Administration of COVID-19 mRNA vaccines to individuals aged 18 years and over National Protocol

Reference No.:	Administration of COVID-19 mRNA vaccines to individuals aged 18 years and over National Protocol
Protocol Version no:	V05.0
Valid from:	19 March 2025
Review date:	30 August 2025
Expiry date:	31 August 2025

1. About the National Protocol

This protocol is for the supply and administration of COVID-19 mRNA vaccines to individuals aged 18 years and over in accordance with the national COVID-19 vaccination programme.

This protocol is for the supply and administration of COVID-19 mRNA vaccines by appropriately trained persons in accordance with regulation 247A of the Human Medicines Regulations 2012 .

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 the 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.

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 a 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.

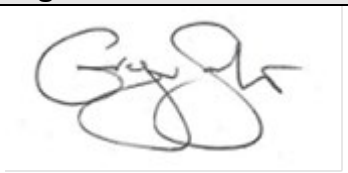
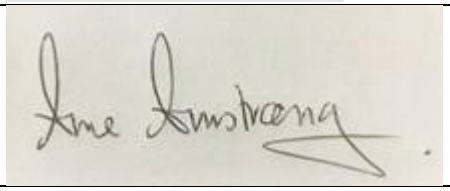
Providers must check that they are using the current version of this protocol. Amendments may become necessary prior to the published expiry date. Current versions of protocols authorised by the Scottish Ministers in accordance with regulation 247A of the Human Medicines Regulation 2012 can be requested by emailing ImmunisationPolicy@gov.scot. Any concerns regarding the content of this protocol should also be sent to this email address.

2. Approval and Clinical Authorisation

This protocol is not legally valid, in accordance with regulation 247A of the the Human Medicines Regulations 2012 until approved by the Scottish Ministers.

On 27 August 2024 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, Chief Pharmaceutical Officer and Chief Nursing Officer 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) onlyunder the conditions set out in the authorisation for supply or license set out by the Medicines and Healthcare products Regulatory Agency.

Clinical authorisation			
Role	**Name**	**Sign**	**Date**
CMO	Gregor Smith		19 March 2025
Interim CNO	Anne Armstrong		19 March 2025
CPO	Alison Strath		19 March 2025

3. Change history

Version number	Change details	Date
V01.00	New protocol for administration of COVID-19 vaccines to individuals aged 18 years and over	30 August 2023
V02.00	Clinical annex updated	21 September 2023
V03.00	Review following expiry of version 02.00 and clinical annex updated	8 March 2024
V04.00	Protocol and clinical annex updated for 2024/25 autumn/winter season	19 September 2024
V05.00	Protocol and clinical annex updated for 2025 spring programme	19 March 2025

4. Characteristics of staff

The provider is responsible for the designation and authorisation of persons withinthe 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 mRNA vaccines to individuals aged 18 years and over.
b) have met the requirements of the relevant NES Vaccination Proficiency document as appropriate at 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 asingle 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 administerunder 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).
- Pharmacy technicians currently registered with the General Pharmaceutical Council (GPhC).
- Chiropodists/podiatrists, dieticians, occupational therapists, operating departmentpractitioners, 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 currently registered with the General Dental Council.
- Optometrists currently 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 therequirements set out below:

- Healthcare support workers
- 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
- Scottish Ambulance Service Ambulance Technicians

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 relevant NES Vaccination Proficiency document.

2. Competency

- Those providing clinical supervision to those administering the vaccine must be competent to assess individuals for suitability for vaccination, identify any contraindications / exclusions 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 Vaccination Proficiency document. 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 Vaccination 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.

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 (SPC) 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 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 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 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 of, 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

Administration of COVID-19 mRNA vaccines to individuals aged 18 years and over is indicated for active immunisation 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	30 August 2023	Version 1.0 new Annex A
2.0	21 September 2023	• Updated throughout to include Pfizer and Moderna XBB.1.5 variant vaccines. • Cautions section updated to remove deferral for two weeks after COVID-19 infection. • Frequency section updated to align with Green Book chapter advice on additional doses for those identified as meeting the definition for severe immunosuppression. • Use outwith SmPC – updated following change in SmPC for Comirnaty BA4.5 and minor changes to wording on post vaccination observation. • Observation following vaccination section - minor changes.
3.0	8 March 2024	• updated to reference mRNA vaccines only. • updated to remove reference to bivalent Original/Omicron BA. 4-5 vaccines. • Inclusion criteria amended to include individuals invited, or eligible in accordance with the recommendations in Green Book Chapter 14a, and/or in line with subsequent correspondence/publications from Scottish Government. • Inclusion criteria, frequency, is the use outwith the SmPC and additional reference sections updated to include reference to the Scottish Haematology Society schedule for

