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

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Scottish Government
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National Protocol

Reference no:	Comirnaty® (COVID-19 mRNA Vaccine, Pfizer/BioNTech) Protocol
Version no:	v1.1
Valid from:	24 August 2021
Review date:	30 November 2021
Expiry date:	31 December 2021

1. About the National Protocol

This protocol is for the supply and administration of Comirnaty® (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® (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.

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: TBC

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

2. Approval and Clinical Authorisation

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

On 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, Chief Pharmaceutical Officer and Deputy 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) only under 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**		**24 August 2021**
DCNO	**Anne Armstrong**		**24 August 2021**
CPO	**Alison Strath**		**24 August 2021**

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® (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 August 2021
V01.10	Clinical annex updated	18 September 2021

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.

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

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

Stage 2	• Vaccine Preparation	Registered Healthcare Professionals, non-registered professionals or non-registered Armed Forces staff
Stage 3	• Vaccine Administration	Registered Healthcare Professionals, non-registered professionals or non-registered Armed Forces staff
Stage 4	• Record Keeping	Registered Healthcare Professionals, non-registered professionals or non-registered Armed Forces staff

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

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

- Nurses and midwives currently registered with the Nursing and Midwifery Council (NMC).
- Pharmacists currently registered with the General Pharmaceutical Council (GPhC).
- Chiropodists/podiatrists, dieticians, occupational therapists, operating department practitioners, orthoptists, orthotists/prosthetists, paramedics, physiotherapists, radiographers and speech and language therapists currently registered with the Health and Care Professions Council (HCPC).
- Dental hygienists and dental therapists registered with the General Dental Council.
- Optometrists registered with the General Optical Council.
- Doctors currently registered with General Medical Council.
- Dentists currently registered with General Dental Council.

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

- Healthcare support workers.
- Pharmacy technicians, provisionally registered pharmacists, pre-registration pharmacists and other pharmacy support practitioners.

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

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

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

Requirements

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

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

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

1. Training

- They must have undertaken training appropriate to this protocol and relevant to their role, as required by local policy and health board standard operating procedures and in line with the training recommendations for COVID-19 vaccinators.
- They must have met the requirements set out in the NES Proficiency document - COVID-19 vaccine administration for registered staff or the NES Proficiency document –COVID-19 vaccine administration- Healthcare support workers

2. Competency

- Those providing clinical supervision to those administering the vaccine must be competent to assess individuals for suitability for vaccination, identify any contraindications or precautions, discuss issues related to vaccination and obtain informed consent from the individuals being vaccinated.
- All persons must either be an appropriate prescriber or one of above noted registered professionals. Those that are not registered professionals, and those returning to immunisation after a prolonged interval (more than 12 months), should be assessed and signed off as meeting the requirements of the relevant NES Proficiency document -COVID-19 vaccine administration. They should be observed administering the vaccine until both they, and their supervisor or trainer, feel confident that they have the necessary knowledge and skills to administer vaccines safely and competently.
- Experienced vaccinators should use the relevant NES Proficiency document to self-assess that they are able to meet all the competencies listed and confirm that they have the knowledge and skills necessary to administer COVID-19 vaccine.
- They must have completed local IPC training and comply with the vaccination guidance with the National C OVID-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 .
- 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® (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 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	24 August 2021	Version 1.0 new Annex A
1.1	18 September 2021	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 12th 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 SPC 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. Clinical condition or situation to which this Protocol applies

Category	Description
Indication	Comirnaty® (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'; • JCVI statement on priority groups for COVID-19 vaccination from 30th December 2020; • JCVI statement on phase 2 of the vaccination programme from 13th April 2021; • JCVI statement on COVID-19 vaccination of children and young people aged 12 to 17 years from 15th July 2021; • JCVI statement on vaccination of 16 and 17 year olds from 4th August 2021 JCVI advice on third primary dose vaccination from 1st September 2021;

