Spikevax® bivalent Original/Omicron (Moderna COVID 19) vaccine

National Protocol

Reference no:	Spikevax® bivalent Original/Omicron (Moderna COVID 19) vaccine Protocol
Version no:	v1.0
Valid from:	31 August 2022
Review date:	01 March 2023
Expiry date:	31 March 2023

1. About the National Protocol

This protocol is for the supply and administration of Spikevax® bivalent Original/Omicron (Moderna COVID 19) vaccine to individuals in accordance with the national COVID-19 vaccination programme. This protocol only allows administration during or in anticipation of COVID-19 pandemic where the disease represents a serious risk or potentially serious risk to human health.

This protocol is for the supply and administration of Spikevax® bivalent Original/Omicron (Moderna COVID 19) vaccine by appropriately trained persons in accordance with regulation 247A of the Human Medicines Regulation 2012, as inserted by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020

The Scottish Government has developed this protocol which has been approved by the Scottish Ministers to facilitate the delivery of the national COVID-19 vaccination programme by Health Boards in Scotland and any organisation a Health Board makes arrangements with to deliver such services on its behalf, referred to as "the provider". Please note that in the context of this protocol, "the provider" means:

(a) a Health Board,
(b) a Health Board working with Armed Forces staff where Armed Forces staff are working in Health Board settings, or
(c) an organisation delivering services on behalf of a Health Board.

This protocol may be followed wholly from patient assessment through to post-vaccination by a single person. Alternatively, obtaining consent and patient assessment may be undertaken by a registered healthcare professional with the process of administration undertaken by a non-registered professional or a non-registered Armed Forces staff member under clinical supervision.

Where multiple person models are used the provider must ensure that all elements of the protocol are complied with in the provision of vaccination to each patient.

The provider is responsible for ensuring that persons are trained and competent to safely deliver the activity they are authorised to provide under this protocol. As a

minimum, competence requirements stipulated in the protocol under 'Characteristics of staff' must be adhered to.

The provider must identify a clinical supervisor who has overall responsibility for provision of vaccinations under the protocol at all times. This includes overall responsibility for the activities of any Armed Forces staff working under the protocol.

The clinical supervisor must be a registered healthcare professional trained and competent in all aspects of the protocol and provide clinical supervision for the overall provision of clinical care provided under the protocol.

The clinical supervisor must be identifiable to service users. Whenever the protocol is used, the name of the clinical supervisor taking responsibility and all of the people working under different activity stages of the protocol must be recorded for the session using the schedule in Annex C or maintaining an equivalent electronic record. The clinical supervisor has ultimate responsibility for safe care being provided under the terms of the protocol. Persons working under the protocol may be supported by additional registered healthcare professionals, but the clinical supervisor retains responsibility.

Persons working to the protocol must understand who the clinical supervisor for their practice is at any time and can only work under their authority. The clinical supervisor may withdraw this authority for all persons or individual persons at any time and has authority to stop and start service provision under the protocol as necessary. All members of staff have a responsibility to, and should, report immediately to the clinical supervisor any concerns they have about working under the protocol in general or about a specific individual, process, issue or event.

Individual practitioners must be designated by name to work to this protocol. Individuals working in accordance with this protocol must ensure they meet the staff characteristics for the activity they are undertaking, make a declaration of competence and be authorised in writing by the provider. This can be done by completing Annex B of this protocol or maintaining an equivalent electronic record.

It is a Health Board's responsibility to adhere to this protocol. Where the Health Board is not the provider, it is the Health Board's responsibility to ensure that the provider adheres to this protocol. The final authorised copy of this protocol should be kept, by Health Boards for 8 years after the protocol expires. Providers adopting authorised versions of this protocol should also retain copies, along with the details of those authorised to work under it, for 8 years after the protocol expires.

Providers must check that they are using the current version of this protocol. Amendments may become necessary prior to the published expiry date. Current versions of protocols authorised by the Scottish Ministers in accordance with regulation 247A of the Human Medicines Regulations 2012 can be found on the

Scottish Government website: https://www.gov.scot/collections/coronavirus-covid-19-vaccine-protocols/

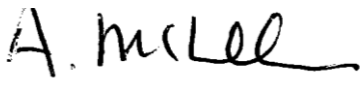
Any concerns regarding the content of this protocol should be addressed to: VaccinationsDelivery@gov.scot

2. Approval and Clinical Authorisation

This protocol is not legally valid, in accordance with regulation 247A of Human Medicines Regulation 2012, as inserted by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020, until approved by the Scottish Ministers.

