Comirnaty® 30 micrograms/dose (COVID-19 mRNA Vaccine, Pfizer/BioNTech)
National Protocol

Reference no:	Comirnaty® 30 micrograms/dose (COVID-19 mRNA Vaccine, Pfizer/BioNTech) Protocol
Version no:	2.2
Valid from:	04 October 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 Comirnaty® 30 micrograms/dose (COVID-19 mRNA Vaccine, Pfizer/BioNTech) 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 Comirnaty® 30 micrograms/dose (COVID-19 mRNA Vaccine, Pfizer/BioNTech) 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.
This issue of consent for children and young people under the age of 16 is complex. In Scotland, the legal age of capacity is 16. However, children under the age of 16 can consent to medical treatment if they understand what is being proposed.

Providers should ensure that capacity is assessed in line with current established practice, seeking advice from their legal advisers on consent as required.

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/

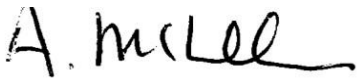
Any concerns regarding the content of this protocol should be addressed to: vaccineoperationaloversight@gov.scot

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 24 August 2021 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**		**04 October 2022**
CNO	**Alex McMahon**		**04 October 2022**
CPO	**Alison Strath**		**04 October 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 Comirnaty® 30 micrograms/dose (COVID-19 mRNA Vaccine, Pfizer/BioNTech) 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 Comirnaty® (COVID-19 mRNA Vaccine, Pfizer/BioNTech)	24/08/21
V01.10	Clinical annex updated	18/09/21
V01.20	Clinical annex updated About the Protocol updated Characteristics of Staff- Competency updated Description of Treatment update	13/10/21
V01.30	Clinical annex updated	05/11/21
V01.40	Clinical annex updated	16/11/21
V01.50	Clinical annex updated	01/12/21
V01.60	Clinical annex updated	14/12/21
V01.70	Clinical annex updated	24/12/21
V01.80	Clinical annex updated	19/01/22
V01.90	Clinical annex updated	01/03/22
V2.0	Expiry date extended to 31 March 2023 and clinical annex updated	25/03/22
V2.1	Clinical annex updated	31/08/22
V2.2	Clinical annex updated	04/10/22

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 d. Capacity for under 16's should be assessed in line with current practices for existing childhood vaccination programmes	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.
   - The issue of consent when offering vaccination to children and young people is complex. In Scotland, the legal age of capacity is 16. However, children under the age of 16 can consent to medical treatment if they understand what is being proposed. Capacity should be assessed in line with current established practice, with persons undertaking activities under the remit of this protocol seeking advice from their Immunisation Co-ordinator as required.
   - 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 (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 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 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

Comirnaty® 30 micrograms/dose (COVID-19 mRNA Vaccine, Pfizer/BioNTech) 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.

Most Recent Changes

Version	Date	Summary of changes
2.2	04/10/22	Frequency section updated with advice for individuals who started the schedule and who attend for vaccination where the same vaccine is not available or suitable, Use outwith SmPC section updated to highlight the use of heterologous schedules for primary immunisation is off label but supported by JCVI as set out in Green Book Chapter 14

1. Clinical condition or situation to which this Protocol applies

Category	Description
Indication	Comirnaty® 30 micrograms/dose (COVID-19 mRNA Vaccine, Pfizer/BioNTech) 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 Green Book **Chapter 14a** and subsequent correspondence/publications from Scottish Government.
Inclusion criteria	Comirnaty® 30 micrograms/dose (COVID-19 mRNA vaccine, Pfizer/BioNTech should be offered to all individuals aged 12 years and over 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:

Category	Description
	• have had a previous systemic anaphylaxis reaction to any COVID-19 vaccine. • have had a prior systemic allergic reaction to any component (excipient) of Comirnaty® 30 micrograms/dose (COVID-19 mRNA vaccine, Pfizer/BioNTech) e.g. polyethylene glycol. Practitioners must check the marketing authorisation holder's summary of product characteristics (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 • are aged under 12 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 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.

Category	Description
	• 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 vaccine. 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. **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

Category	Description
	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. **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** As all of the early COVID-19 vaccines 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 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. A UK study of co-administration of AstraZeneca and Pfizer BioNTech COVID-19 vaccines with inactivated influenza vaccines

Category	Description
	confirmed acceptable immunogenicity and reactogenicity. Where co-administration does occur, patients should be informed about the likely timing of potential adverse events relating to each vaccine. If the vaccines are not given together, they can be administered at any interval, although separating the vaccines by a day or two will avoid confusion over systemic side effects. **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. 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.

