration Of MVA-BN Vaccine By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles

Lead Author: Adapted from Public Health Scotland Administration of MVA-BN vaccine Patient group direction (PGD) template Version 2.0 – PHS Publication date 1 June 2024		**Approver:** NoS PGD Group **Authorisation:** NHS Grampian
Signature: 		**Signature:** 
NoS Identifier: NoS/PGD/MVA-BN/1500	**Review Date:** 31st May 2026 **Expiry Date:** 31st May 2026	**Date Approved by NoS:** 30th May 2024 **Valid from:** 1st June 2024

NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles have authorised this Patient Group Direction to help individuals by providing them with more convenient access to an efficient and clearly defined service within the NHS Boards. This Patient Group Direction cannot be used until Appendix 1 and 2 are completed.

Uncontrolled when printed

Version 2.0

Revision History for NoS:

NoS PGD that has been superseded	NoS/PGD/MVA-BN/MGPG1295, Version 1.1

Most recent changes NoS

Version	Date of change	Summary of Changes	Section heading
2.0	21 May 2024	Reference to NoS Appendix 1 and 2.	Authorisation
		Training requirements for NoS	Continuing education and training

PHS recent changes

Version	Date	Summary of changes
2.0	1 June 2024	Previous PGD (version 1.2) expired. The following changes to version 1.2 of the PGD have been made: • Minor rewording, layout and formatting changes for clarity and consistency with other PHS PGDs. • Removal of reference to individual batch numbers. • Additional information section updated to include advice on immunosuppression assessment in those living with HIV.

Review date: The review date for a PGD needs to be decided on a case-by-case basis in the interest of safety. The expiry date should not be more than 3 years, unless a change in national policy or update is required.

Contents

Authorisation

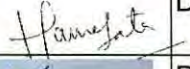
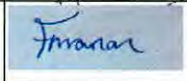
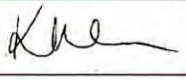
This specimen Patient Group Direction (PGD) template has been produced by Public Health Scotland and adapted by North of Scotland PGD Group (NoS) to assist NHS Boards. NHS Boards should ensure that the final PGD is considered and approved in line with local clinical governance arrangements for PGDs.

The qualified health professionals who may administer vaccine under this PGD can only do so as named individuals. It is the responsibility of each professional to practice within the bounds of their own competence and in accordance with their own Code of Professional Conduct and to ensure familiarity with the manufacturer's product information/Summary of Product Characteristics (SmPC) for all vaccines administered in accordance with this PGD.

NHS Board governance arrangements will indicate how records of staff authorised to operate this PGD will be maintained. Under PGD legislation there can be no delegation. Administration of the vaccine has to be by the same practitioner who has assessed the patient under the PGD.

All authorised staff are required to read the PGD and sign the Agreement to Administer Medicines Under PGD (Appendix 1).

A Certificate of Authorisation (Appendix 2) signed by the authorising professional/manager should be supplied. This should be held in the individual health professional's records, or as agreed within the individual Health Board.

This PGD has been produced for NoS by:					
Doctor	Hame Lata	Signature		Date Signed	27/05/2024
Pharmacist	Fiona Marion	Signature		Date Signed	30/05/2024
Nurse	Kimberley MacInnes	Signature		Date Signed	29/05/2024

Approved for use within NoS by:

NoS Group Chair	**Signature**	**Date Signed**
Lesley Coyle		30/05/2024

Authorised and executively signed for use within NoS by:

NHS Grampian Chief Executive	**Signature**	**Date Signed**
Adam Coldwells – Interim Chief Executive		30/05/2024

Version 2.0 – Approved for NoS from: 30th May 2024 - **Valid from:** 1st June 2024

1. Clinical situation

1.1. Indication

MVA-BN vaccine is indicated for active immunisation against mpox in accordance with Scottish Government immunisation programme and recommendations given in Green Book Chapter 29; and subsequent correspondence and publications from Scottish Government.