On 31 August 2022 the Scottish Ministers, approved this protocol in accordance with regulation 247A of the Human Medicines Regulation 2012. Approval of clinical information in Annex A is via the Scottish Government Chief Medical Officer (CMO), Chief Pharmaceutical Officer (CPO) and Chief Nursing Officer (CNO) for the delivery of the national COVID-19 vaccination programme, with defined limitations to authorisation that may be updated from time to time as may be required.

Authorised for use by the following organisations and/or services
All Health Boards in Scotland, and organisations Health Boards make arrangements with to deliver services on their behalf.
Limitations to authorisation
This authorisation applies to the supply and administration of the vaccine(s) only under the conditions set out in the authorisation for supply or licence set out by the Medicines and Healthcare products Regulatory Agency.

Clinical authorisation			
Role	**Name**	**Sign**	**Date**
CMO	**Gregor Smith**		**31 August 2022**
CNO	**Alex McMahon**		**31 August 2022**
CPO	**Alison Strath**		**31 August 2022**

It is Health Boards' responsibility to ensure they and any organisations they make arrangements with to deliver services on their behalf operate the specified vaccination services in accordance with the protocol. Any provider administering Spikevax® bivalent Original/Omicron (Moderna COVID 19) vaccine under protocol must work strictly within the terms of this protocol.

The national COVID-19 vaccination programme may also be provided under patient group direction, under written instruction for supply and administration in the course of an occupational health scheme, or on a patient specific basis, by or on the directions of an appropriate prescriber. Supply and administration in these instances are not related to this protocol.

3. Change history

Version number	Change details	Date
V01.00	New protocol for Spikevax® bivalent Original/Omicron (Moderna COVID 19) vaccine	31/08/22

4. Characteristics of staff

The provider is responsible for the designation and authorisation of persons within the classes set out below permitted to administer medicinal products under this protocol. In doing so the provider must establish that those persons

a) demonstrate appropriate knowledge and skills to work under the National Protocol for the supply/administration of COVID-19 vaccine.
b) have met the requirements of the NES Proficiency document -COVID-19 vaccine administration for registered staff or the NES Proficiency document – COVID-19 vaccine administration - Healthcare support workers as appropriate https://learn.nes.nhs.scot/37676/immunisation/covid-19-vaccines

Classes of persons permitted to administer medicinal products under this protocol
This protocol may be adhered to wholly from assessment through to post-vaccination by a single appropriately specified registered healthcare professional. Alternatively, multiple persons may undertake specific activity stages in the vaccination pathway in accordance with this protocol.

Activity stages of the vaccination pathway under this protocol

Stage 1	a. Assessment of the individual presenting for vaccination b. Provide information and obtain informed consent c. Provide advice to the individual	Registered Healthcare Professionals Only
Stage 2	Vaccine Preparation	Registered Healthcare

		Professionals, non-registered professionals or non-registered Armed Forces staff
Stage 3	Vaccine Administration	Registered Healthcare Professionals, non-registered professionals or non-registered Armed Forces staff
Stage 4	Record Keeping	Registered Healthcare Professionals, non-registered professionals or non-registered Armed Forces staff

Providers are responsible for assessing the competency of, designating and recording the names of all those persons permitted to supply and administer under this protocol.

The following specified registered healthcare professionals are permitted to administer under the protocol subject to the requirements set out below:

- 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, operating department practitioners, 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.
- Doctors currently registered with General Medical Council.
- Dentists currently registered with General Dental Council.

The following professionals (who are in the main non-registered) are permitted to administer under the protocol with appropriate supervision as set out below, subject to the requirements set out below:

- Healthcare support workers.
- Pharmacy technicians, provisionally registered pharmacists, pre-registration pharmacists and other pharmacy support practitioners.
- Retired clinical practitioners such as doctors, dentists, pharmacists, nurses, optometrists, chiropodists/podiatrists, dieticians, occupational therapists, orthoptists, orthotists/prosthetists, paramedics, pharmacy technicians, physiotherapists,

radiographers, speech and language therapists, dental hygienists and dental therapists not currently registered.
- Student doctors, dentists, pharmacists, nurses, midwives, optometrists, chiropodists/podiatrists, dieticians, occupational therapists, orthoptists, orthotists/prosthetists, paramedics, physiotherapists, radiographers, speech and language therapists, dental hygienists and dental therapists not currently registered.
- Healthcare Scientists.
- Dental nurses.
- Physician's assistants.