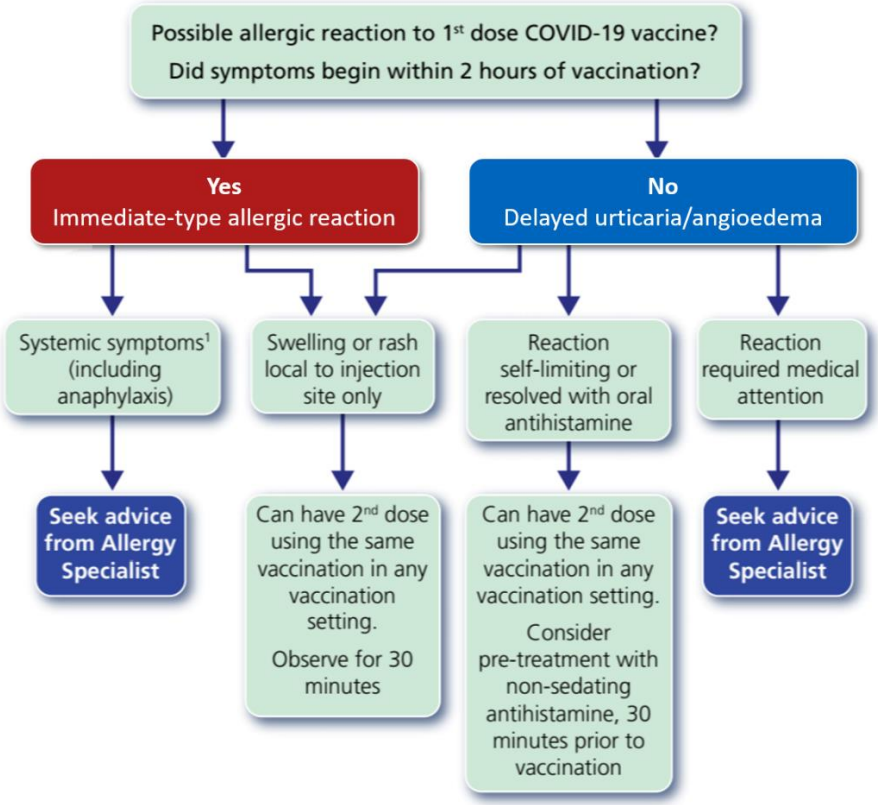
Category	Description
	• JCVI statement on COVID-19 vaccination of children aged 12 to 15 years from 3rd September 2021; • JCVI statement regarding COVID-19 booster vaccination programme for winter 2021/22 from 12th September 2021 and subsequent correspondence/publications from Scottish Government.
Inclusion criteria	National policy must be followed in relation to the priority groups eligible for vaccination at a particular point in time. Comirnaty® (COVID-19 mRNA Vaccine, Pfizer/BioNTech) should be offered to the following individuals: • Residents in a care home for older adults and their carers • All those 80 years of age and over • Frontline health and social care workers (as included in COVID-19 –SARS-Cov-2 chapter of Green Book, JCVI statement and Scottish Government CMO letters) • All those 75 years of age and over • All those 70 years of age and over • Clinically extremely vulnerable (CEV) individuals (not including those under 18 years) as defined by Scottish Government under Coronavirus (COVID-19): advice for people at highest risk • All those 65 years of age and over • Individuals aged 16 years to 64 years with underlying health conditions which puts them at higher risk of serious disease and mortality included in Table 3 COVID-19 –SARS-Cov-2 chapter 14a of Green Book* this also includes adult household contacts of adults with severe immunosuppression • All those 60 years of age and over • All those 55 years of age and over • All those 50 years of age and over • All those 40 years of age and over

Category	Description
	• All those 30 years of age and over • All those aged 18 years to 29 years • All those aged 16 and 17 years of age (first dose only) • All those aged 12 to 15 years of age (first dose only) • Children and young people aged 12 years and over with specific underlying health conditions that put them at risk of serious COVID-19 in line with JCVI recommendations • Children and young people aged 12 years and over who are household contacts of persons (adults or children) who are immunosuppressed • Pregnant women should be offered vaccination at the same time as non-pregnant women, based on their age and clinical risk group. Pfizer and Moderna vaccines are the preferred vaccines for pregnant women, because of more extensive experience of their use in pregnancy. Comirnaty® (COVID-19 mRNA Vaccine, Pfizer/BioNTech) is authorised and recommended for use in those aged 12 years and over and COVID-19 vaccine Moderna while authorised for use from 12 years it is not recommended in those aged 12-17 years. Clinicians (such as obstetricians, mid-wives, GPs or other healthcare professionals authorised to offer COVID-19 vaccination) should discuss the risks and benefits of vaccination with the woman, who should be told about the limited evidence of safety for the vaccine in pregnancy. • Those requiring a different type of COVID-19 vaccine for the second dose than that given as the first dose when clinically indicated. • Those aged from 12 years 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 in accordance with recommendations in the JCVI advice on third dose primary vaccine. • • Those who received vaccination in phase 1 of the COVID-19 vaccination programme (priority groups 1-9) should be offered a COVID-19 booster vaccine in accordance with recommendations in the JCVI statement regarding a