1.2. Inclusion criteria

- MVA-BN vaccine should be offered to individuals in accordance with the recommendations in Green Book Chapter 29, JCVI advice and Scottish Government policy.
- National policy must be followed in relation to the groups eligible for vaccination at a particular point in time.
- Valid consent has been given to receive the vaccine.

1.3. Exclusion criteria

Individuals who:

- have had a confirmed anaphylactic reaction to a previous dose of **MVA-BN** containing vaccine.
- have had previously a sudden life-threatening allergic reaction to any ingredient of MVA-BN vaccine. MVA-BN vaccine includes trace residues of chicken protein and eggs, benzonase, gentamicin and ciprofloxacin.
- are aged under 12 months of age.
- are acutely unwell, including those with symptoms or signs of possible mpox infection – immunisation should be postponed until they have fully recovered.
- are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation).

See cautions section for information on vaccination in pregnancy or in those with atopic dermatitis.

1.4. Cautions/need for further advice/circumstances when further advice should be sought from a doctor

The Green Book advises that there are very few individuals who cannot receive MVA-BN vaccine. Where there is doubt, rather than withholding vaccination, appropriate advice should be sought from the relevant specialist, or from the local immunisation coordinator or health protection team.

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.

If, following risk assessment, the clinician and patient are content to proceed vaccination using this PGD is permissible.

Individuals with a history of developing keloid scarring may be offered a 0.5mL subcutaneous (SC) / intramuscular (IM) dose of MVA-BN vaccine in preference to a fractional dose intradermally (ID).

Whether prior mpox infection protects against future infection is currently unknown, but based on analogy from smallpox infection and from live smallpox vaccine, it seems likely that re-infection will be unusual, particularly in the short term. Although previous mpox infection is not a contra-indication to vaccination, in a situation of constrained vaccine supply, it is therefore recommended that vaccination of confirmed cases is deferred. If supply allows, vaccination may be considered for those at on-going risk once fully recovered.

The presence of a neurological condition is not a contraindication to immunisation but if there is evidence of current neurological deterioration, deferral of vaccination may be considered, to avoid incorrect attribution of any change in the underlying condition. The risk of such deferral should be balanced against the risk of the preventable infection, and vaccination should be promptly given once the diagnosis and/or the expected course of the condition becomes clear.

Pregnancy and breastfeeding

Although MVA-BN vaccine has not formally been evaluated in pregnancy, animal studies (three studies in female rats) identified no vaccine related fetal malformations. Use of MVA-BN in pregnant women is limited to less than 300 pregnancies without leading to any adverse events on pregnancy. As it is a non-replicating vaccine, there is no theoretical reason for concerns in pregnancy and the adverse events profile would be expected to be similar to that in non-pregnant vaccinees. Whilst it is not routinely recommended for use in pregnancy, any theoretical concern needs to be weighed against the maternal risks from mpox in 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. In pregnant women clinicians should discuss the risks and benefits of vaccination with the woman, who should be told about the limited evidence of safety for the vaccine in pregnancy. If, following this discussion, the clinician and patient are content to proceed vaccination using this PGD is permissible.

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. Individuals who are breast feeding should therefore be offered vaccination, after discussion about the risks of mpox to themselves and to the breast-fed child.

Syncope

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 that procedures are in place to avoid injury from faints.

Co-administration with other vaccines

Although no data for co-administration of MVA-BN vaccine with other vaccines exists, in the absence of such data first principles would suggest that interference between inactivated (non-replicating) vaccines with different antigenic content is likely to be limited. Based on experience with other vaccines, any potential interference is most likely to result in a slightly attenuated immune response to one of the vaccines. There is no evidence of any safety concerns, although it may make the attribution of any adverse events more difficult. MVA-BN can also be co-administered with live vaccines and in those on HIV PrEP.

As the non-replicating MVA-BN is considered inactivated, where individuals in an eligible cohort present having recently received one or more inactivated or another live vaccine, MVA-BN vaccination should still be given. The same applies for most other live and inactivated vaccines where MVA-BN vaccination has been received first or where a patient presents requiring two or more vaccines.