The following non-registered Armed Forces staff are permitted to administer under the protocol with appropriate supervision as set out below, subject to the requirements set out below:

- Combat Medical Technician – Class 1,2 &3 (CMT)
- Royal Navy Medical Assistant (RN MA)
- Royal Air Forces Medic
- Defence Medic
- Healthcare Assistant (HCA)
- Military General Duties Vaccinators

Requirements

All those working under this protocol must have undertaken training, be assessed as competent and receive supervision appropriate to the stage of activity they are undertaking. Where multiple person models are used, the provider must ensure that all elements of the protocol are complied with in the provision of vaccination to each individual. The provider is responsible for ensuring that persons are trained and competent to safely deliver the activity they are employed to provide under this protocol. As a minimum, competence requirements stipulated in the protocol must be adhered to.

All persons must be designated by name by the provider as an approved person under the current terms of this protocol before working to it, and listed on the practitioner authorisation sheet in Annex B. All staff listed on the sheet will be covered by NHS indemnity extended by the Health Board who is responsible for the COVID 19 vaccination programme in that locality. Protocols do not remove inherent obligations or accountability. All practitioners operating under this protocol must work within their terms of employment at all times; registered healthcare professionals should also abide by their professional code of conduct.

There are three underpinning principles to which every person undertaking activities under the remit of this protocol must adhere

1. Training
    - They must have undertaken training appropriate to this protocol and relevant to their role, as required by local policy and health board standard operating procedures and in line with the training recommendations for COVID-19 vaccinators.

- They must have met the requirements set out in the NES Proficiency document - COVID-19 vaccine administration for registered staff or the NES Proficiency document –COVID-19 vaccine administration- Healthcare support workers

2. Competency

- Those providing clinical supervision to those administering the vaccine must be competent to assess individuals for suitability for vaccination, identify any contraindications or precautions, discuss issues related to vaccination and obtain informed consent from the individuals being vaccinated.
- All persons must either be an appropriate prescriber or one of above noted registered professionals. Those that are not registered professionals, and those returning to immunisation after a prolonged interval (more than 12 months), should be assessed and signed off as meeting the requirements of the relevant NES Proficiency document -COVID-19 vaccine administration. They should be observed administering the vaccine until both they, and their supervisor or trainer, feel confident that they have the necessary knowledge and skills to administer vaccines safely and competently.
- Experienced vaccinators should use the relevant NES Proficiency document to self-assess that they are able to meet all the competencies listed and confirm that they have the knowledge and skills necessary to administer COVID-19 vaccine.
- They must have completed local IPC training and comply with the vaccination guidance with the National COVID-19 IPC guidelines available: National Infection Prevention and Control Manual: Scottish COVID-19 Infection Prevention and Control Addendum for Acute Settings

In addition and where indicated as relevant to the role:

- They must be familiar with the vaccine product and alert to any changes in the manufacturers summary of product characteristics (SmPC) and familiar with the national recommendations for the use of this vaccine.
- They must be familiar with, and alert to changes in relevant chapters of Immunisation Against Infectious Disease: the Green Book COVID-19: the green book, chapter 14a - GOV.UK (www.gov.uk).
- They must be familiar with, and alert to changes in the relevant provider's standard operating procedures (SOPs) and provider's arrangements for the national COVID-19 vaccination programme.
- They must be competent in the correct handling and storage of vaccines and management of the cold chain if receiving, responsible for, or handling the vaccine.
- They must be competent in the recognition and management of anaphylaxis, have completed basic life support training and be able to respond appropriately to immediate adverse reactions.
- They must have access to the provider's protocols and relevant COVID-19 vaccination programme online resources.
- They must be competent in intramuscular injection technique if they are administering the vaccine, this should include a practical element.
- For those preparing the vaccine, they must be competent in the handling of the vaccine product, procedure for dilution of the vaccine and use of the correct technique for drawing up the correct dose.
- For those in record keeping roles, they must understand the importance of making sure vaccine information is recorded on the vaccination management app.

- They should fulfil any additional requirements defined by local policies developed in accordance with any national guidance.

3. Supervision
   - A period of supervised practice to allow observation and development of skills in vaccine administration and application of knowledge to practice is essential. Supervision for new immunisers and support for all immunisers is critical to the safe and successful delivery of the COVID-19 immunisation programme.
   - Non-registered professionals and non-registered Armed Forces staff must be supervised and supported by a registered healthcare professional at all times.
   - The clinical supervisor must be a registered healthcare professional trained and competent in all aspects of the protocol and provide clinical supervision for the overall provision of clinical care provided under the protocol.