Category	Description
	COVID-19 booster vaccine programme for winter 2021/22. This includes: • Those living in residential care homes for older adults • All adults aged 50 years or over • Frontline health and social care workers • All those aged 16 to 49 years with underlying health conditions that put them at higher risk of severe COVID-19 (as set out in the Green Book), and adult carers • Adult household contacts of immunosuppressed individuals *This also includes those who are in receipt of a carer's allowance, or those who are the main carer of an elderly or disabled person whose welfare may be at risk if the carer falls ill. The list above is not exhaustive, and clinician should apply clinical judgment to take into account the risk of COVID-19 exacerbating any underlying disease that a patient may have, as well as the risk of serious illness from COVID-19 itself. COVID-19 vaccine should be offered in such cases even if the individual is not in the clinical risk groups specified above, this may be provided under a Patient Specific Direction (PSD).
Exclusion criteria	The vaccine should not be given to: • Those who have had a previous systemic allergic reaction (including immediate-onset anaphylaxis) to a previous dose of this COVID-19 vaccine • Those who have had a prior allergic reaction to another mRNA vaccine e.g. Moderna COVID-19 vaccine • Those who have had a previous systemic allergic reaction (including immediate-onset anaphylaxis) to any component (excipient) of the COVID-19 vaccine e.g. polyethylene glycol • Those with 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 • Those with a history of anaphylaxis to a vaccine, injected antibody preparation or a medicine likely to contain PEG

Category	Description
	(e.g. depot steroid injection, laxative) unless the advice from relevant specialist, local immunisation or health protection team is that vaccination should proceed • Those with a history of idiopathic (unexplained) anaphylaxis unless the advice from relevant specialist, local immunisation or health protection team is that vaccination should proceed • Those in whom no valid consent has been received • Those who are under 12 years of age • Those with confirmed COVID-19 infection to avoid confusing the differential diagnosis. As clinical deterioration can occur up to two weeks after infection, ideally vaccination should be deferred until around four weeks after onset of symptoms or from the first PCR positive specimen in those who are asymptomatic. • Those with evidence of current deterioration of COVID-19 symptoms, deferral of vaccination may be considered to avoid incorrect attribution of any change in the person's underlying condition to the vaccine. • Those who are participating in a clinical trial of COVID-19 vaccines • Those with acute febrile illness – consider postponing immunisation until individual has fully recovered. • Those 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.
Cautions/need for further advice/ circumstances when further advice should	The COVID-19 chapter of 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.

Category	Description
be sought from a doctor	The Pfizer BioNTech (Comirnaty®) and Moderna mRNA vaccines contain polyethylene glycol (PEG). PEGs (also known as macrogols) are a group of known allergens commonly found in medicines, many household products and cosmetics. Medicines containing PEG include some tablets, laxatives, depot steroid injections, and some bowel preparations used for colonoscopy. Known allergy to PEG is rare but would contraindicate receipt of mRNA vaccines. It is unclear whether PEG is the only cause of allergic reactions in patients with systemic allergic symptoms after the first dose of Pfizer-BioNTech (Comirnaty®) vaccine. Figure 1 summarises the management of patients with a history of allergy. **Figure 1: Management of patients with a history of allergy** **PATIENT CHARACTERISTICS** **Proceed with vaccination** • previous allergic reaction (including anaphylaxis) to a food, insect sting and most medicines (where trigger has been identified) • family history of allergies • previous non-systemic reaction to a vaccine • hypersensitivity to non-steroidal anti-inflammatory drugs e.g. aspirin, ibuprofen • mastocytosis **Special precautions** • history of immediate anaphylaxis to multiple, different drug classes, with the trigger unidentified (this may indicate PEG allergy) • history of anaphylaxis to a vaccine, injected antibody preparation or a medicine likely to contain PEG (e.g. depot steroid injection, laxative) • history of idiopathic anaphylaxis **Vaccination contra-indicated** • prior systemic allergic reaction to the COVID-19 vaccine • for an mRNA-based COVID-19 vaccine, prior allergic reaction to another mRNA vaccine • prior allergic reaction to a component of the vaccine, including PEG **ACTIONS** • proceed with vaccination as normal, according to local guidelines • discuss with allergy specialist and consider possibility of PEG-allergy • consider observation for 30 minutes if vaccination proceeds (see precautions) • some patients may benefit from pretreatment with antihistamine, however this may mask initial symptoms of a reaction • do not give vaccine in question • refer to allergist Figure 2 shows the Green Chapter flowchart for managing patients who have allergic reactions to the first dose of COVID-19 vaccine.