It is generally better for vaccination with any required vaccines (including MVA-BN, hepatitis A, hepatitis B and HPV) to proceed to avoid any further delay in protection and to reduce the risk of the patient not returning for a later appointment.

When administering at the same time as other vaccines, care should be taken to ensure that the appropriate route of injection is used for all the vaccinations. The vaccines should be given at separate sites, preferably in different limbs. If given in the same limb, they should be given at least 2.5cm apart. The site at which each was given should be noted in the individual's records.

1.5. Action if excluded

Specialist advice must be sought on the vaccine and circumstances under which it could be given. Immunisation using a patient specific direction may be indicated. The risk to the individual of not being immunised must be taken into account.

Document the reason for exclusion and any action taken in accordance with local procedures.

Inform or refer to the clinician in charge.

In case of postponement due to acute severe febrile illness, advise when the individual can be vaccinated and ensure another appointment is arranged.

1.6. Action if patient declines

Advise the individual about the protective effects of the vaccine, the risks of infection and potential complications of disease.

Advise how future immunisation may be accessed if they subsequently decide to receive the vaccine.

Document advice given and decision reached.

Inform or refer to the clinician in charge.

2. Description of treatment

2.1. Name of medicine/form/strength

MVA-BN vaccine Smallpox vaccine (Live Modified Vaccinia Virus Ankara).

JYNNEOS® suspension for subcutaneous injection.

Please note: This PGD does not apply where unlicensed vaccine is used. The administration of unlicensed product must only progress in accordance with a patient specific direction.

2.2. Route of administration

The vaccine should be allowed to reach room temperature before use. Swirl the vial gently before use for at least 30 seconds.

The normal appearance of the vaccine is a light yellow to pale milky suspension.

The vaccine should be visually inspected for particulate matter and discoloration prior to administration. In the event of any foreign particulate matter and/or variation of physical aspect being observed, do not administer the vaccine.

The vaccine can be given by intradermal, deep subcutaneous or intramuscular injection – see dose section for information of dose by different route of administration.

For adults, the preferred sites for both subcutaneous and intramuscular injection is the deltoid area of the upper arm; for small children the anterolateral aspect of the thigh is preferred.

The JCVI has endorsed the use of a fractional dose given by intradermal injection in those aged 18 years and above during periods of supply constraints.

A fractional dose intradermal injection may be administered on the deltoid (the same site recommended for BCG) or on the volar aspect (palm side) of the forearm around 2-4 inches below the ante-cubital fossa (same site as used for Mantoux testing).

Where fractional doses administered by intradermal injection are being used the contents of the vial can remain at room temperature for up to one hour. Up to five doses may be extracted from the vial. Each dose should be drawn up and given immediately. Remaining doses should be discarded after one hour.

Where fractional doses are being used, after thawing and swirling, the first dose should be withdrawn using the correct needle and syringe. Appropriate infection control and aseptic technique should be used at all times and is particularly important when using vials for multiple doses.

A correctly given intradermal injection results in a tense, blanched, raised bleb of around 7mm diameter with a 0.1mL injection. If little resistance is felt when injecting and a diffuse swelling occurs as opposed to a tense blanched bleb, the needle is too deep.

Where a fractional 0.1mL dose has been inadvertently administered by subcutaneous injection rather than by an intended intradermal injection, i.e. if little resistance is felt when injecting and a diffuse swelling occurs as opposed to a tense blanched bleb, the needle is too deep. In such cases a single replacement fractional 0.1mL dose by intradermal injection should be repeated immediately (no minimum interval); the repeated dose should be placed at least 2 inches (5cm) away from the incorrectly given dose.

The route of injection and site at which MVA-BN vaccine was given should be noted in the individual's records.

2.3. Dosage

0.5mL if given by subcutaneous or intramuscular injection.

0.1mL if given by intradermal injection (during supply constraints).

2.4. Frequency

The initial priority is to deliver first doses to as many individuals in the highest risk group as possible. JCVI advise that the next priority is to offer a second dose to GBMSM at highest risk from around 2-3 months after their first dose. This will aim to provide longer lasting protection and to protect the community against subsequent introduction from countries where the virus is still circulating at higher levels.