Category	Description
	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 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

Category	Description
	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. In younger people, after natural infection or a single dose of vaccine, protection from serious complications of COVID-19 infection is likely to be high for a period of months. Limited evidence suggests that countries with longer intervals between primary doses (eight to twelve weeks) may have a lower rate of myocarditis after the second dose. Based on extrapolation from this limited evidence, JCVI have taken a precautionary approach to mitigate the very rare risk of post-vaccine myocarditis. Therefore vaccination should ideally be deferred until twelve weeks from onset (or sample date) in children and young people under 18 years who are not in high risk groups(see * below). This interval may be reduced to eight weeks in healthy under 18 year olds when rapid protection is required, for example high incidence or circulation of a new variant in a vulnerable population. Current advice in PIMS-TS cases also suggests that an interval of 12 weeks should be observed, although earlier administration can be considered in those at high risk of infection and/or who are fully recovered. 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 and 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 14aand includes clinical risk groups and individuals who expect to share living accommodation on most days (and therefore for whom continuing close contact is unavoidable) with individuals who are immunosuppressed.

Category	Description
Action if excluded	Specialist advice should be sought on the vaccine and circumstances under which it could be given as vaccination using a patient specific direction may be indicated. In case of postponement due to acute illness advise when the individual can be vaccinated and ensure another appointment is arranged. 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. Document the reason for exclusion and any action taken in accordance with local procedures.
Action if patient declines	Advise the individual/carer about the protective effects of the vaccine, the risks of infection and potential complications if not immunised. Advise how future immunisation may be accessed if they subsequently decide to receive the COVID-19 vaccine Inform or refer to the clinician in charge. Document patient's declined consent and advice given.

2. Description of treatment

Category	Description
Name of medicine	Comirnaty® 30 micrograms/dose concentrate for dispersion for injection COVID-19 mRNA Vaccine (nucleoside modified) Comirnaty® 30 micrograms/dose (COVID-19 mRNA vaccine, Pfizer/BioNTech)
Form/strength	Comirnaty® 30 micrograms/dose (COVID-19 mRNA vaccine, Pfizer/BioNTech) 30 micrograms/0.3mL dose concentrate for dispersion for injection multidose vials Comirnaty® 30 micrograms/dose (COVID-19 mRNA vaccine, Pfizer/BioNTech) is a multidose vial and must be diluted with 1.8mL of 0.9% sodium chloride before use. 1 vial contains 6

Category	Description
	doses of 30 micrograms of COVID-19 mRNA vaccine (embedded in lipid nanoparticles).
Route of administration	After dilution, vials of Comirnaty® 30 micrograms/dose (COVID-19 mRNA Vaccine, Pfizer/BioNTech) contain 6 doses of 0.3 mL of vaccine. In order to extract 6 doses from a single vial, low dead-volume syringes and/or needles should be used. If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial. Irrespective of the type of syringe and needle: Each dose must contain 0.3 mL of vaccine. If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3mL, discard the vial and any excess volume. Do not pool excess vaccine from multiple vials Any unused vaccine should be discarded 6 hours after dilution. Comirnaty® 30 micrograms/dose (COVID-19 mRNA Vaccine, Pfizer/BioNTech) 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. Inspect visually prior to administration and ensure appearance is consistent with the description in the manufacturer's product literature or summary of product characteristics. 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

