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

Patient Group Direction For The Administration of Comirnaty® 30micrograms/dose (COVID-19 mRNA Vaccine, Pfizer/BioNTech) by Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles

Version 2.4

Effective from 15th September 2022

NoS/PGD/COVID19_Comirnaty/MGPG1193

Note: Other COVID19 vaccines are not covered by this PGD – separate PGDs will be available

This Patient Group Direction (PGD) has been adopted from the PGD template produced by Public Health Scotland on 6th September and updated on 16th September (not issued), 17th September 2021, 24th September 2021, 29th September 2021, 4th November 2021, 18th November 2021, 30th November 2021, 14th December 2021, 23rd December 2021, 17th January 2022, 1st March 2022, 25th March 2022, 22nd August 2022 and 15th September 2022.

Version history

Version	Date	Summary of changes
1.0	06/09/21	Version 1.0 new PGD
1.1	16/09/21	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 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 COVID-19 booster vaccination 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 third dose COVID-19 booster vaccine.
1.2	17/09/21	The following sections have been updated: • Duration of treatment section updated to remove wording about booster doses.

Version	Date	Summary of changes
1.3	24/09/21	The following sections have been updated: • 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 • Appendix 3 added with accessible version of management of patients with severe allergy table adapted from COVID-19 chapter of Green Book
1.4	29/09/21	The following sections have been updated: • 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 with to advise in those identified as requiring a booster vaccine dose the booster dose should be administered no earlier than six months (24 weeks) after completion of the primary vaccine course.
1.5	04/11/21	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.
1.6	18/11/21	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.

Version	Date	Summary of changes
		• 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.
1.7	29/11/21	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. • Action if excluded section updated to include action required in children and young people under 18 years who are not in clinical risk groups following a positive COVID test. • 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
1.8	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).

Version	Date	Summary of changes
		• 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.
1.9	23/12/21	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 COVID-19). • 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. • Appendix 3 – management of patients with a history of allergy updated to reflect changes to Figure 1.
2.0	17/01/22	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).

Version	Date	Summary of changes
		• 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. • Appendix 3 – management of patients with a history of allergy updated to reflect changes to Figure 1.
2.1	01/03/22	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 • Appendix 3 updated to align with amendments to figure 1 on managing patients with a history of allergy. • Reference section has been updated.
2.2	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. • Frequency section updated to clarify eligibility for spring booster 2022 programme. • Advice to patient or carer section updated with advice on fever following vaccination.
2.3	22/8/22	This PGD has undergone minor rewording, layout, formatting changes for clarity and consistency with other PHS national specimen PGDs. 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

Version	Date	Summary of changes
		• 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
2.4	15/09/22	The following sections have been updated: • 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

Contents

Authorisation

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

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

The qualified health professionals who may administer Comirnaty® 30 micrograms/dose (COVID-19 mRNA vaccine, Pfizer/BioNTech) under this PGD can only do so as named individuals. It is the responsibility of each professional to practice within the bounds of their own competence and in accordance with their own Code of Professional Conduct and to ensure familiarity with the manufacturer's product information/summary of product characteristics (SPC) for all vaccines administered in accordance with this PGD.

NHS board governance arrangements will indicate how records of staff authorised to operate this PGD will be maintained. Under PGD legislation there can be no delegation. Administration of the vaccine has to be by the same practitioner who has assessed the patient under the PGD.

This PGD has been produced for NoS by					
Doctor	Dr Susan Laidlaw	Signature		Date Signed	07/09/2021
Pharmacist	Sharon Pfleger	Signature	Sharon Pfleger	Date Signed	06/09/2021
Nurse	Pauline Merchant	Signature		Date Signed	30/08/2022

Approved for use within NoS Boards by;

North of Scotland (NoS) PGD Group Chair	**Signature**	**Date Signed**
Lesley Coyle		06/09/2021

Authorised and executively signed for use within NoS Boards by;

NHS Grampian Chief Executive	**Signature**	**Date Signed**
Professor Caroline Hiscox		19/09/2022

Version 2.4 effective from 15th September 2022 review date 31st March 2023.

Clinical situation

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 JCVI advice/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 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 • 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 history of idiopathic (unexplained) anaphylaxis unless the advice from relevant specialist, local immunisation or health protection team is that vaccination should proceed. • are 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.

Category	Description
	• are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation) • are bone marrow and peripheral blood stem cell donors who have commenced GCSF, the vaccination (first or second dose) must be delayed at least until 72 hours after stem cell collection (both peripheral blood stem cell and bone marrow donation). This is a precautionary advice to avoid vaccination when receiving Granulocyte-colony stimulating factor (GCSF) and allow for post donation recovery period. • have developed myocarditis or pericarditis following a previous dose of COVID-19 vaccination
Cautions/ need for further advice/ circumstances when further advice should be sought from a doctor	The Green Book advises that there are very few individuals who cannot receive COVID-19 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 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

Category	Description
	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 the response to the live virus in the older population and because of the potential difficulty of attributing systemic side effects to the newer adjuvanted shingles vaccine. Where individuals attend requiring both vaccines, however, and require rapid protection or are considered likely to be lost to follow up, co-administration may still be considered. A UK study of co-administration of AstraZeneca and Pfizer BioNTech COVID-19 vaccines with inactivated influenza vaccines 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.