5. Clinical condition or situation to which this Protocol applies

Spikevax® bivalent Original/Omicron (Moderna COVID 19) vaccine is indicated for active immunisation as a booster against COVID-19 disease caused by SARS-CoV-2 virus in accordance with Scottish Government COVID-19 immunisation programme and recommendations given in Chapter 14a of the Immunisation Against Infectious Disease: the 'Green Book' COVID-19: the green book, chapter 14a - GOV.UK (www.gov.uk) and Scottish Government CMO letters relating to COVID-19 vaccination.

ANNEX A: Clinical Information

This Annex provides information about the clinical situation or condition and treatment in relation to the National Protocol.

Annex Version History

Version	Date	Summary of changes
1.0	31 August 2022	Version 1.0 new Annex A

1. Clinical condition or situation to which this Protocol applies

Category	Description
Indication	Spikevax® bivalent Original/Omicron (Moderna COVID-19) vaccine is indicated for active immunisation as a booster against COVID-19 disease caused by SARS-CoV-2 virus in accordance with Scottish Government COVID-19 immunisation programme and JCVI advice/recommendations as set out in Green Book **Chapter 14a** and subsequent correspondence/publications from Scottish Government.
Inclusion criteria	Spikevax® bivalent Original/Omicron (Moderna COVID-19) vaccine should be offered in accordance with the recommendations in Green Book Chapter 14a. National policy must be followed in relation to the priority groups eligible for vaccination at a particular point in time. Individuals are eligible for different dose schedules based on their age and recognised risk group (see the frequency section). Valid consent has been given to receive the vaccine.
Exclusion criteria	Individuals who: • have had a confirmed anaphylactic reaction to a previous dose of COVID-19 vaccine. • have had a confirmed anaphylactic reaction to any component of the vaccine or residual products from manufacture, these include polyethylene glycol. Practitioners must check the marketing authorisation holder's summary of product characteristics (SmPC) for details of vaccine components.

Category	Description
	• have a history of immediate anaphylaxis to multiple, different drug classes, with the trigger unidentified (this may indicate PEG allergy) unless the advice from relevant specialist, local immunisation or health protection team is that vaccination should proceed. • have a history of anaphylaxis to a vaccine, injected antibody preparation or a medicine likely to contain PEG (e.g. depot steroid injection, laxative) unless the advice from relevant specialist, local immunisation or health protection team is that vaccination should proceed. • have a history of idiopathic (unexplained) anaphylaxis unless the advice from relevant specialist, local immunisation or health protection team is that vaccination should proceed. • are under 18 years of age • with evidence of current deterioration of COVID-19 symptoms, deferral of vaccination may be considered to avoid incorrect attribution of any change in the person's underlying condition to the vaccine. • are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation) • are bone marrow and peripheral blood stem cell donors who have commenced GCSF, the vaccination (first or second dose) must be delayed at least until 72 hours after stem cell collection (both peripheral blood stem cell and bone marrow donation). This is a precautionary advice to avoid vaccination when receiving Granulocyte-colony stimulating factor (GCSF) and allow for post donation recovery period. • have developed myocarditis or pericarditis following a previous dose of COVID-19 vaccination
Cautions/need for further advice/ circumstances when further advice should	The Green Book advises that there are very few individuals who cannot receive COVID-19 vaccines. Where there is doubt, rather than withholding vaccination, appropriate advice should be sought from the relevant specialist, or from the local immunisation or health protection team.

Category	Description
be sought from a doctor	**Individuals with a history of allergy** Those with a personal history of allergy should be managed in line with table 5 Green Book **Chapter 14a**. Where individuals have experienced a possible allergic reaction to a dose of COVID-19 vaccine, follow the guidance in the flowchart in Green Book **Chapter 14a** in relation to administration of subsequent doses. Green Book **Chapter 14a** states individuals with non-allergic reactions (vasovagal episodes, non-urticarial skin reaction or non-specific symptoms) to the first dose of a COVID-19 vaccine can receive the second dose of vaccine in any vaccination setting. Observation for 15 minutes is recommended. No specific management is required for individuals with a family history of allergies. **Individuals with thrombocytopenia** Guidance produced by the UK ITP Forum Working Party advises discussing the potential for a fall in platelet count in patients with a history of immune thrombocytopenia (ITP) receiving any COVID-19 vaccine and recommends a platelet count check 2-5 days after vaccination. **Guillain-Barré syndrome (GBS)** Very rare reports have been received of GBS following COVID-19 vaccination. Healthcare professionals should be alert to the signs and symptoms of GBS to ensure correct diagnosis and to rule out other causes, in order to initiate adequate supportive care and treatment. Individuals who have a history of GBS should be vaccinated as recommended for their age and underlying risk status. In those who are diagnosed with GBS after the first dose of vaccine, the balance of risk benefit is in favour of completing a full COVID-19 vaccination schedule. On a precautionary basis, however, where GBS occurs within six weeks of an Astra Zeneca vaccine, for any future doses Pfizer or Moderna COVID-19 vaccines are preferred. Where GBS occurs following either of the mRNA vaccines, further vaccination can proceed as normal, once recovered.