		the revaccination of patients following haematopoietic stem cell transplant or CAR-T treatment. • Frequency section updated to reflect updated Green Book Chapter advice for severely immunosuppressed individuals. • Is the use outwith the SmPC and observation following vaccination sections updated to remove advice from Scottish Government on 5 minute wait.
4.0	19 September 2024	• Updated throughout to include JN.1 vaccines. • Co-administration with other vaccines updated to include RSV vaccine. • Warnings section updated to include statement that Erythema Multiforme has been reported associated after vaccination.
5.0	19 March 2025	• Cautions section updated to include pregnant women can safely have Abrysvo® co-administered with influenza vaccine, anti-D immunoglobulin or COVID-19 vaccine. • Minor formatting in frequency section • Is the use outwith the SmPC section updated to clarify SmPC is for Comirnaty JN.1 in relation to 15 minute observation

1. Clinical condition or situation to which this Protocol applies

Category	Description
Indication	COVID-19 mRNA vaccines are indicated for active immunisation against COVID-19 disease caused by SARS-CoV-2 virus in those aged 18 years and over 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.

Category	Description
Inclusion criteria	COVID-19 mRNA vaccines should be offered to those aged 18 years and over invited, or eligible in accordance with the recommendations in Green Book **Chapter 14a**, and/or in line with subsequent correspondence/publications from Scottish Government. National policy must be followed in relation to the priority groups eligible for vaccination at a particular point in time including vaccination for travel entry certification and ad-hoc occupational purposes internationally. Individuals who have received a haematopoietic stem cell transplant or CAR-T therapy and who require revaccination, in accordance with the Scottish Haematology Society Revaccination Schedule. Valid consent has been given to receive the vaccine.
Exclusion criteria	Individuals who: • have had a confirmed anaphylactic reaction to a previous dose of a mRNA COVID-19 vaccine. • have had a confirmed anaphylactic reaction to any component of the vaccine or residual products from manufacture, these include polyethylene glycol (PEG). Practitioners must check the marketing authorisation holder's SmPC for details of vaccine components. • 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.

Category	Description
	• are under 18 years of age. • have 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 Granulocyte-colony stimulating factor (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 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 be sought from a doctor	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. **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.

Category	Description
	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. **Capillary leak syndrome** Extremely rare reports of capillary leak syndrome have been reported after Moderna vaccines in individuals with a prior history of this condition. Individuals with a history of capillary leak syndrome, should be carefully counselled about the risks and benefits of vaccination and advice from a specialist should be sought. **Guillain-Barré syndrome (GBS)** Very rare reports have been received of GBS following COVID-19 vaccination. 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. Where GBS occurs following either of the mRNA vaccines, further vaccination can proceed as normal, once recovered. **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

Category	Description
	time or in the same settings (including inactivated influenza vaccine, pneumococcal polysaccharide vaccine, shingles vaccine, pertussis-containing vaccines and influenza vaccines in pregnancy). It is recommended that RSV vaccine is not routinely scheduled to be given to an older adult at the same appointment or on the same day as an influenza or COVID-19 vaccine. No specific interval is required between administering the vaccines. If it is thought that the individual is unlikely to return for a second appointment or immediate protection is necessary, RSV vaccine (Abrysvo®) can be administered at the same time as influenza and/or COVID-19 vaccination. Pregnant women can safely have Abrysvo® co-administered with influenza vaccine, anti-D immunoglobulin or COVID-19 vaccine. 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 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.

Category	Description
	Vaccination should be offered for eligible pregnant women in accordance with recommendations in Green Book **Chapter 14a**, following a discussion of the risks and benefits of vaccination with the woman. 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 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 are no safety concerns from vaccinating 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 although individuals with suspected COVID-19 infection should not attend vaccination sessions to avoid infecting others. There is no need to defer immunisation in individuals after recovery from a recent episode with compatible symptoms, whether or not they are tested for COVID-19. During care home outbreaks, vaccination of residents with confirmed COVID-19 may go ahead provided the residents are

Category	Description
	clinically stable and infection control procedures can be maintained.
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. ***Temporary exclusion*** In case of postponement due to acute severe febrile illness, advise when the individual can be vaccinated and ensure another appointment is arranged. In case of deferral due to COVID-19 symptoms advise when the individual can be vaccinated and how future vaccination may be accessed.
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/form/strength	Comirnaty JN.1 30 micrograms/dose dispersion for injection COVID-19 mRNA Vaccine. Multidose vial that contains 6 doses of 0.3 mL. One dose (0.3 mL) contains 30 micrograms of bretovameran, a COVID-19 mRNA Vaccine (embedded in lipid nanoparticles).