Category	Description
	Figure 2: Flowchart for managing patients who have allergic reactions to the first dose of COVID-19 vaccine  The COVID-19 chapter of the Green Book 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. Individuals with a bleeding disorder may develop a haematoma at the injection site (see Route of Administration). 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 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. An exception to this is shingles vaccination,

Category	Description
	where a seven-day interval should ideally be observed given the potential for an inflammatory response to COVID-19 vaccine to reduce the response to the live virus. 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. 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. Although clinical trials on the use of COVID-19 vaccines during pregnancy are not advanced, the available data do not indicate any harm to pregnancy. JCVI has therefore advised that women who are pregnant should be offered vaccination at the same time as non-pregnant women, based on their age and clinical risk group. There is now extensive post-marketing experience of the use of the Pfizer BioNTech (Comirnaty®) and Moderna vaccines in the USA with no safety signals so far. These vaccines are therefore the preferred vaccines to offer to pregnant women. Clinicians (such as obstetricians, mid-wives, GPs or other healthcare professionals authorised to offer COVID-19 vaccination) should discuss the risks and benefits of vaccination with the woman, who should be told about the limited evidence of safety for the vaccine in pregnancy. 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. The developmental and health benefits of breastfeeding should be considered along with the woman's clinical need for immunisation against COVID-19, and the woman should be informed about the absence of safety data for the vaccine in breastfeeding women.
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.

Category	Description
	Individuals who are participating in a clinical trial of COVID-19 vaccines who present for vaccination should be referred back to the investigators. In case of postponement due to acute illness advise when the individual can be vaccinated and ensure another appointment is arranged. In case of postponement due to COVID-19 symptoms or positive COVID test in the last four weeks 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 Document patient's declined consent and advice given.

2. Description of treatment

Category	Description
Name of medicine	Comirnaty® concentrate for dispersion for injection COVID-19 mRNA Vaccine (nucleoside modified) Comirnaty® (COVID-19 mRNA vaccine, Pfizer/BioNTech)
Form/strength	Comirnaty® (COVID-19 mRNA vaccine, Pfizer/BioNTech) 30micrograms/0.3mL dose concentrate for dispersion for injection multidose vials Comirnaty® (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 doses of 30 micrograms of COVID-19 mRNA vaccine (embedded in lipid nanoparticles).

Category	Description
Route of administration	After dilution, vials of Comirnaty® (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® (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 applied to the site without rubbing for at least 2 minutes. The

Category	Description
	individual/parent/carer should be informed about the risk of haematoma from the injection. The site at which each vaccine was given should be noted in the individual's records.
Dosage	The dose of Comirnaty® (COVID-19 mRNA Vaccine, Pfizer/BioNTech) is 30 micrograms contained in 0.3mL of the diluted vaccine.
Frequency	Comirnaty® (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. Operationally, this consistent interval should be used for all vaccines with a two-dose primary schedule to avoid confusion and simplify booking, and will help to ensure a good balance between achieving rapid and long-lasting protection. 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. At this time, Scottish Government policy is that all 12 – 15-year olds should be offered a first dose of Comirnaty® COVID-19 mRNA vaccine. This is separate to the existing offer of two doses of vaccine to 12-15 year olds with specific underlying health conditions that put them at risk of serious COVID-19 in line with JCVI recommendations and to 12-15 year olds who are household contacts of persons (adults or children) who are immunosuppressed. Pending further evidence on effectiveness and safety in this age group, a