Category	Description
	Individuals with a bleeding history Individuals with a bleeding disorder may develop a haematoma at the injection site (see Route of Administration). **Co-administration with other vaccines** The COVID-19 vaccines in use in the UK are considered inactivated, where individuals in an eligible cohort present having recently received another inactivated or live vaccine, COVID-19 vaccination should still be given. The same applies for most other live and inactivated vaccines where COVID-19 vaccination has been received first or where a patient presents requiring two or more vaccines. It is generally better for vaccination to proceed to avoid any further delay in protection and to avoid the risk of the patient not returning for a later appointment. This includes but is not limited to vaccines commonly administered around the same time or in the same settings (including influenza and pneumococcal polysaccharide vaccine in those aged over 65 years, pertussis-containing vaccines and influenza vaccines in pregnancy, and LAIV, HPV, MenACWY and Td-IPV vaccines in the schools programmes). An exception to this is shingles vaccination, where a seven-day interval should ideally be observed given the potential for an inflammatory response to COVID-19 vaccine to interfere with the response to the live virus in the older population and because of the potential difficulty of attributing systemic side effects to the newer adjuvanted shingles vaccine. Where individuals attend requiring both vaccines, however, and require rapid protection or are considered likely to be lost to follow up, co-administration may still be considered. When administering at the same time as other vaccines, care should be taken to ensure that the appropriate route of injection is used for all the vaccinations. The vaccines should be given at separate sites, preferably in different limbs. If given in the same limb, they should be given at least 2.5cm apart. The site at which each vaccine was given should be noted in the individual's records. **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

Category	Description
	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. **Pregnancy and breastfeeding** JCVI advise there is no known risk associated with giving these types of vaccines during pregnancy. These vaccines cannot replicate, so they cannot cause infection in either the woman or the unborn child. Vaccination in pregnancy should be offered in accordance with recommendations in Green Book Chapter 14a, following a discussion of the risks and benefits of vaccination with the woman. In December 2021, following the recognition of pregnancy as a risk factor for severe COVID-19 infection and poor pregnancy outcomes during the Delta wave, pregnancy was added to the clinical risk groups recommended COVID-19 vaccination. Because of the wider experience with mRNA vaccines, these are currently the preferred vaccines to offer to pregnant women. For those under 18 years Comirnaty® (COVID-19 mRNA vaccine, Pfizer/BioNTech) is preferred. When mRNA vaccines are not considered clinically suitable, Nuvaxovid (Novavax COVID-19 vaccine recombinant, adjuvanted) vaccine may be used for primary vaccination of pregnant women, including to complete a course or as a booster, although experience in pregnancy is relatively limited. If a woman finds out she is pregnant after she has started a course of vaccine, she should complete vaccination at the recommended interval. There is no known risk associated with giving non-live vaccines whilst breastfeeding. JCVI advises that breastfeeding women may be offered vaccination with any suitable COVID-19 vaccine. Emerging safety data is reassuring: mRNA was not detected in the breast milk of recently vaccinated and protective antibodies have been detected in breast milk. The developmental and health benefits of breastfeeding should be considered along with the woman's clinical need for immunisation against COVID-19. **Clinical trial participants** Individuals who have participated in a clinical trial of either primary or booster COVID-19 vaccines should be provided with written