Category	Description
	Spikevax JN.1 COVID-19 mRNA Vaccine 0.1mg/1ml dispersion for injection. Multidose vial that contains 5 doses of 0.5 ml each. One dose (0.5 ml) contains 50 micrograms of mRNA-1273.167, a COVID-19 mRNA Vaccine (embedded in lipid nanoparticles).
Route of administration	COVID-19 vaccines 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. 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 dose is administered. Where a full 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

Category	Description
	event of any foreign particulate matter and/or variation of physical aspect being observed, do not administer the vaccine.
Dosage	Comirnaty JN.1 30 micrograms/dose dispersion for injection COVID-19 mRNA Vaccine dose is 0.3mL Spikevax JN.1 COVID-19 mRNA Vaccine 0.1mg/1ml dispersion for injection dose is 0.5mL
Frequency	A single dose regardless of prior COVID-19 vaccination status. For individuals who have previously been vaccinated with a COVID-19 vaccine, the dose should be given at least three months (12 weeks) after the previous dose of COVID-19 vaccine (regardless of the vaccine given for the previous dose). The only exception to the three months interval would be where individuals were about to receive or increase the intensity of an immunosuppressive treatment, and therefore a better response would be made if immunised prior to that treatment commencing. In this unusual scenario, the interval for all vaccine products may be reduced to a minimum of three weeks. **Individuals identified as meeting the definition for severe immunosuppression** Additional doses for those identified as meeting the definition for severe immunosuppression (as defined in Green Book Chapter 14a) may be required. From 2023, for most individuals aged 5 years and above, the primary course of COVID-19 vaccine is an offer of a single dose of vaccine, provided only during seasonal campaigns. Individuals who become or have recently become severely immunosuppressed (i.e. those commencing immunosuppressive therapy or

Category	Description
	those who have developed an immunosuppressive condition) should be considered for additional doses (as outlined below). Previously unvaccinated individuals who become or have recently become severely immunosuppressed should be considered for a first dose of vaccination, regardless of the time of year. Further doses should then be offered on the basis of specialist clinical judgement (see below). Vaccinated individuals who become or have recently become severely immunosuppressed should be considered for an additional dose of COVID-19 vaccine, regardless of their past vaccination history and the time of year. The additional dose of vaccine should be offered at a minimum interval of three months from any previous doses, to extend protection until the next seasonal campaign. Clinical judgement should be used to decide which individuals should be given an additional dose soon after their diagnosis rather than waiting for the next campaign and thus getting extra protection during the season, particularly over the winter, and at the same time as other high risk groups. The optimal timing should also take account of the degree of immune suppression (see Green Book Chapter 14a section on timing). Second doses should ideally be given between 8-12 weeks from the previous dose, to extend protection. This interval may be reduced to three weeks on specialist clinical advice to maximise short term protection, bearing in mind that response may be less durable. As above, subsequent doses may be optimally delivered during the next regular campaign. In contrast to other eligible risk groups, those who are eligible for a vaccination due to severe immunosuppression but miss vaccination during the campaign period, may be considered for a booster at a later date based on individual clinical judgement,

Category	Description
	balancing their immediate level of risk against the advantages of waiting till the next seasonal campaign. Additional doses are covered by this National Protocol. **Revaccination of individuals who have received a haemopoietic stem cell transplant** In accordance with the schedule recommended by the Scottish Haematology Society **Revaccination of patients following haematopoietic stem cell transplant or CAR-T treatment.**
Duration of treatment	See above.
Maximum or minimum treatment period	See above.
Quantity to supply/administer	See above.
▼ black triangle medicines	Yes. All COVID-19 vaccines are subject to additional monitoring and is 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 SmPC?	The vaccine marketing authorisation holder's SmPC for Comirnaty JN.1 30 micrograms/dose dispersion for injection COVID-19 mRNA Vaccine states that close observation for at least 15 minutes is recommended following vaccination. The UK CMOs, 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

Category	Description
	individuals without a history of allergy. It was also agreed by the Commission on Human Medicines. The advice to suspend the routine 15 minute observation period applies to all the currently available COVID-19 vaccines, including the variant mRNA products. Revaccination of patients following haematopoietic stem cell transplant of CAR-T treatment is considered off-label but is in accordance with the **Scottish Haematology Society schedule**. 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	**General requirements** 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. 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.