Category	Description
	second vaccine dose may be offered later to increase the level of protection and contribute towards longer term protection. At this time, JCVI advises that all 16 – 17-year olds should be offered a first dose of Comirnaty® (COVID-19 mRNA Vaccine, Pfizer/BioNTech). This is in addition to the existing offer of two doses of vaccine to 16 – 17 year olds who are in 'at-risk' groups (including those clinically extremely vulnerable, with a specific underlying health condition, a frontline health or social care worker, an unpaid carer or within 3 months of their 18th birthday). Pending further evidence on effectiveness and safety in this age group, a second vaccine dose is anticipated to be offered later to increase the level of protection and contribute towards longer term protection. People within 3 months of turning 18 will be offered two doses. Once an individual is 17 and 9 months, they will have entered the adult programme and therefore receive two doses. 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 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. 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 in accordance with recommendations in the **JCVI advice on third dose primary vaccine**. 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

Category	Description
	dose should be delayed until two weeks after the period of 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. If an interval longer than the recommended interval is left between doses, 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.
	Evidence from trials of co-administration suggest that those who receive mixed schedules, including mRNA and AstraZeneca COVID-19 Vaccine (ChAdOx1-S [Recombinant]) make a good immune response, although rates of side effects at the second dose are higher. Therefore, every effort should be made to determine which vaccine the individual received and to complete with the same vaccine. For individuals who started the schedule and who attend for vaccination at a site where the same vaccine is not available, or if the first product received is unknown, it is reasonable to offer one dose of the locally available product to complete the schedule. This option is preferred if the individual is likely to be at immediate high risk or is considered unlikely to attend again. Further doses would not then be required. 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. JCVI advises a preference for the Pfizer-BioNTech (BNT162b2/ Comirnaty®) vaccine to be offered as the booster dose irrespective of which product was used in the primary schedule. There is good evidence that the Pfizer-BioNTech (BNT162b2/ Comirnaty®) vaccine is well tolerated as a third dose and will provide a strong booster response. Alternatively, individuals may be offered a half dose (50µg) of the Moderna (mRNA-1273/Spikevax®) vaccine, which should be well tolerated and is also likely to provide a strong booster response. A half dose (50µg) of Moderna (mRNA-1273/Spikevax®) vaccine is advised over a full dose due to

Category	Description
	the levels of reactogenicity seen following boosting with a full dose within the COV-BOOST trial. Where mRNA vaccines cannot be offered e.g. due to contraindication, vaccination with the AstraZeneca (ChAdOx1-S/Vaxzevria®) vaccine may be considered for those who received AstraZeneca (ChAdOx1-S/Vaxzevria®) vaccine in the primary course (please refer to the Green Book for further details)
Duration of treatment	See Dose and frequency of administration above. The need for booster doses is still under consideration by JCVI as the need for, and timing of boosters has not yet been determined.
Maximum or minimum treatment period	See Frequency of administration above.
Quantity to supply/administer	Administer 30 micrograms in 0.3mL per administration.
▼ black triangle medicines	Yes, Comirnaty® (COVID-19 mRNA vaccine, Pfizer/BioNTech) has been designated ▼ All adverse reactions occurring in individuals of any age after vaccination should be reported to the MHRA using the Coronavirus Yellow Card Scheme. Anyone can report a suspected adverse reaction to the MHRA using the Coronavirus Yellow Card Reporting Scheme
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 of a minimum interval of eight weeks between doses of all the available COVID-19 vaccines where a two-dose primary schedule is used.

Category	Description
	And by JCVI advice for third primary dose vaccination in those with severe immunosuppression in proximity of their first or second doses in the primary schedule. And by JCVI advice for COVID-19 booster vaccine which recommends a third dose at least six months after completion of the primary vaccine course.
Storage requirements	Comirnaty® (COVID-19 mRNA vaccine, Pfizer/BioNTech) must be stored in accordance with manufacturer's advice. Once removed from the freezer Comirnaty® COVID-19 mRNA vaccine 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. Comirnaty® (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. 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. 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

Category	Description
	unwell, immunisation should be postponed until they have fully recovered. There is no 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. Vaccination of individuals who may be infected but asymptomatic or incubating COVID-19 infection is unlikely to have a detrimental effect on the illness. Vaccination should be deferred in those with confirmed infection to avoid confusing the differential diagnosis. As clinical deterioration can occur up to two weeks after infection, ideally vaccination should be deferred until around four weeks after onset of symptoms or from the first PCR positive specimen in those who are asymptomatic. 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	Local reactions at the injection site are fairly common after Comirnaty® (COVID-19 mRNA Vaccine, 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