Category	Description
	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	The dose of Comirnaty® 30 micrograms/dose (COVID-19 mRNA Vaccine, Pfizer/BioNTech) is 30 micrograms contained in 0.3mL of the diluted vaccine.
Frequency	**Primary Vaccination** Comirnaty® 30 micrograms/dose (COVID-19 mRNA Vaccine, Pfizer/BioNTech) course consists of two separate doses of 0.3ml each, a minimum of 21 days apart. For both AstraZeneca COVID-19 Vaccine (ChAdOx1-S [Recombinant]) and mRNA vaccines, there is evidence of better immune response and/or protection where longer intervals between doses in the primary schedule are used. Based on this evidence, longer intervals are likely to provide more durable protection. JCVI is currently recommending a minimum interval of eight weeks between doses of all the available COVID-19 vaccines where a two-dose primary schedule is used. If an interval longer than the recommended interval is left between doses in the two dose primary schedule, the second dose should still be given (preferably using the same vaccine as was given for the first dose if possible). The course does not need to be restarted. The main exception to the eight-week lower interval would be those about to commence immunosuppressive treatment. In these individuals, the minimal intervals outlined above may be followed to enable the vaccine to be given whilst their immune system is better able to respond. Individuals who are about to receive planned immunosuppressive therapy should be considered for vaccination prior to commencing therapy (ideally at least two weeks before), when their immune system is better able to make a response. Where possible, it would also be preferable for the 2-dose schedule to be completed prior to commencing immunosuppression. This would entail offering the second

Category	Description
	dose at the recommended minimum for that vaccine (three or four weeks from the first dose) to provide maximum benefit that may not be received if the second dose was given during the period of immunosuppression. **12-15 year olds** Children and young people aged 12 to 15 years who are in recognised risk groups (as defined in Green Book **Chapter 14a** or who expect to share living accommodation on most days (and therefore for whom continuing close contact is unavoidable) with individuals of any age who are immunosuppressed (as defined in Green Book **Chapter 14a**) should receive two 30µg doses of Pfizer BioNTech vaccine at an interval of at least eight weeks. For children and young people aged 12 to 15 years who are not in a risk group or share living accommodation on most days with individuals of any age who are immunosuppressed JCVI have now recommended that a second dose of vaccine should be offered after an interval of 12 weeks. This interval reflects the strong evidence of high levels of protection against severe disease from the first dose, although could be shortened to eight weeks when rapid protection is required, for example in periods of high incidence or circulation of a new variant in a vulnerable population. **16-17 year olds** Young people aged 16 to 17 years who are in a recognised clinical risk group (as defined in Green Book **Chapter 14a** and those who work in health and social care should receive two doses of vaccine at an interval of at least eight weeks. This includes those aged 16 to 17 years who expect to share living accommodation on most days (and therefore for whom continuing close contact is unavoidable) with individuals of any age who are immunosuppressed (as defined in Green Book **Chapter 14a**). Initially JCVI advised that young people aged 16-17 years who are not in a risk group should receive their first dose of vaccine. A second dose of vaccine is now offered at an interval of 12 weeks. This longer interval in this age group reflects the strong evidence of high levels of protection

Category	Description
	against severe disease from the first dose, although could be shortened to eight weeks when rapid protection is required, for example in periods of high incidence or circulation of a new variant in a vulnerable population. Emerging evidence also suggests that countries with longer schedules (eight to twelve weeks) may have a lower rate of myocarditis after the second dose. Although this latter evidence is limited, JCVI have taken a precautionary approach to mitigate the very rare risk of post-vaccine myocarditis. Young people should be fully informed about the benefits and risks of the second dose and able to discuss the optimal timing for them. If the course is interrupted or delayed, it should be resumed using the same vaccine but the first dose should not be repeated. Evidence suggests that those who receive mixed schedules, including mRNA and adenovirus vectored vaccines, make a good immune response, although rates of side effects with a heterologous second dose are higher. Accumulating evidence now supports the use of heterologous schedules for primary immunisation, and these are now recognised by the European Medicines Agency. For individuals who started the schedule and who attend for vaccination where the same vaccine is not available or suitable, or if the first product received is unknown or not available, one dose of the locally available product should be given to complete the primary course. Individuals who experienced severe expected reactions after a first dose of AstraZeneca or Pfizer BioNTech vaccines should be informed about the higher rate of such reactions when they receive a second dose of an alternate vaccine. **Severely Immunosuppressed – Third Primary Dose** For those identified as meeting the definition for severe immunosuppression in proximity of their first or second vaccine doses in the primary schedule, in line with specialist advice, for a third primary dose (as defined in Green Book **Chapter 14a**) The third primary dose should be given at least 8 weeks after the second dose, with special attention paid to current or planned immunosuppressive therapies guided by the following principles: a) where possible the third primary dose should be delayed until two weeks after the period of