Where first dose has been given by subcutaneous/intramuscular injection the second dose can be given by intradermal injection and vice versa.

Pre-exposure vaccination of immunocompetent individuals aged 18 years and above, including people with atopic dermatitis, previously not vaccinated against smallpox

0.5mL subcutaneous/intramuscular injection **or** 0.1mL intradermal injection (during supply constraints).

Plus

0.5mL subcutaneous/intramuscular injection any time from 28 days after first dose **or** 0.1mL intradermal injection (during supply constraints) any time from 28 days after first dose.

Pre-exposure vaccination of children and young people aged under 18 years, individuals who are immunosuppressed (as defined in the Green Book), and those with a history of keloid scarring, previously not vaccinated against smallpox

0.5mLsubcutaneous/intramuscular injection.

Plus

0.5mL subcutaneous/intramuscular injection any time from 28 days after first dose.

Pre-exposure vaccination of immunocompetent individuals aged 18 years and above, including people with atopic dermatitis, previously vaccinated against smallpox

0.5mL subcutaneous/intramuscular injection **or** 0.1mL intradermal injection (during supply constraints).

Pre-exposure vaccination of children and young people aged under 18 years, individuals who are immunosuppressed (as defined in Chapter 7 of the Green Book), and those with a history of keloid scarring, previously vaccinated against smallpox.

0.5mL subcutaneous/intramuscular injection.

In the event of an 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 scenario, 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 vaccine is given after 28 days, the first dose should not be repeated.

Where a fractional 0.1mL dose has been inadvertently administered by subcutaneous injection rather than by an intended intradermal injection i.e. if little resistance is felt when injecting and a diffuse swelling occurs as opposed to a tense blanched bleb, the needle is too deep. In such cases a single replacement fractional 0.1ml dose by intradermal injection should be repeated immediately (no minimum interval); the repeated dose should be placed at least 2 inches (5cm) away from the incorrectly given dose.

Post-exposure of individuals

Individuals aged 18 years and above

A single 0.5mL subcutaneous/intramuscular injection or 0.1mL intradermal injection.

Individuals under 18 years of age

A single 0.5mL subcutaneous/intramuscular injection.

To maximise the chance of preventing infection, MVA-BN vaccine should preferably be administered within 4 days from the date of exposure to mpox.

Vaccination may still be offered up to 14 days after exposure, with the aim of reducing the symptoms of disease, for those who are not already displaying symptoms. This may be considered in those at higher risk of serious mpox infection (children under five years of age, the immunosuppressed and pregnant women). Vaccination up to 14 days after exposure may also be offered to those at on-going risk to commence a pre-exposure course.

Individuals who have previously received a two dose course of MVA-BN vaccine, with the second dose given in the past two years, do not need a further dose of vaccine after exposure. The exception is those who are immunosuppressed, who may have made a lower or less durable immune response, when an additional dose can be considered.

Previous incomplete vaccination

If the MVA-BN course is interrupted or delayed, it should be resumed using the same vaccine but the first dose does not need to be repeated.

2.5. Duration of treatment

See frequency section.

2.6. Maximum or minimum treatment period

See frequency section.

2.7. Quantity to supply/administer

See frequency section.

2.8. ▼ black triangle medicines

Yes.

All adverse reactions occurring in individuals of any age after vaccination should be reported to the MHRA using the Yellow Card Scheme. Anyone can report a suspected adverse reaction to the MHRA using the Yellow Card reporting scheme http://www.mhra.gov.uk/yellowcard

2.9. Legal category

Prescription only medicine (POM).

2.10. Is the use outwith the SmPC?

JYNNEOS® vaccine has been approved by MHRA for use in the current program for NHS management of mpox.

Bavarian Nordic has a licensed vaccine containing Live Modified Vaccinia Virus Ankara (MVA-BN) to prevent disease due to an infection with smallpox. This vaccine has also shown to be able to prevent mpox and other orthopox diseases. The MVA-BN vaccine is licensed in UK, Europe, US and Canada but no stock of the UK-licensed Imvanex product is immediately available.