Category	Description
	advice on whether and when they should be safely vaccinated in the routine programme. Advice should also be provided from the trial investigators on whether any individual could receive additional doses for the purposes of vaccine certification. Trial participants who are eligible for boosters should be offered vaccination in line with the general population, at least three months after the dose considered as the final primary dose or the final revaccination (if the latter is required for certification purposes). **Individuals with a past history of COVID-19 infection** There is no convincing evidence of any safety concerns from vaccinating individuals with a past history of COVID-19 infection, or with detectable COVID-19 antibody. Vaccination of individuals who may be infected or asymptomatic or incubating COVID-19 infection is unlikely to have a detrimental effect on the illness. As clinical deterioration can occur up to two weeks after infection, vaccination of adults and high risk children* should ideally be deferred until clinical recovery to around four weeks after onset of symptoms or four weeks from the first confirmed positive specimen to avoid confusing the differential diagnosis. The four-week interval may be reduced to ensure operational flexibility when rapid protection is required, for example high incidence or circulation of a new variant in a vulnerable population. Currently, the JCVI consider that, in care home residents and the housebound, there may be an advantage in offering vaccination to some individuals with recent confirmed COVID-19, without a four-week deferral, where individuals are clinically stable and when infection control procedures can be maintained. These populations are likely to be highly vulnerable and will facilitate vaccination without the need for multiple visits. There is no need to defer immunisation in individuals after recovery from a recent episode with compatible symptoms who were not tested unless there are strong clinical or epidemiological features to suggest the episode was COVID-19 infection. *high risk will include children and young people under 18 years as defined in tables 3 and 4 of Green Book **Chapter 14a** and includes clinical risk groups and individuals who expect to share living accommodation on most days (and therefore for whom continuing

Category	Description
	close contact is unavoidable) with individuals who are immunosuppressed.
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 deferral due to COVID-19 symptoms or recent positive COVID test advise when the individual can be vaccinated and how future vaccination may be accessed. 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/carer 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

Category	Description
Name of medicine	Spikevax® bivalent Original / Omicron (Moderna COVID-19) Vaccine dispersion for injection Spikevax® 0 (Zero)/O (Omicron) (Moderna COVID-19) Vaccine dispersion for injection
Form/strength	Spikevax® bivalent Original / Omicron (Moderna COVID-19) Vaccine dispersion for injection 0.10mg/ml, multi dose vial

Category	Description
	Spikevax® 0 (Zero)/O (Omicron) (Moderna COVID-19) Vaccine dispersion for injection 0.10mg/ml, multi dose vial
Route of administration	Each vial contains at least the number of doses stated. It is normal for liquid to remain in the vial after withdrawing the final dose. Care should be taken to ensure a full 0.5 mL dose is administered. Where a full 0.5 mL dose cannot be extracted, the remaining volume should be discarded. 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. Spikevax® bivalent Original / Omicron (Moderna COVID-19) Vaccine must be administered by intramuscular (IM) injection preferably into the deltoid area of the upper arm. Where administration into the deltoid is not possible the anterolateral thigh can be considered. Individuals with bleeding disorders may be vaccinated intramuscularly if, in the opinion of a doctor familiar with individual's bleeding risk, vaccines or similar small volume intramuscular injections can be administered with reasonable safety by this route. If the individual receives medication/ treatment to reduce bleeding, for example treatment for haemophilia, intramuscular vaccination can be scheduled shortly after such medication/treatment is administered. Individuals on stable anticoagulation therapy, including individuals on warfarin who are up-to-date with their scheduled INR testing and whose latest INR is below the upper level of the therapeutic range, can receive intramuscular vaccination. A fine needle (23 or 25 gauge) should be used for the vaccination, followed by firm pressure applied to the site without rubbing for at least 2 minutes. The individual/parent/carer should be informed about the risk of haematoma from the injection.
Dosage	0.5mL

Category	Description
Frequency	Spikevax® bivalent Original / Omicron (Moderna COVID-19) vaccine as a booster in those who have received primary immunisation (and previous boosters) should be offered a single dose at least 3 months (12 weeks) after previous COVID-19 dose. Someone in the eligible group who has received a full course of primary vaccination (two or three doses) but has not received a booster before September 2022, may be given a booster provided there is at least three months from the previous dose. Additional doses are not then required.
Duration of treatment	See above.
Maximum or minimum treatment period	See above.
Quantity to supply/administer	See above.
▼ black triangle medicines	Yes, Spikevax® bivalent Original/Omicron (Moderna COVID 19) vaccine is subject to additional monitoring and id designated as ▼ 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://www.mhra.gov.uk/yellowcard**
Legal category	Prescription only medicine (POM).
Is the use outwith the SPC?	Spikevax® bivalent Original/Omicron (Moderna COVID 19) vaccine has been granted a Conditional Marketing Authorisation (CMA) by the MHRA. The vaccine marketing authorisation holder's SmPC states that close observation for at least 15 minutes is recommended following vaccination. The UK CMO's, in recognition of the