Category	Description
	immunosuppression, in addition to the time period for clearance of the therapeutic agent, b) if not possible, consideration should be given to vaccination during a treatment 'holiday' or at a nadir of immunosuppression between doses of treatment. For those aged over 18 years, JCVI advises a preference for mRNA vaccines - Pfizer BioNTech (Comirnaty®) or Moderna (Spikevax®) - for the third primary dose for those with severe immunosuppression. Pfizer BioNTech (Comirnaty®) is preferred for 12-17 year olds. When mRNA vaccines are not consdered clinically suitable, Novavax COVID-19 vaccine may be used for vaccination of adults from 18 years of age. **Reinforcing vaccination** Comirnaty® 30 micrograms/dose (COVID-19 mRNA Vaccine, Pfizer/BioNTech) 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,

Category	Description
	Comirnaty® 30 micrograms/dose (COVID-19 mRNA vaccine, Pfizer/BioNTech) is subject to additional monitoring and has been designated ▼ 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 out with the SPC?	The vaccine marketing authorisation holder's summary of product characteristics states that the vaccine should be given as a series of two doses (0.3mL, each) 21 days apart. This is superseded by the JCVI recommendation, as detailed in Chapter 14a of the green book, of a minimum interval of eight weeks between doses of all the available COVID-19 vaccines where a two-dose primary schedule is used. The vaccine marketing authorisation holder's summary of product characteristics states that a booster dose (third dose) of Comirnaty may be administered intramuscularly at least 6 months after the second dose in individuals 18 years of age and older. This is superseded by the JCVI advice as set out in the Green Book Chapter 14a for third primary dose vaccination in those with severe immunosuppression in proximity of their first or second doses in the primary schedule; by the JCVI advice on the UK vaccine response to the Omicron variant for interval between completion of primary course and booster vaccination; by JCVI advice for booster vaccination of those aged 12-15 in clinical risk groups plus those aged 16 and 17 years,by JCVI advice for fourth/fifth doses in eligible groups and by JCVI advice for a further autumn 2022 booster dose. 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 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.

Category	Description
	This was in individuals without a history of allergy. It was also agreed by the Commission on Human Medicines. The Scottish Government has made further recommendations that all doses of COVID-19 mRNA vaccines be followed by a 5 minute observation period. The vaccine marketing authorisation holder's summary of product characteristics states that the interchangeability of Comirnaty with COVID-19 vaccines from other manufacturers to complete the primary course has not been established. This is superseded by the JCVI advice as set out in Green Book **Chapter 14a** for individuals who started the schedule and who attend for vaccination where the same vaccine is not available or suitable. Vaccine should be stored according to the conditions detailed below. However, in the event of a deviation of these conditions where vaccine is assessed as appropriate for continued use, administration under this National Protocol is allowed.
Storage requirements	Comirnaty® 30 micrograms/dose (COVID-19 mRNA vaccine, Pfizer/BioNTech) must be stored in accordance with manufacturer's advice. **Thawed vial** Once removed from the freezer unopened Comirnaty® 30 micrograms/dose COVID-19 mRNA vaccine vials can be stored for 31 days in a fridge between +2 to +8°C prior to dilution. NHS Board guidance on Storage and Handling of vaccines should be observed. **Diluted Product** Comirnaty® 30 micrograms/dose (COVID-19 mRNA vaccine, Pfizer/BioNTech) should be diluted as close to use as possible. However, reconstituted vaccine which is not required immediately must be used within 6 hours from the time of dilution and stored between +2°C to +30°C.

Category	Description
	The vaccine vial has space to write the date and time that the vial should be discarded following dilution (calculation: time of dilution + 6 hours); write this on the vial label. **Precautions for storage** During storage, minimise exposure to room light and avoid exposure to direct sunlight and ultraviolet light. 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.
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. Inclusion of antibody positive individuals in the Pfizer phase 3 analysis did not give any safety signals. 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	Local reactions at the injection site are fairly common after Comirnaty® 30 micrograms/dose (COVID-19 mRNA Vaccine,

