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

Version 1.1

Effective from 11th October 2022

NoS/PGD/MVA-BN/MGPG1295

Note:

Only Jynneos® batches FDP00012 and FDP00072 are covered by this PGD.

Imvanex® brand of MVA-BN vaccine is not covered by this PGD as the batches available are unlicensed in UK and must only be administered in accordance with a patient specific direction

Jynneos® (batch FDP00059) of MVA-BN vaccine is not covered by this PGD as this batch is unlicensed in UK and must only be administered in accordance with a patient specific direction.

This Patient Group Direction (PGD) has been adopted from the PGD template produced by Public Health Scotland on the 8th of August and 11th of October 2022.

Most recent changes

Version	Date	Summary of changes
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.

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Authorisation

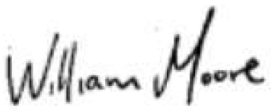
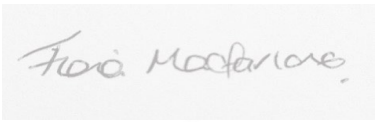
PGD administration of MVA-BN vaccine

This specimen Patient Group Direction (PGD) template has been produced by Public Health Scotland to assist NHS Boards. NHS Boards should amend/adapt this PGD template and must ensure that the PGD is considered and approved in line with local clinical governance arrangements for PGDs

The qualified health professionals who may administer MVA-BN 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 marketing authorisation holder's 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.

This PGD template has been adopted by NoS for use across all 6 NoS Health Boards.

This PGD has been produced for NoS by				**Date Signed**
Doctor	Dr William Moore	Signature		26/08/2022
Pharmacist	Fiona Macfarlane	Signature		19/08/2022
Nurse	Julia Penn	Signature		17/08/2022

Approved for use within NoS Boards by;

North of Scotland (NoS) PGD Group Chair	**Signature**	**Date Signed**
Lesley Coyle		18/08/2022

Authorised and executively signed for use within NoS Boards by;

NHS Grampian Chief Executive	**Signature**	**Date Signed**
Professor Caroline Hiscox		11/10/2022

Version 1.1 effective from 11th October 2022 review date 31st July 2023

Clinical situation

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

Category	Description
	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 monkeypox 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 monkeypox to themselves and to the breast-fed child. Whether prior monkeypox 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 monkeypox 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. 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.

Category	Description
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 at the clinic or GP as appropriate. In case of postponement due to acute severe febrile illness, advise when the individual can be vaccinated and ensure another appointment is arranged.
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. In NHS clinic setting, inform or refer to the clinician in charge. Inform or refer to the clinician in charge.

Description of treatment

Category	Description
Name of medicine/form strength	MVA-BN vaccine Smallpox vaccine (Live Modified Vaccinia Virus Ankara) Jynneos® (batches FDP00012 and FDP00072) Jynneos® (batch **FDP00059**) of MVA-BN vaccine is **not covered** by this PGD as this batch is unlicensed in UK and must only be administered in accordance with a patient specific direction. Imvanex® brand of MVA-BN vaccine is **not covered** by this PGD as the batches available are unlicensed in UK and must only be administered in accordance with a patient specific direction.
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.

Category	Description
	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

Category	Description
	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.
Dosage	0.1mL if given by intradermal injection. 0.5mL if given by subcutaneous or intramuscular injection.
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** 0.1mL intradermal injection OR 0.5mL subcutaneous/intramuscular injection Plus 0.1mL intradermal injection any time from 28 days after first dose OR 0.5mL subcutaneous/intramuscular injection 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** 0.5mL subcutaneous/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** 0.1mL intradermal injection OR 0.5mL subcutaneous/intramuscular injection

Category	Description
	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 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 0.1mL intradermal injection or 0.5ml subcutaneous/intramuscular 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 monkeypox. 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 monkeypox 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

Category	Description
	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.
Duration of treatment	See above.
Maximum or minimum treatment period	See above.
Quantity to supply/ administer	See above.
▼ Black triangle medicines	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.
Legal category	Prescription Only Medicine (POM)
Is the use out with the SmPC?	JYNNEOS® vaccine has been approved by MHRA for use in the current program for NHS management of monkeypox. 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 monkeypox 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. In view of the urgency of the need to manage the monkeypox outbreak, a Batch-Specific Variation for batch FDP00012 has been granted by MHRA to allow importation of the Food and Drug Administration (FDA)-licensed JYNNEOS® brand of the MVA-BN vaccine in the US. 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 monkeypox. The vaccine marketing authorisation holder's summary of product characteristics 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 monkeypox.

Category	Description
	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 monkeypox 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.
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.

Category	Description
	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.
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 monkeypox. Specialist medical advice on other measures may be required and additional doses should be considered for those at ongoing-risk of exposure. 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.

Category	Description
	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.

Warnings

Category	Description
Adverse reactions and management	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.
Reporting procedure for adverse reactions	Healthcare professionals and individuals/carers should report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on http://yellowcard.mhra.gov.uk/ 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.

Category	Description
Advice to patient or carer including written information	Written information to be given to individual: • Provide manufacturer's consumer information leaflet/patient information leaflet (PIL) provided with the vaccine. • Immunisation promotional material may be provided 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: https://yellowcard.mhra.gov.uk/ • 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.
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 fainting can occur following vaccination, all those vaccinated with MVA-BN should be advised to not drive for 15 minutes after vaccination.
Follow-up	As above.
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.

Characteristics of staff authorised under the PGD

Category	Description
Professional qualifications	The following classes of registered healthcare practitioners are permitted to administer this vaccine:

Category	Description
	• 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.
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 manufacturers 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.
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.

Audit trail

Category	Description
Record/audit trail	Record: • that valid informed consent was given • name of individual, address, date of birth and GP with whom the individual is registered • name of person that undertook assessment of individual's clinical suitability for vaccine • name of person that 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 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.
Additional references	Practitioners operating the PGD must be familiar with: Immunisation against Infectious Disease [Green Book] https://www.gov.uk/government/organisations/public-health-england/series/immunisation-against-infectious-disease-the-green-book Immunisation against Infectious Disease [Green Book] Chapter 29 https://www.gov.uk/government/publications/smallpox-and-vaccinia-the-green-book-chapter-29 Manufacturer's product information/ Summary of Product Characteristics. Educational resources for registered professionals produced by National Education for Scotland.

Category	Description
	All relevant JCVI statements. All relevant Scottish Government advice including the relevant CMO letter(s).

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

Appendix 1

Healthcare Professional Agreement to Administer Vaccine Under Patient Group Direction

I: _____ (Insert name)

Working within: _____ e.g. Health Board, Area Practice

Agree to administer the vaccine 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 1.1 – Valid from 11th October 2022)

I have completed the appropriate training to my professional standards enabling me to administer the vaccine under the above direction. I agree not to act beyond my professional competence, nor out with the recommendations of the direction. **PGDs do not remove inherent professional obligations or accountability.**

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 Vaccine 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 vaccine 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 vaccine 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 1.0 – Valid from 11th October 2022)
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

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 1.0 – Valid from 11th October 2022)					
Name of Healthcare Professional	**Signature**	**Date**	**Name of Manager**	**Signature**	**Date**

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.