Category	Description
	Vaccination in pregnancy should be offered in accordance with recommendations in Green Book **Chapter 14a**, following a discussion of the risks and benefits of vaccination with the woman. In December 2021, following the recognition of pregnancy as a risk factor for severe COVID-19 infection and poor pregnancy outcomes during the Delta wave, pregnancy was added to the clinical risk groups recommended COVID-19 vaccination. Because of the wider experience with mRNA vaccines, these are currently the preferred vaccines to offer to pregnant women. For those under 18 years Comirnaty® (COVID-19 mRNA vaccine, Pfizer/BioNTech) is preferred. When mRNA vaccines are not considered clinically suitable, Nuvaxovid (Novavax COVID-19 vaccine recombinant, adjuvanted) vaccine may be used for primary vaccination of pregnant women, including to complete a course or as a booster, although experience in pregnancy is relatively limited. If a woman finds out she is pregnant after she has started a course of vaccine, she should complete vaccination at the recommended interval. There is no known risk associated with giving non-live vaccines whilst breastfeeding. JCVI advises that breastfeeding women may be offered 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.

Category	Description
	The four-week interval may be reduced to ensure operational flexibility when rapid protection is required, for example high incidence or circulation of a new variant in a vulnerable population. Currently, the JCVI consider that, in care home residents and the housebound, there may be an advantage in offering vaccination to some individuals with recent confirmed COVID-19, without a four-week deferral, where individuals are clinically stable and when infection control procedures can be maintained. These populations are likely to be highly vulnerable and will facilitate vaccination without the need for multiple visits. There is no need to defer immunisation in individuals after recovery from a recent episode with compatible symptoms who were not tested unless there are strong clinical or epidemiological features to suggest the episode was COVID-19 infection. 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 14a** and 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.
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.

Category	Description
	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. Inform or refer to the clinician in charge.

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) 30micrograms/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 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

Category	Description
	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 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 is 30 micrograms contained in 0.3mL of the diluted vaccine.
Frequency	**Primary immunisation** 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.

Category	Description
	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. 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 30microgram 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 COVID-19 chapter of Green Book) 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 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

Category	Description
	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. **Severe 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 (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 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 considered 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.

Category	Description
Duration of treatment	See above.
Maximum or minimum treatment period	See above.
Quantity to supply/administer	See above.
▼ black triangle medicines	Yes, 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 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 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 summary of product characteristics states that close observation for at least 15 minutes is recommended following vaccination. In recognition of the need to accelerate delivery of the programme in response to the emergence of the Omicron variant, the UK Chief Medical Officers have recommended temporary suspension of this requirement. This temporary suspension in individuals

Category	Description
	without a history of allergy has also been agreed by the Commission on Human Medicines The Scottish Government has made further recommendations that all doses of COVID-19 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 PGD is allowed.
Storage requirements	Comirnaty® 30 micrograms/dose (COVID-19 mRNA vaccine, Pfizer/BioNTech) must be stored in accordance with manufacturer's advice. Once removed from the freezer Comirnaty® 30 micrograms/dose 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® 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. 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 unwell, immunisation should be postponed until they have fully recovered.

Category	Description
	There is no convincing evidence of any safety concerns from vaccinating individuals with a past history of COVID-19 infection, or with detectable COVID-19 antibody. 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.

Adverse reactions

Category	Description
Warnings including possible adverse reactions and management of these	Local reactions at the injection site are fairly common after Comirnaty® 30 micrograms/dose (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 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 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

Category	Description
	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 adverse reactions	Healthcare professionals and individuals/carers should report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Coronavirus Yellow Card reporting scheme on: **https://coronavirus-yellowcard.mhra.gov.uk/** Any adverse reaction to a vaccine should be documented in accordance with locally agreed procedures in the individual's record and the individual's GP should be informed. 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 • 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.

Category	Description
	• 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: o chest pain o shortness of breath o 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 Summaries of Product Characteristics, it is recommended that all recipients of the Pfizer BioNTech, Moderna and Novavax vaccines are kept

Category	Description
	for observation and monitored for a minimum of 15 minutes. In recognition of the need to accelerate delivery of the programme in response to the emergence of the Omicron variant, the UK Chief Medical Officers have recommended suspension of this requirement. This temporary suspension in individuals without a history of allergy has also been agreed by the Commission on Human Medicines. The Scottish Government has made further recommendations that all doses of mRNA COVID-19 vaccines be followed by a 5 minute observation period. A longer observation period when indicated after clinical assessment in individuals with a history of allergy as set out in Table 5 and flowchart in Green Book Chapter 14a Vaccinated individuals should be informed about how to access immediate healthcare advice in the event of displaying any symptoms. In some settings, for example domiciliary vaccination, this may require a responsible adult to be present for at least 15 minutes after vaccination. As syncope (fainting) can occur following vaccination, all vaccinees should either be driven by someone else or should not drive for 15 minutes after vaccination.
Follow up	Not applicable
Additional facilities	A protocol for the management of anaphylaxis and an anaphylaxis pack must always be available whenever vaccines are given. Immediate treatment should include early treatment with intramuscular adrenaline, with an early call for help and further IM adrenaline every 5 minutes. The health professionals overseeing the immunisation service must be trained to recognise an anaphylactic reaction and be familiar with techniques for resuscitation of a patient with anaphylaxis.