Public Health Scotland, the UK Health Security Agency (UKHSA) and the Joint Committee on Vaccination and Immunisation (JCVI) recommends the use of MVA-BN vaccine as part of the response to cases of mpox.

The vaccine marketing authorisation holder's summary of product characteristics (SmPC) states that MVA-BN vaccine should be used in adults. This is superseded by the JCVI advice as set out in Green Book chapter 29 which advises the vaccine should be offered to children considered to be at risk, as children seem to have a more severe presentation of mpox.

The vaccine marketing authorisation holder's summary of product characteristics states that MVA-BN vaccine should not be used in pregnancy. This is superseded by the JCVI advice as set out in Green Book chapter 29 which advises the vaccine whilst not routinely recommended for use in pregnancy, any theoretical concern needs to be weighed against the maternal risks from mpox in 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.

The MVA-BN SmPC advises that the vaccine should be administered by the deep sub-cutaneous (SC) route. As there is published evidence suggesting an adequate immunological response and extensive experience of using MVA containing vaccines given by the IM route, UKHSA has advised that intra-muscular administration is an acceptable alternative.

In August 2022, following the emergency use approval by the US Food and Drug Administration, JCVI endorsed the use of a fractional dose (0.1mL) of MVA-BN given by intradermal injection during periods of supply constraints. The approach has also been advised by the European Medicines Agency Emergency Task Force.

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 national Vaccine Incident Guidance. Where vaccine is assessed in accordance with these guidelines as appropriate for continued use this would constitute off-label administration under this PGD.

Where a vaccine is recommended off-label consider, as part of the consent process, informing the individual/parent/carer that the vaccine is being offered in accordance with national guidance but that this is outside the product licence.

2.11. Storage requirements

MVA-BN is supplied frozen in packs of 20 vials. The remaining shelf life at clinic level will depend on previous storage temperature, please refer to documentation on the product.

MHRA has approved for JYNNEOS® a shelf-life of 8 weeks starting from the time of thawing and transfer from –20°C storage to the refrigerator at 2-8°C in line with the UK/EU approval, whereas FDA approval for the US market only allow a holding time of 12 hours at 2-8°C.

Where fractional doses administered by intradermal injection are being used the contents of the vial can remain at room temperature for up to one hour whilst the five doses are used. Each dose should be drawn up and given immediately. Remaining doses should be discarded after one hour.

NHS Board guidance on Storage and Handling of vaccines should be observed.

During storage, minimise exposure to room light and avoid exposure to direct sunlight and ultraviolet light.

The manufacturer may advise of updated storage requirements and product stability as new data becomes available, vaccine may be stored in accordance with updated recommendations from the manufacturer.

2.12. Additional information

Minor illnesses without fever or systemic upset are not valid reasons to postpone immunisation. If an individual is acutely unwell, immunisation may be postponed until they have fully recovered.

MVA-BN is a replication defective virus and should pose no risk to those who are immunosuppressed. The safety and immunogenicity of MVA-BN in persons living with HIV infection (with CD4 cell counts above 100 cells/mm3) has been demonstrated. However, the immune response to the vaccine could be reduced in severely immunosuppressed individuals. Vaccination should generally proceed in accordance with recommendations, as these individuals are also at significant risk of the complications of mpox. Specialist medical advice on other measures may be required and additional doses should be considered for those at ongoing-risk of exposure. Individuals living with HIV who are virally suppressed and have a CD4 count above 200 cells/mm3 are not considered immunosuppressed for the purposes of this guidance.

3. Adverse reactions

3.1. Warnings including possible adverse reactions and management of these

Common adverse events include local site reactions and influenza-like symptoms. These events were mainly mild to moderate in intensity and resolved without intervention within seven days following vaccination. Adverse event rates reported after either vaccination dose (1st, 2nd or booster) were similar, but anecdotally the frequency of adverse events, particularly local site reactions, appears to be higher in those who had received previous live smallpox vaccine.