Category	Description
	need to accelerate delivery of the programme in response to the emergence of the Omicron variant, recommended a temporary suspension of this requirement for mRNA vaccines. This was in individuals without a history of allergy. It was also agreed by the Commission on Human Medicines. This also applies to Spikevax® bivalent Original/Omicron (Moderna COVID 19) vaccine. The Scottish Government has made further recommendations that all doses of COVID-19 mRNA vaccines be followed by a 5 minute observation period. 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 Protocol.
Storage requirements	Spikevax® bivalent Original/Omicron (Moderna COVID 19) vaccine must be stored frozen at minus 50ºC to minus 15ºC in accordance with manufacturer's advice. Once thawed, the vaccine should not be re-frozen and may be stored refrigerated at +2°C to +8°C protected from light for up to 30 days if not used (needle-punctured). During storage it is recommended that the vials are stored in the original packaging/cartons, away from direct sunlight to protect from light and kept upright. NHS Board guidance on Storage and Handling of vaccines should be observed. 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 use or appropriate disposal. After first use – use as soon as practically possible and within six hours. The vaccine may be stored between +2 and +25°C during the in-use period in accordance with manufacturer's advice. The vaccine vial has space to write the date and time

Category	Description
	that the vial should be discarded following first puncture; write this on the vial label. 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 should be postponed until they have fully recovered. There is no convincing evidence of any safety concerns from vaccinating individuals with a past history of COVID-19 infection, or with detectable COVID-19 antibody. Having prolonged COVID-19 symptoms is not a contraindication to receiving COVID-19 vaccine but if the patient is seriously debilitated, still under active investigation, or has evidence of recent deterioration, deferral of vaccination may be considered to avoid incorrect attribution of any change in the person's underlying condition to the vaccine.

3. Adverse reactions

Category	Description
Warnings including possible adverse reactions and management of these	A high proportion (more than 75%) of vaccine recipients had localised pain at the injection site after both dose 1 and dose 2. of Spikevax® (COVID-19 Vaccine Moderna dispersion for injection). Redness and swelling were also seen after the second dose and local pain tended to last longer (around 3 days). Mild systemic effects were also common, including headache, fatigue, joint and muscle aches and chills. Systemic events were more severe after dose 2 and fever was only seen after dose 2, and both local and systemic reactions were less common in older participants. Adverse events were less common in those with pre-existing SARS-CoV-2 antibody. Axillary lymphadenopathy on the same side as the injection site was detected in more than one in ten recipients.

Category	Description
	Bell's palsy was reported by three participants in the vaccine group and one participant in the placebo group. As for the Pfizer vaccine, this will be monitored closely post-implementation. There were no cases of severe COVID-19 disease in the vaccine group, and thus no signal for enhanced disease. A number of cases of myocarditis and pericarditis have been reported after Pfizer BioNTech vaccine from Israel and the USA. The reported rate appears to be highest in those under 25 years of age and in males, and after the second dose. Onset is within a few days of vaccination and most cases are mild and have recovered without any sequalae. The MHRA has advised the benefits of vaccination still outweigh any risk in most individuals. Individuals who have had myocarditis or pericarditis should be investigated, and a second or booster dose can be given once they are fully recovered in line with advice in the Green Book **Chapter 14a**, under a PSD. Reactogenicity was similar between the original and bivalent vaccine. In the event of a severe adverse reaction individual should be advised to seek medical advice. For full details/information on possible adverse reaction, refer to manufacturer's product literature or summary of product characteristics.
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. Anaphylaxis is a very rare, recognised side effect of most vaccines and suspected cases should be reported via the MHRA Yellow Card Scheme. Chapter 8 of the Green Book gives detailed guidance on distinguishing between faints, panic attacks and the signs and symptoms of anaphylaxis. If a case

Category	Description
	of suspected anaphylaxis meets the clinical features described in Chapter 8, this should be reported via the Yellow Card Scheme as a case of 'anaphylaxis' (or if appropriate 'anaphylactoid reaction'). Cases of less severe allergic reactions (i.e. not including the clinical features of anaphylaxis) should not be reported as anaphylaxis but as 'allergic reaction'. Programmatic Adverse Events should be recorded in line with local procedures and where appropriate escalated in accordance with the national framework.
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. • Provide copy of Public Health Scotland post-vaccination leaflet • Provide copy of Pregnant, planning a pregnancy or breastfeeding, a guide to COVID-19 vaccine to women of child bearing years **Individual advice / follow up treatment** Inform the individual/carer of possible side effects and their management. Vaccinated individuals should be advised that it is common to develop a fever after vaccination and that this normally happens within 48 hours after the vaccination and usually goes away within 48 hours. This is a common, expected reaction, and self-isolation and testing for COVID-19 are not required. Vaccinated individuals should be advised that if the fever started 48 hours after the vaccination or lasts longer than 48 hours, they should seek medical advice as they may have COVID-19 or another infection. They may be advised to take a COVID-19 test. Vaccinated individuals should be advised that feeling generally unwell, shivery, achy and tired were also symptoms commonly reported by vaccine recipients in the clinical trials. Generally, these symptoms were found to