Characteristics of staff authorised under the PGD

Category	Description
Professional qualifications	The following classes of registered healthcare practitioners are permitted to administer vaccines: • nurses and midwives currently registered with the Nursing and Midwifery Council (NMC) • pharmacists currently registered with the General Pharmaceutical Council (GPhC) • chiropodists/podiatrists, dieticians, occupational therapists, orthoptists, orthotists/prosthetists, paramedics, physiotherapists, radiographers and speech and language therapists currently registered with the Health and Care Professions Council (HCPC) • dental hygienists and dental therapists registered with the General Dental Council • optometrists registered with the General Optical Council
Specialist competencies or qualifications	Persons must only work under this PGD where they are competent to do so. All practitioners operating this PGD must: • demonstrate appropriate knowledge and skills to work under the PGD for the administration of COVID-19 vaccine. • 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. This NES Proficiency document can be found at TURAS Learn at: **https://learn.nes.nhs.scot/37676/immunisation/covid-19-vaccines** All persons operating this PGD: • must be authorised by name by their employer as an approved person under the current terms of this PGD before working to it • must be familiar with the vaccine product and alert to changes in the manufacturers product information/summary of product information, • must be competent to undertake immunisation and to discuss issues related to immunisation to assess patients for vaccination and obtain consent • must be competent in the correct storage of vaccines and management of the cold chain if receiving, responsible for, or handling the vaccine • must be competent in the recognition and management of anaphylaxis or under the supervision of persons able to respond appropriately to immediate adverse reactions

Category	Description
	• must have access to the PGD and associated online resources • should fulfil any additional requirements defined by local policy All practitioners operating under the PGD are responsible for ensuring they remain up to date with the use of COVID-19 vaccines included. If any training needs are identified these should be discussed with the individuals in the organisation responsible for authorising individuals to act under the PGD Employer • The employer is responsible for ensuring that persons have the required knowledge and skills to safely deliver the activity they are employed to provide under this PGD • As a minimum, competence requirements stipulated in the PGD must be adhered to.
Continuing education and training	All practitioners operating under the PGD are responsible for ensuring they remain up to date with the use of COVID-19 vaccines included. If any training needs are identified these should be discussed with the individuals in the organisation responsible for authorising individuals to act under this PGD.

Audit trail

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 and subsequently 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

Name	Description
	• details of any adverse drug reactions and actions taken • administered under PGD Records should kept 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.

Additional 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 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)

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

Appendix 1

Professional Agreement to Administer Vaccine Under Patient Group Direction

I: _____ (Insert name)

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

Agree to administer the vaccine contained within the following Patient Group Direction:

Patient Group Direction For The Administration of Comirnaty® 30 micrograms/dose (COVID-19 mRNA Vaccine, Pfizer/BioNTech) by Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles (Version 2.4 – valid from 15th September 2022)

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

Signed: _____

Print Name: _____

Date: _____

Profession: _____

Professional Registration number/PIN _____

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

Appendix 2

Healthcare Professionals Authorisation to Administer Vaccine Under Patient Group Direction

The Lead manager/Professional of each clinical area is responsible for maintaining records of all clinical areas where this PGD is in use, and to whom it has been disseminated.
The Senior Nurse/Professional who approves a healthcare professional to administer the vaccine under this PGD is responsible for ensuring that he or she is competent, qualified and trained to do so, and for maintaining an up-to-date record of such approved persons.
The Healthcare Professional that is approved to administer the vaccine under this PGD is responsible for ensuring that he or she understands and is qualified, trained and competent to undertake the duties required. The approved person is also responsible for ensuring that administration is carried out within the terms of the direction, and according to his or her individual code of professional practice and conduct.
Patient Group Direction For The Administration of Comirnaty® 30 micrograms/dose (COVID-19 mRNA Vaccine, Pfizer/BioNTech) by Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles (Version 2.4 – valid from 5th September 2022)
Local clinical area(s) where the listed healthcare professionals will operate under this PGD:

Name of Healthcare Professional	Signature	Date	Name of Manager	Signature	Date

Patient Group Direction For The Administration of Comirnaty® 30 micrograms/dose (COVID-19 mRNA Vaccine, Pfizer/BioNTech) by Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles (Version 2.4 – valid 15th September 2022)

Name of Healthcare Professional	Signature	Date	Name of Manager	Signature	Date