As with all vaccines there is a very small possibility of anaphylaxis and facilities for its management must be available.

In the event of a severe adverse reaction individual should be advised to seek medical advice.

For full details/information on possible side effects, refer to the marketing authorisation holder's SmPC adverse reaction individual should be advised to seek medical advice.

3.2. Reporting procedure for adverse reactions

Healthcare professionals and individuals/carers should report all suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on http://www.mhra.gov.uk/yellowcard
Any adverse reaction to a vaccine should be documented in accordance with locally agreed procedures in the individual's record and the individual's GP should be informed.

3.3. Advice to patient or carer including written information

Written information to be given to individuals:

- Provide manufacturer's consumer information leaflet/patient information leaflet (PIL) provided with the vaccine.
- Supply immunisation promotional material as appropriate.

Individual advice / follow up treatment

- Inform the individual/carer of possible side effects and their management.
- The individual should be advised to seek medical advice in the event of a severe adverse reaction.
- Inform the individual that they can report suspected adverse reactions to the MHRA using the Yellow Card reporting scheme on: http://www.mhra.gov.uk/yellowcard

- Immunosuppressed individuals should be advised that they may not make a full immune response to the vaccine and they should continue to take appropriate measures to protect themselves against this infection.
- When administration is postponed advise the individual how future vaccination may be accessed.
- When applicable, advise individual/parent/carer when the subsequent dose is due.

3.4. Observation following vaccination

There is no routine requirement for observation following MVA-BN administration, but individuals should be observed for any immediate reactions whilst they are receiving any verbal post vaccination information and exiting the centre.

As syncope (fainting) can occur following vaccination, all vaccinees should either be driven by someone else or should not drive for 15 minutes after vaccination.

3.5. Follow up

As above.

3.6. Additional facilities

A protocol for the management of anaphylaxis and an anaphylaxis pack must always be available whenever vaccines are given. Immediate treatment should include early treatment with intramuscular adrenaline, with an early call for help and further IM adrenaline every 5 minutes.

The health professionals overseeing the immunisation service must be trained to recognise an anaphylactic reaction and be familiar with techniques for resuscitation of a patient with anaphylaxis.

4. Characteristics of staff authorised under the PGD

4.1. Professional qualifications

The following classes of registered healthcare practitioners are permitted to administer this vaccine:

- nurses and midwives currently registered with the Nursing and Midwifery Council (NMC)
- pharmacists 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
- optometrists registered with the General Optical Council.

4.2. Specialist competencies or qualifications

Persons must only work under this PGD where they are competent to do so.
All persons operating this PGD:

- must be authorised by name by their employer as an approved person under the current terms of this PGD before working to it
- must be familiar with the vaccine product and alert to changes in the manufacturer's product information/summary of product information
- must be competent to undertake immunisation and to discuss issues related to immunisation to assess patients for vaccination and obtain consent
- must be competent in the correct storage of vaccines and management of the cold chain if receiving, responsible for, or handling the vaccine
- must be competent in the recognition and management of anaphylaxis or under the supervision of persons able to respond appropriately to immediate adverse reactions
- must have access to the PGD and associated online resources
- should fulfil any additional requirements defined by local policy

Employer

The employer is responsible for ensuring that persons have the required knowledge and skills to safely deliver the activity they are employed to provide under this PGD.

As a minimum, competence requirements stipulated in the PGD must be adhered to.

4.3. Continuing education and training

All practitioners operating under the PGD are responsible for ensuring they remain up to date with the use of vaccines included. If any training needs are identified these should be discussed with the individuals in the organisation responsible for authorising individuals to act under this PGD.

- Have undertaken NoS PGD module training on TURAS Learn
- Have attended basic life support training either face to face or online and updated in-line with individual Board requirements
- Have undertaken immunisation training where available
- Have undertaken NHS e-anaphylaxis training or equivalent which covers all aspects of the identification and management of anaphylaxis updated in-line with individual Board requirements
- Maintain their skills, knowledge and their own professional level of competence in this area according to their individual Code of Professional Conduct.