Category	Description
possible adverse reactions and management of these	Pfizer/BioNTech) primarily pain at the injection site, usually without redness and swelling. Systemic events reported were generally mild and short lived. In the final safety analysis of over 21,000 participants 16 years and older, the most common events were injection site pain (>80%), fatigue (>60%), and headache (>50%). Myalgia, arthralgia and chills were also common with fever in 10-20% mainly after the second dose. Most were classified as mild or moderate. Lymphadenopathy in the axillary, supraclavicular or cervical nodes on the same side as the injection was reported in less than 1%. Four cases of Bell's palsy were reported in vaccine recipients in the trial. Although within the expected background rate, this will be monitored closely post-implementation. Side effects were less common in those aged over 55 than those aged 16 to 55 years. Severe systemic effects, defined as those that interfere with daily activity, included fatigue in 4% and headache in 2%. There was no signal to suggest that prior vaccination led to enhanced disease with only 1 case of severe COVID-19 in the 8 vaccine failures. A number of cases of myocarditis and pericarditis have been reported after Pfizer BioNTech (Comirnaty®) 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 Green Book Chapter 14a, under a PSD. 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.

Category	Description
	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 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 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

Category	Description
	• Provide copy of Pregnant, planning a pregnancy or breastfeeding, a guide to COVID-19 vaccine to women of child bearing years • For eligible children and young people under the age of 16, clear information on the potential risks and benefits of vaccination should be provided to the parent/carer of the eligible child or young person prior to vaccination. Information provided should be accessible for children and young people under the age of 16 should they wish to consent for vaccination. 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: ➢ chest pain ➢ shortness of breath

Category	Description
	➢ 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://yellowcard.mhra.gov.uk. • Immunosuppressed individuals should be advised that they may not make a full immune response to the vaccine and they should continue to take appropriate measures to protect themselves against this infection. • When administration is postponed advise the individual how future vaccination may be accessed. • When applicable, advise the individual/carer when to return for vaccination or when a subsequent vaccine dose is due.
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 vaccines 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 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.

Category	Description
	A longer observation period should be observed when indicated after clinical assessment as set out in Figure 1 and Figure 2 (above). 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 for vaccine • name of person that administered the vaccine • name and brand of vaccine • date of administration

Name	Description
	• 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 protocol Records should kept in line with local procedures. Ideally records should be kept within the NHS Scotland COVID-19 vaccine administration app. 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 https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19 Educational resources for registered professionals produced by National Education for Scotland

Name	Description
	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

Comirnaty® 30 micrograms/dose (COVID-19 mRNA Vaccine, Pfizer/BioNTech) 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

Comirnaty® 30 micrograms/dose (COVID-19 mRNA Vaccine, Pfizer/BioNTech) 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 d. Capacity for under 16s should be assessed in line with current practices for existing childhood vaccination programmes	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.

Annex Version History

Version	Date	Summary of changes
1.0	24/08/21	Version 1.0 new Annex A
1.1	18/09/21	The following sections have been updated: • Indication section updated to include JCVI advice on third primary dose vaccination from 1st September 2021. • Indication section updated to include JCVI statement on COVID-19 vaccination of children aged 12 to 15 years from 3rd September 2021. • Indication section updated to include JCVI statement on COVID-19 booster vaccination from 14th September 2021 • Inclusion section updated to include those aged from 12 years identified as meeting the definition for severe immunosuppression at the time of vaccination, in line with specialist advice, for a third primary dose in accordance with recommendations in the JCVI advice on third dose primary vaccine. • Inclusion section updated to include those aged 12 – 15 years in line with Scottish Government policy. • Inclusion section updated to include those as meeting the definition for a COVID-19 booster dose in line with JCVI advice. • Inclusion section updated to include information about use of vaccine in different age groups in pregnancy. • Frequency section updated with advice on third dose primary vaccine for those identified as meeting the definition for severe immunosuppression at the time of vaccination, in line with specialist advice, and recommendations in the JCVI advice. • Frequency section updated to align with Scottish Government policy on vaccination of those aged 12 – 15 years. • Frequency section updated to align with JCVI advice on COVID-19 booster vaccination