Category	Description
	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. Recently 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. A protocol for the management of anaphylaxis and an anaphylaxis pack must always be available whenever Comirnaty® (COVID-19 mRNA Vaccine, Pfizer/BioNTech) is given. Immediate treatment should include early treatment with 0.5mg intramuscular adrenaline (0.5ml of 1:1000 or 1mg/ml adrenaline), with an early call for help and further IM adrenaline every 5 minutes. For children aged 12-17 years who are small or prepubertal administer 0.3mg intramuscular adrenaline (0.3mL of 1:1000 or 1mg/mL 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. 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	Healthcare professionals and individuals/carers should report suspected adverse reactions to the Medicines and Healthcare

Category	Description
adverse reactions	products Regulatory Agency (MHRA) using the Coronavirus Yellow Card Reporting Scheme. As this vaccine is labelled with a black triangle, all adverse reactions occurring in individuals of any age after vaccination should be reported to the MHRA using the Coronavirus Yellow Card Scheme. Anyone can report a suspected adverse reaction to the MHRA using the Coronavirus Yellow Card Reporting Scheme . 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 Coronavirus 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 • Provide copy of Pregnant, planning a pregnancy or breastfeeding, a guide to COVID-19 vaccine to women of child bearing years

Category	Description
	• 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 young people 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 unless the individual has other COVID-19 symptoms; has been told by NHS Test and Protect they are a close contact of someone who has tested positive for COVID-19; they live with someone who has recently tested positive for COVID-19; or they live with someone who has symptoms of COVID-19. • Vaccinated individuals should be advised that if the fever started 48 hours after the vaccination or lasts longer than 48 hours, they should self-isolate and book a test. • Vaccinated individuals should be advised that feeling generally unwell, shivery, achy and tired were also symptoms commonly reported by vaccine recipients in the clinical trials. Generally, these symptoms were found to 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	Vaccine recipients should be monitored for 15 minutes after vaccination, with a longer observation period when indicated after clinical assessment. As syncope (fainting) can occur following vaccination, all vaccines should either be driven by someone else or should not drive for 15 minutes after vaccination. Individuals with a localised urticarial (itchy) skin reaction (without systemic symptoms) to the first dose of a COVID-19 vaccine should receive the second dose of vaccine with prolonged observation (30 minutes) in any setting.
Follow up	Not applicable
Additional facilities	A protocol for the management of anaphylaxis and an anaphylaxis pack must always be available whenever Comirnaty® (COVID-19 mRNA Vaccine, Pfizer/BioNTech) is

Category	Description
	given. Immediate treatment should include early treatment with 0.5mg intramuscular adrenaline (0.5ml of 1:1000 or 1mg/ml adrenaline), with an early call for help and further IM adrenaline every 5 minutes. For children aged 12-17 years who are small or prepubertal administer 0.3mg intramuscular adrenaline (0.3mL of 1:1000 or 1mg/mL 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 • 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

Name	Description
	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] Immunisation against Infectious Disease [Green Book Chapter 14a] COVID-19 JCVI: advice on priority groups for COVID-19 vaccine 30th December 2020 JCVI: Final statement on phase 2 of the COVID-19 vaccination programme: 13 April 2021 JCVI statement on COVID-19 vaccination of children and young people aged 12 to 17 years: 15 July 2021 Updated JCVI statement on COVID-19 vaccination of children and young people aged 12 to 17 years: 04 August 2021 JCVI: Third primary COVID-19 vaccine dose for people who are immunosuppressed: 1st September 2021 JCVI: COVID-19 vaccination of children aged 12 to 15 years: 3rd September 2021

Name	Description
	JCVI: Statement regarding a COVID-19 booster vaccine programme for winter 2021/22; 12th September 2021 Universal vaccination of children and young people aged 12 to 15 years against COVID-19. Letter from the UK Chief Medical Officers: 13th September. Regulatory approval of Vaxzevria (previously COVID-19 Vaccine AstraZeneca) Educational resources for registered professionals produced by National Education for Scotland Coronavirus (COVID-19) - vaccine: letter from the Chief Medical Officer updating on the vaccination programme - 1 January 2021

ANNEX B: Practitioner authorisation sheet

Comirnaty® (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® (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	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.

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