Category	Description
	Vaccine specific requirements <u>Comirnaty JN.1 30 micrograms/dose dispersion for injection COVID-19 mRNA Vaccine</u> Once thawed, the vaccine may be stored refrigerated at +2°C to +8°C protected from light for up to 10 weeks (within shelf life) if not used (needle-punctured). Once thawed the vaccine should not be re-frozen. After first use – use as soon as practically possible and within 12 hours. The vaccine can be stored at +2°C to +30°C during the in-use time. Thawed vials can be handled in room light conditions. The vaccine vial has space to write the date and time that the vial should be discarded following was first puncture; write this on the vial label. <u>Spikevax JN.1 COVID-19 mRNA Vaccine 0.1mg/1ml dispersion for injection</u> 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). 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 has a transport time of 36 hours at 2°C to 8°C (maximum of 30 hours by road and up to 6 hours by air). The vaccine vial has space to write the date and time that the vial should be discarded following first puncture; write this on the vial label.
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.

Category	Description
	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	The most frequently reported adverse reactions are injection site pain, swelling or redness, fatigue, headache, myalgia, chills, arthralgia, pyrexia, nausea, diarrhoea and vomiting. These reactions are usually mild or moderate in intensity and resolve within a few days after vaccination. Uncommon side effects include enlarged lymph nodes, feeling unwell, arm pain, insomnia, injection site itching, allergic reactions such as rash or itching, feeling weak or lack of energy/sleepy, decreased appetite, excessive sweating and night sweats. Lymphadenopathy: Swollen axilla or neck glands on the same side as the vaccination site can occur as an uncommon reaction, which can last for up to 10 days. If the vaccine recipient is due to attend for a mammogram, they should be advised to inform clinicians regarding date of vaccine administration. Myocarditis and pericarditis: Very rare reports of myocarditis and pericarditis have been observed following vaccination with mRNA COVID-19 vaccines. These cases have primarily occurred within 14 days following vaccination, and more often in younger men. Available data suggest that the course of myocarditis and pericarditis following vaccination is not

Category	Description
	different from myocarditis or pericarditis in general. Healthcare professionals should be alert to the signs and symptoms of myocarditis and pericarditis. Recipients should be instructed to seek immediate medical attention if they develop symptoms indicative of myocarditis or pericarditis such as (acute and persisting) chest pain, shortness of breath or palpitations following vaccination. Healthcare professionals should consult guidance and/or specialists to diagnose and treat this condition. Heavy menstrual bleeding has been reported after COVID-19 vaccination. In most cases, this is self-limiting. Uncommonly, benign and self-limiting cases of Erythema Multiforme have been reported associated after vaccination. 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 SmPC.
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 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

Category	Description
	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 **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. • 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 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:

Category	Description
	○ 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 Pfizer BioNTech vaccine are kept for observation and monitored for a minimum of 15 minutes following vaccination. The UK CMOs, 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 without a history of allergy. It was also agreed by the Commission on Human Medicines. The advice to suspend the routine 15 minute observation period applies to all the currently available COVID-19 vaccines, including the variant mRNA products.

Category	Description
	An 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 of person that administered the vaccine • name and brand of vaccine

Name	Description
	• 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 : Comirnaty JN.1 30 micrograms/dose dispersion for injection COVID-19 mRNA vaccine Summary of Product Characteristics

Name	Description
	Spikevax JN.1 30 micrograms/dose dispersion for injection COVID-19 mRNA vaccine 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) **Scottish Haematology Society Advice on the revaccination of patients following haematopoietic stem cell transplant or CAR-T treatment**

ANNEX B: Practitioner Authorisation Sheet

Administration of COVID-19 mRNA vaccines to individuals aged 18 years and over 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

Administration of COVID-19 mRNA vaccines to individuals aged 18 years and over Protocol

Valid from:
Expiry:

This sheet must record the name of the clinical supervisor taking responsibility and all 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.