		• Use outwith SmPC section updated to highlight the marketing authorisation holder's summary of product characteristics states that the vaccine should be given as a series of two doses (0.3mL, each) 21 days apart. This is superseded by JCVI advice for third primary dose vaccination in those with severe immunosuppression at the time of vaccination and for a COVID-19 booster vaccine.
1.2	30/09/21	The following sections have been updated: • About the National Protocol updated to include paragraphs on consent for under 16s • Approval and Clinical Authorisation – Competency updated to include section on consent for under 16's • Exclusion criteria section updated to align with COVID-19 chapter of Green Book advice on contraindications and precautions in individuals with a history of allergy. • Exclusion criteria section updated to include those who developed myocarditis or pericarditis following a previous COVID-19 vaccination. • Cautions section updated to align with COVID-19 chapter of Green Book advice on contraindications and precautions in individuals with a history of allergy, including updated figure and flowchart. • Cautions section updated to align with COVID-19 chapter of Green Book advice on co-administration with shingles vaccine and inactivated influenza vaccine • Duration of treatment section updated to remove wording about booster doses. • Frequency section updated with new flow and advice from Green Book chapter on vaccine choice for third primary dose for those with severe immunosuppression • Frequency section updated to advise in those identified as requiring a booster vaccine dose the booster dose should be administered no earlier than six months after completion of the primary vaccine course.

		• Duration of treatment updated to include information on Boosters • Advice for parent / carer updated to include guidance for children and young people Annex C updated to include line on capacity for under 16's
1.3	05/11/21	The following sections have been updated: • Exclusion section updated to remove participation in a COVID-19 vaccine clinical trial as an exclusion. • Cautions section updated to align with wording on co-administration with other vaccines in COVID-19 chapter of Green Book. • Cautions section updated to align with wording on safety in breastfeeding in updated COVID-19 chapter of Green Book. • Cautions section updated to align with wording on use of COVID-19 vaccine in those who participated in a COVID-19 vaccine clinical trial. • Action if excluded section updated to reflect that participation in a clinical trial for COVID -19 vaccine is no longer an exclusion. • Frequency section updated to align with wording on interval for booster doses in updated COVID-19 chapter of Green Book. • Frequency section updated to align with wording on choice of vaccine for booster doses in updated COVID-19 chapter of Green Book. • Use out with SPC section updated to align with wording on interval for booster doses in updated COVID-19 chapter of Green Book.
1.4	16/11/21	The following sections have been updated: • Inclusion section updated to align with wording on JCVI advice on groups who should be offered a booster dose as set out in COVID-19 chapter of Green Book. • Exclusion section updated to align with wording in updated COVID-19 chapter of Green Book for children and young

		people under 18 years who are not in clinical risk groups with confirmed COVID-19 infection. • Cautions section updated to align with wording on use of COVID-19 vaccine in those who participated in a COVID-19 vaccine clinical trial. • Frequency section updated to align with wording on JCVI advice on vaccination of young people aged 16 and 17 years. • Frequency section updated to align with wording on interval for booster doses in updated COVID-19 chapter of Green Book (removal of 22 weeks as interval but retaining 5 months). • Frequency section updated to align with wording that third doses given to those who were severely immunosuppressed at/around the time of their first or second primary dose do not count as booster doses in updated COVID-19 chapter of Green Book. • Use out with the SPC section updated following changes to Comirnaty vaccine summary of product characteristics. • Warnings section updated to align with Green Book advice on vaccination in those with myocarditis or pericarditis. • Additional information section updated to align with wording in updated COVID-19 chapter of Green Book for children and young people under 18 years who are not in clinical risk groups with confirmed COVID-19 infection.
1.5	30/11/21	The following sections have been updated: • Indication section updated to include JCVI advice on the UK vaccine response to the Omicron variant from 29 November 2021 • Inclusion section updated include a generic statement of inclusion in with Green Book chapter and JCVI advice rather than listing all groups.

		• Caution section updated to reflect updated advice on interval for booster vaccination in those have participated in a clinical trial of COVID-19 vaccines. • Frequency section updated to align with wording on interval between booster vaccine and completion of primary course as set out in JCVI advice on the UK vaccine response to the Omicron variant from 29 November 2021 • Frequency section updated to align with JCVI advice on second doses for those aged 12-15 years and 16-17 years as set out in JCVI advice on the UK vaccine response to the Omicron variant from 29 November 2021 • Use out with SPC section updated to highlight JCVI advice on the UK vaccine response to the Omicron variant from 29 November 2021
1.6	14/12/21	The following sections have been updated: Exclusion criteria section updated to include JCVI advice on between positive COVID test and vaccination in healthy under 18 year olds during periods of high incidence or where there is concern about vaccine effectiveness (for example a new variant). Action if excluded section updated to include JCVI advice on between positive COVID test and vaccination in healthy under 18 year olds during periods of high incidence or where there is concern about vaccine effectiveness (for example a new variant). Frequency section updated to indicate that booster vaccination should not be given within three months (12 weeks) of completion of the primary course. Use out with the SPC section updated to reflect updated advice for observation following vaccination. Observation following vaccination section updated to reflect updated advice for observation following vaccination.
1.7	16/12/21	The following sections have been updated: Cautions section updated to align with updated Green Book chapter advice on managing individuals with a history of allergy (including changes to figures 1 and 2).