5. Audit trail

Record the following information:

- valid informed consent was given
- name of individual, address, date of birth and GP with whom the individual is registered if possible
- name of person that undertook assessment of individual's clinical suitability and subsequently administered the vaccine
- name and brand of vaccine
- date of administration
- dose, form and route of administration of vaccine
- batch number
- where possible expiry date
- anatomical site of vaccination
- advice given, including advice given if excluded or declines immunisation
- details of any adverse drug reactions and actions taken
- administered under PGD.

Records should be kept in line with local procedures

Local policy should be followed to encourage information sharing with the individual's General Practice

All records should be clear, legible and contemporaneous and in an easily retrievable format.

6. Additional references

- Immunisation against Infectious Disease [Green Book]
- Immunisation against Infectious Disease [Green Book] Chapter 29
- Manufacturer's product information/ Summary of Product Characteristics
- Educational resources for registered professionals produced by National Education for Scotland
- All relevant JCVI statements
- All relevant Scottish Government advice including the relevant CMO letter(s)

7. PHS Version history

Version	Date	Summary of changes
1.0	08 August 2022	New PGD produced
1.1	11 October 2022	• Cautions section updated with advice on vaccination of individuals with a history of developing keloid scarring. • Route of administration updated to include intradermal injection. • Name of medicine section updated to highlight batch number FDP00072 is covered by the PGD. • Name of medicine section updated to highlight batch number FDP00059 is not covered by the PGD. • Dosage section updated to include dose for intradermal injection. • Frequency section updated to align with JCVI advice on prioritisation of doses. • Frequency section updated to include details for administration by intradermal injection. • Outwith SmPC section updated to include administration by intradermal injection. • Observation following vaccination updated to align with advice in Green Book Chapter 29.
1.2	1 June 2023	Change from monkeypox to mpox to align with advice from WHO.
2.0	1 June 2024	Previous PGD (version 1.2) expired. The following changes to version 1.2 of the PGD have been made: • minor rewording, layout and formatting changes for clarity and consistency with other PHS PGDs. • removal of reference to individual batch numbers. • Additional information section updated to include advice on immunosuppression assessment in those living with HIV.

Appendix 1 - Healthcare Professional Agreement to Administer Medicine(s) Under Patient Group Direction

I: _____ (Insert name)

Working within: _____ e.g. Area, Practice

Agree to administer the medicine(s) contained within the following Patient Group Direction:

Patient Group Direction For The Administration Of MVA-BN Vaccine By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles, Version 2.0

I have completed the appropriate training to my professional standards enabling me to administer the medicine(s) under the above direction. I agree not to act beyond my professional competence, nor out with the recommendations of the direction.

Signed: _____

Print Name: _____

Date: _____

Profession: _____

Professional Registration number/PIN: _____

NHS Grampian NHS Highland NHS Orkney NHS Shetland NHS Tayside NHS Eileanan Siar Western Isles

Appendix 2 - Healthcare Professionals Authorisation to Administer Medicine(s) Under Patient Group Direction

The Lead manager/Professional of each clinical area is responsible for maintaining records of all clinical areas where this PGD is in use, and to whom it has been disseminated.
The Senior Nurse/Professional who approves a healthcare professional to administer the medicine(s) under this PGD is responsible for ensuring that they are competent, qualified and trained to do so, and for maintaining an up-to-date record of such approved persons.
The Healthcare Professional that is approved to administer the medicine(s) under this PGD is responsible for ensuring that they understand and are qualified, trained and competent to undertake the duties required. The approved person is also responsible for ensuring that administration is carried out within the terms of the direction, and according to their individual code of professional practice and conduct.
Patient Group Direction For The Administration Of MVA-BN Vaccine By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles, Version 2.0
Local clinical area(s) where the listed healthcare professionals will operate under this PGD:

Name of Healthcare Professional	Signature	Date	Name of Manager	Signature	Date

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Name of Healthcare Professional	**Signature**	**Date**	**Name of Manager**	**Signature**	**Date**