Category	Description

	resolve within one to two days without treatment but paracetamol can be taken if necessary to relieve any of these symptoms.
	• Inform the individual/carer that anyone who has any of the following symptoms after vaccination should seek medical advice urgently:
	  ○ chest pain
	  ○ shortness of breath
	  ○ feelings of having a fast-beating, fluttering, or pounding heart
	• As has always been recommended, any fever after vaccination should be monitored and if individuals are concerned about their health at any time, they should seek advice from their GP or NHS24
	• 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.

Observation following vaccination	Following COVID-19 vaccine administration, individuals should be observed for any immediate reactions whilst they are receiving any verbal post vaccination information and exiting the centre. According to the SmPC, it is recommended that all recipients of the Moderna vaccine are kept for observation and monitored for a minimum of 15 minutes following vaccination. The UK CMO's, in recognition of the need to accelerate delivery of the programme in response to the emergence of the Omicron variant, recommended a temporary suspension of this requirement for mRNA vaccines. This was in individuals

Category	Description
	without a history of allergy. It was also agreed by the Commission on Human Medicines. More recently, the Scottish Government has recommended that all doses of mRNA COVID-19 vaccines should be followed by a 5 minute observation period. A longer observation period when indicated after clinical assessment in individuals with a history of allergy as set out in Table 5 and flowchart in Green Book Chapter 14a Vaccinated individuals should be informed about how to access immediate healthcare advice in the event of displaying any symptoms. In some settings, for example domiciliary vaccination, this may require a responsible adult to be present for at least 15 minutes after vaccination. 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.
Follow up	Not applicable
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. Audit Trail/Records

Name	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

Name	Description
	• 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 national protocol 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

5. References

Name	Description
Additional references	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] COVID-19 **https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a** Manufacturer's product information/ Summary of Product Characteristics **Summary of Product Characteristics for Spikevax - GOV.UK (www.gov.uk)**

Name	Description
	Educational resources for registered professionals produced by National Education for Scotland **https://learn.nes.nhs.scot/37676/immunisation/covid-19-vaccines** All relevant JCVI statements All relevant Scottish Government advice including the relevant CMO letter(s)

ANNEX B: Practitioner authorisation sheet

Spikevax® bivalent Original/Omicron (Moderna COVID 19) vaccine Protocol

Valid from:
Expiry:

Before signing this Protocol, check that the document has had the necessary authorisations in section 1 and 2. Without these, this Protocol is not lawfully valid.

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

Protocols do not remove inherent professional obligations or accountability.

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

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

Person authorising on behalf of Provider

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

Note to person authorising on behalf of Provider
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 Protocol.

ANNEX C: Clinical Supervision sheet

Spikevax® bivalent Original/Omicron (Moderna COVID 19) vaccine Protocol

Valid from:
Expiry:

This sheet must record the name of the clinical supervisor taking responsibility and all of the people working under different activity stages of the protocol.

Activity stages of the vaccination pathway under this protocol:

Stage 1	a. Assessment of the individual presenting for vaccination b. Provide information and obtain informed consent c. Provide advice to the individual	Registered Healthcare Professionals Only
Stage 2	Vaccine Preparation	Registered Healthcare Professionals, non-registered professionals or non-registered Armed Forces staff
Stage 3	Vaccine Administration	Registered Healthcare Professionals, non-registered professionals or non-registered Armed Forces staff
Stage 4	Record Keeping	Registered Healthcare Professionals, non-registered professionals or non-registered Armed Forces staff

The clinical supervisor has ultimate responsibility for safe care being provided under the terms of the protocol. Persons working under the protocol may be supported by additional registered healthcare professionals, but the clinical supervisor retains responsibility.

Before signing this Protocol, check that the document has had the necessary authorisations. Without these, this Protocol is not lawfully valid.

Clinical Supervisor

Name	Designation	Signature	Date

Practitioner(s) and Activity Stages

Name	Activity Stage(s)	Signature	Date

Note to Clinical Supervisor

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 clinical supervision arrangements for those working under this Protocol.