		Cautions section updated to align with JCVI advice that women who are pregnant should be considered as falling into a clinical risk group (JCVI Priority Cohort 6 for COVID19). Frequency section updated to align with updated Green Book chapter advice for individuals who started the schedule and who attend for vaccination where the same vaccine is not available or suitable, or if the first product received is unknown or not available. Frequency section updated to align with updated Green Book chapter advice on booster vaccination where mRNA vaccines are clinically contra-indicated. Frequency section updated to align with JCVI advice on booster vaccination for those aged 12-17 years. Use out with the SPC section updated to include JCVI advice on booster vaccination in 12-17 year olds. Observation following vaccination section updated to align with updated Green Book chapter and Scottish Government advice on post vaccination observation including more detail on the circumstances in which a longer observation period when indicated after clinical assessment as set out in Figure 1 and Figure 2.
1.8	14/01/22	The following sections have been updated: There have been minor typographical changes to align with current COVID-19 Green Book chapter. Name of vaccine changed to Comirnaty® 30 micrograms/dose (COVID-19 mRNA Vaccine, Pfizer/BioNTech) to differentiate from 10 micrograms/dose vaccine. Indication section updated to remove listing of all JCVI statements. Exclusion section updated with removal of JCVI advice on individuals with a past history of COVID-19 infection (added to cautions section). Cautions section updated to include advice on individuals with a past history of COVID-19 infection added to cautions section. Cautions section updated to align with updated Green Book chapter advice on managing individuals with a history of allergy (including changes to figure 1).

		Action if excluded section updated with advice on deferral of vaccination in individuals with a past history of COVID-19 infection Frequency section updated to align with updated Green Book chapter advice on third primary dose for those with severe immunosuppression with AstraZeneca COVID-19 vaccine (Vaxzevria®) where mRNA vaccines are clinically contraindicated. Use outwith SPC section updated to include information on use of vaccine in the event of a deviation of these recommended storage conditions. Warnings section advice on management of anaphylaxis modified. Additional facilities section updated with advice on management of anaphylaxis modified.
1.9	28/02/22	The following sections have been updated: Caution section updated to include updated figure on managing patients with a history of allergy from Green Book chapter. Caution section updated with minor changes to align with Green Book chapter advice on vaccination of clinical trial participants. Caution section updated with to align with Green Book chapter advice on vaccination of individuals with a past history of COVID-19 infection. Frequency section updated with minor changes to align with Green Book chapter advice on interval between doses for those aged 12-15 years not in a risk group. Frequency section updated with recommendations in Green Book chapter for a further booster dose for adults aged 75 years and over; residents of any age in a care home for older adults, and; individuals aged 12 years and over who are immunosuppressed. Is the use out with the SPC section updated to highlight that further booster dose for adults aged 75 years and over; residents of any age in a care home for older adults, and; individuals aged 12 years and over who are immunosuppressed if out with SPC but aligned with JCVI advice as set out in Green Book chapter Reference section has been updated.
2.0	25/03/22	The following sections have been updated:

		Cautions section updated to clarify advice on vaccination of individuals with a past history of COVID-19 infection. Advice to patient or carer section updated with advice on fever following vaccination.
2.1	31/08/22	This protocol has undergone minor rewording, layout, formatting changes for clarity and consistency The following sections have been updated: Cautions section updated to present more concise advice for individuals with a history of allergy Cautions section updated to present advice for individuals with thrombocytopenia Cautions section updated to present advice for individuals with Guillain-Barré syndrome Cautions section updated to align with Green Book chapter advice on vaccination in pregnancy Frequency section updated to align with advice for autumn 2022 vaccination programme
2.2	04.10.22	Frequency section updated with advice for individuals who started the schedule and who attend for vaccination where the same vaccine is not available or suitable. Use outwith SmPC section updated to highlight the use of heterologous schedules for primary immunisation is off label but supported by JCVI as set out in Green Book Chapter 14